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Aim & Scope

The aim of the journal is to contribute to the literature by publishing clinical and experimental research articles, case reports, letters to the editor, and and editorial comments prepared in accordance with the ethical guidelines in all disciplines of health sciences. The target audience of the journal includes specialists and medical professionals working in all disciplines of health sciences.

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Performance Evaluation of Deep Learning Models for Dental Caries Classification via Panoramic Radiograph Images

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ABSTRACT

Objective: The purpose of this study is to evaluate the ability of deep learning models to classify mandibular molar teeth according to the presence and proximity of caries to the dental pulp. This research summarizes the progress of artificial intelligence and potential dental problems in diagnosis, treatment, and disease prediction in medicine. It discusses data limitations, computational power, ethical considerations, and their implications for dentists. This can lay the groundwork for future research in this rapidly expanding field.

Methods: The dataset used in this study consists of 1200 panoramic radiographs, which have been evaluated and classified into three categories: free of dental caries, coded as (H); enamel-dentin caries lesions treated with restorative filling, coded as (R); and deep dental caries that underwent root canal treatment, coded as (E). The images are prepared for the training-testing process using the k-fold cross-evaluation technique and then fed into the pre-trained deep learning models for classification.

Results: The VGG-19 model achieved superior results compared to the other models, with macro-average scores of 0.9111 for precision, 0.9127 for recall, and 0.9115 for f1-score, respectively.

Conclusion: The promising results obtained in this study give confidence in endorsing the use of deep learning models in the dental treatments sector.

Keywords: Artificial intelligence; deep learning; dental caries; panoramic radiology.

1. INTRODUCTION

One of the common chronic oral diseases is dental caries, which mostly affects adults and teenagers worldwide (1). In the United States, the prevalence of dental caries between the age group of children 2-11 years (in primary teeth) is 41%, in children and adolescents 6-19 years of age is 42%, and in adults ≥ 20 years of age (in permanent teeth) is approximately 90 % according to a survey carried out by National Health and Nutrition Examination (2-4). Early detection of dental caries is essential to prevent pulpitis and periapical diseases in advanced stages (5).

Visual tactile inspection and dental radiographs are crucial for detecting dental caries (6). While occlusal surface caries is easily identifiable through direct examination, diagnosing caries in deep fissures, tight interproximal contacts, and secondary lesions is more challenging. As a result, various methods have been developed to improve the detection

of dental caries across different anatomical morphologies of teeth (7,8). However, panoramic radiographs are not definitive for diagnosing dental caries due to issues with superimposition and distortion. Still, they were routinely taken during the examination to give a general overview of the dentition and periodontal supporting tissues (9). However, it is considered a good evaluation that may help to reduce the chairside examination time and give the required information about the required diagnostic methods to make the final differential diagnosis (10). Radiographically, dental caries appears as radiolucency in the tooth structure. Mostly, teeth without radiolucency are considered healthy. A small area of radiolucency that does not extend to the pulp chamber indicates the need for a restorative filling. Deep radiolucency, encompassing the pulp chamber, indicates that the tooth requires endodontic treatment (8).

Researchers in the field of artificial intelligence (AI) have come a long way in data processing. AI researchers played a crucial role in data processing (11). The achievements in AI contributed to medical diagnostics (12-14). Medical diagnostics are mostly data problems by nature; therefore, advancements in AI can transform this field (15). The advantage of deep learning is that it extracts details from the input data (16). A sub-category of machine learning known as deep learning takes detailed characteristics out of data (17). This methodology is considered influential in such processing (18). The deep learning offers an accurate solution for various tasks such as Natural Language Processing (NLP), speech recognition and synthesis, signal analysis, and computer vision (19-21). The Convolutional Neural Networks (CNNs), have positive effects on segmentation, object recognition, and classification of various types of images, including medical images (22). Deep learning demands extensive data to achieve an promising result. Transfer learning, a machine learning technique, is implemented to overcome the problem of the limited amount of data. It enables a retraining process with fewer input data that leads to less computational time to achieve more accurate results. According to the chosen model and data, the pre-trained model can lead to acceptable output (23).

The CNN-based applications use dot products of weight matrices and input matrices. A CNN model is divided into two sections: feature learning and classification. Future learning computes the input and future matrices to obtain a feature map. Another critical point is to reduce computational time. Commonly, the pooling operation is adopted to overcome such a problem. The completion of the feature learning and classification process yields the output, as described in the papers (24,25).

This study aimed to evaluate the efficiency and performance of deep learning models to identify the differential diagnosis between three different cases of dental caries depending on the radiographic evaluation of panoramic radiographs to assist the extension of coronal lesions toward the pulp.

2. METHODS

This section presents the collected dataset, the deep learning models considered, and the experimental design.

2.1. Dataset

This study is conducted at the Department of Endodontics, Faculty of Dentistry, Near East University, and received ethical approval from the Scientific Research Ethics Evaluation Board (approval no. YDU/2021/89-1306). The database is collected from the archive between 2018 and 2023 panoramic image files of the dental hospital. The inclusion criteria are based on cases where root canal treatment or restorative filling is performed for one of the lower molars due to a carious lesion. The case selection relied on the diagnosis of the dentist who performed the treatment after establishing professional clinical and radiographic evaluation to improve

the diagnosis. Additionally, other healthy mandibular molar teeth in the same patients are included in the study.

The panoramic radiographs previously collected using the X-ray device (Orthophos SL, Sirona, Bensheim, Germany) from the included cases constituted the dataset. These panoramic radiographs are separated from any personal identifiers and anonymized. The collected X-ray image datasets are manually cropped in a standard size to obtain radiographs showing only one molar tooth per image (excluding deciduous teeth) in an optimum position and then calibrated all the images to standardize the contrast between grey/white scales.

The low-resolution radiograph, proximal overlap, retained deciduous, and third molar teeth are excluded from the dataset. 1200 X-ray images including first and second mandibular molars are collected and classified into 400 molars (33.3%) diagnosed as Healthy (non-dental caries), 400 molars (33.3%) diagnosed as enamel-dentin caries, and 400 molars (33.3%) that are diagnosed as root canal treatment. Dental caries were defined as a low-density shadow on dental hard tissue with a rough boundary in the panoramic radiograph. All images were revalidated, and dental caries, including enamel and dentinal carious lesions (excluding deciduous teeth), were distinguished from non-dental caries by calibrated board-certified dentists. The dataset is categorized into three groups: dental caries, which involved the pulp for the teeth underwent root canal treatment (E), caries lesion without pulpal involvement which received restorative filling treatment (R), and healthy molar without caries (H). Figure 1 presents sample images of panoramic radiographs for each group. The dataset is available at https://github.com/ailhan-NEU/Dental-Dataset.
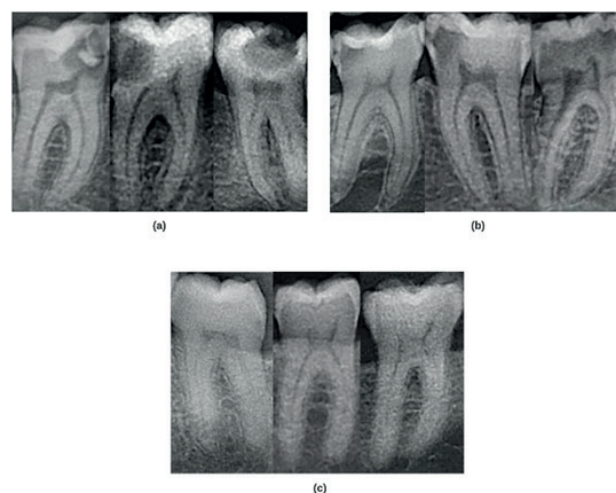
Figure 1. *Examples of panoramic radiography images: (a) Endodontic, (b) Restorative, and (c) Healthy images.*

2.2. Models

In this study, EfficientNet-b0 (26), GoogLeNet (27), Inception-v3 (28), ResNet-50 (29), and VGG-19 (30) deep

learning models are considered for the dental caries classification task.

2.2.1. EfficientNet

The EfficientNet is one of the deep learning models that uses a mixed scaling method. This method allows the width, depth, and resolution dimensions to scale together using a mixed coefficient. There are different models available in EfficientNet, ranging from b0 to b7. The EfficientNet model consists of the Mobile inverted Bottleneck Convolution (MBConv) blocks and squeeze-and-excitation (SE) blocks found in MobileNet-v2. The use of MBConv and SE blocks has been observed to improve accuracy with a small number of parameters.

2.2.2. GoogLeNet

The GoogLeNet was inspired by the pioneering models LeNet and AlexNet but designed as a deeper and more efficient model using a parallel structure and fewer parameters. This design improved the training performance. The success of the GoogLeNet has raised the popularity of deep learning and led to new studies in the field. Therefore, GoogLeNet is a model that has contributed to the significant development of research in deep learning.

2.2.3. Inception

The Inception model is a sophisticated deep learning model renowned for its prowess in image recognition tasks. It employs modules that integrate multiple filter sizes and pooling operations in parallel to capture features at various scales, balancing computational efficiency with high accuracy. Building on this foundation, Inception-v2 incorporates advancements like factorized convolutions and batch normalization. Further refining these improvements, the Inception-v3, introduces additional techniques like label smoothing and auxiliary classifiers, boosting model accuracy.

2.2.4. ResNet

The key innovation of the ResNet is the feature of residual blocks and skip connections. By this feature, higher model accuracy and the problem of gradient loss in weight updates were targeted to be solved. ResNet models uses global average pooling to reduce the size required to process the input. In this way, the depth and the complexity of the model can be increased and the information obtained from each layer will be preserved with skip connections. There are various variants with different depths of the ResNet model, including ResNet-18, ResNet-34, ResNet-50, ResNet-101, and ResNet-152.

2.2.5. VGG

The VGG model shows similarities with the AlexNet, which has an important place among the deep learning models. There are two models available in VGG, 16 and 19. The model consists of sequential convolutional layers, where the filter size increases as the layer depth increases. Research has shown that the performance does not only depend on the increase in filter size but can also be achieved with filters of different sizes. In addition, the smaller filter sizes preferred in the VGG model have been thought to improve the performance by reducing the number of parameters in the training process of the model.

2.3. Experimental Design

The experimental design phase can be summarized in three stages. In the first stage, the images are resized according to the input sizes of considered models to make them suitable for the training and testing process. In the second stage, a k-fold cross-validation (k = 5) technique is applied to determine training and test sets. This technique splits the dataset into k subsets, where in each iteration, one subset is used for testing and the remaining k-1 subsets are used for training. The process is repeated k times, ensuring that each subset serves as the test set exactly once. Lastly, the pre-trained models trained on the ImageNet dataset are fine-tuned using the dental dataset particularly collected for this study. This process enhances their ability to classify dental caries samples by leveraging pre-existing knowledge. The schematic representation of the experimental design is presented in Figure 2.
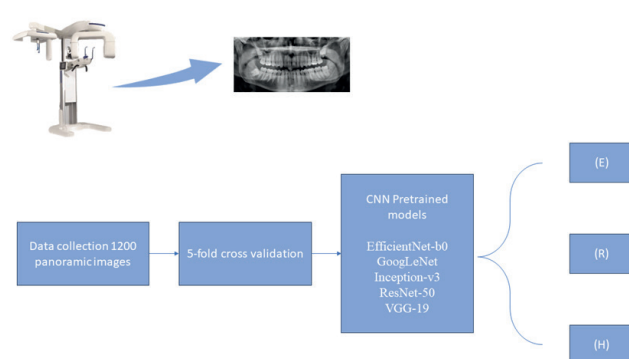
Figure 2. *The block diagram of the experimental design.*

The experiments are carried out via the MATLAB environment. The computer used for the experiments is configured with 32 GB of RAM, an NVIDIA GeForce RTX 2080-Ti GPU, and a 9th generation i9 CPU. Each model is trained using the Adam optimizer with a batch size of 32, a learning rate of 0.0001, and for a maximum of 100 epochs. The performance of the models is evaluated by precision, recall and f1-score metrics. The formulations of these metrics are as follows:

$$\text{Precision } = \frac{TP}{TP + FP} \tag{1}$$

$$\text{Recall } = \frac{TP}{TP + FN} \tag{2}$$

$$\text{F1} - \text{Score } = \frac{2TP}{2TP + FP + FN} \tag{3}$$

Where TP represents true positives, FN represents false negatives, and FP represents false positives.

3. RESULTS

The performance evaluation of the pre-trained models based on five-fold cross-validation is presented in Table 1-5.

Table 1. Performance evaluation of EfficientNet-b0 model based on five-fold cross-validation.

Fold	Class	Precision	Recall	F1-Score
Fold 1	Endodontic	0.8533	0.8767	0.8649
	Healthy	0.8824	0.9146	0.8982
	Restorative	0.8375	0.7882	0.8121
Fold 2	Endodontic	0.8659	0.8452	0.8554
	Healthy	0.8902	0.9241	0.9068
	Restorative	0.7895	0.7792	0.7843
Fold 3	Endodontic	0.8625	0.8415	0.8519
	Healthy	0.7629	0.9250	0.8362
	Restorative	0.7937	0.6410	0.7092
Fold 4	Endodontic	0.8939	0.7973	0.8429
	Healthy	0.8913	0.8817	0.8865
	Restorative	0.7439	0.8356	0.7871
Fold 5	Endodontic	0.8861	0.8046	0.8434
	Healthy	0.7647	0.9848	0.8609
	Restorative	0.8421	0.7356	0.7853
Average	Endodontic	0.8723	0.8331	0.8517
	Healthy	0.8383	0.9261	0.8777
	Restorative	0.8013	0.7559	0.7756

In addition, the confusion matrices of the models are presented in Figure 3.

Figure 3. *Confusion matrices of models.*

3.1. Comparison of the Model Performances

The ranking of the models is determined according to the macro-averages of the metrics. Evaluation results show that the VGG-19 model achieved superior results and is defined as the 1st ranking model. Table 6 presents the comparative results for the models.

Table 2. Performance evaluation of GoogLeNet model based on five-fold cross-validation.

Fold	Class	Precision	Recall	F1-Score
Fold 1	Endodontic	0.7882	0.9178	0.8481
	Healthy	0.9620	0.9268	0.9441
	Restorative	0.8947	0.8000	0.8447
Fold 2	Endodontic	0.8765	0.8452	0.8606
	Healthy	0.9383	0.9620	0.9500
	Restorative	0.8077	0.8182	0.8129
Fold 3	Endodontic	0.8611	0.7561	0.8052
	Healthy	0.8941	0.9500	0.9212
	Restorative	0.7590	0.8077	0.7826
Fold 4	Endodontic	0.7500	0.8919	0.8148
	Healthy	0.9872	0.8280	0.9006
	Restorative	0.7703	0.7808	0.7755
Fold 5	Endodontic	0.8795	0.8391	0.8588
	Healthy	0.8182	0.9545	0.8811
	Restorative	0.8500	0.7816	0.8144
Average	Endodontic	0.8311	0.8500	0.8375
	Healthy	0.9200	0.9243	0.9194
	Restorative	0.8163	0.7977	0.8060

Table 3. Performance evaluation of Inception-v3 model based on five-fold cross-validation.

Fold	Class	Precision	Recall	F1-Score
Fold 1	Endodontic	0.9333	0.9589	0.9459
	Healthy	0.9302	0.9756	0.9524
	Restorative	0.9620	0.8941	0.9268
Fold 2	Endodontic	0.9059	0.9167	0.9112
	Healthy	0.9367	0.9367	0.9367
	Restorative	0.8816	0.8701	0.8758
Fold 3	Endodontic	0.8333	0.8537	0.8434
	Healthy	0.8295	0.9125	0.8690
	Restorative	0.8382	0.7308	0.7808
Fold 4	Endodontic	0.8481	0.9054	0.8758
	Healthy	0.9362	0.9462	0.9412
	Restorative	0.8806	0.8082	0.8429
Fold 5	Endodontic	0.9512	0.8966	0.9231
	Healthy	0.8205	0.9697	0.8889
	Restorative	0.9125	0.8391	0.8743
Average	Endodontic	0.8944	0.9062	0.8999
	Healthy	0.8906	0.9482	0.9176
	Restorative	0.8950	0.8285	0.8601

Table 4. *Performance evaluation of ResNet-50 model based on five-fold cross-validation.*

Fold	Class	Precision	Recall	F1-Score
Fold 1	Endodontic	0.9155	0.8904	0.9028
	Healthy	0.9000	0.9878	0.9419
	Restorative	0.9241	0.8588	0.8902
Fold 2	Endodontic	0.9241	0.8690	0.8957
	Healthy	0.9048	0.9620	0.9325
	Restorative	0.8831	0.8831	0.8831
Fold 3	Endodontic	0.9221	0.8659	0.8931
	Healthy	0.9048	0.9500	0.9268
	Restorative	0.8481	0.8590	0.8535
Fold 4	Endodontic	0.9565	0.8919	0.9231
	Healthy	0.9381	0.9785	0.9579
	Restorative	0.8784	0.8904	0.8844
Fold 5	Endodontic	0.9710	0.7701	0.8590
	Healthy	0.7683	0.9545	0.8514
	Restorative	0.8315	0.8506	0.8409
Average	Endodontic	0.9378	0.8575	0.8947
	Healthy	0.8832	0.9666	0.9221
	Restorative	0.8730	0.8684	0.8704

Table 5. *Performance evaluation of VGG-19 model based on five-fold cross-validation.*

Fold	Class	Precision	Recall	F1-Score
Fold 1	Endodontic	0.9333	0.9589	0.9459
	Healthy	0.9518	0.9634	0.9576
	Restorative	0.9268	0.8941	0.9102
Fold 2	Endodontic	0.9125	0.8690	0.8902
	Healthy	0.9512	0.9873	0.9689
	Restorative	0.8590	0.8701	0.8645
Fold 3	Endodontic	0.8675	0.8780	0.8727
	Healthy	0.9268	0.9500	0.9383
	Restorative	0.8267	0.7949	0.8105
Fold 4	Endodontic	0.8831	0.9189	0.9007
	Healthy	0.9468	0.9570	0.9519
	Restorative	0.8841	0.8356	0.8592
Fold 5	Endodontic	0.9753	0.9080	0.9405
	Healthy	0.9028	0.9848	0.9420
	Restorative	0.9195	0.9195	0.9195
Average	Endodontic	0.9143	0.9066	0.9100
	Healthy	0.9359	0.9685	0.9517
	Restorative	0.8832	0.8629	0.8728

Table 6. *Comparison of pre-trained model performances.*

Model	Macro Precision	Macro Recall	Macro F1-Score
EfficientNet-b0	0.8373	0.8384	0.8350
GoogLeNet	0.8558	0.8573	0.8543
Inception-v3	0.8933	0.8943	0.8925
ResNet-50	0.8980	0.8975	0.8957
VGG-19	**0.9111**	**0.9127**	**0.9115**

4. DISCUSSIONS

The panoramic radiograph is considered an important tool to identify the abnormalities of the jaws and adjacent tissues (9). In addition, panoramic and periapical radiographs are the main methods for evaluating and diagnosing dental and periapical lesions, except for some specific cases. However, it is considered a very effective method to evaluate the extension of dental caries, which helps to reduce the time of clinical evaluation and determine the required diagnostic method to make a definitive diagnosis (10). Panoramic radiography offers a rapid, simple means of providing a broad overview of both jaws and teeth and is likely to be well accepted by patients and/or study participants. It is, therefore, commonly used in studies. Variables such as number of remaining teeth, restorative therapy, and endodontic treatments are accurately disclosed. Panoramic radiography provides an adequate overview with a low x-ray dose compared to bitewing and periapical radiographs in taking all teeth and surrounding structures in one image (31). Thomas et al. used an electronic caries meter to validate occlusal caries diagnosis from bitewing and panoramic radiographs. There was no difference in overall diagnostic performance between bitewing and panoramic radiographs to diagnose occlusal dentine caries (32). The use of a panoramic radiograph to diagnose caries in a child's mouth during a general diagnosis has a high advantage compared to every effort that needs to be made to take a bitewing radiograph. Furthermore, the patients who have a gagging reflex, patients who cannot open their mouths due to trismus and infection, and disabled or mentally retarded patients (33-34).

Applying computer-aided diagnosis systems in different dental and medical fields has shown promising effectiveness, and the outcomes were improved. Regarding image analysis, such as classification, segmentation, and detection, convolutional neural networks have been developed speedily in recent years and demonstrate excellent performance compared to public research technologies of deep learning (35). However, although deep CNN algorithms have excellent performance and reliability, clinical applications and basic research in the field of dentistry are limited (33). The purpose of this study was to demonstrate the efficacy of a CNN algorithm for the identification and classification of dental caries using panoramic radiographs. Besides the importance of applying AI in many fields, the information regarding using AI to diagnose dental caries from the panoramic radiographs is limited or could not be available in the literature. Thus, comparing and discussing the results of this study with similar previous studies could be restricted and difficult.

In previous research, deep CNN revealed periapical lesions on the data set of 2001 tooth pieces of panoramic radiographs. A custom-made 7-layer deep neural network, parameterized by 4.299.651 weights, was trained and validated via 10 times repeated group shuffling. In that research, the reference test was the majority vote of 6 independent examiners, comparing the sensitivity and the accuracy of the moderately trained deep convolutional neural networks on a limited amount of

data showed a satisfying ability to detect the apical lesions on panoramic radiographs (36).

The same university applied the same data set used in the previously mentioned article in another study to detect periodontal loss on panoramic dental radiographs. A collection of 2001 image segments from panoramic photography has been established. This study revealed that a deep CNN model, which has been trained on a small number of dental radiographs, has similar accuracy in assisting the periodontal loss compared with the control group, which was assisted by certified dentists, despite the advantage of reducing the effort of dentists and reducing the required chairside time during the conventional diagnosis workflow (37).

Similar to our study, the author designed his study by concentrating on the first lower molar. The study's objective was to detect the presence of extra roots on the distal side of the lower first molar, which can directly affect the outcome of endodontic therapy. A total of 760 cone-beam computed tomography (CBCT) images and panoramic radiographs for vital lower molars have been collected from 400 patients for evaluation and training of the model). The CBCT images have been used as a reference to determine the presence of the Extra distal root, and the panoramic images have been used as material for training. The study showed that trained models can make an accurate differential diagnosis for cases with a fourth distal root in the mandibular molar (38).

Lee et al. (39) used 5390 panoramic and 5380 periapical radiographic images from 3 types of dental implant systems to practice convolutional neural networks to recognize the type and brand of the implant. The board-certified periodontist did the reference test for the selected date. The accuracy of the digital system and the board-certified examiner was very close which means that the digital system, after moderate training, was able to recognize the implant and the brand of the implant among the three different brands used in this study.

Lee, in his study (8), similar to our research, trained a model to diagnose cavitated teeth. The evaluation in the study has been done on periapical radiographs for the teeth. In contrast, the dataset has been established by cropping the molar's teeth from panoramic radiographs. The paper (8) demonstrated that the deep CNN model detected dental caries effectively in periapical radiographs. The established model was expected to be one of the most efficient methods for diagnosing dental caries. For this reason, the authors in the present study try to prove the efficiency of the AI technologies to diagnose caries on the panoramic radiograph, considered the most used X-ray imaging during diagnosis in dentistry.

Lee (40) has also published another article for dental diagnosis using deep learning. In the study, the technology of AI has been evaluated in the revelation and diagnosis of three forms of odontogenic cystic lesions, including odontogenic keratocysts, periapical cysts, and dentigerous cysts using cone-beam computed tomography and panoramic radiography images. This study showed that the pre-trained model using cone-beam computed tomography images revealed efficient diagnostic performance. This performance was more significant than that performed by other models using panoramic radiography images significantly.

In another study, a deep learning model was built using DetectNet with DIGITS version 5.0 for detecting vertical root fractures on 300 panoramic radiography data with visible fracture lines. Two radiologists and one endodontist did the reference test. The results showed that the model was suitable for detecting vertical root fractures in panoramic radiographs (41).

Orhan et al. (42) have used deep learning to detect the periapical pathosis on cone-beam computed tomography (CBCT) images. A human observer has done the reference test. The evaluation was done for 153 periapical lesions taken from 109 patients. In this study, the deep CNN was successful in detecting teeth and numbering specific teeth.

In this study, various pre-trained models are used to classify the dental samples as H, R, and E. The VGG-19 model achieved more efficient results compared to the other models.

Panoramic radiograph images are less accurate than periapical and bitewing images for detecting dental caries. However, they offer a rapid and straightforward way to obtain a broad overview of both jaws and teeth, which tends to make them well accepted by patients and study participants. The use of panoramic radiographs, particularly when cropped to include only the lower molar tooth, can impact the performance of the model and present limitations in this study. Therefore, future studies should aim to overcome these limitations by utilizing different types of radiographic images and new-generation deep learning models.

5. CONCLUSION

Deep learning models have been widely applied in caries to identify further treatment requirements. Experimental results obtained from real patient data in this study suggest the usage of deep learning models in identifying E or H treatment similar to the experts with high accuracy and precision. Applications like the one in this study can be useful assistance as an expert opinion for less experienced. With the promising performance of deep learning-based medical image classification, we trust that commercial Computer-Aided Diagnosis systems are not far in the future. It will encourage biomedical scientists to apply deep learning models for solving other challenging research problems in the wide field of medicine.

Author Contributions:
Research idea: OM, AI, MA, MS, AK
Design of the study OM, MA
Acquisition of data for the study: MA, MS, AK
Analysis of data for the study: OM, AI, BB
Interpretation of data for the study: OM, BB, AI, MA, MS, AK
Drafting the manuscript: OM, MA
Revising it critically for important intellectual content: OM, MA, AI
Final approval of the version to be published: OM, BB, MA, MS, AK, AI

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Evaluation of the Association Between Sociodemographic Characteristics, Systemic Diseases and Oral Health in the Turkish Suppopulation: A Cross-Sectional Study

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ABSTRACT

Objective: This study aimed to evaluate the relationship between sociodemographic characteristics and systemic diseases with oral health in individuals aged 18-65 with the decayed, missing, filled teeth (DMFT) index.

Methods: This cross-sectional study included 367 volunteers aged 18-65 years. The sixty seven people who reported that they ate completely sugar-free and received orthodontic treatment were excluded from the study and 300 people (170 female/130 male; average age:38.64±14.19) were evaluated. The patients' sociodemographic information (age, gender, education, brushing), systemic diseases, medication use and DMFT scores were recorded by the specialist researcher. Data were analyzed by using Kolmogorov Smirnov, Man Whitney-U, Kruskall Wallis test and Post-hoc Tamhane's T2 test in SPPS software (22.0).

Results: The difference in DMFT score with sociodemographic information (age, education, brushing) other than gender was statistically significant (p< .05). DMFT score was found in asthma (12.39±5.17), cardiovascular disease (14.56±7.23) and diabetes (14.00±3.42); was significantly higher compared to healthy (9.39±3.67) people (p< .05). The difference between gastrointestinal disease, thyroid disease, kidney disease and healthy people wasn't statistically significant (p> .05). However the mean DMFT score in kidney patients (9.00±2.85) was significantly lower compared to asthma, diabetes and cardiovascular disease (p< .05). DMFT score was significantly higher in people using medication (13.77±5.58) than in people not using medication (9.42±3.70)(p< .05).

Conclusion: Oral health may be negatively affected by some systemic diseases and drug use. In addition, sociodemographic characteristics have an important effect on oral health. The individual's sociodemographic characteristics, systemic diseases and medication use should be evaluated in detail in treatment planning and oral health motivation.

Keywords: DMFT index, general health, systemic diseases, oral health

1. INTRODUCTION

Systemic diseases are important in dental practice because they allow dentists to take precautions for the current general health condition or before the disease occurs (1). Knowing the incidence of systemic diseases and the systemic and oral findings related to these diseases allows reducing the problems and risks that may develop during and after dental treatment (2,3).

Oral health is defined as the absence of any disease of the craniofacial complex, which includes the mouth, teeth and skull tissues. In the oral health report of the American General Health Association in 2000, it was emphasized that oral health is not just about good teeth and should be examined as a component of general health, and a connection was established between dental health and general health (4,5). Oral health and general health share similar risk factors (6). In addition to various oral symptoms of systemic diseases, current oral health is also related to the general health of

the individual (7). Poor oral health can affect overall health in the long term. For this reason, in dentistry, it is necessary to evaluate individuals more comprehensively in terms of their general health status, the course of their disease, if any, the medications they use and other variables that may affect the treatment process (8).

The World Health Organization has reported that collecting epidemiological data on dental health and diseases is of primary importance (9). Dental caries, one of the most common infectious diseases worldwide, is one of the most common causes of deterioration in oral health (10). Their etiology is multifactorial, including socio-demographic data such as age, gender, education, smoking and oral hygiene practices (11). Epidemiological studies on caries use the decayed, missing and filled teeth (DMFT) index as a marker of the cumulative outcome of caries in permanent teeth (12). The DMFT index collects data on decayed, missing and filled

teeth. In calculating the DMFt index in individuals under 30 years of age, teeth coded as missing due to caries are taken as basis, while in individuals over 30 years of age, teeth coded as missing due to both caries and other reasons are taken as basis. In this index, all permanent teeth are evaluated, but teeth with abutments, crowns, implants and fissure sealants are not evaluated (13).

Although untreated dental caries has a direct impact on oral health and associated quality of life, identifying indirect relationships between dental caries and systemic health has received little attention (14). The ability of oral microbiota to spread from dental caries to the systemic circulation is plausible. In dental caries, involvement of the root canal space or marginal periodontium is the most likely route for direct systemic dissemination of oral microbiota(15). Inflammation of oral tissues and the contribution of microbiota to diseases such as atherosclerosis, hypertension, diabetes, rheumatoid arthritis, lung diseases, and the relationship between periodontitis and systemic diseases have been further studied (16-18). In addition, while studies focus on children on the relationship between oral health status and systemic diseases, studies on the adult population are limited (19,20). This study aimed to evaluate the relationship between sociodemographic characteristics and systemic diseases with oral health in individuals aged 18-65 with the decayed, missing, filled teeth (DMFT) index.

2. METHODS

This study was approved by Clinical Research Ethics Committee of Ordu University (2022-270) and all procedures in the study were carried out in accordance with the principles of the Declaration of Helsinki. The minimum sample size was calculated in G Power 3.1.9.2 software for 0.85 power, 0.40 effect size and 300 participants were found sufficient. This cross-sectional study included 367 volunteers aged 18-65 (average:38.64±14.19) who applied to the Restorative Dental Treatment Department of Ordu University Faculty of Dentistry between January 2023 and July 2023. All participants were given necessary information about the study, and they signed consent forms stating that they agreed to participate in the study. A survey was applied to the participants, including sociodemographic information (age, gender, education level, brushing frequency), nutritional status, systemic diseases and medication use information. Sociodemographic characteristics were categorized as age range 18-34, 35-49 and 50-65, education level as primary school, high school, university and doctorate, and brushing frequency as once a day, twice a day and irregular brushing. Systemic disease status was categorized as healthy, asthma, diabetes, cardiovascular system disorder, gastrointestinal system disorder, thyroid disorder, kidney diseases. Individuals with more than one systemic disease were excluded from the study. A sugary food consumption frequency survey was applied to standardize nutritional status. According to the frequency of sugary food consumption; 1-2 times a day (5 points), 4-5 times a week (4 points), 3 times a week (3 points), 1-2 times a week (2 points), 1-2 times a month (1 point) and sugar-free diet (0 points) was scored as. While participants in the common score range were included in the study, 67 participants who received orthodontic treatment and reported that they ate completely sugar-free were excluded from the evaluation and 300 people were included in the study.

Participants were examined visually and radiographically using a panoramic radiograph by a researcher experienced in the field of restorative dentistry. The DMFT index was used to determine the oral health status of the participants and the number of decayed (D), missing (M), and filled (F) teeth were recorded and the total DMFT score was obtained.

2.1. Statistical Analysis

The obtained data were analyzed in SPSS (version 22.0) software. The suitability of the data for normal distribution was determined by the Kolmogorov Smirnov and Shapiro Wilk test, and the homogeneity of variances was determined by the Levene test. Analysis of normally distributed data was done with One Way Anova, and analysis of non-normally distributed data was done with Man Whitney U and Kruskall Wallis tests. Post-hoc Tamhane T2 test was used for pairwise comparison of groups. The findings were evaluated at the $\alpha = .05$ significance level.

3. RESULTS

This study was conducted in a total of 300 patients. 41.3% of the patients were between the ages of 18-34, 33.7% were between the ages of 35-49, and 25% were between the ages of 50-65. The relationship between age-related DMFT score was found to be statistically significant ($p < .001$). The average DMFT score in the 50-65 age range was found to be (13.27±5.75), and this average was significantly higher than the 18-34 age range (8.56±3.47) ($p < .05$). There was no significant difference between the ages of 35-49 (12.26±4.05) ($p > .05$).

When gender-related findings were examined, 43.3% of the participants were men and 56.7% were women. There was no significant difference between the DMFT score averages in women (11.33±5.12) and men (10.53±4.64) ($p > .05$).

The education level of the participants included 33% primary school, 32.7% high school, 32% university and 2,3% doctoral degree. The difference between education levels and DMFT score averages was statistically significant ($p < .05$). DMFT average score of participants whose education level is primary school is (12.39±5.59); the education level was significantly higher than that of individuals with high school (10.45±4.44), university (10.31±4.47) and master's/doctoral degree (7.71±2.43) ($p < .05$). There was no significant difference in DMFT score averages between high school, university and master's and doctoral education levels ($p > .05$).

When the tooth brushing habits of the participants were evaluated, 50% reported that they brushed twice a day, 32.7%

reported that they brushed once a day, and 17.3% reported that they brushed irregularly. There was a statistically significant difference between brushing frequencies and DMFT score averages (p< .05). While there was no significant difference between brushing once a day (11.08±4.68) and brushing twice a day (9.82±4.29), irregular tooth brushing (14.15±5.71) significantly increased the DMFT score (p< .05).

Distribution on individuals' systemic diseases are listed in figure 1. In the presence of asthma (12.39±5.17), diabetes (14.00±3.42) and cardiovascular system disease (14.56±7.23), the DMFT score was significantly higher than in healthy individuals (9.39±3.67) was high (p<.05). There was no significant difference in the mean DMFT score compared to healthy individuals in gastrointestinal system disease (13.60±5.77), thyroid disorder (9.90±4.02) and kidney disease (9.00±2.85). However, the mean DMFT score in kidney patients was significantly lower compared to asthma, diabetes and cardiovascular system disease (p<.05). DMFT distributions of individuals according to systemic diseases are summarized in figure 2.

When the medication use information of the participants was examined, 36% reported that they used medication and 64% reported that they did not use any medication. A significant increase was observed in the mean DMFT score due to medication use (13.77±5.58) compared to those not using medication (9.42±3.70). Data regarding the criteria evaluated in the study are summarized in Table 1.

***Table 1.** Comparison of groups in terms of sociodemographics, brushing habits, systemic diseases and medication use*

Parameters		n	DMFT Mean(±SD)	p value
Age	18-34	124	8.56 (±3.47)^A	p<.001*
	35-49	101	12.26 (±4.05)^B	
	50-65	75	13.27 (±5.75)^{BC}	
Sex	Female	170	11.33 (±5.12)	p=.191
	Male	130	10.53 (±4.64)	
Education	Primary school	99	12.39 (±5.59)^A	p=.009*
	High school	98	10.45 (±4.44)^B	
	University	96	10.31 (±4.47)^B	
	Doctorate	7	7.71 (±2.43)^B	
Brushing	One	98	11.08 (±4.68)^A	p<.001*
	Two	150	9.82 (±4.29)^A	
	Irregular	52	14.15 (±5.71)^B	
Systemic disease	Healthy	150	9.39 (±3.67)^A	p<.001*
	Astma	36	12.39 (±5.17)^B	
	Diabetes	32	14.00 (±3.42)^{BC}	
	CVS disorder	36	14.56 (±7.23)^{BC}	
	GIS disorder	10	13.60 (±5.77)^{AB}	
	Thyroid disorder	10	9.90 (±4.02)^{AB}	
	Kidney diseases	26	9.00 (±2.85)^A	
Medication	Yes	108	13.77 (±5.58)	p<.001*
	No	192	9.42 (±3.70)	

DMFT: Total of decay,missing and filling teeth, CVS: Cardiovascular system
GIS: Gastrointestinal system
*For each variable section; Mean with different letters in the same column indicate statistically significant difference, *: significant (p < .05).*
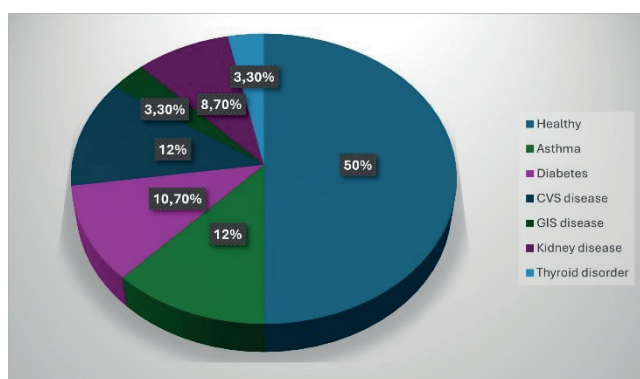
***Figure 1.** Systemic disease distribution of participants*
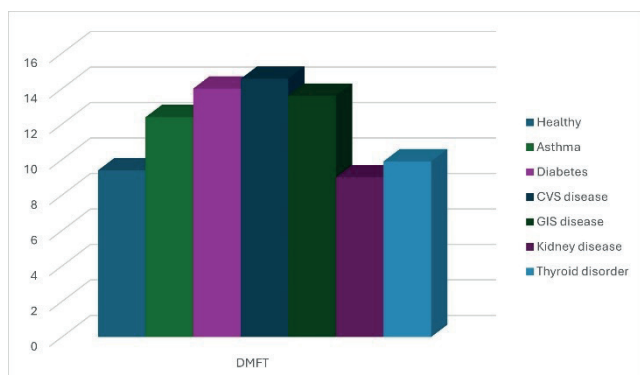
***Figure 2.** DMFT distributions of participants due to systemic disease*

4. DISCUSSION

Comprehensive evaluation of the factors affecting the individual's oral health status in treatment planning and oral hygiene motivation sheds light on clinicians in terms of precautions that can be taken against possible complications and treatment plans for the individual. Therefore, the current study evaluated how the individual's oral health status was affected by sociodemographic characteristics, systemic diseases and medication use. An individual's oral health status is affected by many factors such as age, gender, nutrition, educational status, brushing habits, and the individual's chronic systemic diseases and medication use (21). It has been reported in many studies in the literature that DMFT scores increase with increasing age in adults (22,23). Consistent with previous studies, a significant increase in the DMFT score was observed in the 50-65 age range in this study (p< .05). Although the length of time a tooth remains in the mouth is an important factor in exposure to caries, it has been reported that the incidence of caries decreases as we age. Aging of the tooth enamel with increasing age and the disappearance of retaining areas as a result of wear on the teeth are factors that contribute to the inverse relationship between age and caries (1). In addition, it is known that tooth

loss due to periodontal diseases increases with increasing age (18). In this study, we think that the number of missing teeth and weakened oral skills are effective in the increase in DMFT score with increasing age.

Previous studies have reported that oral health indicators are worse in women and oral health-related quality of life (OHRQoL) is more likely to be poor in women (24,25). Unlike these studies, there was no significant difference in the mean DMFT score between men and women in this study, although the mean DMFT score was relatively higher in women than in men. The differences in the results may be due to differences in the population studied.

The most commonly used socioeconomic indicators of social health inequalities are education, income, carieer and social class. The relatively more constant of these determinants is the level of education (26). For this reason, we used educational status as a socioeconomic determinant in the study. Education level can affect the way a person interacts with oral health services and uses information (27). In the results of this study, the mean DMFT score was significantly higher at lower education levels. The results are consistent with systematic reviews concluding that low socioeconomic status is associated with increased dental caries experience (28,29). Tsakos et al. In their study, they used the OHIP-14 index to determine oral health status and found that individuals with higher education had lower OHIP-14 scores, indicating a better oral health status (30). Although oral health status was evaluated with a different index than this study, the results indirectly support the results of this study.

It has been reported that tooth brushing habits contribute significantly to reducing the prevalence of dental caries (31,32). 50% of the participants in this study reported that they brushed their teeth twice, 32.7% reported that they brushed their teeth once a day, and 17% reported that they brushed their teeth irregularly. DMFT score was significantly higher in participants who brushed their teeth irregularly. Brushing teeth once a day and twice a day did not cause a significant difference in DMFT score. Similar to the results of this study, Farooqi et al., Schwarz et al. Mallineni et al. In their study, irregular tooth brushing significantly increased the prevalence of tooth decay (31-33). These results reveal that tooth brushing habits are one of the important factors that can affect oral health.

In this study, 12% of the participants had asthma, and there was a significant increase in the DMFT score, which is a measure of oral health status, in asthma patients compared to healthy individuals. In the study of Elyassi Gorji N et al., a significant increase in DMFT score was found, consistent with the results of this study (34). Although the nature of the association of asthma with dental caries appears unclear, previous studies have shown genetic variation in ameloblastin in asthma patients (35), an association between higher rates of dental caries in the tablet form of asthma medications (36) and inhaled corticosteroids (37), and increased numbers of Veilonella in asthma patients that can metabolize lactate

produced by cariogenic streptococci (38). These results support the increased DMFT score in asthma patients.

In this study, 10.7% of the participants were diabetic patients, and the DMFT score was significantly higher in diabetic patients compared to healthy individuals. A study in caries-active diabetics reported that salivary calcium was significantly reduced and alkaline phosphatase was increased (39). Another similar study found that salivary pH decreased significantly and the number of lactobacilli increased in children with diabetes (40). Again, in a study conducted on rodents, hyperglycemia was shown to be associated with increased tooth decay (41). Additionally, increased alveolar bone loss and periodontitis in diabetics are factors that negatively affect oral health status (42). All of these support the increased DMFT score in diabetics and is an expected result.

In this study, hypertension, heart valve diseases, congenital heart diseases and the presence of a pacemaker were included in the cardiovascular diseases category. 12% of the participants had cardiovascular system disease and there was a significant increase in DMFT score compared to healthy individuals. In the study of Soto Barreras et al. in which they evaluated cardiovascular disease, dental caries experience and periodontal status, dental caries were not found to be significantly different compared to controls, but it was reported that the overall oral inflammatory burden increased due to the increase in periodontal problems (43). In another study, Ostalska-Nowicka et al. found a relationship between dental caries and primary hypertension (44).

The rate of participants with kidney disease was 8.7%. In the study, patients with chronic kidney failure, polycystic kidney disease and kidney stones were included in the kidney disease category. While the mean DMFT score was significantly lower in the presence of kidney disease compared to asthma, diabetes and cardiovascular disease, there was no difference with healthy individuals. Consistent with the results of this study, DMFT scores were found to be lower in patients with renal failure in the studies of Andolora et al. (45) and Ertuğrul et al. (46). Again, in the studies of Silva et al. (47), it was reported that the prevalence of dental caries in chronic kidney disease was significantly lower. These results may be caused by the presence of large amounts of urea in saliva and inhibition of plaque development in chronic kidney diseases (48).

Previous studies have reported that many medictions used for chronic systemic disease cause dry mouth and are associated with increased prevalence of dental caries (49,50). In this study, DMFT score related to medication use showed a positive correlation.

One of the limitations of this study is that the sample size is small and the data includes self-reported information, which is the most commonly used method. Another limitation is that oral health status was assessed only with the DMFT index, and periodontal status such as gingival bleeding index and plaque index were not assessed. Studies with larger sample sizes and studies that evaluate oral health status with other indices are needed to support the accuracy of the results.

5. CONCLUSION

Within the limitations of this study, it can be concluded that the DMFT index, which we use to evaluate the oral health status of the individual, is affected by many factors such as sociodemographic factors, systemic diseases and medication use. Informing patients about the risk factors that may affect oral health, oral findings of existing systemic diseases, or prevention-oriented national health projects aimed at the effect and relationship of the current oral condition on general health will provide benefits for the future.

Author Contributions:
Research idea: SAK, EK
Design of the study: SAK, EK
Acquisition of data for the study: EK
Analysis of data for the study: SAK
Interpretation of data for the study: SAK, EK, SA
Drafting the manuscript: SAK, SA
Revising it critically for important intellectual content: SAK, SA
Final approval of the version to be published: SAK

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Evaluation of the Role of Music and Bach Flower Remedies in the Management of Anxious Pediatric Dental Patients: A Randomised Clinical Trial

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ABSTRACT

Objective: Dental fear and anxiety describe negative feelings towards the dental environment, particularly significant in pediatric dentistry due to their cognitive, behavioral, and physical impacts on children. Managing this anxiety through positive dentist-child relationships and behavioral guidance techniques is crucial. This study aims to evaluate the effectiveness of passive distraction using music and Bach flower remedy in reducing dental fear and anxiety in children aged 6-8 years.

Methods: This randomized controlled clinical study included 12 children (n=4 for each group) aged 6-8 years, randomly assigned to Group 1 (control), Group 2 (Bach flower remedy), or Group 3 (passive distraction with music) for treating superficial dentin caries in primary teeth without local anesthesia. Dental fear and anxiety levels were assessed using objective (heart rate, oxygen saturation, systolic and diastolic blood pressure) and subjective (Facial Image Scale and Venham's Picture Test) measures before and after treatment.

Results: The study included 12 children (6 female, 6 male) with a mean age of 7.3±0.8 years. In Group 2, heart rate significantly decreased after treatment (97.8 ± 10.1 to 90.5 ± 8.8, p<.05). However, no statistically significant differences were found between Groups 1, 2, and 3 in either objective or subjective measures when comparing before and after treatment results (p>.05).

Conclusion: In this study, although passive distraction with music and Bach flowers did not have a significant effect on physiological and projective measurement tools in children with dental fear and anxiety, a decrease in heart rate was observed in children exposed to Bach flowers.

Keywords: Dental fear, dental anxiety, Bach flower remedy, passive distraction with music

1. INTRODUCTION

Dental fear is defined as a reaction to a stimulus perceived as threatening, and dental anxiety is defined as the worry that something negative will happen in the dentist environment. Since it can be difficult to differentiate dental fear and anxiety in clinical situations, the term dental fear and anxiety (DFA) is used to describe negative feelings about the dentist environment. DFA is an important concept in pediatric dentistry and can result in cognitive, behavioral and physical reactions (1,2).

When DFA is considered from a clinical perspective; it causes patients to visit the dentist irregularly or totally avoid treatment, resulting in oral health problems, an increase in the prevalence of tooth decay and extraction, and a decrease in quality of life. At the same time, all these results require more complex treatment planning and may hinder the physician's success. (1,3,4). The key to overcoming all these consequences is to manage DFA by developing a positive dentist-child relationship with an empathetic approach using behavioral guidance techniques (1,5,6).

Pharmacological behavior guidance techniques should not be preferred in the first step due to their undesirable side effects, risks, costs and invasive nature (4,7,8). Keeping these points in mind, in addition to traditional behavior guidance with documented success, it should be a priority to investigate innovative alternative complementary non-pharmacological behavior guidance techniques such as hypnosis, active and passive distraction, homeopathy and aromatherapy (7,9-11).

The distraction techniques are often used to shift the focus of the child away from the ongoing unpleasant treatment process and incluede music; video, or a combination of both

(passive distraction) and play therapy (active distraction) (8,9,12). Music theorists such as Bonny and Gfeller report that music distracts people from stressful stimuli and provides physical and mental relaxation. Classical music is used in neuroscience studies as a stimulant of the right temporal region, which is responsible for musical cognition, especially in terms of calming behavior (12). The use of music, one of passive distraction tools, is the subject of many medical and dental studies due to its effects on the mood and vital functions of the human body (8,13-15). Bach flower remedy as an aromatherapy is a complementary and alternative medicine practice developed by British homeopathic physician Dr. Edward Bach in the 1930s, when he discovered 38 essences from wildflowers (11). The practice was recognized by the World Health Organization (WHO) within the scope of Traditional Medicine Strategies in 2013 (16).

The need to further investigate alternative complementary behavior guidance techniques that will potentially contribute to the management of DFA and to obtain more information about these applications in the literature led us to this study.

The aim of this study is to evaluate the effectiveness of the use of passive distraction with music and Bach flower remedy in reducing DFA in children aged 6-8 years.

The null hypothesis of the study is that passive distraction with music and the use of Bach flower remedy have no effect on reducing DFA.

2. METHODS

This study received approval from the Clinical Research Ethics Committee of the Medical School of Tokat Gaziosmanpaşa University (Approval No. 22-KAEK-068 and dated 31.03.2022). The study was conducted in accordance with the Helsinki Declaration guidelines. The study complied with the Consolidated Standards of Reporting Trials (CONSORT) guidelines. Informed consent was obtained from all patients prior to the commencement of treatment.

The sample size was estimated using G Power software v.3.1.9.2. A minimum of 12 children was required to detect a significant difference using the "ANOVA: Fixed effects, omnibus, one-way" test, with a type I error (α) of 0.05, power (1-beta) of 95%, and effect size of 1.544 (11).

This randomized controlled clinical study was conducted at Tokat Gaziosmanpaşa University Faculty of Dentistry, Department of Pediatric Dentistry.

Inclusion Criteria:

- Systemically healthy children

- Children aged between 6 to 8 years

- Children with no previous dental experience

- Children with a Children's Fear Survey Schedule (CFSS-DS) scale value of 35 and above

- Presence of carious lesions in primary molars on the mandibular quadrants that have recently passed from enamel to dentin and can be treated without the need for local anesthesia

- Children who voluntarily agree to work with parental consent

Exclusion Criteria:

- Children with any mental or physical disability

- Children with medication use

- Presence of essential oil allergy

Randomisation was performed by the researchers at the beginning of the study and children were randomly assigned to 3 groups via the "random.org" website, taking into account the order of application.

The CFSS-DS scale was used when the children came to the examination for the first time with the aim of identifying children with DFA (17). Fifteen questions on various aspects of dental treatment were directed to the child by a research assistant (research assistant responsible for the first examination who performs oral and dental examination of the child for the first time). The possible response to each item was scored from 1 (not afraid) to 5 (very afraid). Total scores ranged from 15 to 75 on this scale and 15 children who met the inclusion criteria and scored 35 and above were included in the study (Figure 1).
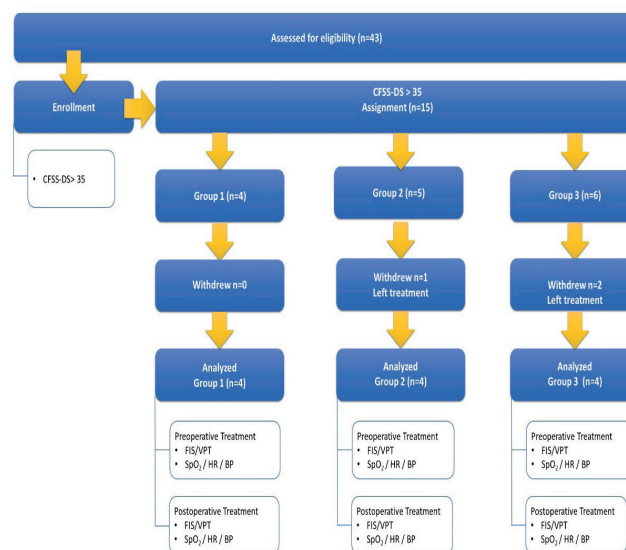
Figure 1. *Study diagram*

After the examination was completed, an appointment schedule was created for restorative treatments (superficial dentin caries). The assigned group information was delivered to the child and his/her parents in a closed envelope by the research assistant, taking into account the order of the child's application and the group assigned from the random.org website.

Group 1: Children were treated with the traditional behavioural guidance technique of tell-show-do behaviour management technique (Control).

Group 2: Four drops of "rescue remedy (clematis, star of Bethlehem, impatiens, cherry plum, rock rose)" diluted in 40 mL of water were given orally 15 minutes before the treatment (Bach flower remedy).

Group 3: After the children were given a headset, classical instrumental music (In the Enchanted Garden – Kevin Kern) was played during the planned dental treatment (passive distraction with music).

When the pediatric patients were admitted to the unit for treatment, their dental anxiety was determined with the projective self-report scales Facial Image Scale (FIS) and Venham's Picture Test (VPT) before and after treatment. With the FIS scale, children were shown a card with printed faces consisting of five faces ranging from very unhappy to very happy. They were asked to show which face they most resembled at that moment. The face with the most positive affect was given 1 point and the face with the most negative affect was given 5 points (18). The VPT scale, consisting of eight pairs of pictures of a child displaying each of the emotional states such as surprise, fear and anger in opposite ways, was shown to the children on the cards on which it was printed. The child was asked to choose one of the pair of pictures that best reflected how he/she felt at that moment, and if he/she chose the anxious picture from the pair of pictures, 1 point was given, and if he/she chose the non-anxious picture, 0 point was given. Thus, the score of the scale varied between 0-8 for each child (19).

For objective parameter measurement, vital signs of each child were evaluated before and after treatment. Heart rate (HR) and oxygen saturation (SpO_2) were recorded by pulse oximetry. Systolic blood pressures (SBP) and diastolic blood pressures (DBP) were determined using a stethoscope. All vital signs were documented by a research assistant (who do not know the intervention groups).

Treatments were carried out by a paediatric dentist with 9 years of experience (CBN) who opened the envelope before starting the treatment following projective self-report and objective measurements.

2.1. Statistical Analysis

Data analysis was performed using the IBM Statistical Package for the Social Sciences (SPSS for Windows, version 26.0, SPSS Inc., Chicago, IL, USA). Descriptive statistics, including frequencies and percentages for categorical data, as well as means and standard deviations for continuous data, were calculated. The normality of the data was assessed using the Shapiro-Wilk test. Participant characteristics were compared using Chi-square tests for categorical variables and one-way analysis of variance (ANOVA) for continuous variables. Paired samples t-tests and Wilcoxon tests were utilized to compare data before and after treatment within the group. One-way

ANOVA was employed to compare the differences in data before and after treatment between groups. A p values less than .05 was considered statistically significant.

3. RESULTS

A total of 12 children, 4 participants in each group, participated in the study (Figure 1). All demographic data of the participants are presented in Table 1. The mean age of the 12 children included in the study was 7.3 ± 0.8 years and there was no statistically significant difference between the groups (p>.05). When the genders of the participants were analysed, the number of females and males were equal in each group and no statistically significant difference was found (p>.05). When dental fear scores were analysed according to the CFSS-DS scale, the highest value was observed in Group 3 (39.8 ± 12.1) and the lowest value was observed in Group 1 (37 ± 14.7), but there was no statistically significant difference between them (p>.05).

Table 1. Characteristics of children included in the study

	Group			Test-statistics	p
	Group 1	Group 2	Group 3		
Age					
N (%)	4 (%33.3)	4 (%33.3)	4 (%33.3)	0.552	.594[1]
Mean ± sd	7.5 ± 0.7	6.9 ± 0.9	7.5 ± 0.9		
Gender					
Female	2 (50%)	2 (50%)	2 (50%)		1[2]
Male	2 (50%)	2 (50%)	2 (50%)		
CFSS-DS					
N (%)	4 (%33.3)	4 (%33.3)	4 (%33.3)	0.057	.945[1]
Mean ± sd	37 ± 14.7	37.5 ± 9.5	39.8 ± 12.1		
[1] *One-way ANOVA*					
[2] *Chi-square test*					
N: Number of the children, sd:Standart deviation, CFSS-DS: The Children's Fear Survey Schedule					
p<.05 statistically significant					

When intra-group comparisons before and after treatment were analysed, no statistically significant difference was observed in Group 1 and Group 3 when both vital signs (SpO_2, HR, SBP, DBP) and anxiety scales (FIS, VPT) were considered (p>.05). In group 2, HR decreased statistically significantly (p<.05), while no statistically significant difference was observed in other vital signs (SpO_2, SBP, DBP) and anxiety scales (FIS, VPT) (p>.05) (Table 2).

The comparison of the differences between the groups in vital signs (SpO2, HR, SBP, DBP) and anxiety scales (FIS, VPT) values before and after treatment is shown in Table 3. When the data obtained from the table are analysed, no statistically significant difference was observed between the groups (p>.05) when both vital signs (SpO2, HR, SBP, DBP) and anxiety scales (FIS, VPT) were considered before and after treatment.

Table 2. Evaluation of intra-group before and after treatment dental fear and anxiety measurements

		Before Treatment	After Treatment	ΔChange	r	t/Z	p
Group 1	SpO$_2$	92 ± 6.3	90 ± 3.8	2 ± 9.8	-0.888	0.407	.711[1]
	HR	100 ± 6.3	91.5 ± 10.6	8.5 ± 10.1	0.380	1.686	.190[1]
	SBP	99.5 ± 7.4	98.8 ± 21.5	0.8 ± 18.9	0.499	0.079	.942[1]
	DBP	61 ± 10.8	66.8 ± 22.9	-5.8 ± 12.4	-	-0.73	.465[2]
	FIS	2.5 ± 1.9	1 ± 0	1.5 ± 1.9	-	1.567	.215[1]
	VPT	2.5 ± 3.7	0 ± 0	2.5 ± 3.7	−	-1.633	.102[2]
Group 2	SpO$_2$	95.3 ± 6.4	92.3 ± 14.3	3 ± 8.3	0.967	0.724	.521[1]
	HR	97.8 ± 10.1	90.5 ± 8.8	7.3 ± 2.5	0.975	5.800	**.010[1]**
	SBP	103.3 ± 19.8	93.8 ± 17.3	9.5 ± 6.6	0.946	2.897	.063[1]
	DBP	75.8 ± 18.2	63 ± 3.9	12.8 ± 17.8	0.219	1.432	.247[1]
	FIS	3.5 ± 1.7	1 ± 0	2.5 ± 1.7	-	2.887	.063[1]
	VPT	3.5 ± 3.7	0.3 ± 0.5	3.3 ± 3.6	-	-1.604	.109[2]
Group 3	SpO$_2$	96.5 ± 3.1	98 ± 2.2	-1.5 ± 2.4	0.645	-1.260	.297[1]
	HR	91.3 ± 7.5	88 ± 7.1	3.3 ± 7.9	0.412	0.819	.473[1]
	SBP	99.8 ± 3.6	96.3 ± 5.9	3.5 ± 4.7	0.606	1.504	.230[1]
	DBP	69 ± 3.4	67.5 ± 5.1	1.5 ± 2.9	0.840	1.039	.375[1]
	FIS	2.5 ± 1.9	1 ± 0	1.5 ± 1.9	-	1.567	.215[1]
	VPT	3.5 ± 3.1	0.3 ± 0.5	3.3 ± 3.3	-	-1.841	.066[2]

[1]*Paired samples t test,*
[2]*Wilcoxon test,*

SpO$_2$: oxygen saturation; HR: heart rate, SBP: systolic blood pressure, DBP: diastolic blood pressure, FIS: Facial Image Scale, VPT: Venham's Picture Test
ΔChange: difference between before and after treatment, r: correlation coefficient, t/Z: Test statistics
p<.05 statistically significant

Table 3. Evaluation of the change in dental fear and anxiety measurements between groups

	ΔChange			F	p
	Group 1	Group 2	Group 3		
SpO$_2$	2 ± 9.8	3 ± 8.3	-1.5 ± 2.4	0.392	.687
HR	8.5 ± 10.1	7.3 ± 2.5	3.3 ± 7.9	0.528	.607
SBP	0.8 ± 18.9	9.5 ± 6.6	3.5 ± 4.7	0.570	.585
DBP	-5.8 ± 12.4	12.8 ± 17.8	1.5 ± 2.9	2.172	.170
FIS	1.5 ± 1.9	2.5 ± 1.7	1.5 ± 1.9	0.387	.690
VPT	2.5 ± 3.7	3.3 ± 3.6	3.3 ± 3.3	0.060	.942

One-way ANOVA
SpO$_2$: oxygen saturation; HR: heart rate, SBP: systolic blood pressure, DBP: diastolic blood pressure, FIS: Facial Image Scale, VPT: Venham's Picture Test
F: Test statistics
ΔChange: Evaluation of the change in dental fear and anxiety measurements between groups at baseline and after treatment
p<.05 statistically significant

4. DISCUSSION

Dentistry fear and anxiety in children may result in poor oral health, as well as negative effects on nutrition, sleep disturbance, delay in growth and development, and peer bullying due to the appearance of their teeth (1,4). Due to these results of DFA and the important role of the physician in its management, empirical studies have also been the subject of research, in addition to the increasing evidence of non-pharmacological behavior guidance techniques, in order

to manage this situation and create a positive treatment experience in children (13,16,20).

In this study, the effectiveness of distraction with music and the use of Bach flower remedy was evaluated in pediatric patients with DFA between the ages of 6-8. It has been reported that children at 4-8 years exhibit the most negative behaviors during dental procedures and are the most difficult to manage (21,22). However, considering that the mental status of 4-year-old children is different from 8-year-old children and that cognitive development is insufficient in terms of the reliability of subjective scales in young children under 6 years of age (7,21), the study was conducted on children in the 6-8 age group. In pediatric patients with DFA, a single session and a procedure without local anesthesia was preferred for all children in order to minimize the variables and the importance of performing a simple, painless procedure at the first appointment planned to help them get used to the dentistry environment (16). Considering that anxiety is a two-way psychological and physiological structure, that its physiological component is objectively measured by central nervous system activity, heart rate and respiration, and that measurement tools are used in its psychological component, objective and subjective measurement tools were used together in the evaluation of DFA in the study (4,23,24).

When considering the data obtained from the group in which passive distraction with music was applied in this study, no significant effect was observed although a decrease was observed in the objective-subjective values of DFA. These results are in contradiction with many studies examining the positive effects of distraction with music on anxiety in pediatric patients (4,23,25). In addition, study results showing that music is not an effective tool in reducing anxiety in pediatric patients consistent with the results of this study were presented. In their study examining the effect of listening to music on anxiety in children aged 4-6 in three groups, relaxing music, active music and a control group, Aitken et al. (26) showed that distraction with music did not have a significant effect on anxiety. Similarly, Gupta et al. (6) examined the effect of listening to music on anxiety in children aged 3-7 in three groups: control group, active music group and relaxing music group, and revealed that distraction with music did not have a significant effect on anxiety. When evaluating all these studies, consistent and contradictory with our study results, contradictory results may have been produced due to the number of samples used, patient pool and methodological differences (13,26). The results obtained with the music group in this study may be related to many issues. The limited number of samples, which is among the limitations of the study, may have been the first parameter that affected the result. Due to concerns about the Bach flower remedies in the empirical group of the study, the calculated but limited sample size was not increased. The main cause for concerns is the lack of insufficient data on the application method of the remedy in pediatric patients since the Bach flower remedies have been used in only one study in the literature and it is the first study conducted in the field of dentistry in our country. Secondly,

unlike Singh et al. (25), Jindal and Kaur (23), Janthasila et al. (4), the choice of music was not left to the patient's choice, which may have affected the results. Klein and Winkelstein (27) suggested that when the music selection is made by the child himself/herself, it will help the child gain control over an unpleasant situation. In addition, it has been demonstrated that classical music has a direct effect on the cardiovascular system and respiratory responses, thus acting as a calming and psychosomatic regulator and reducing the effects of sensory stimuli (12). Contrary to all these generalizations that can be made about music, reactions to music are individual and context-dependent; Variations depending on personality, experience, environment, age, taste and cultural background may have affected the study results (13). Finally, patient selection may have affected the results. In the light of current literature, it has been suggested that children's coping styles should be taken into account when using distraction tools. It has been reported that children can be considered in two main points as those who prefer to know what will happen during dental procedures and those who prefer to focus their attention elsewhere, and this issue should be addressed when choosing the behavior guidance technique (1). When all studies, including this study, were examined, this issue was not taken into account.

Considering the data obtained in the Bach group, although a decrease was observed in the subjective values of anxiety, no significant effect was obtained; however, significant difference was obtained in heart rate from vital signs. Since heart rate is a direct measure of physiological arousal and its increase has been associated with stress during dental treatment, these results may have provided important data for studying Bach flower remedies in larger sample groups. In the study of Dixit and Jasani (11), the only study in the literature that deals with Bach flowers on dental anxiety, discussed Bach flowers in three groups as music and control groups in their study and evaluated anxiety measurement tools as preoperative, intraoperative and postoperative. As in the study of Dixit and Jasani (11), rescue remedy from Bach flowers was preferred in this study. "Rescue Remedy", also known as "Five Flower Remedy" is the combination of star of Bethlehem (Ornithogalum umbellatum), rock rose (Helianthemum nummularium), impatiens (Impatiens glandulifera), cherry plum (Prunus cerasifera), and clematis (Clematis vitalba). It is the only combination of Bach flower remedies identified by Bach himself and has become the preferred choice as it is recommended as a multi-purpose emergency agent in cases of acute anxiety. Considering the results of the Bach group in the Dixit and Jasani study (11), no significant difference was obtained postoperatively in the anxiety self-report measurement tool FIS values compared to the control group. Among the objective measurement tools, only intraoperative significant difference was obtained in pulse rate values, but no significant difference was obtained in systolic blood pressure values. When the music group results were considered in the same study, no significant postoperative difference was observed in FIS values compared to the control group. Significant differences were

obtained only in intraoperative values of pulse rate values and systolic blood pressure values, which are objective measurement tools. When the results of Dixit and Jasani's study (11) and this study are considered together, as the authors we think that the effect of the use of Bach flowers and music is open to discussion. In this study, unlike Dixit and Jasani (11), intraoperative evaluation was not made using subjective-objective anxiety tools, but evaluation was made based on preoperative-postoperative data. This choice was influenced by the fact that the empathic language used between the physician and the patient during the treatment was not interrupted and the possibility that the continuous physiological measurement tools throughout the treatment could increase the patient's anxiety. In addition, as a negative consequence of this choice, children may not have been able to transfer the positive experience they had during the appointment to the post-treatment scales, as they were able to choose a score based on their experience in the last few minutes of the appointment instead of the entire session (26).

In addition to the group-specific conditions that may have affected the above-mentioned results, sufficient effect may not have been obtained from behavioral guidance techniques as the patient pool selected was children with DFA, unlike other studies. At the same time, unlike this study, homogeneity was not achieved in the study groups before treatment in many studies (16,23,25).

When the results of the study were evaluated, it was revealed that musical distraction and Bach flower remedies had no measurable effect on anxiety in children aged 6-8 years. In addition, although there was no significant effect was obtained on anxiety, the Bach flower remedy and passive distraction with music had a positive effect and has been received with pleasure. Contrary to the concerns about Bach flower remedies, parents easily accepted the rescue remedy in the hope that it would benefit their childrens's treatment anxiety. They were also very interested in the rescue remedy and wondered whether it would provide relief from everyday situations that cause anxiety for both them an and their children. Children said that listening to music and Bach flower remedies could be tried again at the next appointment.

When all the results are evaluated; we think that further research should be conducted and new strategies should be designed, taking into account children's coping styles, using higher sample numbers in different age groups, or using alternative behavior management techniques together.

This study has some limitations. The sample group consisted of a small number of child patients within a limited age range. Another limitation is that Bach flower remedies were used only once before the treatment, due to insufficient information in the literature about the anxiety treatment protocol.

5. CONCLUSION

In this study, we attempted to evaluate the use of Bach flowers and passive distraction with music. Although passive distraction with music and Bach flowers did not have a significant effect on physiological and projective measurement tools on children with DFA, the statistical decrease in heart rate in children subjected to Bach flowers should be considered as a result that should be interpreted correctly. There is a need to investigate non-pharmacological behavior guidance techniques in the management of DFA, which is an important issue in pediatric dentistry.

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Evaluation of Serum Cortisol Level, Hepatitis B and C Virus Infection and Elevated Aminotransferase Enzymes in a Group of Patients with Oral Lichen Planus

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ABSTRACT

Objective: Oral Lichen planus (OLP) is a common oral disease that can be caused by a variety of circumstances, including the hepatitis B and C virus (HCV). Stress, as a psychological component, raises cortisol levels, which is linked to a cytokine imbalance that may predispose to the development of autoimmune disorders. An association between OLP and serum cortisol levels has been also widely established. In this study, we aimed to evaluate the relationship of serum cortisol levels, hepatitis B/C virus infections and alanine transaminase (ALT), aspartate transaminase (AST) in patients with oral lichen planus and to compare to healthy controls.

Method: Forty adult patients with OLP and 40 age gender matched healthy controls were participated in the study. All patients were subjected to routine blood test and the estimation of serum cortisol levels, detection of anti-HCV antibody, hepatitis B surface antigen (HBsAg), alanine transaminase (ALT), aspartate transaminase (AST) by using the enzyme immunoassay. The data were statistically analyzed using Student-t, Mann-Whitney U, Chi-Square and Fischer's Exact test.

Results: Serum cortisol level of OLP patients was found to be 13.38±5.93, and that of the control group was 12.80±3.93. The OLP patients' ALT-AST levels were 19.91±10.66, 20.81±9.85, and those of the control group were 19.91±10.66, 20.81±9.85, respectively. There was no statistical difference of serum cortisol levels, hepatitis B/C virus infections and ALT-AST levels in OLP patient compared to the healthy control group (p>.05).

Conclusion: This study identified that there was no association between OLP and healthy controls regarding elevated serum cortisol levels, hepatitis B/C virus infection and aminotransferaze enzymes.
Keywords: Oral lichen planus, oral mucosal diseases, hepatitis, serum cortisol.

1. INTRODUCTION

Oral lichen planus (OLP) is a chronic inflammatory condition that primarily affects middle-aged and older female, with an estimated global incidence of 0.1-2%. The etiology is still unknown (1-6). The disease is classified as reticular/plaque, erythematous/erosive, or ulcerative, and a patient may exhibit many clinical forms (7). OLP is distinguished by a reticular white line pattern (Wickham striae), which occurs bilaterally and symmetrically. It is a condition that is often asymptomatic, and its frequency varies with age and is more prevalent in female than in male (7–10). Although the specific etiology is unknown, the lesions are thought to be the result of a T cell reaction to epithelial cells in response to a variety of stimuli, including psychological, viral factors and some diseases (7, 11,12).

Stress as a psychological factor causes an increase in cortisol levels and this alteration is associated with a cytokine imbalance that may predispose to the development of autoimmune diseases in which cytokines may play a role in its progression and etiology (13-17). Cortisol is the major glucocorticoid in humans and has a wide range of effects on metabolism, vascular reactivity, immune regulation, cognition and behavior (18,19). Salivary cortisol levels have been linked to psychological alterations in OLP patients, and cortisol has been identified as a biological marker of stress and anxiety (20, 21). However, the findings of the studies have been inconsistent. A further psychological condition that might raise cortisol levels is anxiety (22). It is known that in around 10–68% of instances, stressful events take place prior to the beginning of OLP. Furthermore, during times of stress,

symptoms may worsen or intensify (23-25). In situations like pain and anxiety, there are several metabolic and endocrine changes that take place. High anxiety has been employed as an indication in anxiety assessment studies since it can increase the production of cortisol, often known as the stress hormone (26-29). Numerous studies have looked at the association between OLP instances and salivary and serum cortisol levels (18,26,30).

Various completely unrelated conditions, including diabetes mellitus, lupus erythematosus, primary biliary cirrhosis, and chronic active hepatitis, have been linked to OLP (31,32). Hepadnaviruses include the Hepatitis B virus (HBV). Hepatitis B surface antigen (HBsAg)-positive people may have twice the chance of getting LP compared to HBsAg-negative patients, suggesting a possible link between LP and HBV infection. Furthermore, after receiving several HBV vaccinations, LP patients with lichenoid eruption have been shown to have anti-HBV antibodies (31-33).

In 1989, the single-stranded ribonucleic acid (RNA) virus known as Hepatitis C virus (HCV) was discovered (34). Since OLP was originally associated with HCV in 1991 (35), several studies have demonstrated a favorable correlation between OLP and HCV infection; in fact, some have even suggested that OLP patients should be screened for HCV (36-39). Lichen planus has been connected to the hepatitis C virus (HCV), particularly when the oral cavity is affected and it is a condition that affects 20% of people with C hepatitis (37,40,41). OLP patients with liver illness associated to HCV had a worse quality of life, according to a few publications (18,30). Several studies in the literature have examined the relationship between OLP and chronic liver disease (42-46).

Liver disease is diagnosed by measuring the levels of aspartate aminotransferase (AST) and alanine aminotransferase (ALT) (47,48). Studies investigating the association between OLP and liver disease have also searched for ALT and AST levels (36,47,48). They claimed that more information is needed to understand the association between OLP exacerbations (48). The relationship between OLP, the etiology of which is not clearly known, and chronic liver diseases, is still uncertain and controversial.

Therefore, the aim of this study was to compare the serum cortisol levels, prevalence of Hepatitis B, C and hepatic amino transferase levels of individuals with OLP with the control group.

2. METHODS

A total of 40 individuals between the ages of 18 and 75, who applied to Marmara University, Faculty of Dentistry, Department of Oral and Maxillofacial Radiology were included in the study as a patient group, who were diagnosed with "OLP" as a result of clinical and histopathological evaluation in accordance with the WHO criteria updated by the American Academy of Oral and Maxillofacial Pathology in 2016 and who had not undergone any treatment related to this diagnosis (Figure 1a,b; Figure 2a,b,c). The study protocol was approved

by the Ethics Committee of Marmara University, Faculty of Medicine with protocol number 09.2022.999. Biopsies were obtained from all patients with a preliminary diagnosis of OLP, and the diagnosis was confirmed.
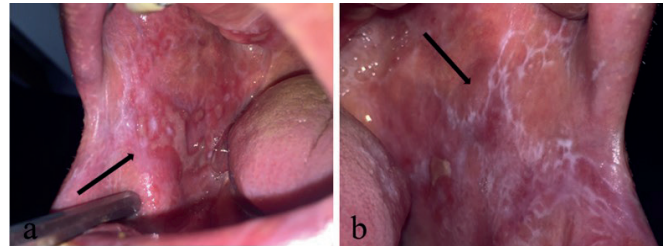
Figure 1a,b. *Widespread erosive and reticular lesion involvement on bilateral buccal mucosa*
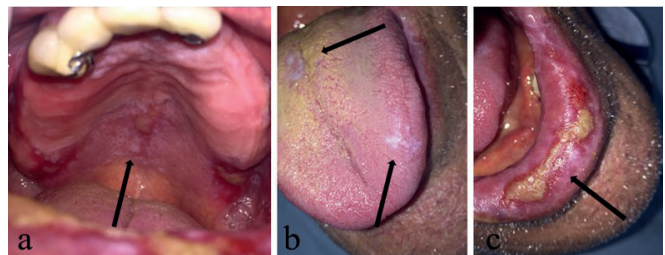
Figure 2a, b, c. a. *Reticular type lesions in the palatal mucosa b. Reticular type lesions on the dorsum of the tongue c. Fibrin-coated areas on the severe erosive type lesions on the lower lip mucosa (Note all images belong to an HBsAg positive male patient)*

As a result of the Power analysis performed using the G*Power programme to determine the sample size, when the effect size d (effect size): 0.956 and SD: 11.86 were taken, the minimum sample size for Power: 0.80 and α: 0.05 was determined as n=19 for each group.

Forty age-gender matched individuals who agreed to participate in the study, who had applied to our clinic for any reason, who did not have any mucosal changes (hyperkeratinisation, erythema, ulceration, erosion, atrophy, etc.) and related complaints in the oral mucosa during or before the intraoral examination, and who did not have any autoimmune disease were evaluated as a healthy control group. Routine hematological values of all patients who agreed to participate in the study were examined and serum cortisol level, hepatitis B/C markers and ALT-AST were noted just before the biopsy procedure.

2.1. Statistical Analysis

While evaluating the study's findings, statistical analyses were performed using the IBM SPSS Statistics 22 software. The Kolmogorov-Smirnov test was used to determine if the parameters were suitable for normal distributions. In addition to descriptive statistical methods (minimum, maximum, mean, standard deviation, median, and frequency), the Student t test was used for comparisons between two groups of parameters with normal distribution, and the

Mann Whitney U test was used for comparisons between two groups of parameters without normal distribution. The qualitative data was compared using the chi-square test, Fisher's exact test, and continuity (Yates) correction. Significance was determined at p<.05 level.

3. RESULTS

The study was conducted with a total of 80 patients, 22 (27.5%) males and 58 (72.5%) females, aged between 33 and 80 years. The mean age was 59.32±11.37 years. The cases were evaluated in two groups of 40 patients each as "Case" and "Control" groups. In our study, no statistically significant difference was found between the groups in terms of cortisol levels (Table 1) (p>.05).

Table 1. *Evaluation of groups in terms of cortisol levels*

	Cortisol level	
	Mean±SD	p
Case(n=40)	13.38±5.93	.657
Control (n=40)	12.80±3.93	

Student t Test

HBsAg was positive in 2.7% of the case group and 12.9% of the control group, with no statistically significant difference (p>.05) (Table 2). Anti-HBs was positive in 35.1% of the case group and 35.5% of the control group, with no statistically significant difference (p>.05). Moreover, Anti-HBC IgG was positive in 16.2% of the case group and 12.9% of the control group, with no statistically significant difference (p>.05). Both groups were not positive for anti-HBC IgM or anti-HCV (Table 2).

Table 2. *Evaluation of groups in terms of Hepatitis markers*

	Case (n=37)	Control (n=31)	
	n (%)	n (%)	p
HBsAg	1 (2.7%)	4 (12.9%)	[1] .170
Anti – HBs	13 (35.1%)	11 (35.5%)	[2] .000
Anti-HBC IgG	6 (16.2%)	4 (12.9%)	[1] .745
Anti-HBC IgM	0 (0%)	0 (0%)	-
Anti-HCV	0 (0%)	0 (0%)	-

[1] *Fisher's Exact Test* [2] *Continuity (yates) correction*

There was no statistically significant difference between the groups in terms of AST and ALT levels (p>.05) (Table 3).

Table 3. *Evaluation of groups in terms of AST and ALT levels*

	Case (n=40)	Control (n=40)	
	Mean±SD (median)	Mean±SD (median)	p
ALT (SGPT)	19.91±10.66 (16.3)	18.85±10.57 (18)	.592
AST (SGOT)	20.81±9.85 (19)	20.60±6.67 (18.5)	.924

Mann Whitney U Test

4. DISCUSSION

The etiology of OLP, which mostly affects adults and has a worldwide distribution, is not known for certain (1-3,49). Various studies have indicated that stress and psychological situations (especially depression and anxiety) and liver diseases are among the important etiological factors, but their role in the pathogenesis of the disease is controversial (26,27).

Cortisol is one of the most important glucocorticoids in humans, influencing metabolism, vascular reactivity, immunological control, cognition, and behavior (18,19). In literature, cortisol levels were evaluated in serum, saliva and urine samples of OLP patients and healthy control groups (6,26,30). Chaitanya et al. (26) evaluated the serum cortisol levels of 30 symptomatic OLP cases and 30 healthy control groups without a history of depression and anxiety by chemiluminescent method in the morning hours (08:00-09:00). They found that OLP cases had higher serum cortisol levels than the healthy control group. Moreover, Nadendla et al. (30) aimed to analyze salivary cortisol levels in 20 OLP cases and the twenty age-gender matched healthy control groups and collected samples in the morning hours (09.00:09.15) to prevent daily variations. They found that salivary cortisol level was significantly increased compared to the control group. Lopez-Jornet et al. (18) examined the salivary cortisol levels of 33 OLP cases in comparison with 32 healthy control groups and reported higher cortisol levels in OLP cases compared to the healthy control group.

Koray et al. (12) investigated anxiety and salivary cortisol levels in their study involving 40 OLP cases and 40 control groups. Saliva samples were collected in the morning hours (09.00-09:15). They found that salivary cortisol, state and trait anxiety levels were significantly higher in the OLP group than in the control group. Researchers have stated that psychological support may be beneficial in addition to treatments in cases of OLP.

Despite these studies, there are studies reporting that there is no significant change in cortisol levels in serum and saliva samples (6,21). Pekiner et al. (6) measured blood cortisol levels in 30 OLP patients and 30 control groups and found no statistically significant differences between the groups. In addition, Girardi et al. (21) showed no statistically significant difference in salivary cortisol levels between 31 OLP patients and 31 age and sex-matched controls. Similarly, our research discovered no significant differences between the groups.

Therefore, the findings from studies investigating blood cortisol levels in OLP patients are debatable. The data provided in the cortisol level comparison may be influenced by patient selection, disease type, collection time of the samples and analyzed bodily fluid cortisol levels. Different methods utilized in various research may explain varied outcomes.

It has been reported in literature studies that the risk of developing LP is increased in HBsAg-positive patients compared to HBsAg-negative patients, and that anti-HBV

antibodies are seen in LP patients who develop lichenoid lesions after different HBV vaccines (33). Tozun et al. (50) investigated the seroprevalence of hepatitis B/C in urban and rural areas in the Turkish population in 5460 individuals. Researchers found the prevalence of HBV in the Turkish population as 4% in their study and stated that it may vary according to regions, for example, this rate was 3.8% in the Marmara region. In our study, in parallel with Tozun et al., 3.4% of the individuals who participated in the study were found to be HbsAg positive and the rate was 2.7% in the patient group. The authors also reported that there was no significant relationship between OLP and hepatitis B infection. Moreover, Anti-HBV antibodies have been reported in OLP patients with lichenoid eruption after receiving several HBV vaccinations (33).

After the identification of hepatitis C virus (HCV), the most important cause of chronic liver disease, the association of OLP with hepatitis C has been reported in various studies (42-44, 46-48). It has been reported that the prevalence of chronic hepatitis C in patients with OLP may vary between 0.5-35% according to different geographical regions (45).

Ali and Suresh (47) evaluated Anti HCV, ALT and AST values in 40 OLP patients and 40 healthy control groups with routine hematological test and found higher ALT-AST ratios in OLP cases, while anti-HCV value was negative in all individuals participating in the study. Geraylı et al. (46) evaluated liver function tests and HCV infection in 134 OLP patients and 134 healthy control subjects and found that ALT-AST levels were higher in the healthy control group compared to the study group. While 2.23% of OLP patients were anti-HCV and HCV-RNA positive, none of the individuals in the control group were positive and no statistically significant difference was found. In our study, no statistically significant difference was found between ALT-AST and hepatitis B and C values in the patient and control groups.

It should be highlighted that our findings are based on a small but statistically significant cohort, as determined by the power analysis, and should be validated by a larger multicenter investigation in Türkiye. Given our study's prevalence, future research should alter sample size calculations accordingly.

5. CONCLUSION

This study could not find a correlation between OLP and serum cortisol levels, aminotransferaze enzymes and hepatitis B/C virus infection in a group of patients. This might be due to a decreased incidence of hepatitis viruses in comparison to countries with high endemicity, genotypic variation of the viruses, or other etiological variables affecting the current patient population. To get more accurate results, future research should use a larger sample size.

Author Contributions: (Initials only)
Research idea: FNP
Design of the study: FNP, HY
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Analysis of data for the study: HY
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Morphometric Evaluation of the Maxillary Arch Using Cone Beam Computed Tomography

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ABSTRACT

Objective: Anatomically, a dental arch is a result of natural teeth being positioned on the alveolar bone. The purpose of this study is to assess the morphological characteristics of various maxillary arch types using Cone Beam Computed Tomography (CBCT) and ascertain their prevalence.

Methods: This retrospective study analyzed 200 randomly selected maxillary CBCT images from patients aged 18–65. Measurements were interpreted using various planes, and maxillary arch forms were classified according to the House dental arch classification in the axial region of the CBCT images.

Results: Patients over 45 years old had significantly higher mean canine-palate and first molar-palate measurements compared to younger groups, particularly the 18–25 age group, which showed a higher hard palate–anterior mean than the 25–35 group. Class II cases had a significantly higher mean canine-palate than Class I and III cases. Class II cases also exhibited higher first molar-palate and canine-anterior means compared to Class I and III. In contrast, Class I cases had a higher canine-canine mean than the other classes.

Conclusion: Morphologic measurements are crucial for guiding specialists in diagnosis and treatment, enhancing the ease and accuracy of clinical practice.

Keywords: Maxillary arch dimension, morphometric analysis, CBCT

1. INTRODUCTION

Children's primary dentition should be as close to ideal as achievable for the permanent dentition to function properly and for the children to have normal dental traits in adulthood, such as normal mastication and appearance, space, and occlusion. Human behavior and self-esteem are strongly influenced by one's physical appearance, and dental health issues such as tooth loss, gum disease, malocclusions, and dental caries require early intervention and treatment to ensure a normal permanent dentition in later life (1,2). The maintenance of the canine, incisor, and molar teeth during childhood is important for the formation of the space and occlusion features during permanent dentition. Additionally, emphasizes the significance of the arch dimensions in maintaining a balanced facial profile, stabilizing the form, preventing arch crowding, and correctly aligning teeth. Arch size has been seen to be more important than even teeth size (3,4).

The human dental arch has been mathematically modeled many times, although terminology like elliptic, parabolic, and so forth were initially used to characterize the dental arch. The length, width, and depth of the dental arch were traditionally used to measure the arch's curve. Several specialists have measured angles, linear distances, and ratios using biometry to determine the dental arch's curvature (5,6).

Cone Beam Computed Tomography (CBCT) for measuring the dimensions of the arch and teeth; allows fast, reliable, exact, and remeasurable measurement. Measurements made in CBCT overlap with measurements made on 2D models obtained by digital methods (7). Hand rulers, drawings various scales, etc. in the measurement of tooth and arch length through working models and measurements are used (8).

Technological developments enable the acquisition of 3D images, enabling more accurate analyses along with exact and reliable measurements (8,9). In addition, with 3D models, more models can be stored at less cost and allow analysis with advanced computer programs. 3D models obtained with CBCT are used in many dentistry fields such as orthodontics, prosthesis, implantology, and oral diagnosis (10,11). Although

there are studies that evaluated the measurement of the maxillary arch on plaster models obtained from patients, since these measurements may vary according to both the materials used and the patient's soft tissue thickness, evaluation of hard tissue with CBCT images can provide a more thorough examination of the maxillary arch and its morphologies and provides better information (6).

CBCT is frequently used in the evaluation of hard tissues in the head and neck region since it provides 2 and 3-dimensional imaging by minimizing superpositions (9). Jayasinghe et al. published a study in which they evaluated the maxillary arch shapes and measurements in CBCT sections of 106 patients, they found oval shape at a rate of 64% and statistically, the measurements were found to be higher in male individuals (6).

The purpose of this retrospective study is to assess the morphometric properties of the maxillary arch forms and ascertain the frequency of these forms in individuals whose maxilla have CBCT images in our archive. Previous research using cast models have been published in the literature. Using study casts, Arambawatta et al.'s study evaluated the arch shapes (7). There are issues when study casts are used to estimate the dimensions, even if this is permissible to determine the arch shape. The accuracy and dimensional stability of the resulting cast would depend on the characteristics of both the cast and impression materials. Furthermore, the exact proportions of the underlying skeletal shape may not be shown by the morphology of the gingival tissue. Therefore, it is possible to hypothesize that CBCT measurements, as opposed to those made using study casts, would show the skeleton dimensions with more accuracy. To the best of our knowledge, this is Türkiye's first study on the morphometric assessment of the maxillary arch using CBCT.

2. METHODS

2.1. Patient Selection

In this study, the study group included in the clinical archive, who applied to Marmara University Faculty of Dentistry, Department of Oral, Dental and Maxillofacial Radiology, over 18 years of age, had no developmental anomaly, did not use orthodontic treatment, did not use drugs affecting the bone, did not have tooth loss in the maxilla (except for wisdom teeth). An a priori power analysis was performed using G*Power 3.1 software to determine the necessary sample size for detecting a medium effect size (d = 0.5) with a power of 0.95 and an alpha level of 0.05. The analysis indicated that a minimum of 128 participants (64 per group) would be required. Our study, with a total sample size of 200 participants (100 males and 100 females), exceeds this requirement, ensuring adequate power to detect significant differences between the groups. Ethics committee approval was obtained from the Marmara University School of Medicine Clinical Research Ethics Committee (Approval number: 2023.677 / 05.05.2023).

2.2. Radiographic Examination

Radiographic examination was made using CBCT (Planmeca Promax 3D Mid (Planmeca Oy, Helsinki, Finland, 2012), and images taken from the study group patients evaluated in axial, sagittal, and coronal sections. Maxillary arch shapes were grouped using House dental arch classification in the axial section over CBCT images of the patients participating in the study (Figure 1). Morphometric analyses on the sections performed as shown in the examples (Figure 2). To guarantee a professional and efficient evaluation, clinical images were assessed by clinicians and specialists from the Department of Oral Diagnosis and Radiology. In preparation for the pilot study, these clinicians and radiology specialists received training in tomographic image evaluation from an expert with over 20 years of experience in oral diagnosis and radiology. An agreement on the objective criteria for the qualitative evaluation of the images was forged among the evaluators.During this process, the evaluators collectively established objective criteria for the qualitative assessment of the images. In preparation for the pilot study, these clinicians and radiology specialists received training for image evaluation. Standardization was achieved with these trained individuals, and quality control was overseen by an expert with over 20 years of experience in oral diagnosis and radiology. An agreement on the objective criteria for the qualitative evaluation of the images was forged among the evaluators.
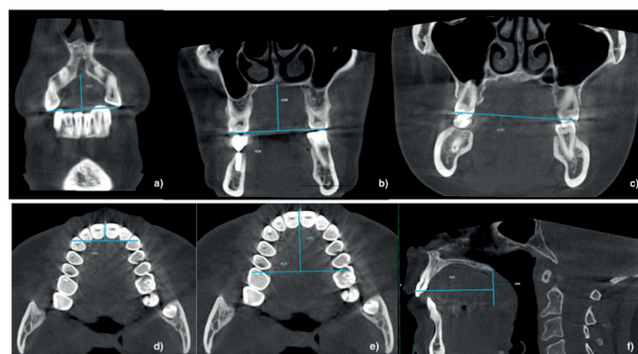
Figure 1. *House dental arch classification (House MM. Full denture technique. Whittier, Calif.: Private printing, 1937).*

2.3. Statistical Analysis

The IBM SPSS Statistics 22 application was utilized for statistical analysis in assessing the study's results. The Kolmogorov-Smirnov test was used to assess the parameters' eligibility for the normal distribution, and the results showed that they were appropriate. In addition to descriptive statistical methods (mean, standard deviation, frequency) for analyzing the study data, Oneway Anova test was used to compare parameters between age groups and maxillary shapes; Tukey HDS test was applied if the group variances were homogeneous; and Tamhane's T2 test was employed to identify the group responsible for the difference in the quantitative data. The parameters were compared between

the genders using the student's t-test. The significance level was set at p< .05.
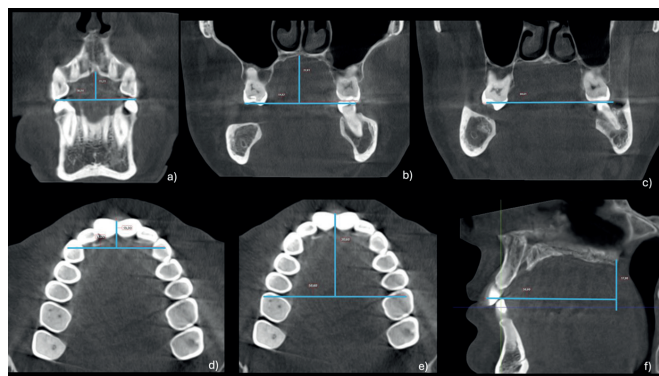
Figure 2. *a)The distance between the incisal edges of the canines and the distance between the incisal edges of the canines to the hard palate (coronal); b)The distance between the mesiobuccal cusp crests of the 1st molars and the distance between the mesiobuccal cusp crests of the 1st molars and the distance to the hard palate (coronal); c)The distance between the mesiobuccal cusp crests of the 2nd molars (coronal); d)The distance from the incisal edges of the canines to the vestibule of the central teeth (axial); e)The distance between the mesiobuccal cusp crests of the 1st molars to the vestibule of the central teeth (axial), f) Distance of posterior nasal spine from line of occlusion and the distance from the most vestibule point of the centrals perpendicular to the line connecting the posterior nasal spina and the occlusion line (sagittal).*

3. RESULTS

The study group consists of a total of 200 cases, 100 female and 100 male between the ages of 18-65. The mean age is 30.02±11.01 years. According to the arch classification of the study group, 37% is class I, 12.5% is class II, 50.5% is class III. (Table1).

The age ranges of 18-25, 25-35, 35-45, and 45-65 for our study to analyze differences between young adulthood and subsequent decades. Additionally, we combined the 45-65 age range into a single category due to the more minimal changes typically observed in this period compared to the more distinct variations seen in younger decades.

Table 1. *Demographic characteristics*

		n	%
Age	18-25	86	43
	25-35	52	26
	35-45	41	20.5
	45-65	21	10.5
Gender	Female	100	50
	Male	100	50
Arch Type	Class I	74	37
	Class II	25	12.5
	Class III	101	50.5

The minimum, maximum and average values of the morphometric measurements obtained, as well as their standard deviations, were found as follows (Table 2).

Table 2. *Morphometric measurements of all patients*

Localization	N	Minimum	Maximum	Mean	Sd
Canine-Canine	200	26.8	44.0	35.73	2.95
Canine-palatinal	200	5.8	16.8	10.54	2.23
1. molar	200	42.0	67.2	54.32	3.54
1. molar-palatinal	200	16.2	56.6	21.95	4.31
2. molar	200	45.2	72.4	59.37	3.74
Canine-anterior	200	6.0	13.4	9.63	1.45
1. molar – anterior	200	24.0	36.2	28.88	2.21
Occlusion-palatinal	200	13.4	34.0	21.35	3.61
Hard palate-anterior	200	45.8	66.2	55.89	4.01

Sd, Standard deviation

It was observed that cases over the age of 45 had a statistically significant difference from the 25-45 age group when evaluated in terms of canine-palatal distance (p<0.05), and from all age groups when evaluated in terms of 1st molar and 2nd molar distances, respectively (p<0.05) (Table 3). The 1st molar-anterior and the hard palate-anterior among 18-25 years, canine-palatal among cases over the age of 45 are significantly higher than the other age groups (p< .05). There is no statistically significant difference between the age groups in terms of canine-canine, first molar-palatinal, canine-anterior and occlusion-palatinal averages (Table 3).

Table 3. *Evaluation of morphometric measurements by age groups*

	18-25 (n=86)	25-35 (n=52)	35-45 (n=41)	45-65 (n=21)	
	Med±Sd	Med±Sd	Med±Sd	Med±Sd	p
Canine – canine	35.88±3.2	35.7±2.59	35.04±2.93	36.54±2.69	.252
Canine- palatinal	10.05±2.16	10.55±2.21	11.03±2.34	11.56±1.95	.014*
1. molar	54.01±3.45	54.25±3.4	53.91±3.19	56.58±4.22	.020*
1. molar- palatinal	21.23±2.46	22±5.46	23.07±5.71	22.56±3.59	.132
2. molar	59.1±3.93	59.14±3.4	59.07±3.43	61.66±3.8	.031*
Canine- anterior	9.84±1.52	9.29±1.4	9.66±1.55	9.57±1.05	.205
1. molar – anterior	29.55±2.43	28.37±2.03	28.24±2.03	28.68±1.14	.002*
Occlusion- palatinal	21.01±3.55	22.1±3.34	21.14±3.67	21.26±4.38	.375
Hard palate- anterior	56.71±4.21	54.88±3.69	55.31±4.18	56.14±301	.049*

Oneway ANOVA Test   *p< .05
Med, Median; Sd, Standard deviation

The canine-canine averages of Class I cases are significantly higher than those of Class II (p<.01) and Class III (p<.05) groups. (p< .05) (Table 4) First molar-Palatal and Canine-Anterior values' averages of Class II cases are significantly higher than those of Class I (p= .005; p= .001) and Class III (p= .016; p= .001) respectively.

The canine-palatal mean values of Class II cases are significantly higher than those of Class I (p<.01) and Class III (p<.05) groups (p< .05). The canine-palatal mean values of Class III cases are significantly higher than those of the Class I group (p= .003; p< .05).

There is no statistically significant difference between the maxilla shapes in terms of the averages of 1st molar, 2nd molar, 1st molar-anterior, occlusion-palatinal and hard palate-anterior. There is no statistically significant difference between the maxilla shapes in terms of 1.molar, 2.molar, 1.molar-anterior, occlusion-palatinal and hard palate-anterior averages (Table 4).

Table 4. Evaluation of morphometric measurements according to the shape of the maxilla

	Class I (n=37)	Class II (n=25)	Class III (n=101)	
	Med±Sd	Med±Sd	Med±Sd	p
Canine-Canine	36.63±2.33	34.31±3.21	35.43±3.12	.001*
Canine-palatinal	9.71±2.00	12.00±2.16	10.78±2.19	.001*
1. molar	54.55±3.51	52.82±3.52	54.53±3.50	.075
1. molar-palatinal	21.32±4.89	24.43±6.4	21.79±2.80	.006*
2. molar	58.96±3.57	59.44±4.76	59.66±3.59	.470
Canine-anterior	9.36±1.36	10.77±1.35	9.55±1.43	.001*
1. molar – anterior	28.93±1.98	29.73±2.11	28.64±2.36	.088
Occlusion-palatinal	20.77±3.14	21.44±3.58	21.75±3.92	.205
Hard palate-anterior	56.53±3.99	55.15±3.4	55.60±4.14	.194

*Oneway ANOVA Test *p< .0*
Med, Median; Sd, Standard deviation

All measured distances are significantly greater in males compared to females. For example, measurements such as the distance between canine teeth, the 1st molar distance, and the hard palate to anterior distance are consistently higher in males. This pattern suggests that males generally have larger dental structures compared to females across all examined parameters.All morphometric measurements of male were statistically significantly higher than female (p< .05) (Table 5).

Table 5. Evaluation of morphometric measurements by gender

	Male (n=100)	Female (n=100)	
	Med±Sd	Med±Sd	p
Canine-Canine	36.44±2.64	35.02±3.09	.001*
Canine-palatinal	11.18±2.01	9.90±2.27	.001*
1. molar	55.31±3.66	53.34±3.13	.001*
1. molar-palatinal	22.66±3.01	21.23±5.22	.018*
2. molar	60.51±3.70	58.24±3.44	.001*
Canine-anterior	9.91±1.42	9.35±1.45	.006*
1. molar – anterior	29.23±2.32	28.54±2.05	.026*
Occlusion-palatinal	22.89±3.87	19.81±2.56	.001*
Hard Palate-anterior	57.25±3.92	54.53±3.65	.001*

*Student t Test   *p<.05*
Med, Median; Sd, Standard deviation

4. DISCUSSION

Numerous dental disciplines, including prosthodontics, orthodontics, the design of sports-related protective oral devices, forensic dentistry, and implant dentistry, depend on an accurate assessment of maxillary arch proportions (6,11).

The ability to provide an effective complete denture in prosthodontics significantly depends on the proportions of the maxillary arch before tooth loss. This is crucial in order for the denture to complement the patient's face structure and look, from the choice of impression trays to its construction. The maxillary arch dimension, which may vary depending on the population and other circumstances, is very important when choosing imprint trays and keeping track of the inventory of trays (10,12).

Stock trays can be difficult to adapt and modify frequently, and if they were, especially the metal trays, they would become useless (10).

The average arch length and width in a study of young Korean adults were 44.13 mm and 64.12 mm, respectively. The ovoid morphology was determined to be the dominating form. The arch length in the current study, however, was 62.71 mm for male and 45.88 mm for female, which is significantly different from the Korean population (13). The Sri Lankan study revealed that the width is greater compared to the Korean population even when the width at the 2nd molar region is compared (7). The recent research showed bigger dimensions, even when contrasted with a study conducted on Saudi Arabian individuals. According to the current study, there are clear disparities between the genders in arch length and width at all locations of measurement (15). This would indicate that these gender and ethnic disparities should be taken into account when producing or ordering stock imprint trays in order to choose the proper sizes.

Additionally, arch dimensions are crucial for establishing orthodontic tooth movement and determining the durability of the aligned dentition after treatment. When evaluating the arch type, the most common shape was ovoid, which was typical of the populations in Korea and Saudi Arabia. Orthodontic planning and final results are greatly influenced by arch size. Arch wires are made with the width, length, and form of the arch in mind (16).

Therefore, orthodontic components like arch wires and other inter maxillary devices need to be modified depending on the study population and the changes in the maxillary arch's proportions. The gender differences in arch length and intermolar width were found to be substantial in this study, indicating the need for careful selection of these devices. Additionally, these findings would be helpful in deciding the upper and lower bounds of the therapy outcomes as well as the viability of such techniques when arch growth is envisaged (17,18).

Mouthguards and other sports-related protective equipment are frequently suggested. In sports stores, the majority of these items are readily available off the shelf. The prevalence

of the various arch forms, including oval, U, and V shapes, as well as the length and width, must be carefully considered while planning the inventory of these goods. Additionally, as was already said, consideration needs to be given to the significant gender variances of these factors (19,20).

The results of this study will assist define the norms of the Turkish population in terms of maxillary dimensions, and such information will also be extremely helpful in forensic dentistry for estimating the approximate race of forensic material in unidentified remains. Due to the fact that there are gender variations, this would help identify the gender and facilitate forensic reproduction (21,22).

The preferred approach to restoring missing teeth is implant dentistry. When choosing the size and length of implants, consideration should be given to the height and width of the arch. Therefore, it is important to choose and plan for the proper implant lengths when placing teeth, especially when performing immediate implants, to achieve the best results. When planning implant stock inventories, this can also be a relevant factor (23).

According to Kook et al., the average number of intercanine distances was 30 mm for White people and 32 mm for Korean people. The mean intercanine distance was determined to be 35 mm in our study. Following molar distance evaluation, the mean measures for White individuals were 52.2 mm, the mean for Korean individuals was 52.6 mm, and the mean for Turkish individuals was 54.3 mm (24). The literature on morphometric analyses using CBCT is relatively limited. Our study on a group of the Turkish population could serve as a foundational reference for future research in this area. However, to draw more comprehensive and generalizable conclusions, it is essential to include a broader and more diverse patient population in subsequent studies. Future research should consider including different demographic and ethnic groups, which would help expand the literature on CBCT morphometric analyses and lead to more robust findings.

5. CONCLUSION

Morphologic measures are critical for directing professionals through diagnosis and therapy, making clinical practice more efficient and accurate.There are notable variations in the maxillary arch based on gender and age. We found that in our study there were statistically significant difference between three classes among age groups and gender. With the data acquired, the Turkish population should review and reexamine the criteria that can be created based on patient needs in areas like forensic medicine, prosthetics, and orthodontics.

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Phenotypic and Genotypic Investigation of the Resistance of Pathogenic *Bacteroides fragilis* Group Bacteria to Carbapenems

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ABSTRACT

Objective: *Bacteroides fragilis*, predominantly found in the intestinal microbiota, is one of the most frequently encountered anaerobic pathogens and exhibits resistance to many antimicrobials. The carbapenem-resistant *B. fragilis* (CR-BF) isolates have been reported in several countries recently with increasing global attention. The high frequency of CR-BF in our hospitalized patients has become an important problem. For this reason, *B. fragilis* isolated in our hospital need to be closely monitored for carbapenem resistance. Therefore, we aimed to determine carbapenem resistance in *B. fragilis* isolated from clinical samples and the presence of the *cfiA* gene, which encodes for carbapenemase.

Methods: *B. fragilis* strains isolated from various clinical samples collected between January 2018 and December 2022 were included in the study. Identification of the isolates was performed using MALDI-TOF MS. The susceptibility testing for meropenem and imipenem was determined by the agar dilution method. The *cfiA* gene was detected by PCR.

Results: A total 89 *B. fragilis* strains were studied, mostly from intra-abdominal abscesses (31%) and blood cultures (27%). Susceptibility rates for meropenem and imipenem were 85.4% and 89%, respectively. Notably, 12 out of 13 *cfiA* gene-positive isolates were resistant, suggesting this gene as a marker for carbapenem resistance. However, resistance in one *cfiA*-negative isolates implies alternative resistance mechanisms.

Conclusion: Routine anaerobic culture, determination of antibiotic susceptibility profiles of isolates, and close monitoring are crucial for managing infections. Regular antimicrobial susceptibility testing helps predict the risk of developing carbapenem resistance, assists clinicians in selecting appropriate antibiotics for empirical therapy, and improves treatment success rates.

Keywords: *Bacteroides fragilis*, carbapenem, *cfiA* gene

1. INTRODUCTION

Bacteroides, a genus of gram-negative, obligate anaerobic bacteria, are important members of the intestinal microbiota. *Bacteroides fragilis* is the most clinically significant species due to its virulence factors and antimicrobial resistance. While a normal resident of the colon, *B. fragilis* can also opportunistically cause serious mixed infections. Typically, this bacterium can spread during intra-abdominal surgery, abdominal trauma, intestinal perforation, or in immunocompromised individuals, leading to serious and potentially life-threatening infections (1).

Bacteroides fragilis species is one of the most resistant anaerobic bacteria. This speces is only susceptible to a few antibiotics, such as beta-lactam/beta-lactamase inhibitors, carbapenems, and metronidazole. However, recent studies show increasing resistance to even these antibiotics (2,3).

Bacteroides fragilis species employs various mechanisms to resist carbapenems. The most common mechanism involves an enzyme called a carbapenemase, encoded by the *cfiA* gene integrated into the bacterial DNA. This enzyme, a metallo-beta-lactamase containing zinc (Zn+2) in its active site, breaks down carbapenems. Metallo-beta-lactamases are not inhibited by classical beta-lactamase inhibitors, but are inactivated by the presence of ethylenediaminetetraacetic acid (EDTA) (4). Interestingly, the cfiA gene can be present silently in B.fragilis bacteria, meaning it doesn't produce the enzyme yet. This silent gene can be activated by a mobile DNA element (insertion sequence: IS element) that inserts itself in front of *cfiA* gene, triggering enzyme production (5,6).

Studies worldwide report that 2-7% of *B. fragilis* isolates carry the *cfiA* gene, but only about 1% are truly carbapenem-resistant. The reported resistance rates for imipenem and meropenem vary geographically: 0.2-1% in the US, Canada, and Europe, 2-4% in Japan, 7-12% in Taiwan and 18.2-29.5% in China (3,7,8). The high incidence of carbapenem-resistant *B. fragilis*

(CR-BF), isolated from our hospitalized patients, has become an important problem. The first imipenem-resistant *B. fragilis* strain was isolated at Marmara University Hospital's laboratory in 1999 (9). Over the past decade, our carbapenem resistance rate climbed to 8%. Alarmingly, molecular studies revealed that 27% of our isolates carried the *cfiA* gene (10,11).

In this study, we aimed to determine carbapenem resistance in *B. fragilis* isolated from clinical samples and the presence of the *cfiA* gene, which encodes for **carbapenemase.**

2. METHODS

In this study, *B. fragilis* strains isolated from clinical materials in a 650-bed tertiary university hospital were studied.

2.1. Bacterial Isolates

A total of 89 non-duplicate *B. fragilis* strains isolated from various clinical samples collected from different clinics; general surgery (36%), gynecolog/urology (14.6%), emergency unit (14.6%), internal medicine (10%) and intensive care unit care (9%), between January 2018 and December 2022 were studied. The strains were mainly isolated from intra-abdominal abscesses (34.8%), blood culture (27%), abscesses (14.6%), and tissue biopsies (13.5%).

The clinical samples were inoculated on Brucella Blood Agar (BBA) (Becton Dickinson, USA), supplemented with hemin and vitamin K. After incubation at 36°C for 2–4 days in an anaerobic chamber (Bactron-I, SHELLAB, USA), several colonies from each plate were tested for aerotolerance. Strict anaerobic colonies were chosen for identification using MALDI-TOF MS (Vitek MS, bioMérieux, France) automated system (2).

2.2. Identification by VITEK MS

All isolates, grown on BBA at 36 °C for 48 h in an anaerobic chamber, were identified following the manufacturer's instructions. Briefly, a single colony was spotted as a homogeneous smear on the target slide using a 1 µL loop. The bacteria were subsequently covered with 1 µL of α-cyano-4-hydroxycinnamic acid (HCCA) matrix solution (bioMérieux, France). After drying at room temperature, the target slide was loaded into the VITEK MS machine (bioMérieux, France). Microbial identification relied on comparing the generated spectra of the bacterial strains to the reference spectra stored in the VITEK MS version 3.0 database

Viable strains were stored at −80 °C in 10% skimmed milk until use.

2.3. Susceptibility Tests

Antimicrobial susceptibility tests against imipenem and meropenem were performed by agar dilution based on recommendations of the CSLI (2007) (12). Meropenem and imipenem powders used were obtained from Sigma (St. Louis, MO, USA). The Minimal Inhibitory Concentration (MIC) was defined as the lowest concentration that prevented visible growth of the tested microorganism; MIC: ≤ 1 µg/mL was accepted as meropenem or imipenem susceptible, and MIC: >1 µg/mL as resistant according to EUCAST breakpoints (v13.1) (13). A standardized bacterial inoculum (10^5 CFU/mL) was efficiently transferred onto BBA containing half-diluted antibiotics and incubated at 36°C for 48 h in anaerobic chamber. The *Bacteroides fragilis* ATCC-25285 (American Type Culture Collection, Rockville, MD, USA) was included as controls in all assays to assess the reliability of the methods.

2.4. DNA extraction and cfiA Carbapenemase Gene Amplification

Bacteroides fragilis colonies were picked from culture plates and bacterial DNA was extracted by heating. The *cfiA* gene was detected by polymerase chain reactions (PCR) using specific primers; *cfiA*1: 5'-CCA TGC TTT TCC CTG TCG CAG-3' and *cfiA*2: 5'-GGG CTA TGG CTT TGA AGT GC-3' (5). PCR conditions comprised 94°C for 2 min, followed by 35 cycles of 45 s at 94°C, 45 s at 51°C, and 45 s at 72°C, followed by 2 min at 72°C (14). The *cfiA* gene positive *B. fragilis* strain D-5, previously identified in our laboratory, was used as a positive control, and ATCC 25285 strain as negative control.

Amplification products were separated by agarose gel electrophoresis, visualised by UV illumination following staining with ethidium bromide, and identified by comparison with reference markers.

2.4. Statistical Analysis

Statistical analysis of the study data was conducted using the SPSS 20.0 software program.

3. RESULTS

Our analysis of antibiotic susceptibility, following the latest EUCAST guidelines (v13.1), revealed resistance in 10.1% (9 isolates) of *B. fragilis* strains to imipenem and 14.6% (13 isolates) to meropenem. Imipenem MIC_{50} and MIC_{90} were 0.25 and 4 µg/mL, respectively. Meropenem MIC_{50} and MIC_{90} were 0.25 and 32 µg/mL, respectively.

The cfiA gene was identified in 13 B. fragilis isolates (14%). All but one of the meropenem-resistant and imipenem-resistant isolates harbored the cfiA gene. However, one cfiA-positive isolate was susceptible to meropenem, while five were susceptible to imipenem, with a MIC of 1 µg/mL for these particular isolates. This suggests that meropenem may be more sensitive for detecting carbapenem resistance in phenotypic testing. Additionally, a bacteremia isolate of *B. fragilis* from a 54-year-old patient who underwent intra-abdominal surgery displayed resistance to both imipenem and meropenem without harboring the *cfiA* gene. Details of antibiotic susceptibility testing for all resistant and *cfiA*-positive isolates are provided in Table 1. Figures 1 and 2 depict

the correlation between minimum inhibitory concentrations (MICs) of imipenem and meropenem, and the presence of the *cfiA* gene in *B. fragilis* isolates.

Table 1. *Characterization of isolates phenotypically resistant to imipenem and meropenem and presence of cfiA gene.*

N	ID	Age	Clinical samples	Hospital ward	IMP MIC (µg/mL)	MER MIC (µg/mL)	Presence of cfiA gene
1	18094	43	Tissue biopsy	Infectious diseases	2	64	+
2	18185	79	Intraabdominal abscess	Emergency department	2	16	+
3	18207	55	Intraabdominal abscess	General surgery	4	32	+
4	18230	7	Intraabdominal abscess	General surgery	64	256	+
5	18233	73	Wound/Abscess	Urology	1	1	+
6	18595	58	Intraabdominal abscess	General surgery	1	4	+
7	19232	33	Blood	General surgery	32	32	+
8	20079	66	Intraabdominal abscess	General surgery	1	4	+
9	20577	65	Tissue biopsy	Urology	1	4	+
10	21120	11	Cerebrospinal fluid	General surgery	1	4	+
11	21497	53	Tissue biopsy	Internal medicine clinic	16	128	+
12	22179	71	Blood	Emergency department	2	8	+
13	22379	71	Blood	Intensive Care Units	128	256	+
14	22488	54	Blood	General surgery	2	8	(-)
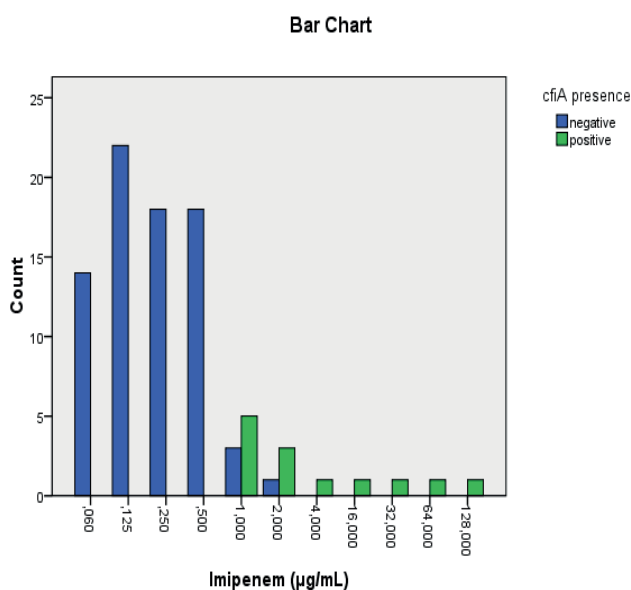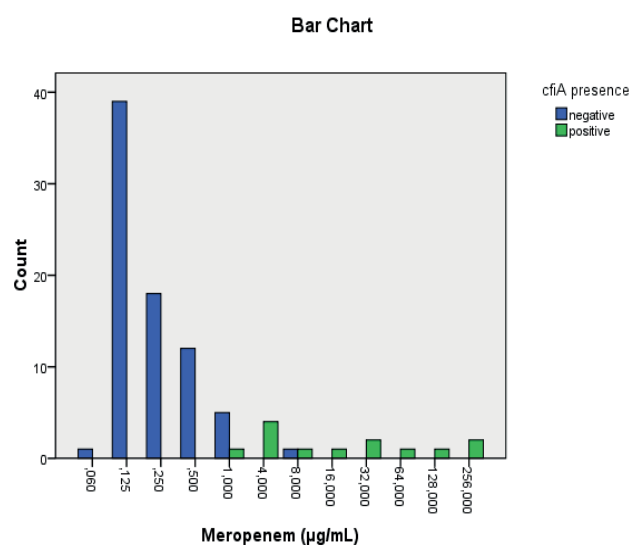
Figure 2. *Correlation between meropenem MIC values and the presence of the cfiA gene in Bacteroides fragilis isolates*

4. DISCUSSION

In this study, carbapenem resistance and the prevalence of the *cfiA* gene were investigated in *B. fragilis* isolates obtained from a tertiary hospital in Türkiye. The findings reveal a worrying increase in carbapenem resistance compared to our previous results and highlight the increasing threat of multidrug-resistant *B. fragilis* (9-11). A significant proportion of *B. fragilis* isolates displayed resistance to imipenem (10.1%) and meropenem (14.6%), exceeding national estimates.

Anaerobic bacterial culture is performed in very few laboratories worldwide and in our country due to the difficulties, time, and cost associated with isolation and identification. When an anaerobic infection is suspected, empirical treatment with antibiotics thought to have an antianaerobic effect is applied (2). However, the increasing prevalence of antibiotic resistance in recent years has made the susceptibility of anaerobic bacteria, especially *Bacteroides* isolates, unpredictable. Studies have shown that resistance can develop even to the most effective antibiotics, including carbapenems, piperacillin/tazobactam, amoxicillin/clavulanic acid, and metronidazole, although the rates vary between countries, cities, hospitals, and even different clinics within the same hospital. The significant rise in case reports of multidrug-resistant *B. fragilis* isolates is noteworthy (3). In contrast to previous studies in our country that reported no carbapenem resistance in a small number of *Bacteroides* isolates, our study found a high resistance rate (15-17). Reported resistance rates for imipenem and meropenem vary in various world countries; 0.2-1% in the USA, Canada and Europe, 2-4% in Japan, 7-12% in Taiwan and18.2-29.5% in China (3,7,8). This high rate compared to both national and international data may be due to our hospital's frequent use of carbapenems in empirical treatment (18).

Figure 1. *Correlation between imipenem MIC values and the presence of the cfiA gene in Bacteroides fragilis isolates*

The *cfiA* gene, encoding a carbapenemase enzyme, was detected in 14% of isolates and strongly correlated with carbapenem resistance in most cases. Interestingly, some *cfiA*-positive isolates remained susceptible to carbapenems, it may be due to the absence of IS elements in front of the *cfiA* gene, while the presence of these mobile DNA elements could potentially integrate into the cfiA gene and activate carbapenemase production, leading to resistance (5).

Notably, one carbapenem-resistant isolate lacking the *cfiA* gene, indicating the existence of additional mechanisms not investigated in this study. These mechanisms may include porin-mediated resistance, which reduces carbapenem uptake, efflux pumps that remove the antibiotic from the cell, or the acquisition of alternative carbapenemase genes (2,4).

The increase in CR-BF poses a significant problem; because carbapenems are often the last-line treatment for serious *B. fragilis* infections. The *cfiA* gene appears to be a significant contributor to carbapenem resistance in this hospital setting. However, the presence of *cfiA* does not always guarantee resistance and other mechanisms may also be involved (4,6,7). The identification of CR-BF strains lacking the *cfiA* gene highlights the need for further investigation of alternative resistance pathways.

There are some limitations in this study: First, this single-center study limits the generalizability of the findings to other hospitals. Second. The specific mechanisms responsible for carbapenem resistance in *cfiA*-negative isolates were not discussed in detail in the study. Third, the presence of IS elements was not investigated.

The results of our study indicate that continuous surveillance of carbapenem resistance in *B. fragilis* is crucial to monitor trends and guide antibiotic stewardship programs. Infection control measures must be strictly implemented to prevent the spread of multidrug-resistant *B. fragilis.* Clinicians should be aware of the increasing prevalence of carbapenem-resistant *B. fragilis*, especially considering that more than half of our study population was over 50 years of age and one-third was over 65 years of age, (mean: 52.72) (Table1). This highlights the importance of considering alternative treatment options when necessary for this age group with a higher risk of infections caused by carbapenem resistant *B. fragilis.* More research is needed to develop effective strategies to combat multidrug-resistant *B. fragilis* infections. Further research is also required to elucidate the mechanisms of carbapenem resistance in *cfiA*-negative isolates. Investigation of the potential impact of mobile DNA elements on *cfiA* gene activation deserves further study.

5. CONCLUSION

This study highlights the alarming trend of increasing carbapenem resistance among *B. fragilis* isolates, with a prevalence of 10.1% for imipenem and 14.6% for meropenem. The *cfiA* gene, which encodes a carbapenemase enzyme, was identified in 14% of the isolates and showed a strong correlation with carbapenem resistance in most cases. However, some inconsistencies suggest that alternative resistance mechanisms or limitations in *cfiA* detection are involved. Additionally, the absence of the *cfiA* gene in a carbapenem-resistant isolate indicates the existence of additional mechanisms not investigated in this study.

Overall, this study adds valuable data to the growing concern regarding carbapenem-resistant *B. fragilis*. The findings highlight the need for continuous monitoring of carbapenem resistance, investigation of alternative resistance mechanisms, and implementation of effective infection control strategies.

Author Contributions:
Research idea: N.U.T
Design of the study: N.U.T and A.O
Acquisition of data for the study: N.U.T, S.O and A.O
Analysis of data for the study: N.U.T and A.O
Interpretation of data for the study: N.U.T and A.O
Drafting the manuscript: N.U.T and A.O
Revising it critically for important intellectual content: N.U.T
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Orthorexia Nervosa and Physical Activity: Impact On Food Choices and Quality of Life In Healthcare Workers

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ABSTRACT

Objective: Orthorexia Nervosa (ON) which is formed by the combination of many factors such as biological, psychological and social factors, reduce the quality of life by affecting food choices. To evaluate the relationship between ON and physical activity status with food selection and quality of life among healthcare personnel at Balıkesir State Hospital in Türkiye.

Methods: Sociodemographic characteristics and nutritional status, " Orthorexia Nervosa Rating Scale (ORTO-15 Scale)," "International Physical Activity Questionnaire (IPAQ)", "Quality of Life Scale (WHOQOL-27)", "Food Consumption Frequency (FFQ)", and "3-Day Food Consumption Record Form (2 weekdays-1 weekend day)" administered in person to 400 participants.

Results: The participants exhibited signs of orthorexia in 80.2% of cases. Other healthcare professionals were most active group (22.5%), while doctors were most inactive (29.7%). Healthcare workers with orthorexic tendencies frequently consumed water, beverages, and dairy products, whereas individuals with typical eating habits commonly consumed fats. Very active health workers most frequently consume fats, inactive nurses and doctors consume water and beverages, and inactive health workers consume milk. Physical activity status affects quality of life, and as "IPAQ Total" scores increased, "General Health Status", "Physical Health" and "Environment" sub-factor scores of WHOQOL-27 increased (p<.05). ON also affects quality of life, and as the "Food Choice, Eating Attitudes and Behaviours" sub-factor scores of ORTO-15 increase, the "Social Relationships" sub-factor score of WHOQOL-27 increases (p<.05). As the "Food Choice and Value" sub-factor scores of ORTO-15 increase, the "Physical Health" sub-factor scores of WHOQOL-27 decrease (p<.05).

Conclusion: The high workload and stress of healthcare workers, along with poor working conditions, have led to a low quality of life and their food choices have impacted their quality of life.

Keywords: Orthorexia nervosa, health care workers, physical activity, quality of life

1. INTRODUCTION

Nutrition, starting from the womb and continuing throughout life, is an action that involves consuming nutrients that the body needs in sufficient and balanced amounts and at appropriate times to improve quality of life, enhance health, and provide protection (1). Some individuals, due to their concern over body weight and body image and their reluctance to consume foods they consider unhealthy, restrict their diet or skip meals. This can lead to inadequate and imbalanced nutrition, which may result in eating disorders and significantly affect physical health and psychosocial functioning, focusing on weight, body shape, and eating (2,3). Orthorexia Nervosa (ON), a new eating disorder, is a psychological condition characterized by an obsessive-compulsive disorder involving an excessive focus on eating healthily (4).

The prevalence of ON has been increasing recently, driven by beauty standards associated with being thin, media-promoted diets, and coverage that increased concerns over food additives, hormones, preservatives, carcinogens (5,6). Prevalence varies by country, patient groups, and assessment tools, ranging from 6.9% to 75.2% in the general population, with certain groups reaching up to 90.6% (7).

A study on healthcare professionals explored levels of ON, finding 49.5% exhibited orthorexic behaviors, attributed to desires for a particular body image and thinness (8).

For individuals with ON, the quality of food is more important than quantity and calorie content (4,6). Individuals with ON avoid foods with preservatives, artificial colors, sweeteners, pesticides, excessive fats, sugars, salts, or genetically modified ingredients due to health concerns (7). One study has shown that individuals with a high tendency towards ON prefer foods

they consider healthy and pure, such as vegetables, fruits, and whole grains (9). Another study demonstrated that individuals with a higher tendency for ON consume more vegetables, fruits, nuts, meat and legumes, and less sweets, animal fats, and snacks compared to others (10).

Exercise and sports, while essential for health, are also important for healthy nutrition (11). Physical activity is defined as any bodily movement produced by skeletal muscles that results in energy expenditure (12).

One study investigating the physical activity levels of healthcare workers have found their physical activity level to be low, attributed to lack of free time, long and demanding work hours, and neglecting exercise (13).

In another study, the physical activity levels of healthcare professionals working in hospitals were examined and the individuals' physical activity levels were found to be low. The participants stated that the reasons for not being able to do sports were fatigue and insufficient time (14).

Since body image is important in individuals with ON symptoms, physical activity is valued, which makes physically individuals a risky group in terms of ON (15). A study on the physical activity levels of individuals with orthorexic tendencies found higher levels of physical activity compared to others, viewing physical activity not as a pleasure but as a necessary requirement (9).

Quality of life reflects an individual's perception of their physical, emotional, and social status. A study examining the quality of life of healthcare workers during the COVID-19 pandemic found their quality of life to be low (16).

Ensuring a high quality of life requires attention to food choices (17). One study has shown that individuals with restrictive eating habits and those who exclude certain foods from their diet have a lower quality of life (18).

Regular physical activity positively affects quality of life. A meta-analysis of 59 studies concluded that exercise improves individuals' quality of life and mental health (19).

Particularly for healthcare workers, challenging work conditions, lack of physical activity, unhealthy eating habits, and a high risk of professional burnout contribute to lower quality of life (13).

Therefore, in this study it was aimed to investigate the effect of orthorexia nervosa and physical activity on food choices and quality of life in health workers.

2. METHODS

The study began after receiving approval from Üsküdar University's Non-Interventional Research Ethics Committee on December 28, 2022, under the number 61351342/ December 2022-90. Participants were administered a face-to-face survey including sociodemographic characteristics, ORTO-15 Scale, IPAQ, WHOQOL-27, FFQ, and a 3-day food consumption record (2 weekdays-1 weekend day). Data

analysis was performed using SPSS v26 (IBM Inc., Chicago, IL, USA).

This relational screening model and cross-sectional study was conducted between January 2023 and March 2023 using a face-to-face survey collection method. The universe of the research consisted of healthcare professional working at Balıkesir State Hospital. Based on the power analysis, a minimum sample size of 197 was deemed sufficient, and 400 individuals participated in the study.

Body weight was measured with a calibrated electronic scale, on an empty stomach, wearing thin clothing and no shoes. Height was measured with a stadiometer on a Frankfort plane without shoes, with feet side by side. BMI was calculated by dividing body weight by the square meter of height. BMI classification was made according to WHO criteria. waist circumference (cm) was measured with a tape measure.

Professional groups were divided into three categories. nurses, doctors, and other healthcare professional. The latter group included a wide range of healthcare occupations such as EMT, dietitian, dialysis technician, health officer, midwife, audiologist, medical secretary, civil servant, paramedic, pharmacist, social worker, physiotherapist, audiometrist, medical imaging specialist, psychologist, orthosis prosthesis technician, biomedical engineer, x-ray technician, anesthesia technician, radiology technician, laboratory technician, orthopedic technician, and language and speech therapist.

2.1. Orthorexia Nervosa Rating Scale (ORTO-15 Scale)

The Orthorexia Nervosa Rating Scale (ORTO-15 Scale) is a 15-item Likert-type scale developed in 2005 by Donini et al., based on a questionnaire originally created by Bratman and Knight (20,21). It was adapted to Turkish by Bağcı Bosi et al. in 2006, with validity and reliability studies conducted by Arusoğlu et al. in 2008 (22,23).

The questions are answered in the present tense on a 4-point Likert scale (always, often, sometimes and never) and investigate the obsessive behaviors of individuals in choosing, purchasing, preparing and consuming foods that they consider healthy. Answers that are the distinguishing criteria for orthorexia are given "1" point, and answers that show a tendency to normal eating behavior are given "4" points. In total, a minimum of 15 and a maximum of 60 points can be received. If the scores obtained are low, they indicate an orthorexic tendency. ORTO-15 scale score ≤40 was considered orthorexic, and those with >40 scores were considered normal (23).

2.2. The International Physical Activity Questionnaire (IPAQ)

The International Physical Activity Questionnaire (IPAQ) was adapted to Turkish by Öztürk in 2005 with validity and reliability studies conducted (24). It comes in short and long forms, with the short form consisting of 7 questions about vigorous, moderate physical activities, and walking. Physical

activity is categorized based on MET-minute scores, listed below:

Vigorous physical activity = 8.0 METs

Moderate physical activity = 4.0 METs

Walking = 3.3 METs

2.3. Categorical classification of physical activity:

Sedentary/Inactive: Physical activity less than 600 MET-minutes per week

Moderately active: Physical activity equivalent to 601-3000 MET-minutes per week

Very active: It is defined as more than 3001 MET-minutes of physical activity per week (24).

2.4. Quality of Life Scale (WHOQOL-27)

The Quality of Life Scale (WHOQOL-27) was developed by the World Health Organization in the 1980s, with a short form consisting of 27 questions covering physical health, psychological health, social relationships, and environment (25).

The validity and reliability of the Turkish version were established by Eser et al. (26). It is a Likert-type scale scored between 1-5 for the 27 questions that make up WHOQOL-27. As the score from the total score increases, the quality of life also increases (27).

2.5. Food Consumption Frequency Survey (FFQ)

The reliability of the FFQ was conducted by Uncu Soykan in 2007 (28). In this study, the consumption frequencies of frequently consumed dairy products, meat, chicken, fish, oilseeds, bread types, pastries and desserts, fruits and fruit juices, vegetables and vegetable juices in the last 28 days were questioned.

2.6. The 3-Day Food Consumption Record Form

The 3-Day Food Consumption Record Form was used to document all consumed foods and beverages over 2 weekdays and 1 weekend day, with details on the type, amount, and content of the foods verified using replicas and food atlases. Foods were classified into 7 groups according to the Türkiye Nutrition Guideline (29).

2.7. Data Analysis

In data analysis Methods included descriptive statistics for categorical variables (demographic characteristics) presented as frequency and percentage. The normality of numerical variables was checked using the Shapiro-Wilk Test. Descriptive statistics for numerical variables were presented as mean±standard deviation for normally distributed data and median (min-max) for non-normally distributed data. The Spearman's Rank Correlation Coefficient was used to examine relationships between quantitative variables for non-normally distributed data. Statistical significance

levels were considered as "p<.05, p<.01, p<.001" for all calculations and interpretations, and hypotheses were tested bidirectionally. Statistical analysis was conducted using SPSS v27 (IBM Inc., Chicago, IL, USA).

3. RESULTS

In the study, 9.3% of the healthcare workers participating in the study were doctors, 35.2% were nurses, and 55.5% were other healthcare staff. The average age was 36.30±8.96 years, waist circumference was 81.98±9.64 cm, hip circumference was 97.31±9.49 cm, waist/hip ratio was 0.84±0.06 cm, and BMI was 24.75±3.34 kg/m². In the study, 33% of the healthcare workers were male and 67% were female, 63.2% were married and 36.8% were single, 6.5% had been working for ≤ 1 year, 23.0% for 1≤5 years, 15.0% for 5≤10 years, and 55.5% for more than 10 years. 9.0% worked shifts (Evening, Morning), 43.3% had fixed hours (8.00-17:00), and 47.7% worked on call. 1.2% were underweight, 55.5% had a normal weight, 34.0% were pre-obese, and 9.3% were obese. 60.4% had a low health risk based on waist circumference, 23.8% had a high health risk, and 15.8% had a very high health risk. In the study, 48.2% of the participants smoke, 43.5% do not smoke and 8.3% quit smoking. Daily cigarette smoking average of smokers is 15.04±7.60 pieces. 33.5% of the participants drink alcohol, 62.0% do not drink alcohol and 4.0% have quit drinking alcohol. Monthly alcohol consumption average of alcohol drinkers is 17.81± 19.00 glasses. In the study, 63.5% of the participants skip meals and 36.5% do not skip meals, and the most skipped meal is in the morning with 46.9% and the least skipped meal is in the evening with 4.3%. In the study, 21.5% of the participants use nutritional supplements regularly and 78.5% do not use them, and the most used nutritional supplement is Vitamin C with 27.9%. In the study, 78.4% of the doctors participating in the research were orthorexic and 51.4% were minimally active, 78.7% of the nurses were orthorexic and 50.3% were minimally active. 81.5% of other health professionals were orthorexic and 54.5% were at a minimally active level (Table 1).

According to food consumption groups, doctors participating in the research consumed water and beverages the most frequently (100%), nurses consumed water and beverages most frequently (98.6%), and other healthcare professionals consumed dairy products most frequently (99.1%). According to the occupational groups of the healthcare professionals participating in the research, dairy products are consumed most frequently by other healthcare personnel (99.1%), while meat, chicken, fish, eggs, legumes, oily seeds, and nuts are consumed most frequently by doctors (91.1%), fresh vegetables and fruits group foods are consumed most frequently by nurses (80.1%), bread and cereals group foods are consumed most frequently by other healthcare personnel (96.8%), fats group foods are consumed most frequently by other healthcare personnel (98.6%), sugar group foods were consumed most frequently by nurses (55.3%), and water and beverage group foods were consumed most frequently by doctors (100%) (not shown).

Table 1. Descriptive statistics of demographic, anthropometric, habit, nutritional findings, orthorexia level and physical activity level findings of healthcare professionals according to professional groups

	Doctor (n=37)		Nurse (n=141)		Other Health Professional (n=222)		Total (n=400)	
Sex	n	%	n	%	n	%	n	%
Male	25	67.6	26	18.4	81	36.5	132	33.0
Female	12	32.4	115	81.6	141	63.5	268	67.0
Age (years) (X±SD)	34.00±7.14		34.89±9.15		37.57±8.94		36.30±8.96	
Marital Status								
Single	18	48.6	62	44.0	67	30.2	147	36.8
Married	19	51.4	79	56.0	155	69.8	253	63.2
Work Experience								
≤ 1 year	3	8.1	13	9.2	10	4.5	26	6.5
1≤5 years	14	37.8	35	24.8	43	19.4	92	23.0
5≤10 years	6	16.2	19	13.5	35	15.8	60	15.0
>10 years	14	37.8	74	52.5	134	60.4	222	55.5
Type of Work								
Shifts (Evening. Morning)	2	5.4	14	9.9	20	9.0	36	9.0
Fixed Hours (8.00-17:00 Work Hours)	2	5.4	55	39.0	116	52.3	173	43.3
On Call	33	89.2	72	51.1	86	38.7	191	47.7
BMI Group								
Underweight (<18.5 kg/m^2)	0	0.0	1	0.7	4	1.8	5	1.2
Normal Weight (18.5-24.9 kg/m^2)	18	48.6	77	54.6	127	57.2	222	55.5
Pre-obese (25-29.9 kg/m^2)	16	43.3	47	33.3	73	32.9	136	34.0
Obese (^{3}30 kg/m^2)	3	8.1	16	11.4	18	8.1	37	9.3
BMI (kg/m^2) (X±SD)	25.38±2.91		24.74±3.48		24.65±3.32		24.75±3.34	
Waist Circumference Risk Status								
Low health risk (M: <94; F: <80 cm)	27	73.0	77	54.6	138	62.2	242	60.4
High health risk (M ^{3}94 – <102; F: ^{3}80 – <88 cm)	6	16.2	39	27.7	50	22.5	95	23.8
Very high health risk (M: ^{3}102; F: ^{3}88 cm)	4	10.8	25	17.7	34	15.3	63	15.8
Waist Circumference (cm) (X±SD)	83.95±10.32		81.62±9.72		81.88±9.47		81.98±9.64	
Hip Circumference (cm) (X±SD)	97.00±11.05		97.81±10.53		97.04±8.50		97.31±9.49	
Waist/Hip Ratio Risk Status								
Risk exists (M: ≤0.90; F: ≤0.85)	25	67.6	89	63.1	149	67.1	263	65.8
No risk (M: >0.90; F: >0.85)	12	32.4	52	36.9	73	32.9	137	34.3
Waist/Hip Ratio (X±SD)	0.87±0.04		0.84±0.06		0.84±0.06		0.84±0.06	
Cigarette Smoking Status								
Yes	26	70.3	56	39.8	111	50.0	193	48.2
No	11	29.7	70	49.6	93	41.9	174	43.5
Former smoker	0	0.0	15	10.6	18	8.1	33	8.3
Frequency of Smoking (amount/day) (X±SD)	21.04±10.14		14.79±6.88		13.77±6.61		15.04±7.60	
Alcohol Drinking Status								
Yes	24	64.9	32	27.7	78	35.1	134	33.5
No	13	35.1	103	73.0	132	59.5	248	62.0
Former Drinker	0	0.0	6	4.3	12	5.4	18	4.5
Frequency of Drinking (glasses/month) (X±SD)	21.33±14.16		11.50±12.41		19.32±21.89		17.81±19.00	
Status of Skipping Meals								
Yes	23	62.2	87	61.7	144	64.9	254	63.5
No	14	37.8	54	38.3	78	35.1	146	36.5
Meals Skipped*								
Breakfast	11	47.8	24	27.6	59	41.0	94	37.0
Late Morning	11	47.8	39	44.8	69	47.9	119	46.9
Lunch	3	13.0	35	40.2	32	22.2	70	27.6
Late Afternoon	11	47.8	34	39.1	58	40.3	103	40.6
Dinner	1	4.3	1	1.1	9	6.3	11	4.3
Late Night	4	17.4	24	27.6	38	26.4	66	26.0
Status of Using Regular Supplements								

Yes	9	24.3	26	18.4	51	23.0	86	21.5
No	28	75.7	115	81.6	171	77.0	314	78.5
Supplements Used*								
Vitamin D	2	22.2	6	23.1	5	9.8	13	15.1
Vitamin C	1	11.1	6	23.1	17	33.3	24	27.9
Propolis	2	22.2	3	11.5	3	5.9	8	9.3
Level of Orthorexia								
Orthorexic	29	78.4	111	78.7	181	81.5	321	80.2
Normal	8	21.6	30	21.3	41	18.5	79	19.8
Level of Physical Activity								
Inactive	11	29.7	41	29.1	51	23.0	103	25.7
Minimally Active	19	51.4	71	50.3	121	54.5	211	52.8
Very Active	7	18.9	29	20.6	50	22.5	86	21.5

*: Multiple answers given

Table 2. *Descriptive statistics of food group consumption of healthcare professionals according to their professional groups and food obsession levels*

	Professional Group											
	Doctor (n=37)				Nurse (n=141)				Other Health Professional (n=222)			
	Orthorexic		Normal		Orthorexic		Normal		Orthorexic		Normal	
Dairy Products	n	%	n	%	n	%	n	%	n	%	n	%
Consumes	28	96.6	8	100.0	105	94.6	29	96.7	179	98.9	41	100.0
Does not consume	1	3.4	0	0.0	6	5.4	1	3.3	2	1.1	0	0.0
Red Meat, Chicken, Fish, Egg, Legumes, Oily Seeds and Nuts												
Consumes	26	89.7	8	100.0	97	87.4	29	96.7	166	91.7	37	90.2
Does not consume	3	10.3	0	0.0	14	12.6	1	3.3	15	8.3	4	9.8
Fresh Vegetables and Fruits												
Consumes	21	72.4	7	87.5	86	77.5	27	90.0	131	72.4	33	80.5
Does not consume	8	27.6	1	12.5	25	22.5	3	10.0	50	27.6	8	19.5
Bread and Grains												
Consumes	27	93.1	8	100.0	106	95.5	28	93.3	177	97.8	38	92.7
Does not consume	2	6.9	0	0.0	5	4.5	2	6.7	4	2.2	3	7.3
Fats												
Consumes	27	93.1	8	100.0	108	97.3	30	100.0	178	98.3	41	100.0
Does not consume	2	6.9	0	0.0	3	2.7	0	0.0	3	1.7	0	0.0
Sugars												
Consumes	8	27.6	3	37.5	59	53.2	19	63.3	89	49.2	19	46.3
Does not consume	21	72.4	5	62.5	52	46.8	11	36.7	92	50.8	22	53.7
Water and Beverages												
Consumes	29	100.0	8	100.0	109	98.2	30	100.0	179	98.9	39	95.1
Does not consume	0	0.0	0	0.0	2	1.8	0	0.0	2	1.1	2	4.9

Table 3. *Descriptive statistics of food group consumption of healthcare professionals according to their occupational groups and physical activity levels*

	Doctor (n=37)						Nurse (n=141)						Other Healthcare Professional (n=222)					
	Inactive		Minimally Active		Very Active		Inactive		Minimally Active		Very Active		Inactive		Minimally Active		Very Active	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Dairy Products																		
Consumes	10	90.9	19	100.0	7	100.0	37	90.2	69	97.2	28	96.6	51	100.0	119	98.3	50	100.0
Does not consume	1	9.1	0	0.0	0	0.0	4	9.8	2	2.8	1	3.4	0	0.0	2	1.7	0	0.0
Red Meat, Chicken, Fish, Egg, Legumes, Oily Seeds and Nuts																		
Consumes	11	100.0	17	89.5	6	85.7	37	90.2	63	88.7	26	89.7	45	88.2	112	92.6	46	92.0
Does not consume	0	0.0	2	10.5	1	14.3	4	9.8	8	11.3	3	10.3	6	11.8	9	7.4	4	8.0
Fresh Vegetables and Fruits																		
Consumes	10	90.9	13	68.4	5	71.4	29	70.7	59	83.1	25	86.2	39	76.5	90	74.4	35	70.0
Does not consume	1	9.1	6	31.6	2	28.6	12	29.3	12	16.9	4	13.8	12	23.5	31	25.6	15	30.0
Bread and Grains																		
Consumes	9	81.8	19	100.0	7	100.0	40	97.6	67	94.4	27	93.1	48	94.1	119	98.3	48	96.0
Does not consume	2	18.2	0	0.0	0	0.0	1	2.4	4	5.6	2	6.9	3	5.9	2	1.7	2	4.0
Fats																		
Consumes	10	90.9	18	94.7	7	100.0	39	95.1	70	98.6	29	100.0	49	96.1	120	99.2	50	100.0
Does not consume	1	9.1	1	5.3	0	0.0	2	4.9	1	1.4	0	0.0	2	3.9	1	0.8	0	0.0
Sugars																		
Consumes	3	27.3	7	36.8	1	14.3	31	75.6	31	43.7	16	55.2	25	49.0	62	51.2	21	42.0
Does not consume	8	72.7	12	63.2	6	85.7	10	24.4	40	56.3	13	44.8	26	51.0	59	48.8	29	58.0
Water and Drinks																		
Consumes	11	100.0	19	100.0	7	100.0	41	100.0	69	97.2	29	100.0	50	98.0	119	98.3	49	98.0
Does not consume	0	0.0	0	0.0	0	0.0	0	0.0	2	2.8	0	0.0	1	2.0	2	1.7	1	2.0

Table 4. *Correlation coefficients between ORTO-15, IPAQ and WHOQOL-27 sub-factor and total scores of healthcare workers*

		Anxiety About Healthy Diet	Food Choice, Eating Habits, and Behavior	Food Choice and Value	ORTO-15 Total	IPAQ Total	General State of Health	Physical Health	Psychological	Social Relations
Anxiety About Healthy Diet	s	1.000								
	p	.								
Food Choice, Eating Habits, and Behavior	s	0.355	1.000							
	p	<.001***	.							
Food Choice and Value	s	0.470	0.256	1.000						
	p	<.001***	<.001***	.						
ORTO-15 Total	s	0.915	0.608	0.649	1.000					
	p	<.001***	<.001***	<.001***	.					
IPAQ Total	s	0.058	0.039	-0.054	0.014	1.000				
	p	.248	.438	.279	.776	.				
General State of Health	s	-0.005	-0.011	-0.039	-0.024	0.126	1.000			
	p	.914	.827	.435	.633	.012*	.			
Physical Health	s	-0.070	-0.012	-0.113	-0.096	0.316	0.484	1.000		
	p	.161	.812	.024*	.056	<.001***	<.001***	.		
Psychological	s	-0.057	0.041	-0.027	-0.049	0.072	0.612	0.587	1.000	
	p	.251	.418	.585	.325	.148	<.001***	<.001***	.	
Social Relations	s	0.041	0.099	0.014	0.041	0.050	0.444	0.496	0.658	1.000
	p	.417	.048*	.787	.415	.323	<.001***	<.001***	<.001***	.
Environment	s	0.062	0.019	0.066	0.035	0.100	0.433	0.551	0.655	0.654
	p	.213	.711	.187	.480	.046*	<.001***	<.001***	<.001***	<.001***

*s: Spearman Rank Difference Correlation Coefficient *p<.05; ***p<.001*

All occupational groups that are orthorexic, doctors, nurses and other healthcare professional, most frequently consume water and beverages, and dairy products. Among these professional groups, doctors consume water and beverages with the highest rate, 100%. And the highest consumption of dairy products belongs to other healthcare professionals, with 98.9% (Table 2).

Non-orthorexic doctors most frequently consume dairy products, meat, chicken, fish, eggs, legumes, oily seeds and nuts, bread and cereals, oils, and water and beverages, with 100%. Nurses most frequently consume Oils and water and beverages with 100%. Other healthcare personnel consume dairy products and oils most frequently with 100% (Table 2).

In other words, all occupational groups of healthcare workers with orthorexic tendencies most frequently consume water and beverages, and dairy products. In all occupational groups, healthcare workers who eat normally consume fats most frequently (Table 2).

Inactive doctors most frequently consume, with 100%, meat, chicken, fish, eggs, legumes, oilseeds and nuts, and water and beverages. Minimally active doctors consume most frequently, with 100%, Dairy Products, Bread and Cereals, and Water and Beverages (Table 3). Very active doctors most frequently consume, with 100%, Dairy Products, Bread and Cereals, Oils, Water and Beverages. Inactive nurses most frequently consume, with 100%, Water and Beverages. Minimally active nurses most frequently consume, with 98.6%, Fat. Very active nurses most frequently consume, with 100%, Oils, Water and Beverages. Other inactive healthcare personnel most frequently consume, with 100%, Dairy Products. Other minimally active healthcare personnel most frequently consume, with 99.2%, Fats. Other very active healthcare personnel most frequently consume, with 100%, Dairy Products and Fats (Table 3).

In other words, the food group most frequently consumed by inactive doctors and nurses is water and beverages. Nurses and other healthcare professional who are minimally active consume Oils most frequently. The most active people in all occupational groups consume oils most frequently (Table 3).

As healthcare workers' ORTO-15 "Concerns About Health and Nutrition" sub-factor scores increase, ORTO-15's "Food Selection, Eating Attitudes and Behaviors", "Food Selection and Value" sub-factor and "ORTO-15 Total" scores increase, by 35.5%, 47% and 91.5%, respectively (p<.001) (Table 4).

As healthcare workers' ORTO-15 "Food Selection, Eating Attitudes and Behaviors" sub-factor scores increase, ORTO-15's "Food Selection and Value" sub-factor and "ORTO-15 Total" scores and WHOQOL-27's "Social Relations" increase, by 25.6%, 60.8%, 9.9% respectively (p<.05; p<.001) (Table 4).

As healthcare workers' ORTO-15 "Food Selection and Value" sub-factor scores increased, there was a 64.9% increase in ORTO-15's "ORTO-15 Total" scores and a 11.3% decrease in WHOQOL-27's "Physical Health" sub-factor scores (p<.05; p<.001) (Table 4).

It was found that as the "IPAQ Total" scores of healthcare workers increased, there was an increase of 12.6%, 31.6% and 10% in the "General Health Status", "Physical Health" and "Environment" sub-factor scores of WHOQOL-27, respectively (p <.05; p<.001) (Table 4).

As the WHOQOL-27 "General Health Status" sub-factor scores of healthcare workers increased, the WHOQOL-27 "Physical Health", "Psychological", "Social Relations" and "Environment" sub-factor scores increased by 48.4%, 61.2%, 44.4%, and 43.3%, respectively (p<.001) (Table 4).

As the WHOQOL-27 "Physical Health" sub-factor scores of healthcare workers increased, the WHOQOL-27 "Psychological", "Social Relations" and "Environment" sub-factor scores increased by 58.7%, 49.6% and 55.1%, respectively (p<.001) (Table 4).

It was found that as the WHOQOL-27 "Psychological" sub-factor scores of healthcare workers increased, there was a 65.8% and 65.5% increase in the WHOQOL-27 "Social Relations" and "Environment" sub-factor scores, respectively (p<.001). (Table 4).

As the WHOQOL-27 "Social Relations" sub-factor scores of healthcare workers increased, it was found that there was a 65.4% increase in the WHOQOL-27 "Environment" sub-factor scores (p<.001) (Table 4).

4. DISCUSSION

In this study, the highest average BMI, waist circumference, and waist-to-hip ratio were found among doctors. Conversely, in Arslan's study, the group with the lowest obesity rate was found to be physicians. (30). This could be explained by factors such as high workload and stress, shift work, lack of a balanced diet, snacking habits, and insufficient physical activity leading to weight gain; this increase in body weight and fat may parallel the higher waist-to-hip ratios observed (31).

The group that skipped meals the most in this study was other health professionals, particularly skipping the late morning snack. Yılmaz and Ayhan found lunch to be the most skipped meal (32). Similarly, Yılmaz noted the late morning snack as the most commonly skipped meal (31). This could be due to the demanding work schedule and shift work making it difficult to have three regular meals, the intense working conditions of healthcare workers, irregular working hours, skipping meals, and preferring sleep over breakfast due to lack of sleep (31).

Doctors were the group that most regularly used dietary supplements in this study, with vitamin D and propolis being the most used. Conversely, Koyu et al. found that pharmacists were the profession that most used dietary supplements (33). Similarly, in the study conducted by Arslan and Atmaca, healthcare workers used vitamin D and differently used vitamin C, vitamin B12 and multivitamins (34). This might be explained by doctors' knowledge in the health field, high health awareness, and sufficient knowledge about dietary supplements (35).

The most orthorexic health workers in this study were other health professional. Similarly, Tatlı's research found that auxiliary health workers were the most orthorexic (31). Conversely, Yazkan found the highest orthorexic tendency among nurses (36). This may be explained by certain professional groups in the health field increasing their obsession with healthy eating as their knowledge of balanced nutrition increases (37).

Other health professionals were found to be the most active professional group in this study. Yıldırım et al. found that doctors had higher physical activity levels than nurses (38), while Jun et al. found that doctors had lower physical activity levels compared to nurses and other support staff (14). This might be explained by some health workers in certain professions adopting physical activity as a lifestyle due to being role models and the high performance and endurance required by their professional duties and having less time due to their job descriptions (39).

Doctors were found to be the most inactive professional group in this study. Conversely, Yıldırım et al.'s study found that doctors had higher physical activity levels than nurses (38), while Jun et al. found doctors to be more inactive compared to nurses and other support staff (14). This could be explained by doctors' irregular working hours, such as patient shifts, choosing to sleep instead of engaging in physical activity during their free time, and lack of time for exercise (31).

In this study, health workers with orthorexic tendencies commonly consumed water and beverages, and dairy products, while those with normal eating habits commonly consumed fats. This could be due to the increase in consumption of beverages like tea/coffee to stay awake due to shift work and intense work pace, and because milk is a practical and readily available beverage and knowing the importance of water consumption for cellular vital activities, body functions, and maintaining body water balance (40).

In this study, inactive doctors and nurses most consumed water and beverages; inactive other health professional most consumed dairy products. Similarly, Kang and Yang's study on nurses found that individuals commonly consumed energy drinks during work hours for their stimulant effects (41). This could be because doctors and nurses increase their consumption of stimulating drinks like tea/coffee/water to stay awake during work hours (41); inactive other health professional consume dairy products and derivatives as a good source of protein and calcium (42).

In this study, the most active individuals in all professional groups consumed fats most frequently. This may be explained by healthcare workers under intense work pace having few breaks during work hours and preferring snacks and fast-food style ready meals instead of regular meals, leading to an increase in fat consumption (43).

In this study, when 'IPAQ Total Scores' increased, there was an increase in 'General Health Status, Physical Health, and Environment' sub-factor scores of WHOQOL-27. Similarly,

Elmas' research found that individuals who regularly engaged in physical activity had a higher quality of life than those who did not, and statistical significance was seen in the environmental quality of life dimension (44). Conversely, Marquez's study did not find a significant relationship between the increase in 'IPAQ Total Scores' and quality of life sub-factors; however, a decrease was observed in 'Environment' scores as individuals' activity levels increased (45). This could be explained by the positive impact of physical activity on individuals' bodily, physical, and mental health (46).

In this study, as the "Food Selection, Eating Attitude and Behaviors" sub-factor scores of ORTO-15 increased, the "Social Relationships" sub-factor score of WHOQOL-27 also increased. This could be explained by individuals who pay attention to food selection and eating attitudes in healthy eating sharing their nutrition knowledge with others, believing it will improve the community's quality of life, positively affecting their social relationships (47).

As the "Food Selection and Value" sub-factor scores of ORTO-15 increased, there was a decrease in the "Physical Health" sub-factor scores of WHOQOL-27. Similarly, Sfeir et al.'s study associated individuals with orthorexic tendencies with disorders in physical health quality of life (18). This could be explained by orthorexic individuals avoiding certain foods they consider unhealthy and their excessive concerns about body weight leading to deterioration in their physical health (48).

Strengths and Limitations of the Study

This study is significant for revealing the health and quality of life status of healthcare workers, who are at the forefront during processes such as societal and natural disasters, and for contributing to the development status of communities in subsequent stages. Moreover, it serves as a pioneering study in the literature on this topic. A limitation of the study is the low participation in the survey due to the participants' busy work schedules and shift work.

5. CONCLUSION

Healthcare workers, who have sufficient knowledge about healthy eating, had high levels of orthorexia and were found to be physically inactive. The high workload and stress of healthcare workers, along with poor working conditions, have led to a low quality of life and their food choices have impacted their quality of life. There is a lack of studies on this topic in the literature, and more research with larger samples is needed.

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The Effect of Dietary Approaches to Stop Hypertension (DASH) Plan on Quality of Life in Hypertensive with Acute Coronary Syndrome Patients

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ABSTRACT

Objective: The aim of the study was to evaluate the effect of Dietary Approaches to Stop Hypertension (DASH) on quality of life in hypertensive patients with acute coronary syndrome (ACS).

Methods: This study was designed and conducted with 34 patients using a single-group and pre-test/post-test design in two public hospitals. Descriptive characteristics of the patients were obtained through a questionnaire. The questionnaire included socio-demographic characteristics, dietary habits, physical activity levels and quality of life using the MacNew Heart Disease Health-Related Quality of Life scale. The DASH diet plan was planned individually based on the daily energy requirement and explained to the patients. Patients were requested to achieve maximum adherence to the DASH diet plan for 12 weeks. Patients' adherence to the DASH diet and quality of life were compared at the baseline and at study completion using SPSS 25.0 paired sample t-test.

Results: Patients' adherence to the DASH diet showed a statistically significant increase compared to the baseline ($p<.05$). In addition, patients' quality of life scale scores, including overall awnd sub-dimensions, statistically increased endline of the study ($p<.001$). A significant correlation was found between the change in adherence to the DASH diet and quality of life score changes ($p<.05$).

Conclusion: The DASH diet may improve quality of life in hypertensive patients with ACS. More clinical and long-term studies are needed to clarify the possible mechanisms in relation to these findings.

Keywords: Acute coronary syndrome, cardiovascular disease, DASH diet, hypertension, quality of life

1. INTRODUCTION

The prevalence of cardiovascular diseases (CVD) and mortality rates related to the diseases are gradually increasing in the Türkiye and worldwide. It is one of the primary causes of death (1). The World Health Organization (WHO) estimated that 16.0% of all deaths are caused by ischaemic heart disease (2). The primary cause of death is coronary heart disease (CHD) with a rate of 13.0% in United States of America, whereas in Europe, 37.0% of deaths are associated with circulatory system diseases and ischaemic heart disease is responsible for 12.0% of the deaths (3). The results of the Heart Diseases and Risk Factors in Turkish Adults (TEKHARF-2017) epidemiological study conducted in Türkiye; it was reported that 42.0% of the causes of death between 1990-2016 were coronary-related. Base on the findings, 420 000 coronary events occur annually, of which 120 000 are recurrence of acute events in patients referrred as coronary artery disease (CAD), 180 000 are new acute coronary syndromes (ACS),

and 120 000 are CAD characterized as "silent" development in seemingly healthy (4).

Diabetes, hypertension, hyperlipidemia, obesity, homocysteinuria, psychological and mental stress, smoking, age, gender, ethnicity, nutritional status, sedentary life and family history are among the risk factors for CAD (5). Long-term exposure to risk factors, progressive maintenance of the chronic inflammation leads to gradual closure of the artery, partial or complete interruption of blood flow to the heart and consequently to ACS (6). In addition, especially the persistence of modifiable factors adversely affects the structure or functions of the heart, and impairs the patients' quality of life. Low levels of physiological, psychological and social wellbeing, which are included in health-related life quality, are commonly observed in patients diagnosed with ACS (7, 8). The target of secondary prevention care planning for patients is to optimize cardiac structure and function,

improve life quality and prevent recurrent adverse cardiac events by reducing risk factors (9).

The literature suggests that Dietary Approaches to Stop Hypertension (DASH), one of the healthy eating patterns, has positive effects on diseases such as hypertension, diabetes, obesity and cancer (10, 11). The DASH diet plan includes high vegetable, fruit, whole grain products, low-fat/non-fat dairy products, nuts, oilseeds and legumes, lean meat and products with reduced consumption of fat and sugar/sugary foods. In addition, the plan is rich in fibre, magnesium, potassium, calcium and low in sodium, saturated fat, cholesterol and refined carbohydrates, depending on the consumption of the food groups (12). The beneficial effects of the mentioned food groups and components on modifiable risk factors of CAD and ACS, especially metabolic syndrome, have been presented in many studies (13, 14). In a meta-analysis study analysing the association between CHD risk and daily consumption of food groups, a negative association was found with consumption of vegetables, fruits, dairy products, whole grains, legumes, oilseeds and fish, and a positive association was determined with consumption of red meat, processed meat and sugary drinks (15). Although there is evidcnce that the relationship of different nutrients and food groups with heart diseases, there is no study evaluating effect of DASH diet plan on quality of life in CAD and ACS sample in an experimental design. Therefore, the study aimed to evaluate the effect of 12-week DASH diet plan intervention on quality of life in hypertensive patients with ACS.

2. METHODS

This study was carried out in patients admitted to the cardiology outpatient clinics of two public hospitals in Türkiye between June 2020 and September 2021. Using G Power 3.1 computer-assisted software, it was determined that at least 24 participants were required with an effect size of 0.2, 80% power and margin of error of 0.05 according to similar studies (16, 17). The study was approved Scientific Research and Publication Ethics Committee of Gümüşhane University (Decision number: 95674917-108.99-E.10275, date: 11/03/2020). Details about the study were given to patients, and the voluntary consent form was signed accepting to participate. The study is registered at ClinicalTrials.gov (Referans Number: NCT06485765).

The study sample included patients aged 20-64 years, diagnosed ACS within the last month, with a measured blood pressure above 140/90 mmHg or using antihypertensive drugs (history of hypertension), not obese (Body mass index<30.0 kg/m^2), not diagnosed with a disease requiring a specific medical nutrition therapy (chronic renal failure, diabetes, cancer, etc.) and volunteered. The study enrolled 66 male and 8 female hypertensive patients diagnosed with ACS meeting the inclusion criteria. However, the study was completed with 34 male hypertensive patients with ACS due to reasons such as individuals requesting to leave the study, not attending the visits for various reasons, not complying with the nutrition plan given and inability to communicate.

2.1. Data Collection Tools

2.1.1. Questionnaire

The descriptive data of the study were obtained with a questionnaire desingned by the researchers after reviewing the literature and expert views. The questionnaire form consists of four sections. The first section includes demographic information of the patients (age, gender, marital status, educational status, occupational information, cohabitants and social security); information about health-related diseases, smoking and alcohol consumption, some eating habits (number of main and snack meals, skipping meals, etc.) in the second section; physical activity levels in the third section; the MacNew Heart Disease Health-Related Quality of Life Scale in the fourth section.

2.1.1.1. MacNew Heart Disease Health-Related Quality of Life Scale

Patients' quality of life at baseline of the study and at the end of the 12th week was evaluated using the MacNew Heart Disease Health-Related Quality of Life Scale. The scale is a different form of the post-MI (Myocardial Infarction) Quality of Life Scale, which was developed to determine especially depression and anxiety with acute MI and which can be evaluated by patients responding to the scale. The scale can be used in different cardiac patients such as MI, angina pectoris and heart failure patients and there is a high correlation between it and other tools that assess quality of life (18). The scale Turkish validity and reliability study was performed by Daskapan et al (19). The scale consists of three sub-dimensions (emotional, physical and social) and 27 items in 7-point Likert type (19, 20). The answer to each item is between 1-7. A low score indicates poor quality of life, while a high score indicates better quality of life (21).

2.1.2. Anthropometric Measurements

Anthropometric measurements of the patients were collected at baseline of study. Body weight (kg) of the patients was measured in the morning on an empty stomach using Tanita BC 601 brand bioelectrical impedance analyser. It was ensured that the patients did not perform heavy physical activity 24 hours before the measurement, did not consume beverages (such as tea, coffee, etc.) at least 4 hours before the measurement, and did not have metal objects on them at the time of measurement (22). Height (cm) was measured with a stadiometer without shoes in the Frankfurt plane (23).

2.2. Planning the DASH Diet

Patients' daily energy requirement was calculated by multiplying the physical activity level (PAL) based on 24-hour physical activity recording and the Harris-Benedict basal metabolic rate formula (24).

Harris-Benedict Formula

Male = 66.5 + 13.75 x Weight (kg) + 5.003 x Height (cm) – 6.775 x Age (years)

Female = 655.1 + 9.563 x Weight (kg) + 1.85 x Height (cm) – 4.676 x Age (years)

After calculating the daily energy requirement, DASH diet plan was prepared for the patients and were requested to follow it for 12 weeks. Information about the foods was given and the changes that individuals could make in the nutrition plan were informed using the meal and food photo catalogue (25). Patients were also informed about nutritional behaviours such as cooking methods (grilling or boiling instead of frying, etc.), preparation (not adding salt while preparing food, using spices instead of salt, etc.), and reading food labels (fat, salt and sugar contents etc.). Also, given about foods with high salt content (salted or pickled foods, pickles, homemade tomato paste, etc.) that patients should not consume during the diet plan. In order to control DASH diet plan, digital or face-to-face interviews were occured every 15 days about the recommended intake level of the food groups (cereals, low-fat milk and dairy products, vegetables, fruits, meat-chicken-fish, fat, nuts-oily seeds-legumes, sugar and sugary foods). In addition, the private contact information of the researcher was shared with the patients for any about to the nutrition plan.

2.2.1. Assessment of Adherence to DASH Diet Plan

Studies on adherence to DASH diet were reviewed and a checklist related to the plan was formed at the baseline (26, 27). Patients' adherence to the diet plan was checked with the checklist, and necessary changes and information were made to ensure their adaptation. The patients' adherence to the recommended DASH diet plan portion amount according to the their daily energy requirement at baseline and 12th week was scored by the researcher through asking questions. In this context, patients was scored as "Yes" (1 point) if the recommended portion amount is fully complied with (consumption of 100% or more recommended portion), if "Partially" (0.5 point) complied with (66-99% of the recommended portion), and "No" (0 points) if they do not comply (consumption of 66.0% or less of the recommended portion). Lean meat-chicken-fish, solid-liquid fat and sugar/sugary foods were reverse scored. In addition, some dietary behaviors under other recommendations (cooking and preparation methods, reading food labels, etc.) were also considered as a variable. DASH diet plan adherence score was obtained according to the answers given for the food groups and other recommendations in the DASH diet plan (27). The score range can be 0-9, with a higher score showing better dietary adherence.

2.3. Statistical Analysis

The data were analysed with the SPSS 25'(Statistical Package for the Social Sciences)' computer software. Continuous quantitative data are given as mean (X̄) and standard deviation (±SD), and categorical variables are given as number (n) and percentage (%).

The data conformity to normal distribution was analysed by visual (histogram etc.) and analytical methods (skewness and kurtosis). Paired Sample t-test was performed for differences were normally distributed the baseline and end of study variables in repeated measures comparing. Pearson correlation analysis was used to evaluate the relationship between the changes in the MacNew Heart Disease Health-Related Quality of Life and the DASH diet plan adherence score. p value <.05 was accepted statistically significant (28).

3. RESULTS

This study was conducted with 34 hypertensive male patients diagnosed with ACS. General information about the patients is shown in Table 1. The patients' mean age was 55.50±7.00 (38-64) years, all of them were married and living with their families, 32.4% were primary school graduates and 47.1% were employed in the private sector. In addition, 67.6% of the patients were diagnosed with STEMI'(ST Segment Elevation Myocardial Infarction)'and 64.7% reported a family history of heart disease. 44.1% of the patients declared that they had been diagnosed with hypertension 1-3 years ago, 64.7% of them did not regularly monitor their blood pressure, and 58.8% of them had not visited a dietitian before.

The patients' general eating and lifestyle habits are presented in Table 2. 64.7% of whom stated that they skipped the lunch meal and 20.6% of them thought that their nutrition was unhealthy. The rate of those who had the habit of adding salt without tasting was 50.0%, whereas the rate of those who preferred foods with little salt based on the salt content was 58.9%. In addition, 82.4% of the patients reported that they did not regularly physical activity. Also, the majority of them (64.7%) declared that they smoked cigarettes and did not consume alcohol (88.2%).

The findings related to the patients' DASH diet plan according to the food groups are summarised in Table 3. According to the findings revealed that 20.6% of the patients adhered to the grain-cereals group recommendation according to the DASH diet plan baseline, whereas this rate was 58.8% endline. At baseline, non-adherence to dairy products according to the DASH diet plan was 73.5%; in the end, this rate was 11.8%. The rates of non-adherence to vegetable and fruit consumption were 20.6% and 11.8%, respectively, baseline; these rates were 82.4% and 70.6%, respectively, endline. Adherence of patients to other nutrition and dietary behavior recommendations was found to be 5.9% at baseline and 55.9% endline. The total adherence to the DASH diet plan score was 2.86±1.10 baseline and 6.72±0.93 endline (p<.05).

Table 4 shows the changes of patients' MacNew Heart Disease Health-Related Quality of Life scores. Baseline and end of the study, the emotional, physical and social scores of the MacNew Heart Disease Health-Related Quality of Life scale sub-dimensions increased by 0.55±0.83, 0.39±0.69 and

0.51±0.74, respectively, and this difference was found to be statistically significant (p<.001). In addition, the overall MacNew Quality of Life scores of the patients increased by an mean of 0.45±0.55 endline compared to the beginning, and this increase was statistically significant (p<.001).

Table 5 presents the correlation of the changes in the 'MacNew Heart Disease Health-Related Quality of Life' scores with adherence to the DASH diet plan. Accordingly, it was found that the emotional score (r=0.390; p<.05), physical score (r=0.420; p<.05) and general score (r=0.368; p<.05) had a statistically significant correlation with adherence to the DASH nutrition plan.

Table 1. Characteristic details of the patients

	n	%
Age (years)		
38-49	11	32.4
50-59	9	26.5
60-64	14	41.1
(X̄±SD) (Minimum-Maximum)	55.50±7.00 (38-64)	
Marital status		
Married	34	100.0
Educational status		
Primary school	11	32.4
Secondary school	9	26.5
High school	10	29.4
University	4	11.7
Occupation		
Officer	6	17.6
Retired	12	35.3
Private Sector	16	47.1
ACS Type		
NSTEMI/USAP	11	32.4
STEMI	23	67.6
Family history of heart disease		
Yes	22	64.7
No	12	35.3
Time to diagnosis of hypertension (year)		
< 1	5	14.7
1-3	14	41.2
> 3	15	44.1
Regular blood pressure monitoring habits		
Yes	12	35.3
No	22	64.7
History of dietitian visit		
Yes	14	41.2
No	20	58.8
History/intervention of heart disease		
Yes	13	38.2
No	21	61.8

ACS: Acute Coronary Syndrome, NSTEMI: non-ST-elevation myocardial infarction, STEMI: ST-elevation myocardial infarction, USAP: Unstabil Angina Pektoris

Table 2. Dietary habits and lifestyle activities of the patients

	n	%
Main meal skipping and frequently skipped meal status		
Never	4	11.8
Breakfast	5	14.7
Launch	22	64.7
Dinner	3	8.8
Snack skipping and frequently skipped meal status		
Never	4	11.8
Mornings	17	50.0
Afternoon	8	23.5
Night	5	14.7
Reason for skipping meals		
Loss of appetite	12	50.0
Lack of time	6	25.0
Environment	6	25.0
Main meal (number/day)		
2	28	82.4
3	6	17.6
Snack meal (number/day)		
No	12	35.2
1	16	47.1
2	2	5.9
3	4	11.8
Healthy dietary thought		
Yes	10	29.4
Partial	17	50.0
No	7	20.6
Adding salt without tasting the food		
Yes	17	50.0
No	17	50.0
Salt prefer in food		
Unsalted	6	17.6
Low salted	20	58.9
Salty	8	23.5
Preference for milk and dairy products		
Fat free	2	5.9
Low-fat	13	38.2
Fat	19	55.9
Whole grain product consumption		
Yes	10	29.4
No	24	70.6
Regular physical activity*		
Yes	6	17.6
No	28	82.4
Smoking		
Yes	22	64.7
No	7	20.6
Quit	5	14.7
Number/day (X̄±SD) (n:22)	24.10±10.50	
Period (years) (n:22) (X̄±SD)	13.70±6.00	
Alcohol		
No	30	88.2
Quit	4	11.8

*At least 5 days a week for a total of 150 minutes

Table 3. Assessment of patients' adherence to the DASH diet at at baseline and endline of the study

Adherence variables	Baseline						Endline					
	Yes (1 points)		Partial (0.5 points)		No (0 points)		Yes (1 points)		Partial (0.5 points)		No (0 points)	
	n	%	n	%	n	%	n	%	n	%	n	%
Grains-cereals	7	20.6	5	14.7	22	64.7	20	58.8	8	23.5	6	17.6
Low-fat dairy products	4	11.8	5	14.7	25	73.5	14	41.1	16	47.1	4	11.8
Vegetable	7	20.6	9	26.5	18	52.9	28	82.4	4	11.8	2	5.8
Fruit	4	11.8	14	41.1	16	47.1	24	70.6	7	20.6	3	8.8
Meat, chicken, fish	8	23.5	10	29.4	16	47.1	22	64.8	10	29.4	2	5.8
Nuts, oilseeds, legumes	19	55.9	8	23.5	7	20.6	18	52.9	12	35.3	4	11.8
Fats and oils	7	20.6	9	26.5	18	52.9	14	41.1	16	47.1	4	11.8
Sugar/sugary food	4	11.8	7	20.6	23	67.6	12	35.3	10	29.4	12	35.3
Other suggestions	2	5.8	16	47.1	16	47.1	19	55.9	12	35.3	3	8.8
Total Score (X̄±SD) (Minimum-Maximum)	2.86±1.10 (1.50-4.50)						6.72±0.93 (5.00-8.50)*					

§ *There is a statistically significant change compared to baseline of the study (p<.05).*

Table 4. MacNew Heart Disease Health-Related Quality of Life scores of patients at baseline and endline of the study

MacNew Heart Disease Health-Related Quality of Life Scale	Baseline		Endline		Change (Δ)		
	X̄±SD	Min-Max	X̄±SD	Min-Max	ΔX̄±SD	t	p¹
Emotional (0-7)	4.11±0.82	2.68-5.95	4.67±0.59	3.59-5.57	0.55±0.83	-3.866	**<0.001**
Physical (0-7)	4.13±0.56	3.09-5.09	4.52±0.60	3.76-5.97	0.39±0.69	-3.312	**0.002**
Social (0-7)	4.23±0.83	2.05-5.28	4.74±0.25	4.27-5.25	0.51±0.74	-3.979	**<0.001**
Total (0-7)	4.27±0.48	3.36-4.95	4.73±0.31	4.00-5.17	0.45±0.55	-4.752	**<0.001**

p¹: *Paired Sample t-Test, Δ: Last value – first value*

Table 5. The relationship between the changes (Δ) in MacNew Heart Disease Health-Related Quality of Life scores at endline of the study and adherence to the DASH diet

MacNew Heart Disease Health-Related Quality of Life Scale	r	p
Δ Emotional	0.390	**0.023**
Δ Physical	0.420	**0.013**
Δ Social	0.193	0.274
Δ Total	0.368	**0.034**

p: *Pearson correlation test, r: Correlation coefficient Δ: Last value – first value*

4. DISCUSSION

The present study was planned and conducted with 34 male participants to determine the effect of DASH diet on hypertensive patients' life quality diagnosed with ACS. According to the outcomes of the study, positive changes were determined in the patients' quality of life with DASH diet intervention.

Health-related-quality of life related to an individual's physiological, psychological and sociological level of life and well-being (29). The having of acute and chronic diseases, including ACS, negatively affects the individuals' quality of life of (30). Considering the structural functions of the heart in cardiac diseases, which is a life-threatening disease group, it

may further affect the quality of life (31). In a study evaluating 85 ACS and 63 control groups' life quality, it was determined that patients diagnosed with ACS had higher level of anxiety, lower levels of general health perception, physical function, physiological capacity, social function, life belief, mental health and overall life quality compared to the control group (32). In another similar study, 24 patients' diagnosed with MI MacNew Quality of Life scores were evaluated, the general score of the patients was 4.6±1.0, the physical score was 4.4±1.2, the emotional score was 4.9±1.0 and the social score was 4.4±1.2 (33). Endline of another similar study, the physical score was found to be 4.8, the emotional score 5.1 and the social score 4.7 in MI patients (34). It was also found that 43.8% of coronary patients and MacNew Quality of Life scores in patients diagnosed with heart disease in overall as general 4.4±1.0; physical 4.6±1.5; emotional 4.4±0.9 and social 4.4±1.4 (35). The MacNew Quality of Life score found baseline of the present study was in accordance with the cross-sectional studies in the literature. This result may be associated with the physiological and psychological health problems, such as depression and breathing difficulties, of patients in relation to the risk factors of ACS.

Psychological (emotional or spiritual) disorders, such as depression, common in patients with ACS, are closely related to healthy nutrition and reduce the quality of life (36). Healthy, adequate and balanced nutrition may prevent the occurrence

of psychological disorders, facilitate treatment in case of possible diagnosis, and thus improve quality of life (37). In a randomized controlled design, 33 intervention and 34 control groups of patients diagnosed with major depression, aimed to investigate depression levels and changes at the end of 12 weeks. Dietary intervention was conducted by a dietitian and included whole grains (5-8 servings per day), vegetables (6 servings per day), fruits (3 servings per day), legumes (3-4 servings per week), low-fat dairy products (2-3 servings per day), raw and unsalted oilseeds (1 serving per day), fish (2 servings per week), lean red meat products (3-4 servings per week), chicken (2-3 servings per week), while sugar, salt and processed products were recommended to be consumed the least possible. As a result of this dietary intervention, similar to the DASH diet, it was found that individuals had more positive improvements in depression, anxiety, mood, self-confidence and well-being compared to the control group. Also, it was interpreted that healthy diet intervention and the role of dietitian is crucial, especially in patients with psychological disorders (38). In another study, low potassium-low magnesium-low calcium intake; low sodium-high potassium-high magnesium (DASH diet plan) intake and low sodium-low calcium intake in a randomised crossover design study; the most positive improvements were seen in the case of the diet based on the DASH diet plan (39). As a result of a study analysing the association between DASH diet and neuropsychological functions, it was found that the DASH diet plan had a negative correlation with depression, anxiety, stress and a positive correlation with quality of life (40). The present study' outcomes were consistent with the literature, and it is thought that the DASH diet' impacts on psychological condition is related to the reduces oxidative stress resulting from the high level of micronutrients with antioxidant properties, and the adequate intake of elements that improve neural functions such as high folate and vitamin B_{12} (41).

Physical well-being, which is another important parameter of quality of life, is closely related to healthy, adequate and balanced nutrition, especially the maintenance of muscle and bone health (42). The intake of high magnesium, potassium and vitamins with antioxidant properties (such as vitamin C and E) through the DASH diet; muscle weakness and loss can be prevented with improvements in energy metabolism, nerve conduction and muscle contraction; it can also reduce fatigue with increased oxygen capacity and consequently have a positive effect on physical well-being (43, 44). In a study assessing muscle mass according to dietary patterns, and it was found that individuals with a healthy diet (high consumption of vegetables, fruits, seafood, legumes, legumes, whole grains, dairy products) had higher muscle mass than individuals with a western-style diet (frequent consumption of red meat, fast food, cakes, sugary drinks) in both men and women (45). In another study, according to the food consumption records of 809 participants, a high antioxidant content diet (frequent consumption of vegetables, fruits, whole grains, pulp, fish) was positively associated with muscle mass and strength (46). In a study involving

522 male individuals with a follow-up of 15 years, based on food consumption frequency were grouped as western style, vegetable (vegetables and fruits) and traditional (vegetables, whole grains and animal-derived protein), and it was found that traditional dietary style adopters had higher muscle mass and muscle function compared to other groups (47). The diet planning of 100 patients with heart failure was calculated by a dietitian with 30% fat, 1.2 kg/g protein and the remaining proportion from carbohydrates (similar to the DASH diet), daily energy intake was calculated according to the their requirement, patients were advised to maintain this pattern for 20 weeks, and their adherence to the plan was checked by telephone contact every two weeks. As consequence of the study, more favourable changes were found in the patients' metabolic parameters, life quality and exercise capacity (48). In a study involving 43 male patients with CAD aged 42-76 years, within the scope of lifestyle changes, the nutritional planning of the patients was planned by a dietitian to meet 50-55% of the daily energy requirement from carbohydrates, 20-25% protein and 25-30% fat; it was aimed to reduce saturated fat intake, sugar and sugary drinks and sodium consumption (similar to the DASH diet). One-year results of the intervention were evaluated and significant increases were recorded in exercise duration and the capability to oxygenate skeletal muscle compared to baseline (49).

There is no study using experimental design of the DASH diet directly with ACS patients in the literature. Although this study is the first in the literature, it is in parallel with the results of other studies in which DASH diet components were partially included. Stated differently, a positive change was found in patients' overall quality of life parameters. Positive significant correlation was determined between adherence to the recommended DASH diet plan and changes in total MacNew Heart Disease-Related Quality of Life score, physical and emotional sub-dimension scores (p<.05). It is thought that the main reason for overall findings is that the DASH diet plan, which is one of the healthy eating patterns, includes the recommended food groups (such as high vegetables, fruits, oil seeds; low sugar, salt, fatty meat) and macro-micro nutrients associated with physical and psychological well-being. In addition, periodic communication with patients to increase compliance with the recommended diet may be effective for patients acting more consciously to improve their health after the diagnosis (50).

5. CONCLUSION

It was determined that there was a statistically significant relationship between the increase in emotional, physical and general scores patients' quality of life and adherence to DASH diet. Although it is possible to treat arterial diseases with the developing technology in the field of health, it is necessary to eliminate the risk factors that trigger the disease, lifestyle changes and healthy eating habits. Considering a multidisciplinary approach in heart diseases, as it should be in the management of many diseases, a treatment plan should be designed for the patient to maintain a healthier

and better life quality. More effective treatment may be achieved with lifestyle and healthy eating habits changes, medication compliance, social, physical and psychological support by conducting periodic interviews with patients. In addition, experimental design and long-term clinical studies are needed to more clearly explain the role of nutrition in cardiovascular diseases.

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Primary Fears of Childbirth of Couples Who have not Yet had Children in Türkiye

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ABSTRACT

Objective: This study aims to describe and compare the fear of primary childbirth (FOC) among women and partners who have not yet experienced childbirth according to various demographic characteristics.

Methods: This cross-sectional descriptive study was conducted between July and August 2020 including couples residing in metropolitan or district regions. The 289 participants had the age period of 18–35 and had never been pregnant before. The FOC among the couples and their demographic characteristics were compared in terms of readiness for pregnancy, birth, postpartum period, baby care, breastfeeding, and readiness to provide social support in coping with FOC. Individual descriptive forms and the Women and Men Childbirth Fear – Prior to Pregnancy Scale (WCF-PPS/MCF-PPS) were used for evaluation of the responses.

Results: The findings of this study reveal that women experience a higher level of fear of childbirth compared to men. The fear of childbirth among women was slightly above average, while it was at a moderate level among men. No significant relationship was found between the WCF-PPS/MCF-PPS scores and FOC scores of women and men (p>.05). WCF-PPS/MCF-PPS and FOC scores were not found to differ significantly based on age, place of residence, income level, or educational status (p>.05). Also ıt was found to have a significant impact on WCF-PPS/MCF-PPS scores at a 0.05 significance level. Specifically, a one-unit increase in the score for FOC question 4 was associated with a 0.864-unit increase in the WCF-PPS/MCF-PPS score.

Conclusions: The study reveals that no significant difference was found between men and women in terms of fear of childbirth and the level of FOC was found to be moderate among couples. This study reveals that couples who have never had children yet need more information about the pregnancy and birth process. Incorporating the FOC criteria into the content of pre-pregnancy and pre-conception counselling as well as providing information packages to couples can help to reduce pre-pregnancy FOC. Providing information to this population that is individualized and culturally sensitive may ensure that this information is more internalized by couples.

Keywords: The fear of Childbirth (FOC), Childbirth, Couples, Fear, Demographic

1. INTRODUCTION

Tokophobia, which is called the fear of childbirth (FOC), is a pathological fear of pregnancy and may lead to avoidance of childbirth (1). It is classified as primary or secondary types. Primary FOC is the fear of childbirth in a woman with no previous pregnancy experience whereas the secondary one is the morbid fear of childbirth that develops after a traumatic obstetric experience in previous pregnancies (2). The primary one may develop in childhood or adolescence (3,4) and can be in very mild or severe forms (5,6).

FOC is categorized as a serious anxiety disorder that closely concerns women and couples' decisions regarding pregnancy and delivery (7). It is observed in 13.6% of pregnant women and 3.5% of men (8). The same rate in Turkey is determined to be 82.6% for women and 54.3% for their partners (9).

The couple's fear can be generalised as fear of excessive labour pain, harm or death of the baby, inability to cope with vaginal delivery, and an assumption of indifferent attitudes from healthcare personnel. However, unlike women, men experience fears while performing wrong interventions during childbirth. The necessity of interventions (such as vacuum, forceps, or caesarean section), the inability to provide sufficient support to their partners, and the adverse effects on their sexual lives (8-13) are other factors to experience fear.

The present study addresses the experiences linked to the FOC in various circumstances. During pregnancy, FOC can result in a preference for either voluntary abortion or caesarean delivery. During labour, FOC is linked to dystocia,

the requirement for interventional delivery, difficulties in managing vaginal delivery, and a feeling of losing control (14-16). In addition, FOC has been associated with hypertension and the occurrence of 'toxaemia' during childbirth (13), as well as extended labor (17), heightened risk of asphyxia (17, 18), and poorer Apgar scores in newborns (19, 20).

FOC can negatively impact the parental role, attachment to the baby (13), and the couple's relationship, potentially leading to postpartum depression. Women who have previously experienced it are five times more likely to have a bad birth experience (21). This fear undermines their self-confidence, frequently leading to a predilection for caesarean delivery and prolonged hospitalization (12). To an extreme degree, individuals may completely abstain from pregnancy and childbirth (2).

Until now, the studies on FOC have primarily focused on women who are pregnant or have given birth (12,16,21,22) but no specific studies conducted on couples without children. For this reason, the fundamental objective of this study is to provide a detailed and comparative analysis of the main fears experienced by couples during childbirth based on their demographic factors. The other objective is to reveal the knowledge and aspirations of individuals of reproductive age regarding their intentions for pregnancy and their perspectives on pregnancy, childbirth, and the period following childbirth. To accomplish these goals, the FOC scores were assessed and contrasted across various demographic factors.

2. METHODS

2.1. Ethical consideration

An ethics committee report was obtained from the Süleyman Demirel University of Medicine Clinical Research Ethics Committee with an Approval Number of 163 on June 4 2020.

2.2. Study design and setting

This cross-sectional comparison study was conducted between July 2020 and August 2020 in a metropolitan state hospital with high-level technical equipment and a district hospital.

2.3. Participants

Participants (n = 289) aged 18–35, residing in metropolitan (n = 189) and a district (n = 100), who had no prior pregnancies and no history of abortion, were included in the study. The district is a rural area located 72 km from the city, where residents primarily engage in agriculture and livestock breeding. These regions experience minimal migration and have limited sources of income.

Participants were volunteers from couples who visited the women's health outpatient clinics of hospitals, initially

between July 1 and August 15, 2020. The study was primarily conducted online due to the COVID-19 pandemic.

Couples who spoke Turkish, who were married or living together, were considered eligible for the study. Those who had dysmenorrhea, simple vaginal yeast infections, cystitis, received family planning counselling, had abortions, known psychiatric disorders, prolonged medicine use, and those who did not complete the questionnaire were excluded from the study.

The study was concluded with 289 participants. Only 36 of them were conducted face-to-face due to the pandemic. Researchers and citizens were restricted from going to hospitals because of this period so the researchers decided to continue running the study online. The couples who first participated in the survey were also contacted again by phone. At this stage, the researchers who conducted the research only called the participants to protect the confidentiality of the participants' contact addresses. Further participants were recruited by existing participants who were encouraged to refer any friends who may meet the study criteria.

Firstly, an informative phone message was sent to the new participants about the content and ethical aspects of the study. Then, the survey was sent to the couples who were considered eligible. Using this method, only 30 (n=60) couples were recruited. The rest of the participants were recruited from individual social circles of researchers, such as close and distant relatives, colleagues, relatives of students, and professional social media groups(n=199). Thus, the data were collected in three ways (face-to-face) n=36, phone calls n=60, and other communications n=199. Some participants (n=6) did not fill out the form so they were excluded from the analysis and the total number of participants was equal to n=289.

Written consent was obtained from the participants for face-to-face surveys in the hospital environment. Verbal consent was taken by phone for online participants before enrolment and was later recorded when they were confirmed as part of the survey.

2.4. Data Collection

The researchers prepared the Women and Men Childbirth Fear – Prior to Pregnancy Scale (WCF-PPS/MCF-PPS) and an individual descriptive form for before and after the pregnancy. The participants were asked seven questions, excluding demographic characteristics.

The online participant group was recruited and screened through phone calls while the rest were conducted online. While dealing with online participants, no means of personal information like name, address, telephone number, or e-mail address is asked. They are all recorded automatically as anonymous.

2.5. Measurements

The first form used in the study was the individual descriptive form, which gathered demographic information from participants, including age, place of residence, educational status, and economic status. This form also included seven questions about pregnancy planning and expectations, knowledge about pregnancy, birth, and postpartum, and thoughts on social support (Appendix 1).

The second form was the WCF-PPS/MCF-PPS, which was developed by Stoll et al. (8). In this study, a six-point Likert-type scale is designed to measure the prenatal fear of childbirth in young women and men. The scale, ranging from 10 (min.) to 60 (max.), comprises dimensions such as labour pain, loss of control, inability to cope with labour, complications, and irreversible physical damage where higher total scores indicate greater fear. Responses are scored from 1 (strongly disagree) to 6 (strongly agree). The original scale had a Cronbach's alpha value of 0.868. This scale was modified by Uçar and Taşhan (23) and used for university students in 2018. In their study, Cronbach's alpha internal consistency coefficient was 0.89 for the WCF-PPS and 0.84 for the MCF-PPS.

Cronbach's alpha is a measure of internal consistency and it indicates the close relation of items as a group. It is generally accepted that an alpha of 0.700 or above is indicative of good internal consistency while a value below this threshold suggests that the items may not be adequately measuring the same underlying construct. In this study, the Cronbach's alpha for the WCF-PPS was 0.075 while it was 0.072 for the MCF-PPS. Such results indicate that the data was reliable and are considerably lower than those reported in the original study by Stoll et al. (8), which documented a range of 0.81-0.89.

2.6. Data Analysis

The data obtained from 289 participants were analysed using appropriate statistical methods in IBM SPSS Statistics 22 (SPSS Inc., Chicago, IL) and AMOS 21.0 package programme. The study included demographic questions, the Preconception Fear of Childbirth Scale, and FOC questions compiled by the researcher from the literature on pregnancy planning and expectations, level of pregnancy-delivery-postnatal knowledge, and thoughts about social support. Before proceeding to the data analysis stage, skewness and kurtosis values were examined whether the data related to the scale questions were suitable for normal distribution. In the analysis of the data; descriptive categorical data were shown as number and percentage, quantitative data as mean and standard deviation values, skewness, kurtosis, minimum and maximum values. Confirmatory factor analysis was conducted to examine the validity of the FOC questions. In comparisons related to scale scores, Independent Sample T Test was used to compare the averages of two groups, One Way ANOVA test was used to compare the averages of more than two groups, and Pearson Correlation analysis was used to examine the relationship between scale scores. In the research, alpha=0.05 margin of error at 95% confidence level was taken as a basis. Variance Inflation Factor (VIF) and tolerance values were analysed to determine the multicollinearity problem between independent variables. VIF is expected to be below 10 and tolerance value is expected to be above 0.2. Durbin-Watson (DW) analysis was performed to examine autocorrelation and the DW value in the range of 1.5-2.5 showed that there was no autocorrelation. Regression analyses were performed with WCF-PPS/MCF-PPS total score as the dependent variable and FOC questions as the independent variables.

3. RESULTS

It was observed that 16.3% of the female participants and 24.4% of the male participants were 30 years of age or older, 68.5% of the women and 58.1% of the men lived in metropolises. It was observed that 55.7% of the women and 55.8% of the men had an income equal to their expenses and the majority of the participants were university graduates. Almost half of the female participants stated that they did not want to have children in the next year (Table 1).

It was found that the pre-pregnancy fear of childbirth scale female and male scores and FOC questions scores showed normal distribution (Table 2).

In Figure 1, it is seen that χ^2/df of the model is a good fit, NFI, TLI, SRMR and RMSEA values are among acceptable fit index values (χ^2/df=2.374<5, CFI=0.940<0.95, NFI=0.902≤0.90, TLI=0.923>0.90, SRMR=0.055<0.10, RMSEA=0.069<0.08). In order to improve the goodness of fit indices of the model, modification was required by drawing covariance between the error terms between question 10 and question 11.
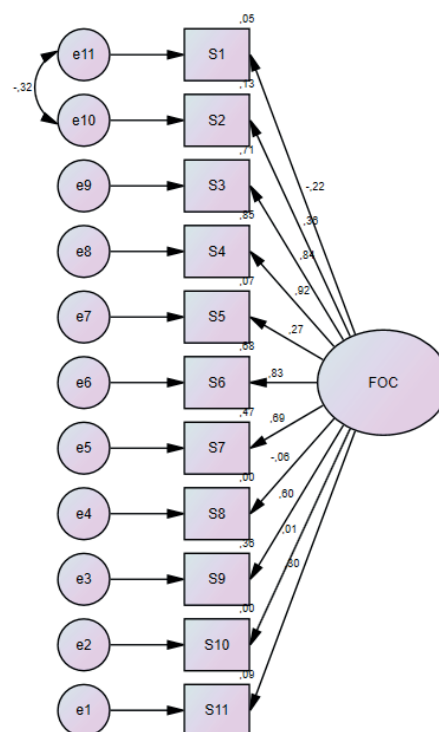
Figure 1. Confirmatory factor analysis for FOC questions

Table 1. *Socio-demographic Properties (n = 289)*

Variables	Categories		n	%
Age	Female	18-23 age	77	37.9
		24-29 age	93	45.8
		30 age and upper	33	16.3
	Male	18-23 age	23	26.7
		24-29 age	42	48.8
		30 age and upper	21	24.4
Residence	Female	Metropol	139	68.5
		District	64	31.5
	Male	Metropol	50	58.1
		District	36	41.9
Income Status	Female	Income is less than my expenses	48	23.6
		Income is equal to my expenses	113	55.7
		Income is more than my expenses	42	20.7
	Male	Income is less than my expenses	9	10.5
		Income is equal to my expenses	48	55.8
		Income is more than my expenses	29	33.7
Education Status	Female	High school and below	20	9.9
		University	159	78.3
		Master's degree-PhD	24	11.8
	Male	High school and below	14	16.3
		University	61	70.9
		Master's degree-PhD	11	12.8
Do you want to bear a child in the next year?	Female	No	144	49.8
		Uncertain	17	5,8
		Yes	42	14.5
	Male	No	45	15.5
		Uncertain	15	5.1
		Yes	26	8.9

Table 2. *Descriptive statistics related to pre-pregnancy fear of childbirth scale and FOC questions (n = 289)*

Scales	n	Mean⎵SD	Minimum	Maximum	Skewness	Kurtosis
Pre-Pregnancy Fear of Childbirth Scale (WCF-PPS/MCF-PPS)-Female	203	35.54⎵5.67	24	47	-0.125	0.244
Pre-Pregnancy Fear of Childbirth Scale (WCF-PPS/MCF-PPS)-Male	86	30.08⎵3.47	20	40	0.163	0.500
FOC Questions	289	28.12⎵4.64	15	40	0.230	0.120

A significant difference was found in the WCF-PPS/MCF-PPS mean scores of women and men ($p<0.001$). The mean WCF-PPS/MCF-PPS score of women was higher than that of men (Table 3).

Table 3. *Comparison of women and men in terms of WCF-PPS/MCF-PPS and FOC scores (n= 289)*

Scales	Sex	n	Mean SD	t	p
WCF-PPS/MCF-PPS	Female	203	35.294.36	10.776	0.001**
	Male	86	30.083.47		
FOC	Female	203	28.314.87	1.044	0.297
	Male	86	27.684.05		

*t:Independent Sample T Test, **p<0.001*

As a result of the comparison of WCF-PPS/MCF-PPS and FOC questions scores according to the demographic characteristics of the participants; it was observed that WCF-PPS/MCF-PPS and FOC scores of women and men did not differ according to age, residence, income status and educational status ($p>0.05$).

No significant correlation was found between WCF-PPS/MCF-PPS scores and FOC scores of women and men ($p>0.05$).

Regression analysis was performed with WCF-PPS/MCF-PPS total score as the dependent variable and FOC questions as the independent variables. As a result of the regression analysis, the explanation rate (R^2) of the model was calculated as 0.4% and the F statistic was found significant ($p<0.05$). In addition, FOC question 4 (I do not have enough information about the moments of birth) was found to be effective on WCF-PPS/MCF-PPS at 0.05 significance level and a one unit increase in FOC question 4 caused a 0.864 unit increase in WCF-PPS/MCF-PPS score (Table 4).

Table 4. *Analysing the effect of FOC questions on WCF-PPS/MCF-PPS*

Dependent variable	Independent variables		t	p
WCF-PPS/MCF-PPS Total Points	Constant term	32.187	15.438	**0.001**
	S1	-0.347	-1.124	0.262
	S2	0.073	0.148	0.882
	S3	-0.180	-0.294	0.769
	S4	0.864	2.557	**0.011**
	S5	-0.286	-0.549	0.584
	S6	0.839	1.827	0.069
	S7	-0.063	-0.182	0.855
	S8	-0.195	-0.436	0.663
	S9	0.008	0.026	0.979
	S10	-0.051	-0.117	0.907
R^2=0.043, F=1.245 , p<0.05 WCF-PPS/MCF-PPS =32.187*+ 0.864* S4				

Multiple linear regression R^2: 0.043, p;0.05

In the regression equation in which the dependent variable was determined as WCF-PPS/MCF-PPS total score and the independent variables were determined as FOC questions,

the coefficient of determination (R2) was calculated as 0.043 and the F statistic was found significant (p<0.05). Accordingly, it can be said that the rate of independent variable explaining the dependent variable is 0.4%. In addition, it was determined that FOC4(I do not have enough information about the moments of birth) question contributed to the model at 0.05 significance level on WCF-PPS/MCF-PPS. In the model; while the other variable is fixed, it can be said that a one unit increase in FOC question 4 causes a 0.864 unit increase in WCF-PPS/MCF-PPS. In this case, FOC question 4 shows an enhancing effect on WCF-PPS/MCF-PPS (Table 4).

4. DISCUSSION

The findings of this study indicate that women tend to greater fear of childbirth than men. The scores obtained show that fear of childbirth was slightly above average in women participating in this study and at a moderate level in men. In the study conducted by Gür et al. (25) on women and men who had not yet had children, the mean total score of WCF-PPS/MCF-PPS was 40.25 for women and 33.83 for men, and the results were similar to the results of this study (24) In a study conducted by Onchonga et al. (32) with 376 pregnant women, it was reported that 40.4% of women had moderate fear (25). Moderate fear of labour experienced during pregnancy and before pregnancy may be related to individuals' ability to cope with problems.

Interestingly, in this study half of the participating women did not want to become pregnant in the coming year. Only eight percent of men wanted to get pregnant. This may be due to the fact that this study coincided with the COVID 19 pandemic closure period.

There is no significant correlation was identified between women's and men's fear of childbirth and factors such as education level, economic status, residence of places and age in present study. Even though the results are like this women with higher levels of education (university or postgraduate) tended to have higher FOC, though this result was not statistically significant in this study. Some studies have suggested that a lower education is associated with more FOC (26,27). While the study of Serçekuş et al. (9) indicated that men with higher education levels experienced higher FOC, studies by Fairbrother et al. (28) and Žigić et al. (2018) did not find a significant relationship between educational status and FOC in women (24,28). The contrasting results between education levels and FOC in this study could be due to differences in the participants' demographic, perinatological, and cultural characteristics. Additionally, the results should be influenced since the majority of the participants are university graduates. Culturally, highly educated women are expected to contribute to the workforce in Turkish society. For this reason, the conflict between career aspirations and the responsibilities of pregnancy or child-rearing for highly educated women may affect their FOC.

This present study found no correlation between women's and man's income level with FOC and WCF-PPS/MCF-PPS.

But men whose income exceeded their expenses had higher FOC levels than others, although not statistically significant. This suggests that men in better economic conditions fear childbirth more. A study found that the fear of birth scores among young women at all income levels was higher than among men (25,29). According to a study with nursing students, there was no relationship between income level and WCF-PPS – MCF-PPS scores in terms of FOC (30) but is linked to experiences of pregnancy and adapting to fatherhood roles (31) among prospective and new fathers. However, in this study, the fact that the fear of childbirth scores of the economically well-off young men who did not have children were higher than the others may be due to the difculties they observed in their environment related to pregnancy and fatherhood. This situation may be attributed to their perception of fatherhood as a major source of stress, concerns about disruptions in their life arrangements, witnessing negative examples of pregnancy and birth, and concerns about possible decreases in the performance and subsequent income of those whose economic well-being depends on their jobs. Therefore, the extent to which these factors trigger FOC can be investigated in future studies.

In this study, gender was not a significant factor in the relationship between FOC. Similarly, Ataman and Berber's study found no significant difference in FOC levels between genders among university students (29). FOC is more common in men and women who are expecting a baby. The reason for this can be interpreted as the fact that they have a concrete reality in front of them that will result in the birth of the baby and that they are waiting for with excitement (9,32).

This FOC question 4 (I do not have enough information about the moments of birth) had an increasing effect on the WCF-PPS/MCF-PPS on the fear of childbirth. As a result, inadequate information about the birth processes increased the fear of childbirth in both men and women. Therefore, this result indicates that focusing on informing couples about childbirth in the pre-pregnancy period is an important factor in reducing the fear of childbirth. Studies show that receiving education about childbirth preparation during reproduction reduces the fear of childbirth (33,34). However, no source has yet been found that proves that the fear of childbirth before childbirth can be reduced with education.

Since the study was conducted during the COVID-19 pandemic, it is also possible that it has increased anxiety and depression levels and mental burnout in individuals (35,36) in addition to the FOC levels of individuals (37,38). Since most of the interviews were conducted via the internet, it became difficult to reach male participants, who were recruited through interpersonal communication.

Even though couples were invited to the study, women showed more interest. It is also possible that men did not answer the questionnaire due to birth privacy, which is considered a cultural taboo in Turkish society. In addition, it is also possible that some men were not interested in the subject and they believed that the FOC is only a concern for

the women. This reality prevented this study from equalising the number of male and female participants.

5. CONCLUSION

In this study, no significant difference was found between men and women in terms of fear of childbirth and the level of FOC was found to be moderate among couples. Future research should investigate whether counselling provided during the preconceptional period in non-pregnant couples can effectively reduce FOC. Such interventions may help prevent FOC or related problems during and after pregnancy and ultimately improve the well-being of mothers and their babies.

Reproductive health professionals and other relevant specialists should follow relevant guidelines and be knowledgeable about FOC to ensure early diagnosis. To reduce primary FOC in young individuals, it may be advantageous to include specific FOC-related criteria in preconceptional counselling procedures and develop comprehensive information packages.

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Appendix 1. WCF-PPS/MCF-PPS and FOC questions

		Strongly Agree (4)	Agree (3)	Disagree (2)	Strongly Disagree (1)
1	I feel ready to be a parent				
2	I feel sufficiently informed about how to prepare for pregnancy (pre-pregnancy blood tests, dental treatment, etc.)				
3	I feel sufficiently informed about the pregnancy period				
4	I do not have sufficient information about the moments of birth				
5	I feel sufficiently informed about the situations experienced in the first 40 days after birth				
6	I feel sufficiently informed about baby care				
7	I attend a pregnancy school with my wife during pregnancy				
8	I feel sufficiently informed about the fact that the baby needs to be breastfed for 2 years				
9	I do not know the family planning methods that can be used to protect against pregnancy during the postpartum period				
10	I think that I can support my wife sufficiently as a parent during the postpartum period				

Questions derived from reading the references cited (9, 11, 12, 22, 26, 27, 31)

Plantar Pressure Topography Based Sports Branch Prediction System Modeling in 7-11 Years Old Athletes

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ABSTRACT

Objective: The sole of foot plays a crucial role in sports movements, as it applies pressure to the ground and transfers loads. The foot pressing types vary depending on the sport played by the athlete. The aim of this study is to develop a model that can predict sports branches from the plantar pressure types of athletes.

Methods: A total of 80 athletes, 54 athletics and 26 combat athletes, between the ages of 7-11 were included in the study where static pedobarographic measurements of the participants were collected. First we applied conventional statistical analysis on the featured obtained from the measurements of the data using Fisher Freeman Halton Exact test. Then, we implemented sports branch prediction based on the data obtained from these measurements using advanced machine learning and deep learning techniques.

Results: There was no statistically significant difference between the plantar compression types of the participants according to the branches ($p > .05$). In the machine learning classification based on foot plantar compression, the best success was found to be 56.9% with Linear Support Vector Machine. When the branch prediction successes made with deep learning were examined, it was found that the average branch prediction was $82.58 \pm 7.62\%$ in the foot with pes planus, $87.84 \pm 17.56\%$ in the normal foot, and $85.95 \pm 21.19\%$ in the foot with pes cavus.

Conclusion: In the study, it was determined that the success of branch prediction made with machine learning techniques was low, and the success of deep learning was high. With the development of the method used in this study in future studies, an idea can be obtained about which branch of the foot plantar pressure type is more prone to and innovations can be brought to the branch selection methods.

Keywords: Deep learning, machine learning, foot, plantar pressure, sports

1. INTRODUCTION

The foot, which has a complex structure consisting of many bones, synovial joints and ligaments, has the task of carrying the body weight and pushing the body forward by acting as a lever arm during movement (1, 2). The medial, lateral and transverse arches of the foot ensure load transfer and create a static and dynamic order (3). Pes planus and pes cavus, which result from changes in height in the medial longitudinal arch due to muscular imbalances and changes in Body Mass Index, can be cited as the major examples of the disruption of this order (3-5). While pes cavus is defined as the elevation of the medial arch of the foot above normal, pes planus is defined as flattening of the medial arch of the foot, i.e., a decrease in the normal height of the medial arch of the foot (3).

The pressure exerted by the foot on the ground plays a crucial role in the transmission of force during movements such as running, walking and jumping. For this reason, the sole of the foot has important functions in athletic movements. Pressure changes in the foot in pes planus and pes cavus can lead to various musculoskeletal problems (6-9). Therefore, there has long been great interest in the literature in the study of plantar pressure and the detection of these pressure problems (10-13). Plantar pressure measurements are used to assess plantar pressure and some indices are used to determine the individual foot pressure types (14, 15).

Machine learning and deep learning methods can also be used to evaluate foot pressure types for various purposes. In a study that aimed to determine the severity of Parkinson's disease based on the plantar pressure of individuals, four supervised machine learning algorithms were used, namely decision tree (DT), support vector machine (SVM), ensemble classifier (EC), and Bayes classifier (BC) (16). In the study by Chae et al (17), a deep learning model based on artificial intelligence was developed

to classify foot deformities as concave, normal and flat feet. As you can see, these studies focused on determining foot types, estimating the severity of the condition based on plantar pressure, and determining the foot problem caused by the condition.

Studies in the literature investigating the relationship between type of branch and type of foot pressure have shown that the type of foot pressure varies depending on the type of sport branch. However, these studies were limited to statistical methods (18, 19). When examining other literature studies that evaluate foot type using artificial intelligence methods, there are studies based on estimating the population of people who run with or without shoes or studies that use deep learning models that can make predictions about foot injuries (20, 21). Again, studies have been conducted in the literature to differentiate foot images (22). However, no study was found that made predictions about sports branches based on foot type. The main objective of this study is to develop artificial intelligence algorithms that can predict sports branches of athletes based on foot type. Machine learning and deep learning methods, i.e. artificial intelligence methods, were used for the study. In addition, the development of these algorithms may lead to the creation of new test criteria for talent selection in the future.

2. METHODS

2.1. Participant

The sample of the study consists of child athletes of both genders, aged 7-11, registered in athletics and combat sports branches (karate, taekwondo, and judo) registered at the sports center in Üsküdar district of Istanbul. The criteria for inclusion in the study included participating in athletics or combat branches for at least one year, being an athlete registered in the sports centers of Üsküdar district of Istanbul, training at least 2 days a week, and participating in the study voluntarily. Exclusion criteria for the study included having any neurological or musculoskeletal system disorders. According to the G-Power analysis, a total of 80 athletes from 54 athletics and 26 combat sports were included in the study within the framework of a 95% confidence interval and 5% margin of error. The mean age of the participants was 9.88±1.38; the mean age of starting sports was 6.55±2.01; the duration of the branch (months) was 27.51±12.83. Demographic information based on the sports branches is given in Table 1.

Table 1. Other demographic information of the participants by sport branch

Branches	Variables	N	Min	Max.	Mean	Sd.
Athletics sport	Age	54	7	11	9.815	1.36
	Sport starting age	54	3	10	6.444	2.03
	Duration of sports month	54	12	60	27.111	12.19
Combat sportsThis	Age	26	7	11	10.000	1.44
	Sport starting age	26	4	10	6.769	1.99
	Duration of sports month	26	12	61	28.346	14.27

N.: Number; Min.: Minimum; Max.: Maksimum; Sd.: Standart Deviation

2.2. Procedure

Static pedobarographic measurements were carried out on the participants as part of the study. The devices were positioned before the measurement. The participants, accompanied by their parents, were invited to the measurement area and informed about the study. The participants and their parents completed the informed consent form and the participants were voluntarily enrolled in the study. Participants who had completed the participant information form were taken to the measurement area in turn. The study was approved by the Ethics Committee of Marmara University Institute of Health Sciences with the approval date and number T7.01.2022-03.

2.3. Data Collection Tools

The pedobarographic measurement was performed with the GHF550 Foot Checker device. The device enables a weight measurement between 16-150 kg. The device, which consists of a matrix sensor system, has a sensor area of 480mm x 480mm, dimensions of 590mm x 525mm x 55mm, and input and output pads can be added without sensors. There are 2304 sensors in the device and each sensor has a frequency of up to 60 Hertz.

Static pedobarographic measurements were taken with the Pedabarograph while participants were facing a fixed point in front of them, feet open at shoulder level, arms relaxed on both sides and in an upright position. The measurements were taken with bare feet. The purpose of this measurement is to reveal the pressure distribution and foot deformities of the subjects while they are pressing on the floor in a static position.

2.4. Data Preparation

Calculation Chippaux Smirak Index

Many indices are used to detect pressure problems in static sole analysis. One such index is the Chippaux-Smirak Index (CSI), an index commonly used in screening for pes planus and claimed to have better predictive capacity (23, 24). In this study, the CSI index was used to classify the participants' feet as pes planus, pes cavus and normal foot. The index is calculated by dividing the narrowest width of the mid-arch area of the foot (a) by the maximum width of the metatarsal region (b) (Figure 1). The lengths of regions a and b were determined by measuring the length using the Analysis System application. This data was then transferred to Excel and the CSI values were determined using the b/a equation. If the CSI≤0.299, it was classified as a pes cavus foot, if 0.3≤CSI≤0.399, it was classified as a normal foot, and if CSI≥0.4, it was classified as a pes planus foot (25). Additionally, Information on the foot classes obtained is given in Table 2.
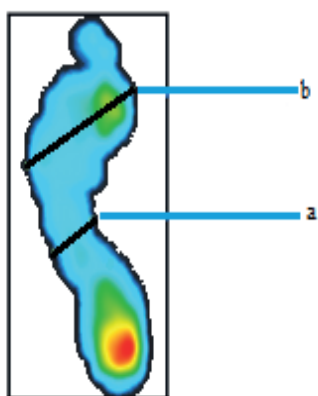
Figure 1. The a and b length regions used in Chippaux Smirak Indeks

Table 2. Information on the foot images obtained

Branches	Foot type	Right foot	Left foot	Number (N) of foot images raw data	Number (N) of foot images after data augmentation
Atletics sports	Pes cavus	43	42	85	12240
	Normal	6	6	12	1728
	Pes planus	5	6	11	1634
Combat sport	Pes cavus	17	17	34	4896
	Normal	7	7	21	2016
	Pes planus	2	2	6	576

Preprocessing for Image Data with Data Augmentation for Deep Learning Classification

The data augmentation method is a technique that increases the amount of data. The Convolutional Neural Network (CNN) is a deep learning method and a commonly used technique for image classification. Even though deep learning techniques are very successful, the imbalance of the dataset or the lack of sufficient training data can cause some difficulties (26). To overcome such problems, the data is augmented and synthesized by methods such as cropping, zooming in and out, flipping, shifting, and changing the color (27, 28). This increases the size and quality of the training datasets (29). In this study, data augmentation methods were applied to the dataset to improve the result of the deep learning method for foot type classification. MATLAB2021b software was used to process foot image data, standardize it, and apply data augmentation methods. MATLAB is a programming tool used to analyze data and to develop and create models (30).

First, the foot plantar pressure images obtained from the pedobarography device were processed with MATLAB software and converted into two images, the image of the right foot and the image of the left foot, and the texts such as participant number, date, etc. on the image were deleted with a different code.

In the next phase of the study, rotation, vertical flipping, color, and Gaussian filtering were used as data augmentation techniques. Random deleting and random cropping were not favored to avoid data loss. By writing code for each data

augmentation method used in the study, the codes were run in MATLAB software and the data size was increased. Rotation involved rotating the images 45, 90, 135, 180, 225, 270, and 315 degrees. Each data augmentation method was applied to the raw data and the data obtained from the previous data augmentation step. Thus, 144 foot images were obtained from one foot image. A total of 15,552 foot images were obtained for athletics sport (N=54) and 7488 foot images were obtained for combat sports (N=26). The image examples obtained through the data augmentation are shown in Figure 2.
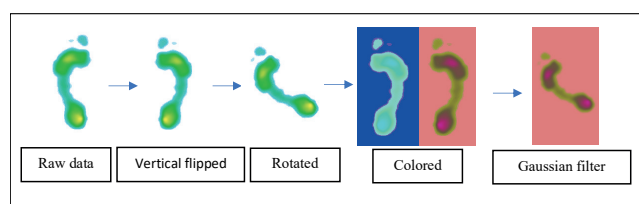
Figure 2. Schematic representation of the images obtained by data augmentation

The images of the plantar pressure are divided into three folders: pes cavus, normal and pes planus, according to the type of footprint, which is derived from the Chippaux-Smirak Index. The data numbers in the foot pressure type classes are given in Table 2. The data obtained were used for branch prediction using the deep learning technique.

2.5. Data Analysis and Classification

Foot Type Classification with Machine Learning Technique

In the preparatory phase, the foot data obtained from the pedobarography device was processed with the MATLAB program. The values of the pressure falling on each sensor were included in the foot data and the color distribution indicated the foot pressure density. Using the code created in MATLAB, the toes were removed from the data. The forefoot, midfoot and hindfoot areas were then determined separately for the left and right feet (Figure 3). The top, bottom, right and left edges of each foot were determined with the code and the total area of the foot was calculated in MATLAB and the foot was divided into three parts. As a result, the data was converted into 6 features. The features obtained were the right forefoot, right midfoot, right hindfoot, left forefoot, left midfoot and left hindfoot pressure amounts.

The dataset, which consists of six features (right forefoot, right midfoot, right hindfoot, left forefoot, left midfoot and left hindfoot pressure) and 2 classes (athletics and combat branches), was subjected to classification using all possible kernels of the Support Vector Machine (All SVM) in Matlab Machine Learning Toolbox. Linear, quadratic, cubic, fine Gaussian, medium Gaussian and coarse Gaussian classifiers of SVM were used.
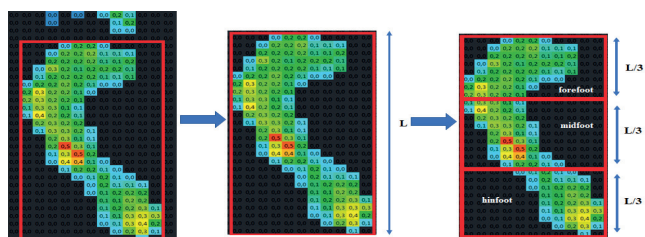
Figure 3. *Determination of fore, mid and hind foot regions separately in MATLAB*

Foot Type Classification with Deep Learning Technique

Deep learning is based on representation learning, in which several features of the data are used. In representation learning, the data is used for pixel density vectors, edge sets, etc., which are learned, and algorithms are used to extract data features (31). Since classification with machine learning could not achieve high classification success, the plantar pressure images were processed with deep learning techniques for branch prediction. The Convolutional Neural Network (CNN) method, one of the deep learning techniques, was used in the study. CNN is a widely used deep learning technique for image data classification (32). This method was used to classify the participants' foot images.

The foot images of the participants according to their branches were divided into the classes pes planus, normal, pes cavus foot folder according to CSI. The number of images present in the foot pressure type folders of each branch is shown in Table 2. The data in the obtained folders were classified using the deep learning method. A separate deep learning algorithm was created for each foot folder.

Figure 4 shows the deep learning algorithm for the normal foot, Figure 5 for pes planus, and Figure 6 for pes cavus. To create learning models, the entire dataset used is divided into 80% for training and 20% for testing. The summary of the algorithms created for each plantar compression type can be found in Tables 3, 4 and 5.

Table 3. *Summary of the proposed model for normal foot*

Layer (type)	Output Shape	Parametres
Convolution 1	(None, 256, 256, 16)	448
Max Pooling 1	(None, 128, 128, 16)	0
Dropout 1	(None, 128, 128, 16)	0
Convolution 2	(None, 128, 128, 16)	2320
Max Pooling 2	(None, 64, 64, 16)	0
Dropout 2	(None, 64, 64, 16)	0
Convolution 3	(None, 64, 64, 32)	4640
Max Pooling 3	(None, 32, 32, 32)	0
Dropout 3	(None, 32, 32, 32)	0
Convolution 4	(None, 32, 32, 32)	25632
Max Pooling 4	(None, 16, 16, 32)	0
Dropout 4	(None, 16, 16, 32)	0
Convolution 5	(None, 16, 16, 64)	18496
Flatten	(None, 16384)	0
Dense 1	(None, 128)	2097280
Dense 2	(None, 2)	258

Table 4. *Summary of the proposed model for pes planus*

Layer (type)	Output Shape	Parametres
Convolution 1	(None, 256, 256, 16)	1216
Max Pooling 1	(None, 128, 128, 16)	0
Dropout 1	(None, 128, 128, 16)	0
Convolution 2	(None, 128, 128, 16)	2320
Max Pooling 2	(None, 64, 64, 16)	0
Dropout 2	(None, 64, 64, 16)	0
Convolution 3	(None, 64, 64, 32)	12832
Max Pooling 3	(None, 32, 32, 32)	0
Dropout 3	(None, 32, 32, 32)	0
Convolution 4	(None, 32, 32, 32)	9248
Max Pooling 4	(None, 16, 16, 32)	0
Dropout 4	(None, 16, 16, 32)	0
Convolution 5	(None, 16, 16, 32)	25632
Max Pooling 5	(None, 8, 8, 32)	0
Dropout 5	(None, 8, 8, 32)	0
Convolution 6	(None, 8, 8, 32)	9248
Flatten	(None, 2048)	0
Dense 1	(None, 128)	262272
Dense 2	(None, 2)	258

Table 5. *Summary of the proposed model for pes cavus*

Layer (type)	Output Shape	Parametres
Convolution 1	(None, 254, 254, 16)	448
Max Pooling 1	(None, 127, 127, 16)	0
Dropout 1	(None, 127, 127, 16)	0
Convolution 2	(None, 123, 123, 16)	6416
Max Pooling 2	(None, 61, 61, 16)	0
Dropout 2	(None, 61, 61, 16)	0
Convolution 3	(None, 57, 57, 32)	12832
Flatten	(None, 103968)	0
Dropout 3	(None, 103968)	0
Dense 1	(None, 128)	13308032
Dropout 4	(None, 128)	0
Dense 2	(None, 2)	258

(a) Diagram of proposed model for normal foot type
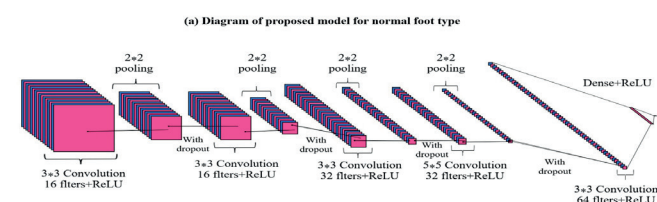
Figure 4. *Diagram of the proposed network model for normal foot type*

(b) Diagram of the proposed model for pes planus
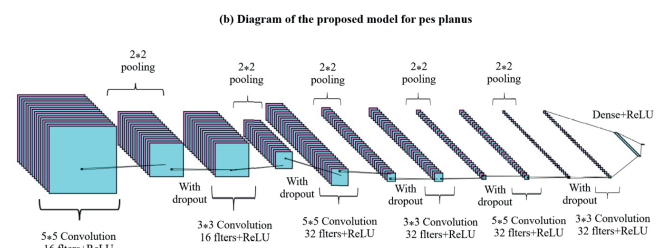
Figure 5. *Diagram of the proposed network model for pes planus*

(c) Diagram of the proposed model for pes cavus
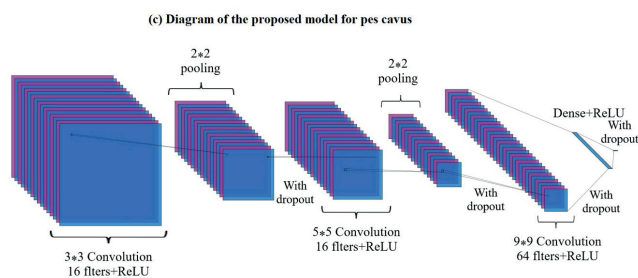
Figure 6. *Diagram of the proposed network model for pes cavus*

2.6. Statistical Analysis

The analyses were carried out using the Statistical Package for the Social Sciences (SPSS) 26.0. The significance value was set at $p < .05$. Descriptive statistics such as minimum, maximum, mean value, standard deviation and Fisher Freeman Halton Exact Test were used to analyse the data.

In data analysis, in order to determine whether there was a difference between foot pressure types according to branch, a 2x3 cell chi-square test had to be used, since both of our variables consist of categorical data, branch (athletics, combat) and foot pressure type (pes cavus, pes planus, normal). Additionally, the expected number of cells with values less than 5 exceeded 20%. For this reason, the Fisher Freeman Halton Exact test was used in data analysis. The analysis was done separately for the right and left foot.

3. RESULTS

3.1. Examining the Difference between Foot Classes According to CSI Based on Branch

The participants' foot types were classified according to CSI as pes planus, pes cavus and normal foot. When analyzing the obtained data with Fisher Freeman Halton Exact, no significant difference was found between the types of foot pressure according to the branch (for the left foot: $X^2=3.127$, $p > .05$; for the right foot: $X^2=3.153$, $p > .05$). On this basis, we decided to investigate whether the athletes' branch predictions could be made using artificial intelligence methods. In the second and third steps, we predicted the participants' branching based on their foot types using machine learning and deep learning techniques.

3.2. Machine Learning Classification

Machine learning classification was performed on the basis of branch prediction based on foot plantar pressure. The accuracy data of the test data obtained with each method is shown in Figure 7. The best classification

success was found to be 56.9% with Linear SVM. From this we can conclude that this classification success is not very good, as it can be assumed that the discrimination rate of two random groups is perhaps 50%. For this reason, we decided to apply the classification method using deep learning techniques.
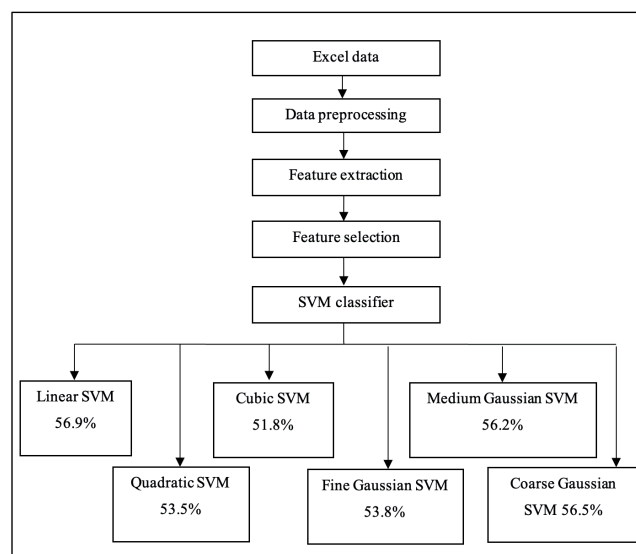
Figure 7. *Machine Learning Classification Method and Accuracy Result of Test Data (SVM: support vector machine)*
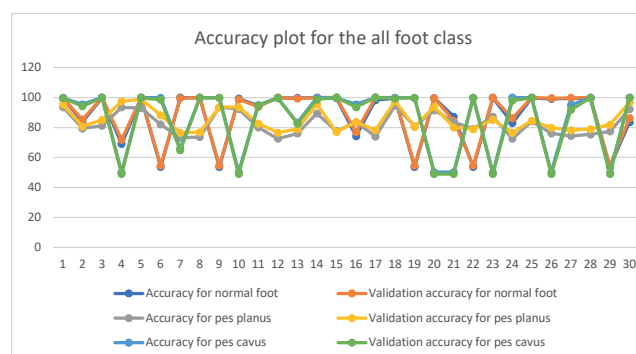
Figure 8. *Accuracy plot for the all foot class*

3.3. Deep Learning Classification

In this study, the CNN method, one of the deep learning techniques, was used because the data to be used for classification are images. When processing the data in the algorithms, 80% of the total data was used as test data and 20% as training data. Each classification was repeated 30 times. The graphs of the percentages of success obtained are given in Figures 8 for each class. When the average success rates of the algorithms were examined, it was found that the average branch prediction was 82.58%±7.62% for the pes planus foot, 87.84±17.56% for the normal foot, and 85.95±21.19 for the pes cavus foot (Table 6).

Tablo 6. Deep learning accuracy ratio descriptive statistic values

Foot type	Accuracy ratio	N	Min.	Max.	Mean	Sd.
Pes planus	Accuracy	30	72.51	94.62	82.58	7.62
	Validation accuracy	30	76.62	98.84	85.06	7.76
Normal	Accuracy	30	53.67	99.93	87.84	17.56
	Validation accuracy	30	54.55	100.00	88.44	17.15
Pes cavus	Accuracy	30	48.82	100	85.95	21.19
	Validation accuracy	30	48.82	100	85.22	21.52

N.: Number; Min.: Minimum; Max.: Maksimum; Sd.: Standart Deviation

4. DISCUSSION

The aim of the study was to determine if there exists a statistical difference between branches in terms of foot type and to use artificial intelligence methods to make predictions about the branch based on the foot pressing types of athletes. The lack of a similar study in the literature accounts for the originality of the study. In addition, it was determined which method is more successful in predicting branches.

Artificial intelligence (AI) technology has become a very active technology in recent years and is used in many fields such as education, and health (33, 34). Machine learning and deep learning methods, which are fields of artificial intelligence, are among the methods whose effectiveness has been demonstrated for such research (35). Recently, these methods have been used in sports science-based studies to predict the performance of athletes and to detect sports injuries, etc. was used for the purpose (36, 37). In this study, branch prediction was generated from the footstep pictures of the athletes by using support vector machine method from machine learning techniques and convolutional neural network methods from deep learning techniques.

Athletes can have different foot types depending on the sport. Klingele et al. (38) found in their study that endurance runners have an increased risk of flat feet. Ślężyński and Dębska (39) explained in their study that elite wrestlers have the highest level of medial longitudinal arch and that pes planus rarely or only slightly occurs in these athletes. In the study by Ramos-Álvarez et al (18), the incidence of pes planus was found to be highest in taekwondo players and lowest in track and field athletes. Lessby et al (19) found that susceptibility to pes cavus was higher in powerlifters, swimmers and field athletes than in pes planus. In another study conducted on sedentary women and female athletes, the pes cavus foot type was found to be most common in both groups (40). In this study, there are two branches, namely athletics and combat (karate, judo, taekwondo). As you can see, the literature argues that there is a difference in foot type depending on the sports branch. When examining the statistical analyzes of the study, no significant difference was found between the foot types of the two branches. The reason for this difference not occurring could be the inclusion of three different sports branches within the combat sports branch. This fact is a limitation of the study and it is recommended that combat

sports be examined separately in similar studies conducted in the future. In addition, the inbalance number of participants in athletics (N=54) and combat (N=26) branches included in the study may have resulted in the difference not occurring. It is recommended to select an equal number of athletes from the branch in future studies.

In the study, a branch classification was performed based on the Support Vector Machine Classifier, one of the machine learning techniques, and the plantar pressure images. In this study, the success rate of SVM classification based on six features from the participants' footprints was about 50%. The success of branch prediction with machine learning was found to be low.

In traditional machine learning, engineers or data scientists typically compute features from the raw data before feeding them into the algorithms. And these features become a representation of the input data that make it easier for the algorithms to learn patterns. On the other hand, deep learning algorithms can automatically learn feature representations from the raw data which is useful in eliminating the need for manual feature engineering. Deep learning performs representational learning-based learning by learning multiple features of data. In representation learning, features such as pixel density vectors, edge sets, etc. of the data are learned and algorithms are used to extract data features (31, 41, 42). In addition, with deep learning, low-dimensional features of the data are extracted and converted into high-dimensional features (32). Thus, a model with high classification success can be produced by performing a more detailed data analysis in deep learning. The superiority of deep learning over traditional machine learning methods depends on the specific task, dataset characteristics, and available computational resources. Deep learning is particularly popular in recent years because people learn that we can automate the process of feature construction rather than have human labor to work on that as in traditional machine learning. Also, given the progress of modern technology, which has much more complicated structure and large dataset, the deep learning method can take advantage of that and a better and better performance in many different applications such as image recognition, computer games and so on.

Studies have shown that deep learning has better classification success than the machine learning method in large-scale data (43, 44). However, it is known that obtaining large datasets is quite difficult (32, 45). Obtaining datasets used especially for medical diagnoses is costly, labor-intensive and can be difficult due to patient protection reasons, etc. In such cases, the data augmentation method can be used (28, 46-49). To increase the classification success with deep learning, this study preprocessed the data and augmented the foot images showing the plantar pressure distributions using the data augmentation method. Random deletions and random clipping are not favored to avoid data loss. The success of deep learning has been enhanced by increasing the amount of data based on

the preferred methods. Increasing the number of datasets using these methods is the strength of the study. In the results obtained with CNN, the average success of branch prediction from images of pes planus feet is 82.58%±7.62%, the average success of branch prediction from images of normal feet is 87.84±17.56%, and the average success of branch prediction from images of pes cavus feet is 85.95±21.19%. It should be noted that, logically, there is a 50% probability of guessing which of the two branches the athlete belongs to. However, the predictions made with deep learning methods show accuracy rates of over 80%. These high estimates show that the deep learning models developed provide sound and reliable results.

The use of an inbalance dataset in the study constitutes the limitations of the study. It is recommended to use a balanced dataset in similar studies using the machine learning method in the future. The strength of the study is that it is a first in the literature and that the data augmentation method is used to increase the success of deep learning. In addition, creating sports branch predictions based on each foot type (pes planus, pes cavus, normal foot) increases the level of detail of the study and represents one of the strengths of the study. These results lay the foundation for the development of technological products to be produced in the future for talent selection methods.

5. CONCLUSION

Studies show that there is a correlation between the type of athlete's foot and the type of sport. Starting from this point, we tried to predict the type of sport the participants would play step by step based on their foot type. The statistical results showed that athletes from two different branches had similar foot types. The machine learning technique was not sufficient to predict the sports based on foot type. In contrast, the deep learning models developed for branch prediction based on foot type showed high success rates in the study. We have developed deep learning models for predicting sports branches, and these methods can give an idea of which sports people are more likely to play based on their foot types. Using these deep learning models, future studies can ensure that athletes choose their sports branch based on their foot type as part of talent selection.

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Edpuzzle Application in Improving Nursing Students' Metric and Drug Dose Calculation Skills in a Virtual Learning Environment: Mixed Methods Study

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ABSTRACT

Objective: This study aims to determine the effect of Edpuzzle application on nursing students' metric conversion and drug dose calculation skills.

Methods: 84 nursing students participated in parallel groups in the mixed model single-blind randomized controlled study, conducted between April and June 2021.Data were collected using a descriptive features form, metric and drug dose calculation skill test. After all students completed the theoretical lessons, a pre-application of the skill test was made. After the experimental group students watched the interactive videos in the Edpuzzle application for fifteen days, a final skill test was applied to all students. Then, four focus group interviews were conducted with 28 experimental group students.

Results: The last scores of the students in the experimental group, pertaining to metric and drug dose calculation skill test, were higher than those of the students in the control group and were statistically significant (p<.05). In the focus group discussions, the students said that the Edpuzzle application is useful, increases the memorability, but they encountered the problem that the videos could not be fast forwarded.

Conclusion: This is the first study on which Edpuzzle application was used to calculate metric conversion and drug dose in nursing students. It was determined that Edpuzzle application in the virtual learning environment increased the metric and drug dose calculation skills of nursing students. Based on the results of the study, it is recommended to integrate Edpuzzle as an innovative teaching technology into the nursing education curriculum and to be used in the courses.

Keywords: Drug dose, edpuzzle, metric conversion, nursing education, virtual learning

1. INTRODUCTION

Drug administration is one of the most basic functions and legal responsibility of nurses. In order for drugs to be administered safely, drug doses must be calculated correctly. Errors in drug dose calculation account for more than 15% of drug errors and may lead to the death of patients (1,2). It is reported that nurses spend approximately 40% of their time on medication administration. Therefore, it is very important to prevent medication errors with accurate dose calculations (3). Nursing students have difficulties in this regard because drug dose calculations require complex skills where the patient's age and weight are taken into consider (4). Many studies show that nurses and nursing students have a low rate of calculating the drug doses correctly (5-10). In a study, the rate of students who solved the questions on drug dose calculation without making any mistakes was determined as 16.7% (5). In another study, it was found that after training on drug dose calculations only 26.8% of

the nursing students were sufficient in calculating the drug dose and 33% knew how to calculate the dose (6). These rates show that drug dose calculation teaching methods are not sufficient in nursing education. Another study found that nursing students had poor basic maths calculation skills and therefore students needed support in calculating drug dosage (7). In a study examining the drug dose calculation skills of graduating nursing students, it was determined that the students made simple drug calculations, but a significant number of students had difficulty in calculations that required more than one operation and more conceptual understanding skills (8). In a retrospective study, a total of 285 exam papers and 1034 drug dose calculation questions of 1st, 2nd and 3rd year nursing students were examined, and it was determined that the most common errors were related to more complex operations such as unit conversion and dilution. Other common mistakes were found to be not

understanding the question and not using basic units when answering (9). In another study, it was determined that senior nursing students had low drug dose calculation skills (10).

In the emergence of these results; reasons such as the fact that adequate practice in the clinical setting is not possible for every students (5), lack of resources for drug calculations (1,3), students' lack of conceptual understanding, low numerical skills (3,9), anxiety, low self-efficacy (3), insufficient physical conditions of schools, high number of students in classrooms (11), the low number of instructors per student and the inability to solve a sufficient number of sample questions due to the dense curriculum (2,6) are effective. Therefore, students may be prone to medication errors and they need various interventions to increase their drug dose calculation skills (2). Although the approaches to these requirements differ, it is vital that nursing students acquire the skills to calculate adequate medication doses. Because, when they start professional practices, they will be responsible for the administration of medicines.

It is stated that education programs are effective in improving the mathematical and drug dose calculation skills of nursing students (12). In the 21st century digital learning era, Web 2.0 tools such as Edpuzzle, Edmodo, Kahoot have started to be used. In our study, Edpuzzle application was used to improve the metric conversion and drug dose calculation skills of nursing students.

The virtual classroom that provides virtual learning is defined as a computer-based environment. In the virtual classroom, the instructor and students can work together and use multiple communication channels such as audio, video and whiteboard (13). One of the preferred platforms for virtual learning is Edpuzzle. Edpuzzle is a free video sharing program that helps students examine the lesson as a whole and determine whether the subject is understood or not, and provides the opportunity of using interactive videos online in learning (14). Edpuzzle was officially founded in 2013. Before it existed as it is known today, Edpuzzle CEO and math teacher Quim Sabrià began creating his own video lessons to reach all students. Sabrià shared this idea with his friends Jordi Gonzalez, Santi Herrero, Xavi Vergés, and the four friends founded Edpuzzle, which is known today (15).

Edpuzzle enables students to focus their attention throughout the video and interact with the video while watching, with its features such as cutting the video, voice-over, adding voice notes, adding open or closed-ended Questions (16). It also allows sharing interactive videos prepared by instructors in virtual classrooms and accessing student analyses for videos (14). Recent studies show that Edpuzzle application has positive effects on students' knowledge and skills. For example, Kaplan and Tüzer (17) a randomized controlled study with 67 students reported that Edpuzzle increased stoma care knowledge and skill scores of the nursing students.

There are researches used by Edpuzzle in different disciplines. Similarly, although there are studies conducted in the field of nursing, no study has been found in which Edpuzzle was used on nursing students' metric and drug dose calculation skills. Our research is an original study conducted to determine the effects of Edpuzzle application on the development of nursing students' metric and drug dose calculation skills in a virtual learning environment.

The hypotheses of the study are:

H_1-1: Edpuzzle application increases the metric conversion skills of nursing students.

H_1-2: Edpuzzle application increases the drug dose calculation skills of nursing students.

2. METHODS

2.1. Design

It is a mixed model single-blind randomized controlled study in parallel groups.

2.2. Participants

The population of the research consisted of 131 students enrolled in the Fundamentals of Nursing course in the Faculty of Health Sciences, Department of Nursing at a state university in a Turkey April-June 2021. Inclusion criteria for the study: (1) Registered for the first time in the Fundamentals of Nursing course and (2) Students who volunteered to participate in the research. Exclusion criteria: (1) Graduated from a health-related high school or university, (2) Having difficulties in speaking and understanding Turkish and (3) Students who do not have sufficient internet. Since it was planned to reach the entire population in the research, the remaining students after exclusions were included in the sample. In this context, 12 health-related high school and university graduates, 23 students who had difficulty in speaking and understanding Turkish, 7 students who did not have sufficient internet, and 5 students who re-took the Fundamentals of Nursing course were excluded from the study. After exclusions, 84 students were randomly assigned to control (n= 42) and experimental (n= 42) groups using the simple randomization method according to gender. At the qualitative stage, all experimental group students (n= 42) were invited to focus group interviews. A sample of 28 students, who volunteered to participate in the interviews, was created.

Before starting the study, the registration number (ID: NCT04800380) was obtained from "ClinicalTrials.gov". Written approval was obtained from the university ethics board (01.03.2021/19) and from the institution involved (16.03.2021/E-52950036.045.9490). The students were informed about the purpose and method of the research and their consent was obtained. This study was conducted

in accordance with the principles of the Declaration of Helsinki.

2.3. Data collection and measures

The data were collected with the "Descriptive Characteristics Form", "Metric and Drug Dose Calculation Skill Test" and "Semi-structured Focus Group Interview Form" prepared by the researchers through scanning the literatüre (4,18). The descriptive features form consisted of 12 closed-ended questions. The skill test consisted of 20 five-choice and multiple-choice questions. 1st – 4th questions were on metric conversion calculation, 5th – 8th questions on oral drug dose, 9th – 12th questions on local drug dose, 13th – 16th questions on parenteral drug dose and 17th – 20th questions were on liquid drug dose calculation. Wrong answers were evaluated as "0" points and correct answers as "5" points. The lowest score that could be obtained from this test was "0" and the highest score was "100". After the test was prepared, opinions were received from a faculty member who is an expert in the field of Mathematics and two faculty members who are experts in the field of Nursing Fundamentals. Necessary adjustments were made in the knowledge test based on expert opinions. Content Validity Ratio (CVR) and Content Validity Index (CVI) were determined by creating a specification are provided in Table 1.

The interview form consisted of three open-ended questions in order to evaluate the opinions of the experimental group students about the Edpuzzle application. For the interview form, opinions were obtained from three faculty members who are experts in qualitative research. According to expert opinions, necessary adjustments were made to the form.

2.4. Creation process of video lessons and edpuzzle assignment

Five video recordings were made with the OBS Studio 26.1.1 program (Open Broadcaster Software) in order to improve the metric and drug dose calculation skills of the students. OBS is an open source, free video recorder and live broadcast tool. The software is available and can be accessed on its original site (19). Videos consisted of solving 50 sample problems on 1. Metric calculation, 2. Oral drug dose calculation, 3. Local drug dose calculation, 4. Parenteral drug dose calculation, 5.

Liquid drug dose calculation. The videos provided answers to the study questions. All of the videos were created by the responsible researcher in order to eliminate interpersonal differences in teaching. The camera angle has been zoomed in to ensure image clarity while video recordings are being taken. The shortest video was 13 minutes and the longest was 31 minutes.

To become a member of Edpuzzle for free, the link https://edpuzzle.com was entered on the web. A new account has been opened from the trainer section and a virtual classroom has been created under the name of "ÇAKÜ-Nursing". "My Content" was selected and the videos were uploaded to the Edpuzzle application in order, after clicking the "Add Content" button. Four multiple-choice questions were added to the uploaded videos for students to answer, using the "Questions" and "Multiple-choice question" options. Answer options for each question were created and the correct answer was marked. In addition, the option of not advancing the video without the answer of the student to the question was selected and the editing process was completed through clicking the "Finish" button. Edited interactive videos were assigned to the "ÇAKÜ-Nursing" virtual class by determining the "Start Date" and "Due Date". After all interactive videos were assigned to the virtual classroom, they appeared in the "My Classes" tab (Fig. 1).
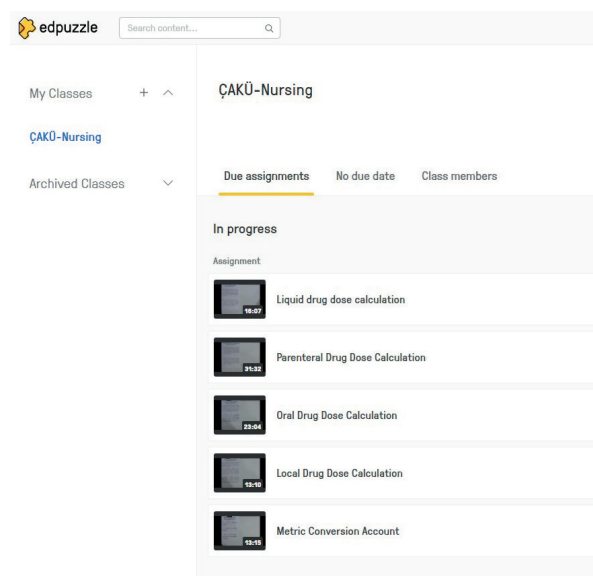
Figure 1. *Interactive videos in the edpuzzle virtual classroom*

Table 1. *Specification table*

Question	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	CVR
Expert 1	√	√	√	√	√	√	√	√	☒	√	√	√	√	√	√	☒	√	√	☒	√	0.7
Expert 2	√	√	√	√	√	√	√	√	☒	√	√	√	☒	√	√	√	√	√	☒	√	0.7
Expert 3	√	√	√	√	√	√	√	√	√	√	√	√	☒	√	√	☒	√	√	√	√	0.8
																			Mean CVI		0.7

CVR= Content Validity Ratio; CVI: Content Validity Index

Then, "class code" was created from "Class members" option. After registering for free to Edpuzzle, students joined the "ÇAKÜ-Nursing" virtual class with the class code given to them. The date of watching the videos and their answers to the questions in the videos appeared in the "Students" tab (Fig. 2). A pilot test was conducted with 10 nursing students who had successfully passed Fundamentals of Nursing course before starting the study. Pilot test data were not included in the study.

Figure 2. Monitoring analysis of students' liquid drug dose calculation

2.5. Application of the study

Web-based theoretical training for metric and drug dose calculation was given to all students via the "Advancity Learning Management System (ALMS)" (https://karatekin.almscloud.com/Account/LoginBefore) of the university where the study was conducted. Then, two separate WhatsApp group was created covering the students in the experimental and control groups. The "Descriptive Characteristics Form" created via Google forms was sent to control and experimental student groups and asked to fill in. On the same day, the students were informed about that they will take the skill test for calculating metric and drug dose, and they were given a week to prepare. The questions in the skill test were added to the ALMS system sequentially, the correct answers were marked, and the virtual exam was created, giving the students 40 minutes. Then, in order to make a score analysis for each subject, the option to "mix the answer choices but not the questions" was selected. One week after the theoretical training, students participated in the virtual exam, which was the pre-test application of the "Metric and Drug Dose Calculation Skill Test". In order to ensure online exam security, each student was given a certain amount of time to answer a question. At the same time, the student did not have the opportunity to go back and re-examine a question he had answered. After the exam, a detailed document on the scores received by the students was obtained from the ALMS system.

After the pre-test application, no intervention was made to the students in the control group. The students in the experimental group were informed about the Edpuzzle application, the class

code was sent, and they were given fifteen days to watch the interactive videos in the "ÇAKÜ-Nursing" virtual class. Then, students' access to the Edpuzzle application was automatically closed. The next day, all students were informed about that they were going to undergo the skill test for calculating metric and drug dose, and they were given a week to prepare. The questions in the skill test were added to the ALMS system sequentially, the correct answers were marked, and the virtual exam was created by giving 40 minutes to the students. Three weeks after the pre-test, the students took the virtual exam, which was the last test application of the "Metric and Drug Dose Calculation Skill Test" (Fig. 3). After the exam, a detailed document on the scores received by the students was obtained from the ALMS system. After the study was completed, all other students in the control group and the ones who were excluded from the study were able to access the Edpuzzle application.

At the qualitative stage, four focus group interviews were conducted in groups of seven to evaluate the opinions of the voluntery students in the experimental group about the Edpuzzle application. The time and place of the interviews were planned with the students. Before starting the interviews, students were informed about the purpose, scope and approximate duration of the interview. It was explained that audio recording will be taken during the interviews. After the consent of the students was received, negotiations were started. A total of 28 students and researchers participated in the interviews. Each of the interviews lasted 30-40 minutes. The researchers conducting the interviews are experienced (Fig. 3).
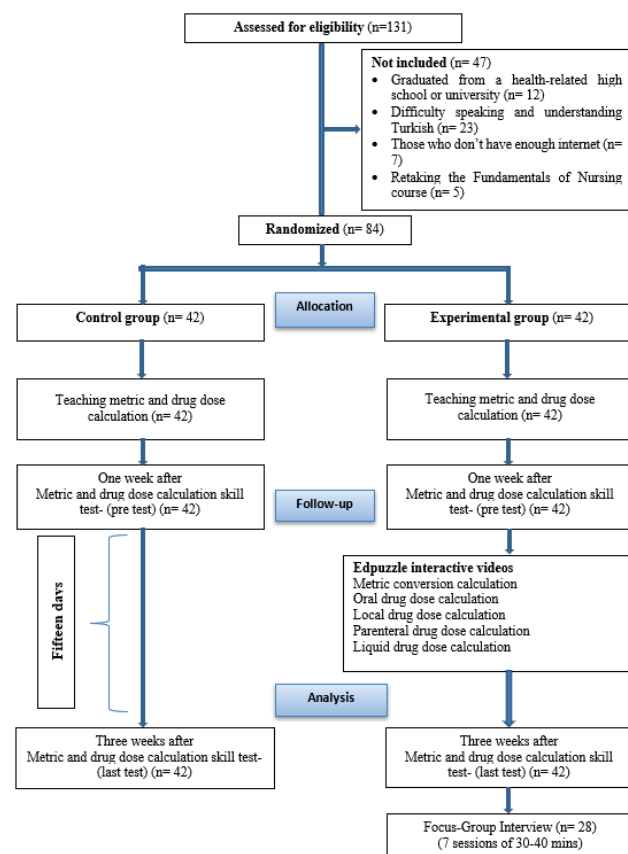
Figure 3. CONSORT diagram of this study

2.6. Data analysis

The data were analyzed with the SPSS package program (version 22.0; SPSS, Inc., USA). Number, percentage, mean and standard deviation were used in descriptive statistics. Kolmogorov Smirnov Test was used to determine normal or non-normal distribution. Parametric tests (df=84, p>.05) were used to indicate the normal distribution, and the Independent-Samples T-Test was used to evaluate differences between groups. The relationship between the grouped variants was tested by Chi-Square (χ^2) analysis. Paired-Samples T-Test was used to determine the differences between the initial and post-test scores for the matched groups. The data were evaluated at a significance level of p<.05 at 95% confidence level. The data obtained from the focus group interviews were coded by three independent researchers and thematic content analysis was performed. Themes, sub-themes and codes were created for frequently repeated expressions.

3. RESULTS

3.1. Quantitative findings of the study

66.7% of the students in the control group and 71.4% of the students in the experimental group are women. 73.8% of the students in the control group and 80.9% of the students in the experimental group are between the ages of 19-20. 80.9% of the students in the control group and 83.3% of the students in the experimental group were graduates of anatolian high school. It was determined that 95.2% of the students in the control group and 92.8% of the students in the experimental group liked mathematics. No statistically significant difference was observed between the control and experimental groups in the distribution of their descriptive characteristics (p>.05) and are provided Table 2.

There was no statistically significant difference between the initial scores of control and experimental groups on the metric and drug dose calculation skill test (p>.05). Metric and drug dose calculation skill test final scores (19.52 ± 1.48; 68.45 ± 7.28) of the students in the experimental group were significantly higher than the control group (17.38 ± 2.75; 52.97 ± 11.31) (p=.000) (Table 3).

While there was no significant difference in the initial scores of control and experimental groups regarding oral, local, parenteral and liquid drug dose calculation scores (p>.05), the final scores of the students in the experimental group (19.52 ± 1.85; 15.83 ± 3.96; 17.26 ± 3.16; 16.07 ± 3.03) were found to be significantly higher than the control group (17.61 ± 3.70; 13.80 ± 4.24; 12.02 ± 4.69; 9.04 ± 4.84) (p<.05) (Table 4).

Table 2. *Distribution of control and experimental group students according to their descriptive characteristics (n=84)*

Characteristics	Control n = 42 (%)	Experimental n = 42 (%)	χ^2**	p
Gender				
Female	28 (66.7)	30 (71.4)	0.073	.840
Male	14 (33.3)	12 (28.6)		
Age				
17-18	7 (16.7)	5 (11.9)	0.852	.584*
19-20	31 (73.8)	34 (80.9)		
21 and above	4 (9.5)	3 (7.2)		
Graduated high school				
Anatolian High School	34 (80.9)	35 (83.3)	0.173	.931*
Science High School	5 (11.9)	4 (9.5)		
Other[a]	3 (7.2)	3 (7.2)		
Liked Mathematics				
Yes	40 (95.2)	39 (92.8)	0.267	.718*
No	2 (4.8)	3 (7.2)		
Uses calculator in calculations				
Yes	25 (59.5)	27 (64.2)	0.271	.745
No	17 (40.5)	15 (35.8)		
Internet use monthly				
3-4 GB	42 (100)	40 (95.2)	1.016	.552*
5 GB and above	-	2 (4.8)		
Internet Access tool[b]				
Computer	3 (7.2)	2 (4.8)	1.245	.504*
Mobile phone	12 (28.6)	9 (21.4)		
Computer + Mobile phone + Tablet	27 (64.2)	31 (73.8)		
Metric conversion and drug dose resources[b]				
Course notes	10 (23.8)	9 (21.4)	0.307	.848
Course notes + Books	21 (50)	23 (54.8)		
Course notes + Books + Internet	11 (26.2)	10 (23.8)		
Virtual learning experience				
Yes	15 (35.8)	17 (40.5)	0.267	.747
No	27 (64.2)	25 (59.5)		
Problems in metric and drug dose calculations[b]				
Metric conversion	7 (16.7)	8 (19)	5.358	.600*
Oral drug dose calculation	2 (4.8)	1 (2.3)		
Local drug dose calculation	1 (2.3)	-		
Parenteral drug dose calculation	4 (9.5)	4 (9.5)		
Liquid drug dose calculation	1 (2.3)	2 (4.8)		
Metric + drug dose calculation	20 (47.7)	19 (45.4)		
None	7 (16.7)	8 (19)		

[a] *Vocational high school of commerce, open education high school and private high school*
[b] *Since more than one answer was given, they were given as percentage results*
* *Fisher's Exact Test,*
** *Chi-Square Test*

Table 3. Comparison of pre-test and last test scores of control and experimental group students pertaining to the metric and drug dose calculation skill test (n=84)

	Metric calculation skill test scores				Drug dose calculation skill test scores			
	Skill score (min:0-max:20)				Skill score (min:0-max:80)			
	Groups				Groups			
	Control X±SD ^{d}	Exp^a X± SD ^{d}	t^b	p	Control X± SD ^{d}	Exp^a X± SD ^{d}	t^b	p
First	16.30 ± 4.28	15.95 ± 3.53	0.417	.678	53.33 ± 13.86	54.04 ± 12.84	-0.245	.807
Last	17.38 ± 2.75	19.52 ± 1.48	-4.433	.000	52.97 ± 11.31	68.45 ± 7.28	-7.452	.000
p^c	.048	.000			.706	.000		

^{a} Experimental, ^{b} Independent sample t-test , ^{c} Paired sample t-test, ^{d} X: mean value, SD: standard deviation

Table 4. Comparison of the pre-test and the last test scores of the control and experimental group students regarding the sub-data of the drug dose calculation skill test (n=84

	Oral drug dose calculation scores				Local drug dose calculation scores				Parenteral drug dose calculation scores				Liquid drug dose calculation scores			
	Skill score (min:0-max:20)				Skill score (min:0-max:20)				Skill score (min:0-max:20)				Skill score (min:0-max:20)			
	Groups				Groups				Groups				Groups			
	Control X±SD ^{d}	Exp^a X±SD ^{d}	t^b	p	Control X±SD ^{d}	Exp^a X±SD ^{d}	t^b	p	Control X±SD ^{d}	Exp^a X±SD ^{d}	t^b	p	Control X±SD ^{d}	Exp^a X±SD ^{d}	t^b	p
First	19.16 ± 2.90	18.45 ± 3.02	1.104	.273	13.69 ± 5.18	12.85 ± 5.31	0.727	.469	13.09 ± 5.51	14.52 ± 5.15	-1.226	.224	7.38 ± 5.97	7.97 ± 5.41	-0.478	.634
Last	17.61 ± 3.70	19.52 ± 1.85	-2.982	.004	13.80 ± 4.24	15.83 ± 3.96	-2.256	.027	12.02 ± 4.69	17.26 ± 3.16	-5.998	.000	9.04 ± 4.84	16.07 ± 3.03	-7.966	.000
p^c	.011	.037			.812	.001			.071	.005			.021	.000		

^{a} Experimental, ^{b} Independent sample t-test,^{c} Paired sample t-test, ^{d} X: mean value, SD: standard deviation

3.2. Qualitative findings of the study

Table 5. Interviews: Context, themes, and sub-themes (n=28)

Context	Themes	Sub-themes
Opinions for calculating metric and drug dose	Metric and drug dose calculation	➢ Professional Requirement ➢ It is vital ➢ Difficult topics ➢ Not making mistakes
Opinions on the Edpuzzle application	Effect on metric and drug dose calculation skills	➢ Technical problem ➢ Useful on-line content ➢ Usability ➢ Inexpensive and available ➢ Persistence in mind ➢ Increasing learning
Opinions on the virtual learning experience	Positive opinions about virtual learning with Edpuzzle	➢ Being Instructive ➢ Flexibility in education ➢ Trustable
	Negative opinions about virtual learning with Edpuzzle	➢ Preference of face-to-face education ➢ Not being able to receive a feedback

3.2.1. Opinions for calculating metric and drug dose

Students, expressed opinions such as professional necessity, vital importance, difficult issues, not making mistakes regarding metric and drug dose calculation. Sample comments:

"Very necessary for our profession, but quite difficult subjects" (S.27).

"Making a small mistake can harm human life. That is why it is very important" (S.5).

3.2.2. Opinions on edpuzzle application

The students stated that Edpuzzle is useful, cheap and accessible, and that the useful online content in the videos increases memorability and learning, but they encountered

technical problems such as the inability to fast forward the videos in the application. Sample comments:

"*The questions in the videos are very useful, but when I wanted to pass some places faster, the application did not allow me to fast forward the videos. The practice is bad in this aspect*" (S.18).

"*The app is very useful. It doesn't charge users either. I could easily log in with my e-mail address and password*" (S.9).

"*The questions we came across during the videos were very useful. As we solved the questions, it became instructive and more memorable*" (S.23).

3.2.3. Opinions on virtual learning experience

Students stated that Edpuzzle provides flexibility in education through the opportunity to watch it over and over again in the desired place, time and space, it is instructive and increases the sense of confidence. Some students stated that they preferred face-to-face training because of problems such as not being able to receive immediate feedback. Sample comments:

"*Of course, it is more beneficial than face-to-face training. I could open and watch as much as I wanted whenever I wanted*" (S.1).

"*At first I couldn't understand, then I watched it over and over. Now I can easily understand what the question is asking of me. My self-confidence has increased in this regard*" (S.21).

"*If I were in the classroom, I could instantly ask where I couldn't understand and get an answer back. I think face-to-face education is more beneficial*" (S.16).

4. DISCUSSION

In our study, it was determined that the Edpuzzle application in the virtual learning environment, increased the metric and drug dose calculation (oral, local, parenteral and liquid drug dose calculation scores) skills of nursing students. In various nursing students studies in the literature, it has been found that analytical thinking, creativity, technological skills of the students have improved and their level of knowledge has increased in lessons where Edpuzzle is used (17, 20-23). Edpuzzle was determined that the flipped classroom using interactive videos increased nursing students' biostatistics knowledge scores (22). In the other study, Edpuzzle was used as one of the digital material preparation tools in flipped learning. As a result of the study, it was determined that nursing students' knowledge of asepsis increased (20). Similarly, Edpuzzle, one of the digital materials, was used in flipped learning. In this study, it was found that nursing students' knowledge of patient safety increased (23). Edpuzzle is stated as an interactive online material that nurse educators can use to enhance learning (24). Edpuzzle, used as a digital material in a flipped learning environment, was found to increase first-year nursing students' blood pressure knowledge (21). Kaplan and Tüzer (17) determined comparing

Edpuzzle with web-supported education and peer education that both methods increased the stoma care knowledge of nursing students. The emergence of these results can be attributed to the positive effects of the students' ability to access and rewatch the videos whenever and wherever they want, and the fact that the questions in the videos increase the motivation and interaction of the students. In addition, taking into account individual differences in learning, providing an autonomous learning environment by Edpuzzle may contribute to the increase of student skills.

In the qualitative findings of our study, students stated that metric and drug dose calculations are necessary and vital, and that Edpuzzle application increases memorability, is useful and accessible. In their experiences with virtual learning, some students stated that Edpuzzle application provides flexibility in education, is instructive, but some others prefer face-to-face education due to problems such as not receiving immediate feedback. In nursing education, a study was found in which student (22) and nurse educators' (25) opinions were taken about the Edpuzzle application. In the study where student views were taken about the Edpuzzle, students stated that the Edpuzzle was instructive, fun, made it easier for them to prepare for exams and that they were satisfied (22). Similarly, in the study in which nurse educators' opinions about the Edpuzzle were taken, educators stated that the Edpuzzle increases students' interest in learning with its audio-visual content and positively supports students' learning (25). Since there has not been any other study in which user opinions about Edpuzzle have been obtained in the field of nursing, the data of this study have been discussed with similar research results conducted in the literature. In the qualitative researches, it was determined that the students' views on the Edpuzzle application were positive. The qualitative findings of our study support the previous studies, such as the following: Gómez-García et al (26) examined the effect of Edpuzzle application on healthy habits and diet in primary school sixth grade students and determined that Edpuzzle increased students' motivation and autonomy. Abou Afach et al (16) reported that the use of Edpuzzle in the education of children with special requirements, increased the awareness of the students. Su and Chiu (27) examined the experiences of primary school students on using Edpuzzle interactive video and reported that 76.4% of the students had a positive attitude towards Edpuzzle. The fact that Edpuzzle increases visual and auditory interaction, contributes to learning, is fun, helps prepare for exams and increases the desire to learn may have contributed to the positive student opinions in this study.

In our research, students encountered technical problems in the Edpuzzle application and stated that the videos could not be fast forwarded. In a study, nursing students expressed negative opinions that an extra internet package was needed to watch Edpuzzle interactive videos and that watching the videos was a waste of time (22). The nursing students who participated in this study are Generation Z. Regarding the lack of function of fast forwarding in the Edpuzzle videos as a problem by the Z generation students, can be attributed to the fact of active

use of technology by this generation. Additionally, the fact that Edpuzzle requires the use of the internet and that time must be spared to watch may have caused negative student opinions. The positive and negative opinions of the students on the virtual learning experience may be due to individual learning differences. The results of our study show us that supporting nursing students with Edpuzzle application has a positive effect on their learning levels.

5. CONCLUSION

The rapid development of technology has necessitated the use of information technologies as an important tool in education. In this direction, nurse educators tend to include instructional technologies that will stimulate the students' affective domains into the nursing education curriculum. The results of this study showed that Edpuzzle application in virtual learning environment increased the metric and drug dose calculation skills of nursing students. Based on the results of the study, we suggest Edpuzzle to be integrated and used as an innovative teaching technology in the nursing education curriculum.

The study is limited to first-year students in the faculty of nursing at a state university in a Turkey and agreed to participate in the research.

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Knowledge Levels and Health Beliefs of Turkish Young Women About Breast Cancer

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ABSTRACT

Objective: This study was conducted to determine the knowledge levels and health beliefs of young women studying at university regarding breast cancer and breast self-examination (BSE).

Methods: This descriptive study's sample consisted of 812 female students. Data were collected using the Personal Information Form, Comprehensive Breast Cancer Knowledge Test (CBCKT) and Champion Health Belief Model Scale (CHBMS). The data were transferred to SPSS for Windows 22.0. The descriptive statistical analysis and Pearson Correlation Analysis was used to evaluate the relationships between parameters. Predictive factors associated with breast self-examination among young women were tested with multivariate logistic regression analysis. The results were evaluated bidirectionally at 95% confidence interval and significance level $p < .05$.

Results: The participants mean age was 20.09 (1.64) years and 12% had a family history of breast cancer. 12.1% of the participants stated that they performed BSE regularly. The mean total score of the participants in the CBCKT was 12.48(2.41); the mean scores in the sub-dimensions of sensitivity, caring/seriousness, health motivation, benefit perception, barrier perception, and self-efficacy/confidence of the CHBMS were 8.26(2.42); 20.80(3.21); 19.20(2.70); 16.50(3.02); 18.28(3.36); 39.92(3.40), respectively. Married young women had a 4.86 times higher likelihood of performing BSE compared to unmarried young women (AOR = 4.86, 95% CI: (2.16–10.48)). A family history of breast cancer was significantly associated with the practice of BSE. It was determined that young women with a family history of breast cancer were 3.46 times more likely to engage in BSE compared to those without a family history (AOR = 3.46, 95% CI: (1.68–9.86)). Young women who perceived their knowledge about breast cancer as sufficient were found to have a 1.86 times higher likelihood of performing BSE compared to those who did not (AOR = 1.86, 95% CI: (1.00–3.40)). Holding other factors constant, there was a 1.72 times increase in the likelihood of conducting breast self-examinations with a one-unit increase in age (AOR = 1.72, 95% CI: 1.06–1.20).

Conclusion: This study found that as participants' knowledge levels about breast cancer / BSE increased, their sensitivity, concern/seriousness, health motivation, perceived benefits, and self-efficacy/confidence also increased, while perceived barriers decreased. There is an urgent need to increase knowledge and practice of breast self-examination to prevent and detect breast cancer at its early stage.

Keywords: Breast cancer, breast self-examination, knowledge, health belief, women

1. INTRODUCTION

Breast cancer is the most common cancer among women worldwide and the leading cause of cancer-related deaths. According to estimates by the International Agency for Research on Cancer (IARC), a subsidiary of the World Health Organization (WHO), approximately 2.3 million new cases of breast cancer were reported worldwide in 2020, indicating that 1 in 8 diagnosed cancers will be breast cancer (1). Again in 2020, breast cancer caused 685,000 deaths and ranked 5th among the cancers that cause death worldwide. In women, breast cancer is responsible for 1 in 4 cancer cases and 1 in 6 cancer-related deaths. In addition, this disease ranks first in terms of mortality (death rate) and incidence (new case rate) in many countries (2). According to 2020 statistics, breast

cancer ranks first among the top 5 most common cancers in women in Turkey. The average age of women diagnosed with breast cancer is 51 and 17 percent of patients are under 40 years of age (3). The disease is not only life-threatening, but the medical and surgical treatment process from the time of diagnosis negatively affects a woman's body image, family relationships, roles, sexual health, quality of life, social and professional life. Patients and their families have to cope with this devastating disease and its effects. Treatment and care services provided in the period following the diagnosis of breast cancer impose great economic costs on both individuals and countries (4-6).

Breast cancer is one of the most preventable and curable diseases in case of early diagnosis. Early detection of breast cancer causes 90% of women to live at least 5 years after diagnosis and increases survival (7). The widespread use of screening programs and advances in treatment methods contribute to early detection, treatment and follow-up of the disease. For this reason, WHO recommends the establishment and dissemination of early diagnosis and screening programs for breast cancer based on countries' own realities, taking into account economic, social and cultural factors, and eliminating existing barriers (7). In this context, for early diagnosis of breast cancer, it is necessary to increase women's breast cancer awareness (education), breast self-examination (BSE), clinical breast examination (CBE) and screening mammography (8). But BSE a recommended method for early detection of breast cancer in less developed countries, albeit relatively early, because it is economical, easy and can be easily performed by women themselves. Particularly in developing countries, including Turkey, when socio-economic realities are taken into consideration, it is accepted that BSE is an indisputably important necessity and an inevitable practice (9). One of the important methods for early detection of breast cancer is CBE. When performed in combination with mammography, it is reported to increase the detection rate of cancer by 5-20%. Mammography is the most important screening method that reduces breast cancer mortality. Studies show that mammographic screening (with or without CBE) is effective in women aged 50-69 years (8). The American Cancer Society recommends that women in the 20-39 age group should undergo monthly BSE and every 3 years CBE; women in the 40-49 age group should undergo monthly BSE every month, yearly CSE, and mammography every 1-2 years; women aged 50 years and older are recommended to undergo monthly BSE, yearly CBE, and yearly mammography (8). In our country, as part of the National Cancer Screening Program for breast cancer, women aged 40-69 undergo a clinical breast examination once a year and a mammogram every two years (11). The Ministry of Health emphasizes the importance of BSE training and recommends that women perform a self-examination of their breasts every month starting at the age of 20 (11).

Although the effect of early diagnosis and screening on prognosis is known, many studies in the literature reveal that women do not benefit from early diagnosis due to many factors such as lack of knowledge about disease symptoms / screening programs, economic problems, inadequate access to health services, fear of pain, embarrassment, beliefs that their privacy will be ignored and that screening is unnecessary (6,8-10). At this point, informing women about the subject from their youth and raising awareness about breast cancer in the society emerges as an important requirement. Young women are the key stakeholders of "breast cancer" themed health education programs. This is because knowledge about breast cancer, positive health beliefs and healthy lifestyle behaviors are acquired early in life. The decision to participate in screening programs is often strongly influenced by the level of knowledge / attitudes / beliefs of individuals. Informing young women and enabling them to

effectively use screening services that contribute to early diagnosis is the most effective way to reduce breast cancer-related mortality rates. In this context, firstly, young women's level of knowledge about breast cancer and their health beliefs related to breast cancer should be determined. There are studies evaluating the level of knowledge about breast cancer in the literature (10,12-14). However, the level of knowledge alone may not be sufficient to create behavioral change on that subject. The Health Belief Model is used to explain health-related behavior change and to plan intervention research on health maintenance and preventive health behavior. The model was developed to explain why some people exhibit health maintenance behaviors while others participate poorly in disease prevention and screening programs. The model is also used to evaluate the factors affecting breast cancer early diagnosis/ screening behaviors as well as other protective behaviors (15-17). According to the Health Belief Model, individuals' health behaviors are influenced by their values, beliefs and attitudes. The model argues that the value placed on health is influenced by beliefs about illness and its consequences. If individuals have the belief that a health problem will cause serious harm to them, they think that when they take action to reduce the risk, the harm to themselves will decrease. Therefore, people who perceive themselves to be at risk for negative outcomes may control their risky behaviors or existing risk factors more than those who do not perceive themselves to be at risk (17,18). It is aimed to evaluate women's health beliefs as well as their level of knowledge about breast cancer and breast self-examination. The data obtained can be used in determining the scope of health education and structuring the content of education.

2. METHODS

2.1. Design

This study was a cross-sectional study. The study was conducted in the fall semester (October, 10-November, 30) of the 2022-2023 academic year at the Vocational School of Health Services of a state university.

2.2. Participiants and study size

The population of the study consisted of 1959 female students enrolled in 15 programs of the Vocational School of Health Services of a state university in the fall semester of the 2022-2023 academic year. When the population was known, the number of samples was calculated as 756 with 95% reliability (with α=0.05 error) with the help of the formula used to examine the frequency of the event (n= Nt2pq/d2(N-1)+t2pq). Then, the number of participants to be included in the sample from each program was determined by stratified sampling method. The determined number of participants from each program was included in the study by simple random sampling method. The sample consisted of 812 participants who were willing to participate in the study and completed the data collection tools completely.

2.3. Assessment tools

The data of the study were collected with three separate data collection tools: Personal Information Form, Comprehensive Breast Cancer Knowledge Test, Champion Health Belief Model Scale.

Personal Information Form: The form prepared by the researchers includes 17 questions. The form includes questions to determine some socio-demographic characteristics of the participants (age, class, marital status, income status) and questions to determine their history of breast cancer (such as having a history of breast cancer in the family/close environment, finding the level of information about breast cancer sufficient, information sources).

Comprehensive Breast Cancer Knowledge Test (CBCKT): It was developed by Stager in 1993 (19). The scale included two dimensions: 'General Knowledge' and 'Curability'. There are a total of 20 knowledge questions in the scale. Questions from 1 to 12 include general knowledge about breast cancer, while questions 13 to 20 include information about the curability of breast cancer. The scale is answered as True-False. Questions with correct answers are evaluated with 1 point each, questions with incorrect answers and questions with no answer are evaluated with 0 points. There are 8 true and 12 false statements in the questions. Questions 1, 2, 5, 6, 11, 12, 14, 15, 17, 18, 19 and 20 contain false statements, while the other questions contain true statements (19). The validity and reliability in Turkey was conducted by Başak in 2015 and the Alpha value of the 'General Knowledge' dimension was found to be 0.49, the Alpha value of the 'Curability' dimension was found to be 0.80 and the total scale was found to be 0.90 (20). In this study, total Cronbach Alpha coefficient were 0.78; the 'General Knowledge' dimension was found to be 0.56, the 'Curability' dimension was found to be 0.73.

Champion Health Belief Model Scale (CHBMS): The scale was developed and later revised by Champion to determine women's beliefs and attitudes about breast cancer and BSE and contains 42 items (21-24). The scale was adapted into Turkish by Karayurt and Dramalı (28). CHBMS has 6 sub-dimensions and the items are included in the scale in the following order. The "sensitivity perception" sub-dimension of breast cancer refers to the perceived individual risks of developing breast cancer and consists of 3 items. The "caring / seriousness" sub-dimension of breast cancer defines the degree of individual threat perceived from breast cancer and consists of 7 items. The "benefit perception" sub-dimension refers to the perceived advantages of BSE and consists of 4 items. The "barriers perception" subscale defines the perceived barriers related to the practice of BSE and consists of 11 items. The "self efficacy / confidence" subscale refers to the perceived individual competence in the ability to perform BSE to detect abnormal breast masses and consists of 10 items. The "health motivation" subscale refers to individuals' interest and concern about their health status and consists of 7 items. Each sub-dimension of the scale is evaluated separately; the total score including the whole scale is not calculated. A low score on the "barrier perception" subscale and high scores on other subscales indicate that women have positive attitudes and beliefs about breast cancer and BSE practices (25). In the Turkish adaptation of the scale, Cronbach Alpha reliability coefficients were found between 0.58 and 0.89 for the subscales (28). In this study, Cronbach Alpha coefficients were 0.84 for the "sensitivity" sub-dimension, 0.81 for the "caring / seriousness" sub-dimension, 0.90 for the "benefit perception" sub-dimension, 0.73 for the "barrier perception " sub-dimension, 0.87 for the self efficacy / confidence sub-dimension, and 0.84 for the health motivation sub-dimension.

2.4. Statistical analysis

SPSS (Statistical Package for the Social Sciences) for Windows 22.0 (IBM Corp. Armonk, NY: USA. Released 2013) was used for all statistical procedures. The normality of the data was assessed by the Kolmogorov-Smirnov test. The descriptive statistical analysis (Mean, Standard Deviation, Frequency, Minimum, Maximum), Pearson Correlation Analysis was used to evaluate the relationships between parameters. Predictive factors associated with breast self-examination among young women were tested with multivariate logistic regression analysis. The results were evaluated bidirectionally at 95% confidence interval and significance level $p < .05$.

2.5. Ethics approval

Before starting the study, the necessary permissions for the use of the scales, ethics committee approval (2022-202980) and implementation permission. The participants were informed about the subject and purpose of the study. Data collection tools were administered online to the participants who agreed to participate in the study.

3. RESULTS

The mean age of the participants was 20.09 ± 1.64 years. 1.8% were married, 75.2% had a moderate economic status, 12% reported a family history of breast cancer. Among those who family member diagnosed with BC, 45.4% stated that their aunt, 31.9% mother, 22.7% sister/cousin had been diagnosed with breast cancer. 79.0% of the participants stated that perceived suffiency of knowledge about BC was 'sufficient' and 71.6% stated that they knew the symptoms of breast cancer. Among those who stated that they knew the symptoms of breast cancer, 82% listed a palpable mass in the breast or armpit, 76.2% listed discharge from the nipple, and 63.4% listed retraction or deformity of the nipple as the first three symptoms. The internet (60.9%), health professionals (58.5%) and mass media (42.5%) were the top three sources of information. 68% of the participants stated that they heard about BSE, 12.1% of them performed BSE regularly, 11.8% of them heard about CBE, and 0.8% of them had at least one CBE. 96.4% of the participants stated that they had heard of the mammography procedure. 62.3% thought that breast cancer is not a fatal type of cancer if detected early (Table 1).

Table 1. Distribution of young women according to certain characteristics

Characteristics	Category	n	%
Marital status (n=812)	Single	798	98.2
	Married	14	1.8
Economic status (n=812)	Low	86	10.6
	Moderate	610	75.2
	High	116	14.2
BC in the family history (n=812)	Yes	97	12.0
	No	715	88.0
Family member diagnosed with BC*(n=97)	Aunt	44	45.4
	Mother	31	31.9
	Sister / Cousin	22	22.7
Perceived suffiency of knowledge about BC (n=812)	Sufficient	642	79.0
	Unsufficient	170	21.0
Sources of knowledge*(n=642)	Internet	391	60.9
	Health professionals	376	58.5
	Media (TV, radio, newspaper)	273	42.5
Heard about BSE (n=812)	Yes	552	68
	No	260	32
Perform BSE*(n=552)	Yes (reguler)	67	12.1
	No (irreguler)	485	87.8
Heard about CBE (n=812)	Yes	95	11.8
	No	717	88.2
Heard about mammography (n=812)	Yes	782	96.4
	No	30	3.6
Opinions on the fatality of breast cancer (n=812)	Yes, it is fatal.	307	37.7
	No, it isn't fatal if detected early	505	62.3

*Abbreviations: BC, Breast Cancer; BSE, Breast Self Examination; CSE, Clinic Breast Examination, * percentages are based on 'n'*

The participants' scores on the total, general knowledge, and curability sub-dimensions of the CBCKT were 12.48 (2.41); 7.42 (1.20); 5.20 (1.48), respectively (Table 1). Participants' scores on the sensitivity, caring/seriousness, health motivation, benefit perception, barrier perception, self-efficacy / confidence perception subscales of the CHBMS were 8.26 (2.42); 20.80 (3.21); 19.20 (2.70); 16.50 (3.02); 18.28 (3.36); 39.92 (3.40), respectively (Table 2).

There was a statistically significant positive correlation between the mean score of the general knowledge sub-dimension of the CBCKT and the mean scores of the sensitivity, caring/seriousness, health motivation, benefit perception, self-efficacy/confidence sub-dimension of the CHBMS, and a statistically significant negative correlation between the mean score of the barriers perception sub-dimension (p< .05). A statistically significant positive correlation was found between the mean score of the curability sub-dimension of the CBCKT and the mean scores of the sensitivity, self-efficacy / confidence, caring / seriousness sub-dimension of the CHBMS (p< .05). A statistically significant positive correlation was found between the mean total score of the CBCKT and

the sensitivity, caring / seriousness, self-efficacy / confidence sub-dimensions of the CHBMS (p<.05) (Table 3).

Table 2. Total and sub-dimension mean scores of the CBCKT ve CHBMS

SCALE TOTAL and SUB-DIMENSIONS	Scale Min – Max Score	Study Min-Max Score	m (sd)
CBCKT			
General Knowledge	0-12	2-11	7.42 ± 1.20
Curability	0-8	0-8	5.20 ± 1.48
Total	0-20	6-18	12.48 ± 2.42
CHBMS			
Sensitivity	3-15	3-15	8.26 ± 2.42
Caring/Seriousness	7-35	8-32	20.80 ± 3.21
Health Motivation	7-35	7-28	19.20 ± 2.70
Benefit Perception	4-20	5-20	16.50 ± 3.02
Barrier Perception	11-55	11-32	18.28 ± 3.76
Self-Efficacy / Confidence	10-50	12-50	38.92 ± 3.40

Abbreviations: CBCKT, Comprehensive Breast Cancer Knowledge Test; CHBMS, Champion Health Belief Model Scale; m: mean; sd: standart deviation

Table 3. Correlation of total and sub-dimension scale scores

CHBMS	CBCKT General Knowledge r	p	Curability r	p	Total r	p
Sensitivity	0.270	.000	0.452	.000	0.158	.005
Caring/Seriousness	0.260	.001	0.275	.000	0.280	.048
Health Motivation	0.170	.000	0.078	.112	0.040	.120
Benefit Perception	0.346	.000	0.096	.062	0.072	.058
Barrier Perception	− 0.340	.005	0.076	.110	0.057	.250
Self-Efficacy / Confidence	0.502	.000	0.450	.000	0.230	.000

Abbreviations: CBCKT, Comprehensive Breast Cancer Knowledge Test; CHBMS, Champion Health Belief Model Scale; r, Pearson's correlation coefficient

According to the multivariate logistic regression analysis, married young women had a 4.86 times higher likelihood of performing BSE compared to unmarried young women (AOR = 4.86, 95% CI: (2.16–10.48)). A family history of breast cancer was significantly associated with the practice of BSE. It was determined that young women with a family history of breast cancer were 3.46 times more likely to engage in BSE compared to those without a family history (AOR = 3.46, 95% CI: (1.68–9.86)). Young women who perceived their knowledge about breast cancer as adequate were found to have a 1.86 times higher likelihood of performing BSE compared to those who did not (AOR = 1.86, 95% CI: (1.00–3.40)). Holding other factors constant, there was a 1.72 times increase in the likelihood of conducting breast self-examinations with a one-unit increase in age (AOR = 1.72, 95% CI: 1.06–1.20) (Table 4).

Table 4. *Predictive factors associated with breast self-examination among young women*

	Category	Yes	No	COR (95% CL)	AOR (95% CL)
BSE Practice					
Constant					
Age [a]				1.80(1.10–1.48) *	1.72(1.06–1.20)**
Marital status	Married	9	5	3.16(2.02–9.86) *	4.86(2.16–10.48)**
	Single	18	780	1	1
BC in the family history	Yes	86	11	3.24(1.18–10.46) **	3.46 (1.68–9.86)**
	No	46	669	1	1
Perceived suffiency of knowledge about BC	Sufficient	148	494	1.46 (1.10–2.82) **	1.86 (1.00–3.40) *
	Unsufficient	66	104	1	1

* p-value < .001; ** p < = .05; a continuous variables; CI: 95% confidence interval
Reference categories: 1; Variables: marital status: 1 married; BC in the family history: 1 yes; perceived suffiency of knowledge about BC: 1 sufficient

4. DISCUSSION

In this section, the data obtained have been discussed within the relevant literature framework. As participants' level of knowledge about breast cancer increases, sensitivity towards breast cancer (BC) and breast self-examination (BSE), concern/seriousness, health motivation, perceived benefits, and self-efficacy/confidence perception also increase, while perceived barriers decrease. Additionally, it has been determined that young women who find their knowledge about breast cancer sufficient are 1.86 times more likely to engage in BSE behavior compared to those who do not find their knowledge sufficient. This can be considered a noteworthy finding of this study. Many studies have shown a significant relationship between participants' overall knowledge score and BSE practice (10,14,26,29). This data indicates that as knowledge about breast cancer increases, breast awareness and the practice of BSE may also increase.

Compared to the perception of cancer risk in the general population, having a relative with a history of cancer can significantly influence individuals' level of knowledge and health beliefs. In this study, it was determined that participants with a family history of breast cancer exhibited increased sensitivity to breast cancer, increased seriousness and concern about breast cancer, increased health motivation, increased perceived benefits, and increased self-efficacy/confidence. According to the multivariable logistic regression analysis, young women with a family history of breast cancer were found to be approximately 3.5 times more likely to engage in breast self-examination (BSE) behavior compared to those without a family history of breast cancer. In a study conducted by Manisha and Kaphle, a significant relationship was found between participants with a family history of breast cancer and a history of mastectomy in the family, and the practice of BSE (27). Another study that respondents with a family history of breast cancer were more likely to be knowledgeable about BSE (OR = 1.41, 95% CI = 0.15–13.18), exhibited a positive attitude towards BSE (OR = 1.15, 95% CI = 0.16–4.50) and had good BSE practices (OR = 1.44, 95% CI = 0.24–8.34) (28). However Meilina and Masluroh showed

a but there was no relationship between family breast cancer history and BSE behavior (29).

Marital status is another factor that can be associated with breast cancer. Although the number of married participants in our study was low, it was found that married participants had higher sensitivity to breast cancer, seriousness/concern, and health motivation compared to single participants. It was determined that the likelihood of engaging in breast self-examination (BSE) behavior was 4.86 times higher for married young women compared to unmarried young women. Being married may provide women with strong spousal support, help them undergo more regular screenings for breast cancer, and increase awareness of early detection. For example, married women aged from 45 to 55 years and knowledge were found to significantly moderate the relationship between perceived benefits and behavioral adoption of BSE (30). Similarly, another study reported that being married (AOR = 5.31, 95% CI = 2.19–12.90) was all significant predictors of BSE practice (31). This could be due to spousal support that influences health-related behavior, such as in encouraging them to perform BSE. However in a study conducted by Urunti et al. respondents who were single were more likely to be knowledgeable about BSE (OR = 1.17, 95% CI = 0.13–10.20) and exhibited a positive attitude towards BSE (OR = 2.47, 95% CI = 0.58–10.49) and good BSE practices (OR = 3.05, 95% CI = 0.36–25.67) (28).

In our study, it was determined that breast cancer sensitivity, seriousness/concern, health motivation, perceived benefits, self-efficacy/confidence, and breast cancer knowledge increase as participants' ages increase. When all other factors were held constant, it was found that the likelihood of performing breast examination increased by 1.72 times with a one-unit increase in age. As age increases, women may have a higher likelihood of acquiring knowledge about breast cancer, accessing screening and diagnostic tests, and interacting more frequently with healthcare professionals. Increased knowledge about breast cancer with age may lead to more positive health beliefs about breast cancer (12,16,17). As age decreases, women may perceive their risk

of breast cancer to be lower and thus may have negative health beliefs about breast cancer. In a study conducted by Urunti et al. respondents aged 31–35 years were more likely to be knowledgeable about BSE (OR = 4.00). 95% CI = 0.29–41.99), exhibited a positive attitude towards BSE (OR = 2.39, 95% CI = 0.28–12.32) and practice of BSE (OR = 2.66, 95% CI = 0.38–18.41) (28).

5. CONCLUSIONS

In this study, it was found that the participants' level of knowledge about breast cancer / BSE increased, sensitivity, caring / seriousness, health motivation, benefit perception and self-efficacy / confidence increased, and barriers perception decreased. With the educational programs structured on the data obtained, it may be possible for young women to reach the correct information they need. The fact that the participants are educated in health-related fields may also provide a sense of self-responsibility in recognizing cancer symptoms in professional life, applying prevention behaviors to life and participating in screening programs. There is an immediate need to increase the knowledge and practice of breast self-examination to prevent and detect breast cancer in its early stage.

The data obtained from the study were obtained only from female students studying at the Vocational School of Health Services of a state university. Therefore, it can only be generalized to this group. Similar studies can be conducted in groups with different sociodemographic characteristics where male students are also included in the sample.

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The Effectiveness of the 'My Hands Are Clean Program' Based on the Health Promotion Model Conducted with Virtual Reality Method

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ABSTRACT

Objective: Hand hygiene is very important as the hand is the organ that contains the most microorganisms. On the other hand, the school environment is an important environment for raising awareness of hand hygiene and acquiring handwashing behavior. This research was conducted to determine the effectiveness of the 'My Hands are Clean Program', which is carried out with the virtual reality method based on the health promotion model.

Methods: This research is a quasi-experimental study with a pre-test and post-test model. The research population is 4th-8th grades in a school. Data were collected by socio-demographic characteristics form, hand hygiene observation form, and decision scale. Measurements were made before the training, after the training, the first follow-up after one month and the second follow-up after two months. Data were analyzed using IBM SPSS 26.0, Kolmogorov-Smirnov, Wilcoxon Test, Fridman Test, Mann Whitney U test, Kruskal Wallis test, and Bonferroni-corrected pairwise comparisons in further analysis. The "TREND checklist" was used to report it.

Results: The students got the highest score on the hand hygiene observation form at the first follow-up. It was determined that students' post-test, first follow-up and second follow-up mean scores were significantly higher than the pre-test mean scores. In Gpower Post hoc power analysis, the power of the study was determined to be 99%.

Conslusion: It can be said that the use of technology-based methods in developing handwashing behavior, which will affect lifelong health, is effective for school-age students.

Keywords: Hand hygiene, virtual reality, health promotion model

1. INTRODUCTION

School is an ideal environment for preserving and maintaining the physical, social, and spiritual well-being of children, preventing diseases, promoting health, and providing positive behavioral changes. Various health problems seen in school-age affect the learning process negatively. Childhood is a suitable period to change health habits in a positive way. Hygiene, which is the most important way to protect health, is defined as the purification of polluted substances in the environment (1). Hand hygiene is of great importance as we use our hands the most in daily life, transporting contaminated materials, preparing food, and cleaning goods (2–5).

Studies emphasize that hand washing is very effective in preventing infection transmission. According to a study conducted in the daycare center, it was found the use of disinfectant during hand washing decreased and fewer antibiotics were prescribed for children hospitalized in the care center due to infection (6). In a study examining the effectiveness of the comprehensive hand hygiene module on preschool children, it was emphasized that the hand hygiene scores of the children increased significantly after the training compared to before (7). As a result of the hand hygiene activity, which was organized with a semi-experimental design for kindergarten children, it was concluded that the knowledge level of the children increased and they could use the appropriate hand washing technique (8).

It is aimed to provide clean water and personal hygiene in primary health services for school health. Personal hygiene behaviors are those that should be acquired in the family environment at an early age before coming to school. At school, under the supervision of school health professionals, it is necessary to eliminate the deficiencies, to acquire and

maintain these behaviors (9). Thus, health professionals working at the school have unique opportunities to diagnose students with handwashing deficiency in the early stages, for reasons such as general health screening, school entrance examination, regular follow-up of the child throughout the school term, and so on. School health professionals can plan interventions to take precautions by observing the potential risks that may occur due to not washing the hands of students or not washing their hands with the right technique based on behavior change models. These initiatives may also be based on behavior modification models (eg health promotion model etc.). With the behavior change plan they have prepared, they try to facilitate the change by providing education and counseling to the student, their families, and teachers, by conducting motivational interviews, and by applying/enforcing the right-hand washing technique. With the education to be given by a health professional that students know and trust, students can increase their compliance and commitment to the behavior change plan (4,10). In our country, health education is mostly given by a teacher assigned to the school. However, the health knowledge of teachers and the health education they provide are limited. Therefore, health education in schools needs to be provided by a health professional raising the permanence of the information, and the student's attitudes toward the subject (11).

Even if children know and applies the importance of handwashing as taught in the lessons, it is unclear whether they know and apply effective handwashing steps. As a result of hand washing, the hands appear clean, which makes them believe that their hands are clean. However, as a result of many studies, it has been revealed that there are many health problems due to ineffective hand washing (5,12–14). As a result of the fact that hand washing is not performed at the desired level in accordance with the correct hand washing techniques in ensuring hand hygiene, various innovative training approaches should be developed and the effectiveness of the training should be increased (15–18). Microorganisms on hand are made visible with virtual reality technology, which is one of the innovative educational approaches, and offers individuals an experiential learning opportunity (19,20). It is thought that the presence of gel residues under ultraviolet light after using soap and water with the help of a fluorescent gel will help the behavior to occur more carefully and following the principles in the next hand washing behaviors (21,22).

This research, it was aimed to determine the effectiveness of the Health Promotion Model (HGM)-based My Hands are Clean Program carried out with the virtual reality method in ensuring the effective implementation of hand hygiene and its effect on the handwashing behaviors of the students.

2. METHODS

2.1. Type of Research

This research is a quasi-experimental study with a pre-test and post-test model.

2.2. Research Hypothesis

In the pre-test, follow-up, and post-tests of the students who participated in the 'My Hands are Clean Program'; There is a significant difference in hand hygiene effectiveness between the total hygiene scores of the palm, fingertip, interdigital, thumb, back of the hand, and wrist regions.

2.3. Variables of the Study

The observation form score showing the effectiveness of hand hygiene was taken as the dependent variable, and the 'My Hands are Clean Program' based on the EGM given by the virtual reality method was taken as the independent variable.

2.4. Research Place and Time

This study was conducted with students at a school in Istanbul between December 2021 and March 2021.

2.5. Population and Sampling of the Research

The research population is 4th-8th grades in a school. It consisted of 228 students studying in classrooms. 169 people participated in the pre-test of the study, and the post-test was completed with 156 people. Since the study was conducted during the pandemic, the first follow-up was completed with 115 people and the second follow-up with 85 people due to dropout and absenteeism. After the study, in the G power post hoc power analysis, when the eta square, effect size, and number of participants obtained from our data were 85, the alpha value was 0.05, and the correlation coefficient was 0.202, the power of the study was determined to be 99% as a result of the power analysis.

2.6. Data Collection Tools

The data were collected by the researcher and observers using a socio-demographic characteristics form and a hand hygiene observation form.

2.6.1. Socio-Demographic Characteristics Form

Developed by the researchers. Students' age, class, education level of parents, hand washing habits, access to water and soap, etc. It was composed of 24 questions questioned (1,6,12).

2.6.2. Hand Hygiene Observation and Decision Form

This form was developed by the researchers to evaluate the effectiveness of virtual reality training on hand washing. The observation form was structured in such a way that the observation result could be evaluated quantitatively and to ensure correct decision-making among the observers. Before the application, a pilot application was made to 10 students and the application was started after the observers were harmonized. Observers were trained on how to use the observation form. This form was used before and after the hand washing training and in follow-ups. For this purpose, the hand area was divided into 6 sections. These were; palm, fingertip, inter-finger, thumb, back of the hand and wrist. Scoring was done as follows: In the evaluation of the washing efficiency of the hand divided into 6 regions, 2 points were given to the region where the Glo Germ material was cleaned and 1 point was given to the region where it was not cleaned. As a result of the 6 regions observed, the maximum score was 6x2=12 points, indicating that hand washing was complete and effective. The lowest score was 6x1=6 points, indicating that handwashing was quite ineffective. In the evaluation; all scores below 12 points indicated that the hand washing technique should be improved and the training should be repeated. A score of 1-6 points indicated completely inadequate handwashing, 7-11 points indicated that there were areas to be improved in handwashing behavior, and 12 points indicated correct handwashing behavior. Expert opinions were obtained from 3 faculty members who are experts in the field of public health for the observation and decision form.

Student's sociodemographic characteristics, handwashing behavior and perceptions specific to its output, form of handwashing experiences;

A form containing questions about age, gender, income level, handwashing frequency, previous handwashing behavior, whether they had received handwashing training, knowledge of the harms of not washing hands, whether they had their own towel, self-confidence in correct handwashing, handwashing behaviors of people around them, situations in which they wash their hands frequently, and willingness to receive handwashing training was used.

Behavior Output is the result of the Hand Hygiene Observation and Decision Form.

2.7. My Hands are Clean Program

Hand hygiene training developed by the researchers was explained to all classes in a three-week period by the senior nursing students in a 40-minute school lesson period with video and demonstration methods. The training program was prepared by considering the basic components of Pender's Health Promotion Model. Health Promotion Model has three basic components: individual characteristics and experiences, perceptions specific to behavior, and behavioral outcomes. In this study, all interventions were conducted taking into account the components of the model. In the first

week of the program, the presentation and announcement of the study were made and pre-tests were applied. My Hands are Clean training program was implemented for three weeks. Post-tests were administered in the fourth week. Two follow-ups were conducted to determine the effect of the "My Hands are Clean Program". Handwashing behaviors were repeated at one-month intervals and scored by the same independent observers. (Figure 1).

Initiatives for the 'individual characteristics and experiences' component of the Health Promotion Model;

Experiences are behavioral factors that have direct and indirect effects. The success or failure of the previous behavior affects the outcome of the next behavior (23). In this scope, students were helped to understand the effect of hand washing behaviors with the virtual reality method so that they could see the difference between their previous and subsequent behaviors. Glo Germ bacteria simulation gel was applied for virtual reality. When the hands are washed with the correct technique, a spotless clean hand appearance is obtained when viewed with a special lighted lamp. On the other hand, bright and colorful bacteria are seen on hands that are not washed with the correct technique. This gel was squeezed a little on the students' hands and they were allowed to apply it all over their hands like hand cream. They were made to wash their hands in the same way as they did in the pre-test before the training and the effectiveness of their washing with light was checked and scored. The areas that were not washed well were shown to the students and explained.

Attempts towards the 'behavior-specific perceptions' component of the Health Promotion Model;

The Health Promotion Model is influenced by the perceived benefit specific to the behavior, barriers to performing the behavior, social norms and self-efficacy to perform the behavior (23). In this context, the stages of this model were implemented in the "My Hands are Clean" program as follows; in the training program for 'perceived benefits' and 'perceived barriers'; the focus was on the benefits and advantages of hand washing behavior. Individual measures (such as creating a hand hygiene kit and keeping it in the bag) were discussed to overcome the barrier of lack of hand washing materials at school. In order to increase self-efficacy; the effectiveness of hand washing was discussed with the students through the concrete colored view obtained with virtual reality. Good washes were praised for receiving high scores, and the washing process was repeated with the observers for the hand areas that were not washed well and received low scores. Students were given motivating messages such as "you can do it", "you were able to clean the bacteria when you washed with the right technique". For the social norms part of the model; students who washed their hands with the correct technique and scored high became peer role models in the classroom and provided motivation for others to develop correct handwashing behavior. For the situational factor of the model, teachers in the school

community gave positive feedback and reminders by showing the videos in their lessons from time to time.

Initiatives for the 'Behavioral outcomes' component of the Health Promotion Model; After the "My Hands are Clean Program" and at the follow-up, the previous hand washing behavior scores and the current ones were compared with the observers for hand washing behavior with the correct technique with the hand hygiene observation form and the areas that needed to be improved were discussed with the student.
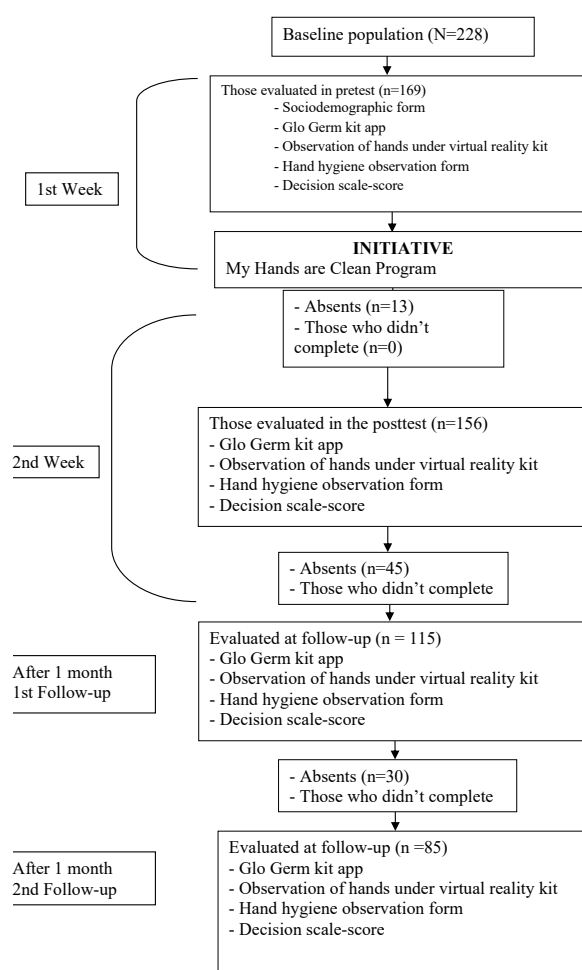
Figure 1. Flow diagram of the Study

2.8. Statistical Analysis

Statistical evaluation of the data database was created in IBM SPSS 26.0 program and percentage, mean, and median were looked for descriptive statistics. The Kolmogorov-Smirnov test used the Kolmogorov-Smirnov test to check for compliance with the normal distribution of the data, and the Wilcoxon Test, Fridman Test, Mann Whitney U test, Kruskal Wallis test, and Bonferroni-corrected pairwise comparisons were used to compare the hand hygiene observation form scores.

2.9. Ethical Considerations

Ethics Committee approval numbered 09.2019.975 (date: 07.02.2020) and written consent from students and parents were obtained from Marmara University Interventional Ethics Committee for this research. Institutional permission from the school where the study was conducted (number: E-16911314.900.00000143273, date: 28.05.2021) and permissions from the researchers who adapted the scales into Turkish were obtained. Verbal and written consent was obtained from each participant before the study, and they were asked to fill in the informed consent form, and only the participants who gave consent were included in the study.

3. RESULTS

It was determined that 26% of the students participating in the study were in the 4th grade (n=44) 52.1% of students were male (n=88), 66.3% of the parents were in secondary school or below-educated (n=112). 45 % of the students were 12-13 years old (n=76). 78.1% of the students stated that they have the necessary materials for hand hygiene at home (n=132) and the materials required for hand hygiene at school 47.9% (n=81). 93.5% of the students reported they were confident in washing their hands with the correct technique (n=158).

The mean scores of the students' Hand Hygiene Observation Form are presented in Table 1, and it was observed that there was a significant difference according to time (p<0.001). According to the results of the Wilcoxon test with Bonferroni correction, which was performed to determine between which groups the difference was, it was determined that the post-test, first follow-up and second follow-up mean scores were significantly higher than the pre-test mean scores. In addition, the mean scores of the Hand Hygiene Observation Form at the first follow-up and at the second follow-up were significantly higher than the mean scores of the post-test (Table 1).

Table 1. Comparison of the scores of the students from the hand hygiene observation form

	Duration	X±SS (Med)	χ^2	p
Hand Hygiene Observation Form	Pre-test[a]	6.46±0.96 (6)	147,731	**0.000** a<b<c,d*
	Final test[b]	8.61±1.58 (8)		
	First Follow-up[c]	10.25±1.40 (10)		
	Second Follow-up[d]	9.80±1.70 (10)		

χ^2: Fridman Test, *Wilcoxon Test with Bonferroni correction

A significant difference was found between pretest-posttest-follow-up tests between socio-demographic variables (gender, age, parental education level) and students' self-confidence in washing their hands with the right technique, and the availability of hygienic materials at home and at school (p<0.001) (Table 2).

Table 2. Scores from the hand hygiene observation form according to socio-demographic variables and time

Variables	Pre-Test	Final Test	First Follow-up	Second Follow-up	Statistics	
	X±SS	X±SS	X±SS	X±SS	¹χ²	p
Gender						
Female (n=81)	6.44±0.92	8.45±1.4	10.53±1.14	9.73±1.63	80.757	**0.000**
Male (n=88)	6.47±1.03	8.75±1.72	10.02±1.57	9.86±1.77	69.068	**0.000**
Z	-0.225	-1.029	-1.585	-0.636		
p	0.822	0.303	0.113	0.525		
Age						
8-9 (n=26)	6.46±1.17	8.23±1.56	9.47±1.37	10.06±1.64	24.829	**0.000**
10-11 (n=56)	6.34±0.84	8.53±1.57	10.2±1.26	9.45±1.86	45.037	**0.000**
12-13 (n=76)	6.54±1.04	8.68±1.6	10.58±1.32	9.93±1.56	75.924	**0.000**
14 and above (n=11)	6.45±0.69	9.5±1.43	9.83±2.23	10.25±2.36	6.536	0.088
²χ²	2.393	5.46	9.153	2.293		
p	0.495	0.141	**0.027**	0.514		
Parent educational background						
Middleschool and below (n=112)	6.58±1.1	8.74±1.55	10.31±1.44	9.9±1.68	102.501	**0.000**
Highschool and above (n=57)	6.21±0.59	8.37±1.63	10.15±1.35	9.58±1.73	45.899	**0.000**
Z	-2.379	-1.465	-0.716	-0.950		
p	**0.017**	0.143	0.474	0.342		
Confidence in washing your hands with the right technique						
Not sure (n=11)	6.45±1.51	9.11±2.03	10.71±1.38	10.43±0.79	13.800	**0.003**
Sure (n=158)	6.46±0.93	8.58±1.56	10.22±1.41	9.76±1.73	134.247	**0.000**
Z	-1.065	-0.841	-1.021	-0.805		
p	0.287	0.400	0.307	0.421		
Availability of hygienic materials at home						
Yes (n=132)	6.42±0.91	8.55±1.63	10.14±1.43	9.9±1.66	135.160	**0.000**
Sometimes (n=37)	6.57±1.19	8.83±1.42	10.79±1.13	9.28±1.84	18.714	**0.000**
Z	-0.151	-1.066	-1.816	-1.409		
p	0.880	0.286	0.069	0.159		
Availability of hygienic materials at school						
Yes (n=81)	6.44±0.97	8.58±1.56	10.3±1.45	9.84±1.65	83.079	**0.000**
No (n=38)	6.37±0.88	8.67±1.71	10.12±1.42	9.5±2.02	19.583	**0.000**
Sometimes (n=50)	6.54±1.05	8.6±1.55	10.27±1.35	9.91±1.58	45.902	**0.000**
²χ²	0.471	0.113	0.316	0.343		
p	0.790	0.945	0.854	0.842		

1χ²: Fridman Test, 2χ²: Kruskal Wallies Test, Z: Mann Whitney U Test

4. DISCUSSION

In this study, hand hygiene behaviors of students aged 8-14 years, whose parental education level was middle school or below and who were studying in a primary school with low school attendance, and behavioral changes after the training were examined. The results of the study showed that the 'My Hands are Clean Program' was effective in improving hand washing behaviors in school children. In addition, desired behavior change was observed not only in the post-test conducted two weeks later but also in the first follow-up conducted one month later. We think that the interventions made for the "behavior-specific perceptions" component of the Health Promotion Model were effective in this success of the program. Although there was a minimal decrease in the mean score at the second follow-up according to the hand hygiene observation form, statistical significance did not change. We can say that the 'My Hands are Clean Program'

is effective in maintaining the behavior not only in the short term but also in the long term. According to the Health Promotion Model used in this study, perception is affected by the perceived benefit specific to the behavior, barriers to performing the behavior, social norms and self-efficacy to perform the behavior (23). In this scope, the interventions made in line with the stages developed based on the model in the 'My Hands are Clean Program' were effective. We think that the model-based interventions may have increased children's perception of self-efficacy in both short and long term effectiveness of the expected behavioral outcome. In addition, the implementation of the application in the classroom environment may be the desire of peers to be role models for each other. Moreover, the fact that the teachers at the school ensured the reinforcement of hand washing behavior by watching the hand washing videos once a week during class hours may have affected the process. Most importantly, it was observed that the students immediately saw the difference in hygiene before and after hand washing with the virtual reality kit and instantly saw the effect of effective hand washing or not washing and increased the effect on concrete situation perception and behavior. It is known that the acquisition of effective hand washing behavior provides significant benefits especially in the protection of primary school children from infections (24,25). In similar studies conducted with school-age children reported that a large proportion of students practiced the correct hand washing steps in their study conducted to improve hand hygiene practices with a social robot-assisted intervention in a school in India (26). In another study, Arbi Care, an android-based educational intervention, was implemented twice a week for five weeks for children aged 4-6 years. It was found that the self-efficacy development scores of children in the intervention group increased significantly over time compared to the control group (27). In order to prevent diarrhea in vulnerable children, a handwashing intervention was carried out by means of soaps with toys in them. The control group was given a normal soap with traditional expression. After the intervention, it was found that children in the control group were four times more likely to get diarrhea compared to children in the intervention group (28). In another quasi-experimental study titled 'Hand hygiene Fun Month' for kindergarten students, it was found that after an intervention focusing on the right time, right duration and right steps, the intervention group's knowledge level on the subject increased significantly compared to the control group, and the intervention group had significantly higher levels of left palm, back of hand, right palm and general hand hygiene compared to the pre-intervention group (8). In a study examining parent-child interaction and children's hand washing behaviors during a STEM activity at home, the importance of using soap in hand washing was conveyed. In the measurements made one week after the parent-child participated in the intervention together, it was reported that the use of soap supported children to gain the belief that they could protect themselves from certain diseases (29). One of the studies in the literature implemented an intervention to improve hand hygiene in children with digital intervention, including animated instructions triggered by the use of soap and water and a symbolic reward displayed on the screen during and immediately after hand washing. After the intervention, they concluded that children's time to soap their hands increased by 5.30 seconds (30). Similar to the results of this study, it has been concluded in the literature that the interventions carried out to implement the hand hygiene trainings given to children with the right steps in digital environments and with an embodied system are more beneficial for children to ensure hand hygiene. Although the absence of a control group in our study constitutes a limitation, when the literature is examined, it is concluded that it is very important to teach the event by concretizing the event with technological tools in the acquisition of hand washing behavior with the correct technique, especially in school-age children. It can be said that peer and family support is very useful in maintaining the behavior. In the absence of correct handwashing behaviors, it is known that reinforcing the correct handwashing behavior with demonstration, giving encouraging feedback, and providing social and peer support are important in teaching the correct behavior (31,32). In a systematic review of adolescents aged 12-15 in eighty countries, the low rates of inappropriate hand-washing behavior and especially after the toilet in countries with low socioeconomic status are similar to the data of this study. In addition, it was emphasized that handwashing with water and soap provides effective protection for the improvement of handwashing behavior, especially during the pandemic process, and they stated that there are few studies on adolescents (33). In this study, it can be said that although the majority of the sample consisted of adolescent students and they had knowledge about the importance of hand washing, they had difficulty in putting it into behavior. One study of the literature, it was determined that although students' awareness of the importance of handwashing in the prevention of infectious diseases was high, their behavior towards handwashing was low (34). There are studies in the literature that emphasize the necessity of transforming knowledge about hand washing into behavior (35–37). In the study conducted with the virtual reality method applied to primary school children in Budapest, statistical significance was found when the scores they got from the pretest-posttest and first follow-up-second follow-up after the handwashing training supported by visuals were compared. In addition, in the same study, students' self-efficacy in effective hand washing was found to be statistically significant (38). In a study conducted using a prospective design, the effect of handwashing on self-efficacy was found to be significant when the relationship between students' handwashing and self-efficacy was examined (39). In this study, it can be said that the handwashing skills of the students improved and their self-efficacy on this subject improved. In this study, it can be said that it was observed that students' hand washing skills improved and their self-efficacy in hand washing improved.

In this study, it was observed that the results of the Health Promotion Model-Based 'My Hands are Clean Program'

conducted with the Virtual Reality Method were similar to other studies in terms of results, but it was more motivating in learning because it provided visual feedback in teaching effective hand washing. The most important factor that distinguishes our study from other studies is that the virtual reality method and model-based education process was carried out. We think that it would be useful for researchers who will work on a similar subject to use innovative technology-based methods and model-based interventions that increase concrete learning with a control group to develop behaviors and make a qualified contribution to the literature.

5. CONCLUSION

As a result of the 'My Hands are Clean Program' carried out with the virtual reality method based on the health promotion model, it was determined that the scores of the students from the hand hygiene observation form increased compared to the scores obtained before the program and this continued to increase over time. It can be said that the use of technology-based methods in developing handwashing behavior, which will affect lifelong health, is effective for school-age students. The results of this study point to several implications and recommendations for school health professionals; proper handwashing prevents diseases, and protects and improves health. Therefore as school health professionals, we must provide students with information and counseling about hand washing. Health professionals should take the initiative to increase the handwashing levels of students, parents, and school administration.

This research is limited to the findings obtained after the 'My Hands are Clean Program' was applied to students in the relevant school. It is thought that conducting follow-up tests by the randomized controlled research design while planning health education provided with virtual reality technology in the future will increase the level of evidence of the research.

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Efficacy of Alternate Nostril Breathing on Pulmonary Function and Physical Functional Capacity in Healthy Adults Across Different Age Groups: Randomized Control Trial

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ABSTRACT

Objective: Lung function and functional capacity gradually decline even in asymptomatic individual with age. Alternate nostril breathing (ANB) is a breathing exercise used to modulate the pace of breathing. The present study aimed to evaluate the efficacy of ANB on pulmonary function and physical functional capacity in normal adults across different age groups.

Methods: 48 participants aged 20-50 years were stratified based on age and were assigned into young (experimental and control group) and old age strata (experimental and control group) for this randomized controlled trial. Pulmonary function (FEV_1, FVC, FEV_1/FVC, PIFR, and PEFR) and physical functional capacity (6MWD) were assessed before and after the test. Experimental groups practiced ANB for 15 minutes for 4 weeks (6 days/week) in front of primary researcher. No intervention was given to control groups. Between groups analysis was done by Mann Whitney U test whereas, Wilcoxon signed rank test was used for within group analysis.

Results: Significant differences were found in median values of FEV_1 (2.21-2.47, p=.002), FVC (2.39-2.77, p=.003), PEFR (5.30-6.45, p=.002), and PIFR (3.85-4.22, p=.05) between total experimental and total control groups, but not in FEV_1/FVC (p=.41)and PIFR (p=20). Post treatment analysis of total experimental group showed significant improvement in FEV_1 (p= .0001), FVC (p=.0001), PEFR (p= .0001), PIFR (p= .002) and 6MWD (p= .0001), while total control group had no significant improvement in any component (p>.05).

Conclusion: Alternate nostril breathing can be used as a maneuver to improve age related lung function decrement.

Keywords: Adults, breathing exercise, lung function, peak expiratory flow rate

1. INTRODUCTION

The physiological functions of human body are examined to diagnose the development of disease or prognosis of individuals (1). Pulmonary function tests (PFTS) are an investigative procedure that measure the function, capacity and condition of lung (2).

Both the physical and psychological health depend on cardiopulmonary endurance (3). But factors including poor diet, sedentary lifestyle, rapid industrialization, stress, environment pollution, overcrowding can influence the normal health (4). Improper lifestyle has an impact on cardiopulmonary functions. Reduction of cardiopulmonary function progressively result in reduced functional capacity (5). Moreover, the normal function of lung changes minimally from 20 to 35 years of age but thereafter starts declining gradually due to various anatomical and physiological changes with aging (6,7).

Breathing can be regulated voluntarily among all other autonomic functions of human body (3). Voluntary control of breathing can assist in functions of autonomic nervous system

to provide a harmonic state (8). Regular practice of specific techniques can also improve physical, as well as, psychological health of individual in everyday life (9). Alternate nostril breathing (ANB) is a type of slow, deep breathing techniques that allows voluntary regulation of breath through the alternate use of right and left nostrils (10). During breathing exercise, the heart and the lungs come into their action. The lungs involve in bringing of oxygen into the body, providing energy, and also removal of carbon dioxide (11).

Authors from previous reports suggested that practice of ANB breathing can enhance psychological health by relieving stress (12). It has also been proved to modulate sympatho-vagal activity with improved lung functions (8). Breathing exercises are very common step in different exercise forms (9). This is also beneficial for maintaining health status of individual among all age groups (13). Diaphragmatic breathing, deep breathing, paced breathing, buteyko breathing, ANB were used in different experimental studies (14-16). Among them, ANB is a simple voluntary breathing

technique that can be easily performed at home. So, it is important to understand the effect of ANB exercise among population of young, as well as old age groups.

Slow and deep breathing with alternate nose consists of inhalation, retention and exhalation phases (17). Different types of breathing exercises are included in yogic practice which can be done either fast or slow manner (18). But the physiological effects of slow and fast breathing can vary among individual. Fast, deep breathing replenishes air in each part of lung, whereas, slow, deep breathing is effective in reducing ventilation in dead spaces of lung (19). Recently, Leelarungrayub J et al. conducted a study that compared the effect of slow and fast breathing technique using volume-oriented incentive spirometer and found that slow deep breathing is more effective in improving functional capacity, whereas fast deep breathing is effective in improving both pulmonary function and functional capacity in patients with mild to moderate chronic obstructive pulmonary disease (20). Rapid reduction of FEV_1 is an important marker of COPD as it directly explains about the progression of disease. It is observed that FEV_1 declines at a rate of 25–30 ml/year at 35–40 years of age and 60ml/year after the age of 70 years in normal adults (6). It can be inferred that the use of ANB may have similar effects on healthy asymptomatic individuals.

To the best of our knowledge, the effect of ANB exercise on physical functional capacity had not been studied yet. This study is aimed to find out the efficacy of ANB on pulmonary function and functional capacities in adults across different age groups.

2. METHODS

2.1. Study Design

This is a pretest posttest, randomized experimental study.

2.2. Ethical Statement

The study obtained the ethical clearance from Institutional Ethics Committee and had been registered in the Clinical Trials Registry-India with universal trial number CTRI/2019/06/01976. The study was performed under Indian Council of Medical Research (2017) National Ethical Guidelines for biomedical and health research involving human participants and the ethical principles for medical research involving human subjects stated in the Declaration of Helsinki (revised 2013).

2.3. Eligibility Criteria

Asymptomatic male and female participants of aged 20-50 years with body mass index 18.5-24.9 kg/m², and stable vitals were included in the study. Volunteers were nonsmokers and had no acute disease 6 weeks preceding the study. Any documented conditions (cardiopulmonary disease, musculoskeletal disorders, neuromuscular diseases, kidney disease, metabolic diseases, blood diseases, any recent surgery, cancer etc.), use of any medications, participants who perform regular exercises or sports and any "YES" on PAR-Q Scale were excluded from the study.

2.4. Sample Size Estimation

The sample size was estimated by G*Power software, version 3.1.9.2.21, based on the effect size of FVC values from a previous study (22). The parameters include: assuming tests with family distribution means: difference between two independent means (two groups) with effect size 1.61,22 a type I error of 0.05, a power equal to 0.95. The sample size is 12 in each group. The total sample size considering 4 groups was 48. Considering 10% drop out, the total sample size was 52.

2.5. Study Participants

The researchers orally communicated and distributed information sheet about the study in brief to the students and staff of the institute and nearby community dwellings. People who were interested reported to the primary and secondary researchers within the due date. Normal adults were recruited among them. Prior to the intervention, all participants were asked to sign the informed consent.

2.6. Procedure

Individuals who voluntarily wanted to participate were recruited and explained about the research. Informed consent forms were taken from those who were agreed to participate. The samples were taken by stratified random sampling and divided into two strata of different age groups: Young group (20-35 years of age) and old group (36-50 years of age) (6). Then randomization was done for both the strata's. Block randomization was done by sequentially numbered opaque sealed envelope method for dividing them into experimental and control group (23). A total of four blocks with six rows had been created for 24 samples in young strata, whereas, four blocks with seven rows had been designed for old strata with sample size 28. Sequentially numbered opaque sealed envelope was applied to perform random allocation sequence (24). The data was collected in between 12th May 2019 to 21st January, 2020.

The samples of young group strata were allocated into young experimental group (YEG) and young control group (YCG). Participants of old group strata were allocated into old experimental group (OEG) and old control group (OCG).

Measurement of force vital capacity (FVC), force expiratory volume in one second (FEV_1), ratio of FEV_1 and FVC (FEV_1/FVC), peak inspiratory flow rate (PIFR), peak expiratory flow rate (PEFR) and distance covered during six minutes' walk test (6MWD) were recorded before starting the experiment.

Pulmonary function test was measured by using RMS Helios 401 – computerized spirometer as per standardized

guidelines (25). Before performing the test, all the participants were allowed to take rest period of 30 minutes to prevent measurement error. Participants were performed the test for at least three times to obtain the best value. The participants were asked to sit comfortably in erect position with feet firmly rest on floor. The lips of participant were sealed around a disposable mouth piece, and a nose clip was attached to the nose of subject to ensure that there was no chance breathing through the nose. Then they were instructed to breathe in fully through the mouth and then blast out air through the mouth piece.

The 6MWT was performed according to the guidelines of ATS (25). Before doing the test, the participants were allowed to sit in a chair at rest for at least 10 minutes.

BP of participants was recorded using sphygmomanometer. The participants were instructed to stay and quite during measurement. Systolic and diastolic BP was taken and noted (26). Then the rate of perceived exertion of participants was assed using the Borg scale.

The primary researcher asked the participants to walk along a 30 m straight, long track of corridor of hospital at their own pace for 6 minutes. The participants were instructed to walk to cover as much distance as possible, in the duration of 6 minutes. Participants were encouraged continuously during the test. In case participants developing any symptoms like severe breathlessness, pain in chest, dizziness, pain in leg, or diaphoresis during the 6 minutes' walk test, the patients were allowed to stop. But during the test, none of the participants experienced any such symptoms. After 6 minutes, the participants were asked to stop at the point, they were at that time. Before and after completion of 6 minutes, PR, SpO2, and BP were assessed and RPE is recorded (27).

Experimental groups of both strata performed ANB exercise for 15 minutes per day for 4 weeks (six days in a week) under face-to-face supervision of primary researcher, while the control groups did not perform any exercise. After completion of 4 weeks, again the measurements of FVC, FEV_1, FEV_1/FVC, PIFR, PEFR and 6MWD were taken in both the groups.

2.7. Intervention Description

Instruction was given by the primary researcher. Participants were asked to sit crossed leg, with erect spine. With the help of right thumb, they were instructed to block the nostril of right side, and then to inhale slowly and deeply through the left nostril for 6 seconds. Then they were asked to block the left nostril with right index finger (both the nostrils were closed), and to hold the breath for 6 seconds. After 6 second, they were advised to release the right thumb from the right nostril to exhale for the same time with right nostril.

Air was then again breathed in through the right nostril for 6 seconds that was still opened. Then, with the right thumb, right nostril was also blocked (closed both nostrils) for the same time. Then, the left nostril was opened to exhale for 6 seconds, thus completing one cycle (28). The cycle was

repeated for 15 minutes per day for 4 weeks (six days in a week). No external stimuli, such as music or meditative sounds were used during the ANB exercise. The participants were instructed to concentrate solely on their breathing.

Control group did not perform any exercises.

2.8. Outcome Measures

Our outcomes measures were pulmonary function parameters: force vital capacity (FVC), force expiratory volume in one second (FEV1), ratio of FEV1 and FVC (FEV1/FVC), peak inspiratory flow rate (PIFR), peak expiratory flow rate (PEFR) and physical functional capacity: distance covered during six minutes' walk test (6MWD). Pulmonary function was measured by using RMS Helios Spirometer, while, functional capacity was measured by calculating the distance covered during six minutes' walk test. All outcomes were assessed at baseline and 4 weeks after the intervention.

2.9. Statistical Analysis

Data were analyzed using Statistical Package for the Social Sciences (SPSS) version 21.0. Shapiro Wilk test was used to analyze normality of the data. The data were not normally distributed and represented as median and inter quartile range in Table 1. Mann Whitney U test was used to compare experimental with control group. Wilcoxon signed rank test were used to compare within groups. Level of significance, i.e. p value, was set as < .05; p value > .05 was considered as statistically insignificant.

Table 1. *Baseline characteristics of the experimental group and no-treatment control group.*

Variables	Total sample (n=58)		p-value for normality test
	Experimental group	Control group	
	Median (IQR)	Median (IQR)	
Age (years)	30 (21-56)	30 (21-49)	.0001
Height (meter)	1.61 (1.52-1.87)	1.59 (1.50-1.74)	.04
Weight (Kg)	56 (48-86)	56.50 (45-68)	.0001
BMI (Kg/m²)	22.55 (18.70-24.80)	21.10 (19.50-24.80)	.002

Shapiro Wilk test was employed to check normality distribution of the data.
n: Number of subjects, IQR: Inter Quartile Range
BMI=Body Mass Index.

3. RESULTS

Total 58 individuals expressed interest in this study and were assessed for eligibility. Total 48 participants of 20-50 years of age recruited for analysis. Subjects' recruitment flow diagram was represented in Figure 1. Demographic data of the participants is reported in Table 1. Significant improvement was found in experimental groups of both strata in comparison with control groups (YEG vs YCG) (OEG vs OCG) in the domain of pulmonary function parameters (FEV_1, FVC, and PEFR) as shown in Table 2.

Table 2. *Between and within group comparison of young strata*

Variables	Young experimental group				Young Control group				z-value	p-value
	Pre test	Post test	z-value	p-value	Pre test	Post test	z-value	p-value		
	Median (IQR)	Median (IQR)			Median (IQR)	Median (IQR)				
FEV$_1$ (l)	2.19 (1.93-3.77)	2.66 (2.14-4.19)	-3.05	.002*	2.29 (2.02-4.35)	2.24 (2.02-4.00)	-1.059	0.28	-2.16	.03†
FVC (l)	2.26 (1.91-4.61)	2.87 (2.20-4.83)	-3.05	.002*	2.45 (2.26-3.75)	2.47 (2.13-3.73)	-0.589	0.55	-2.33	.01†
FEV$_1$/ FVC (%)	92.67 (81.78-98.11)	95.18 (81.78-100)	-1.86	.06	93.59 (81.00-97.82)	91.94 (81.25-99.45)	-1.647	0.09	-0.80	.41
PEFR (l)	5.27 (4.68-8.77)	6.54 (5.33-9.31)	-3.05	.002*	5.67 (4.77-7.75)	5.23 (4.46-8.18)	-1.156	0.24	-2.13	.03†
PIFR (l)	3.78 (2.94-8.18)	4.51 (3.37-8.57)	-3.07	.002*	4.36 (2.31-6.57)	4.20 (1.63-6.76)	-2.354	0.01	-1.27	.20
6MWD (m)	444.50 (432.60-510.00)	446.87 (434.00-512.00)	-3.07	.002*	438.82 (420.00-500.83)	439.25 (419.75-502.00)	-0.432	0.66	-1.81	.06

Between groups' comparison: Mann Whitney U test., Within group comparison: Wilcoxon signed rank test., FEV$_1$: Force expiratory volume in 1 second, FVC: Force vital capacity, PEFR: Peak expiratory flow rate, PIFR: Peak inspiratory flow rate, 6MWD: 6-minutes walk distance, IQR: Inter Quartile Range, *: Statistically significant for within group comparison., †: Statistically significant for between group comparison.

Table 3. *Between and within group comparison of old strata*

Variables	Old experimental group				Old control group				z-value	p-value
	Pre test	Post test	z-value	p-value	Pre test	Post test	z-value	p-value		
	Median (IQR)	Median (IQR)			Median (IQR)	Median (IQR)				
FEV$_1$ (liter)	2.23 (1.77-2.90)	2.43 (1.96-3.19)	-2.82	.005*	2.14 (1.87-2.58)	2.17 (1.89-2.56)	-1.181	.238	-2.34	.01†
FVC (liter)	2.46 (2.18-3.51)	2.56 (2.21-4.00)	-2.23	.025*	2.32 (1.96-3.08)	2.38 (2.08-3.09)	-0.550	.582	-1.93	.05†
FEV$_1$/ FVC (%)	90.59 (78.63-98.03)	93.09 (79.75-96.49)	-1.17	.239	89.42 (79.46-95.95)	92.76 (81.00-96.37)	-1.413	.158	-0.14	.88
PEFR (liter)	5.30 (4.35-6.61)	6.41 (4.53-7.79)	-3.06	.002*	5.54 (4.76-6.43)	5.56 (4.40-6.60)	-1.173	.241	-2.34	.01†
PIFR (liter)	3.87 (1.02-5.43)	3.94 (1.84-5.56)	-1.88	.06*	3.60 (2.76-5.14)	3.31 (2.74-5.16)	-0.235	.814	-1.12	.26
6MWD (meter)	419.3 (408.80-442.73)	420.50 (429.00-444.00)	-2.98	.003*	422.00 (410.00-448.00)	423.00 (408.69-449.00)	-1.339	.210	-0.86	.37

Between groups' comparison: Mann Whitney U test., ithin group comparison: Wilcoxon signed rank test., FEV$_1$: Force expiratory volume in 1 second, FVC: Force vital capacity, PEFR: Peak expiratory flow rate, PIFR: Peak inspiratory flow rate, 6MWD: 6-minutes' walk distance., IQR: Inter Quartile Range, *: Statistically significant for within group comparison., †: Statistically significant for between group comparison

Table 4. *Between and within group comparison of total sample*

Variables	Total experimental group				Total control group				z-value	p-value
	Pre test	Post test	z-value	p-value	Pre test	Post test	z-value	p-value		
	Median (IQR)	Median (IQR)			Median (IQR)	Median (IQR)				
FEV$_1$ (liter)	2.21 (1,77-3.77)	2.47 (1.96-4.19)	-4.20	.0001*	2.26 (1.87-4.35)	2.19 (1.89-4.00)	-0.15	.87	-3.08	.002†
FVC (liter)	2.39 (1.91-4.61)	2.77 (2.20-4.83)	-3.92	.0001*	2.39 (1.96-3.75)	2.42 (2.08-3.73)	-0.22	.81	-2.96	.003†
FEV$_1$/ FVC (%)	89.67 (86.33-93.02)	91.34 (88.18-94.49)	-0.33	.738	91.37 (79.46-97.82)	91.70 (81.00-99.45)	-0.11	.90	-0.52	.59
PEFR (liter)	5.30 (4.35-8.77)	6.45 (4.53-9.31)	-4.28	.0001*	5.60 (4.76-7.75)	5.54 (4.40-8.18)	-1.66	.09	-3.10	.002†
PIFR (liter)	3.85 (1.02-8.57)	4.22 (1.84-8.18)	-3.14	.002*	3.96 (2.31-6.57)	3.53 (1.63-6.76)	-2.01	.04*	-1.94	.05†
6MWD (meter)	437.50 (408.80-510.00)	439.25 (409.00-512.00)	-4.26	.0001*	428.50 (410.00-500.83)	429 (408.69-502.00)	-1.13	.25	− 0.88	.37

Between groups' comparison: Mann Whitney U test., Within group comparison: Wilcoxon signed rank test., FEV$_1$: Force expiratory volume in 1 second, FVC: Force vital capacity, PEFR: Peak expiratory flow rate, PIFR: Peak inspiratory flow rate, 6MWD: 6-minutes' walk distance., IQR: Inter Quartile Range

*: Statistically significant for within group comparison., †: Statistically significant for between group comparison

Within group comparison showed significant improvement in FEV_1, FVC, PEFR, PIFR and 6MWD in both young experimental group and old experimental group after practicing ANB for 4 weeks (Table 3). Significant difference was observed in between group analysis of total sample in FEV_1, FVC, and PEFR. Significant improvement was observed in combine sample of total experimental group (Table 4). In addition, inter group analysis was also mentioned in Table 5 between YEG and. OEG, YCG and OCG. But no significant difference was found.

Table 5. *Inter-group analysis: Young experimental vs old experimental group and young control vs old control group*

Variables	Young experimental group vs Old experimental group		Young Control group vs Old Control group	
	z-value	p-value	z-value	p-value
FEV_1 (liter)	-1.41	.15	-0.98	.42
FVC (liter)	-2.28	.22	-0.66	.86
FEV_1/ FVC (%)	-2.25	.24	-2.02	.40
PEFR (liter)	-0.28	.79	-0.14	1.00
PIFR (liter)	-0.98	.34	-1.38	.50
6MWD (meter)	-1.70	.08	-0.34	.82

Between groups' comparison: Mann Whitney U test. FEV1: Force expiratory volume in 1 second, FVC: Force vital capacity, PEFR: Peak expiratory flow rate, PIFR: Peak inspiratory flow rate, 6MWD: 6-minutes' walk distance

4. DISCUSSION

ANB is a simple voluntary breath regulation technique that is commonly performed to relieve stress and improve physical and physiological functions (24). Regulation of breath voluntarily is usually performed with the aim to make rhythmic respiration and to provide calming effect of the mind (29). The main finding of our study was an improvement in several components of lung functions after performing ANB exercise by both the age groups.

FEV1 denotes the highest amount of expelling rate of breath in one second after maximal inhalation (30). Age can affect the average FEV1 value even in healthy subjects (30). Regular practice of ANB stimulates the stretch receptors of lung which helps to relax laryngeal smooth muscles and trachea bronchial tree. This probably helps to modulate the caliber of airways and reduction of resistance of airways and smooth exhalation (29). FEV1 depends upon the resistance of airway (31). Improvement in FEV1 may be due to the result of reduction of airway resistance after ANB exercise.

Secondly, the present study considered that practice of ANB irrespective of age also showed significant improvement in FVC. FVC is an indicator of the state of lung's elastic property (31). The component is considered as a measure of health

for the evaluation of the normal individual and patients with pulmonary conditions (31). Regular practice of a slow deep breathing causes recruitment of muscles of respiration. Recruitment of these muscles results in strengthening of respiratory muscles that might have improved the lung's elastic property (31). Regular practice of ANB by slow and deep inspiration and expiration for a prolonged time, leads to strengthening of the respiratory muscles (32). Hence improvement in FVC could be due to strengthening of muscles of respiration.

Similar result was observed in a study conducted by Chetan K et. al. where the authors concluded that daily practice of ANB for 3 months provide significant improvement on FEV1 and FVC among college students of 17 and 21 years (32).

PEFR, which is an indicator of variation of elastic recoil pressure or of the distal airways resistance had also been improved in this study (33). Improvement in PEFR is mostly depend on volume of lungs and pulmonary airway mechanics (31). Slow deep breathing exercises have been considered to expand the lungs more than the normal breathing. This may recruit opening of alveoli that may be closed previously, result in increasing surface area of pulmonary membrane and diffusion of air across this membrane (34). This may lead to improve alveolar perfusion through widening of the pulmonary bronchioles (31). ANB is one of the self-regulated slow, deep breathing exercise that may raise the depth of breathing by using the spaces of lung, which are inert in normal breathing (35). So the increase in PEFR after practicing of ANB may the result of small airway opening of lung and lowering the resistance of distal airways. This result is in line with the study that was conducted by Garg S et al. in 2016 to identify effect of 6 weeks of nadi shodhan pranayama on PEFR (35).

No significant difference was observed in FEV1/FVC in line previous reports (36,37). Result of the present study showed no significant difference in PIFR.

Physical functional capacity is capacity of individual to perform activities of sub maximal level, which is assessed by variety of tests. One of the useful tests to measure functional capacity is 6-minute walk test. (38). 6MWD was statistically improved within YEG and OEG, as well as total experimental group. But no significant improvement had shown in YCG, OCG and total control group. Analysis between YEG and YCG found no significant difference in 6MWD. No significant difference was also observed between OEG and OCG group in terms of 6MWD. Result of previous study conducted by Kaminsky DA et. al. on yogic breathing in COPD showed significant difference in 6MWD after practicing long 12 weeks of breathing exercise (39).

This was the first study that evaluated the efficacy of ANB on pulmonary function on people of different age groups. ANB exercise is a simple and cost-effective technique that can be practiced in home by the participants themselves.

The study had few limitations: The present study was not being able to measure the level of physical activity of the

subjects. Also, we were not able to examine the effect of ANB on other important parameters of PFT like maximum voluntary ventilation (MVV) and slow vital capacity (SVC).

5. CONCLUSION

The study concluded that regular practice of Alternate nostril breathing for 4 weeks produces a significant effect on FEV1, FVC, and PEFR. Practice of this breathing exercise has been proven to improve pulmonary function of young as well as older adults. So ANB exercise can be used as a maneuver to improve age related lung function decrement.

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Examining the Breastfeeding Self-Efficacy of Mothers Diagnosed with COVID-19

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ABSTRACT

Objective: It is an important issue to determine the effects and health behaviors of mothers and babies, who are among the vulnerable groups, in particular situations that affect the perceptions and orientations of societies in many dimensions, such as the pandemic. The present study was carried out in order to investigate the breastfeeding-related knowledge and practices of mothers diagnosed with COVID-19 and their breastfeeding self-efficacy.

Methods: This descriptive and cross-sectional study was carried out on mothers diagnosed with COVID-19 and having a baby aged between 0 and 24 months. Data were obtained through a questionnaire form including participants' descriptive characteristics and the breastfeeding self-efficacy scale: short form, administered through telephone interviews.

Results: The study included participants with a mean age of 29.39±5.34 years, of whom 86% resided in urban/rural centers. The average number of pregnancies was 3.46±2.34, and the average number of living children was 2.80±1.79. The percentage of mothers who continued to breastfeed their babies after being diagnosed with COVID-19 was 73.9%. The mean score of breastfeeding self-efficacy in the study group was 54.4±7.2, and the average scores of breastfeeding self-efficacy for mothers who continued to breastfeed after being diagnosed with COVID-19 were significantly higher.

Conclusion: In this study, it was determined that mothers with high breastfeeding self-efficacy scores continued breastfeeding after COVID-19 diagnosis.

Keywords: COVID-19, breastmilk, breastfeeding, self-efficacy.

1. INTRODUCTION

In 2019, a respiratory illness called COVID-19 characterized by severe acute respiratory syndrome and transmitted among people through respiratory droplets emerged in the city of Wuhan, China (1). The World Health Organization (WHO) declared this disease a pandemic on 11th March 2020 since it began to affect the whole world and spread rapidly (2). As of 1st June 2023, the WHO reported a total of 767 million cases and 6.9 million deaths worldwide (3). In Türkiye, the first case was seen on 13th March 2020 and there have been reported 17.2 million cases and 102.000 deaths as of 7th April 2023 (4).

The COVID-19 pandemic has affected all aspects of health care in every region of the world. Promotion of breastfeeding was also among the services affected. Guidelines and systematic reviews containing recommendations on breastfeeding have started to be published during the COVID-19 period. In a systematic review carried out by Çınar et al. in 2022,

46 studies on the breastfeeding status of mothers with diagnosed with or suspected for COVID-19 were examined, and it was reported that breastfeeding should continue for the protection of both mothers and babies (5). Moreover, there is no evidence of vertical transmission of COVID-19 to infants through breast milk (1,6–8). However, studies have shown that breast milk from mothers diagnosed with COVID-19 contains coronavirus antibodies (9,10) and breastfed infants have better clinical outcomes compared to non-breastfed infants (11,12).

Self-efficacy perception plays an important role in the sustainability of breastfeeding among breastfeeding mothers (13). Breastfeeding self-efficacy is defined as the mother's confidence in her ability to breastfeed her baby (14) and is one of the factors influencing the continuation of breastfeeding in the first 6 months after birth (15). Self-efficacy is one of the

essential components of Bandura's social cognitive theory (1997) and includes a person's belief and confidence in their ability to engage in healthy behaviors, including successful breastfeeding (16).

Although there are numerous studies on breastfeeding and breast milk, limited research has been conducted on the experiences of mothers diagnosed with COVID-19 and the factors influencing their breastfeeding experiences and self-efficacy during the COVID-19 pandemic, which has affected societies in many dimensions (17–19). In light of this information, this study aims to determine the breastfeeding experiences and self-efficacy of mothers diagnosed with COVID-19 and effecting factors (descriptive characteristics related to mother and infant, characteristics related to the disease, etc).

2. METHODS

2.1. Study Design and Sampling

This study has a descriptive and cross-sectional design. The study universe consists of mothers residing in Şanlıurfa province, who were diagnosed with COVID-19 and have a baby aged between 0 and 24 months old. Individuals, who were diagnosed with COVID-19 and had a baby between 0 and 24 months old, were identified from the sequential list obtained from the Şanlıurfa Provincial Health Directorate for the study (3009 individuals). The identified names were sorted in ascending order according to their national identification numbers, and a systematic sampling method was used to select participants. The contact and address information of the selected participants was recorded by making use of the data obtained from the Provincial Health Directorate's database. It was attempted to reach the participants through phone calls. Due to incorrect phone numbers of 73 mothers, unanswered calls from 58 mothers, unwillingness to participate from 26 mothers, and inability to establish communication due to not speaking Turkish by 1 mother, they could not participate in the study, and the study was completed with 142 mothers.

The inclusion criteria were having a diagnosis of COVID-19, having a baby between 0 and 24 months old, not having any complications related to breastfeeding, having no communication barriers, and agreeing to participate in the study. The exclusion criteria, mothers who refused to participate in the study, who had a barrier to breastfeeding and who had a communication barrier were not included in the study.

The study received approval from the Ministry of Health on 21st April 2021, data supply and processing approval from the Şanlıurfa Provincial Health Directorate (11/06/2021, Barcode Number: 141658715), and ethical approval from the Harran University Clinical Research Ethics Committee (Approval date: 26/04/2021, Meeting Decision No: HRÜ/21.09.05). Permission for the use of the scale was obtained from the author, who conducted the adaptation. At the beginning of the telephone call with the participants, verbal consent was obtained by explaining the purpose of the call, assuring the confidentiality of their identity and responses, stating that the obtained information would be used solely for scientific purposes, and emphasizing the voluntary nature of participation. All procedures were conducted in accordance with the ethical standards of our institution's human experimentation committee and the Helsinki Declaration.

2.2. Data Collection Tools

In this study, data were obtained using a questionnaire that included descriptive characteristics of the participants and a breastfeeding self-efficacy scale: the short form.

The descriptive characteristics questionnaire consisted of 61 questions about the mother, infant, breastfeeding status and the disease and was prepared by the researchers.

The Breastfeeding Self-Efficacy Scale is a 5-point Likert-type (ranging from 1 = "not at all confident" to 5 = "always confident") scale consisting of 14 items. The minimum possible score from the scale is 14, and the maximum score is 70. All items are evaluated positively. A higher score indicates higher breastfeeding self-efficacy. Its adaptation into the Turkish language was conducted by Aluş Tokat in 2017 (22). The Cronbach's alpha value of the adapted version was found to be 0.86. In this study, Cronbach's alpha value was found to be 0.81.

The data were obtained through telephone interviews with individuals sampled between April and December 2021, following the necessary administrative and ethical permissions. The principle of voluntarism was adopted in the research, and after explaining the purpose of the study to the participants, the questions in the data collection form were asked. The questionnaires were filled out based on the answers given. An average of 20 minutes of interview was conducted for each participant.

2.3. Statistical Analysis

The data obtained were saved and analyzed using IBM SPSS Statistics v.22.0 (IBM Corp.; Armonk, NY, USA) software package. Mean ± standard deviation, minimum-maximum values were used for continuous variables and frequency and percentages for nominal variables in statistical analyses. The suitability of continuous variables for normal distribution was determined by examining the Kolmogorov-Smirnov test, normal distribution graphs, skewness, and kurtosis coefficients together. The significance of the difference in terms of continuous variables was investigated using independent samples t-test and F-test (One-way ANOVA). Pearson correlation analysis was used to determine the degree and direction of the relationship between two numerical variables. A p-value less than .05 was considered statistically significant for all analyses.

2.4. Limitations

Although the participants of the study were determined through a sampling conducted within a single province, no stratification was performed based on the regions and characteristics of the settlements within the province. This did not provide us the opportunity to observe the differences in health behavior patterns adopted by cultural characteristics in this province. Additionally, we believe that evaluating the behavioral tendencies regarding breastfeeding before and after the pandemic would better explain the possible effects of being diagnosed with COVID-19 on breastfeeding behavior.

3. RESULTS

When examining the distribution of information regarding the sociodemographic characteristics of the mothers participating in the study, the average age was found to be 29.39±5.34 years (Min-max: 19-42). While 86.0% of the mothers reside in the city/district center, 79.6% live in nuclear families. Moreover, 77.5% of the mothers do not work in any income-generating occupation and 19.7% of the participants have not received any formal education. However, participant mothers described their perception of the family's economic situation as "Our income is less than our expenses" with a rate of 63.3% (Table 1).

Table 1. Distribution of participants' sociodemographic characteristics

n:142	X̄ ± SD (Min-Max)	
Maternal age (Years)	29.39±5.34 (19-42)	
	n	%
Place of living		
City/district center	122	86.0
Village/County	20	14.0
Family type		
Nuclear Family	113	79.6
Extended Family	29	20.4
Employment status of mother		
Yes	32	22.5
No	110	77.5
Educational level of mother		
Illiterate/Literate	28	19.7
Elementary and Secondary School	78	54.9
University and Higher	36	25.4
Economic condition perception of mother for the family	90	63.3
Income lower than expenses	40	28.2
Income equals expenses	12	8.5
Income higher than expenses		

x̄: *Mean*, **SD**: *Standard Deviation, Min: Minimum, Max: Maximum*

When examining the distribution of information regarding the obstetric history of the mothers, the average age of the participants at their first childbirth was found to be 22.79±4.08 years (Min-max: 16-38). The average total

number of pregnancies for the mothers was 3.46±2.34 (Min-max: 1-13), and the average number of living children was 2.80±1.79 (Min-max: 1-10). The rate of receiving prenatal care among mothers was determined to be 67.6%. It was determined that 75.4% of the recent pregnancies were planned, and 53.5% of the births were performed via cesarean section. Furthermore, 18.3% of the infants in the last birth had a health problem (Table 2).

Table 2. Distribution of participants' obstetric history, babies' personal characteristics, and breastfeeding-related knowledge and behaviors

n:142	X̄ ± SD (Min-Max)	
Maternal age of first birth **(Year)**	22.79±4.08 (16-38)	
Total number of pregnancies	3.46±2.34 (1-13)	
Number of living children	2.80±1.79 (1-10)	
Number of dead/stillbirths	0.67±1.03 (0-6)	
Last baby's gestational week of birth	38.51±1.84 (26-42)	
Age of the last baby (month)	13.82±1.73 (5-19)	
Birthweight of the last baby (gram)	3149±626 (900-5000)	
Mother's mean breastfeeding duration for other babies (month)	11.60±9.85 (0-36)	
	n	%
Prenatal care		
Yes	96	67.6
No	46	32.4
Last pregnancy was planned		
Yes	107	75.4
No	35	24.6
Birth method of the last baby		
NSVB	66	46.5
C/S	76	53.5
Health problem at birth for the last baby		
Yes	26	18.3
No	116	81.7
Gender of baby		
Female	58	40.8
Male	84	59.2
Current feeding situation of baby		
Only breastmilk	3	2.1
Breastmilk and formula	7	4.9
Breast milk and supplementary nutrition	80	56.3
Other (without breastmilk)	52	36.7
Feeding method (n:139)		
Spoon	97	69.8
Feeding bottle	22	15.8
Both	20	14.4
Mother's belief in the benefit of breastmilk	140	98.6
Yes, beneficial	2	1.4
No, not		
Should the baby be fed only on breastmilk for the first 6 months?	95	66.9
Yes	47	33.1
No		
Breastfeeding training		
Yes	44	31.0
No	98	69.0

Source of breastfeeding training (n:44)		
Physician/nurse/midwife	28	63.64
Written and/or visual sources of information	6	13.64
Family/Relatives	10	22.72
Is your knowledge of breastfeeding sufficient?		
Yes	131	92.3
No	11	7.7
Spousal support in breastfeeding		
Yes	132	93.0
No	10	7.0
Spousal support for baby care		
Yes	105	73.9
No	37	26.1
The person offering help in baby care after the birth		
Only mother	34	23.9
Only spouse	30	21.2
Spouse/Parents	78	54.9

X̄: Mean, SD: Standard deviation, Min: Minimum, Max: Maximum, NSVB: Normal spontaneous vaginal birth, C/S: Cesarean

The distribution of information regarding the mothers' knowledge and attitudes toward breastfeeding is presented in Table 2. The average duration of breastfeeding for their previous infants is 11.60±9.85 months (Min-max: 0-36). 98.6% of the mothers stated that breast milk is a beneficial source of nutrition. The rate of participants who believe that exclusively breastfeeding, including water, is sufficient for the first 6 months, is 66.9%, 31.0% of the participants declared that they received any education about breastfeeding, 92.3% of the mothers reported that they have sufficient knowledge about breastfeeding, 93.0% of the mothers stated that their partner supports them in breastfeeding, and 73.9% declared that their partner helps them in taking care of the baby after birth.

The distribution of some characteristics of the participating mothers regarding COVID-19 infection is presented in Table 3. The number of mothers requiring hospitalization after diagnosis is 3 (2.1%), and the rate of medication use for treatment is 40.8%. During this period, 96 (67.6%) mothers reported being concerned about transmitting the infection to their babies, 26.1% of the mothers stopped breastfeeding after being diagnosed with COVID-19. 66.9% of the mothers stated that they use personal protective equipment, and 68.3% of the participants reported receiving information about breastfeeding during the COVID-19 disease from any source. The rate of those who reported being supported in breastfeeding during the infection process was 45.1%. The mothers stated that, during the illness, 57.0% of them were in the same room but away from the bed, 23.2% were in a different room, 16.3% were next to the bed, and 3.5% were in different houses from their babies. Moreover, 59.9% of the mothers stated that there was no decrease in their breast milk during the illness. 89.4% of the mothers did not receive the COVID-19 vaccine, while 10.6% were vaccinated. 55.9% of the mothers stated

that they did not receive the vaccine due to the lack of priority, 33.1% expressed hesitation/ lack of trust in the vaccine, 7.1% believed that it would harm their baby while breastfeeding and 3.9% mentioned that they did not receive the COVID-19 vaccine because they were pregnant.

Table 3. Distribution of participants' characteristics regarding COVID-19 infection

	n	%
Hospitalization status during treatment		
Yes	3	2.1
No	139	97.9
Medication use during treatment		
Yes	58	40.8
No	84	59.2
Concern about transmitting the infection to the baby		
Yes, does	96	67.6
No, doesn't	46	32.4
Continuation of breastfeeding after diagnosis		
Yes, I breastfed	105	73.9
No, I did not breastfeed	37	26.1
Reasons for not breastfeeding after diagnosis (n:37)		
Medication use	2	5.4
Concern about transmission	5	13.5
Belief that the baby can be adequately nourished with formula	30	81.1
Feeding method for the baby after diagnosis		
Breastfeeding only	45	31.7
Breastfeeding with complementary food and formula	59	41.5
Expressing breast milk and feeding with a bottle	1	0.7
Only complementary food and formula	37	26.1
Use of personal protection equipment after diagnosis		
Yes	95	66.9
No	47	33.1
Information-seeking status about breastfeeding after diagnosis		
Yes	97	68.3
No	45	31.7
Support received for breastfeeding during the infection process		
Yes	64	45.1
No	78	54.9
Proximity to the baby after the infection		
Beside the bed	23	16.3
In the same room but away from the bed	81	57.0
In a different room	33	23.2
In a different house	5	3.5
Feeling of decreased breast milk production during the infection process		
Yes	57	40.1
No	85	59.9
COVID-19 vaccination status		
Yes	15	10.6
No	127	89.4
Reasons for not getting the COVID-19 vaccine (n:127)		
Not being prioritized for vaccination	71	55.9
Concern that it would harm the baby	9	7.1
Being pregnant	5	3.9
Hesitation/lack of trust towards the vaccine	42	33.1

Table 4. *Comparison of breastfeeding self-efficacy scale mean scores with various characteristics of participants*

	n	Test/p	X̄ ± SD
Maternal age groups			
19-25 years	44	**F:** 0.442	53.61±7.23
26-35 years	79	**p:** 0.643	54.89±7.37
36 years and older	19		54.42±6.85
Mother's educational level			
Illiterate/Literate	28	**F:** 1.015	55.32±5.95
Elementary and secondary school	78	**p:** 0.365	53.65±7.37
University and higher	36		55.44±7.80
Family type			
Extended family	29	**t:** 0.084	54.51±5.24
Nuclear family	113	**p:** 0.934	54.41±7.68
Place of living			
City/district center	122	**t:** 2.433	55.02±7.29
Village	20	**p: 0.016***	50.85±5.82
Employment status of mother			
Yes	32	**t:** 1.140	55.71±7.95
No	110	**p:** 0.256	54.06±7.00
Economic condition perception of mother for the family	90	**F:** 2.311	53.46±7.14
Income lower than expenses	40	**p:** 0.103	55.92±7.24
Income equals expenses	12		56.75±7.11
Income higher than expenses			
Total number of pregnancies			
1	27	**F:** 0.774	55.88±7.15
2	34	**p:** 0.463	53.61±6.70
3 and more	81		54.29±7.48
Was the last pregnancy planned?			
Yes	107	**t:** 2.416	55.26±6.70
No	35	**p: 0.017***	51.91±8.26
Health problem in pregnancy			
Yes	36	**t:** − 0.039	54.38±9.14
No	106	**p:** 0.969	54.45±6.51
Prenatal care			
Yes	96	**t:** 0.596	54.68±6.71
No	46	**p:** 0.552	53.91±8.26
Age of the last baby			
0-12 month	24	**t:**-0.138	54.25±5.83
3 months or older	118	**p:**0.890	54.47±7.50
Gender of the baby			
Female	58	**t:**0.191	54.58±8.73
Male	84	**p:**0.849	54.33±6.03
Concern about transmitting the infection to the baby	96	**t:**-2.977	53.21±7.24
Yes	46	**p:0.003***	56.97±6.58
No			
Use of medication in treatment			
Yes	58	**t:**-2.558	52.60±6.65
No	84	**p:0.012***	55.70±7.38
Support in breastfeeding during the infection process	64	**t:**0.933	55.06±6.62
Yes	78	**p:**0.352	53.92±7.70
No			
Continuation of breastfeeding after diagnosis	105	**t:**4.038	55.81±7.05
Yes, I breastfed	37	**p:0.0001***	50.51±6.32
No, I didn't breastfed			

	n	Test/p	X̄ ± SD
Use of personal protection equipment after diagnosis	95	**t:**1.348	55.01±6.79
Yes	47	**p:**0.180	53.27±8.00
No			
Covid-19 vaccine			
Yes	15	**t:**0.657	55.60±8.06
No	127	**p:**0.512	54.29±7.15
Breastfeeding training			
Yes	44	**t:**0.470	54.86±7.33
No	98	**p:**0.639	54.24±7.21
Perception of having sufficient knowledge about breastfeeding	131	**t:**1.829	54.75±7.22
Yes	11	**p:**0.070	50.63±6.51
No			

*t: Independent sample t-test, **F**: F test, ***p < 0.05, x̄: Mean, **SD**: Standard deviation*

The average score of the mothers on the Breastfeeding Self-Efficacy Scale is 54.4±7.2 (min: 34, max: 70). The comparison between the average scores of the Breastfeeding Self-Efficacy Scale with various characteristics of mothers, who had a COVID-19 infection, is presented in Table 4. There was no significant difference in the scale score averages between age groups, but the lowest score average was observed in those aged between 19 and 25 years (p>.05). The average self-efficacy score of mothers residing in the city/district center was found to be higher (p<.05). Mothers with only one pregnancy had a higher total scale score average compared to those who had multiple pregnancies (p>.05). Mothers who had a planned and desired pregnancy had a higher average self-efficacy score for breastfeeding (p<.05). The average total scale score was significantly higher for mothers who did not have concerns about transmitting the infection to their babies (p<.05). Mothers who did not use medication for treatment after the diagnosis and continued breastfeeding had a statistically significantly higher self-efficacy score for breastfeeding (p<.05). Participants who considered their knowledge about breastfeeding sufficient had a higher total score (p>.05).

Table 5. *Comparison of sociodemographic, fertility, and infant characteristics by maternal breastfeeding self-efficacy scale scores*

Characteristics*	Maternal Breastfeeding Self-Efficacy Scale Score	
	r	p
Maternal Age **(years)**	0.046	0.586
Baby's age **(months)**	0.087	0.302
Mother's age of first birth **(years)**	0.071	0.400
Gestational week of birth **(week)**	-0.057	0.500
Weight at birth **(gram)**	0.079	0.348
Total number of pregnancies	-0.056	0.510
Number of living children	-0.025	0.771
Mean breastfeeding duration **(months)**	0.061	0.470

*Pearson's correlation analysis, r: correlation coefficient

The comparison of sociodemographic, fertility, and baby-related characteristics according to the scores of the

Breastfeeding Self-Efficacy Scale is presented in Table 5. The correlation analysis showed that the mother's age and the baby's age did not cause a significant change in the total scale score. Similarly, the mother's age at first birth, birth weight of the last baby, total number of pregnancies, and average duration of breastfeeding did not lead to a significant differentiation in the scale score average.

4. DISCUSSION

In this study carried out to identify the behaviors of mothers diagnosed with COVID-19 regarding breastfeeding and the factors influencing breastfeeding, 73.9% of the participants continued to breastfeed their babies after diagnosis. However, the rate of breastfeeding during the course of the infection was reported to be 54.5% in another study (20) and it was emphasized that the rate of breastfeeding in the first 6 months of the pandemic was not at the desired level in another study (18). There are limited studies in the literature that determine the breastfeeding rates of mothers diagnosed with COVID-19. Regarding this issue, WHO has recommendations during the pandemic for mothers diagnosed with COVID-19 to continue using breast milk, (23) and the rate of breast milk usage is considered to be low according to previous studies. Evaluating the physical, psychological, and sociological factors that prevent individuals from engaging in breastfeeding behavior during this process both before and after the pandemic will be more helpful in identifying the problem.

It is important for mothers and babies to be together as much as possible and share the same room in order to meet their physiological and psychological needs and to establish a secure attachment between them. In addition, it is necessary for the continuity of breastfeeding (24,25). In this study, 73.3% of the mothers preferred to be in the same room with their babies during the illness period. This situation can be considered to be one of the reasons for the higher rates of breastfeeding when compared to similar studies in the literature (18,20).

The most common reason for mothers diagnosed with COVID-19 to discontinue breastfeeding during the illness process is seen to be the fear of transmitting the infection (26–28). In this study, however, mothers stated that they did not breastfeed because they believed that formula feeding would be sufficient temporarily, followed by fear of transmission and fear of harming the baby due to medication use. In addition to the lack of concrete evidence showing vertical transmission of COVID-19 through breast milk and the fact that it can be a protective factor for the baby and can potentially alter the course of the disease, authorities recommend breastfeeding the baby by taking precautions (7,8). Another factor that hinders breastfeeding is the use of medication during the illness. In this study, the percentage of mothers who stated that they discontinued breastfeeding due to the belief that medication use would cause side effects was 5.4%, whereas this rate was reported as 62.5% in a similar study (20). Examining the recommendations

of health authorities and the studies carried out, it can be seen that the dominant reasons for mothers to discontinue breastfeeding during the illness process are different. This can be attributed to different cultural approaches of societies, the perception of the severity of the disease, and the general view of breastfeeding behavior.

In this study, 40.1% of the participants stated that they felt a decrease in breast milk secretion during the infection process. In a study examining the anxiety levels of breastfeeding mothers during the pandemic, (18) a significant inverse relationship was found between the frequency of breastfeeding their babies and their anxiety levels. In light of this information, controlling the level of anxiety caused by COVID-19 may be important for the continuity of breastfeeding.

In this study, the average self-efficacy score for breastfeeding among mothers diagnosed with COVID-19 was determined to be 54.4±7.2. In a study carried out by Durmuş and Öztaş (19) with breastfeeding mothers who were confirmed or had a history of contact with COVID-19, the average self-efficacy score for breastfeeding was reported to be 51.74±10.47. In another study that evaluated the breastfeeding status of healthy mothers during the pandemic, (18) the average self-efficacy score for breastfeeding was found to be 46.48±12.58. The findings of this study are similar to some studies in the literature.

A significant difference was found between the participants' continued breastfeeding status after diagnosis and their self-efficacy scores for breastfeeding (p<.05). The average self-efficacy score for breastfeeding among mothers who continued breastfeeding was higher compared to those who did not continue. In a similar study, (20) the average self-efficacy scores for breastfeeding among mothers who continued to breastfeed their babies were found to be higher. However, it was found that maternal age and educational status did not cause a significant difference in the self-efficacy scores for breastfeeding. On the other hand, it was found that the location where the mothers lived, specifically rural or urban areas, influenced breastfeeding self-efficacy. Mothers who reported living in the city center had higher breastfeeding self-efficacy scores. The idea of being able to easily access healthcare providers may cause this relationship to emerge.

Providing social support to mothers is an important issue for the sustainability of breastfeeding (29). It was reported that in the pandemic period when sufficient social support was not provided to breastfeeding mothers, criteria related to breastfeeding were negatively affected (30). In this study, 45.1% of the mothers stated that they received any support regarding breastfeeding. In a qualitative study carried out with 29 mothers, it was determined that mothers experienced stress regarding breastfeeding due to the illness and did not receive sufficient support from their relatives and healthcare personnel due to isolation (31). Another study carried out in the UK reported that there was a decrease in the quality and quantity of support received from relatives and healthcare

professionals during the COVID-19 quarantine period (32). In a similar study, (33) it was reported that support during the breastfeeding process was interrupted due to the restrictions on social distancing and the decrease in face-to-face meetings during the pandemic. These results explain the studies indicating a decrease in breastfeeding rates during the pandemic. This study should be guiding for healthcare providers in order to identify all the reasons that may cause interruptions in maternal and infant health and implement appropriate approaches within the framework of the safe motherhood program.

In this study, 10.6% of the mothers received the COVID-19 vaccine. The participants who did not receive the vaccine mostly stated that they did not receive priority for vaccination and had doubts about the vaccine. Although COVID-19 vaccination is recommended for pregnant and lactating women, the vaccination rates are found to be low. In a study examining the views on vaccine administration for non-pregnant, pregnant, and lactating women, it was found that non-pregnant women had a higher acceptance rate compared to pregnant or lactating women (34). The low vaccination rate in this study may be due to the ongoing efforts to develop vaccines and the prioritization of risk groups due to vaccine supply at the time when the data were collected.

5. CONCLUSIONS

In this study, it was determined that mothers with high breastfeeding self-efficacy scores continued breastfeeding after COVID-19 diagnosis. Providing counseling and education on breastfeeding to parents and conducting remote consultations via phone when face-to-face meetings are not possible are also recommended. It was recommended that studies should be carried out to develop strategies to facilitate breastfeeding in case of pandemics and infectious diseases.

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Suprahyoid Muscle Activation During Isometric Chin-Tuck Exercises in Different Body Positions

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ABSTRACT

Objective: The aim of the current study was to investigate the suprahyoid muscle activation during isometric chin-tuck exercises in different body positions.

Methods: Thirty-two healthy volunteers were enrolled. Suprahyoid muscle activation was recorded with surface EMG sensors placed under the chin. Isometric Shaker Exercise (SE) and isometric chin-tuck exercises were performed in five different body positions for 3 repetitions. Maximum voluntary isometric contraction (MVC) of the suprahyoid muscles was recorded. The normalization procedure was applied by proportioning the maximum suprahyoid muscle activation recorded during each exercise to the MVC, and recorded as a percentage (MVC%).

Results: Significantly higher suprahyoid muscle activation was detected during isometric SE compared to isometric chin-tuck exercises in supine and prone press up on elbows positions ($p < .008$). Suprahyoid muscle activation was found to be similar during isometric SE and isometric chin-tuck exercises in sitting, quadruped and prone positions ($p > .008$).

Conclusions: In conclusion, similar suprahyoid muscle activation was obtained during isometric chin-tuck exercises in sitting, quadruped and prone positions as during isometric SE. Thus, isometric chin-tuck exercises in these positions could be used as an alternative option to increase suprahyoid muscle activation with the possible potential for less fatigue and better patient compliance during dysphagia management.

Keywords: Deglutition, deglutition disorders, suprahyoid muscles, electromyography, exercise

1. INTRODUCTION

Exercise-based approaches have an important place in dysphagia management and are used to improve the functions of deglutitive muscles to maintain airway protection. The most critical parameters for airway protection are hyolaryngeal excursion and the opening of the upper esophageal sphincter (UES), facilitated by the suprahyoid muscles (1,2).

The Shaker exercise (SE) is the first defined, widely used and extensively studied exercise that focuses on the involvement of the suprahyoid muscles and includes both isometric and isotonic head lifts (3). The isotonic part of the SE involves raising the head high and forward for 30 consecutive repetitions in the supine position. The isometric portion is performed by raising the head up and forward for one minute in the supine position, which can cause muscle fatigue and affect patient compliance (4,5). To minimize these effects, the Chin Tuck Against Resistance (CTAR) exercise was developed as a less strenuous exercise to train

the suprahyoid muscles. The rationale for using the chin-tuck movement as a swallowing exercise is that both head flexion and neck flexion activate suprahyoid muscle contractions (6). During the CTAR exercise, resistance is achieved through the compression of an inflatable rubber ball placed between the patient's chin and the manubrium sterni in the sitting position. The primary limitation of the CTAR exercise is the inability to control the intensity of the resistance (7).

Looking at the literature on exercise-based dysphagia management, no standard progression procedure has been established (8). However, further improvement requires a systematic increase in the load via changing such variables as volume, intensity, number of repetitions, repetition speed and rest periods. It is important to adjust these variables according to patients' needs (9). As mentioned above, the inability to control the intensity of resistance during CTAR could be a limitation for the progression of the exercise (7). It is worth nothing that one of the alterations to adjust the

workload is adjusting body position during the exercise. Since the chin-tuck movement can be performed in several positions besides the sitting position, including the supine, prone, prone pressing up on elbows, and quadruped positions, we believe that isometric chin-tuck exercises in different body positions can be used as alternative exercises for dysphagia management.

There is no extant study evaluating the suprahyoid muscle activation during isometric chin-tuck exercises performed in different body positions. Determining the instantaneous suprahyoid muscle activation during the performance of chin-tuck exercise in different body positions will guide the creation of new exercise protocols to be used in dysphagia rehabilitation and could guide the exercise progression procedure. Therefore, the purpose of this study is to compare suprahyoid muscle activation during isometric chin-tuck exercises in different body positions with isometric SE.

2. METHODS

This is a cross-sectional study, which was performed at the Faculty of Physical Therapy and Rehabilitation of a university hospital. The ethical permission was received from the Non-interventional Clinical Researches Ethics Board of the university (Approval number=GO22/534, Approval Date= 31 May 2022).

2.1. Participants

Thirty-two healthy volunteers were included in the study. The inclusion criteria were as follows,

(i) Aged between 18 to 40 years,

(ii) Having a score of less than 3 on the Turkish version of the Eating Assessment Tool (T-EAT-10),

(iii) Not having any disease that could affect swallowing function,

(iv) Not having any pathology such as disc herniation or neck pain in the cervical region,

(v) Not having any temporomandibular joint problem that could affect joint biomechanics and muscle function. Written informed consent forms were signed by the participants prior to recruitment.

2.2. Evaluations

Descriptive information including age (year), gender, height (cm), weight (kg) and education level was recorded. The T-EAT-10, which measures the severity of dysphagia symptoms, was used to identify participants. It has 10 questions which are scored from 0 (no problem) to 4 (severe problem). The total score ranges from 0 to 40, with a score below 3 indicating normal swallowing function (10). Therefore, participants with a score of less than 3 on the T-EAT were included in the study.

Evaluations were performed in a quiet room at normal room temperature. Suprahyoid muscle activation was measured using the Trigno Wireless Biofeedback System (Delsys Inc., Natick, MA, USA). Prior to evaluation, the skin was cleaned with an alcohol wipe. After allowing the skin to dry for 30 seconds, two Delsys Trigno Duo dual-channel wireless superficial sensors integrated into this software were placed under the chin over the mylohyoid, geniohyoid and anterior digastric muscle complexes on either side of the midline with a distance of 1 cm between the sensors. The dual-channel Delsys Trigno Duo sensors were fixed with adhesive tape to prevent artifacts during recording. Voluntary muscle activation was measured and recorded in microvolts (mV). Surface electromyography (sEMG) signals were digitally recorded at 1500 Hz. The data were analyzed using the analysis program called Delsys EMG-Works analysis software. In the analysis, a bandpass filter was applied to the sEMG signals (high filter pass 10 Hz, low filter pass 500 Hz), with a notch filter will be applied at 60 Hz. sEMG values were presented in the microvolt root mean square (RMS) (11).

Figure 1. Suprahyoid muscle activation measurements during isometric Shaker exercise and isometric chin-tuck exercises in sitting, supine, prone, prone press up on elbows and quadruped positions

Jaw opening was used to measure the maximum voluntary isometric contraction (MVC) of the suprahyoid muscles. All participants were seated in an upright position in a chair during the MVC assessment. A semirigid cervical neck orthosis allowing only jaw opening was used, as described by Kılınç et al. (12). Participants were asked to open their mouth as wide as possible against the orthosis for a period of 10 seconds. Three repetitions were performed with a 1 minute rest period to eliminate fatigue. The maximum electrical muscle activity obtained during each measurement was recorded, and the highest value obtained from the measurements was used for statistical analysis.

Five minutes after the MVC assessment, suprahyoid muscle activations were evaluated during isometric SE and isometric chin-tuck exercises in the sitting, supine, prone, prone press up on elbows and quadruped positions. To control for order effects, the sEMG measurements during different positions were performed in a randomized order by using a random number generator. For isometric SE, the participants were asked to lift their head high and forward enough to see their own feet without lifting their shoulders for 10 seconds in the supine position during suprahyoid muscle activation recordings (Figure 1a). This was repeated for 3 times with a 1 minute rest break. Each participant was asked to perform an isometric chin-tuck exercise for 10 seconds for 3 times with a 1 minute rest break in the sitting (Figure 1b), supine (Figure 1c), prone (Figure 1d), prone press up on elbows (Figure 1e) and quadruped (Figure 1f) positions during suprahyoid muscle activation recordings. There was a 5 minute rest period between each position to eliminate fatigue. The maximum electrical activities obtained in each measurement were recorded in mV, and the highest value was used for statistical analysis.

For the normalization procedure, the calculation including the recorded maximum electrical activity during each movement / MVC of the suprahyoid muscles was used. The results were recorded as a percentage (MVC%).

2.3. Statistical Analysis

Statistical power analysis was performed by using G*Power version 3.1. A total of 32 participants gives an effect size of 0.5, a type I error margin of 5%, and 81% statistical power conditions to detect the significant changes between six different exercises as statistically significant.

The IBM-SPSS for Windows version 20 (IBM Corp., Armonk, NY, USA) was used for statistical analysis. Descriptive statistics were calculated as a number/percent for qualitative data and mean, standard deviation for quantitative data. Normality tests were performed using the visual (histograms, probability plots) and analytical (Kolmogorov-Simirnov/Shapiro-Wilk's test) methods.

The Friedman test was conducted to test whether there was a significant change between exercises. If there was a significant difference, pairwise comparisons were conducted using the Bonferroni adjusted Wilcoxon test. A p-value of less than .008 was considered to show a statistically significant result.

3. RESULTS

A total of 32 participants were included in the study, of whom 87.5% (n=28) were female. The mean age, height and weight were 22.80±3.16 (min=19, max=33) years, 165.59±6.28 (min=155, max=182) cm and 62.40±12.33 (min=42, max=108) kg, respectively. A percentage of 84.4 (n=27) had a bachelor's degree and 18.6% (n=5) had a postgraduate degree.

Mean suprahyoid muscle activations during isometric SE and isometric chin-tuck exercises in the sitting, supine, prone, prone press up on elbows and quadruped positions are presented in Table 1.

Table 1. The mean suprahyoid muscle activation (MVC%) during isometric Shaker exercise and isometric chin-tuck in sitting, supine, prone, prone press up on elbows and quadruped positions

	Suprahyoid MVC%	
	X (SD)	Min-Max
Isometric Shaker exercise	29.94 (18.20)	4.84-82.23
Isometric chin-tuck in sitting	21.27 (19.07)	3.95-81.57
Isometric chin-tuck in supine	20.48 (14.58)	5.19-56.22
Isometric chin-tuck in prone	24.60 (18.56)	6.78-87.11
Isometric chin-tuck in prone press up on elbows	18.96 (12.38)	5.63-60.83
Isometric chin-tuck in quadruped	23.44 (12.78)	7.41-53.59

Isometric SE caused significantly higher suprahyoid muscle activation than isometric chin-tuck exercise in prone press up on elbows and supine positions (p< .008). Suprahyoid muscle activation was similar for isometric SE and isometric chin-tuck exercise in the sitting, prone and quadruped positions (p> .008) (Table 2).

Table 2. Comparison mean activation (%MVC) of isometric Shaker exercise and isometric chin-tuck in sitting, supine, prone, prone press up on elbows and quadruped positions

	iSE-Csitting	iSE-Csupine	iSE-Cprone	iSE-Cquadruped	iSE-Celbows	Csitting-Csupine	Csitting-Cprone	Csitting-Cquadruped	Csitting-Celbows	Csupine-Cprone	Csupine-Cquadruped	Csupine-Celbows	Cprone-Cquadruped	Cprone-Celbows	Cquadruped-Celbows
p	.018	.005*	.161	.043	.003*	.911	.278	.217	.400	.104	.308	.940	.852	.070	.003*

Abbreviations: isometric Shaker: iSE, isometric chin-tuck in sitting: Csitting, isometric chin-tuck in supine: Csupine, isometric chin-tuck in prone: C-prone, isometric chin-tuck in quadruped: Cquadruped, isometric chin-tuck in prone press up on elbows: Celbows
*p< .008 (Bonferroni's correction for multiple comparisons)

4. DISCUSSION

This study was performed to determine the suprahyoid muscle activation during isometric chin-tuck exercises in different body positions by comparing the isometric SE. Suprahyoid muscle activation was found to be similar for isometric SE and isometric chin-tuck exercise in the sitting, prone and quadruped positions, whereas isometric SE produced significantly higher suprahyoid muscle activation than isometric chin-tuck exercise in the prone press up on elbows and supine positions.

The isometric part of the SE has been reported to be more challenging than the isotonic part, and the supine position is not always well tolerated (5,13,14). Thus, it is clinically important to develop new therapeutic exercises that specifically compensate for the limitations of the isometric part of the SE. As an alternative option to the isometric part of SE, we thought that the chin-tuck exercise could be used as a swallowing exercise to activate suprahyoid muscle contractions. In addition, to achieve improvements in exercise training, it is necessary to systematically increase the load by varying variables such as volume, intensity, number of repetitions, repetition speed and rest periods according to the patients' needs (9). The CTAR exercise, which was developed as an alternative to the SE, also has shortcomings in this respect. The inability to control the intensity of the resistance during the exercise and its use in a seated position can limit the progress of the exercise. (6, 7, 15, 16). It is worth noting that one of the changes that can be made to adjust the workload is to adjust the position of the body during the exercise. In physical therapy for neck and shoulder problems, chin-tuck exercises could be performed in different body positions (17-19). Therefore, the effect of chin-tuck exercise on suprahyoid muscle activation in different body positions could be investigated to provide new exercise options for clinical practice. In this study, it was aimed to compare isometric SE with isometric chin-tuck exercises in different body positions in terms of the suprahyoid muscle activation. According to the results of the current study, the isometric chin-tuck exercises in the sitting, prone and quadruped positions were found to be as effective as the isometric SE in increasing the suprahyoid muscle activation. Thus, isometric chin-tuck exercises in sitting, prone and quadruped positions could be used as alternative exercises to isometric SE. While the chin-tuck movement in the prone and quadruped positions is performed in the horizontal plane, the movement in the sitting position is performed in the sagittal plane. Thus, the possible reasons for activation of the suprahyoid muscles in these positions may be different, as they involve the realization of movement in different planes. Sitting position during isometric chin-tuck exercises may not require an effort against gravity, but the similar activation to SE may be due to the fact that people can focus more easily on the submental area, and their orientation is easier in this position due to the wider field of vision. Therefore, more loading to the suprahyoid muscles can be provided voluntarily in sitting position. The possible reason for maintaining similar suprahyoid muscle activation during isometric chin-tuck exercises in the quadruped and prone positions may be related to (i) gravity and (ii) the extra effort required to perform the isometric chin-tuck exercise while trying to maintain the body in the quadruped and prone positions.

In this study, it was detected that performing isometric chin-tuck exercise in the supine and prone press up on elbows positions resulted in less suprahyoid muscle activation compared to isometric SE. In a study evaluating suprahyoid muscle activations during water swallowing in terms of study design, it was reported that chin tuck movement in the supine position caused less electrical activation in the suprahyoid muscles compared to the neutral position (20). Supine position may provide a more stable position that may cause less electrical activation of the suprahyoid muscles during the same movement. However, there is no study evaluating chin-tuck exercise in the prone press up on elbows in terms of swallowing related muscles. We thought that the elbow support may have resulted in the exercise being performed with less activation by providing comfort against gravity and body weight. These findings are also important for clinical practice. The literature underscores the importance of a structured and gradually progressive exercise program to enhance exercise compliance and effectiveness (4). Therefore, especially for individuals who could not successfully perform isometric head lift in the supine position, the rehabilitation program could be started with chin-tuck exercises in these positions.

There are also some limitations in this study. Fatigue and/or compliance of participants could be questioned for each exercise for comparison, however these were not evaluated. These parameters are very important for clinicians for attainment of the exercise goals (5,13). Future studies could be design to investigate fatigue and/or exercise compliance during isometric chin-tuck in various positions. In addition, the long-term effects of isometric chin-tuck exercises in different positions could also be investigated to increase our understanding of their impact on swallowing function before replication of these studies with older adults and patients with dysphagia.

5. CONCLUSION

In conclusion, isometric chin-tuck exercises in sitting, quadruped and prone positions provide suprahyoid muscle activation similar to that of isometric SE. Therefore, isometric chin-tuck exercises in these positions could serve as alternative options to target suprahyoid muscles with the potential for less fatigue and greater patient compliance during dysphagia management.

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Is the Stigma Experienced by Infertile Women Related to Being Affected by Infertility and the Level of Self-Efficacy?

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ABSTRACT

Objective: This study was conducted to determine the relationship between the stigma experienced by infertile women, and the level of infertility distress and self-efficacy with the affecting factors.

Methods: This descriptive study carried out 352 infertile women diagnosed with primary infertility. Data were collected with the Personal Information Form, the Infertility Distress Scale (IDS), the Infertility Stigma Scale (ISS), and the Infertility Self-Efficacy Scale–Short Form (TISE-SF).

Results: he total IDS, ISS, and TISE-SF mean scores of the women included in the study were found to be 43.62±12.00, 64.24±27.40 and 19.70±5.69, respectively. While there was a high positive correlation between total IDS and ISS mean scores, there was a moderate negative correlation between total TISE-S, IDS, and ISS mean scores (p<.001). Variables such as women's income and working status, the infertility treatment process and its number, and social support factors affected infertility distress, stigma, and self-efficacy (p<.05).

Conclusions: It was concluded that infertility stigma and distress decreased with the increase in self-efficacy perception in primary infertile women, and distress increased with the increase in the level of stigma.

Keywords: Infertility, stigma, affect, self-efficacy

1. INTRODUCTION

Infertility is a male or female reproductive system disease in which pregnancy can't be able to get despite regular and unprotected sexual intercourse for 12 months or more (1). While the prevalence of infertility in countries varies between 6.7% and 49.91%, this rate is 8.1% in Turkey (2-8). In recent years, the prevalence of infertility has tended to decrease in high-income countries, while tending to increase in middle-income and low-income countries, including our country (9).

Infertility is a community health problem that negatively affects couples especially women, biologically, physically, and psychosocially. Besides, the treatment methods applied for infertility can cause difficulty for the couples psychologically, cause stress and anxiety, and cause a crisis in marital relations by negatively affecting them financially (10). One of the social challenges caused by infertility is stigma. It has been observed that infertile women feel inadequate or incomplete because they are unable to fulfill the role of motherhood assigned to women by society, and they face stigma because they are unable to conceive (11).

Stigma causes infertile individuals to be humiliated, shamed, and discriminated from social life (12-14) and one out of every five infertile women is exposed to physical or psychological violence (15). Furthermore, self-stigmatization of infertile individuals as a result of the behaviors of others leads to feelings of failure and guilt, a decrease in self-esteem and self-efficacy (12-14,16), an increase in stress and psychological distress, and social isolation (11).

Nowadays, infertility treatment options have increased with technological developments. However, the treatment process can exacerbate the multidimensional effect of infertility, and individual self-efficacy becomes important for process management (10,16). Self-efficacy in infertility is defined as individuals' belief in their competencies and abilities and giving more positive emotional and behavioral responses during the infertility diagnosis and treatment process (16). Studies have shown that the self-efficacy levels of infertile women range from low to moderate (17,18) and that a decrease in self-efficacy has a negative effect on depression, anxiety, fertility behaviors during infertility treatment, and marital adjustment (18). In addition, it is reported that the increase in self-efficacy of women during the infertility treatment process increases fertility adjustment (16) and coping (19) but it has no effect on pregnancy (20). Nursing interventions applied to women during the infertility treatment process were found to be effective in reducing stigma and increasing self-efficacy

(21). Therefore, it is important to determine the relationship between stigma, which is expected to negatively affect the infertility process and infertility distress and self-efficacy.

Health professionals working in the infertility clinic have the responsibility to communicate with infertile couples, make observations, and develop an infertility counseling education program for the problems they detect during this crisis, which is very difficult to cope with (10). It is possible to ensure that effective coping mechanisms are developed, self-efficacy is increased and the individual's well-being is maintained by identifying the individual's infertility distress and the psychosocial problems they experience (10,11,21).

This study was conducted to determine the relationship between stigma experienced by infertile women, and the level of infertility distress and self-efficacy with the affecting factors.

2. METHODS

This cross-sectional study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee of Nuh Naci Yazgan University under protocol number 2022/9187. Written informed consent was obtained from all subjects included in the study.

2.1. Design and participants

This cross-sectional study was conducted between 1 July-31 October 2022 in the IVF center of a private hospital. The population of the research consists of women who applied to the IVF center of a private hospital for IVF treatment. The sample size of the study was calculated with the sample selection formula for which the universe is known. The number of women who applied to the IVF center with the diagnosis of primary infertility in 2021 was 2630, and when the 95% confidence interval was considered as α= 0.05, it was found that the sample size should be 335. Considering that there may be data loss, it was determined that 352 women should be included in the sampling. In the posthoc analysis performed at the end of the study, the power of the sample size of .30 was found to be 99%. The criteria for inclusion in the study are as follows: being diagnosed with primary infertility, having no children, no chronic disease, being literate, no communication problem, and volunteering to participate in the study. Women using any psychiatric medication will be excluded from the study. The purpose of the study was explained to the women who came to the infertility and assisted reproductive techniques clinic to have a baby and met the inclusion criteria. After obtaining the consent of the women to participate in the study, the data collection tools prepared with the google form were sent to their phone numbers.

2.2. Data collection

Data were collected with the Personal Information Form, the Infertility Distress Scale (IDS), the Infertility Stigma Scale (ISS) and the Infertility Self-Efficacy Scale–Short Form (TISE-SF).

2.2.1. Personal Information Form: This form is prepared to determine the sociodemographic and obstetric characteristics of primary infertile women and consists of 13 questions.

2.2.2. Infertility Distress Scale (IDS): Infertility Distress Scale (IDS), developed by Akyuz et al. (22) in 2008. The scale consists of 21 items that determine the level of psychological effects caused by infertility and the treatment process in Turkish women. The scores that can be obtained from the scale vary from 21-84. High scores indicate high infertility distress. Cronbach's alpha value for the scale was found to be .89 (22). In the current study, the Cronbach's alpha value was .90.

2.2.3. Infertility Stigma Scale (ISS): The Turkish reliability and validity study of the scale that was developed in 2014 by Fu et al. was conducted in 2019 by Capık et al (23). The scale scores range between 27 and 135. As the score increases, the stigma felt by women increases. Cronbach's alpha was found to be .93 by Capık et al (23) and .95 in this study.

2.2.4. The Infertility Self-Efficacy Scale–Short Form (TISE-SF): The TISE-SF was developed by Cousineau et al. in 2006 to measure an infertile woman's perception of self-efficacy in terms of cognitive, emotional, and behavioral coping skills related to infertility. The scale consists of 16 items. A 10-item short form of the scale was created by Cousineau et al. in 2006. The Turkish reliability and validity of the scale were made by Arslan Ozkan et al. (24) in 2014. The Turkish adaptation of TISE-SF consists of 8 items. The total score that is possible to obtain on the scale ranges from 8 to 32. The higher scores indicate a greater degree of infertility self-efficacy. The Cronbach's alpha of the original form is .78 (24). In the current study, Cronbach's alpha was .82.

2.3. Data analysis

Statistical analyses were performed using SPSS for Windows version 28.0 (IBM, SPSS Statistics 20). Descriptive statistics in the study were number (n), percentage (%), mean and standard deviation (SD). Normality was evaluated with skewness and kurtosis. The data were normally distributed in the IDS (skewness: .540, kurtosis: $-$ .105), ISS (skewness: .559, kurtosis: $-$ .664), TISE-SF (skewness: .222, kurtosis: $-$ .701). Since the data were normally distributed, an independent sample t-test was used for two independent groups, and an ANOVA was used for comparisons with more than two groups. In order to determine which group was different from the others, Tukey tests were used for those who provided the homogeneous assumption and Tamhane's tests for those who did not. The Pearson correlation coefficient was used to determine the relationship, and the results were evaluated at the 95% confidence interval, at $p < .05$ significance level.

2.4. Ethical considerations

Before the study, ethics committee approval (23.06.2022, 2022/9187) from Nuh Naci Yazgan University Ethics Committee and institution permission were obtained from the institution where the study was to be conducted. After the purpose of

the study was explained to the primary infertile women who applied to the IVF center of the hospital, written and verbal consents were obtained from those who agreed to participate in the study and they were asked to fill out the questionnaires. In accordance with the Declaration of Helsinki, informed consent was obtained from all the participants.

3. RESULTS

The mean ages of the women participating in the study were 32.27±6.38 years. The mean marriage duration of the couples was 7.03±4.72 years and the mean of the infertility treatment process was 3.74±3.59 years. While 29.3% of the couples received infertility treatment for the first time, 60.8% received infertility treatment between 2-5 times (Table 1).

Table 1. Descriptive characteristics of the participants

Characteristics		n: 352
		n (%)
Women's education level	Primary school	39 (11.1)
	Secondary school	62 (17.6)
	High school	92 (26.1)
	University	159 (45.2)
Spouse's education level	Primary school	28 (8.0)
	Secondary school	76 (21.6)
	High school	116 (33.0)
	University	132 (37.5)
Income	Income more than expenses	67 (19.0)
	Equal income and expenses	258 (73.3)
	Income less than expenses	27 (7.7)
Women's working status	Employed	117 (33.2)
	Unemployed	235 (66.8)
Spouse's working status	Employed	321 (91.2)
	Unemployed	31 (8.8)
Duration of treatment (years)	<1	51 (14.5)
	1-5	222 (63.1)
	6-11	61 (17.3)
	12-17	18 (5.1)
Number of treatments	1	103 (29.3)
	2-5	214 (60.8)
	6-9	26 (7.4)
	10-14	9 (2.6)
Person(s) receiving support	Unsupported	70 (19.9)
	Spouse	194 (55.1)
	Family	64 (18.2)
	Doctor/nurse	24 (6.8)
		Mean±SD
Women mean age year		32.27±6.38
The mean age of spouse year		36.17±19.51
Average year of marriage		7.03±4.72
Average duration of treatment year		3.74±3.59
Average number of treatments		2.24±2.47

The total IDS, ISS, and TISE-SF mean scores of the women included in the study were found to be 43.62±12.00, 64.24±27.40, 19.70±5.69, respectively. The mean scores of women's ISS self-devaluation, social withdrawal, public stigma, and family stigma sub-scales were 17.22±9.01, 14.94±6.05, 20.96±10.17, and 11.09±6.10, respectively (Table 2).

Table 2. The total ISS, IDS and TISE-SF mean scores of infertile women (n=352)

Scales / Scales' sub-dimensions	Scales' total and sub-scales averages		
	Min – Max	X±SD	Cronbach α
ISS total score	27-135	64.24±27.40	.95
Self-devaluation	7-35	17.22±9.01	
Social withdrawal	5-25	14.94±6.05	
Public stigma	9-45	20.96±10.17	
Family stigma	6-30	11.09±6.10	
IDS total score	22-82	43.62±12.00	.90
TISE-SF total score	8-32	19.70±5.69	.82

ISS: Infertility Stigma Scale, IDS: Infertility Distress Scale, TISE-SF: The Infertility Self-Efficacy Scale–Short Form

A significant positive correlation was found between the total IDS and the total ISS mean scores (r= .76, p<.001). Women with high infertility stigma also experienced increased infertility distress. A negative, moderate, and statistically significant relationship was found between the total TISE-SF mean scores and both the total IDS (r= − .42, p<.001) and ISS (r= − .31, p<.001) mean scores. It was determined that women with high self-efficacy experienced less infertility distress and less stigma (Table 3).

Table 3. Correlation between the mean scores of the IDS, ISS and TISE-SF of infertile women (Pearson correlation test) (n=352)

Scales		1	2	3
1. IDS	r	1.000	.767	-.429
	p		.000*	.000*
2. ISS	r	.767	1.000	-.319
	p	.000*		.000*
3. TISE-SF	r	-.429	-.319	1.000
	p	.000*	.000*	

p<.001*. ISS: Infertility Stigma Scale, IDS: Infertility Distress Scale, TISE-SF: The Infertility Self-Efficacy Scale–Short Form

The total IDS mean scores of low-income women are higher than other income levels (F= 8.30, p<.001) and the total TISE-SF mean scores are lower than other income levels (F= 4.88, p<.01) (Table 4). The TISE-SF mean scores of women who were unemployed were found to be higher than those of employed women (t= − 2.17, p<.05) (Table 4). A statistically significant correlation was found between the infertility treatment process and the total mean scores of all scales. The total IDS (F= 9.72, p<.001) and ISS mean scores (F= 13.574, p<.001) of women undergoing infertility treatment for less than one year are lower than other years of treatment; the total TISE-SF mean scores were found to be higher than the group treated for 6-11 years (F= 3.43, p<.01) (Table 4). The total IDS (F= 9.63, p<.001) and ISS mean scores (F= 15.987, p<.001) of women undergoing infertility treatment for the first time were found to be lower than the other groups. Women undergoing infertility treatment for the first time and undergoing treatment for 2-5 times had higher total TISE-SF mean scores than women undergoing infertility treatment for 10-14 times (F= 7.10, p<.001) (Table 4). The total IDS mean scores of women who did not receive support during the infertility treatment process and who received support from

Table 4. A comparison of IDS, ISS, TISE-SF mean scores with infertile women's descriptive characteristics (n=352)

Characteristics		IDS		ISS		TISE-SF	
	n	X±SD	F, t, p	X±SD	F, t, p	X±SD	F, t, p
Women's education level							
Primary school	39	44.79±13.11	F: 0.505	62.54±31.10	F: .294	17.69±5.59	F: 1.872
Secondary school	62	42.73±12.94	p: .679	61.85±28.34	p: .830	20.15±5.72	p: .134
High school	92	42.76±11.67		64.71±28.09		19.83±5.40	
University	159	44.17±11.59		65.31±25.82		19.95±5.82	
Spouse's education level							
Primary school	28	46.89±10.78	F: 1.141	64.18±25.49	F: .049	18.00±5.31	F: 1.478
Secondary school	76	44.30±13.21	p: .333	64.33±29.80	p: .986	19.16±5.69	p: .220
High school	116	42.46±12.31		63.50±28.64		20.25±5.90	
University	132	43.55±11.21		64.84±25.48		19.89±5.55	
Income							
Income more than expenses[a]	67	41.64±11,52	F: 8.304	60.60±24.40	F: 2.431	20.37±5.42	F: 4.888
Equal income and expenses[b]	258	43.23±11,53	p<.001*	64.13±27.12	p: .089	19.86±5.63	p: .008*
Income less than expenses[c]	27	52.22±14,37		74.30±34.85		16.52±6.13	
Post hoc		a,b>c				a,b>c	
Women's working status							
Employed	117	44.99±11.40	t: 1.518	66.21±27.08	t: .955	18.77±5.30	t: − 2.179
Unemployed	235	42.93±12.26	p: .130	63.25±27.57	p: .340	20.17±5.83	p: .03*
Duration of treatment (years)							
<1[a]	51	36.90±10.16	F: 9.722	47.27±20.05	F: 13.574	21.75±5.98	F: 3.436
1-5[b]	222	43.77±11.39	p: .000*	64.91±26.35	p: .000*	19.64±5.61	p: .017*
6-11[c]	61	47.23±13.73		72.30±29.22		18.36±5.03	
12-17[d]	18	48.44±10.62		76.67±31.88		19.22±6.72	
Post hoc		b,c,d>a		b,c,d>a		a>c	
Number of treatments							
1[a]	103	38.84±11.66	F: 9.631	50.46±22.99	F: 15.987	20.99±6.50	F: 7.106
2-5[b]	214	45.01±11.18	p: .000*	68.20±26.07	p: .000*	19.51±5.16	p: .001*
6-9[c]	26	48.35±13.82		79.42±30.75		18.08±5.43	
10-14[d]	9	51.33±13.43		83.89±33.26		14.22±4.08	
Post hoc		b,c,d>a		b,c,d>a		a,b>d	
Person(s) receiving support							
Unsupported[a]	70	46.10±14.99	F: 7.271	62.79±31.26	F: 1.354	19.34±6.40	F: 0.534
Spouse[b]	194	41.05±10.35	p<.001*	62.45±26.22	p: .257	19.91±5.41	p: .659
Family[c]	64	47.77±12.01		69.47±25.85		19.91±5.88	
Doctor/nurse[d]	24	46.08±10.11		68.92±28.22		18.54±5.41	
Post hoc		a,c>b					

*p<.05, F: Anova test, t: independent sample t test. ISS: Infertility Stigma Scale, IDS: Infertility Distress Scale, TISE-SF: The Infertility Self-Efficacy Scale–Short Form

their families were found to be higher than those who received support from their spouses (F= 7.27, p<.001) (Table 4).

4. DISCUSSION

The results of this study, which evaluated the relationship between infertility distress and self-efficacy levels in Turkish infertile women of infertility stigma, were discussed in the literature. Especially in societies with a patriarchal cultural structure, women are expected to give birth to children in order to become adult women and gain status, and when they cannot have children, they are thought to be unable to perform in terms of gender (25). In studies in Turkey where the same scale was used, it was determined that infertile women experienced moderate stigmatization and were most affected by social and social stigma (26,27). The results of

study are similar with previous research, and the moderate level of stigma experienced by infertile women is influenced by social stigma.

In the current study, infertile women reported that they felt moderate self-devaluation and social stigma, and low family stigma. In a systematic review of women from different countries and cultures, it was identified that infertile individuals experience stigma due to social gender roles and internalize it. Infertile women described themselves as "half women" or "incomplete women" because they couldn't fulfill the motherhood and fertility roles that society assigned to them (11). Infertile women living in the United States reported that they experienced a high level of stigma, were insulted by their family and friends, and were judged for their treatment decisions, this situation made them feel inadequate and increased their stress levels significantly (15).

In Jordan, infertile women said being called "dry bough" and "dead tree" by their spouses, families, neighbors, and friends (12). In the study of Zhao et al. (28), it was determined that Chinese infertile women experienced stigmatization by both their family members and their friends and women around them. In Turkey, infertile women are said to be exposed to social isolation by their friends and relatives, blamed, pitied and talked behind their backs (29). Infertile couples may be vulnerable to the negative effects of their perceived stigma (30). Our study results are similar to the results of the studies in the literature. Like the infertile women in other studies, the infertile women in our study were subjected to stigmatization by their social environment and families and felt worthless.

Although there are individual differences in the responses to infertility distress, problems such as stress, marital adjustment problems and sexual dysfunctions may occur during the diagnosis and treatment process (10) and these make the daily life of the woman difficult (12). In the study of Wang et al. (31) it was determined that women receiving infertility treatment experienced anxiety, depression and their sleep quality was negatively affected. In this study, it was determined that women were moderately affected by infertility. Similar to our study, in different studies, it was determined that infertile women were moderately affected by infertility (22,32).

Individual self-efficacy is critical in reducing the multidimensional influence in the infertility diagnosis and treatment process, as well as in using coping mechanisms (10,16). Parwez and Banaras (19) reported that infertile women with high self-efficacy used adaptive coping strategies. In this study, it was found that the self-efficacy perceptions of infertile women were moderate. Similarly, Durgun Ozan and Duman (16) found the self-efficacy of infertile women to be moderate and reported that an increase in the level of self-efficacy also increased compliance with infertility treatment.

In this study, it was determined that the distress of infertile women who experienced stigma was also high (r= .76, p<.001). It has been found that there is a strong relationship between stigma and anxiety, depression, and psychological problems in women undergoing infertility treatment in Japan (33). In other studies in the literature, it has been observed that stigma causes psychosocial problems by negatively affecting the psychology of infertile couples (14,26-28,30,34). The results of the studies point out the importance of coping skills with the effects of stigma in order to prevent infertility distress and to be able to spend the difficult treatment processes comfortably.

In this study, it was found that women with high self-efficacy had decreased infertility distress (r= − .42, p<.001) and experienced less stigma (r= − .31, p<.001). Similarly, Jafari et al. (35) study found that infertile women with high self-efficacy were less affected by infertility. In the study of Zhao et al. (28), it was determined that women with high psychological resilience had lower levels of distress. As women's self-efficacy levels and psychological resilience levels increase, they can use effective coping methods with the negative effects of infertility and treatment processes, seek social support, and avoid situations that will make them feel bad. (28)

In the current study, the level of infertility stigma and distress was found to be lower in women undergoing infertility treatment for less than a year and undergoing treatment for the first time (p<.05) (Table 4). The reason for this may be that the women and relatives around them have high hopes regarding the treatment process they are just beginning, and that they are exposed to less social and internal pressure regarding the role of fertility and motherhood. In our study, it was found that the level of being affected by infertility increased in women who defined low-income levels and did not receive support during treatment, and the level of self-efficacy decreased (p<.05) (Table 4). Similarly, in the study of Wang et al. (31), it was determined that infertile women with high-income levels showed less distress and avoidance behavior. The high cost of infertility treatment processes has a financial impact on couples with low-income levels. In addition, it is thought that the coping behaviors of women increase and their negative effects decrease thanks to the support they receive from both their spouses and their social environment during the difficult treatment process.

5. CONCLUSION

In this study, it was determined that women experienced moderate stigma, and infertility distress and self-efficacy levels were moderate. The increase in infertility stigma also increased infertility distress. It was determined that women with high self-efficacy had less infertility distress and less stigma. According to these results, since all stages of infertility treatment processes are female body-oriented, the levels of infertility stigma, distress and self-efficacy should be determined by multidimensional evaluation before starting the treatment. It is recommended to provide appropriate support and counseling services for the identified risk factors and to support infertile women to strengthen their coping skills. On the other hand, it is important to include infertile men in the studies to be planned.

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University Students' Transtheoretical Model-Based Sedentary Behaviors, Physical Activity Levels and Related Factors

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ABSTRACT

Objective: The aim of the study was to determine university students' sedentary behaviors based on the Transtheoretical Model (TTM), physical activity levels (PAL) and related factors.

Methods: The study was carried out using a descriptive design with 504 students at a university in Istanbul. Data were collected using the socio-demographic characteristics diagnostic form, the Transtheoretical Model Sedentary Behavior Scales (TTM-SBS) and the International Physical Activity Questionnaire short form (IPAQ-SF). Kruskal-Wallis analysis of variance, Mann-Whitney-U test and Chi-Square test were used for statistical analysis and significance level p < .05 was accepted.

Results: While 18.9% of the students midly obese or obese, 81% of them did not participate in regular physical exercise. The majority of females were in the sedentary behaviors change preparation stage (29.4%) and the majority of males (29.1%) were in the action stage (p < .05). Sedentary behavior change pros perception score was above average, while cons perception and self-efficacy scores were below average. According to IPAQ-SF, 31.3% of the students were low active, 45.7% were moderate active, 23.0% were high active, and 18.2% had a sitting time of eight hours or more per day. Women were found moderate active, whereas men, workers and smokers were very active (p < .05).

Conclusions: Males, underweight, first-grade students, those with no family history of physical activity, and those without a mentor were found to be more resistant to sedentary behavior change.

Keywords: Transtheoretical Model, sedentary behavior, university students, physical activity, assessment

1. INTRODUCTION

The university period is the time when students strive to adapt to academic studies, career planning, a competitive environment, and an independent new lifestyle. During this adaptation process, students may adopt unhealthy lifestyle behaviors for various reasons (smoking, drinking alcohol, consuming fast food, etc.) (1). In particular, sedentary behaviors increase during this period and physical activity levels of many university students gradually decrease after high school (2). In various studies, it has been reported that more than 50% of university students adopt a sedentary behavior (3). The World Health Organization (WHO) reports that 34.3% of university students are not involved in any physical activity (men 25%, women 43%), and 32.5% of those who are involved do it less than three times a week (15.8% once a week, 16.7% two-three times a month) (5). Many studies have also reported that the sitting time of university

students is at least 6.73 hours/day and at most over 9 hours/day (1-4). However, WHO suggests that young people should engage in moderate to vigorous-intensity aerobic physical activity for at least 60 minutes a day, as well as activities that strengthen muscles and bones at least three days a week (5). Physical activity at the specified intensity supports the development of physical, mental and social health in young people (1,6).

Sedentary behavior is defined as any activity that leads to energy consumption of 1.5 MET (Metabolic Equivalent) or less in the awake, lying, or sitting position (26). Sedentary behavior in young individuals is associated with a decrease in cardiometabolic fitness level, an increase in body fat and Body Mass Index (BMI) values, sleep quality, cognitive health (academic performance, motivation, self-confidence, etc.),

mental health (depression, stress, etc.) (1,7). Moreover, sedentary behavior is the fourth leading risk factor for death worldwide (5). Inadequate physical activity levels increase the risk of cancer, heart disease, stroke and diabetes by 20-30%, and shorten life span by 3-5 years. Therefore, there is a need to determine students' sedentary behaviors and physical activity levels with valid and reliable measurement tools (2,8-10). Assessing the current situation is necessary and crucial in terms of shedding light on the solution of the problem.

In the literature, one of the models used to alter behaviors in sedentary individuals is the Transtheoretical Model (TTM). In TTM, behavior change is defined as a gradual, continuous, and dynamic process. The key feature that differentiates this model from other behavior change models is its assertion that behavior change is a process (2). The main components of the TTM are the stages of change: precontemplation, contemplation, preparation, action, and maintenance. Additionally, the processes of change, decision-making (the pros and cons of change), and self-efficacy (the individual's belief in their ability to maintain health behaviors despite challenging environments) are other components that constitute the model (23). The model includes behavior-specific scales that are developed to measure change, which are sensitive, valid, and reliable. The effectiveness of the model has been proven in changing numerous unhealthy behaviors, such as smoking cessation and alcohol reduction, as well as in promoting healthy behaviors like increasing physical activity (9-12). The TTM has been validated by the development of scales for sedentary behaviors, demonstrating its validity and reliability in measuring behavior change.

The International Physical Activity Questionnaire Short Form (IPAQ-SF) was developed by the WHO to assess individuals' physical activity levels. The questionnaire measures the type, duration, and intensity of physical activities performed by individuals over the past 7 days (26). Diagnosing students' physical activity levels using the IPAQ-SF and sedentary behaviors using the TTM will guide the development of intervention/change programs (2,10,13,14). Therefore, this study was conducted to identify university students' TTM-based sedentary behaviors, physical activity levels, and related factors.

1.1. Research questions:

- What is the Transtheoretical Model Sedentary Behavior (TTM-SB) score?
- What is the International Physical Activity Questionnaire-short form (IPAQ-SF) scale score?
- What are the variables affecting the TTM-SB score?
- What are the variables affecting IPAQ-SF?
- Is there a relationship between the TTM-SB and IPAQ-SF scores?

2. METHODS

2.1. Research Design

The study was conducted with a descriptive and correlational design.

2.2. Place and Date of the Study

The study was conducted between October and December 2021 with students enrolled in the health program of a vocational school of a foundation university in Istanbul.

2.3. Selection Criteria

Students who were between the ages of 18-25, who voluntarily agreed to participate in the study and who completed the data collection forms correctly and completely were included.

2.4. Research Population and Sample

The research population consisted of a total of 657 students studying in five departments of vocational school health programs. The entire population was included in the research without using the sampling method. 638 of 657 students completed the data collection tools. A control question was added to all scales to check that students carefully read and answered the data collection forms. After 134 forms, which incorrectly answered the control questions in the data collection tools, were removed from the sample, and the study was completed with 504 students. In this research, in the Operating Room Services program, all 127 students (100%); in the Anesthesia program, 127 out of 145 students (87.5%); in the Oral and Dental Health program, 77 out of 103 students (75%); in the Medical Imaging Techniques program, 47 out of 133 students (35%); and in the First and Emergency Aid program, 126 out of 149 students (85%) participated. For a sample size of 504 participants, a post hoc power analysis yielded a value of 0.999. This result indicates that the sample size enhances the accuracy and reliability of the test.

2.5. Data Collection Method

According to the literature, the survey questions were converted into an electronic format via Google Forms (2,8,10,14). Students were invited to participate by receiving information about the research, ethics committee and institutional approval, the informed consent form, and the data collection form link through class representatives. Students experiencing issues with the survey were monitored and assisted by class representatives and researchers.

2.6. Data Collection Tools

2.6.1. Socio-Demographic Characteristics Diagnostic Form

The form consists of 11 closed-ended questions that are about students' socio-demographic characteristics, physical activity and lifestyle behaviors (2,8,10,14). Students were asked to write down their body weight (kg) and height (cm) values by measuring them themselves. Height and weight measurements are based on student statements. Body mass index (BMI) was calculated by the researchers. Body mass index (BMI) categories were determined as underweight below 18.5, normal weight 18.5-24.99, Overweigh 25.00-29.99 and, Obese 30 and above according to WHO (15).

2.6.2. Transtheoretical Model Sedentary Behavior Scales (TTM-SBS)

It was developed by Han et al. (8) and its Turkish validity and reliability study was performed by Tok (10) with young people aged. The scale consists of four different sections: stages of change, change process, decision-making and self-efficacy scales (8,10).

Sedentary Behavior Stages of Change (SB-SOC-1 and SB-SOC-2): The questionnaire reflects the individual's attitude, intention and behavior towards change. SB-SOC-1 inquires the status of doing enough physical activity every day as yes or no. SB-SOC-2 evaluates the stage of behavior change in five stages: precontemplation, contemplation, preparation, action and maintenance (2,10).

TTM Sedentary Behavior Self-Efficacy Scale (SB-SES): The scale consists of six items including self-confidence in quitting sedentary behavior. It is a five-point Likert type (1: Do not trust at all, 5: Trust completely). Cronbach alpha values are 0.75 (10). In this study, Cronbach Alpha reliability coefficient was determined as 0.836. High scores are an indicator of high self-efficacy.

TTM Sedentary Behavior-Decisional Balance Scale (SY-DBS): The decision-making scale consists of two scales measuring the pros and cons of behavior change. It is a five-point Likert type (1: Not at all important, 5: Extremely important). The "pros of behavior change" subscale includes six items (questions 1, 3, 5, 7, 9, and 11) and measures the perceived benefits of modifying sedentary behavior. The "cons of behavior change" subscale consists of six items (questions 2, 4, 6, 8, 10, and 12) and evaluates the perceived drawbacks of changing sedentary behavior. Cronbach's alpha values are 0.87 and 0.73, respectively (10). In this study, Cronbach's alpha values were determined as 0.828 and 0.500, respectively. High scores indicate high perceptions of pros and cons.

2.6.3. International Physical Activity Questionnaire Short Form (IPAQ-SF)

The International Physical Activity Questionnaire (IPAQ) was developed by a group of scientists formed by the World Health Organization (WHO) and other international health organizations in 1998 (26). The questionnaire was adapted to Turkish and its reliability and validity were performed by Öztürk (13). The short form consists of seven questions to determine the average daily time spent sitting, walking, moderate and vigorous action action in the last seven days. The scoring is calculated as "MET-minutes/week" by multiplying the days, minutes and Metabolic Equivalent (MET) value of physical activities (13). IPAQ-SF is categorized according to total MET scores. 599 METs and below is low active level, 600 METs-3000 METs is moderate active level, 3001 METs and above is high active level.

2.7. Research Variables

Dependent variables of the study are SB-SOC-I and II, SD-SES score, SB-decision making, pros perception and cons perception mean scores, physical activity MET score and categories (low active, moderate active, high active) according to IPAQ-SF, and sitting times.

The Independent Variables of the study are socio-demographic characteristics such as age, gender, employment status and BMI categories and variables that may affect physical activity status.

2.8. Data analysis

Statistical analyses were performed using IBM SPSS 25 (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp) package program. Descriptive data were presented using frequency, percentage and mean scores. The normal distribution of the data was tested with the One-Sample Kolmogorov-Smirnov Test and it was found that the data were not normally distributed. Independent variables and mean scale scores were tested by Kruskal Wallis Analysis of Variance, Mann Whitney-U test and Post-hoc Games Howell test. The data indicated by counts were evaluated by Chi-Square test. Statistical significance level was accepted as $p < .05$.

2.9. Ethical considerations

For the use of the scales, permission was obtained via e-mail from Tok. Before running the study, ethical permission (09.2021.713) was obtained from the clinical research ethics committee of the medical faculty of the university. This research was derived from pre-test data collected before the interventional study. Institutional permission (E-61952817.044.21669/21143) from the university where the study was conducted, and informed consent was obtained from the students prior to data collection.

3. RESULTS

Socio-demographic characteristics are shown in Table 1. The average age of the students is 20.03 ± 2.09 years, with 82.9% being female. The average BMI is 22.05 ± 3.95, and 65.3% have the normal range. Among the participants, 45.6% are first-grade students, and 74.4% are not employed. The smoking rate is 29.4%, and the alcohol consumption rate is 16.3%. Additionally, 64.3% spend more than 3 hours daily on their phones, while 75.4% use computers and televisions for less than 1 hour. The most common barriers to physical activity among students are lack of time (54.6%), the high expensive of gyms (29%), and the lack of suitable environments for physical activity (27%) (Table 1).

Table 1. Socio-demographic characteristics of the students (n= 504)

Variables		n	%
Age group	17-20 years old	372	73.8
	21-24 years old	114	22.6
	25 years and above	18	3.6
Gender	Female	418	82.9
	Male	86	17.1
BMI	Underweight (< 18.5)	80	15.9
	Normal (18.5-24.99)	329	65.3
	Overweight (25.00-29.99)	78	15.5
	Obese (30 and over)	17	3.4
Grade	1st grade	230	45.6
	2st grade	274	54.4
Employment status	Yes	129	25.6
	No	375	74.4
Smoking	Yes	148	*29.4
Alcohol consumption	Yes	82	*16.3
Time spent on the phone per day	1 hour ↓	14	2.8
	1 hour – 3 hours ↓	166	32.9
	3 hour – 5 fours ↓	217	43.1
	5 hours ↑	107	21.2
Daily time spent with computers, televisions	1 hour ↓	380	75.4
	1 hour – 3 hours ↓	86	17.1
	3 hour – 5 hours ↓	21	4.2
	5 hours ↑	17	3.4
PA Barriers	Lack of time*	275	54.6
	Not needing*	103	20.4
	Lack of suitable environment*	136	27.0
	No incentive*	85	16.9
	Expensive gyms*	146	29.0
	Friends not doing PA*	85	16.9
	Family not doing PA*	49	9.7

PA: Physical activity. Percentage of those answering yes.*

According to the TTM-SB-SOC-1, 81.0% of the students stated that they did not do enough physical activity almost every day (Figure 1).
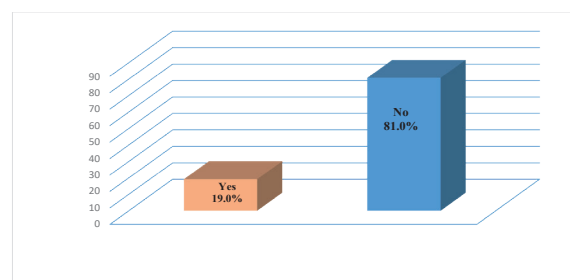
Figure 1. TTM SB-SOC-1-Doing regular physical activity every day

According to the TTM-SB-SOC-2, the majority of students were found to be in the preparation stage (27.8%) of changing sedentary behaviors (Figure 2).
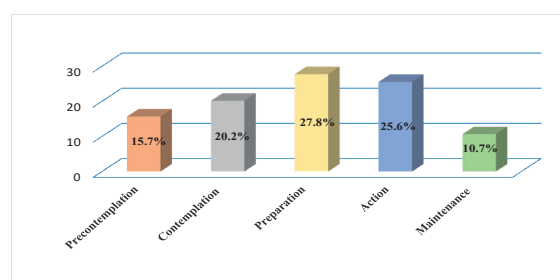
Figure 2. TTM-SB-SOC-2-sedantery behaviors

Table 2 shows the comparison of variables with the Transtheoretical Model (TTM) stages of change for sedentary behavior. According to TTM SB-SOC-1, 83.0% of women, 69.8% of men, 94.1% of individuals with obesity, 86.5% of first-grade students, and 86.1% of those spending 3 hours or more on their phones did not engage in regular physical activity (p < .05). According to TTM SB-SOC-2, 29.4% of women and 29.1% of men were in the preparation stage, while 26.1% of first-grade students and 29.6% of second-grade students were in the contemplation and preparation stages, respectively. 31.0% of employed students and 28.3% of those who spent less than 3 hours on the phone were in the action stage; 29.6% of unemployed students and 29.9% of those who spent more than 3 hours on the phone were in the preparation stage (p < .05) (Table 2).

The comparison of the mean TTM-SBS scores of the students in terms of some variables is shown in Table 3. The study found that women (21.38±5.35), individuals with obesity (24.94 ± 5.37), second-grade students (23.38 ± 4.94), those without an environment conducive to physical activity (23.61 ± 4.88), and those with family members who engage in physical activity (23.95 ± 4.73) had higher scores on the pros of sedentary behavior change (SB-DBS-P) (p < .05). Additionally, first-grade students (16.38 ± 3.45) and individuals without family members leading physical activity (16.68 ± 3.65) had higher scores on the cons of sedentary behavior change (SB-DBS-C) (p < .05). Second-grade students (17.19 ± 5.15) and those with family members who engage in physical activity exhibited higher self-efficacy levels (p < .05) (Table 3).

Table 2. *Comparison of variables and Transtheoretical Model sedentary behaviors change stages 1-2*

Variables		TTM SB-SOC (1)		TTM SB-SOC (2)				
		Yes	No	PC	CO	PR	AC	MA
		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Gender	Female	71 (17.0)	347 (83.0)	69 (16.5)	88 (21.1)	**123 (29.4)**	104 (24.9)	34 (8.1)
	Male	26 (30.2)	60 (69.8)	10 (11.6)	14 (16.3)	17 (19.8)	**25 (29.1)**	20 (23.3)
	Statistics	x^2= 8.053; p = .005		x^2= 19.99; p = .001				
BMI	Underweight	8 (10.0)	72 (90.0)	16 (20.0)	20 (25.0)	25 (31.3)	15 (18.8)	4 (5)
	Normal	66 (20.1)	263 (79.9)	52 (15.8)	64 (19.5)	83 (25.2)	88 (26.7)	42 (12.8)
	Overweigh	22 (28.2)	56 (71.8)	10 (12.8)	13 (16.7)	25 (32.1)	22 (28.2)	8 (10.3)
	Obese	1 (5.9)	16 (94.1)	1 (5.9)	5 (29.4)	7 (41.2)	4 (23.5)	0 (0.0)
	Statistics	x^2= 10.523; p = .015		x^2= 14.77; p = .254				
Grade	1st grade	**31 (13.5)**	199 (86.5)	42 (18.3)	**60 (26.1)**	59 (25.7)	52 (22.6)	17 (7.4)
	2nd grade	**66 (24.1)**	208 (75.9)	37 (13.5)	42 (15.3)	**81 (29.6)**	77 (28.1)	37 (13.5)
	Statistics	x^2=9.056; p = .003		x^2= 15.48; p = .004				
Employment status	Yes	32 (24.8)	97 (75.2)	15 (11.6)	20 (15.5)	29 (22.5)	**40 (31.0)**	25 (19.4)
	No	65 (17.3)	310 (82.7)	64 (17.1)	82 (21.9)	**111 (29.6)**	89 (23.7)	29 (7.7)
	Statistics	x^2= 3.449; p = .063		x^2= 19.62; p = .001				
Smoking	Yes	32 (21.6)	116 (78.4)	19 (12.8)	32 (21.6)	37 (25)	41 (27.7)	19 (12.8)
	No	65 (18.3)	291 (81.7)	60 (16.9)	70 (19.7)	103 (28.9)	88 (24.7)	35 (9.8)
	Statistics	x^2= 0.761; p = .383		x^2= 3.10; p = .541				
Time spent on the phone per day	0-3h↓	52 (28.9)	128 (71.1)	22 (12.2)	35 (19.4)	43 (23.9)	**51 (28.3)**	29 (16.1)
	3 hours ↑	45 (13.9)	279 (86.1)	57(17.6)	67 (20.7)	**97 (29.9)**	78 (24.1)	25 (7.7)
	Statistics	x^2= 16.752 ; p = .000		x^2= 12.17; p = .016				

x^2= chi-square; Transtheoretical Model (TTM); Sedentary Behavior (SB); Stages of Change (SOC); PC= Precontemplation, CO= Contemplation, PR=Prepariton, AC=Action, MA= Maintenance

Table 3. *Comparison of Transtheoretical Model sedentary behavior scales mean scores in terms of some variables*

Variables		SB-DBS-P Total Score	SB-DBS-C Total Score	SY-SES Total Score
		Mean ± SD	Mean ± SD	Mean ± SD
Gender	**Female**	22.60 ± 5.24	15.82 ± 3.89	16.38 ± 5.05
	Male	21.38 ±5.35	16.33 ± 3.33	17.40 ± 5.77
Statistics		**z=2.01; p=.04**	z=1.26; p = .21	z=1.41; p = .16
BMI	***Underweight[a]**	21.68 ± 4.69	16.50 ± 3.88	16.97 ± 4.85
	Normal[b]	22.52 ± 5.42	15.74 ± 3.73	16.39 ± 5.14
	Overweigh[c]	22.05 ± 5.06	16.25 ± 3.99	16.78 ± 5.75
	Obese[d]	24.94 ± 5.37	14.88 ± 3.80	16.82 ± 5.02
Statistics		**x^2=8.90; p=.03** **a<c<b<d**	x^2=6.01; p=.11	x^2=1.22; p=.74
Grade	**1st grade**	21.22 ± 5.42	16.38 ± 3.45	15.80 ± 5.13
	2nd grade	23.38 ± 4.94	15.52 ± 4.04	17.19 ± 5.15
Statistics		**z=4.60; p=.00**	**z=2.39; p=.01**	**z=3.01; p=.00**
Suitable environment for PA	**Yes**	21.94 ± 5.35	15.80 ± 3.90	16.61 ± 5.36
	No	23.61 ± 4.88	16.20 ± 3.53	16.41 ± 4.70
Statistics		**z=3.16; p=.00**	z=0.77; p=.43	z=0.25; p=.79
Person leading PA	**Yes**	22.04 ± 5.33	15.75 ± 3.82	16.76 ± 5.22
	No	24.16 ± 4.64	16.68 ± 3.65	15.57 ± 4.93
Statistics		**z=3.30; p=.00**	**z=2.06; p=.03**	z=1.49; p=.13
PA structure of the family	**Yes**	23.95 ± 4.73	16.20 ± 4.35	17.79 ± 4.80
	No	22.23 ± 5.30	15.88 ± 3.74	15.42 ± 5.28
Statistics		**z=2.20; p=.02**	z=0.10; p=.91	**z=2.73; p=.00**

*z=Mann-Whitney U, Kwx^2= Kruskal Wallis chi-square test. SB: Sedentary Behavior; S: Scale; SB-DBS: Sedentary Behavior – Decision Making Scale; P: Pros Perception; C: Cons Perception. SB-SES: Sedentary Behavior – Self-efficacy Scale. PA: Physical activity.

Table 4 shows the students' total walking MET Score and total moderate-intensity and vigorous-intensity MET scores according to the IPAQ-SF. According to the IPAQ-SF, 77.0% of the students were low and moderate active, with the highest score in walking. 18.2% of students had a sitting time of eight hours or more per day (Table 4).

In IPAQ-SF, a statistically significant difference was found between PAL and mean scores of SB-SOC-1, SB-SOC-2 and SB-DBS-P (p < .05), (Table 6).

Table 4. According to IPAQ-SF, students' MET scores, physical activity levels, sitting times and Moderate-Intenstiy PA performance

According to the IPAQ-SF;		Mean ± SD	Min-max
Total Walking MET Score		1924.88 ±3396.39	0–18018
Total Moderate-intensity MET Score		511.11±1980.17	0-21840
Total Vigorous-intensity MET Score		1178.14±4727.90	0-43680
Variables		n	%
PAL	Low active	158	31.3
	Moderate active	230	45.7
	High active	116	23.0
Sitting (n=438)	5 mins – 1 hour ↓	124	28.3
	1 hour – 4 hours ↓	132	30.1
	4 hours – 8 hours ↓	102	23.3
	8 hours – 12 hours ↓	37	8.4
	12 hours ↑	43	9.8
Currently engage in moderate-intensity PA	Yes	229	52.3
	No	209	47.7
Intention to increase participation in moderate-intensity PA in the next six months	Yes	360	82.2
	No	78	17.8
Currently doing regular moderate-intensity PA	Yes	165	37.7
	No	273	62.3
Regular moderate-intensity participation in PA for the last six months	Yes	142	32.4
	No	296	67.6
Moderate-intensity regular PA for at least three months in the past	Yes	274	62.6
	No	164	37.4

*Percentage of those who answered yes; IPAQ-SF; International Physical Activity Questionnaire; PA; Physical Activity; PAL:Physical Activity Level.

There was statistically significant difference between gender, employment status, smoking, and not feeling the need for PA and IPAQ-SF PAL (p < .05), (Table 5).

Table 5. Comparison of IPAQ-SF physical activity levels of students in terms of some variables (n=504)

		Physical Activity Levels (IPAQ-SF)			
Variables		**Low active** n (%)	**Moderate active** n (%)	**High active** n (%)	**Statistics** x^2/p
Gender	Female	77 (18.4)	246 (58.9)	95 (22.7)	**18.70; p = .000**
	Male	11 (12.8)	36 (41.9)	39.0 (45.3)	
BMI	Underweight	14 (17.5)	48 (60.0)	18 (22.5)	3.10; p = .796
	Normal	57 (17.3)	185 (56.2)	87 (26.4)	
	Overweigh	15 (19.2)	38 (48.7)	25 (32.1)	
	Obese	2 (11.8)	11 (64.7)	4 (23.5)	
Grade	1st grade	39 (17)	136 (59.1)	55 (23.9)	1.96; p= .375
	2nd grade	49 (17.9)	146 (53.3)	79 (28.8)	
Employment	Yes	13 (10.1)	59 (45.7)	57 (44.2)	**28.84; p= .000**
	No	75 (20)	223 (59.5)	77 (20.5)	
Smoking	Yes	22 (14.9)	75 (50.7)	51 (34.5)	**6.73; p= .034**
	No	66 (18.5)	207 (58.1)	83 (23.3)	
Time spent on the phone per day	0-3 hours↓	31 (17.2)	98 (54.4)	51 (28.3)	0.44; p= .801
	3 hours ↑	57 (17.6)	184 (56.8)	83 (25.6)	
PA Barriers	Lack of time*	46 (17.8)	145 (52.7)	81 (29.5)	3.04; p= .219
	Not needing*	17 (16.5)	70 (68.0)	16 (15.5)	**9.35; p= .009**
	Lack of suitable environment*	20 (14.7)	82 (60.3)	34 (25.0)	1.61; p= .446
	No incentive*	16 (18.8)	47 (55.3)	22 (25.9)	0.13; p= .934
	Expensive gyms*	30 (20.5)	80 (54.8)	36 (24.7)	1.45; p= .482
	Friends not doing PA*	17 (20.0)	50 (58.8)	18 (21.2)	1.65; p= .437
	Family not doing PA*	10 (20.4)	29 (59.2)	10 (20.4)	1.15; p= .562

*Percentage of those who said yes; x^2= Pearson Chi-Square; PA: Physical Activity; PAL: Physical Activity Level.

Table 6. *According to the IPAQ-SF physical activity levels of the students, the mean scores of the Transtheoretical Model Sedentary Behaviors scales*

TTM-SB-SOC Low active n (%)		Physical Activity Level (IPAQ-SF)			x^2 /p
		Moderate active	High active		
		n (%)	n (%)		
SB-SOC (1)	Yes	6 (6.2)	47 (48.5)	44 (45.4)	25.87/p=.00
	No	82 (20.1)	235 (57.7)	90 (22.1)	
SB-SOC (2)	PC	17 (21,5)	51 (64.6)	11 (13.9)	41.73/p=.00
	CO	23 (22.5)	61 (59.8)	18 (17.6)	
	PR	23 (16.4)	85 (60.7)	32 (22.9)	
	AC	21 (16.3)	66 (51.2)	42 (32.6)	
	MA	4 (7.4)	19 (35.2)	31 (57.4)	
TTM-SBS sub-dimensions		Mean (±SD)	Mean (±SD)	Mean(±SD)	kwx^2 /p
SB-DBS	P	20.48(5.81)*	23.35 (4.74)	23.10 (4.84)	8.65/p= .01
	C	16.17 (3.56)	15.70 (3.95)	16.00 (3.82)	0.69/p= .70
SB-SES		14.42 (4.67)	17.66 (5.05)	17.23 (5.33)	5.35/p= .06

x^2= Pearson Chi-Square, kwx2= Kruskal Wallis Chi-Square. *= Mann-Whitney U test, TTM: Transteoretik Model; SB: Sedentary Behavior; S: Scale; SOC: Stages of Change; PC= Precontemplation, CO=Contemplation, PR=Preparation, AC=Action, MA= Maintenance. SB-DBS-Sedentary Behavior-Decisional Balance Scale; P: Pros; C: Cons. SB-SES; Sedentary Behavior Self-Efficacy Scale.**

4. DISCUSSION

The study aimed to determine university students' TTM-based sedentary behaviors (SB), physical activity levels (PAL), and related factors. The results indicated that the majority of students (81%) were not engaging in sufficient physical activity (PA), with 27.8% being in the preparation stage of behavior change for SB. According to the IPAQ-SF, the majority of students (77%) were classified as moderate or low active, spending an average of 4 hours and 24 minutes per day sitting. Time constraints, the high expensive of gyms and absence of a suitable environment for PA were identified as the top three barriers. Additionally, higher perceptions of the pros of SB change were found among women, individuals with obesity, second-grade students, those without a suitable environment for PA, and those whose families do not engage in PA. Conversely, first – grade students and those without a PA leader had higher perceived cons of SB change. Second-grade students and those with family members who engage in PA had higher self-efficacy scores.

This study findings show that the PA of university students may seriously affect their health status in the future. In this study, 81% of students were not engaging in regular PA. These findings are similar to the results of literatüre studies (2,7,10,14). For example, a study conducted in the United States reported that approximately 80% of adolescents do not engage in sufficient PA and 20% are low active (17). Similarly, another study conducted in Turkey found that approximately 82% of students did not meet PA recommendations and exhibited SB for an average of nine hours or more (16). These results suggest that school staff and parents should devote

more effort and resources to encourage young people to engage in PA.

This study showed that the majority of students were at the preparation stage (27.8%) for sedantery behavir change. Kim and Lee (14) reported that 66.7% of the students were in the preparation stage. A study conducted with Macedonian students determined that 43.50% were in the precontemplation stage (11). A study conducted in Turkey determined that 32.4% of students were in the preparation stage (10). These results show that students do not have enough motivation and self-confidence to start exercising.

In this study, it was found that women were mostly in the preparation stage (29.4%) and men were in the action stage (29.1%). In contrast to these findings, Han et al. (2) reported that 33.6% of male students and 49.5% of female students were in the preparation stage. Elezim et al. (11) found that 29.1% of men and 52.9% of women were in the precontemplation stage. Therefore, it is recommended that gender differences be taken into account when creating PA programs.

In this study, women had higher scores on the perceived pros of SB change (22.60 ± 5.24) compared to men, but lower scores on the perceived cons of SB change (15.82 ± 3.89) and self-efficacy (16.38 ± 5.05). In parallel with our research findings, some studies in the literature found that women's SB-behavior change pros and men's cons scores were higher (2,18,19). For example, Tok (10) found that women had higher scores on the perceived pros of sedentary behavior change compared to men, while their scores on perceived cons and self-efficacy were lower. These findings suggest that women are more aware of the cons of SB than men. However, it suggests that women may require additional support to adopt a more active behaviors and enhance their self-efficacy.

In this study, self-efficacy were found to be higher in second-grade students (17.19 ± 5.15) and students whose families engaged in PA (17.79 ± 4.80) (p < .05). Similarly, Elezim et al. (11) reported that individuals receiving social support from their families had higher levels of self-efficacy compared to those who did not. Therefore, it is suggested that priority should be given to developing self-efficacy in first-grade students and those whose families do not engage in physical activity.

In this study, students had higher scores for walking MET (1924.88 ± 3396.39), moderate-intensity MET score (511.11 ± 1980.17), and total vigorous-intensity MET score (1178.14 ± 4727.90). Similar to our results, the literature has determined that university students prefer walking more (2,3). Studies evaluating the physical activity levels (PAL) of students according to gender revealed that women mostly preferred walking and moderate-intensity PA, while men preferred very vigorous PA (3). This may be because women and men have different physical performance levels. A study by Tergerson and King (29) reported that women perceive PA as leisure time exercise to maintain physical fitness, reduce stress, increase self-confidence, and/or promote weight loss. The

study reported that men, on the other hand, perceived PA as competitive sports to improve their strength and for peer acceptance (21). It is important that students are encouraged, regardless of their motivation, to engage in PA and continue to do so as they transition from adolescence to adulthood.

This study found that the average sitting time of students in a day was 4 hours and 24 minutes. The literature reports that university students spend at least 6.5 hours and at most 9 hours a day sitting (1-4,14). These results indicate that students have a significant level of sedentary behavior and suggest that support is needed to reduce their sitting time.

This study found 45.7% of the students to be moderate active. In most of the research with the IPAQ-SF, university students have been found to be moderate active (26). Another study found that 51.4% of university students were classified as low active, 28.2% as moderate active, and 20.4% as high active (17). Alkhawaldeh et al. (22) also reported that 51.9% of students were low or moderate active (sedentary). A study conducted in China found that 48% of nursing students and 38% of medical students were high active (25). Similarly, a study in Brazil reported that 55% of undergraduate students were high active (27), while a study in Saudi Arabia found that only 42% of health college students were high active (28). Studies conducted with students studying in health departments have also indicated that PA is the least paid attention among healthy lifestyle behaviors (3,20).

According to the IPAQ-SF, 58.9% of women were classified as moderate active, while 45.3% of men were found to be high active. Awadalla et al. (28) reported that 43.7% of men and 41.2% of women were low or moderate active. Research examining physical activity levels has often found that women are generally classified as moderate active at higher rates (4,14,16). The higher levels of moderate activity among women may be related to social and cultural factors.

This study found a significant difference between TTM-SB-SOC 1 and 2 and IPAQ-SF levels. According to TTM-SB-SOC-2, those in the maintenance phase were found to be high active, while others were found to be moderate active. Studies with similar results have shown that individuals with low PAL are more likely to stay behind in change stages and are less motivated to take action (14,23). Elezim et al. (11) stated that SB has direct and indirect effects on PAL. Some contrary research results indicate that SB and PAL are independent of each other and that individuals may be active but exhibit SB (24). Therefore, it may be recommended to determine students' motivations for SB and plan interventions accordingly.

5. CONCLUSION

According to the results of the study, it is recommended that university health professionals assess students' physical activity levels, sedentary behaviors, and Body Mass Index (BMI). It is recommended to motivate students to engage in physical activity. For those preparing to change their sedentary behaviors, it is suggested to provide counseling and educational

programs aimed at promoting action, encouraging physical activity, and increasing self-efficacy. Additionally, forming walking groups could help students enhance their preferred walking activities, and using step count tracking programs with rewards could be beneficial. Based on the research results, planning educational and counseling interventions to support and guide individuals and communities in changing sedentary behaviors is also advised.

This study was conducted with students enrolled in health programs at a vocational school within a university. Therefore, the results are generalizable only to students in health programs at this specific vocational school. A limitation of the study is that the students' height and weight measurements were based on self-reports. Future research on the Transtheoretical Model and its main constructs could explore the relationships and/or variations of this model or its key components across different age groups (e.g., adults and elderly) and occupational groups (e.g., clerks, workers, managers). Additionally, longitudinal and experimental studies could be conducted to better assess the impact of the Transtheoretical Model's main constructs on physical activity behavior.

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Evaluation of the Distance of the V3 Segments of the Vertebral Artery to the C1 Lateral Mass and C2 Pedicle on the Dominant and Non-Dominant Sides: A Cadaver Study

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ABSTRACT

Objective: Aim of this study is investigation of the risk of vertebral artery injury on the dominant and non-dominant vertebral artery sides at the craniocervical junction on cadavers.

Methods: A total of five cadavers and 10 vertebral arteries injected with red latex were studied. Dissection was performed on all of the cadavers. The study also involved CT scans obtained from all of the cadaver specimens. Distance of C1 lateral mass medial wall to the V3 segment of the vertebral artery, distance of C1 lateral mass lateral wall to the V3 segment of the vertebral artery, distance of C2 pedicle medial wall to the V3 segment of the vertebral artery, and distance of C2 pedicle lateral wall to the V3 segment of the vertebral artery were measured and statistically analyzed.

Results: There was no statistically significant difference between anatomical measurements on cadavers and on CT scan measurements. The data in the study demonstrated that the non-dominant (hypoplastic) vertebral artery follows a much closer course to the pedicle and the lateral mass, compared to the dominant artery.

Conclusion: In conclusion, it has been shown that the vertebral artery may be easily injured during surgical procedures due to the anatomical proximity of the pedicle and lateral mass and the screws' entry points being much closer on the non-dominant side.

Keywords: Vertebral Artery, Injury, Dominant, Non-dominant, Cadaver, Craniocervical Junction

1. INTRODUCTION

The unique anatomy of the atlantoaxial region makes surgical interventions challenging in this region. The vertebral artery to run through the C1-2 region varies from other cervical regions and may be subject to injury during surgical procedures. Surgical procedures performed in this region are due to cervical fractures-dislocations, spine and spinal cord tumors, congenital anomalies and degenerative diseases. Injuries may occur through direct contact with surgical instruments used during surgical procedures.

The vertebral artery injury (VAI) has been published that be as high as 8.2% during C1-2 region surgery. Transarticular screws are found to violate the C2 vertebral artery 9.5%, and pedicle screws are found to violate the C2 vertebral artery 8 % in several studies [1] [2]. Additionally high riding vertebral artery increases the injury rate during surgery [2].

VAI may cause a decrease in blood supply to the vertebrobasilar system, resulting in infarcts in the brainstem and cerebellum, and may result in death. Injuries may occur while drilling the entry point in the vertebra and during the placement of the screw. The screw may injure the vertebral artery or it may completely occlude it.

Aim of this study is investigation of the risk of VAI on the dominant and hypoplastic vertebral artery sides of cadavers during surgical procedures involving C1-2 at the craniocervical junction together with measurements performed on computed tomography (CT) scans of the cadaver specimens.

2. METHODS

2.1. Study Permissions and Ethical Statement

The study was conducted at Marmara University Neurological Sciences Institute. Ethical approval form was obtained

from the Marmara University Faculty of Medicine Ethics Committee.

2.2. Study Design

A total of five cadavers and 10 vertebral arteries injected with red latex were studied.

Dissection was performed on all of the cadavers with midline skin incision extending from the occiput to the level of the C3 vertebra at the nuchal line. Muscles on both sides are dissected in the cervical region by proceeding from the nuchal ligament toward the midline. The muscles from the posterior elements of the vertebrae and suboccipital triangle were dissected bilaterally as a single layer of skin.

The Vertebral Groove and transverse process were revealed by performing a lateral dissection from the C1 Posterior arch. The V3 segment of the vertebral artery was exposed from where the artery exits from the C1 transverse process to the vertebral groove. The C2 lamina and the Transverse foramen were dissected and exposed. The site of the vertebral artery exit from the transverse process was determined and the artery was exposed by fine dissection. In the study, it was detected at the C1-2 level of the vertebral arteries on both sides. Dominant and hypoplastic vertebral artery were identified. Distance of C1 lateral mass medial wall to the vertebral artery (A), distance of C1 lateral mass medial wall to the vertebral artery (B), distance of C2 pedicle medial wall to the vertebral artery (C), and distance of C2 pedicle lateral wall to the vertebral artery (D) were measured and statistically analyzed (Figure 1).
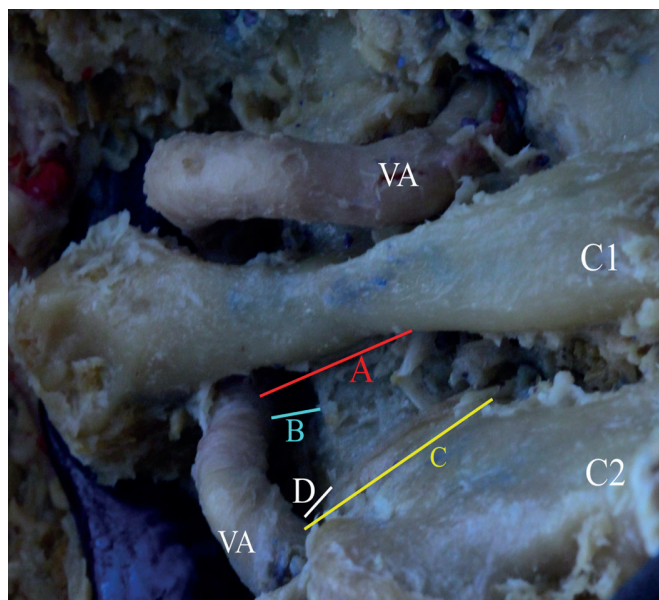
Figure 1. *The distances of C1 lateral mass and C2 pedicle to the vertebral artery.*

A-Red line: Distance of C1 lateral mass medial wall to vertebral artery, B-Blue line: Distance of C1 lateral mass lateral wall to vertebral artery, C-yellow line: Distance of C2 pedicle medial wall to vertebral artery, D-White line: Distance of C2 pedicle lateral wall to vertebral artery, VA: vertebral artery.

2.3. Radiology

The study also involved CT scans obtained from all of the cadaver specimens. The vertebral artery's distance to the medial wall of lateral mass and medial wall of pedicule were measured in the CT scans and statistically investigated (Figure 2, Table 1).
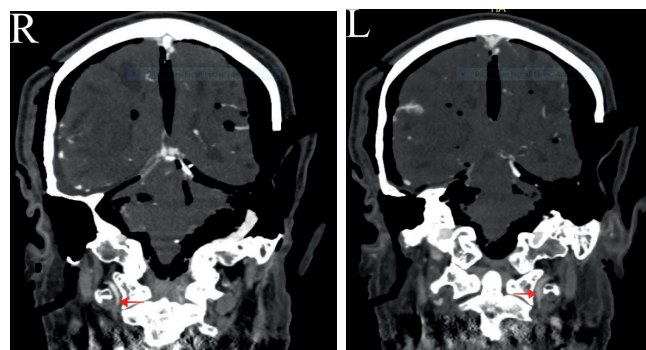
Figure 2. *CT image sample of a cadaver. Red arrow shows the vertebral artery. R:Right, L:Left.*

3. RESULTS

Dissections were performed on all of the cadaver specimens. Anatomical distances were physically measured on the cadavers, in addition to the CT scan measurements of the same specimens (Figure1, 2; Table 1). The results of the anatomical properties of C1, C2 and VA measurements of all cadavers are demonstrated in the Table 1.

3.1. Statistical Analysis Results

GraphPad Prism version 10.0.0 for MacOS (GraphPad Software, Boston, Massachusetts USA) was used in statistical analyses. The means and the standard deviations were calculated for parameters based on the measurements on the left and the right, respectively (Table 1). A paired samples t-test was used to compare the cadaver and CT scan measurements. A *p*-value < 0.05 was considered statistically significant (Table 2).

The mean distance of the C1 lateral mass medial wall to the vertebral artery (A) on the right side was 15.32 ± 1.12 mm on cadavers and 15.42 ± 1.23 on the CT scans. The same mean distance on the left side was 15.36 ± 0.5683 on the cadavers and 15.42 ± 0.497 on the CT scans (Figure 1 and 2).

The C1 lateral mass lateral wall distance to vertebral artery (B) on the right side was 1.12 ± 0.21 mm on cadavers and 1.22 ± 0.24 on CT scans. Whereas it was 1.62 ± 0.44 on the left side of cadavers and 1.82 ± 0.58 on CT scans (Figure 1 and 2).

The C2 pedicle medial wall distance to the vertebral artery (C) on the right side was 14.12 ± 0.64 mm on cadavers and 14.08 ± 0.66 on CT scans. It was 14.94 ± 1.17 on the left side of cadavers and 15.08 ± 1.27on CT scans (Figure 1 and 2).

Table 1. Measurement of the Vertebral Artery with anatomical structures in cadaver and tomography

	Right								Left								D.S.
	A		B		C		D		A		B		C		D		
	Cad	CT	Cad	CT	Cad	CT	Cad	CT	Cad	CT	Cad	CT	Cad	CT	Cad	CT	
1	14,1	14	1,5	1,6	15	14,8	2,2	2,4	15	15,1	2	2,2	16	16,1	1,5	1,6	L
2	16,5	16,6	1	1,2	13,5	13,2	1	1,1	15,5	15,9	1	1,1	16	16,4	1,5	1,5	L
3	16,5	16,8	1,1	1,3	14,1	14,3	1	1	16,3	16	2,1	2,6	13,2	13,2	1	1,1	L
4	15	15,1	1	1	14,5	14,5	1	1	15	14,9	1,5	1,6	15	15	1	1	L
5	14,5	14,6	1	1	13,5	13,6	1	1	15	15,2	1,5	1,6	14,5	14,7	1	1	L
M	15,32	15,42	1,12	1,22	14,12	14,08	1,24	1,3	15,36	15,42	1,62	1,82	14,94	15,08	1,2	1,24	
SD	1,123	1,234	0,2168	0,249	0,6496	0,6611	0,5367	0,6164	0,5683	0,497	0,4438	0,5848	1,17	1,272	0,2739	0,2881	

A: Distance of C1 lateral mass medial wall to vertebral artery, B: Distance of C1 lateral mass lateral wall to vertebral artery, C: Distance of C2 pedicul;e medial wall to vertebral artery, D: Distance of C2 pedicule Lateral wall to vertebral artery, Cad: Cadaver, CT: Computed Tomography, M: mean, Sd: standard deviation, DS: Dominant Side

The pedicle lateral wall distance to vertebral artery (D) on the right side was 1.24 ± 0.53 mm on cadavers and 1.3 ± 0.61 on CT scans. It was 1.2 ± 0.27 on the left side of cadavers and 1.24 ± 0.28 on CT scans (Figure 1 and 2).

The dominant vertebral artery was on the left side in all cadavers. There was no statistically significant difference between anatomical measurements on cadavers and on CT scan measurements.

Statistical analyses demonstrated no statistical significance in all right and left side measurements between the cadaver and CT scan measurements. P values of the analyses are provided in table 2.

Table 2. *Statistical comparison of the measurements made on cadavers and the CT images*

	RIGHT	LEFT
Comparison "A" Cadaver/CT	p=0,1890	p=0,6455
Comparison "B" Cadaver/CT	p=0,0890	p=0,0612
Comparison "C" Cadaver/CT	p=0,6885	p=0,2080
Comparison "D" Cadaver/CT	p=0,2080	p=0,1778

The data in the study demonstrated that the hypoplastic vertebral artery follows a much closer course to the pedicle and the lateral mass, compared to the dominant artery.

4. DISCUSSION

The vertebral arteries originate as the first branches of the subclavian arteries. Commonly, a dominant vertebral artery with a contralateral hypoplastic vertebral artery is observed in the patients. The vertebral artery is divided into 4 segments according to the anatomical location. Vertebral arteries enter the transverse foramen throught the C6 vertebral level (V1 segments). V2 segment is from the transverse foramen of the C6 to the transverse foramen of the C2 vertebra. V3 segment is the portion from the transverse foramen of C2 to dura mater. Finally, V4 segment is described as the intradural or the intracranial segment. The neck is very mobile at the C2 and C1 levels, and V3 segment continues freely in this region between the C1 and C2 transverse foramina devoid of any bony relation. Additionally, it courses over the vertebral groove on the C1 posterior arc and enters through the dura and provides the posterior circulation of the brain. This region is exposed to an increased risk of arterial injuries due to its varying location and course in the VA C1-2 region compared to other cervical regions. However, it is not clear in the literature whether if there are crucial differences in the anatomical course of the dominant and hypoplastic vertebral arteries. The current study discusses the course of the vertebral artery V3 segment between C1-2 on the dominant and hypoplastic vertebral artery sides and its relationship with the spine. VAI is a serious problem that can lead to catastrophic complications. VAI may occur mostly after trauma, but it may also occur after iatrogenic interventions. Iatrogenic injuries can be seen in all anterior and posterior surgeries of the cervical region. However, the most commonly encountered region in means of iatrogenic injuries is the craniocervical region surgeries, especially C1-2 posterior intervention surgery. Posterior C1-2 surgeries may occur due to tumors of this region, posttraumatic fractures, and congenital anomalies. In such surgeries, it may be essential to dissect and isolate the vertebral artery during tumor resection or during an instrument placement to C1-C2 vertabrae and iatrogenic VAI may occur during these procedures. Drilling and instrumentation are the most common causes of injuries [3]. VAI has been reported 32.4 % in C1-C2 spine fixation, 11.7 % in posterior approaches, 9.5 % in C1-C2 transarticular screws and 8 % in pedicle screws and 5.4 % in laminectomies in the literature [1, 2, 4-6].

VAI may cause a decrease in blood supply to the vertebrobasilar system, resulting in infarcts in the brainstem and cerebellum, and may result in death. VAI should be managed by intraoperative and postoperative methods. Intraoperative managements techniques are local control of hemorrhage, tamponade, packing with a hemostatic agent, electrocoagulation, direct repair and clipping, and ligation. Postoperative management of VAI are coil embolization, stenting and etc. .These procedures are performed to prevent vertebrobasilar ischemia and prevent cerebrovascular

complications[7]. According to the literature, the general condition of patients after VAI occurence worsens in 13% of patients and is mortal in 8% of patients [3].

VAI may occur as a result of the screw being directed laterally or superiorly while trying to place the screw to the C1 lateral mass. While placing the C2 pedicle screw, medial movement of the screw may cause VAI. In patients with high-riding vertebral artery placement, there is a possibility of direct injury to the artery when placing a screw in the C2 pedicle. These two conditions have been discussed in detail in the literature and alternative surgical techniques have been suggested. At the C2 level, the lateral orientation of the screw may also cause VAI. If the C2 pedicle is narrow, the lateral orientation of the screw may also cause VAI. In craniocervical junction tumors, C1-2 bone tumors grow in the bone and push the vertebral artery laterally. In certain cases, the tumors may surround the vertebral artery. In all cases, the course of the vertebral artery at the C1-2 level and its proximity to anatomical structures must be well known. The course of the C2 Vertebral artery from where it exits the transverse foramen and where it enters the C1 transverse foramen should be essentially very well defined by the surgeons.

In the study, the examination of the medial wall of the C2 pedicle and the medial wall of the C1 lateral mass was taken as a guide by checking these anatomical structures during surgical interventions. Because these anatomical structures are used as guides for surgical applications in clinical practice. It is estimated how lateral the vertebral artery is away from these guide points during surgery. These guide points assist in finding the entry point of the C1 lateral mass screw and the entry point of the C2 pedicle screw. Additionally, while the C1 lateral mass screw is placed, lateral wall of the lateral mass is also controlled with the help of a nerve hook in some cases. While the C2 pedicle screw is placed, the lateral wall of the intersection of the pedicle and lamina may be controlled with a nerve hook. These markers were investigated in the current study since they are widely used checkpoints in clinical practice.

This study demonstrates that the proximity of the dominant and hypoplastic vertebral artery sides of the vertebral artery to the anatomical structures in the spine is variable. The side of the dominant vertebral artery must be checked in preoperative radiological examinations before the craniocervical junction surgical procedures. The reason for this is to avoid severe posterior system infarction that may occur due to possible injures to the dominant artery. However, it should not be forgotten that since the hypoplastic vertebral artery is very close to the pedicle and lateral mass, the risk of injury to the hypoplastic vertebral artery is higher on contrary to the common belief in the practice. But there is no any study about it in the litrature. This study demonstrates that there are differences between the distance of the vertebral artery to C2 pedicle and C1 lateral mass on the dominant and hypoplastic vertebral artery sides.

5. CONCLUSION

It was shown in the study that the vertebral artery on the hypoplastic side is very close to the lateral wall of the C2 pedicle and the C1 lateral mass. We found that the distances of the vertebral artery to the C2 pedicle and C1 lateral mass were greater on the dominant artery side. It is physiologically correct to pay more attention to avoid damaging the dominant vertebral artery, which is the main feeder of the posterior fossa. However, since the dominant vertebral artery is anatomically farther away from the surgical area, the probability of injury is lower than the hypoplastic side.

In conclusion, it has been shown that the vertebral artery may be easily injured during surgical procedures due to the anatomical proximity of the pedicle and lateral mass and the screws's entry points being much closer on the hypoplastic vertebral artery side.

Author Contributions:
Research idea: YG
Design of the study: YG,UV,BT
Acquisition of data for the study: YG,UV,BT,EB
Analysis of data for the study: YG,UV,BT,EB
Interpretation of data for the study: YG,UV
Drafting the manuscript: YG,İZ
Revising it critically for important intellectual content: YG,İZ
Final approval of the version to be published: YG,UV,İZ

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Determination of Compassion Fatigue and Work Volition of Nurses Working in Intensive Care Units During COVID-19: A Cross-Sectional Survey

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ABSTRACT

Objective: This study aimed to determine the compassion fatigue and work volition of nurses working in the intensive care units during the COVID-19 pandemic.

Methods: This descriptive, cross-sectional study was conducted with a sample of 308 nurses working in the COVID-19 intensive care units of the pandemic hospitals affiliated with the Ministry of Health in the Istanbul province, Turkey, between February and May 2021. Data were obtained using the Personal Characteristics Form, the Compassion Fatigue-Short Scale and the Work Volition Scale. The obtained data were asses with the SPSS 22.0 statistical program.

Results: It was determined that the mean age of the nurses participating in the study was 30.32±10 years; 80.2% were female, and 23.4% had been working for 1-3 years. The compassion fatigue total mean score was 79.91±25.04, while the work volition total mean score average was 50.28±10.65, which was found to be moderate. In the nurses' compassion fatigue sub-dimensions, the mean for occupational burnout was 49.12±15.61, and the secondary trauma mean was 30.78±10.92. A weak positive correlation was found between the nurses' compassion fatigue and work volition total scores (r= 0.235, p<.001).

Conclusion: Overall, this studyfindings indicated that a significant increase in compassion fatigue was associated with increased work volition. The findings suggest that organizational factors affecting nurses' working conditions are important and should not be ignored.

Keywords: Compassion fatigue; COVID-19; intensive care nurse; work volition.

1. INTRODUCTION

Intensive care units are special areas where the care of patients with critical health conditions is provided; they contain apparatus equipped with advanced technological systems. These units are known to have high mortality and morbidity rates, and the holistic nursing care provided in these units is of critical importance (1,2). Nurses should evaluate the healthy/sick individual and provide care in line with the requirements of contemporary nursing philosophy (3,4). Due to the rapidly increasing number of patients in the novel coronavirus disease (COVID-19) epidemic worldwide, intensive care units in many hospitals were converted into COVID-19 intensive care units, displaying a rising need for nurses (5,6). The insufficientnumber of nurses and the increased number of patients per nurse harmed the care process. In addition, there were ethical problems, such as nurses having to make choices between patients due to limited resources and an insufficient supply of equipment (7). Consequently, in such cases, it is important that nurses use decision-making processes correctly and effectively. It is known that the perception of conscience and compassion closely affects the thoughts and practices of nurses as they go through the decision-making process. Compassion is one of the factors that enable the greatest possible patient care, as well as one of the most significant aspects of the nursing profession. Compassion fatigue, on the other hand, is understood to be the negative effect of aiding sick people who suffer, are in pain, or experience horrific experiences (8). It is known that nurses who take an active role in health care services often experience compassion fatigue (8,9). In view of the COVID-19 pandemic, it was expected that some factors such as the increasing number of patients, nurses having to choose between patients, and insufficient availability of equipment would affect the level of compassion fatigue among nurses. Because of the prevalence of COVID-19 patients requiring critical care in intensive care units, nurses suffered physical, mental, and social exhaustion over time,

which had the potential to lead to burnout. Burnout among nurses can have a long-term impact on their work motivation. The Work Psychology Framework defines work volition as "the perceived capacity to make occupational choices despite constraints(10-12).As a result, the individual's view of his or her ability to make career-related choices despite the barriers encountered constitutes the individual's work volition (13,14).

It is considered that the compassion fatigue that nurses may have experienced during the COVID-19 pandemic may have affected their work volition. Additionally, it was reported that nurses who were found to have compassion fatigue faced serious issues in their work performance and personal health (15).

This study intented to ascertain the degrees of compassion fatigue and work volition among nurses working in intensive care units during the recent COVID-19 outbreak. Well-designed studies should be undertaken to provide evidence-based knowledge about communities from different socioeconomic and religious backgrounds.High quality research should be planned and carried out to determine possible external factors that may affect employees' work load and an attempt should be made to harmonize these circumstances with their socioeconomic status.

2. METHODS

This research is a descriptive, cross-sectional study.

2.1. Research Questions

- What was the level of compassion fatigue of intensive care nurses in the COVID-19 pandemic?
- What was the level of work volition of intensive care nurses in the COVID-19 pandemic?
- Is there a relationship between the compassion fatigue of intensive care nurses and their work volition during the COVID-19 pandemic?
- Is there an effect of their compassion fatigue on the work volition of intensive care nurses during the COVID-19 pandemic?

2.2. Study Design

This research is a descriptive, cross-sectional study.

2.2.1. Participants

This study was conducted between February and May 2021 with nurses working in the intensive care units of nine hospitals affiliated with the Ministry of Health in Istanbul. According to the Raosoft sample calculation program, it was determined that 267 nurses working in intensive care units should be included in the study with a 95% confidence interval and 5% margin of error. The study's sample included 308 nurses who volunteered to participate in the study within the specified period, worked in a COVID-19 Intensive Care Unit, and completed the form in its entirety.

2.2.2. Data Collection Tools

The data of the research were obtained by using the Individual Characteristics Form, the Work Volition Scale, and the Compassion Fatigue Scale.

2.2.3. Individual Characteristics Form

This form, produced by the researchers based on the literature, contains seven questions. The form asks for personal information such as age, gender, marital status, educational status, time working as a nurse, intense care, and COVID-19 intensive care working time (16,17).

2.2.4. Work Volition Scale

The Work Volition Scale (WVS), first known as the Work Volition Scale, was created by Duffy, Diemer, Perry, Laurenzi, and Torrey (12) to assess work volition. Work volition refers to individuals' view of their ability to make professional decisions in spite of challenges. In 2019, a study was undertaken in Turkey to assess the validity and reliability of the scale. The results of the study confirmed that the scale is a valid and reliable tool for measuring(18). The Work Volition Scale comprises three subscales, including willpower, financial restrictions, and structural restraints. A total of 13 items have been assessed and evaluated using a seven-point grading system, ranging from 1 (strongly disagree) to 7 (strongly agree). The 1st, 2nd, 12th and 9th items belong to the Willpower subscale, the 5th, 10th, 6th, 7th and 8th items belong to the Financial constraints subscale, and the 3rd, 11th, 13th and 14th items belong to the Structural constraints subscale. The items in the financial and structural constraints subscales are scored in reverse (3, 4, 5, 6, 7, 8, 10, 11, 13) and summed with the willpower subscale, and the total score yields the work volition score. The researchers determined the internal consistency coefficient to be 86 for the overall scale, 75 for the Willpower subscale, 72 for the Structural limitations subscale, and 82 for the Financial constraints subscale (12). The study determined that the Cronbach's alpha coefficient for the Work Volition Scale was 0.86.

2.2.5. Compassion Fatigue Scale

The Compassion Fatigue Scale was established by Adams et al. (19). The Turkish study on the scale's validity and reliability concluded that it is a dependable and accurate measurement tool (20). The scale is a self-reporting evaluation instrument that prompts users to evaluate the degree to which each scale item accurately represents their personal experience. The Likert scale consists of 10 points, ranging from 1 (rarely/never) to 10 (very often). The scale comprises two sub-dimensions, namely secondary trauma and occupational burnout.The elements ''c, e, h, j, l'' on the scale pertain to secondary trauma, while items "a, b, d, f, g, i, k, m" assess professional burnout. The subscales of the scale exhibit Cronbach's alpha coefficients ranging from 0.80 to 0.90,

indicating satisfactory internal reliability. The scale does not specify any scoring algorithm or cut-off point. The minimum score on this scale is 13, while the maximum value is 130. According to Adams et al. (19), there is a positive correlation between the scores on the scale and the level of compassion fatigue experienced by the individual. Dinc and Ekinci (20) determined Cronbach'salpha coefficientas 0.88, the study determined that the Cronbach's alpha coefficient for the Compassion Fatigue Scale was 0.92.

2.3. Data Collection

The research data was obtained by sending out the link for the survey that was created with Google Forms. In the first part of the prepared questionnaire, a voluntary consent form explaining the purpose and scope of the study was included. The second part of the questionnaire included questions belonging to the Individual Characteristics Form, the Work Volition Scale, and the Compassion Fatigue Scale. The responses of individuals who had approved the voluntary consent form were evaluated. Only the participants accessed the research questions and only the researchers accessed the data. The necessary importance was given to voluntary participation and data privacy. Google Forms link was sent to the participants via WhatsApp.The time for answering the survey questions is approximately 8-10 minutes.

2.4. Ethical Consideration

Firstly the approval was obtained from the Scientific Research Platform established by the Ministry of Health of the Republic of Turkey for carrying out the research and collecting the data. After getting approval from the Ministry of Health,. Ethical approval was obtained from the Ethics Committee of Hamidiye Scientific Research of the T.R. Health Sciences University (Date: 25.12.2020, Decision No: 20/523). Permissions were obtained for the Compassion Fatigue questionnaire and the Work Volition questionnaire applied to the participants in the study.The study was conducted in compliance with the principles of the Helsinki Declaration.

2.5. Data Analysis

The research data was evaluated using the Statistical Package for the Social Sciences (SPSS 22.0 for Windows, SPSS Inc., Chicago, IL) application. In the data evaluation, the Kolmogorov-Smirnov test was used to evaluate the conformity of the relevant variables to normal distribution in order to determine the statistical method to be used. The analysis of descriptive data was evaluated with numbers, percentages, medians, minimum, maximum, mean and standard deviation values. Spearman's correlation coefficient was used to indicate the relationship between the two variables. Regression analysis was used to measure associations between two or more variables.Statistical significance was accepted as $p<.05$. In addition, the survey results were evaluated collectively using Principle Component Analysis (PCA). The analysis was

performed using the open-source code of R (V3.6.1, https://www.r-project.org).

3. RESULTS

The survey revealed that 64% of the participating nurses were aged 30 or below. Additionally, 80% of the nurses were female, 58% were unmarried, and the analysis of their educational status showed that 85% held a Bachelor's degree while 14.9% had a Master's degree. Table 1 reveals that 42.5% of the nurses had a work experience of 6 months or less in COVID-19 intensive care units (Table 1).

Table 1. Distribution of nurses according to descriptive characteristics (N=308)

Characteristics	n	%
Age		
30 and below	199	64.6
31-40	74	24.0
40 and above	35	11.4
Sex		
Male	61	19.8
Female	247	80.2
Marital status		
Married	129	41.9
Single	179	58.1
Education Degree		
Bachelor's degree	262	85.1
Master's degree	46	14.9
Years Working as a Nurse		
0-1 Years	45	14.6
2-3 Years	72	23.4
4-5 Years	42	13.6
6-10 Years	55	17.9
11-20 Years	65	21.1
20 Years or more	29	9.4
Years Working in an Intensive Care Unit		
0-1 years	87	28.2
2-3 years	87	28.2
4-5 years	47	15.3
6-10 years	48	15.6
10 years or more	39	12.7
Period of working in the COVID-19 intensive care unit		
6 months or less	131	42.5
7-12 months	116	37.7
More thanone year	61	19.8

The compassion fatigue total mean score of the participants was 79.91±25.04. In the subscale sof compassion fatigue, mean occupational burnout was 49.12±15.61, and the mean of secondary traumawas 30.78±10.92. The overall mean of the participants' work volition was found to be 50.28±10.65. In the subscales of work volition, the structural constraints mean was 18.13±5.13, the financial constraints mean was 17.67±7.34, and the willpower mean was 14.48±5.31 (Table 2)

Table 2. Compassion fatigue and work volition mean scores (N=308)

Scales	Mean±SD	Min	Max
Work Volition Total	50.28±10.65	14.000	77.000
Willpower	14.48±5.31	4.000	28.000
Financial constraints	17.67±7.34	5.000	35.000
Structural constraints	18.13±5.13	4.000	28.000
Compassion Fatigue total	79.91±25.04	20.000	130.000
Secondary trauma	30.79±10.92	5.000	50.000
Occupational burnout	49.12±15.61	8.000	80.000

SD: Standard Deviation; Min: Minimum; Max: Maximum.

The study revealed a modest positive link between the overall levels of compassion fatigue and work willingness among the participating nurses (r=.235, *p<.001*). The nurses' compassion fatigue and willpower exhibited a fairly significant negative connection (r= − .367, *p<.001*). The study revealed a significant and moderate association between the total score of the compassion fatigue scale and the subscales of financial limitations (r=.356, *p<.001*) and structural restrictions (r=.356, *p<.001*) in the work volition scale (Table 3).

Table 3. Correlation analysis between compassion fatigue and work volition scores (N=308)

Scales		Work Volition Total	Willpower	Financial Constraints	Structural Constraints
Compassion Fatigue Total	r	.235**	-.367**	.356**	.356**
	p	.001	.001	.001	.001
Secondary trauma	r	.116*	-.279**	.230**	.199**
	p	.042	.001	.001	.001
Occupational burnout	r	.295**	-.393**	.410**	.432**
	p	.001	.001	.001	.001

*p<.05; **p<.01; r: Spearman's correlation coefficient

The regression analysis conducted to establish the cause-effect link between the overall compassion fatigue score and the total labor volition score yielded a significant result (F=17.808; *p<.001*).Out of the total change in the level of work volition, 5.2% is explained by the total of compassion fatigue (R2=0.052). It was found that the total level of compassion fatigue increased the total level of work volition (ß=.100) (Table 4).

When we look at the distribution of the participants by gender, approximately 26% of the women and less than 5% of the men were found to have compassion fatigue. High levels of compassion fatigue were detected in approximately 33% of men and 26% of women (Figure 1A-1B). When this distribution was broadened to individuals' marital status, it was found that approximately 11% of women with low compassion fatigue were married, and 15% were single. About 10% of the women with high compassion fatigue were married, and 15% were single. In males, this condition was approximately 20% in married men and 13% in singles (Figure 1C-1D).

While individuals with low compassion fatigue differed from the others in questions 12, 1, 2 and 9, individuals with high compassion fatigue differed from the others in questions 14, 15, 8, 11, 3, 13, 7, 5, 6, 10 and 4. Individuals with moderate compassion fatigue differed from the others in the rest of the questions (Figure 2A). The highest compassion fatigue was observed in males, with married and university-graduate individuals representing approximately 16% of the total sample, followed by single-female university graduatex (12%), single-male university graduates (11%) and married-female university graduates (9%), respectively. (Figure 2B). The lowest compassion fatigue was observed in female-unmarried university graduates (13%) (Figure 2C) and female-married university graduates (9%) (Figure 2C).

Table 4. The effect of compassion fatigue on work volition (N=308)

The Dependent Variable	The Independent Variable	ß	t	p	F	Model (p)	R²
Work Volition Total	Constant	42.318	21.381	.001	17.808	.001	.052
	Compassion Fatigue Total	.100	4.220	.001			
Work Volition Total	Constant	41.553	21.621	.001	20.450	.001	.112
	Secondary Trauma	-.272	-3.290	.001			
	Occupational Burnout	.349	6.020	.001			
Willpower	Constant	20.927	22.319	.001	28.237	.001	.151
	Secondary Trauma	.031	.770	.442			
	Occupational Burnout	-.151	-5.331	.001			
Financial Constraints	Constant	8.800	6.918	.001	35.119	.001	.182
	Secondary Trauma	-.146	-2.660	.008			
	Occupational Burnout	.272	7.092	.001			
Structural Constraints	Constant	11.826	13.668	.001	45.907	.001	.226
	Secondary Trauma	-.158	-4.232	.001			
	Occupational Burnout	.227	8.720	.001			

Regression analysis, p<.05 value indicates statistically significant.

A
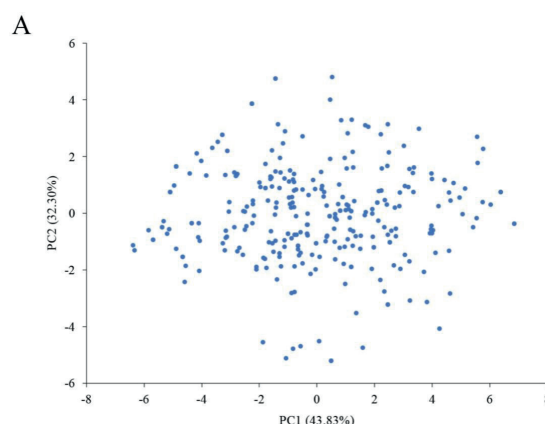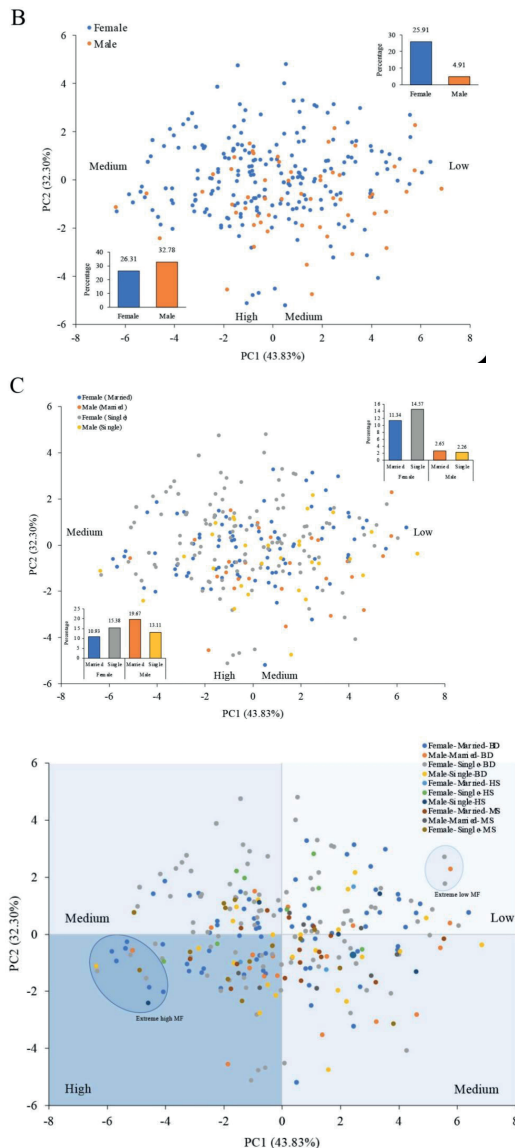
Figure 1. *Differentiation of compassion fatigue scores by descriptive characteristic*
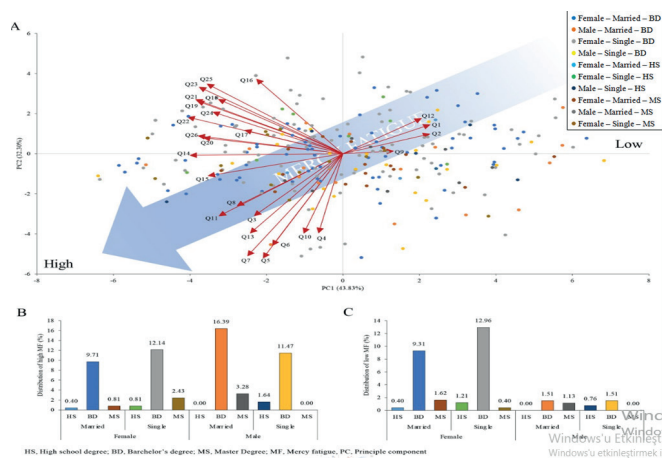
Figure 2. *Variation of will to work scores according to descriptive characteristics*

4. DISCUSSION

This study aimed to assess the prevalence of compassion fatigue and work volition among intensive care nurses who had been employed in intensive care units during the COVID-19 pandemic. The study revealed notable demographic characteristics among participating nurses, with a significant majority being young and predominantly female. A considerable portion of the nurses were unmarried, and the majority held at least a Bachelor's degree. These results are similar to other studies (21-23). These demographics provide context for understanding the profile of nurses working in intensive care units during the COVID-19 pandemic, highlighting potential factors influencing their experiences of compassion fatigue and work volition.

The results revealed a high prevalence of compassion fatigue and a moderate level of work volition. Another study among emergency department health professionals in Turkey found a strong negative association between burnout and job satisfaction. (24). Additionally, it has been reported that as nurses' compassion fatigue levels increase, they do not reflect their knowledge and skills in their care practices (25-27). These scores underscore the challenges faced by ıntensive care units nurses in maintaining motivation and overcoming various barriers to effective job performance amidst the demanding conditions imposed by the pandemic.

The study identified a substantial causal link between work volition, secondary trauma, and professional burnout. The study observed that the overall score of compassion fatigue among critical care nurses was found to correlate with an increase in their whole degree of job motivation. Professional burnout heightened the overall degree of work motivation. Compared with study among Chinese clinical nurses in Shanghai (28), our current findings represent similar levels of compassion fatigue, but higher burnout and secondary traumatic stress. Studies have also, nurses with secondary traumatic stress were more likely to consider a change of career (29). This suggests that the results might be related to societal cultural values and the socioeconomic status of the individuals in the community. More well-designed studies are needed in different socioeconomic and social surroundings so that evidence in this context can be produced.

The study underscore the multifaceted nature of compassion fatigue and its implications for nurses' work volition in intensive care settings. It is reported that nurses who choose their profession voluntarily develop better professional relations and work with greater satisfaction (30,31). It is believed in the context of work volition that when nurses willingly choose their profession, they are more successful in achieving holistic care in crucial units of the hospital, such as intensive care; they are better able to make and apply decisions quickly, are less affected emotionally, and are generally more equipped to cope with any professional difficulties they may encounter.

The regression analysis conducted to establish the cause-effect link between the overall compassion fatigue score and

the total labor volition score yielded a significant result. Five percent of the total change in the level of willingness to work is explained by total compassion fatigue. Total compassion fatigue level was found to increase total willingness to work level. In studies, it was stated that nurses with compassion fatigue had changes in their work performance, work-related attitudes and behaviours (32,33). The regression findings highlight the critical role of compassion fatigue, secondary trauma, and occupational burnout in shaping nurses' work volition and overall job engagement in intensive care settings. Healthcare organizations should prioritize interventions aimed at reducing compassion fatigue and mitigating its detrimental effects on nurse well-being and performance.

Gender and marital status differences were evident in the distribution of compassion fatigue levels among participants.Higher proportions of men exhibited high levels of compassion fatigue compared to women, despite women overall experiencing compassion fatigue more frequently. The study conducted by Sacco et al. revealed that the prevalence of compassion fatigue was greater among unmarried nurses employed in the intensive care unit (34).This may be attributed to the fact that since men were perhaps taking on more financial and social responsibilities in their marriage, they felt the burden of added responsibility as a result of the new situation.

The results thus indicate that in critical periods such as a global pandemic, healthcare personnel who face an increased workload need to be supported in their social environment, family life, and financial situation to ensure improvements in healthcare.

There are various constraints in this study. Firstly, the study is limited to intensive care nurses working in nine hospitals in Istanbul. Furthermore, the data obtained from the participants are limited to their responses to the Compassion Fatigue Scale and the Work Volition Scale via Google Forms. Consequently, the findings cannot be extrapolated to encompass all nurses employed in intensive care units.

5. CONCLUSION

The findings of our study revealed a positive correlation between the escalation of compassion fatigue among intensive care nurses during the COVID-19 epidemic and an increase in their work volition. The findings underscore the complex interplay between compassion fatigue, work volition, and demographic factors among intensive care nurses during the COVID-19 pandemic. Addressing compassion fatigue requires multifaceted interventions that encompass organizational support, mental health resources, and policy initiatives aimed at promoting resilience and well-being among healthcare professionals. By understanding these dynamics, healthcare organizations, and policymakers can better support intensive care nurses and ensure sustainable healthcare delivery.Further research is recommended to explore longitudinal effects and interventions that effectively

mitigate compassion fatigue in intensive care settings, thereby fostering a resilient and motivated nursing workforce.

Author Contributions:
Research idea: FŞ.
Design of the study: FŞ, SG
Acquisition of data for the study: FŞ, SG, EG
Analysis of data for the study: FŞ, SG, EG
Interpretation of data for the study: FŞ, SG, EG
Drafting the manuscript: FŞ, SG, EG
Revising it critically for important intellectual content: FŞ, SG, EG
Final approval of the version to be published: FŞ, SG, EG

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Diabetes Burden and Activation Levels in Elderly Individuals with Diabetes

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ABSTRACT

Objective: This research has been conducted to determine the diabetes burden and patient activation levels in elderly individuals with diabetes.

Methods: The sample of this descriptive study is composed of 230 individuals aged 65 years and over and individuals with a diagnosis of diabetes. Data has been collected at the internal medicine clinic of a state hospital between May 2021 and January 2022. Data collection has been collected using the Personal Information Form, Elderly Diabetes Burden Scale and Patient Activation Measure.

Results: It has been determined that 37.4% of geriatric diabetics were at the first activity level, and 14.3% at the second activity level. The average Patient Activation Measure score has a significant correlation with Elderly Diabetes Burden Scale. It has been determined that the situation of age, high school degree or a higher level of education, lack of any acute or chronic complications, another chronic disease, having a diabetes education, use of oral antidiabetic medications and total elderly diabetes burden have a significant effect on activity levels.

Conclusions: This study, it has shown that the burden of diabetes in geriatric patients has a significant difference by the patient activity levels.

Keywords: Activation Level, Diabetes, Burden, Elderly

1. INTRODUCTION

There are approximately 537 million adults living with diabetes in the world and it is predicted that this number will increase to 783 million in 2045. In Turkey, there are nearly 7 million individuals with diabetes between the ages of 20-79 according to the data of 2020, and nearly 20% of this number composes of those individuals over the age of 65 (1, 2). Diabetes is one of the most common chronic diseases in geriatric individuals notwithstanding, it is an increasingly important burden on geriatric individuals since it brings about organ damage, causes addiction and reduces quality of life (2-4). The burden of diabetes is felt more in geriatric individuals, particularly owing to the physiological changes caused by old age, poor well-being and other existing chronic diseases (5, 6). Studies conducted in this field have indicated that increased diabetes burden in geriatric individuals increases the risk of mortality and morbidity, causes drug non-compliance, and has a significant correlation with variables that negatively affect diabetes management, such as high HbA1c level, insufficient exercise, and poor self-efficacy (2-4, 7).

It has been specified that it is crucial to reduce the burden of diabetes on geriatric individuals, and for this, individuals should be empowered and self-management levels should be increased. The most efficient method to increase self-management in diabetes patients is possible by assuring the active participation of the individual and family in treatment (8-11). Patient activation is closely connected with many conditions such as maintaining healthy lifestyle behaviors, predicting health outcomes, and individuals having the ability to make decisions about their health conditions (12-14). High levels of patient activation have been detected as being connected with positive health outcomes (for example, fewer depressive, more frequent use of healthcare services, and glucose levels target). Conversely, lower patient activation levels are connected with unhealthy behaviors (eg, physical inactivity) and less positive health outcomes (eg, higher glucose levels) in individuals with type 2 diabetes (12, 13).

Type 2 diabetes is a complex chronic condition that necessitates continuous care. For this reason, a high degree of self-management and high activity levels are required to improve outcomes and prevent diabetes-related complications (15). In the literature review using the

keywords diabetes burden, elderly, and patient activity level, even though there are a few studies evaluating the diabetes burden, it has been detected that there is not any study in the literature forming an estimate of patient activity levels in individuals with geriatric diabetes, and there is no any available study that evaluates diabetes burden and patient activity levels together (5,16-18). Accordingly, our objective in this study is to determine the diabetes burden and patient activity levels in individuals with diabetes geriatric.

2. METHODS

2.1. Design and Sample

This study was conducted as a descriptive study to determine the diabetes burden and patient activity levels in geriatric diabetics.

The study population consists of individuals with geriatric diabetes who applied to a state hospital's internal medicine clinic. G power analysis was utilized to calculate the sample number of the study. Based on the study conducted by Koşar et al. (2018), 192 individuals were planned to be included in the study, according to the calculation made by utilizing patient activity level scores, one of the main outputs of the study, at 80% power (1-β), 95% confidence (1-α) range and 0.35 effect level (14).

The sample of the study consists of those who are 65 years or older, diagnosed with type 1 and type 2 diabetes for at least one year, who were hospitalized in the internal medicine clinic of a state hospital, did not have any cognitive problems, did not have any psychiatric diseases, and has presented written and verbal consent for participation in research after they received information about the research.

2.2. Procedures

Data were obtained at patient rooms in the internal medicine clinic through face-to-face and personal interviews. Out of 249 patients contacted between May 2021 and January 2022, They were not included in the sample as 2 of them had a psychiatric disorder, 2 of them were not capable of facilitating self-care activities, 4 of them felt tired and 11 of them did not give consent for participation in the study. The study was completed with 230 patients.

2.3. Instruments

Data were collected by using a personal information form, Diabetes Burden Scale and Patient Activation Measure.

In the personal information form, gender, marital status, age, education level, income status, duration of diagnosis, diabetes treatment, diabetes-related acute/chronic complication development status, presence of additional chronic disease, physical exercise status, and diabetes education status have been assessed.

The Elderly Diabetes Burden Scale, which was developed to identify the diabetes burden of individuals with geriatric diabetes, consists of 6 sub-items and a total of 23 items. The sub-dimensions of the scale are symptom burden, dietary restriction, worry about diabetes, treatment dissatisfaction, burden by tablets or ınsulin, and social burden. Responses in scale; "no; 0 points", "If yes, none: 1 point; very little: 2 points; a little: 3 points; a lot: 4 points". A high score on the scale reveals that there is a high diabetes burden. The highest score that can be obtained from the scale is 88 and the lowest score is 18. The validity and reliability study of the Elderly Diabetes Burden Scale was conducted by Yıldırım and the Cronbach alpha value was determined as 0.92 (19).

Patient Activation Measure (PAM), which was developed to evaluate the patient activity levels of individuals with chronic diseases, consists of 13 items. The scale consists of four stages. Individuals who think that they are not yet active participants in taking an active role in their healthcare and care are situated in the first stage. Individuals lacking in knowledge and unable to establish a connection between their health and the recommended health arrangement are situated in the second stage. Individuals who are able to take action and eager but lack the skills and confidence to support new attitudes are situated in the third stage. Patients who accept new attitudes but are unable to preserve and maintain these attitudes in health crises and stress situations are situated in the fourth stage. The activity scores obtained from the measurement tool ranged between 0-100. Level 1: lowest activity: <47 points, Level 2: 47-55 points, Level 3: 55 – 72 points, Level 4: highest activity:>72.5 points (13). The validity and reliability study of the scale in Turkish was conducted by Koşar & Besen and the cronbach alpha value was determined as 0.81 (14).

2.4. Statistical Analysis

The data analysis has been implemented by using the IBM SPSS Statistics 18 program. Since parametric test assumptions were not provided, Mann Whitney U test was used for comparisons of two groups median, Kruskal Wallis test and post hoc Bonferroni tests were used for comparisons of means of more than two groups. The relationship between continuous variables was examined with the Pearson correlation test. Univariate and multivariate regression analysis was performed for the factors affecting the activity level and variables with $p<0.05$ were included in the multivariate model. In the study, the statistical significance level has been accepted as <0.05.

2.5. Ethical Consideratin

Ethics committee approval was obtained from a university non-invasive clinical research ethics committee before starting the study (Date: April 8, 2021 Decision no: 50). Institutional permission was obtained from the Provincial Health Directorate to conduct the research. Written and verbal consent was obtained from the individuals who agreed to participate in the study.

3. RESULTS

The statistical power of the study has been determined as 90%, with a 95% confidence interval, d=0.43 effect size, according to the result of the post hoc power analysis calculated at the end of the study. The mean age of geriatric diabetic individuals is 73.46±7.06, 46.5% are female, 53.5% are male, the majority (72.2%) are married, and 38.7% are high school graduates. It has been detected that 93.5% of the individuals participating in the study have been diagnosed with type 2 diabetes and the mean year of diagnosis was 20.95±9.82, 47.0% used only insulin therapy, 34.8% used oral antidiabetic and insulin therapy together (Table 1).

It has been determined that the mean PAM score of individuals with geriatric diabetes is 53.33±14.49. The majority of the individuals have been in the first stage (37.4%) with the lowest patient activity level, 14.3% have been in the second stage, 34.4% have been in the third stage, and 13.9% have been in the fourth stage with the highest activity level (Table 2).

It has been determined that the average scores of the "symptom burden", "dietary restriction", "worry about diabetes", "burden by tablets or ınsulin" and "total elderly diabetes burden scale of the individuals with the activity level 1 were higher than the individuals with the activity level 3 and 4, It was determined that the average "social burden" and "treatment dissatisfaction" scores of the individuals with activity level 1 were higher than those with activity level 2, 3 and 4 (p<0.05) (Table 3).

In the Logistic Regression model, in which patient activity levels were the dependent variables, diabetes burden scale and descriptive features were independent variables, it was determined that the independent variables and total diabetes burden explained 67.2% of the total variance in activity levels (p<0.05). When the regression coefficients were examined, age (OR=0.957), education level being high school and above (OR=7.036), no acute complication (OR=23,536), no chronic complication (OR=18.501), no other chronic disease (OR=4.071), diabetes education (OR=20.245), oral antidiabetic use (OR=4.030) and total elderly diabetes burden (OR=0.903) had a significant effect on activity levels (p<0.05) (Table 4).

Table 1. Distribution of disease-related characteristics of individuals

Disease-related characteristics	n	%
Types of Diabetes		
Type 1	15	6.5
Type 2	215	93.5
Individual with diabetes in the family		
Yes	187	81.3
No	43	18.7
Diabetes treatment		
Oral antidiabetic	80	34.8
Insulin	108	47.0
Insulin and oral antidiabetic medication	42	18.2
Acute complication		
Yes	185	80.4
No	45	19.6
Chronic complication		
Yes	73	31.7
No	157	68.3
Other chronic disease		
Yes	171	74.3
None	59	25.7
Diabetes education		
Yes	69	30.0
No	161	70.0
	Mean±SS	Median (Min-Max)
Diagnosis time	20.95±9.82	19(6-63)

Table 2. Distribution of patient activity levels of individuals

Activity levels	n	%
First level	86	37.4
Second level	33	14.3
Third level	79	34.4
Fourth level	32	13.9

Table 3. Diabetes burden scores according to activity levels

Elderly Diabetes Burden Scale	Activity Levels				p*	Difference
	First Level Median (Min-Max)	Second Level Median (Min-Max)	Third Level Median (Min-Max)	Fourth Level Median (Min-Max)		
Syptom burden	12 (2-16)	11 (0-16)	8.96 (0-16)	6 (0-14)	<0.001	1>3-4 2,3>4
Social burden	19 (11-20)	18 (10-20)	15 (8-20)	15 (10-20)	<0.001	1>2,3,4
Dietary restrictions	13 (8-16)	12 (4-16)	12 (6-16)	12 (7-16)	<0.001	1>3,4
Worry about diabetes	14 (8-16)	14 (8-16)	12 (6-16)	12 (8-16)	<0.001	1>3,4
Treatment dissatisfaction	6 (2-8)	4 (2-8)	4 (2-7)	2 (2-6)	<0.001	1>2,3,4 2, 3>4
Burden by OAD or insulin	11 (6-12)	11 (7-12)	9 (4-12)	8.5 (6-12)	<0.001	1>3,4 2 >4
Total Elderly Diabetes Burden Scale	74 (45-124)	68 (39-80)	62 (37-79)	5 54.5 (40-74)	<0.001	1>3,4 2 >4

Kruskal Wallis test

Table 4. Analysis of logistic regression for factors affecting activity levels

Activity level (2-4)	Univariate	
Variables	OR (%95 CI)	p
Gender (male)	1.291 (0.767-2.170)	0.336
Age (year)	0.957 (0.921-0.994)	0.025
BKI (kg/m²)	0.951 (0.902-1.002)	0.061
Marital status (single)	0.849 (0.476-1.514)	0.579
Education degree (high school and the BA)	7.036 (3.939-12.569)	<0.001
Cohabitation (spouse or child)	1.076 (0.499-2.322)	0.851
Type of Diabetes (type 2 diabetes)	0.602 (0.207-1.749)	0.351
Any family member with diabetes (no)	0.867 (0.447-1.683)	0.673
Acute complication (not available)	23.536 (7.028-78.819)	<0.001
Chronic complication (not available)	18.501 (7.936-43.131)	<0.001
Other chronic disease (not available)	4.071 (2.124-7.802)	<0.001
Diabetes training (yes)	20.245 (8.648-47.392)	<0.001
Treatment (oral antidiabetic)	4.030 (2.252-7.214)	<0.001
Total Elderly Diabetes Burden Scale	0.903 (0.876-0.930)	<0.001

Nagelkerke R Square: 0.672

4. DISCUSSION

4.1. Discussion of Patient Activity Levels

Patient activity in diabetes is the basis of gaining self-management behaviors and successful diabetes management (20). In the study of Hendricks and Rademakers with individuals with chronic diseases; it was found that 23% of the patients were at the first level, 23% at the second level, and 31% at the third level (21). In our study, it was determined that the majority of geriatric diabetics were in the first stage (37.4%), which is the lowest activity level, and only 13.9% were in the fourth stage, which is the highest activity level. The results of the study show that the activity levels of geriatric diabetic individuals are not at the desired level.

One of the most important factors affecting patient activity in diabetes management is advanced age (21). In the study

of Bostouwen et al., a significant difference was found between age and activity scores (22). In the study of Magnezi and Glasser, there was no significant relationship between age and patient activity levels (23). In this study, it was determined that there was a negative significant relationship between the age of individuals with geriatric diabetes and their activity levels, and the activity levels decreased as the age increased. The decrease in all functional living areas with increasing age and other comorbid diseases may have negatively affected the activity levels. The results of the research reveal the necessity of planning different activation initiatives for geriatric individuals.

It has been found that the education level of individuals is closely related to active participation in treatment (14). In

the study of Yadav et al., it was determined that the level of activity of individuals with COPD decreases as the education level decreases (24). Similar to the literature, it was found that the activity scores of individuals with diabetes who were at undergraduate or higher education level were higher. As the level of education increases, reaching, acquiring and using information gradually increases, and this may have positively affected the activity levels of individuals.

An individual with diabetes is expected to be able to perform treatment practices and adapt to lifestyle changes in patient activation (8). In this study, it was determined that the activity levels of individuals using only oral antidiabetic or only insulin were higher than individuals using both treatment methods. In diabetes management, people may need to change their lifestyle or take oral antidiabetic treatments to reach target HbA1c levels. Individuals using insulin therapy should monitor their blood sugar regularly, inject the correct insülin dose. The necessity of multiple activation applications may have caused a decrease in activation levels in individuals using both treatment methods.

Diabetes gives rise to organ and function losses owing to the complications it develops in the individual and negatively affects the quality of life (10). In our study, it was detected that the mean PAM scores of individuals with acute and chronic complications were lower than those without complications. Considering that individuals' adherence to treatment increases as their activation levels increase, it is thought that successful diabetes management and high activation reduce complications, while low activation increases complications.

Multiple chronic diseases make the medical management of the disease more challenging, which increases the burden of disease in individuals. It was determined that the activity levels of diabetic individuals with additional chronic diseases were lower (25). It was determined that the mean PAM scores of individuals with other chronic diseases were lower. In addition to diabetes, individuals may have difficulty in maintaining multiple treatment and care practices due to other chronic diseases, and this may be the reason for low patient activity.

4.2. Discussing the Relationship Between Patient Activity Level and Diabetes Burden

It has been stated that to minimize the negative effects of the disease and improve the quality of life in individuals with diabetes, self-management should be increased and patient activation should be provided for this. Studies in the literature have shown that patient activation is associated with healthy lifestyle behaviors, disease complications, and healthcare use (26, 27). In a study by Cibeles et al., individuals with high levels of activity were found to be more likely to exercise regularly, eat healthy, participate in their self-care, and apply to the emergency department less frequently (28). The fact that individuals with high activity levels had lower diabetes burdens in our study is compatible with the literature. It is thought that individuals with high levels of activity cope with the disease and adapt to the current situation with their active participation in treatment and care.

Patient activation is also important for the emotional management of illness. Sacks et al. concluded that individuals with high patient activity had lower levels of depression (26, 27). In our study, it was determined that the burden arising from anxiety had a negative and significant relationship with patient activation levels.

Patient activation influences health behaviors across a wide range of outcomes, such as health information use and the ability to make health-related or treatment-related decisions. It has been reported that individuals with diabetes at activity levels 2 and 4 have much more information about their existing diseases than individuals at level 1, and they have a higher frequency of foot and eye control in the last 12 months (21, 29). In other studies, it was found that higher patient activation was associated with better biometric values such as normal blood pressure and lower lipid levels, and also reduced hospitalizations and emergency room visits (9, 12, 25). In our study, it was found that patient activation levels were negatively correlated with treatment-related burdens such as disease symptoms, insulin, and diet.

5. CONCLUSION

The most important strategy to improve self-management in chronic diseases is to provide patient activation or involve patients in their care. In this study, patients with diabetes were found to have low patient activation levels. Increasing interest in providing individual care has made the concept of patient activation and the factors affecting it important. In this study, it was determined that patient activation was affected by diabetes burden and some patient characteristics. In line with the results; It is recommended to monitor the activity of individuals with diabetes at regular intervals over time, to reduce the diabetes burden of geriatric individuals with low activity levels, to increase the supportive practices aimed at reducing the diabetes burden and increasing their activity levels.

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Clinical and Experimental Health Sciences

Secondary Findings in Turkish Pituitary Neuroendocrine Patients

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ABSTRACT

Objective: A secondary finding (SF) is characterized as a genetic variant that could have medical significance but is not connected to the primary purpose of the testing. SFs were published in various communities with diverse ethnic backgrounds, however, there is limited data for patient groups with specific clinical conditions.

Methods: A total of 46 PitNETs patients were included in this study. The 81 genes recommended by the latest ACMG SF guideline (v3.2) were screened in 46 Turkish pituitary neuroendocrine tumor (PitNET) patients.

Results: For the NGS study, ''The TrueSight One Expanded'' sequencing kit containing 6.704 genes (including all ACMG SF v3.2 genes) was used, and sequencing was performed using the Illumina Nextseq 550 platform. In the 81 genes included in ACMG v3.2, a total of 9.430 variants were detected in 46 patients. After filtration steps, in 3 (6.5%) patients, a total of 4 different pathogenic variants were detected in *LMNA, APOB, RYR2*, and *TTN* genes. The heterozygous c.5464del (p.Ile1822Serfs*8) variant in the *RYR2* gene was novel. Additionally, in 11 patients (23.9%), a total of 13 heterozygous known variants were detected in 5 different genes (*BTD, HFE, GAA, MUTYH*, and *ATP7B*) associated with autosomal recessive diseases.

Conclusion: The limited knowledge about the genetic etiology of PitNETs makes it inevitable that studies conducted in this field will contribute to shedding light on the etiology. This study, being the first investigation of SFs in PitNET patients, will make a valuable contribution to the literature..

Keywords: Pituitary neuroendocrine tumors, secondary finding, next-generation sequencing, american college of medical genetics and genomics

1. INTRODUCTION

Pituitary neuroendocrine tumors (PitNETs, previously known as pituitary adenomas), are tumors that result from abnormal cell growth in the pituitary gland (1). These tumors can affect the function of the pituitary gland and can lead to various hormonal disorders. While most PitNETs are sporadic and not associated with a known genetic cause, there are certain genetic syndromes and familial cases where genetic factors are implicated. In the literature, the most commonly detected variants in cases of PitNETs are found in the *AIP* and *MEN1* genes. Besides these genes, *CDKN1B, PRKAR1A, DICER1, TSC1, TSC2*, and *SDHx* genes also play a role in the etiology of PitNETs, although the genetic etiology can be elucidated in only about 5% of cases (2).

With the widespread use of next-generation sequencing (NGS) technologies, it has become possible to sequence many genes simultaneously. This provides a significant advantage, particularly in cases with genetic heterogeneity, by offering speed and convenience in elucidating the molecular etiology. With NGS, pathogenic variants in genes that may not be directly related to the patient's clinical presentation can be detected. This can create an ethical dilemma regarding whether or not to report these variants to the patient. American College of Medical Genetics and Genomics (ACMG) published recommendations in 2013 on these incidental findings (3). These recommendations focused on reporting pathogenic variants in 56 specific genes, irrespective of the patient's clinical presentation. After several versions and the decision to refer to these findings as secondary findings (SFs), the final version (v3.2) was published in 2023, including

the addition of *CALM1*, *CALM2*, and *CALM3* genes, bringing the total number of genes to 81 (4).

SFs had been studied in many ethnic groups (5, 6, 7, 8, 9, 10). However, investigating SFs in specific medical conditions where the genetic etiology is not fully understood, such as PitNETs, can indeed provide valuable insights into the genetic mechanisms underlying these conditions. Additionally, it could help identify patients who may be at risk for other diseases or conditions, allowing for early intervention and treatment.

Aim of the study is to analyze SFs in Turkish PitNET patients. This is the first report that investigates SFs in patients diagnosed with PitNET.

2. METHODS

2.1. Study participants

Written informed consent was obtained from all patients. For pediatric patients, consent was obtained from their parents. The study was approved by the Ethics Committee of Marmara University (Approval number:09.2022.113).

A total of 46 patients were included in this study. The ages of the cases ranged from 13 to 72, with a mean age of 40 years. Four patients were diagnosed under the age of 18. Of the 46 patients included in this study, 25 were male (54.4%), and 21 were female (45.6%). Only one patient had a positive family history for PitNET. All patients had macroadenoma. The demographic characteristics of the patients are summarized in the Table 1.

2.2. Molecular studies

Whole blood samples were collected from the patients. For DNA isolation, the "Lab-Aid 824 DNA Isolation Kit" (Xiamen Zeesan Biotech Co., Ltd., P.R. China) and the "Lab-Aid 824s Nucleic Acid Isolation Device" (Xiamen Zeesan Biotech Co., Ltd., P.R. China) were used. The purity and concentrations of DNA samples were measured using the Qubit 3.0 Fluorometer (Thermo Fisher Scientific, Waltham, MA). DNA samples that met the purity criteria and had an initial concentration of at least 100 ng in 15 µL were included in the study.

For the NGS study, ''The TrueSight One Expanded'' sequencing kit (Illumina, San Diego, CA, USA) containing 6.704 genes (including ACMG SF v3.2 genes) was used, and sequencing was performed using the Illumina Nextseq 550 platform (San Diego, CA, USA). The analysis of variants was performed using the Sophia DDM® v4 platform (Sophia Genetics, SA, Switzerland). Variants were aligned to the human reference genome, hg19. All variants reported as pathogenic and/or likely pathogenic in ClinVar, as well as variants not reported in ClinVar with a minor allele frequency of <0.1% and classified as pathogenic and/or likely pathogenic according to ACMG criteria (11), were documented. The Varsome (12) and

Franklin (Genoox Ltd, Tel Aviv, Israel) were used to assess the pathogenicity of novel variants according to ACMG criteria.

3. RESULTS

In the 81 genes included in ACMG v3.2, a total of 9.430 variants were detected in all 46 patients. Four of these variants were pathogenic/likely pathogenic variants associated with autosomal dominant inherited disease that the ACMG SF guideline recommends reporting. The rate of identifying SFs in the patients was 6.5% (3/46). Two patients were male and one patient was female. No SF was detected in the pediatric age group of 4 patients. In total, pathogenic variants were detected in *APOB*, *RYR2*, *LMNA*, and *TTN* genes (Table 2). Pathogenic variants were detected in two different genes (*RYR2* and *APOB*) in one patient. All detected variants were in the heterozygous state. Out of the 4 variants, 3 had been previously described variants, while one was a novel variant (c.5464del, p.Ile1822Serfs*8 variant in the *RYR2* gene). There were no common pathogenic variants identified among different patients. Of the identified pathogenic variants, 50% were missense variants, and the remaining 50% were truncating variants. The variant identified in the *LMNA* gene (c.1633C>T, p.Arg545Cys) was submitted to ClinVar once as a pathogenic variant and ten times as a variant of unknown clinical significance (VUS). The variant was evaluated as likely pathogenic based on the comprehensive study by Kandert et al., in 2009 (13) and the pathogenicity classifications in Varsome and Franklin. In one patient, heterozygous known c.1102_1104del (p.Glu368del) pathogenic variant in the *MEN1* gene was detected. Even though the *MEN1* gene is included in ACMG SF v3.2, it was considered a primary finding because it explained the patient's clinical presentation.

In 11 patients (23.9%), 13 heterozygous variants were detected in genes associated with autosomal recessive diseases. In one patient, heterozygous variants were detected in both the *MUTYH* and *BTD* genes, while in another patient, heterozygous variants were found in both the *ATP7B* and *BTD* genes. The variants were detected in the following genes; *BTD* (7/13, 53.8%), *MUTYH* (2/13, 15.3%), *ATP7B* (2/13, 15.3%) *HFE* (1/13, 7.6%), and *GAA* (1/13, 7.6%) (Table 3). Apart from the c.1330G>C variant detected in four different patients and the c.1595C>T variant found in three different patients in the *BTD* gene (NM_000060), no other common variants were observed in the patients. Overall, 8 different variants were detected in genes associated with autosomal recessive diseases. Two truncating variants were detected in the *MUTYH* and *ATP7B* genes, one inframe insertion was found in the *MUTYH* gene, and five missense variants were identified in the *BTD*, *GAA*, *ATP7B*, and *HFE* genes. All variants were known as pathogenic and/or likely pathogenic. None of the 3 patients who had pathogenic variants in genes associated with autosomal dominant diseases were carriers of autosomal recessive diseases.

Table 1. The demographic characteristics of the patients and detected variants in the patients

Patient no.	Age	Gender	Age at Diagnosis	Family history of pituitary adenoma	PitNET subtype	Variant detected in the patient
1	17	Male	11	-	Somatotroph	-
2	44	Male	42	-	Somatotroph	-
3	54	Male	32	+	Somatotroph	-
4	43	Female	41	-	Gonadotroph	-
5	50	Female	49	-	Somatotroph	*TTN* heterozygous c.69415C>T p.Arg23139*
6	57	Female	55	-	Gonadotroph	1-*MUTYH* heterozygous c.411_416dup p.Trp138_Met139insIleTrp 2 – *BTD* heterozygous c.1330G>C p.Asp444His
7	63	Male	60	-	Corticotroph	-
8	49	Female	47	-	Gonadotroph	1-*ATP7B* heterozygous c.3583G>A p.Ala1195Thr 2-*BTD* heterozygous c.1330G>C p.Asp444His
9	29	Male	27	-	Prolactinoma	-
10	30	Male	29	-	Prolactinoma	*LMNA* heterozygous c.1633C>T p.Arg545Cys
11	66	Female	65	-	Corticotroph	-
12	36	Female	35	-	Gonadotroph	-
13	41	Female	37	-	Corticotroph	-
14	38	Female	36	-	Somatotroph	-
15	36	Male	35	-	Somatotroph	-
16	52	Male	48	-	Gonadotroph	-
17	26	Male	22	-	Somatotroph	-
18	32	Female	31	-	Somatotroph	*MEN1* heterozygous c.1102_1104del p.Glu368del (not a secondary finding)
19	17	Male	8	-	Thyrotroph	*BTD* heterozygous c.1595C>T p.Thr532Met
20	42	Female	36	-	Corticotroph	-
21	49	Male	47	-	Gonadotroph	-
22	53	Female	48	-	Corticotroph	*BTD* heterozygous c.1595C>T p.Thr532Met
23	72	Male	67	-	Gonadotroph	*ATP7B* heterozygous c.19_20del p.Gln7Aspfs*14
24	25	Female	20	-	Somatotroph	*GAA* heterozygous c.896T>C p.Leu299Pro
25	56	Male	51	-	Null-cell	-
26	48	Male	47	-	Gonadotroph	-
27	20	Female	15	-	Prolactinoma	-
28	44	Female	41	-	Corticotroph	*BTD* heterozygous c.1330G>C p.Asp444His
29	31	Male	29	-	Prolactinoma	*MUTYH* heterozygous c.817del p.Ala273Profs*32
30	65	Male	50	-	Somatotroph	-
31	51	Male	43	-	Somatotroph	-
32	49	Female	38	-	Somatotroph	-
33	44	Female	33	-	Somatotroph	*RYR2* heterozygous c.5464del p.Ile1822Serfs*8 *APOB* heterozygous c.13151T>C p.Leu4384Pro
34	33	Male	22	-	Somatotroph	-
35	36	Male	33	-	Somatotroph	-
36	49	Male	46	-	Prolactinoma	-
37	65	Female	62	-	Corticotroph	*BTD* heterozygous c.1595C>T p.Thr532Met
38	36	Male	35	-	Prolactinoma	*BTD* heterozygous c.1330G>C p.Asp444His
39	26	Female	23	-	Corticotroph	-
40	38	Male	23	-	Somatotroph	-
41	25	Female	24	-	Somatotroph	-
42	43	Female	38	-	Plurihormonal	-
43	28	Female	18	-	Plurihormonal	-
44	49	Male	47	-	Somatotroph	-
45	46	Male	45	-	Prolactinoma	*HFE* heterozygous c.845G>A p.Cys282Tyr
46	36	Male	35	-	Prolactinoma	-

Table 2. *Pathogenic variants detected in 81 ACMG recommended genes*

Gene	Refseq mRNA	Zygosity	Nucleotide change	Amino acid change	Clinvar	Varsome	Franklin	Turkish variome	Disease
TTN	NM_001256850	het.	c.69415C>T	p.R23139*	P,LP	P	P	N/A	DCM
LMNA	NM_005572	het.	c.1633C>T	p.R545C	P,VUS	LP	LP	N/A	DCM
RYR2	NM_001035	het.	c.5464del	p.I1822Sfs*8	-	LP	LP	N/A	CPVT
APOB	NM_000384.3	het.	c.13151T>C	p.L4384P	P	LP	LP	0.0354%	FH

het: heterozygous; P: Pathogenic, LP: Likely pathogenic, VUS: Variant of unknown clinical significance, N/A: not available, DCM: Dilated cardiomyopathy, CPVT: Catecholaminergic polymorphic ventricular tachycardia, FH: Familial hypercholesterolemia

Table 3. *Variants detected in genes associated with autosomal recessive diseases*

Gene	Refseq mRNA	Zygosity	Nucleotide change	Amino acid change	Clinvar	Disease	No. of cases	Turkish variome
BTD	NM_000060	het.	c.1595C>T	p.T532M	P	Biotinidase deficiency	3	0.19%
			c.1330G>C	p.D444H	P,LP,VUS		4	N/A
MUTYH	NM_001048171	het.	c.817del	p.A273Pfs*32	P,LP	MUTYH-associated polyposis	1	N/A
			c.411_416dup	p.W138_M139insIW	P		1	N/A
ATP7B	NM_000053	het.	c.3583G>A	p.A1195T	LP,VUS	Wilson disease	1	0.13%
			c.19_20del	p.Q7Dfs*14	P,LP,VUS		1	0.06%
HFE	NM_000410	het.	c.845G>A	p.C282Y	P	Hereditary hemochromatosis	1	0.3275%
GAA	NM_000152.5	het.	c.896T>C	p.L299P	P	Pompe disease	1	N/A

het: heterozygous, N/A: not available; P: Pathogenic, LP: Likely pathogenic, VUS: Variant of unknown clinical significance

4. DISCUSSION

The aim of this study was to investigate variants in the 81 genes from the ACMG SF v3.2 in Turkish PitNET patients. Four different pathogenic variants were detected in 3 out of the 46 patients (6.5%). Pathogenic variants were detected in *APOB*, *RYR2*, *LMNA*, and *TTN* genes. In a study conducted with 622 cases in the Turkish population, no pathogenic variants were detected in the *TTN* and *LMNA* genes in any of the patients (7). However, variants were found in the *RYR2* and *APOB* genes in one case each (7). But different variants were detected compared to the variants identified in this study. Hence, it is not yet possible to discuss founder variants in these genes within the Turkish population. The variants identified in the *LMNA*, *TTN*, and *RYR2* genes were not found in the 3.362 Turkish exome/genome data (14). The variant identified in the *APOB* gene was found at a frequency of 0.0354% in the Turkish variome data (14). This indicates that it is a very rare variant in the Turkish population. In this study, the frequency of the variant identified in the *APOB* gene was 0.02%, and there was no significant difference compared to the Turkish variome.

Functional studies had previously been conducted on the effect of the c.1633C>T (p.Arg545Cys) variant in the *LMNA* gene (15). This variant had been shown to cause nuclear morphological changes such as a continuous double membrane with lobulation. Additionally, an abnormal distribution of transcriptionally active RNA polimerase II had been demonstrated in the myoblasts of patients with this variant. This variant had also been shown to cause impaired distribution and function of proteasomes. In summary, both clinically and functionally, the pathogenicity of the variant had been demonstrated.

It had been shown that tissues with the p.Glu368del variant in the *MEN1* gene exhibit reduced expression of menin (16). Additionally, it has been shown that the intracellular stability of the produced menin protein is affected (16).

Functional studies for the identified *TTN* (c.69415C>T; p.R23139*) and *RYR2* (c.5464del; p.I1822Sfs*8) variants have not been found in the literature. Therefore, detailed molecular studies are needed for these variants to understand their implications.

Since 2013, studies aiming to determine the frequency of SFs have been published in various communities with diverse ethnic backgrounds (5, 6, 7, 8, 9, 10, 17, 18). In these publications, the frequency of SFs varies between 1.2% (16) and 12% (18), while in Turkish literature (7), the frequency was 2.1%. It is important to emphasize that the difference in frequencies is not solely attributable to different ethnic groups. The significant disparity in the findings of the two studies conducted within Qatar can likely be attributed, at least in part, to the differences in the sequencing techniques (19, 20). Furthermore, differences in variant classification criteria and the inclusion of more recent evidence at the time of publication may have contributed to these disparities.

There is limited data available for patient groups with specific clinical conditions. To the best of our knowledge, there are two publications in the literature that have studied populations with specific clinical conditions (21, 22). In one of the studies, a total of 85 medically actionable genes, including the 59 genes from ACMG SF v2.0, were analyzed in 836 non-obstructive azoospermia patients (21). The rate of detecting SFs was determined to be 3.6% in the 85 genes and 3.3% in the ACMG v2.0 genes. SFs were detected most frequently in genes associated with cardiac

diseases and cancer. In the other study, ACMG SF v3.0 genes and an additional four genes (*HBB*, *HSD32B*, *G6PD*, and *ACADM*) were investigated in 130 trios from African families with non-syndromic orofacial clefts (22). In a total of 390 patients, pathogenic/likely pathogenic variants in the ACMG SF v3.0 genes were detected in 9 individuals (2.3%). Pathogenic variants were identified in *PALB2*, *RYR1*, *LDLR*, and *PRKAG2* genes. Additionally, pathogenic variants of *HBB* were identified in 45 individuals, which accounts for 11.5% of the cases. The frequency of SF detected in this study (6.5%) is higher than that in the two previous studies. When genes were selected based on ACMG SF v3.0 and v2.0, the SF detection frequencies in this study were 6.5% and 4.3%, respectively, which are also higher than those in previous studies. Therefore, the high frequency cannot be solely attributed to the greater number of genes in ACMG SF v3.2. In addition to differences in ethnic background, sequencing methods, and variant analysis, this study has also demonstrated that the selected patient group can influence SF detection rate. When examining the relationship between the clinical characteristics of the patients and the detection rates of SFs, no significant relationship was found with either the type of PitNETs or the age at diagnosis.

It is not recommended to report heterozygous variants in the *BTD*, *ATP7B*, *MUTYH*, *HFE*, and *GAA* genes. Furthermore, as highlighted in previous literature, informing the patient about carrier status in countries with a high rate of consanguineous marriages is important for enabling the planning of prenatal and preimplantation genetic tests for future generations (7, 10). Moreover, there is broad consensus that individuals with the monoallelic *MUTYH* allele have an increased risk of colorectal cancer (23). So, it is important to follow-up these patients to provide early diagnosis. Two different heterozygous pathogenic variants have been identified in the *MUTYH* gene in two different patients. One of the variants was a truncating variant, while the other was an in-frame duplication. The carrier frequency identified in this study (4.3%) is significantly higher than the previously reported frequency of 1.2% (7). There are studies that demonstrate a relationship between *MUTYH* and pancreatic neuroendocrine tumors (24, 25), however no relationship between *MUTYH* and PitNET has been reported to date. Considering the common genetic characteristics of neuroendocrine tumors and high expression of MUTYH in the pituitary gland , it can be hypothesized that there might be a potential relationship between *MUTYH* and PitNET. The higher frequency of *MUTYH* variants detected in our study could be related to this potential association with PitNET pathogenesis; however, further research is needed on this topic.

While there have been publications reporting an increased frequency of PitNET in association with pathogenic variants in Lynch syndrome related genes (26), in our study, no pathogenic variants were found in cancer susceptibility genes, including Lynch syndrome related genes. This result suggests that there could be a different process involved in the development of PitNET, distinct from known

cancer-related genes/pathways. Nevertheless, the limited number of patients in the study should be considered.

5. CONCLUSION

Overall, investigating secondary findings in diseases with unknown or complex genetic etiologies can significantly advance our knowledge of these conditions, improve clinical management, and potentially lead to novel therapeutic strategies. It underscores the importance of ongoing genetic research and the integration of genetics into clinical practice. Therefore, this study, by investigating secondary findings in PitNET cases for the first time, will make a significant contribution to the literature.

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Non-Structural Protein-13 Mutations in European Isolates of SARS-CoV-2 Changed Protein Stability

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ABSTRACT

Objective: Severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) became one of the most important health problems of the 21st century. Non-structural protein-13 (nsp13/helicase) plays an important role in the replication of the viral genome and the viral life cycle. The SARS-CoV-2 genome has undergone thousands of mutations since the disease first appeared. Mutations pose a threat to the validity of therapeutics due to changes in protein structure. Modeling alterations caused by mutations in the viral proteome contributes to the development of effective antivirals. The changes in protein structure and stability caused by mutations seen in European isolates of SARS-CoV-2 were analyzed in the study with the aim of contributing to studies on the development of new anti-virals and the validity of existing therapeutics.

Methods: The changes in protein structure after mutation were modeled with deep learning algorithms. The alterations in protein stability were analyzed by SDM2, mCSM, DUET and DynaMut2.

Results: The mutation analysis revealed four (Pro77Leu, Gly170Ser, Tyr324Cys, and Arg392Cys) missense mutations in the nsp13 protein in European isolates of SARS-CoV-2. Mutations caused changes in protein structure (rmsd 0.294 Å) and stability (-4.37 ≤ ΔΔG ≤ .085 kcal.mol^{-1}). The atomic interactions formed by the mutant residues in the three-dimensional conformation of the protein have changed.

Conclusions: The mutations seen in European isolates for nsp13 of SARS-CoV-2 may lead to the emergence of different phenotypes in terms of viral activity. For this reason, the study may contribute to the success of the fight against the virus with different treatment approaches in different regions.

Keywords: SARS-CoV-2, COVID-19, helicase, nsp13, mutation

1. INTRODUCTION

Severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), the pathological agent of Coronavirus Disease-2019 (COVID19), one of the most important health problems of the 21st century, is a positive polarity RNA virus (1). SARS-CoV-2 has caused 704 million people to become ill and more than 7 million deaths since its emergence in December 2019 (2). The SARS-CoV-2 genome, which is 29.9 kb in size, consists of two overlapping open reading frames (ORF1ab and ORF1a), four structural proteins (spike, envelope, nucleocapsid and membrane) and six accessory proteins (ORF3a, ORF6, ORF7a, ORF7b, ORF8 and consists of ORF10) (3). The twelve open reading frames (ORFs) encoded by the RNA genome of SARS-CoV-2 regulate the viral cycle. Non-structural protein (nsp) – 13 is one of sixteen non-structural proteins encoded by ORF1ab. nsp13 is a non-structural protein belonging to helicase superfamily 1B. SARS-CoV-2 helicase (nsp13) catalyzes a 5'–3'

direction unwinding process in the presence of nucleotide three phosphate to transform duplex oligonucleotides (RNA or DNA) into single strands (4,5). Helicases perform numerous biological functions like as transcription, mRNA splicing, mRNA export, RNA stability, translation, mitochondrial gene expression, and nucleic acid packaging into virions. The SARS-CoV-2 helicase plays a vital role in the replication of the viral genome and the maintenance of the viral life cycle. Therefore, inhibition of the helicase of SARS-CoV-2 is one of the main targets of anti-viral drug studies (6–8). The genomes of RNA viruses face a high risk of mutation with each replication cycle (9). Thousands of mutations have been seen in the SARS-CoV-2 genome since the disease was first detected (10). These mutations resulted in significant changes in the clinical manifestations of the disease. For the SARS-CoV-2 genome, some of these mutations aggravated

clinical findings, increased human-to-human transmission, and mortality rates, while others caused a decrease in the severity of the disease (11,12). Mutations also pose a threat to the validity of therapeutics due to changes in protein structure (13,14). Modeling alterations caused by mutations in the viral proteome contributes to the development of effective antivirals.

A thorough understanding of the functional roles and responses of viral genomes is necessary for success in controlling viral epidemics, which occur every eight years. In this study, the changes in protein structure caused by helicase mutations seen in European isolates of SARS-CoV-2 were investigated with the aim of contributing to the development of valid therapeutics.

2. METHODS

2.1. Study group, genome and proteome data

The mutation data for 1,616 European isolates were obtained from the NCBI Virus database (15). NC_045512.2 and YP_009725308.1 sequences were taken as reference for the SARS-CoV-2 virus nsp13 protein. The sequence data was aligned with the MAFFT (v7.511) multiple sequence alignment program L-INS-i algorithm (16). The scoring matrix BLOSUM 80, and 1 PAM was chosen for the amino acid sequences, and nucleotide, respectively (17,18). The gap opening penalty was used as 2.0. The mutated residues were analysed MegaXI (19). The detected mutant residue information was processed using MegaXI and the mutant nsp13 protein sequence was compiled.

2.2. Protein modelling and quality assessment

The changes caused by the mutations detected in the helicase protein structure were modeled using deep learning algorithms (20). 7NIO was used as a template in protein modelling (21). The quality evaluation of the created mutant protein models was made with QMEAN and MolProbity (22,23). The changes in mutant protein conformation were visualized with PyMOL.

2.3. Protein stability analyses

The changes in helicase protein stability and atomic interaction caused by nsp13 mutations of SARS-CoV-2 detected in European isolates were analysed with SDM2, mCSM, DUET, and DynaMut2 tools.

3. RESULTS

The mutation analysis revealed four (Pro77Leu, Gly170Ser, Tyr324Cys, and Arg392Cys) missense mutations in the nsp13 protein in European isolates of SARS-CoV-2 (Figure 1). Mutant sequence data were modeled on reference sequence (Figure 2).
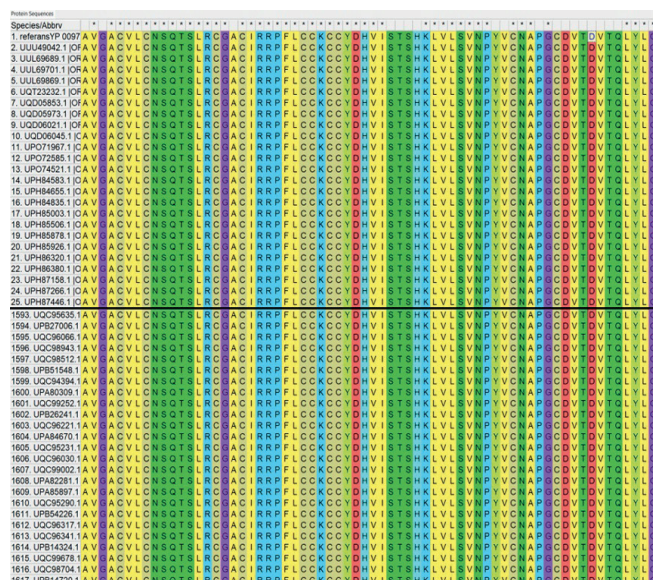
Figure 1. Aligned sequence representation of the nsp13 protein of SARS-CoV-2 in European isolates

Figure 2. Aligned representation of wild and mutant nsp13 proteins.

The obtained mutant protein sequence data were modelled with the Robetta tool using deep learning algorithms. The quality of the mutant protein models created was highly reliable and within acceptable limits (Figure 3). Z-score was in the .55 ± .34 – .13 ± .32 range. Model confidence values were .88. Mutations caused changes in nsp13 protein conformation and topological structure. The rmsd value at superimpose was .294 Å (Figure 4). The Pro77Leu mutation in the nsp13 protein of SARS-CoV-2 caused a decrease in protein stability (-.58≤ ΔΔG≤.003 kcal.mol^{-1}). A change in the nsp13 tertiary structure atomic interaction was observed after the Pro77Leu mutation in the nsp13 protein of the SARS-CoV-2 European isolates. The tertiary structure stability provided by proline with one polar, one hydrogen bond, and two hydrophobic interactions at the 77th position in the wild type was provided with one polar and four hydrophobic interactions after the mutation (Figure 5).
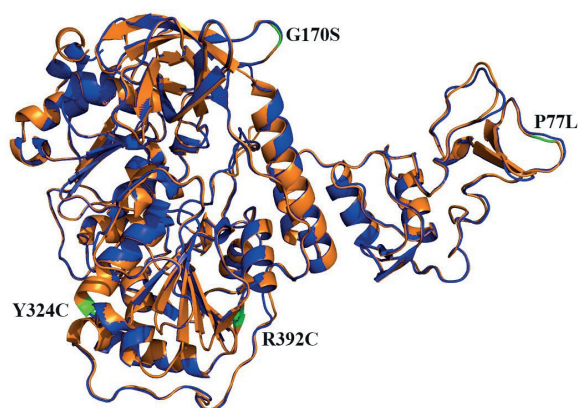
Figure 3. Cartoon illustration of the nsp13 mutations detected in European isolates of SARS-CoV-2 on the protein tertiary structure.
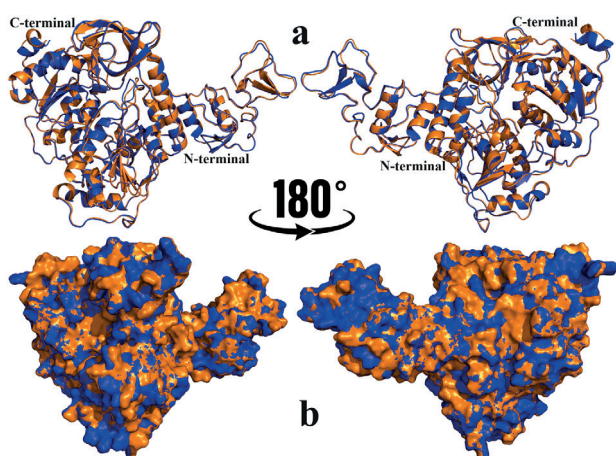
Figure 4. Superimposed illustration of the nsp13 protein of SARS-CoV-2 (blue color indicates wild type nsp13, orange color indicates mutant type nsp13). a) Superimposed cartoon illustration of the nsp13 protein of SARS-CoV-2, b) Superimposed of the nsp13 protein of SARS-CoV-2.
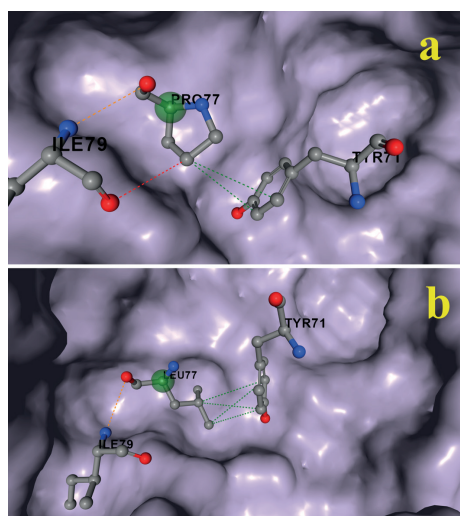
Figure 5. Illustration of the change in the atomic interaction of residue 77 in the P77L mutation of nsp13 detected in European isolates of SARS-CoV-2. a) wild type nsp13, b) mutant type nsp13 (indicates that green dots-hydophobic, orange dots-polar interaction, red dots-hydrogen bond)

The Gly170Ser mutation in the nsp13 protein of SARS-CoV-2 caused a decrease in protein stability ($-4.37 \leq \Delta\Delta G \leq -.75$ kcal.mol^{-1}). A change in the tertiary structure atomic interaction was observed after the nsp13 protein Gly170Ser mutation in European isolates of SARS-CoV-2. While Glycine at the 170th position in the wild type ensured the stability of the tertiary structure with one polar interaction, it did not form an interaction with the surrounding residues after mutation.

The Tyr324Cys mutation in the nsp13 protein of SARS-CoV-2 caused a decrease in protein stability ($-1.581 \leq \Delta\Delta G \leq -.46$ kcal. mol^{-1}). A change in the tertiary structure atomic interaction was observed after the Tyr324Cys mutation detected in the nsp13 protein in European isolates of SARS-CoV-2. The tertiary structure stability provided by Tyrosine at the 324th in the wild type with five polar, twelve hydrophobic, and one Van der Waals interaction was reduced to three polar, four hydrophobic interactions after mutation (Figure 6).
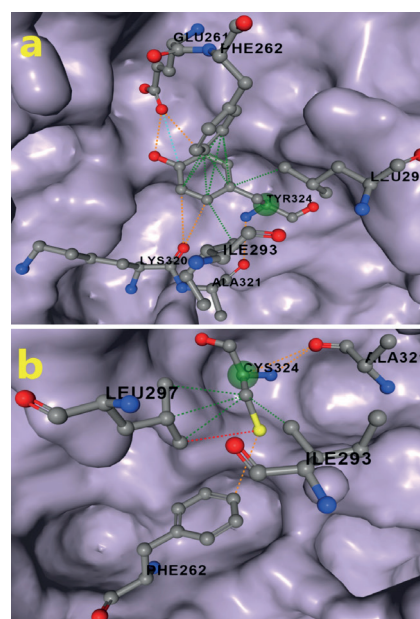
Figure 6. Illustration of the change in the atomic interaction of residue 324 in the Y324C mutation of nsp13 detected in European isolates of SARS-CoV-2. a) wild type nsp13, b) mutant type nsp13 (indicates that green dots-hydophobic, orange dots-polar interaction, red dots-hydrogen bond)

The Arg392Cys mutation in the nsp13 protein of SARS-CoV-2 caused a decrease in protein stability ($-.496 \leq \Delta\Delta G \leq .85$ kcal. mol^{-1}). A change in the tertiary structure atomic interaction was observed after the nsp13 protein Arg392Cys mutation in European isolates of SARS-CoV-2. The tertiary structure stability provided by arginine with four polar interactions and one hydrogen bond at the 392th position in the wild type was reduced to four polar interactions after mutation (Figure 7).
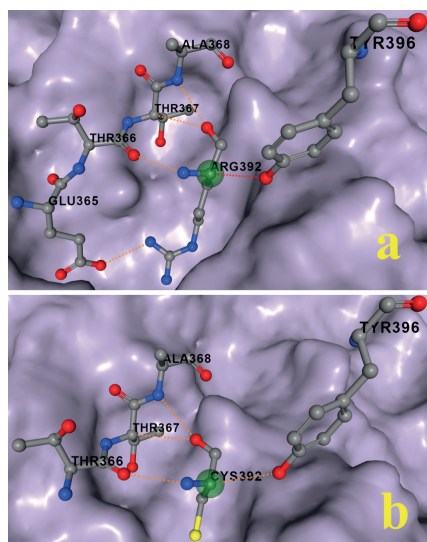
Figure 7. *Illustration of the change in the atomic interaction of residue 392 in the R392C mutation of nsp13 detected in European isolates of SARS-CoV-2. a) wild type nsp13, b) mutant type nsp13 (indicates that green dots-hydophobic, orange dots-polar interaction, red dots-hydrogen bond)*

4. DISCUSSION

The study revealed that mutations seen in European isolates of SARS-CoV-2 nsp13, an important antiviral target, caused changes in protein stability. The functional roles of proteins are formed by the dynamic movement and stability of their molecules (24,25). Mutations in the primary sequences of proteins can alter tertiary structure, stability and function (26,27).

Regional-based evaluation of mutations, especially in viral epidemics, is important in terms of the behavior of the virus in the cellular invasion process, the progression of the epidemic, and determination of treatment options (28). SARS-CoV-2 has undergone thousands of mutations since the beginning of the epidemic, resulting in significant changes in its genome and protein structure (29–31).

Many of these changes have emerged as viral properties such as increased affinity for the angiotensin-converting enzyme-2 receptor and faster host transmission (32–34). The increase of virus in the host cell is associated with increased replication cycle and helicase activity. The opposite is also possible. Viral proteome rearrangements caused by mutations in the virus can increase or decrease the virulence effect (35).

The interaction of active protein molecules and the target nucleic acid sequence in the activation and regulation of replication, transcription, and translation processes occurs with the contribution of special structural motifs such as zinc fingers (36,37). Zinc finger domain mutations cause changes in target nucleic acid/protein and protein/protein interactions (38–40). Our findings showed that the Pro77Leu mutation in the zinc finger region located at the N-terminus of SARS-CoV-2 nsp13 caused a decrease in protein stability ($\Delta\Delta G^{Pro77Leu}$ range from -.58 to +.003 kcal.mol^{-1}) and a change in its conformation.

Considering the functional roles of zinc finger structural motifs, these changes in protein stability are likely to lead to significant changes in the functional properties of the helicase (41,42). Akbulut, in his in-slico study analysing the mutations seen in Chinese isolates, showed that mutations in the zinc finger structural motif located in the N-terminal region caused changes in protein structure and stability, and these changes resulted in a decrease in protein-nucleic acid affinity (35).

The mutations, Tyr324Cys and Arg392Cys, detected in the 1A domain of nsp13 of SARS-CoV-2 indicate a decrease in protein stability. Domains 1A and 2A of nsp13 of SARS-CoV-2 contain the Rossman fold, one of the common structural motifs in nucleotide binding regions. It is thought that the changes in stability caused by the two mutations in the 1A domain, where this structural motif, which stands out with its substrate binding properties, is located, may also trigger changes in the activity of the helicase. Grimes et al. in their study, they revealed that the Ala336Val mutation in the 1A domain preserved the ability of the SARS-CoV-2 helicase to associate with core replication proteins nsp 7, 8 and 12, but caused impairment in helicase unwinding and ATPase activity (43).

5. CONCLUSION

The study data revealed that four missense mutations detected in the helicase protein in European isolates of SARS-CoV-2 caused a decrease in protein stability. The mutations and resulting changes are not only a threat to the functional roles of viral proteins but are also important for the validity of existing therapeutics. Topological and stability changes in targeted therapeutic binding sites are important for the validity of developed therapeutics. The changes resulting from these mutations may increase or, conversely, reduce the effectiveness of inhibitors. The mutations seen in European isolates for nsp13 of SARS-CoV-2 may lead to the emergence of different phenotypes in terms of viral activity. For this reason, the study may contribute to the success of the fight against the virus with different treatment approaches in different geographical regions.

Author Contributions:
Research idea: EA
Design of the study: EA
Acquisition of data for the study: MEA
Analysis of data for the study: MEA
Interpretation of data for the study: EA, MEA
Drafting the manuscript: EA, MEA
Revising it critically for important intellectual content: EA
Final approval of the version to be published: EA

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Is Bruxism an Influential Factor on Mandibular Condyle Morphology?

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ABSTRACT

Objective: The objective of this study is to assess condyle morphology through panoramic radiographs and investigate the impact of variables such as bruxism, age, gender, education level, chewing habits, and income level on the morphology of the condyle.

Methods: Condyle morphology was assessed across four categories (bird's beak, diagonal diamond, crooked fingers, and oval) in panoramic radiographs featuring 200 patients in this study. Bruxism, age, gender, education level, chewing habits, and income level were classified based on the responses provided in the questionnaires by the individuals in the study.

Results: Among the 100 bruxist patients, 3 exhibited awake, 41 displayed sleep, and 56 manifested both awake and sleep bruxism. Significant differences were observed in the morphology of the left condyle (p < .05). In the 26-40 age group, there was an increase in the appearance of bird's beak, diagonal diamond, and crooked fingers, while the oval condyle's appearance decreased (p < .05). Males showed a greater prevalence of bird beak appearance (p < .05). A rise in education level correlated with increased occurrences of bird beak, diagonal diamond, and crooked finger appearances (p < .05). In the presence of bruxism, there was a statistically higher prevalence of bird's beak and diagonal diamond-shaped condyles (p < .05).

Conclusion: The outcomes of this study on condyle morphology are influenced by bruxism, age, gender, and education level. Individuals experiencing both awake and sleep bruxism exhibit a more pronounced impact on condyle morphology. To ascertain a genuine causal relationship, prospective cohort studies are imperative.

Keywords: Mandibular condyle, bruxism, gender, educational status

1. INTRODUCTION

The temporomandibular joint (TMJ) is a diarthrodial joint positioned just in front of the external auditory canal, between the mandibular fossa below the temporal bone and the condyle of the mandible. The TMJ serves to maintain equilibrium among craniomandibular structures. The interplay of occlusion, TMJ, and masticatory muscles contributes to the overall balance within this system. Continuous restructuring of the TMJ is a dynamic process aimed at preserving the mechanical and functional relationship between its articular surfaces (1,2). Temporomandibular disorders (TMD) are prevalent conditions affecting the TMJ, masticatory muscles, and associated structures, marked by pain and limitations in mouth movements. Pain, predominantly arising from the chewing muscles, often prompts suspicion of bruxism as a potential etiological factor. (3).

Bruxism is a repetitive jaw muscle activity characterized by grinding and clenching of the teeth. This detrimental parafunctional habit imposes excessive stress on the stomatognathic system (4). Despite indications of psychosocial, pathophysiological, and environmental factors in its etiology, some argue that bruxism is more physiological

than pathological, given its prevalence in the general population. As such, it is believed to have a multifactorial etiology (5). Bruxism manifests in two subtypes: 'Awake Bruxism' and 'Sleep Bruxism' (6,7).

In the literature, TMJ morphology has been investigated through diverse methods, including dry and autopsy human skulls, radiographic examinations, magnetic resonance imaging, computed tomography, and cone beam computed tomography (CBCT) (8). The American Academy of Oral and Maxillofacial Radiology advocates for the use of panoramic radiography to assess the structural components of TMJ, citing its advantages of lower radiation dose and cost in comparison to computed tomography (9).

In cases where there is a discrepancy between occlusion, TMJ, and masticatory muscles, a natural balance ensues. However, this equilibrium may lead to alterations in the foundational elements, manifested through structural changes in the condyle, occlusal issues, muscle tension, and the resulting loads. Internal joint diseases and similar symptoms may arise as a consequence of this balance

formation. These symptoms may either be inconspicuous or signify an inconsistency, indicating destabilization during the establishment of equilibrium between the newly configured morphological form and function. Consequently, while formulating treatment plans for this region, due consideration should be given to the function of the craniomandibular system and the factors influencing it (10). Moreover, studies in the field of public health highlight that individuals with low socioeconomic status face more health problems, which can impact the morphological structure discussed earlier (11). Therefore, income level and education level may also be effective factors in the craniomandibular system. In this study, in addition to the effects of bruxism, age, gender, and chewing habits on condyle morphology, it was aimed to investigate the accuracy of the stated hypothesis by evaluating the relationship between income level-condylar morphology and education level-condylar morphology.

2. METHODS

2.1. Study Design and Sample

Using the G*Power program (3.1.9.2, Franz Faul, Universität Kiel, Germany), it was ascertained that the study population should be a minimum of 58 individuals, considering actual $\alpha= 0.03$, $\alpha=0.05$, and power $(1-\beta) =0.95$ at a 95% confidence level (12). In this study, the number of patients was set as 200, with 100 individuals allocated to each group (bruxist and non-bruxist). All participants received detailed information about the study and willingly signed an "Informed Consent Form" if they opted to participate. The study protocol, conducted in adherence to the Helsinki Declaration of Human Rights guidelines, received approval from the Necmettin Erbakan University, Faculty of Dentistry, Noninvasive Clinic Ethics Committee (Approval Number 2022/168).

The research excludes patients with missing teeth, excluding third molars, as well as those with neurological disorders, connective tissue and autoimmune diseases, current use of steroids, muscle relaxants, antidepressants, and narcotic drugs. Additionally, individuals who are pregnant or in a pregnancy status, those who have previously used an intraoral splint for bruxism, those younger than 16 years old, with a history of prior TMJ surgery, major trauma to the TMJ, and dentofacial deformities are also excluded from the study.

The study group comprised 100 bruxists (55 females and 45 males, with a mean age of 32.62 years and an age range of 16–69) and 100 non-bruxists (59 females and 41 males, with a mean age of 37.09 years and an age range of 16–68). These individuals sought routine examinations at the Necmettin Erbakan University, Faculty of Dentistry Oral, Dental, and Maxillofacial Radiology Clinic and were assessed based on the criteria for bruxism outlined by the American Sleep Medical Academy (AASM) in 2014 (13).

2.2. Questionnaire

All participants completed a questionnaire (Table 1) based on sociodemographic, chewing habits, and bruxism self-reports. Education and income level information indicating socio – economic status were defined. In figuring out the education level, it was divided into 4 categories: literate, primary education, high school, and university and beyond, based on the Turkish Education System. The income level, on the other hand, was evaluated in 3 categories, based on the Turkish Ministry of Finance, as below the minimum wage, the minimum wage, and above the minimum wage. Chewing habits were evaluated in three categories: Right, left, and bilateral. The presence of bruxism was examined in three categories: Awake bruxism, sleep bruxism, and both awake and sleep.

Table 1. Questionnaire

a. Evaluation of sociodemographic situation and chewing habits		
a.1. Gender	☐ Female ☐ Male	
a.2. Age group	☐ 16-25 ☐ 26-40 ☐ 41-69	
a.3.Education level	☐ Literate ☐ Primary ☐ High ☐ University and above	
a.4. Income level	☐ Below the minimum wage ☐ Minimum wage ☐ Above the minimum wage	
a.5. Chewing habits	☐ Right ☐ Left ☐ Bilateral	
b. Evaluation of awake bruxism		
b.1. During the last 6 months, have you ever been aware of clenching or grinding your teeth while awake? (Yes / No)		
c. Evaluation of sleep bruxism according to the Diagnostic Criteria of the American Sleep Medical Academy in 2014		
c.1. Have you or anyone noticed that you grind your teeth frequently while you sleep? (Yes / No)		
c.2. Have you noticed that your teeth are wearing down more than they should? (Yes / No)		
c.3. Did you notice any of the following symptoms when you woke up? If your answer is yes. mark it. (Yes / No)		
c.3.a. Feeling of tiredness. stiffness or pain in your jaw after waking up (Yes / No)		
c.3.b. A feeling of clenching of your teeth or pain in the jaw after waking up (Yes / No)		
c.3.c. Pain when waking up at your jokes following waking up (Yes / No)		
c.3.d. Difficulty in mouth opening after waking up (Yes / No)		
c.3.e. After waking up. is there a feeling of contraction in the jaw and moving your lower jaw to relax? (Yes / No)		
c.3.f. Clicking sound from the chin following waking up and then passing (Yes / No)		
Presence of bruxism: ☐ None ☐ Awake ☐ Sleep ☐ Both		

To diagnose sleep bruxism, questions aligned with the AASM Diagnostic Criteria were employed (13). For the diagnosis of active sleep bruxism, c.1. of the criteria in Table 1 was used, and sleep bruxism was coded as present if/or at least one symptom from c.2. and an additional c.3. were present. According to both tests, patients with both sleep and awake bruxism were coded as both awake and sleep.

2.3. Clinical Examination

In addition to the objective findings of bruxism, such as wear on teeth, frequent breakage of restorations, and hypertrophy of the masseter muscle, there are also subjective symptoms, such as pain in the temporomandibular, temporal, and neck regions, as well as waking up ("I wake up while biting my tongue") (14).

In the study, the TMJ, masticatory muscles (including the masseter and temporal muscle anterior parts), and trapezius muscle were examined by palpating them extraorally. The examination focused on muscle stiffness, pain during palpation, limited mouth opening, and deviation. The inspection also assessed the presence of facial asymmetry, a square face, and muscle hypertrophy.

The intraoral examination evaluated the presence of bite marks on the tongue, cheek, and lip, tooth wear, fractures in teeth and restorations, xerostomia, and hypermobility.

As a complement to the clinical examination, the radiographic examination evaluated the presence of hypercementosis, periodontal damage, alveolar ridge resorption, pulpal necrosis, and pulp stones.

According to the bruxism categorization proposed by Lobbezoo et al. (4), patients with bruxism were classified with "probable" bruxism based on the questionnaire and clinical examination.

2.4. Radiographic Evaluation

In this study, all panoramic radiographs were captured using a 2D Veraviewpocs instrument (J MORITA MFG corp., Kyoto, Japan) with parameters set at 70 kVp, 5 mA, and an exposure time of 15 s, in accordance with the manufacturer's guidelines.

Condyle morphology was evaluated in four categories: Oval (Figure 1a), crooked finger (Figure 1b), bird beak (Figure 1c), and diagonal diamond (Figure 1d) shape in panoramic radiographs (15).

A seven-year experienced radiologist (SU) evaluated all condyle morphologies. To assess intra-observer agreement, the evaluations were repeated three times with 2 weeks intervals, blinded to the first measurements. According to Cronbach's alpha analysis, intraobserver agreement was excellent (0.903).
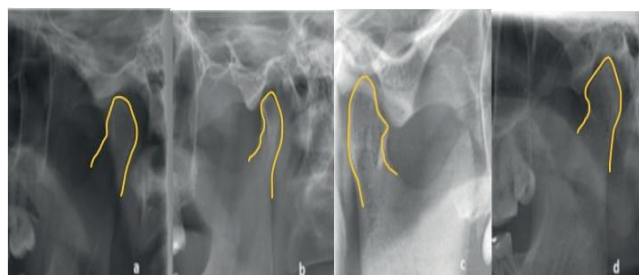
Figure 1. *Types of condyle morphology on panoramic radiography. a. oval; b. crooked finger; c. bird beak; d. diagonal diamond*

2.5. Statistical Analysis

Statistical analysis of the collected data in the study was performed using the IBM SPSS Statistics 22 program (IBM SPSS, Türkiye). The normal distribution of parameters was assessed with the Kolmogorov-Smirnov test, indicating that the parameters did not exhibit a normal distribution. Descriptive statistical methods, including mean, standard deviation, and frequency, were employed to evaluate the study data. The Chi-Square test was utilized for comparing qualitative data, and significance was assessed at the $p < .05$ level.

3. RESULTS

The current study was conducted on 86 males (45 bruxists and 41 non-bruxists) and 114 females (55 bruxists and 59 non-bruxists). The mean age of all individuals was 27 ± 5.7 years (for females 34.36 ± 13.67, for males 35.0 ± 13.75). The distribution of all individuals according to gender, age group, education level, income level, chewing habit, and bruxism status is shown in Table 2. There was no statistically significant difference in the age distribution of individuals based on gender ($p > .05$).
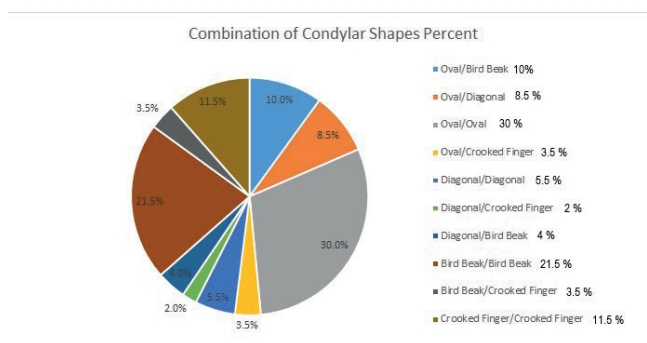
Figure 2. *Combination of the right and left condylar morphology shapes*

Table 2. The distribution of parameters according to the condyle morphology

Parameters	n	%	Right Condyle				p value	Left Condyle				p value
			Oval	Bird Beak	Diagonal diamond	Crooked finger		Oval	Bird Beak	Diagonal diamond	Crooked finger	
Total Sample	200	100.0	87	59	26	28		77	62	25	36	
Gender												
Female	114	57.0	48	29	17	20	.207	46	24	18	26	.002**
Male	86	43.0	39	30	9	8		31	38	7	10	
Age Groups												
16-25 years	64	32.0	36	15	8	5		37	16	6	5	
26-40 years	76	38.0	28	24	11	13	.287	20	26	12	18	.009**
40-69 years	60	30.0	23	20	7	10		20	20	7	13	
Education Level												
Literate	1	0.5	1	0	0	0		0	0	1	0	
Primary	45	22.5	17	10	7	11	.127	13	15	5	12	.018*
High	52	26.0	28	11	8	5		27	15	1	9	
University and above	102	51.0	41	38	11	12		37	32	18	15	
Income Level												
Below the minimum wage	63	31.5	30	16	11	6		29	18	9	7	
The minimum wage	40	20.0	15	10	6	9	.323	15	7	5	13	.056
Above the minimum wage	97	48.5	42	33	9	13		33	37	11	16	
Chewing Habit												
Right	64	32.0	25	19	9	11		24	22	8	10	
Left	36	18.0	17	8	6	5	.821	13	11	6	6	.951
Bilateral	100	50.0	45	32	11	12		40	29	11	20	
Bruxism												
None	100	50.0	50	23	13	14		51	24	7	18	
Awake	3	1.5	1	1	0	1	.396	1	2	0	0	.016*
Sleep	41	20.5	17	15	6	3		10	16	8	7	
Both awake and sleep	56	28.0	19	20	7	10		15	20	10	11	

* p <.05. ** p <.01

Figure 2 shows the distribution of the four condyle types evaluated on the right and left sides. A statistical difference was found between the distribution of right and left condyle morphologies (p = .00). The oval shape was dominant on the right, while the bird's beak and crooked finger shape were dominant on the left (Table 2). Further, looking at the combination of right and left condyle shapes, the statistics in Figure 2 showed the most observed combination was oval/ oval with 30%, and the least observed combination was diagonal/ crooked finger with 2%. While right mandibular condyle morphology was not affected by the factor evaluated (p>0.05), differences were detected in left condyle morphology (p <.05) (Table 2). The bird beak appearance was more dominant in males (p <.05) (Table 2). While the appearance of the bird's beak, diagonal diamond, and crooked fingers increased in individuals in the 26–40 age group, the appearance of oval condyles decreased (p <.05) (Table 2). As the education level increased, there was a significant increase in the occurrence of bird beak, diagonal diamond, and crooked finger appearances (p < .05) (Table 2). The effect of chewing habits and income level on condyle morphology could not be determined (p > .05) (Table 2).

Table 3. The distribution of the right and left condyle shapes according to the presence of bruxism

	Right Condyle				Left Condyle			
	Oval	Bird Beak	Diagonal diamond	Crooked finger	Oval	Bird Beak	Diagonal diamond	Crooked finger
None	50	23	13	14	51	24	7	18
Awake	1	1	0	1	1	2	0	0
Sleep	17	15	6	3	10	16	8	7
Both awake and sleep	19	20	7	10	15	20	10	11
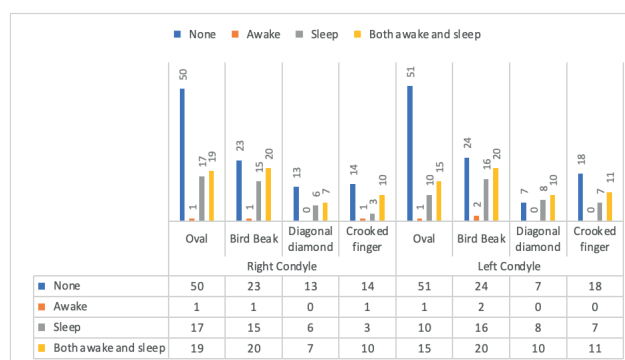
Among 100 bruxist patients, 3 exhibited awake bruxism, 41 had sleep bruxism, and 56 had both awake and sleep bruxism (Table 2). No significant differences were observed between gender and bruxism status, education level and bruxism status, income level and bruxism status, or chewing habit and bruxism status (p > .05). However, the presence of bruxism was statistically higher in individuals 26–40 (p = .01). Table 3 shows the distribution of the right and left condyle shapes according to the presence of bruxism. In the presence of bruxism, the

presence of the bird's beak and diagonal diamond-shaped condyles was statistically higher (p < .05) (Table 2). Multinomial logistic regression analysis, assessing factors influencing left condyle morphology, revealed gender to be significantly more impactful than other factors (p = .003).

4. DISCUSSION

This research meticulously delves into the intricacies of mandibular condyle morphology, utilizing panoramic radiographs as a lens to investigate its nuanced relationships with various factors such as bruxism, age, gender, education level, chewing habits, and income level. The comprehensive nature of this study is carefully designed, not only to advance our current comprehension of mandibular condyle morphology but also to unravel the intricate interplay between lifestyle, demographics, and socioeconomic aspects, shaping the anatomical intricacies of the condyle. Through this exploration, we aim to shed light on the subtle yet significant ways in which these diverse factors collectively contribute to the morphological features of the mandibular condyle, thus enriching our understanding of dental anatomy within the realms of individual diversity and broader societal influences.

The etiology, diagnosis, and treatment of bruxism, as well as its effects on teeth, dental implants, and the stomatognathic system, are becoming increasingly popular topics in the medical literature (16,17). There is currently no universally accepted approach to detect bruxism, given its controversial, ambiguous, and subjective nature, with each diagnostic method having inherent limitations (17). Questionnaires while useful in large-scale studies, may introduce subjective biases. Clinical examinations are suitable for broader study groups, but tooth wear alone is not a conclusive indicator of bruxism due to its cumulative nature and various potential differential diagnoses. Although electromyography (EMG) is useful in small populations, its availability is limited. On the other hand, polysomnography (PSG) is the gold standard for identifying sleep disorders but is only suitable for small samples due to its high cost and limited availability (4). Therefore, a recently proposed diagnostic grading system is recommended for both clinical and research purposes in bruxism. This system encompasses possible bruxism (self-report, questionnaires, anamnestic part of a clinical examination), probable bruxism (self-report plus the inspection part of a clinical examination), and definite bruxism (self-report, clinical examination, and a polysomnographic recording, preferably accompanied by audio/video recordings) (4).

The primary objective of this study was to assess the impact of probable bruxism on mandibular condyle morphology relative to other factors. A study by Rompre et al. (18) delved into the efficacy of polysomnography in diagnosing bruxism, establishing clinical criteria for bruxism based on jaw clenching frequency, tooth erosion, soreness, masseter muscle hypertrophy, and morning chewing muscle pain. Significant differences were noted between the bruxism and control groups. However, the cost and complexity of obtaining electromyographic and polysomnographic recordings for bruxism diagnosis present challenges (4). Pintado et al. (19) addressed this by developing a user-friendly questionnaire method, aligning with the clinical diagnostic criteria proposed by Rompre et al. (18). Given the multitude of parameters and the focus on a larger population, our study utilized a questionnaire and clinical examination for bruxism diagnosis. Moreover, this research provides the added advantage of radiographic analysis, enabling a comprehensive evaluation of the relationship between bruxism and the temporomandibular joint.

The temporomandibular joint (TMJ) stands out as a unique joint, characterized by numerous anatomical and functional features that distinguish it from other joints in the human body (20). Anatomically, the TMJ comprises the mandibular condyle, mandibular fossa, articular processes of the temporal bone, and the soft tissue components of the articular disc and joint cavity (1). Developmental variations, remodeling, diseases, trauma, endocrine disorders, and radiotherapy can induce diverse morphological changes in the size and shape of the mandibular condyle (15). The classification of condyle morphology varies across studies, with CBCT tomography commonly categorizing it as round, angled, convex, or flat (20,22,23). A similar classification, involving round, angled, pointed, and straight categories, was employed by Oliveira et al. (24), Sonal et al. (15) and Anisuzzaman et al. (25) adopted a similar condyle shape classification, dividing it into four groups: Oval, bird's beak, diamond, and crooked finger, akin to the current study. This classification was applied after assessing condyle morphology through panoramic radiographs. Panoramic radiographs persist as the primary screening tool for temporomandibular joint (TMJ) abnormalities among various imaging modalities used for TMJ imaging (26). This method is valued for its simplicity, affordability, and ability to assess the bony components of the TMJ. The utilization of panoramic radiography and double TMJ views is justified by their low radiation dose, accessibility, cost-effectiveness, and capacity to offer substantial morphological information about the TMJ. It proves to be a valuable screening method for identifying condylar abnormalities, including erosions, sclerosis, osteophyte development, resorption, and fractures (8). Additionally, by excluding odontogenic causes and other jaw abnormalities, panoramic radiographs provide information about the teeth, mandible, and maxilla, contributing to the comprehensive diagnosis (27).

In this study, 200 pairs of condyles (100 bruxists (55 females and 45 males) and 100 non – bruxists (59 females and 41 males)) were examined on panoramic radiographs. The shape of the condyle was found to be oval (41%), bird's beak (30.25%), crooked finger (16%), and diamond (12.75%), respectively. In similar studies, oval condyle morphology was found to be the most common, which is consistent with our study, while crooked finger was the least common condyle type, which is different from our study (12,15,25). As in this study, Anisuzzaman et al. (25) and Sonal et al. (15) claimed that the bird's beak follows the oval shape. However,

according to Al-Sadi et al. (12), diamond condyles (15.67%) were the second most common type of condyle.

In contrast to other studies, this investigation specifically assessed whether the studied factors influenced the morphology of both the right and left condyles. The examined factor did not show a significant effect on the morphology of the right mandibular condyle (p > .05). However, changes in the morphology of the left condyle were observed (p < .05). Analyzing the temporomandibular joint for typical symmetry features, the oval-oval combination (%30) emerged as the most prevalent, supporting the findings of Sonal et al. (15). and Al-Saedi et al. (12). The oval-oval combination was deemed the most typical, aligning with the outcomes of another research. Conversely, the combination involving crooked fingers was identified as the least common (12,15). This study found that the combination of crooked finger morphology with other morphologies was less common, with the combination of crooked finger and crooked finger ranking third at 11.5%. 50% of individuals who chew bilaterally may explain this. Because the condyle morphologies in combination are oval-oval (30%), bird beak-bird beak (21.5%), and crooked finger-crooked finger (11.5%). After evaluating all the investigated factors, the most frequently observed condyle morphologies on the right and left were the bird beak and crooked finger following the oval morphology. So, with their symmetrical combinations being more common than the diagonal-diagonal combination.

In our study, a significant difference in condylar morphology between males and females was observed (Table 2). While the oval shape was the most common in both genders, the bird's beak appearance was more prevalent in males (p < .05) (Table 2). This finding aligns with the conclusions of Maqbool et al. (28) and Al-Saedi et al. (12) Comparable results were reported in a dry skull study by Gindha et al. (29). Contrary to previous studies that found no significant association between condyle shape and age, our study revealed that the appearance of bird's beak, diagonal diamond, and crooked finger increased, while oval condylar appearance decreased in individuals aged 26 to 40 years (p < .05) (Table 2) (12,22,23,25,30). This difference in results from other studies on this topic is noteworthy. When the region and culture where the research was conducted are examined, it can be revealed that the age range of 26–40 is the period in which individuals may experience the highest level of stress. Therefore, it can be assumed that the study results stem from the rise in parafunctional habits triggered by heightened stress and anxiety. The main reasons for this include factors such as graduation, job search, marriage, care of dependents, financial concerns caused by increasing expenses, and the effort to balance both materially and spiritually between work and private life. Additionally, the following paragraphs delve into these scenarios, examining the correlation between income level-condyle morphologies and education level-condyle morphologies.

While the overall results of this study align with previous research, it contributes to the field by exploring relationships between financial status and condyle morphology, as well as educational level and condyle morphology topics not extensively investigated in the literature. A significant correlation was found between condyle morphology and educational level. Specifically, bird beak, diagonal diamond, and crooked finger appearances increased with higher education levels (p < .05) (Table 2). This novel insight adds a valuable dimension to our understanding of the factors influencing condyle morphology. However, at this point, it should be considered that since there is no significant difference between economic status and condyle morphology, there may be individual differences in economic level, quality of life, and enjoyment of life. This represents one of our study's limitations. Although almost 50% of the individuals in the study have an economic level of minimum wage or above, the absence of a statistically significant difference shows that there is no decrease in stress levels at the same rate. Tang (31) presents findings that corroborate this assertion in his research on the correlation between income level and quality of life. Tang (31) establishes in his study that there is a positive correlation between income level and the quality of life of individuals. Nevertheless, when he included a criterion of "love of money" in the research, he noticed a negative association between income level and quality of life. It reveals that the obsession with making money affects happiness, satisfaction, and quality of life. On the other hand, the existence of a significant difference with increasing education levels can be attributed to the fact that they do not have the same economic earnings as their peers with lower education levels, nor do they have similar or even more expenses such as accommodation, transportation, and education. Furthermore, the fear of graduating, achieving success, and securing a job, along with the perception of lagging behind peers in life, could potentially link to heightened stress and dysfunctional behaviors, ultimately explaining the outcomes of the study. Robotham and Julian (32) offer evidence for this scenario, referencing a direct relationship between stress levels and the number of students in their comprehensive literature review. Their review covers various aspects of student stress, including factors such as academic pressure, exam stress, financial burdens, the transition to university, and stress related to studying.

Upon thorough literature review, no studies were identified that describe the normal condyle shape in relation to individual chewing patterns. In contrast, Singh et al. (8) reported a statistically significant association (p = .003) between chewing behavior and bilaterally similar condyle morphology. In this study, the round shape was more prevalent in individuals with undetermined chewing habits and those with bilateral chewing habits. Singh et al. (8) categorized condyle shape morphologies according to Chaudhary's classification (33), revealing that the majority of participants had no detectable chewing habits, with 120 (68%) exhibiting bilateral round condyles, 51 (29%) demonstrating bilateral chewing habits, 2 (1%) displaying unilateral left habits, and 3 (2%) having unilateral right habits. Similar findings were reported by Halicioglu et al. (34).

Indeed, there is limited research exploring the association between bruxism and condyle morphology in the literature. Singh et al. (8), in their study examining condyle morphology and parafunctional habits based on Chaudhary's classification (33), observed a higher incidence of bilaterally comparable round condyles in patients without parafunctional habits. Notably, all subjects with parafunctional habits exhibited differences in their condyles. Tao et al. (35) reported similar findings. Our study aligns with the results of Singh et al. (8) and Tao et al. (35). Specifically, a robust association between bruxism and condyle morphology was identified in our investigation, with a statistically higher presence of bird's beak and diagonal diamond condyles in individuals with bruxism ($p < .05$). In contrast, Mortazavi et al. (36) mentioned in their systematic review, the meta-analysis of articles that considered both types of bruxism (awake bruxism and sleep bruxism) did not show a significant association between bruxism and TMJ. These varying outcomes highlight the complexity of the relationship between bruxism and condyle morphology.

Acknowledging the limitations of this study, it is important to note that the demographic studied may not be entirely representative of the entire Turkish population. Enhancing the study's generalizability could be achieved by including a larger and more diverse study group from various locations, ensuring a more homogeneous distribution across factors such as gender, age group, chewing habits, and bruxism. Additionally, factors like different malocclusions, prior bruxism treatment, treatment techniques, duration, and orthodontic treatment could influence mandibular condyle morphology. Including these parameters in future studies could enhance the meaningfulness of the results. Despite these limitations, the study contributes valuable information to the existing body of knowledge.

5. CONCLUSION

In conclusion, this study highlights that various factors such as bruxism, age, gender, and educational level can influence condyle morphology. The observed changes in individuals experiencing both awake and sleep bruxism suggest a more comprehensive impact on condyle morphology than previously understood. Our study offers valuable insights into these complex interactions and underscores the urgent need for prospective cohort studies to further explore cause-and-effect relationships. Such research is crucial for developing effective interventions. Therefore, this study establishes an important foundation for future investigations into the factors affecting condyle morphology.

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Determining Expression Profile of Leucine-Rich Repeating Transmembrane Protein4 (LRRTM4) in Suicide Cases

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ABSTRACT

Objective: Suicide is important in forensic medicine. Studies conducted to determine the etiology of suicide have shown that genetic factors have a critical role along with neuroendocrine changes occurring in the brain. It has been shown that dysregulation in the glutamatergic signaling pathway plays an essential role. One of the glutamatergic genes that causes suicide is the leucine-rich repeating transmembrane protein4 (LRRTM4). In our study, unlike previous studies, we planned to investigate LRRTM4 gene expression levels at mRNA and protein levels by taking samples from the dorsolateral prefrontal cortex (DLPFC) of the brain from autopsy cases. It was aimed to determine whether there is a statistically significant difference in LRRTM4 gene expression levels between suicide and non-suicide cases.

Methods: The study group consisted of 38 suicides. The control group consisted of 30 non-suicidal cases. Samples were taken from the DLPFC in the brain from these cases at autopsy. In the tissue samples obtained LRRTM4 gene expressions were analyzed at the mRNA and protein level using quantitative PCR and western blot methods.

Results: LRRTM4 gene expression values of suicides and non-suicide cases were compared. It was found to be 1.6 times higher in the study group than in the control group.

Conclusion: It has been determined that there is a statistically significant positive relationship between suicide and the LRRTM4. Our findings will contribute positively to the pre-detection of risk factors in suicidal individuals and the medicolegal evaluation. Furthermore, our study will guide further research on the role of genetic factors in the etiology of suicide.

Keywords: Gene expression, leucine-rich repeating transmembrane protein4, glutamate, suicide.

1. INTRODUCTION

Glutamate is the most abundant excitatory neurotransmitter in the central nervous system. It is responsible for memory, learning, and cognitive functions. It also acts as a signal molecule in peripheral tissues and organs and takes part in various steps such as cell migration, cell differentiation, synapse induction. Glutamate exerts its effects through AMPA (α-amino-3-hydroxy-5-methyl-4-isoxazole propionic acid/kainate) and NMDA (N-Methyl-D-Aspartate) receptors located on presynaptic and postsynaptic cell membranes. When glutamate receptors are activated in the postsynaptic cell, some events occur inside the cell, such as activation/inhibition of some enzymes and secondary messengers, and expression/regulation of Ca^{+2}-dependent genes (1).

Gene expression and epigenetic studies have shown that dysregulation of the glutamatergic signaling pathway plays

an important role in suicidal behavior (2,3). Genome-wide association studies (GWAS) are the most common approach used to identify genetic risk factors for suicide. According to these studies, one of the glutamatergic genes involved in suicide is the leucine-rich repetitive transmembrane protein4 (LRRTM4) (4).

The leucine-rich repetitive transmembrane protein (LRRTM) gene family is located on chromosome 2p12 and encodes neuronal leucine-rich repetitive transmembrane protein (4). These genes are expressed in the hippocampus, cerebral cortex, and striatum. LRRTM proteins are synaptic adhesion molecules located on postsynaptic membranes. These molecules form synaptic connections between the presynaptic and postsynaptic membranes and stabilize the membranes. Moreover,

these proteins facilitate the recognition of targets at synapses, determine the specificity of presynaptic and postsynaptic regions, and contribute to synaptic plasticity. LRRTM proteins act as initiators at selectively excitatory synapses but have no effect on inhibitory synapses (5,6). LRRTM proteins perform their functions through three mechanisms: direct association with AMPARs, indirect association with AMPARs by binding to postsynaptic density protein 95 (PSD-95), and transsynaptic interaction with their presynaptic ligand neurexins (7).

The LRRTM gene family is composed of four members: LRRTM1, LRRTM2, LRRTM3, and LRRTM4. LRRTM4 is more similar to LRRTM3, while LRRTM1 is more similar to LRRTM2 (6). Genome-wide association studies have revealed a significant correlation between LRRTM4 and suicide attempts (4). Different studies have linked variations on chromosome 2p12 to suicide attempts in bipolar disorder, alcoholism, or major depression (8,9,10,11).

In our study, we planned to investigate LRRTM4 gene expression levels at mRNA and protein levels by taking samples from the dorsolateral prefrontal cortex of the brain from autopsy cases. It was aimed to determine whether there is a statistically significant difference in LRRTM4 gene expression levels between suicide and non-suicide cases. In our study, unlike previous studies, LRRTM4 gene expressions were investigated at mRNA and protein levels in samples taken directly from the dorsolateral prefrontal cortex localization of the brain.

2. METHODS

Prior to commencing the study, we submitted an application to the Pamukkale University Faculty of Medicine Clinical Research Ethics Committee and obtained approval with decision number 60116787-020/53631 dated 09/09/2020 Our study was supported by Pamukkale University Scientific Research Projects Coordination Unit under project number 2021TIPF007.

2.1. Samples Set

Our study included 68 autopsy cases performed between 10/09/2020 and 09/09/2021 in the Department of Forensic Medicine at Pamukkale University Faculty of Medicine.

The study group consisted of 38 suicide cases, 31 male and 7 female. The causes of death in suicide cases were hanging, oral drug intake, parenteral drug intake, gunshot wounds, strangulation, and jumping from a height. The control group consisted of 30 cases, 27 male and 3 female, whose cause of death was not suicide. The control group included sudden cardiac deaths, firearm injuries, traffic accidents, murders, and other accidents (work accidents, drowning in water).

During the autopsy, we took 1 cm³ brain tissue samples from the BA9 (Brodmann Area9) area of the dorsolateral prefrontal cortex (DLPFC) from the cases. We stored tissue samples in cryotubes in RNA later solution at − 80°C.

2.2. RNA Isolation and cDNA Synthesis

We isolated total RNA from brain tissue samples using the Hybrid-R RNA isolation kit (Geneall Biotechnology). Then, we synthesized cDNA using the High Capacity cDNA Reverse Transcription Kit (Applied Biosystems/Life Technologies). We stored these cDNAs at − 20°C until PCR.

2.3. Determination of Expressions by Real-Time Quantitative PCR

We used cDNAs synthesized from RNAs obtained from tissue samples for the analysis of LRRTM4 gene expression. We performed relative quantitation analysis for LRRTM4 (target gene) and β-actin (reference gene) using the real-time PCR system (LightCycler 480 Real-time PCR System, Roche Diagnostics). We used the Primer-BLAST program (NCBI) to select the primer sets for expression analysis of the target gene and reference gene at the mRNA level.

To evaluate the relative expression of the LRRTM4 gene at the mRNA level in the study and control groups, we prepared a real-time PCR mix with the 2X qPCR SYBR-Green Mastermix (Without Rox) kit (Applied Biosystems/Life Technologies). We applied this protocol for the target gene LRRTM4 and the reference gene β-actin. We performed the real-time qPCR reaction of the reaction mixture on the Applied Biosystems 7500 Real-time PCR system (Applied Biosystems, Foster City, CA, USA).

We performed analyses with negative control reaction mixtures containing PCR-grade water instead of DNA. We calculated quantification of LRRTM4 mRNA expression levels based on the quantification cycle (Cq) for each well and normalized it to β-actin as endogenous controls in both study and control groups. We processed raw data using LightCycler 480 software (Roche Diagnostics GmbH, Mannheim, Germany). We calculated the expression of LRRTM4 mRNA using the ΔΔCq method and compared it with the expression in the control group. We considered the difference significant when the ρ value was <0.05. We represented the value as the mean fold of RNA expression compared with the controls (We calculated the ΔCT value for each case by subtracting the CT beta-actin (reference gene expression) from the CT LRRTM4 (target gene expression), which gave us the ΔCT (normalized gene expression). We calculated mean ΔCT values for both the study group and control group to compare their expression levels. We also calculated the mean "fold change" value of the LRRTM4 gene expression for the study group by determining the ΔΔ Ct value.).

2.4. Western Blotting

We obtained total protein extracts from cells using ProtinEx Total Protein Extraction Solution (GeneAll, Cat No: 701-001). We performed protein quantification using Qubit® Protein Assay Kits (Thermo Fisher Scientific, Cat No: Q33211) and Qubit® 3.0 Fluorometer (Thermo Fisher Scientific, Cat No: Q33216). Then we started the electrophoresis step.

We prepared the mixture using a 100 µg protein sample, 4X NuPAGE LDS Sample Buffer (Thermo Fisher Scientific, Cat No: NP0004), and 10X NuPAGE Sample Reducing Agent (Thermo Fisher Scientific, Cat No: B0004), and performed protein denaturation. We placed samples in the Buffer core vertical gel system tank (XCell SureLock, Invitrogen). We loaded a 5 µl marker (Prime-Step™ Prestained Broad Range Protein Ladder, Biolegend, Cat No: 773301) to the top and bottom of the wells in the gel cassette and performed the execution process. Then we performed blotting using the Iblot Gel Transfer System. We added 5% BSA (Bovine Serum Albumin) to the PBS-T solution containing 0.1% Tween-20 and performed the blocking process with the prepared solution. After this process, we washed it and applied Anti-LRRTM4 at a dilution rate of 1/50000 and Anti-beta actin antibodies at a dilution rate of 1/500. After applying the primary antibody, we applied a secondary antibody using the Secondary Goat-Anti-Rabbit IgG H&L (HRP) antibody (ab205718) blocking solution (5%BSA-PBST). Then we washed it again. We took membranes in 6 ml of ECL Solution (NZY Supreme ECL HRP Substrate, Nzytech, Cat No: Mb19301) and placed them in the imaging device (ChemiDoc-It2, UVP), and performed imaging. We analyzed band intensities of cases in the control and study groups using the Image J program.

2.5. Statistical Analysis

We analyzed the data obtained in the study using the SPSS (Statistical Package for Social Sciences) for Windows 25.0 statistical package program. We expressed continuous variables as mean±standard deviation and median (minimum-maximum values), while categorical variables were expressed as numbers and percentages. We evaluated the conformity of the data to the normal distribution using the Shapiro-Wilk and Kolmogorov Smirnov tests. In independent group reviews, we used the Independent groups t-test when parametric test assumptions were provided. When parametric test assumptions were not met, we used the Mann-Whitney U test. We used chi-square and Fisher exact chi-square tests to examine differences between categorical variables. We used Pearson and Spearman's correlation analyses to examine relationships between numerical variables. We considered a p-value of <0.05 statistically significant in all analyses.

3. RESULTS

3.1. Evaluation of LRRTM4 Expression at the mRNA (Transcript) Level

Our study included 68 cases, with 38 cases in the study group and 30 cases in the control group.

The mean ΔCT value for the study group was 9.39±3.32, while the mean ΔCT value for the control group was 5.78±4.27. We found a statistically significant difference between these two groups (p< .001)(Table 1). The ΔΔCt value of the Study/Control group was calculated as 1.6. In other words, we found that LRRTM4 gene expression was 1.6 times higher in the study group than in the control group.

3.2. Evaluation of LRRTM4 Expression at Protein Level-WB Band Intensity Values

The mean of LRRTM4 expression band intensity values for the cases in the study group was 14238907.18±3427656.35, while the mean for the control group was 11779693.87±3919453.19. We found a statistically significant difference between the study and control groups (p< .01)(Table 1).

When all the cases included in the study were evaluated together, we observed a statistically significant, positive and strong correlation between the normalized expression values(ΔCT) of the LRRTM4 gene and the WB band intensity values (n=68; r=0.798; p< .001).

When the cases in the study and control groups were evaluated within their groups, we observed a statistically significant, positive, and strong correlation between the normalized expression values(ΔCT) of the LRRTM4 gene and the WB band intensity values (Table 2).

When the brain weights of the cases were evaluated, we found that the mean brain weight of the study group was 1412±146 g, while the mean brain weight of the control group was 1478±147 g. In the control group, we found that there was a statistically significant, positive weak correlation between the normalized expression values(ΔCT) of LRRTM4 and brain weight, but this relationship was not found in the study group cases (Table 3).

The mean age of the study group was 42±16, with the youngest case being 18 and the oldest being 84 years old. The mean age of the control group was 40±12, with the youngest case being 21 and the oldest being 58 years old. When the cases were evaluated in terms of age groups, we found that most cases in the study group were in the 30-44 age group with 15(39.5%) cases, and a few were in the group over 60 years old with 5(13.2%) cases. In the control group, we found that most cases were in the 30-44 and 45-60 age groups, with 11(36.7%) cases. When we compared the study and control groups according to age distribution, we found no statistically significant difference between the two groups (p> .01). We also found that there was a statistically significant, negative, and weak correlation between WB band intensity values and age in the study group, but this correlation was not found in the control group (Table 3).

When the groups were compared in terms of weight, we found that in the control group, there was a statistically significant, positive, weak correlation between normalized expression values(ΔCT) and weight, but this relationship was not found in the study group (Table 3).

In the study group, 81.6%(n=31) of the cases were male, and 18.4%(n=7) were female. However, 90%(n=27) of the cases in the control group were male, and 10%(n=3) were female. When we compared the study and control groups according to sex distribution, we found no statistically significant difference between the two groups (p> .05). When we evaluated the WB band intensity values and normalized expression values(ΔCT) of the cases in the study and control groups according to sex, we found no statistically significant difference between sex and WB band intensity values or normalized expression values(ΔCT)(Table 4).

Table 1. *Comparison of age, height, weight, BMI, brain weight, ΔCT values, and WB band intensity values of study and control groups.*

		Mean±S.D.	Med (min-max)	p
Age	Study	42±16	39 (18-84)	.533*
	Control	40±12	40 (21-58)	
Height (cm)	Study	169±10	170 (146-190)	.373*
	Control	171±6	170 (157-185)	
Weight (kg)	Study	77±20	73 (49-160)	.354**
	Control	78±13	77 (53-101)	
BMI (kg/m²)	Study	27±5	26 (19-45)	.795**
	Control	27±4	26 (19-35)	
Brain weight (g)	Study	1412±146	1375 (1200-1740)	.063**
	Control	1478±147	1503 (1155-1900)	
Δct (normalized expression values)	Study	9.39±3.32	8.96 (3.38–18.2)	.0001*
	Control	5.78± .27	5.75 (-3.09-17.83)	
WB Band intensity	Study	14238907.18±3427656.35	14249577 (6882.870.23140406)	.008*
	Control	11779693.87±3919453.19	11900844.5 (2157.870.17417406)	

* Independent Samples T Test was performed. **Mann Whitney U Test was performed. *** p< .05 was considered significant. BMI: Body Mass Index

Table 2. *The relationship between the normalized expression values (ΔCT) of the LRRTM4 gene and the WB band intensity values of the study and control groups.*

Groups			WB Band Intensity Values
Control	Normalized Expression Values (ΔCT)	r	.753**
		p	.000*
Study	Normalized Expression Values (ΔCT)	r	.796**
		p	.000*

* p< .05 was considered significant. **r: The Pearson correlation coefficient.

Table 3. *Comparison of age, height, weight, BMI, brain weight of study and control groups.*

		Control		Study	
		Normalized Expression Values (ΔCT)	WB Band Intensity Values	Normalized Expression Values (ΔCT)	WB Band Intensity Values
Brain Weight	r	.398*	.226	.175	.221
	p	.029	.230	.294	.183
Age	r	.132	.230	-.287	-.325*
	p	.488	.222	.080	.046
Height	r	.179	.078	.092	.129
	p	.343	.683	.584	.441
Weight	r	.384*	.227	.133	.088
	p	.036	.228	.427	.599
BMI	r	.286	.183	.103	.043
	p	.126	.334	.537	.800

* p< .05 was considered significant. *r: Spearman correlation coefficient. BMI: Body Mass Index

Table 4. *The relationship between the sex of the cases in the study and control groups, WB band intensity values, and normalized expression values (ΔCT).*

		Sex	Mean±S.D.	Med (min – max)	p
Control	Normalized Expression Values (ΔCT)	male (n=27)	6.24±4	5.96 (-0.71-17.83)	.074
		female (n=3)	1.61±5.26	0.6 (-3.09-7.3)	
	WB Band Intensity Values	male (n=27)	12111135.93±3361932.97	11991991 (4327.284.17417406)	.540
		female (n=3)	8796715.33±7809395.7	6831163 (2157.870.17401113)	
Study	Normalized Expression Values (ΔCT	male (n=31)	9.35±3.46	9.03 (3.38-18.2)	.882
		female (n=7)	9.57±2.82	8.21 (6.32-13.45)	
	WB Band Intensity Values	male (n=31)	14374560.1±3674634.08	14375991 (6882.870.23140406)	.614
		female (n=7)	13638158.57±2102451.94	14246870 (11368.991.16426113)	

*Independent Samples T Test was performed, p< .05 was considered significant.

4. DISCUSSION

The frontal and prefrontal cortex play an important role in suicidal behavior as they are involved in the regulation of mood and cognitive functions. Activation of the prefrontal cortex ends the inhibition of impulsive behaviors and increases the risk of suicide (12). In a study, glutamatergic signaling pathways, especially localized in the dorsolateral prefrontal cortex, were found to be associated with neuropsychiatric disorders and suicide risk (13).

With the advent of molecular techniques, recent extensive research has focused on the genetic risk factors underlying the behavioral patterns associated with suicide. Transcription of messenger mRNAs encoded by glutamatergic genes is induced by calcium-mediated activation of specific genes. The mRNA level is a significant measure of the function of the relevant gene, as it shows the amount of transcription (14). Genome-wide association studies on suicide attempts have revealed a significant relationship between suicide attempts and the LRRTM4 gene, which is involved in glutamatergic pathways (15). When previous studies are examined, it can be seen that LRRTM4 gene expression has not been analyzed at the tissue level before. Therefore, our study investigated LRRTM4 gene expressions at the mRNA and protein levels in samples taken from the brain's dorsolateral prefrontal cortex for the first time. Our data analysis revealed a statistically significant positive correlation between LRRTM4 gene expression levels and suicide. These findings were also confirmed by the western blotting method.

LRRTM4 has an intron-3 region containing HREs (hormone response elements), which are the binding sites for the hormone-receptor complex. Studies have shown that variations in HREs may cause changes in the binding of hormones to receptors and the activation of receptors. It has been demonstrated that changes in gene expression may lead to an increased risk of disease (16,17). The data indicate that hormones affect the LRRTM4 gene and provide an understanding of genetic factors in sex-specific differences in suicide. In a genome-wide association study of patients with bipolar disorder, the LRRTM4 gene was found to be associated with the risk of suicide attempts in women (4). Similarly, in a study performed on bipolar disorder cases with and without suicide attempts, five male-specific haplotypes and one female-specific haplotype were detected in the LRRTM4 gene analysis in the intron-3 region. These haplotypes were thought to be associated with gender-specific risk of suicide attempts in bipolar disorder (15). When the LRRTM4 gene expression level in suicide cases in our study was evaluated according to gender, no statistically significant difference was found between both genders. The reason for this result may be the presence of the majority of male cases in the study. It can be concluded that there is a significant relationship between the LRRTM4 gene and sex in studies with a balanced and sufficient sample size for sex.

In our study, the median age of suicide cases was 39(18-84), while the median age of the control group was 40(21-58). In Zhao et al.'s (18) study on the expression of glutamatergic genes in the DLPFC, the median age of suicide cases with major depressive disorder was 40(24-63), while the median age of the control group without psychiatric disorders was 47(24-63). In our study, we observed a weak negative correlation between LRRTM4 protein density values and age in the study group. However, this relationship was not observed in the control group. We found no statistically significant relationship between age and LRRTM4 expression values. When we reviewed gene expression studies in the literature, we didn't find any studies that obtained similar data to our study (18,19).

In our study, the median brain weight of suicide cases was 1375 g, while the median brain weight of the control group was 1503 g. In Zhao et al.'s (18) study on the expression of glutamatergic genes in the DLPFC, the median brain weight of suicide cases with major depressive disorder was 1480 g. The median brain weight of the control group without psychiatric disorders was 1444.83 g. In our study, we observed a weak positive correlation between the LRRTM4 gene expression level and brain weight of the control group. However, this relationship was not observed in the study group. We found no statistically significant correlation between brain tissue weight and protein density values. When we examined gene expression studies in the literature, we didn't find any studies that obtained similar data to our study (18,19).

5. CONCLUSION

In conclusion, in our study, it was found that LRRTM4 gene expression was increased in samples taken from the dorsolateral prefrontal cortex in suicide cases. Our study is pioneering as it is the first study to analyze the mRNA and protein levels of the LRRTM4 gene directly in brain tissue.

Our study will contribute positively to the early detection of risk factors in suicidal individuals, establishing of treatment-prevention protocols, and the forensic medicine evaluation process. We also believe that the studies evaluating the localization, function and interactions of LRRTM4 in various central nervous system circuits will lead to a holistic understanding of the synaptic mechanisms underlying the etiology of suicide.

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The Nursing Needs Assessment Scale for Women with Infertility: Turkish Validity and Reliability Study

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ABSTRACT

Objective: This study was designed and conducted to establish the Turkish validity and reliability of "The Nursing Needs Assessment Scale for Women with Infertility (NNASIW)."

Methods: Originally developed in Korean, the scale contains 18 items, and a sample of 262 infertile women was included, multiplying each item by 10. In the analysis of this methodological study, second-order multifactor Confirmatory Factor Analysis (CFA), independent samples t-test, split-half reliability analysis, and Cronbach's alpha were utilized.

Results: The CFA goodness-of-fit values of the scale were: χ^2 = 221.326, χ^2/df = 1.72, AGFI = .89, CFI = .98, GFI = .91, RMSEA = .052, and NFI = .96. Factor loadings for all variables ranged from .39 to .99, and they were found to contribute significantly to the scale (p<.001). Statistically significant differences were noted between the lower and upper 27% groups for the total score and sub-dimensions of the scale, which originally had four sub-dimensions (p < .001). A high, positive, and significant correlation was found between the two halves of the scale (p <.001). The overall Cronbach's alpha value of the scale was .88, with sub-dimension alpha values ranging between .70 and .99.

Conclusion: The NNASIW is confirmed to be a valid and reliable measurement tool for assessing the nursing needs of infertile women.

Keywords: Care needs, infertility, nursing, reability, scale, validity.

1. INTRODUCTION

The World Health Organization (WHO) classifies infertility as a disease affecting the reproductive systems of both men and women, characterized by the failure to conceive after 12 months or more of regular, unprotected sexual intercourse. The incidence and reasons for infertility differ across various populations. Recognized by WHO as a significant international health issue, infertility impacts millions globally who are of reproductive age. Current statistics indicate that approximately one in six individuals worldwide will experience infertility at some point in their lives (1). According to Turkey Demographic and Health Survey (TDHS-2013) data, the prevalence of infertility in Turkey is 8.6%, and the proportion of women who have used assisted reproductive techniques (ART) at least once is 4.2%, which is an increase compared to previous years. However, although there is no precise data on the prevalence of infertility in our country in recent years, the demand for infertility treatment has been increasing year by year (2).

Infertility, impacting millions globally and frequently leading to severe consequences, is a crucial aspect of sexual and reproductive health and rights. It is addressed within this context, underscoring its significance in global health discussions. Therefore, it is critical to understand the extent of infertility to ensure access to quality fertility care, reduce risk factors and outcomes, and develop appropriate interventions (1, 3). The diagnosis of infertility is defined as a life crisis that is unique to the individual, has uncertain outcomes, brings medical, psychological, social, and economic problems, and has cultural, religious, and class aspects (4). Each cycle of infertility diagnosis may bring a bumpy journey in emotions such as anger, betrayal, guilt, sadness, and hope/hopelessness. It can also affect sexual confidence, desire, and performance (5). In addition to the diagnosis of infertility, ART also increases the physical, emotional, social, and economic burdens of women and couples and may cause an increase in stress, anxiety, depression, etc (6). Individuals or couples

may enter into a life crisis that they have to cope with. Even family unity is disrupted, and divorces increase.

To cope with this life crisis, individuals and couples need information and professional counseling about infertility, ART, procedures, what to expect, etc., medical support, and holistic, individual/couple-specific nursing care that covers all these (7). Counseling is a fundamental aspect of nursing care, particularly in the realm of infertility, where it involves a three-stage process. These stages include patient-centered care, which focuses on collecting and analyzing information, followed by inferential and decision-making counseling. The second stage, infertility counseling, encompasses decision-making, support, and crisis counseling. The final stage, psychotherapy, involves crisis and therapeutic counseling (8). When there is a gap between an individual's actual health and optimal health level, meeting nursing needs is essential to achieve the goal of optimal health (9), and infertile women often need to be informed about treatment, symptom management, psychosocial, supportive, and spiritual needs (10, 11).

The nursing requirements for women experiencing infertility can differ significantly from the diagnostic phase to the treatment stage and may vary individually (12, 13). Therefore, nursing care should be provided with an individualized, holistic, humanistic approach to the needs of infertile women. In order to plan and provide nursing care wholly and accurately, the personal status of individuals, their physical and psychological care needs, their general health status, their level of knowledge about infertility, their perception, understanding, and concerns about diagnosis and treatment, their support needs and preferences should be taken into consideration. In this context, there is a need for an accurate assessment of these women's needs for nursing care, information, education, and support systems, and for this, measurement tools are needed. When the measurement tools in the literature are examined, we come across tools such as infertility stress assessment (14), coping with stress (15), and quality of life assessment (16).

In Turkey, a specific measurement tool to assess the nursing care needs of infertile women has yet to be established.

This study seeks to fill that gap by evaluating the validity and reliability of the Turkish version of the "Nursing Needs Assessment Scale for Women with Infertility" (NNASIW), with the goal of enriching the literature and aiding nurses who work in this field.

2. METHODS

2.1. Design and Setting

This methodological scale validity-reliability study was conducted between February and June 2022 in Istanbul In Vitro Fertilization and Women's Health Center in 262 infertile women who applied for treatment and volunteered to participate. First, written permission was obtained from the experts who developed NNASIW.

Following the necessary permissions, the scale underwent language and content validation. The ethics committee of Maltepe University granted approval for the study (Decision no: 2021/04-07; Date: 05.02.2021), and written permission was secured from the institution to carry out the research. During the implementation of the scale, infertile women who volunteered for the study were provided with a brief overview and signed an informed consent form (Figure 1).

Evaluation of the validity of the scale was carried out in 6 consecutive stages. These are: translation, synthesis, back translation, content validity, pilot study and construct validity (Figure 1).

2.1.1. Translation

It is recommended that the first translation should always be done by at least two people working independently of each other and that one of the experts should be informed about the subject matter and the other should be uninformed (17). Therefore, during the translation of the NNASIW into Turkish, one expert translator in Korean and two experts in English Language and Literature performed the translation process independently.

1st Stage **Translation**	• One translator specialized in Korean and two translators specialized in English Language and Literature independently carried out the translation process.
2nd Stage **Synthesis**	• The semantic, idiomatic, conceptual, linguistic and contextual differences of the translations obtained from the experts were evaluated. As a result of the evaluations, the translations were synthesized into a single translation.
3rd Stage **Back Translation**	• Two experts in the field of English Language and Literature, who were not involved in the first translation, performed a back-translation process and compared the scale with the original. The scale was finalized.
4th Stage **Content validity of the scale**	• In order to test the content validity of the scale, the opinions of 10 experts in the field were consulted.
5th Stage **Pilot Study**	• Thirty-two infertile women with similar characteristics to the study population were invited to participate in the study. • Thirty-two volunteer infertile women completed the pilot study.
6th Stage **Construct Validity of the Scale**	• 270 infertile women were invited to participate. • 8 participants were excluded from the study. • 262 volunteer infertile women completed the study

Figure 1. The stages of the study

2.1.2. Synthesis

The translation versions obtained from the experts were compared by the researchers, and their linguistic, semantic, idiomatic, conceptual, and contextual similarities/differences were evaluated. As a result of the evaluations, a consensus was reached on the wording of the items.

2.1.3. Back translation

According to Coster and Mancini (17), it is advisable that the back-translation process be conducted by experts who were not included in the first translation to ensure objectivity and accuracy. Consequently, two experts in English Language and Literature, who had no part in the first translation, undertook the back-translation of the document. This method helps in verifying the translation's fidelity to the original text and maintaining the precision of the technical terms used in the scale. The back-translations were compared with the original scale, and it was decided, in collaboration with the scale's author, that they were linguistically, semantically, and expressively similar, and no adaptive changes were needed.

2.1.4. Content validity

Following the translation of the trial form, the next step recommended by the literature involves soliciting expert opinions to pinpoint any inadequate translation concepts and discrepancies between the two languages, necessitating further translation adjustments (18). Experts review each item using a Likert-type scale categorized as "Necessary," "Useful but not necessary," and "Not necessary" to express their evaluations (19). For this study, the Content Validity Ratio (CVR) and Content Validity Index (CVI) were determined in accordance with the evaluations of between 5 and 40 experts, as suggested by Lawshe (20). To assess the content validity of the scale in question, the translated and language-validated trial form was presented to a total of 10 experts—six academicians and four clinician nurses, all specialists in their fields. They were requested to evaluate the items in terms of content validity, ensuring the scale accurately reflects the necessary concepts and terminology relevant to infertility nursing care.

2.1.5. Pilot study

In accordance with the guidelines suggested by Erkuş (21) the pilot study's sample should mirror the target group of the original scale in terms of key demographic characteristics such as age range, education level, and gender. This is crucial for ensuring that the findings are relevant and applicable to the intended population. Following these principles, a pilot study involving 32 infertile women who share similar characteristics with the study population was conducted. This sample size aligns with the recommendations Şeker and Gençdoğan (22), who suggest that 30-50 participants typically provide sufficient data for pilot studies. The purpose was to assess if the Turkish language and content-validated trial form was understandable to the target group. The outcomes of the pilot study indicated that the scale items were well understood by the participants, and consequently, no revisions were deemed necessary for the scale items. This step is essential to confirm the scale's usability and ensure its items are interpreted correctly before broader application.

2.1.6. Construct validity

The original NNASIW has four factors that explain a latent construct. In this study, a second-order multifactor model was used as CFA for the scale's construct validity. Before factor analysis, Kaiser-Meyer-Olkin (KMO) value and Bartlett's Test of Sphericity ($\chi 2$) analysis were performed to determine the suitability of the data set for factor analysis and the factorizability of the scale. Then, a second-level multifactor CFA diagram was created for factor analysis, and the Maximum Likelihood estimation method was utilized because the data were normally distributed. To evaluate the reliability of the scale, the Cronbach Alpha reliability coefficient and two-half test consistency were used (for two-half test consistency, odd-numbered items in the scale were ranked as the first half and even-numbered items as the second half). The internal consistency of the items was analyzed using a "t-test in independent groups." For the total score and sub-dimensions of the scale, 27% lower and upper group comparisons were made.

2.2. Participants

In this study, adherence to sample size recommendations is critical for establishing the reliability and validity of the NNASIW. Following the guidelines set forth by Mokkink et al. (23), the sample size for a validity-reliability study should range from five to ten times the number of items on the scale. Additionally, the International Test Commission suggests a minimum sample size of 200 to effectively uncover a scale's psychometric structure (24). To meet these standards, the study initially included 270 infertile women who volunteered to participate. However, eight participants were later excluded for not meeting the sampling criteria, resulting in a final sample size of 262 women. This sample size is sufficient to perform a robust analysis of the scale's validity and reliability, ensuring the results are statistically significant and reflective of the target population's characteristics.

Inclusion criteria

- Those who are at 20-50 years of age,
- Those who are diagnosed with infertility and in the process of treatment,
- Those who do not have a psychological or chronic illness that requires treatment,
- Those who can speak, read, and write Turkish and are capable of understanding and accurately responding to questions,
- Participants who volunteered to take part in the study were included in the sample.

2.3. Instruments

Data were collected using the Participant Identification Form and Nursing Needs Assessment Scale for Women with Infertility – NNASIW.

Participant Identification Form: It is a questionnaire consisting of 25 structured questions to determine the participants' socio-demographic, obstetric, and infertility-related characteristics.

Nursing Needs Assessment Scale for Women with Infertility (NNASIW): It was developed by Park, Shin, and Lee (2020) to assess the nursing needs of infertile women. This four-point Likert-type scale comprises 18 items and four sub-dimensions. Sub-dimensions of the scale are "Physical and psychological nursing care needs (Items 1-6)", "General information needs about infertility (Items 7-11)", "Perception, understanding, and concerns about infertility treatment (Items 12-15)" and "Support needs (Items 16-18)". The items of the scale are scored between 1-4 as "Not at all necessary=1", "Not always necessary=2", "Necessary=3" and "Absolutely necessary=4". The scores to be obtained from the subgroups of the scale are 6-24 points for the first sub-dimension, 5-20 points for the second, 4-16 points for the third, and 3-12 points for the fourth. The minimum total score achievable on the scale is 18, while the maximum is 72. Higher scores indicate more significant nursing needs among infertile women. Cronbach's alpha value was reported as .92 in the original scale, and the subgroups' alpha values were reported between .88—.91 (7).

Data Collection

Women who met the sampling criteria were included in the sample by random sampling method, one of the simple random sampling methods. After consent was obtained from the women, they were given a Diagnostic Form and a Scale Form and were asked to answer the forms by self-report.

2.5. Data Analysis

In the data analysis phase, the SPSS 26 package program was used for descriptive statistics, and the AMOS 23 package program was used to examine model fit. Statistically, $p<.05$ was considered statistically significant. Frequency, mean, and standard deviation (SD) were calculated as descriptive statistics for primary socio-demographic, obstetric, and infertility-related data, including general characteristics of the participants. KMO value and Barlet's Sphericity Tests were conducted to evaluate the suitability of the data set, including the normality and factorizability of the scale. CVI and CVR were calculated for content validity. Second-order multifactor CFA was performed for construct validity. Factor loadings, chi-square statistic ($\chi 2$), chi-square statistic/degree of freedom ($\chi 2 /df$), goodness-of-fit index (GFI), comparative fit index (CFI), adjusted goodness-of-fit index (AGFI), normalized fit index (NFI) and root mean square error of approximation (RMSEA) were used to evaluate the fit of the model. Independent samples t-test was employed to assess

internal consistency. The tool's reliability was examined using two-half test consistency and Cronbach's alpha.

3. RESULTS

The mean age of the 262 infertile women who participated in the study was 36.7±6.0 years; 50% had undergraduate/graduate degrees, and 51.5% were employed. Primary infertility was present in 54.6% of the women; the female factor was the most common cause of infertility with 55.0%, 45.4% had a history of pregnancy, and 35.9% had a history of miscarriage/abortion. The rate of experiencing the first ART was 21.8%, the rate of undergoing more than one In Vitro Fertilization-Embryo Transfer/Intracytoplasmic Sperm Injection-Embryo Transfer (IVF-ET/ ICSI-ET) treatment was 73.6%, the median number of attempts was 2/time, and the median duration of treatment was 18/month (Table 1). Among those who experienced two or more treatments, the rate of IVF/ICSI +ET was 84.4% and Intrauterine Insemination 27.1%.

***Table 1.** Characteristics of participants*

Characteristics	N=262	
	n (%)	
Socio-economic and obstetric characteristics		
Education		
<8 years	39	(14.9)
8 years	33	(12.6)
High School	59	(22.5)
Undergraduate and postgraduate	131	(50.0)
Social security		
Exist	241	(92.0)
None	21	(8.0)
Employment status		
Working	135	(51.5)
Not working	127	(48.5)
Cycle regularity	181	(69.1)
History of pregnancy	119	(45.4)
Experience in childbirth	43	(16.4)
Experience with miscarriage/abortion	94	(35.9)
Specific characteristics of infertility		
Type of infertility		
Primer	143	(54.6)
Secondary	119	(45.4)
Infertility factor		
Female factor	144	(55.0)
Male factor	26	(9.9)
Both male and female factors	38	(14.5)
Unexplained cause	54	(20.6)
Number of infertility treatment (ART) trials		
Newly diagnosed and not yet started treatment	12	(4.6)
First ART trials	57	(21.8)
Those with ≥2 ART trials	193	(73.6)
Mean values	**Mean±SD (min-max)**	
Mean age of women/year	36.7±6.0 (21-49/year)	
Mean age of spouse/year	39.4±6.7 (24-57/year)	
Median values	**Median (min-max)**	
Duration of marriage/month	60.0 (6-360/month)	
BMI	25.2 (17.3-40.6)	
Infertility diagnosis time /month	24.0 (1-288/month)	
Infertility treatment duration/month	18.0 (1-276/month)	
Number of IVF/ICSI +ET trials	2.0 (0-11 trials)	

BMI:Body Mass Index

3.1. Content Validity

In the study, the CVR values of the opinions of 10 experts on the items in the trial form with a 3-point rating ranged between .80 and 1.0, the CVI value for the whole form was .98, and CVI>CVR, so the items were not changed.

3.2. Construct Validity

In the study, KMO = .88; χ2= 4783.16; p<.001. According to the results of the CFA diagram, the goodness of fit values of the scale were: χ2=221.326, χ2 /df=1.72, GFI=.91, CFI=.98, AGFI=.89, NFI=.96 and RMSEA=.052 (Figure 2). In the CFA, the factor loadings and significance of the latent variables of the scale were examined, and it was seen that the factor loadings of all variables ranged between .39 and .99 and contributed significantly to the scale (t: 5.149 / 53.846; p< .001) (Table 2).

3.3. Reliability

Given that the factor loadings for the items on the scale exceeded .39, none of the items were eliminated. A statistically significant difference was observed between the lower and upper 27% quantiles in terms of both the total score and the sub-dimensions of the scale. (p< .001) (Table 3).

The total Cronbach α value of the scale was found .88. The sub-dimension Cronbach α values were found F1= .72, F2= .99, F3= .94, and F4= .70. In the split-half reliability analysis, a high, positive, and significant correlation was found between the two halves of the scale, indicating consistent internal reliability (r²:.77; p< .001). The mean total score of the scale was found 50.1±9.7 (Table 3).
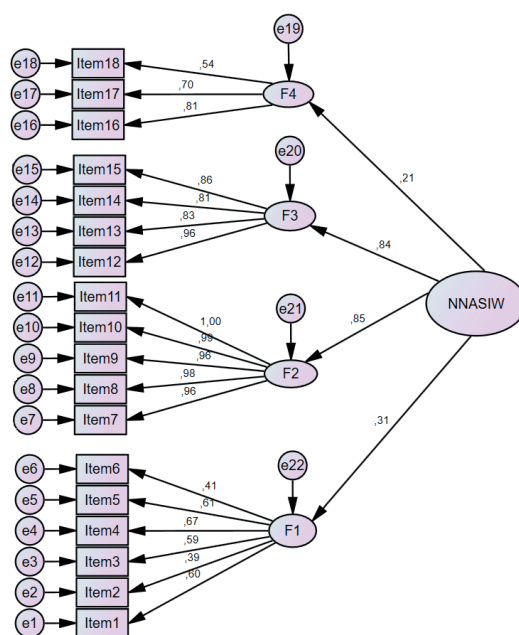
Figure 2. *Second-order multifactor CFA diagram for the structure of the scale*

Table 2. *Confirmatory factor analysis results*

No	x̄	SD	Factor Load	t	p	No	x̄	SD	Factor Load	t	p
Item1	2.00	.98	.60	7.01	.000	Item10	3.13	.96	.99	48.71	.000
Item2	1.77	.97	.39	5.15	.000	Item11	3.15	.95	.99	52.03	.000
Item3	2.09	1.07	.59	7.01	.000	Item12	3.30	.94	.96	19.42	.000
Item4	2.26	1.02	.67	7.01	.000	Item13	3.24	.97	.83	7.32	.000
Item5	2.21	1.05	.61	6.58	.000	Item14	3.27	.91	.81	18.34	.000
Item6	1.39	.78	.41	5.16	.000	Item15	3.27	.94	.86	21.10	.000
Item7	3.14	.96	.96	39.82	.000	Item16	3.46	.84	.81	18.41	.000
Item8	3.15	.95	.98	53.85	.000	Item17	3.47	.69	.70	7.22	.000
Item9	3.18	.96	.95	39.82	.000	Item18	2.63	1.01	.54	6.87	.000

Table 3. Reliability analysis results of the scale

NNASIW Factors and Total	Group	N	x	SD	t	p	Cronbach α	Mean±SD (Min-Max)
F1	Subgroup	70	7.33	1.05	-36.334	.000	.72	11.7±3.8 (6-24)
	Upper Group		16.79	1.91				
F2	Subgroup	70	9.57	3.86	-22.549	.000	.99	15.7±4.7 (5-20)
	Upper Group		20.00	2.90				
F3	Subgroup	70	8.47	2.74	-22.913	.000	.94	13.1±3.4 (4-16)
	Upper Group		16.00	2.85				
F4	Subgroup	70	6.96	1.66	-23.177	.000	.70	9.6±2.0 (3-12)
	Upper Group		11.73	.45				
TOPLAM	Subgroup	70	37.10	6.43	-28.158	.000	.88	50.1±9.7 (18-68)
	Upper Group		60.64	2.75				
Split-Half Method Results		n	**Mean**	**SD**	r	r^2	p	
First Half			25.8	5.4				
		262			.88	.77	.000	
Second Half			24.4	4.6				

4. DISCUSSION

This study is for the Turkish validity of the **NNASIW** developed by Park, Shin, and Lee (7). The study confirmed that the scale retained its 4-factor and 18-item structure with the second-level multifactor CFA. The fit values were found to be at the desired level. The t-values, factor loadings, 27% lower and upper group comparison, Cronbach α reliability coefficient, and two-half test consistency values of all items were excellent.

The degree of validity of a scale is determined by how well it fulfills the intended purpose for which it was designed. Various techniques are available for evaluating the validity of a scale, each tailored to explore different aspects of its effectiveness (19). This study evaluated the content, construct, and internal validity of the scale. CVR and CVI values were used for content validity. Ten expert opinions were consulted for the scale. For CVR, a minimum CVR value of .80 obtained from 10 experts is accepted as the necessary criterion for content validity (25). This study determined that the CVR values for the items varied from .80 to 1.0; the CVI value for all items was .98 in total and CVI>CVR. In parallel with these results, it was concluded that the Turkish version of the scale met the necessary criteria for content validity at an excellent level, and no changes were made to the items. In the original version of the scale, it was reported that the CVR values were .80 and above, as in our results as a result of the 4-point rating for content validity (7).

Factor analysis may only be suitable for some data sets. The suitability of the data set for factor analysis is assessed using the KMO coefficient and Bartlett's Test of Sphericity. The KMO coefficient is used to determine the adequacy of the sample size for factor analysis in research. Unlike Bartlett's Test of Sphericity, which provides a test statistic, the KMO value serves as a criterion to assess the proportion of variance

in the variables that might be caused by underlying factors (19), and .50 is unacceptable .90 is regarded as excellent, .80 as very good, .70 and .60 as mediocre, and .50 as poor (26). Bartlett's Test of Sphericity assesses the suitability of data for factor analysis by testing the hypothesis that the correlation matrix is an identity matrix. If the calculated test statistic is significant, it is interpreted that the data matrix meets the normality assumption required for factor analysis (19). In addition, the significance of the chi-square statistic calculated for Barlett's test of sphericity can be seen as evidence of the normality of the scores (27). According to the findings obtained in this study, the KMO value (KMO=.88; $\chi 2$=4783.16; p < .001) was similar to the original study (KMO =.93; $\chi 2$=11.121; p <.001) (7) and was suitable for factor analysis.

CFA is recognized as a distinct research method within structural equation modeling (28). It builds upon Exploratory Factor Analysis (EFA), which examines the underlying structure of the data (29). While EFA helps generate hypotheses by identifying potential patterns and relationships among variables, CFA rigorously tests these hypotheses. It evaluates whether there is a significant relationship among the factors, which variables are associated with specific factors, whether the factors operate independently of each other, and whether they adequately explain the model (30). In scale development studies, verification of the measurement model obtained after EFA with CFA is important for the validity of the construct (31). To assess the model fit following a CFA, the factor loadings, t-values, and goodness of fit indices of the items are considered essential (32). Each item's t-value should exceed 1.96 to be statistically significant (33). Harrington (2009) (34) suggests that factor loadings should not fall below .30, with loadings of .71 and above considered excellent, .63 very good, .55 good, .45 good/acceptable, and .32 poor. $\chi 2$ p>.05, x2/df<5, AGFI>.90, CFI>.90, GFI>.90,

RMSEA<.08 (35) and NFI>.90 (36). The CFA results confirmed the 4-factor structure of the original scale. The factor loadings of the latent variables of the scale varied from .39 to .99., whereas in the original study, they ranged between .63 and .93 (7). The t-value of each item was above 1.96. When the findings related to the sub and upper 27% groups were evaluated together, it was evident that both in the sub-dimensions and in the total scale, those who scored low on the scale and those who scored high on the scale could be distinguished significantly. When the goodness of fit indices related to the model were analyzed, it was seen that all indices gave very good results. The outcomes of the factor loadings, t-values, and fit indices for the scale items, which range from good to acceptable levels, indicate that the model is adequately explanatory of the desired structure.

Reliability can be defined as the ability of a test or scale to consistently reflect the phenomenon aligned with the conceptual framework. This means that the measurement tool should yield consistent results when applied across different locations, at various times, and among different subsets drawn from the same overall population (37). While a reliability coefficient of ≥.70 is generally considered acceptable for a Likert-type scale, it is desired to be as close to 1 as possible. A Cronbach's alpha coefficient between .80 and 1.0 signifies excellent reliability, values from .60 to .80 suggest moderate reliability, scores between .40 and .60 denote poor reliability, and a range from .00 to .40 indicates unreliability of the scale (38). In this study, the total Cronbach's alpha value of .88 showed high reliability, and the Cronbach's alpha values of F2 and F3 sub-dimensions showed high reliability similar to the original scale (F1:.91; F2:.88; F3:.89; F4:.89) (7). and the Cronbach's alpha values of F1 and F4 showed moderate reliability.

The Split-Half Method divides the form into two halves. After the two halves are administered to the subjects simultaneously, reliability is estimated by the correlation between the scores obtained by the subjects from the halves. In the two-half test consistency, the correlation between the two halves is anticipated to be as high and statistically significant as possible (19). This study observed a high, positive, and significant correlation between the two halves of the scale (r^2=.77; p< .001). In the original scale, all correlation coefficients were reported to be between .75 and .94 (7). Considering the two-half test consistency, Cronbach α reliability coefficient in the sub-dimensions of the scale, and the total scale, it was concluded that the 4-factor structure of the scale could reliably be measured.

5. CONCLUSION

Based on the analysis conducted in the study, it was concluded that the Turkish version of the Nursing Needs Assessment Scale for Women with Infertility (NNASIW) achieved the necessary criteria for content validity at an excellent level. The sample size was deemed adequate for factor analysis as per the Kaiser-Meyer-Olkin (KMO) measure, and the Confirmatory Factor Analysis (CFA) model

successfully explained the intended structure. Furthermore, the overall Cronbach's alpha value of the scale indicated high reliability, affirming that the 4-factor structure of the scale could reliably measure the constructs it intended to assess. Thus, the Turkish version of the NNASIW is a valid and reliable tool that can be used to assess the nursing needs of infertile women within the Turkish population.

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Evaluation of the Impact of Mothers' Attitudes Towards Healthy Eating on their Children's Dietary Habits and Oral Health

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ABSTRACT

Objective: This study aims to determine the effects of mothers' attitudes towards healthy eating on children's dietary behaviour and oral health.

Methods: A total of 328 children and mothers, including 180 girls and 148 boys aged between 3-10 years, were included in the study. After recording socio-demographic data of mothers and their children, Attitude Scale for Healthy Nutrition (ASHN) was administered to mothers, and Children's Heart Health Promotion Attitude Scale (CCHAS) was administered to children face-to-face. Intraoral examinations of children were performed, and Decay, Missing, Filling, Teeth (DMFT, dmft), Plaque Index (PI), Gingival Index (GI), and Bleeding on Probing Index (BPI) were calculated. The effects of all parameters on verbal indexes were evaluated using hierarchical linear regression analysis for statistical analysis.

Results: The mean DMFT score of children was found to be 0-2, and the mean dmft score was 7-6. The mean PI, GI, and BPI scores were 1-1.20, 0.60-0.70, and 10 respectively. The mean Attitude Scale for Healthy Nutrition score of mothers in the study was 71-70, and the average score for Nutrition Knowledge was 21-20 respectively. There was a positive significant relationship between mothers' ASHN and CCHAS.

Conclusion: Based on this study's results, we can conclude that mothers' positive attitudes towards nutrition contribute to the development of their children's positive dietary attitudes. ASHN of the mother is a risk determinant for the child's DMFT score. Therefore, it can be said that proving healthy eating behaviour by mothers is important for their children's oral health.

Keywords: Oral health, mother, dietary behaviour, child

1. INTRODUCTION

Balanced and healthy nutrition is extremely important for children to sustain their growth and development in a healthy manner, protect them from diseases, and enable them to lead a quality life (1, 2). Healthy eating involves enjoying the food consumed, maintaining a varied and balanced diet, consuming all nutrients in the amount needed for the individual, and maintaining the ideal body weight (3, 4).

Nutritional behaviour is directly connected to oral and dental health (5-7). Dental caries, one of the most significant issues in oral and dental health, involves the destruction and loss of material in the enamel and dentin of the tooth. Dental caries begins with the formation of organic acids by bacterial secretions on fermentable carbohydrates adhered to the enamel surface, known as dental plaque (8-10). There is a close relationship between nutrition and dental caries. While dental caries negatively affect nutrition, improper nutrition also leads to dental caries and deterioration of oral health (11). The intake of carbohydrates (especially sucrose) in the mouth rapidly lowers the pH of the environment surrounding the tooth from 7 to 5.5 (12, 13). A pH below 5.5 creates a conducive environment for bacterial growth, leading to demineralization of the enamel. Adequate intake of protein during nutrition helps to buffer the acid in the mouth by providing sources of amines and urea, thus contributing to the prevention of demineralization in the teeth (14, 15). Clinically, issues related to the formation of dental caries and the deterioration of oral health due to improper nutrition are frequently encountered (16).

Various environmental factors determine children's food intake and eating habits. Family, social environment, peer influence, and various media sources shape nutritional behaviour (17, 18). In the attitude development process, considered the first step towards healthy eating behaviour, children are reported to model their parents' eating behaviours, lifestyles, and body image satisfaction (19, 20). Parental feeding practices and nutritional knowledge also influence children's eating behaviours and food preferences. Since parents do not offer foods they dislike to their children, the children do not have the chance to try these foods (2). Thus, it can be said that a mother's dietary habits influence her child's dietary habits from a very early age (7).

Considering the above information, this study aims to determine the impact of mothers' attitudes towards healthy eating on their children's nutritional behaviour and oral and dental health. The null hypothesis (H0) of this study is that the mother's attitude towards healthy eating does not affect the child's nutritional attitude and oral and dental health; the alternative hypothesis (H1) is that the mother's attitude towards healthy eating affects the child's nutritional attitude and oral and dental health.

2. METHODS

2.1. Ethical Approval

The ethical approval for this study was obtained from the Non-Interventional Clinical Research Ethics Committee of the Faculty of Medicine, Recep Tayyip Erdoğan University (Date: 16.03.2023, Protocol No. 2023/80). Informed consent forms were obtained from mothers and children who agreed to participate in the study.

2.2. Sample Size

The sample size was calculated using G Power 3.0.10 (University of Kiel, Germany) software to determine the effect size. Based on the data from the literature(21-23) and considering a linear regression model with oral and dental health indices as continuous dependent variables and scales as covariates, an effect size of $f2 = 0.15$ was used, indicating a medium effect size. To achieve 99% power, a minimum of 146 subjects was required. The study included a total of 328 children, 180 girls and 148 boys, aged 3-10 years, who visited the Department of Paediatric Dentistry at the Faculty of Dentistry, Recep Tayyip Erdoğan University, for examination or treatment.

Inclusion Criteria:

- Children aged 3-10 years.
- Children in this age group without any systemic diseases or any syndromes
- Children who did not visit the clinic for an emergency reason (e.g., trauma, acute dental abscess, etc.)
- Children and their mothers who agreed to participate in the study.

2.3. Study Design

This study is a descriptive survey that included each mother and child, gathering socio-demographic data and the mothers' educational status through a five-question questionnaire. Additionally, mothers were administered the 21-item Attitude Scale for Healthy Nutrition (ASHN) and children were administered the 4-item Children's Heart Health Promotion Attitude Scale (CCHAS) face-to-face (23). The validity and reliability of the CCHAS were established by Haney et al.(24). The validity and reliability of the ASHN, a twenty-one-item Likert scale, were established by Demir

and Cicioğlu. The scale inquired about concepts such as the nutritional content of carbohydrates, proteins, vitamins, and habits of consuming junk food and sugary snacks. Each question on the scale had five response options: "strongly disagree," "disagree", "neutral", "agree", and "strongly agree." The questionnaire was divided into sections: Information on Nutrition (IN), Emotion for Nutrition (EN), Positive Nutrition (PN), Malnutrition (MP). IN and PN sections included positive items rated from 1 to 5. The negative attitude items were in the EN and PN sections and scored inversely. The total score ranged from 21 to 105, with higher scores indicating a better level of healthy eating habits (23).

CCHAS nutrition subscale, developed by Arvidson, consists of four items. Each item is rated from 1 to 4 (1-strongly disagree, 4-strongly agree), with total scores ranging from 4 to 16. Higher scores indicate a positive attitude (25).

Additionally, the oral examinations of the participating children were conducted by an examiner (F.Y.) according to the standards established by the WHO. To ensure the consistency and reliability of data collection, intra-observer calibration was conducted. The primary examiner evaluated 20 children in two separate sessions, two weeks apart, and the results were compared for consistency. Cohen's kappa statistic was used to assess reliability, with a kappa value of >0.80 indicating excellent agreement and demonstrating high consistency in the examiner's measurements.The DMFT (Decay, Missing, Filled Teeth) index was used for evaluating permanent teeth, and the dmft (decay, missing, filled teeth) index was used for evaluating primary teeth. These indices are calculated by summing the decayed, missing, and filled teeth (26). An increase in the dmft/DMFT index value indicates a higher risk of caries (27).

The plaque index (PI) of the participating children was assessed by scoring each of the four gingival areas of the tooth (mesial, mid, distal, lingual) from 0 to 3. The scores for the four areas of each tooth are summed and divided by four. The individual's plaque index is obtained by summing the scores for all teeth and dividing them by the number of teeth examined (28).

The gingival index (GI) is calculated by scoring each of the four gingival areas of the tooth (mesial, mid, distal, lingual) from 0 to 3. These values represent the gingival index for the respective areas. The scores for the four areas of each tooth are summed and divided by four to find the gingival index of the tooth. The individual's gingival index is obtained by summing the scores for all teeth and dividing by the number of teeth examined (28).

The Bleeding on Probing Index (BPI), developed by Ainamo and Bay, was used to evaluate the gingival health of the children. Areas that bleed on probing are marked as (+), and areas without bleeding are marked as (-) (29).

2.4. Statistical Analysis

Statistical analysis was performed using Jamovi software (version 2.3.21). Normal distribution was assessed using the Kolmogorov-Smirnov test, and normality was confirmed. Chi-square test was performed to evaluate the association between several factors and age range. The effects of all parameters on the oral health indices were assessed using hierarchical linear regression analysis. No multicollinearity was found among the parameters, and the variance inflation factor (VIF) was below 3. The level of statistical significance was set at p < .05.

3. RESULTS

The chi-square test results showed no statistically significant association between gender and age groups, with similar distributions of males and females across both age ranges. Similarly, there was no significant difference in the mother's age between the two age groups, although more mothers in the older age group fell into the 36-45 years range. The education levels of mothers also did not significantly differ between the two age groups, but a higher proportion of mothers with elementary school education were observed in the older age group. In terms of clinical indices, significant differences were found between the two age groups. The DMFT and dmft scores, PI, GI, and BPI were all higher in the older age group, indicating a greater burden of dental and gingival issues. Additionally, CCHAS scores were significantly higher in the younger age group. On the other hand, there were no significant differences in other scales such as IN, EN, PN, MP, and ASHN between the age groups (Table 1).

In the analysis where DMFT was the dependent variable, demographic attributes were added to model 1, explaining 4% of the variance. A positive and significant relationship was found between the increase in DMFT and demographic data. When the subscales of ASHN, IN, EN, PN, and MP were added to model 2, the explanation rate increased by 2%. A negative and significant relationship was found between DMFT and ASHN. When CCHAS was added to model 3, 6% of the DMFT variance was explained in the final model (p < .01) (Table 2).

In the analysis where dmft was the dependent variable, demographic attributes were added to model 1, explaining 8% of the variance. When the subscales of ASHN, IN, EN, PN, and MP were added to model 2, the explanation rate decreased by 1%. When CCHAS was added to model 3, 7% of the dmft variance was explained in the final model (p < .001) (Table 3).

In the analysis where the plaque index was the dependent variable, demographic attributes were added to model 1, explaining 2% of the variance. When the subscales of ASHN, IN, EN, PN, and MP were added to model 2, the explanation rate increased by 3%. When CCHAS was added to model 3, 5% of the PI variance was explained in the final model (p < .001) (Table 4).

Table 1. Chi-square test that evaluated the association between several factors and age range.

Characteristic	N	3-6 ages	7-10 ages	p-value
	328			
Gender				.330
Male		45 (49%)	103(43%)	
Female		46 (51%)	134(57%)	
Mother's age (%)				.130
18-25		1 (1.1%)	1 (0.4%)	
26-35		46 (51%)	91 (38%)	
36-45		40 (44%)	126 (53%)	
46-55		4 (4.4%)	19 (8.0%)	
Education (%)				.140
Literate		2 (2.2%)	3 (1.3%)	
Elementary School		27 (30%)	100 (42%)	
High school		36 (40%)	75 (32%)	
University		22 (24%)	55 (23%)	
Master's degree or PhD		4 (4.4%)	4 (1.7%)	
DMFT		0 (0, 0)	2 (0, 4)	**<.001**
dmft		7 (4, 9)	6 (3, 7)	**<.001**
Plaque index		1.00 (0.70, 1.30)	1.20 (0.90, 1.40)	**.003**
Gingival index		0.60 (0.20, 0.80)	0.70 (0.40, 0.90)	**.005**
Bleeding on Probing Index		10 (0, 11)	10 (8, 15)	**.028**
IN		21 (20, 24)	20 (19, 22)	.180
EN		19 (16, 22)	19 (16, 21)	.480
PN		20 (18, 23)	20 (18, 22)	.440
MP		11 (9, 12)	10 (9, 12)	.290
ASHN		71 (67, 76)	70 (67, 74)	.390
CCHAS		12 (10, 14)	12 (10, 14)	**.040**

*: Number of samples: n, percent: %, Median (IQR), IN: Information on Nutrition, EN: Emotion for Nutrition, PN: Positive Nutrition, MP: Malnutrition, ASHN: Attitude Scale for Healthy Nutrition, CCHAS: Children's Heart Health Promotion Attitude Scale.

Table 2. Presentation of Hierarchical linear regression analysis outcomes for the DMFT parameter.

Model Coefficients – DMFT		95% Confidence Interval						
Predictor	Stand. Estimate	Lower	Upper	*p*-value	R	R^2	Adjusted R^2	*p*-value
Model 1 (Demographic attributes)					0.497	0.247	0.224	**<.001**
Gender								
Female – Male	0.269	0.074	0.464	**.007**				
Age range 7-10 – 3-6	0.935	0.717	1.152	**< .001**				
Mother's age								
26-35 – 18-25	0.324	-0.980	1.629	.625				
36-45 – 18-25	0.263	-1.045	1.571	.692				
46-55 – 18-25	0.520	-0.834	1.874	.451				
Education								
Elementary School – literate	0.780	-0.088	1.647	.078				
High school – literate	0.669	-0.198	1.536	.130				
University – literate	0.707	-0.186	1.600	.121				
Master's degree or PhD – literate	0.449	-0.625	1.523	.411				
Systemic Disorder: Present – None	0.110	-0.176	0.397	.451				
Model 2 (ASHN)					0.517	0.268	0.235	**<.001**
IN	-0.147	-0.255	-0.039	**.008**				
EN	0.018	-0.087	0.124	.733				
PN	0.027	-0.076	0.130	.602				
MP	-0.058	-0.165	0.049	.287				
Model 3 (CCHAS)					0.519	0.269	0.234	**<.001**
CCHAS	-0.037	-0.137	0.063	.469				

*: IN: Information on Nutrition, EN: Emotion for Nutrition, PN: Positive Nutrition, MP: Malnutrition, ASHN: Attitude Scale for Healthy Nutrition, CCHAS: Children's Heart Health Promotion Attitude Scale.

**: p values in bold indicate a statistically significant difference

Table 3. Presentation of Hierarchical linear regression analysis outcomes for the dmft parameter.

Model Coefficients – dmft		95% Confidence Interval						
Predictor	Stand. Estimate	Lower	Upper	*p*-value	R	R^2	Adjusted R^2	*p*-value
Model 1 (Demographic attributes)					0.385	0.148	0.122	<.001
Gender								
Female – Male	-0.306	-0.516	-0.096	.004				
Age range: 7-10 – 3-6	-0.473	-0.707	-0.239	< .001				
Mother's age								
26-35 – 18-25	-1.481	-2.886	-0.077	.039				
36-45 – 18-25	-1.492	-2.900	-0.084	.038				
46-55 – 18-25	-1.429	-2.887	0.029	.055				
Education								
Elementary School – literate	-0.200	-1.134	0.734	.674				
High school – literate	0.029	-0.904	0.962	.951				
University – literate	-0.415	-1.376	0.547	.397				
Master's degree or PhD – literate	-1.086	-2.242	0.069	.065				
Systemic Disorder: Present – None	-0.310	-0.619	-0.002	.049				
Model 2 (ASHN)					0.391	0.153	0.115	<.001
IN	0.033	-0.083	0.149	.581				
EN	-0.004	-0.118	0.110	.945				
PN	-0.060	-0.171	0.051	.285				
MP	-0.039	-0.154	0.076	.504				
Model 3 (CCHAS)					0.391	0.153	0.112	<.001
CCHAS	0.024	-0.084	0.131	.668				

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**: p values in bold indicate a statistically significant difference

Table 4. Presentation of Hierarchical linear regression analysis outcomes for the plaque index parameter.

Model Coefficients – Plaque index		95% Confidence Interval						
Predictor	Stand. Estimate	Lower	Upper	*p*-value	R	R^2	Adjusted R^2	*p*-value
Model 1 (Demographic attributes)					0.275	0.076	0.047	**.005**
Gender								
Female – Male	0.063	-0.152	0.278	.564				
Age range: 7-10 – 3-6	0.374	0.135	0.614	**.002**				
Mother's age								
26-35 – 18-25	-0.770	-2.206	0.666	.292				
36-45 – 18-25	-0.851	-2.290	0.589	.246				
46-55 – 18-25	-0.736	-2.226	0.755	.332				
Education								
Elementary School – literate	-0.879	-1.834	0.076	.071				
Highschool – literate	-0.653	-1.607	0.301	.179				
University – literate	-0.877	-1.860	0.106	.080				
Master's degree or PhD – literate	-1.188	-2.370	-0.006	.049				
Systemic Disorder: Present – None	0.220	-0.095	0.535	.171				
Model 2 (ASHN)					0.337	0.114	0.074	**<.001**
IN	-0.140	-0.259	-0.022	**.021**				
EN	-0.111	-0.227	0.005	.060				
PN	-0.035	-0.149	0.078	.540				
MP	-0.153	-0.270	-0.035	**.011**				
Model 3 (CCHAS)					0.338	0.114	0.072	**<.001**
CCHAS	-0.031	-0.141	0.079	.584				

IN: Information on Nutrition, EN: Emotion for Nutrition, PN: Positive Nutrition, MP: Malnutrition, ASHN: Attitude Scale for Healthy Nutrition, CCHAS: Children's Heart Health Promotion Attitude Scale.

**: p values in bold indicate a statistically significant difference*

Table 5. Presentation of Hierarchical linear regression analysis outcomes for the gingival index parameter.

Model Coefficients – Gingival index		95% Confidence Interval						
Predictor	Stand. Estimate	Lower	Upper	*p*-value	R	R^2	Adjusted R^2	*p*-value
Model 1 (Demographic attributes)					0.288	0.083	0.054	**.002**
Gender								
Female – Male	0.007	-0.209	0.223	.950				
Age range: 7-10 – 3-6	0.335	0.096	0.575	**.006**				
Mother's age								
26-35 – 18-25	-1.266	-2.706	0.173	.084				
36-45 – 18-25	-1.298	-2.740	0.145	.078				
46-55 – 18-25	-1.206	-2.702	0.291	.114				
Education								
Elementary School – literate	-1.000	-1.958	-0.043	**.041**				
Highschool – literate	-0.799	-1.755	0.157	.101				
University – literate	-0.974	-1.959	0.011	.053				
Master's degree or PhD – literate	-1.621	-2.806	-0.437	.007				
Systemic Disorder: Present – None	0.173	-0.143	0.489	.283				
Model 2 (ASHN)					0.333	0.111	0.071	**<.001**
IN	-0.117	-0.236	0.002	.054				
EN	-0.100	-0.217	0.016	.090				
PN	-0.019	-0.132	0.095	.749				
MP	-0.142	-0.260	-0.024	.019				
Model 3 (CCHAS)					0.333	0.111	0.068	**.001**
CCHAS	0.008	-0.102	0.119	.881				

IN: Information on Nutrition, EN: Emotion for Nutrition, PN: Positive Nutrition, MP: Malnutrition, ASHN: Attitude Scale for Healthy Nutrition, CCHAS: Children's Heart Health Promotion Attitude Scale.

**: p values in bold indicate a statistically significant difference*

Table 6. Presentation of Hierarchical linear regression analysis outcomes for the Bleeding index parameter.

Model Coefficients – Bleeding on Probing Index		95% Confidence Interval						
Predictor	Stand. Estimate	Lower	Upper	*p*-value	R	R²	Adjusted R²	*p*-value
Model 1 (Demographic attributes)					0.192	**0.037**	**0.007**	.280
Gender								
Female – Male	0.062	-0.158	0.282	.579				
Age range:								
7-10 – 3-6	0.240	-0.006	0.485	.055				
Mother's age								
26-35 – 18-25	0.083	-1.391	1.557	.912				
36-45 – 18-25	0.022	-1.455	1.500	.977				
46-55 – 18-25	0.080	-1.450	1.610	.918				
Education								
Elementary School – literate	-0.294	-1.275	0.686	.555				
Highschool – literate	-0.132	-1.111	0.848	.792				
University – literate	-0.405	-1.414	0.604	.430				
Master's degree or PhD – literate	-0.795	-2.008	0.418	.198				
Systemic Disorder:								
Present – None	0.211	-0.112	0.535	.200				
Model 2 (ASHN)					0.256	0.066	**0.024**	.085
IN	-0.085	-0.207	0.037	.170				
EN	-0.080	-0.199	0.040	.191				
PN	-0.103	-0.219	0.014	.083				
MP	-0.152	-0.273	-0.031	**.014**				
Model 3 (CCHAS)					0.259	0.067	**0.022**	.105
CCHAS	0.038	-0.075	0.151	.507				

IN: Information on Nutrition, EN: Emotion for Nutrition, PN: Positive Nutrition, MP: Malnutrition, ASHN: Attitude Scale for Healthy Nutrition, CCHAS: Children's Heart Health Promotion Attitude Scale.

**: p values in bold indicate a statistically significant difference*

The relationship between the GI and demographic data, ASHN, and CCHAS is shown in Table 5. In the analysis where the gingival index was the dependent variable, demographic attributes were added to model 1, explaining 3% of the variance. When the subscales of ASHN, IN, EN, PN, and MP were added to model 2, the explanation rate increased by 2%. When CCHAS was added to model 3, 5% of the gingival index variance was explained in the final model (p < .01).

The relationship between the BPI and demographic data, ASHN, and CCHAS is shown in Table 6. In the analysis where the bleeding index was the dependent variable, demographic attributes were added to model 1, explaining 0% of the variance. When the subscales of ASHN, IN, EN, PN, and MP (p < .05) were added to model 2, the explanation rate increased by 2%. When CCHAS was added to model 3, 1% of the bleeding index variance was explained in the final model.

For some notable variables, estimated marginal means plots were generated and presented in Fig 1. IN, DMFT, PI, and GI showed significant negative correlations. MP showed significant negative correlations with the PI, BPI, and GI (p < .05). No significant relationship was found between other scale parameters and oral index.

The graph showing the relationship between CCHAS and ASHN is shown in Figure 2. A significant statistical relationship was observed between CCHAS and ASHN. Parents with higher ASHN scores had children with higher CCHAS scores.
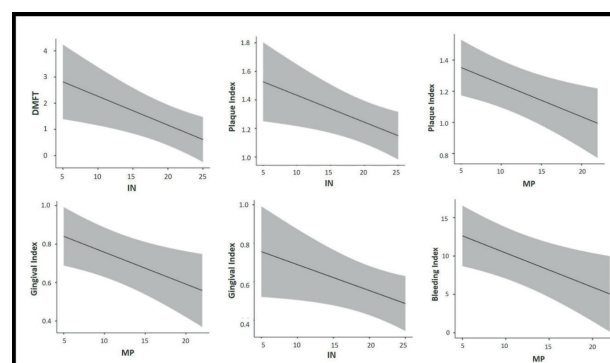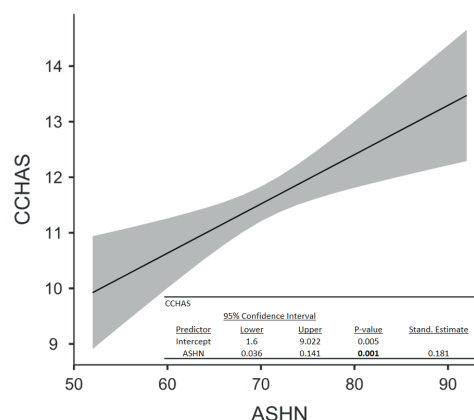

Figure 1. Estimated marginal means plot were generated.

Figure 2. Linear regression analysis regarding the prediction capability of ASHN on CCHAS.

4.DISCUSSION

In this study, the attitudes of mothers with children aged 3-10 towards healthy eating were evaluated for their impact on the child's eating habits and oral health. Mothers' attitudes towards healthy eating were assessed using the ASHN scale, the impact on children's eating habits was evaluated using the CCHAS scale, and the effects on oral and dental health were assessed using DMFT/dmft, PI, GI, and BPI. As a result of these findings, while the null hypothesis (H0) of this study was rejected, the alternative hypothesis (H1) was accepted. According to this literature review, no study examining the effect of mothers' knowledge about nutrition on children's eating habits and oral health using the ASHN and CCHAS scales has been encountered. In this respect, this study is original.

Literature review reveals that in studies examining the relationship between parental education level and dmft, DMFT, no significant correlation was found between the number of cavities in children and the parent's education level (30-32). Similarly, in another study comparing the dmft level of 5-year-old children with the parent's education level, it was reported that dmft was not affected by the education level (33). Lin et al. conducted a study examining the one-year effect of cariogenic foods on permanent teeth and found that new cavity formation was particularly observed in children of parents with lower education levels (34). It is reported in the literature that parents' education level and racial differences affect their awareness of oral care habits and therefore the frequency of caries in their children (35). Likewise, an increase in maternal education level was shown to be associated with a decrease in DMFT scores in another study (36). In this study, a significant relationship between DMFT and dmft and demographic variables was observed, but there was no direct relationship with maternal education level.

When evaluating the effect of gender on cavities, a study by Abbas et al. found that the DMFT and dmft levels of boys were higher than those of girls, accompanied by lower parental education levels (37). A similar literature study reported that the incidence of cavities was similar in both genders (30), however, according to a study conducted on Italian children, the DMFT of boys (3.20) was found to be higher than that of girls (1.96) (38). In this current study, similar to literature studies, it was found that dmft was lower in girls, while contrary to the literature studies, the DMFT of girls was higher but there was no significant.

Saraiva et al.'s (39) study investigating the effect of maternal age on DMFT and dmft scores reported an increase in DMFT with increasing maternal age, while Fraiz et al. (40) reported that maternal age did not have a significant contribution to the child's DMFT and dmft scores. In this study, higher dmft scores were observed in cases where maternal age ranged from 18 to 25 compared to other maternal age groups. According to a study, young parents were found to be less competent than more experienced parents in setting rules for their children, such as brushing their teeth and limiting

sugar consumption (41). In this context, we can say that the high dmft scores in the children of young mothers in this study may be due to inadequate oral care habits and nutrition. High cavity activity is associated with unhealthy eating and high carbohydrate consumption in the literature (42). In the current study, the average DMFT was found to be 2±0.4 between 7-10 ages, while dmft was found to be 7±4.9 between 3-6 ages and 6±3.7 between 7-10 ages. According to this study, as mothers' knowledge about nutrition decreased, DMFT increased significantly and was statistically significant. Specifically, a significant increase in DMFT problems was observed as mothers IN scores in ASHN decreased. It is understood that a decrease in knowledge about nutrition is associated with an increase in cavity frequency.

Periodontal diseases are not very common in children; however, due to poor oral hygiene, dental plaque forms, and gingival bleeding may occur following gingival inflammation (43). Studies have linked higher parental education levels to lower PI and GI scores in children (44, 45), However, there are also studies in the literature indicating that education level does not have a direct effect on PI and GI (46). While a study suggests that there may be differences in oral hygiene habits between genders and consequently differences in dental plaque formation, according to the study by Akçakoca et al. (46) parameters regarding PI and GI were reported to be similar between girls and boys. Similarly, in this current study, no significant difference was observed between genders in terms of oral hygiene habits, but it was found that only mothers with a master's or doctoral level of education had lower PI and GI scores compared to literate mothers, and the difference was significant. This may be attributed to higher-educated mothers having a higher awareness of oral hygiene practices and routine check-ups.

In this study, a significant relationship was observed between the child's PI scores and ASHN. Particularly, as IN decreased, PI scores increased. It is possible that an increase in the mother's knowledge about nutrition did not parallel an increase in the level of knowledge about oral hygiene habits. Additionally, as the PI score increased, the MP score decreased. Children's eating habits are influenced not only by their mothers but also by school and siblings (18). While CCHAS scores of children decreased, PI scores increased. There was a significant relationship between GI and CCHAS scores. In the study conducted by Akçakoca et al. in 2021 (46), it was observed that children who consumed sugary drinks daily had higher PI and GI averages. In our study, children with a positive nutritional attitude were found to have lower plaque index. The scales used in the study were found to be significantly useful in predicting PI and GI. An increase in mothers' knowledge about nutrition may have led to a decrease in the frequency of cariogenic food consumption, which increases plaque and gingival inflammation in children, and consequently, a decrease in periodontal parameters.

Fışkın and Ölçer (21) conducted a study using ASHN to investigate the impact of mothers' nutrition attitudes on their children's eating behaviour. In this study, the mean

total ASHN score was found to be 83.862±9.158, and the IN mean was calculated as 22.137±2.805, indicating a high level of healthy eating (23) The study did not find a significant relationship between mothers' nutrition attitudes and their children's eating behaviour. However, the research indicated that as mothers' knowledge about nutrition increased, it positively influenced their children's eating behaviour, and poor eating habits could negatively affect their children's eating behaviour (21).

In this study, the mean ASHN score was calculated as 71±67.76 between 3-6 ages, 70±67.74 between 7-10 ages, and the IN mean was 21±20.24 and 20±19.22, respectively, indicating that mothers had a high level of healthy eating attitude (23). The impact of mothers' nutrition attitudes on their children's eating behaviour was evaluated using the CCHAS scale in the current study, and a significant relationship was found between CCHAS and ASHN. According to a study, parents' own food consumption preferences, beliefs, or knowledge about the subject have been reported to influence the shaping of their children's eating behaviour (47). Similarly, in this study, it was observed that as mothers' positive attitudes towards nutrition increased, their children's eating behaviour was also positively affected.

According to studies conducted in different cultures, the mother's nutrition attitude has been reported to be the main factor in shaping the child's eating behaviour (48, 49). When the importance of healthy eating is explained to children, it has been observed that their awareness about the subject develops, they understand the importance of foods for their development, and they develop appropriate behaviours (50). Additionally, imposing a rule on foods that should not be consumed by their families is effective for children.

Considering all this information, considering the effectiveness of the family in raising an individual, the importance of the mother's role in acquiring eating behaviour should be taken into account. The data from this study indicate that the mother's nutrition attitude contributes to the development of positive eating behaviour in children. A decrease in the mother's knowledge about nutrition may also lead to deterioration in the child's oral and dental health.

This study was conducted on a limited population with similar nutrition attitudes and behaviours belonging to a specific region. Conducting studies in larger populations involving different ethnic backgrounds could provide broader insights into nutrition attitudes and oral health. Furthermore, the limited number of scales used in the study is among its limitations. Therefore, studies using different scales in larger populations would contribute to the literature.

5. CONCLUSION

Positive nutrition attitude of the mother positively influences the child's eating behaviour. An increase in the mother's knowledge about nutrition has positively affected the oral and dental health of their children. The ASHN scale was found to be useful in predicting dental caries in the data

of this study. An IN value in ASHN is a risk factor for DMFT. However, it was observed that as the mother's poor nutrition attitude increased, the PI, GI, and BPI parameters of their children decreased. The scales used in the study cannot be used strongly to predict PI, GI, and BPI. ASHN was found to be useful in predicting CCHAS, and there is a positive relationship between them.

Author Contributions:
Research idea: AK
Design of the study: AK, FYŞ
Acquisition of data for the study: AK, İO
Analysis of data for the study: AK, İO
Interpretation of data for the study: AK, FYŞ, İO
Drafting the manuscript: AK, FYŞ, İO
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The Impact of Transition of Paper-Based Consent Forms to Digital Format on Dental Healthcare Efficiency

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ABSTRACT

Objective: To evaluate the perceptions and attitudes of patients of different ages and education levels regarding the transition of paper-based consent forms to digital format.

Methods: Ninety-four patients were divided into three groups according to their age range (18–39, 40–59, over 60) as well as education level (primary/secondary school, high school, university). Participants were administered a digital consent form along with an online questionnaire aimed at determining perceptions and attitudes of patients towards paper-based and digital consent. Demographic data was analyzed using descriptive statistics. Pearson's Chi-Square test was used to compare the answer rates between patient groups categorized according to age ranges and educational levels (p=.05).

Results: 79.8% and 90.4% of participants reported that converting paper-based consent forms to digital format would be more advantageous for the workflow of healthcare services and in terms of functionality and usability, respectively. The proportion of participants stating they had sufficient knowledge about informed consent was higher in the university graduate group (p<.05). While 47.8% of the primary and/or secondary school graduates and 48.2% of high school graduates preferred written consent, 34.1% of the university graduate group was in favor of digital consent (p<.05). No other differences were obtained among patient groups regarding answers given to the questionnaire (p>.05).

Conclusion: Digital consent may provide advantages for the workflow and efficiency of healthcare services and the quality of consent process. However, using digital forms as a part of in-person dentist-patient communication may be more favorable in obtaining trust-based patient consent.

Keywords: Informed consent; digital conversion; digital consent; healthcare efficiency

1. INTRODUCTION

The physician-patient relationship creates a trust-based communication within the framework of certain ethical principles that impose obligations and responsibilities on both parties. Accordingly, it becomes mandatory to obtain patient consent to ensure the legality of any medical intervention. However, in contemporary practice, "consent" alone does not suffice enough to make medical interventions legal, and therefore the term informed consent begins to acquire increasing significance (1,2). In the medical and dental fields, informed consent refers to the process where, firstly, the physician informs the patient about the diagnosis and treatment options, alternative treatment methods, and the potential outcomes of accepting or rejecting relevant treatments, and secondly, the patient accepts or rejects the proposed treatment with his/her free will. In addition to its significance regarding the legal liabilities of physicians, informed consent also poses great importance in terms of patient rights and clarifies the medical, ethical, and legal aspects of the dentist-patient relationship (2,3).

Within the scope of daily dentistry practice, informed consent is obtained before numerous dental procedures (1), and paper-based consent forms are used for this purpose in many institutions. However, the implementation of paper-based consent forms poses several challenges such as slowing down the workflow, loss of time spared for diagnosis and treatment and a series of costly manual processes including duplication, supervision, and storage of the forms (4-7). These problems become more prevalent especially in university hospitals where patient circulation is usually more evident than in other health institutions. Therefore, the transition of paper consent forms

to digital format becomes imperative to save time for both the patient and the physician, increase the efficiency of healthcare services, and secure the storage of patient information.

Digitalization of consent forms is also necessary to align with the evolving landscape of digital dentistry practices. Due to global COVID-19 and the disruption of routine healthcare services, digitalization studies in dentistry have begun to focus especially on the field of diagnosis, and accordingly, new terms and concepts such as telemedicine and teledentistry have gained importance (8-10). Teledentistry can be defined as facilitating diagnosis and treatment planning procedures through intraoral photographs and communication technologies, and marks a significant step in the digitalization of diagnostic processes (10). However, despite these digitalization initiatives, it is noteworthy that the impact of digital consent forms on the efficiency of dental healthcare services has not been previously investigated.

Therefore, the aim of this study was to evaluate the perceptions and attitudes of patients of different age groups and education levels regarding paper-based consent forms and their transition to digital format, and to point out the possible disadvantages of paper consent in terms of dental healthcare efficiency.

2. METHODS

2.1. Ethical Approval

The present study was approved by the Scientific Research and Publication Ethics Board of the university (approval date: 31.01.2023, approval number: 1805) and followed the principles of the Declaration of Helsinki.

2.2. Study Group

Patients who applied to the Department of Oral and Maxillofacial Radiology between March and April 2023 were invited to participate in the study. The sample size of the study group was determined based on similar previous studies conducted in the medical field (11,12). Accordingly, the effect size was selected as w = 0.44, the degree of freedom as 3 and the confidence interval as 95%. As a result of the power analysis conducted with G*Power 3.1 software, the total sample size required for the present study was calculated to be approximately 89 patients. Participants who were over the age of 18, were able to communicate one-on-one without a companion, and had enough cognitive level to fill out the digital consent form were included. Care was taken to ensure that the number of included patients were homogeneously distributed in the age ranges of 18-39 years, 40-59 years and over 60 years in order to represent individuals from all age groups.

2.3. Preparation of the Questionnaire

The questionnaire was prepared after scanning similar studies in the literature held in the field of medicine (11-13).

The questions used in the study were determined by two oral and maxillofacial radiologists (ES, EA) with different years of experience (20 years, 3 years). The questionnaire consisted of a total of two sections and eighteen questions. The first part included 3 questions regarding the demographic characteristics (gender, age, education level) of the participants. The second part consisted of 15 questions aimed at determining patients' attitudes, perceptions and trust levels towards digital informed consent forms. The questionnaire was first administered to a pilot group of 20 patients in order to verify the reliability and comprehensibility of the questions. The survey was revised and updated in line with the suggestions and responses received regarding the structure and understandability of the questions.

2.4. Application of the Questionnaire

The paper-based informed consent form used in our dental hospital was converted to digital format and transferred to Metasoft patient database. Then, the digital consent form was administered to the patients who agreed to participate in the study and was signed by the participants using Techsign DOC Document Signing Platform (Techsign Information Technologies Inc., Istanbul, Türkiye) installed on an Android tablet. All digital consent forms were stored as electronic records in Metasoft database. Following the informed consent process, a questionnaire aimed at investigating the attitudes and perceptions of the patients towards paper-based and digital consent forms was applied to the participants by three 5th grade dental students (OK, MEK, AK).

2.5. Statistical Analysis

Data analysis was performed using the IBM SPSS Statistics 20.0 (SPSS Inc., Chicago, IL, USA).

Demographic data and the proportional distribution of the responses collected from each question in the second section were analyzed using descriptive statistical methods.

Pearson's Chi-Square test was used to compare the answer rates obtained from the second section of the questionnaire between patient groups aged 18–40 years, 40–60 years, and over 60 years as well as patient groups with different education levels (primary/secondary education, high school, university). For questions revealing a significant difference between patient groups of different age ranges or education levels, pairwise comparisons were performed using adjusting residual analysis (14,15). The statistical significance level was determined as $p < .05$ for all comparisons.

3. RESULTS

3.1. Demographic Characteristics

Among a total of 500 patients invited to participate in the study, 94 patients, 51 female and 43 male (mean age: 45.13 ± 18.37), agreed to be included.

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Thirty-eight patients were between the ages of 18-39 (mean age: 25.55 ± 5.75), while 27 were between 40-59 years of age (mean age: 50.9 ± 6.53), and 29 patients were over the age of 60 (mean age: 67.08 ± 5.8).

According to the education levels of the participants, 23 patients were primary and/or secondary school graduates, while 27 patients were high school graduates. The remaining 44 patients were in the group of university graduates (Table 1).

Table 1. Demographic characteristics of the participants.

Demographic characteristic		N (%)	Mean Age ± SD
Gender	Female	51 (54.3)	
	Male	43 (45.7)	
Age	18-39	38 (40.4)	25.55 ± 5.75
	40-59	30 (31.9)	50.90 ± 6.53
	≥60	26 (27.7)	67.08 ± 5.8
Education Level	Primary & Secondary school	23 (24.5)	59.70 ± 9.14
	High school	27 (28.7)	40.52 ± 18.44
	University	44 (46.8)	40.34 ± 18.2

SD: Standard deviation

3.2. Overall Perceptions and Attitudes of Patients Towards Consent Forms

Overall perceptions and attitudes of the participants towards paper-based and digital informed consents are presented in Table 2.

Table 2. Overall perceptions and attitudes of patients towards paper-based and digital consent forms based on the answers obtained from the second section of the questionnaire.

Question	Obtained Answer
➢ **Answers**	n (%)
1. How do you rate your knowledge about informed consent?	
➢ Sufficient	80 (85.1)
➢ Partially Sufficient	9 (9.6)
➢ Insufficient	5(5.3)
2. Is obtaining informed consent from patients necessary before a dental examination?	
➢ Yes	83 (88.3)
➢ No	7 (7.4)
➢ Not sure/I don't know	4 (4.3)
3. Is the informed consent requested from you before your dental examination sufficiently understandable?	
➢ Yes	84 (89.4)
➢ No	2 (2.1)
➢ Not sure/I don't know	8 (8.5)
4. How do you think informed consent should be obtained?	
➢ Written (Signed by both patient and dentist)	39 (41.5)
➢ Verbal	5 (5.3)
➢ Written and verbal	26 (27.7)
➢ Digital	24 (25.5)

Question	Obtained Answer
5. Do you think paper-based consent forms in the healthcare services slow down the workflow?	
➢ Yes	23 (24.5)
➢ No	63 (67)
➢ Not sure/I don't know	8 (8.5)
6. Do you think paper-based consent forms reduce the time spared for diagnosis/treatment?	
➢ Yes	31 (33)
➢ No	53 (56.4)
➢ Not sure/I don't know	10 (10.6)
7. Are you uncomfortable sharing your personal data in the paper-based informed consent form?	
➢ Yes	15 (16)
➢ No	75 (79.8)
➢ Not sure/I don't know	4 (4.3)
8. Do you think transitioning paper-based consent forms to digital format would be advantageous for the workflow of healthcare services?	
➢ Yes	75 (79.8)
➢ No	10 (10.6)
➢ Not sure/I don't know	9 (9.6)
9. Do you consider transitioning paper-based consent forms to digital format would positively contribute to the environment by reducing paper and pen waste?	
➢ Yes	86 (91.5)
➢ No	4 (4.3)
➢ Not sure/I don't know	4 (4.3)
10. Do you think transitioning paper-based consent forms to digital format would be advantageous in terms of environmental sustainability and saving resources?	
➢ Yes	87 (92.6)
➢ No	2 (2.1)
➢ Not sure/I don't know	5 (5.3)
11. Do you think transitioning paper-based consent forms to digital format would provide more advantages in terms of functionality and usability?	
➢ Yes	85 (90.4)
➢ No	7 (7.4)
➢ Not sure/I don't know	2 (2.1)
10. Which one do you find safer for the personal data you declared in the consent form to be stored: paper-based or digital format?	
➢ Paper-based	19 (20.2)
➢ Digital	67 (71.3)
➢ Not sure/I don't know	8 (8.5)
11. Which do you find more valid/reliable for your official transactions, wet-ink or digital signature?	
➢ Wet-ink signature	55 (58.5)
➢ Digital signature	29 (30.9)
➢ Not sure/I don't know	10 (10.6)
14. Would you prefer smart tablets over paper in the informed consent procedure?	
➢ Yes	81 (86.2)
➢ No	8 (8.5)
➢ Not sure/I don't know	5 (5.3)
15. Would you prefer using smart pens and keyboards over normal pens in the informed consent procedure?	
➢ Yes	79 (84)
➢ No	10 (10.6)
➢ Not sure/I don't know	5 (5.3)

88.3% (n=83) of the patients reported that obtaining informed consent was necessary before a dental examination. While 79.8% (n=75) noted that transitioning paper-based consent forms to digital format would be more advantageous for the workflow of healthcare services, 71.3% (n=67) preferred digital consent form as a safer storage format to keep their personal data.

86.2% (n=81) and 84% (n=79) of the participants declared that they preferred smart tablets and smart pens or keyboards in the informed consent procedure, respectively. On the other hand, while 41.5% (n=39) of the participants preferred written consent, 25.5% (n=24) were in favor of obtaining digital consent.

3.3. Comparison of Patient Groups Categorized by Age

Proportions and comparisons of answers regarding the perception, attitude and trust levels of the patient groups aged 18-39, 40-59 and over 60 towards paper-based and digital informed consent are summarized in Tables 3 and 4.

94.7% (n=36) of patients aged 18–39, 88.9% (n=24) of patients aged 40–59 and 79.3% (n=23) of patients aged over 60 noted that informed consent should be obtained before dental examinations. On the other hand, the proportion of patients who declared they had sufficient knowledge about informed consent and found the informed consent adequately understandable was higher in the 18-39 age group (89.5%, n=34) (p>.05).

84.2% (n=32) of the 18–39 group, 81.5% (n=22) of the 40–59 group, and 72.4% (n=21) of the over 60 group declared that transitioning paper-based consent forms to digital format would be more advantageous for the workflow of healthcare services. However, the ratio of patients noting that paper-based consent forms slow down the workflow in the healthcare services and reduce the diagnosis/treatment time was higher in the 40-59 age group (33.3%, n=9) (p>.05).

Table 3. Comparison of perceptions and attitudes of three patient groups aged 18–40 years, 40–60 years, and over 60 years towards paper-based informed consent.

Question	18-39	40-59	Over 60	p value*
➤ Answers	n (%)	n (%)	n (%)	
How do you rate your knowledge about informed consent?				
➤ Sufficient	34 (89.5)	22 (81.5)	24 (82.8)	.395
➤ Partially Sufficient	4 (10.5)	3 (11.1)	2 (6.9)	
➤ Insufficient	0 (-)	2 (7.4)	3 (10.3)	
Is obtaining informed consent from patients necessary before a dental examination?				
➤ Yes	36 (94.7)	24 (88.9)	23 (79.3)	.416
➤ No	1 (2.6)	2 (7.4)	4 (13.8)	
➤ Not sure/I don't know	1 (2.6)	1 (3.7)	2 (6.9)	
Is the informed consent requested from you before your dental examination sufficiently understandable?				
➤ Yes	36 (94.7)	22 (81.5)	26 (89.7)	.194
➤ No	0 (-)	2 (7.4)	0 (-)	
➤ Not sure/I don't know	2 (5.3)	3 (11.1)	3 (10.3)	
How do you think informed consent should be obtained?				
➤ Written (Signed by both patient and dentist)	14 (36.8)	11 (40.7)	14 (48.3)	.14
➤ Verbal	1 (2.6)	4 (14.8)	0 (-)	
➤ Written and verbal	12 (31.6)	8 (29.6)	6 (20.7)	
➤ Digital	11 (28.9)	4 (14.8)	9 (31)	
Do you think paper-based consent forms in the healthcare services slow down the workflow?				
➤ Yes	8 (21.1)	9 (33.3)	6 (20.7)	.683
➤ No	27 (71.1)	15 (55.6)	21 (72.4)	
➤ Not sure/I don't know	3 (7.89)	3 (11.1)	2 (6.9)	
Do you think paper-based consent forms reduce the time spared for diagnosis/treatment?				
➤ Yes	11 (28.9)	11 (40.7)	9 (31)	.766
➤ No	22 (57.9)	13 (48.2)	18 (62.1)	
➤ Not sure/I don't know	5 (13.2)	3 (11.1)	2 (6.9)	
Are you uncomfortable sharing your personal data in the paper-based informed consent form?				
➤ Yes	4 (10.5)	4 (14.8)	7 (24.1)	.328
➤ No	31 (81.6)	23 (85.2)	21 (72.4)	
➤ Not sure/I don't know	3 (7.89)	0 (-)	1 (3.4)	

*Pearson's Chi-Square test

Table 4. Comparison of perceptions, attitudes and trust levels of three patient groups aged 18–40 years, 40–60 years, and over 60 years towards digital informed consent.

Question	18-39	40-59	Over 60	p value*
➢ Answers	n (%)	n (%)	n (%)	
Do you think transitioning paper-based consent forms to digital format would be more advantageous for the workflow of healthcare services?				
➢ Yes	32 (84.2)	22 (81.5)	21 (72.4)	.423
➢ No	3 (7.89)	4 (14.8)	3 (10.3)	
➢ Not sure/I don't know	3 (7.89)	1 (3.7)	5 (17.2)	
Do you consider transitioning paper-based consent forms to digital format would positively contribute to the environment by reducing paper and pen waste?				
➢ Yes	35 (92.1)	25 (92.6)	26 (89.7)	.925
➢ No	1 (2.6)	1 (3.7)	2 (6.9)	
➢ Not sure/I don't know	2 (5.3)	1 (3.7)	1 (3.4)	
Do you think transitioning paper-based consent forms to digital format would be advantageous in terms of environmental sustainability and saving resources?				
➢ Yes	36 (94.7)	24 (88.9)	27 (93.1)	.752
➢ No	1 (2.6)	1 (3.7)	0 (-)	
➢ Not sure/I don't know	1 (2.6)	2 (7.4)	2 (6.9)	
Do you think transitioning paper-based consent forms to digital format would provide more advantages in terms of functionality and usability?				
➢ Yes	36 (94.7)	25 (92.6)	24 (82.8)	.421
➢ No	1 (2.6)	2 (7.4)	4 (13.8)	
➢ Not sure/I don't know	1 (2.6)	0 (-)	1 (3.4)	
Which one do you find safer for the personal data you declared in the consent form to be stored: paper-based or digital format?				
➢ Paper-based	10 (26.3)	3 (11.1)	6 (20.7)	.452
➢ Digital	24 (63.2)	21 (77.8)	22 (75.9)	
➢ Not sure/I don't know	4 (10.5)	3 (11.1)	1 (3.4)	
Which do you find more valid/reliable for your official transactions, wet-ink or digital signature?				
➢ Wet-ink signature	17 (44.7)	18 (66.7)	20 (69)	.255
➢ Digital signature	16 (42.1)	6 (22.2)	7 (24.1)	
➢ Not sure/I don't know	5 (13.2)	3 (11.1)	2 (6.9)	
Would you prefer smart tablets over paper in the informed consent procedure?				
➢ Yes	35 (92.1)	22 (81.5)	24 (82.8)	.496
➢ No	1 (2.6)	3 (11.1)	4 (13.8)	
➢ Not sure/I don't know	2 (5.3)	2 (7.4)	1 (3.4)	
Would you prefer using smart pens and keyboards over normal pens in the informed consent procedure?				
➢ Yes	36 (94.7)	21 (77.8)	22 (75.9)	.482
➢ No	1 (2.6)	2 (7.4)	7 (24.1)	
➢ Not sure/I don't know	1 (2.6)	4 (14.8)	0 (-)	

*Pearson's Chi-Square test

While 69% (n=20) of patients aged over 60 preferred wet-ink signature for their official transactions, the rate of patients who preferred smart tablets and pens over paper and normal pens during the informed consent process was higher in the group of 18–39 (92.1%, n=35; 94.7%, n=36) (p>.05).

Comparison of response rates obtained from the second section of the questionnaire revealed no significant difference between patient groups of different ages (p>.05) (Tables 3 and 4).

3.4. Comparison of Patient Groups Categorized by Education Level

Proportions and comparisons of responses obtained from the patient groups graduated from primary and/or secondary school, high school and university are given in Tables 5 and 6.

According to Table 5, the ratio of patients with sufficient knowledge about informed consent forms was lower in primary and/or secondary school graduates (65.2%, n=15) and higher in university graduates (93.2%, n=41) (p<.05).

While 47.8% of primary and/or secondary school graduates and 48.2% of high school graduates reported that they preferred written consent, the proportion of patients who was in favor of digital consent was higher in the university graduate group. The ratio of patients preferring verbal consent was higher in the primary and/or secondary school graduates (17.4%, n=4)

(p<.05). The pairwise comparisons of three patient groups disclosed no other significant difference (p>.05).

None of the other responses obtained from the second section of the questionnaire revealed any difference between patient groups of different levels of education (p>.05).

Table 5. Comparison of perceptions and attitudes towards paper-based informed consent in three patient groups categorized according to their education levels.

Question Answers	Primary& Secondary n (%)	High School n (%)	University n (%)	p value*
How do you rate your knowledge about informed consent?				
Sufficient	15 (65.2) **(p=.002)****	24 (88.9) (p=.513)	41 (93.2) **(p=.039)****	**.013**
Partially Sufficient	4 (17.4) (p=.143)	3 (11.1) (p=.748)	2 (4.5) (p=.120)	
Insufficient	4 (17.4) **(p=.003)****	0 (-) (p=.145)	1 (2.3) (p=.217)	
Is obtaining informed consent from patients necessary before a dental examination?				
Yes	18 (78.3)	26 (96.3)	39 (88.7)	.382
No	3 (13)	1 (3.7)	3 (6.8)	
Not sure/I don't know	2 (8.7)	0 (-)	2 (4.5)	
Is the informed consent requested from you before your dental examination sufficiently understandable?				
Yes	19 (82.6)	23 (85.2)	42 (95.4)	.259
No	1 (4.4)	0 (-)	1 (2.3)	
Not sure/I don't know	3 (13)	4 (14.8)	1 (2.3)	
How do you think informed consent should be obtained?				
Written (Signed by both patient and dentist)	11 (47.8) (p=.478)	13 (48.2) (p=.406)	15 (34.1) (p=.172)	**.021**
Verbal	4 (17.4) **(p=.003)****	0 (-) (p=.145)	1 (2.3) (p=.217)	
Written and verbal	3 (13) (p=.071)	10 (37) (p=.197)	13 (29.5) (p=.701)	
Digital	5 (21.7) (p=.671)	4 (14.8) p=(.130)	15 (34.1) (p=.074)	
Do you think paper-based consent forms in the healthcare services slow down the workflow?				
Yes	6 (26.1)	3 (11.1)	14 (31.8)	.266
No	14 (60.9)	21 (77.8)	28 (63.7)	
Not sure/I don't know	3 (13)	3 (11.1)	2 (4.5)	
Do you think paper-based consent forms reduce the time spared for diagnosis/ treatment?				
Yes	9 (39.1)	9 (33.3)	13 (29.5)	.755
No	13 (56.5)	14 (51.9)	26 (59.1)	
Not sure/I don't know	1 (4.4)	4 (14.8)	5 (11.4)	
Are you uncomfortable sharing your personal data in the paper-based informed consent form?				
Yes	5 (21.7)	4 (14.8)	6 (13.7)	.937
No	17 (73.9)	22 (81.5)	36 (81.8)	
Not sure/I don't know	1 (4.4)	1 (3.7)	2 (4.5)	

*Pearson's Chi-Square test
**Adjusted residual analysis
p< .05

Table 6. Comparison of perceptions and attitudes and trust levels towards digital informed consent in three patient groups categorized according to their education levels.

Question Answers	Primary& Secondary n (%)	High School n (%)	University n (%)	p value*
Do you think transitioning paper-based consent forms to digital format would be more advantageous for the workflow of healthcare services?				
Yes	18 (78.3)	19 (70.4)	38 (86.4)	.494
No	2 (8.7)	4 (14.8)	4 (9.1)	
Not sure/I don't know	3 (13)	4 (14.8)	2 (4.5)	
Do you consider transitioning paper-based consent forms to digital format would positively contribute to the environment by reducing paper and pen waste?				
Yes	21 (91.3)	25 (92.6)	40 (90.9)	.529
No	2 (8.7)	1 (3.7)	1 (2.3)	
Not sure/I don't know	0 (-)	1 (3.7)	3 (6.8)	
Do you think transitioning paper-based consent forms to digital format would be advantageous in terms of environmental sustainability and saving resources?				
Yes	22 (95.7)	25 (92.6)	40 (90.9)	.877
No	0 (-)	1 (3.7)	1 (2.3)	
Not sure/I don't know	1 (4.3)	1 (3.7)	3 (6.8)	
Do you think transitioning paper-based consent forms to digital format would provide more advantages in terms of functionality and usability?				
Yes	20 (87)	25 (92.6)	40 (90.9)	.671
No	3 (13)	1 (3.7)	1 (2.3)	
Not sure/I don't know	0 (-)	1 (3.7)	3 (6.8)	
Which one do you find safer for the personal data you declared in the consent form to be stored: paper-based or digital format?				
Paper-based	4 (17.4)	5 (18.5)	10 (22.7)	.816
Digital	18 (78.3)	20 (74.1)	29 (65.9)	
Not sure/I don't know	1 (4.3)	2 (7.4)	5 (11.4)	
Which do you find more valid/reliable for your official transactions, wet-ink or digital signature?				
Wet-ink signature	18 (78.3)	12 (44.5)	25 (56.8)	.097
Digital signature	3 (13)	10 (37)	16 (36.4)	
Not sure/I don't know	2 (8.7)	5 (18.5)	3 (6.8)	
Would you prefer smart tablets over paper in the informed consent procedure?				
Yes	19 (82.6)	24 (88.9)	38 (86.4)	.795
No	3 (13)	1 (3.7)	4 (9.1)	
Not sure/I don't know	1 (4.4)	2 (7.4)	2 (4.5)	
Would you prefer using smart pens and keyboards over normal pens in the informed consent procedure?				
Yes	17 (73.9)	25 (92.6)	37 (84.1)	.152
No	5 (21.7)	2 (7.4)	3 (6.8)	
Not sure/I don't know	1 (4.4)	0 (-)	4 (9.1)	

*Pearson's Chi-Square test

4. DISCUSSION

Informed consent is an indispensable part of the physician-patient relationship since it establishes a trust-based communication between the physician and the patient and upholds essential values of medical ethics, including beneficence, non-maleficence, and the respect for individual autonomy. Nonetheless, the routine implementation style of the consent form poses some difficulties in daily clinical practice due to its paper-based format. Despite numerous studies evaluating the advantages and outcomes of digital consent forms in medical surgical procedures (4,5,11,12), radiation therapy (6), pharmacy (13) and in the field of biomedical research (7,16), the influence of digital consent forms in dental practice has not been investigated. Accordingly, this is the first study aimed at determining the effect of the transition of paper-based consent forms to digital format on dental healthcare efficiency.

Implementation of paper-based consent forms leads to a number of problems that may affect the quality of the consent process, including lost consent forms, illegible handwriting, missing patient data, incorrectly completed forms, difficulties with form transfer, and the financial burden of documentation (4-6,17). Several studies comparing informed consent-related errors between paper-based and digital formats have reported a significant improvement in the error rate with the use of digital consent forms (4,5,17-19). Furthermore, digital consent appears to have a large impact on patient satisfaction, especially in younger age groups, since patients find digital consent more interesting, easier to use and better for understanding (7,16). Consistent with these statements, 90.4% of total participants in our study reported that they think digital consent forms would provide more advantages in terms of functionality and usability, and the rate of patients noting this statement was higher in the 18-39 age group (94.7%). Moreover, 71.3% of our total participants declared that they found the digital consent format safer than paper-based in terms of storing their personal data. Although older patients have been reported to be more skeptical about sharing their personal data electronically (17), 75.9% of older patients in our study supported the safety of storage conditions of the digital consent forms.

Interestingly, despite the common agreement regarding the functionality, usability and storage safety of digital consent forms, the ratio of participants who preferred written consent (41.5%) was still higher than that of those who preferred digital consent (25.5%). This discrepancy observed in our results may be caused by concerns about the possible loss of face-to-face communication between patient and dentist during the digital consent process. Additionally, another potential explanation for this inconsistency may be patients' greater dependence on wet-ink signature and the fact that more than half of our participants (58.5%) found wet-ink signature more reliable for their official transactions supports this interpretation. However, further multi-center studies investigating perceptions of larger patient groups about digital consent forms are required to validate our findings.

World Health Organization (WHO) encourages the development of person-centric digital health technologies in their report of global strategy on digital health 2020–2025 (20). In accordance with this strategy, the use of digital consent forms personalized to the patient and/or specific to the procedure has been proposed by different authors to establish a more effective patient information process (5,7,21). In the field of dentistry, personalized consent forms may provide benefits in many dental procedures, particularly in surgical treatments, where a more detailed and procedure-specific consent is required to ensure that the patient is properly informed about the benefits, risks, and alternatives of the planned treatment. Accordingly, the results of our study showing that 86.2% and 84% of the participants preferring smart tablets and pens over paper and regular pens may be considered promising regarding the future development and improvement of personalized digital consent. However, as already mentioned, the digital consent process still upholds some obstacles since electronic signatures or signing platforms may not reach a wide usage area among some societies with variable socioeconomic levels and older age groups (19). Accordingly, the results of our study revealed that approximately half of primary and/or secondary graduates as well high school graduates tend to prefer written consent forms over digital format. Therefore, further studies should focus on the development and validation of personalized digital consent forms by taking into account the personal preferences of different societies with variable socioeconomic levels and patients of different age groups.

Previous studies focusing on the effect of digital consent forms in the field of biomedical research emphasize the importance of face-to-face communication in the consent process in terms of ensuring the understanding of participants, regardless of the format of the consent form (16,21,22). It can be anticipated that the same concern would also apply to dental and medical fields, especially in invasive and/or surgical treatments since patients tend to be more stressed and hesitant about these procedures and thereby may be in greater need of face-to-face communication with their dentists. Accordingly, the use of digital consent creates an advantage in this regard by reducing the time loss caused by the administration process of paper-based consents and providing more time for a face-to-face patient and physician conversation to discuss the diagnosis and treatment processes comprehensively (4). Nevertheless, instead of converting the paper-based consent process to a fully digital format, adding various digital features to consent forms and preserving face-to-face communication may offer a better option in terms of the digitalization of the informed consent (23-26). Although only 33% of participants in the present study stated that paper-based consent forms may reduce the time spared for diagnosis/treatment, the perspectives of different groups of patients applying various dental departments should be investigated to accurately interpret the impact of paper-based consent forms on the diagnosis/treatment time.

In addition to the patient-related benefits of digital consent, the transition of paper-based consent forms to digital format may also contribute to the environment by preventing unnecessary paper use in healthcare services and thus saving resources. In accordance with this, over 90% of our participants agreed with the perception of digital consent format would be advantageous in terms of reducing paper and pen waste and environmental sustainability. Aside from the environmental contribution, digital consent may also provide financial benefits by the development of cost-effective electronic consent systems to reduce unintended costs caused by the errors associated with paper-based format (17). However, it also should be remembered that the technical requirements of digital consent systems such as smart tablets, phones or multimedia features may also impose another financial burden on healthcare institutions (19). Therefore, further investigations should aim to develop

reliable cost-effective consent formats with minimal technical requirements.

One of the limitations of this study was the failure to include different health institutions and compare the attitudes of larger patient groups. Therefore, multicenter studies including larger patient groups from different socioeconomic levels, various societies and age ranges should be conducted to confirm the global impact of the digital consent forms on dental healthcare efficiency and to generalize our results. Nevertheless, despite the possible advantages of digital consent forms in terms of workflow and efficiency of healthcare services and the quality of the consent process, the in-person physician-patient relationship continues to be a crucial intermediary step in obtaining patient consent in a trust-based clinical environment. Therefore, it can be anticipated that the digital consent format would provide more benefits and may be more preferable if it is used as a part of face-to-face physician-patient communication.

This was the first study in the dental field evaluating patients' perceptions towards the transition of paper-based consent forms to digital format by implementing a digital consent form combined with an electronic document signing platform. Further studies with larger groups of participants may enable more concrete data on the efficiency and reliability of the digital consent format and may provide guidance on its routine use as a part of face-to-face communication.

5. CONCLUSION

The transition of paper-based consent forms to digital format may provide several advantages in terms of workflow and efficiency of healthcare services, time spared for diagnosis and treatment processes, better patient understanding, security of storing patient information and, accordingly, the quality of the consent process. However, face-to-face physician-patient communication still upholds an important part in trust-based patient consent. Therefore, rather than converting the paper-based consent process to a fully digital format, the use of digital consent forms as complementary to in-person physician-patient communication may provide a more qualified consent process in dental clinical practice.

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Acquisition of data for the study: OBK, AK, MEK
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Assessment of the Relationship Between Maxillary Sinus Membrane Thickness and Various Anatomical Factors Before Implant Treatment

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ABSTRACT

Objective: This study aimed to evaluate the maxillary sinus mucosal thickness (MSMT) and factors that may affect this thickness in individuals with a posterior edentulous region.

Methods: Cone beam computed tomography (CBCT) images of 130 patients with edentulous posterior maxilla were retrospectively examined. MSMT was measured. The relationship between MSMT and age, gender, residual alveolar bone length/width, nasal septum deviation angle, ostium obstruction, and pneumatization were examined. Descriptive statistics, nonparametric tests, Spearman correlation, and chi-square analyses were used. The significance level was set at .05.

Results: The study included 130 maxillary sinuses. Pathological mucosal thickening was present in 67 (51.5%) of maxillary sinuses. Mucosal thickness was significantly thicker in the presence of maxillary sinus ostium obstruction, in the presence of pneumatization and in males. No statistically significant differences were found between nasal septum deviation angle groups.

Conclusion: MSMT is affected by gender, the alveolar bone length, maxillary sinus ostium obstruction, and pneumatization as results of this study. When planning implant treatment, these factors that will affect the MSMT should be considered for the success of the treatment, and the planning should be done together by the oral and maxillofacial surgeon and the dentomaxillofacial radiologist.

Keywords: Cone beam computed tomography, implant, maxillary sinus mucosal thickness

1. INTRODUCTION

Implant treatment is a preferred method to replace the missing tooth. In the posterior maxilla, resorption is observed after tooth loss, leading to progressive sinus pneumatization and a decrease in the alveolar ridge in the cranial direction (1). After this resorption, maxillary sinus floor augmentation (MSFA) is performed in cases where the existing bone is insufficient for implant treatment. However, some complications related to MSFA may occur. One of the most common complications during the MSFA is sinus membrane perforation, with 0–60% incidence (2,3). The main risk factors causing sinus membrane perforation are the presence of septa in the sinus, differences in sinus morphology (angle of sinus walls), sinus membrane thickness, and application errors during osteotomy or membrane elevation (4). In a previous study, it was reported that one of these risk factors, sinus membrane thickness less than 0.8 mm or more than 3 mm, significantly increased the risk of perforation and caused an increase in postoperative inflammation (5). Another previous study

stated that sinus membrane thickness outside the range of 1-2 mm significantly increased the risk of perforation (6). In this context, measuring the MSMT and the size of the existing bone before the surgical procedure for implant placement and detailed evaluation of the pathologies and anatomical structures that will affect the membrane thickness is essential for the success of the treatment.

Situations where the sinus membrane is greater than the physiological thickness limit are referred to as increased mucosal thickening. Different physiological mucosal thicknesses have been mentioned in many previous studies (6-9). However, a mucosal thickness of 2 mm is considered a reliable threshold, and when it is more than 2 mm, it is classified as pathological/increase in thickening in recent studies (2,8,10). Increase in sinus membrane thickness; it may be associated with various pathological conditions such as rhinosinusitis, pseudocyst, retention cyst, mucocele, allergy, and odontogenic infections (11). In addition, some

studies show that there may be a correlation between sinus membrane thickness, obstructed sinus ostium (12), and the height of the residual alveolar crest (13). Another study stated that it could not find a relationship between residual bone and MSMT (6). The relationship between nasal septum deviation and maxillary sinus mucosa thickening has been a matter of debate in the literature. While a study by Bayrak et al. (14) emphasizes that there is no relationship, another study by Munakata et al. (2) argues that there is a relationship.

Cone beam computed tomography (CBCT) is the most reliable 3D imaging method used for treatment planning before implant treatment. In CBCT images, the alveolar bone, as well as the maxillary sinus, can be visualized, and the anatomy and pathologies of the maxillary sinus can be evaluated (15). To reduce the risk of infection and obtain good clinical results during sinus lifting, the maxillary sinus membrane should be evaluated in detail on CBCT.

In this study, MSMT was examined in patients who were planned to receive implant treatment in the maxillary posterior edentulous area in order to evaluate the correct patient selection, accurate surgical-prosthetic planning, and possible complications before the operation.

In addition, the relationship between membrane thickness and bone height in the relevant region, bone width, maxillary sinus ostium obstruction, maxillary sinus pneumatization, maxillary sinus septum, and nasal septum deviation angle were evaluated.
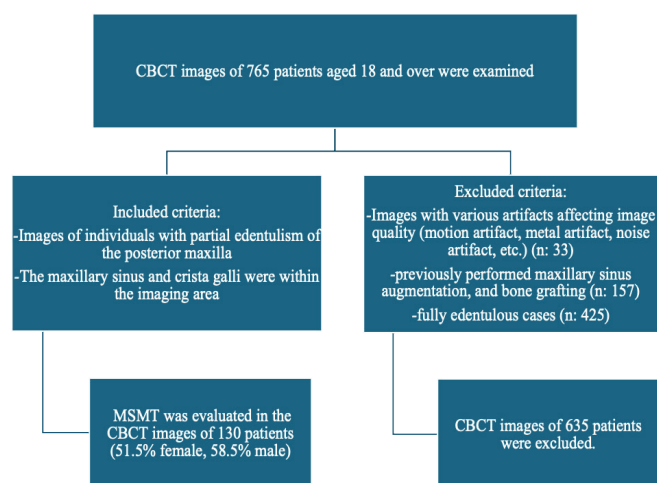
2. METHODS

Ethics committee approval was obtained before starting the study (Research No: 2022-1069).

G* Power package program (G* Power ver. 3.0.10, Franz Faul, Üniversitat Kiel, Germany, http://www.psycho. unidusseldorf. de/aap//projects/gpower) was used to determine the minimum number of individuals to be included in the study. The calculation of our sample size is based on the assumption that certain anatomical factors, which form the basis of the present study, may influence maxillary sinus mucosal thickness. Given the descriptive nature of the present study, our focus is specifically on estimating the relationship between the maxillary sinus mucosal thickness of individuals and these identified anatomical factors. To increase the accuracy of our estimates and ensure the reliability of the results, we used a margin of error $(\alpha) = .05$, effect size $f = .30$, and test power $(1-\beta) = .80$. As a result of the calculations, the sample size that would provide the power of the test $(1-\beta) = .80$ was determined as 128. The width of the confidence interval was determined in accordance with the objectives of the present study and the chosen analytical methods and will contribute to the assessment of the significance of the data obtained.

The CBCT images of 765 patients aged 18 and over who applied to our Faculty of Dentistry, Department of Oral and Dentomaxillofacial Surgery for implants between 2017 and 2018 examined in this retrospective study. All the CBCT images obtained from the maxillofacial region (Field of View (FOV) 16.0 cm × 9.2 cm) or maxilla (FOV: 16.0 × 5.2 cm) were examined using the Planmeca Promax 3D-Mid (Planmeca, Helsinki, Finland) device with the parameters 90 kVp, eight mA, 13.5 seconds exposure time and 400 μm voxel size. Among the CBCT images examined, images of partially edentulous individuals, in whom at least one of the premolar and molar teeth in the posterior maxilla was missing, were included in the study. Care was taken to ensure the maxillary sinus and crista galli were within the imaging area. Images with various artifacts affecting image quality (motion artifact, metal artifact, noise artifact, etc.) (n: 53), previously maxillary sinus augmentation (n:157), bone grafting, and fully edentulous cases (n: 425) were excluded from the study. In line with these criteria, MSMT was evaluated unilaterally in the CBCT images of 130 patients (51.5% female, 58.5% male) with an average age of 55.3 ± 10.7 years.

CBCT images of 765 patients aged 18 and over were examined

Included criteria:
-Images of individuals with partial edentulism of the posterior maxilla
-The maxillary sinus and crista galli were within the imaging area

Excluded criteria:
-Images with various artifacts affecting image quality (motion artifact, metal artifact, noise artifact, etc.) (n: 33)
-previously performed maxillary sinus augmentation, and bone grafting (n: 157)
-fully edentulous cases (n: 425)

MSMT was evaluated in the CBCT images of 130 patients (51.5% female, 58.5% male)

CBCT images of 635 patients were excluded.

All the CBCT images were examined in sagittal, coronal, and axial sections. The radiographic evaluations were performed by a radiologist with at least seven years of experience in the Department of Dentomaxillofacial Radiology. All images were analyzed in a light-reduced environment, on a medical monitor with a 24-inch screen with ideal resolution, from a distance of approximately 50 cm, using the measurement function in Planmeca Romexis 4.6.2.R, the original program of the device.

The presence/absence of maxillary sinus mucosal thickening was assessed unilaterally on images of the posterior edentulous region of the maxilla where the implant was planned, and its extent was measured from the widest area in the sagittal section (16). Pathological mucosal thickening was considered to be present when the MSMT was more than 2 mm (2).

The alveolar bone size was measured from the coronal section. The measurement in the coronal section was made from the part corresponding to the region with the highest mucosal thickening in the sagittal section. A vertical guide plane was used to determine this region in the coronal section

Table 1. *Maxillary sinus mucosa thickness according to gender*

| | | Gender | | | | | | Mann Whitney U Test | |
		n	Mean	Median	Minimum	Maximum	sd	Mean rank	U	p
Maxillary sinus mucosal thickness (mm)	Female	67	4	2	0	16	4	58.74		
	Male	63	7	2	0	31	9	72.69		
	Total	130	5	2	0	31	7		1657.5	.03*

*p< .05

(Figure 1). The bone width was measured at the widest point closest to the ridge top in the determined coronal section.
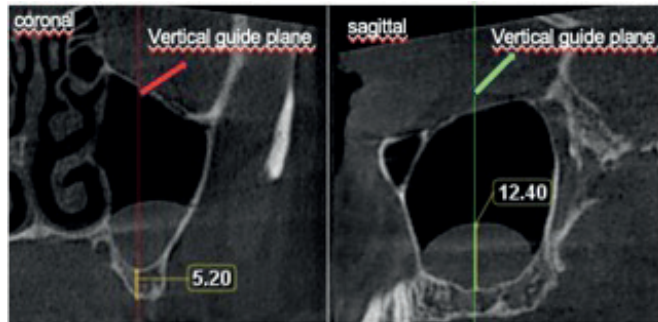
Figure 1. *CBCT sagittal section showing the region with the highest mucosal thickening, and mucosal thickness measurement. Measurement of alveolar bone length in CBCT coronal section. The vertical guide plane used to determine the area to be measured in the coronal section is visible in both sections.*

Table 2. *Correlation between alveolar bone length/width and maxillary sinus mucosal thickness*

		Alveolar bone length (mm)	Alveolar bone width (mm)
Maxillary sinus mucosal thickness (mm)	r	-0.17*	-0.13
	p	.04*	.12
	n	130	130

*p< .05

Figure 2. *CBCT coronal section showing ostium of the maxillary sinus and septa of the maxillary sinus*

Figure 3. *CBCT coronal section showing maxillary sinus pneumatisation*

The presence/absence of ostium obstruction of the relevant maxillary sinus, the presence/absence of septa of the maxillary sinus, and maxillary sinus pneumatization were evaluated (Figure 2-3).

The nasal septum deviation angle is the angle made by the line between crista galli and spina nasalis anterior (point projection on the horizontal plate of the maxillary or palatine bone) on the coronal section with the line between crista galli and the most lateral part of the nasal septum (2). The angle was determined by measuring in the coronal section (Figure 4). According to the measured angle, individuals were classified as mild < 9°, 9°≤ moderate <15°, and severe ≥ 15° (17).

Figure 4. *Measurement of nasal septum deviation angle in CBCT coronal section.*

The data obtained from the study were analyzed through the SPSS v.22 package program (IBM, Chicago, IL, USA). Since the data were not normally distributed, the Mann-Whitney U test was used for comparisons between two groups, and the Kruskall Wallis H test was used for comparisons between three or more groups. Spearman correlation analysis was used for relationships between variables. The relationship between categorical data was examined with Chi-Square analysis.

A descriptive statistical method (Mean, Median, Standard Deviation, Minimum-Maximum) was used when evaluating the study data.

In the study, .05 was used as the significance level, and if p< .05, it was stated that there was a significant difference/relationship, and if p> .05, it was stated that there was no significant difference/relationship.

3. RESULTS

The study included 130 patients (51.5% female, 58.5% male, with an average age of 55.3 ± 10.7 years) and 130 maxillary sinuses. It was observed that 61 (46.9%) of the maxillary sinuses were on the right, a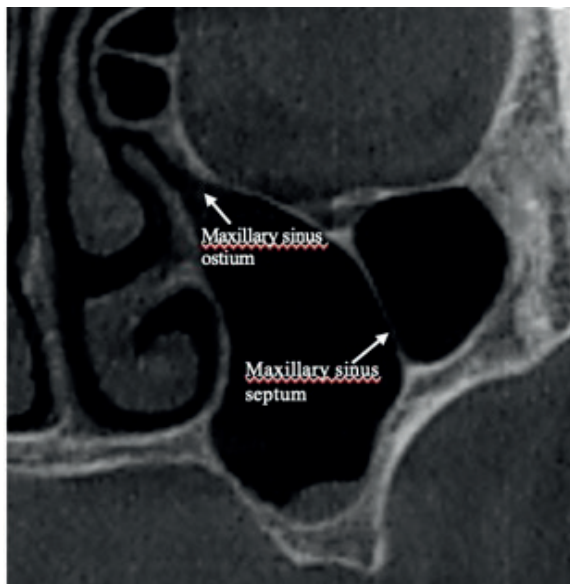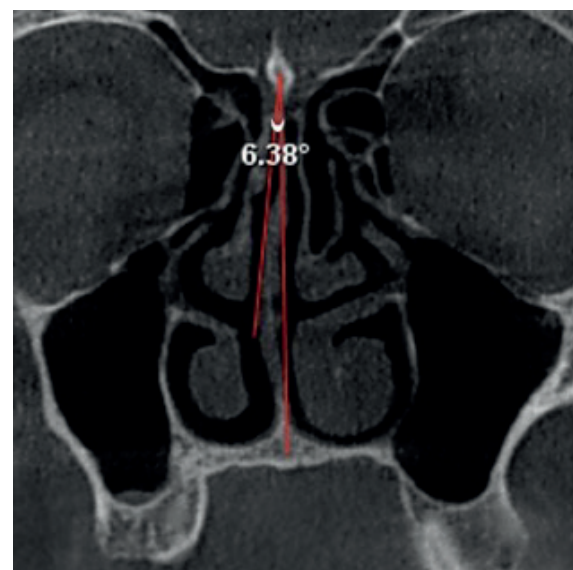nd 69 (33.1%) were on the left. Pathological mucosal thickening was present in 67 (51.5%) of 130 maxillary sinuses. There was pathological mucosal thickening in 35 (57.4%) of the right maxillary sinus and 31 (44.9%) of the left maxillary sinus.

The average MSMT was 5 ± 7 mm, and the median was 2 mm. Mucosal thickness was maximum 31 mm and minimum zero. There was a statistically significant difference in MSMT between genders (p< .05). MSMT was significantly higher in males than in females (Table 1). There was no statistically significant relationship between age and MSMT values (p> .05).

There was a negative and significant relationship between the amount of MSMT and bone length (r=-.174; p< .05). Accordingly, as MSMT increases, alveolar bone length decreases. There was no statistically significant relationship between MSMT and alveolar bone widths (p> .05) (Figure 5) (Table 2). However, as the amount of mucosal thickness increased, bone width decreased.

A significant difference was found between the presence of pneumatization in terms of the amount of MSMT. The maxillary sinus mucosa thickness in the maxillary sinus with pneumatization was statistically significantly thicker than in those without (p< .05) (Table 3).

A significant difference was observed between the ostium obstruction conditions regarding mucosal thickness amount (mm) (p< .05). MSMT was significantly greater in maxillary sinuses with ostium obstruction than those without (Table 4).

There was no statistically significant difference between the presence/absence of maxillary sinus septum in terms of maxillary sinus mucosa thickness (p> .05).

Table 3. Maxillary sinus mucosa thickness according to pneumatization

		Pneumatization						Mann Whitney U Test		
		n	Mean	Median	Minimum	Maximum	sd	Mean rank	U	p
Maxillary sinus mucosal thickness (mm)	Absence	54	3	2	0	16	4	53.74		
	Presence	76	7	4	0	31	8	73.86	1417	.003*
	Total	130	5	2	0	31	7			

*p< .05

Table 4. Maxillary sinus mucosa thickness according to ostium obstruction

		Ostium obstruction						Mann Whitney U Test		
		n	Mean	Median	Minimum	Maximum	sd	Mean rank	U	p
Maxillary sinus mucosal thickness (mm)	Absence	113	4	2	0	24	5	59.31		
	Presence	17	16	14	0	31	11	106.65	261	.0001*
	Total	130	5	2	0	31	7			

*p< .05

Table 5. Maxillary sinus mucosa thickness according to nasal septum deviation angle

		Nasal Septum Deviation Angle						Kruskal Wallis H Test		
		n	Mean	Median	Minimum	Maximum	sd	Mean rank	H	p
Maxillary sinus mucosal thickness (mm)	Group 1	82	5	2	0	29	6	61.31		
	Group 2	43	6	3	0	31	7	70.06	4.748	.093
	Group 3	5	16	22	0	28	13	95.00		
	Total	130	5	2	0	31	7			

*p<.05

The number of patients in the groups according to the severity of nasal septum deviation was as follows: mild 82, moderate 43, and severe 5. There was no statistically significant difference in maxillary sinus mucosa thickness between groups classified according to nasal deviation severity ($p > .05$). Although not statistically significant, it was found in our study that the maxillary sinus mucosa thickness was higher in the severe (Table 5).
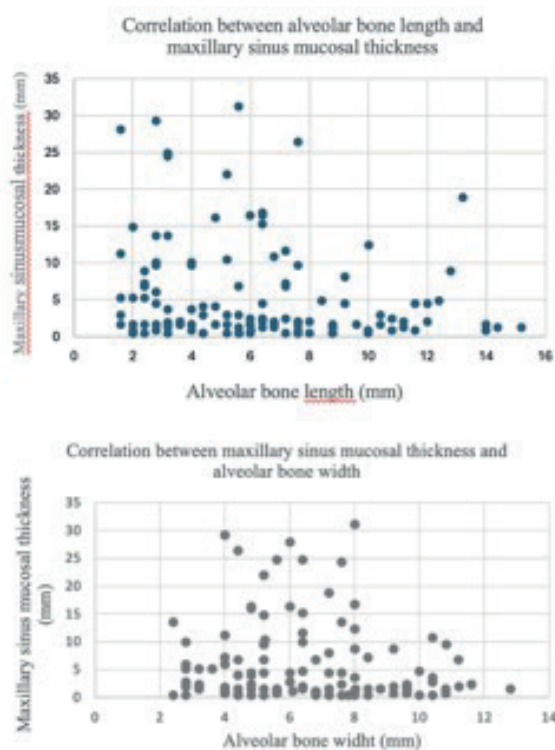

Figure 5. *Correlation between alveolar bone length/width and maxillary sinus mucosal thickness*

4. DISCUSSION

Perforation in the maxillary sinus membrane may reduce the chance of success in implant treatment and cause various symptoms in the patient. Therefore, it is important to evaluate MSMT when planning implant treatment in the posterior maxilla region. is essential when planning implant treatment in the posterior maxilla region.

Computed tomography and magnetic resonance imaging are essential for the evaluation of the maxillary sinus because they provide multiple sections through the sinuses in different planes (18). However, it has recently been shown that CBCT can also be used in the evaluation of the maxillary sinus (19). While CBCT has advantages such as lower radiation dose and faster speed compared to computed tomography, it has advantages compared to magnetic resonance imaging, such as lower cost. Additionally, CBCT is the preferred 3D imaging method in implant treatment planning. (18). Therefore, the CBCT images were preferred to evaluate MSMT for our study.

Previous studies have no consensus on how much physiological thickness of the sinus membrane should be. Eggesbo et al. (20), Cakur et al. (21), and Kalyvas et al. (7) accepted that the sinus membrane thickens when its physiological thickness is 4 mm or more. Lozano-Carrascal et al. (9) stated this limit of physiological membrane thickness as 3 mm. In their study, Cagici et al. (22), Shanbhag et al. (23) and Janner et al. (8) reported that the sinus anatomy was affected when the maxillary sinus mucosa thickness was more than 2 mm, and they accepted this value as pathological mucosal thickness. In recent similar studies, a maxillary sinus mucosal thickness of more than 2 mm was evaluated as pathological/the increase of mucosal thickness (2,10). Differences in opinion regarding physiological mucosal thickness may arise from differences in race and ethnicity. In addition, when clinical and radiographic findings are evaluated together, it has been stated that some of the causes of pathological thickening may also present an asymptomatic (10). Ignoring this situation may have caused the physiological mucosal thickness to be determined as thicker in some studies. Therefore, in the present study, pathological MSMT was evaluated as more than 2 mm. With this, the increase of mucosal thickness was present in 51,5% of the maxillary sinuses. In previous studies, this rate varies between 25% and 53.6% (2,7,12,24). The reason for this difference between studies may be due to different populations. Additionally, in some studies, dentulous regions were evaluated, while in others, edentulous regions were considered. In the study conducted by Dursun et al. (25), it was emphasized that the increase of mucosal thickness was higher in edentulous regions than in the dentulous regions. However, we think more studies need to be done on this subject.

Guo et al. (26) reported the MSMT value as 1.93 ± 2 mm. Lin et al. (6) and Lozano-Carrascal et al. (9) were found this value as 1.32 ± 0.87 and 1.82 ± 1.59 mm in their CBCT study, respectively. In other studies conducted for this purpose, Yıldırım et al. (27) declared it as 4.19 ± 5.84, Kalyvas et al. (7) found this value to be 1.60 ± 1.20 mm and Munakata et al. (2) reported it as 1.09 ± 1.30 mm. MSMT was measured as 5 ± 7 mm in the present study. The reason why the sinus mucosa thickness was relatively higher in this study compared to other studies may be due to the examination of areas where there were no teeth and the inclusion of maxillary sinus diseases that cause mucosal thickening in the maxillary sinus (except for those that cause bone destruction).

Although the amount of MSMT that causes perforation during implant treatment was known in studies, there are few studies on the factors that may affect this thickness in edentulous areas (2). Therefore, in the present study, in addition to age and gender, the relationship between alveolar bone length and width, presence of pneumatization, maxillary sinus ostium obstruction, maxillary sinus septum, and nasal septum deviation were examined.

There are many studies in the literature examining the relationship of MSMT with gender and age (2,7,8,21,28). In these studies, when the maxillary sinus mucosa thickness

was evaluated in terms of gender, it was found to be thicker in males than in females (2,7,8,21). Kalyvas et al. argued that the age factor did not affect the anatomical features of the sinus (7). In a meta-analysis study by Monje et al., it was stated that age did not affect MSMT (28). Munakata and colleagues found that there was an increase in sinus mucosa thickness with age, but there was no statistical correlation between the two data in another meta-analysis study (2). Findings regarding age and gender in the present study are consistent with these previous studies.

Although there were several studies on residual alveolar crest length with MSMT, to our knowledge, no previous study has examined the relationship between alveolar bone width and sinus mucosa thickness. In addition, it has been reported in many studies that there is no relationship between alveolar bone length in edentulous areas and maxillary sinus mucosa thickness (2,29). It was also stated that MSMT showed a positive correlation with alveolar ridge size in those with a residual ridge height of less than 3.5 mm in another study (30). The present study revealed that as the maxillary sinus mucosa thickness increased, the alveolar bone length decreased statistically significantly, and the maxillary sinus mucosa thickness increased as the bone width decreased, this was not statistically significant. The reason for these differences between the studies may be related to different populations, reasons for tooth extraction and the process after extraction and the presence of prosthesis used in this process. It may also be related to the determination of alveolar crest length using a vertical reference plane in our study. We believe that the use of the vertical reference plane prevented random measurements and introduced an innovative approach for the measurement method. In addition, since this was a retrospective study based on the imaging archive, the reasons for tooth extraction, the process after extraction and the presence of prosthesis used in this process were not known.

There were very few studies in the literature examining the relationship between MSMT and the presence of pneumatization. A previous study showed that there was no relationship between pneumatization and mucosal membrane thickness (31). The reason for the inconsistency with our study may be related to the evaluation of the maxillary sinus in the edentulous region in our study. Remodeling of the alveolar crest after tooth extraction in the posterior maxilla may trigger growth in the maxillary sinus and cause pneumatization (32). Another previous study has shown that there was a risk of sinus membrane perforation in cases where the membrane thickness was above the pathological limit (5). Considering the results of this study (5) and the finding in the present study that the membrane thickness was statistically significantly thicker in the presence of pneumatization in the maxillary sinus, the presence of pneumatization may cause thickening of the sinus membrane and, therefore, perforation during implant treatment. However, more studies are needed on this topic.

Previous studies have reported that mucosal thickness was ticker in with ostium obstruction presence than without, which is consistent with the present study (12,33). The maxillary sinus ostium provides the passageway for the mucosa released from the mucociliary cells lining the maxillary sinus into the nasal cavity (33). Maxillary sinus ostium obstruction occurring for various reasons may cause mucus retantion, maxillary sinus mucosal thickening, and rhinosinusitis (33,34). Rhinosinusitis negatively affects the chances of success of implant surgery (35). Generally, after implant surgery and sinus augmentation, facial pain or pressure on the treated side, nasal congestion, thick purulent discharge and foul odor, and oroantral fistula may occur (33). For this reason, ostium obstruction should also be evaluated in the presence of mucosal thickening on CBCT taken during implant treatment planning. In the presence of ostium obstruction, the patient should be consulted to the otolarhinlaryngology department before implant surgery.

There are few studies examining the relationship between MSMT and the presence of septa in the sinus. Munakata et al. (2) showed that they could not find a relationship between the presence and absence of septa in individuals with MSMT more than 2 mm. Our study is consistent with the previous study. In their computed tomography (CT) study, Iizuka et al. (36) found that the presence of maxillary sinus septa was associated with the presence of mucosal thickening. On the other hand, there were also CBCT studies reporting a negative correlation between MSMT and the presence of septa (21,37). Discrepancies between studies and the present study may result from differences in study methodology and differences in the population.

Bayrak et al. (14) reported that there was no correlation between nasal septum deviation and maxillary sinus mucosa thickness. Taghiloo and Halimi (38) evaluated the MSMT in their CBCT study by classifying nasal septum deviation according to its type. The study stated that there was no difference between the type of nasal septum deviation and maxillary sinus mucosa thickness (38). In the present study, nasal septum deviation angle was divided into three groups to examine the relationship between maxillary sinus mucosa thickness and the severity of nasal septum deviation angle. There was no statistically significant difference in maxillary sinus mucosa thickness between groups classified according to nasal deviation severity. However, the maxillary sinus mucosa thickness was greater in the group with severe nasal septum deviation angle than in the other groups. Contrary to these studies, one study concluded that there was a relationship between nasal deviation angle and maxillary sinus mucosa thickness (2). Considering that the deviation seen in the nasal septum, a part of the osteomeatal complex, is a pathological condition, more studies are needed to evaluate the relationship between maxillary sinus mucosa thickness and nasal septum deviation.

5. CONCLUSION

The amount of maxillary sinus mucosa thickness is important in terms of the risk of perforation that may occur in the membrane during implant treatment and sinus augmentation. According to the results of this study, maxillary sinus mucosa thickness is affected by gender, the alveolar bone length, maxillary sinus ostium obstruction, and the presence of maxillary sinus pnematization. When planning implant treatment, these factors that will affect the maxillary sinus mucosa thickness should be taken into consideration, and planning should be made together by the oral and maxillofacial surgeon and the dentomaxillofacial radiologist. However, clinical studies that can compare before and after implant treatment should be conducted to evaluate the implications of the findings on implant treatment success.

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Ethics Committee Approval: This study was approved by Ethics Committee of Gazi University University, Noninvasive Clinic Ethics Committee (Approval date: 2022; Number:1069)
Peer-review: Externally peer-reviewed.
Author Contributions:
Research idea: NGI, ZFZ, MT
Design of the study: NGI, ZFZ, MT
Acquisition of data for the study: NGI
Analysis of data for the study: NGI, ZFZ, MT
Interpretation of data for the study: NGI, ZFZ, MT
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Sexual Function Status, Depression and Marital Adjustment in Postmenopausal Women: A Cross-Sectional Study

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ABSTRACT

Objective: In this study, it was aimed to examine the sexual function, depression and marital adjustment of postmenopausal women.

Methods: In this descriptive and cross-sectional study conducted with 502 postmenopausal women, data were collected using the participiant description form, Female Sexual Function Scale, Menopause Rating Scale, Beck Depression Inventory, Dyadic Adjustment Scale. Data were evaluated with descriptive statistics, chi-square and correlation analysis.

Results: In the study, it was found that 48% of the women had sexual dysfunction, 8.2% had severe depressive symptoms and their marital adjustment was low. It has been determined that women with sexual dysfunction have increased depression levels, low marital adjustment, and women with low marital adjustment have increased depression levels.

Conclusion: The postmenopausal period is a period that constitutes an important part of a woman's life, has its own symptoms and is a period in which women experience significant changes. It is recommended that education and counseling be provided for sexual problems and depression experienced during this period, that spouses be included in the process, and that women be evaluated with a holistic care focus.

Keywords: Adjustment; depression; postmenopause; sexual dysfunction.

1. INTRODUCTION

During menopause, many physical and psychological changes occur as a result of decreased ovarian functions and estrogen deficiency. As a result of these changes, women may experience some problems and their quality of life may be adversely affected (1,2). The decrease in vaginal and cervical blood flow and secretion results in dryness in the vagina by causing mucosal atrophy. Concomitant estrogen deficiency aggravates atrophy and dryness of the associated vaginal epithelium, negatively affecting sexual intercourse (2). Problems such as decreased sexual desire, arousal and satisfaction, orgasmic disorder, loss of vaginal lubrication and dyspareunia occur. In studies examining sexual dysfunctions in postmenopausal women, it has been determined that women experience sexual desire, sexual satisfaction, orgasm, sexual arousal, lubrication and pain disorders (3).

One of the changes emphasized in the menopause period is the increase in the risk of depressive symptoms that occur independently of each other in the pre and postmenopausal periods. It has been reported that mood changes in women can affect feelings and behavior, since hormonal changes occurring during these periods affect the central nervous system (4). It has been pointed out that as a result of the decrease in estrogen levels, the mood is negatively affected, hot flashes and sweating, sleep disorder due to hormonal changes and stressors in life can cause depression (4,5).

Anxiety and depression experienced in the postmenopausal period can negatively affect sexual life. It has been stated in studies conducted for this subject that anxiety and depression experienced during this period cause an increase in sexual dysfunction (6,7). In a study of 540 menopausal women, it was reported that depression is a strong factor associated with sexual dysfunction and menopause has a significant negative impact on women's sexual lives. In the same study, while vaginal dryness and decreased sexual

desire were reported as the most common problems, it was concluded that information and understanding of spouses are important to help women manage menopause (8).

The understanding of the spouse and positive marital relationships can help the woman resolve the depression and sexual problems caused by menopause, but depression and sexual problems experienced during this period also negatively affect the marital relations of the couples. Problems in marriage can cause deterioration in sexual life, and sexual problems can cause depression and marital adjustment (9,10).

Women in the menopausal period should be considered in a biopsychosocial and cultural integrity, individuals at risk for mental problems should be identified in the early period and psychological symptoms should be evaluated, the detected mental problems and the effectiveness of the treatment methods to be applied should be closely monitored. If healthcare providers fail to exhibit a favorable demeanor towards addressing sexual health issues, the impact of sexual health on overall well-being and potential remedies may be overlooked (11). Healthcare practitioners should establish supportive environments that facilitate open discussion of sexual concerns, evaluation of sexual capabilities, and educational opportunities for sexual health protection. This is important in terms of protecting and improving of the sexual health of menopausal women, increasing their quality of life and improving marital relations. The purpose of this research is to assess the sexual function, depression levels, and marital adjustment of postmenopausal female, and to investigate the correlation between them. The study questions were as follows:

– What are the sexual function levels of women?

– What are the depression levels of women?

– How is the marital adjustment of women?

– Is there a correlation between sexual function status, depression levels and marital adjustment of women?

2. MATERIALS AND METHODS

2.1. Study Type

This study is a descriptive and cross-sectional type study.

2.2. The Sample Size of the Study

The study population comprised all postmenopausal female who visited the gynecology outpatient clinic of a hospital in Izmir between January and November 2019. Sample calculation was done with the GPower 3.1 program. The sample size was determined using a calculation that took into account the scales employed in the study, along with the mean scores and prevalence rates obtained from prior studies on similar groups, as the number of women in the population was unknown (9,12,13). In these studies, the

prevalence of sexual dysfunction in women was found to be 56.4%, the prevalence of depression was found to be 27.5% and the mean score of the Dyadic Dyadic Adjustment Scale was found to be 92.11±11.2. Using these prevalences and mean scores, the largest sample size was found to be 379 in the calculation made with a 5% margin of error and a 95% confidence interval. The study was participated by 502 women who fulfilled the criteria for inclusion in the research. The acceptance criteria were as follows: women aged 45-60, who have not menstruated for the past year, who have entered menopause naturally, who do not use hormone replacement therapy, who are married, can speak Turkish, volunteering to participate for this study.

2.3. Measures

2.3.1. Participant Information Form: The form, prepared by researchers using literature, consists of 17 questions questioning women's sociodemographic (age, education level, income level, spouse's age, duration of marriage, Body Mass Index) and obstetric characteristics (number of living children) and information about menopause (age of menopause, duration of menopause, status of receiving information about menopause, what menopause means to them) (9,12-15).

2.3.2. Menopause Rating Scale (MRS): This tool was measured severity of menopausal symptoms. A 5-point Likert-type scale consisting of 11 items can be scored between 0-44. Scores of 0-11 were considered "mild," 12-23 as "moderate," 24-33 as "severe," and 34-44 as "very severe". The Cronbach alpha value was found 0.84 by Can Gürkan adapted into Turkish in 2005 (16) and it was found 0.89 in this study.

2.3.3. Female Sexual Function Index (FSFI): It is a scale that evaluates sexual dysfunction in female. The scale consists of 19 items and six subscale. The subscales are desire, lubrication, sexual success, orgasm, arousal, and pain. The score that can be obtained from the scale varies between 2-36, and a high score indicates improved sexual function (17). In the studies, the functional status was classified as good if the FSFI score was >30, moderate if it was between 23-29, and bad if it was <23 (17,18). In this study sexual dysfunction was accepted in women with a score of 23 and below. The Cronbach alpha value was determined to be 0.82 by Rosen et al., 0.95 by Oksuz and Malhan adapted into Turkish in 2005, and 0.97 in the present study (17).

2.3.4. Beck Depression Inventory (BDI): This 21-item scale, developed in 1961, was adapted into Turkish by Hisli in 1988 (19). The BDI measures specific behaviors associated with depression through its 21 items. A score ranging from 0 to 63 can be obtained from the scale, with a higher total score indicating a more severe case of depression. 0-9 points from the scale can be interpreted as minimal; 10-16 points as mild, 17-29 points as moderate and 30-63 points as severe depressive symptoms. The Cronbach alpha value was

reported to be 0.80 by Hisli, and 0.90 in the current study (19).

2.3.5. Dyadic Adjustment Scale (DAS): It is a scale developed to measure marital adjustment, the quality of marriage and the quality of adjustment. It is a likert type scale that can be applied to married or couples living together. The scores obtained from the scale, which consists of a total of 32 items and four sub-dimensions (satisfaction, consensus, affectional expression, and cohesion) range from 0 to 151. A high total score indicates good marital adjustment. The Cronbach alpha value was reported to be 0.96 by Spainer, 0.92 by Fişiloğlu and Demir, who conducted the Turkish validity and reliability study and 0.85 in this study (20).

2.4. Data Collection

The data were obtained from women who applied to the Gynecology Outpatient Clinic of Izmir Health Sciences University Tepecik Training and Research Hospital between January and November 2019 and met the sampling criteria. In order to protect the privacy of the women, the data were collected by the researchers in approximately 30 minutes using data collection tools in the interview room in the outpatient clinic using face-to-face interviews.

2.5. Data Analysis

Statistical Package for Social Sciences 22.0 (Version 22, SPSS Inc., Chicago, IL, USA) for Windows was utilized for analyzing the data. The suitability of the variables for normal distribution was evaluated with the Kolmogorov-Smirnov test. It was determined that the data were not normally distributed, and nonparametric tests were used. Data were evaluated with descriptive statistics (number, percent, mean, standart deviation, median and interquartil range). The dependent variable of the study is being in the climacteric period, and the independent variables are women's sexual function, marital adjustment and depression level. Pearson correlation analysis was used to examine the relationship between the scale score averages. If the correlation coefficient is 0.00-0.25, it is accepted that there is a very weak relationship between the variables, 0.26-0.49 weak, 0.50-0.69 medium, 0.70-0.89 high, 0.90-1.00 very high (21). The relationship between depression and sexual function levels according to the severity of menopausal symptoms of women and the relationship between depression levels according to sexual function levels (using row percentages) was analyzed using the chi-square test. In chi-square analysis, Fisher exact test was performed if the number of data in the eyes was <5. It was accepted as statistical significance when the $p < 0.05$ condition was met.

2.6. Ethical Approval

The study was approved by Health Science University Izmir Tepecik Research and Training Hospital's Non Interventional Clinical Studies Institutional Review Board (Date:14.11.2018

IRB: 13-17). This research conforms to the provisions of the Declaration of Helsinki. In this study all participants gave informed consent for the research, and that their anonymity was preserved.

2.7. Research Flowchart
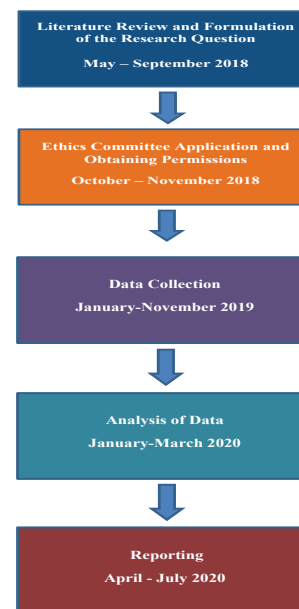
3. RESULTS

In this study, the mean age of the female was 52.23±4.37 years. The majority of them had a primary school education (57.2%) and reported lower income compared to expenses (63.5%). The mean length of their marriages was 32.38±5.92 years. 75.5% of women stated that they did not receive information about the menopause period, and 46.2% stated that they perceived menopause as a natural, normal process. The mean age at menopause was 47.83±2.46 years, and the mean duration of menopause was 4.40±3.12 years. MRS mean score of the participants was 19.41±8.75 and it was determined that 19.3% of women experienced mild menopausal symptoms, 49.2% moderately, 25.9% severe and 5.6% very severe (Table 1).

The mean FSFI score for the participants was 31.66±21.27. It was discovered that 48% of the female had sexual dysfunction (FSFI score <23 points), 14.4% had moderate sexual function, and 37.6% had good sexual function (FSFI score >30 points). The mean BDI score of participants was 13.71±9.63. The results indicated that 42.8% had minimal, 27.5% mild, 21.5% moderate, and 8.2% had severe depressive symptoms. In addition, it was determined that the DAS total (63.82±18.66) and subscale mean scores of the participants were low (Table 2).

In this study, it was defined that there was a weak negative correlation between women's MRS mean score and FSFI mean score (r=-0.276 p=0.000), a moderate positive correlation with BDI mean score (r=0.542 p=0.000), a very weak negative correlation with their DAS mean score (r=-0.213 p=0.000). It

was found that there was a very weak negative correlation (r= − 0.136 p= 0.002) between the FSFI mean scores of the participants and their BDI mean scores, and a very weak positive correlation with the DAS mean score (r=0.106 p=0.017). A weak negative correlation (r=-0.094, p=0.036) was found between the mean scores of the BDI and the DAS in the female (Table 3).

Table 1. *Characteristics of women (n=502)*

Variables	Mean±SD	min-max
Mean age (year)	52.23±4.37	45-60
Mean age of spouse (year)	56.78±6.20	46-75
Mean mariage period (year)	32.38±5.92	17-48
Mean menopause age (year)	47.83±2.46	42-57
Mean duration menopause (year)	4.40±3.12	1-14
	n	%
Education level		
Illiterate	54	10.8
Literate	52	10.3
Primary school	287	57.2
Secondary school	87	17.3
Higher school	22	4.4
Income level		
Income<expense	319	63.5
Income=expense	159	31.7
Income>expense	24	4.8
Number of children		
0	6	1.2
1	44	8.8
2	226	45.0
3	132	26.3
4 and more	94	18.7
Body Mass Index		
Normal (18.5-24.9)	119	23.7
Over weight (25.0-29.9)	200	39.8
Obese (30.0 – 34.9)	135	26.9
Morbid obese (>35)	48	9.6
Status of obtaining ınformation on menopause period		
Yes	123	24.5
No	379	75.5
The meaning of menopause for women		
A natural, normal process	232	46.2
The disappearance of femininity	52	10.4
End of productivity	87	17.3
Feeling old	121	24.1
Decrease / end of sexuality	10	2.0
TOTAL	**502**	**100**

In the study, 4.2% of women with mild menopausal symptoms, 20.3% of women with moderate symptoms, 18.7% of women with severe symptoms, and 4.8% of women with very severe symptoms scored less than 23 on the FSFI, and the outcome is statistically significant (x^2=83.246; p=0.000). In addition, 15.7% of women experiencing mild menopausal symptoms and 23.5% of women experiencing moderate symptoms had minimal depressive symptoms. It was determined that the majority (10.3%) of women who experienced severe menopausal symptoms experienced moderate depressive symptoms (x^2=164.188; p=0.000) (Table 4).

Table 2. *Female Sexual Function Index, Beck Depression Inventory and Dyadic Adjustment Scale mean score of women*

	Mean±SD (min-max)	Median (IQR)
MRS Total Score	19.41±8.75 (0-44)	19.00 (12.00)
	n (%)	
Mild (0-11 points)	97 (19.3	
Moderate (12-23 points)	247 (49.2	
Severe (24-33 points)	130 (25.9	
Very severe (34-44 points)	28 (5.6)	
	Mean±SD (min-max)	Median (IQR)
FSFI Total Score	31.66±21.27 (4-88)	23.00 (52.00)
Sexual desire	7.17±4.54 (2-10)	8.00 (3.00)
Arousal	5.85±4.90 (0-20)	3.00 (12.25)
Lubrication	5.84±4.66 (0-20)	4.00 (13.00)
Orgasm	4.32±3.68 (0-15)	4.00 (9.00)
Satisfaction	4.07±3.39 (0-15)	5.00 (7.00)
Pain	4.56±3.59 (2-15)	5.00 (9.00)
	n (%)	
Bad (<23 puan)	241 (48.0)	
Moderate (23-29 puan)	72 (14.4)	
Good (>30 puan)	189 (37.6)	
	Mean±SD (min-max)	Median (IQR)
BDI Total Score	13.71±9.63 (0-51)	11.00 (11.25)
	n (%)	
Minimal (0-9 points)	215 (42.8)	
Mild (10-16 points)	138 (27.5)	
Medium (17-29 points)	108 (21.5)	
Severe (30-63 points)	41 (8.2)	
	Mean±SD (min-max)	Median (IQR)
DAS Total Score	63.82±18.66 (29-123)	61.00 (18.00)
Dyadik concensus	19.13±14.08 (0-65)	17.00 (17.00)
Dyadik satisfaction	28.72±4.71 (17-45)	28.00 (5.00)
Affectional expression	4.21±2.36 (0-12)	4.00 (4.00)
Dyadik cohesion	11.75±3.02 (2-19)	12.00 (4.00)

IQR: Interquartil range, MRS: Menopause Rating Scale, FSFI: Female Sexual Function Index, BDI: Beck Depression Inventory, DAS: Dyadic Adjustment Scale

Table 3. *The Correlation Between Mean Scores of the women's Menopause Rating Scale, Female Sexual Function Index, Beck Depression Inventory and Dyadic Adjustment Scale*

Scale	FSFI	BDI	DAS
MRS	r= − 0.276* p= 0.000	r= 0.542* p= 0.000	r= − 0.213* p= 0.000
FSFI		r= − 0.136* p= 0.002	r= 0.106* p= 0.017
BDI			r= − 0.094* p= 0.036

*Pearson correlation analysis, MRS: Menopause Rating Scale, FSFI: Female Sexual Function Index, BDI: Beck Depression Inventory DAS: Dyadic Adjustment Scale

In the study, it was defined that the majority of female with good sexual function according to FSFI, experienced minimal (18.9%) and mild (9.8%) depressive symptoms. It was determined that 13.1% of women with poor sexual functions experienced moderate depressive symptoms and 5.8% experienced severe depressive symptoms. It was defined that the levels of sexual function in women had a significant impact on their depression status (x^2=37.943; p=0.000) (Table 5).

Table 4. *Sexual Function and Depression Levels of Women According to the Severity of Menopausal Symptoms*

MRS	FSFI				BDI				
	Good	Medium	Bad	Total	Minimal	Mild	Moderate	Severe	Total
Mild	51 (10.2)	25 (5.0)	21 (4.2)	97 (19.3)	79 (15.7)	8 (1.6)	5 (1.0)	5 (1.0)	97 (19.3)
Moderate	113(22.5)	32 (6.3)	102(20.3)	247(49.2)	118(23.5)	79(15.7)	43 (8.6)	7 (1.4)	247(49.2)
Severe	23 (4.6)	13 (2.6)	94 (18.7)	130(25.9)	12 (2.4)	46 (9.2)	52 (10.3)	20(4.0)	130(25.9)
Very severe	2 (0.4)	2 (0.4)	24 (4.8)	28 (5.6)	6 (1.2)	5 (1.0)	8 (1.6)	9 (1.8)	28 (5.6)
Total	189(37.7)	72 (14.3)	241(48.0)	502(100.0)	215(42.8)	138(27.5)	108 (21.5)	41(8.2)	502(100.0)
Statistical Analysis	x^2= 83.246* p= 0.000				x^2=164.188 p= 0.000				

Fisher exact test, Chi-square analysis was performed by taking row percentages, MRS: Menopause Rating Scale, FSFI: Female Sexual Function Index, BDI: Beck Depression Inventory

Table 5. *Depression Status of Women by Sexual Function Levels*

FSFI	BDI				
	Minimal	Mild	Moderate	Severe	Total
Good	95 (18.9)	49 (9.8)	36 (7.2)	9 (1.8)	241 (48.0)
Moderate	46 (9.2)	17 (3.4)	6 (1.2)	3 (0.6)	72 (14.3)
Bad	74 (14.7)	72 (14.3)	66 (13.1)	29 (5.8)	189 (37.7)
Total	215 (42.8)	138 (27.5)	108 (21.5)	41 (8.2)	502 (100.0)
Statistical Analysis				x^2= 37.943 p= 0.000	

Chi-square analysis was performed by taking row percentages.
FSFI: Female Sexual Function Index BDI: Beck Depression Inventory

4. DISCUSSION

The study aimed to assess the sexual function, depression and dyadic adjustment in postmenopausal women and examine their corelation. For this purpose, the questions of this study are;

- What is the sexual function status of women in the climacteric period?

- What are the depression levels of women in the climacteric period?

- What is the dyadic adjustment of women in the climacteric period?

- Is there a relationship between the sexual function status, depression and dyadic adjustment of women in the climacteric period?

The results showed that 48% of the women participated in the study suffered from sexual dysfunction. In studies conducted in different countries using FSFI to examine the sexual function of postmenopausal female, the rate of sexual dysfunction ranges from 88.7-58% (22-25). In the study conducted in the west of Turkey, it was reported that 86.4% of women experienced sexual dysfunction (15), and in the study of in the east, this rate was found to be as 59.7% (14). Half of female in the perimenopausal period and three-quarters of female in the postmenopausal period experience one or more sexual problems. Sexual problems is seen more frequently in the postmenopausal period than in the perimenopausal period (11). In this study, the prevalence of sexual dysfunction was found to be lower than in other studies in the literature. The reason for this is thought to be related to mean age of menopause and the mean duration of menopause of the women.

It was defined that 21.5% of the women included in the study experienced moderate depressive symptoms and 8.2% had severe depressive symptoms. A systematic review in China found that among women in the climacteric period, 15.3% had moderate and 3.7% had severe depression (26). In a study conducted with 287 women aged 45-60 years in Poland, 39% of women had moderate levels and 2% had severe levels (3). In a study of 435 female in Bangladesh, 24.5% of women had moderate levels and 7% had severe levels (27). In another study conducted in Iran (1520 women aged 40-64 years), it was defined that 55% of female had minimal, 26% mild, 11% moderate and 8% severe depressive symptoms (28).

Although the cause of depression is not known exactly, it was stated that it has a potential relationship with menopause and hormonal changes in menopause (29). The results of this study were found to be in a similar range with the previous studies, and it was thought that the severity of the depressive state experienced in the climacteric period was related to the menopausal symptoms experienced. In the study, it was determined that the depression levels of women increased with the increase in menopausal symptoms. It was stated that 23.5% of female who experienced menopausal symptoms moderately, and the majority of women who experienced severe symptoms experienced moderate depressive symptoms. In the literature, it has been stated that problems experienced during menopause increase the stress and depression levels in women (4,13,30-32). In addition, the majority of women with good sexual functions in the study experienced minimal and mild depressive symptoms. It was defined that female who experienced sexual dysfunction experienced moderate and severe depressive symptoms. In the literature, it was seen that depression causes sexual dysfunction in the climacteric period (6,15,29,33-35). The correlation between sexuality and depression is often complex and depression can be both a cause and a result of a sexual problem. Although low desire, depression or anxiety are the most common sexual side effects, reaching orgasm can be more difficult in the presence of depression. In addition, mood swings can cause relationship problems due to sexual problems (5,13).

It was found that the marital adjustment of the female included in the study was low. The dyadic compatibility score obtained in studies conducted in different countries using the same scale was found to be higher than the score obtained in this

study (5,8,34). The reason why the dyadic adjustment of the women included in this study was found to be lower than in other studies with similar samples in the literature was thought to be related to the sexual dysfunction, depressive state and menopausal symptoms. In the study, it was determined that postmenopausal women with good sexual functions and low depression levels had better marital adjustment.

In the literature, it was determined that the quality of the relationship with the partner and the adjustment were related to the sexual function, and the sexual dysfunction decreased the adjustment in the marriage (5,33,35). In a study with 1520 female aged 40 to 64, it was determined that women with low marital adjustment had more depressive symptoms than women with good marital adjustment (28). In the study with 100 women, marital adjustment was found to be negatively related to depression, and it was determined that depression levels increased in women with marital adjustment problems (36). With the effect of the changes experienced, the spouse, family and friend relationships of women in the menopausal period may deteriorate, and their physical and mental problems are exacerbated. Sexuality has important functions in reinforcing the intimacy between spouses, sharing pleasure, and reducing the tension that will occur while coping with the problems in marriage. It is reported that sexual dysfunctions have negative effects on intimacy in marriage (9,33). and the results obtained from the study support this information too. The increase in marital adjustment can also positively affect the psychological health of the individual and reduce the symptoms of emotional stress.

This study has some limitations. The research sample is limited to women who agreed to participate in the study at the university hospital. Therefore, the results obtained from the study cannot be generalized to the whole population.

5. CONCLUSION

In this study, it was found that approximately half of the postmenopausal women experienced sexual dysfunction, one third experienced moderate and mild depression, and their marital adjustment was low. Women with sexual dysfunction have higher depression levels and lower marital adjustment. It was determined that women with low depression levels had better marital adjustment. Nurses and health professionals should include spouses in education and counseling services regarding the problems and solutions they may experience during this period in order to increase the social support and marital adjustment of postmenopausal women. They should inform women and their partners in the climacteric period about possible sexual problems, their causes and solutions, and create environments where women and their partners can express their sexual problems comfortably. They should evaluate women in this period both gynecologically and psychologically, question how the woman perceives this period and support her to express herself comfortably. Women in the postmenopausal period should be routinely screened for depression, and if there are

signs and symptoms specific to depression, they should be referred to the necessary units.

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Nursing Students' Thoughts and Knowledge Levels about Global Warming

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ABSTRACT

Objective: The aim of this study is to determine nursing students' thoughts and knowledge levels about global warming.

Methods: This descriptive study was conducted with 236 nursing students studying at the faculty of health sciences of a state university between May and July 2022. Data were collected using a Sociodemographic Form, the Global Warming Questionnaire. Independent Samples t-test, One-Way ANOVA were used to evaluate the data.

Results: Ninety-seven percent of the students stated that global warming was a public health issue. Students' mean score on the global warming knowledge scale was 90.02 ± 8.76. There was a significant difference between the mean scale score participating in activities on the subject, having received information/education on environment, climate change aside from undergraduate education, wanting to become a member of an environmental non-governmental organization, and school year ($p < .05$).

Conclusion: Participants' knowledge level about global warming was above the average value of the scale. However, they still needed information, greater sensitivity to participate in environmental non-governmental organizations, global warming activities. For all these reasons, it is recommended that nursing students increase their knowledge and sensitivity during their undergraduate education, learn ways to combat the adverse effects of climate change, put them into practice.

Keywords: Global warming, knowledge, nurses, thinking,

1. INTRODUCTION

The most obvious effect of global warming is climate change. In addition to causing negative consequences such as the melting of glaciers and the inundation of many coastlines because of sea level rise, it is thought that global climate change has and will also cause negative effects in social, economic, and health areas (1,2). Its health effects are heat waves, air pollution, floods and fires, vectorial and infectious diseases, water – and food-borne diseases, respiratory diseases, and allergic diseases (1). Changes in climate and weather conditions also cause the emergence of new infectious diseases by affecting pathogens, vectors, hosts, and their habitats (3). It is argued that the pandemic occurring between 2019 and 2022 has links to climate change (4). In addition, has recently reported that climate change may cause chronic and serious mental health disorders, as well as anxiety-related reactions, depression, aggressive behavior, and violence in people (5).

Most nurses work in settings that meet the needs of individuals, families, or the community. They should be aware of factors related to social determinants of health, such as economic, political, cultural, and environmental influences, as well as national policies. Nowadays, the roles of nurses are increasing both regionally and internationally in extraordinary situations, such as disasters, pandemics, and climate change (6).

The concept of environment, which is not a new concept and is among the basic concepts in the nursing curriculum, has maintained its place since Florence Nightingale. Many nursing theorists have included the environment as a component in their conceptual models. The importance of the topic is frequently emphasized in undergraduate and graduate education. However, nurses need to improve their knowledge and practices on a global basis to protect and support health. Nurses have an important role in addressing and evaluating environmental health issues at the individual, family, and community levels (7).

According to the Association of Nurses for Healthy Environments (ANHE), nurses should make a great contribution to greenhouse gas emissions and global warming with their individual measures in the fight against climate

change, by using consumables and energy appropriately while working in hospitals and by using public transportation more in daily life. Therefore, they are in a critical position to influence the decisions made in healthcare institutions and advocate for regulations that will help reduce global warming (8). Newly graduated nurses will be more likely to experience the negative effects of global warming on individuals, families, groups, and public health. Nursing students, who will be health professionals of the future, need to know and be aware of the subject very well. Nurses, as health educators, are advocates on behalf of society regarding risks or dangers, which will be fundamental to the prevention of environmentally related diseases and the success of other interventions. At the same time, nurses play a key role in making individuals, families, and society aware of the effects of climate change and taking measures to protect and improve health. For all these reasons, we think that determining nursing students' knowledge levels about global warming will guide future studies. The aim of this study is to determine nursing students' thoughts and knowledge levels about global warming.

2. METHODS

Ethics committee approval was obtained (Number: 61351342/April 2022-55). Written permission of the author of the scale to be used in the study was obtained via e-mail. Participants' informed consent was obtained. Institutional permission was obtained.

2.1. Study Design and Participants

A descriptive study design was used. The research was conducted with students studying in the nursing department of the faculty of health sciences at a state university between May 2022 and July 2022. The population consisted of students studying in the nursing department (N=1033). The sample size of the research was calculated as at least 215 subjects using the sampling the known population formula, based on a population size of 1.033 individuals, a margin of error of 5%, a confidence interval of 90%, and an incidence value of 50%. The study was completed with 236 individuals. Inclusion criteria: Being a student in the nursing department of the faculty of health sciences and volunteering to participate in research. Exclusion criteria: Filling out the forms incompletely.

2.2. Data collection tools

In the study, data were collected using a Sociodemographic Form and the Global Warming Questionnaire.

2.2.1. Sociodemographic Form

This form consists of 19 questions about age, gender, school year, parents' education level, place of residence, global warming, and climate change (1). A pilot study was conducted.

2.2.2. The Global Warming Questionnaire

This scale was developed by Eroğlu and Aydoğdu (9) and its validity and reliability studies were conducted. It is used to evaluate global warming knowledge levels using questions about the occurrence of global warming, its causes, consequences, and how it can be prevented. It is a 26-item scale with a five-point Likert scale (absolutely true, 5 points – absolutely false, 1 point). Scores on the scale range between 26 and 130. A high score on the total scale indicates a high level of knowledge about global warming. Cronbach's alpha value of the scale was found to be 0.85.9 The alpha value was found to be 0.87 in this study.

2.3. Data analysis

Data were analyzed on the SPSS software package by using mean and percentage values, independent samples t-test, and One-Way ANOVA. The significance level was accepted as $p < .05$.

2.4. Limitations of the research

The results of the study are specific to the school where the data were collected and cannot be generalized to all nursing students.

3. RESULTS

Nursing students' mean score on the Global Warming Questionnaire was 90.02±8.76. When students' descriptive characteristics were examined, it was determined that 78.8% were female, 47.5% were first-year students, and that the mothers of 59.3% and the fathers of 56.4% had primary school education. Fifty percent of the students said they studied global warming as part of their school curriculum, but it was determined that some of them did not know global warming (1.2%), the greenhouse effect (3.8%), and the concept of carbon footprint (6.4%) (Table 1). The mean global warming knowledge score was the highest in seniors and the lowest in freshmen ($p < .05$). It was determined that the mean global warming knowledge score was significantly higher in students who found global warming preventable, had knowledge about climate change agreements, participated in activities on climate change, had received education on environment and climate change other than undergraduate education, and wanted to become a member of an environmental non-governmental organization ($p<.001$) (Table 1). Students stated that the most important signs of climate change were drought (80.1%) and a decrease in biodiversity (74.6%). They thought that global warming may cause an increase in epidemics (83.1%), cancer (75.8%), psychological diseases (64.4%), respiratory system diseases (63.1%), cardiovascular diseases (65.3%) and premature deaths (47.5%) now and in the future and that global warming is a public health problem (97%). Most of them stated that they followed information about climate change on social media (90.7%). They also added that global warming might cause the emergence of new unknown diseases (90.2%) and an increase in the immune system (86.8%) and infectious diseases (86.4%) (Table 2).

Table 1. Nursing students' mean score on the Global Warming Questionnaire according to their descriptive characteristics

		n	%	Mean	SD	Statistics	p*
Gender	Female	186	78.8	89.92	8.74	-.329	.742
	Male	50	21.2	90.38	8.93		
School year	1	112	47.5	88.98	7.99	3.141	**.026**
	2	24	10.2	92.17	8.77		
	3	62	26.3	89.03	9.82		
	4	38	16.1	93.32	8.38		
Mother's education	Non-literate	27	11.4	90.37	8.34	.767	.513
	Elementary-middle school	140	59.3	89.94	8.35		
	High school	38	16.1	91.47	8.73		
	Associate-undergraduate	31	13.1	88.29	10.87		
Father's education	Elementary-middle school	133	56.4	90.29	8.63	.581	.560
	High school	69	29.2	89.10	8.44		
	Associate-undergraduate	34	14.4	90.82	9.96		
Finding global warming preventable	Yes	180	76.3	91.16	8.47	3.691	**.001**
	No	56	23.7	86.34	8.74		
If yes, how	Personal measures	18	9.4	86.33	10.40	2.159	.075
	By the activities of local governments	10	5.2	93.30	8.37		
	Social measures	62	32.3	90.02	9.18		
	Legal measures implemented at a national level	34	17.7	92.59	8.44		
	Global measures	68	35.4	91.68	7.18		
If no, why	Difficulty changing habits	22	23.9	90.68	9.17	.973	.382
	Lack of social awareness	45	48.9	87.42	8.88		
	Irreversible damage	25	27.2	89.04	9.56		
Having information about agreements on climate change	Yes	34	14.4	95.76	7.41	15.194	**.001**
	No	135	57.2	87.67	8.37		
	Somewhat	67	28.4	91.82	8.49		
Participating in activities on climate change	Yes	50	21.2	95.70	7.63	18.536	**.001**
	No	116	49.2	87.31	8.51		
	Somewhat	70	29.7	90.44	7.97		
Having received information/education on environment and climate apart from undergraduate education	Yes	85	36.0	94.42	8.68	6.247	**.001**
	No	151	64.0	87.54	7.81		
Desire for membership in an environmental non-governmental organization	Yes	146	61.9	91.68	7.80	3.814	**.001**
	No	90	38.1	87.32	9.58		

n: number; %: percent; SD: Standart deviation; p*<.05

Table 2. Nursing students' thoughts about climate change

		n	%
What do you think are the important symptoms of climate change?	Spread of infectious diseases	130	55.1
	Changing biodiversity	176	74.6
	Effects of greenhouse gases on health	164	69.5
	Drought	189	80.1
	Heat waves	156	66.1
What do you think its future health effects will be?	Cancer	179	75.8
	Epidemic diseases	196	83.1
	Psychological diseases	152	64.4
	Respiratory system diseases	149	63.1
	Increase in premature deaths	112	47.5
	Premature births	108	45.8
	Cardiovascular diseases	154	65.3
	Eye problems	106	44.9
Where do you most often get information about climate change?	Radio	17	7.2
	Television	142	60.2
	Newspaper	33	14.0
	Social media	214	90.7
	Scientific studies	112	47.5
	Courses taken at school	122	51.7
Does global warming cause infectious diseases?	Yes	204	86.4
	No	34	13.6
Will global warming cause the emergence of new unknown diseases?	Yes	213	90.2
	No	23	9.8
Does global warming cause suppression of the immune system?	Yes	205	86.8
	No	31	13.2
Do you think global warming is a public health problem?	Yes	229	97
	No	7	3

*More than one response was given.

4. DISCUSSION

In this study, nursing students' knowledge levels about global warming were examined. Participants' knowledge level about global warming was found to be above average. While some studies on the concept of global warming have shown that university students have enough knowledge, (9-11) others have indicated the opposite (12,13). In the present study, participants were nursing students, and the concept of environment was frequently included in their curriculum, which may have increased their knowledge level scores on this subject above the average. However, students' high knowledge of global warming and climate change alone is not enough. They need to be supported in putting their knowledge into practice to prevent global warming because many studies still show that nurses and student nurses lack knowledge of climate change (14-16). To achieve the 2030 Sustainable Development Goals, it is necessary to educate healthcare professional groups and equip them with the necessary knowledge, skills, and responsibility to ensure the health of future generations in the context of human rights (17).

When participants' knowledge levels about global warming were examined according to students' school years, it was found that the knowledge level of the 4th-year participants was higher. In the study conducted by Ay and Yalçın Erik (18) on university students, it was seen that the global warming knowledge level did not change according to the school year, while other studies conducted with university students showed that the knowledge level of 4th-year students was higher. In our study, it is thought that the increasing level of knowledge in parallel with the school year might have stemmed from the fact that the concept of environment was discussed together with climate change as one of the roles of public health nursing, the concept of environment, which is one of the four main concepts of nursing, had been addressed during the participants' education starting from the first year, and that the climate crisis was discussed during studying the environment topic in the public health course curriculum. However, while environmental theory and theorists are frequently emphasized in the lessons before the 4th year, the effect of global warming on health should also be emphasized and integrated into every course in the curriculum.

In this study, the global warming knowledge score of the participants who participated in climate change activities was high. Similarly, in the study conducted by Ergin et al. (19) with nursing students, the knowledge score of the students who participated in environment and climate change activities was high. However, in our study, most students unfortunately stated that they had not participated in any climate change activities. Participating in climate change and environment activities improves the leadership and advocacy roles of nursing. For this reason, the subject of these activities should be introduced during undergraduate education and students should be encouraged in this regard. As Article 56 of the Constitution of the Republic of Türkiye puts it, "Everyone has the right to live in a healthy and balanced environment. It is the duty of the State and citizens to improve the environment, protect environmental health, and prevent environmental pollution." However, students are hesitant about participating in such actions. To reverse this situation, the importance of the role of the whole society in protecting environmental and climate health and participating in various activities should be given by families and schools from an early age.

Participants who had received information/education on environment and climate change aside from their undergraduate education had higher global warming knowledge scores than those who had not. Similarly, it was determined that the knowledge levels of students who had received information/education on environment and climate apart from undergraduate education were higher (18, 20). For this reason, it is thought that the issue of global warming should be integrated into education at all levels.

In this study, three-quarters of the participants stated that they found global warming preventable. This finding is promising in that they can combat the causes that increase global warming during clinical practices in the hospital, at home, in society, and in their daily lives. Additionally, 32.3% of the participants stated that social measures were as important as global measures. They also thought that legal measures implemented at the national level were important. However, it is noteworthy that only 18 participants stated that global warming could be prevented by taking personal precautions. Contrary to these findings, Ergin et al. (19) found that only 8.2% of the medical students in their study thought global warming was completely preventable. Of those who thought it could be prevented, 49.4% thought it could be prevented through education/public awareness, and 26% thought it could be prevented through international collaborations and partnerships. Nursing students who participated in this study thought that global, legal, and social measures were important in preventing global warming. This is a positive finding. However, in addition to all these, there are also climate change problems such as the greenhouse gas effect, which can be prevented with easier and more feasible individual efforts. Therefore, students should be told what these preventive activities are in their daily and professional lives. For example, strategies, such as paying more attention to the consumption of consumables used during patient care in the hospital, using public transportation and renewable energy, and supporting recycling are just some of the individual measures taken. Nurses must be aware of factors related to social determinants of health, such as economic, political, cultural, and environmental influences, as well as national policies that affect health beyond their area of practice. Today, nurses should know that some occurrences, such as disasters, pandemics, and climate change, may have regional as well as international or global effects.

More than half of the students stated that they heard information about climate change from sources such as social media and television. Similarly, in other studies, a majority of students stated that they had heard about

global warming from television and social media (12,20). According to these results in the literature, it can be said that social media and television provide important information about global warming and have positive effects. Therefore, effective use of social media is of great importance in raising public awareness. Health professionals can emphasize the significance of this issue to society through social media.

Almost all of the participants stated that they had no knowledge about agreements on climate change and more than half of them stated that they had not participated in any event to prevent global warming and were not members of an environmental organization. Similarly, Belleli et al (12) found that more than half of the students in their study had not heard of any international environmental agreements. Considering other studies, the rate of participating in an event to prevent global warming and becoming a member of an environmental organization was very low (12, 20). Students' recognition of the regulations and agreements that fight against climate change nationally, internationally, or globally and membership in activities and organizations on this topic is valuable in terms of showing the public's resistance and struggle against global warming and nursing students' taking on an advocacy role on this issue. It is thought that this subject should be included more in nursing curricula and students' awareness should be increased.

In this study, it was determined that nursing students had not taken a separate course on environment and climate change aside from their undergraduate education. In the study conducted by Ay and Yalçın Erik (18) with university students, it was observed that 53.7% of the students had not taken courses on environment and climate change. In line with these results, it can be said that courses on climate change are not enough in undergraduate nursing education in Türkiye. However, environmental theory, one of the four important theories of nursing, is taught to students from the first year. The relationship between environment and health is addressed with this theory. However, today, climate change has surpassed environmental theory. For this reason, the health effects of climate change should be integrated into all levels of nursing education as soon as possible. It is quite noteworthy that the rate of education about global warming, which is a global issue, is so low at universities. In higher education, students should be informed about global warming, which is the most important environmental problem that concerns the future of our world, both in the education curriculum and through events such as conferences and seminars.

5. CONCLUSION

Student nurses' knowledge level about global warming was above the average. Those who thought that global warming was preventable had a high level of knowledge.

Most participants were aware that global warming was a public health problem.

The effects of global warming and climate change on the environment and health should be updated in today's conditions in undergraduate nursing education, the awareness of students should be increased by giving it more space in the curriculum, and students should be encouraged to participate in events such as congresses and seminars on this subject. The study can be repeated using a larger sample size.

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Comparative Evaluation of Bisphosphonate Effects: Periapical Lesion Frequency, Size, and Radiomorphometric Indices in Osteoporotic Patients

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ABSTRACT

Objective: The aim of the study was to evaluate the effects of bisphosphonate use on periapical lesion frequency, size, and through radiomorphometric indices on jaws.

Methods: This study includes 220 postmenopausal women (110 patients who use bisphosphonate and 110 patients who do not use bisphosphonate) with diagnosis of osteoporosis and 110 women who have a healthy bone structure control group. The complex periapical index (CPI), mental index (MI), panoramic mandibular index (PMI), and mandibular cortical index (MCI) values was evaluated.

Results: The both right and left MI/PMI means in the osteoporotic patients using bisphosphonate were significantly lower than the others (p < .001). It was found that while the duration of bisphosphonate use increased, the right MI and right-left PMI means decreased significantly (p < .05). The right MI and the right/left PMI means were significantly higher in the group using bisphosphonate via intravenous injection compare to those using it orally. The total number of periapical lesions was significantly less in the group using bisphosphonates than the other two groups (p = .002). The number of teeth with the periapical lesions up to 3 mms in diameter was also significantly lower in the group using bisphosphonate than it was in the other two groups (p = .04).

Conclusions: It was found that the use of bisphosphonates is associated with a lower mandibular index, which indicates greater severity of osteoporosis. The total number and size of periapical lesions in these patients were significantly less than the other two groups.

Keywords: Osteoporosis, bisphosphonate, mandibular index, periapical lesion, panoramic radiography

1. INTRODUCTION

Osteoporosis has been defined as a progressive metabolic bone disease characterized by increased bone fragility and risk of fracture resulting from low bone mass and defects in the microarchitecture of bone tissue (1). It is highly correlated with aging and mostly affects postmenopausal women (2). In the diagnosis of osteoporosis, dual-energy X–ray absorptiometry (DXA) which measures the bone mineral density of the lumbar spine and proximal femur region is accepted as the gold standard of imaging method (3). Although DXA is a simple non-invasive method, the high cost makes its application impossible for a routine examination (4). In addition to this, panoramic radiography, which is a routinely used imaging technique for patients who consult to a dentist, can be used as a valuable imaging tool for the diagnosis of osteoporosis (5). In the literature, radiomorphometric analyses using panoramic radiographs— such as the mandibular cortical index (MCI) (6), mental index (MI) (7), and panoramic mandibular index (PMI) (8)— have been shown to correlate with bone mineral density (BMD) values in the femur and lumbar spine, making them useful for detecting low BMD (3, 9-13). Furthermore, radiomorphometric analyses such as PMI, MI, and MCI have been successfully used to assess the effects of medication and systemic diseases on jawbones (14,15).

In osteoporosis treatment, bisphosphonates are used to prevent bone loss and increase bone mass. Antiresorptive drugs, such as bisphosphonates, exert their effect by reducing the activity of osteoclasts and increasing their apoptosis (16). Thus, bisphosphonates cause a decrease in bone cycle and provide a net gain in bone mass (17). Considering their effects on the treatment of osteoporosis, bisphosphonates are expected to cause an increase in MCI, MI and PMI values which are used in the diagnosis of osteoporosis. There are

few studies on the effects of bisphosphonate usage on MCI, MI, and PMI. While no difference was found in some of these studies (5,18), an increase in the indices was observed in others (19,20).

Periapical lesion is an inflammatory disorder which affects the tissues around the apex of the tooth, caused by an infection in the root canal system, and is characterized by the destruction and loss of periapical bone (21). In periapical lesion, pathogens stimulate the innate immune response by releasing chemicals that lead to the production of pro-inflammatory cytokines, which are key to disease progression (22). Based on the evidence, osteoporosis is believed to be unidirectionally associated with periapical lesions (23). It is thought that estrogen deficiency plays a role in the development of periapical lesion in osteoporosis by causing the imbalance of periapical bone metabolism (22,23). Estrogen reduces bone resorption and enhances bone formation by increasing osteoprotegerin (OPG) levels and decreasing receptor activator of nuclear factor kappa-B ligand (RANKL) expression (24). On the other hand, estrogen affects immune cells, and its deficiency results in a chronic low-grade pro-inflammatory state, leading to increased release of inflammatory mediators such as interleukin-1β (IL-1β), IL-6, and tumor necrosis factor-α (TNF-α), which contribute to increased bone resorption (25,26). There are few studies investigating the prevalence of periapical lesions in postmenopausal women with osteoporosis (27-29). Data suggest that osteoporosis contributes to a higher occurrence and larger size of periapical lesions, with estrogen serving as a crucial factor in the relationship between these conditions (23). Studies evaluating the effect of bisphosphonates on periapical lesion size appear to be limited, and more research is needed (29-33).

The aim of study was to evaluate the effects of bisphosphonate use periapical lesions frequency, size and through radiomorphometric indices on jaws in the patients using bisphosphonate due to osteoporosis.

2. METHODS

For this retrospective study complied with the Declaration of Helsinki and, research ethics committee approval was taken from The Ethics Committee of Süleyman Demirel University, Noninvasive Clinic Ethics Committee with the decision of 13/07/2021/245. In the light of the preliminary information obtained from literature, power analysis was performed in determining the sample size; first type error α=0.05; The minimum sample size for each group was found to be 110, with the power of the test being a minimum of 0.80.

2.1. The study group

The participants of this study were postmenopausal 220 women with osteoporosis aged 50-78, who have attended of Suleyman Demirel University, Faculty of Dentistry, Department of Dental and Maxillofacial Radiology with various reasons between 2016-2020. From the medical records of the patients, the following information was obtained; age, systemic diseases, drugs used for osteoporosis, types of these drugs (Alendronic acid, Ibandronic acid, Zoledronic acid, Denosumab) duration of use (0-1 years, 1-3 years, 3-4 years, 4-5 years, 5-6 years) and type of use (orally, intravenously, both orally and intravenously). Two study groups from patients with osteoporosis were created: 110 post-menopausal female patients using bisphosphonate for osteoporosis and 110 post-menopausal female patients not using bisphosphonate for osteoporosis.

2.2. The control group

It consists of 110 post-menopausal female patients.

- The patients who applied to Department of Dental and Maxillofacial Radiology, Suleyman Demirel University, Faculty of Dentistry between 2016-2020 with various dental complaints, whose examination were completed and panoramic radiographs were taken

- Patients aged 50 to 75 years with healthy bone structure (T scores equal to or greater than -1 SD) were selected from the medical records of those who had DXA measurements performed at the Nuclear Medicine Unit of Süleyman Demirel University, Research and Application Hospital.

DXA measurements of the control patients were taken in the GE Lunar Prodigy device at 76 kilovolt, 3000 milliampere (mA), 43 seconds recording protocol. Digital panoramic radiographs of the all patients who were evaluated retrospectively were taken by Planmeca Promax, (Helsinki, Finland) device with recording parameters of 66-68 kVp, 7-13 mA and 16 sec. All radiographs were obtained by the same type of panoramic device with 1.2 nominal magnification factor. By using Planmeca Romexis 3.8.3 (Helsinki, Finland) program, the analysis on panoramic radiographs were made by single observer with a 3-years of experience on Oral and Maxillofacial Radiology.

Those who were not included in the study are;

- Patients whose medical records could not be accessed.

- Patients where the location of the mental foramen could not be determined.

- Patients with a history of cancer, who received radiotherapy to the head and neck region.

- Patients with a systemic disease or condition that may affect bone metabolism (e.g., Paget disease, hyperparathyroidism, hypoparathyroidism, renal osteodystrophy, etc.).

- Patients using drugs that may affect bone metabolism (e.g., antiepileptics, corticosteroids, cytostatics, estrogen, etc.).

- Patients with any lesion that may cause destruction in the jawbones.

- Patients with a history of trauma or surgical operations.

- Patients with total edentulism.

The analysis made on the panoramic radiograph;

- Radiomorphometric indices MI (7) and PMI (8) were measured bilaterally, while MCI (6) was also evaluated bilaterally.
- The size of the periapical lesions, the relationship between the root and the radiolucent lesion, and the complex periapical index, which evaluates the location of bone destruction, were evaluated.

2.3. Mandibular Inferior Cortical Thickness (MI)

To measure the thickness of mandibula inferior, a line tangent to mandibular cortex and at the level of mental foramen was drawn in the premolar region; A second line passing through foramen mental region was also drawn as perpendicular to this one. At the intersection of these two lines, mandibular cortex thickness was measured (Figure 1).

2.4. Panoramic mandibular index (PMI)

PMI values were calculated by dividing the cortical thickness in the mental foramen by the distance from the lower border of the mental foramen to the lower border of the mandible (Figure 1).
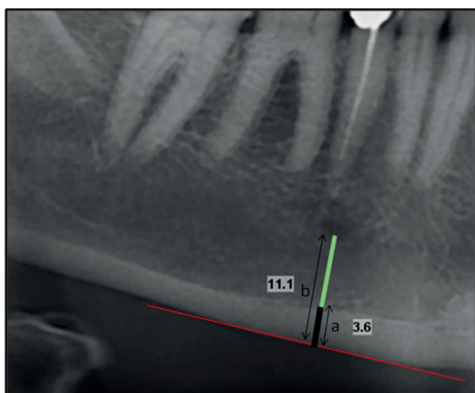

Figure 1. Mandibular inferior cortical thickness (a), distance from the lower border of the mental foramen to the lower border of the mandible (b), panoramic mandibular index (a/b)

2.5. Mandibular cortical index (MCI)

MCI, is a qualitative index that evaluates existing porosities in the mandibular cortical bone posterior to the mental foramen on both sides of mandible in three grades as C1, C2 and C3 (Figure 2).
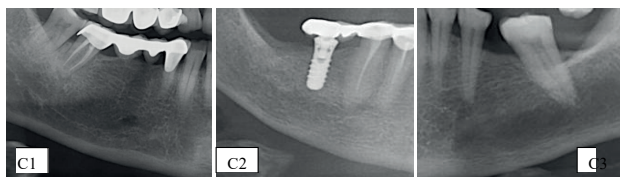

Figure 2. Mandibuler Cortical Index Stages: C1 The endosteal border of the cortex is even and sharp on both sides of the mandible. C2 The endosteal margin with semilunar defects (lacunar resorption) or endosteal cortical residues on one or both sides. C3 The endosteal margin consists of heavy cortical residues and is clearly porous.

The complex periapical index (CPI), which was defined by Venskutonis et al. (34) in order to define and classify periapical lesions on panoramic radiography images, was used. In this index, there are 3 parameters; size of the lesion (S), the relationship between lesion and root (R), the location of bone destruction (D) (Figure 3). Lesion size was measured with the largest diameter on panoramic radiography by using Planmeca Romexis 3.8.3 (Helsinki, Finland) program. While S0R0D0 score corresponds to a healthy periapical tissue, all scores except S0R0D0 indicates presence of a periapical lesion. The study group and the control group were evaluated based on the number of missing teeth: no missing teeth, fewer than 10 missing teeth, and more than 10 missing teeth.
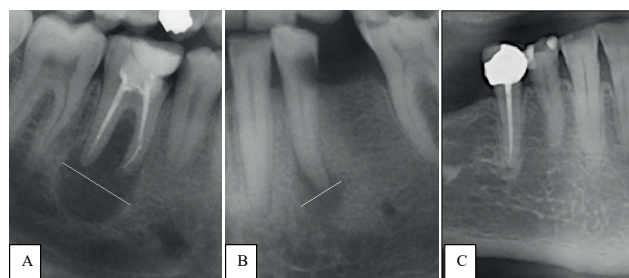

Figure 3. A. S3R3D2 Cropped panoramic radiographic image of a lesion larger than 5 mm involving both roots and extending into the furcation B. S3R1D1Cropped panoramic radiographic image of a lesion larger than 5 mm involving a single root.C. S0R0D0 Cropped panoramic radiograph image of healthy periapical tissues.

2.6. Statically Analysis

The data obtained for this study was analyzed through IBM SPSS Statistics V20,0 program (IBM Corp., Armonk, N.Y., USA). The compatibility of the examined features with normal distribution was checked via Kolmogorov–Smirnov Test. Having $p < .05$ in the evaluation was accepted as there was significant difference among groups. One-Way Analysis of Variance (ANOVA) and LSD multiple comparison tests were used to compare the difference of means. Pearson correlation analysis was used to determine the significance and direction of linear correlation among variables. The Chi-square testwas used to examine the relationship among categorically classified variables. One month after the first images were assessed, 30% of them were retaken in order to examine intra-observer reliability. In the evaluation of the intra-observer reliability, kappa analysis was used for categorical variables, and Cronbach alpha coefficient test was used for continuous variables.

3. RESULTS

All of the participants of this study were post-menopausal women. The group using bisphosphonate (65.76 ± 6.87) has a significantly higher mean age than the group not using bisphosphonate (62.01 ± 6.38) and the control group (62.06 ± 4.88). The most commonly used drugs in the group using bisphosphonate were respectively; Alendronic acid

(28.2%), Ibandronic acid (22.7%), Zoledronic acid (11.8%), and the combination of Ibandronic acid and Alendronic acid (10.9%). Additionally, 23 patients used denosumab, an antiresorptive drug, alongside bisphosphonates. In terms of bisphosphonate use, 63.6% of the patients were using it orally, 25.5% intravenously, 10.9% orally and intravenously. When it comes to the duration of bisphosphonate use, 35.5% of the patients had used the drugs between 0-1 year, 35.5% 1-3, 21.8% 3-4 years.

Compared to the control group, the mean MI and PMI values on both the right and left sides were significantly lower in the other two groups (p < .001). The group using bisphosphonates had lower right and left MI and PMI means than both the group not using bisphosphonates and the control group (p < .001) (Table 1).

Table 1. Values of MI and PMI in the three examined groups

MI ve PMI	The osteoporosis group not using bisphosphonates Mean ± SD	The osteoporosis group using bisphosphonates Mean ± SD	Control group Mean ± SD	P value
MI right	$3.14 \pm 0.70_a$	$2.71 \pm 0.70_b$	$3.86 \pm 0.65_c$	< .001
MI left	$3.18 \pm 0.73_a$	$2.85 \pm 0.69_b$	$3.83 \pm 0.64_c$	< .001
PMI right	$0.30 \pm 0.07_a$	$0.26 \pm 0.07_b$	$0.35 \pm 0.07_c$	< .001
PMI left	$0.30 \pm 0.07_a$	$0.27 \pm 0.07_b$	$0.35 \pm 0.07_c$	< .001

SD: Standard deviation MI: mental index PMI: panoramic mandibular index One-way Analysis of Variance (ANOVA), a,b,c: Intra-group differences (LSD Post Hoc Test). In each row, the means with the same letter were not found to be different (p > .05).

The most common MCI categories were C1 and C2 in the group not using bisphosphonates, C2 and C3 in the group using bisphosphonates, and C1 in the control group (Table 2). Although the C3 category was most common in the bisphosphonate group, a significant difference was found among all three groups (p < .001).

Table 2. Mandibular cortical index distribution by the groups

MCI (Klemetti Index)		The osteoporosis group not using bisphosphonates n(%)	The osteoporosis group using bisphosphonates n(%)	Control group n(%)	P value
C1	Right	35_a (24.3)	18_b (12.5)	91_c (63.2)	< .001
	Left	38_a (27)	22_b (15.6)	81_c (57.4)	< .001
C2	Right	57_a (44.9)	52_a (40.9)	18_b (14.2)	< .001
	Left	54_a (41.5)	48_a (36.9)	28_b (21.5)	< .001
C3	Right	18_a (30.5)	40_b (67.8)	1_c (1.7)	< .001
	Left	18_a (30.5)	40_b (67.8)	1_c (1.7)	< .001

One-way Analysis of Variance (ANOVA), a,b,c: Intra-group differences (LSD Post Hoc Test). In each row, the means with the same letter were not found to be different (p > .05).

There was no significant difference between the types of bisphosphonates used and MI, PMI, and MCI (p > .05). It was found that, while the duration of the bisphosphonate use increased, the means of right MI and both right/left

PMI significantly decreased (p < .05) (Table 3). There was no significant difference in mean right MI or right and left PMI between patients receiving denosumab in addition to bisphosphonates and those receiving bisphosphonates alone (p > .05). However, the mean left MI was significantly higher in patients receiving bisphosphonates alone (p = .018).

Table 3. Correlation coefficients and significance levels between duration of bisphosphonate use and MI, PMI, and age of the patients

		Age	MI Right	PMI Right	MI Left	PMI Left
Duration of bisphosphonate use	Pearson Correlation	0.24*	-0.23*	-0.21*	-0.16	-0.19*
	P value	0.01	0.01	0.02	0.09	0.044

* Correlation is significant at the .05 level (2 – tailed) MI: mental index PMI: panoramic mandibular index

The mean right MI was significantly higher in individuals using bisphosphonates intravenously compared to those using them orally (p = .05), while the mean left MI was significantly higher in those using bisphosphonates intravenously compared to both oral and oral + intravenous users (p = .018). The mean of right and left PMI was found to be significantly higher in intravenous bisphosphonate users compared to oral users (p < .05). There was no significant difference between the type and duration of bisphosphonate use and MCI categories (p > .05).

Periapical lesions numbers were close to each other in all three groups. The group not using bisphosphonates had the highest total number of periapical lesions. Significantly fewer periapical lesions were detected in the group using bisphosphonates due to osteoporosis compared to the other two groups (p = .002).The number of teeth with periapical lesions of diameter (S1) up to 3 mm was higher in the control group compared to the other two groups. Additionally, the number of the teeth with a lesion diameter (S3) greater than 5 mm was found to be 51.2% in the group not using bisphosphonates. The presence of periapical lesions involving more than one root was significantly higher in the control group than in the other two groups. Fewer such lesions were observed in the bisphosphonate group compared to the other two groups (p < .05).

There was no significant difference between the groups regarding the location of endodontically induced bone destruction. Additionally, no significant relationship was found between the type of bisphosphonate, the method of administration, the duration of use, and the size of the lesion, root radiolucent lesions, or the location of bone destruction in the bisphosphonate group (p > .05) (Table 4).

A statistically significant inverse correlation was observed between age and right MI, as well as right/left PMI, in both the group not using bisphosphonates (p < .05) and the group using bisphosphonates (p < .05). However, no such correlation was found between age and right/left MI or PMI in the control group (p > .05).

Table 4. Evaluation of periapical lesions by groups

		The group with osteoporosis but not using bisphosphonates n(%)	The group with osteoporosis using bisphosphonates n(%)	Control group n(%)	P value
S	S0	14$_a$ (56)	8$_a$ (32)	3$_b$ (12)	
	S1	33$_a$ (33.3)	23$_a$ (23.2)	43$_b$ (43.4)	.042
	S2	18$_a$ (42.9)	12$_a$ (28.6)	12$_a$ (28.6)	
	S3	21$_a$ (51.2)	11$_a$ (26.8)	9$_a$ (22)	
R	R0	14$_a$ (56)	8$_a$ (32)	3$_b$ (12)	
	R1	55$_a$ (39.6)	41$_a$ (29.5)	43$_a$ (30.9)	.002
	R2	12$_a$ (35.3)	2$_b$ (5.9)	20$_c$ (58.8)	
	R3	5$_a$ (55.6)	3$_a$ (33.3)	1$_a$ (11.1)	
D	D0	14$_a$ (56)	8$_a$ (32)	3$_b$ (12)	
	D1	59$_a$ (38.8)	41$_a$ (27)	52$_a$ (34.2)	.290
	D2	11$_a$ (42.3)	4$_a$ (15.4)	11$_a$ (42.3)	
	D3	2$_a$ (50)	1$_a$ (25)	1$_a$ (25)	

S: size of the lesion R: the relationship between lesion and root D: the location of bone destruction

One-way Analysis of Variance (ANOVA), a,b,c: Intra-group differences (LSD Post Hoc Test). In each row, the means with the same letter were not found to be different (p > .05).

There was no significant difference between the group using bisphosphonates for osteoporosis and the group with osteoporosis but not using bisphosphonates in terms of having more than 10 missing teeth. However, significantly fewer people in the control group had more than 10 missing teeth (p = .007). It was found that mandibular cortical thickness decreased significantly as the number of missing teeth increased in all study participants (p < .01). Additionally, the frequency of C2 and C3 categories increased significantly with the number of missing teeth (p < .05).

In this study, Cronbach's alpha coefficient values ranged from 0,88 to 0,99 (good) in the intraobserver agreement assessment of mandibular index measurements. In the evaluation of categorical variables, intraobserver agreement Kappa Test coefficient values were between 0,863 and 1 (excellent).

4. DISCUSSION

In this study, the effects of bisphosphonates on mandibular indices and periapical lesions in patients using bisphosphonates for osteoporosis were evaluated.

Morphological and radiomorphometric analyses evaluated on panoramic radiographs of postmenopausal women have demonstrated high sensitivity and specificity for detecting low BMD (9-13). Similarly, in this study, indices used for detecting bone mineral density were evaluated on panoramic radiographs.

In the literature, there are a limited number of studies evaluating the changes that may occur in the cortical and trabecular structure of the jaw bones due to bisphosphonate use (5,19,35-39). Barngkgei et al. (5) reported that the use of bisphosphonates in patients with osteoporosis had no effect on the MI value. In another study, it was reported that bisphosphonate used for osteoporosis caused a significant increase in mandibular cortical thickness, but did not cause any change in trabecular bone (37). In some studies, a significant increase in mandibular cortical thickness was found in patients using bisphosphonates compared to control patients (19,39). Yajima et al. (36) found no significant difference in terms of MI in postmenopausal female patients who received bisphosphonate treatment and alternative treatments (Selective Estrogen Receptor Modulator (SERM) and parathormone). Kubo et al. (40) found, in their study, MI was significantly less in the non-bisphosphonate-related osteonecrosis of the jaw (BRONJ) group using bisphosphonate compared to the BRONJ group and the control group. The result of this study was similar to Kubo et al.'s study. In the osteoporotic group using bisphosphonates, the mean MI was significantly lower compared to both the control group and the osteoporotic group not using bisphosphonates (p = .000). Unlike the present study, in the majority of the studies that found an increase in mandibular cortical thickness, the patients were under bisphosphonate therapy for multiple myeloma and cancers capable of bone metastasis. Such situations require the use of high doses of bisphosphonates. The patients in this study mostly used low-dose bisphosphonates orally due to osteoporosis, and the duration of bisphosphonate use was between 0-3 years in 79% of the patients.

Torres et al. (19) found no significant difference in the mean MI between patients using Zolendronate and patients using other bisphosphonates. Similarly, in this study there was no significant difference in terms of MI and type of drugs since the patients used 4 types of antiresorptive drugs and their combination. Yajima et al. (36) reported that mandibular cortical thickness increased with increasing duration of bisphosphonate use. Barngkgei et al. (5) found that bisphosphonate therapy used over a period of 4.3-5 years had no effect on mandibular thickness. Diniz-Freitas et al. (20) found statistically inverse correlation between MI and the duration of use of oral bisphosphonates. In this study, similar to the study of Diniz-Frietas et al. (20), it was determined that MI values decreased significantly with increasing duration of bisphosphonate use (p = .015). In a study by Musulluoğlu et al. (38) investigating the effect of oral and intravenous bisphosphonate use on jaw bone density in patients with osteoporosis, it was found that the MI values of dentate individuals using intravenous bisphosphonates were higher than those of dentate individuals using oral bisphosphonates, although the difference was not significant.In this study, mean MI, PMI was significantly higher in individuals on intravenous bisphosphonates compared with those on oral bisphosphonates.

Tanrıkol et al. (39) reported that the mean of PMI values in patients using bisphosphonates and the control group were not statistically significant. In this study, it was determined that PMI value in the group using bisphosphonate was significantly lower than the other two groups (p = .000).

The difference between the two studies may be due to the smaller sample size in Tanrıkol et al.

In a study of osteoporosis patients treated with denosumab, lower T-scores were associated with significantly lower MI values (41). Furthermore, a significant increase in PMI over one year was observed in patients with osteoporosis or osteopenia. In this study, the mean right MI and PMI were similar between patients receiving both Denosumab and bisphosphonates and those receiving bisphosphonates alone, but the left MI was significantly higher in the latter group. The difference between the two studies can be attributed to variations in their methodologies.

Tanrıkol et al. (39) detected that the most dominant category for right and left MCI values in patients using bisphosphonates was C1. Yamada et al. (35) observed significantly more C2 and C3 categories of MCI in patients using bisphosphonate due to osteoporosis. In their study, Grgić et al. (18) reported that the C3 category of MCI was higher in osteoporosis groups with and without bisphosphonate use, but this difference was not significant. In this study, the most common MCI category in the group using bisphosphonates due to osteoporosis was C2 and C3. In the group using bisphosphonates due to osteoporosis, the C3 category was detected in significantly more people than the other groups (p = .000). The studies reported C1 category was predominant in the patients using bisphosphonates, unlike this study, were evaluated in cases with bisphosphonate-induced osteonecrosis or patients using bisphosphonates due to malignancy (39,40,42). The results of our study were similar to the work of Yamada et al. (35) and Grgić et al. (18).

There are studies in literature evaluating the frequency of periapical lesions in patients using bisphosphonates due to osteoporosis. In a study conducted by Lopez et al. (27), in postmenopausal women, they reported that at least one periapical lesion was detected in 25% of patients with both osteopenic and osteoporotic bone structure, while this rate was only 7.4% in the healthy group. In another study by Katz and Rotstein (28), the prevalence of periapical lesions was found to be significantly higher in patients with osteoporosis compared to the general patient population of the hospital. In addition, it was reported that the prevalence of periapical lesion was lower in the osteoporosis group using bisphosphonates than in the osteoporosis group not using bisphosphonates. In the study by Cadoni et al., patients with osteoporosis were found to have a lower rate of periapical lesions compared to the control group, with no significant difference in the number of teeth affected. In addition, the prevalence of periapical lesions was found to be lowest in patients using bisphosphonates (29). Despite there was no significant difference in the number of individuals with periapical lesions among the groups in this study, when the total number of periapical lesions in each group was examined, significantly fewer lesions were detected in the group using bisphosphonates for osteoporosis compared to the other two groups (p = .002). The result of this study is in agreement with the studies of Cadoni et al. and Kats

and Rotstein. The reason for this situation may be that the treatment of the teeth that could be the focus of infection was completed before starting to use bisphosphonates. In addition to this, the inhibitory effect of bisphosphonate on bone resorption may also have been effective in bone structure.

Although there are studies evaluating the effect of bisphosphonate use on periapical lesion size in animals (26,30-32), there is limited evidence on this topic human study in the literature (29). In animal studies, it was found that the periapical lesions were significantly larger in the ovariectomized group compared to the control groups (26,30-32). The bone resorption observed in periapical lesions is largely carried out by osteoclasts. Bisphosphonates were thought to provide direct lesion expansion control by inhibiting the activity of these cells. Animal studies have shown that when periapical lesions are treated with bisphosphonates, resorption is greatly reduced; however, bisphosphonates were observed to increase the risk of BRONJ in the presence of pre-existing periapical lesions (30-32). In this study, periapical lesions were evaluated using CPI. The number of teeth with periapical lesions up to 3 mm in the control group was higher than the other two groups. In addition, the number of the teeth with a lesion diameter (S3) greater than 5 mm was found to be 51.2% in the group not using bisphosphonates. This is in line with the results of animal studies (26,30-32). There was no significant difference in lesion sizes in the group using bisphosphonates with osteoporosis compared to the other two groups. Since this retrospective study lacks clinical information, it was not possible to distinguish whether the existing periapical lesions in the patients were healing lesions or not.

Dereci et al. (43) found that as the duration of bisphosphonate use increased, the number of non-healed and partially healed teeth increased after the treatment of periapical lesions. Hisao et al. (44) reported that periapical lesions healed less, in a non-significant way, in the group using bisphosphonates orally compared to the control group. In this study, no significant relationship was found between the type of bisphosphonate, the type of use, the duration of use and the size of the lesion in the osteoporotic group using bisphosphonates.

The main strength of this study is that it included only patients using bisphosphonates for postmenopausal osteoporosis and patients with osteoporosis who were not using bisphosphonates, with the control group consisting of individuals who underwent DXA measurements.

This study has several limitations. Due to its retrospective design, the patients' eating habits, smoking habits, and age at menopause are not known. It is important to note that many variables—such as low body weight, family history of osteoporotic fractures, and lifestyle—may influence bone structure and increase susceptibility to osteoporosis. Patients used four different types of bisphosphonates and their combinations; additionally, 23 patients used denosumab. Bisphosphonates were mostly administered orally, and the

duration of use was short. Future studies should include homogeneous populations undergoing long-term use of the same bisphosphonate type and route of administration. Moreover, prospective studies are considered more reliable for measuring individual changes in mandibular indices and periapical lesion size. The most significant limitation of this study is the lack of DXA values in patients with osteoporosis. Previous studies (3, 9-13) have shown a correlation between lower DXA scores, which indicate lower bone mineral density, and lower mandibular indices. In this study, the mandibular index values of the group using bisphosphonates for osteoporosis were significantly lower than those of the other two groups. This finding could be better explained with access to their DXA scores. Planning future studies with these limitations in mind will provide us with more valuable information in this area.

5. CONCLUSION

According to the results of our study, it was found that osteoporosis patients using bisphosphonates have a lower mandibular index. The absence of an increase in mandibular indices might be attributed to the lower dosage of bisphosphonates typically administered for osteoporosis treatment. In addition, the fact that bisphosphonates were primarily used orally and the duration of use was short may have affected the results of our study. Both the total number and size of periapical lesions were significantly smaller in the bisphosphonate group compared to the other two groups. Bisphosphonates used in the treatment of osteoporosis may have favorable effects on the healing of periapical lesions.

Author Contributions:
Research idea: ÖY, EB
Design of the study: ÖY, EB, MA, SSŞ, HO
Acquisition of data for the study: ÖY, EB, MA, SSŞ,
Analysis of data for the study: ÖY, EB, HO
Interpretation of data for the study: ÖY, EB, MA, SSŞ, HO
Drafting the manuscript: ÖY, EB, MA, SSŞ, HO
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Clinical and Experimental Health Sciences

Cost Analysis of Hemodialysis Session: A Comparison Between Activity-Based Costing and Traditional Costing Methods

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ABSTRACT

Objective: This study, aims to determine the cost of hemodialysis sessions by using traditional costing and activity-based costing (ABC) methods, to provide a tool for controlling costs and to contribute to the financial planning studies of health managers.

Methods: The research was carried out in the hemodialysis unit of a university hospital in Türkiye. Medical, administrative, financial, and statistical data of the hospital for 2018 were used for the cost data. Hemodialysis cost per session was calculated by analyzing the obtained data both traditional cost analysis and the ABC method.

Results: As a result of the analysis through traditional cost analysis, the unit cost per hemodialysis session was 49.54 $, while in the ABC analysis, the cost of hemodialysis sessions was calculated as 41.16 $.

Conclusion: As a result of the study detected differences between the hemodialysis costs per session obtained through traditional cost analysis and ABC analysis. The study concludes that the unit cost calculated by the ABC method provides more detailed and more realistic information than the cost calculated with the traditional costing method. Additionally, the cost of a hemodialysis session reached within the scope of the study was determined to be higher than the price of the reimbursement institution. As the cost of a hemodialysis session is higher than the price paid back to the hospital, it is recommended that the hospital develop practices that increase efficiency and that reimbursement prices be increased.

Keywords: Activity-based costing, chronic kidney disease, cost analysis, hemodialysis, traditional cost analysis.

1. INTRODUCTION

Being among the basic health problems in the world, chronic diseases are gradually increasing and placing a big burden on patients, service providers, and the healthcare system. Chronic kidney disease is both an important public health problem and an important financial problem for the healthcare system. Chronic kidney disease (CKD) is often diagnosed with a chronic decrease in renal function and structural renal failure. CKD usually progresses slowly and silently, and renal function becomes already significantly impaired by the time the symptoms appear [1]. The end-stage of CKD is called end-stage renal disease (ESRD) and refers to a drop in renal function below 15% [2].

The national data, regularly gathered by the Turkish Society of Nephrology (TSN), revealed that the prevalence of ESRD in Türkiye was 1,016 per million population and its incidence was 161 per million population, including pediatric patients, in 2022 [3]. Unfortunately, the incidence and prevalence of ESRD have been increasing over the years in Türkiye. The number of patients with ESRD, which was 324 per million population in 2001, reached 1,016 in 2022. Such an increasing trend is expected to be persistent in the coming years, particularly due to the aging of the population and the increase in the prevalence of diabetes, among the most apparent reasons for the emergence of ESRD. Therefore, the increase in the number of ESRD patients over the years may be a robust indicator that relevant treatment options will inevitably be on the agenda of health policymakers soon.

An ESRD patient has to start one of the treatment options called renal replacement therapy (RRT) to be able to survive. RRT, consisting of dialysis or kidney transplant, is an artificial treatment to eliminate or minimize the problems occurring due to renal failure [4]. Hemodialysis refers to a process of regulating the liquid-solute content of blood with the help of a membrane and a machine outside the body and returning it to the patient [5]. Worldwide, approximately 89% of patients with ESRD receive hemodialysis treatment [5,6]. In-centre HD remains the most common treatment modality for ESRD by a large margin worldwide. In 2021, Montenegro (97.8%), Bangladesh (91.4%), and Romania (86.8%) were the countries with the highest use of in-center hemodialysis for ESRD patients, respectively [7]. Similarly, the most frequently reported treatment option for patients with ESRD is hemodialysis in Türkiye. According to the 2022 data, there were 61,723 (73.21%) hemodialysis patients in Türkiye. It is known that 97.37% of these patients undergo hemodialysis in a relevant center [3]. ESRD, together with the RRT, brings a severely compelling economic burden on national healthcare budgets. Accordingly, the global cost of RRT is estimated at over $1 trillion [8]. The increasing frequency of the disease and the increase in the number of treated patients raise the expenditures for treatment and cause more financial resources to be allocated for health from the budgets of countries. Thus, increasing costs in healthcare institutions and pressure to control the inflation in treatments urge performing a cost analysis for hemodialysis, the most prevalently adopted therapy option in ESRD across the world.

Today, rapidly developing technology leads to substantial transformations in the production and management structures of businesses, which also leads to changes in their production and pricing strategies. As a result, the structure of cost elements (raw materials, labor, and production overhead costs) also changes. Whereas the share of production overhead costs in total costs increases in all technology-intensive organizations, particularly healthcare institutions, it is vice versa for direct labor costs. Therefore, a cost analysis based on traditional costing in a novel production environment has begun to fall short in finding ways to help organizations better understand their processes and costs. It has also elevated the efforts of organizations to "find the right product cost" to ensure that their costing structures are compatible with the changing technology. Moreover, it has become a necessity to utilize different methods in costing products to be able to manage increased overheads and decide which processes verily add value to a product or service [9]. Based on the assumption that there is a causal relationship between the activities and the costs of these activities, the Activity-Based Costing (ABC) method, introduced as an alternative method to traditional costing methods, proposes that costs reflect the actual situation of a business more accurately [10 – 12].

In traditional costing, it is accepted that expenses are incurred for the products produced, and a relationship is established between these expenses and the products. Since this relationship is direct for raw material and labor costs, the related costs are directly charged to the cost of the products to which they belong. In the case of overheads, since the expense-product relationship is indirect, the expenses are charged to the products produced by using the cost driver. In the ABC approach, expenses are incurred for the realization of activities and products benefit from these activities. This is the main point where ABC and traditional costing approaches differ [13].

ABC models the use of business resources according to the activities performed and then relates the cost of these activities to outputs such as products, customers, and services [14]. In its simplest form, ABC is a method that attempts to break down production into its basic activities, identify the costs of these activities, and then allocate these costs to products according to how much of a particular activity is needed to produce products [15]. The ABC method basically uses a two-stage allocation process. In the first stage, the costs of consumed resources are allocated to activities with the help of appropriate resource cost drivers, and in the second stage, the costs allocated to activity pools or activities in the first stage are allocated to cost objects using appropriate cost drivers [16]. ABC is a method that tries to overcome the perceived shortcomings of traditional costing methods by matching activities more closely with products [15].

Increasing costs in healthcare institutions highlight the significance of measuring the costs of services produced in these organizations. The service costs can be calculated using the data of costs emerging in healthcare institutions [17]. Having the proper knowledge of costs brings with it the correct pricing strategies. Nevertheless, one may question the reliability of the costs in complex organizations (e.g., hospitals) calculated through only traditional costing methods. Ultimately, we believe that the ABC method will be helpful in determining costs in healthcare institutions since it reveals cost information closest to the actual situation.

ESRD patients receiving dialysis therapy are considered a unique population. The relevant statistics confirm that the number of ESRD patients and the costs of treatment and follow-up of these patients are on the rise and that such costs are projected to create a tremendous burden on the financial resources allocated for healthcare in the near future. In addition, hemodialysis is among the services demanding high resource allocation in healthcare service delivery. Hemodialysis patients who come to the hospital for an average of 3 sessions per week may require more resource consumption than other outpatients. For this reason, it seems essential to conclude accurate cost information for a robust planning of hemodialysis services and to use scarce and expensive resources effectively and efficiently. Thus, the original findings in the present study may guide managing bodies of hospitals, reimbursement institutions, and further research, contribute to increasing awareness of hemodialysis costs among healthcare managers, policymakers, and researchers, and enrich the relevant literature.

Although the literature hosts research on determining hemodialysis costs, these studies seem to have utilized various costing methods, particularly traditional ones [18-25]. Yet, there are almost no studies, except for a few, resorting to the ABC method to determine the costs of hemodialysis treatment [26, 27]. Although the ABC method was used in these studies, it is noteworthy that costs were determined using a single method. In line with such a gap in the literature, we aimed to utilize both a traditional costing method and the ABC method to acquire more realistic costs for the procedures and applications within hemodialysis treatment, to compare and evaluate the findings, and to make recommendations for further research. We also compared the costs per hemodialysis session calculated using both methods and payment per session set by the reimbursement institution within the relevant period.

2. METHODS

We carried out the present study in the Hemodialysis Center of the Nephrology Department at Ibni Sina Hospital, a university hospital in Türkiye. The scope of the research covers determining the costs incurred in the provision of hemodialysis services in the relevant center from the perspective of the service provider.

This is cross-sectional and descriptive research because the cost analysis is based on the data of a certain period. Medical, administrative, financial, and statistical data of the hospital for 2018 were used for the cost data. The data related to the determination of the activities and activity durations of the hemodialysis process were obtained by the researcher using the time study method. The data obtained within the scope of the study were transferred to the computer environment, and the Microsoft Excel package program was used in the analysis of the collected data. We calculated the costs using traditional costing and ABC methods. Within the traditional costing method, we detected the hospital's expense locations, types, and amounts, calculated the relevant costs, and presented them in three cost allocation tables. On the other hand, within the scope of the research, the determination of the activities and activity durations of the hemodialysis process, which is one of the basic stages in the ABC method, was obtained by the researcher by making

actual measurements. To determine the hemodialysis activities in the ABC method, observations were made in the Hemodialysis Unit for the hemodialysis process. As a result of the observations, each activity related to the hemodialysis method and the first materials and materials used during the related activity were determined. In cases where observations were insufficient, expert opinion was sought by interviewing the doctors and nurses in the unit. The 36 activities determined for the hemodialysis session were collected under 8 activity pools by applying expert opinion. Then, we converted the cost per hemodialysis session into dollars based on the average US dollar rate of the Central Bank of the Republic of Türkiye in 2018 to generate a base for further studies and to be able to compare the costs with those calculated in other studies.

3. RESULTS

The results obtained using the traditional costing and ABC methods are presented below:

3.1. Results of the Traditional Costing Method

The findings revealed the total cost of the hospital in 2018 to be $59.854.435,13. Personnel costs constituted 55.64% of the total cost. The shares of raw material costs and production overhead costs in the total cost were 31.50% and 12.86%, respectively.

The total cost incurred in the hemodialysis center as a result of the first allocation was found to be $761.037,16. The second and third allocations yielded it to be $828.478,73 and $835.214,39, respectively. Of the total cost, 44.39% ($370.792,27) corresponded to personnel costs, 26.84% ($224.192,30) was raw material costs, and 28.76% ($240.229,81) corresponded to production overhead costs.

Table 1 presents the conversion coefficients and criteria used to calculate unit costs in the hemodialysis center. Accordingly, the total cost was calculated to be $835.214,39. In addition, we found the total number of converted sessions to be 17,872.98 and the unit price of a converted session to be $46,73. Following the third allocation, the unit cost per hemodialysis session was calculated to be $49,54 for up to 700 sessions and $46,73 for 701 sessions and above (Table 1).

Table 1. Hemodialysis Session Unit Cost According to Traditional Costing Method

	NCHI Score	Conversion Coefficient	Actual Production Quantity	Number of Converted Sessions	Actual Unit Cost	NCHI Price
Emergency hemodialysis	334	1,06	1875	1987,5	49,54	41,12
Hemodialysis, up to 700 sessions (including 700 sessions)	334	1,06	9208	9760,48	49,54	41,12
Hemodialysis, 701 sessions and above	315	1	6125	6125	46,73	38,84
Total Cost	835.214,39					
Total Converted Sessions	17872,98					
Converted Session Unit Price	46,73					

NCHI: National Communiqué on Healthcare Implementation

Table 2. *Hemodialysis Session Cost According to ABC Method*

Activity Pool	Total of raw material costs ($)	Total of raw material costs per session ($)*	Total of personnel costs ($)	Total of personnel costs per session ($)*	Total of production overhead costs ($)	Total of production overhead costs per session ($)*	Hemodialysis Session Unit Cost ($)
F1 – Patient Registration	0,00	0,00	347,09	0,02	187,63	0,01	0,04
F2 – Preparation of materials to be used	68.781,05	4,49	3.263,60	0,21	15.047,84	0,98	5,68
F3 – Activities for the initiation of hemodialysis	90.816,46	5,92	24.091,80	1,57	40.825,35	2,66	10,16
F4 – Care activities during hemodialysis	29.378,78	1,92	168.444,07	10,99	59.093,44	3,85	16,76
F5 – Technical Affairs	0,00	0,00	693,73	0,05	15.986,16	1,04	1,09
F6 – Activities to terminate hemodialysis	3.343,52	0,22	20.164,84	1,31	40.825,35	2,66	4,20
F7 – Patient exit procedures	0,00	0,00	4.679,02	0,31	9.934,96	0,65	0,95
F8 – Cleaning activities at the end of the session	0,00	0,00	0,00	0,00	35.139,55	2,29	2,29
Total	**192.319,81**	**12,54**	**221.684,15**	**14,46**	**217.040,29**	**14,16**	**41,16**

*Hemodialysis cost per session was obtained by dividing the total of raw material, personnel and production overhead costs by the number of hemodialysis sessions (15333).

F1-planning of dialysis sessions and treatment, obtaining dialysis consent, preparation of patient files, etc. activities

F2-Bringing the first materials and supplies used from the warehouse and distributing them to the patient beds (materials used: basic bicarbonate solution, acidic bicarbonate solution)

F3-Activities such as attaching the sets of the hemodialysis device, preparing the patient's current vascular access route, connecting the patient to the hemodialysis device and operating the device, etc. (material used: dialyzer artery/vein set, s-isotonic 09% Nacl 500 ml)

F4-preparation and administration of heparin, checking vital signs 3 to 4 times, checking/examining the patient by the doctor, etc.

F5-the activity of water analyses

F6 – stopping the machine at the end of the session and separating the patient from the hemodialysis device, closing the patient's arm, etc. activities (material used: sterile sponge, plaster 0.2m, gloves)

F7 – The activity of recording the material used for each patient through the system

F8 – Activities such as wiping the surface of the appliance, changing the linen of sofas or beds, etc.

3.2. Results of the ABC Method

We also utilized the ABC method to calculate the cost per hemodialysis session for chronic hemodialysis patients receiving sessions on a weekly basis. Chronic hemodialysis patients were recruited for a total of 15333 hemodialysis sessions in 2018 (9208 for up to 700 sessions and 6125 for 701 sessions and above). Accordingly, we calculated the total cost of the center to be $631.044,25 for chronic hemodialysis patients. The share of raw material costs in the total cost ($192.319,81) was 30.48%. While personnel costs ($221.684,15) corresponded to 35.13% of the total cost, it was 34.39% for production overhead costs ($217.040,29). Overall, we calculated the cost per hemodialysis session of the hospital in 2018 to be $41,16 (Table 2).

4. DISCUSSION

The traditional costing method yielded the unit cost per hemodialysis session to be $49.54, while it was $41.16 according to the ABC analysis. The difference between the costs calculated based on both methods was found to be $8.38. We realized that such a difference in the unit cost originated from the differences in personnel costs ($7.53),

raw material costs ($0.75), and production overhead costs ($0.09) (Table 3). It is clear that personnel costs contributed the most to the difference between the unit costs per hemodialysis session. Since the ABC method determines personnel costs considering activity-based labor time, it does not take idle capacity into account. Therefore, the difference is thought to arise from the use of standard labor time determined for activities when calculating personnel costs in the ABC method, that is, the fact that this method does not consider idle capacity in the analysis.

Since the ABC method considers all the procedures for patients, we also determined the use of standard drugs and medical supplies for each procedure while analyzing the activities. On the other hand, we considered all raw materials directly supplied to the hemodialysis center in the traditional costing method. Therefore, the cost of raw materials was found to be $0.75 more in the traditional costing method when compared to the ABC method (Table 3). The difference may be explained by the fact that the ABC method considered only raw materials already used for chronic hemodialysis patients, but the warehouse in the center may have been loaded with materials not yet used for patients.

Table 3. Comparison of Hemodialysis Session Costs Calculated by ABC with Traditional Costing

Cost type	Traditional Costing			ABC			Difference
	Amount	Unit Price Per Session	Percentage	Amount	Unit Price Per Session	Percentage	
Raw material costs	224.192,30	13,30	26,85	192.319,81	12,54	30,48	0,75
Personnel costs	370.792,27	21,99	44,39	221.684,15	14,46	35,13	7,53
Production overhead costs	240.229,81	14,25	28,76	217.040,29	14,16	34,39	0,09
Total	835.214,39	49,54	100,00	631.044,25	41,16	100	8,38

ABC: activity-based costing

Nevertheless, we realized a negligible difference between both methods in terms of production overhead costs. It may be because the center has only a single output (hemodialysis session). Moreover, we calculated the cost per session only for chronic hemodialysis patients within the ABC method.

Despite the lack of studies utilizing the traditional costing and ABC methods together to calculate the cost per hemodialysis session, some studies are using both methods in different departments (general surgery, obstetrics, radiological imaging) in healthcare institutions. In such studies, the findings of the ABC method generally yielded lower numbers than those of the traditional costing method [28-30]. In this sense, our findings overlap with what was concluded in the literature.

We calculated the cost per hemodialysis session to be $49.54 within the traditional cost method. About 1/4 (26.84%) of the actual cost per session consisted of raw material costs. While 44.39% corresponded to personnel costs, the share of production overhead costs was 28.76%. The previous research concluded the cost per hemodialysis session to be about $74 [20] in Iran and $44.47 [31] in Malaysia. In a prospective study carried out in hemodialysis centers of three public and two private hospitals in Sri Lanka, the scholars calculated the mean cost per hemodialysis session to be $56 [21]. In their study, Vanholder et al. (2012) found significant differences between dialysis reimbursements in 7 countries. In the study, they calculated the cost per hemodialysis session to be $230 in the United States, $248 in the United Kingdom, $248 in Canada, $454 in France, $556 in the Netherlands, $536 in Belgium, and $225-377 in Germany [22]. In another study, the mean cost per hemodialysis session was calculated to be $297. The study also concluded that 12.47% of the total cost consisted of pharmaceutical costs, 13.64% corresponded to material costs, 41.11% was personnel costs, and 18.85% was production overhead costs [19]. Our findings were similar to the study by Al Saran and Sabry (2012), concluding personnel costs to be a category accounting for the largest cost within the total cost.

In general, the previous findings differed by country and institution. Thus, we think that the differences in the calculated costs may have derived from variances in adopted healthcare systems and policies, differences in economic structures, and organizational and time-related differences. Costs are also affected by the quality of service provided, personnel wages, medical equipment and consumables,

and reimbursement systems. Ranasinghe et al. (2011) stated that the gaps between the costs reported in the literature are pretty high, which cannot be explained only by annual per capita income between countries [21]. Accordingly, variances in factors, such as inpatient care, local labor costs, management protocols, and import duties, may account for the gaps between the relevant costs. It was also asserted that the reason behind the substantial variance in costs may be that some items are not considered while calculating costs [21].

We calculated the unit cost per hemodialysis session to be $41.16, according to the ABC method. A previous study utilized this method and calculated the total cost of hemodialysis procedures to be IDR1,750,936,588.0 ($119,744.66) and the unit cost per hemodialysis session to be IDR724,725.00 ($49.56)* in 2018 [26]. In a study in Yazd Shahid Sadoughi Hospital in Iran, Mohammadi et al. (2012) calculated the total cost of dialysis services to be IRR1,723,906,772 ($141,652.16)* and the cost per session to be IRR442,028 ($36.32) [27].

The only reimbursement institution in Türkiye is the Social Security Institution (SSI). In Türkiye, SSI adopts the bundle pricing strategy in pricing hemodialysis treatment. The bundled payment per hemodialysis session (up to 700 sessions – 700th session included) to the hospital was $41,12 (TRY198) TL in 2018. In this regard, we discovered that there was a gap between the cost per hemodialysis session ($49,54) that we calculated using the traditional costing method and the payment ($41,12) to the hospital by SSI in 2018. The previous findings of hemodialysis treatment and its costs in Türkiye overlap our results. Moreover, similar to our findings, the previous research concluded that the unit costs per hemodialysis session in healthcare institutions were generally higher than the bundle prices specified in the National Communiqué on Healthcare Implementation (NCHI) by SSI [24, 32, 33].

Moreover, despite the insignificant, we concluded that the payment by SSI to the hospital remained lower than the cost per hemodialysis session we calculated using the ABC method. Accordingly, the amount paid by SSI per session was $0,04 less than the calculated unit cost. Although this finding seems to be in favor of SSI, it is more likely to reach a larger gap between the unit cost and bundle price specified in the NCHI. The drugs used in the treatment of complications developed during sessions and inpatient bed day cost, included in the

bundle price determined in the NCHI, were not considered while calculating the costs of the hemodialysis center using the ABC method.

Even though the literature has no other research using the ABC method to calculate costs in hemodialysis centers in Türkiye, some studies utilized this method in different units in healthcare institutions. Similarly, those studies concluded that the calculated costs with ABC are higher than the bundle prices offered by SSI [34, 35].

5. CONCLUSIONS

We carried out the present study in a hemodialysis center operating at Ibni Sina Hospital of Ankara University and calculated the unit cost per hemodialysis session using traditional costing and ABC methods. Then, we compared both the unit costs per hemodialysis session and the total costs of hemodialysis procedures calculated using both methods with the bundle price offered by the relevant reimbursement institution in 2018.

In healthcare institutions with elevated resource consumption, administrators need to obtain accurate information to ensure efficient and effective use of such resources. Pricing without accurate and sufficient cost information may result in over – or under-pricing the services. Considering this situation from the perspective of SSI, which is the largest and only reimbursement agency for the services offered in healthcare institutions in Türkiye, we believe that research on costing may be guiding for cost-based pricing policies of healthcare services since inappropriate pricing is more likely to result in inefficient allocation of limited public resources.

Hemodialysis service is among those requiring high resource utilization, and a hemodialysis patient visiting the hospital on average three times a week is likely to consume more resources than a regular patient. Therefore, considering the findings of the present study, the institutions should robustly plan their hemodialysis services to utilize scarce and expensive resources efficiently. In addition, since SSI offers bundled payments to hospitals for hemodialysis sessions, it is essential to calculate the cost per hemodialysis session in hemodialysis centers with diversified cost items.

Overall, we concluded that the unit costs in a hemodialysis center calculated using the ABC method became more realistic and detailed than those calculated using the traditional costing method. The detailed and reliable data obtained using the ABC method based on the activities in healthcare service delivery are believed to bring significant contributions to hospital management in different aspects. Additionally, the cost of a hemodialysis session reached within the scope of the study was determined to be higher than the price of the reimbursement institution. Future research may comprehensively address the costs of hemodialysis services by considering the comorbidities and indirect patient costs.

The data obtained in the study and the results of the study are limited to Ankara University Faculty of Medicine, Department of Nephrology, Hemodialysis Unit. Therefore, the fact that the results of this study cannot be generalized to other hemodialysis centers constitutes the limitation of the study. In addition, since the most recent hospital data that could be obtained during the research period belonged to 2018, the data from that year were used in the study.

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Evaluation of the Reliability of Color-Based Phenotype Probes in the Determination of Gingival Phenotype

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ABSTRACT

Objective: This study aimed to determine gingival thickness with newly developed color-based phenotype probes and to compare the results with the traditional method (transgingival probing).

Methods: 100 individuals with a mean age of 38.37 ± 11.03 years who had Miller I class gingival recession in the anterior region were included in the study. In measurements performed with color-based phenotype probes, white (thin), green (medium), and blue (thick) colored tips were used. In the transgingival probing method, a digital caliper with a penetration depth of 0.01 mm sensitivity was used.

Results: Of the teeth included in the analysis, 45% were in the maxillary anterior region, and 55% were in the mandibular anterior region. The mean tissue thickness was 0.76 ± 0.17 mm in the mandibular jaw and 1.22 ± 0.36 mm in the maxillary jaw (p= .001). A statistically significant relationship was found between the values determined with the transgingival method and the observed probe color (p= .001). The tissue thickness values of the cases whose observed probe color was white were significantly lower compared to those with green, blue, and no color (p< .05). When the mean tissue thicknesses were compared according to colors, tissue thickness significantly increased toward the blue color (p= .001). There was a statistically significant relationship with the gingival thickness measurement values (p= .001), and a low level of agreement was determined (Kappa=0.159). In addition, it was determined that different colors were observed with the color-based phenotype probes in the same quantitative ranges.

Conclusion: Based on the assumption that color-based phenotype probes yield more subjective results, we believe that they can be used in clinical practice to determine gingival phenotype, but when quantitative data are required, preferring to use the transgingival method woud give more accurate results.

Keywords: Phenotype, gingiva, tissue

1. INTRODUCTION

The integrity of the gingival tissues is necessary to ensure ideal treatments and long-term clinical results (1). The thickness of the gingival tissue and the width of the keratinized tissue are important in terms of protecting soft tissue health around the teeth and implants (2). Gingival recession is defined as atrophic periodontal changes. The term "atrophy" refers to a decrease in the volume and cellular population in an organ or tissue as a result of certain processes such as hypoxia, mechanical compression, and locally diminished vascularization (3). Gingival recession can be induced by periodontal diseases, dental plaque, wrong use of dental floss, aggressive toothbrushing, wrong occlusal relations, and off-arch teeth (4). Gingival recession can be seen in areas where the gingival phenotype is thin and tooth cleaning is difficult. In the 2017 World Workshop on Classification of Periodontal and Peri-Implant Diseases and

Conditions, the term periodontal phenotype was proposed to jointly evaluate the characteristics of soft tissue and bone morphology (5).

Measurement of periodontal soft tissue size is very important in terms of treatment planning, function, aesthetics, and prognosis (6). Aimetti et al. defined the periodontal phenotype as thin(<1 mm) or thick(>1 mm) (7). In addition, Kan et al. described thick gingiva as more dense and fibrous in appearance, and thin ones as more sensitive and almost transparent (8).

It is suggested that thin and thick gingival phenotypes respond differently to orthodontic treatment, periodontal treatment, surgery, and restorative dental treatment (9). Gingival recession may develop in individuals with thin phenotypes due to insufficient amount of soft tissue after orthodontic movements, implant surgery, crown prolonging

procedures, non-surgical periodontal treatment, and prosthetic treatment (10).

Since gingival phenotype is an important factor regarding periodontal health and treatment success, various measurement methods have been defined to determine it (11,12). One of the important parameters evaluated in the gingival phenotype is gingival thickness (5). Various methods such as visual examination (13), transgingival probing (12), ultrasound device (14), and visibility of the periodontal probe along the gingival groove have been used to evaluate gingival thickness (11). Recently, new types of periodontal probes have been mentioned in the literature to be used in determining phenotypes (15–17). There is no definite consensus in the literature on which method is the most accurate and appropriate for the measurement of gingival thickness. Although color-based phenotype probes offer a simple and visualized method for clinicians, very limited studies evaluating (6) their reliability (15,16) were encountered in the literature.

In this context, the present study aimed to determine the gingival thickness in cases with a gingival recession in the anterior region with the newly developed colored-tip color-based phenotype probe and to validate it with the transgingival probing method, which is the traditional measurement method.

2. METHODS

2.1. Patient Selection

100 patients between the ages of 19 and 65 who applied to the Department of Periodontology of Van Yüzüncü Yıl University Faculty of Dentistry with a complaint of gingival recession were included in our study. A written consent form was signed by all individuals who voluntarily participated in the study. The research was started with the approval of the Van Yüzüncü Yıl University Clinical Research Ethics Committee (17.06.2020/Decision no:15).

Inclusion criteria were determined as the (18) presence of Miller 1 class gingival recession in at least one of the mandibular and maxillary anterior teeth, volunteering for the study, being periodontally healthy, or the inflammation in the gingiva being limited to the gingiva (gingivitis).

Exclusion criteria were determined as the presence of systemic disease, smoking, pregnancy or breastfeeding, history of surgery in the relevant region (19), presence of significant melanin pigmentation, diagnosis of periodontitis, (20) and use of any drug affecting periodontal tissues (21).

2.2. Patient Data Records

After the systemic and dental anamnesis of 100 patients (46 females and 54 males) who met the study criteria were taken in detail, they were given detailed information about their diagnosis and the procedures to be followed.

2.3. Randomization

Before proceeding to the randomization process, all participants were evaluated in terms of gingival recession areas and jaws (mandible-maxilla). In cases with Miller 1 class gingival recession in the anterior region of a single jaw, the jaw with recession was included in the study. In cases with Miller 1 class gingival recession in both jaws, the jaw to be included was determined by the coin toss method. If there was more than one Miller 1 class gingival recession in a jaw, the tooth to be included was again randomly selected. Teeth with Miller 1 class gingival recession were written on a piece of paper in a way the patients could not see them. Each tooth was assigned a letter, and the patients were asked which letter they chose. The tooth corresponding to the letter chosen by the patient was included in the study, and its measurements were made. All measurements were made by a single clinician and based on a single tooth with Miller 1 class gingival recession.

2.4. Gingival Thickness and Phenotype Measurement

Gingival thickness was determined using a newly developed tool, color-based phenotype probe, and transgingival probing method.

When measuring with a color-based phenotype probe, the white-colored probe was first placed in the gingival sulcus with a force of less than 0.25 N. If the color appeared, that is, if the probe was reflected from the gingival tissue, the phenotype was recorded as thin. If the white color was not visualized, the green-colored probe was used in the same way, and if the color was reflected, the phenotype was recorded as medium thickness. If the green-colored tip was not visualized from the gingival tissue, the blue-colored probe was used, and if the only color seen was blue, the phenotype was classified as thick. If the blue tip was not visualized, the gingival tissue was recorded as very thick (12,17) (Figure 1).

Figure 1. Color-based phenotype probe

In a recent study investigating the reliability of color-based phenotype probes, (22) cases were divided into four categories according to tissue thickness measured by an endodontic file [(< 1 mm(thin), ≥ 1 to < 1.25 mm (medium), ≥ 1.25 to < 1.5 mm (thick), and ≥ 1.5 mm (very thick)], and part of the analysis was performed according to these values (22). It was also examined whether the data in our study were consistent with these ranges presented by the literature.

In the transgingival probing method, measurements were made for each tooth from 2 points: the apical of the free gingival groove and the coronal of the mucogingival junction. After the gingival thickness measurement points were determined with a marker pen, a topical anesthetic spray (Xylocaine® spray; Vemcaine 10%, lidocaine) was applied so that the patient did not feel pain. The 15-point endodontic spreader (G-STAR Medical Co.,Ltd.,Guangdong,China) with a silicone stopper on it was advanced perpendicularly to the gingiva until contact with hard tissue was felt, and gingival thickness was determined. The penetration depth between the stopper and the tip of the file was measured using a digital caliper (Mitutoyo Corporation, Kanagawa, Japan) with a precision of 0.01 mm (16, 23) (Figure 2).
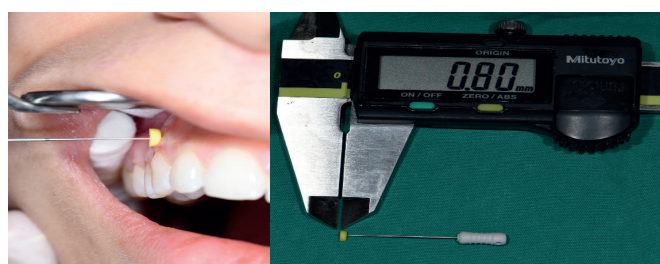

Figure 2. Transgingival probing method

The averages of the gum thicknesses obtained from both measurement points were taken and recorded as the first measurement. After 10 minutes, after the same procedures were repeated for the second time by the same researcher, the average of the two measurements was taken, and the final gingival thickness of the included tooth was determined.

2.5. Statistical Methodology

G*Power 3.1. software was used to calculate the sample size of the study. Based on the theoretical power value of 80% with a 5% margin of error, 95% confidence level, and moderate effect size, it was determined that at least 100 observations were required, and the research was conducted on 100 participants in total. The data obtained in this study were analyzed by the Licensed IBM SPSS Statistics Version 21 software. While the normal distribution of variables was being researched, the Shapiro-Wilk test was employed because of the unit numbers. While interpreting the results, 0.05 was used as the level of significance, and in the case of p< .05, it was suggested that the variables did not have a normal distribution, but in the case of p> .05, the variables had a normal distribution.

The Chi-Square analysis was applied to examine the correlation between the groups of nominal variables. If the nominal values did not display sufficient volumes in the cells of 2X2 tables, Fisher's Exact Test was used. The Pearson Chi-Square test was used to analyze RXC tables with the help of the Monte Carlo Simulation. When examining the differences between the groups, the Mann-Whitney U Test and the Kruskal Wallis H Test were used in intergroup comparisons if

the variables did not display a normal distribution. In case of a significant difference in comparisons with more than two groups, groups with significant differences were determined with the help of Post Hoc (Mann Whitney U test with Bonferroni correction) tests.

Spearman's Correlation Coefficient was used to examine the relationships between non-normally distributed variables.

Kappa coefficient was used to evaluate the agreement with the gingival thickness scale given in the literature.

3. RESULTS

46 of the individuals participating in the study were female, and 54 were male (p= .276). The mean age of the patients was 38.37 ± 11.03 (p= .079) with a range of 19-65 years. 45% of the teeth with gingival recession were located in the maxillary anterior region and 55% in the mandibular anterior region (p< .05).

There was a statistically significant difference between the visualized probe color and the jaws (p< .05). The visualized probe color of 65.45% of the regions included in the mandible and 62.22% of those included in the maxilla was green, that is, medium thickness. No probe color was visualized in 8.89% of the regions included in the maxilla (very thick). The distribution of the measured clinical parameters of the individuals is presented in Table 1.

Table 1. Relationship between jaws in terms of visualized probe color

		Included Jaw						Chi-Square Test	
		Mandible		Maxilla		Total			
		n	%	n	%	n	%	Chi-Square Test	p
Probe Color Visualized	White	19	34.55	1	2.22	20	20	-	.001*
	Green	36	65.45	28	62.22	64	64		
	Blue	0	0	12	26.67	12	12		
	None	0	0	4	8.89	4	4		
	Total	55	100	45	100	100	100		

*n: number of patients; %: percentage; significance: * p< .05*

While the mean tissue thickness of the teeth in the mandibular jaw was 0.76 ± 0.17, the mean tissue thickness of the teeth in the maxillary jaw was 1.22 ± 0.36 mm (p< .05) (Table 2).

There was a statistically significant relationship between all tissue thickness values measured regardless of the included jaws and the visualized probe color (p< .05). The tissue thickness value of the cases with visualized white color was significantly lower than the ones with green color, blue color, and no visualized color, and the tissue thickness value of the cases with visualized green color was significantly lower than the ones with blue color and no visualized color (p< .05) (Table 3).

Table 2. Relationship between jaws in terms of tissue thickness values

					Included Jaw			Mann-Whitney U Test		
		n	Mean	Median	Min	Max	Sd	Mean Rank	z	p
Tissue Thickness (mm)	Mandible	55	0.76	0.77	0.33	1.1	0.17	31.84		
	Maxilla	45	1.22	1.13	0.79	2.08	0.36	73.31	-7.115	.001*
	Total	100	0.97	0.88	0.33	2.08	0.36			

*n: number of patients; Sd: standard deviation; mean: mean; median; median, Min: minimum; Max: maximum; *p< .05*

Table 3. Relationship between tissue thickness measurement values and visualized probe color

		Tissue Thickness (mm)						Kruskal–Wallis H Test		
		n	Mean	Median	Min	Max	Sd	Mean Rank	H	p
Probe Color Visualized	White	20	0.66	0.68	0.33	0.91	0.17	20.55		
	Green	64	0.92	0.88	0.52	1.77	0.23	50.09	50.708	.001*
	Blue	12	1.41	1.29	1,14	1.8	0.25	87.33		
	None	4	1.87	1.97	1.45	2.08	0.29	96.38		
	Total	100	0.97	0.88	0.33	2.08	0.36	*W-G, * W-B, *W-H, * G-B, *G-H		

*n: number of patients; Sd: standard deviation; Min: minimum; Max: maximum; significance *: p< .05, W: white, G: green, B: blue, H: no color*

Figure 3 shows the average values of the recorded tissue thickness values in cases where white, green, and blue colors were seen and no color was seen. The tissue thickness value increased significantly from white to green, from green to blue, and where no color was seen (p< .05).
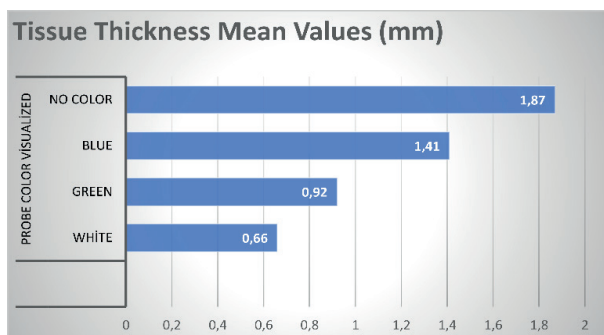

Figure 3. Tissue thickness trend by probe color visualized

The minimum and maximum values of the measured tissue thickness values following the recording of the Visualized Probe Color are shown in Figure 4. It was determined that the white-colored probe was observed at a gingival thickness within the range of 0.33-0.91 mm. It was observed that the green-colored probe was visualized at a minimum thickness of 0.52 mm and a maximum thickness of 1.77 mm. Measurements of other colors are also expressed in the graph.

According to the scale provided by Bertl et al. in their study, the cases were divided into four categories according to the measured tissue thickness [(<1 mm (thin), ≥ 1 to < 1.25 mm (medium), ≥ 1.25 to<1.5 mm (thick), and ≥ 1.5 mm (very thick)], and these values were associated with the visualized probe color (22). Since our study aimed to determine the reliability of color-based phenotype probes, an additional statistical analysis was performed to show its consistency with the values in this literature (Table 4). Although the relationship between the relevant literature and our research results was statistically significant (p< .05), it was determined

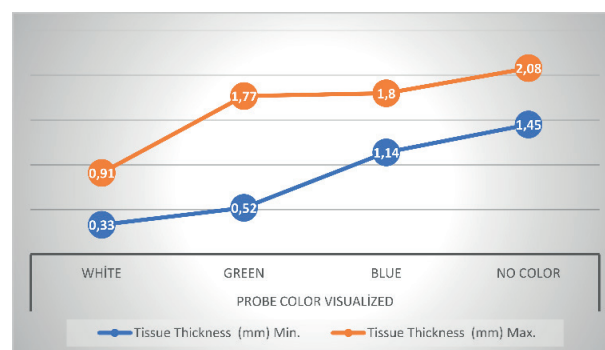that there was a low level of agreement when the kappa level was taken into consideration (Kappa=0.159).

Figure 4. Minimum and maximum tissue thickness values of visualized probe colors measured with the caliper

According to our research results, it was observed that the cases with the visualized probe color white (n=20) were compatible with the given scale by 28.99%. The fact that 49 cases, which were visualized to be green, had a thin phenotype according to the scale decreased the compatibility rate.

It was observed that the cases with the green probe color (n=10) were compatible with the given scale by 71.43%, and the 4 cases determined as blue were also in the medium thickness phenotype class according to the scale.

It was determined that those with blue probe color (n=3) were 50% compatible with the scale. It was observed that 2 cases that were visualized as green and 1 case where no color was visualized (very thick) were blue according to the scale.

According to our study, it was determined that cases in which no color was seen (n=3) were compatible with the scale by 27.27%. It was observed that 3 cases seen as green and 5 cases seen as blue had very thick phenotype (no color was seen) according to the scale. Since the agreement increases with the approximation of the Kappa value to 1, our analysis result indicates a low compatibility (Kappa=0.159).

Table 4. *Analysis of the compatibility between gingival thickness scale and probe color visualized*

		Phenotype Given in Gingival Thickness Scale										Kappa Compliance Test	
		Thin (white)		Moderate (green)		Thick (blue)		Very Thick (no color)		Total			
		n	%	n	%	n	%	n	%	n	%	Kappa	p
Probe Color Visualized	White	20	28.99	0	0	0	0	0	0	20	20	0.159	.001*
	Green	49	71.01	10	71.43	2	33.33	3	27.27	64	64		
	Blue	0	0	4	28.57	3	50	5	45.45	12	12		
	(No color)	0	0	0	0	1	16.67	3	27.27	4	4		
	Total	69	100	14	100	6	100	11	100	100	100		

*n: number of patients; %: percentage; significance * p< .05*

4. DISCUSSION

Gingival phenotype is a critical factor that significantly affects the clinical decision process of dentistry and aesthetic results (11, 24, 25). Determination of gingival phenotype is necessary to manage periodontal health and plan restorative or orthodontic treatment, especially in areas with thin-narrow gingivae (11).

In the literature, there is a probe transparency method in which the periodontal probe is advanced in the direction of the mucogingival line and the transparency of the gingiva is determined (26). In the probe transparency method, the gingival phenotype is characterized as thin if the contour of the probe can be seen from the gingival edge, and thick if it cannot be visualized (27). Accordingly, Rasperini et al. introduced easy-to-use (17), non-invasive color-based phenotype probes for the evaluation of gingival phenotype. In our study, the evaluation of the gingival phenotype was performed using the aforementioned color-based phenotype probe.

Transgingival probing, which is considered the current gold standard for ensuring the use of the gingiva, is likely to affect patient comfort and provides the advantage of providing lens data, although anesthesia in some areas is an invasive method (28). This method, which provides accurate quantitative data, was used as a reference to determine the reliability of the probes investigated in our study.

When the tissue thickness of the mandible and maxilla were evaluated, our study results were similar to many studies in the literature and it was confirmed that the tissue thickness detected in the mandibular anterior teeth was lower than that of the maxillary anterior teeth (29). In the measurements made within the current population limits, it was observed that the color-based phenotype probes and the transgingival method were generally compatible (the probe color changed from white to blue as the thickness increased), and the mandible tissue thickness was significantly lower than the maxilla.

In a study analyzing the relationship between gingival phenotype and gingival thickness with ultrasound, visual evaluation, and color-based phenotype probes, it was reported that ultrasound measurements were consistent with measurements made with color-based phenotype probes and that color-based phenotype probes were adequate to determine different gingival phenotypes (30). In another recent study, the gingival thickness of 86 (16) periodontally healthy teeth was measured by transgingival probing and cone beam computed tomography (CBCT). In addition, color-based phenotype probes were also used in the study to explain the relationship between gingival thickness and gingival phenotype. As a result of the study, a strong significant relationship between transgingival probing and CBCT and a significantly strong correlation with color-based phenotype probes were reported (16). Similar to the literature, in our study, it is seen that as the value of gingival thicknesses measured by caliper increased, the tendency towards the blue color expressing the thick phenotype increased.

A recent clinical study compared the diagnostic accuracy of two different transparency methods using steel and color-coded probes to identify (31) thin and thick gingival phenotypes. In the study, which accepted the transgingival probing method as a reference, it was stated that probe transparency methods were highly sensitive to diagnose the thin phenotype but showed a weakness for the thick phenotype (31). In an animal study using the probe transparency method, 3 different probes were used to determine the gingival phenotype in a total of 24 sections with different tissue thicknesses (32). It was attempted to determine the phenotype by making thin/thick evaluation with a periodontal probe, thin/medium/thick evaluation with a double-tip periodontal probe, and thin/medium/thick/very thick evaluation with a color-based phenotype probe. With color-based phenotype probes, the transition threshold from thin phenotype to medium phenotype was shown in the range of 0.4 to 0.5 mm, and the transition range from "medium" to "thick" was not observed. However, a very thick phenotype was observed starting from the threshold of 0.7 to 0.8 mm. Gingival phenotype classification is presented as thin (< 0.5 mm, high risk), medium (0.5-0.8 mm, medium risk), and thick (> 0.8 mm, low risk). In the study, it was stated that these probes could be easy and reliable tools to use for routine clinical practice (Fischer ve ark., 2021). Another recent study expressed gingival phenotype reference ranges as < 1 mm (thin), ≥ 1 to < 1.25 mm (medium), ≥ 1.25 to < 1.5 mm (thick), and ≥ 1.5 mm (very thick) (22). When our study results were compared with the literature data, it was

determined that the colors visualized and the measured minimum-maximum caliper values were in a variable range, that is, different colors could be seen in the same value ranges. This finding is consistent with the literature. However, in the thin phenotype in which the white color was seen, although it seemed statistically significantly correlated with the gingival thickness scale values given by Bertl et al., the low level of compliance (28.99% (Kappa=0.159, p< .05) conflicts with the study of da Costa et al (31). These differences may develop due to anatomical features such as gingival pigmentation, collagen content, and blood flow and circulation of individuals (32). In addition, it is thought that the subjective evaluations made by clinicians through inspection may have led to different results.

When the results are examined in detail, itis pointed out that color-based phenotype probes are not sensitive in quantitative measurements and are a subjective technique due to different colors seen in different ranges in both thin phenotype and thick phenotype, different clinicians presenting different colors in the same range, and even a single clinician seeing different colors in the same ranges. However, the tendency of the color observed from white to blue in parallel with the increase in tissue thickness measured by the caliper seems to provide easy and applicable advantages in clinical practice.

The limitations of this study are that only Miller 1 class gingival recession was included for standardization purposes, the depth of recession was not taken into account, the gingival color differences of individuals were not evaluated, and the effect of gender and age-related variables on the gingival phenotype was ignored. It may be beneficial to conduct more comprehensive research including these aspects. Another limitation of the study is that the presence of fenestration and dehiscence defects may cause erroneous results in transgingival thickness measurement, and these factors were not evaluated.

5. CONCLUSION

In parallel with the increase in tissue thickness values detected by the transgingival method, it was observed that the measurement of color-based phenotype probes changed in accordance with white, green and blue colors, respectively. It was determined that different colors were seen in the same quantitative ranges as color-based phenotype probes and proved weak compared to the traditional method in terms of providing quantitative values. Therefore, in the gingival phenotype evaluation, it was observed that the use of the transgingival method yielded more accurate results when quantitative data were required. In routine clinical practice, it is thought that color-based phenotype probes may be an alternative to the traditional method as they offer a non-invasive method and ease of application in cases where phenotype detection would be performed.

In this study, the usability of color-based phenotype probes in gingival thickness and phenotype detection was investigated, and since this method is new, its diagnostic accuracy was examined in comparison with the transgingival probing method. Our study findings showed that color-based phenotype probes were weak in quantitative measurements in terms of presenting different colors at different intervals based on the values determined by transgingival measurement; however, they may provide an advantage in clinical practice in terms of the similarity of measurement trends in both methods.

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Predictive Role of The Trauma Level of Nursing Students Affected by The Earthquake Disaster in Turkey on Their Psychological Distress

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ABSTRACT

Objective: The study investigated the predictive role of the post-earthquake trauma level of nursing students affected by the earthquake on their psychological distress.

Methods: This study has a descriptive and cross-sectional design. The research sample consisted of 217 nursing students enrolled in a university in the western part of Türkiye who were affected by the earthquake. Data were collected using the Nursing Students Information Form, The Scale Determining the Level of Trauma, and the General Health Questionnaire-12.

Results: The level of risk of psychological distress was high for 59% of the students. There was a statistically significant difference between their level of psychological distress in relation to their characteristics such as gender, income status and damage to the house/apartment and their level of trauma. According to the results of the regression analysis, the risk of experiencing psychological distress was 2.5 times higher for those whose houses/apartments were damaged than for those whose houses/apartments were not damaged. The risk of experiencing psychological distress was 6.6 times higher for those with high levels of trauma than for those with low levels of trauma.

Conclusion: The present study was to the predictive role of post-earthquake trauma level of nursing students affected by the earthquake on their psychological distress. It was emphasized that the results of the present study are important because they revealed the factors that affect the psychological distress of nursing students who were affected by the last two earthquakes in Türkiye.

Keywords: Earthquake, psychological distress, disaster, trauma

1. INTRODUCTION

Natural disasters are events that cause significant damage to humans and nature. One of the most hazardous natural disasters faced by the world is earthquakes. Since it is not easy to erase the traces of earthquakes in people's hearts, the possibility of new earthquakes constantly threatens societies. Earthquakes are special among natural disasters because they occur suddenly, destroy property, and cause deaths and injuries (1). In addition, earthquakes are traumatic events because of their negative psychological, social, political, and economic effects on people (2-4). Traumatic events are defined as phenomena experienced or witnessed by people that threaten not only their lives but also their physical and mental well-being, pose a real threat to their lives and physical health, and cause serious injury (5). Traumatic events can affect people's physical and mental health.

Health is a dynamic process in which individuals maintain their well-being by adapting to the situations in their internal and external environments (6). Natural disasters such as earthquakes can affect individuals' adaptation processes, the level of perception of their health, and their physical and psychological health (7). One of the conditions that affect people's health is psychological distress. The transition from adolescence into young adulthood, in which mental, physical, cognitive, and social changes are evident and important, coincides with university years; thus, university students are at risk of developing psychological distress (8,9). In studies conducted with university students, the authors state that the psychological distress levels of health students are higher than those of non-health students (10,11). The research by Labrague et al. indicated that nursing students encountered greater stress levels than the general student population (12). A longitudinal study involving 622 nursing students in Italy revealed that more than 70% of participants experienced substantial psychological distress (13). In a study involving

121 nursing students from a university in England, researchers found that these students displayed elevated levels of psychological distress relative to the general population (14). Eweida et al. (2023) discovered that implementing the psychological first-aid model during the pandemic mitigated psychological distress among nursing students (15). A study investigating the impact of mindfulness-based interventions on post-traumatic stress disorder in nursing students found that such interventions effectively reduced post-traumatic stress symptoms among this population (16).

In addition to all these, understanding the mental health effects of earthquakes on people living in a country that has many active earthquake faults and was recently struck by strong earthquakes and raising them as individuals ready to cope with such effects are of great importance. In a previous study, the authors emphasized the importance of identifying groups at risk for psychological distress in raising generations resistant to the negative mental effects of a possible trauma (17). Two earthquakes of magnitude (Mw) 7.8 and 7.5, whose epicenters were the Pazarcık and Elbistan districts of Kahramanmaraş, a province located in south Türkiye, struck 11 provinces on February 6, 2023. The earthquakes affected 16% of Türkiye's population, or 14 million people. According to the United Nations Development Report, the earthquakes left 1.5 million people homeless (18). The official death toll announced by the government was 50,783 (19). A state of emergency was declared for three months in 10 of the 11 provinces hit by the earthquakes, and the World Health Organization declared the post-earthquake situation in Türkiye a level 3 emergency (20).

Nursing students have been identified as the group of students most affected by exceptional situations such as natural disasters and pandemics (21,22). Nursing is a social profession that requires sensitivity. This sensitivity begins in the early years of nursing education and increases throughout the professional life (23). For this reason, assessment of the mental health of nursing students can guide the provision of psychosocial support according to their needs. Psychosocial support for nursing students can reduce the negative effects of disaster in physical, mental, social, and spiritual dimensions. In this way, the role and contribution of nursing students in health services can be more effectively sustained. Disasters such as earthquakes can affect health services. Nursing students should be prepared to ensure the continuity of health services by acquiring the skills to cope with such situations. Following traumatic events such as earthquakes, health professionals should have the skills to deal with the post-traumatic stress that can occur after such events. Nursing students' stress management skills can reduce long-term psychological effects (22,24). For this reason, the stress and emotional reactions experienced by health students, such as nursing students, who will be the health professionals of the future, during emergencies such as earthquakes are essential. For this reason, the emotional reactions of health students, such as nursing students, who will be the health professionals of the future, during emergencies such as earthquakes are essential.

Earthquake trauma experienced by nursing students is thought to increase their risk of developing psychological distress and negatively affect their health. This study investigated the impact of the major earthquake disaster that struck 11 provinces, including Kahramanmaraş, in Türkiye on 6 February 2023 on students' psychological distress, revealing a gap in the literature. In this study, it is investigated that the predictive role of post-earthquake trauma level of nursing students affected by the earthquake on their psychological distress.

2. METHODS

2.1. Study Design

This study was descriptive and cross-sectional.

2.2. Participants

The research population consisted of 350 students studying at a university in the west of Türkiye who were affected by the earthquake because the school was closed for the semester break and were with their families in the earthquake zone. A total of 217 nursing students affected by the earthquake were accepted into the study. The participation rate in the research was 59.40%. Inclusion criteria; Volunteering to participate in the research, being over 18 years old, studying at the Faculty of Nursing, and being affected by the earthquake. The exclusion criterion was to be a student unaffected by the earthquake zone.

2.3. Data Collection Tools

The data were collected by the Nursing Students Information Form, The Scale that Determines the Level of the Trauma, and General Health Questionnaire-12.

2.3.1. Nursing Students Information Form: The researchers developed this 6-item form to assess the participants' characteristics such as age, gender, year of school, income level, place of residence, and damage to the house/apartment (25).

2.3.2. Post-Earthquake Trauma-Level Determining Scale: The scale that determines the level of the trauma, developed by Tanhan and Kayri in 2013. It was used for 1505 individuals (401 females, 1104 males) aged between 15 and 86 years living in the areas affected by the Van earthquake in 2012 to assess the impact of the disaster on various health and psychological outcomes (26). The scale consists of 20 questions evaluating behavioral problems, emotional limitation, affective cognitive configuration, and sleep problems. There is no cut-off score for the scale. Items 11 and 12 are scored reverse-scored. Responses given to the items are rated on a five-point Likert-type scale ranging from 1 to 5 ("I do not agree at all," "I agree on little," "I agree at a moderate level," "I agree very much," and "I completely agree"). The lowest and highest possible scores obtained from the scale are 20 and 100, respectively. The increase in the scores obtained from the scale indicates that the individuals' levels of were affected by the earthquake increases. A score of 52.385 ± 5.051 obtained from the

scale indicates the threshold value at which individuals are traumatized. A score above this threshold value indicates a high level of traumatization, whereas a score below this threshold value indicates a low level of traumatization. The Cronbach's alpha value of the scale was 0.87 in Tanhan and Kayri's study and .93 in the present study.

2.3.3. General Health Questionnaire-12: The General Health Questionnaire was developed by David Goldberg to reveal the psychological distress and mental illness levels of the general population and those of patients presenting to nonpsychiatric clinics. This easy-to-apply questionnaire is administered to assess the mental symptoms of a person within the last week. The General Health Questionnaire has 12-, 28-, 30-, and 60-item forms (27); however, the 12-item form is widely preferred because its sensitivity and specificity in separating cases is high, and it can be used in various sociocultural settings (17,28,29). There are four response options for each item: 1= Never, 2= As usual, 3= More often than usual, and 4= Very often. Responses given to the items can be scored either on a four-point Likert-type scale or by giving "0" points to each of the first two options and "1" points to each of the last two options. A person with a score of four or more has a high level of psychological distress, a person with a score of 2 or 3 has a moderate level of psychological distress, and a person with a score less than 2 has a low level of psychological distress. Participants whose General Health Questionnaire score is ≥4 are in the at-risk group for mental illnesses. The validity and reliability study of the Turkish version of the General Health Questionnaire was conducted by Kılıç; the specificity was .84. In this study, the sensitivity of the questionnaire was .74, and Cronbach's alpha value was .87.

2.4. Data Collection

After the ethical permission was obtained, the Department of Student Affairs of that institution informed the students living in the earthquake zone about the study and shared the contact information of the researchers with the students.

The researchers informed all the students who contacted them about the purpose of the study, told them that this study would not affect their grades, and that participation in the study was voluntary. Then, the students who agreed to participate in the study gave their written consent, and the Google form link was shared with the students. In line with the decision taken by the government after the earthquake, education was conducted online in all universities in Türkiye. Therefore, data were collected between May 2023 and June 2023 which shows the first 5 months' results of the students via a Google form.

2.5. Analysis of The Data

Data were analyzed using IBM SPSS (Statistical Package for the Social Sciences) 29.0. Based on the result of the Kolmogorov –Smirnov test, which is used to test normality, the data were normally distributed. Psychological distress,

which was the dependent variable in the primary analysis, was divided into two groups as high (≥4) and low (<4). The independent variables are categorical variables, and their relationship with the dependent variable was analyzed with the X^2 test.

Logistic regression analysis was performed to evaluate the variables (damage to the house/apartment and trauma level) that were significant according to the primary analysis. P-values of .05 were considered statistically significant. The Hosmer-Lemeshow test was conducted to assess the fit of the model. If the P value is above 0.05, the predictive value of the model can be considered high. In this study, the value obtained using the Hosmer-Lemeshow test was .915, which indicated that the model's predictive value was high.

2.6. Ethical Considerations

Before conducting the study, ethical approval (approval number: 2023/16-09) and written permission from the Dokuz Eylül University Noninvasive Clinic Ethics Committee where the study was conducted were gathered (approval number: 8087-GOA). After informing the students about the aim of the study, written and verbal informed consent was obtained.

3. RESULTS

Based on the analysis, the mean age of the participating students was 21.49 years. Of them, 52.10% were men, 54.80% had low income, 79.70% had slightly damaged or undamaged houses/ apartments, 41% lived in tents or containers, and 57.60% suffered from a high level of trauma after the earthquake.

According to the results of the General Health Questionnaire-12, the participating students' psychological distress scores were divided into two groups as low (<4) and high (≥4). The level of the risk of psychological distress was high in 59% of the students. The mean score on the General Health Questionnaire was 4.91 ± 3.72 (0–12).

Psychological distress assessments of the participating nursing students affected by the earthquakes according to their characteristics and trauma levels are presented in Table 1. The total mean score on the post-earthquake trauma level determination scale was 56.89 ± 15.01 (range 21-92). There was a statistically significant difference between their psychological distress levels in terms of their characteristics such as gender, income status, and damage to the house/ apartment, and their trauma levels (relationship between their psychological distress levels and their characteristics such as gender, income status and damage to the house/ apartment and their trauma levels) (p < .05) (Table 1). There was not a statistically significant difference between their psychological distress levels in terms of variables such as year at school and place of residence after the earthquakes (relationship between their psychological distress levels and

the variables such as year at school, the place of residence after the earthquakes) (p > .05) (Table 1).

Table 1. Comparison of participating students' general health questionnaire scores according to their characteristics (n=217)

Characteristics	The presence of psychologic distress (≥4)	Absence of psychologic distress (<4)		
	n (%)	n (%)	Test	p
Gender			$X^2=7.114$	**.008**
Women	71 (68.30)	33 (31.70)		
Men	57 (50.40)	56 (49.60)		
Income status			$X^2=4.687$	**.030**
Income less than expenses	78 (65.50)	41 (34.50)		
Income equal to expenses	50 (51)	48 (49)		
Year at school			$X^2=1.127$	.771
First-year student	29 (64.40)	16 (35.60)		
Second-year student	32 (54.20)	27 (45.80)		
Third-year student	30 (60)	20 (40)		
Fourth-year student	37 (58.70)	26 (41.30)		
Damage to the house/apartment			$X^2=11.893$	**.001**
Yes	36 (81.80)	8 (18.20)		
No	92 (53.20)	81 (46.80)		
The current place of residence			$X^2= 862$	.650
A relative's house or apartment	30 (63.80)	17 (36.20)		
Tent/container	53 (59.60)	36 (40.40)		
Their own house or apartment	45 (55.60)	36 (44.40)		
Trauma level			$X^2= 49.796$	**.000**
Low	29 (31.50)	63 (68.50)		
High	99 (79.20)	26 (20.80)		

Note: Bold values indicate statistically significant p values (p < .05).

Binary logistic regression analysis was used to assess the effects of the characteristics and trauma levels of the participating nursing students affected by the earthquakes on their psychological distress. Significant variables in the primary analysis, such as gender, income status, damage status of the house/apartment, and trauma levels, were included in the logistic regression analysis. The created regression model correctly predicted the psychological distress levels of the participating nursing students affected by the earthquake at a rate of 74.7% (Table 2). According to the results of the regression analysis, the risk of psychological distress was 2.5 times higher in those whose houses/apartments were damaged than in those whose houses/apartments were not damaged. The risk of psychological distress was 6.6 times higher in those with a high level of trauma than in those with a low level of trauma. According to the logistic regression analysis results, gender and income status variables did not have a predictive effect on the psychological distress levels of the participating nursing students affected by the earthquakes (Table 2).

Table 2. Examining the risk factors affecting the psychological distress levels of the participating student nurses (n=217)

Risk factors	Odds ratio	95% C.I. for OR		p
		Lower	Upper	
Gender	.735	.383	1.412	.355
Income status	.546	.290	1.028	.061
House damage	2.532	1.029	6.229	**.043**
The presence of trauma	6.657	3.473	12.763	**.000**
Nagelkerke R^2: 0.325, p<0.001				
The rate at which the model correctly predicts psychological distress: 74.7%				
The Hosmer-Lemeshow test p-value of the model: 0.915 The predictive value of the model is high. Because the p-value of the model is greater than .05, it has a sufficient fit.				

Note: Bold values indicate statistically significant p values (p < .05).95% confidence interval for OR; C.I.: Confidence Interval

4. DISCUSSION

In this study, it was investigated the predictive role of the individual characteristics and trauma levels of nursing students affected by the earthquakes that hit Türkiye on February 06, 2023, in their psychological distress levels. Based on the results of this study, having a damaged house and a high level of trauma increased the risk of psychological distress. People who lost their houses/apartments after the Great East Japan Earthquake suffered from depression and post-traumatic stress disorder (30). According to Kin and Onuma (2012), reasons such as witnessing death-related events, experiencing physical pain, having losses, having a disrupted routine, having to leave the place where one lives, and experiencing loss of income and occupation can expose individuals to trauma (31). In the study conducted by Arata et al. on medical students, students experienced loss, injury, or damage to their surroundings during the disaster, much of which was due to damage to homes and property. Based on the results, the proportion of students who experienced the destruction of buildings or injury to themselves or others was approximately 5%; these were possible sources of trauma (32).

The loss of a house/apartment may have disrupted routines and may have affected the students' psychological distress levels. In addition, the participating students witnessed their houses/apartments being damaged by the earthquakes. They were in their hometowns as the earthquakes that hit them coincided with their mid-term break. So that they were caught in the earthquake in their homes when the first earthquake occurred early in the morning. Sociologically, home is not only a place where the need for shelter is met but also a place full of memories in which people feel safe and comfortable (33). Damage to the house/apartment may have affected individuals' perception of security and thus caused them to experience psychological distress.

The findings of the study revealed nursing students affected by the earthquake with high levels of trauma were at greater risk of developing psychological distress than nursing students with low levels of trauma. In a study conducted with 188 individuals who were caught in the February 6

earthquakes whose epicenters were Kahramanmaraş, the participants had high levels of trauma after the earthquakes (34). In another study, it was stated that the Kahramanmaraş earthquake caused post-traumatic stress disorder in 43.50% of medical students (35). In a study conducted with medical students after the Great East Japan Earthquake in 2011, 20% of the participants suffered from physical and mental problems even six months after the earthquake (32). After the earthquake in Japan, it has been reported that medical students experienced negative emotions such as feeling confused, angry, sad, guilty, or anxious (22). Earthquakes adversely affect earthquake victims' mental health both in the short and long term. The fact that the participants of the present study suffered from high levels of trauma was probably because the earthquake was long-lasting and devastating in a wide region affecting 11 provinces and because it was a major disaster in which 50,783 people died, according to official figures (20). Several studies in the literature describe the relationship between post-traumatic stress disorder and depression (36-39). In a study, Cheng et al. (2018) pointed out that the symptoms of post-traumatic stress predicted future depression (40). In the study conducted by Arata et al. on medical students, the trends in disaster-related harm and physical and mental distress were found to be significant. The results demonstrated that each type of problem gradually decreased in the year following the disaster, although physical and mental distress took two years to resolve (32). Within the scope of the prevention of mental illnesses, it seems important to screen individuals displaying trauma symptoms and having high levels of trauma and to refer them to healthcare professionals to receive psychological support as soon as possible. Since the Kahramanmaraş earthquakes in Türkiye occurred over a wide area, it is a great possibility for nurse educators in Türkiye to encounter nursing students affected by the earthquakes. The results of this study also indicate the importance of nurse educators identifying these students and referring them to healthcare professionals to receive psychological support.

According to the results of the present study, variables such as gender and income status did not affect the participants' psychological distress levels. Unlike this study's results, a study conducted on medical students after the 2019 Albania Earthquake found that women experienced more post-traumatic distress than men (41). In the study conducted by Öztürk and Dönmezler (2024) on medical students after the February 6 Kahramanmaraş earthquake, female participants had significantly higher post-traumatic distress symptom severity compared to their male counterparts with a large effect size (35). Consistent with the study results, in another study conducted in 2019, there were no differences between men and women in terms of developing psychological distress (42). The literature demonstrated that the results of this study on the gender variable were different from those of other studies, which suggests that further research should be conducted to investigate the effect of gender on psychological distress after disasters such as earthquakes that affect large masses.

Like the gender variable, the income status variable did not affect psychological distress. The results of the study conducted on medical students after the Kahramanmaraş earthquake are similar to this study. In that study, age, years in medical school, household income, and financial losses post-earthquake were not significantly associated with post-traumatic distress (35). Within the scope of psychological first aid activities, meeting individuals' physical needs in the acute period positively protects their psychological health (43). The present study was conducted in the early stages after the two earthquakes, the basic physical needs (water, food, clothing, etc.) of people affected by the earthquake were met with aid provided by the government, people from the regions of Türkiye that were not affected by the earthquakes, and other countries. Therefore, in this study, it is believed that income status did not affect psychological distress in the early stages of the earthquake.

4.1. Limitations

This study has some limitations. Earthquake trauma leads to different psychological effects in the early and long term. Since this study was conducted in the early stages after the earthquakes, it only reflects the first 5 months' results of the psychological distress of the students. Therefore, further studies should be conducted to reveal the long-term psychological effects of earthquakes. In this study, no questions were asked about whether students received psychological support. It is unclear how psychological support affects nursing students' psychological distress and trauma levels.

5. CONCLUSION

It was emphasized that the results of this study are important because they revealed the factors affecting the psychological distress of nursing students who were affected by the last two earthquakes in Türkiye, which caused many deaths. Nurse educators' screening nursing students affected by the earthquake regarding psychological distress and referring them to psychosocial support when deemed necessary seem important. They can refer their students to universities' psychological support services. Within the scope of the study findings, it is recommended that the psychological support needs of students whose trauma levels are high and whose houses/apartments are damaged should be questioned. For these students, cognitive behavioral therapy or social support group-based psychoeducation sessions can be provided by psychiatry nurse specialists. It is considered that creating a psychosocial support network with counseling systems in nursing schools for these students and referring them to health professionals for psychosocial support will improve their mental health and prevent them from developing mental illness. It is recommended that longitudinal studies be conducted to investigate the psychological distress and trauma levels of nursing students.

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Relaxant Effect of Rosuvastatin in Isolated Rat Aorta with Perivascular Adipose Tissue

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ABSTRACT

Objective: Rosuvastatin displays favorable pleiotropic effects on vascular system to reduce the risk of cardiovascular events besides providing an intensive reduction in LDL-C levels. The role of perivascular adipose tissue (PVAT) in modulating the vasorelaxant effect of rosuvastatin is not evaluated so far. The present study aimed to investigate the vascular relaxant effect of rosuvastatin in rat aortic rings with intact PVAT, as well as to evaluate the possible mechanisms underlying this effect in relation to nitric oxide (NO) and prostaglandin pathways.

Methods: Thoracic aorta rings with intact PVAT, isolated from male Wistar rats (n=5), were mounted on an isolated organ bath system. Endothelium-dependent responses to acetylcholine (Ach,10^{-6}-10^{-4}M) were obtained in aortic rings precontracted submaximally with phenylephrine (Phe,10^{-6}-3×10^{5}M). The concentration-dependent relaxant effect of rosuvastatin (10^{-7}-10^{-4}M) was examined in the absence and presence of NO inhibitor, L-NOARG (10^{-4}M, 30min.) and cyclooxygenase inhibitor, indomethacin (10^{-5}M, 30min.). Vascular relaxation capacity of aortic rings was checked by the nitrovasodilator, sodium nitroprusside (SNP,10^{-6} M) at the end of the experiments.

Results: Rosuvastatin (10^{-7}-10^{-4}M) produced concentration-dependent relaxations in Phe-precontracted rat aortic rings with intact PVAT. Pretreatment with L-NOARG significantly attenuated the relaxant responses to rosuvastatin in isolated rat aortic rings with intact PVAT. However, pretreatment with indomethacin did not modify the relaxations to rosuvastatin. In the aortic rings, maximal relaxation responses to Ach and SNP were determined to be 75.87±2.68% and 102.54±2.92%, respectively.

Conclusions: This study will provide a basis for investigating the interaction between PVAT and statins in vascular homeostasis.

Keywords: Rosuvastatin Calcium, Perivascular adipose tissue, Vasodilation, Nitroarginine, Indomethacin

1. INTRODUCTION

Statins, which play a crucial role in both the prevention and treatment of atherosclerotic cardiovascular diseases, are primarily recognized for their lipid-lowering effects. However, research has shown that statins also exert a variety of pleiotropic effects on the vascular system, including anti-inflammatory, antioxidant, and antithrombotic properties, independent of their lipid-lowering mechanisms (1-5). Additionally, several in vitro studies have reported relaxant effects of statins on vascular and non-vascular preparations (6-17). These findings suggest that statins not only reduce lipid levels but also have broader biological effects on vascular function, highlighting their therapeutic potential beyond cholesterol reduction.

Rosuvastatin is one of the most clinically preferred and potent statins with a long half-life (18-20). Its acute

vasorelaxing effects have been demonstrated in various isolated vascular and non-vascular preparations, primarily through the inhibition of spasmogen-induced contractions (9,10,15,16,17,21). Moreover, with the increasing recognition of perivascular adipose tissue (PVAT) as a key player in vascular function, the potential PVAT-mediated effects of statins have become an intriguing area of research (22). PVAT, which surrounds blood vessels, plays a central role in maintaining vascular homeostasis via releasing various vasoactive substances and displaying an anticontractile effect (23-25). A previous in vivo study demonstrated that treatment with atorvastatin, but not pravastatin, augmented the anticontractile effect of PVAT most likely via H_2S and K_{ATP} channel-dependent manner (26). However, the possible influence of PVAT on the vasorelaxant effect of other statins

as well as other mechanisms such as nitric oxide (NO) and prostaglandin pathways remains unclear.

In this study, we aimed to investigate the vascular relaxant effect of rosuvastatin on rat aortic rings with intact PVAT, as well as to evaluate the possible mechanisms underlying this effect in relation to NO and prostaglandin pathways. For this purpose, the concentration-dependent relaxant effect of rosuvastatin was examined in isolated rat thoracic aorta with intact PVAT in the absence and presence of NO inhibitor, L-NOARG and cyclooxygenase inhibitor, indomethacin.

2. METHODS

2.1. Animals and Preparation of Aortic Rings

Male Wistar Albino rats (8-10 weeks old, ~250 g) were obtained from Istanbul University, Aziz Sancar Institute of Medical Sciences, Experimental Animals Laboratory (DETAE) and housed under standard laboratory conditions (21±2°C, 45–65% relative humidity, 12h light/dark cycle, with ad libitum access to food and water). All procedures were carried out in the Experimental Animal Care and Research Unit of Istanbul University Faculty of Pharmacy (EDEHAB), according to the approval of the Local Ethics Committee of Animal Experiments of Istanbul University (IU-HADYEK) (22/11/2023, No:2267678). The Arrive Guidelines 2.0. was followed in all procedures (27).

After one week of acclimatization, the rats (n=5) were anesthetized via intraperitoneal injection (i.p.) of ketamine/xylazine (100 mg/kg /10mg/kg) and the thoracic aortas were immediately excised and placed in Krebs Ringer-bicarbonate solution of the following composition (mM): NaCl 118, KCl 4.7, KH_2PO_4 1.2, $NaHCO_3$ 25, $MgSO_4.7H_2O$ 1.2, $CaCl_2$ 2.5, glucose 10 and disodium EDTA 0.026. Isolated thoracic aorta was divided into four rings 3-4mm, and PVAT was left intact. Then isolated rat aortic rings were immediately transferred to the laboratory for studying vascular reactivity in the isolated organ bath system, with each ring assigned to a different experimental protocol.

Isolated rat aortic rings with intact PVAT were mounted between two stainless steel L-shaped hooks in 10mL jacketed organ baths containing Krebs-Ringer bicarbonate solution, maintained at 37°C, and aerated with a mixture of 95% O_2 and 5% CO_2. One hook was fixed at the base of the organ bath, while the other was attached to a force-displacement transducer (Grass Model FT03; Grass Telefactor, West Warwick, RI). The contractile responses were recorded using a computer-controlled polygraph system (PowerLab-ADInstruments, Oxford, UK). The isolated organ bath experiments were conducted as described previously (8).

2.2. Vascular Experiments

Briefly, the aortic rings were equilibrated for 1 hour under a resting tension of 1g. Subsequently, two consecutive contractions were induced using 40mM potassium chloride

(KCl) to standardize the aortic rings, and preparations that produced a contraction of less than 0.5g were discarded. The functional integrity of the endothelium was assessed by the cumulative administration of acetylcholine (Ach, 10^{-6}-10^{-4}M), an endothelium-dependent vasodilator, to aortic rings submaximally precontracted by the selective α1-adrenergic agonist, phenylephrine (Phe, 10^{-6}-$3x10^{-5}$M). The vasorelaxant capacity of the aortic rings was further evaluated by the administration of sodium nitroprusside (SNP, 10^{-6}M), a directly-acting nitrovasodilator, at the end of each experiment.

The experimental protocol aimed to investigate the vascular effects of rosuvastatin on rat aortic rings with intact PVAT, which had been precontracted submaximally (70–80% of maximal contraction) with Phe (10^{-6}-$3x10^{-5}$M). When Phe-induced contractions had reached a stable plateau, rosuvastatin was applied cumulatively at increasing concentrations (10^{-7}-10^{-4}M). To examine the role of vasodilator factors namely NO and prostaglandins, the effects of rosuvastatin were evaluated after pre-incubation of the aortic rings with NO synthase inhibitor, L-NOARG (10^{-4}M) and the cyclooxygenase inhibitor, indomethacin (10^{-5}M) respectively, for 30min. In order to analyse the possible effect of the vehicle for rosuvastatin, cumulative application of DMSO was provided. Additionally, in the preliminary experiments time-matched control group was performed in order to confirm that the precontractions induced by Phe remained stable for the experimental period.

2.3. Statistical Analyses

Values are presented as mean ± S.E.M. In all experiments, "n" refers to the number of rats from which the aortas were isolated. The relaxant responses to Ach, SNP and rosuvastatin are expressed as the percentage of Phe-induced precontraction in that vessel ring. The sensitivity of aortic rings to rosuvastatin is given as the effective concentration required to produce 50% of the maximal response (EC_{50}), which was calculated for each concentration-response curve by using probit analysis. Maximal relaxation responses are shown as E_{max} (%), while EC_{50} values are expressed as-log M (pEC_{50}). Data distribution for normality was checked and statistical analyses were performed by using one-way analysis of variance (ANOVA) followed by Tukey-Kramer post hoc test. A p-value < .05 was considered statistically significant. Statistical analyses were performed by using GraphPad® Prism version 9.4.0. for Windows (GraphPad® Software, Boston, Massachusetts USA).

2.4. Drugs and Chemicals

All drugs used were purchased from Sigma Chemical Co, USA. Rosuvastatin calcium was donated by World Medicine (Türkiye). Rosuvastatin was dissolved in DMSO and final concentration of DMSO did not exceed 0.1% in the organ bath. Indomethacin was prepared in 5% (w/v) in sodium bicarbonate and all other drugs in distilled water.

3. RESULTS

3.1. Endothelium-Dependent and – Independent Relaxant Responses

Endothelium-dependent vasodilator Ach (10^{-7}-10^{-4}M) produced concentration-dependent relaxations on isolated rat aortic rings with intact PVAT (Figure 1). The maximal relaxation response to Ach was determined to be 75.87±2.68 % (n=5). On the other hand, the directly acting endothelium-independent vasodilator SNP (10^{-6}M) produced complete relaxations in isolated rat aortic rings with intact PVAT (102.54±2.92%, n=5).

3.2. Relaxant Effect of Rosuvastatin on Isolated Rat Aorta with Intact PVAT

As shown in Figure 2, rosuvastatin (10^{-7}-10^{-4}M) induced concentration-dependent relaxations in isolated rat aortic rings with intact PVAT which were precontracted submaximally with Phe (10^{-6}-3×10^{-5}M). The vehicle administration did not produce an important influence on the precontractile tone (7.87± 3.83 %, n=4) but were significantly different from rosuvastatin (87.43±3.94 %, *p < .001, n=5) (Figure 2 and Table 1).
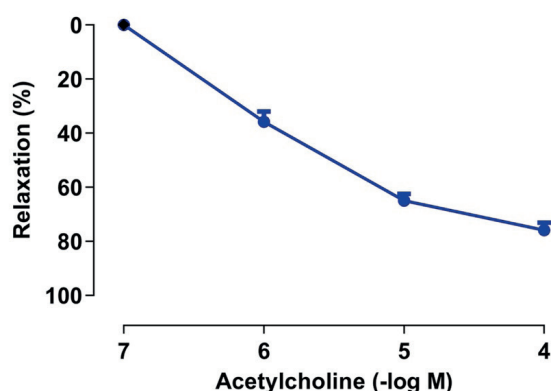

Figure 1. *Concentration-dependent relaxant effects of Acetylcholine (Ach, 10^{-7}-10^{-4}M) on isolated rat aortic rings with intact PVAT which were precontracted submaximally with Phenyleprine (Phe, 10^{-6}-3×10^{-5}M) (n=5).*
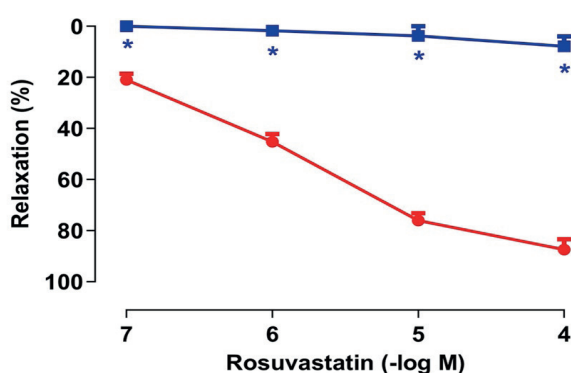

Figure 2. *Effects of rosuvastatin (10^{-7}-10^{-4} M) (•) and the vehicle, DMSO (■) on isolated rat aortic rings with intact PVAT which were precontracted submaximally with phenylephrine (Phe, 10^{-6} – 3×10^{-5}M).*p< .001 Rosuvastatin vs. DMSO, one-way analysis of variance (ANOVA) followed by Tukey-Kramer post hoc test, (n=4-5).*

3.3. Role of NO on the Relaxant Effect of Rosuvastatin

Pretreatment with NO synthase inhibitor, L-NOARG (10^{-4}M, 30min.) significantly attenuated the concentration-dependent relaxant responses to rosuvastatin (10^{-7}-10^{-4}M) on isolated rat aortic rings with intact PVAT (Rosuvastatin+L-NOARG *vs.* Rosuvastatin, *p < .001, n=5) (Figure 3 and Table 1). On the other hand, the relaxation response to SNP in aortic rings pretreated with NO synthase inhibitor, L-NOARG (109.60±4.06 %, n=5) was similar compared to corresponding control.
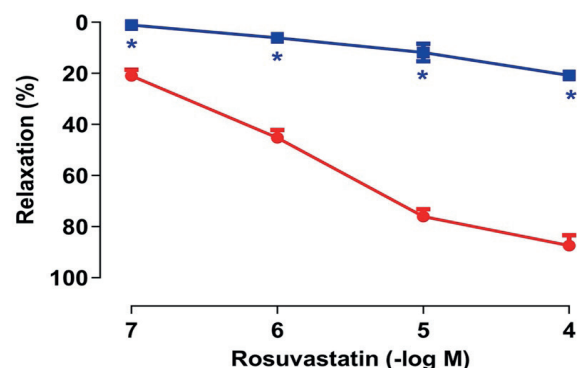

Figure 3. *Relaxant effect of rosuvastatin (10^{-7}-10^{-4} M) on isolated rat aortic rings with intact PVAT in the absence (•) and presence (■) of L-NOARG (10^{-4}M).*p< .001 Rosuvastatin+L-NOARG vs. Rosuvastatin, one-way analysis of variance (ANOVA) followed by Tukey-Kramer post hoc test, (n=5).*

3.4. Role of Prostaglandins on the Relaxant Effect of Rosuvastatin

Pretreatment with cyclooxygenase inhibitor, indomethacin (10^{-5}M, 30min.) did not modify the relaxation responses to rosuvastatin (10^{-7}-10^{-4} M) on isolated rat aortic rings with intact PVAT (Rosuvastatin+Indomethacin *vs.* Rosuvastatin, p> .05, n=5) (Figure 4 and Table 1). On the other hand, the relaxation response to SNP in aortic rings pretreated with cyclooxygenase inhibitor, indomethacin (87.60±8.93 %, n=5) was similar compared to corresponding control.

In order to achieve a comparable precontractile tone in rat aortic rings with PVAT, whether pretreated with inhibitors or not, the concentration of Phe (10^{-6}-3×10^{-5}M) was adjusted as appropriate (data not shown).
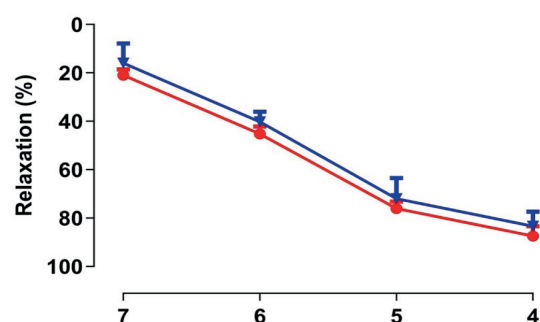

Figure 4. *Relaxant effect of rosuvastatin (10^{-7}-10^{-4} M) on isolated rat aortic rings with intact PVAT in the absence (•) and presence (■) of INDO (10^{-5}M) (p> .05, n=5).*

Table 1. E_{max} and pEC_{50} values of rosuvastatin (10^{-7}-10^{-4}M) on phenylephrine (Phe, 10^{-6}-3×10^{-5}M) precontracted rat aortic rings with intact PVAT in the absence and presence of the inhibitors of NO (+L-NOARG) and prostaglandins (+INDO).

Groups	E_{max} (%)	pEC_{50}
Rosuvastatin	87.43±3.94	5.85 ±.13
+ L-NOARG (10^{-4}M)	20.82±1.88*	5.07±.26
+ INDO (10^{-5}M)	83.35±5.88	5.90±.19

Values are shown as mean±SEM. E_{max} values are expressed as the percentage of Phe-induced precontractions.*p< .001 Rosuvastatin+L-NOARG vs. Rosuvastatin. Statistical analyses were performed by using one-way analysis of variance (ANOVA) followed by Tukey-Kramer post hoc test (n=5).

4. DISCUSSION

Rosuvastatin is one of the most clinically preferred and potent statins with various pleiotropic effects, including relaxation of vascular and nonvascular tissues (18-20). Although its vasorelaxant effect has been demonstrated in previous studies, the role of PVAT in modulating the direct vasorelaxant effect of rosuvastatin is unknown. This study demonstrated for the first time that rosuvastatin produced concentration-dependent relaxations in Phe-precontracted rat aortic rings with intact PVAT. Our findings suggest that the NO pathway, rather than the prostaglandin pathway, plays a role in the vascular relaxant effect of rosuvastatin in PVAT intact aortas.

Briefly, rosuvastatin which applied cumulatively (10^{-7}-10^{-4}M) in Phe-precontracted rat thoracic aorta with intact PVAT, produced vasorelaxation in a concentration dependent manner. This finding is in line with previous in vitro studies which demonstrated the relaxant effect of rosuvastatin in various vascular and nonvascular isolated preperations, including rat aorta, pulmonary artery and trachea (9,10,16,17). Notably, the current study demonstrated that the maximum vasorelaxation response to rosuvastatin obtained in rat aortic rings with intact PVAT is similar with the results of previous studies performed in rat aortic rings without PVAT (9,10,16,17).

On the other hand, in vivo treatment with rosuvastatin (15-20mg/kg/day) for 4-7 weeks demonstrated to restore endothelium-dependent relaxant responses to Ach in isolated aorta and electric field stimulation (EFS)-induced relaxation in corpus cavernosum obtained from Streptozotocine(STZ)-induced diabetic mice as well as diminished EFS-induced contractions in mesenteric arteries from high fat diet (HFD)-induced obese rats (21,28). The ameliorative role of rosuvastatin in NO mediated nerve and vascular function is likely to depend on the inhibiton of mevalonate pathway (21). Moreover, it has been shown that direct vasorelaxant effect of rosuvastatin in rat aorta (9,16), rat pulmonary artery (17) and calf cardiac vein (15) is partly endothelium and NO dependent. Consistent with these previous studies, our findings demonstrated that NO synthase inhibitor, L-NOARG significantly attenuated the relaxant responses to rosuvastatin in rat aortic rings with intact PVAT. Concerning

that, vascular endothelium, vascular smooth muscle and PVAT are potential sources for NO (29,30), further studies will be intriguing to determine their contribution to the vasorelaxant effect of rosuvastatin in aortic rings with intact PVAT.

On the other hand, prostaglandins, particularly prostacycline, also contributes to the vasorelaxation responses of various statins, including atorvastatin, pravastatin and cerivastatin, as shown by the experiments performed in the presence of a cyclooxgenase inhibitor (8). However, present findings, in the presence of indomethacin ruled out the involvement of prostaglandins in the relaxant effect of rosuvastatin in rat aortic rings with intact PVAT, similar to a previous study in isolated rat aorta without PVAT (9). On the other hand, this finding is in contrary with a recent study conducted with rosuvastatin on isolated rat pulmonary arteries and tracheas as well as on aortic rings from rats fed with Cafeteria style (CAF) diet (10,17). This difference may be related to the presence of PVAT as well as the vascular bed and animal model studied.

PVAT plays a critical role in maintaining vascular homeostasis by releasing various bioactive molecules that can regulate vascular tone. In this respect, understanding the influence of PVAT in the vasorelaxant effect of rosuvastatin may provide a novel insight into pleitropic effects of statins through the modulation of the vascular tone to promote cardiovascular health. This study presents a potent and NO sensitive vasorelaxation profile of rosuvastatin in rat aortic rings with intact PVAT, comparable with previous studies performed in aortic preperations without PVAT. This may suggest that the relaxant effect of rosuvastatin is not modulated by PVAT. However, identifying the main source of NO in terms of vascular endothelium, vascular smooth muscle and PVAT may be a promising issue to be evaluated in future studies. As a limitation of the present the study, we examined only rosuvastatin, and thus the related findings can not be extrapolated to other statins that have different physicochemical properties.

5. CONCLUSION

Overall, the current study provides original findings regarding the vascular effects of rosuvastatin and suggests that NO, rather than prostaglandins, plays an important role in the vasorelaxation response to rosuvastatin in isolated rat aortic rings with intact PVAT. This data broadens our understanding of PVAT's physiological importance and suggests that PVAT can be a critical player in vascular homeostasis, emphasizing its regulatory role in mediating rosuvastatin-induced vasorelaxation through NO pathways. Further studies investigating the possible modulatory role of PVAT in the vasorelaxant effect of other statins would be promising.

Conflicts of interest: The authors declare that they have no conflict of interest.

Ethics Committee Approval: This study was approved by Ethics Committee of Istanbul University, Local Ethics Committee of Animal Experiments (Approval date:22/11/2023; Number:2267678)

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Author Contributions:

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Design of the study: DKD

Acquisition of data for the study: GRA, MA

Analysis of data for the study: DKD, GRA, MA

Interpretation of data for the study: DKD, BSUD,

Drafting the manuscript: DKD, BSUD, GRA, MA

Revising it critically for important intellectual content: DKD, BSUD,

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