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Evaluation of the Position of Lingula Mandible, Mental Foramen and Lingual Foramen of Individuals in the 7-17 Age Groups Via Cone-Beam Computed Tomography

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ABSTRACT

Objective: The identification of landmarks in mandible is an important stage before dental procedures in pediatric patients. The purpose of this study was to determine the location of lingula mandible, mental foramen (MF) and lingual foramen (LF) in a pediatric population.

Methods: The distance of lingula mandible to the anterior, posterior, superior, and inferior borders of mandible and to distal edge of the alveolar socket of the 1st molar tooth were measured in 296 cone-beam CT. MF and LF distance to the top of the alveolar crest and the inferior edge of the basis mandibulae were determined. The horizontal location of MF was evaluated.

Results: The distance between lingula mandible and the sigmoid notch, the inferior border of the ramus, the anterior border of the ramus and the posterior border of the ramus was 18.63±4.52 mm, 24.81 ± 5.19 mm 14.67±2.39 mm, and 15.14 ± 3.06 mm respectively. The MF was mostly located between long axes of first and second premolar teeth. LF is closer to the inferior edge of the basis mandibulae.

Conclusion: It is necessary to determine anatomical landmarks in children prior to the surgical operations to prevent the possible neurovascular complications.

Keywords: anatomic landmarks, cone beam computed tomography, lingual foramen, lingula, mental foramen.

1. INTRODUCTION

Knowing the actual location of anatomic structures containing neurovascular bundles in children is important to minimize the risk of transient or permanent nerve damage during anaesthesia before operations such as comprehensive restorative therapies, surgical procedures, treatment of mandibular fractures and orthognathic surgery (1, 2). These important anatomical landmarks in children have been reported as; incisive canal, mental foramen (MF), mandibular canal and lingual foramen (LF) (3).

Neurovascular structures in the mandible begin with the mandibular foramen (ManF). Lingula mandible is a reliable anatomical landmark used to determine the position of ManF. Lingula is a tongue-shaped bone protrusion that forms the medial border of the MF on the medial surface of the mandible. Due to its close proximity to ManF and neurovascular nerve bundles, it is an important anatomical landmark during maxillofacial surgery and is used to avoid nerve during inferior alveolar nerve block anaesthesia (4). Lingula mandible is also an important marker of sagittal split-ramus osteotomy. During sagittal split-ramus osteotomy, the horizontal cut of the mandible is made just above the lingula (5). In the literature, it is reported that the location of the lingula mandible is variable (4, 6). This variation refers to a specific risk of injury to the inferior alveolar nerve (7, 8). In a study on children of different ethnic background has reported that the ManF moves horizontally in a growing mandibular ramus in anterior or posterior direction or remains stable (9).

Neurovascular structures are opened to the outside of the bone structure through the MF in the premolar region on both sides of the mandible. The location of mental foramina in children can be determined radiographically or by clinical palpation (10). In the summary of the literature, according to the Green classification, mental foramen in children are mostly localized in the premolar area (11). In children, the MF is closer to the alveolar crest and migrates to the middle triple and lower triple region in vertical direction and posteriorly / distally in horizontal direction with the development of the dentition. (12). This change in position is thought to be caused by a combination of bone growth in the region and mesial drift of the dentition (9, 12).

The neurovascular structures are opened out of the bone again in the LF region of the mandible. The LF is usually at the level of the mandibular symphysis, at the level of or above

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the mental spines, and includes an artery developing from the anastomosis of the two sublingual arteries. It includes the lingual artery, sublingual artery, mandibular incisive nerve, branches of the mylohyoid nerve and lingual nerve (13). In children, the number and localization of the LF are important in surgical procedures such as genioplasty, orthognathic surgery, during graft removal of the jawbone, and for screw and/or plaque placement in mandibular rehabilitation after trauma in the anterior region (14).

The reliability of the definition of anatomical landmark in children is influenced by various factors such as the intensity and sharpness of the images, the anatomical complexity, and superposition of the tissues, the classification of landmark and the experience of observers. The cone-beam CT (CBCT) has a number of tools, allowing 3-D image reproduction in all directions to allow correct identification of landmarks. Previous studies reported excellent accurateness with CBCT (15, 16). The size and morphology of the anatomical structure can be easily evaluated with 3D images obtained by CBCT.

The aim of this study was to evaluate the position of mandibular lingula, mental foramina and LF and the prevalence of accessory MF and LF in patients with pediatric age group by CBCT.

2. METHODS

The study was ethically approved by the Bolu Abant Izzet Baysal University Clinical Research Ethics Committee (Decision no:2018/291)

296 CBCT images which belonged to the pediatric age group patients (age range between 7 and 17 years) were randomly selected from the existing archive of the Department of Oral and Maxillofacial Radiology at the Bolu Abant İzzet Baysal University. CBCTs of the patients were taken for reasons such as embedded teeth, supernumerary teeth, pathology, orthodontic treatment and temporomandibular joint (TMJ) problem. The patients who had pathology in area of interest, Class III malocclusion and mandibular asymmetry were excluded from the study.

CBCT images were taken with the same exposure parameters (120 kVp, 15 mA, 0.3 mm^3 voxel size and 4.8 sec) with I-CAT CBCT System (Imaging Sciences International, Hatfield, PA, USA). CBCTs which the entire mandible enters the image area, the relevant regions can be seen clearly in all sections and have no image artefact were evaluated.

All CBCTs were evaluated on 3 different anatomic landmark regions on the right and left sides on the mandible and following measurements were recorded: 1. Lingula of mandible, 2. Mental foramen and 3. Lingual foramen:

1. Lingula of Mandible (ML): Measurements of the lingula mandible were made on 3D CBCT images on the inner surface of the mandible.

ML-MA: Anterior distance by drawing a horizontal line between the most peak of the ML and the most anterior point of the ramus mandible (MA);

ML-MP: Posterior distance by drawing a horizontal line between the peak of the ML and the most posterior point of the ramus mandible (MP);

ML-MS: The superior distance by drawing a vertical line between the peak of the ML and the lowest point of the sigmoid notch;

ML-MI: Lower length by drawing a vertical line between the peak of the ML and the most inferior point of the ramus mandible (MI);

ML-1. Molar: The occlusal distance was measured between the peak of ML and the most distal edge of the alveolar socket of the 1st molar tooth, as millimetres (Figure 1 A-F). (15)

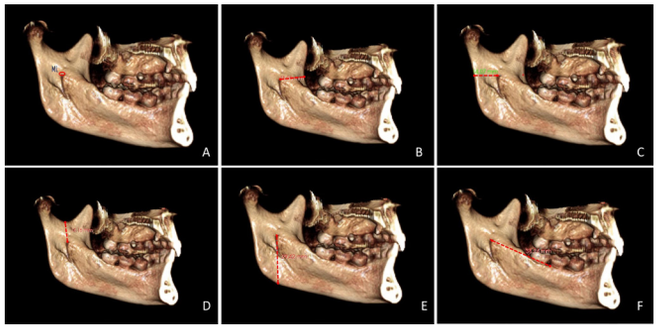

Figure 1. *Measurements of lingula mandible were performed in three-dimensional. A. Location of ML (red circle), B. ML-MA: Distance of the lingula to the anterior of the mandible, C. ML-MP: Distance of the lingula to the posterior of the mandible, D. ML-MS: Distance of the lingula to the superior border of the mandible, E. ML-MI: Distance of the lingula to the inferior border of the mandible, F. ML-1. Molar: Distance of the lingula to the most distal edge of the alveolar socket of the 1st molar tooth.*

2. Mental foramen: On the cross-section images obtained from the midpoint of the MF, the distance between the upper limit of the MF and the top of the alveolar crest and the distance between the lower border of the MF and the lower edge of the basis mandible were measured in millimetres. (Figure 2A) (17).

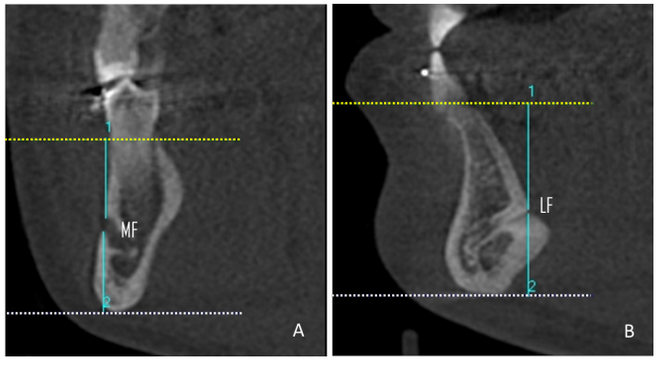

Figure 2. *A. Measurements of the distance between the upper limit of the mental foramen (ML) and the top of the alveolar crest and the distance between the lower border of the mental foramen and the lower edge of the basis mandibulae on the cross-section images, B. Measurements of the distances of the lingual foramen (LF) to the top of the alveolar crest and the lower edge of the basis mandibulae in sagittal sections.*

5 points were determined in order to evaluate the horizontal localization of the MF (18);

- Point: Front of the long axis of the 1. premolar
- Point: At the level of the long axis of the 1. premolar

Point: Between long axes of 1., and 2. premolar

- Point: At the level of the long axis of the 2. premolar
- Point: Located at distal side of the long axis of the second premolar

The accessory MF presence for both sides was recorded in each image.

3. Lingual foramen: In sagittal sections, the distances of the LF to the top of the alveolar crest and the lower edge of the basis mandible were measured and the presence of accessory LF was evaluated (Figure 2B) (19).

All measurements were performed independently by two observers. Observers were calibrated by measuring 10% of images at the beginning of the study. If the observations between 2 observers differ by more than 2 mm, a consensus was obtained and a kappa score was determined (ranged from 0.85 to 1.00). After all measurements were completed, 2 observers re-evaluated 20% of the CBCT images and the kappa score was ranged from 0.91 to 1.00. In the statistical analysis, the mean of both observers' measurements was used.

Statistical Analysis

The sample size was calculated based on the previous study (15), considering Type I errors (0.05), targeted power (0.80) and effect size (0.50) due the distance of lingula from posterior border of ramus ($p<0.05$) by G* power 3.1.9.4 software program (Heinrich Heine University, Dusseldorf, Germany). Statistical software package SPSS version 20 (IBM Corp, New York, NY, USA) was used to analyze obtained data. Descriptive values were assessed by using descriptive statistics. T-tests were used to analyse data according to side and gender. The significance level was set as $p< 0.05$.

3. RESULT

A total of 296 patients (120 male, 176 female) age ranging from 7 to 17 years (mean 14.26 ± 1.91) were included in the study. Descriptive values of the measurements of lingula are shown in Table 1. The measurements were performed separately for the right and left sides of each patient, and there was no significant difference between the right and left and between the genders in lingula measurements ($P > 0.05$). The lingula was located at 18.63±4.52 mm from the sigmoid notch, 24.81 ± 5.19 mm from the inferior border of the ramus, 14.67±2.39 mm from the anterior border of the ramus and 15.14 ± 3.06 mm from the posterior border of the ramus. The mean distance to the distal surface of the alveolar socket of the mandibular 1. molar from the lingula from was 34.88 ± 4.23 mm.

The results of the vertical and horizontal position of the right and left mental foramina were shown in Table 2 and Table 3, respectively. On the right and left sides, the MF was at the highest (66.9% and 74.3%, respectively) in the 3. Point region; between long axes of first and second premolar teeth. This is followed by the 4. Point region; at the level of the long axis of the second premolar teeth. No significant difference was found between sides in MF measurements ($P > 0.05$). Gender difference was found only for the distance between the MF and the lower edge of the mandible ($P < 0.001$).

Table 4 shows the measurement results of the distance of the LF to the alveolar crest and the inferior edge of the basis mandible. The LF was found to be closer to the inferior edge of the basis mandible (11.68 ± 4.26 mm). In 7.1% of cases, accessory LF was observed (Table 5). No significant difference was found between sides and gender in LF measurements ($P > 0.05$).

Table 1. *Distance of lingula mandible from various mandibular landmarks*

			Minimum	Maximum	Mean	Std. Deviation
Right	ML-MS	148	9,64	30,72	18,63	4,52
	ML-MI		12,62	37,27	24,81	5,19
	ML-MA		8,57	21,06	14,67	2,39
	ML-MP		9,19	30,12	15,14	3,06
	ML-1. molar		19,90	46,39	34,88	4,23
Left	ML-MS	148	11,20	41,14	18,79	4,84
	ML-MI		9,85	38,17	25,16	5,58
	ML – MA		0,00	20,47	14,96	2,82
	ML – MP		9,21	24,68	14,12	2,70
	ML – 1. molar		21,91	45,14	35,74	4,37

N: Number, Std: Standard. ML: Mandibular Lingula, MS: Superior border of mandible, MI: Inferior border of mandible, MA: Anterior border of mandible, MP: posterior border of mandible.

Table 2. *Vertical location of the mental foramen (MF)*

		N	Minimum	Maximum	Mean	Std. Deviation
Right	**MF–inferior border**	148	7,80	17,70	12,68	1,80
	MF – Alveolar crest		4,80	17,70	12,23	2,32
Left	**MF–inferior border**	148	8,41	16,20	12,41	1,58
	MF – Alveolar crest		5,71	23,77	12,42	2,65

N: Number, Std: Standard.

Table 3. *Horizontal location of the mental foramen*

Side	Point	Point	Point	Point	Point
Right	4 (2,7%)	12 (8,1%)	99(66,9%)	29 (19,6%)	4 (2,7%)
Left	2 (1,4%)	7 (4,7%)	110 (74,3%)	26 (17,6%)	3 (2%)

Point; In front of long axis of the first premolar tooth
Point; In line with the long axis of the first premolar tooth
Point Between long axes of first and second premolar teeth
Point; In line with the long axis of the second premolar tooth
Points; Distal of the long axis of the second premolar tooth

Table 4. *Location of lingual foramen*

Distance to	N	Minimum	Maximum	Mean	Std. Deviation
Inferior border of mandible	148	1,20	19,20	11,68	4,26
Alveolar crest	148	2,70	29,40	16,20	4,80

N: Number, Std: Standard.

Table 5. *Prevalence of accessory lingual foramen*

Accessory Lingual Foramen	Frequency	Percent (%)
Absent	275	92,9
Present	21	7,1

4. DISCUSSION

Craniofacial imaging techniques with CBCT are becoming increasingly popular and have introduced new directions to morphological evaluation (20, 21). In this study, anatomical landmarks in the mandible were evaluated on multiplane reconstructed CBCT images of the pediatric population.

Lingula mandible is an important clinical marker and the location of lingula varies according to various ethnic and racial groups (7, 22-24). There are several studies in the literature measuring the distance of the lingula mandible to the specific points in the mandible. In studies evaluating the distance of the lingula mandible from the anterior of the mandible (ML-MA distance) on the adult population; Senel et al. (21) reported as 18.5 ± 2.3 mm, Sheonoy et al. (25) as 16 mm, Samantha and Kharb (26) as 20.0 ± 2.4 mm, Sekerci and Sisman (27) as 16.77 ± 2.74 mm, and Jansisyanot et al. (8) as 20.6 ± 3.5 mm. Sekerci et al. (15) reported the same distance in the pediatric population as 13.3 ± 2.3 mm. In this study, the mean ML-MA distance was 14.82 ± 2.61 mm. This result was similar to Sekerci et al. (15) but lower than the results of other studies and the possible reason is that the mandible is smaller in children.

In previous studies, the ML-MP distance was reported as 16.9 ± 3.5 mm (21), 15 ± 2.7 mm (26), and 10.2 ± 1.6 mm (15); ML-MS distance was reported as18.1 ± 3.6 mm (21), 15.4 ± 2.7 mm (26), 15.32 ± 2.46 mm (27), 16.6 ± 2.9 mm (8), and 16.6 ± 2.9 mm (15); ML-MI distance as 38.3 ± 5.3 mm (21) and as 23.1±3.2 mm (15). In this study, the mean ML-MP, ML-MS, and ML-MI distances were 14.63 ± 2.93, 18.71 ± 4.68 and 24.99 ± 5.38, respectively. These findings are similar to those of Sekerci et al. (15). However the numerical differences between the other studies might be due to the difference in the average age of the populations.

The mean distance of the ML to the distal surface of the alveolar socket of the mandibular 1. molar tooth was 35.31 ± 4.31 mm in the present study as higher which reported by Sekerci et al. (15) as 24.7 ± 3.7 mm. The difference in the results may be due to the higher mean age as 14.26 ± 1.91 years of the patient population in this study.

There is general evidence that lengths of anatomical structures are shorter than or equal to men in women. Sekerci and Sisman (27) reported that some measurements for location of lingula were higher in males. On the contrary, Jung et al. (4) reported that the location of lingula did not show a statistically significant difference between the genders. Similar to Jung et al. (4), in this study, there were no significant differences in the measurements between genders.

As reported in previous studies, the location of the mental foramina shifts distally along with the growth of the mandible (12, 28, 29). In our study, one MF was detected on both sides of all children, and on the right and left sides, respectively, 66.9% and 74.3% of MFs located between long axes of 1., and 2. premolar teeth; 19.6% and 17.6% located in line with the long axis of the 2. premolar tooth. Similarly in Lim et al.'s study (9) a single MF was observed in all children and were located between the root apices of the 1. and 2. premolars followed by the root apex of the 2. premolar. On Caucasian children, Gerhenson and colleagues (30) analyzed children in primary and mixed dentition, and children before the eruption of teeth. In children in mixed dentition, MF was commonly located at the root apex of the first premolar (48%) and between the root apices of the first and second premolar (34%). Assuming that the children in this study were in the mixed dentition period, this location difference may be caused by racial difference.

Gershenson et al. (30) reported that the position of the MF was closer to the upper borders in the primary dentition in children and decreased to the middle third of the mandible during the mixed dentition. They also stated that the MF was positioned closer to the inferior border of the mandible in adults. In this study, the distance between the MF and the inferior border of the mandible was 12.68 ± 1.80 on the right side and 12.41 ± 1.58 mm on the left side. Similarly, Gungor et al. (31) reported similarly on both sides in a population age range between 10-70 years. Also, similar results have been reported in a study conducted in the Turkish population; 12.86 ± 1.55 mm on the right and 13.13 ± 1.89 mm on the left) (17). This similarity in the results may be due to the fact that the measurements were made on similar populations. In a study of skulls, Udhaya et al. (18) reported this distance as similar mean value. Neiva et al. (32) reported lower value and Apinhasmit et al. (33) reported higher value in males and in females. This difference may be because of this that

they measured the distance between the inferior border of the mandible and the middle of the MF, but we measured the distance between the inferior border of the MF and the inferior border of the mandible.

Gungor et al (31) reported the distance between the top of the alveolar crest and the MF as 13.22 ± 2.76 mm and 13.36 ± 2.84 mm on the left and right sides, respectively. Udhaya et al. (18) found as 12.02 ± 2.48 mm and 12.21 ± 2.61 mm on the right and left sides, respectively. Caglayan et al. (17) gained 12.08 ± 3.12 mm on the left and 11.86 ± 2.75 mm on the right. In all studies, the difference compared to our results (12.23 ± 2.32 mm on the right and 12.42 ± 2.65 mm on the left) was 1–2 mm. No difference was found between the sides in the measurement between the MF and the top of the alveolar crest not only in our study (P = 0.508) but also in that by Gungor et al. (31) and Caglayan et al. (17). However, in both studies, gender difference was found in the distance of the MF to the inferior border of the mandible and the alveolar crest (P ≤ 0.01). In our study, the gender difference was found only for the distance measurement between the inferior edge of the mandible and the MF (P < 0.001).

As stated in several cadaver studies (19,34-36), neurovascular structures come into the mandible through the LF and so there is a risk during mandibular surgery in this region. The present study showed a mean distance of 11.68 mm from the inferior mandibular border to the LF. This finding is lower than those reported by Mraiwa et al. (37) (12.3) and Makris et al. (19) (12.28 mm). While, this mean distance is higher than in many other studies (10.0 mm (38), 10.2 mm, (39) and 10.6 mm (35). These numerical differences between studies may depend on the distribution of population, race and methodology. In addition, accessory LF was found in 7.1% of the cases in the study. We think that the possibility of an accessory foramen and canal should not be ignored during surgical interventions in the relevant region.

The present study results provide navigational information during dental procedures of the mandible. Clinicians should insert a needle approximately 14.6 mm from the anterior border of the ramus and approximately 24.81 mm from the lower border of the ramus while performing mandibular nerve block anaesthesia on pediatric patients. The high rate of mental foramen being between the 1st and 2nd premolar teeth in children and the presence of accessory lingual foramen should be taken into account during dental procedures to avoid vascular and nerve damage.

In conclusion, the identification of anatomical landmark in children is an important stage before dental procedures and the location of the landmarks may show differences according to race, age, gender, dentition, and growth pattern. Detailed evaluation of anatomical structures with CBCT in children is important to prevent complications in order not to damage neurovascular structures before surgical procedures.

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Clinical and Experimental Health Sciences

The Reliability and Validity of the Turkish Version of the Mental Fatigue Scale In Healthy Individuals

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ABSTRACT

Objectives: The aim of the study was to investigate the reliability and validity of the Turkish version of the Mental Fatigue Scale (MFS) in healthy Turkish population.

Methods: This study was held in Hacettepe University, Faculty of Physical Therapy and Rehabilitation between April and August 2019. A total of one hundred thirty-two healthy participants aged between 18-50 years were recruited. Reliability was investigated using test-retest reliability. The internal consistency of MFS was calculated using Cronbach's alpha coefficient. The validity of the MFS was assessed by comparing the MFS score with the 36-item Short Form Health Survey (SF-36) and Checklist Individual Strength Questionnaire (CIS-T) scores. Pearson correlation coefficient was used to evaluate validity.

Results: The test–retest reliability of the MFS were excellent in healthy Turkish population (ICC: 0.91, with a 95% confidence interval of 0.88–0.94). The scale had high internal consistency (Cronbach's α 0.86). For the validity, the correlations between the MFS and the total/subscales of CIS-T scores and SF-36 scores were good ($p<0.001$). The correlations between the MFS and CIS-T subscales (subjective feeling of fatigue, $r=0.50$; concentration, $r=0.53$; motivation, $r=0.42$) and CIS-T total ($r=0.56$) were good ($p<0.001$). Significant correlations were found between the MFS and SF-36 subscales (energy/fatigue, $r=0.54$; emotional well-being, $r=0.54$, general health, $r=0.41$) ($p<0.001$).

Conclusion: The Turkish version of the Mental Fatigue Scale has been demonstrated to be valid and reliable to assess mental fatigue in Turkish population. The Turkish Mental Fatigue Scale is suggested to be a valuable tool for assessment of mental fatigue in healthy Turkish population.

Keywords: Mental fatigue, fatigue, reliability, validity, Turkish

1.INTRODUCTION

Fatigue is a common phenomenon in healthy persons and patients (1). Although there are many definitions of fatigue in the literature, there is a consensus that fatigue is a subjective, multidimensional and multifactorial phenomenon (2). Fatigue is defined as a decrease in the level of efficiency of the individual in terms of mental and physical activities, decrease in the capacity of physical and mental activity, or exhaustion and lack of energy separately from weakness or sadness due to working or other reasons (3, 4). Two main subheadings are often used to classify fatigue: – Physical and Mental fatigue. Mental fatigue is defined as a biopsychological condition characterized by tiredness and lack of energy during or after prolonged periods of cognitive activity (5).

According to the International Classification of Diseases, 10th revision (ICD-10) mental fatigue is included in the "mild cognitive disorder" or "neurasthenia" diagnostic groups, while in the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (6), mental fatigue is contained in the "mild neurocognitive disorders" group. As a result of mental fatigue, various symptoms can be seen, namely subjective, behavioral and physiological. Subjectively, increased fatigue, decreased motivation and lack of energy; behaviorally, a decrease in performance during a cognitive task; physiologically, symptoms such as changes in brain activity can be cited as examples (5, 7-10). In addition, symptoms such as reduced concentration capacity, sensitivity to noise and light, irritability, stress sensitivity and sleep disturbance may also be seen (11). Mental fatigue is a widespread complaint in modern life. According to the study conducted in the Netherlands, half of working women and a third of men reported complaints about mental fatigue (5). In the United States survey conducted by Ricki et al., 38% of the working population reported fatigue (12). In addition, the rate of one year after a stroke fatigue was reported to be ~70% (13, 14).

Mental fatigue has a negative effect on many activities in our social or business life. According to the studies, it is stated that

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mental fatigue decreases the desire to continue the present activity, the level of commitment to the task at hand (15-17) and causes a decrease in cognitive and behavioral performance (7, 18, 19). In order to understand the cause of mental fatigue, which is commonly seen today and causes many problems in daily life, it is important to evaluate the problem from a broad perspective. There are many scales and questionnaires evaluating fatigue in the literature (20-22).

Various generic and disease-specific fatigue rating scales are used to evaluate fatigue in patients. The Mental Fatigue Scale (MFS) developed by Johansson et al. specifically assesses mental fatigue (23). However, this scale has no Turkish adaptation with validity and reliability in healthy population. Therefore, the aim of this study was to investigate the Turkish translation of the Mental Fatigue Scale with its validity and reliability.

2.METHODS

2.1.Participants

This was a methodological, validity, and reliability study. A face-to-face interview was performed. It was planned that the sample size to be 10 times (140) the number of items in the scale (24, 25) and 140 people were participated in the study. A total of 132 healthy participants (out of 140) aged between 18-50 years were recruited between April and August 2019. Eight participants were excluded from the study because they had diabetes mellitus and used antidepressants. Participants who had psychiatric comorbidities (e.g. use of antidepressants, hypnotics, sedatives, or antipsychotics), cancer history, neurological diseases (e.g. Stroke) and diabetes mellitus were excluded from the study. Participants who met the inclusion criteria were informed about the study and volunteers were invited to participate in the study (Figure 1). Participants who agreed to participate in the study signed a written consent form before participating in the study. Ethical approval received from Hacettepe University Non-invasive Clinical Studies Ethical Board (Date:18.12.2018, Number: GO 18/1197-25).

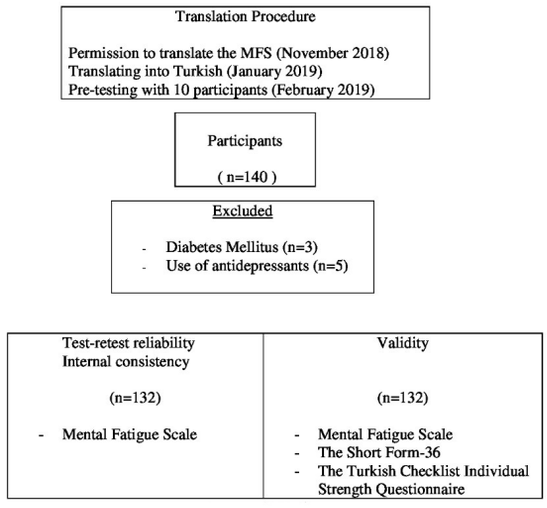

Figure 1. *Study Design*

2.2.Translation Procedure

The permission was obtained for the Mental Fatigue Scale from its developers (Lars Rönnbäck and Birgitta Johansson) and the translation procedures were followed according to a recommended procedure (23). Firstly, the original scale was translated from English into Turkish separately by two bilingual Turkish physiotherapists who have an advanced level of English. In order to create the first Turkish translation, both translations were compared by a bilingual person and the mismatches between the two translations were corrected. Then, the first Turkish translation was translated into English by two native speakers of English who know a good level of Turkish. The Turkish-to-English back-translation was then compared with the original scale. Following the completion of the translation procedure, pre-testing was conducted on 10 participants who met the inclusion criteria of the study to decide their comprehension of the Turkish version. The translated version was revised according to the difficulties of the participants in understanding the questions and the final Turkish version of MFS was decided.

A total of 132 participants filled the Turkish translation version of the MFS twice for test-re-test reliability assessment. The Turkish MFS was administered to all participants seven days later. To evaluate the validity of the MFS, the Short Form-36 (SF-36) and the Turkish Checklist Individual Strength Questionnaire (CIS-T) were also completed by all participants during the first application of the MFS. We chose the CIS-T scale because there was no other Turkish scale evaluating mental fatigue parameters and the questions of the CIS-T scale were similar to the MFS scale questions. The reason for choosing SF-36 was that it contains mental fatigue subscale.

2.3.Main Outcome Measurements

Mental Fatigue Scale (MFS)

The Mental Fatigue Scale (MFS) is a 15-item questionnaire that specifically evaluates mental fatigue. It includes affective, cognitive and sensory symptoms, duration of sleep and daytime variation in symptom severity. The questions related to fatigue in general, lack of initiative, mental fatigue, mental recovery, concentration difficulties, memory problems, slowness of thinking, sensitivity to stress, increased tendency to become emotional, irritability, sensitivity to light and noise, decreased or increased sleep as well as 24-hour symptom variations. It has a 7-point Likert-type scale and is scored between 0 and 3. A rating of 0 indicates normal function, 1 slight problem, 2 significant problems and 3 maximum problems. There are also items such as 0.5, 1.5, 2.5 for marking when individuals fall between 2 items (0.5, 1.5, 2.5). The total score of the scale is obtained by summing the scores of the first 14 questions. The last question is evaluated as yes or no. The scores range from 0 to 42 and 0-10 indicates no mental fatigue problem, 10.5-14.5 indicates slight mental fatigue, 15-20 indicates fairly serious mental fatigue, and ≥ 20.5 indicates serious mental fatigue (23).

Turkish Checklist Individual Strength Questionnaire (CIS-T)

CIS is a scale of 20 questions used to assess various aspects of fatigue. The CIS evaluates 4 parameters of fatigue: (1) the subjective experience of fatigue (eight items); (2) reduction in motivation (four items); (3) reduction in activity (three items); and (4) reduction in concentration (five items). It has a 7-point Likert-type scale and is score between 1 and 7. A rating of 1 indicates 'Yes, that is true' and 7 indicates 'No, that is not true'. The total CIS score is calculated by summing the scores from four dimensions. Higher scores show a higher degree of fatigue, more concentration problems, lower motivation, and less activity (26). The validity and reliability of the Turkish version of CIS was made in 2011 by Ergin et al (27).

Short-Form Health Survey (SF-36)

The SF-36 was used to evaluate 8 dimensions of health. These eight dimensions include physical functioning, role limitations due to physical health, role limitations due to emotional problems, energy/fatigue, emotional well-being, social functioning, pain, general health. Gives a total score individually for each sub-dimension and points range from 0 to 100. A low score shows poor health status, while a high score shows good health status (28). The validity and reliability of the Turkish version was made in 1999 by Koçyiğit et al (29).

2.4.Statistical Analysis

All statistical analyses were completed using SPSS version 22.0 (SPSS Inc, Chicago, IL), with a level of significance of 5 %. Frequencies and descriptive statistics were used to calculate demographic variables. The measurement properties analyzed in this study for the instruments contained test–retest reliability and validity. For all variables, test–retest reliability was determined by the intraclass correlation coefficient (ICC) using a one-way random model with under consistency. The minimum value recommended for this measurement property is 0.70 (Cronbach, 1951). Cronbach's alpha coefficient was used to estimate the internal consistency of MFS in our study, and a value of 0.70–0.9 was considered acceptable (30).

The validity of the MFS was assessed with analyzing the correlation between the SF-36 and CIS-T. The concurrent validity was determined using Pearson correlation analysis. The qualitative indicators for the relative ranges of correlation values were analyzed as follows: : r ≥ 0.81–1.0 was excellent, 0.61–0.80 was very good, 0.41–0.60 was good, 0.21–0.40 was fair, and 0.00–0.20 was poor (31).

3.RESULTS

Demographic characteristics of the participants were shown in Table 1.

Table 1. *Demographic characteristics (n = 132)*

Age (year)(X ± SD)	33.28 ± 10.01
Gender, n (%)	
Female	88 (66.7)
Male	44 (33.3)
BMI (kg/m2), n (%)	
Thinness	11 (8.3)
Normal	60 (45.5)
Overweight	42 (31.8)
Obese Class I	17 (12.9)
Obese Class II	2 (1.5)
Obese Class III	0 (0)
Marital Status, n (%)	
Single	59 (44.7)
Married	68 (51.5)
Divorced	5 (3.8)
Education, n (%)	
Primary education	15 (11.4)
Secondary education	21 (15.9)
University	81 (61.4)
Postgraduate	15 (11.4)
Working Hours (min.) (X ± SD)	506.82 ± 56.00
Sleep Hours (min.) (X ± SD)	433.64 ± 79.62
Social Activity, n (%)	
Yes	32 (24.2)
No	100 (75.8)
Sport Activity, n (%)	
Yes	51 (38.6)
No	81 (61.4)
Sport Activity Hours (min.) (X ± SD)	236.18 ± 97.25
Smoke, n (%)	
Yes	34 (25.8)
No	98 (74.2)

3.1.Reliability of the MFS

One-hundred and thirty-two participants were used to calculate test-retest reliability. The test–retest reliability, as assessed by the ICC, was 0.91, with a 95% confidence interval of 0.88–0.94, thus showing very high degree of reliability. Internal consistency was assessed using Cronbach's alpha and Cronbach's alpha was found 0.86. Also, we calculated item-total score correlations for each item and these correlations were adequate ranged between 0.43 and 0.69 (Table 2). Thus, there was no need to remove any item.

3.2.Validity of the MFS

For the validity, the correlations between the MFS and the total/subscales of CIS-T scores and SF-36 scores were good ($p<0.001$). The correlations between the MFS and CIS-T subscales (subjective feeling of fatigue, r=0.50; concentration, r=0.53; motivation, r=0.42) and CIS-T total (r=0.56) were good ($p<0.001$). Significant correlations were found between the MFS and SF-36 subscales (energy/fatigue, r=0.54; emotional well-being, r=0.54, general health, r=0.41) ($p<0.001$). Fair correlations were found between the MFS

and CIS-T (physical activity, r=0.24), SF-36 subscales (role limitations due to physical health, r=0.26; role limitations due to emotional problem, r=0.32; social functioning, r=0.35; pain, r=0.35) (p<0.001). Poor correlation was found between the MFS and SF-36 subscale (physical functioning, r=0.19) (p=0.005). All correlation coefficients for the comparisons described, including the comparison between the MFS and CIS-T and the SF-36 are demonstrated in Table 3.

Table 2. *Corrected item-total correlation, item mean, and standard deviation for the MFS (n = 132)*

Questions of MFS	Mean	SD	Item-total correlation	Cronbach's a if item deleted
MFS-1	1.36	0.78	0.48	0.86
MFS-2	0.92	0.74	0.69	0.84
MFS-3	1.08	0.93	0.65	0.85
MFS-4	0.88	0.84	0.59	0.85
MFS-5	0.98	0.75	0.58	0.85
MFS-6	1.00	0.75	0.57	0.85
MFS-7	0.79	0.66	0.67	0.85
MFS-8	1.25	1.03	0.48	0.86
MFS-9	1.06	0.86	0.59	0.85
MFS-10	0.95	0.83	0.49	0.86
MFS-11	0.90	0.77	0.35	0.86
MFS-12	1.11	0.66	0.49	0.86
MFS-13	0.77	0.73	0.26	0.87
MFS-14	0.55	0.79	0.43	0.86

MFS Mental Fatigue Scale, SD standard deviation

Table 3. *Correlation between MFS with the other outcome measurements*

Outcome measurements	n = 132 Mean (X±SD)	r [95 % CI]	p
CIS-T – Subjective feeling of fatigue	29.62 ± 11.32	0.50 [0.32–0.66]	0.001
CIS-T – Concentration	16.78 ± 7.57	0.53 [0.39–0.65]	0.001
CIS-T – Motivation	12.73 ± 5.20	0.42 [0.23–0.57]	0.001
CIS-T – Physical activity	9.11 ± 4.45	0.24 [0.08–0.40]	0.001
CIS-T – Total	68.23 ± 23.06	0.56 [0.39–0.69]	0.001
SF-36 – Physical functioning	81.68 ± 19.83	-0.19 [-0.38–0.00]	0.005
SF-36 – Role limitations due to physical health	76.51 ± 35.45	-0.26 [-0.42–(-0.09)]	0.001
SF-36 – Role limitations due to emotional problems	62.62 ± 41.40	-0.32 [-0.50–(-0.14)]	0.001
SF-36 – Energy/fatigue	55.83 ± 20.18	-0.54 [-0.67–(-0.40)]	0.001
SF-36 – Emotional well-being	68.51 ± 15.94	-0.54 [-0.66–(-0.41)]	0.001
SF-36 – Social functioning	71.02 ± 24.09	-0.35 [-0.52–(-0.17)]	0.001
SF-36 – Pain	77.51 ± 20.33	-0.35 [-0.53–(-0.16)]	0.001
SF-36 – General health	63.44 ± 17.80	-0.41 [-0.57–(-0.24)]	0.001

p < 0.001

CIS-T Turkish Checklist Individual Strength Questionnaire, SF-36 Short-Form Health Survey

4.DISCUSSION

Turkish adaptation of the Mental Fatigue Scale (MFS) was performed and psychometric properties were examined in the present study. The results demonstrated that the Turkish version of the MFS is valid and reliable. Although mental fatigue affects all populations today, there are insufficiencies in detecting its presence and determining its severity. The Mental Fatigue Scale developed to measure mental fatigue has proven validity and reliability in neurological patients (23).

Reliability is defined as a measure of invariance with respect to time or to obtain similar results if a measurement process is repeated (32). The internal consistency level of the scale was found to be high (Cronbach's α = 0.86) in the present study. All the corrected item-total correlations were adequate. The internal consistency findings of our study are consistent with the original version (Cronbach's α = 0.94) and the Chinese version (Cronbach's α = 0.92) of the MFS (23, 33).

The test-retest method is another method used to determine the reliability coefficient based on the fact that a test is applied twice to the same individuals under the same conditions and at a given time interval (32). In our study, the test-retest test was applied at 7-day intervals and the ICC value was found to be 0.91. The test-retest was also found to be high. These results are very similar to other language version of the MFS (Chinese version of the MFS scale), (ICC: 0.97) (33). This finding suggest that the MFS is reliable measure in Turkish language.

Validity is a concept that indicates how accurately a method measures what it is intended to measure (32). In this study, SF-36 and CIS-T scales were used to test validity. In the Chinese version of the MFS scale, the validity of the scale was tested with 'Chalder Fatigue Scale (CFS)' and 'The Clinically Useful Depression Outcome Scale (CUDOS)'. There was a very good correlation between MFS and CUDOS. There was a good correlation between physical fatigue dimension and MFS, which is one of the two subscales of the CFS scale, and a very good correlation was found between mental fatigue dimension (33).

Similarly, in present study, the correlations of the MFS with the subjective feeling of fatigue, concentration and motivation subscales of the CIS-T were good. These results suggest that the MFS includes motivation, concentration and fatigue parameters. Also, a good correlation was found between emotional well-being and energy/fatigue subscales of the SF-36. Therefore, the MFS scale also support the quality of life aspects. On the other hand, the relationship between physical activity, which is the subscales of CIS-T scale related to physical fatigue, and MFS scale was found to be fair in the present study. In addition to this, the relationship between SF-36 sub-parameters related to physical functions and MFS scale was poor. As the MFS scale is a mental fatigue specific measurement, these results are not surprising.

The present study had some limitations. The major limitation is that there are no other language versions (except Chinese

version) of the MFS to compare our results. Secondly, our participants did not show a homogeneous distribution in terms of gender and age. Our study is a single-centered study, and therefore, all the participants were from the same region (Ankara). These factors may limit the generalizability of the results.

Moreover, determining the type of fatigue or determining the contribution of mental fatigue to total fatigue has a key role in the fight against fatigue and appropriate treatment planning. In this respect, the fact that the first mental fatigue scale, which was shown to be valid and reliable in Turkish, could be used in this group of patients increases the importance of our study. Fatigue is also an important problem that should not be overlooked in people with neurological diseases. It is one of the most important problems of patients, especially in patients with stroke, multiple sclerosis and traumatic brain injury. In further studies, this scale is recommended to be used in neurological patients.

Conclusions

The results of the present study demonstrated that the MFS has good measurement properties to quantify mental fatigue in Turkish population. The Turkish Mental Fatigue Scale is suggested to be a valuable tool for assessment of mental fatigue in healthy Turkish population.

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Conflict of interest

The authors report that they have no conflicts of interest.

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Clinical and Experimental Health Sciences

The Relationship Between Health-Promoting Lifestyle Behaviors and Sleep Quality of Nurses Working in the Pediatrics Clinics

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ABSTRACT

Objective: The study was conducted to determine the relationship between health-promoting lifestyle behaviors and sleep quality of nurses working in the pediatrics clinics.

Methods: The study was conducted among nurses working in the pediatrics clinic of a training and research hospital located in Istanbul. Nurse Information Form, Health-Promoting Lifestyle Profile-II (HPLP-II), and Pittsburg Sleep Quality Index (PSQI) were applied to the nurses. Ethics committee and institutional permission, permission from the scale authors via e-mail, and written consent from the nurses were obtained in the study.Besides the descriptive statistics, Mann Whitney U test, Kruskal Wallis test, and Spearman's Rho Correlation analysis were used for the analysis of the study.

Results: Among the 200 nurses that were surveyed, 121 (60.5%) responded.81% of the nurses (n=98) were female, and 80.2% had a bachelor's degree. Age average of the nurses was 25.74±3.86 years and the average weekly working hours was 49.40±7.70 hours. It was determined that total mean score of HPLP-II was 125.26±16.40 and PSQI total mean score was 12.13±2.29. The lowest mean HPLP-II subscale score was 16.19±4.64 for exercise and 17.71±3.74 for stress management. A statistically significant correlation was found between the HPLP-II total scores and PSQI total scores ($r = -0.19$; $p < 0.05$).

Conclusion: It was determined that the health-promoting lifestyle behaviors of the nurses were above the moderate level, their sleep quality was poor, and there was a significant correlation between the health-promoting lifestyle behaviors and the sleep quality of the nurses. It can be suggested by nursing to conduct the studies determining the practices that will improve the health-promoting lifestyle behaviors of the nurses and enhance their sleep quality.

Keywords: Health Behavior, Health Promotion, Nursing, Pediatric Clinic, Sleep Quality

1. INTRODUCTION

The largest number of healthcare professionals in United States of America is the nurses with 4.1 million (1). According to 2018 data, it has been reported that the number of nurses in Turkey is 190.499 (2). Wellbeing and health of nurses may directly also affect the health of population along with patient care (3,4). Additionally, the quality of nursing care has a direct effect on the patient health outcomes (5). Hospitalized patients need nursing care practices for 24 hours (6,7).

Due to irregular shift schedules, hard work conditions such as fulfillment of physically and psychologically intense nursing tasks, low income andcontractual employment, the tendency of nurses to have a unhealthy lifestyle increases (8) but their tendency to exhibit health-promoting behaviors decreases (9). Nutrition and exercise take place among the most studies health-promoting behaviors (10). In a study conducted with 3132 nurses, it was found that 50% of nurses did appropriate exercise and 62% consumed fast food at least twice a week (11). In a meta-analysis conducted with 145 studies, it was reported that social isolation posed a major risk factor for mortality depending on smoking and alcohol consumption (12). In the study by Etienne (13), it was found that 48% of nurses were exposed tobullying at workplace and 12% were bullied several times a week. Of the nurses, 92% had moderate and high level of stress (14).

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Due to the high level of stress, it has been found that nurses experience physical and psychological problems such as poor health (14) and sleep disorders (15,16). Sleep quality is an important factor allowing the nurses to get rid of the work stress, fatigue, and psychological stress. (17). It is stated that due to shift work, nurses experience sleep and mental health problems (15) and nurses reporting poor sleep quality have higher level of 10-year cardio-metabolic risks (18). The poor sleep quality of the nurses increased the malpractice rates at emergency departments (19), it was found that 64% of the nurses working in the day shift, 75.1% of those working in the evening shift, and 79.9% of those working in the night shift had poor sleep quality (20). In a study conducted with 865 nurses, nurses working in the night shift were reported to have poor sleep quality and higher depression rates (21).

Even though severalstudies for the health-promoting behaviors of the nurses have been conducted in the literature (9,11,13,22,23), no study on the health-promoting behaviors of nurses working in the pediatrics clinics has been found. Also, although in the literature there are studies for the sleeping states of the nurses working at pediatric intensive care services (24,25), no study examining the correlation between the health-promoting behaviors and sleeping states of the nurses working at all the pediatric clinics has been found. Thus, the aim of this study wasto determine the relationship between health-promoting lifestyle behaviors and sleep quality of the nurses working in the pediatric clinics.

2. METHODS

2.1. Design and setting

The study was conducted with descriptive-correlational design at a Training and Research Hospital in Istanbul between January and February 2019. Total number of beds in the pediatrics clinics of the hospital where the study was conducted was 183. Of these beds, 28 were at the internal medicine clinic, 22 at surgery, 78 at intensive care, 26 at emergency department, and 29 at hematology-oncology clinic.

2.2. Sample

The population of the study consisted of 200 nurses working in the pediatric clinic. The inclusion criteria were determined as being older than 18 years, being present at the hospital between these dates, speaking Turkish, and being voluntary to participate in the study. It was planned to include all the nurses meeting the criteria in the sample. The exact count method was used in the selection of the sample. However, the sample of the study included 121 nurses (60.5%) since 40 nurses (20%) were not present at the clinic between the study dates and 39 nurses (19.5%) declined to participate in the study. The nurses were working in three shifts as 8.00 am – 4.00 pm, 4.00 pm – 8.00 am, and 8.00 am – 8.00 am.

2.3. Measurements

2.3.1. Nurse Information Form

The information form prepared by researchers for the nurses included the questions about age, gender, weekly working hours, educational background, marital status, having a child, duration of working in the pediatrics clinic, service, and status of liking the profession of nursing.

2.3.2. The Health-Promoting Lifestyle Profile-II (HPLP-II)

The Health-Promoting Lifestyle Profile-II was developed by Walker et al. (26). Turkish validity and reliability study of the HPLP-II scale was conducted by Bahar et al. (27). The profile is a 4-point likert type and consists of 52 items and six factors. These factors are self-actualization, interpersonal support, nutrition, exercise, health responsibility, and stress management. In the assessment of the scale, the lowest score is 52 and the highest score is 208. As the total score increases, it is accepted that the individuals have more health-promoting lifestyle behaviors. Scores in every sub-group are classified in three categories. According to the scores, sub-group is divided in three categories: Weak level (≤49%), moderate level (50-74%) and good level (75 ≤%). Cronbach's alpha value of the scale was between 0.79 and 0.87 for six factors and 0.94 for overall scale (26). Cronbach's alpha value of the Turkish version of the scale was between 0.64 and 0.80 for six factors and 0.92 for overall scale (27). In the present study, Cronbach's alpha value of the scale was found between 0.63 and 0.84 for six factors and 0.89 for overall scale.

2.3.3. The Pittsburgh Sleep Quality Index (PSQI)

The Turkish validity and reliability study of PSQI, which was developed by Buysse et al. (28), was conducted by Ağargün et al. (29). PSQI consists of seven components as subjective sleep quality, sleep latency, sleep duration, habitual sleeping efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. Total score of the seven components gives the total score of PSQI. Each component is scored between 0 and 3. Total score is between 0 and 21. High values show poor sleep quality and high level of sleep disorder. A total score of > 5 shows that sleep quality is clinically poor (29). Cronbach's alpha value of the original version and Turkish version of the index was 0.80 (28,29). In the present study, the Cronbach's alpha value was found as 0.79 for the overall scale.

2.4. Procedure

Data collection tools were applied by the researchers by conducting face-to-face meetings with the nurses. The nurses, who accepted to participate in the study completed data collection forms in a quiet and empty room for averagely 15 minutes.

2.5. Ethical Considerations

Institutional permission from Provincial Directorate of Health of Istanbul (Date: 02.04.2018; No: 16867222 – 604.01.01), approval from Social and Human Sciences Research Ethics Committee of Istanbul University (Date: 08.01.2018; No: 1), permission from the scale authors via e-mail, and written consent from the nurses were obtained in the study.

2.6. Data Analysis

While assessing the results obtained in the study, the IBM SPSS Statistics 22 program was used for the statistical analyses. Compatibility of the variables to the normal distribution was assessed by Shapiro Wilks test, Q-Q plots, and histograms. In the data assessment, Mann Whitney U test was used for the evaluations between two groups along with the descriptive statistical methods (mean, standard deviation, frequency, percentage). Kruskal Wallis test was used for the assessment of quantitative data between more than two groups. Pearson's Correlation Analysis was used for the assessment of the correlation between the scale scores. Significance was assessed at the level of $p<0.05$.

3. RESULTS

The study was conducted with a total of 121 nurses working in the pediatrics clinic 81% (n = 98) female and 19% (n = 23) male. Age average of the nurses was 25.74±3.86 (min = 20; max = 40) years. Average weekly working hours of the nurses were 49.40±7.70 (min = 40; max = 72) hours.

Five nurses were only working in the 8.00 am – 4.00 pm shift. Table 1 shows the sociodemographic characteristics of the nurses.

It was determined that total mean score of HPLP-II was 125.26±16.40 and PSQItotal mean score was 12.13±2.29. Table 2 shows subscale and total score distribution of HPLP-II and PSQI scales.

Table 3 shows the correlation assessment of the subscale and total scores of HPLP-II and PSQI.

In terms of sociodemographic characteristics, no statistically significant difference was found between the total scores of HPLP II and PSQI ($p> 0.05$).

Table 1. *Sociodemographic Characteristics of Nurses Working in Pediatrics Clinics (N=121)*

		n	%
Education	High school	10	8.3
	Associate	5	4.1
	BSN	97	80.2
	MSN	9	7.4
Marital status	Married	33	27.3
	Single	88	72.7
Having children	Yes	8	6.6
	No	113	93.4
Working duration in the pediatric clinics	< 1 year	26	21.5
	1 – 5 years	86	71.1
	6 – 10 years	5	4.1
	11 – 15 years	4	3.3
Work unit	Medical	40	33.1
	Surgical	8	6.6
	Intensive care	39	32.2
	Emergency	24	19.8
	Hematology-Oncology	10	8.3
Liking the nursing profession	Yes	104	86.0
	No	17	14.0

Table 2. *Distribution of Health-Promoting Lifestyle Profile-II (HPLP-II), Pittsburg Sleep Quality Index (PSQI) subscale and total scores*

Scale	Subscale	Min – max	M ± Sd
HPLP-II	Health responsibility	11-32	21.60±3.68
	Physical activity	8-29	16.19±4.64
	Nutrition	9-31	19.57±4.19
	Spiritual growth	17-35	25.42±3.62
	Interpersonal relationships	16-35	24.77±3.64
	Stress management	10-30	17.71±3.74
	Total	88-178	125.26±16.40
PSQI	Subjective sleep quality	0-3	1.36±0.92
	Sleep latency	0-3	1.60±0.69
	Sleep duration	1-10	6.14±1.56
	Habitual sleeping efficiency	0-2	0.09±0.32
	Sleep disturbances	0-3	1.30±0.56
	Use of sleeping medication	0-3	1.64±0.75
	Daytime dysfunction	0-2	1.07±0.83
	Total	5-17	12.13±2.29

Table 3. *Relationship between Health-Promoting Lifestyle Profile-II (HPLP-II), Pittsburg Sleep Quality Index (PSQI) subscale and total scores*

PSQI	HPLP-II						
	Health responsibility	Physical activity	Nutrition	Spiritual growth	Interpersonal relationships	Stress management	Total
	r; p	r; p	r; p	r; p	r; p	r; p	r; p
Subjective sleep quality	-0.078; 0.397	-0.135; 0.140	-0.042; 0.646	-0.195; 0.032	-0.037; 0.683	-0.321; 0.001**	-0.191; 0.036*
Sleep latency	-0.087; 0.343	-0.026; 0.779	-0.019; 0.835	0.004; 0.964	-0.004; 0.968	-0.152; 0.097	-0.066; 0.471
Sleep duration	-0.067; 0.463	-0.081; 0.377	0.063; 0.489	0.026; 0.778	0.006; 0.951	0.145; 0.113	0.018; 0.843
Habitual sleeping efficiency	-0.147; 0.107	-0.154; 0.092	0.049; 0.597	-0.063; 0.494	0.062; 0.500	-0.210; 0.021*	-0.112; 0.220
Sleep disturbances	0.043; 0.640	-0.061; 0.508	0.180; 0.048	-0.025; 0.782	0.071; 0.438	-0.082; 0.369	0.030; 0.745
Use of sleeping medication	-0.206; 0.023*	-0.246; 0.007**	-0.295; 0.001**	-0.042; 0.644	-0.146; 0.109	-0.402; 0.001**	-0.325; 0.001**
Daytime dysfunction	-0.018; 0.842	-0.204; 0.025*	-0.156; 0.087	0.098; 0.284	0.112; 0.22	-0.234; 0.011*	-0.108; 0.236
Total	-0.181; 0.057	-0.234; 0.011*	-0.026; 0.780	-0.088; 0.335	-0.034; 0.708	-0.257; 0.004**	-0.199; 0.029*

*r: Pearson Correlation analysis, *p<0.05, **p<0.01*

4. DISCUSSION

In the present study, it was found that the nurses working in the pediatrics clinics had moderate level of health-promoting lifestyle behaviors. Similar to the present study, in the literature (9,22,23,30) it was reported that the health-promoting lifestyle behaviors of general nurses were at a moderate level. It is stated that the decrease in health-promoting lifestyle behaviors of the nurses affects not only them but also the care of nurses, and indirectly affects the quality of nursing services, and community health (31). It is reported that the nurses know the health-promoting lifestyle behaviors, but cannot put them into practice. Insufficient time or talent or not having a strong belief may be regarded among the reasons (32,33).

In the current study, the lowest health-promoting lifestyle behaviors of the nurses working in the pediatrics clinics were determined as exercise and stress management. When examining the results of the study and the studies in the literature conducted on general nurses (9,23), it is seen that the lowest health-promoting lifestyle behaviors are exercise and stress management. In a study, it was reported that the nurses did not have sufficient time for exercise due to their long shifts and long monthly working hours (9). The studies have revealed that the increase in the work stress of the nurses is related to the increasing depression and lower resiliency, job satisfaction, and decreased lifestyle behavior (34,35). The use of holistic approaches or mental health practices (applied awareness, cognitive training, praying, meditation, healing touch, yoga, massage, reiki, etc.) is associated withthe ability of the individual to see and care for himself as a whole and the relevant positive health effects (36,37,38).

In the current study, the highest health-promoting lifestyle behaviors of the nurses working in the pediatrics clinics were determined as self-actualization and interpersonal support. When examining the results of the study and the studies in the literature conducted on general nurses (22,23), it is seen that the highest health-promoting lifestyle behaviors are self-actualization and interpersonal relations. The founder of nursing, Florence Nightingale, stated in her theory that “the nurse should help the patient according to his/her vital needs and see this as the purpose of nursing” (39). The main role of nursing is care giving and the main purpose is to help the individuals and population, to find solutions for health problems, and acquire qualification for life. Moreover, profession of nursing sees human as the most valuable being and aims at providing the best quality service to humans by respecting for dignity, values, individuality, integrity, and decisions of human being (40,41).

In the present study, it was determined that the nurses working in the pediatrics clinics had poor sleep quality. In a study conducted on the nurses working in the pediatric and neonatal units, it was reported that the sleep quality of the nurses was poor (24). The same result has been also found in the studies conducted on general nurses (42,43,44,45,46). Changes in the sleeping habits of the nurses working in the shift system affect their sleep qualities and cause sleeping disorders by leading to difficulties in falling asleep (43,44). It is reported that insufficient sleep quality is correlated with drug use (47,48), occupational diseases, and work accidents (48). In a study, it was found that yoga enhanced the sleep quality and decreased the work stress (49).

In the present study, it was determined that there was a significant negative relationship the health-promoting lifestyle behaviors and sleep quality of the nurses working

at the pediatrics clinics. Wrong adjustment of the circadian rhythm due to the shift system causes awake-asleep disorders and affects the sleep quality (50). Poor sleep quality causes fatigue because it affects the decision making process of the nurse and therefore the patient safety and thus, it is a serious issue (51). Insufficient sleep among the nurses working in shifts is correlated with insufficient self-health (52). Thus, a good sleep quality is important to increase the health and work performances of the nurses (53).

The limitations of the study may be that the study was conducted within a certain time period, the other time periods are not known, it was conducted only in a single hospital, no other hospitals were included and the sample belonged to only one institution.

5. CONCLUSION

In the present study, it was found that the nurses working in the pediatrics clinics had moderate level of health-promoting lifestyle behaviors. Additionally, it was determined that the nurses working in the pediatrics clinics had poor sleep quality. Following applications can be recommended in order to improve health-promoting lifestyle behaviors and sleep quality of the nurses; training programs such as undergraduate, graduate, in-service for increasing such behaviors, certificate and/or course programs, regular shift schedules, regular and sufficient rest period, workplace environments providing better conditions, follow up of these behaviors by nurse managers, and formation of protocols supporting these behaviors.Also, studies examining the effect level of such practices on the health-promoting lifestyle behaviors and sleep quality of the nurses can also be conducted.

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Clinical and Experimental Health Sciences

Effect of Disposable Sheaths on the Vickers Microhardness of Resin Composites

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ABSTRACT

Objective: The aim of this study was to evaluate the effect of disposable sheaths on microhardness of resin composites.

Methods: A total of 40 resin composite specimens were fabricated with disc-shaped perspex molds (5x2 mm). Specimens were divided into 4 groups: Irradiated by 1-Elipar LCU (EL), 2-Elipar LCU with sheath (ELS), 3-Valo LCU (VL), 4-Valo LCU with sheath (VLS), (n=10). The specimens were subjected to surface microhardness (SMH) test (Tronic, Digital Microhardness Tester DHV-1000) on the top and bottom surfaces under 200 g load applied for 10 s with a Vickers indenter. The specimens were stored in the distilled water at 37 °C for 24 hours and the same measurements were repeated. One-way ANOVA test, Tukey and Tamhane post-hoc tests were used for intergroup comparisons. Also paired sample t-test was used for comparisons of the different time results.

Results: According to the 1st-hour data from the top and bottom SMH measurements, EL and VL groups have significantly higher microhardness values than VLS and ELS groups ($p<0.05$). There was a dependent change in the top surface measurements with the time ($p=0.000$), but also interaction with the LCU ($p=0.000$). All groups showed significant microhardness decrease from 1st to 24th-hour for both top and bottom values ($p<0.05$) except for top SMH of VLS group ($p=0.151$).

Conclusion: Disposable sheaths decreased the light output of the LCU's and caused reduction in the SMH. Although they are effective in preventing cross-infection, they significantly reduced the polymerization efficiency, thereby mechanical properties of resin composites.

Keywords: Dental Curing Lights, Hardness, Composite Resins

1. INTRODUCTION

Dental composites are the most commonly used materials in restorative dentistry. With the introduction of light-cured composites, polymerization quality has become the greatest concern of many researchers. Therefore, light-curing units (LCU) have been produced which enable the production of the appropriate amount of light required for efficient conversion of resin composites and to increase their physical and mechanical properties (1). There are four types of polymerization sources currently available; Quartz-tungsten-halogen light-curing units (QTH), plasma arc light devices (PAC), Argon-ion laser and light-emitting diode (LED) (2).

In light-cured composite resins, polymerization is initiated by a photoinitiator that absorbs photons (3). Polymerization occurs when the carbon double bonds in the monomer structure form polymer chains by turning into single bonds. Both physical and chemical properties of composites are directly related to the conversion of monomers into polymers. The greater amount of the polymer means greater resin hardness. Low conversion rates can affect almost every physical property, including resolution, dimensional stability, color change, biocompatibility and it plays an important role in determining the ultimate success of the restoration (4). Additionally, unreacted components may leak from the restoration and lead to cytotoxicity and also may cause microleakage, which can cause caries and pulpal irritation. The minimum light intensity required for proper polymerization is reported to be between 280 and 300 mW/cm^2 for 1.5 – 2 mm resin composite (5).

Many variables affect the amount of light absorbed on the top and bottom surfaces of the light-cured composite resin restorations, which can lead to failure of the polymerization. These are; the type of the LCU, diameter of the device tip, distance between the device tip and the restoration surface, power of light, duration of light application, thickness of the resin composite, composition and color of the material (6). Light output can be affected by low voltage, condition of the

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bulb and the filters, the accumulation of resin in the tip of the device and the breaking of the fiber-optic bundles on the LCU. Therefore, regular measurement with a radiometer should be performed.

The Center for Disease Control and Prevention (CDC) refers to tools and equipment that come in contact with the mucose membranes as "semi-critical" and recommends heat or vapor sterilization (7). LCU tips also fall into the "semi-critical" instrument category. Therefore; to protect patients and staff when using LCU, high levels of infection control is needed to be performed. Studies have shown that there may be cross-infection during the use of light devices (8,9). Various infection control methods are available for the tips of the light devices, including; disinfectant wipes, autoclavable tips, pre-sterilized disposable plastic sheaths.

The LCU tips can be autoclaved for sterilization, but the procedure can reduce the light output of the device. It was observed that the light intensity of the device could be reduced to 50% of the original value after 3 times autoclaving of the tip (10,11). If the LCU tips are polished after autoclaving, the light intensity may return to its original value (12). Although polishing can restore light transmission, autoclaving and polishing the tip take time.

Disinfectant solutions such as ethyl alcohol, glutaraldehyde, hypochlorite solutions, iodine-containing solvents, and benzalkonium chloride can be used to clean the LCU tips (6). Some studies have shown that glutaraldehyde-based solutions can reduce light transmission or damage the fiber in the LCU. Also, cold sterilization can be an effective infection control method but requires substantially longer treatment times (10 hours) than autoclaving (13).

Disposable sheaths are a cost-effective method to prevent contamination of the LCU tip. The usage of the plastic sheaths is a non-invasive technique and prevent contact between the oral tissues and the tip. It also eliminates the risk of damage caused by autoclaving or disinfection methods (14). However, several studies have reported that the usage of disposable sheaths significantly reduces the light intensity (10,15). As mentioned before, polymerization quality of the dental composite materials means better physical properties such as high wear resistance or microhardness. Hardness measurement is commonly used to assess the polymerization of composites and consequently the efficiency of the light source (16).

The null hypotheses tested were that (1) there would be no significant difference between the microhardness of polymerized composites when two different LED LCU's were used as uncovered or with a disposable plastic sheath, (2) the surface microhardness (SMH) at the bottom surface of the samples would show lower values than the top surface and (3) after 24 hours, SMH values of all groups would be significantly increased.

2. METHODS

The light-cured resin composite used in the present study was Clearfil Majesty Esthetic, shade A2 (Kuraray Medical Inc., Tokyo, Japan). The total inorganic filler ratio of this nano-hybrid composite is about 40% by volume and the particle size of the inorganic fillers ranges from 0.37 µm to 1.5 µm. The composition and application procedure of the material were presented in Table 1.

Table 1. *The composite material used in the study.*

Material (Manufacturer)	Composition	Application Procedure	Lot No.
Clearfil Majesty Esthetic (Kuraray Medical Inc., Tokyo, Japan)	Silanated barium glass filler (40% by volume) Pre-polymerized organic filler Bis-GMA* Hydrophobic aromatic dimethacrylate di-Camphorquinone	Apply in 1-2 mm increments and light cure for 20 s.	4H0158

**Bis-GMA; Bisphenol A-glycidyl methacrylate*

In this study, two different LED light devices were used; Elipar ™ DeepCure-S (3M ESPE, St. Paul, MN, USA) and Valo LED (Ultradent Products Inc., South Jordan, UT, USA), (Table 2).

Table 2. *Light curing units used in the study.*

Light Curing Unit (Manufacturer)	Curing Mode	Light Intensity	Emission Spectrum (nm)	Stated Tip Diameter (mm)
Elipar™ DeepCure-S (3M ESPE, St, Paul, MN, USA)	Standard Power	1.470 mW/cm^2 (−10%/+20%)	430–480 nm	10
Valo LED (Ultradent Products Inc, South Jordan, UT, USA)	Standard Power	1.000 mW/cm^2 (±10%)	395–480 nm	12

The molds allow a series of resin composite discs to be produced (5mm diameter x 2mm thickness) that were constructed from perspex. These molds were placed on a flat glass surface and a mylar strip was placed underneath to prevent the resin composite from adhering to the surface.

The resin composite was packed into the mold according to manufacturer's instruction and covered with the mylar strip again to prevent the formation of oxygen inhibition layer in the top layer and then gently pressed with a glass plate to extrude excess material. The light-curing for 20 s performed according to four groups: 1 – Irradiated by Elipar LCU (EL), 2 – Irradiated by Elipar LCU with sheath (ELS), 3 – Irradiated by Valo LCU (VL), 4 – Irradiated by Valo LCU with sheath (VLS), (n=10 per group).

The disposable sheath used at the second and fourth groups was the disposable hygienic barrier that is available for sale

with the Valo LED light device. The LCU's tip was positioned in an additional plexiglass jig to standardize the distance and ensure that the tip was directly in the nearest alignment to the top surface of the sample. After polymerization, upper surfaces are marked with an indelible marker pen.

During the use of the LCU's, the power output is measured with a radiometer (SDI LED Radiometer, SDI, Germany) to provide standardization. Also, the Elipar LCU has a test area built into the charger, enables control of the light intensity output. Before each cure, the light intensity output was checked to ensure maximum output. The sheaths were the single-patient use and replaced after each use. While the sheath was placed, it was pulled tight over the tip to ensure that no air was trapped.

The hardness of the specimen was measured at the Vickers hardness tester (Tronic, Digital Microhardness Tester DHV-1000) without delay. Each specimen (n=10) was tested on the top and bottom surfaces under a 200 g load applied for 10 s. Six measurements were recorded on both sides of each sample and averaged for the statistical analysis. The specimens were stored in the distilled water at 37°C for 24 hours and the same measurements were repeated.

Statistical Analysis

The results of microhardness were analyzed by using statistical software, SPSS 22.0 (SPSS Inc., Chicago, IL, USA). The normality of the distributions was confirmed by skewness, kurtosis, and the Kolmogorov-Smirnov test. Besides the descriptive statistics, One-way ANOVA test, Tukey and Tamhane post-hoc tests were used for intergroup comparisons. Also paired sample t-test was used for intragroup comparisons of the different time results. All results were considered significant at $p<0.05$.

3. RESULTS

The average top and bottom surfaces SMH values of the samples at the 1st and 24th hours were shown in Table 3. According to the Box's M table, the matrices of covariances were equal (p=0.447).

Table 3. *The average top and bottom SMH values of samples at the 1st and 24th hours.*

	1st h Top SMH	1st h Bottom SMH	24th h Top SMH	24th h Bottom SMH
EL	30.56±1.2 [a]	23.53±1.0 [a]	27.67±0.5 [a]	22.27±0.6 [a]
ELS	26.94±0.6 [b]	22.03±0.6 [b]	25.31±0.5 [b]	21.42±0.4 [b]
VL	31.52±0.8 [a]	23.28±0.8 [a]	30.12±0.7 [c]	21.62±0.4 [b]
VLS	28.76±0.6 [c]	21.22±0.7 [b]	29.16±0.6 [d]	20.39±0.5 [c]

Different capital letters in the table represent significant differences between groups (columns), (p<0.05).

In the 1st-hour top surface measurements, the highest and lowest SMH values were obtained with the VL and ELS groups, respectively. There was a dependent change in the top surface measurements with the time (p=0.000), but also interaction with the LCU (p=0.000). According to the 1st-hour data from the top SMH measurements, EL and VL groups presented significantly higher microhardness values than VLS group which also had higher microhardness than ELS group (Table 3).

In the 1st-hour bottom surface measurements, the highest and lowest SMH values were obtained with the EL and VLS groups, respectively. The values of the bottom surface microhardness were decreased with the time (p=0.000) and there was no group interaction due to LCU (p=0.103), (Table 4). EL and VL groups had significantly higher microhardness values than VLS and ELS groups for the bottom SMH measurements (p=0.000).

Table 4. *The average percentage of SMH difference between the 1st and 24th hour measurements for the top and bottom surfaces of samples.*

Groups	1st to 24th h Top SMH Difference (%)	1st to 24th h Bottom SMH difference (%)
EL	%9.3±3.7 [a]	%5.2±5.7 [a]
ELS	%6.0±2.9 [ab]	%2.7±2.5 [a]
VL	%4.4±2.9 [b]	%7.0±3.9 [a]
VLS	%1.4±2.9 [c]	%3.8±4.1 [a]

Different capital letters in the table represent significant differences between groups(columns), (p<0.05).

The average percentage of SMH difference between the top and bottom measurements of the samples at the 1st and 24th-hours were shown in Table 5. For the 1st hour, data percentage of SMH difference between the top and bottom measurements was significantly higher for both Valo groups than ELS group. EL group had a high standard deviation and didn't have a significant difference from other groups (p>0.05).

Table 5. *The average percentage of SMH difference between top and bottom measurements of the samples at the 1st and 24th hours.*

Groups	1st h Top-Bottom SMH Difference (%)	24th h Top-Bottom SMH Difference (%)
EL	%22.9±4.2 [a]	%19.5±2.9 [a]
ELS	%18.2±2.7 [ab]	%15.3±2.6 [b]
VL	%26.1±2.4 [ac]	%28.2±1.9 [c]
VLS	%26.2±1.4 [ac]	%30.0±2.3 [c]

Different capital letters in the table represent significant differences between groups (columns), (p<0.05).

According to the 24th-hour data from the top SMH measurements, all groups had significant differences from each other. VL group had the highest microhardness values which is followed by VLS, EL and ELS groups, respectively. According to the bottom SMH measurements at the 24th-hour, EL group had a significantly higher microhardness values than the other groups. ELS and VL groups showed similar results and also both had significantly higher values than VLS group (Table 3). For the 24th-hour data percentage of SMH difference between the top and bottom measurements was

significantly higher for both Valo LCU groups than the both Elipar LCU groups. EL group also had a higher percentage of SMH difference than ELS group (Table 5).

The average percentage of SMH difference between the 1st and 24th-hours measurements for the top and bottom surfaces of samples was shown in Table 4. All groups showed significant microhardness decrease from 1st to 24th-hour for both top and bottom values ($p<0.05$) except for top SMH of VLS group which didn't show any significant change between 1st and 24th hours ($p=0.151$). For the top measurements, 1st to 24th-hour difference percentage was significantly higher for EL group than both Valo LCU groups. ELS and VL groups showed similar results which were significantly higher than VLS group. For the bottom measurements, percentage of SMH difference between 1st and 24th-hours was similar for all groups.

4.DISCUSSION

There are several methods for measuring the degree of conversion of monomers into polymers in the resin composites. These are direct methods such as Laser Raman spectroscopy, Infrared spectroscopy, electron resonance, Fourier Transform Infrared (FTIR) spectroscopy, and indirect methods like scraping and surface hardness test (14). Although the direct microhardness measurement methods are quite time-consuming, difficult and expensive (17), they are the methods that frequently referenced to determine the conversion rates and depth of cure in dental composites, to evaluate the surface hardness and consequently to examine the efficiency of the light source.

Knoop and Vickers are the most commonly used hardness measurement tests. Even though the Knoop hardness test is more frequently used for the evaluation of polymeric materials, such as resin composites because it minimizes the plastic recovery effect (18), several studies have indicated that there is no significant difference between both Knoop and Vickers values (19). Also, the Vickers hardness test which was used at the present study is often preferred because it can predict the degree of polymerization of the resin composites (20).

A square-base diamond pyramid with a 136˚ angle between opposite faces is used as the indenter in the Vickers microhardness test (21). In this method, the Vickers hardness values are obtained by measuring the length of the diamond indenter formed on the material under a given load. In micro-hardness tests, the magnitude of the load has a significant impact on the results. It should be in the range of 1 gf to 1 kgf, commonly 100–500 gf. Indentation with higher load penetrates deeper into the composite, reaches the harder layer and therefore measures greater hardness values (22). The load and duration of the Vickers test have not yet been standardized. Different values were used in various studies. In the present study, the most frequently encountered value of 100 gf and the residence time of 10 s was applied.

There can be significant changes in the values obtained by the penetration of the intender on the resin matrix or the filler particle during application. Therefore, it is recommended not to take extremely high values into account because they may affect the result (23). Also, when determining the hardness values, at least three measurements should be made from a surface and the average of these values should be taken as a basis.

The studies showed that the content of composite resins, the structure of the resin matrix, the volume and the ratio of inorganic fillers and shade may affect the hardness values of the material (2, 24). Resins containing high fillers show high hardness values. Since the effect of the hygienic sheath on polymerization was measured in this study, the same resin composite was used to avoid the differences due to the material.

The standard incremental placement of the resin composite is 2 mm, if the increment placed was slightly over 2 mm, it may lead to incomplete polymerization of the resin and thus poorer mechanical performance (25). Pollington et al. stated that there were no significant differences between the depth of cure of resin composite cured at 0-2 mm. However, as the thickness progressed from 3 mm to 5 mm, they noted a significant reduction in hardness values (14). For this reason, the molds were produced with a height of 2 mm according to the manufacturer's instructions for each layer.

If the wavelength of light from the LCU is significantly affected when a sheath is used, the composite can not be fully polymerized. It is reported that the hygienic barrier can reduce the light output by 5-10% in the Valo manual. On the other hand, studies have shown that light intensity can be reduced by up to 35% when some plastic sheaths were used (11, 12, 14). Similarly, according to the result of the present study, the usage of the hygienic sheaths reduced the light output of two LCU's, thereby microhardness of the samples. This is thought to be since the protective sheaths reduce the light output power of the light device (26). Thus, the first null hypothesis was rejected. These findings were consistent with the studies of Warren et al. and Scott et al. (7, 12). However, McAndrew et al. (26). were reported that infection control barriers do not significantly reduce power output. Likewise, Pollington et al. were observed no significant difference with or without the use of the sheath. They also reported that the use of the sheaths provided an acceptable depth of cure when used with the 2 mm increment rule. It was not until 3 mm that the use of sheaths compromised the performance of the resin composite (14).

When the Valo LCU was used without the sheath, the highest surface hardness results were obtained on the top surface. Even though Elipar LCU had a higher light intensity, on the top surface highest microhardness values withouth sheath were obtained with Valo LCU. This result can be attributed to the unique tip design, beam collimation and uniformity of Valo LCU. Considering the surface microhardness values, there was a significant difference between LCU's, and this

proves that the type of the LCU can affect the microhardness values (4).

As a result of the present study, higher microhardness values were obtained on the top surfaces than the bottom surfaces (Table 3), as in the previous studies (2,23). The second hypothesis was accepted. This is explained by the fact that the light passes through the mass of the restorative material, its density decreases greatly, and therefore reduces its curing potential (4). Also, filler content and particle size of the material play an important role in the degree of polymerization at the bottom surface (27,28).

When the measurements on the top surfaces at the 1st and 24th hours were compared, it was observed that there was a statistically significant difference in time in all groups except VLS group. On the bottom surface, there was a significant difference between the 1st and 24th hours measurements of all groups. Considering these results, it was determined that the microhardness of the samples with storage in 37˚C distilled water decreased. As known, approximately 75% of the polymerization takes place in the first 10 minutes after the initiation of light polymerization and continues after 24 hours (29). Many studies have shown that the dry storage of the composite resin samples can cause an increase in SMH values in time as an effect of continuous polymerization (30-32), however dry storage can not simulate the oral environment. The decrease in SMH in lower surface might be caused by water solubility of resin composites especially during the first 24 hours after curing (33,34). Thereby, the third null hypothesis was rejected.

The SMH values of the present study can not be compared with literature because of the limited studies about hygienic sheaths. These studies focused on either the light output of LCU's or degree of conversion at the different thickness and none of them considered changes by the time (7,12,14,26).

Chong et al. reported significant differences in light intensity output when different barriers were used. However, all their recorded values remained above the threshold (300 W/m^2) required for adequate curing of the composite resins. Additionally, they considered a plastic glove and cellophane to be the best methods for prevention of contamination, as they allowed for the highest light intensity output (6).

According to the results of a study comparing the methods of various disposable barriers, transparent sheaths and cling film do not cause a significant change in the light power, while gloves and opaque barriers reduce light output by up to 71%, leading to a decrease in polymerization efficiency (26).

Price et al. reported that the distance from the tip of the LCU to the composite resin had a much greater impact on the power density than the disposable barriers. They reported that a distance of 1 mm between the tip and the composite could cause a reduction in power density between 8% and 16% (35). Also, Aravamudhan et al. showed that the distance between the tip and the resin composite will influence the recorded degree of conversion (36). Therefore, to prevent the effects of the distance, all the samples were polymerized at the same distance. The minimum distance between the tip and the composite resin was ensured by using a plexiglass jig.

The sterility and correct use of sheaths should be considered during treatment. Avoiding contact of the sheath surroundings and being coated by resin adhesives which may influence polymerization before use are important. Often, the sheaths are not placed correctly on the tip and the air may be trapped in, which causes the light-curing tip to be more distant from the restoration and consequently decrease the curing efficiency.

Polymerization is one of the major concerns of restorative dentistry and can be affected by the thickness and type of composite material, infection control method and LCU. Therefore, further studies are needed to determine the relationship between the infection control methods and the polymerization efficiency of the LCU.

5. CONCLUSION

In the present study, it was observed that the plastic sheaths decreased the light output of the LCU's and caused a decrease in the SMH of the composite. Although the plastic sheaths were successful in infection control and preventing physical damage to the tips of the LCU's, they significantly reduced the polymerization efficiency.

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Clinical and Experimental Health Sciences

Self-Efficacy and Its Association with Locus of Control in Diabetes in Turkey

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ABSTRACT

Objective: This descriptive-relational study was conducted to determine self-efficacy levels of individuals with type 2 diabetes, relationship between these levels both some sociodemographic characteristics and health locus of control.

Methods: The sample of this study was occurred 325 patients with diabetes who applied to the health care center constituted. Data were collected via 'Questionnaire Form', 'Self-efficacy in Diabetes Scale' and 'Multidimensional Health Locus of Control Scale'.

Results: The average age of participants was 53.3±8 years, 51.4% of participants were women. It was found that the diagnosis time 8.7±7.2 years, the level of HbA1c was 8.2±1.1. In the sub dimensions of Diabetes Self-efficacy Scale, the patients got points as follows; sub dimension of Diet+Foot Control 39.4±12.5, sub dimension of Medical Treatment 22.6±3,1, sub dimension of Physical Exercise 9.0±4.5. It was determined that in Multidimensional Health Locus of Control Scale, the patients got the highest points from the sub dimension of Powerful Others Locus of Control. A positive but weak level relation was determined between self-efficacy both total and subdimensions grades dimensions of health locus of control scale ($p<0.05$). According to mulltiple regression analysis, variables in the model were the age range of 30-40 years, not exercising, not obeying the diabetes regimen has been detected.

Conclusion: It is seen that patients with DM have medium level of self-efficacy and tend to believe the effects of external forces at a higher rate in the management of the disease.

Keywords: Health locus of control, nursing, self-efficacy, type 2 diabetes

1. INTRODUCTION

It is important for diabetic population to acquire positive health behaviors by arranging their life style, as diabetes mellitus (DM) is a chronic disorder affecting all aspects of life. Described as individuals' believing themselves, self-efficacy is a determinant so as to develop and maintain positive health behaviors and a significant factor defining how individuals feel, consider and behave (1-3). One of the concepts accounting for different behaviors individuals exhibit for DM, the locus of control is the perception explaining that positive or negative events affecting individual health status occur as a result of the behaviors or with the effect of external forces such as chance or accidents (4, 5). While those perceiving the consequences of events as an extension of their direct behaviors are described as "internally controlled individuals", others believing that the consequences are independent of their own behaviors, and that the control are due to other factors out of their own are described as "internally controlled". Internally controlled individuals consider that the control of the events encountered and consequences is in their hands, and tend to take the responsibility of their own health and to display positive health behaviors in order to maintain and develop a healthy life style. Externally controlled individuals, however, seek the consequences of the events they face in the forces out of their domain. Such individuals do not wish to take responsibilities due to the factors, such as the sensivity to psychological problems and the association between satisfaction, and social and environmental conditions, and consider their health status is dependent on fate and chance (5-8).

In the nursing management of chronic disorders such as DM, such indicators as health control focus are important to be evaluated to develop patients' self-efficacy. In studies investigating the effects of health control focuses on DM, the rates of regular diet and exercises, HbA1c values, self-efficacy levels and self-care behaviors were observed to be affected positively, when internal control focus increased (9-12).

Given that health control focus is the determinant of patients' behaviors, and self-efficacy is also an important component of maintaining these behaviors, nurses' determination of health control focus and self-efficacy levels of patients plays a part in individualized health care. Because the number of studies assessing both of these variables is limited, the

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present study was designed and performed to determine the levels of health control focus and self-efficacy in patients with type 2 DM.

1.1. Study Questions

1. What are the self-efficacy levels of patients with type 2 DM?
2. Is there an asscіation between health control focuses and self-efficacy levels of type 2 diabetic individuals'?
3. What are the determinants of the self-efficacy level of diabetes patients?

2. METHODS

2.1. Study Type

The present study was designed and performed as a descriptive-relational type of research.

2.2. Study Setting and Features

The study was performed in three health care centers in three counties in the city centre, for the samples include and represent all regions in the province of Konya/Turkey (Konya is a region in Central Anatolia in Turkey). The reasons why health care centers were chosen were associated with the following: the wish to evaluate patients with type 2 DM in settings where they live, lack of factors to affect directly the health control focus and self-efficacy levels of type 2 DM patients and others such as access to health facilities and performing diabetic treatment regularly in medical settings.

2.3. Sample Size

The samples participating in the study were composed of diabetic population registered to the automation system of The Turkish Ministry of Health in 2015. While detecting the number of samples, the sample size was defined as 325 with the acceptance of 95% confident interval (CI), 0.05 as significance and 0.10 as the effect of anticipation (13). Inclusion criteria for the study were; (i) to have diagnosis of type 2 DM at least fort he last six months, (ii) to be between the ages of 18-65, (iii) to be graduation at least from a primary school. Those with the history of a diagnosed psychiatric disorder and communication problems due to different native languages were excluded out of the study.

2.4. Tools and Methods for Data Collection

The questionnaire was prepared by the researchers in light of literature (14-16). Developed by Van Der Bijl et al. (17), the Self-Efficacy Scale (SES) consisting of four subdimensions and 20 items was also used. In Turkish version of SES, the validity and reliability of which were developed by Kara et al. (18), three subscales were put into the scale. The Cronbach's alpha value was found as 0.89 for the scale. In our study, the Cronbach's alpha value was found as 0.91.

Developed by Wallston et al. (19) and with 18 items and three subscales, the Multidimensional Health Locus of Control Scale (MHCL), including the control focuses of internal health, powerful others and chance, was used as the second scale in the study (19, 20). The relaibility and validity of Turkish version were implemented by Ustundag and Budak. The in-consistency coefficient of MHCL was found as 0.63. The Cronbach alpha was calculates as 0.61 in our study.

2.5. Data Collection

In collecting data, patients with DM were informed about the design of the study by practitioners in the centers, and all patients with DM were consecutively included into the study by starting from the first patient. On reaching the targeted number in the calculation of the sampling, data collection was discontinued. Due to including human participants, the study was reviewed by the local ethics committee and performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments, Informed consent was also obtained from all participants prior to their inclusion into the study.

2.6. Variables

Dependent Variables : Total score of self-efficacy

Independent Variables : *Sociodemographic Characteristics* (Age, gender, marital status, educational status, profession, perception of economic status, individual cohabited, number of family members) *and Health/Disease Characteristics* (Body mass indeks-BMI, Use of alcohol and cigarette smoking, diagnostic time of DM, level of HbA1c, History of DM in family, training for DM, status of considdering sufficient training, status of regular health controls/follow-ups, type of diabetic treatment, status of regular drug use, status of regular exercise, compliance with regular diabetic dieting, subdimension scores of MHLCS)

2.7. Data Analysis

For statistical analysis of the data, a licensed SPSS 22 (IBM SPSS Inc, USA) package program was used. Data are summarized as number, percentage, mean, standard deviation. The suitability of normal distribution was determined by Kolmogorov-Smirnov test. Independent groups used t-test, pearson corelation and one-way analysis of variance. Tukey HSD test was used to search for variance. The relationship between self-efficacy and Health Control Center was assessed by pearson correlation analysis. Multiple regression analysis-Backward model was used to determine the self-efficacy determinants. The following assumptions were taken into account while applying the multiple regression model: (i)linear relationship (ii)multivariate normality (iii)no multicollinearity (iv)homoscedasticity. Significance was evaluated as $p < 0.05$.

2.8. Ethics

Approvals for this study were received from Selçuk University Health Sciences Faculty, Non-Interventional Clinical Researches Ethics Committee Decision no 2015/31 and

Konya Public Health Directorate no 86104336/600. Written informed consent was obtained from each of the participate.

3. RESULTS

Of the patients with type 2 DM in the study, mean age was found as 53.3±8.0, and 51.4% were women, 88.9% were married, and 43.8% were housewives. While 63.4% of the study participants reported the perceived economic status as moderate, 58.9% declared that they lived with partners and children, and mean number of family members was found to be 3.76±1.8. It was observed that mean body mass index (BMI) of the study participants was 30.1±4.8 kg/m2, 76.9% were composed of non-users of tobacco, mean duration of cigarette smoking was 15.5±7.9 years in users, 98.5% were non-users of alcoholic drinks, mean duration of using alcohol was as 12.6±4.8 years among alcohol users, 52.6% had no exerciseon a regular basis, 66.5% did not comply with diabetic dieting, and 80.9% were regularly followed-up as to health controls. Among the study participants, it was also determined that mean duration of diagnosis of DM was 8.7±7.2 years, while the level of HbA1c was detected as 8.2±1.1, 54.2% had no familial history of DM, 87.7% were trained as to DM, and 76.8% had diabetic training at sufficient level. Of the patients with DM, 69.2% were found to absorb only oral antidiabetic drugs, while 88% were detected to take in drugs regularly (Table 1).

Table 1. *Baseline characteristics in the participants*

	Mean±SD	
Age	53.3±8.0	
Body mass index	30.1±4.8 kg/m^2	
	Number	**%**
Gender		
Female	167	51.4
Male	158	48.6
Marital status		
Married	289	88.9
Single	36	11.1
Perceived economic status		
Bad	41	12.6
Average	206	63.4
Good	78	24.0
Status of regular exercise		
Yes	79	24.3
No	171	52.6
Sometimes	75	23.1
Status of compliance with regular diabetic dieting		
Yes	216	66.5
No	109	33.5
Status of regular health controls		
Yes	263	80.9
No	62	19.1
Status of training for DM		
Yes	285	87.7
No	40	12.3
Total	**325**	**100.0**

It's found that total score of self-efficacy scale is 71.1±16.8, score of diet+foot control subdimension is 39.4±12.5, score of medical treatment subdimension is 22.6±3.1 and score of physical exercises subdimension is 9.0±4.5. From the Multidimensional Health Locus of Control Scale, it's determined that score of internal health control focus is 25.3±6.8, score of powerful others health control is 27.3±4.7 and score of chance control focus is 17.9±5.5. The scores of the scales are presented in Table 2.

Table 2. *The distribution scores from the subscales of the self-efficacy and multidimensional health locus of control scales*

	Mean±SD	Median	Minimum	Maximum
Self-efficacy Scale				
Diet+Foot Control	39.4±12.5	43.0	12	60
Medical Treatment	22.6±3.1	25.0	5	25
Physical Exercises	9.0±4.5	10.0	3	15
Total	71.1±16.8	75.0	20	100
Multidimensional Health Locus of Control Scale				
Internal Health Control Focus	25.3±6.8	27.0	6	36
Powerful Others Health Control Focus	27.3±4.7	27.0	6	36
Chance Control Focus	17.9±5.5	27.0	6	36

When the association between subscale of diet+foot control of SES and health control focus scale was investigated, it was seen that internal health control and powerful others control focuses displayed a significant association, but there was no association between chance control focus and subscale of diet+foot control. It was observed that as the scores of internal health control and powerful others focuses increased, the score of diet+foot control increased and affected the internal health control focus weakly, while affecting the powerful others focus too weakly. However, as to the medical treatment subscale, a positive and too weak association was seen to be present only in powerful others focus. Also, in the physical exercise subscale, a positive and weak association was found with all the subscales of health control focus scale. Likewise, except for self-efficacy total score and the chance subscale of health control scale, an association at positive and weak level was observed with the other two subscales ($p<0.05$). Association with the self-efficacy scale and health locus of control are presented in Table 3. In order to evaluate the effect of the independent variables, multiple regression analysis was used in all variables which affecting the total self-efficacy scale score were included in the analysis and it is presented in Table 4. According to analysis by Backward method, the most recent variables in the model were the age range of 30-40 years ($p=0.008$), not exercising ($p=0.009$), not obeying the diabetes regimen ($p=0.000$) has been detected.

Table 3. *Association with the self-efficacy scale and health locus of control*

	Diet+Foot Control	Medical Treatment	Physical Exercises	Total
Internal Health Control Focus	r=0.351 **p<0.001**	r=0.100 p=0.072	r =0.394 **p<0.001**	r=0.386 **p<0.001**
Powerful Others Control Focus	r=0.202 **p<0.001**	r=0.177 **p=0.001**	r=0.305 **p<0.001**	r=0.265 **p<0.001**
Chance Control Focus	r=0-.028 p=0.615	r=-0.065 p=0.244	r=0.265 **p<0.001**	r=0.038 p=0.494

Table 4. *Self-efficacy determinants of individuals with type 2 diabetes (Multiple regression analysis-Backward model)*

Determinant Factors	Beta	t	p
Age (30-40 ages=1)	-0.125	-2.705	0.008
Exercise (No=1)	-0.129	-2.630	0.009
Adherence to diabetic regimen (No=1)	-0.739	-15.144	<0.001
Perceived efficency of training (insufficient=1)	-0.121	-2.625	0.010
F=80.422 p<0.001	**R=0.823**	**R_{Square}**	**=0.678**

4. DISCUSSION

Patients' total score of self-efficacy was determined as 71.1±16.8. Previous studies were mostly evaluated in terms of self-efficacy total score, and the score was seen to range between 52-74 (21-23). Based on these findings, it may be suggested that diabetic population has moderate level of self-efficacy. It was seen that the lowest subscale score the participants received in our study was related to physical exercise, and the finding was cosistent with that found in the study by Al-Khawaldeh et al. in 2012 (22). We consider that individuals receive lower scores from physical exercise subscale, because physical exercises require behavioral changes and extra time, and due to obesity and other disorders associated with advanced age such as respiratory diseases or osteoarthritis. In terms of MHCL scores of the participants, it seems that individuals with DM tend to believe in the effects of external forces more in the disease management. In other studies, the internal control, the powerful others control and the chance control focuses were found as 27.2±6.3, 30.8±5.2 and 15.6±6.6 in the study performed by Al Nawafa'h and Hamdan-Mansour (21) as 26.0±4.2, 24.9±4.6 and 20.9±5.9 in the study by Aflakseir and ZarrinPour (24), as 25.9±5.6, 23.7±5.6 and 17.4±5.9 in the study by Williams et al. (25), and 27.9±6.3, 18.9±6.6 and 25.3±5.6 in the study conducted by Zahednezhad et al. (26), respectively. In various studies, it was observed that the internal control and powerful others control focuses were higher in the individuals with DM (9, 27). However, no studies related to the control perception of the patients with DM have been encountered in Turkey. The fact that the scores of internal control focus are close to those obtained from the powerful others control focus can be referred to higher rate of disease perception in patients. Individuals may also need others' assistance because the disease lead to complications and due to the chronic nature of the disease. This may also give rise to an increase in powerful others control focus. In addition, the fact that the priorities of the powerful others control and internal control focuses are variable in previous studies is considered to originate from educational and socio-cultural differences.

Given that the health control focus is the determinant of health behaviors (16, 26, 28, 29), the determination of health control focuses is of an importance in order to define self-efficacy in patients with type 2 DM. When the association between internal health focus and self-efficacy was investigated, as the score of internal control focus increased, the scores of diet+foot control, physical exercise and total self-efficacy were observed to be also increased. It is accepted that individuals with internal control focus believe their coping strategies against any negative events (29). The internal control focus was found to have a positive significance with mean score of self-efficacy (9). It may be suggested that the patients with higher rates of internal control focus comply with treatment modalities and believe their own strengths to cope with health challenges at a higher rate (26, 30). Despite the study reporting that those with higher rates of internal control focus care about their health status more (10), another study emphasizes that the internal control focus has no effects on the compliance with diet (24). It is also reported that the internal control focus is associated with age (28), economical status (28, 31, 32), physical and mental health status, and health behaviors (33). The fact that individuals with higher rates of internal control focus consider their problems encountered in daily life originate from their own features and strive to cope with these problems may increase such individuals' motivation, and the increase is one of the reasons demonstrating the association between self-efficacy and internal control focus.

In addition, we consider that the reason why the score of internal control focus in study participants was not so high is associated with lower rates of mean age and educational level. The fact that no significance was present in the medical treatment subscale may be explained by patients' adherence to drug regime and the inexistance of forceful behaviors in medical treatment. When the association between the powerful others control focus and self-efficacy was investigated, a significant difference was found to be present in all subscales. In the chance control focus, however, the difference was observed only in physical exercise subscale.

The patients in the study group are seen to increase the score of self-efficacy with the effects of external factors, such as family, friends or health professionals. In a study where the control perceptions of nurses and patients were compared, nurses and patients are seen to have higher rates of external control focus (21). In another study performed by Aflakseir and Zarrin Pour (2014) it was observed that while the individuals with external control focus had higher adherence to diet, those with chance control focus had lower adherence (24). In a study performed by Grotz et al. (2011) in German population, it was found that the elderly, those from lower socio-economic levels and emigrants had higher rates of

powerful others control and chance control focuses (34). It was also reported in the same study that chance health focus was less related to health behaviors, such as physical activity, dental health or regular hospital visits.

Because individuals with external control and chance control focuses consider that all their failures are out of their own control, the rate of such individuals' motivation may be suggested to be lower. In addition, the socio-cultural environment including individuals with higher religious attitudes or faith also affects almost all types of control focuses (6). It should be kept in mind that patients with more fatalistic attitudes and approaches to health challenges are treated as a risk factor in terms of health behaviors, and chance may have some indirect effects on health behaviors.

Multiple regression analysis suggests that being ages between 30 and 40 years (β 0.125), not doing exercise (β= – 0.129), not obeying the diabetes regimen (β =-0.739) and perceived insufficient diabetes training (β =-0.121) are determinants of the self-efficacy score. Other variables that were found to be significant in analyses were not identified as determinants. There are studies reporting that self-efficacy is related to age (35, 36), exercise (23, 37, 38), compliance with the diabetes diet (37) and training (3, 39, 40) in the literature.

5. CONCLUSIONS

It is seen that patients with DM have medium level of self-efficacy and tend to believe the effects of external forces at a higher rate in the management of the disease. Based on these findings, control focuses of diabetic population should be defined meticulously, and the internal control focus should be improved to obtain their independency. Due to the limited sample size of our study, it is recommended to conduct studies with a larger sample size.

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Clinical and Experimental Health Sciences

Pain Management and Life Satisfaction in Elderly Individuals: A Single Centred Study

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ABSTRACT

Objective: This study was conducted to find out the pain management status and life satisfaction of elderly individuals living in a nursing home and to determine the relationship between these.

Methods: This descriptive cross-sectional study was conducted in a nursing home in Turkey in November 2019. The data were collected by the researchers with face-to-face interview technique by using "Personal Information Form", "Geriatric Pain Measure (GPM)", "Pain Management Inventory (PMI)" and "Life Satisfaction Scale (LSS)".

Results: GPM total score was 48.95±11.24, and average LSS was 14.37±6.85. There is a positive statistically significant association between GPM and PMI (r=0.385; p<0.01), while there is a negative statistically significant association between GPM and LSS (r=-0.369; p<0.01). There is a negative statistically significant association between PMI and LSS (r=-0.344; p<0.01).

Conclusion: It was found that elderly individuals had moderate level of pain and poor life satisfaction. It was found that as level of pain increased, elderly individuals' life satisfaction decreased.

Keywords: Pain, Life Satisfaction, Elderly Nursing Home.

1. INTRODUCTION

Aging is the irreversible functional change in the organism with the passing of time. With this change, physical and cognitive functions regress and the individual's potential to balance between systems decrease (1, 2). As in the whole world, the elderly population is increasing gradually in Turkey. In Turkey, the rate of 65 years and older population which was 4.3% in 1990 consensus increased to 8.8% in 2018. In 2040, it is estimated that the rate of 65 years and older population will reach 16.3% (3).

Pain is an important health problem (4) which negatively affects the lives of elderly individuals, especially those staying in nursing homes (5,6). Musculoskeletal system problems, neuropathies, cardiovascular diseases and other chronic situations are considered as the most common causes of pain in elderly individuals (6, 7). General pain prevalence in the elderly has been reported to be between 50% and 67% (8-10). This rate has been reported to differ between 3.7% and 79.5% in individuals living in nursing homes (6).

American Pain Association used the expression "pain: fifth sign of life" to emphasize the importance of pain and to increase the awareness of health professionals about pain control (11). Effective pain management is one of the basic human rights and it is among the most important responsibilities of health professionals (12). In pain management, while pharmacologically used drugs have been reported to be effective on somatic pain (emotional and physical), methods such as exercise, cold-hot application, movement restriction, positioning, resting, hydrotherapy, acupuncture, massage and transcutaneous electrical stimulation (TENS) have been found to influence cognitive, emotional, behavioural and socio-cultural dimensions of pain (13). For elderly patients, pain management should improve health and decrease health care expenses. A plan with realistic and correct purposes can provide pain management in elderly individuals (14). In addition, finding our the coping methods that the patient makes use of and increasing their use can provide support to the patient in reliving chronic pain (15). It has been reported that frequent experiences of pain have a negative effect on physical, psychological and social state of well-being (16).

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Life satisfaction is the condition or result that is obtained with the comparison of what the individual wants and has. Life satisfaction expresses the state of well-being in different aspects such as satisfaction, happiness, spirits, etc. in the whole life, not just the satisfaction about a specific condition (17). In elderly individuals, life satisfaction has been associated with the combination of a great number of factors such as personal characteristics, physical possibilities and coping methods (1).

Pain is a personal experience and for this reason, it has a personal effect on life satisfaction (16). It is known that insufficient or untreated pain causes the deterioration of mobility and other functions, sleep disorders, anxiety, depression and in general low quality of life (18). Since functional decrease causes increased care dependence, it has been stated that sufficient pain management is especially important in this sensitive population (19). Due to the multidimensional nature of pain, the way of pain management should be addressed in elderly individuals (20). For the development of elderly health, psychological determinants of health such as life satisfaction should be evaluated. In parallel with this evaluation, it is reported that nurses should plan interventions appropriate to increase suitable pain management and to integrate these to the care plan (21, 22). In a meta analysis conducted, it has been stated that the health professionals working in a nursing home frequently consider pain and suffering as a normal part of life (23). This common belief causes limited pain reports on the one hand and undiagnosed conditions by health professionals on the other hand. In nursing homes, it is important to research and understand all the information about the pain and treatment of all elderly individuals to improve pain management (19). In addition, the methods most commonly used in the pain management of elderly individuals should be determined (22). Based on all these, the present study was conducted to find out the pain management states and life satisfaction of elderly individuals living in a nursing home and to find out the associations between pain management and life satisfaction.

2. METHODS

Place and Characteristics of the Study

This cross sectional descriptive study was conducted to find out the pain management states and life satisfaction of elderly individuals living in a nursing home and to find out the associations between pain management and life satisfaction.

Population and Sample of the Study

The population of the study consisted of all elderly individuals (n:300) staying in a nursing home in November 2019. The sample of the study consisted of 160 patients aged 65 and older who did not have any mental problems that could prevent participation, who had the cognitive competence to answer the questions and who volunteered to participate in the study. Data were collected between 1-30 November 2019.

Data Collection Tools

The data were collected by the researchers with face-to-face interview technique by using “Personal Information Form”, “Geriatric Pain Scale”, “Pain Management Inventory” and “Life Satisfaction Scale”.

Personal Information Form: This form includes questions about demographic characteristics of the patients such as gender, age, marital status and level of education and questions including the features of the nursing home and pain.

Geriatric Pain Measure

Geriatric Pain Measure (GPM) is a 24-item multi-dimensional scale developed by Ferrell et al. in 2000. Its Turkish validity and reliability was conducted by Dursun and Bektaş in 2017. The scale consists of 5 dimensions as disengagement (6, 17, 18, 19, 20, 21, 24), pain intensity (1, 2, 3, 4, 5, 22, 23), pain with ambulation (9, 10, 11, 12), pain with strenuous activities (8, 13, 14) and pain with other activities (7, 15, 16, 17, 22). Two of the items in the measure (17, 22) are in two of the sub-dimensions together and there are 3 open-ended questions about pain in the scale. 22 of the items in the scale are scored in pairs and the other 2 items are scored according to 0-10 scale. Total score is found by adding the answers “Yes” and it is between 0 and 42. Each item in the scale is multiplied by 2.38 and converted into 0-100 system. The final score of the scale is calculated by converting into 0-100 scale. In the assessment of GPM, scores differ between 0 and 100 and a score lower than 0-30 is evaluated as mild pain, a score between 30 and 69 is evaluated as moderate pain and a score of 70 and higher is evaluated as intense pain. GPM Cronbach alpha value was found as 0.85 (24). In our study, Cronbach alpha value was found as 0.89.

Pain Management Inventory

Pain Management Inventory (PMI) was developed to examine pain management methods and the effects of these methods. PMI is a 22-item, Likert-type (0-6) scale. If the individual filling in the inventory is not using a method, he will tick the appropriate option and if he used any method in the last week, he will tick the appropriate option and also tick the option/number that best defines how useful the method was in pain management. There are three different results of the scale: (a) the list of the last methods used, (b) the total number of the methods used, (c) usefulness of each method. PMI Cronbach alpha value was found as 0.76 (25). In our study, Cronbach alpha value was found as 0.78.

Life Satisfaction Scale (LSS)

It is a 5-item 7-Likert type scale developed to measure life satisfaction (26). Turkish validity and reliability study of the

scale was conducted by Yetim (2003) (27). The score taken from each item in the scale differs between 1 and 7, while the total score differs between 5 and 35. Higher score taken from the scale shows higher life satisfaction. Cronbach alpha value of the scale was found as 0.86 (27). In our study, Cronbach alpha value was found as 0.81.

Evaluation of the Data

In the study, descriptive statistics of the variables were given as number, percentage, arithmetic mean and standard deviation. Spearman's correlation coefficient was used in the assessment of the data obtained. Statistical analyses were conducted with SPSS 25 program and significance level was taken as 0.05 (p-value).

Ethical principles of the study

Approval was taken from the Ethical Board of the Health Sciences Faculty of the Sabahattin Zaim University the study was conducted in (2019/11 numbered) and written permission was taken from the institution the study was conducted in. In addition, written and oral consent was taken from the individuals who participated in the study after the purpose was explained. Permission was taken from the authors who conducted the Turkish validity and reliability study of the scales.

3. RESULTS

Average age of the participants was 68.79±12.26, 51,9% were women, 78.1% were single, 22.5% were illiterate and 20.7% were retired. It was found that 68.8% of the participants had social security, 46.2% had children, 61.9% of the elderly individuals had someone to help them with their care, while 29.6% were independent in their daily life activities and 65% were satisfied with the nursing home (Table 1).

It was found that 73.1% of the participants had pain during the day, 47.5% expressed the type of their pain as tingling, 17.4% had back pain, 7.4% had hand and elbow pain, 13.8% regular exercise and 15% defined their health status as good. While 8.7% of the participants needed support about eating and drinking, 11.1% needed assistance for going to toilet and 12.4% needed assistance for walking (Table 2).

Table 3 shows the distribution of pain management frequencies and pain management effectiveness scores. While 32.9% of the participants preferred to rest frequently to manage pain; 28.1% preferred to take the pain killer prescribed by the physician and 23.1% preferred to avoid physical activity that would increase pain. However, it was found that the participants did not prefer relaxing methods such as meditation or daydreaming with a guide and TENS (Table 3). The highest pain management effectiveness score averages of the participants are taking the pain killer prescribed by the physician, resting and focusing on the support from personal religious belief. The lowest score averages are using relaxation methods such as meditation and daydreaming (Table 3).

The results of the study showed that GPM total score average was 48.95±11.24; 27.7% (n=44) of the elderly individuals felt mild pain, while 47.1% (n=75) felt moderate pain and 25.2% (n=41) felt intense pain. Average LSS was found as 14.37±6.85.

There is a positive and weak statistically significant association between GPM and PMI (r=0.385; p<0.01) (Table 4). There is a negative and weak statistically significant association between GPM and LSS (r=-0.369; p<0.01) (Table 4). There is a negative and weak statistically significant association between PMI and LSS (r=-0.344; p<0.01) (Table 4).

Table 1. *Socio-demographic characteristics of the participants (n:160)*

		Ave±Sd	Min-Max (Median)
Age		68.79± 12.26	24-99 (69.00)
Number of children		1.28± 1.59	0-6 (0.00)
Total time in the nursing home		7.41± 7.84	1-42 (5.00)
Number of people staying in the room		4.62± 1.19	1-7 (4.00)
		n	%
Gender	Female	83	51.9
	Male	77	48.1
Marital Status	Married	35	21.9
	Single	125	78.1
Level of education	Illiterate	36	22.5
	Literate	24	15.0
	Primary	50	31.3
	Secondary	26	16.3
	High school	20	12.5
	Undergraduate and higher	4	2.5
Profession	Retired	33	20.7
	Worker	22	13.8
	Self-employed	37	23.3
	Housewife	67	42.1
Presence of Social Security	Yes	110	68.8
	No	50	31.2
Presence of Children	No	86	53.8
	Yes	74	46.2
Presence of assistant in care	No	61	38.1
	Yes	99	61.9
State of smoking	No	100	62.5
	Yes	60	37.5
Daily life activities	Independent	46	29.6
	Semi-dependent	85	53.1
	Fully dependent	29	18.1
State of being satisfied with the nursing home	No	56	35
	Yes	104	65

Table 2. *Some of the health habits of participants*

		n	*%*
Pain during the day	**No**	43	26.9
	Yes	117	73.1
Type of pain*	**Tingling**	57	47.5
	Strenuous	19	15.9
	Sensitive	10	8.3
	Throbbing	24	20.0
	Contracting	10	8.3
Area of pain*	**Head**	47	13.9
	Neck-Shoulder	38	11.2
	Waist	54	15.9
	Back	59	17.4
	Hip	37	10.9
	Hand and elbow	25	7.4
	Knee	43	12.7
	Ankle	36	10.6
State of doing regular exercise	**Yes**	138	13.8
	No	22	86.2
Health Status	**Good**	24	15
	Moderate	106	66.2
	Bad	30	18.8
Issues that need assistance*	**Eating-drinking**	56	8.7
	Shopping	90	14.0
	Going to hospital	110	17.0
	Buying drug from pharmacy	110	17.0
	Going to toilet	72	11.1
	Having bath	88	13.6
	Walking	80	12.4
	Speaking on the phone	40	6.2

**More than one option ticked.*

Table 4. *Correlation analysis between LSS*, GPM** and PMI****

		LSS	*GPM*
LSS	*r*	1	-0.369
	p	-	***0.001*******
GPM	*r*	-0.369	1
	p	***0.001*******	-
PMI	*r*	-0.344	0.385
	p	***0.001*******	***0.001*******

**LSS: Life Satisfaction Scale, **GPM: Geriatric Pain Measure, PMI: Pain Management Inventory, Spearman's Korelasyon ****p<0,01*

Table 3. *Distribution of the frequency of pain management and pain management effectiveness scores.*

	Frequency of pain management		**Pain management effectiveness**	
	n	%	Average	Standard Deviation
Massage to the area/s with pain	12	7.5	3.08	1.88
Using one of the methods that help to take stress under control (talking to someone, respiration exercise, etc.)	20	12.5	3.59	1.78
Talking to people whom I think can understand me	33	20.3	4.31	1.63
Resting	53	32.9	4.72	1.69
Cold application to the area/s with pain	5	3.2	2.08	1.54
Using distracting techniques such as watching TV, reading something or working	25	15.7	3.92	1.6
Using biofeedback by monitoring heart rate, blood pressure or other physiological measurements (respiration, body temperature, etc.)	5	3.2	2.15	1.42
Using hot water pool or bathtub or taking a hot shower	15	9.4	3.12	1.95
Using a pain killer not recommended or prescribed by the physician	7	4.4	2.15	1.77
Avoiding food that start or increase pain	12	7.2	2.95	1.83
Joining support groups about pain (patient associations, meetings, etc)	4	2.5	1.75	1.39
Doing exercise	5	3.1	2.45	1.66
Hot application to the area/s with pain	4	2.5	2.31	1.54
Taking antidepressant prescribed by the physician	9	5.3	2.83	1.84
Using relaxation methods such as meditation or daydreaming with a guide	-	-	-	-
Using transcutaneous electrical stimulation (TENS)	-	-	-	-
Supporting the area/s in pain by using splint or band	3	1.5	1.86	1.48
Taking pain killer prescribed by the physician	45	28.1	4.83	1.45
Avoiding physical pain that will increase pain	37	23.1	423	1.75
Using positive suggestions such as "I can ....."	6	3.8	2.73	1.65
Planning resting periods between activities	27	16.9	4.26	1.58
Focusing on the support from personal religious belief	34	21.3	4.4	1.46

4. DISCUSSION

This study was conducted to find out the pain, pain management and life satisfaction levels of elderly individuals living in nursing homes and the association between these. In the study, it was found that the highest rates of pain were in the areas of back, waist, head, knee, hips, ankle and hand with knee. In different studies conducted, it was found that pain in elderly individuals were similar to the results of this study (16, 22, 28, 29).

In the study, 47.5% of the elderly individuals experienced tingling pain, while 20% experienced throbbing pain and 15.9% experienced strenuous pain. In their study, Yıldız et al. (2009) found that 36.4% of the elderly individuals experienced tingling pain, while 3.6% experienced blunt pain. In Özel et al.'s study (2014), it was found that 59.8% of the elderly patients experienced tingling pain, while 50% experienced strenuous pain, 75.6% experienced sensitive pain and 11% experienced contracting pain. Our study showed similar results with the studies conducted.

In the present study, it was found that in pain management, elderly individuals preferred mostly resting, taking pain killers prescribed by the physician, avoiding physical activity that can increase pain, focusing on the support from personal religious belief and talking to someone that could understand them. Different studies conducted have shown that pain management methods of elderly individuals were similar to those in our study (22, 30-31).

In the study, it was found that the methods used with the lowest rates were supporting the area/s in pain by using splint or band, joining support groups about pain, hot and cold application to the area with pain and biofeedback. In addition, it was found that elderly individuals did not use the methods of relaxation such as meditation or daydreaming with a guide in the management of pain. Similar results were found in Özel et al.'s (2014) study. It is thought that elderly individuals do not use these methods since they do not know about these methods exactly and they do not know how to do these methods.

Average GPM total scores of the elderly individuals was 48.95±11.24 and it can be said that they had moderate level of pain. In a study they conducted on elderly women, Kapucu and Ünver (2017) found that average GPM total score was 57.6±17.5 (32). In their study they conducted on elderly individuals who referred to Family Health Centre, Arli et al. (2018) reported average GPM total score as 53.23±29.40. In their study they conducted on 1059 elderly individuals in Europe and United States of America, Blozik et. al. (2007) found average GPM total score as 36.0±21.7 in Europe (as 36.0±21.90 in England (London), as 39.3±22.00 in Germany (Hamburg), as 32.7±21.3 in Sweden (Solothurn)) and as 42.5±25.4 in United States of America. Gökkaya et al. (2012) and Motta et al. (2015) found average GPM total score as 60.4±22.1 and 53.0±17.9, respectively. The data found in the present study supports the literature data that elderly individuals in the society experience moderate level of pain.

In this study, it was found that according to GPM average scores, 27.7% of the elderly individuals experienced mild pain, while 47.1% experienced moderate pain and 25.2% experienced intense pain. In their study they conducted on elderly women, Kapucu and Ünver (2017) found that 6.7% experienced mild pain, while 67.3% experienced moderate pain and 26% experienced intense pain. According to a study conducted by Dursun and Bektaş (2016), it was found that 48.8% of the elderly individuals experienced mild pain, while 43% experienced moderate pain and 8.2% experienced intense pain. In a study by Gökkaya et al. (2012), it was found that 50.9% experienced moderate pain and 37.6% experienced intense pain (35). In their study, Park et. al. (2009) found that 33% of elderly individuals experienced mild pain, while 56% experienced moderate pain and 11% experienced intense pain (37). When these results are examined, it can be thought that the differences in the rates of experiencing pain found in literature can be due to the different features such as the age, gender and life conditions of the elderly individuals in each sample.

In this study, it was found that average LSS total score of elderly individuals was 14.37±6.85. As a result of this study, it can be said that elderly individuals have poor life satisfaction levels. In their study they conducted on elderly individuals living in nursing homes, Altay and Avcı (2009) and Altıparmak (2009) found average LSS scores as 20.3±5.9 and 23.1±6.3, respectively. In their study conducted on elderly individuals Kiarsipour et al. (2017) found average LSS scores as 22.39±6.19 (39). Average LSS scores in our study were found to be lower than those of the studies conducted in literature. When these results are examined, it can be thought that the differences in the rates of experiencing life satisfaction found in literature can be due to the different features such as life conditions of the elderly individuals in each sample.

In the present study, a positive significant association was found between GPM and PMI. In literature, it is stated that with the increase in the frequency of using pain management methods, the intensity of pain decreases (40, 41). In line with this result, it can be said that pain decreases as pain management increases in elderly individuals. In the study, a negative significant association was found between LSS, GPM and PMI. Arli et al. (2018) found a negative association between elderly individuals' pain and their life satisfaction. In literature, pain is a subjective experience that can occur in very different quality and intensities and it is stated that it has a negative effect on the life quality, physical functions and well-being of elderly individuals (16). It is stated that increase in pain causes depression, social isolation, sleep problems, deteriorated activity and economic loss with the use of health services in elderly individuals. As a result of this, quality of life and life satisfaction decreases in elderly individuals (10, 22, 42-44). The results of the studies conducted support our results. In parallel with this result, it can be said that as life satisfaction decreases in elderly individuals, pain and pain management methods which are used to decrease pain increase.

5. CONCLUSION

The present study gives significant information about pain, pain management and life satisfaction in elderly individuals. In the study, it was found that elderly individuals experienced back, waist, head and knee pain the most. It was found that elderly individuals experienced tingling, throbbing and strenuous pain and in pain management they preferred the methods of resting, taking pain killer prescribed by the physician and avoiding physical activity that can increase pain. It was found that elderly individuals experienced moderate level of pain and they had poor life satisfaction levels. A negative statistically significant association was found between LSS, GPM and PMI. Pain decreases life satisfaction in elderly individuals. For this reason, individuals' pain must be well-defined and treated.

In line with these results, it can be recommended to include individuals working in the nursing homes in the methods used by elderly individuals in pain management and the personnel working in nursing homes and patients should be trained about how to use these. In addition, it is recommended to conduct studies to find out when it is the best to use pharmacological or non-pharmacological interventions and to learn how to find the best intervention and to know the pain beliefs of all stakeholders clearly.

Limitations

Since the present study is limited to the elderly individuals living in a nursing home, it cannot be generalized to the whole population.

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Clinical and Experimental Health Sciences

Comparing the Effect of Insulin Infusion Alone and in Combination of Insulin Infusion with Salbutamol Nebulization in Treatment of Hyperkalemia in Diabetic and Non-Diabetic Patients

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ABSTRACT

Objective: To evaluate the clinical efficacy and comparison of potassium lowering effect of insulin infusion alone and insulin infusion with salbutamol nebulization.

Methods: This interventional study was conducted in a tertiary care hospital, for a period of one year. A total of 190 patients with hyperkalemia were divided into two groups. Group-A (diabetic [D] and non-diabetic [ND] patients) received salbutamol 20 mg three times daily (TDS) (nebulizer 5mg/2.5mL) administered over a period of 15 minutes with 10 units of regular insulin (diluted with 25% dextrose in non-diabetic only) over 30 minute TDS via infusion. Group-B (diabetic and non-diabetic patients) received 10 units of regular insulin (diluted with 25% dextrose in non-diabetic patients only) administered over 30 minute TDS via infusion. Potassium and glucose level was measured in patient blood sample after 0, 6, 12 and 24 hrs of treatment.

Results: The potassium level was decreased by 30.09% (D) and 31.98% (ND) in Group-A, whereas by 31.98% (D) and 20.49% (ND) in Group-B, after 24 hrs. Whereas blood glucose level in diabetic patients of Group-A and Group-B was found to decrease up to 28.85 % and 40.78 % respectively after 6 hours. Both the treatments were found to be effective without any complication i.e. hypoglycaemia and hypokalaemia. Moreover, renal, liver, cardiac and respiratory function test also did not show significant changes after treatments when recorded bihourly.

Conclusion: From the results, salbutamol nebulizer with insulin is more effective in the treatment of hyperkalemia in diabetic and non-diabetic patients.

Keywords: Hyperkalemia, diabetes, Insulin infusion, Salbutamol nebulizer,

1. INTRODUCTION

Hyperkalemia, usually defined as serum potassium concentrations greater than 5.5 mmol/L, is widely recognized as a direct and life-threatening complication. It is encountered more frequently in current medical practices due to the increasing incidence and prevalence of common chronic diseases, such as diabetes and chronic kidney disease, which disturb potassium homeostasis (1). Renal failure is associated with predictable abnormalities in composition of body fluids (2). Hyperkalemia mainly due to failure of renal adaptation to potassium imbalance resulting from a combination of intrinsic and extrinsic factors (3-5). Intrinsic factors includes decreased glomerular filtration rate, decreased distal delivery of sodium, selective reduction in distal tubule secretory function, impaired mineralocorticoid activity, and metabolic disturbances, such as acidosis and hyperglycemia (1). Common extrinsic factors are drugs that impair physiologic responses to hyperkalemia (e.g., various inhibitors of the renin-angiotensin-aldosterone system (RAAS), and potassium intake (e.g., a diet rich in potassium, or potassium supplements) (6). The frequency of chronic hyperkalemia is increased in current medical practice because RAAS inhibitors have undisputed beneficial effects in patient groups that are most susceptible to the development of hyperkalemia; for example, patients with chronic kidney disease (CKD), diabetes mellitus, or congestive heart failure (7). Intracellular shift of potassium is major defense against acute rise in serum potassium levels in patients with renal failure (8-9). Insulin via infusion and epinephrine are two major physiologic factors which promote this extrarenal potassium disposal (6). Renal potassium excretion is an effective but time consuming treatment for potassium homeostasis. During this long period of time, additional renal mechanism which are in action within minutes useful to lower acute potassium load (8).

In the management of hyperkalemia, combination therapy with an angiotensin-converting enzyme (ACE) inhibitor and

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an angiotensin receptor blocker (ARB) should not be used in diabetic and non-diabetic patients with CKD and hypertension because more adverse events like severe hyperkalemia, kidney dysfunction, and hypotension can occur without any increase in benefits (10-12). Aggravating kidney function and hyperkalemia can arise in some CKD patients after starting Renin-Angiotensin-Aldosterone System (RAAS) inhibitor (ACE-I or ARB), it can lower glomerular filtration rate and can slower potassium secretion. Therefore, it is useful to monitor serum potassium and roughly glomerular filtration rate within several weeks of starting or accelerating a RAAS (13). Terminating these drugs is helpful in controlling or treating hyperkalemia, but it can enhance the risk for kidney disease advancement and cardiovascular events.

The spectrum of hyperkalemia ranges from single episodes, sustained, recurrent or severe cases of hyperkalemia that require dialysis; but consistently mild, moderate, or severe hyperkalemia are not defined. Moreover, the cardio toxic effects of a particular potassium concentration depend on the baseline value, the rate of increase in potassium concentration, as well as the acid-base status, and serum calcium concentration (14). Mild to moderate hyperkalemia is commonly asymptomatic. Patients with moderate to severe hyperkalemia may complain of nausea, palpitations, muscle weakness, or paresthesia. Therefore, moderate and especially severe hyperkalemia can lead to cardiac arrhythmias and conduction abnormalities that may be dangerous. Rapid decline in serum potassium is generated by administration of insulin via infusion and salbutamol (nebulization) but electrocardiographic (ECG) changes is a medical emergency (15). Intravenous calcium gluconate should be given in patients with characteristic ECG changes because of hyperkalemia. Lower the potassium by giving intravenous insulin with glucose or a $beta_2$ agonist by nebulizer, or both. Total body potassium should usually be lowered with sodium polystyrene sulfonate. (16-18). The aim of our study was to evaluate the clinical efficacy and comparison of potassium lowering effects of insulin infusion alone and insulin infusion with salbutamol nebulization in diabetic and non-diabetic patients.

2. METHODS

2.1. Study Design

A prospective observational study was conducted in tertiary care hospital for a period from July 2018 to June 2019. Total patient included in this current study from Medical Intensive Care Unit (MICU) and their medical case files were used to note the relevant clinical information in specific case record form (CRF). A total of 190 patients were enrolled after analysis of their present illness and on the bases of inclusion/ exclusion criteria. Patients having serum potassium level more than 6 mmol/L were included in the study. The patients having an Ischemic heart disease and already receiving one or more of the following drugs *i.e.* Beta blocker, digoxin, beta agonist and diuretic therapy were excluded from study. These patients were randomly divided into two groups (Group-A & Group-B) and each group having ninety five (95) patients. These two groups were further categorized into diabetic (D) and non-diabetic (ND). Group A received salbutamol 20 mg TDS (nebulizer 5mg /2.5mL) administered over a period of 15 minutes with 10 units of regular insulin (Insulin diluted with 25 % dextrose only in non-diabetic patients) administered over 30 minute TDS via infusion. Group B received 10 units of regular insulin (Insulin diluted with 25% dextrose only in non-diabetic patients) administered over 30 minute TDS via infusion only. Blood samples were taken immediately after starting the treatment *i.e*. 0 min (at the time of treatment means 30 min after meal), 6, 12 and 24 hrs after treatment. Potassium and glucose levels were measured in these samples. Blood pressure, pulse, temperature, respiratory rate were monitored during the study period. Electrocardiography (ECG) was recorded for each patient at specified interval. During the study period patients were given treatment according the protocol and patients were not received any other medication that effecting serum potassium levels like furosemide, bicarbonate, beta blockers. Any unwanted effects observed or complained by the patient were recorded. The study protocol was approved by Institutional Ethic Committee (MMIEC/2019/1314). All patients provided the written informed consent to participate after a full explanation of the study. The current study was conducted in accordance with the code of Good Clinical Practice (GCP). Results are expressed as Mean ± standard deviation (SD). The level of significance established at a *P* value of less than 0.05.

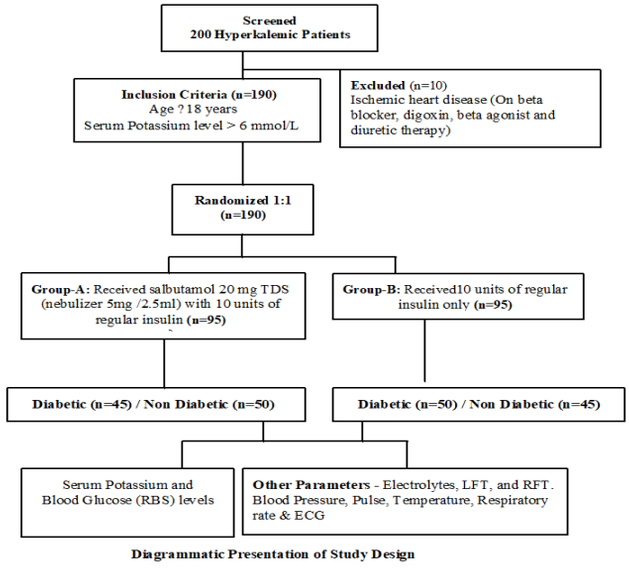

Figure 1. *Study Design*

3. RESULTS

In this study, total number of patient encountered were one hundred ninety (n=190). Out of them 95 patient were received insulin via infusion with salbutamol (nebulization) (Group-A) and other ninety five (n=95) were received

insulin via infusion alone (Group-B) (Fig 1). On the basis of demographic details, most of patients in both the Group-A and Group-B were in range of 51-65 year of age (Table-1). Majority of patients were male 62 (95) i.e. 65% in both the groups while female patients were lesser only 33(95) i.e. 35% in both the groups respectively. The percentage of diabetic and non-diabetic patients in Group-A were 47% and 53% and in group B were 53% and 47% respectively.

Table 1. *Distribution of patients on the basis of age*

Group	Group-A: Insulin via infusion with Salbutamol (nebulization) (n=95)		Group-B: Insulin via infusion (n=95)	
Age	No. of Patient	Percentage	No. of Patient	Percentage
35-50	39	41%	34	36%
51-65	44	46%	45	47%
66-80	12	13%	16	17%

(Results showed in percentage)

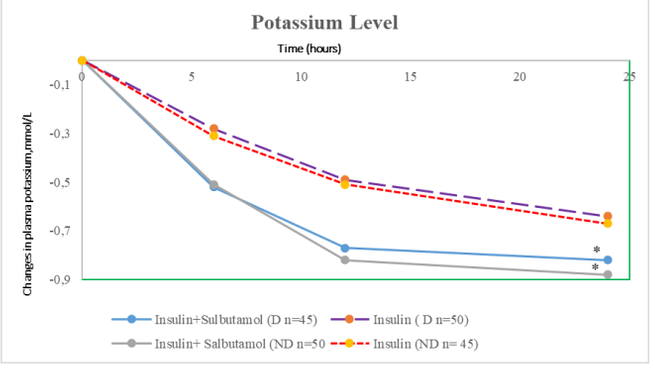

Figure 2. *Comparison of Potassium level between group A (Insulin via infusion with Salbutamol nebulization) and group B (Insulin via infusion) after 6, 12, 24 hours of interval in diabetic (D) and Non Diabetic (ND) patients. *p<0.05 other treatment regimens group.*

Table 2. *Comparison between group A and group B on potassium level after 6, 12, 24 hours of interval in diabetic and non-diabetics patients*

Laboratory parameter	Group-A : Insulin (infusion) with Salbutamol (nebulization) (D n=45) (ND n=50)		Group-B: Insulin (infusion) alone (D n=50) (ND n=45)	
Potassium (Initial)	7.01±0.61	6.91±0.45	6.88±0.54	6.76±0.72
Potassium (after 6 hours)	6.49±0.76	6.40±0.66	6.60±0.73	6.45±0.56
Potassium (after 12 hours)	5.72±0.50	5.58±0.48	6.11±0.69	5.94±0.65
Potassium (after 24 hours)	4.90±0.54*	4.70±0.51*	5.47±0.62	5.27±0.59
% Decreased (After 24 hours)	30.09%	31.98 %	20.49%	22.04 %

**p<0.05 consider as significant when compare with initial level of Potassium in serum.*

Values are in mean ± standard deviation (Units – mmol/L)

The plasma potassium concentration at baseline (initial) was approximately similar in all the patients of both the groups (Fig 2). The results clearly showed that the serum potassium levels was started to fall in both the group after initiation of therapy. Serum potassium level in diabetic patients (7.01±0.61mmol/L to 4.90±0.64 mmol/L) (30.09%) and non-diabetic patients (6.91±0.45 to 4.70±0.51 mmol/L) (31.98 %) of Group-A was significantly ($p<0.05$) decreased after 24 hours of treatment (Table-2). But the level of serum potassium in diabetic patients (6.88±0.54 mmol/L to 5.47±0.62 mmol/L) (20.49%) and non-diabetic patients (6.76±0.72 mmol/L to 5.27±0.59 mmol/L) (22.04%) of Group-B was not significantly decreased after 24 hours of treatment.

The mean ± SD blood glucose level in diabetic and non-diabetic patients after 6hrs of treatment in Group-A were 151±13 mg/dL and 104±6 mg/dL, respectively. Moreover, in Group-B the mean ± SD blood glucose level in diabetic and non-diabetic patients after 6 h were 180±21 mg/dL and 101±10mg/dL, respectively (Table 3). In both the groups, the blood glucose level in non-diabetic patients was controlled (not significant change) with dextrose infusion but in diabetic patients the level of blood glucose was significantly decreased i.e. 40.78% (Group-A) and 28.85% (Group-B) respectively, 6 hrs after the treatment.

Table 3. *Comparison between group A and group B on blood glucose*

Laboratory parameter	Time	Group-A: Insulin via infusion with Salbutamol nebulization		Group-B: Insulin via infusion	
		D (n-45)	ND (n=50)	D (n=50)	ND (n=45)
Blood glucose concentration (mg/dL)	0 min	255±32	103±11	253±37	109±12
	1 hr	200±16	112±9	209±27	107±11
	3 hr	175±11	110±10	189±19	101±8
	6 hr	151±13*	104±6	180±21 *	101±10
	%	40.78	5.4	28.85	7.3

*D = Diabetic; ND = Non Diabetic, *p<0.05; Values are in mean ± standard deviation*

0 min (initial reading or at the time of Treatment) means 30 min after meal.

The results clearly indicates that, there is no significant difference and changes in the level of Liver Function Test (LFT i.e. SGOT, SGPT, alkaline phosphatase) (Fig 3), Renal Function Test (RFT i.e. urea, creatinine, uric acid) (Fig 4), and the level of electrolytes (i.e. sodium & chloride) (Fig 5) in group A and group B respectively after and before the treatment (Table-4).

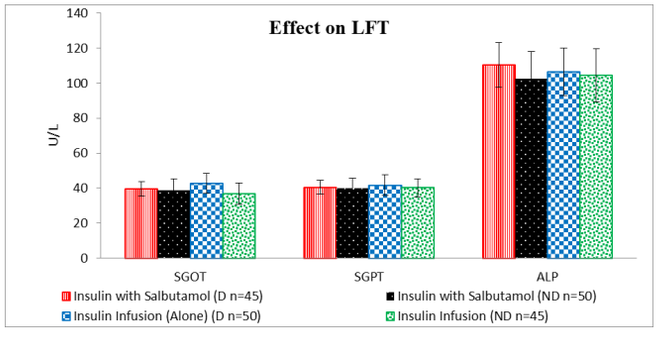

Figure 3. *Comparison of LFT parameter (SGOT, SGPT, ALP) between group A (Insulin via infusion with Salbutamol nebulization) and group B (Insulin via infusion) in diabetic and Non Diabetic Patients.*

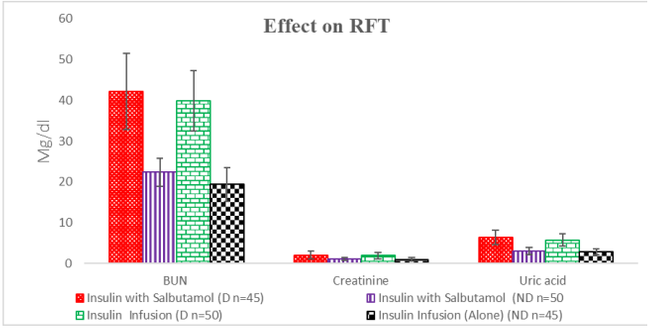

Figure 4. *Comparison of RFT parameters (urea, creatinine, uric acid) between group A (Insulin via infusion with Salbutamol nebulization) and group B (Insulin via infusion) in diabetic and non-diabetic patients*

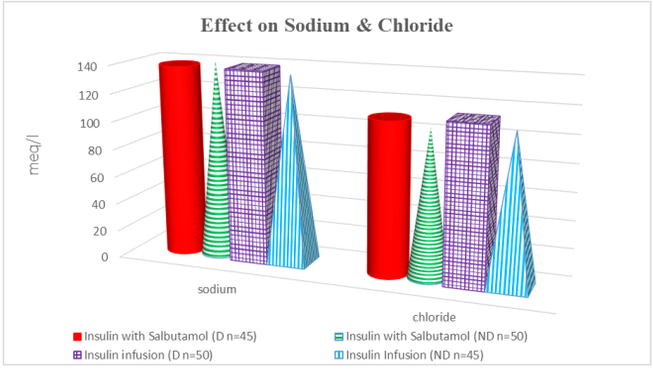

Figure 5. *Comparison of electrolytes (sodium, & chloride) between group A (Insulin via infusion with Salbutamol nebulization) and group B (Insulin via infusion alone) in diabetic and non-diabetic patient*

Table 4. *Comparison of various biochemical parameters between group A and group B*

System	Parameters	Group-A		Group-B	
		Before Treatment	After 24 hrs of Treatment	Before Treatment	After 24 hrs of Treatment
Blood Pressure	Systolic (mmHg)	132.21±11.25	127.42±13.86	129.32±8.9	122.11±7.6
	Diastolic (mmHg)	83.03±9.12	76.94±10.16	80.37±5.8	79.51±7.7
	Heart Rate (Beats / Minute)	85.11±6.65	81.88±8.44	80.15±7.27	78.08±5.80
Respiratory System	Respiratory Rate (Breaths / minute)	21.09±1.97	20.22±2.24	20.35±1.09	20.08±1.77
	Arterial Oxygen Saturation (%)	94.31±6.80	95.12±4.65	93.48±4.72	94.36±4.19
Haemogram Test	HB (g/dL)	11.98±1.98	12.04±1.66	10.62±1.19	10.96±2.20
	TLC (10^9/liter)	11.35±1.79	11.99±1.16	7±0.97	7±1.09
	Platelet (10^9/ liter)	2.81±0.21	2.89±0.43	3.42±0.54	3.45±0.90
Liver Panel Tests	Total Bilirubin (mg/dL)	0.96±0.15	0.90±0.26	0.95±0.20	0.89±0.35
	Direct Bilirubin (mg/dL)	0.33±0.04	0.31±0.19	0.34±0.09	0.33±0.11
	Total Protein (g/dl)	6.81±0.90	7.02±0.94	6.51±1.44	6.79±1.12
	Serum Albumin (gm/dl)	3.41±0.55	3.56±0.70	3.39±0.62	3.44±0.75
	SGOT (U/L)	39.65±4.2	40.05±3.9	38.95±8.48	38.40±6.71
	SGPT (U/L)	40.07±4.11	40.59±3.92	39.90±8.66	38.83±5.87
	ALP (IU/L)	105.48±17.7	102.35±10.1	103.6±19.62	102.6±13.31
Renal Function Test	Blood Urea Nitrogen (mg/dL)	22.25±3.71	21.98±3.24	27.51±5.5	26.23±6.1
	Serum Creatinine (mg/dL)	3.96±0.33	3.04±0.29	3.62±0.39	3.23±0.52
	Serum Uric acid (mg/dL)	7.01±0.69	6.94±0.90	6.7±0.50	6.6±0.54
Electrolytes	Sodium (mEq/L)	140.28±10.87	135.28±12.30	139.62±6.28	138.62±7.39
	Chloride (mEq/L)	100.94±6.05	101.36±7.033	101.74±6.10	103.09±5.35

**p<0.05 consider as significant when compare with initial level. Values are in mean ± standard deviation*

No significant change was noted in heart rate, blood pressure, temperature, respiratory rate and electrocardiogram. All the treatment modalities were well tolerated. No side effect in any patient was noted.

4. DISCUSSION

Regulation of potassium in the nephron depends on passive and active mechanisms. Potassium is filtered in the glomerulus and approximately 60-75% of the filtered potassium is reabsorbed in the proximal tubule (PT) by diffusion. Approximately 15-20% of the filtered potassium is reabsorbed in the thick ascending limb of the Loop of Henle by several co-transporters and ion channels. Excretion mainly occurs in the cortical collecting duct (19). Hyperkalemia may result by an increase in total body potassium secondary to imbalance of intake vs. excretion or from maldistribution between intra and extracellular space. Acid-base balance can affect the balance between cellular and extracellular potassium concentration. Acidosis increases the plasma K^+ concentration by inducing a net shift of K^+ from the cellular to the extracellular compartment in exchange with H^+, also leading to a reduced tubular secretion of potassium (20). Low level of insulin in diabetes mellitus results to accumulation of potassium in the extracellular space. Insulin shifts potassium into cells by stimulating the activity of Na^+-H^+ antiporter on cell membrane, promoting the entry of sodium into cells, which leads to activation of the Na^+-K^+ ATPase and inhibition of potassium efflux (21).

In clinical Practice management of hyperkalemia provide only transitory improvement by shifting K^+ into intracellular space without actually eliminating potassium. Insulin infusion/dextrose administration is important in preventing a large change in extracellular fluid (ECF) K^+ concentration as it increases potassium uptake into liver and muscle cells by stimulating Na^+/K^+ ATPase. Moreover, beta-adrenergic agonists (salbutamol) bind to beta-2 receptors on muscle cells, stimulate Na^+/K^+ ATPase and increase K^+ shift into cells (22). Salbutamol can be applied via nebulizer or given intravenously. It was reported that, salbutamol via nebulizer has a profound effect in lowering the serum potassium level in dose dependent manner but several limitations associated such as tremor, hypokalemia, hyperglycemic ketoacidosis and tachycardia (23-24). Therefore, we were investigating and comparing the effect of these modalities with mentioned possibility in diabetic and non-diabetic patients.

According to the results of this studies, the mean potassium level in group A (both diabetic and non-diabetic patients) was significantly reduced within twenty four hours of treatment administration. This finding is consistent with results of a multi-systemic review study in which it was reported that the significant decrease level of potassium occur after 60 min of treatment (3). Decrease in mean potassium levels was (D-30.09%) and (ND-31.98 %) in Group-A (treated by insulin infusion with salbutamol nebulization) than Group-B (insulin infusion alone) probably due to the stimulation of beta – adrenergic receptors in pancreas resulting in insulin release which causes an additive effect. Our study showed that there was slightly increase in blood glucose level after one hour of nebulized salbutamol only in non-diabetic patients, this finding is similar to results of previous study (25). Moreover, in the current study, electrolytes, LFT, RFT was not significantly changed in both treated groups. Appropriate care and close monitoring should be considered during treatment of non-diabetic patients by insulin infusion with nebulized salbutamol.

5. CONCLUSION

In treatment of hyperkalemia, the combination of medications with different therapeutic approaches is usually effective. Our study confirms that, insulin infusion (intravenous) and beta-adrenergic agonist's nebulization have the quickest onset and appear to be effective and safe when administered together, than intravenous insulin infusion alone in diabetic and non-diabetic patients. Ideally combination should be preferred under control conditions for treating hyperkalemia without hypokalemia and hyperglycemic ketoacidosis.

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Clinical and Experimental Health Sciences

Mutations and Expression Profile of EDIL3 and Correlation with HIF1A and Tumor-Associated Carbonic Anhydrases in Pancreatic Cancer

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ABSTRACT

Objective: Epidermal growth factor-like repeats and discoidin I-like domains 3 (EDIL3) expression is upregulated in some types of cancer which means that it can be used as a candidate tumor marker. The expression level of EDIL3 as a marker of the hypoxic microenvironment of pancreatic cancer was assessed by studying its relationship with the expression of tumor-associated carbonic anhydrases (CA IX and CA XII) and Hypoxia-inducible factor-1 (HIF-1) in tumor development.

Methods: Gene expression and mutation profiles of pancreatic cancer patients and healthy tissue samples were downloaded The Cancer Genome Atlas (TCGA), and the genetic alterations and expression levels of the EDIL3, HIF-1α, CA IX and CA XII genes were analyzed. Additionally, PolyPhen-2 and SNAP tools were used to prediction and confirmation of detected alterations pathogenicity and survival analysis was performed.

Results: Expression levels of EDIL3, HIF-1α and CA IX were found to be statistically significant higher in the patient compared to healthy group and we showed also positive correlation between EDIL3 and HIF-1α gene expression. Furthermore, low CA IX and CA XII expression levels were found effective on overall survival ($p<0.05$). Additionally, 8 missense mutations were detected in the coding region of studied genes.

Conclusion: We suggested that relationship between EDIL3 and HIF-1α in pancreatic cancer and EDIL3 is a novel molecule cancer development in pancreatic cancer.

Keywords: CAs, EDIL3, HIF-1α, mutation, expression, pancreatic cancer

1. INTRODUCTION

Pancreatic cancer, which has become increasingly frequent in recent years and known as the fourth fatal cancer, is a disease with an aggressive character which develops relatively asymptomatically and usually appears advanced in diagnosis (1). Additionally, the genetic and phenotypic heterogeneity of pancreatic cancers is a significant clinical problem. Understanding the interactions between the molecular mechanisms underlying pancreatic cancer progression will provide a significant improvement in the development of more selective and effective treatment models for medical therapy for pancreatic cancer (2,3). The presence of hypoxic areas in the tumor microenvironment causes more unstable genetic structure, aggressive/invasive phenotype, increase tumor volume, trigger epithelial mesenchymal transmission and escape of cancer cells from the immune system (4,5). In addition, it causes resistance to alternative cancer treatment and a significant decrease in survival rates. Although the underlying mechanisms mediating pancreatic cancer invasion and metastasis are largely unknown, hypoxic microenvironment and hypoxia-related factors have been reported to be critical driving forces in pancreatic cancer metastasis and progression.

Hypoxia-inducible factor-1 (HIF-1) is the main effector in hypoxia activation by generation of the blood vessels, lymphatic vessels, fibroblasts, immune cells, and various extracellular matrix components (6,7). The interaction of these input molecules with tumor cells cause to clinical outcomes. Most solid tumors have hypoxic regions because of abnormal vascularization and low blood supply. This character of hypoxia promotes numerous changes favor cancer progression (4-8). The expression of HIF-1α gene activates signaling pathways related with cell metabolism and supports to glycolytic mode by producing H^+. Furthermore, the activity of carbonic anhydrases (CA) is affected by HIF-1α signalization. Zinc

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containing carbonic anhydrase enzymes have important roles in different physiological functions as gas exchange, ion transport and acid-base balance (10). There are 15 enzymatically active CA isoforms in mammalian and the role of these enzymes, participate in pH regulation, are catalysis of the hydration of CO_2 molecule and dehydration of HCO^3 – ion (10,11). The molecular and cellular structure and functions of several carbonic anhydrases have been characterized. CA IX and CA XII, the major types of tumor associated proteins (11,12). The discovery of transmembrane carbonic anhydrases which are CA IX and CA XII is a hallmark of cancer, especially angiogenesis, tumor invasion, progression and metastasis (10-12). Several studies have shown that cancer-related CA IX and CA X II expression can take place in cancer. These enzymes were identified in numerous cancer types such as human renal cancer, pancreatic, colon, prostate, ovaries, testicles, lung, brain, normal endometrial cells and epididymis duct cells (10-13). The association between malignant transformation and the expression of carbonic anhydrases could not be accentuated until the discovery of CA IX and CA XII from tumor-associated CA isozymes.

Epidermal growth factor-like repeats and discoidin I-like domains 3 (EDIL3 is also called DEL-1) is a secreted and multifunctional extracellular matrix protein that plays an important role in regulating cellular growth, differentiation, adhesion, and apoptosis in many biological systems especially tumor cells (14). EDIL3 has also an anti-inflammatory function because of inhibiting the recruitment of immune cells to inflammatory site. In addition, inflammation is critical in the progression of various types of carcinoma, and donates invasive and metastatic characteristics upon transformed cells (15,16). The tumor microenvironment facilitates tumor metastasis to other organs. Various signaling pathways contribute to this abnormal process. The role of EDIL3 in cancer is complex and paradoxical, varying by cell type and stage of tumorigenesis (17). In the present bioinformatical study was done to determine the relationship between transmembrane carbonic anhydrases and EDIL3 mutation profile and m-RNA expression patterns in the data of pancreatic cancer and healthy samples. The function of EDIL3, HIF-1 accentuated and tumor-associated carbonic anhydrases are poorly understood. In this study, we have used bioinformatics tools to decipher the mutation profiles and expression levels of EDIL3, HIF-1α, CA IX and CA XII genes.

2. METHODS

2.1. Data collection

The pancreatic cancer data set was obtained from TCGA database. Demographic, clinical and genetic data regarding the patient group are summarized in Table 1.

Table 1. *Demographic, clinical and genetic data of patients with pancreatic cancer*

Characteristic	Patient data n:640 (%)
Gender	
Male	340 (53.1%)
Female	281 (43.9%)
NA	19 (3.0%)
Diagnosis age, years	61 (range, 33-90)
Race Category	
White	161(25.2%)
Black or African American	7 (1.1%)
Asian	11 (1.7 %)
NA	461 (72%)
Sample Type	
Primary	560 (87.5%)
Metastasis	3 (0.5%)
NA	77 (12%)
Overall Survival Status	
Living	99(15.5%)
Deceased	85 (13.3%)
NA	456 (71.3%)
Metastasis Stage Code	
M0	84(13.1 %)
MX	95(14.8%)
M1	5(0.8%)
NA	456 (71.3%)
Tumor stage code	
T1	7 (1.1%)
T2	23 (9.1%)
T3	148 (23.1%)
T4	4 (0.6%)
TX	1 (0.2%)
NA	457(71.4%)
Alteration Frequency in pancreatic cancer	**Case (Frequency%)**
HIF-1A Mutation	3 (0.5%)
EDIL3 Mutation	2(0.4%)
CAIX Mutation	13 (2.3%)
CAXII Mutation	1(0.2%)

2.2. Mutation Analysis

The cBio Cancer Genomics Portal (http://cbioportal.org) is an open accessed, The Cancer Genome Atlas (TCGA)-based resource that allows interactive research of multidimensional cancer genomic datasets and provides access to the data of more than 5,000 tumor samples from 20 cancer studies (18,19). Pancreatic cancer was chosen as the type of cancer of interest on the web interface to examine mutations in HIF-1α, EDIL3, CA IX and CA XII genes in pancreatic cancer patients presented in the portal. The selected TCGA data set consists of the genome sequencing data of 640 pancreatic cancer patients. The characteristics of the mutations detected are comprehensively analyzed using the *OncoPrint* and *Mutation* tools provided by the interface.

2.3. In-Silico Analysis

To determine the possible pathogenicity of the mutations which we detected in our study genes; HIF-1α, EDIL3, CA IX and CA XII, we used the scores given by Polymorphism Phenotyping v2 (PolyPhen-2), Scanning of unacceptable polymorphisms (SNAP) and the Catalog of Somatic Mutations in Cancer (COSMIC) databases.

PolyPhen-2, which can be accessed via a web server, helps predict the possible effects of possible mutations on the stability and function of human proteins using the structural and comparative evolutionary analyses of the amino acid positions of these possible mutations. The program estimates the probability of the missense mutation being damaging based on a combination of all these features and provides both a qualitative prediction (probably damaging, possibly damaging, benign or unknown) with a score (20).

SNAP is a machine learning device called "neural network". It distinguishes between effect and neutral variants/non-synonymous SNPs by taking a variety of sequence and variant features into account. It includes evolutionary constraints, structural features and protein annotation information. The most important single feature for SNAP prediction is conservation in a family of related proteins as reflected by PSIC scores (21). In the SNAP software, when the given values are between – 100-0 and 0-100, the mutations are considered neutral and affected, respectively. Finally, the score given by the COSMIC database was used to predict and confirm the pathogenic effect of detected changes (22). Moreover, the evolutionary conservation analyses of the detected mutant amino acids were evaluated among different species via the **"Multiple sequence alignment"** tool in the PolyPhen-2 software.

2.4. Gene Expression, Survival and Correlation Analysis

GEPIA (http://gepia.cancer-pku.cn/) is an online database that contains the expression profiles of 9736 tumor samples and 8587 healthy samples. It is an interactive web server developed to provide customizable analyses such as differential expression analysis in tumor or normal tissues, profiling according to cancer types or pathological stages, patient survival analysis, similar gene detection, correlation analysis, and dimensionality reduction (23). The profiles of HIF-1A, EDIL3, CA IX, and CA XII gene expressions were analyzed as box plot graphs created by the GEPIA database using data from 179 pancreatic cancer patients and 171 healthy tissue samples obtained from TCGA and GTEx data. Furthermore, the correlation analyses between the expression levels of the EDIL3 gene and other study genes were done using the software. The p-values were automatically calculated by the software in both analyzes, and p-values below 0.05 were considered statistically significant. The survival analyses of the study genes according to their varying gene expression levels were done via the web interface.

2.5. Statistical Analysis

All statistical analyzes were carried out on the GEPIA database. Kaplan-Meier curves regarding overall survival. Low and high expression groups were compared used the log-rank test. Pearson test was performed for correlation analyses using online database. $p<0.05$ was considered to indicate a statistically significant difference.

3. RESULTS

3.1. Results of mutation analysis

To identify the genetic changes in HIF-1α, EDIL3, CAIX, and CA XII genes in pancreatic cancer samples, genome sequencing data from 640 pancreatic cancer patients were analyzed via the cBioPortal interface. At least one genetic change (missense mutation) was detected in the HIF-1α, EDIL3, CA IX, and CA XII genes in 3.4% of all pancreatic cancer patients (Figure-1). Eight missense mutations (HIF-1A p.G429R, p.S692Y, p.N827D; EDIL3 p.L9I, p.D52Y; CAIX p.L293V, p.S294C; CA XII p.R240Q) were detected in all study genes. The changes detected in the studied genes as a result of the mutation analysis are shown in Table-2. CA IX was found to be the most frequently changed gene with a rate of 2.3% among the analyzed genes.

Figure 1. *Distribution of mutations in EDIL3, HIF-1A, CA IX and CA XII genes in patients with pancreatic cancer*

HIF-1α has two transactivation domains (TAD) as the NH_2 terminal (N-TAD) and the COOH terminal (C-TAD). These two domains are responsible for the transcriptional activity of HIF-1α. The C-TAD domain (between amino acids 786-826) interacts with coactivators such as CBP/p300 to modulate the gene transcription of HIF-1α under hypoxia. The p.N827D change detected in HIF-1α in our study was located on the C-TAD domain. The oxygen-dependent degradation domain (ODDD) rich in Pro-Ser-Thr amino acids is localized between amino acids 401-603 in the central region of HIF-1A, and it is responsible for the oxygen-dependent degradation of HIF-1α. The p.G429R detected in our study was located on this domain. The p.L293V and p.S294C missense mutations detected in the CA IX gene and the p.R240Q missense mutation detected in the CA XII gene were localized on the carbonic anhydrase active sites in both genes.

Table 2. *Mutations of the EDIL3, HIF-1A, CA IX and CA XII genes in pancreatic cancer patients.*

No	Gene	Nt alteration	Accession Number	Alteration type	Localization	AA position	Previously determined disease/browser	Clinical significance		
								Poly-Phen2 (score)	SNAP (score)	COSMIC prediction
M-1	EDIL3	c.25C>A	COSV56907881	Missense mutation	-	p.L9I	Pancreatic Adenocarcinoma	Benign (0,08)	Neutral (-9)	Pathogenic (0.74)
M-2	EDIL3	c.154G>T	rs117.372.6255	Missense mutation	EGF Doman	p.D52Y	Pancreatic Adenocarcinoma	Benign (0,26)	Effect (42)	-
M-3	HIF-1A	c.1285G>A	COSV60190598	Missense mutation	ODD	p.G429R	Pancreatic Adenocarcinoma	Probably damaing (1,00)	Effect (68)	Pathogenic (1.00)
M-4	HIF-1A	c.2075C>T	rs749686395	Missense mutation	ID	p.S692Y	Pancreatic Adenocarcinoma	Possibly damaging (0,73)	Neutral (-20)	-
M-5	HIF-1A	c.2479A>G	COSV60190475	Missense mutation	C-TAD	p.N827D	Pancreatic Adenocarcinoma	Probably damaing (0,99)	Effect (82)	Pathogenic (score 0.99)
M-6	CAIX	c.877C>G	COSV61406489	Missense mutation	Carb_ anhydrase domain	p.L293V	Pancreatic Adenocarcinoma	Probably damaing (1,00)	Neutral (-13)	Pathogenic (0.81)
M-7	CAIX	c.881C>G	COSV61406510	Missense mutation	Carb_ anhydrase domain	p.S294C	Pancreatic Adenocarcinoma	Probably damaing (1,00)	Neutral (-27)	Pathogenic (0.83)
M-8	CAXII	c.719G>A	COSV51604343	Missense mutation	Carb_ anhydrase domain	p.R240Q	Pancreatic Adenocarcinoma	Probably damaing (0,97)	Neutral (-57)	Pathogenic (1.00)

M: Mutation; EGF: Epidermal Growth Factor; ODD: oxygen-dependent degradation domain; ID: inhibitory domain; C – TAD: terminal transactivation domain; COSV: The genomic mutation identifier

Moreover, 6 of the missense mutations mentioned above were recorded as somatic mutations in the COSMIC database. The schematic representation of the domain architecture of the proteins and mutations found in pancreatic cancer is shown in Figure 2.

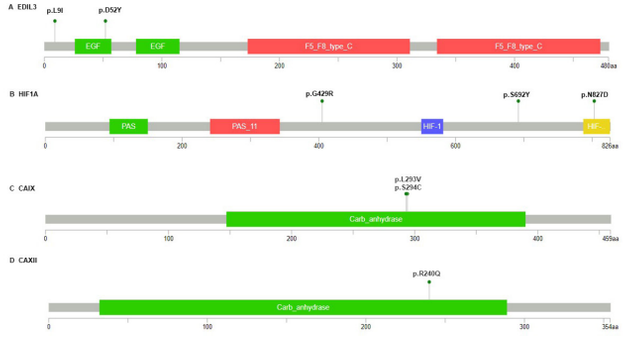
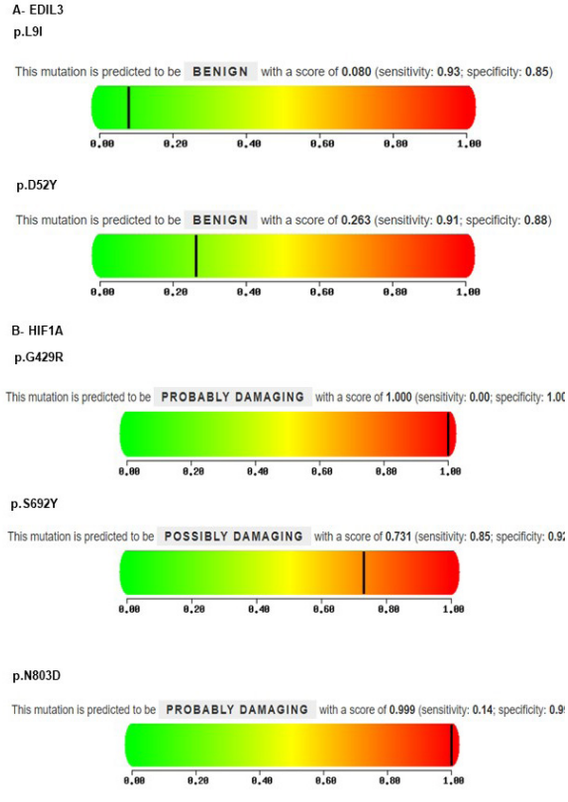


Figure 2. *Schematic representation of domain architecture of the EDIL3, HIF-1A, CA IX and CA XII proteins and mutations found in pancreatic cancer patients.* ***(A)*** *Human EDIL3 is a polypeptide of 480 amino acids.* ***(B)*** *Human HIF-1A is a polypeptide of 826 amino acids* ***(C)*** *Human CA IX is a polypeptide of 459 amino acids.* ***(D)*** *Human CA XII is a polypeptide of 354 amino acids.*

3.2. Results of in-silico Analysis

According to Poly-Phen2 database analysis results, 6 of the 8 missense mutations that were detected in the study genes and that are given in detail in Table-1 (HIF-1α p.G429R, p.S692Y, p.N827D; CA IX p.L293V, p.S294C; CA XII p.R240Q) had a pathogenic score close to 1, suggesting that they might have pathogenic characteristics.

The estimations for the pathogenic characteristics using the Poly-Phen2 software are given in detail in Figure-3 (a-d).



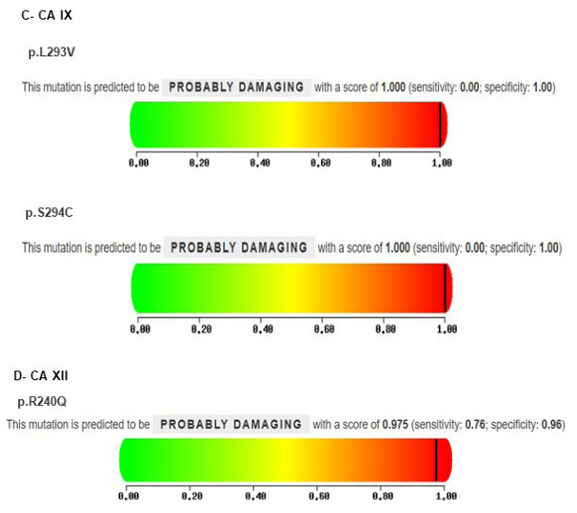


Figure 3. *Estimation of possible functional effects of mutations in EDIL3, HIF-1A, CA IX and CA XII genes with PolyPhen-2 program.*

In addition, the comparison of the amino acid sequences affected by the missense mutations detected in different species using the "Multiple sequence alignment" option in the Poly-Phen2 software showed that the p.G429R, p.S692Y, and p.N827D missense mutations detected in HIF-1α, the p.L293V, and p.S294C missense mutations detected in CA IX and the p.R240Q missense mutation detected in CA XII replaced their amino acids at critical points, which have been conserved among different species throughout their evolutionary process (Figure-4).

3.3. Results of Gene Expression, Survival and Correlation Analysis

Gene expression analysis was done to determine whether the gene expression profiles of HIF-1α, EDIL3, CA IX, and CA XII genes showed variation between pancreatic cancer patients and healthy samples. According to our results, the expression levels of HIF-1α, EDIL3, and CA IX were significantly higher in pancreatic cancer patients compared to normal tissues. CA XII was found to be lower in pancreatic cancer patients compared to the healthy group. The gene expression profile analyses for each gene were found to be statistically significant between the groups. In addition, the Pearson correlation between HIF-1α, CA IX, and CA XII mRNA expression results and EDIL3 expression levels was evaluated separately, and a positive correlation with a low correlation coefficient was determined between HIF-1α and EDIL3 expressions. No correlation was found between CA IX, CA XII, and EDIL3 expressions (Figure 5). Additionally, in Figure 6, according to the log-rank test and p-value, the low expression levels of CA IX and CA XII were found effective on overall survival (p=0.009 and p=0.000056 respectively).

Figure 4. *The evolutionary conservation analyses of the mutated amino acids in HIF-1A, CA IX and CA XII genes in the present study. The mutated amino acids were demonstrated. The detected mutant amino acids were evaluated among different species.*

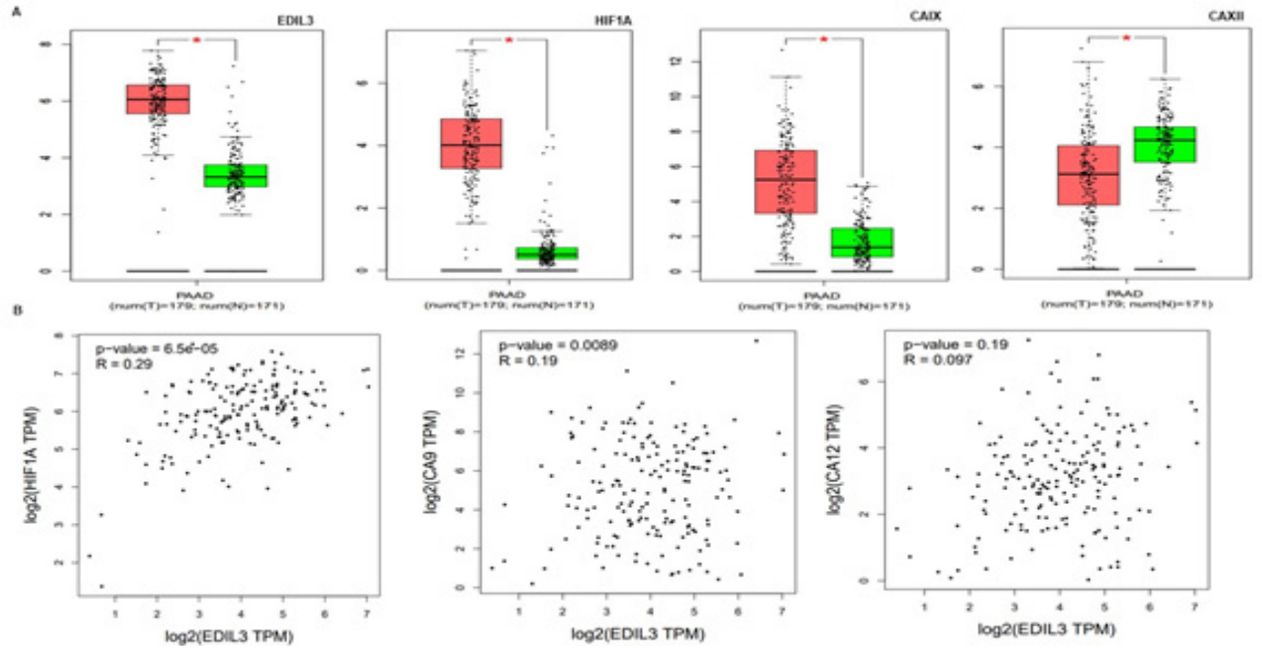


Figure 5. *Validation of the m-RNA expression levels of (A) EDIL3, HIF-1A, CA IX and CA XII in pancreatic cancer tissues and normal pancreas tissues using GEPIA. These four box plots are based on 179 pancreatic cancer samples (marked in red) and 171 normal samples (marked in green). (B) Pearson correlation analyses of HIF-1A, CA IX and CA XII m-RNA expressions with EDIL-3 expression. (*indicates p<0.05).*

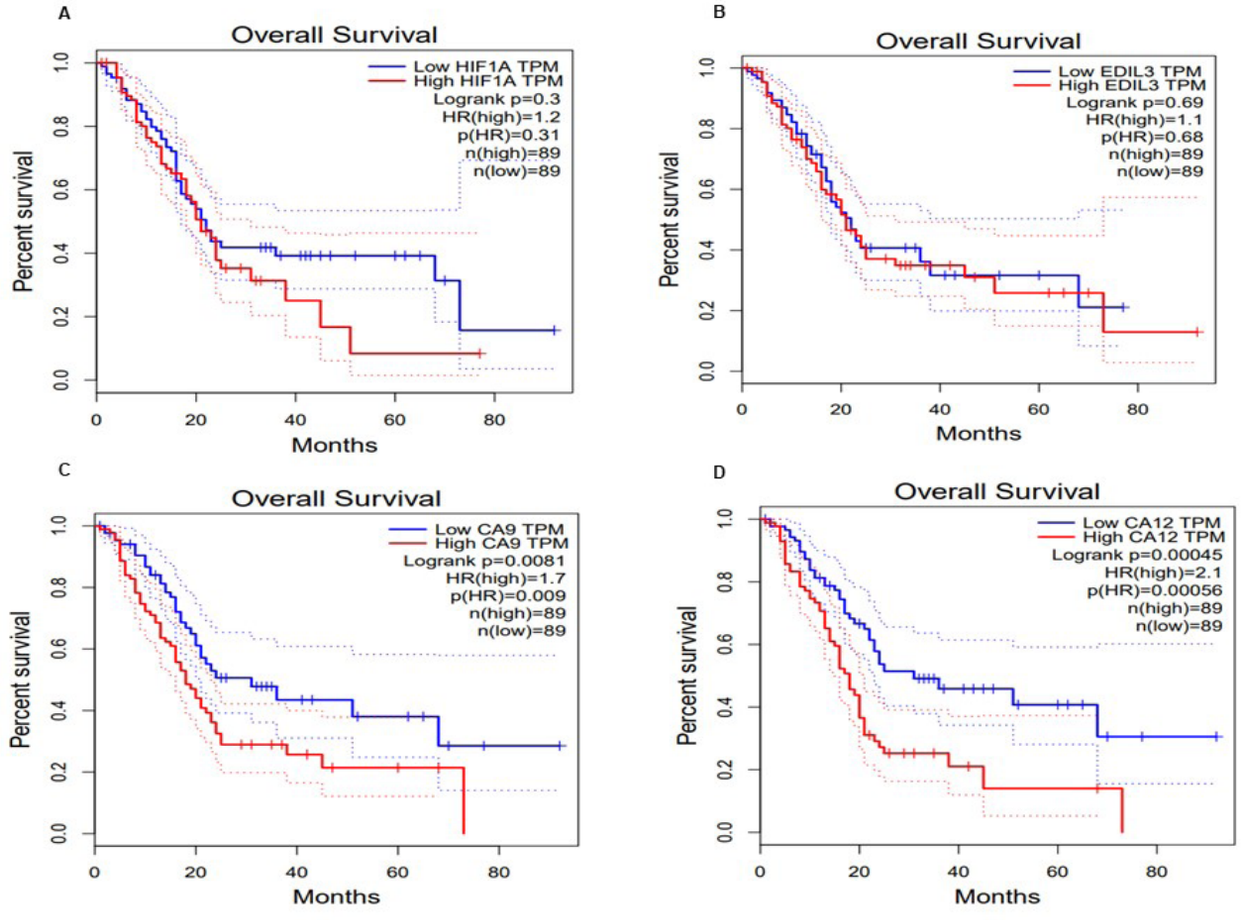


Figure 6. *Kaplan–Meier analysis of overall survival and disease free survival of the 179 pancreatic patients according to different HIF-1A (A), EDIL3 (B), CA IX (C) and CA XII (D) levels. (*indicates p<0.05).*

4. DISCUSSION

The adaptation of hypoxic tumor environment related to tumor progression and hypoxic nature is a unique characteristic in advanced pancreatic cancer like other solid tumors (24). The measurement of cellular responses to hypoxia may be clinical correlation with prognosis and prediction in treatment. HIF-1α is a good hypoxia marker and also transcription factor (5-7,24). Activation of HIF-1α signal protein may lead to cell proliferation, prevention of programmed cell death and accelerating of tumor progression (24, 25). Carbonic anhydrase IX is one of the target gene of HIF-1α and is known to play an important in angiogenesis, abnormal cell invasion and metastasis. Previous studies demonstrated that the induction of CA IX by HIF-1 in various cancer under hypoxic conditions (9-12,24,25). The association of HIF-1α, CA IX and EDIL3 expression has not yet been assessed in pancreatic cancer. In the present study, a significant association among CA IX, HIF-1α and EDIL3 expression was reported in pancreatic cancer patients. Furthermore, we observed that CA IX and EDIL3 expressions were markedly increased at m-RNA level, accompanied by increased level of HIF-1α in pancreatic cancer patients compared to healthy subjects. HIF-1α regulates tumor angiogenesis and its overexpression has been associated with tumor angiogenesis as in our study group. It has been also reported that high HIF-1α expression has a poor effect on the overall survival of pancreatic patients (26,27). CAIX, which is a membrane-bound protein regulated by HIF-1α under hypoxic conditions, also has a very high expression level in the pancreatic patient group, which includes our study group, compared to the healthy group. Interestingly, a positive correlation was identified between CA IX and HIF-1α expression. Therefore, CA IX expression induced by hypoxia appears to critical role in tumor development by induction of neovascularization and enhancing inflammation relevance to EDIL3 expression. Considering the prognostic significance of EDIL3 expression status may be more reliable marker for predicting tumor aggressiveness associated with tumor hypoxia. Besides, patients with low CA IX and CA XII expression levels were found to have longer survival times than those with higher expression levels.

To determine the mutation profiles of EDIL3, HIF-1α, CA IX and CA XII genes, which are among the genome sequencing results of 640 pancreatic cancer patients in TCGA datasets, were comprehensively analyzed. We found that 3.4% of the patient group had a mutation and that the most frequent genetic changes occurred in CA IX (2.3%). Missense mutations were identified in the study genes, especially in the sequences that encoded their important domains. According to the evolutionary analyses of the missense mutations we detected (HIF-1α p.G429R, p.S692Y, p.N827D; CAIX p.L293V, p.S294C; CA XII p.R240Q), we think that the mutations may have led to the formation of HIF-1α, CAIX, and CA XII genes with impaired functions and the genes were likely to have potential pathogenic characteristics since the functional pathogenic effects analyses showed that the mutations affected the amino acids that have been preserved throughout the evolutionary processes of these genes. Because these missense mutation points were locations that were highly conserved among species in the evolutionary process. Moreover, the missense mutations detected in all four genes were listed as somatic mutations in the COSMIC database. As there are no studies in the literature indicating the mutation profiles of the EDIL3, HIF-1α, CA IX, and CA XII genes and the role of the association between expression patterns in the pathogenesis of pancreatic cancer, our study is the first study stating the cancer-guiding roles of the mutations and expression profiles. Additionally, a further large-scale wet-lab study is needed to evaluate the roles of EDIL3, HIF-1α, CA IX, and CA XII genes in pancreatic cancer.

5. CONCLUSION

The key findings of this in-silico analysis are that the overexpression of CA IX is induced by HIF-1α in pancreatic cancer and also high level of CA IX expression are predictor of clinical outcome and decrease survival but no the correlation of EDIL3 and cancer-associated carbonic anhydrases. On the contrary, the relationship between EDIL3 and hypoxic marker HIF-1α was found. In addition, the high expression level of EDIL3 might be good predictive and prognostic marker and as a novel research target related with tumor hypoxia in pancreatic cancer.

Conflict of interest

Authors declare no scientific and financial interest.

Acknowledgements

The data used in our study are obtained from public database the TCGA Research Network: https:// www.cancer.gov/tcga. We thank the TCGA and GEPIA databases for the availability of the data.

Disclosure statement

No potential conflict of interest was reported by the author(s).

Funding

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Ethical approval and ethical standards

The data used in our study were obtained from public database TCGA, therefore, ethical approval was not required.

Availability of data and materials

The datasets generated and analyzed during the current study are available in TGCA database (https:// www.cancer.gov/tcga), The cbio cancer genomics portal (http://www.cbioportal.org/).

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Clinical and Experimental Health Sciences

Women's Experiences and Frequency of Vaginal Examination during Labour

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ABSTRACT

Objective: Vaginal examinations (VE's) are techniques that are widely used by midwives, nurses or doctors to assess the progress of labor. The present study aimed to determine the women's experiences and frequency of VE during labor.

Methods: A total of 328 women who gave vaginal birth were included in this descriptive study conducted in Turkey between January and October 2019. Data were collected in the first 24 h after birth using the "Personal Information Form" and "The Women's Experiences of Vaginal Examinations in Labour Scale".

Results: VE was performed 4.05±1.72 (range,1–12) times and by 2.41±1.24 (range,1–7) different medical personnel during labor. During VE, women mostly experience fear, pain, and shame. The average score of women on the WEVEL scale was 74.18±10.08 (good level). VE experiences of women to whom information was provided before the procedure, for whom the sex of medical personnel did not matter, whose privacy was protected, and on whom VE was performed by the same medical personnel were more positive; the difference was statistically significant ($p<0.05$).

Conclusion: VE should be performed while considering the sociocultural characteristics of the woman, paying attention to her privacy, only in cases where it is necessary and by the same medical personnel, as much as possible.

Keywords: Labor, Vaginal Examinations, Pain, Privacy, Women's Health

1. INTRODUCTION

Vaginal examination (VE) during labor is performed to determine the color/ smell of the amniotic fluid, the suitability of the pelvic structure for delivery, the effacement and dilatation of the cervix, the presentation and position of the fetus, and the deviations during labor (1,2). The World Health Organization (WHO) recommends that in low-risk women, VE should be performed every 4 h and by the same staff personnel in the active phase of the first stage of labor (3). The National Institute of Health and Clinical Excellence (NICE) concludes that there is no evidence that frequent VE at short intervals is beneficial and that it should be performed when necessary and to facilitate decision-making during active management of delivery (4). However, there are reports that VE is performed at frequent intervals in clinical practices (5,6,7,8,9,10,11,12). In addition, the NICE emphasizes that women are in a different environment during labor and experience pain; therefore, they should be informed about the procedure, and their privacy should be protected (4).

Frequent VE and lack of proper care leads to more pain, discomfort, anxiety, fear, shame, guilt, weakness, and decreased birth satisfaction during this process (7,13,14).

There are limited studies in Turkey examining the frequency of VE during vaginal delivery and the views as well as the feelings of women and their expectations from healthcare staff (15,16,17) Therefore, the present study aimed to investigate the women's experiences and frequency of VE during labor.

2. METHODS

2.1. Participants

This descriptive study was conducted in the education and research hospital of a province in northern Turkey between January and October 2019. This study included 328 women aged between 20 and 45 years with single pregnancy and

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vertex presentation who did not receive epidural analgesia, early membrane rupture, genitourinary infection, and latex allergy as well as those who gave vaginal birth.

2.2. Data collection tools

Data were collected in the first 24 hours after delivery by face-to-face interviews using the "Personal Information Form" (5,6,7,8,9,10,11,12,13) and "The Women's Experiences of Vaginal Examinations in Labor Scale" (18).

Personal Information Form: The form contains five questions related to age, level of education, profession, parite and gestational week, as well as the following questions which aimed to determine: "Have you been given information before VE?," "Was your privacy protected during VE?," "Did you feel discomfort during VE?," "What are the feelings you experienced during VE?," and "What were your expectations from the health staff performing VE?,".

The Women's Experiences of Vaginal Examinations in Labor (WEVEL): This scale was developed by Lewin et al. (9); the reliability and validity study of the Turkish version was conducted by Afacan (18). The cronbach alpha value of the scale is 0.86. WEVEL is a 5-point Likert-type scale consisting of 20 items. A minimum of 20 points and a maximum of 100 points can be obtained from the scale. Higher scores indicate positive VE experience. The cronbach alpha value of the scale was found to be 0.84 in this study.

2.3. Analysis

Statistical analysis was performed using SPSS (Statistical Package for the Social Sciences) for Windows 24.0 software. The Kolmogorov Smirnov test were used to determine whether the data obtained were normally distributed. Data were presented as number, percentage, mean, and standard deviation. In the study, independent groups t-test was used for comparison of normally distributed binary groups and a non-parametric Mann Whitney U test was used for comparison of non-normally distributed binary groups. In the study, the nonparametric Kruskal-Wallis H test was used for comparison of more than two groups that were non-normally distributed. $p<0.05$ was accepted as statistically significant in all analyses.

2.4. Ethical Considerations

To conduct the study, ethics committee approval by the KTU Faculty of Medicine Scientific Researches Ethics Committee (dated 14.01.2019 and numbered 24237859-41) were obtained. Women meeting the inclusion criteria were informed about the study, and the VE application and oral consent were received. Data collection took about 20–30 min for each woman. Verbal informed consent was obtained from women who agreed to participate in the study.

3. RESULTS

In this study, it was determined that 34.1% of women were in the 25–29 age group, most were primary school graduates (43.9%), unemployed (83.8%), multiparous (63.4%), and at 37–39 gestational week (55.2%) (Table 1).

Table 1. *Distribution of women according to some sociodemographic and obstetric characteristics (n = 328)*

Characteristics	n	%
Age group		
20–24 ages	84	25.6
25–29 ages	112	34.1
30–34 ages	85	25.9
35–39 ages	38	14.3
40 ages and above	9	2.7
Education status		
Primary school	144	43.9
High school	110	33.5
University and above	74	22.6
Employment status		
Employed	53	16.2
Unemployed	275	83.8
Parity		
Primiparous	120	36.6
Multiparous	208	63.4
Gestational week at admission to the hospital		
37–39 weeks	181	55.2
40–42 weeks	147	44.8

Vaginal examination was performed 4.05±1.72 (range,1–12) times and by 2.41±1.24 (range,1–7) health staff on both the examination table and their bed (62.8%), and majority of women were informed prior to performing VE (62.2%), and attention was paid to their privacy (98.2%) (Table 2). It was found that 70.7% of women did not experience discomfort during VE (Table 2). While VE was performed in most cases to assess the progress of labor (83.5%), most women stated that the sex of the health staff performing the examination was important to them (66.2%), and more than half of the participants asked for midwives to perform VE (51.5%) (Table 2). During VE, the majority of women experienced fear (57.9%) and/or pain (50%) (Table 2). It was determined that 80.2% of women requested only the person performing the examination to be present in the room during VE (Table 2). Participants expected the medical staff performing the examinations to be understanding (92.1%), friendly (90.9%), and caring (89.0%) (Table 2).

Table 2. *Characteristics of vaginal examination performed on women during labor, information, feelings and expectations of women (n = 328)*

Characteristics	Number/ Mean ± SD	Percentage/ Min-max
Total number of VEs*	4.05 ±1.72	1–12
1	3	0.9
2	55	16.8
3	83	25.3
4	79	24.1
5	55	16.8
6	24	7.3
7	12	3.7
8	12	3.7
9	3	0.9
10	0	0
11	1	0.3
12	1	0.3
Number of personnel performing VE*	2.41±1.24	1–7
1	83	25.3
2	113	34.5
3	79	24.1
4	32	9.8
5	11	3.4
6	9	2.7
7	1	0.3
Was VE performed by different medical staff? (Yes)	245	74.7
Where was VE performed?**		
Only on the examination table	94	28.7
Only in bed	28	8.5
Examination table and bed	206	62.8
Were you informed before VE? (Yes)	214	65.2
Who informed you before VE? (n = 214) (Midwife)	209	97.7
Was your privacy protected during VE? (Yes)	322	98.2
Did you feel any discomfort during VE? (No)	232	70.7
Degree of discomfort during VE***	1.28±2.29	0-10
Cause of discomfort during VE		
The fact that it's painful	16	4.9
Painful examination/pain	14	4.3
Disturbing behavior of the midwife	2	0.6
Examination performed by male doctor	3	0.9
Being examined by different persons	3	0.9
Climbing on the examination table	3	0.9
Not to be respected/no attention to privacy	3	0.9
Frequent examinations	7	2.1
The attitude of the doctor	1	0.3
Why do you think the VE is performed for? **		
To assess the progression of childbirth	274	83.5
For maternal health	38	11.6
For fetal health	32	9.8
Is the sex of the health personnel performing VE important to you? (Yes)	217	66.2
Which healthcare personnel would you like to perform a VE?		
Midwife	169	51.5
Physician	54	16.5
It doesn't matter.	105	32.0
What are the feelings you experience during VE? **		
Fear	190	57.9
Pain	164	50.0
Shame	79	24.1
Anxiety/stress	53	16.2
Joy/excitement	51	15.5
Nothing	2	0.6
Sadness	1	0.3
Disgust	1	0.3
Loneliness	1	0.3
Would you like to have someone with you during the VE?		
Just the person performing the examination	263	80.2
One member of my family	26	7.9
My mother	18	5.5
My husband	14	4.3
My friend	4	1.2
Midwife	2	0.6
Physician	1	0.3
What do you expect from the health personnel performing VE? **		
To be understanding	302	92.1
To be friendly	298	90.9
To be caring	292	89.0
Provide information	274	83.5
To be knowledgeable	263	80.2
To be attentive	259	79.0
To be careful	258	78.7

Data is from patient file (Delivery room observation form); **More than one response was given; * Rated by a 10-point system (0:none, 10:many)*

The mean score of women from WEVEL was 74.18±10.08 (good level), and the mean scores of the approval/ confirmation, perception, privacy, information, and pain subdimensions were 75.55±9.96 (good), 76.17±14.75 (good), 81.63±14.06 (good), 73.79±15.44 (good), and 55.85±18.85 (moderate), respectively.

It was found that VE experiences of women for whom information was provided before the application, and whose privacy was protected during VE practice were more positive. Additionally, it was found that VE experiences of women for whom the gender of medical staff performing vaginal examination did not matter, and whom VE was performed by the same medical staff were more positive. The difference was found to be statistically significant ($p<0.05$) (Table 4).

Table 3. *Descriptive statistics of the scores received by women from WEVEL and its subdimensions (n = 328)*

Scale and subdimensions		Min-max	Mean ± SD
The Women's Experiences of Vaginal Examinations in Labour		40–98	74.18±10.08
Sub dimensions	Approval/Confirmation	30–97	75.55±9.96
	Perception	25–100	76.17±14.75
	Privacy	27–100	81.63±14.06
	Information	32–100	73.79±15.44
	Pain	20–100	55.85±18.85

Table 4. *WEVEL score distribution according to several vaginal examinations (VE) characteristics (n = 328)*

Characteristics	n	%	The Women's Experiences of Vaginal Examinations in Labour	
			Mean ± SD / Median (Min-Max)	Statistical analysis
Number of VEs				
1–4	220	67.1	74.68±9.72	t*=1.297 p=0.196
5 and above	108	32.9	73.15±10.73	
Has VE been performed by different health staff?				
Yes	245	74.7	73 (40-98)	MWU**=8064.00 **p=0.005**
No	83	25.3	77(47-92)	
Number of staff				
1	83	25.3	77 (47-92)	KW***=8.166 **p=0.017**
2–3	192	58.5	74 (43-98)	
4–7	53	16.2	72 (40-94)	
Have you been informed prior to VE?				
Yes	214	65.2	77 (55-98)	MWU**=4187.50 **p<0.001**
No	114	34.8	67 (40-83)	
Is the gender of the health staff performing VE important to you?				
Yes	217	66.2	72.74±10.25	t*=-3.674 **p<0.001**
No	111	33.8	76.98±9.14	
Was your privacy protected during the VE?				
Yes	322	98.2	74.53±9.79	t*=4.865 **p<0.001**
No	6	1.8	55.00±5.36	

Student T-test; **Mann Whitney U; * Kruskal Wallis*

4. DISCUSSION

The WHO and NICE guidelines recommend that VE should be done every 2–4 h during labor and by the same health staff, as much as possible (3,4). In the present study, it was determined that VE was performed on an average of 4.05±1.72 (range, 1–12) times during labor and by 2.41±1.24 health staff (Table 2). It was also found that VE performed by the same health staff resulted in more positive experiences for women. When the relevant literature was examined, it was seen that the average number of VE performed during labor varied between 2.8 and 5.6 (range, 1-15) times (5-10) and that the number of health staff performing VE varies between ranged 2 and 7 (7,8). Although the results of this study are consistent with the WHO recommendations and some studies, there is no consensus on how often VE should be performed on average during labor and by how many medical staff (1,5).

One of the supportive care activities provided by the midwife or nurse during labor is to provide information about the procedure to be performed (19). In the present study, the majority of women were informed by midwives before VE. Furthermore, participants received a good score (73.79±15.44) from the "information" subdimension of the scale, and majority of women stated that VE was performed to assess the progress of delivery, which supports this result (Table 2). Contrary to the results of the present study, Hatamleh et al. (8) and El-Moniem and Mohamady (6) reported that consent was not received from women prior to VE and that the women were not informed before, during, and after the application. However, studies state that information provided using effective communication skills allows women to be more comfortable during the application (6,20).

Personal privacy within the scope of reproductive rights also has an important place in nursing care services, as stated in the item of "Protection of Patient Rights and Respect for Privacy" in the Declaration of Patient Rights (21). In the present study, attention was paid to the privacy of majority of the women prior to VE. It was determined that the participants obtained a score from the "privacy" subdimension of the scale that can be considered as quite good (81.63±14.06 points) (Table 3), and paying attention to privacy resulted in more positive VE experiences (Table 4). Similarly, in the study of Lewin et al., (9) women stated that their privacy was always protected during VE, while Afacan (18) reported a good average score in the subdimension of "privacy" (73.77±13.73 points). Contrary to the results of the present study, Hassan et al. reported that attention was not paid to privacy during VE application (7). Women in the present study requesting that only the person performing the examination to stay in the room during VE suggest that privacy is a real concern. The difference between the studies may be due to the fact that hospital where the present study was conducted is a mother-friendly hospital; thus, the maternity units consist of "single person rooms based on privacy," and the examinations of pregnant women can be performed on their beds, which can also function as examination tables.

Socio-cultural characteristics of society can affect women's sex preference in the field of health (17). In the present study, the majority of women stated that the gender of the personnel performing VE was important to them and that they wanted VE to be performed by midwives. However, it was found that the VE experiences of women who stated that the sex of the health staff performing VE did not matter to them were more positive. Similarly, other studies also reported that the healthcare staff performing VE were mostly women, and patients prefered women staff to perform the examination (22,23,24). Phumdoung and Youngvanichsate (10) reported that women who were planned to be examined by male staff wanted a female nurse to stay with them during the examination. Unlike the results of the present study, El-Moniem and Mohamady (6) reported that the majority (93.9%) of the staff performing VE was men, and women examined by male health staff felt more embarrassment and discomfort. These results show that women prefer VE to be performed by female health staff.

The situations such as VE performed in lithotomy position, attitude and sex of health staff, intimate parts of the body being exposed, and lack of consent or information before the application can cause women to experience feelings such as fear, shame, pain, and discomfort (25). In the present study, feelings most commonly experienced by women during VE were fear, pain, and embarrassment, and women

received a low score in the "pain" subdimension of the scale (55.85±18.85 points), which supports these results. Similar studies also reported that women experienced pain, shame, fear, guilt, and weakness during VE (6,7,8,10,13,16). Maiita et al. (26) also stated that even though women experienced pain, shame, and discomfort during VE, VE was useful during labor. These studies also acknowledge the need for VE during labor despite reporting that women experienced unpleasant feelings during VE (15,17).

The WHO recommends that effective communication using simple and culturally acceptable methods should be established between health care professionals and women for positive birth experience, and respectful maternal care should be provided, which allows them to receive constant support to protect their self-respect, confidentiality and privacy (3). In the present study, it was found that women mostly expected health staff performing VE to be understanding, friendly, attentive, and knowledgeable by provide information. It is reported in the literature that women want health staff to treat them kindly, friendly and attentively, by providing necessary explanations, and information (15,16,22). In this context, health staff should take into account the expectations of women to ensure positive communication between health staff and women, and to increase the quality of care given and maternal satisfaction.

5. CONCLUSION

It was found that women underwent VEs on average 4 times during labor. On the other hand it was determined that women experienced pain, embarrassment, fear, and anxiety during VE, but their VE experiences were positive. In this respect, information and explanation should be provided prior to the examination, and attention should be paid to their privacy during the examination by performing VE only when necessary by the same health staff to ensure that VE experiences of women are positive. Moreover, it was observed that more than half on the participants asked for midwives to perform VE.

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Clinical and Experimental Health Sciences

Adaptation of Chronic Kidney Disease-Self Management Knowledge Tool (CKD-SMKT) into Turkish

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ABSTRACT

Objective: The aim of the study is adaptation of Chronic Kidney Disease-Self Management Tool (CKD-SMKT) into Turkish language.

Methods: The study was conducted with chronic kidney disease patients in a training and research hospital. Initially, translation and cultural adaptation of the Turkish tool was performed, afterwards the internal consistency was evaluated with Kuder-Richardson (KR-20) coefficient.

Results: The total of 48 patients (mean of age [years]: 62.13±15.19) were included the study. An acceptable internal consistency with a KR-20 value of 0.71 was determined for the tool. 62.5% of participants answered correctly to all self-management knowledge items, however only 10.4% of them indicated that they behaved in line with the correct answers of all self-management knowledge items.

Conclusion: The Turkish version of CKD-SMKT is a reliable and appropriate tool to assess the self-management knowledge of chronic kidney disease patients.

Keywords: Chronic kidney disease, knowledge, self-management.

1.INTRODUCTION

Chronic kidney disease (CKD) is a serious worldwide public health condition affecting 12-15% of the adult population (1). CKD is defined as an abnormality in renal structure or function for 3 months or longer, with implications for health (2).

Since CKD has several complications (e.g., anemia, bone-mineral disorders, cardiovascular disease) in addition to medical conditions (e.g., diabetes mellitus, hypertension) that accompany the development of CKD, self-management of CKD is a multifaceted and complicated process. Therefore, adults with CKD often have complex medication regimens and need to adapt a compelling treatment regimen that even conscious patients may have difficulty with it (3). In that case, they should be aware of their medications and access recent information about their treatment. The patients also should regularly monitor their diseases with various parameters, control fluid and dietary intake, adopt the regular physical activity habits and regularly communicate with their health care providers (4).

It is important for patients to have sufficient knowledge about their diseases in order to carry out the self-management process (5). The tools that measure the knowledge of patients with chronic kidney disease are present in the literature, however most of these tools are intended only for patients receiving dialysis treatment (6-10). Although there are several tools for pre-dialysis stages, the focus of them is not the knowledge of the basic behaviors in the management of kidney disease which is the most important factor that may affect the patients' treatment outcomes. The major concern of these tools is the knowledge of renal disease and/or function of kidney (11-13). Only a few tools were available to directly target the evaluation of CKD self-management knowledge (14-16).

Chronic Kidney Disease Self-Management Knowledge Tool (CKD-SMKT) was developed by Devraj et al. (16) to meet the instrument need regarding evaluation of CKD self-management knowledge. This tool includes items related with knowledge of patients' self-management behaviors, also past performance on those essential behaviors.

A tool that measures self-management knowledge for the general population of chronic kidney patients was not available in Turkish language. Although there are various studies on this topic, these studies only include patients treated with dialysis (17-20). To address this gap, it is

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aimed to adapt the CKD-SMKT into Turkish language for the evaluation of self-management knowledge of patients with CKD in Turkey.

2.METHODS

2.1.Study Population

This study was conducted between the dates of April 2018 – October 2018 in a training and research hospital in Istanbul. Adult CKD patients (≥18 years) hospitalized for more than 24 hours during the study period with at least one medication use were evaluated for including in the study. The patients on routine dialysis treatment and using no antihypertensive agent were excluded.

The sociodemographic and clinical information of the patients were obtained from manual patient records or the electronic database of the hospital and through face-to-face interviews. Chronic kidney disease stage was determined with estimated glomerular filtration rate (eGFR) according to KDOQI guidelines (2). The self-management knowledge of the study population regarding chronic kidney disease was evaluated using the Chronic Kidney Disease Self-Management Knowledge Tool. The original tool was targeted for patients with CKD stage 1-4, but we included the patients with CKD stage 5 also (non-dialysis). Initially the tool was adapted to Turkish and then applied to the participants.

The study protocol was approved by Clinical Researches Ethical Committee of Marmara University Faculty of Medicine with number of 09.2018.165 and written informed consent was obtain from all participants.

2.2.Chronic Kidney Disease Self-Management Knowledge Tool (CKD-SMTK)

The tool, developed and validated by Devraj et al. (16), measures the knowledge of self-management behaviors such as nutrition, exercise, smoking avoidance, fluid intake management, alcohol consumption restriction and nonsteroidal anti-inflammatory drug use. It also provides information related with patient's past performance on these behaviors. The scale consists of 10 items. A general question about how much information patients have about their kidney health is also included in the scale (4).

2.3.Adaptation Process

CKD-SMKT was translated from the original language (English) into Turkish by two fluent English-speaking pharmacists whose native language is Turkish and who knew the purpose and scope of the study after obtaining permission for adaptation from the researcher who developed the tool. The translations were reconciled as a single translation under the supervision of an expert on the subject. This Turkish translation was translated into English by professional translators whose native language are English, and who have a medical background, also speak Turkish fluently but do not know the purpose and scope of the study.

The differences between the English translations and the original scale were evaluated, and then the latest version was translated back to Turkish. Next, the latest Turkish translation was overviewed for grammar correction and revised for cultural and conceptual content and equivalence.

For cultural adaptation of the Turkish version of CKD-SMTK as the last step of translation process; it was applied to a group of individuals who were independent of the study population (n=15; including nurse, nephrologist, physician and pharmacist) and evaluated in terms of language and comprehensibility by receiving feedback.

Since, questioning self-management behavior information and past performances related to these behaviors in a one item complicate the comprehensibility in Turkish, participants were questioned separately for their knowledge and past performance. Kuder-Richardson-20 (KR-20) coefficient was used to evaluate the internal consistency of the Turkish version, which was finalized by the mentioned stages.

2.4.Statistical Analysis

Descriptive statistics were calculated as mean ± SD (standard deviation) and median (interquartile range) or frequency and percentage for categorical variables. To examine differences in participant characteristics and continuous data was evaluated through Kruskal-Wallis test and Mann Whitney U test. KR-20 coefficient values above 0.70 indicated a good internal consistency (21). Spearman's correlation was used to assess the correlations. For all statistical analyses, $p \leq 0.05$ was determined as the level of statistical significance. SPSS (Statistical Package for Social Sciences) version 25.0 (IBM Corp., Armonk, NY) was used for performing statistical analyses.

3.RESULTS

3.1.Demographics

Seventy-three inpatients were evaluated in this study and forty-eight patients were included. Twenty-five patients were excluded due to the being on routine dialysis treatment before hospitalization (22) and using no antihypertensive agent (3). The mean age of the 48 patients (29 women) was 62.13±15.19 and the majority of the participants were married (56.3%). Most of them had not completed 8 years (at least required education years in Turkey) of school (66.7%). Approximately 70% of them had CKD stage 4 or stage 5. Table 1 shows the demographics of the participants.

Table 1. *Characteristics of participants*

Age (Mean±Standard Deviation)	61.13±15.19
Age n (%)	
28-44 years	7 (14.6%)
45-64 years	21 (43.8%)
≥ 65 years	20 (41.7%)
Gender – Female (%)	29 (60.4%)
Education n (%)	
< 8 years	32 (66.7%)
≥ 8 years	15 (31.3%)
Marital status – Married n (%)	27 (56.3%)
Duration of CKD (years) (patient-reported) (%)	10 (20.8%)
≤1	16 (33.3%)
2-5	7 (14.6%)
6-10	12 (25.0%)
>10	3 (6.3%)
Unknown	
CKD stage (%)	
Stage 3a: GFR 45-59 ml/min/1.73 m^2, n (%)	5 (10.4%)
Stage 3b: GFR 30-44 ml/min/1.73 m^2, n (%)	9 (18.8%)
Stage 4: GFR 15-29 ml/min/1.73 m^2, n (%)	17 (35.4%)
Stage 5 (non-dialysis): GFR <15 ml/min/1.73 m^2, n (%)	17 (35.4%)
Length of hospitalization (Median-IQR)	10.5 (8-21)
Number of concomitant chronic diseases (Median-IQR)	3 (2-4)

CKD: chronic kidney disease; GFR: glomerular filtration rate; IQR: interquartile range. The education and marital status data of 1 and 3 participants were not available, respectively.

3.2.Chronic Kidney Disease Self-Management Knowledge Tool (CKD-SMKT)

The rates of correct answers by item for CKD-SMKT are shown in Table 2. More than half of the individuals (62.5%) answered correctly to all self-management knowledge items. However only 10.4% of them indicated that they behaved in the past 3-6 months in accordance with the correct answers of all self-management knowledge items. 35.5% of the participants stated that they knew 'very little' or 'nothing' about their kidney health.

There was a positive weak correlation between self-management behavioral score and both age (r=0.400, p<0.01) and CKD years (r=0.457, p<0.01). There was no correlation with self-management knowledge score age and CKD years (Table 3). A statistically significant difference was observed in knowledge scores of participants with different education level, where significantly higher knowledge mean scores were obtained for participants educated ≥ 8 years (p<0.05). The self-management knowledge and behavioral scores were not statistically different by gender and CKD stage (p>0.05).

KR-20 coefficient was used to evaluate the internal consistency reliability of the tool and it was detected as 0.71 for CKD-SMKT (0.71 for overall tool, 0.70 for knowledge and 0.49 for behavioral items).

Table 2. *The rates of correct answers and behaviors by item for CKD-SMKT*

Knowledge instrument items	Correct answer	Correct answer (%)	Who have done this in the last 3-6 months (%)
Section A			
To help my kidneys I need to;			
Know what my blood pressure goal is.	T	85.4	29.2
Take my blood pressure medicine(s) like my doctor tells me to	T	87.5	89.6
Have my urine ('pee') tested at least once a year.	T	95.8	83.3
Get my blood checked every few months	T	93.8	83.3
Eat more salt	F	97.9	16.7
Keep a healthy body weight	T	83.3	58.3
Not take some types of over-the-counter medicines (Diclofenac, Ibuprofen, Naproxen etc.)	T	83.3	71.2
Section B			
Do you have diabetes? If YES, then answer the following: (n=25) **To help my kidneys I need to**;			
Keep track of my blood sugar each day	T	80.0	56.0
Eat less sugar	T	92.0	84.0
Take my diabetes medicine (s) like my doctor tells me to.	T	88.0	96.0
Section C			
Overall knowledge: How much do you know about your kidney health?			(%)
I know everything I need to know			25.0
I know a lot			10.4
I know some			29.2
I know a little			16.7
I know nothing			18.8

CKD-SMTK: Chronic Kidney Disease Self-Management Knowledge Tool

Table 3. *Correlation between CKD-SMKT scores and patient characteristics*

	Coefficient of correlation (Spearman's rho)	
	Self-management knowledge scores	Self-management behavioral scores
Age	0.126 (p>0.05)	0.400 (p<0.01)
CKD years	0.174 (p>0.05)	0.457 (p<0.01)

CKD-SMKT: Chronic Kidney Disease Self-Management Knowledge Tool

4.DISCUSSION

The self-management of patients with CKD regarding their diseases is one of the substantial factors in treatment. It should be assessed whether they have a sufficient level of knowledge or not in order to conduct the self-management

process. The literature incorporates a few tools developed for this purpose as mentioned above. Among these tools, CKD-SMKT was preferred to adapt to Turkish with the advantage of applicability and lack of numerously and complicated items to evaluate the participants' self-management knowledge.

Content validation of the original scale was provided by the developers, but no reliability test was performed. Therefore, internal consistency of scale was evaluated with KR-20 reliability coefficient. It was observed that the result of internal consistency analysis was similar to the other two scales developed for similar populations and patients with other chronic diseases related with knowledge, self-efficacy or self-management. The reliability coefficients of them were indicating good internal consistency. Different from our study, in these two scales the Cronbach's alpha coefficient was used to determine internal consistency due to type of response options (likert) (22, 23). In another survey developed to assess kidney disease knowledge, KR-20 formula was performed and the consistency level detected as similar to our result with a coefficient of 0.72 (12).

In the present study, the majority of the patients (62.5%) had high levels of CKD self-management knowledge. When the questions of the scale were evaluated individually, it was found that at least approximately 80% of the participants answered correctly for each question. In two studies using the same scale, it was shown that the majority of CKD patients (69.6%) had a high level of self-management knowledge and at least 90% of the participants answered correctly for each question similar to our results (24, 25).

In that encouraging outcome, the least known issues were relevance of blood pressure, blood sugar and body weight with CKD and the risk of NSAID use in CKD. Although they had high level of self-management knowledge, their behaviors were not in the same direction with this result and very few of them indicated that they behaved as it should be about their self-management. The greatest difference was observed between knowledge and behavior in blood pressure goal.

In one of the studies mentioned above, only 14.5% of individuals stated that they knew 'very little or 'nothing' about their kidney health (24). This rate was higher in our study (35.5%), although most of them had high level of self-management knowledge. While our study was conducted with inpatients, the other study was conducted with outpatients. The difference between the two patient groups is understandable with considering the negative psychological effects of hospitalization (26).

The Turkish version of CKD-SMKT is an applicable tool in terms of internal consistency, comprehensibility and duration of implementation. The condition of especially hospitalized patients with CKD may be difficult to communication. Therefore, duration and comprehensibility of a tool can be a crucial point for its practicability. CKD-SMKT can provide these advantages in clinical practice with a short implementation duration and yes/no questions.

Content validation was established in the original language of the scale, but as a limitation construct validation was not provided. As a limitation, the scale has a good internal consistency for knowledge section and overall tool, nevertheless the same situation was not observed when the behavioral section evaluated alone. Although only adaptation of the instrument was performed in this study, a new Turkish scale can be developed as the same direction in further studies by improving content of CKD-SMKT.

5.CONCLUSION

As a conclusion, the Turkish version of CKD-SMKT was determined as an appropriate tool to evaluate the self-management knowledge of chronic kidney patients. The patients with CKD had high level of knowledge, nevertheless it was observed that this encouraging outcome did not reflect to their behavior.

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This study was conducted within the scope of a Clinical Pharmacy PhD thesis at Institute of Health Sciences of Marmara University.

Conflicts of interest

None

Author contribution

OA – study design, data collection, performing of statistical analysis and writing of manuscript, FVI (thesis advisor) – contribution of study design, contribution the writing of manuscript, BO – study design, IHA – contribution of implementation of the research, MS – study design, performing and interpretation of statistical analysis and contribution of writing of manuscript.

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Clinical and Experimental Health Sciences

Assessment of Nursing Students' Stress Levels and Coping Strategies During Their First Clinical Experience

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ABSTRACT

Objective: This study was performed in order to examine the clinical stress levels of nursing students during their first clinical practice and their stress coping styles.

Methods: This descriptive study was performed with 91 freshmen in the nursing department of Namık Kemal University who experienced clinical practice for the first time. Data was collected using a student identification form, the clinical stress questionnaire and the stress-coping patterns scale.

Results: The students' mean age was 19.94±2.91. The mean stress score of the students during their first clinical experience was found to be 29.16±7.92. When the stress coping styles of the students were examined, their mean self-confidence approach score was 2.93±0.54, their seeking social support score was 2.73±0.48, their optimistic approach score was 2.68±0.61, their helpless/self-accusatory approach score was 2.17±0.50, and their submissive approach score was 1.84±0.44.

Conclusion: The clinical stress levels of the students were found to be low and the students were found to use the confident approach most in coping with stress.

Keywords: Clinical stress, coping with stress, nursing student.

1. INTRODUCTION

Nursing education, which aims to cultivate nurses who can translate their skills and information into practice in a professional and proficient manner, encompasses clinical and theoretic education styles that complement each other (1). Clinical education, which is an essential part of nursing education, provides the student with the opportunity to apply the skills they have learned in a real world environment (2, 3). Thus, it helps the improvement of skills such as critical thinking, analysis, communication, and management among nursing students (4) in addition to knowledge, attitude, and values (5), providing the student with the opportunity to develop a professional identity (2, 6).

The first clinical experience, which signifies the beginning of professional life, is very important for nursing students (5). Positive integration into the health care environment motivates the student, provides positive opportunities for change and improvement, and helps the student stay in the profession. Besides this, a negative first clinical experience can be upsetting for students (5, 7) and cause stress (8). During clinical practice, students can face many difficulties and challenges such as being in a dynamic and complicated environment, forming relationships with clinical staff and tutors, managing changes in patient status that constitute emergencies, and having to perform interventions on real people, and experience stress as a result (9-11).

In actuality, stress is an essential part of daily life and the natural reaction of the body to a situation perceived as involving physical and psychological danger (4). It was stated in the literature that although mild and medium levels of stress can have positive effects on the learning process of students, long term and intense stress experiences can have negative effects on clinical learning and health of the students, affecting patient care quality negatively (3, 9, 12). These positive and negative effects of stress on individuals are actually related to an individual's ability to develop effective coping behaviors (13). An individual who can develop effective coping behaviors can easily adapt to a stressful situation, whereas an individual who develops ineffective coping behavior can experience worsened stress and increased adaptation problems (4, 14). In this context,

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development of effective stress coping behavior by nursing students is very important with regard to decreasing stress, allowing better performance, the formation of a professional identity, and the management of negative situations (1).

There are many studies in the literature examining clinical stress of nursing students. In the study by Shaban et al. (2012), nursing students experienced moderate levels of stress during clinical applications, using the problem-solving approach to cope with stress most (3). In Blomberg et al.'s (2014) study, more than half of the students were seen to experience severe stress during clinical practice (15). In studies performed in Turkey, nursing students were found to experience low (14, 16, 17), moderate (4, 8), or high (18) levels of stress during clinical practice. Alongside this, nursing students were found to mostly use the problem-oriented active style approach to coping with stress (4, 14, 19).

Clinical practice is irrefutably important for nursing students. However, since the students enter an environment they are not used to and encounter many different situations, they may perceive their first clinical applications as a stressful situation. Additionally, if the students have developed appropriate stress coping approaches, they can easily cope with those stressful situations. For the clinical education of nursing students to reach its goal, it is thus very important to know the stress levels of nursing students during their first clinical practice and their stress coping behavior. For this reason, this study was performed in order to examine the clinical stress levels of nursing students during their first clinical practice and their stress coping styles.

2. METHODS

2.1. Study Design

The research was applied in a descriptive and correlational design.

Research Questions:

1. What is the stress level of freshmen nursing students during their first clinical experience?

2. What are the stress coping styles of freshmen nursing students?

3. What are the factors affecting the clinical stress level and coping styles of nursing students?

4. Is there a relationship between stress levels and stress coping styles of freshmen nursing students?

2.2. Study Setting and Sample

The universe of this study consisted of all freshmen (n=102) studying in the nursing department of the health school of Namık Kemal University in the spring semester of the 2016-2017 academic year. The study included students who were in the first year of nursing, had no previous clinical experience, attended classes during the study period, and volunteered to participate in the study. Health vocational high school graduates were excluded from the study because they had previous clinical experience. The research was completed with 91 students who met the appropriate criteria.

2.3. Instruments

Data was collected using a Student Identification Form, the Clinical Stress Questionnaire (CSQ) and the Stress-coping Patterns Scale (SCPS).

The Student Identification Form: The form was prepared by the researcher and included five questions about age, sex, school of graduation, willingly choosing the nursing occupation, and whether there was a nurse in the family.

The Clinical Stress Questionnaire: The questionnaire was developed by Pagana (1989) to determine the initial value of stress that threatens or hinders nursing students in their first clinical experience. In the development of the 5-point Likert type self-report questionnaire, the cognitive evaluation of stress theory by Lazarus et al. was used. The 20-item questionnaire is separated into four categories as threat (6 items), challenge (7 items), benefit (2 items), and harm (5 items). The score range of the questionnaire is 0-80 and higher scores indicate higher stress levels. The Turkish validity and reliability study for the questionnaire was completed by Sendir and Acaroğlu (2006) and the Cronbach's alpha coefficient was found to be 0.70 (20). Cronbach's alpha coefficient was 0.70 in this study.

The Stress-Coping Patterns Scale (SCPS): The scale, which was developed by Folkman and Lazarus and tested for validity and reliability in Turkish by Sahin and Durak, is a 4-point Likert type scale with 30 items. The scale measures two main stress coping styles, namely problem-oriented effective methods (active style) and emotion-oriented ineffective methods (passive style) (14, 19, 21). While efforts to remove the threatening event or decrease its effects are emphasized in problem-oriented coping, denial and avoidance are noted instead of fighting the stressful event in the emotion-oriented style (22). The self-confident approach (SCA), social support seeking approach (SSS), and optimistic approach (OA) sub dimensions are grouped under the active style, while the submissive approach (SA) and helpless/self-accusatory approach (HA) are grouped under the passive style. The scores for each sub dimension are calculated separately and higher scores indicate that the individual uses that style more when coping with stress (14, 19). The Cronbach alpha coefficients of the scales were determined to be 0.45-0.47 for SSS, 0.49-0.68 for OA, 0.62-0.80 for SCA, 0.64-0.73 for HA, and 0.47-0.72 for SA (19). In the present study, it was found Cronbach's alpha coefficients was 0.46 for SSS, 0.51 for OA, 0.81 for SCA, 0.72 for HA, and 0.50 for SA.

2.4. Data Collection

Data was collected by the researchers at the end of the day following the first clinical experience of the students by handing the students the related forms, scales, and questionnaires in their classroom.

2.5. Data Analysis

Statistical analysis of the study data was performed in a computer environment using the SPSS 22.0 software with descriptive tests, comparative statistical methods (Mann Whitney U test, Kruskal Wallis test), and the Pearson correlation analysis to determine the relationship between the scales.

2.6. Ethical Considerations

Before starting the study, approval was obtained from the Namık Kemal University Faculty of Medicine Non-Invasive Clinical Research Ethics Committee (2017/39/03/10) and written permission was obtained from the institution where the study will be conducted. Additionally, each student participating in the study was informed about the aim of the study, what was expected of them, their legal rights, and the confidentiality of the data obtained, and those who agreed to participate in the study provided written consent.

3. RESULTS

The mean age of the students participating in the study was 19.94±2.91 years. It was found that 67.0% of the students were female, 53.8% were Science/Anatolian High School graduates, 63.7% chose the nursing occupation willingly, and 16.5% had nurses in their families.

The mean stress score of the students during their first clinical experience was found to be 29.16±7.92 (min=9, max=48). When the stress coping styles of the students were examined, their mean self-confident approach score was 2.93±0.54 (min=1.71, max=4), their seeking social support score was 2.73±0.48 (min=1.5, max=3.7), their optimistic approach score was 2.68±0.61 (min=1.6, max=3.4), their helpless/self-accusatory approach score was 2.17±0.50 (min=1.0, max=3.0), and their submissive approach score was 1.84±0.44 (min=1.0, max=3.0) (Table 1).

Nursing students graduating from Science/Anatolian High Schools used the submissive passive approach (p=0.049) more to cope with stress, while those who chose the nursing occupation willingly used the active seeking social support approach (p=0.043) more (Table 2).

Among nursing students, those graduating from other high schools received the highest score from the clinical stress total scale (p=0.015), threat (p=0.000), and harm (p=0.041) sub dimensions. Students with nurses in their families received higher scores from the clinical stress sense of benefit (p=0.048) sub dimension (Table 2).

When the relationship between the mean scores obtained from the two scales was examined, a high level positive correlation was found between the optimistic approach sub dimension and the sense of challenge (r=0.827, p=0.000). A low level positive significant correlation was found between the self-confidence approach sub dimension and challenge (r= 0.236, p= 0.024), and a medium level positive significant correlation was found between benefit sub dimensions (r= 0.361, p= 0.000). A low level of positive significiant correlation was found between the sub dimension of submissive approach and sense of threat (r= 0.241, p= 0.021) and harm (r= 0.245, p= 0.019). A negative significant correlation was found between the submissive approach sub dimension and the sense of benefit (r=-0.297, p= 0.004) (Table 3).

Table 1. *Individual characteristics of participants (n=91)*

Characteristics		n	%
Gender	Female	61	67.0
	Male	30	33.0
Graduation School	General High School	25	27.5
	Science/Anatolian High School	49	53.8
	Other High School (Technical and Religious)	17	18.7
Willingly choosing nursing	Yes	58	63.7
	No	33	36.3
Having a nurse in the family	Yes	15	16.5
	No	76	83.5
	Mean± SD		**(min-max)**
Age, (years)	19.94±2.91		18-34
Total CSQ	29.16±7.92		9-48
Threat (6 items)	6.60±3.99		0-19
Challenge (7 items)	15.46±5.60		0-25
Harm (5 items)	2.93±3.18		0-15
Benefit (2 items)	4.19±2.09		0-8
Stress-Coping Patterns			
Self-confident approach	2.93±0.54		1.71-4
Seeking social support	2.73±0.48		1.5-3.7
Optimistic approach	2.68±0.61		1.6-3.4
Helpless/self-accusatory approach	2.17±0.50		1.0-3.0
Submissive approach	1.84±0.44		1.0-3.0

Table 2. *CSQ and SCPS mean scores according to socio-demographic characteristics of participants (n=91)*

Characteristics	CSQ					SCPS				
						Problem-oriented/active patterns			Emotion-oriented/ passive patterns	
	Threat	Challenge	Harm	Benefit	Total	Optimistic approach	Self-confident approach	Seeking social support	Helpless/ self-accusatory approach	Submissive approach
Gender										
Female	6.96±4.29	15.77±5.28	2.93±3.11	4.14±2.08	29.81±7.41	2.60±0.66	2.85±0.53	2.71±0.46	2.23±0.52	1.83±0.46
Male	5.86±3.23	14.84±6.26	2.93±3.39	4.30±2.15	27.93±8.87	2.85±0.47	3.08±0.52	2.76±0.55	2.08±0.46	1.85±0.42
p*	0.130	0.339	0.811	0.902	0.212	0.262	0.545	0.425	0.302	0.576
Graduate School										
General HS[1*]	4.28±2.71	15.80±5.14	1.80±1.77	4.72±1.64	26.60±6.98	2.65±0.44	2.97±0.43	2.68±0.55	2.11±0.45	1.66±0.41
Science/Anatolian HS*	6.85±3.56	15.14±5.81	3.04±3.40	3.93±2.27	28.95±8.26	2.64±0.47	2.90±0.57	2.77±0.48	2.19±0.51	1.93±0.43
Others HS (technical and religious)*	9.20±4.92	15.94±5.92	4.29±3.68	4.17±2.12	33.70±6.54	2.87±1.06	2.94±0.60	2.70±0.42	2.22±0.59	1.83±0.47
p**	**0.000** **3>1-2**	0.824	**0.041** **3>1**	0.321	**0.015** **3>1**	0.404	0.869	0.734	0.746	**0.049** **2>1**
Willing choice nursing										
Yes	5.36±3.32	16.43±5.04	2.20±2.80	4.56±2.01	28.56±7.17	2.74±0.48	3.03±0.50	2.74±0.43	2.10±0.48	1.79±0.44
No	8.78±4.18	13.75±6.20	4.21±3.46	3.54±2.10	30.30±9.11	2.58±0.79	2.74±0.55	2.72±0.59	2.29±0.52	1.91±0.45
p*	0.197	0.087	0.071	0.655	0.053	0.560	0.583	**0.043**	0.536	0.971
Having a nurse in your family										
Yes	6.80±4.93	16.20±3.93	2.86±2.13	4.93±1.57	30.80±7.15	2.72±0.60	3.00±0.55	2.73±0.35	2.16±0.44	1.91±0.49
No	6.50±3.82	15.31±5.89	2.94±3.37	4.05±2.16	28.88±8.07	2.68±0.62	2.91±0.53	2.73±0.51	2.18±0.52	1.82±0.43
p*	0.504	0.066	0.245	**0.048**	0.850	0.561	0.796	0.189	0.385	0.510

[*] *High School, *Mann Whitney U test was used. ** Kruskal Wallis test was used. Statistically significant values (p < 0.05) are shown in bold.*

Table 3. *The relationship between the clinical stress level of participants and their ways of coping with stress*

SCPS \ CSQ		Threat	Challenge	Harm	Benefit	Total
Optimistic approach	r	0.087	0.827	-0.066	0.187	0.083
	p	0.410	**0.000**	0.536	0.076	0.437
Self-confident approach	r	-0.171	0.236	-0.047	0.361	0.158
	p	0.106	**0.024**	0.659	**0.000**	0.135
Seeking social support	r	-0.101	0.124	-0.159	0.068	0.009
	p	0.339	0.241	0.132	0522	0.931
Helpless/self-accusatory approach	r	0.201	0.085	0.166	-0.193	0.057
	p	0.056	0.424	0.166	0.067	0.591
Submissive approach	r	0.241	-0.151	0.245	-0.297	0.035
	p	**0.021**	0.154	**0.019**	**0.004**	0.742

Pearson Correlation test was used. Statistically significant values (p < 0.05) are shown in bold.

4. DISCUSSION

Clinical education is the most important learning experience for nursing students where they translate the knowledge and skills they gain during theoretical education into practice. Clinical practice environments, despite being inevitable for the improvement of the professional skill and knowledge of students, also constitute an important source of anxiety and stress (9, 11, 23). Nursing students' experience with clinical practice may have profound effects on their desire to study nursing as well as their approach to clinical situations. Students' coping with stress in their first clinical experience will also affect the quality of nursing education (24). The factors that create the most stress for students during clinical practice were stated to be clinical stressors (lack of occupational skill and knowledge, communication with patients and clinical personnel etc.) (10, 18) and academic stressors (clinical exams, communication with lecturers etc.) (9, 11).

In this study that was conducted to determine stress experienced by nursing students in their first clinical applications and their stress coping styles, students were generally found to have low levels (29.16±7.92) of clinical stress. This finding answers the first question of the study. Similar to these findings, low levels of perceived clinical stress were reported in other studies as well (14, 16, 17). In the literature, a low level of clinical stress was reported to be desirable because of its stimulating effect, contributing to the creation of a safe learning environment for the student and an increase in academic success (11, 16, 25). Alongside this, low levels of clinical stress may provide the opportunity for better evaluation of patient needs by the student, as well as for better communication with patients and next of

kin, helping clinical education reach its goal (26). The study also demonstrated that average scores in sub-di mensions of clinical stress questionnaire were the highest in challenge and the lowest in harm emotions. This shows that clinical practice is perceived as a low level of harm for the student and increases the student's sense of challenge. Similar results were reported in various studies (8, 14, 26). In a study by Atay and Yilmaz (2011), students reported higher levels of clinical stress with their sense of threat and harm (18). In Tambağ's study, it was reported that the anxiety level of students who went into clinical practice for the first time was high (27). In another study, it was reported that students experienced moderate anxiety before clinical practice (28). The low level of clinical stress found among the students in this study may be caused by the curriculum supporting the student, not much responsibility being given to students on their first clinical day, and adaptation to the hospital environment and personnel being emphasized.

Groups who are under more stress because of their working conditions and work environment need to have effective (active) coping behavior. Developing effective stress coping skills in individuals not only protects their bodily and mental health and their relationships with their environment, but also directly affects the lives of those for whom they provide care (29). In other studies, nursing students were found to mostly use a self-confident approach as well (9, 19, 26). In a study by Chan et al (2009), students with low stress levels were found to use active styles in coping with stress (11). In a study conducted by Al-Gamal et al (2018) in Arabia, nursing students were stated to mostly use the problem-solving strategy to cope with stress (9). In another study, the self-confident approach in coping with stress was found to be related to lower stress levels and the situation adaptation indicator (30). In this study, nursing students were found to mostly use a self-confident approach for coping with stress, thus using an active style. These results also answer the second question of the study.

In the study some demographic variables affecting clinical stress levels of students and their stress coping styles were studied. In this scope, it was determined that gender of students did not make any difference in terms of stress levels of students and their coping style with stress. Karagözoğlu et al. (2013) found that gender did not affect the clinical stress level of nursing students (26). Similarly, in Taşdelen and Zaybak's (2013) study examining the stress level of nursing students in their first clinical experience, it was determined that gender did not affect the clinical stress level of students (8). Other studies indicated that female students experience higher levels of stress than male students (31, 32) and presented as reasons of this difference, expression of emotions and anxieties more by women than men and gender differences in psychological morbidity (31). The fact that no significant differences were established in this study was considered to be a positive finding.

In the country where the study was carried out, there are high schools such as Science high schools, Anatolian high schools, General high schools, Technical high schools, and Religious high schools. Students are admitted to these schools through examinations organized by the Ministry of Education and only students with high scores are accepted to science high schools and Anatolian high schools. In technical high schools and religious high schools, vocational courses are given more importance. In the study, a significant difference was found between the total scores for clinical stress and the mean scores for threat and harm subscales according to the schools the students graduated from. Especially, the stress levels of students who graduated from other high schools (Technical high school, Religious high school) were higher. Graduates from other high schools perceived clinical practice as more threatening and harmful to themselves. This situation is thought to be due to the fact that students come from different educational backgrounds and their academic achievement and awareness are low. When clinical stresses and coping styles of students were assessed according to high schools they graduated from, it was determined that graduates of Science/Anatolian high schools used passive submissive tendency more than general high school graduates. While there were no other studies in the literature supporting this finding, it was noted that students with higher academic successes displayed better coping behaviors (active style approach). It was considered that results of this study could be based on different factors such as the fact that Science/Anatolian high school graduates choose studying nursing unwillingly, they did not like the vocation, and that the vocation fail to meet expectations of these students.

In the study, no significant difference was found between the clinical stress scores of the students who willingly chose nursing. Study by Ergin et al. noted that most of the students choose studying nursing willingly and no relationship could be established between their willingly choosing the vocation and their stress levels (33). In Findik et al.'s study to measure the clinical stress of the students prior to practice in the operating room, choosing the nursing profession voluntarily did not affect the clinical stress level of the students (14). In another similar study, the voluntary choice of nursing did not affect the stress level (34). However, students who willingly chose nursing used more active social support in coping with stress. Requesting social support is asking for assistance by individuals from their close circles and their acceptance of support received (35). Help from the social environment in coping with stress helps stress to be tolerated more easily and coped with better (35, 36). The fact that students who chose nursing willingly had higher social support scores suggests that these students may have received support from individuals in their environment when they chose their occupation. Similar to this finding, study by Yılmaz et al. and study by Okuyan and Deveci found that requesting social support had a higher score among students that choose to study nursing willingly (37-38).

In this study, students with nurses in their families were found to receive higher scores from the clinical stress sense of benefit sub dimension. This result shows that those who work

as nurses in the family constitute positive examples and a good support system in the selection of the nursing occupation. It was also determined that the willingness to choose nursing did not affect coping with stress. Study by Durmuş and Gerçek found that having nurses in the family decreased stress scores (39). Study by Topal Hançer et al. (2019) also found lower stress scores for students with nurses in the family and argued that this was based on choice of students this vocation knowingly, being familiar with its structure (40). These results answered the third question of the study.

Although the first clinical experience is more or less stressful for every student, people can have different styles of coping with stress. Nursing students who used the active style optimistic approach and the self-confident approach more saw their first clinical experience as more of a challenge and beneficial to themselves. Alongside this, nursing students who used the passive style submissive approach more saw their first clinical experience as more of a threat and harmful to themselves, and less beneficial. Study by Evgin et al. (2017) that discussed student anxieties in pre-clinical application period argued that students with high levels of anxiety used silent coping methods when faced with stressful situations (41). Another study determined that as stress levels increase in students, they tend to use passive style stress coping mechanisms such as avoidance more (40). Study by Fındık et al. found that stress levels experienced by students affected their coping styles and that students with low stress levels used active styles while individuals with high stress levels used passive styles in coping with stress (14). Another study by Karaca et al. described that as level of perceived stress increase in nursing students, they use avoidance as coping mechanism more (31). In a study conducted with psychiatric nursing students, Tully (2004) found that students with higher stress levels used negative behavioral patterns such as smoking, consuming alcohol, using drugs, or forgetting about the situation more than active coping methods for coping with stress (30). This study argued that employment of effective coping mechanisms by students demonstrated such methods affect stress levels positively. According to these findings, we think that students who developed active styles for coping with stress saw their first clinical experience as more positive and contributing to their learning. With these results, the fourth question of the study was also answered.

Limitations and strengths of the study

The study had some limitations. Data from the study was limited with one health school. Thus, data cannot be generalized to all nursing schools. There are similar studies in Turkey, however, this study achieved different results. In addition, a significant strength of this study was its being the first study assessing clinical trainings of students while the school where this study was conducted was an established school giving nursing education for almost thirty years. In this scope, the study was expected to be assessed before clinical training period which was an indispensable part of nursing vocation, to guide training processes before and during clinical training provided by trainers, and to contribute to the literature.

5. CONCLUSION

As a result of this study it was determined that nursing students who had their first clinical application experience had low stress levels and that they used active stress coping styles more frequently. Low stress level and high use of self-confidence approach were findings that supported each other in the study. In addition, employment of active styles by students proved that they could effectively cope with stress. Positive results were considered to be a pleasing/hopeful property for nursing training. However, because training is a dynamic process, academics must always assume duties and responsibilities while nursing students recognize such stresses and develop skills to cope with stress. Nurse academics can reinforce student nurses starting from their academic lives to contribute to development of both students and the vocation.

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Clinical and Experimental Health Sciences

Evaluation of C-shaped Canal Configuration in Maxillary Molars: A Retrospective Cone-Beam Computed Tomography Study

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ABSTRACT

Objective: The aim of this retrospective study was to evaluate the prevalence of C-shaped canal configuration in maxillary first and second molars according to age and gender by using cone beam computed tomography (CBCT) in a Turkish population.

Methods: In this retrospective study, 709 first and 739 second maxillary molars were examined. CBCT images of teeth were examined in different axial sections to determine the presence of C-shaped canal configuration. C-shaped canal configuration was classified into five groups according to the fusion of root canals. Prevalence of C-shaped canal configuration between first and second molars, age groups and genders were compared. The chi-square test was used to compare the categorical variables. The differences were considered significant if the p value was less than 0.05.

Results: A total of 1448 teeth were evaluated and 3% (n=43) of them had C-shaped canal configuration. The presence of C-shaped canal configuration was significantly more common in the second molars than the first molars (p = 0.000) No significant difference in the prevalence of C-shaped configuration was observed comparing genders and age groups (p>0.05). Type A and E canal configuration were not detected in first molars.

Conclusion: C-shaped canal configuration is a rare anatomical variation of maxillary molars. This variation includes fins or isthmuses connecting root canals which create challenges during endodontic treatment. Perceiving the variations with CBCT imaging helps clinicians to understand and treat complex cases without complication. Clinicians should be knowledgeable about the rare variations for better outcomes.

Keywords: Canal Variation, Cbct, C-Shaped Canal, Maxillary Molars

1. INTRODUCTION

Successful root canal treatment depends on detailed knowledge about canal configuration, the cleaning of all pulp tissues, shaping walls, and the complete obturation of all root canal spaces (1, 2). The presence of untreated canals and microorganisms due to inadequate cleaning, shaping, and obturation is the main reason for endodontic treatment failure (2, 3). Knowledge of the root and canal variations is one of the most important factors in endodontic procedures in preventing possible complications and in achieving better outcomes (4, 5).

Maxillary molars generally have two buccal canals and one palatal canal (6). Maxillary first molars usually show anatomic variation in mesiobuccal root with more than two canals (7). Although the maxillary second molar has a similar morphology to the maxillary first molar, anatomic variations are more common in second molars, such as root fusions, root canal isthmuses, and accessory canals (6). C-shaped canal is another important variation for some teeth, especially for mandibular second molars (3, 5). It was first described by Cooke and Cox (1979) as a “ribbon-shaped orifice” (8). Despite a lot of the studies about mandibular molars, there are limited numbers of studies reporting C-shaped canal configurations in maxillary molars. The C-shaped canal configuration can occur in permanent maxillary molars with fused roots and can also continue from the floor of the coronal pulp to the apical region of the root (3, 9). This configuration includes grooves, isthmuses, and irregular formations that lead to ineffective cleaning, shaping, and obturation (2).

Periapical radiographs are usually effective for preoperative evaluation of root canal morphology and periapical pathologies (3). These radiographs give 2-dimensional information for 3-dimensional structures. Assessment of root canal in several sections and serial slices is the optimal method for understanding root and canal configurations (3, 10). Plain radiographs are insufficient to visualize C-shaped canals because of the canals’ complex nature and superimpositions

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(2). Cone beam computed tomography (CBCT) is a tool that gives precise information about root canal complexities. CBCT allows high resolution images in different sections with a small field of view and small voxel size (4, 11).

Although the prevalence and types of C-shaped canal configuration in mandibular molars were investigated, there is currently no study on maxillary molars in a Turkish population. The aim of this study is to evaluate the prevalence and types of C-shaped canal configuration in maxillary first and second molars in a Turkish population by using CBCT.

2. METHODS

The study protocol was approved by Aydın Adnan Menderes University Faculty of Dentistry Clinical Research Ethics Committee (protocol number: ADUDHF2021/25, date:01.09.2021). For the evaluation of C-shaped canal configuration in maxillary first and second molars, CBCT images taken at our department of oral and maxillofacial radiology for patients' previous dental problems between 2016 and 2019 were examined. Fully erupted and completely root formed maxillary first and second molars without root canal treatment, fracture and crown restoration were included. Third molars and low-quality images were excluded. Finally, 1448 maxillary molars (709 first molars and 739 second molars) in 517 Turkish patients were examined retrospectively.

The CBCT scans were obtained using standard exposure parameters and patient positioning protocols (resolution: voxel size 0.2mm, 80–84kvp, 10–12mA) with a CBCT unit (Planmeca Promax 3D Max; Helsinki, Finland). Romexis version 4.6.2. software (Planmeca; Helsinki, Finland) was used for evaluation of axial, sagittal, and coronal CBCT planes with optimal contrast and brightness adjustment. Images were examined in a 22-inch LCD monitor (Samsung Business Monitor S22D300HY; UK) with a resolution of 1,920 × 1,080 pixels in a dark room. For the proper assessment, axial sections that were vertical to the long axis of each tooth were examined by rolling the tool bar from the floor of coronal pulp to the apex. All images were evaluated retrospectively by two oral and maxillofacial radiologists with at least two years' experience in performing CBCT. The observers evaluated the images twice in one-month intervals to assess intra – and interexaminer agreement.

Five groups (10-22, 23-36, 37-50, 51-64, 65-77) were created according to age range. Because no well-defined classification could be determined in the case of C-shaped canals in maxillary molars, modified classification of a lower molar C-shaped canal was used according to Martins et al. (5) as below:

The canal system was evaluated at 5 axial levels:

1. 2 mm below the canal beginning
2. Middle interval between coronal and middle
3. Middle interval from the canal beginning and anatomic apex
4. Middle interval between the middle and apical
5. 2 mm above the anatomic apex

Canal systems continuous at 3 axial levels and large C-shaped canal systems with 2 main canal lumens connected by a large isthmus were accepted as a C-shaped canal. C-shaped maxillary molars according to the configuration of the fused root canals were classified (Figure 1, 2).

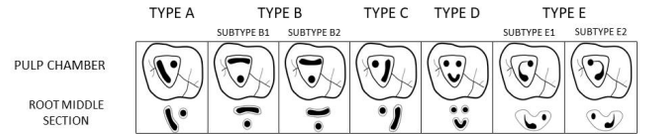

Figure 1. *Schematic drawings of C-shaped canal configurations according to root canal fusion*

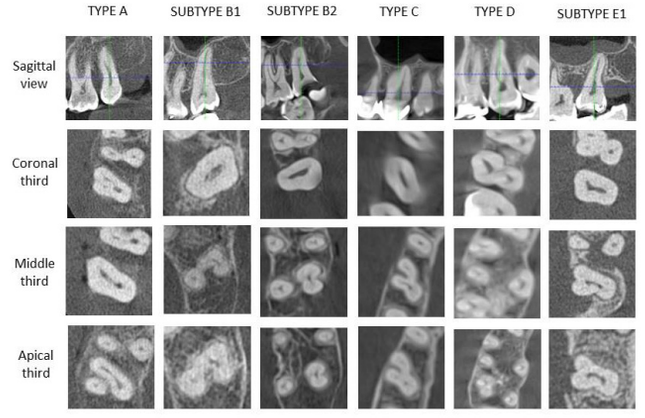

Figure 2. *Axial views of each types of C-shaped canal configurations*

2.1. Statistical Analysis

All the data were analyzed with the SPSS software (IBM SPSS Statistics Version 22; IBM, Armonk, New York). The chi-square test was used to compare the prevalence of C-shaped canals in first and second molars across genders, age groups, and sides. When the p value was < 0.05, the differences were considered significant. Inter – and intraobserver reliability was calculated using the Cohen kappa test.

3. RESULTS

A total of 517 patients (231 men and 286 women) CBCT images including 709 maxillary first molars and 739 maxillary second molars were examined in this study. Mean age of the patients was 34.2 years, ranging from 10 to 77 years. Three percent (43) of all teeth had C-shaped root canals, and 2.9% (24) of women and 3% (19) of men had C-shaped canal in their maxillary molars. There was no significant difference between the genders (p=0.876).

Sides and numbers of maxillary molars with the C-shaped canal configuration were presented in Table 1. Nineteen (2.6%) right maxillary molars and 24 (3.3%) left maxillary molars had a C-shaped canal. There was no significant difference between sides (p=0.423). The C-shape root canal system was more common in maxillary second molars than maxillary first molars with ratios 4.9% and 1%, respectively. The difference between the first and second maxillary molars was considered significant (p=0.000).

Table 1. *C-shaped canal configuration in maxillary first and second molars*

	Right Maxillary Molars Left Maxillary Molars			
	First	Second	First	Second
Present	3	16	4	20
Absent	355	353	347	350
Total	358	369	351	370
	727		721	

Types of C-shaped canal configuration according to first and second molars were presented in Table 2. Type A and E were not found in first molars. The most common type was type B, with a prevalence of 2.3% in maxillary second molars. There was no significant difference between types of C-shaped canals (p=0.563). Prevalence of C-shaped canal configuration according to age groups was presented in Table 3. There was no significant relationship between the presence of C-shaped canal configuration and age groups.

Table 2. *Types of C shaped canals in maxillary first and second molars*

		Maxillary First Molars				Maxillary Second Molars			
		Right	Left	Total	Per cent	Right	Left	Total	Per cent
Types of C shaped Canals	**A**	0	0	*0*	0%	3	1	*4*	0.5%
	B	1	1	*2*	0.3%	8	9	*17*	2.3%
	C	1	1	*2*	0.3%	1	4	*5*	0.7%
	D	1	2	*3*	0.4%	1	1	*2*	0.2%
	E	0	0	*0*	0%	3	5	*8*	1.1%
	Total	3	4	*7*	1%	16	20	*36*	4.8%

Table 3. *Prevelance of C-shaped canal configuration in age groups*

Age Groups	Maxillary molars	C-shaped canal configuration		TOTAL
		Present	Absent	
10-22	First molar	2	297	591
	Second molar	7	285	
23-36	First molar	2	169	338
	Second molar	10	157	
37-50	First molar	5	157	329
	Second molar	11	156	
51-64	First molar	1	86	172
	Second molar	4	81	
65-77	First molar	0	8	18
	Second molar	1	9	
TOTAL		43	1405	1448

The relative technical error of measurements for intra – and interobserver errors ranged from 1.02 to 1.62% and from 1.1 to 1.94%, respectively. The coefficient of reliability values ranged from 0.94 to 0.98.

4. DISCUSSION

Several imaging techniques and demineralization/staining methods have been used to visualize detailed root canal morphology in the literature (12-16). Periapical radiographs, examination of root canals during endodontic treatment, patients' previous records, and CBCT are frequently used in clinical studies of root canal configuration (1, 17-19). Most of these studies have used Vertucci's classification system for root canal identification (13). Unlike previous studies, we classified root canals according to their axial views. Also, this study used CBCT images to investigate the presence of C-shaped canals according to gender, age, and location.

In clinical practice, C-shaped canal configuration can be assessed with periapical radiographs, CBCT and CT (20-23). CBCT has many advantages, such as lower radiation doses, lower exposure time, higher resolution, lower voxel sizes, and more precise measurements. CBCT also allows cross-sectional images without superimposition, which is not possible with intraoral radiographs (24, 25). Because of the radiation dose, CBCT should be used in line with the SEDENTEXCT guidelines (26). In our study, CBCT images that were taken of the patient's previous dental problems, such as intrabony cysts, implant planning, and orthodontic problems, were evaluated retrospectively.

There were a limited numbers of studies that evaluated C-shaped canals in maxillary molars (1, 5, 17). Most studies on C-shaped canals were focused on mandibular molars due to their predisposition to this variation (8, 15, 16). We could not find any reported study in the literature about C-shaped canal configuration in maxillary molars in the Turkish population and highlighted the importance of this variation for clinical practice. In our study, the prevalence of C-shaped canals in maxillary first molars and second molars was 1% and 4.9%, respectively. Similarly, Yang et al. reported a 4.9% prevalence for maxillary second molars by using a clearing method in a Chinese population study (27). In a Korean population study using CBCT, the prevalence of C-shaped root canals in maxillary first molars and second molars was 0.8% and 2.7%, respectively (1). Compared with the present study, our result was lower in the first molars and higher in the second molars. In our study, maxillary second molars were more prone to have C-shaped canals than first molars. In the study of De Moor et al. (17), which was performed on radiographs, reported a lower prevalence (0.091%) than our result in maxillary first molars. The difference may be due to the method of study and ethnic background. Other differences from the previous studies may be due to subject age, study size, imaging types, and racial features.

With the exception of type D, all other types of C-shaped canals were more common in second molars. In contradistinction

to our results, in the Martin et al. study only type C was more common in first molars. The second most common type was type E in second molars with 1.1% prevalence and a deep isthmus and groove. These areas can go undetected clinically, allowing pathogen microorganisms to colonize easily, resulting in failed endodontic treatment. Because of a complex internal configuration, the Type E canal poses more difficulties in root canal treatment compared with Type C. Our results were similar to those of Martin et al., who did not find Types D and E, and we did not find types A and E in first molars. Martin et al. found Type C with a prevalence of 0.2% in second molars and 0.9% in first molars. In our study, Type C had a prevalence of 0.7% in second molars and 0.3% in first molars.

From the previous studies, only Martin et al. (5) investigated C-shaped canal configuration according to sex and side. In their study, a C-shaped canal was more common in females and not related to the right or left side (5). Similarly, there was no significant difference between the right and left side in our study. Most clinical cases of C-shaped canal configuration in maxillary molars were presented in males (2, 7, 28). A previous case report on C-shaped canal configuration in maxillary second molars was presented in a woman with spiral CT(3). In our study, C-shaped canals were more common in females without significant differences (29). The C-shaped canal configuration can gradually disappear due to secondary and tertiary dentine formation during aging. In the literature there is no explicit relationship between age and prevalence of C-shaped canal configuration in maxillary molars. Despite the low prevalence ratio of this variation in our study, we divided patients into age groups to compare possible changes. But we did not find any relationship between age and presence of the C-shaped canal configuration in maxillary molars.

In the literature, the C-shaped canal configuration of maxillary molars was described according to fused roots and only serial sections of axial view (1, 5). There has not been any well-documented or accepted classification for maxillary molars yet. Evaluation of root canal morphology has been done with various methods both in vivo and in vitro (1, 4, 30, 31). There were some limitations in this study. First of all, only an Aegean region population was included in our study. In future studies, patients from all over the country should be included in the study. In future studies, patients from other regions of the world with larger populations should be included. Secondly, root forms and root dentin thickness were not examined in the present study. It would be helpful for instrumentation and obturation of root canals.

5. CONCLUSION

This retrospective CBCT study of a Turkish population showed a low prevalence of C-shaped canal configuration in maxillary molars. Results of future studies including different populations, large samples, and different high-resolution imaging methods may help to elucidate this variation. If the clinician suspects the presence of C-shaped canal configuration in maxillary molar with root fusion, a high-resolution CBCT scan should be performed and examined carefully to prevent endodontic failures.

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Clinical and Experimental Health Sciences

Sleep Quality and Fatigue Level of Patients with Coronary Angiography

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ABSTRACT

Objective: The aim of this study was to determine sleep quality and fatigue levels of patients who underwent angiography in coronary intensive care unit.

Methods: This study was performed among individuals who underwent angiography in the coronary intensive unit of a City Hospital in the center of a city in Turkey between December 15, 2018 and April 15, 2019 (n:205). Data were obtained using the Patient Identification Form, Richards-Campbell Sleep Scale, Brief Fatigue Inventory.

Results: The mean score of Richard's Campbell Sleep Scale was 46.01 ± 18.90 in patients undergoing angiography at the coronary intensive care unit. The mean score of the Brief Fatigue Scale was found to be 4.49 ± 1.99. A negative correlation was found between the mean Richard's Campbell Sleep Scale and Brief Fatigue Inventory and its subdimension scores. The fatigue levels were found to be increased as the sleep quality of the patients decreased.

Conclusions: It was determined that patients undergoing coronary angiography had poor sleep quality and high levels of fatigue, and this was caused by several factors. In line with these results, it is recommended to make nursing care plans and consultancy for sleep hygiene and activity planning at regular intervals for individuals at risk.

Keywords: Coronary intensive care, angiography, sleep quality, fatigue, nursing

1. INTRODUCTION

Coronary artery disease (CAD) is a health problem that occurs as a result of deterioration of myocardial blooe flow due to narrowing or occlusion of coronary arteries with an atherosclerotic plaque.[1,2] According to the American Heart Association (AHA) information, coronary artery disease has been diagnosed in more than 13.2 million people in the United States resulting in an average annual mortality or myocardial infarction in 1.2 million people.[1]Coronary heart diseases were found to be the cause of 42.0% of the deaths among 906 individuals registered and died in 26 years (1990-2016) according to the Turkish Adult Heart Disease and Risk Factors (TEKHARF) study performed in Turkey.[3]

Coronary artery walls become thicker and atherosclerosis develops in coronary artery disease.[1] Coronary angiography (CAG) is used to determine the stenosis of the coronary arteries and to plan surgical or medical treatment. In the screening performed using diagnostic procedure codes of the Health Implementation Statement, 260.995 coronary angiographies were performed in 2009, and theumber was increased to 335.113 in 2010.[4]

After coronary angiography, patients face many problems such as sleep problems, fatigue, and limitations in daily living activities.[5]Not only sleep patterns but also the circadian rhythm is impaired in patients hospitalized in ICU (at least 24 hours) after CAG.[6] REM period is reported in the literature to constitute only 6.0% or less of sleep in patients hospitalized in intensive care units.[7,8] Sleep quality was found to be poor in 68.6% of the patients diagnosed with coronary artery disease in a study by Vural et al. (2007).[9] In the study conducted by Gustafsson and Hetta (2001) in coronary intensive care unit, 42.4% of the patients were found to have problems falling asleep and as a result they felt physically tired.[5]Insomnia and fatigue was found to increase the level of anxiety in patients who underwent CAG and this was reported to lead to increases blood pressure and heart rates in a study performed by Salamon et al. performed in patients in intensive care units. In addition, anxiety may negatively affect the recovery of the

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patients by decreasing their physical activity and emotional energy levels and even augmenting fatigue and insomnia.[10]

The role and responsibility of a nurse during the process of coronary angiography is counselling as providing information and training of the individual in addition to caregiving.[11] The nursing care begins with the admission of the patient to the intensive care unit.[12] Factors such as providing inadequate information of the patiens to be admitted to the intensive care about their disease and treatment, inability to see their relatives, estrangement to the environment and surrounding individuals, to be bedridden, limitation of the movements, stimulations in the intensive unit and anxiety result in problems such as fatigue by disturbing sleep patterns. [13, 14] It is one of the most important responsibilities of the nurses working at the coronary intensive care unit to determine and exclude the physical, environmental and emotional factors that prevent the patients from having a good quality and quantity of sleep, and to provide and maintain a normal sleep process and to relieve the fatigue of the patients.[12]

Sleep problems and fatigue are found to be common in individuals diagnosed to have coronary artery disease in the studies performed.[5,15,16] No study performed in this country has been encountered on the sleep quality and fatigue levels of patients hospitalized after angiography in the CCU and evaluating the troponin value and the risk factors including the drugs used. This present study is considered to contribute to the literature by extensively evaluating sleep and fatigue level after angiography. Therefore, this study was conducted to determine sleep quality and fatigue level after angiography.

The aim of this study was to determine the sleep quality and fatigue level of patients who underwent angiography in coronary intensive care unit.

The study questions include the following:

1. What is the sleep quality of patients undergoing coronary angiography?
2. What is the level of fatigue in patients undergoing coronary angiography?
3. Is there a relationship between sleep quality and fatigue levels of the patients?
4. What are the sleep quality and fatigue levels of the patients according to the troponin value?
5. What are the sleep quality and fatigue levels according to the drugs used by the patients?

2. METHODS

2.1. Study Design

A cross-sectional descriptive design was used for the study.

2.2. Setting, Sample and Data Collection

The universe of the study was composed of individuals who were admitted to the coronary intensive care unit and underwent angiography between December 12, 2018 and April 15, 2019 at a city hospital in Turkey. A total of 390 patients were admitted to the CCU between these dates. Individuals excluded from the study were 35 due to hearing or vision problems, 50 for being over 75 or under 30 years of age, 12 due to administration of psychiatric drugs that have an effect on sleep and fatigue, 45 due to admission to the intensive care unit at 22:00 hours or presence of a sheath around those hours, 25 due to decision of a bypass procedure after the angiography (myocard infactus). and thus referrence of the patient to another place, and 18 due to transfer to the cardiology service or voluntary discharge on the same day. The research was completed with 205 people. The treatment hours in Coronary Intensive Care Unit are generally between 09:00 in the morning and 21:00 in the evening and after 24:00 the lights are turned off except for the nurse's desk. At 3 am, ECG and blood samples are routinely obtained in each patient. If the condition of the patients is appropriate, curtains are drawn during the night hours and care is taken to speak in a low voice. The applications are tried to be performed calmly when needed in emergency conditions and care is taken not to disturb the rest of the patients. No regular sleep hygiene training is provided for the patients during the hospital stay or after the discharge.

Individuals who underwent angiography and included in the sample were with ages between 30 to 75 years and who stayed at least one night in the CCU, were hemodynamically stable, had a pain scale below 3, had no mechanical ventilation and were not sedated, had a glaskow coma score of 15 and were sufficient to answer the research questions and who provided a written and verbal consent to participate in the study.

Patients who had visual and hearing problems, who were using antihistamines and psychiatric drugs, who had sheath after 22:30 hours, who took medication for sleep and were put into pre-treatment were excluded from the study.

One-to-one face-to-face interviews were conducted about the patient's general condition, history of arrival, and disease. Before bedtime (as of 22:30 hours), the patient's questions were answered within the scope of counseling. During the daytime on the second day, the sleep quality and level of fatigue of the patient concerning the previous night's sleep was evaluated by means of face-to-face interviews for 30 minutes using data collection instruments.

2.3. Measures

The data of the research were collected using Patient Identification Form, Richards-Campbell Sleep Scale and Brief Fatigue Inventory.

2.3.1. Patient identification form

This form, which was developed by the researchers by scanning the literature, consists of 2 sections – 17 questions to evaluate the "Socio-Demographic Characteristics" and "Disease Characteristics".[17-20]

1. Socio-demographic characteristics evaluated were age, sex, marital status, level of education, occupation, cigarette smoking and alcohol use and the people living with them.

2. Disease Characteristics evaluated consisted of 9 questions including the presence of previosly diagnosed chronic disease and the diagnosis of the disease, previous MI, the status of using drugs if previous MI was positive, troponin value (high-low), after angiography, and the drugs used and presence of stent implantation.

Figure 1. *Reference range of the biochemistry results*

Biochemistry Result	Reference Range of the Laboratory Findings
Troponin (ng/ml)*	0:00 to 2:00

** The results of the City Hospital Central Laboratory were taken into consideration in the evaluation of the laboratory results given in the reference range in Figure 1. Accordingly, the results below the reference range and the reference range were considered as "normal" and results above the reference range as "high". Troponin" values are taken from the patient file.*

2.3.2. Richards– Campbell sleep scale

Richards C. developed the Richards-Campbell Sleep Scale (RCSS) in 1987.[21] It is a 6-item scale that assesses the depth of night sleep, the time to fall asleep, the frequency of waking up, the duration of staying awake, the quality of sleep and the noise level in the environment. The first 5 questions are included in the scale and the 6th question is excluded from the scoring. Each item is evaluated by the visual analog scale technique with 5 points increments (0-5-10-15...-90-95-100) on the chart between 0 and 100. A score between "0-25" indicates a very poor sleep while a score between "76-100" indicates a very good sleep. The higher the scale score, the better the sleep quality of the patients. The cronbach α value of the scale developed by Richards was found to be 0.82. Turkish adaptation of Richard Campbell sleep scale and evaluation of its reliability and validity was performed by Ozlu and Ozer in 2015. It was decided that this scale could be used in research on the topic in Turkey (Cronbach's alpha 0.91).[22] The Cronbach's Alpha value of the scale was found to be 0.93 in this present study.

2.3.3. Brief fatigue inventory (BFI))

The Cronbach alpha internal consistency coefficient of the BFI which was developed in 1999 by Mendoza et al.[23]and was determined to be appropriate for Turkish society by Cinar et al.[24]was found to be 0.98. BFI evaluates the severity of fatigue (currently, always, worst) (1,2,3) and the effect of fatigue on daily living activities (4a, 4b, 4c, 4d, 4e, 4f). Each item of the BFI consisting of nine items has a value between 0-10 points. Fatigue severity score is calculated by dividing the total score of items 1, 2 and 3 into 3 and the score of effect of fatigue on living activities is calculating the total score of items 4a, 4b, 4c, 4d, 4e, 4f into 6. As the score obtained from the scale increases, it is interpreted as that the severity of fatigue and its effect on daily living activities increase.[23-25] In this present study, fatigue assessment was made based on the total score obtained. In this present study, the cronbach alpha value of the scale was determined as 0.96.

2.4. Statistical Analysis

The data of the study were evaluated by using Statistical Package for Social Sciences (SPSS) (23.0) program. The independent variables of the study were the data on the sociodemographic characteristics of the patient such as age, gender and educational background. Dependent variables of the study were Richard's Campbell Sleep Scale, Brief Fatigue Inventory and its sub-dimensions. The normal distribution of the data was done by Shapiro-Wilk test. Descriptive statistics were used to determine the socio-demographic characteristics. In order to determine the difference between the mean Fatigue and Sleep quality between the groups, t-test was used for independent groups for 2-group comparisons and one-way anova for more than two groups. If a difference was determined as a result of comparisons made in more than two groups, tukey test was performed as post hoc analysis. Pearson correlation analysis was used to determine the results of correlations between Richard's Campbell Sleep Scale, Brief Fatigue Inventory and its sub-dimensions and age variable. Power analysis was used. In the comparisons, $p < 0.05$ was considered statistically significant.

3. RESULTS

3.1. Participant Characteristics and Demographics

Among the participants, 68.8% of the individuals were male, the mean age was 58.06 ± 9.32 years, 85.9% were married and 40.0% were cigarette smokers. In addition, 64.4% of individuals were found to have chronic diseases. Among the patients, 90.2% had chest pain, 81.0% had ECG changes and 73.7% had high Troponin levels. Some 58.5% of the individuals were found to be diagnosed to have MI and 77.1% had never had MI before. 98.5% of the patients were using drugs after angiography. 69.8% were found to use antihypertensives, 94.6% antithrombolytic drugs, 5.9% diuretics, 50.2% lipid lowering drugs, 14.1% coronary vasodilators and 86.8% proton pump inhibitors (Table 1).

3.2. Richards Campbell Sleep Scale and Brief Fatigue Inventory

Mean RCSS score of the subjects was 46.01 ± 18.90. Mean BFI score of the individuals was 4.49 ± 1.99, mean score of Fatigue Severity subscale was 4.88 ± 2.00 and mean score of Fatigue Impact on Daily Living Activities was 4.29 ± 2.14 (Table 2).

Table 1. *Characteristics of the study sample (n=205)*

Specifications	N	%
Gender		
Female	64	31.2
Male	141	68.8
Age (Year Mean±ss) (min-max)	58.06±9,32 (34.0-75.0)	
Marital Status		
Married	176	85.9
Single	29	14.1
Status of Cigarette Smoking		
Positive	82	40.0
Negative	63	30.7
Quit Smoking	60	29.3
Status of Chronic Disease		
Present	132	64.4
None	73	35.6
Status of Chest Pain		
Present	185	90.2
None	20	9.8
Status of ECG Change		
Present	166	81.0
None	39	19.0
Status of High Troponine Value		
Present	151	73.7
None	54	26.3
Diagnosis		
Chest Pain	57	27.8
Myocardial Infarct (MI)	120	58.5
Atherosclerotic Heart Disease	28	13.7
Status of Previous Myocardial Infarction		
Previous Myocardial Infarct Positive	47	22.9
No Previous Myocardial Infarct	158	77.1
Status of Medication Use		
Positive	202	98.5
Negative	3	1.5
Status of Antihypertensive Drug Use		
Positive	143	69.8
Negative	62	30.2
Status of Antithrombotic Drug Use		
Positive	194	94.6
Negative	11	5.4
Status of Diutetic Drug Use		
Positive	12	5.9
Negative	193	94.1
Status of Lipid Lowering Drus Use		
Positive	103	50.2
Negative	102	49.8
Status of Coronary Vasodilator Drug Use		
Positive	29	14.1
Negative	176	85.9
Status of Proton Pump Inhibitor Drug Use		
Positive	178	86.8
Negative	27	13.2

Table 2. *Mean score of RCSS and BFI and its sub-dimensions of individuals*

Scale	*N*	X+ *SD*	Min.	Max.
Richard's Campbell Sleep Scale	205	46.01±18,90	3.33	88.33
Brief Fatigue Inventoryof Individuals	205	4.49±1.99	0.56	9.44
Severity of Fatigue Sub-Dimension Score	205	4.88±2.00	0.67	9.33
Sub-Dimension of Effect of Fatigue on Daily Life Activities	205	4.29±2.14	0.33	9.50

3.3. Comparison of Sub-dimensions of Scales (Brief Fatigue Inventory) According to Descriptive Characteristics of Individuals

There was no significant difference between mean sleep and fatigue scores according to sociodemographic characteristics (p> 0.05). Sleep quality was found to be worse in patients with chronic disease (p <0.05). The mean score of BFI Fatigue Severity Sub-Scale was found to be significantly higher in individuals with chronic disease (p <0.05). There was no statistically significant difference between the mean scores of RCSS according to presence of HT in the participants (p> 0.05). The mean score of BFI Fatigue Severity Sub-Scale was found to be significantly higher in subjects with HT (p <0.05). There was no statistically significant difference between the mean scores of RCSS according to the ECG change status of the participants (p> 0.05). The mean Fatigue Severity Subdimension score was higher in subjects with ECG changes (p <0.05). According to the nausea-vomiting status of the individuals, there was a significant difference in the effect subscale scores of fatigue on daily living activities. It was found that the mean RCSS score was significantly lower in individuals with high troponin levels and the total score of BFI and the Fatigue Severity Subdimension Score was higher in individuals with high troponin levels (p <0.05). There was no statistically significant difference between the mean scores of RCSS according to the diagnosis of the individuals (p> 0.05). The total and subdimension BFI scores of the patients undergoing angiography for MI were significantly higher compared to the remaining group (p <0.05). There was no significant difference between the mean scores of RCSS according to stent implantation status after angiography (p> 0.05). However, STE and subdimension scores were found to be higher in patients with stent implantation after angiography compared to the group without stents (p <0.05). There was no statistically significant difference between the mean scores of RCSS according to the antihypertensive and coronary vasodilator drug use of the individuals. However, scores of BFI and its sub-scales were found to be higher in patients who used antihypertensive drugs compared to those who used no antihypertensives. BFI and sub-scale scores were found to be lower in patients who used coronary vasodilators compared to those who used no coronary vasodilators (p <0.05) (Table 3).

Table 3. *Comparison of sub-dimensions of the scales by descriptive properties of the individuals*

	n	Richard's Campbell Sleep Scale	Brief Fatigue Inventoryof Individuals	Severity of Fatigue Sub-Dimension Score	Sub-Dimension of Effect of Fatigue on Daily Life Activities
Status of Chronic Disease		X+ SD	X+ SD	X+ SD	X+ SD
Present	132	43.14±18,83	4.62±2,06	5.09±2,06	4.39±2,20
None	73	51.22±18.02	4.26±1.87	4.51±1.87	4.14±2.03
		p=0.003*	p=0.224	p=0.049*	p=0.437
Status of HT					
Present	81	44.00±17,81	4.78±2,00	5.33±2,03	4.50±2,15
None	123	47.39±19,61	4.30±1,98	4.58±1,95	4.16±2,14
		p=0.213	p=0.094	p=0.009*	p=0.261
Status of ECG Change					
Present	166	45.41±18,95	4.62±1,97	5.03±1,96	4.42±2,13
None	39	48,59+18,76	3.94±2,04	4.27±2,10	3.77±2,14
		p=0.346	p=0.053	p=0.032*	p=0.261
Status of Nausea/ Vomiting					
Present	48	44.31±19.09	4.98±2.03	5.26±1.87	4.84±2.30
None	157	46.54±18.88	4.34±1.97	4.77±2.04	4.13±2.07
		p=0.476	p=0.054	p=0.141	p=0.045*
Status of High Troponine Value					
Present	151	44.46±18.04	4.68±1.96	5.13±2.00	4.46±2.08
None	54	50.36±18.57	3.96±2.03	4.18±1.87	3.85±2.26
		p=0.049*	p=0.022*	p=0.002*	p=0.072
Diagnosis					
Chest Pain	57	48.18±19.72	3.91±1.93	4.42±2.10	3.67±1.98
Myocardial Infarct (MI)	120	43.82±18.65	4.98±1.94	5.32±1.93	4.80±2.12
Atherosclerotic Heart Disease	28	51.01±17.40	3.59±1.75	3.95±1.68	3.42±1.96
		p=0.115	p<0.001*	p=0.001*	p<0.001*
Status of Stent Implantation after Angiography					
Stent Implanted	151	45.03±18.49	4.76±1.95	5.16±1.96	4.56±2.09
No Stent Implanted	54	48.77±19.93	3.74±1.96	4.11±1.96	3.56±2.13
		p=0.214	p=0.001*	p=0.001*	p=0,003*
Status of Antihypertensive Drug Use					
Present	143	45.00±17.83	4.78±2,00	5.21±2.02	4.55±2.13
None	62	48.36±21.16	3.84±1.84	4.10±1.75	3.71±2.06
		p=0.244	p=0.002*	p<0.001*	p=0.009*
Status of Coronary Vasodilator Use					
Present	29	51.74±18.54	3.52±1.86	3.86±2.03	3.34±1.95
None	176	45.07±18.85	4.65±1.98	5.05±1.96	4.56±2.13
		p=0.078	p=0.004*	p=0.003*	p=0.009*

**Student t test and One way Anova.*

3.4. Bivariate Analysis

A negative and highy significant correlation was found between mean RCSS and BFI and its subscale scores (p <0.05). A highly significant and positive correlation was found between the mean total BFI score and mean Severity of Fatigue sub-dimension and Effect on Daily Living Activities Sub-dimension. There was a very weak and positive correlation between age variable and mean Fatigue Severity Subscale score (p <0.05) (Table 4).

Table 4. *Evaluation of the correlations between RCSS, BFI and its sub-dimensions and age of the individuals*

Correlation Test Results ***	Mean Richard's Campbell Sleep Scale Points	Mean Brief Fatigue Inventory Points	Mean Severity of Fatigue Sub-Dimension Points	Mean Effect of Fatigur on Daily Life Activities Sub-Dimension Points	Age
Mean Richard's Campbell Sleep Scale Points	-	-	-	-	-
Mean Brief Fatigue Inventory Points	-0.302**	-	-	-	-
Mean Severity of Fatigue Sub-Dimension Points	-0.330**	0.897**	-	-	-
Mean Effect of Fatigur on Daily Life Activities Sub-Dimension Points	-0.268**	0.987**	0.786**	-	-
Age	-0.081	0.110	0.160*	0.079	-
p<0.05, ** p<0.01					

****Pearson correlation analysis was performed.*

4. DISCUSSION

Sleep is a biological need and one of the most important predictors of physical and mental health. Exposure of patients to sound, noise, light and many procedures in the intensive care unit increases night wakes, in which case their deep sleep is interrupted and have inadequate sleep, decreased energy levels and increased fatigue.[13,14] In this present study, the mean RCSS and BFI scores in patients who underwent angiography and admitted to the coronary intensive care unit were found to be in a moderate level and fatigue was found to be increased as sleep quality was decreased. Higgins et al. (2000) reported that patients experienced severe anxiety, sleep disturbances, fatigue and sensation of low energy after angioplasty.[26] In a study conducted by Gustafsson and Hetta (2001) in a coronary intensive care unit, 42.4% of the patients stated that they had problems in maintaining sleep and felt physical fatigue due to sleep problems.[5] When the literature is evaluated, fatigue was emphasized to increase due to deterioration in cardiac functions and decrease in daily living activities of the individual.[27,28] Fatigue was suggested to occur secondary to inadequate rest after the procedure, cardiac problems, disruption of nutrition, O_2requirement and sleep pattern of the individual.

The presence of chronic diseases in patients hospitalized in coronary intensive care unit is one of the important factors in the development of sleep problems.[29] Our research findings, similar with the literature, pointed out that individuals with chronic disease had poor sleep quality and higher fatigue levels compared to those without chronic diseases. This finding shows that quality of sleep is affected and fatigue level is increased in individuals with chronic diseases due to more sleep breaks for administration of medication / treatment in addition to the symptoms of the disease itself. Inadequate sleep creates a vicious circle after a certain period of time, leading to increased sensitivity to pain, disgust and distractibility.[30]

In the literature, hypertension and diabetes are the leading risk factors for coronary artery disease.[31] In this present study, patients with HT and on antihypertensives were found to have more fatigue. Angiotensin-containing enzyme inhibitors used in the treatment of hypertension may adversely affect sleep, leading to impaired performance.[32] Similar to our study, Cho, Hyoung-Park (2004) reported in their study that individuals with hypertension had higher levels of fatigue.[33] Increased sympathetic nervous system activity in hypertension leads to overproduction of vasoconstrictors such as endothelin and thromboxane and sodium retaining hormones, inappropriate renin secretion and reduced production of vasodilating agents such as nitric oxide and prostaglandins. These physiological changes may cause fatigue, headache, palpitations, dyspnea and tiredness in individuals.[32]

In this present study, individuals with ECG changes were found to have higher levels of fatigue. In the literature, the presence of diffuse ST segment elevation on ECG has been shown to cause unexplained fatigue in individuals. Individuals with a high troponine level were determmined to have a worse sleep quality and increased fatigue compared to patients without a high troponin value in this present study. Troponin and CK-MB levels are the two most important markers in patients undergoing MI. Elevated troponin levels and ECG changes suggest that patients have more cardiac damage after an MI.[34] As a result of the cardiac damage, fatigue and insomnia may be considered as an expected result.

Individuals with nausea and vomiting were found in this present study to have higher Fatigue Daily Life Activity scores. Nausea and vomiting complaint of the patients result in fatigue, limitation of daily living activities and decreased motivation by causing energy loss in time and increased need to rest.[35] The results of this present study is parallel to the literature findings.

When the scale scores were compared according to the diagnoses of the individuals, the sleep quality of the patients with MI was found t be decreased and fatigue level was found to be increased. Impairment of sleep quality is especially common in patients with acute MI and it adversely affects the healing process. According to the results of many studies and guidelines used, the most common symptoms in patients with coronary artery disease are sleep problems, fatigue, chest pain, sweating, weakness and respiratory distress.[36,37]

It should be kept in mind that individuals who underwent coronary angiography and were admitted to intensive care units due to an MI may experience fatigue and impaired sleep quality, and nursing care should be planned accordingly.

In this present study, sleep quality was worse and level of fatigue was higher in patients with stent implantation, although not significant. Currently, stent application, one of the interventional treatments has become a routine and safe procedure in patients with an MI and in appropriate indications. It has been shown in the literature that patients who underwent coronary angioplasty and intra-coronary stenting had problems such as chest pain, palpitation and difficulty in breathing in the post-procedure period and presented to the hospital with these problems.[38,39] Accordingly, it is thought that long-term lying on the back in an intensive care, stent implantation in addition to angiography and environmental factors affect patients' sleep quality.

In addition, patients using coronary vasodilators were found to have higher sleep quality and less fatigue in this present study. Drugs in this group reduce the myocardial oxygen demand by rapidly expanding the coronary arteries and rapidly eliminating the symptoms.[40] Thus, it can be considered that coronary vasodilators provide better sleep and decrease fatigue in patients with coronary artery disease by alleviating their symptoms.

In our study, it was found that there was a negative, if not significant, relationship between age variable and sleep quality. It was determined that sleep quality was decreased and severity of fatigue was increased with age. In the literature, it is reported that age is one of the leading causes of changes in sleep duration and habits, and that the duration of sleep decreases by one hour for every 10 years starting from the age of 50 years. As the age advances, patients are expected to experience more physical fatigue. It may cause fatigue and decrease the sleep quality in the environment such as intensive care with age. The literature supports the results of our findings.[19]

Many factors impair sleep quality and increase fatigue. Providing nursing care to improve sleep quality of patients who underwent angiography is considered to facilitate the patients' coping capacity with fatigue and thus improve sleep quality.

5. CONCLUSION

In this present study, the sleep quality of the patients was found to be poor and fatigue levels were found to be high. Presence of chronic diseases and hypertension, ECG changes, diagnosis of MI, post-angiography stent implantation, antihypertensive use and high troponin levels decrease the sleep quality of the patients and increase their fatigue levels. The sleep quality of the patients was found to be decreased with increasing age, and fatigue level was found to be increased with decreasing sleep quality. According to the results; as fatigue and sleep quality may change over time, it is recommended to collect data at regular intervals in individuals at risk and to plan nursing interventions and consultancy on the factors causing these problems.

5.1. Limitations

This study had a few limitations that need to be acknowledged. Troponin values were entered as low or high, numerical values could not be reached. While examining the sleep phenomenon which is a complex structure, the severity of the underlying disease, as well as the sleeping habits of the patients in their normal lives, and their awakening cycles vary daily and time to time. This is considered among the uncontrollable factors of the study. A single day of follow-up was possible since the patients were rapidly discharged. Therefore, no intervention was performed in patients other than clinical pain treatment protocol when they had pain in late night hours. No measures for restrictions for pain was taken. The study was terminated in cases such as increased severity of illness, inability to speak due to pain or discomfort, patients's withdrawal from the research on his/her own decision, and transfer of the patient to another clinic from the CCU at the night of the application.

Ethics Committee Approval: Ethics committee approval (2017-KAEK-189_2018.12.12_01) from the Bozok University Ethical Evaluation Commission, written permission from the institution where the research was planned to be conducted and informed consents from the individuals participating in the study on willingness and voluntary basis were obtained after the aim of the study was explained.

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Conflict of Interest

The authors declare no potential conflict of interest with respect to the research, authorship, and/or publication of this article.

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Clinical and Experimental Health Sciences

Awareness, Attitudes, and Infection Control Measures of Dentists in Turkey Regarding COVID-19 Pandemic

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ABSTRACT

Objective: Corona virus disease is a serious acute respiratory infection that has spread worldwide. The aim of this survey study was to evaluate the knowledge levels, attitudes, and approaches of dentists in Turkey and to investigate the infection control measures applied by the dentists in the dental clinics regarding the COVID-19 pandemic.

Methods: This survey consisted of 27 questions and was conducted in May 2020. The questionnaire, which was distributed online to the participants through their personal accounts, included questions about the socio-demographic characteristics of the participants, their knowledge and awareness of COVID-19 infection, their approach to dental procedures before and during the pandemic, and the control measures they took in dental clinics. The collected data were subjected to statistical analysis using Chi-square tests and P values of < 0.05 were accepted as statistically significant.

Results: Eight hundred twenty-eight dentists completed the questionnaire forming a response rate of 51.8%. The majority of the participants demonstrated a high level of knowledge and awareness regarding COVID-19. The statistical analysis showed that there was no association between the gender of dentists and the applied infection control measures ($P > 0.05$), while there were significant associations between the health sectors and experience years with the infection control measures ($P < 0.05$).

Conclusion: These results demonstrated an adequate level of knowledge regarding COVID-19 among dentists in Turkey. Additionally, the rate of using personal protective equipment during dental treatment was high.

Keywords: COVID-19, Dentist, Attitude, Infection control measures, Turkey

1. INTRODUCTION

The new coronavirus disease (COVID-19), which started in Wuhan, China in December 2019, has rapidly turned into a public health crisis and has spread exponentially to other parts of the world (1). On January 31, 2020, the World Health Organization (WHO) identified the COVID-19 outbreak as a universal public health emergency (2). In Turkey, the first case of the new coronavirus was confirmed by the Ministry of Health on March 10, 2020 (3). One day later (March 11, 2020), it was stated by WHO that this disease was declared as a pandemic and there were more than 118,000 cases in 114 countries and 4291 deaths (4).

The novel coronavirus belongs to the family of single-chain RNA viruses known as Coronaviridae (5). This virus family of zoonotic origin and known to be transmitted from animals to humans included diseases such as Severe Acute Respiratory Syndrome CoronaVirus (SARS-CoV), which identified in 2002, and Middle East Respiratory Syndrome CoronaVirus (MERS-CoV), which identified in 2012 (6). Due to the similarity of the genome sequence of this novel coronavirus, which popularly called COVID-19, with other beta-coronaviruses such as SARS-CoV and MERS-CoV, the coronavirus working group of the International Viruses Taxonomy Committee gave the scientific name to the new coronavirus "SARS-CoV-2" (Severe Acute Respiratory Syndrome CoronaVirus 2) (7). It was stated that the transmission rate of SARS-CoV-2 is significantly higher than that of SARS-CoV and MERS-CoV (6,8).

According to the WHO status report on September 12, 2020, more than 28.3 million COVID-19 cases and 911,877 deaths were reported in 216 countries around the world (9). On the same date, it was stated that there were 288,126 cases and 6,951 deaths in the Republic of Turkey (10). Despite the universal efforts to take the spread of this disease under control, the epidemic increased because of the community spread pattern of this infection (1). For this reason, identification, protection, treatment and measures are very important in order to properly stop further spread of this

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disease. Unfortunately, there have been significant changes in our professional lives due to the negative conditions created by the COVID-19 pandemic which affects all countries seriously these days. Considering the widespread contagiousness of SARS-CoV-2 and the reports of its spread to healthcare providers (11-13), dentists, who are healthcare workers too, are at high risk for hospital infection and may become potential carriers of the disease (1).

Patients infected with this viral infection, commonly accompanied by clinical symptoms such as fever, cough, and muscle pain / malaise, have abundant SARS-CoV-2 in their nasopharyngeal and salivary secretions (14,15) and its transmission is thought to be predominantly by droplet and close contact to these patients (16). COVID-19 is also likely to spread when exposed to high concentrations of aerosols in a relatively closed environment (13,17). During performing the dental treatments, dentists usually are close to the patient's oropharyngeal area and may use high-speed instruments that often cause aerosol formation (1). Dentists may encounter patients with suspected or confirmed COVID-19 infection and it is essential that they take this into consideration and follow a specific protocol not only to provide the dental treatment but also to prevent the spread of the infection to the clinic. Unfollowing these special precautions may expose patients to the cross-contamination in the clinic (1,18).

In this challenging period, it is essential to understand the importance of the aerosol spread in the dental clinic and to take some special precautions in addition to the standard measures applied by the dentists. Temporary guidelines were provided by WHO (19), Center for Disease Control and Prevention (CDC) (20), and American Dental Association (ADA) (21) in order to prevent and control COVID-19 infection in dental treatments and to minimize the risk of infection transmission. The aim of this cross-sectional study was to understand the knowledge levels, awareness, and attitudes of dentists worked in Turkey regarding the COVID-19 pandemic, as well as to investigate the treatment approach and control measures in the dental practice before and during the pandemic.

2. METHODS

The present study was approved by the Scientific Research Ethics Evaluation Board with protocol number (YDU/2020/79-1079). Using Google Forms, a questionnaire was designed for this study which included questions about knowledge, awareness and attitudes of dentists in Turkey regarding COVID-19. This online survey was conducted in the first two weeks of May 2020 and distributed to the participants through their personal contact accounts including e-mail, WhatsApp and social media platforms (Facebook and Instagram). Each participant was randomly selected and contacted individually and all participants were registered in the Turkish Dental Association. Surveys were conducted anonymously to protect the confidentiality and privacy of all information obtained from the participants.

The questions in this survey were prepared depending on the data and guidelines provided by WHO (19), CDC (20), ADA (21), and the related literature. The questionnaire consisted of 5 parts and included 27 multiple-choice questions. In the first part of the questionnaire, participants were asked to read the consent form and confirm that they agreed to fill the questionnaire. The second part included questions related to the socio-demographic characteristics of the participants. Questions about dentists' awareness regarding COVID-19 infection and the features of the mask types, which reported by ADA, were included in the third part. The fourth part included questions regarding the approaches to dental procedures before and during the COVID-19 pandemic. The last part's questions were about dental treatments which applied during the pandemic and evaluating the control measures to be taken while performing dental treatments recommended by CDC and ADA. These measures included the following, taking the main complaint of the patients first by phone, measuring the patient's fever and asking if there were any COVID-19 symptoms within 14 days, maintaining the social distance (6 feet, 2 m) between the patients in the waiting room, using extraoral dental radiographs (panoramic or tomography) as an alternative, since intraoral radiographs may cause increased saliva or cough, accepting only the patients in the clinic without relatives, using protective equipment for all dental workers, disinfecting the hands before and after the dental procedure with 60-95% alcohol, or washing them with soap-water for at least 20 seconds, rinse patients' mouths with 1.5% hydrogen peroxide or 0.2% povidone before starting the treatment, using absorbable sutures in surgical cases, avoid using aerosol-generating devices as much as possible, heat sterilizing the handpiece (if used) after each patient, and adequately ventilating the clinic after each patient.

2.1. Statistical Analysis

The data were statistically analyzed using IBM SPSS Statistics for Windows (version 22.0; IBM Corp., Armonk, NY). Descriptive statistics (frequencies, and percentages) were used to describe the quantitative and categorical variables. In order to determine the association between the infection control measures and independent variables including gender, occupation, specialty in dentistry, health sector, and experience years in the profession, Chi-square tests were used and P values of < 0.05 were accepted as statistically significant.

3. RESULTS

In total, 828 out of 1600 participants completed the questionnaire, resulting in a 51.8% response rate. Table 1 showed the profile characteristics of the dentists in this questionnaire. The answers showed that the participants were between the ages of 22-69 years in which the rate of participants under the age of 30 years was 48.8% compared to 51.2% of those aged 30 and over. Of the respondents,

58.9% were female and 41.1% were male. The majority of dentists (87.2%) who completed the questionnaire were practitioners and only 12.8% of them were academics. The results showed that the respondents worked in different health sectors and the lowest percentage was for those who worked in private universities (6.8%). Dentists in this survey had a wide range of years of professional experience.

Table 1. *The characteristics of the 828 dentists enrolled in the study.*

Variable	Number (percent)
1. Age	
<30	404 (48.8%)
≥30	424 (51.2%)
2. Gender	
Female	488 (58.9%)
Male	340 (41.1%)
3. Occupation	
Dental practitioner	722 (87.2%)
Academician	106 (12.8%)
4. Specialty in dentistry	
General practitioner	470 (56.8%)
Specialist	358 (43.2%)
5. Health sector	
Private clinic	202 (24.4%)
Governmental university	142 (17.1%)
Private university	56 (6.8%)
Governmental hospital	230 (27.8%)
Private hospital	198 (23.9%)
6. Experience years in the profession	
1-5 years	406 (49%)
6-10 years	246 (29.7%)
11-15 years	76 (9.2%)
16-20 years	36 (4.3%)
≥ 21 years	64 (7.7%)
7. Have you been in the fillation team?	
Yes	74 (8.9%)
No	574 (91.1%)

In the third part of the questionnaire, 4 questions about the SARS-CoV-2 disease were prepared in order to investigate the participants' awareness (Table 2). All of the COVID-19 symptoms listed in Table 2 were confirmed by the CDC (22). The vast majority of participants (92%) were aware of the main symptoms of SARS-CoV-2 (fever, cough, fatigue, and difficulty breathing). Of the respondents, 86.2% reported that the loss of taste or smell is a COVID-19 symptom, and approximately 75% of them reported symptoms such as muscle and throat aches. More than half of the dentists were also aware of other symptoms. Over 92% of the dentists correctly reported the transmission routes of SARS-CoV-2 which were, people who are in close contact, infected person coughs, sneezes or talks and touching the infected surfaces. Approximately three-quarters of the participants (73.2%) answered the question about the incubation time of SARS-CoV-2 with 2-14 days. The high risk groups regarding COVID-19 which stated by CDC (23) are shown in Table 2. The question regarding these high-risk groups were correctly answered by more than 60% of the dentists in the present survey.

Table 2. *Dentists' awareness regarding SARS-CoV-2 disease and N95 masks.*

Variable	Number (percent)
1. Symptoms of COVID-19	
Fever	818 (98.8%)
Cough	804 (97.1%)
Difficulty breathing	804 (97.1%)
Fatigue	780 (92.2%)
Loss of taste or smell	714 (86.2%)
Muscle aches	626 (75.6%)
Throat ache	312 (75.4%)
Diarrhea	536 (64.7%)
Nausea or vomiting	420 (50.7%)
Chill	416 (50.2%)
Congestion or runny nose	276 (57.5%)
Headache	424 (51.2%)
2. Transmission methods of COVID-19	
Between people who are in close contact	782 (94.4%)
Infected person coughs, sneezes or talks	824 (99.5%)
Touching the infected surfaces	768 (92.7%)
3. Incubation period	
2-14 days	606 (73.2%)
1-7 days	12 (1.4%)
7-14 days	158 (19.1%)
14-21 days	52 (6.3%)
4. People in high risk to get infected	
Older adults (more than 65 years)	802 (96.9%)
People with asthma	784 (94.7%)
People with chronic lung disease	814 (98.3%)
People with liver diseases	518 (62.6%)
People with chronic kidney disease	676 (81.6%)
People with diabetes	662 (80%)
People with severe obesity	584 (70.5%)
People who have serious heart conditions	696 (84.1%)
People who are immunocompromised	794 (95.9%)
People who have hemoglobin disorders	512 (61.8%)
5. N95 masks are available in different sizes	
True	346 (41.8%)
Wrong	362 (43.7%)
No idea	120 (14.5%)
6. In addition to N95, FDA suggested using of equivalent masks such as KN/KP95, PFF2, P2, DS/DL2, KOREAN SPECIAL 1st	
True	456 (55.1%)
Wrong	88 (10.6%)
No idea	284 (34.3%)

Additionally, at the end of the third part, there were two questions about the properties of N95 masks reported by ADA (24) (Table 2). Approximately 41.8% of the respondents answered correctly by stating that N95 masks have different sizes. In addition, the Food and Drug Administration recommended using masks equivalent to N95 quality during the COVID-19 period such as KN/KP95, PFF2, P2, DS/DL2, and Korean special 1st" (24). This information was identified by 55.1% of the respondents in this study.

The questions and answers regarding the participants' approach to dental procedures before and during the COVID-19 pandemic, which was carried out in the fourth part of the questionnaire, were shown in Table 3. The first question of this part was regarding the protective equipment used by dentists to prevent infections. Before the pandemic period, 94.7% of

the participants stated that they used a surgical mask, while only 8% used an N95 mask. During the pandemic, the use of surgical masks decreased (80%) and the use of N95 masks increased significantly (77.1%). During the pandemic period, respondents' use of other protective equipment increased comparing to the period before COVID-19. Two-three times per week was the answer of 44% of the respondents when they asked about the frequency of lab coat washes before the pandemic while 62.1% of them stated that they used a disposable lab coat during the pandemic. In addition, the number of participants who washed their lab coats daily had increased during this period. The percent of dentists who did not leave the clinic with the clothes worn in the dental clinic before the pandemic was less than half (43.5%), while this rate increased to approximately 96% during the pandemic period. Of the participants, 34.3% reported that the frequency of surgical mask changing in the pre-pandemic period was after each patient and 30% of them stated changing the mask after 2-3 patients. However, 63.5% of the dentists stated that they changed the surgical mask after each patient during this period. After the outbreak of the COVID-19 pandemic, the working hours of 79% of the respondents decreased comparing to the pre-pandemic time (Table 3).

Table 3. *The dentists' approaches in the dental practices before and during COVID-19 pandemic.*

Variable	Before COVID-19 Number (percent)	During COVID-19 Number (percent)
1. The used equipment		
Surgical mask	784 (94.7%)	662 (80%)
N95 mask	66 (8%)	628 (77.1%)
Gloves	782 (94.4%)	806 (97.3%)
Protective eyewear	490 (59.2%)	604 (72.9%)
Face shield	446 (53.9%)	762 (92%)
Surgical cap	362 (43.7%)	644 (77.8%)
Shoes cover	142 (17.1%)	284 (34.3%)
Disposable lab coat	292 (35.3%)	652 (78.7%)
Disposable protective coverall	56 (6.8%)	336 (40.6%)
2. Frequency washing the lab coat		
Disposable lab coat (one use)	108 (13%)	514 (62.1%)
Once a day	150 (18.1%)	250 (30.2%)
2-3 times a week	364 (44%)	46 (5.6%)
Once a week	206 (24.9%)	18 (2.2%)
3. Going out somewhere with the same clothes worn in the clinic		
Yes	468 (56.5%)	34 (4.1%)
No	360 (43.5%)	794 (95.9%)
4. Frequency changing the surgical mask		
After every patient	284 (34.3%)	526 (63.5%)
After 2-3 patient	248 (30%)	118 (14.3%)
After using devices produce aerosol	166 (20%)	126 (15.2%)
Once a day	122 (14.7%)	30 (3.6%)
Other	8 (1%)	28 (3.4%)
5. Working hour changing after COVID-19		
Working hours decreased	654 (79%)	
Working hour increased	24 (2.9%)	
Same working hours	36 (4.3%)	
The clinic completely closed	114 (13.8%)	

Table 4. *The dentists' attitude toward dental procedures in preventing COVID-19.*

Variable	Number (percent)
1. The dental procedures that you perform during COVID-19 period	
Only emergency cases	662 (80%)
Stopped all dental procedure during COVID-19	140 (16.9%)
Restorative treatment	72 (8.7%)
Non-emergency endodontic treatment	72 (8.7%)
Non-emergency surgical treatment	38 (4.6%)
Prosthodontic treatment	48 (5.8%)
Periodontal treatment	38 (4.6%)
Orthodontic treatment	52 (6.3%)
2. How many times do you check the dental workers temperatures?	
Once a day	460 (55.6%)
2 times a day	202 (24.4%)
Once a week	54 (6.5%)
Every two weeks	38 (4.6%)
Other	74 (8.9%)
3. When do you change N95 mask if you use it?	
After every patient	52 (6.3%)
Once a day	418 (50.5%)
When becomes dirty, wet or deformed	236 (28.5%)
After using devices produce aerosol	202 (24.4%)
4. Infection control measures in the dental clinic during COVID-19 period	
Taking the main complaint from the patients via telephone before accepting them in the clinic	334 (48.5%)
Taking the patient's temperature and asking about any COVID-19 symptoms within 14 days	562 (81.7%)
Provide the social distance (2 m) between patients in the waiting room	534 (77.6%)
Using extraoral dental radiographs as an alternative to intraoral radiographs	404 (58.7%)
Allow only the patient to enter the clinic without their relatives	588 (85.5%)
Use of personal protective equipment by all dental staff	628 (91.3%)
Disinfecting the hands before and after the dental procedure with 60-95% alcohol, or washing them with soap-water for at least 20 seconds	612 (89%)
Make the patients to rinse their mouth with 1.5% hydrogen peroxide or 0.2% povidone before starting the treatment	372 (54.1%)
Using absorbable sutures in surgical cases	164 (23.8%)
Avoid using devices produce aerosol as much as possible	598 (86.9%)
Heat sterilization of the handpiece if used after every patient	264 (38.4%)
Sufficient ventilation after every patient in the clinic	568 (82.6%)
5. If the devises produce aerosol will be used, the following measures are applied	
4-handed technique (with the nurse)	298 (36%)
Using high vacuum suctions	430 (51.9%)
Using rubber dam	136 (16.4%)
I do nothing	188 (22.7%)
Other	108 (13%)

The summary of the last part's questions and responses, which was regarding the participants' attitudes towards dental procedures in order to prevent the risk of COVID-19 infection, was shown in Table 4. The majority of the participants (80%) stated that they only applied

treatment for emergency cases during the COVID-19 period, while 16.9% of them reported that they postponed all dental procedures. When the dentists were asked about the body temperature measuring of the workers in the clinic, 55.6% of them stated that they checked the body temperature once a day and 24.4% stated that they checked twice a day. In this survey study, only 24.4% of the participants stated that they changed N95 and equivalent masks after dental treatments that cause aerosol production and only 28.5% reported when they got wet, dirty, or deformed.

Seventy participants were excluded from the question regarding the measures in minimizing the risk of COVID-19 transmission in the dental clinic because they postponed accepting patients in this period and 668 dentists' responses were evaluated. The most followed measures by the dentists were, using protective equipment for all dental workers (91.3%), disinfecting the hands before and after the dental procedure (89%), and avoiding aerosol-generating devices (86.9%). When using aerosol-generating devices, it was stated by 51.9% of the participants that the high vacuum suction was used as a precaution.

There was no association between the gender of the participants and the infection control measures (P > 0.05) except for the avoiding aerosol-generating devices measure (P = 000.1). Moreover, the participants' occupation (practitioners or academics) was significant associated only with the measures of maintaining the social distance between the patients (P = 0.03), using protective equipment for all dental workers (P = 0.032), rinse patients' mouths before starting the treatment (P = 0.001), and heat sterilizing the handpiece (P < 0.001).

In addition, significant associations were found between the dentists' specialty and the following measures: evaluating the patient's fever (P = 0.015), using extraoral dental radiographs (P < 0.001), using protective equipment for all dental workers (P = 0.001), rinse patients' mouths before starting the treatment (P < 0.001), avoiding aerosol-generating devices (P = 0.001), and heat sterilizing the handpiece (P < 0.001).

Except for the using extraoral dental radiographs measure (P = 0.404), there was a significant association between the health sector and the infection control measures (Table 5). The associations between the experience years and the control measures were significant (P < 0.05) except for taking the patient's complaint by phone (P = 0.152), measuring the patient's fever (P = 0.120), and using protective equipment for all dental workers (P = 0.184) (Table 6).

Table 5. *Comparison of the agree response of infection control measures in the dental clinic according to the health sector.*

Infection control measures	Private clinic n (%)	Governmental university n (%)	Private university n (%)	Governmental hospital n (%)	Private hospital n (%)	*Chi-Square Test*
Taking the main complaint of the patients first by phone	148 (83.1%)	32 (29.1%)	24 (52.2%)	26 (14.4%)	104 (59.8%)	x^2=240.363; P<0.001*
Measuring the patient's fever and asking if there were any COVID-19 symptoms within 14 days	136 (76.4%)	94 (85.5%)	44 (95.7%)	154 (85.6%)	134 (77%)	x^2=25.103; P=0.005*
Maintaining the social distance between the patients in the waiting room	140 (78.7%)	86 (78.2%)	38 (82.6%)	124 (68.9%)	146 (83.9%)	x^2=22.800; P=0.013*
Using extraoral dental radiographs as an alternative to intraoral radiographs	98 (55.1%)	72 (65.5%)	22 (47.8%)	116 (64.4%)	96 (55.2%)	x^2=4.011; P=0.404
Accepting only the patients in the clinic without relatives	146 (82%)	90 (81.8%)	44 (95.7%)	166 (92.2%)	142 (81.6%)	x^2=28.696; P=0.004*
Using protective equipment for all dental workers	160 (89.9%)	110 (100%)	44 (95.7%)	164 (91.1%)	150 (86.2%)	x^2=40.218; P=0.001*
Disinfecting the hands before and after the dental procedure with 60-95% alcohol, or washing them with soap-water for at least 20 seconds	172 (96.6%)	94 (85.5%)	42 (91.3%)	142 (78.9%)	162 (93.1%)	x^2=45.683; P<0.001*
Rinse patients' mouths with 1.5% hydrogen peroxide or 0.2% povidone before starting the treatment	122 (68.5%)	76 (69.1%)	24 (52.2%)	44 (24.4%)	106 (60.9%)	x^2=97.758; P<0.001*
Using absorbable sutures in surgical cases	56 (31.5%)	24 (21.8%)	16 (34.8%)	30 (16.7%)	38 (21.8%)	x^2=21.697; P=0.006*
Avoid using aerosol-generating devices as much as possible	160 (89.9%)	98 (89.1%)	36 (78.3%)	170 (94.4%)	134 (77%)	x^2=13.446; P=0.009*
Heat sterilizing the handpiece (if used) after each patient	100 (56.2%)	50 (45.5%)	16 (34.8%)	32 (17.8%)	66 (37.9%)	x^2=63.756; P<0.001*
Adequately ventilating the clinic after each patient.	174 (97.8%)	86 (78.2%)	26 (56.5%)	144 (80%)	138 (79.3%)	x^2=46.687; P<0.001*

**Indicates statistically significant.*

Table 6. *Comparison of the agree response of infection control measures in the dental clinic according to the experience years in the profession.*

Infection control measures	1-5 years n (%)	6-10 years n (%)	11-15 years n (%)	16-20 years n (%)	≥21 years n (%)	*P* values
Taking the main complaint of the patients first by phone	150 (46.3%)	96 (45.7%)	38 (59.4%)	16 (50%)	34 (58.6%)	x^2=5.709; *P*=0.152
Measuring the patient's fever and asking if there were any COVID-19 symptoms within 14 days	258 (79.6%)	178 (84.8%)	56 (87.5%)	22 (68.8%)	48 (82.8%)	x^2=3.249; *P*=0.120
Maintaining the social distance between the patients in the waiting room	260 (80.2%)	158 (75.2%)	54 (84.4%)	26 (81.3%)	36 (62.1%)	x^2=11.686; *P*=0.018*
Using extraoral dental radiographs as an alternative to intraoral radiographs	152 (46.9%)	140 (66.7%)	52 (81.3%)	24 (75%)	36 (62.1%)	x^2=51.604; *P*<0.001*
Accepting only the patients in the clinic without relatives	280 (86.4%)	190 (90.5%)	46 (71.9%)	30 (93.8%)	42 (72.4%)	x^2=22.070; *P*<0.001*
Using protective equipment for all dental workers	290 (89.5%)	200 (95.2%)	58 (90.6%)	28 (87.5%)	52 (89.7%)	x^2=9.427; *P*=0.184
Disinfecting the hands before and after the dental procedure with 60-95% alcohol, or washing them with soap-water for at least 20 seconds	278 (85.8%)	186 (88.6%)	62 (96.9%)	32 (100%)	54 (93.1%)	x^2=27.667; *P*=0.015*
Rinse patients' mouths with 1.5% hydrogen peroxide or 0.2% povidone before starting the treatment	140 (43.2%)	114 (54.3%)	50 (78.1%)	22 (68.8%)	46 (79.3%)	x^2=59.780; *P*<0.001*
Using absorbable sutures in surgical cases	70 (21.6%)	42 (20%)	22 (34.4%)	8 (25%)	22 (37.9%)	x^2=13.256; *P*=0.012*
Avoid using aerosol-generating devices as much as possible	268 (82.7%)	198 (94.3%)	58 (90.6%)	28 (87.5%)	46 (79.3%)	x^2=23.615; *P*=0.001*
Heat sterilizing the handpiece (if used) after each patient	92 (28.4%)	84 (40%)	38 (59.4%)	12 (37.5%)	38 (65.5%)	x^2=51.804; *P*<0.001*
Adequately ventilating the clinic after each patient.	260 (80.2%)	166 (79%)	62 (96.9%)	26 (81.3%)	54 (93.1%)	x^2=12.296; *P*=0.015*

* *Indicates statistically significant.*

4. DISCUSSION

The epidemic of COVID-19, which has been spread to 216 countries, areas or territories (9), is a global matter of debate throughout the world, especially among healthcare staff and patients. Many studies reported the risk of spreading infection among healthcare workers (11,12). They are at risk to be infected by SARS-CoV-2 and to be carriers of this infection due to reasons such as being in close contact with patients, being exposed to saliva, blood and other body fluids, and using sharp hand tools (1,25). It was stated that dentists are the occupational group most exposed to the risk of being affected by the new type of coronavirus disease (26). This survey study investigated the level of awareness and approaches of dentists in Turkey regarding COVID-19 and found out the control measures followed in the dental practice to prevent infections before and during the pandemic period.

The number of dentists under 30 years of age and 30 years and over who participated in this study was almost equal in which the majority of the participants were in the 25-33 age group. This could be attributed to the tendency of the younger age groups to participate in online surveys on social media platforms. More than half of the dentists (58.9%) in this survey study were female. Şirinoğlu Çapan et al. (27) reported that many female students preferred studying dentistry because of their working conditions and hours. However, these results were similar to previous COVID-19 studies (28-30), while they were inconsistent with other studies (31-33).

In the present survey, most of the participants were general practitioners, while the academicians formed a rate of 12.8%. These results were in agreement with the results of Kamate et al. (34) but inconsistent with Sezgin and Şirinoğlu Çapan (29). Dentists in Turkey were employed to check and follow-up the COVID-19 infected patients in their home which made the dentists in the first line of the struggle against this virus in this critical period. The participation rate of this group of dentists was 8.9% which could be due to their intense and stressful working pace.

It is extremely important to have reliable and informative resources enough to enable physicians to evaluate the situations that they face regarding COVID-19 in order to take the spread of COVID-19 under control. For dental professionals, the most accurate and reliable resources are the websites of official organizations. This survey study was prepared and designed according to the guidelines and data of the relative literature, WHO (19), CDC (20), and ADA (21).

In this survey study, the participants were asked about the transmission ways of COVID-19 and the results showed that more than 92% of dentists were aware of the correct answers. These results were similar to the results of previous studies regarding the transmission ways.[28,29,34] The incubation period of SARS-CoV-2 was 2-14 days which was confirmed by the CDC.[22] In the present study, approximately 73.2% of the respondents correctly answered the question regarding the incubation time of this infection. It is important to know the incubation time especially because of its role in determining the safe period for the treatment of suspicious patients (35). Nonetheless, Turkish dentists in this study could identify the main symptoms of COVID-19, which helped the dentists to recognize the threat and take the necessary actions and the management and control of the spread of this disease

(28,35). In addition, it is essential to take control measures by the dentists with their patients at all time because some patients could be infected even when the disease progresses asymptomatically (36).

It was believed that the high awareness level of the participants regarding SARS-CoV-2 disease in this study was due to the fact that Turkey was affected by this virus later comparing to other countries, and the great efforts of the Ministry of Health and dental associations in informing the dentists quickly about it.

Coronavirus can survive on nonliving surfaces such as metal, glass, or plastic for up to 9 days, which increases the risk of infection, and could be effectively inactivated using surface disinfection products containing 0.5% hydrogen peroxide, 62-71% ethanol or 0.1% sodium hypochlorite for 1 minute (37). Aerosol transmission is also possible (36). Doremalen et al. (38) reported that the virus can survive and be detected in aerosol for up to 3 hours after procedures that lead to aerosol formation. If dental clinic workers were not wearing appropriate personal protective equipment, these aerosols could potentially be inhaled. The results of this study showed the increased use of personal protective equipment by the dentists during the SARS-CoV-2 pandemic time.

Since the incubation period of this disease is 2-14 days, it is not possible to differentiate asymptomatic infected patients. Thus, the ADA (21) recommended that the treatments in dental clinics should be limited to emergency cases during the COVID-19 pandemic. In the present study, most of the participants (80%) stated that they performed dental procedures only for emergency cases, while 16.9% stopped performing all dental procedures during this period. Similarly, Izzeti et al. (32) stated in their cross-sectional study, which was carried out in Italy, that 75.5% of the respondents performed only the dental procedures for emergency cases, while Gambhir et al. (31) reported that 8.5% of participants in India answered the same response.

CDC (20) recommended measuring the temperature of the workers in dental clinics twice a day. The dentists in this survey checked the body temperatures of the clinic workers once and twice a day with the rates of 55.6% and 24.4%, respectively. ADA (24) reported that N95 and equivalent masks that reduce the exposure to particles, including small aerosols particle and large droplets (non-oil aerosols), should be discarded after dental treatments that produce aerosols. In addition, it was stated that the wet, dirty or deformed masks should also be discarded (24). The results of this survey showed that 24.4% of the respondents discarding the mask after procedures that caused aerosol generation and 28.5% after becoming wet, dirty, or deformed. This could be due to the limited distribution of these masks to dentists and their high cost across the country.

Considering the working conditions of dentists, they should always use personal protective equipment in dental clinics. Also, dentists are at high risk of COVID-19 infection and they need to take additional precautions during the COVID-19 outbreak. Egger et al. (39) demonstrated that both SARS and MERS viruses were highly sensitive to povidone-iodine mouthwash. During the COVID-19 pandemic period, it was recommended that the patients wash their mouths with 0.2% povidone-iodine or 1.5% hydrogen peroxide before dental treatment to reduce the amount of coronavirus in saliva (21). However, only 54.1% of the dentists in this study stated that they rinsed the patients' mouths with hydrogen peroxide or povidone before dental treatment. In a recent study (40) involving participants from different countries around the world, only 24% of them stated that they asked patients to rinse their mouths with antimicrobial mouthwash before dental treatment.

In order to reduce the exposure to possible infectious agents during dental procedures that cause aerosol production, ADA (21) recommended some measures such as the use of a 4-handed technique, high-volume saliva ejectors, and a rubber dam. The present study showed that 51.9% of the participants stated using high-volume saliva ejectors and 36% of them used 4-handed technique.

In this study, using absorbable sutures in surgical cases (23.8%) constituted the least percentage among the infection control measures taken in dental clinics. The reason for this situation may be related to the avoidance of non-urgent surgical interventions during the pandemic period. The measure of first learning about the patient's main complaint by phone in the government hospital (14.4%) and government university (29.1%) sectors were less than the other health sectors. This situation may be related to the fact that the government health sectors continued to work for emergency treatments without an appointment during the pandemic period. More than 95% of the dentists working in private clinics stated that they ventilate the clinic sufficiently after each patient, which was the highest percentage compared to the other health sectors. This situation may be associated with the presence of a single unit in private clinics.

According to the results of this study, the use of protective equipment and the disinfection of hands were observed over 85% in all experience years groups. However, Putrino et al. [41] stated that the aforementioned control measures were applied by almost 26% of the participants in Italy during the COVID-19 process.

It should be noted that dentists who work during the pandemic are at high risk of COVID-19 infection. Therefore, every patient should be considered potentially infected with the virus, and current infection control protocols should be applied during all dental treatments. For this purpose, all dentists should follow the latest information and read reliable and up-to-date resources.

One of the limitations of this study was that the sample size was smaller than the expected. This could be because of data was collected in a short time to keep the study up to date. Since the dentists in this study participated using email and social network platforms, the study was subject to selection bias and sampling error. Another limitation was that younger

dentists constituted the majority of participants who applied in the study. The reason for this situation could be related to the spread of the survey on the internet for a short time due to the pandemic. In addition, it was not determined whether the dentists participating in the study were infected with COVID-19 or not, and therefore it was not clear whether there was a difference between dentists' taking precautions against COVID-19 or not. The prevalence of dentists in Turkey infected with COVID-19 is essential to be investigated in future studies.

5. CONCLUSION

Within the limitations of this study, the level of knowledge about the ways of transmission and symptoms regarding COVID-19 is a quite high among dentists in Turkey. Beside the rate of using personal protective equipment during dental treatment was high, it is important to follow and apply the current infection control measures which published by official institutions to ensure effective infection control. In order to obtain more comprehensive results more studies are needed with larger sample sizes across the country and the world in the future.

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Clinical and Experimental Health Sciences

Effect of watching cartoon during IV treatment on anxiety and fear levels in children: randomized controlled trial

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ABSTRACT

Objective: The study was conducted as a randomized controlled trial to determine the effect of watching cartoon during treatment on anxiety and fear in children.

Methods: The study was carried out in the pediatric service of a maternity and children diseases hospital between October-November 2019. A total of 92 children (43 in the cartoon group and 49 in the control group) were included in the study. The results of the study were obtained using Socio-Demographic Characteristics Form, Children's State Anxiety Scale, and Children's Fear Scale. The children in the cartoon group watched their favourite cartoon during treatment. No distracting method was applied to the children in the control group during their routine treatment. Anxiety and fear levels in children in the cartoon and control groups were evaluated before and during intravenous treatment. Gender variable was compared using the Chi-square test; whereas age, anxiety and fear variables were compared using the independent sample t test between groups and paired sample t test within group. Significance was evaluated at the level of $p< .05$.

Results: It was found that there was a statistically significant difference between anxiety mean scores of both groups during the IV treatment ($p= .001$). In all evaluations (children, parent and researcher), it was determined that mean scores of fear during the IV treatment were higher in children in the control group compared to children in the cartoon group ($p= .001$). Watching cartoon during IV treatment is effective on reducing anxiety and fear in children.

Conclusion: Fear and anxiety levels in children can be reduced through watching cartoon during medical procedures. ClinicalTrials.gov identifier: NCT04127097.

Keywords: Child, Anxiety, Fear, Treatment, Nursing, Distraction, Non-Pharmacologic

1. INTRODUCTION

One of the most common methods of parenteral application in children is intravenous (IV) drug application (1, 2). IV drug application is given as IV push/direct or IV infusion (3). Children may experience fear and anxiety during these applications. Unmanaged fear and anxiety during these applications may cause the child to refuse treatment and medical care and to have a negative attitude towards healthcare professionals (4, 5).

Non-pharmacological practices can decrease fear and anxiety during the treatment to be performed on children in the hospital (6, 7). Distraction methods are among non-pharmacological practices. Distraction method is an attempt to concentrate the child's attention to another stimulus. This method is widely used to reduce children's fear and anxiety. There are many methods used in hospital procedures to distraction. Kaleidescope, distraction cards, virtual reality glasses, music and balloon inflating are some of these methods (7, 8). Watching cartoon which is among distraction methods, distracts the child. Watching cartoon relieves the child emotionally against fear and anxiety (9, 10). There are studies in the literature stating that watching cartoons during treatment reduces anxiety and fear in children (8, 11-17). Healthcare professionals are responsible for reducing fear and anxiety as much as possible while maintaining patient safety. In order to continue the development of children receiving treatment in the hospital, it is necessary to reduce the stress caused by the diseases and the treatment. Nurses who provide health care have an important role in reducing the stress experienced by the children and the family. Pain reduction and the use of non-pharmacological methods are areas where nurses can demonstrate their independent roles (18, 19) With this study, the awareness of pediatric nurses on the use of cartoon watching method in reducing anxiety and fear caused by treatment in children will increase, and children will be provided with atraumatic care with the widespread use of cartoon watching method. The study was conducted to determine the effect of watching cartoon during IV treatment on anxiety and fear levels in children.

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Research hyposes:

Hypothesis 0 (H0): Watching cartoons in children during treatment has no effect on anxiety and fear.

Hypothesis 1 (H1): Watching cartoons in children during treatment has an effect on anxiety and fear.

Hypothesis 2 (H2): There is a difference in anxiety and fear mean scores between the group where children are shown cartoons during treatment and the control group.

2. METHODS

2.1.Objective

The study was conducted to determine the effect of watching cartoon during the IV treatment on anxiety and fear levels in children.

2.2. Study design

A randomized controlled trial.

2.3. Setting and Participants

The study was carried out in the pediatric service of a maternity and children diseases hospital between October-November 2019. The number of beds in the pediatric ward was 60. An average of 150 children per month were being treated in the hospital with the diagnosis of bronchitis. Since the reason for most of the children to be treated in the hospital is bronchitis, the study was conducted with children with this diagnosis.

The inclusion criteria for children were determined as follows; aged between 4-10 years, expressing themselves verbally, having no visual, auditory or developmental problems, having no pain before IV treatment, having no chronic disease, being first exposure to hospitalization, locating IV catheter, having no problems in the IV catheter areas, being hospitalised due to the bronchitis, taking antibiotics containing ceftriaxone active substance (2x1 IV), taking 1/3 isodex 1000cc/24 h iv infusion therapy.

The sample size was calculated based on the study conducted by Al-Namankany, Petrie, & Ashley (2015) with children in order to determine the effect of video watching model on anxiety level during dental treatment (20). The effect size of the study which was conducted with a total of 80 children (40 in each group) was found to be d=1.482 at the level of α=0.05 and confidence interval of 95%. Accordingly, when taking possible data losses into consideration in the study process; it was decided to conduct the study by including a total of 100 children (50 in each group). 100 children in the sample were assigned to the cartoon and control groups randomly. Randomization was done by the closed envelope method (21). A total of 100 cards (50 in each group) with cartoon and control groups were placed in the sealed envelope. The children were asked to choose one of these envelopes. 4 children, who refused to have evaluation after the treatment, and 3 children, who refused to watch cartoon in the cartoon group and 1 child, who refused to have evaluation after the treatment, in the control group were not included in the evaluation. A total of 92 children (43 in the cartoon group, 49 in the control group) were included in the study. The randomization of the study is shown in CONSORT (Consolidated Standards of Reporting Trials) 2010 (Figure 1).

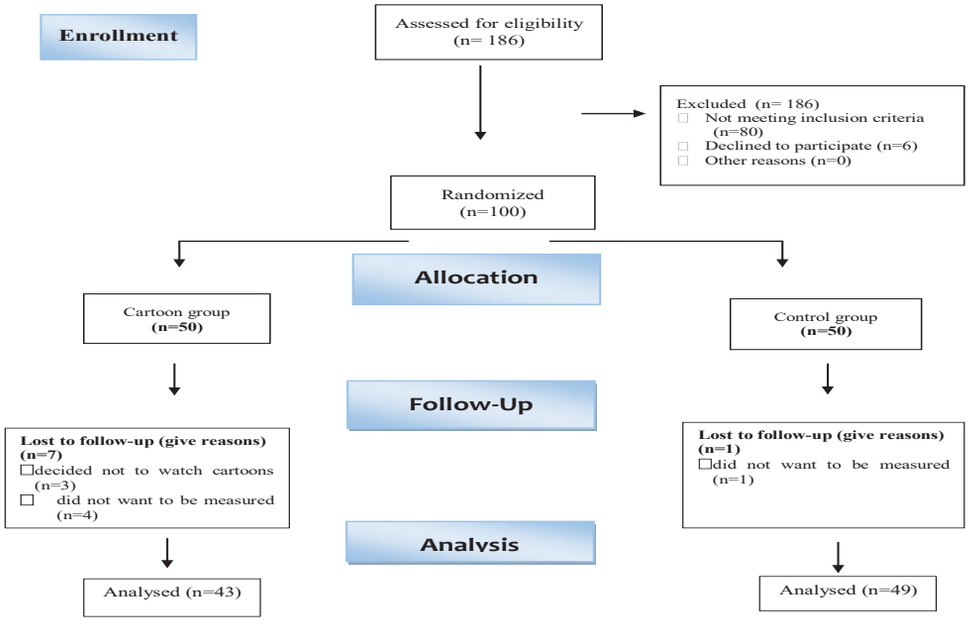

Figure 1. *CONSORT Flow Diagram*

As a result of the power analysis which was performed at the end of the study, the effect size was found to be d=3.762.

2.4. Data Collection Tools

Socio-Demographic Characteristics Form: Prepared by the researcher to obtain information about socio-demographic characteristics in children; the Socio-Demographic Characteristics Form consisted of two questions about the children's gender, age.

Children's State Anxiety Scale (CAS): The scale looks like a thermometer containing a bulb below and horizontal lines with intervals going upward. In the scale which is aimed at children aged four to ten years, the child is asked to mark what she/he feels "at the moment" in order to measure her/his state anxiety. Scoring may range from 0 to 10. (22, 23). Turkish validity and reliability of the scale were conducted by Özalp Gerçeker et al., (2018). The content validity index of the scale is 1.00 (23).

Children's Fear Scale (CFS): The scale developed by McMurtry et al (2011) (24). CFS is a scale making an evaluation between 0-4 and consisting of five facial expressions ranging from neutral expression (0= no anxiety) to scared face (4= severe anxiety). The scale, which can be used to evaluate pain and anxiety levels before and during the procedure and can also be used by families and researchers to evaluate children, is aimed at children aged five to ten years. Turkish validity and reliability of the scale were conducted by Özalp Gerçeker et al. (2018). The content validity index of the scale is 0.89 (23).

2.5. Procedure

The children and parents were showed anxiety and fear scales and were also told how to complete them. The children marked their fear and anxiety levels before the IV treatment on the scales. The parent and researcher (the same researcher) evaluated the level of fear in children before the IV treatment. The children in the groups were determined according to randomisation. The children in the cartoon group watched their favourite cartoon two minutes before the IV treatment until the end of the IV treatment. At the end of the IV treatment, children were asked to mark their fear and anxiety states on the scale. Also the parents and the researcher evaluated children's fear. Only children who had just started intravenous therapy/received the first dose of their treatment were included in the study. These children were not included in the study while receiving their further treatment.

2.6. Statistical analysis

The data were analysed using the IBM SPSS Statistics 22 (SPSS Inc., Chicago, IL, USA) program. Gender variable was compared using the Chi-square test; whereas age, anxiety and fear variables were compared using the paired sample t test. Significance was evaluated at the level of p< .05.

2.7. Ethical considerations

Before starting the study, an ethics committee approval dated 05.07.2019 and numbered 13365 was obtained from the University Scientific Researches and Publications Ethics Committee. After receiving permissions; the children and their parent were informed about the study before starting the study. Written consents were obtained from the parents via the "Informed Consent Form". In addition, they were informed that they could withdraw from the study anytime, without specifying their reason. This study was registered with ClinicalTrials.gov.: NCT04127097.

3. RESULTS

It was determined that there was no statistically significant difference between children in the cartoon and control groups in terms of age, gender, anxiety and fear mean scores (p> .05) (Table 1).

Table 1. *Comparison of socio-demographic characteristics, pre-treatment anxiety and fear scores in children by groups (N = 92)*

	Cartoon Group (n=43)		Control Group (n=49)			
	n	%	n	%	X^2	p
Gender						
Girl	18	41.9	19	38.8	0.008	0.763
Boy	25	58.1	30	61.2		
	X± SD		X± SD		t	p
Age	7.06±1.95		6.73±1.42		0.946	0.346
CAS	2.89±1.57		2.77±1.19		0.414	0.680
CFS						
Child	1.81±1.09		1.67±1.31		0.552	0.582
Parent	1.79±1.08		1.53±1.10		1.140	0.257
Researcher	1.81±1.07		1.51±1.10		1.335	0.185

t: independent sample t test X^2: chi-square test p>0.05
CAS: Children's State Anxiety Scale CFS: Children's Fear Scale SD: Standart Deviation

Table 2. *Comparison of mean anxiety and fear scores during treatment in children by groups (N = 92)*

	Cartoon Group (n=43)	Control Group (n=49)	t	p
	X± SD	X± SD		
CAS	1.34±1.00	7.10±1.92	17.560	.001
CFS				
Child	0.79±0.94	3.61±1.59	10.167	.001
Parent	0.74±0.92	4.26±1.59	12.728	.001
Researcher	0.76±0.99	4.22±1.47	13.304	.001

t: independent sample t test p<0.001
CAS: Children's State Anxiety Scale CFS: Children's Fear Scale SD: Standart Deviation

Table 2 shows a comparison of anxiety and fear mean scores in children in the cartoon and control groups during the IV treatment. It was found that there was a statistically significant difference between anxiety mean scores of both groups during the IV treatment (p= .001). In all evaluations (children, parent and researcher), it was determined that mean scores of fear

during the IV treatment were higher in children in the control group compared to children in the cartoon group (p= .001).

Table 3 shows a comparison of anxiety and fear mean scores before and during treatment within group. It was determined that the anxiety scores of the children in the control group during the IV treatment were statistically significantly higher than before the IV treatment (p=. 000). It was determined that the anxiety scores of the children in the experimental group during the IV treatment were statistically significantly lower than before the IV treatment (p=. 000). In all evaluations (children, parent and researcher), it was determined that the fear score of the children in the control group during the treatment was statistically significantly higher than before the treatment (p=. 000). In all evaluations (children, parent and researcher), it was determined that the fear score of the children in the experimental group during the treatment was statistically significantly lower than before the treatment (p=. 000).

Tablo 3. *Comparison of mean anxiety and fear scores before and during treatment in children by within groups (N = 92)*

	Cartoon Group (n=43)			Control Group (n=49)		
	X± SD	t	p		t	p
CAS						
Before	2.89±1.57	8.600	.000	2.77±1.19	17.439	.000
During	1.34±1.00			7.10±1.92		
CFS						
Child						
Before	1.81±1.09	9.072	.000	1.67±1.31	10.728	.000
During	0.79±0.94			3.61±1.59		
Parent						
Before	1.79±1.08	9.096	.000	1.53±1.10	17.482	.000
During	0.74±0.92			4.26±1.59		
Researcher						
Before	1.81±1.07	8.738	.000	1.51±1.10	16.994	.000
During	0.76±0.99			4.22±1.47		

t: Paired sample t test p<0.001

CAS: Children's State Anxiety Scale CFS: Children's Fear Scale SD: Standart Deviation

4. DISCUSSION

Hospital environment is among places where children are taken frequently apply for health check-up or during diseases as from birth. Children may have to get hospitalised or go through medical procedures, treatments and operations. As a result of these, children may develop fear and anxiety toward diseases, hospital, treatments or procedures (12,25-29). In the study, it was determined that the children experienced fear and anxiety before the treatment (Tablo 1).

Children's anxiety and fear toward medical interventions, staff and hospital environment can be reduced by using the watching video method, which is among distraction methods (16, 30). In the study by Lee et al. (2012), it was reported that making paediatric surgical patients watch animation cartoon was an effective method for relieving preoperative anxiety (11). In their study, Mifflin, Hackmann, & Chorney, (2012), reported that watching videos during inhale induction was an effective method for reducing anxiety in children who underwent ambulatory surgery (12). In their study, Mitrakul et al., (2015) evaluated the effect of visual – auditory glasses on pain and anxiety levels in children aged 5 to 8 years during restorative treatment. In the study, they determined that visual – auditory glasses through which children watched cartoon, reduced their anxiety levels (13). In their study, Nuvvula et al., (2015) examined the effect of 3D glasses on anxiety levels in children who received local analgesia for dental treatment and determined that the video glasses reduced children's anxiety (14). In the study by Al-Khotani, Bello, & Christidis, (2016), it was reported that watching cartoon during dental treatment reduced children's fear and anxiety (15). In their study, Ghadimi et al. (2018), examined the effect of visual distraction method on children's anxiety levels during dental treatment. In the study, they determined that cartoon reduced anxiety levels during the treatment (6). In their study, Çelikol, Tural-Büyük, & Yıldızlar (2019) investigated children's pain, fear and anxiety levels during invasive procedures. In the study, it was reported that children who were made listen to music or watch cartoon during blood collection procedure, had reduced fear and anxiety levels (16). In the study, it was found that there was a statistically significant decrease in the anxiety and fear levels of the children in the cartoon group when the between groups and within group were evaluated (Tablo 2, Tablo 3). It was determined that watching cartoon during the IV treatment reduced fear and anxiety in children.

The main limitation of the study was that randomization was performed without blindness. The blindness could not be made between the children, parent and observer who evaluated the fear of the children. The researcher had to see which children were in the experimental group because they evaluated the children's fears during the IV treatment and the cartoon was watched during the IV treatment.

5. CONCLUSION

In this study which was conducted as a randomized controlled trial to determine the effect of watching cartoon during the IV treatment on anxiety and fear levels in children aged 4 to 10 years, it was found that watching cartoon during the IV treatment reduced children's fear and anxiety levels. Watching cartoon could be used as a non-pharmacological methods to alleviate fear and anxiety during IV treatments, which is one of the most common procedures of hospitalization. Watching cartoon can be used actively in hospitals and can facilitate medical procedures that cannot be performed due to fear.

It can be recommended to conduct studies to compare the watching cartoon, which is among distraction methods, with other non-pharmacological methods in different medical interventions and different age groups.

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Clinical and Experimental Health Sciences

Effect of Education and Monitoring on Developing Foot Care of Elderly with Diabetes Mellitus

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ABSTRACT

Objective: To determine the effect of education and monitoring on developing foot care in elderly with diabetes.

Methods: This study was a controlled experimental research. The study was performed with 45 elderly with diabetes in the control group and 45 in the intervention group who met inclusion criteria for the study. The participants were registered in one center and in a public hospital between the dates of September 2012-September 2013. Training and follow-up on foot care were carried out for the intervention group by performing four-foot examinations in both groups.

Results: Diabetic foot information and foot care behavior scores showed significantly greater increases in the intervention group compared to controls. A significant difference in total foot examination score was determined between groups and in time ($p<0.05$).

Conclusion: The results have shown that education and monitoring were effective in developing foot care in participants.

Keywords: Elderly, diabetes mellitus, foot care, monitoring, education, nursing

1. INTRODUCTION

Diabetes prevalence is growing worldwide and is becoming an epidemic and endemic problem with the social and economic burden. Its prevalence and its co-morbidities and mortality are higher in the elderly than in young people (1). Approximately one-quarter of people over the age of 65 years have diabetes, and this proportion is expected to increase rapidly in the coming decades (2). In 2019, the estimated number of people over 65 years of age with diabetes was 111 million. One in five adults in this age group is estimated to have diabetes. It is projected that by 2030 the number of people over 65 with diabetes will further increase to 195 million. By 2045, it will reach 276 million (1). Furthermore, nearly half of adults aged 65 years or older had prediabetes (3) Aging is considered a major risk factor for diabetes (4). Reasons like decreased independence in elderly with diabetes decreased self-care ability, and comorbidities affect diabetes management in a negative way (5).

With increasing age and duration of disease, both micro and macrovascular complications are more prevalent in the elderly. Together with complications, Peripheral Neuropathy (PN) and foot infections cause non-healing wounds in the elderly, increasing the risk of amputation in the lower extremities. More than 85% of amputations are preceded by an active foot ulcer. Diabetic foot represents the most common cause of hospitalization in patients with diabetes (6). Diabetic foot is one of the most serious and costly complications of diabetes. Lower limb amputation in people with diabetes is 10 to 20 times more common compared to those without diabetes. The 5-year relative mortality after diabetic foot ulcer is 48%. This is clearly higher than most cancers (1). Peripheral Arterial Disease (PAD) is an independent risk factor for subsequent ulceration and limb loss in diabetes. Up to 15-25% of patients with diabetes will develop a foot ulcer sometime during their lives (7).

In addition to increasing neuropathy and vascular disease prevalence with age, it is difficult for the diabetic elderly to take foot and nail care as a result of arthritis, restriction of joint movements, walking abnormalities, lack of movement, dementia and decreased vision (6). Diabetic foot problems often emerge because of insufficient care and follow-up. It was reported in previous studies that half of the foot injuries are reported to be preventable with regular training and foot care. The easiest and cheapest way to prevent foot complications is to observe regularly, which is one of the most

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effective methods (8, 9). Elderly with diabetes are in a high-risk group in terms of diabetic foot management (1). The risk of developing diabetic foot must be identified by nurses by performing an examination of the person with diabetes and relevant training must be planned and followed-up according to the risk category (10). The visual ability and reach-the-feet must also be evaluated in the examination (6). In addition to these precautions, glycemic control is also extremely important in the prevention of diabetic foot (1, 11).

With the increase in the elderly population, foot ulcers increase parallel to diabetes prevalence. No studies were detected in the literature conducted in our country on the follow-up and training intervention by determining the risk of the diabetic foot to prevent foot problems in elderly with diabetes**.** It is important to consider the age factor in the training regarding foot care by evaluating foot risk in elderly diabetics and monitoring the sustainability of foot care and training. We believe that the present study, which was planned with a sampling of elderly with diabetes, is an original nursing study, and will contribute to scientific evidence in this field. Therefore, the aim of the study is to determine the effect of training and monitoring on developing foot care in elderly with diabetes.

Hypothesis

$H_{1\text{-}1}$: The training and follow-ups have effects on improving the foot examination scores of the elderly with diabetes".

$H_{1\text{-}2}$: The training and follow-up have an effect on increasing the foot care behavior of the elderly with diabetes".

$H_{1\text{-}3}$: The training and follow-up have an effect on increasing the knowledge of diabetic foot care of the elderly with diabetes.

2. METHODS

2.1. Study design and setting

This study was conducted as a controlled experimental type study. The universe of the study consisted of 85 elderly with diabetes registered in an elderly center and 680 elderly with diabetes who applied to a diabetes education unit of a public hospital between September 2012 and 2013. Since 16 elderly with diabetes did not comply with the inclusion criteria among the 85 elderly people who had diabetes in the intervention group of the study, 69 were included in the intervention group. As the same number of the elderly with diabetes in the intervention group would be recruited in the control group, it took approximately four months to reach 69 people out of the 680 elderly with diabetes who were recorded in the diabetes education unit of the hospital for their routine treatment and care. A total of 78 elderly people with diabetes applied to the unit in this 4-month period, and 69 people were included in the control group as 9 people with diabetes were not eligible. The study was terminated for 9 elderly with diabetes who met the study termination criteria in the intervention group and 10 in the control group during the follow-up period. When the follow-up of 60 people continued in the intervention group, the data of 45 elderly people with diabetes, whose follow-up was completed, were transferred into the computer, and power analysis was made. The sampling power was found to be 100% in 95% Confidence Interval with Power Analysis in the 45-people sampling by considering the Diabetic Foot Knowledge (SD:1) and Foot Care Behavior (SD: 11) Scale (12, 13). The sampling of the study consisted of 90 elderly people with diabetes. For this reason, as the sufficient sample size was reached, 15 elderly with diabetes from the intervention group and 14 from the control group were excluded from the follow-ups (Figure 1).

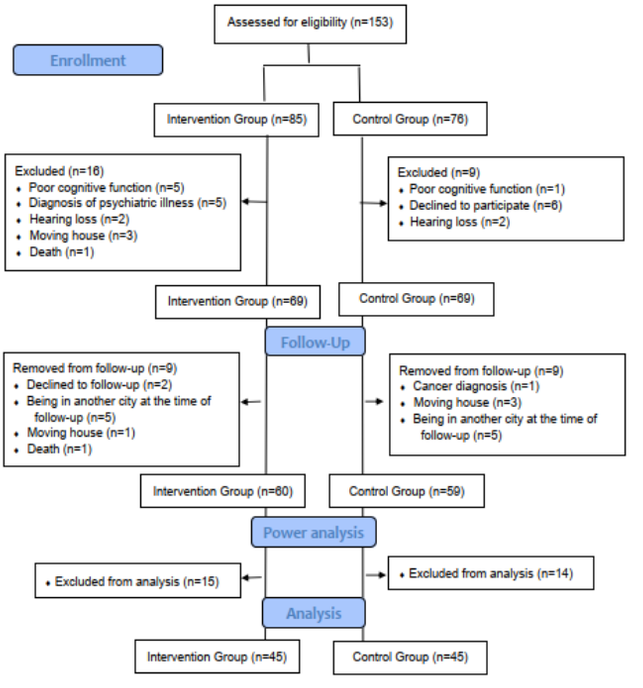

Figure 1. *Flow Diagram*

The inclusion criteria were as follows; having been diagnosed with Type 2 Diabetes, ≥65 years of age, not having received diabetic foot care training, having no problems in communication, having good cognitive functions according to Mini Mental Test, having no diagnosis of psychiatric disease, and accepting to participate in the study. The exclusion criteria were as follows; the desire to leave the study, not attending at least one of the four follow-ups of the study, being out of the city during the follow-up process, being diagnosed with a serious illness that requires treatment, or passing away.

2.2. Sampling and group allocation

Those who were registered in the Elderly Center constituted the Intervention Group, those who applied to the Diabetes Education Unit constituted the control Group. The Elderly Center is a center where the elderly are monitored in their own environment, the health and social problems of the elderly are determined during working hours, and solution services for these problems are provided under the

management of nurses. The center serves individuals who reside in the neighborhood to which it is attached. Home visits are made by nurses with three-month intervals at the latest in this center, although it is more frequent according to the needs of the elderly. As the number of the elderly with diabetes who were registered in the elderly center did not meet the sampling size determined according to power analysis, the intervention and control groups were taken from different centers. Because of the opportunity to be able to follow-up the elderly with diabetes registered in the center in their own environments, they were chosen as the intervention group. The elderly with diabetes admitting to the diabetes education unit of the hospital during the implementation period of the study constituted the control group. In this way, it was prevented that the intervention performed would affect the participants in the control group by taking the study groups in different centers.

2.3. Description of the interventions

Intervention Group

The diabetic foot risk group was determined by carrying out foot examination to the participants in this group, and foot care training and follow-up were performed. A total of four interviews were carried out in the initial, first, third and sixth months. In the first meeting, foot examination was carried out, and individual training was provided to the participants, and the training booklet was given by considering the age factor for diabetic foot care, which lasted 30-45 minutes. Education was performed by using mixed learning methods consisting of lecture, question-answer, demonstration, and practice. Education Booklet included information on: the healthy foot, diabetic foot complications, how diabetes affects your feet, frequently occurring foot problems, surveillance of early foot problems, how to check your feet and problems to look for, nail and skincare, how to choose a shoe and footwear, preventing foot injuries, regular check-up, compliance with diabetes treatment plan, blood glucose, blood pressure and blood lipids monitoring, daily physical movement and quitting smoking (14-19). The foot examination was repeated in the other three interviews, and incomplete information about foot care training was completed, and incorrect information was corrected. Diabetic Foot Knowledge Subscale (DFKS) and Foot Self-Care Behavior Scale (FSCBS) were applied in each interview.

Control Group

When routine follow-ups of the participants in this group were performed in a hospital, foot examination was performed and no interventions were carried out. Foot examination, DFKS and FSCBS application frequency were the same as in the Intervention Group. After the 4th interview, recommendations were made for consultation by providing individual foot care training.

2.4. Measurement instruments

Diabetic foot care and training form, mini mental testing readjusted for the elderly in literate and illiterate individuals and uneducated, participant characteristics form, foot examination form, DFKS and FSCBS were used.

Diabetic foot care and training form: It was determined whether the participant had received previous individual training on diabetic foot care and applications at least for two hours by examining the foot by diabetic training nurse and following-up according to the pre-defined risk group (8, 9, 20).

The Revised Standardized Mini Mental Examination Test: The test evaluates cognitive functions like orientation, record memory, attention and calculation, remembering and language (21). The validity and reliability study of the test was conducted for Turkey (22). Twenty-two points and below show possible cognitive disorders for literate people, and 18 points and below show possible cognitive disorders for illiterate people. The Cronbach Alpha value was 0.59 in the present study.

Participant characteristics form: The form was created by the researchers by scanning the literature. Form consists of five sections questioning socio-demographic characteristics (age, gender, education level, people they live with, etc.), habits (smoking, alcohol, and exercise), characteristics of the disease (diabetes diagnosis time, type of treatment, presence and type of complications, etc.), other chronic diseases and measurements (height, weight, body mass index, HbA1C value, fasting-postprandial blood glucose and blood lipid levels) (23, 24). The data on chronic diseases other than diabetes were obtained by the researcher from file records and with face-to-face interviews, and were grouped according to International Disease Codes (25). Body Mass Index was evaluated as underweight (below 18.5), normal (18.5-24.9), slightly obese (25.0-29.9), obese (30.0-39.9), and excessively obese (40.0 and above) (26). Fasting and postprandial blood glucose measurements were taken with glucometer and capillary blood taken at each follow-up, HbA1c was recorded three times in total in 3-month average glucose levels, and blood lipid levels were recorded twice.

Diabetic foot evaluation form: The form was created by the researchers by scanning the literature. The physical examination of the foot in each follow-up is divided into six sections, and the scoring is made between 0 and 19. In physical examination, each problem (1) was scored, and the total score was scored between 0 and 19. (27, 28).

Presence of foot ulcer: During the examinations, the presence of ulcers was checked. If the patient had an ulcer, (1) point was given, if not (0) point was given.

Evaluation of structural anomalies of the feet and footwear: Deformities like hammertoe or claw toe, hydrocele, callus, fungi, hallux valgus, amputation and Charcot deformity were evaluated. If there were an anomaly in one of both feet, (1) point was given; if not (0) point was given. The width and foot bed, supporting the foot arch, and the suitability to the feet were evaluated, and each item was scored as (1) in there was compliance to each part, if not, (0) point was given (8, 29).

Peripheral neuropathy: The presence of any peripheral neuropathy was determined with PN symptoms in physical examination *(complaints, place, time, etc.)* and findings *(sense of vibration, sharp-cunt perception, Achilies tendon reflex, sensory examination)* scores (30). Even if there were no PN complaints or symptoms according to peripheral neuropathy symptom and finding score, in case there were PN findings ≥6 points (moderate or severe), or in case there were moderate complaints and mild PN findings (3-5 points), it was evaluated as PN (31). If there was neuropathy (1) point was given; if not, (0) point was given.

Circulation: It was evaluated with intermittent limping, feet pulses and Ankle-Brachial Index (ABI) (8, 31, 32). If there was intermittent-limping (1) point was given; if not, (0) point was given; if there was not any of the 4 pulses (1) point was given; if there was, (0) point was given; if ABI was not normal in any of the right or left side, (1) point was given; if normal, (0) point was given.

Self-care knowledge on foot care: Answering "Yes" to any of the 6 questions in any follow-up was deemed to show a deficiency in self-care knowledge (29). If there was knowledge deficiency, (1) point was given; if not, (0) point was given.

Diabetic foot risk and management categories: It was evaluated according to the results of the examination of the feet (8). If the diabetic foot risk group was low (0) point was given; if high, (1) point was given.

Diabetic foot knowledge subscale: The scale consists of five items (33). The validity and reliability were conducted by Kır Biçer and Enç (34). Cronbach Alpha value was 0.67 in the initial measurement, 0.68 in the first month, 0.71 in the third month, and 0.70 in the sixth month.

Foot self-care behavior scale: The scale was developed by Borges and Ostwald (35) in 2008. The validity and reliability were conducted by Kır Biçer and Enç (36). Cronbach Alpha value was 0.79 in the initial measurement, 0.88 in the first month, 0.91 in the third month, and 0.92 in the sixth month.

2. 5. Data collection and procedure

Data collection was performed by the researchers by face-to-face interviews and physical examination. The diabetic foot risk group was determined by performing foot examination to the elderly with diabetes in the Intervention and Control Group. Although the frequency of follow-ups varied according to the risk group (8), a total of four interviews were conducted as the initial interview, and in the first, third and sixth months. The participants who could not come to the Elderly Center were visited at home.

2.6. Ethical considerations

The study was approved by the Ethical Committee of the hospital. Permission was obtained from the institutions in which the application was made. Before beginning the study, the researchers explained its purpose to those who fitted the inclusion criteria, and informed voluntary consent was obtained in writing from those who consented to participate.

2.7. Statistical data analysis

The analyses of the data were made in the Statistical Analysis System Institute, Cary, North Caroline-SAS 9.3 Package Program. The fitness of the points to normal distribution was checked with skewness and kurtosis; the homogeneity of the groups was evaluated with ***t***-test, Chi-Square or Fisher's Exact Test. Variance analysis was used in repeated measurements to compare the mean scores according to measurement times. In significant variables, the group or measurement time(s) that yielded the significance was determined with Duncan's Test. The level of significance was taken as $P<0.05$.

3. RESULTS

3.1. Participant characteristics

The mean age of the participants was 71.49±4.35 in the intervention group, and 70.93±4.89 in the control group. No significant differences ($P>.05$) were detected between the two groups except in cigarette smoking, diabetes treatment types, and diabetes-related complications.

3.2. Findings related to participants' diabetic foot information subscale (DFKS), foot self-care behavior subscale (FSCBS) and foot examination scores

There was a significant difference in the mean DFKS points in the intervention and control group, and changed over time ($P<0.001$). The change increased in every measurement from the initial follow-up in the intervention group compared to the control group (Table 1). This result confirmed the hypothesis that "training and follow-up have an effect on increasing the knowledge of diabetic foot care of the elderly with diabetes".

Table 1. *Comparison of mean scores of the diabetic elderly in intervention and control group in terms of diabetic foot knowledge and foot care behavior during follow-up process*

Measures	DFKS		FSCBS	
	$\overline{x}$ ±SD		$\overline{x}$ ±SD	
	Intervention (n=45)	Control (n=45)	Intervention (n=45)	Control (n=45)
1	2.51±1.27	1.56±1.34	48.69±9.98	45.18±11.24
2	3.18±1.08	1.82±1.27	61.13±7.21	46.53±11.51
3	4.16±0.85	2.40±1.56	66.82±4.95	48.93±11.18
4	4.73±0.50	2.60±1.14	70.64±3.16	50.78±10.76
Test	*p*		*p*	
Time	<0.001		<0.001	
Group	<0.001		<0.001	
Time x Group	0.006		<0.001	

DFKS: Diabetic Foot Knowledge Subscale, FSCBS: Foot Self-Care Behavior Scale, SD: Standard Deviation

There was a difference in terms of the mean FSCBS scores between the intervention and control group, and changed over time (P<0.001) (Table 1). This result confirmed the hypothesis that "training and follow-up have an effect on increasing the foot care behavior of the elderly with diabetes".

The mean foot examination points were compared according to the measurement times in the Intervention and Control Group (Table 2). Although there was a difference in terms of the structural abnormalities of the foot, neuropathy, lack of self-care knowledge, and diabetic foot risk score (P<0.05); there were no differences in terms of footwear, neuropathy, and circulation score (P>0.05). The lack of self-care knowledge score decreased more between the 1st-2nd measurements and the 3rd – 4th measurements in the Intervention Group compared to the Control Group. The total score of foot examination was similar (P=0.005), changed over time (P=0.001), and the change was similar (P>0.05). In the mean foot examination points; there was a significant difference between the 1st – 2nd and the 3rd – 4th measurements in both groups after the first measurement, more pronounced in the Intervention Group, and it was determined that there was an increase in the Intervention Group in the 4th measurement, less pronounced in the Intervention Group. These results confirmed the hypothesis that "The training and follow-ups have effects on improving the foot examination scores of the elderly with diabetes".

3.3. Findings related to physiological measurements

The differences between mean systolic blood pressure, FBG and PBG between groups and the change over time were not significant (P>0.05). In the mean diastolic blood pressure, the difference between groups was significant (P=0.005), and there was no significant difference in change over time (P>0.05). The diastolic blood pressure was low in the Intervention Group compared to the Control Group (Table 3). The difference between groups and the change over time in the mean HbA1c score was not significant (P>0.05) Table 4). The difference between the groups in the first interview and 4th follow-up for mean triglyceride, cholesterol and LDL values and the change over time was not significant (P>0.05). The mean HDL was found to be lower in two follow-ups in the Intervention Group compared to the Control Group, and the difference was found to be significant in the 4th follow-up (P=0.05) (Table 5).

Table 2. *Comparison of mean scores of the diabetic elderly in intervention and control group in terms of foot examination during follow-up process*

	Measures	Foot Examination Findings: Foot ulcer	Structural abnormalities of the foot	Footwear	Neuropathy	Circulation	Deficiency of self-care information	Diabetic foot risk	Total
		$\bar{x}$ ±SD	$\bar{x}$ ±SD	$\bar{x}$ ±SD	$\bar{x}$ ±SD	$\bar{x}$ ±SD	$\bar{x}$ ±SD	$\bar{x}$ ±SD	$\bar{x}$ ±SD
Intervention (n=45)	1	0.00±0.00	2.62±1.19	0.07±0.33	0.31±0.47	0.84±0.60	1.00±0.00	0.89±0.32	5.74±1.51
	2	0.00±0.00	2.51±1.14	0.07±0.33	0.31±0.47	0.84±0.60	0.58±0.50	0.87±0.34	3.40±1.79
	3	0.00±0.00	2.40±1.25	0.00±0.00	0.27±0.45	0.84±0.56	0.44±0.50	0.84±0.37	3.18±1.75
	4	0.00±0.00	2.16±1.28	0.00±0.00	0.76±0.44	0.71±0.59	0.38±0.49	0.84±0.37	3.44±1.67
Control (n=45)	1	0.22±0.15	2.80±0.81	0.02±0.15	0.29±0.46	0.78±0.56	1.00±0.00	0.96±0.21	5.87±1.29
	2	0.22±0.15	2.82±0.83	0.16±0.37	0.29±0.45	0.76±0.58	0.98±0.15	0.98±0.15	3.93±1.62
	3	0.22±0.15	2.71±0.84	0.04±0.21	0.27±0.45	0.67±0.60	0.96±0.21	0.91±0.29	3.69±1.61
	4	0.22±0.15	2.71±0.84	0.04±0.21	0.73±0.45	0.69±0.56	0.96±0.21	0.93±0.25	4.16±1.46
Test		*P*	*P*	*P*	*P*	*P*	*P*	*P*	*P*
	Time	X	0.282	**0.042**	**0.001**	0.602	**0.001**	0.655	**0.000**
	Group	X	**0.002**	0.189	0.728	0.125	**0.001**	**0.008**	**0.005**
	Timex Group	X	0.673	0.302	0.998	0.831	**0.001**	0.951	0.667

SD: Standard Deviation, X: Since there were no foot ulcers in the Intervention Group during follow-up period, the change could not be compared in terms of foot ulcer according to intra and intergroup time.

Table 3. *Comparison of mean scores of the diabetic elderly in intervention and control group in terms of systolic blood pressure, diastolic blood pressure, FBG, and PBG during follow-up process*

	Measures	Systolic Blood Pressure	Diastolic Blood Pressure	FBG	PBG
		$\bar{x}$ ±SD	$\bar{x}$ ±SD	$\bar{x}$ ±SD	$\bar{x}$ ±SD
Intervention (n=45)	1	130.44±13.81	75.78±12.34	136.56±38.87	186.58±71.18
	2	128.89±14.50	77.56±8.83	140.12±55.95	191.911±91.83
	3	126.00±13.21	78.22±8.87	124.09±22.27	156.07±42.01
	4	129.11±13.28	78.22±9.36	127.11±31.10	164.31±53.33
Control (n=45)	1	128.33±13.48	79.56±6.01	133.62±42.86	182.31±72.06
	2	128.22±11.34	79.78±6.90	138.47±65.58	173.98±79.07
	3	126.89±13.11	79.78±3.98	137.22±72.63	177.96±91.97
	4	129.78±13.40	80.44±7.06	144.21±57.05	182.82±77.90
Test		*p*	*p*	*p*	*p*
	Time	0.392	0.562	0.729	0.34
	Group	0.828	**0.005**	0.236	0.565
	Time x Group	0.865	0.830	0.442	0.224

FBG: Fasting blood glucose PBG: Postprandial blood glucose, SD: Standard Deviation

Table 4. *Comparison of mean scores of the diabetic elderly in intervention and control group in terms of hba1c during follow-up process*

		HbA1c
	Measures	$\bar{x}$ ±SD
Intervention (n=45)	1	7.29±1.16
	2	7.05±1.23
	3	7.50±1.50
Control (n=45)	1	6.96±1.67
	2	6.82±1.70
	3	6.96±1.67
p		
Test	Time	0.592
	Group	0.094
	Time x Group	0.848

SD: Standard Deviation,

Table 5. *Comparison of Mean scores of the diabetic elderly in intervention and control group in terms of triglyceride, cholesterol, HDL and LDL in initial interview and fourth follow-up*

Measures	n	Blood Lipids	Intervention Group	Control Group	*p*
			$\bar{x}$ ±SD	$\bar{x}$ ±SD	
Initial interview	22	Triglyceride	163±63	129±44	0.245
	22	Cholesterol	202±32	177±40	0.251
	22	HDL	44±10	51±16	0.523
	22	LDL	123±31	203±30	0.279
Fourth interview	44	Triglyceride	168±63	144±66	0.098
	44	Cholesterol	193±29	189±38	0.117
	44	HDL	42±11	54±51	**0.051**
	44	LDL	122±30	109±32	0.122

4. DISCUSSION

4.1. Discussion of Findings Related to Participants' Diabetic Foot Information Scores

It is important to evaluate problems that might occur after diagnosis, to provide training and regular follow-up and preventive behaviors to prevent diabetic foot development (37). It was reported that 50-85% of amputations can be prevented with early diagnosis, regular follow-up, and training (38).

The significant increase in the mean DFKS score in the Intervention Group compared to the Control Group was at the highest between the second and third measurements, and the least between the third and fourth measurements. In previous studies, it was reported that individuals with diabetes were inadequate in terms of their knowledge on foot care, and had low behavioral scores and poor attitudes (39-42). Guided by Bandura's Social Cognitive Theory, the foot self-care application increased in the 6th week and the following three months after the foot self-care training applied to Type 2 diabetes individuals with low risk of foot ulcers (37). In the present study, which examined the effect of training in developing foot care knowledge and self-care practices, it was determined that there was a significant increase in the knowledge and self-care practices of the Intervention Group in one and a half and third months (43). In a study that examined the effect of foot care training, it was revealed that there was a significant difference between pre-test and post-test foot care knowledge score and patient foot examination and footwear use (44). In another study, individuals with diabetes were given foot care training in a four-week period, were followed up for six months, and the foot care knowledge increased in the Intervention Group in the first month and continued during the follow-up.

There were no significant differences in foot lesions during the follow-up period (45). Similarly, in a study which trained patients 9 times about foot care and overall diabetes care, it was found that there was a significant increase in the knowledge in the application group (46). In the study conducted by Kır Biçer and Enç, the mean foot care knowledge score in the 6-month follow-up process of individuals with diabetes in the planned training program continued to increase as of the beginning in the experimental group, there was no change in the Control Group, and there was a significant difference between the follow-up according to the groups (34).

According to the results of the study, which reported a significant increase in foot care knowledge of individuals with diabetes after six weeks of foot care training (38) and after six months (47). On the contrary, in another study, it was reported that foot self-care knowledge did not increase in 6 months after application. The researchers emphasized that this difference was due to the small number of sampling (48).

In two studies (49, 50), it was shown that being able to obtain the knowledge would last for a longer period like 1-7 years. In our study, on the other hand, the increase in the mean diabetic foot knowledge score was at the highest level between the second and third measurements, and between the third and fourth measurements at the lowest level; and in line with these results, it is possible to speculate that the intervention was effective in increasing foot care knowledge in the first three months. This is because it is considered that the elderly with diabetes must be examined for foot examination every time they arrive for follow-ups to monitor changes, and foot care training would be provided according to the foot examination findings. No studies were detected in the literature in which foot care training and foot examination studies were conducted in each follow-up (37, 43, 46); and it was determined that foot care training was not repeated in every follow-up, and that foot care knowledge was evaluated during the initial training process (43, 45, 47).

4.2. Discussion of Findings Related to Participants' Foot Care Behavior Scores

It was reported in previous studies that self-care behaviors can be provided by increasing diabetes knowledge (51). In our study, the foot care behavior score increased at significant levels more in the Intervention Group. Effective management and control of diabetes require behavioral compliance. Studies showed that training practices increase the level of knowledge, positively affect the level of belief, and provide positive health behaviors (52, 53), three weeks after the training (24), and six months after the training (54) and foot self-care behaviors developed. The results of our study were found to be similar to studies supporting the effect of self-care practices in improving the performance of foot care behaviors (38, 47, 48).

In our study, compared to the Control Group, the increase in the mean FSCBS scores was at the highest level between the $1^{st} – 2^{nd}$ and $3^{rd} – 4^{th}$ measurements, and the intervention was effective in acquiring foot care behavior as soon as in the first month. This might be because of the foot examination in each follow-up and the training given according to the examination findings. DFKS and FSCBS scores increased in the Intervention Group as well as in the Control Group, more pronounced in the Intervention Group. This increase may stem from the fact that participants in the Control Group regularly applied to the hospital with their own wishes for treatment and care of their diseases. In addition, it is considered that the follow-up process creates awareness and curiosity providing the opportunity to learn from experts on foot problems they experience in the elderly with diabetes in the Control Group.

4.3. Discussion of Findings Related to Participants' Foot Examination Findings and Diabetic Foot Self-care Lack of Knowledge

In the present study, the mean foot examination scores of the elderly with diabetes and the lack of self-care knowledge about foot care decreased in time in both groups. In the Intervention Group, the decrease in self-care knowledge scores between the 1^{st}-2^{nd}, and 3^{rd}-4^{th} measurements greater than in the Control Group. In the literature, it was shown that training that focuses on foot self-care in patients in the long term improved self-care and foot care implementations, reducing lower-extremity amputation and foot ulceration in those who were at high risk for foot ulceration (37, 56).

There was a significant difference between structural abnormalities of the foot and the diabetic foot risk in the Intervention and Control Group in terms of mean scores. This difference may be the result of the variable nature of the scores of structural abnormalities of the foot, which can vary by increasing the knowledge and behavior scores of the participants with foot care training and follow-ups. Pieber et al. (57) conducted a study in which they provided training on diabetes and foot care for four weeks, followed up their patients, and compared the results with initial scores, the determined significant decreases in callus formation and inadequate nail care. Positive improvements were detected in foot care in the study, which compared foot examinations before the training, and after three and six months of the training (54). Routine foot care was provided to individuals with foot ulcers, and the risk of recurring foot ulcers decreased in one year (38). In two studies with a follow-up period of 6 months (32) and 18 months (46), no difference was detected between the groups in terms of foot lesions. It was reported that this might be due to the differences in foot examination findings of the participants involved in the sampling.

The difference between the Intervention and Control Group in terms of footwear, neuropathy and circulation scores was not significant. No studies were found in the literature in which diabetics were followed up according to risk groups by performing foot examination and foot care training as in our study. However, it was determined that there were studies in which it was reported that massage (58, 59), and exercise

(60) were effective together with foot care examination in individuals with diabetes.

A significant difference was detected between the Intervention and Control Group in terms of the foot examination total scores, and it was determined that there was a decrease in the first measurement in both groups, more pronounced in the Intervention Group, and there was a decrease in the fourth measurement, less in the Intervention Group. The fact that there were decreases in foot examination score after the first measurement was associated with the follow-up period being 1 month between the first 2 measurements, and the increase in the 4th measurement was associated with the period between the last two follow-ups being 3 months resulting in remembering the instructions given in the training.

It was determined in studies that there were positive improvements in foot care in the 3rd and 6th months after the training intervention (54), and there were significant decreases in callus formation and inadequate nail care at the end of the 6-month follow-up (57). In our study, the total score of foot examination consisted of factors that might vary with foot care training, follow-up, increased foot care knowledge, and behavior scores. The fact that there was a decrease in foot examination total score in the Intervention Group compared to the Control Group was considered as the results of training and follow-up on foot care in our study. The reason why there were decreases in the foot examination scores of the elderly with diabetes in the Control Group was the awareness that was raised when questions were asked about foot care knowledge and behavior to carry out four-foot examinations.

4.4. Discussion of findings related to participants' physiological measurement

In our study, there were no significant differences in the inter – and intragroup comparison in terms of the mean scores of systolic blood pressure, FBG, PBG and HbA1c, but the difference between the groups in terms of the mean diastolic blood pressure scores was significant. The mean diastolic blood pressure was lower in the Intervention Group. This result is considered to be because of the evaluation of blood circulation when foot examinations were made, and the explanation of the results in blood pressure scores that were different from the normal values to diabetic participants, as well as directing them to the specialist physician for evaluation. The mean HDL scores in the Intervention Group were lower in both the beginning and in the 6-month than in the Control Group, and the difference was significant in the 6th month. The reason for this significant difference in the Control Group might be considered as taking into account the warnings for regular referral to the Diabetes Training Unit, and the warnings made in terms of protecting and improving health. In a previous study, no significant relations were found between metabolic control variables and foot care training (54), and in another study, it was found that there was a significant decrease in HBA1c in the final test of the experimental group (35). It is speculated that increased compliance to self-care behaviors, diabetes knowledge, and treatment can be achieved with glycemic control (51). In the present study, the importance of blood sugar, blood pressure, and blood fat checks was emphasized in terms of foot health in the training given to the Intervention Group. It also found that there was a significant difference between the Intervention and Control Group in metabolic control variables other than Diastolic Blood Pressure and HDL value. The reason for this might be considered as that the majority of the elderly with diabetes in the Intervention Group do not go to the hospital regularly for treatment and care and because their metabolic control variables are not at the desired levels.

5. CONCLUSION

The results showed that training and follow-up are effective in increasing the knowledge on foot care, behavior and foot examination scores of the elderly with diabetes. In this respect, the following are recommended; identifying the risk of developing diabetic foot by examining the diabetic elderly by nurses, monitoring and scientifically evaluating the changes in foot care knowledge and behavior with individual foot care training and follow-up according to risk groups, including caregivers of diabetic elderly in training, re-conducting the study to increase the level of evidence, determining the effects of different interventions like exercise and reflexology in addition to training and follow-up interventions, creating evidence-based guidelines, and in this way, minimizing the complications of the foot due to diabetes.

6. Limitations of the Study

Among the limitations of the study are the small sampling size and six-month short-term training and follow-up period. In addition, one-on-one training is effective but time-consuming, thus making it difficult to conduct daily in crowded clinics. To overcome this drawback, the effectiveness of foot care training could be evaluated by conducting training on larger groups.

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Clinical and Experimental Health Sciences

Symptoms and Care Satisfaction in Patients Who Underwent Coronary Artery Bypass Graft Surgery

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ABSTRACT

Objective: This study was conducted to investigate of symptoms and care satisfaction in patients who had a coronary artery bypass graft (CABG) surgery.

Methods: The study population consisted of patients who had a coronary artery bypass graft surgery in a public and a foundation hospital in Istanbul between December 2018 and May 2019 and the study sample 176 patients who met the inclusion criteria and agreed to take part in the study. The study data were collected using the self-report method with the help of a Patient Description Form, the Heart Surgery Symptom Inventory (HSSI) and the Newcastle Satisfaction with Nursing Care Scale (NSNS). The data were analysed on the SPSS version 22.0 software. The data were analysed using numbers, percentages, minimum and maximum values, means and standard deviations, t-test, variance analysis and Pearson correlation analysis.

Results: The patients were found after their CABG surgery to experience pain, shortness of breath, fatigue, lack of appetite, nausea and wound-related symptoms. The most common complaint of the patients after the surgery was sleep problems and the least common wound-related symptoms. The mean HSSI score of the participating patients was 71.22±31.39 and the mean NSNS score 52.87±22.54, which meant that the severity of their post-surgery symptoms and their satisfaction with care were at a moderate level. Post-surgery pain, lack of appetite, nausea and wound-related symptoms were found to have a statistically significant moderate negative correlation with care satisfaction ($p<0.05$) and shortness of breath, fatigue and insomnia to have a statistically significant strong negative correlation with care satisfaction ($p<0.05$).

Conclusion: The results of this study revealed that patients who experienced less symptoms of pain, shortness of breath, fatigue, sleep disorders, lack of appetite, nausea, vomiting, and wound infection after a CABG surgery were more satisfied with the nursing care.

Keywords: Care Satisfaction, Nursing, Coronary Artery Bypass Graft, Symptoms

1. INTRODUCTION

According to the World Health Organization (WHO), noncommunicable diseases (NCDS) cause deaths at global, regional and national levels. The WHO 2017 data shows that 40 million people die every year due to NCDS, which constitute 70% of all deaths worldwide. In 2015, 37% of NCD-associated deaths were caused by cardiovascular diseases (1). They accounted for 1.8 million deaths in European Union (EU) countries and 3.9 million deaths in whole Europe (2). Global deaths due to cardiovascular diseases are estimated to reach 22.2 million in 2030 (3).

The most widely used treatment method for CAD is the Coronary Artery Bypass Graft (CABG) surgery (4). The number of people who undergo a CABG operation annually is estimated to be 400,000 in the U.S. and 20,000 in Turkey (5,6).

CABG is a major surgery and many symptoms can be seen in patients after the operation. These symptoms include respiratory, cardiovascular, neurological, renal, gastrointestinal and wound-related problems, fluid-electrolyte imbalance, pain, anxiety, insomnia, and fatigue (7-10).

Considering possible postoperative CABG symptoms, the nursing care to be provided in the process of recovery becomes extremely important (11,13). The goal of nursing care after a CABG surgery is to prevent symptoms, to raise quality of life, and to establish patients' homeostatic equilibrium to ensure speedy recovery and discharge (14). The most fundamental indicator of quality nursing care is the satisfaction with care (15).

With the qualified nursing care provided in the early postoperative period, symptoms decrease and care satisfaction increases (15,16,17). In a study made by Aydın (2014), patients who experienced less symptoms in the postoperative period have been reported to have better care satisfaction (18). Other studies have also reported that patients who experienced less pain in the postoperative

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period were satisfied with nursing care and had a faster recovery (19,20). Another study has also found that patients who had good quality night sleep were more satisfied with nursing care (21). Good quality sleep also accelerates postoperative wound healing process (20). Yoon et al. (2015) have reported in their study dealing with wound care that patients who had more satisfaction with care had less symptoms developing in their wound site (22).

No study was found in the literature investigating the effect of symptoms seen in patients who had a CABG surgery on their care satisfaction. Therefore, by identifying the effect of the symptoms seen in patients who had a CABG operation on care satisfaction, this study is intended to provide guidance to nurses who will give care to this patient group and contribute to the literature.

2. METHODS

2.1. Design

This study is a descriptive research. The study was conducted in 2 hospitals, one state university hospital and one foundation university hospital in Istanbul between December 2018 and May 2019. According to 2017 data, 502 patients underwent a CABG operation in the state university hospital in a year and 61 patients in the foundation university hospital. The study population consisted of patients who had a CABG operation in these university hospitals in Istanbul. The power analysis performed suggested that at least 152 patients should be included in the study to achieve a significance level of 0.05, a confidence interval of 95% and a power of 80% (23). Accordingly, no sampling was attempted and 176 patients were included in the sample from those who had a CABG operation for the first time, whose hospital stay did not exceed 10 days, who volunteered to take part in the study, and who was aged 18 years and over, conscious with no communication problems and agreed to take part in the study.

2.2. Measures

The study data were collected using the Patient Description Form, Heart Surgery Symptom Inventory, and Newcastle Satisfaction with Nursing Care Scale.

Patient Description Form

Prepared by the investigator, this form consisted of 20 questions in total, 9 questions about the demographic characteristics of the patients who had a CABG operation, such as age, gender, occupation, and education status and 11 questions about the disease and postoperative peculiarities.

Heart Surgery Symptom Inventory (HSSI)

HSSI was developed by LaPier and Jung (2002) to assess symptoms seen in patients after an open heart surgery (24). Its validity and reliability study in Turkish was performed by Altınok and Sağlam (2018) (25). The Turkish version of HSSI consists of a single scale with 35 items. The inventory is of a Likert-type and the symptoms are rated between 0 and 4 as “None”, “Very Little”, “Moderate”, “Many”, and “Quite Many”. The scores obtainable from the inventory range between 0 and 140. With higher scores, the severity of symptoms increases. There are no reverse items in the inventory and its Cronbach alpha coefficient is 0.96.23 The Cronbach alpha coefficient of HSSI was found to be 0.98 in this study.

Newcastle Satisfaction with Nursing Care Scale (NSNS)

NSNS was developed by Thomas et al. (1996) (26). The validity and reliability study of the scale in Turkish was performed by Akın and Erdoğan (2006) (27). It is a 5-point Likert-type scale with a single scale and 19 items measuring nursing care. The scoring used to reveal satisfaction includes “1. Not at all satisfied, 2. Barely satisfied, 3. Quite satisfied, 4. Very satisfied, 5. Completely satisfied”. The scoring involves summing the responses marked across the items and transforming them to 100 to obtain an overall score of 0-100. An overall score of 100 shows that the patient is satisfied with all aspects of nursing care. The Cronbach alpha coefficient of the scale is 0.94.26 The Cronbach alpha coefficient of NSNS was found to be 0.98 in this study.

2.3. Data Collection

To collect data, patients who had a CABG operation and agreed to take part in the study were interviewed in their clinics before their discharge. The patients were informed about the study. The patients who agreed to take part in the study were asked to read and sign an Informed Consent Form. After reading and signing the informed consent form, the patients were administered the Patient Description Form, HSSI and NSNS on the basis of self-report.

2.4. Analysis

The data were analysed on the SPSS 22.0 package program. In data analysis, numbers, percentages, minimum and maximum values, means and standard deviations, t-test, variance analysis and Pearson correlation analysis were used.

2.5. Ethical Considerations

Before commencing the study, permission was obtained from the Ethics Committee of Maltepe University, Health Sciences Institute (Decision No: 2018/07-05) and from the Istanbul Provincial Health Directorate to be able to conduct the study in a state university hospital (Decision No: 16867222-604.01.01). Permission was also obtained from the ethics committee of the foundation university hospital to be able to conduct the study (Decision No: 2019/10-2). Necessary permissions were obtained to use the Heart Surgery Symptom Inventory and the Newcastle Satisfaction with Nursing Care Scale. Written and verbal consents were obtained from the patients who agreed to participate in the study.

3. RESULTS

Of the patients, 59.1% were male, 84.1% married, 52.3% had income equal to expenses, and 28.4% were university graduates. Of the patients, 75% had health insurance

and 57.4% lived in a nuclear family. The mean age of the participants was 62.09±9.28 and 47.7% of them had undergone a prior operation once and 71% have not stayed in intensive care before. Of the patients, 59.1% had a comorbid chronic disease and 85.2% were smokers. Of the patients, 82.4% did not use alcohol, 73.9% did not exercise regularly, 42.6% had their 3 vessels replaced, and 84.1% stayed in intensive care for 24 hours (Table 1, 2). The patients' mean HSSI score was 71.22±31.39 and mean NSNS score 52.87±22.54 (Table 3). The most common symptom of the patients was insomnia (2.4489±1.06) and the least common wound-related symptoms (1.7614±1.09) (Table 4). The pain, lack of appetite-nausea and wound-related symptom scores were found to have a statistically significant moderate negative correlation with the NSNS score ($p<0.05$) and the shortness of breath, fatigue and insomnia scores to have a statistically significant strong negative correlation with the NSNS score ($p<0.05$). There was also a statistically significant, high level negative correlation between the HSSI total score and the NSNS total score ($p<0.05$). As the HSSI total score decreased, the NSNS total score increased (Table 5).

Table 1. *Distribution of descriptive characteristics of participants (n=176)*

Descriptive Characteristics		n	%
Gender	Male	104	59.1
	Female	72	40.9
Marital status	Married	148	84.1
	Single	28	15.9
	Income less than expenses	44	25.0
Income Level	Income equal to expenses	92	52.3
	Income more than expenses	40	22.7
	Able to read and write	29	16.5
	Primary school	41	23.3
Education Status	High school	44	25.0
	University	50	28.4
	Postgraduate	12	6.8
Health Insurance	Yes	132	75.0
	No	44	25.0
	Nuclear	101	57.4
Family Type	Broad	52	29.5
	Fragmented	23	13.1
	Spouse	93	52.8
Household	Spouse and children	55	31.3
	Alone	15	8.5
	Children	13	7.4
	Yes, I work	13	7.4
Employment Status	No, I don't work	163	92.6

	Min.	Max.	Mean	SD
Age	45	83	62.09	9.28
Duration of Disease (Years)	0	20	6.82	3.94

Table 2. *Distribution of disease-related and postoperative characteristics of patients (n=176)*

Characteristics		n	%
	1 time	84	47.7
Past Surgeries	2 times	63	35.8
	3 times and more	14	8.0
	Not at all	15	8.5
Past Intensive Care Stay	Yes	51	29.0
	No	125	71.0
Other Chronic Disease	Yes	104	59.1
	No	72	40.9
Smoking	Yes	150	85.2
	No	26	14.8
Alcohol	Yes	31	17.6
	No	145	82.4
Regular Exercising	Yes	46	26.1
	No	130	73.9
	1	32	18.2
Number of Vessels Replaced	2	63	35.8
	3	75	42.6
	4+	6	3.4
Stay in Intensive Care	24 hours	148	84.1
Duration	48 hours	28	15.9
Postoperative Hospital Stay	5-6 days	97	55.1
	7-10 days	79	44.9
	All the time	144	81.8
Companion	Comes at certain hours	27	15.3
	No companion	5	2.9

Table 3. *Mean total scores obtained by patients from the heart surgery symptom inventory and the newcastle satisfaction with nursing care scale (n=176)*

	Min.	Max.	Mean	SD
Heart Surgery Symptom Inventory	7	140	71.22	31.39
Newcastle Satisfaction with Nursing Care Scale	20	100	52.87	22.54

Table 4. *Mean symptom scores obtained by patients from the heart surgery symptom inventory (n=176)*

	Min.	Max.	Mean	SD
Symptoms				
Pain	.00	4.00	1.9943	1.05558
Shortness of Breath	.00	4.00	2.1705	1.1724
Fatigue	.00	4.00	2.3352	1.09341
Insomnia	.00	4.00	2.4489	1.06781
Lack of appetite-Nausea	.00	4.00	2.1307	0.97978
Wound-Related Symptoms	.00	4.00	1.7614	1.09539

Table 5. *Correlation between patients' post-operative symptoms and care satisfaction (n=176)*

	Newcastle Satisfaction with Nursing Care Scale	
Symptoms	r*	p
Pain	-0.729	**0.000**
Shortness of Breath	-0.823	**0.000**
Fatigue	-0.805	**0.000**
Insomnia	-0.782	**0,000**
Lack of appetite-Nausea	-0.682	**0.000**
Wound-Related Symptoms	-0.748	**0.000**
HSSI Total Score	-0.900	**0.000**

**Pearson correlation analysis* *p<0.05*

4. DISCUSSION

CABG surgery is one of the most widely used surgeries across the world and is one of the most effective and reliable treatment options for CAD (28). CABG surgery is a major procedure and many symptoms can be seen in patients in the postoperative period. These symptoms include respiratory system symptoms, GIS symptoms, cardiovascular system symptoms, neurological symptoms, renal symptoms, wound-related symptoms, fluid-electrolyte imbalance, pain, anxiety, insomnia, and fatigue (7-10). In this study, the patients were found to experience pain, shortness of breath, fatigue, insomnia, lack of appetite-nausea, and wound site-related symptoms in the postoperative period.

It has been reported in the literature that patients with high levels of pain had lower satisfaction with nursing care and the recovery process of pain slowed down (17,18). It has also been reported that when pain cannot be controlled, the risk of developing other symptoms increased and the comfort of patients declined in the postoperative period (31). In this study, the patients who had more pain were found to have a lower level of care satisfaction. Lower care satisfaction in patients with severe pain may have arisen from the failure to exercise effective pain management in the early postoperative period.

Patients who experienced less shortness of breath were found to have better care satisfaction in this study. Shortness of breath is one of the common symptoms seen in patients in the postoperative period (32). In a study made by Treat and Lindquist (2007) on CABG patients, pulmonary symptoms were found to be associated with care satisfaction (33). Other studies have also confirmed that pulmonary symptoms restrict physical activity tolerance in patients resulting in decreased patient comfort and quality of life (34). It is stated in a study made by Yılmaz (2002) that when pulmonary symptoms are controlled, patients' care satisfaction improves (35). It can be said that the patients who did not experience shortness of breath or who experienced it less in this study had better care satisfaction as a result of effective nursing care.

Insomnia and fatigue are among the common symptoms seen after a CABG operation (36). Nursing care is reported to be extremely important in improving sleep quality of patients (37). Some studies have found that patients who have good quality sleep are satisfied with the nursing care provided at night (19,38). In a study made with patients who underwent a CABG surgery, postoperative insomnia and fatigue symptoms were found to be associated with care satisfaction (32). It was also found in this study that patients who experienced less insomnia and fatigue had better nursing care satisfaction. This can be explained by the fact that patients who are made subject to symptom management and whose sleep is kept under control experience less fatigue and thus they report better care satisfaction.

Nausea-vomiting is one of the frequent symptoms experienced by patients in the postoperative period (39). Sung (2016) has reported in their study that nausea-vomiting symptom seen in the postoperative period was associated with care satisfaction (40). In another study made by Royse et al. (2013), GIS symptoms that cannot be controlled were found to reduce nursing care satisfaction (41). It was also found in this study that the patients who experienced less nausea-vomiting symptoms had better care satisfaction. It can be said that the quality of the nursing care provided is directly proportional to care satisfaction in patients who are closely monitored for nausea-vomiting and are given medical treatment and nursing care when necessary in the postoperative period.

It was found in this study that the patients who developed less wound-related symptoms were more satisfied with the care. Studies have reported that wound-related symptoms that may develop in patients in the postoperative period was associated with the quality of care and thus care satisfaction and patients who did not develop a symptom in their wound site were more satisfied with care (22,42,43). Wound-related symptoms prolong the recovery process of patients and therefore their time of hospitalization and prolonged hospital stay decrease patients' care satisfaction (44, 45). The reason for the patients who experienced less wound-related symptoms in the present study to have better care satisfaction was that adequate and appropriate care was given to these patients, the wound care provided diminished their wound-related symptoms (infection, fever, discharge) and in this way, the patients who experienced less symptoms were more satisfied with the care.

In a study carried out with patients who underwent an operation, the symptoms seen after the operation was reported to be associated with nursing care satisfaction (17). Another study also reported that patients who experienced less postoperative symptoms were more satisfied with nursing care (18). Another study made by Velanovich (2004) has reported that patients whose symptom severity was higher in the postoperative period had a slower recovery process and their care satisfaction was lower (46). Similarly, it was also found in this study that the patients experienced moderate symptoms in the postoperative period, they were satisfied with the nursing care at a moderate level and as the symptoms experienced by the patients decreased, their care satisfaction increased. The reason why the patients' care satisfaction improved as the symptoms seen in the postoperative period decreased in this study can be explained by the fact that the nursing care provided in the postoperative period reduced the symptoms seen in the patients, which affected care satisfaction positively.

The limitations of this study include that it was conducted only in the city of Istanbul and that there were only limited number of studies investigating the relationship between postoperative CABG symptoms and care satisfaction.

5. CONCLUSION

The results of this study revealed that patients who experienced less symptoms of pain, shortness of breath, fatigue, sleep disorders, lack of appetite, nausea, vomiting, and wound infection after a CABG surgery were more satisfied with the nursing care. Based on these results, our recommendations would be to raise awareness among nurses that symptoms seen in this patient group can affect care satisfaction and to motivate nurses to provide effective nursing care to patients considering that reduced symptoms lead to better care satisfaction and to employ effective symptom management to reduce symptoms. Conducting similar studies in multiple centres with larger samples is also recommended.

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Author contributions

Bozkurt T and Sağlam R contributed to planning the research and writing the manuscript. Bozkurt T collected the data and Sağlam R reviewed the manuscript with constructive criticisms.

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Clinical and Experimental Health Sciences

The Effect of Ph-cycling and Toothbrushing Simulations on Surface Roughness of Bulk-Fill Composites

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ABSTRACT

Objective: This study aimed to compare surface roughness values (Ra) of different posterior composites after pH-cycling and toothbrushing simulation.

Methods: Fifty disc-shaped specimens (8x2 mm) were prepared by using three bulk-fill composites [Filtek Bulk Fill Posterior (FBF), SonicFill 2 (SF), X-tra fil (XF)], a flowable [G-aenial Universal Flo (GF)], and a microhybrid composite [Filtek Z250 (Z250)]. After initial roughness (Ra_0) measurements were performed with a contact profilometer, the samples were subjected to a pH-cycling model for 10 days and Ra_1 values were recorded. Then, the samples were subjected to toothbrushing simulation for 4 min and final values (Ra_2) were recorded. From each group, a representative sample was analyzed with an optical profilometer. The values were analyzed by two-way ANOVA with repeated measures on one factor (period) followed by Tukey's test ($p<0.05$).

Results: Significant differences were found among materials regardless of experimental periods. The lowest Ra values were determined in GF and Z250 groups. The highest value was obtained in SF, but this value was not statistically significant different from that obtained in XF group. Brushing procedure after chemical degradation led to an increase in surface roughness of all materials except FBF, which was not statistically significant.

Conclusion: While Ra values showed differences depending on the materials, pH-cycling and toothbrushing simulation did not have a significant effect on these values.

Keywords: Bulk-fills, pH-cycling, resin-based composites, surface roughness, toothbrushing

1. INTRODUCTION

Improvements in both the aesthetic and mechanical properties of resin-based materials have resulted in the extensive use of direct composite resin restorations in anterior and posterior teeth (1). Bulk-fill composites represent one of the most remarkable developments in restorative dentistry in recent years. These materials have less polymerization shrinkage than conventional resin composites, as well as greater light transmission resulting from less scattering at the matrix-filler interface, and enhanced polymerization depth resulting from the material's greater translucency. Bulk-fill composites are also easier to manipulate, which helps to accelerate the restoration process in deep cavities (2,3). Despite these advantages, surface roughness remains a problem inherent to the material, and researchers agree that with time direct restorations performed with bulk-fill composites undergo changes in surface roughness (4-8).

Flowable composites have reduced filler loading that typically results in a low viscosity, allowing them to flow easily, spread homogeneously and closely adapt to the cavity form to produce the desired tooth anatomy. However, the lower filler loading also results in inherently inferior mechanical properties, making flowable composites more susceptible to wear and other forms of attrition than conventional composites (9). G-aenial Universal Flo has been introduced as a highly filled injectable composite, which shows higher viscosity and improved mechanical properties, similar to conventional composites. Furthermore, unlike other flowable composites, G-aenial Universal Flo eliminates the need for an additional covering

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layer with a more wear-resistant regular resin composite in areas under occlusal force, thus facilitating the restoration process (4,10,11). This unique composite blends the properties of two types of resin-based composites, flowable and conventional, and showed a smoother surface after wear test compared to other flowable and conventional composites tested (12). However, information regarding the surface roughness of this flowable resin composite is limited.

Oral environment conditions are known to threaten the integrity and longevity of resin-based materials. In particular, the chemical environment of the oral cavity has been shown to affect the surface properties of resin-based restorative materials (13,14). Low environmental pH caused by cariogenic biofilm and acidic drinks, as well as water absorption and erosion can all result in material degradation (1,15), and the degradation of the matrix, filler, and matrix-filler interface on the surface of restoration may further increase roughness and abrasion (16).

The effect of toothbrushing on the surface roughness of resin composites also need to be taken into consideration in assessing the clinical performance of these materials. When softened restorations due to chemical degradation are exposed to brushing abrasion as well as chewing forces, a gradual removal of material occurs (17). Moreover, brushing abrasion is the main cause of material loss, especially in non-stress-bearing areas. Such wear can result in increasing surface roughness, which can be responsible for bacterial colonization and stain accumulation (18). A previous study has indicated that the variations in pH altered the surface characteristics of the restorative materials (19) and these materials may be more prone to brushing abrasion at lower pH values (20).

In clinical situations, there is always a dynamic process between demineralization and remineralization in the oral cavity (21). Many previous studies have used a pH-cycling regime that simulate *in vitro* the chemical degradation that occurs as a result of frequent sugar consumption (18-20). This study evaluated the effect of brushing abrasion, in association with low pH on the surface roughness of three different high-viscosity bulk-fill composites as well as one conventional microhybrid and one flowable composite. The null hypothesis was that there would be no difference between the surface roughness of the tested composites subjected to simulated dynamic pH-cycling prior to the toothbrushing test.

2. METHODS

2.1. Specimen preparation

The composition and manufacturer of the restorative materials used in the present study are listed in Table 1.

Table 1. *The compositions and the manufacturer details of the tested composite resins*

Code	Material	Type	Filler content (wt.% / vol.%)	Filler size (µm)	Manufacturer & Lot no.
GF	G-ænial Universal Flo	nanohybrid	SiO_2, strontium glass 69/50	0.01-0.2	GC Corporation, Tokyo, Japan 1804053
Z250	Filtek Z250 Universal Restorative	microhybrid	zirconium/ silica 82/60	0.01-3.5 avg. 0.6µm	3M ESPE, St Paul, MN, USA N885546
FBF	Filtek Bulk Fill Posterior Restorative	nanofilled	silica, zirconia, YbF_3 76.5/58.4	0.02 silica, 0.004-0.011 zirconia 0.1 YbF_3	3M ESPE, St Paul, MN, USA N938940
XF	X-tra fil	microhybrid	Ba-B-Al-Si glass 86/70.1	0.05-10	VOCO, Cuxhaven, Germany 1447376
SF	SonicFill 2	nanohybrid	ZrO_2, SiO_2 82/68.5	-	Kerr, Orange, CA, USA 6385712

SiO_2, Silicon dioxide; YbF_3, Ytterbium trifluoride.
ZrO_2 : Zirconium dioxide

A teflon mold was used to create 10 disc-shaped specimens (8 x 2mm) from 5 different resin composites for a total of 50 specimens. Specimen surfaces were covered with Mylar strips and a glass slide, and pressure was applied to extrude excess composite. Samples were polymerized with a LED light-curing unit at 1200 mW/cm^2 for 20 s (Elipar S10, 3M ESPE, St Paul, MN, USA), which was periodically monitored with a radiometer (LED radiometer, SDI, Australia). All samples were marked on the bottom surface with an identification number and stored individually in 1 ml of distilled water at 37˚C. After 24 h, the top surfaces of the specimens were ground under water cooling with abrasive silicon carbide paper (600 and 1000 grit). The polishing was performed with one-step diamond micro-polisher cups (PoGo, Dentsply, DeTrey, Konstanz, Germany) with light intermittent pressure for 15 s using a slow-speed handpiece rotating at a maximum of 12,000 rpm to prevent heat and grooves build-up. Samples were cleaned ultrasonically for 10 min and stored in 100% humidity until pH-cycling. All procedures were performed by a single operator.

2.2. Surface roughness measurements

The surface roughness of composite specimens was measured with a surface profilometer (Surfcorder SE 1700, Kosaka Corp, Tokyo, Japan) after polishing (baseline), pH-cycling and toothbrushing test. Measurements were obtained from the top surface of each specimen using a tip with a 2-µm diameter, length of 1.25 mm, a speed of 0.1 mm/s and cutoff of 0.25 mm. Three sequential measurements were taken from each specimen, and the average of the three measurements was

recorded as the Ra value (µm) for that specimen. "Ra_0" was used to define the baseline measurements.

2.3. pH-cycling test

First, samples were stored in 5 ml of a pH 4.3 demineralization solution comprised of 2.0 mM calcium and 2.0 mM phosphate in a buffer solution of 74.0 mM acetate. After 6 h storage at 37˚C, samples were then rinsed with distilled water and immersed for 18 h in a pH 7.0 remineralization solution (5 ml) comprised of 1.5 mM calcium and 0.9 mM phosphate and 150 mM potassium chloride in a buffer solution of 20 mM Tris (hydroxymethyl-aminomethane) at 37˚C (20). The pH-cycling regime was repeated 10 times, with solutions changed daily. All specimens were therefore submitted to surface roughness measurements (Ra_1), as described above.

2.4. Simulation of toothbrushing

Following pH-cycling, samples were subjected to mechanical brushing using a custom-built brushing device. Five electric rechargeable toothbrushes (Vitality Precision Clean, Oral-B Braun GmbH) were screwed to the brushing apparatus (Figure 1). Sample discs were secured in silicon molds and placed under the brush heads to ensure contact between samples and toothbrush bristles. The toothbrushes were operated with a constant load of 200 g, a typical load used in other brushing studies (11,17,22-24), which was measured by a precision scale attached to the machine. Samples were brushed in circular movements for 4 min, with 2 ml of distilled water applied to each sample at 30-s intervals. This was determined to simulate approximately 6 months of brushing based on the mean brushing time per tooth surface corresponding to 2 seconds per day, as indicated in their study using electric brushes by Jasse *et al*. (25). Following brushing, samples were rinsed with deionized water and sonicated in deionized water for 10 min. The final Ra_2 values were measured as described previously.

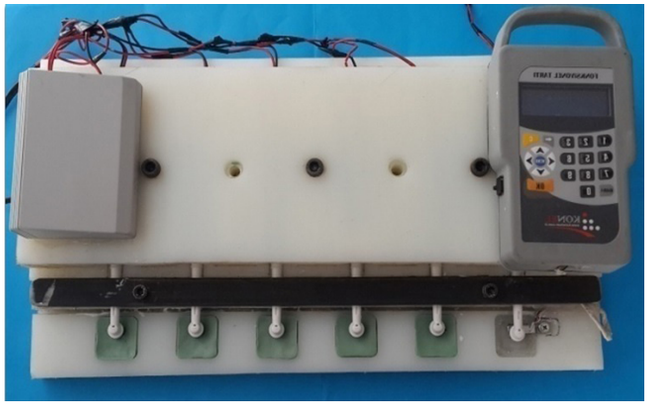

Figure 1. *The custom-built brushing unit used in the study.*

2.5. Three-dimensional (3D) surface images

3D profiling was performed on a randomly selected sample from each composite group with the help of the 3D non-contact optical-profilometer (Contour GT-K, Bruker, Tucson, AZ, USA) after polishing (baseline), pH-cycling and toothbrushing test (Figure 2-6). Scanning was performed using an objective of 5x (in order to include as much of the specimen area as possible in roughness calculations), a scanning zone of 150µm (height) x 3mm (length), and a speed of 40µm/sec.

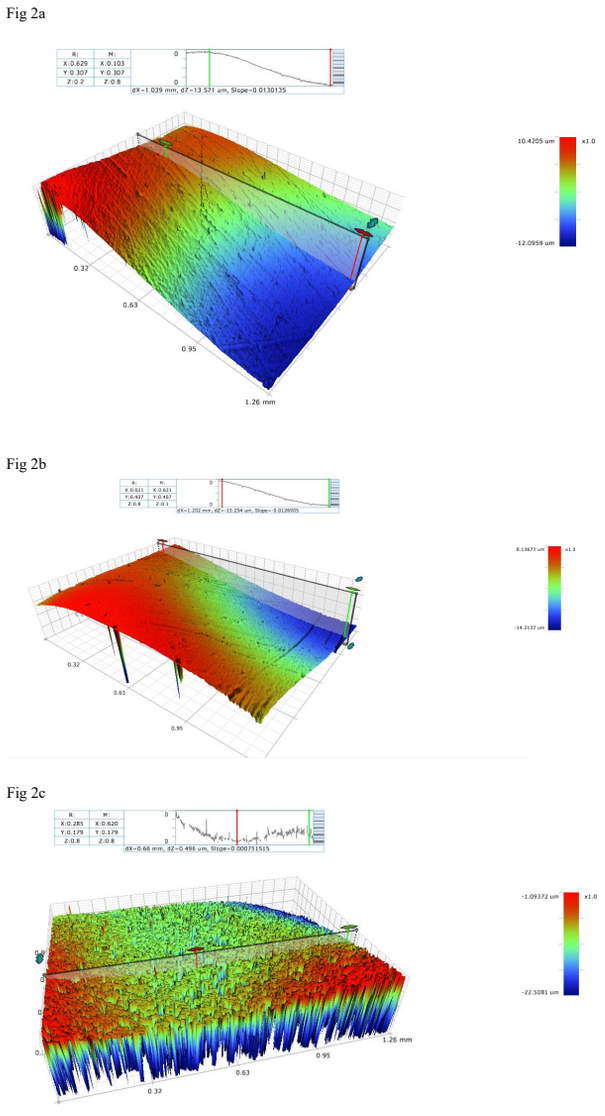

Figure 2. *3D surface images of the specimen in group GF: (a) at baseline; (b) after pH-cycling; (c) after toothbrushing.*

2.6. Statistical analysis

The SPSS 19.0 statistical package program (SPSS Inc., Chicago, IL, USA) was used for the analyses. The recorded data was evaluated for normality of distribution and equality of variance. After this, a two-way ANOVA with repeated measures on one factor (experimental period) was used to analyze the differences in surface roughness values of composite groups. Multiple comparisons were performed using Tukey's HSD test. A level of 0.05 was considered statistically significant.

3. RESULTS

Surface roughness values (Ra) for each material at all experimental periods (baseline, after pH cycling, and after simulated brushing) are given in Table 2.

Table 2. *Mean surface roughness values (µm) and standard deviations (±sd) at baseline (Ra_0), after pH-cycling regime (Ra_1) and after toothbrushing test (Ra_2)*

Group	Ra_0	Ra_1	Ra_2	Average
GF	0.06 (±0.03)	0.07 (±0.02)	0.1 (±0.04)	0.08 (±0.03)^C
Z250	0.09 (±0.03)	0.1 (±0.04)	0.13 (±0.09)	0.11 (±0.06)^C
FBF	0.22 (±0.09)	0.2 (±0.09)	0.21 (±0.1)	0.21 (±0.09)^B
XF	0.25 (±0.05)	0.32 (±0.13)	0.36 (±0.19)	0.31 (±0.14)^A
SF	0.35 (±0.05)	0.34 (±0.06)	0.37 (±0.08)	0.35 (±0.07)^A

n=10; (p<0.05)

Different capital letters indicate statistically significant differences in the columns.

Fig 3a

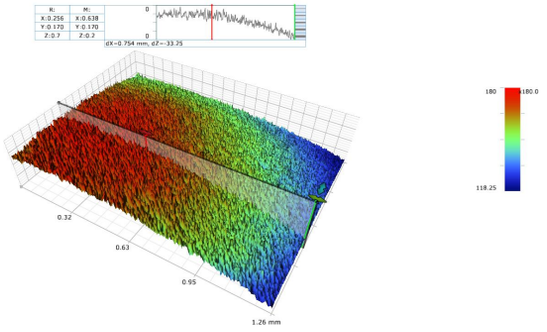

Fig 3b

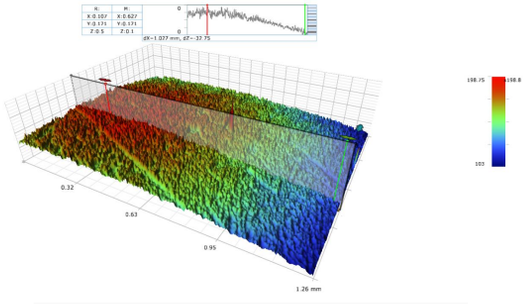

Fig 3c

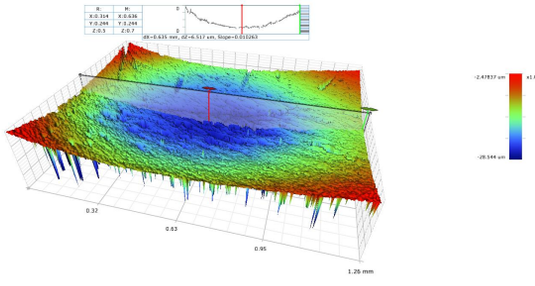

Figure 3. *3D surface images of the specimen in group Z250: (a) at baseline; (b) after pH-cycling; (c) after toothbrushing.*

The two-way ANOVA with repeated measures on one factor (period) revealed a significant effect of the main factor: "restorative materials" (p<0.001). The other main factor, "experimental period" (p=0.064) and the interaction between "restorative materials" * "experimental period" (p=0.650) were not significant.

There were statistically significant differences among the restorative materials regardless of the experimental periods. Tukey's HSD test showed that there was no significant difference between group SF and XF (p>0.05), but both materials had significantly higher surface roughness values than all other groups (p<0.05). Although group FBF exhibited significantly lower surface roughness values than SF and XF groups, this value was significantly higher than Z250 and GF groups (p<0.05). There was no statistically significant difference between GF and Z250 groups with the lowest roughness values (p>0.05).

Apart from the FBF group, the roughness values of all composites tested showed an increase following toothbrushing test (Ra_2) compared to their baseline values (Ra_0); however, none of these increases was statistically significant (p>0.05).

Fig 4a

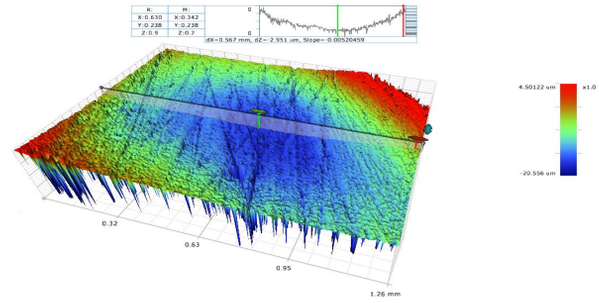

Fig 4b

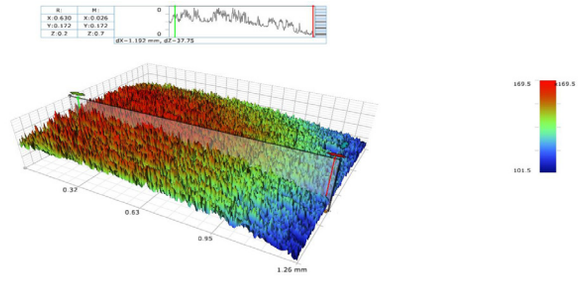

Fig 4c

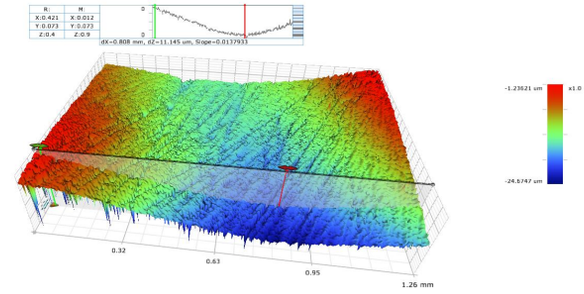

Figure 4. *3D surface images of the specimen in group FBF: (a) at baseline; (b) after pH-cycling; (c) after toothbrushing.*

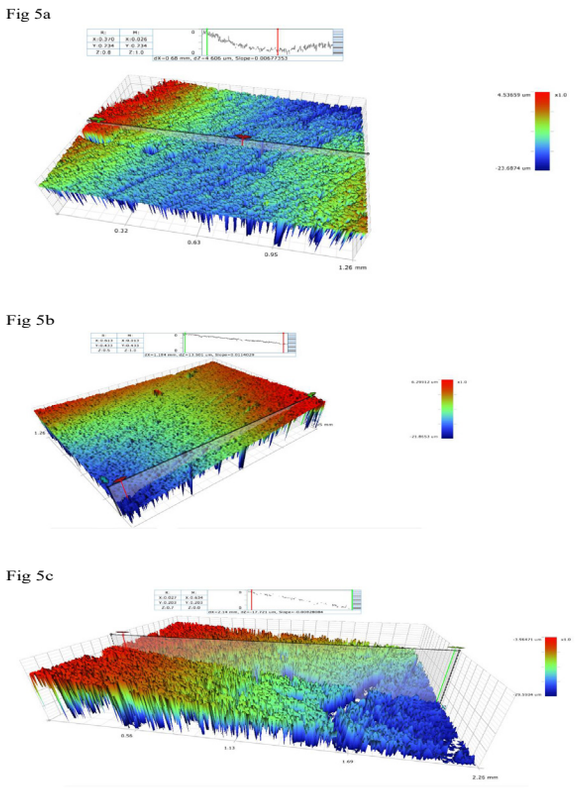

Figure 5. *3D surface images of the specimen in group XF: (a) at baseline; (b) after pH-cycling; (c) after toothbrushing.*

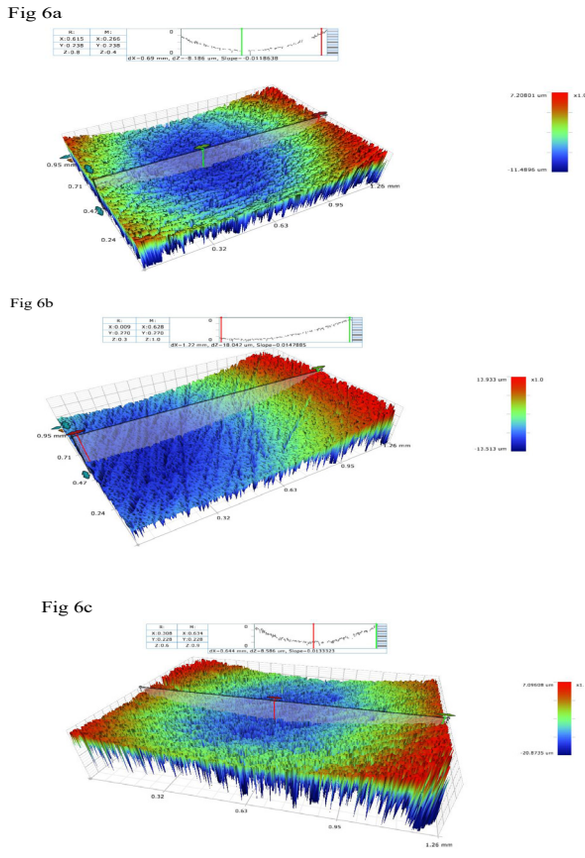

Figure 6. *3D surface images of the specimen in group SF: (a) at baseline; (b) after pH-cycling; (c) after toothbrushing.*

Figure 2-6 shows the 3D optical images of the tested composite materials, at baseline, after pH-cycling and after toothbrushing test. At baseline, images of all the materials displayed largely smooth surfaces with just a few small porosities from grinding. Images of all the tested composites after pH-cycling were similar to the baseline images with the exception of group XF, which clearly exhibited surface damage. After toothbrushing simulation, while groups GF, Z250 and XF exhibited their roughest patterns (Figure 2c, 3c, 5c), other two composites (FBF, SF) did not show any significant change in their images (Figure 4c, 6c). Following toothbrushing test, the surface image of the XF specimen (Figure 5c) appeared to be the roughest of all the specimens tested.

4. DISCUSSION

The null hypothesis was rejected because the surface roughness values and surface patterns showed variations among the tested composite materials, regardless of pH-cycling and toothbrushing tests.

In the oral environment, composite materials may be intermittently or continuously exposed to chemicals present in saliva, food and beverages. While intermittent exposure occurs during eating or drinking and continues until teeth are cleaned, bacterial decomposition of adherent debris may result in continuous exposure (14). The disintegration of the resin composite structure is mainly caused by hydrolytic degradation accelerated by low pH, thereby adversely affecting the abrasion resistance of the materials (26). The *in vivo* behavior of acid-exposed restorative materials can be assessed *in vitro* through the dynamic process of pH-cycling. First proposed in 1986 by Featherstone *et al*. (27), the procedure involves demineralization/remineralization cycles simulated by immersing enamel samples in acidic and supersaturated buffer solutions, respectively. A 2007 study by Silva *et al*. (19) confirmed that the surface properties of restorative materials were influenced by pH variations in pH-cycling. Therefore, this study used dynamic pH-cycling with a pH 4.3 demineralization solution (10 d) to simulate severe acid exposure.

In order to simulate *in vitro* mechanical degradation caused by oral-hygiene procedures, this study used a custom-built toothbrushing device. Mechanical brushing is a convenient way to simulate regular oral hygiene procedures that provides standardization of the amount, distance, and frequency of force applied to specimens by brushing (28,29). The present study simulated approximately 6 months of brushing based on the mean brushing time which corresponds to 2 s per day per tooth surface (25). Moreover, considering that in clinical situations, brushing may be performed following exposure to a chemical agent, this study subjected specimens to toothbrushing test following pH-cycling simulation. In this way, it was also aimed to evaluate their longevity in the oral environment instead of comparing only the performances of different materials.

Mechanical profilometry, which is the most common method used to assess the surface roughness of composite materials, is an easily applied, widely available and relatively inexpensive procedure, but it is restricted by the spatial dimension of the stylus, force of measurement, rate of sampling and z-axis calibration (30). In this study, a non-contact optical profilometer in addition to mechanical profilometer was used to better record the characteristic 3-D nature of resin composite surface topography (31,32).

This study investigated the surface roughness of 3 different high-viscosity bulk-fill composites (FBF, SF and XF) by comparing with conventional microhybrid and flowable resin composites. In the initial roughness measurements, different polishing results were obtained according to the type of resin composite employed despite the same polishing process. While a surface roughness value of 0.28 µm has been reported to be detectable by the human tongue (33), a value of 0.2 µm is considered the critical threshold for bacterial retention (34). In the present study, only GF and Z250 had values below this critical threshold at baseline and in both experimental periods. The final surface quality of resin composites after polishing has been shown to be affected by the size, shape, hardness and amount of filler particles (35,36) In common, a positive correlation is expected between filler size and surface roughness. This pattern is consistent with the results of this study, as the SF and XF, which have a heterogeneous distribution in filler size with large particles (>20 µm) (3), presented the roughest surfaces. This finding may also result from the possibility that the glass particles used as inorganic fillers being harder than the abrasive particles in the polishing system. As indicated by Ergücü and Türkün (35), when the filler particles are harder, the organic matrix is first worn away, filler particles remain protrusive on the surface, and then the roughness increases. In this study, the cups in the Pogo polishing system may be unable to flatten the glass filler particles, thereby resulting in rough surfaces (36). Barkmeier *et al*. (37) have also noted that for SonicFill, Scanning Electron Micrographs after the process of wear simulation showed a surface containing fractured large glass filler particles and voids resulting from plucking out of these particles.

The XF was the only composite group that showed a relatively high increase in roughness values after pH-cycling. Furthermore, its surface texture was significantly affected by both pH-cycling (Figure 5b) and simulated toothbrushing (Figure 5c). Likewise, another surface roughness study demonstrated that X-tra fil had the worst performance at baseline, during and after aging simulation (4). Contrary to this result, *in situ* study of de Brito *et al*. (5) reported that X-tra fil was the only group among composite materials tested that did not exhibit a significant increase in roughness after biodegradation.

Although SF had the highest mean surface roughness value of all the composites tested, the image of SF specimen exhibited no significant alterations in surface patterns following either pH-cycling or toothbrushing test (Figure 6a-c), and the values of surface roughness showed high resistance to degradation. The SF is highly filled nanohybrid type composite resin. Due to the reduced particle dimension by nanotechnology, filler particles situated as close together may have protected the softer resin matrix of SF from abrasion (35). The GF group, another nanohybrid type composite tested, exhibited the lowest surface roughness values and smoothest optical images. These results are in agreement with some studies that reported uniformly polished surfaces after polishing, lower roughness values after toothbrushing (11) and thermocycling (4) in G-aenial Universal Flo. A new silane method used on the surface of nanoparticles to increase adhesion with the resin matrix may also be responsible for maintaining the surface properties of this material even after mechanical and chemical degradation (38). There was no statistically significant difference between GF and the microhybrid composite in the control group. Unlike roughness values, which did not show a significant increase, the optical profilometry images of GF (Figure 2c) and Z250 (Figure 3c) exhibited numerous surface irregularities after toothbrushing simulation. Similarly, Somacal *et al.* (23) have reported that simulated toothbrushing after the pH cycling caused changes in SEM images of composite surfaces, but these changes did not result in a significant increase in roughness values of most of the composite resins tested.

Filtek Bulk Fill Posterior is described by its manufacturer as a nanofilled composite containing nanoclusters and individual silica (0.02 µm) and zirconia (0.004-0.011 µm) nanoparticles (39). This resin group (FBF), which has a more homogeneous filler distribution with small particle size, showed significantly less surface roughness values than the other bulk-fill composites. In previous studies, smaller-particle fillers have been reported to exhibit a lower increase in surface roughness after polishing procedures (40) and brushing simulation tests (20,28). It has also been stated that loosely bound nano-sized particles tend to abrade away rather than the larger nanocluster fillers being plucked from the resin matrix (8,24,35). In line with this assertion, the high resistance to degradation of FBF, shown by the roughness values and surface patterns (Figure 4a-c) obtained in the present study, may be attributed to the nano-sized inorganic filler content. A study examining the SEM images of surface texture of bulk-fill composites also reported that Filtek Bulk Fill Posterior surfaces had slight erosion, while SonicFill and X-tra fil showed deeper surface erosion following aging (4). Another study supported that with AFM and SEM images, each nano-layer or nano-cluster wore away, resulting in a similar nano-layered surface, since there are no large particles to protrude or be plucked out of the resin layer (8).

Unlike previous studies researching the surface roughness of resin composites after toothbrushing, none of the composite groups were significantly affected by the experimental periods in this study. The cleaning effect of dentifrices is mainly supported by abrasive particles (41). Brushing simulation without dentifrice was preferred herein to eliminate the abrasive effect of dentifrice on the surface properties of resin composites. Thus, the use of distilled water in this study may have caused less changes in surface roughness than other

studies that simulate brushing with dentifrices (7,28,42). As another limitation, it can be stated that the specimens were prepared in the form of a disc, but the restoration shapes and surfaces differ in clinical conditions. In further studies, it would be useful to investigate the abrasive effect of brushing with different toothpastes, considering the distance and direction of the brush to the different surfaces of the restoration.

5. CONCLUSION

The toothbrushing performed immediately after chemical exposure increased the surface roughness of most composite materials, even though not statistically significant. Although nanohybrid bulk-fill showed the highest roughness value, it was the most stable group with nanofilled bulk-fill after pH-cycling and toothbrushing simulations.

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Clinical and Experimental Health Sciences

The Relationship Between University Students' Nutritional Status, Cardio-Metabolic Biomarkers and Physical Activity Levels

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ABSTRACT

Objective: This study aimed to evaluate the relationship between nutritional status, cardiometabolic biomarkers and physical activity levels in university students.

Methods: Firstly, fasting plasma total cholesterol, triglyceride, high-density lipoprotein cholesterol (HDL-C) levels were analyzed from participants' blood samples, and the homeostatic model assessment of insulin resistance (HOMA-IR) values were calculated after measuring fasting plasma glucose and insulin. Participants' weight, height, percentage of body fat, waist and hip circumference were measured and body mass index (BMI) was calculated. The International Physical Activity Questionnaire (IPAQ)and a questionnaire on socio-demographic characteristics were applied to participants. Energy and nutrient intakes were calculated from participants'24-hour dietary recall records. The statistical analysis of data was performed with SPSS version 21 software. For statistical significance, the total type-1 error level was determined as 5%.

Results: Most of the participants' energy, dietary fibre, vitamins D and B1, folate, calcium and iron intakes were below recommended levels. HDL-C level was shown to be negatively correlated with total fat and saturated fatty acid intake ($p<0.05$). Omega-3 intakes of participants were negatively correlated with fasting plasma insulin and HOMA-IR ($p<0.05$).HDL-C was negatively correlated with BMI and waist-to-hip ratio, while fasting plasma insulin, triglyceride levels and HOMA-IR values were positively correlated with them ($p<0.05$). According to the IPAQ, it was found that 15.9% of participants had a low level of physical activity and 66.1% of them had a moderate level of physical activity.

Conclusion: It is concluded that providing nutrition education and counselling services to students, improving campus facilities for physical activity are necessary for cardiometabolic health.

Keywords: University students, nutritional status, biomarkers, exercise, health

1. INTRODUCTION

Nowadays, health-threatening and changeable behaviours such as inadequate and imbalanced nutrition, sedentary lifestyle, tobacco/smoking and excessive alcohol consumption, which are frequently observed among young people, are among the risk factors of various chronic diseases (1). It is thought that the university period is a critical period in which lifelong habits are formed and may have a permanent effect on the development of chronic diseases (2).

It is known that biomarkers including weight, body mass index (BMI), waist circumference (WC), blood pressure, lipid profile and glycemic status are used to determine cardiometabolic risk (3, 4). The homeostatic model assessment (HOMA) used in determining insulin resistance (IR) has been proven to be a safe tool (5). Assessment of body composition by various anthropometric measurements is generally used to determine the health status of the population. The data of body fat percentage (body fat%), WC, waist-to-hip ratio (WHR) are reported more sensitive than BMI, which is frequently used to determine the risks of metabolic and cardiovascular diseases (6).

Adequate and balanced nutrition can be defined as providing the right nutritional habits, the number of daily meals and menu diversity, and thus meeting the requirements for energy and nutrients for healthy development (7). Behaviours that negatively affect health, such as insufficient food intake and physical inactivity, are frequently observed in university students (8, 9). They are considered to be in the risk group of nutritional deficiency due to these unhealthy eating behaviours.It is known that a dietary model characterized by high-calorie intake due to high consumption of fat and saturated fat, sugar, alcohol and fast food and insufficient consumption of vegetables and fruits, monounsaturated fatty acids (MUFA), polyunsaturated fatty acids (PUFA) and fish is widely observed in this population. Besides, inadequate intake of dietary fibre, folate, calcium, iron and vitamin A has been reported in this population (10).

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It is predicted that unhealthy eating habits will increase the risk of obesity, metabolic and cardiovascular diseases (10, 11).It is known that inadequate and unbalanced nutrition pattern, which is common in university students, causes atherogenic dyslipidemia, endothelial dysfunction and insulin resistance, and increases the risk of coronary heart disease, inflammation and hepatic fat synthesis in the body (12). Therefore, before cardiovascular and metabolic diseases appear clinically, it is important to evaluate cardiometabolic health with biomarkers such as fasting plasma glucose, insulin, triglyceride, HDL-C and various anthropometric measurements that are affected by dietary habits (13).

Physical activity, which is a globally accepted health promotion means, constitutes an essential factor of public health policies in both developed and developing countries (14). A meta-analysis reported that a rapid decrease in the level of physical activity is observed between the university students with ages of 18-24 (8). An increased sedentary lifestyle is a risk factor for early death and various chronic diseases such as type 2 diabetes, metabolic syndrome and cardiovascular diseases, and this increase is at a higher level in university students compared to the general young population (15).

In this study, it was aimed to evaluate the relationship between university students' nutritional statuses, cardiometabolic biomarkers and physical activity levels.

2. METHODS

This cross-sectionalstudy was carried out with 422 volunteer students studying at Marmara University between January 2018 and March 2020. Approval from Marmara University Faculty of Medicine Ethics Committee and necessary permissions from faculties were obtained for the study (Protocol Number-Date: 09.2017.044 – 06.01.2017).

Participants who are well-communicated and volunteer and do not have any chronic disease, pregnancy, continuous medication, medical nutritional therapy were informed about the study and signed a voluntary consent form. In addition to a questionnaire on socio-demographic characteristics, the short form of the IPAQ was applied to the participants by face-to-face interview technique. MET (metabolic equivalent task) obtained by evaluating the IPAQ, is a physiological measure expressing the energy cost of physical activity and is defined as the ratio of metabolic rate during a specific physical activity to a reference metabolic rate(16).The total physical activity score (MET – min/week) was calculated by multiplying the intensive, moderate activity and walking times with the specified coefficients and converting to MET (metabolic equivalent). Accordingly, the physical activity level of the participants was determined (17).

The 24-hour dietary recall (24HDR) was taken from the participants by the researcher. Energy and nutrient intakes were calculated using the Nutrition Information System (BeBiS 8) program from 24HDR records. According to the recommends of the individuals with the ages of 19-30 stated in the Turkey Specific Food and Nutrition Guide (TSFNG) (18), the status of meeting the energy and nutrient requirements of the participants were determined.

In the morning, after at least 12 hours of fasting the blood samples were taken from the participants. Yellow capped plastic 5 mL BD Vacutainer®SST™gel tubes were used for blood samples to be serum separated. After the blood samplestaken into biochemistry tubes were centrifuged at 4000 rpm for 10 minutes, their serums were separated and stored in a deep freezer at – 20°C until analysis. And thenthey were taken to the clinical laboratory to be analyzed for fastingplasma total cholesterol, triglyceride, HDL cholesterol, insulin and glucose levels without breaking the cold chain.

After blood samples were taken, the body weight and body fat percentage ofthe participants were measured with the Inbody 120 device, which performs bioelectrical impedance analysis (BIA). The height measurement was with a 0.1 cm sensitive stadiometer. WC and hip circumference were measured by an experienced researcher with a non-flexible tape measure.Also, WHR (WC divided by hip), BMI (weight in kilograms divided by the square of height in metres) and HOMA-IR [(fasting plasma glucose level (mg/dL) × fasting plasma insulin level (μIU/mL)) /405] were calculated.The cut-off point of 2.5 was used to separate participants into normal or having IR (5).According to the World Health Organization (WHO), a healthy WHR should be 0.9 or less in men and 0.85 or less for women.

Statistical analysis of the datawas carried out using SPSS version 21 software. The normality of variables was analyzedusing the Kolmogorov-Smirnov test and the histogramgraph. Discrete data are stated as number (n) and percentage (%) distributions, while continuous data are expressed as median and interquartile range (IQR) values. Correlations were determined by using the Spearman test. The Pearson Chi-Square (X^2) test was used to compare qualitative variables. For statistical significance, the total type-1 error level was determined as 5%.

3. RESULTS

The general characteristics of the participants are provided in Table 1. It was shown that 86% of the participants were female, the averageage and the median BMI values were 20.6 ± 1.78 years and 21.3 kg/m^2, respectively. According to the BMI classification of the WHO, 70.1% of the participants were determinednormal and 14.1% pre-obese and obese. Students studying in the Department of Nutrition and Dietetics (ND) constitute 61.8% (n=261) of the participants and 38.2% (n=161) of those studying in other departments. First-year students constitute 41.2% (n=174) and the last year (4th, 5th and 6th grade) students constitute 13.5% (n=57) of the participants.It was observed that 15.9% of the participants had a low, 66.1% moderate, and 18% high physical activity level. The median MET-score of the participants was found 1512.0. Participants, had a family history of heart disease, made up 22.3% of the group. And, participants using

omega-3 supplements made up only 6.2% of the group. It was observed that tobacco smoking and alcohol consumption frequency was 14.7%,13.7%, respectively. Also, according to the HOMA-IR, participants who have IR were found 18% of all of them.

Table 1. *General characteristics of the participants*

	Female (n=363)		Male (n=59)		Total (n=422)	
General characteristics	**N**	**%**	**N**	**%**	**N**	**%**
Department						
Nutrition and Dietetics	**244**	**67.2**	**17**	**28.8**	**261**	**61.8**
Other departments	**119**	**32.8**	**42**	**71.2**	**161**	**38.2**
Physical activity level						
Low	**59**	**16.3**	**8**	**13.6**	**67**	**15.9**
Moderate	**248**	**68.3**	**31**	**52.5**	**279**	**66.1**
High	**56**	**15.4**	**20**	**33.9**	**76**	**18.0**
Body mass index						
Underweight	**61**	**16.8**	**5**	**8.5**	**66**	**15.7**
Normal	**259**	**71.3**	**37**	**62.7**	**296**	**70.1**
Pre-obese	**33**	**9.1**	**14**	**23.7**	**47**	**11.1**
Obese	**10**	**2.8**	**3**	**28.8**	**13**	**3.1**
Insulin resistance						
Yes	**67**	**18.5**	**9**	**15.3**	**76**	**18.0**
No	**59**	**16.3**	**8**	**13.6**	**67**	**15.9**

Discrete data are stated as number (n) and percentage (%) distributions

The anthropometric characteristics, physical activity scores and biochemical findings of participants are presented in Table 2.Findings are divided according to female and male participants.Especially the difference between physical activity scores of female and male participants is remarkable.

Table 2. *Physical activity scores, biochemical findings and anthropometric characteristics of the participants*

	Female (n=363)		Male (n=59)		Total (n=422)	
Anthropometry	**Median**	**IQR**	**Median**	**IQR**	**Median**	**IQR**
Weight (kg)	55.5	11.8	72.9	16.3	57.1	13.8
Height (cm)	163.0	8.0	176.0	8.0	164.0	10.0
BMI (kg/m^2)	21.0	4.1	23.2	5.2	21.3	4.2
Waist/hip ratio	0.80	0.1	0.85	0.1	0.80	0.1
Body fat percentage (%)	26.0	9.0	14.5	9.1	24.9	10.3
Biochemical findings						
Total cholesterol (mg/dL)	156.0	41.5	149.0	53.5	155.0	43.0
HDL-cholesterol (mg/dL)	55.0	19.0	43.0	14.5	54.0	19.0
Triglyseride (mg/dL)	69.0	30.5	75.0	51.5	70.0	32.3
Glucose (mg/dL)	83.0	15.0	85.0	16.5	83.0	15.0
Insulin (µIU/mL)	8.2	5.8	7.3	5.5	8.0	5.6
HOMA-IR	1.57	1.2	1.42	1.2	1.57	1.2
Physical activity						
MET score (MET – minutes/week)	1440.0	1513.0	2010.0	2561.0	1512.0	1568.4

Continuous data were stated as median and interquartile range (IQR) values.Abbreviations; BMI: Body mass index, HOMA-IR: Homeostatic model assessment of insulin resistance, IQR: Interquartile range, MET: Metabolic equivalent task.

Table 3. *Energy and macronutrient intakes of the participants and their meeting conditions according to the TSFNG recommendations*

	Female (n=363)			Male (n=59)				Total (n=422)		
	Median (IQR)	**Below N (%)**	**Above N (%)**	**Median (IQR)**	**Below N (%)**	**Above N (%)**	***p*-value***	**Median (IQR)**	**Below N (%)**	**Above N (%)**
Energy (kcal)	1381.0 (649.5)	202 (55.6)	3 (0.8)	1617.4 (655.0)	45 (76.3)	0 (0.0)	X^2=9.056 ***p*=0.011**	1425.7 (672.7)	247 (58.5)	3 (0.7)
Protein (g)	52.8 (29.6)	49 (13.5)	118 (32.5)	68.6 (29.5)	7 (11.9)	20 (33.9)	X^2=0.133 *p*=0.936	54.8 (30.3)	56 (13.3)	138 (32.7)
Fat (g)	66.8 (31.6)	NA	NA	74.9 (37.7)	NA	NA	-	68.0 (34.0)	NA	NA
Carbohydrate (g)	139.2 (95.9)	NA	NA	155.2 (98.4)	NA	NA	-	144.1 (95.2)	NA	NA
Fructose (g)	6.3 (9.3)	NA	NA	6.5 (10.2)	NA	NA	-	6.3 (9.3)	NA	NA
Dietary fibre (g)	15.2 (9.4)	209 (57.6)	11 (3.0)	16.4 (12.3)	34 (57.6)	2 (3.4)	X^2=0.023 *p*=0.988	15.3 (9.8)	243 (57.6)	13 (3.1)
Cholesterol (mg)	200.0 (209.4)	183 (50.4)	43 (11.8)	285.0 (309.4)	22 (37.3)	19 (32.2)	X^2=16.839 ***p*=0.000**	208.8 (1011.9)	205 (48.6)	62 (14.7)
Saturated fatty acids (g)	21.0 (13.4)	NA	NA	20.6 (11.7)	NA	NA	-	20.9 (12.9)	NA	NA
n-3 (g)	1.3 (1.1)	64 (17.6)	146 (40.2)	1.2 (1.2)	19 (32.2)	11 (18.6)	X^2=12.407 ***p*=0.002**	1.3 (1.1)	83 (19.7)	157 (37.2)
n-6 (g)	15.6 (10.6)	58 (16.0)	174 (47.9)	18.1 (14.9)	15 (25.4)	22 (37.3)	X^2=3.876 *p*=0.144	16.0 (11.0)	73 (17.3)	196 (46.4)
n-9 (g)	22.5 (12.7)	NA	NA	21.5 (8.6)	NA	NA	-	22.2 (12.3)	NA	NA

** p-value for Pearson chi-square. Pearson's chi-square test was applied for the statistical significance of the difference between women and men who meet nutrient recommendations or not (above/below the recommendations). Abbreviations: IQR: Interquartile range, NA: none available. This abbreviation was used for data not in the TSFNG. "Below (%) and Above (%)" is used to indicate the percentage of respondents who are below and above recommendations.*

Table 4. *Micronutrient intakes of the participants and their meeting conditions according to the TSFNG recommendations*

	Female (n=363)			Male (n=59)				Total (n=422)		
	Median (IQR)	Below N (%)	Above N (%)	Median (IQR)	Below N (%)	Above N (%)	*p*-value*	Median (IQR)	Below N (%)	Above N (%)
Vitamin A (mcg)	638.2 (566.7)	110 (30.3)	101 (27.8)	756.6 (910.0)	19 (32.2)	18 (30.5)	X^2=0.448 *p*=0.799	650.9 (598.8)	129 (30.6)	119 (28.2)
Vitamin D (mcg)	1.2 (1.8)	356 (98.1)	6 (1.7)	0.5 (1.9)	58 (98.3)	0 (0.0)	X^2=3.133 *p*=0.209	1.0 (1.8)	414 (98.1)	6 (1.4)
Vitamin E (mg)	16.9 (10.4)	75 (20.7)	113 (31.1)	19.9 (13.5)	9 (15.3)	29 (49.2)	X^2=7.384 ***p*=0.025**	17.2 (11.0)	84 (19.9)	142 (33.6)
Vitamin K (mcg)	264.2 (197.6)	7 (1.9)	326 (89.8)	262.2 (180.9)	2 (3.4)	48 (81.4)	X^2=3.600 *p*=0.165	263.6 (196.1)	9 (2.1)	374 (88.6)
Vitamin B_1 (mg)	0.6 (0.3)	265 (73.0)	3 (0.8)	0.7 (0.4)	36 (61.0)	1 (1.7)	X^2=3.688 *p*=0.158	0.6 (0.3)	301 (71.3)	4 (0.9)
Vitamin B_2 (mg)	1.0 (0.5)	59 (16.3)	74 (20.4)	1.1 (0.7)	13 (22.0)	10 (16.9)	X^2=1.339 *p*=0.512	1.0 (0.5)	72 (17.1)	84 (19.9)
Vitamin B_6 (mg)	1.0 (0.5)	143 (39.4)	18 (5.0)	1.1 (0.6)	15 (25.4)	4 (6.8)	X^2=4.275 *p*=0.118	1.0 (0.5)	158 (37.4)	22 (5.2)
Vitamin B_{12} (mcg)	3.1 (2.7)	90 (24.8)	169 (46.6)	3.5 (2.4)	10 (16.9)	34 (57.6)	X^2=2.798 *p*=0.247	3.1 (2.7)	100 (23.7)	203 (48.1)
Vitamin C (mg)	61.2 (53.1)	178 (49.0)	47 (12.9)	62.6 (60.0)	29 (49.2)	8 (13.6)	X^2=0.022 *p*=0.989	61.2 (55.2)	207 (49.1)	55 (13.0)
Folate (mcg)	190.0 (100.5)	292 (80.4)	1 (0.3)	223.2 (133.1)	38 (64.4)	2 (3.4)	X^2=12.609 ***p*=0.002**	193.1 (104.1)	330 (78.2)	3 (0.7)
Sodium (mg)	3241.0 (1803.5)	33 (9.1)	184 (50.7)	3947.8 (2595.7)	6 (10.2)	37 (62.7)	X^2=3.734 *p*=0.155	3296.2 (1946.5)	39 (9.2)	221 (52.4)
Potassium (mg)	1707.0 (863.8)	NA	NA	1928.1 (854.6)	NA	NA	-	1735.1 (864.3)	NA	NA
Calsium (mg)	560.1 (335.3)	239 (65.8)	3 (0.8)	532.5 (406.4)	39 (66.1)	0 (0.0)	X^2=0.493 *p*=0.782	559.5 (343.8)	278 (65.9)	3 (0.7)
Magnesium (mg)	217.8 (108.6)	162 (44.6)	10 (2.8)	242.6 (114.3)	32 (54.2)	3 (5.1)	X^2=3.334 *p*=0.189	221.3 (107.5)	194 (46.0)	13 (3.1)
Phosphor (mg)	903.1 (380.6)	18 (5.0)	164 (45.2)	1088.0 (479.0)	3 (5.1)	37 (62.7)	X^2=6.616 ***p*=0.037**	918.0 (410.2)	21 (5.0)	201 (47.6)
Iron (mg)	8.6 (4.2)	305 (84.0)	0 (0.0)	10.0 (4.9)	18 (30.5)	11 (18.6)	X^2=116.3 ***p*=0.000**	8.7 (4.3)	323 (76.5)	11 (2.6)
Zinc (mg)	7.5 (3.9)	144 (39.7)	12 (3.3)	9.7 (4.2)	13 (22.0)	5 (8.5)	X^2=8.951 ***p*=0.011**	7.7 (4.1)	157 (37.2)	17 (4.0)

** p-value for Pearson chi-square. Pearson's chi-square test was applied for the statistical significance of the difference between women and men who meet nutrient recommendations or not (above/below the recommendations). Abbreviations: IQR: Interquartile range, NA: none available. This abbreviation was used for data not in the TSFNG. "Below (%) and Above (%)" is used to indicate the percentage of respondents who are below and above recommendations.*

The median values of protein, fat and carbohydrate percentages of all participants are as follows; 16.0%, 42.0% and 43.0%. While these values for women were 16.0%, 42.0% and 43.0%, respectively; It was found to be 17.0%, 40.0% and 41.0% in males.Energy, macro-and micronutrient intakes of the participants are given in Tables 3 and 4. Accordingly, the energy intake of 54.5% of the participants was below TSFNG. Besides, 32.7% of the participants had high intakes of protein, and 13.3% low the recommended. The protein intakes of male participants were higher than female (p<0.05). The median percentage contribution of calories from protein, carbohydrate, and fat, were 16.0%, 43.0% and 42.0%, respectively. Cholesterol intakes were higher in men than in women (p<0.05). According to micronutrients, women's intakes of vitamins E and B6, folic acid, sodium, phosphorus, iron and zinc were less than men (p<0.05). Folic acid intake of 80.4% of women was found below the recommended one. It was determined that 52.4% of all participants had high sodium intake.

In Table 5, HDL-C was shown negatively correlated with BMI and WHR (p<0.05). On the other hand, fasting plasma insulin level and HOMA-IR have a positive correlation with BMI, WHR and body fat% (p<0.05). Triglyceride levels were positively correlated with weight, BMI and WHR (p<0.05). There was no significant relationship between physical activity levels and biochemical findings (p>0.05). In Table 5, the HDL-C level has a negative correlation with total fatty acid and saturated fatty acid (SFA) intake (p<0.05). Omega-3 intakes of the participants were negatively correlated with fasting plasma insulin and HOMA-IR (p<0.05).

Table 5. *Relationship between biochemical findings and anthropometric measurements, physical activity scores, energy and nutrient intake of the participants*

	Total cholesterol		HDL cholesterol		Glucose		Insulin		Triglyseride		HOMA-IR	
Anthropometry	r	*p*	r	*p*	r	*p*	r	*p*	r	*p*	r	*p*
Weight (kg)	.024	0.624	-.295	**0.001**	-.070	0.152	.134	**0.006**	.137	**0.005**	.156	**0.001**
BMI (kg/m^2)	.055	0.256	-.227	**0.001**	-.072	0.138	.123	**0.012**	.148	**0.002**	.171	**0.01**
Waist/hip ratio	.076	0.122	-.165	**0.001**	-.067	0.169	.231	**0.001**	.177	**0.001**	.229	**0.01**
Body fat percentage (%)	.086	0.079	-.005	0.915	-.096	0.050	.199	**0.001**	.013	0.797	.162	**0.001**
Physical activity												
MET score (MET – minutes/week)	.016	0.739	-.083	0.090	.036	0.465	-.072	0.142	.027	0.582	.011	0.819
Energy, macro ve micro nutrients												
Energy (kcal)	-.012	0.805	-.050	0.301	.030	0.545	-.054	0.265	.036	0.465	.031	0.532
Protein (g)	-.065	0.183	-.099	**0.042**	-.056	0.250	-.078	0.111	-.040	0.411	-.044	0.367
Protein (%)	-.077	0.112	-.062	0.205	-.120	**0.014**	-.039	0.421	-.129	**0.008**	-.125	0.010
Fat (g)	-.069	0.156	-.097	**0.046**	-.026	0.591	-.014	0.770	-.009	0.847	-.003	0.944
Fat (%)	-.052	0.290	.019	0.695	-.044	0.366	.057	0.239	-.117	**0.017**	-.093	0.056
Carbohydrate (g)	-.003	0.955	-.059	0.225	.048	0.325	-.033	0.501	.095	0.052	.088	0.070
Carbohydrate (%)	.067	0.168	.016	0.749	.077	0.112	-.028	0.563	.141	**0.004**	.128	**0.009**
Fructose (g)	-.004	0.928	-.065	0.184	.086	0.079	.080	0.100	.007	0.891	.031	0.529
Dietary fibre (g)	-.083	0.090	-.124	**0.011**	.029	0.553	-.039	0.429	-.006	0.904	-.025	0.613
Cholesterol (mg)	.017	0.727	-.025	0.613	-.070	0.151	-.023	0.640	-.186	**0.000**	-.168	**0.001**
Saturated fatty acids (g)	-.080	0.100	-.116	**0.017**	-.059	0.227	.001	0.985	-.081	0.095	-.074	0.131
n-3 (g)	-.017	0.733	-.028	0.561	-.087	0.075	-.022	0.657	-.147	**0.002**	-.136	**0.005**
n-6 (g)	.068	0.160	.027	0.579	.033	0.500	.061	0.213	.050	0.310	.061	0.211
n-9 (g)	-.030	0.539	-.024	0.627	-.026	0.600	-.013	0.796	-.074	0.131	-.061	0.210
Vitamin A (mcg)	-.049	0.315	-.107	**0.028**	-.027	0.581	-.026	0.599	-.158	**0.001**	-.166	**0.001**
Vitamin D (mcg)	.006	0.903	.029	0.547	-.019	0.692	-.036	0.467	-.088	0.072	-.085	0.081
Vitamin E (mg)	-.052	0.285	-.124	**0.011**	.029	0.546	-.018	0.713	.080	0.231	.051	0.298
Vitamin K (mcg)	-.011	0.815	-.018	0.712	-.022	0.657	.035	0.474	-.054	0.269	-.051	0.300
Vitamin B_1 (mg)	-.139	**0.004**	-.153	**0.002**	-.050	0.302	-.051	0.293	-.030	0.537	-.051	0.298
Vitamin B_2 (mg)	-.044	0.367	-.030	0.541	-.020	0.683	.003	0.953	-.104	**0.033**	-.096	0.050
Vitamin B_6 (mg)	-.133	**0.006**	-.108	**0.026**	-.044	0.363	-.031	0.520	-.013	0.794	-.029	0.546
Vitamin B_{12} (mcg)	-.051	0.295	-.145	**0.003**	.022	0.651	-.*43	0.378	-.036	0.461	-.043	0.378
Vitamin C (mg)	-.001	0.983	-.009	0.856	.024	0.630	.045	0.359	-.092	0.059	-.084	0.084
Folate (mcg)	-.098	**0.044**	-.112	**0.022**	-.044	0.368	-.037	0.453	-.121	**0.013**	-.131	**0.007**
Sodium (mg)	-.025	0.607	-.054	0.273	.042	0.393	-.010	0.840	.026	0.598	.030	0.545
Potassium (mg)	-.109	**0.025**	-.114	**0.019**	-.015	0.765	-.038	0.438	-.027	0.574	-.047	0.337
Calsium (mg)	-.011	0.820	.021	0.664	.027	0.579	.021	0.671	-.039	0.422	-.032	0.512
Magnesium (mg)	-.117	**0.016**	-.145	**0.003**	.016	0.748	-.013	0.791	.011	0.829	-.004	0.936
Phosphor (mg)	-.076	0.121	-.102	**0.036**	-.025	0.613	-.031	0.531	-.047	0.335	-.054	0.268
Iron (mg)	-.095	0.051	-.165	**0.001**	-.001	0.982	-.064	0.187	-.038	0.438	-.054	0.267
Zinc (mg)	-.054	0.266	-.137	**0.005**	.011	0.828	-.044	0.366	-.041	0.402	-.043	0.383

Spearmen correlation test. Abbreviations; BMI: Body mass index, HOMA-IR: Homeostatic model assessment of insulin resistance, MET: Metabolic equivalent task.

Table 6. *Relationship between anthropometric measurements of the participants and their energy, macro and micronutrient intakes*

	Body weight		Body mass index		Waist-to-hip ratio	
	r	*p*	r	*p*	r	*p*
Energy (kcal)	.003	.945	-.064	.188	-.056	.255
Protein (g)	.076	.121	.024	.624	.047	.336
Protein (%)	.112	**.021**	.118	**.015**	.104	**.032**
Fat (g)	.022	.654	-.023	.637	-.018	.708
Fat (%)	.068	.161	.130	**.008**	.021	.672
Carbohydrate (g)	-.074	.130	-.156	**.001**	-.067	.169
Carbohydrate (%)	-.096	**.049**	-.155	**.001**	-.068	.166
Fructose (g)	.000	.992	.005	.917	-.010	.831
Dietary fibre (g)	-.042	.387	-.094	.054	-.153	**.002**
Cholesterol (mg)	.105	**.032**	.085	.080	.037	.450
Saturated fatty acids (g)	.036	.463	-.019	.698	-.046	.351
n-3 (g)	.000	.989	-.021	.671	-.055	.262
n-6 (g)	-.002	.973	-.040	.408	.080	.102
n-9 (g)	.005	.920	-.060	.217	-.026	.592
Vitamin A (mcg)	.080	.099	.070	.150	-.071	.144
Vitamin D (mcg)	-.053	.278	-.044	.366	-.146	**.003**
Vitamin E (mg)	.009	.849	-.039	.427	.033	.500
Vitamin K (mcg)	-.059	.225	-.059	.230	-.096	**.048**
Vitamin B_1 (mg)	.027	.580	-.039	.426	-.052	.289
Vitamin B_2 (mg)	.044	.364	.003	.953	-.041	.398
Vitamin B_6 (mg)	-.007	.880	-.057	.246	-.048	.322
Vitamin B_{12} (mcg)	.047	.335	.061	.213	.020	.675
Vitamin C (mg)	.003	.951	.021	.666	-.046	.351
Folate (mcg)	.021	.660	-.005	.914	-.104	**.033**
Sodium (mg)	.054	.267	.040	.410	.025	.612
Potassium (mg)	-.015	.754	-.042	.384	-.056	.255
Calsium (mg)	.019	.695	.011	.829	-.027	.587
Magnesium (mg)	.008	.864	-.040	.414	-.101	**.038**
Phosphor (mg)	.042	.393	-.014	.781	-.030	.539
Iron (mg)	.052	.282	-.017	.728	-.053	.275
Zinc (mg)	.076	.120	.005	.911	.026	.588

Spearmen correlation test.

4. DISCUSSION

Various cardiometabolic risk factors such as obesity, increased BMI and high fasting plasma glucose levels constitute the early onset of chronic conditions in adulthood. So proper diet and adequate physical activity are of great importance in young adulthood (19). In this study, the biochemical findings, food consumptions, physical activity levels and anthropometric properties of university students were evaluated.

The fact that the majority of the participants (70.1%) were within the normal BMI range, according to WHO classifications, is similar to a study conducted with university students (10). However, in some studies, it was shown that the frequency of normal BMI is higher than in this study (20, 21, 22).In this study, the frequency of underweight women was higher than men, while the frequency of pre-obese and obese individuals was found to be lower in female participants. Similarly, in a study in Spain, it was reported that the higher frequency of underweight, because of the recent increase in eating disorders and restrictive food intake behaviour in women (10).

In this study, body fat% was found to be 26.1% in women and 16.1% men. In two studies with students studying on health, in one of them, the body fat% in women (24.1%) was found to be similar to this study (10), while it was observed to be lower (21.9%) in the other one. Unlike this study, a study with university students in Turkey reported that the average body fat% in women was 30% (23). The WHR of both men and women were higher than in various studies (23,24, 25, 26). In a study conducted with 968 participants in Brazil, a similar WHR was reported in men as in this study (27).

The frequency of women with a high level of physical activity was found to be lower than menin this study. Similarly, a study with 704 participants reported that 21.6% of women had a high activity level, while this frequency was 40.0% for men (28). It was determined that physical activity levels of studies with young adults using different physical activity measurement tools differ with this study (21,22, 29).

Anthropometric measurement results were found to be positively correlated with triglyceride and fasting plasma insulin levels while negatively with HDL-C levels. Similarly, Arizaga et al. (2018) found that BMI and body fat% were positively correlated with triglyceride levels (25). Likewise, in a study in Turkey showed that there is a significant relationship between BMI and triglyceride levels (23).In a study conducted to determine cardiovascular risk factors in students, it was reported that BMI and WHR were positively correlated with HDL-C, triglyceride and fasting plasma insulin levels (27). Similarly, a study showed that BMI was negatively correlated with HDL-C level and positively correlated with triglyceride, total cholesterol levels (30).

Although the frequency of IR, determined according to HOMA-IR, appears to be higher in women than men, it was observed that the difference was not significant. Similarly, a study reported that although the HOMA-IR value was higher in women, the difference was not significant (27). This study showed that there is a significant relationship between HOMA-IR level and anthropometric measurements. Similarly, de Carvalho et al. (2015) showed a positive relationship between HOMA-IR value and BMI, WHR in women, while a significant relationship was found withonly WHR in men (27).

It was determined that more than half of the participants' energy intake was below the recommendation when the food consumption was evaluated. Therefore, it was observed similarity with Turkey Nutrition and Health Survey 2019 (TNHS 2019) in energy intakes. TNHS 2019 includes the data about the food consumption of the Turkish adults (18 years and over)(31). Similarly, in some studies with university students, it was reported that the energy intake was below the recommended (10, 23, 32).

This study showed that participants' carbohydrate and dietary fibre intakes were lower than recommended while their fat intakes were high. It has been found that dietary fibre intakes are also below TNHS 2019 (31).The reason is that university students have widespread Western-style dietary habits. A high-fat, low-fibre diet, especially high intake of SFA, contributes to inflammation and lays the ground for various chronic diseases (33). Also, this study showed a positive correlation between total fat, SFA intake and total cholesterol level. Contrary to this, higher carbohydrate and lower fat intakes were reported in various studies (23, 32, 34). Similarly, in a study evaluating compliance with the Mediterranean diet, university students' dietary fibre intake was found to be below the recommended while SFA intake was high (35).

In this study, the polyunsaturated fatty acids (PUFA) of participants were found above the recommended, especially in females, similar to the TNHS 2019 data (31). Also, omega-3 intake is negatively related to fasting plasma insulin level and IR. Cholesterol intakes above the recommended were observed significantly higher in men than in women. Epidemiological studies show that populations with high intakes of omega-3 fatty acids have a low cardiovascular risk. PUFA consumption is known to have anti-arrhythmic and cardioprotective effects (36). Correa-Rodriguez et al. (2018) showed that university students' PUFA intake was similarly higher than the recommended. Besides, similar to this study, when the fatty acid profile of the diet was examined, SFA intake was reported higher than monounsaturated fatty acid intake (10).

The results also showed that the micronutrient content of the diet was generally insufficient. It was observed that the vitamins B1, B6 and folate intakes were also below the TNHS 2019 data (31). In a study in Turkey, the vitamins B1, B6 and folate intakes of the students were below the recommendations, other vitamins were taken adequately (37). In another study, it was also reported that folate intake was insufficient (38). Similarly, Hervás et al. (2018), evaluating the relationship between nutrition and bone health,showed that the calcium intake in university students did not meet the recommendations, although it was higher than this study (39). Unlike our study, in a study with the general Spanish population, 71.8% of the adults were had sufficient vitamin B1 intake (40). Vitamin C, one of the important antioxidants, is known to play a role in cholesterol metabolism as well as a cofactor in many biochemical reactions such as the synthesis of collagen, carnitine and catecholamines (41). B vitamins (especially B6, B12 and folate) are among the important regulators of homocysteine metabolism. Consuming foods rich in B vitamins or taking supplements reduces the risk of developing vascular diseases such as atherosclerosis and stroke by lowering the concentrations of circulating homocysteine (42). Nutrition is critical in the development and maintenance of bone mass, and adequate intakes of magnesium, calcium, vitamins C, D and K are essential for maintaining bone health.Inadequate and imbalanced diet seen in young adults leads to deficiencies in vitamin and mineral intake (39). Vitamin B1, which plays a role in energy metabolism and the growth and development of cells, is found richin foods such as bread, cereals, legumes, meat, liver, and fish (40). Therefore, based on our results, it is thought that insufficient intake of carbohydrate resulted in insufficient vitamin B1 intake.

Without gender difference, in this study, dietary intake of calcium, magnesium and zinc was shown to be insufficient. But intake of iron was observed to be below the recommended in only women. Similarly, Şanlıer (2005) reported that these minerals were below the recommended for both men and women, but phosphorus was taken above the recommended one. Also, iron intake was shown to be significantly higher in men than in women (23). Calcium plays anessentialrole in signal transduction in cells as well as bone health. Magnesium, which acts as a cofactor in many enzymatic reactions, has critical functions in muscle contraction, glucose utilization, synthesis of nucleic acids, fats and proteins (43). Similar to TNHS 2019 and Correa-Rodriguez et al. (2018), in this study, participants' dietary sodium and phosphorus intake was found to be quite high (10, 31). It is known that high sodium intake,threatening cardiovascular health, is an independent risk factor for hypertension (44). Phosphorus, an important component of nucleic acids, plays an essential role in the structure of high-energy nucleotides and cellular signal transmission (43).

The limitations of this study can be explained that not addressing the effect of the living conditions of the participants on the outcome, taking a 24-hour dietary recall, not taking into account the plasma levels of vitamins and minerals while evaluating the dietary intake of micronutrients.

However, supporting this study with the biochemical findings of participants, making the anthropometric measurements by the researcher and the high number of participants can be considered as the strengths of this study.

5. CONCLUSION

This study emphasizes that factors such as inadequate and imbalanced diet, high BMI, WHR, body fat percentage have negative effects on the lipid profile; and these factors are associated with IR in young adults. It also shows that participants'total fat, SFA, sodium, phosphorus intakes were high; and carbohydrate, dietary fibre, vitamin D, folic acid, calcium, iron and zinc intakes were insufficient.For this reason, it is thought that developing nutrition strategies,

providing nutrition counselling, preventing nutrients deficiencies and creating balanced nutrition habits are needed to improve the nutrition habits of university students. The provision of education and counselling services, the development of campus facilities will ensure all students are physically active. Thanks to these facilities, positive changes are expected in the results of university students' anthropometric measurements. Thus, they will be protected from cardiometabolic risks during the university period when lifestyle habits are acquired.

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Clinical and Experimental Health Sciences

Factors Affecting Adherence to Treatment of Inpatients with Alcohol Addiction: a Qualitative Study

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ABSTRACT

Objective: This paper explores those factors affecting adherence to treatment among inpatients with alcohol addiction in Turkey.

Methods: This qualitative and descriptive study was carried out in 2018. The sample consisted of 16 patients with alcohol addiction in a psychiatric clinic. The data were analyzed using content analysis.

Results: Three main themes emerged from these interviews: (1) strengthening of personality; (2) structuring of treatment environment; and (3) completion of social life preparations. Strengthening of personality theme was composed of low self-esteem, anger and ineffective coping, inadequate communication skills, and loneliness sub-themes. Structuring of treatment environment theme consisted of lack of knowledge and insight, a non-therapeutic environment, and lack of treatment motivation sub-themes. Finally, completion of social life preparations theme was composed of lack of leisure activity, fighting the stigma of alcoholism, failure to initiate change and insufficient social support sub-themes.

Conclusion: This study suggests that psychiatric nurses should improve patients' self-esteem, coping and communication skills, and increase patients' knowledge and insight about their disorder and medication, treatment motivation, and social support resources.

Keywords: alcohol addiction, adherence to treatment, qualitative study, nursing

1. INTRODUCTION

Alcohol addiction causes many physical and mental health problems. As a psychiatric disorder, alcohol addiction can result in deterioration in the continuity of family processes, economic problems, and impaired occupational abilities (1-3). Some research has reported that alcohol addiction originates from psychosocial problems causes many psychosocial problems, such as separation/divorce, dismissal, and problems and encounters with the police (4). Despite these problems, alcohol addicts fail to accept their illnesses and to maintain regular treatment (5).

Approximately 10% of women and 20% of men meet the criteria for alcohol abuse throughout their lives, and 3-5% of women and 10% of men are diagnosed with alcohol addiction. The age group in which active alcohol use is most common is the 20-35 age group (4). Existing studies in the field have determined that the majority of alcohol addicts have low levels of education, low course success, and middle or low levels of income; furthermore these researches have shown alcohol addiction to be higher in males, and unemployed and unmarried individuals (4,6). These factors may also impair individual patients' adherence to treatment. Adherence to treatment, which plays an important role in the treatment of individuals with serious mental health problems such as alcohol addiction, is influenced by the patient's social support resources, such as their family and friends, and the attitudes of health workers responsible for providing their care (7,8).

Adherence to treatment is considered to be an important component in the patient's psychiatric treatment regarding their adoption of a treatment program, regular use of medicines as prescribed or recommended by their doctor, and changes to their way of life (7,9,10). In order to increase patients' adherence to treatment, regular implementation of certain practices, such as strengthening coping skills, mobilizing support systems, creating an environment that makes it easier for the individual patient to express their feelings and thoughts, and developing patients' problem-solving skills, must be regularly implemented (3). The literature also states that patients' intrinsic motivation, and their motivation for interpersonal help seeking and treatment is increased by providing a treatment environment

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that enables addictive patients to understand their own feelings and personal problems and to increase their courage to talk with health personnel about themselves and their past (11). In this respect, it is important to configure those clinics in which patients are treated in a therapeutic manner. Therapeutic environments increase the patient's compliance with the medication, which makes it easier for them to cope with problems they encounter in their social life after they have been discharged. Accordingly, the aim of the current study is to determine those factors affecting adherence to treatment among inpatients with alcohol addiction.

2. METHODS

2.1. Participants

This qualitative and descriptive study was conducted in a psychiatry service in northeastern Turkey. This study was reported using the consolidated criteria for reporting qualitative studies (12). The study, which used a purposive sampling method, aimed to explore the factors affecting adherence to treatment among male inpatients with alcohol addiction. Overall, 16 patients were recruited; all these patients met the study's inclusion criteria and were hospitalized in service between 1 January and 31 June 2018. Since only male patients received treatment at the clinic during the study, they were included in the sample. This study was conducted in a 23-bed, adult psychiatric clinic in Giresun University Training and Research Hospital. Five nurses who are high school graduates and seven doctors work in the clinic. At the time of the study, there were no therapeutic studies in the clinic; patients only received drug therapy.

The inclusion criteria were as follows: to be 18–65 years old, to be diagnosed with alcohol addiction and volunteering to participate in the research. The exclusion criteria required that patients had problems related to: hearing or understanding, memory problems, or withdrawal syndrome or patients had other mental illnesses including anxiety disorders and personality disorders. Accordingly, three patients with anxiety disorder, one patient with bipolar disorder, and one patient with memory problems, were excluded from the study. Background data for the 16 patients with alcohol addiction used in this study can be seen in Table 1.

Table 1. *Background Data for 16 Patients with Alcohol Addiction Used in the Current Study*

Patients	Age	Marital status	Educational level	Number of children	Working status	Number of hospitalizations
Patient 1	42	married	primary school	3	working	2nd
Patient 2	41	married	high school	1	working	1st
Patient 3	52	single	high school	3	retired	1st
Patient 4	41	single	primary school	-	not working	4th
Patient 5	44	single	high school	2	working	2nd
Patient 6	57	single	university	2	retired	5th
Patient 7	38	single	primary school	2	not working	2nd
Patient 8	35	married	high school	1	working	2nd
Patient 9	43	single	primary school	2	not working	1st
Patient 10	43	single	secondary school	1	working	3rd
Patient 11	63	married	primary school	3	working	3rd
Patient 12	59	single	primary school	1	working	1st
Patient 13	57	single	primary school	3	not working	2nd
Patient 14	45	married	primary school	3	working	1st
Patient 15	61	single	primary school	3	retired	2nd
Patient 16	49	married	primary school	6	not working	3rd

2.2. Instruments

A "demographic information form" and "semistructured interview form" were used to collect the study data.

***2.2.1. Demographic information form*:** This form comprised questions aimed at identifying the age, educational level, employment status, marital status, and number of children of the study participants.

***2.2.2. Semistructured interview form*:** This form covered semistructured questions prepared for the interviews with male inpatients with alcohol addiction. All interviews were carried out based on previous hospitalization experiences, personality characteristics, familial and social support systems, current treatment processes about hospitalization, characteristics of psychiatric service, leisure time activities, and future plans. A pilot study was conducted with three patients. Questions were understandable. There was no problem when the patients answered the questions. Therefore, the questions were not changed. Questions are as follow: (1) Have you ever been treated for alcohol addiction? If you did, were you able to adherence to the treatment? What were the factors that decreased or increased your adherence to the treatment? (2) Are you able to adherence to the treatment you are currently receiving? What are the factors that decrease or increase your adherence to the treatment? (3) How does your family affect you in this process? Can you get support from them? How does this process affect your family? (4) How do your friends assess your hospitalization for treatment? Do they support you?

(5) How do you evaluate the environment in which you are being treated? How does it affect your treatment process? How is your communication with healthcare professionals? (6) How does alcohol use affect your work-life positively / negatively? (7) Have you ever tried to quit alcohol? What are your experiences? (8) What do you intend to change in your life after leaving here?

2.3. Data Collection

The individual interviews were conducted with the patients in the interview room by using "in-depth interviews method". The patients were informed about the study, and consent was obtained from each voluntary participant. Each interview lasted approximately 45–60 minutes and was audio recorded. The repeated interviews were not conducted with the same patient. The data collection was continued until data saturation had been reached in each interview. First researcher has a qualitative research certificate and conducted the interview. The researchers have a doctorate degree in psychiatric nursing, are female, and work as lecturer during the study. There was no relationship between the patients participating in the study and the researchers before the study. At the time of the study, the researchers had no clinical affiliation. Prior to the research, the first researcher introduced herself and informed the participants about the aims of the research and how it would be conducted.

2.4. Data Analysis

Interviews were transcribed verbatim and interpreted so as to determine themes using the conceptual framework developed by Graneheim and Lundman (13): (1) First, answers given by participants were read through by both authors repeatedly before being subjected to a content analysis. Both authors met several times to reflect upon and discuss their analysis until they reached an agreement about the findings. (2) The meaningful textual units were identified from among the participants' answers. (3) The meaning units were abstracted and labelled with codes. (4) Codes were interpreted and 11 sub-themes were created. (5) Lastly, 3 main themes were determined. The themes, sub-themes, and codes were read by the participants.

2.5. Rigor of the Findings

In this study, the principles of credibility, transferability, consistency, and confirmability were used to ensure validity and reliability (14). The transcriptions of participant responses were read through several times so as to obtain a sense of the whole. To ensure the credibility of the data, the themes and sub-themes were not approve by the patients, but expert opinion had been taken.

2.6. Ethical Consideration

This study was approved by the ethics committee of Medical Sciences of Giresun University (date: 20.12.2017, number: 09/01) and conducted according to the ethics guidelines set out in the Declaration of Helsinki. Verbal and written consent was obtained from all participants. All participants were informed about the purpose and design of this research and were guaranteed anonymity and confidentiality throughout the study.

3. RESULTS

Three main themes were obtained as a result of the study analyses: strengthening of personality, structuring of treatment environment, and completion of social life preparations.

3.1. Theme 1: Strengthening of Personality

3.1.1. Low self-esteem

It was determined that patients who were unable to live individually and without support felt excluded, experienced broken relationships with their family, and experienced negative feelings such as guilt and shame, while also believing themselves to be relatively worthless and hopeless.

I feel strong willed and good when I drink. (P4)

I don't expect anything from the future. I lived as long as I lived. The rest is not very important. Life has little meaning for me. (P13)

I'm a person who is shy and who cares about what people think. (P15)

3.1.2. Anger and ineffective coping

Most of the patients with alcohol addiction defined that they were nervous and had problems in managing their anger.

I'm a little nervous. I'm an emotional person. I can't control myself during a discussion. (P8)

I get very angry. I'm so afraid of hurting someone else when I'm angry. Then I am regretful. (P6)

Patients described many sources of stress relating to their family, work, and social lives, and reported that they used alcohol to cope with these stressors.

I started to use alcohol more to deal with work stress. (P3)

When I was 13, I learned that I had been adopted. I'm very angry with my family. (P5)

Some patients stated that they sometimes directed their anger to themselves or another person.

When I drink, I feel no harm toward someone else, I have more self-harm. I cut my arm with a knife. (P1)

When I get angry, I cry, I yell. I don't hurt anybody else, but I'm hurting myself. I've attempted suicide three times before. In the first instance, I drank drugs. The second time, I cut my wrists. Third, I jumped off a bridge. (P4)

3.1.3. Inadequate communication skills

Patients stated that they had problems expressing their feelings and thoughts, saying no, and asking for help in solving their problems.

After my first admission, one day my friends arrived after I was discharged. They offered me a glass of a drink while they were drinking and chatting. I didn't break them. I don't want to break anybody. I can't say no to people not to hurt them. (P15)

I don't tell anyone about my problem, and can't share my problems. I always try to handle it myself. (P2)

Patients who could not express themselves, and therefore could not communicate with other people, stated that they felt alienated from their environment and felt alone.

For me, drinking is a habit, my best friend. I cannot communicate with people for a long time as personality, I get bored, my soul is shrinking. (P3)

I live in a small environment and I feel alienated from the environment. I get bored in crowded environments. (P6)

3.1.4. Loneliness

Most patients stated that they felt alone, even if there were people around them; they felt lonely and when they were alone, they wished to drink more alcohol.

I usually spend time alone and drink alone. I came back to my hometown 10 years ago and I couldn't find the environment that I wanted. (P11)

I feel alone. I'd feel better if I had a friend or a spouse in my life. (P5)

I'm alone in the village, and I'm alone here. I don't have a friend with whom to share my feelings and thoughts. (P9)

3.2. Theme 2: Structuring of Treatment Environment

3.2.1. Lack of knowledge and insight

The patients stated that they read many side effects of drugs in the package insert, they did not want to use their drugs due to side effects, and they stopped using their drugs without consulting a doctor.

I've been on medication before, but I haven't been able to use the medication all the time. The drugs made me fall asleep. This situation affected my business life. I stopped using the drugs to keep my job. (P2)

The side effects of the drugs I used scared me. That's why I stopped using them. I thought it would be better if I didn't. I read about many side effects of the drugs in the package insert. (P8)

Patients reported that they had symptoms related to alcohol withdrawal syndrome such as insomnia, hand and foot tremors, fever, and palpitations when they abstained from drinking alcohol. Participants also reported that they not know how to cope with these conditions or who to ask for when managing them that they continued to drink alcohol again due to ineffective symptom management.

When I get a drink, my work efficiency is increases, the work stress decreases. My hands shake when I don't drink. I can't do my job. (P13)

I have a sleep problem when I don't drink. I'm experiencing hallucinations. (P16)

3.2.2. Non-therapeutic environment

The most important factor regarding the disruption of the therapeutic environment for alcohol addicts was shown to be patients with different mental illnesses, who were nevertheless being treated using the same service:

All of the patients with different psychological problems were in the same service. Some patients are calling out and yelling, some patients were lashing out. This situation affects me negatively. (P2)

I think it's not right for all patients to stay in the same service. Some patients have unstable movements. I get scared when I think they can hurt me. (P11)

Another issue expressed by patients in relation to their therapeutic environment concerns the absence of any activity, occupation, individual interviews, or group activities with which to spend their time in the service.

I'm lying here empty. I can't find anything to do. Nobody talks to me here. The interviews, while I was previously hospitalized, helped me a lot. Everyone was talking about their problems in group meetings. (P4)

I'm always watching television, having tea, or drinking coffee. There is nothing to do. (P7)

Some patients also stated that they had difficulties in meeting the self-care needs and service was inadequate in terms of cleanliness / hygiene.

I think this place is neglected. I think such a service should appeal to the eye and the environment should be full of flowers. I think it should be cleaner. (P3)

There are deficiencies in care. Nobody helps me meet my cleaning needs. (P4)

3.2.3. Lack of treatment motivation

Most patients reported that they sought out their treatment according to their own wishes, but that they did not decide to quit alcohol; these patients applied to hospital because of the wishes of their families or colleagues, or because of health problems. Patients reported that they were unable to exercise their own will and therefore were unable to abstain from alcohol.

I'm saying I won't drink when I'm coming here, but I can't stop it. In the evening, I think how I'm gonna sleep without drinking. (P13)

I haven't decided to quit alcohol yet. If I decide one day, I can. My people around me now want me to leave, but I don't want what's important. I can stop drinking if I want. I don't drink in Ramadan. (P9)

3.3. Theme 3: Completion of Social Life Preparations

3.3.1. Lack of leisure activity

On the one hand, some patients stated that they could not find anything to do in their leisure time. On the other hand, the patients who evaluated their leisure time reported that they did not feel the desire to drink, or that cravings for alcohol had decreased during leisure time.

In my leisure time, if I do something, if I do not empty my day I do not have the opportunity to drink. (P5)

In my leisure time, I sit in the barbershop and drink tea and coffee until the evening. I'm on the phone. I'm not doing anything else. (P7)

3.3.2. Fighting the stigma of alcoholism

Patients reported that people in their neighborhood and their friends mocked them for both their disease and hospitalization; accordingly, they did not want to tell anyone they were hospitalized. There were even patients who did not tell their family when they were admitted into the clinic.

I think a lot about the negative things the environment says about drinking alcohol. My friends' environment is not very supportive about it. They said you were crazy when they heard I was hospitalized here. (P1)

People at work and around me don't know I'm in the hospital. My wife does not want it to be known. (P2)

I didn't tell my friends and children that I was hospitalized here. (P9)

3.3.3. Failure to initiate change

Most patients stated that they started using alcohol because of their friends. In fact, patients who had previously experienced alcohol withdrawal also reported that they started to use alcohol again because of their friends. However, when patients' future plans were evaluated, some stated that they did not want to change their lives or that it was impossible to make such changes.

I was stubborn with a friend because of drinking. Then I started drinking. (P7)

I don't want to change anything in my life after I'm discharged from here. (P6)

I will continue my life in the same way after I'm discharged from here. (P11)

3.3.4. Insufficient social support

During their treatment for addiction, many patients stated that their families and friends did not support their treatment efforts, and that they mostly consumed alcohol with their friends. Patients reported that their families did not believe that the treatment interventions could fail, and therefore did not support treatment interventions.

My friends were not very supportive about it. They said you were crazy when they heard I was hospitalized here. I don't think I'll see any support from them. (P14)

My wife didn't want me to go to the hospital. She said that you're going to start drinking again. (P5)

My friends don't want me to leave the alcohol. They say you start to drink again tomorrow. (P13)

4. DISCUSSION

The present study found that patients with alcohol addiction also had certain personality characteristics, including: low self-esteem, anger and ineffective coping, ineffective communication skills, and loneliness. In a study by Engin and Savaşan (5) exploring factors affecting the psychotherapy process of alcohol dependents, it was found that suppressed anger scores and internal–external locus of control scores were associated with discontinued treatment among patients. A further study by Ekinci et al. (15) found that, as patients' level of anger increased, the impact of the substance used on the patients' life and the patients' cravings for that substance increased. Mitrovic et al. (16) stated that patients with alcohol addiction were characterized by low self-esteem, higher levels of tension, anxiety, sensitivity to criticism, insecurity and indecisiveness. According to Çam and Ayakdaş-Dağlı (17), patients who have negative emotions, such as guilt and shame, tend to drink alcohol as a way of coping with these emotions. This vicious circle adversely affects the treatment of patients and increases the possibility of relapse (18). Due to increasing treatment motivation, patients should be educated and empowered about managing their anger and improving their self-esteem.

Similar to the present study, a study by Bokhan et al. (19) determined that maladaptive strategies, such as denial, dissimulation, and dissociation, were generally used by alcohol addicts. Stressful life events and ineffective coping strategies were found to play a considerable role in patients' relapsing (20). Furthermore, alcohol addicts with familial problems, such as a failed marriage or conflicts with their children, were found to experience emotional guilt and shame which led to a withdrawal from social relations (21). Research has also found that such patients are aggressive and violent toward their wives and children, leading to conflicts, and frequent arguments which can result in disturbed communication, such as silence, blame, complaints, and guilt (22). Patients with ineffective means of coping strategies and ineffective communication skills can fail to adhere to

treatment. For these reasons, their coping strategies and communication skills must be improved.

The present study determined that the following factors were associated with structuring the treatment environment: lack of knowledge and insight, non-therapeutic environment, and lack of treatment motivation. Patient–nurse interaction is an important component of a patients' therapeutic environment. According to one study by Thurang et al. (23), alcohol addicts defined being connected to professional caregivers as being with a person with whom they felt safe, and that they believed to be secure and confident. Being connected to professional caregivers can increase patients' treatment motivation. A study by Evren et al. (24), determined that treatment motivation and outpatient clinic control, and attendance at an outpatient treatment program, all reduced in a relapsed group of patients compared with a non-relapsed group. A further research study also found that the therapeutic service environment aimed at increasing autonomy, spontaneity, program clarity, confidence in treatment, and personal problem orientation for patients increased patients' motivation for treatment (11). Occupational therapy, sport activities, individual or group therapies are all components of the therapeutic environment. Greater use of individual sessions with relevant health professionals was associated with better quality of life and lower levels of depression, as predictors of patients' adherence to treatment (25). In summary, among patients who did not adhere to treatment it was found that hospitalization, morbidity and mortality increased, occupational and familial problems arose, and the patient's quality of life decreased (26).

Lastly, the present study uncovered several factors associated with the completion of social life preparations: lack of leisure activity, fighting the stigma, failure to initiate change, and insufficient social support. As a barrier disrupting patients' adherence to treatment for alcohol addiction, it was found that changing risky environment increases craving (24). Greater motivation for changing and efforts to control craving decreases alcohol use and craving (27) and, therefore, it is important that patients receive assistance from nurses when changing their environmental contingencies to establish a lifestyle that is more rewarding than their current lifestyle which is centred on or reliant on drinking (28). To initiate changes in their lives, patients need social-support resources. Accordingly, patients experiencing insufficient social support from their family, friends, or health professionals are more likely to experience loneliness (29). Insufficient social support and loneliness increased the risk of suicide among alcohol addicts (30,31). Psychosocial interventions in a therapeutic environment should be planned by nurses so as to enable patients to more effectively initiate change in their lives.

Leisure activities are important if patients are to make successful changes to their lives, conduct activities that lead to a sense of freedom, and experience satisfaction, and successful management and balance of their life needs and activities (32). The problems associated with decreased involvement in social, family and professional activities due to alcohol use result and cause recurrent alcohol consumption, and a deficient role in social and family integration among alcohol patients (33). Furthermore, family and social relations that break down due to alcohol use can lead to social isolation and internalized stigma. In light of these findings within the present study, stigma can be said to be a factor that disrupts patients' adherence to treatment. The perception of stigma as experienced by alcoholism results from internalized stigmatization, which itself stems from cognitive and affective internalization of the patients' actual stigmatization by society at large. Being stigmatized by others results in the experience of negative emotions, such as guilt, shame, feelings of inferiority, deterioration in family and friendship relationships among patients with alcoholism (17). According to Yıldırım et al. (34), internalized stigma among patients with alcohol addiction also results on negative effects such as social isolation, low self-esteem, a sense of exclusion, depression, and negative adherence to treatment in patients.

This study has some limitations. Firstly, the findings of the study cannot be generalized to all patients with alcohol addiction. Secondly, the study sample consisted of a small group. Thirdly, only male alcohol addicts were found in the study. Finally, the data were collected in the hospital environment during the treatment process. This situation may have affected the patients' responses. But treatment of alcohol addiction is a long process. This study has provided valuable findings to the literature in terms of determining the factors affecting adherence to treatment of male inpatients with alcohol addiction.

5. CONCLUSION

The results of the current study show that certain factors, such as strengthening of personality, structuring of treatment environment, and the completion of preparations concerning the patient's social life are important components of treatment for patients with alcohol addiction. Male inpatients with alcohol addiction have low self-esteem, feelings of anger and loneliness, ineffective coping, and inadequate communication skills. The psychiatric clinic has a non-therapeutic environment. Health care professionals in psychiatric clinic are lack of knowledge and insight about alcohol addiction. Male inpatients with alcohol addiction have some social life problems, such as lack of leisure activity, the stigma of alcoholism, failure to initiate change and insufficient social support.

5.1. Relevance for Clinical Practice

Interventions such as individual and group therapies that improve self-esteem, coping and communication skills, increase knowledge and insight about the patients' disorder and medication, treatment motivation and social support resources should be planned and implemented by nurses and other clinicians. Nurses and other healthcare professionals in psychiatric clinics should create a therapeutic environment

for patients. They should improve patients' self-expression, communication and social skills using therapeutic communication techniques. In the struggle against stigmatization, it is important to mobilize social support systems of patients with alcohol addiction. It is important for professionals working in psychiatry clinics to graduate from undergraduate and graduate programs in terms of providing a professional approach to solving problems. High school graduate nurses will not be sufficient to create a therapeutic environment.

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Clinical and Experimental Health Sciences

Traditional Practices Performed by Nurses During Postpartum Period

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ABSTRACT

Objective: In order to provide a quality health service, the awareness of traditional practices of healthcare providers, especially nurses, is as important as the understanding of the illnesses and health perception of those receiving care and their approaches to contemporary and traditional practices, because nurses' own cultural values and beliefs can affect their decisions and attitudes toward the patients. .

Methods: This descriptive study was performed with female nurses with children and working in a university hospital. The sample was not determined by using any special method of selection. The study was completed with the participation of 316 nurses who volunteered to participate in the study. The participation rate was 82%. Data were collected from October 2018 to April 2019 by using a survey form developed by the researchers based on the literature

Results: Of the nurses, 91.5% thought traditional practices were important but 8.5% thought that such practices were unimportant to prevent/resolve health-related problems. The most common first three practices that the nurses implemented to prevent puerperal fever included fortieth-day baths (44.3%), praying (37.3%), and not staying home alone (28.2%).

Conclusion: It is important for nurses to be aware of their viewpoints against traditional practices as to understanding transcultural care and providing service in this direction.

Keywords: Nurse, postpartum period, traditional practices.

1. INTRODUCTION

Culture is defined as "values, beliefs, manners and customs learned, shared, and passed down from generation to generation by a group of people" (1). It shapes attitudes towards health, health beliefs and behaviors. Today, health-related traditions that live and are kept live in Turkey are the product of a vibrant and rich cultural synthesis manifested by civilizations settled in Anatolia. Within this cultural heritage, postpartum practices occupy a very significant place (2, 3).

Postpartum period is a duration referring to various cultural beliefs and values in every country in the world. Perceptions and practices regarding this period vary from culture to culture, but are implemented to protect mother and her baby from all kinds of diseases and troubles. Turkey is a country where diverse civilizations have been established since ancient times. For this reason, it has a rich culture. This, in particular, has formed a multicultural populational structure, which has raised the issue of providing satisfactory care in cultural terms. Consequently, the meaning of the postpartum period in the society served by nurses has become more important in nursing care interventions as well as the identification of cultural practices for this period, and cultural barriers to receiving healthcare during this period. For this reason, understanding cultural beliefs and values during the care period has an important role to play in making clinical nursing care decisions and developing care plans (4,5).

It is necessary for nurses to, first of all, comprehend their own attitudes towards traditions and practices in order for them to deliver transcultural care. Culture can influence people's opinions, decisions and actions in certain ways. For this reason, nurses' own cultural values and beliefs can consciously or unconsciously influence their decisions, attitudes and practices regarding patient care. Moreover, self-awareness can be a starting point for nurses to understand women culturally. Thus, they can identify sociocultural differences between patients and themselves, become attentive to such differences and take such characteristics into consideration when delivering care (4-6). Based on this premise, this study was carried out to identify traditional practices followed

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by nurses for themselves, who are expected to provide transcultural care during the postpartum phase of patients.

2.METHODS

2.1 Research Model

This research is a descriptive type.

2.2.Study Universe and Group

The population of the study was comprised of female nurses who had children and served at a hospital of a Faculty of Medicine in Konya province, Turkey. Participation in this study was voluntary. The sample was not determined by using any special method of selection. The aim was to reach at least 80% of all nurses. The study was completed with the participation of 316 nurses who volunteered to participate in the study. The participation rate was 82%.

2.3. Data Collection and Data Collection Tools

Data were collected from October 2018 to April 2019 by using a survey form developed by the researchers based on the literature (7-9). The Survey Form included 15 questions inquiring sociodemographic characteristics and traditional practices. The survey forms were handed out to the nurses, and they were asked to fill the forms out. It took 10–15 minutes to fill the survey forms.

2.4. Ethical Approval

Ethics committee approval was obtained from the Noninvasive Clinic Ethical Committee of the Medical Faculty at Necmettin Erbakan University (Decision no.72/2018). Institution approval of the study was obtained from the institution in which the study is conducted and verbal consent was obtained from the nurses.

2.5.Data Analysis

The analyses of the data obtained in the study were conducted using SPSS 20 statistical analysis program (Chicago, IL, USA). Number, percentage, mean and standard deviation were used to analyze the data. The significance level was accepted as $p<.05$

2.6. Limitations and Generalizability of the Study

The findings of our study are limited to the hospital where the study was conducted and so cannot be generalized to the other regions of Turkey. The study was conducted on nurses who were all from the same culture, which was a limitation of the study. It was another limitation of the study that the nurses responded to the questions by recalling past knowledge.

3. RESULTS

The average age of the 316 nurses (82%) who participated in the study was 35.9 ± 7.05 of these nurses, 94.9% were married, 57.6% were four-year college graduates, and 83.9% lived in the Central Anatolia region for the most part of their lives. The mean number of the pregnancies of the nurses was 2.06±1.13, and 59.2% had two or more living children (Table 1).

Table 1. *Sociodemographic and obstetric characteristics of nurses (n: 316)*

Characteristics	Median (Min.– Max.)	$\bar{x}$ ±SS
Age	36.0 (22-49)	35.9±7.05
Marriage age	23.5 (17-37)	23.7±3.34
Duration of marriage	10.0 (1-35)	11.8±7.53
Number of pregnancy		2.06± 1.13
	n	**%**
Marital Status		
Married	300	94.9
Single	16	5.1
Educational status		
High School	42	13.3
Two-year college	58	18.4
Four-year college	182	57.6
Post graduate	34	10.8
Evaluating monthly income		
Good	115	36.4
Middle	191	60.4
Bad	10	3.2
Family type		
Nuclear family	301	95.3
Extended family	15	4.7
Number of Children Living		
<2	129	40,8
≥ 2	187	59.2
The longest lived place		
City	271	85.8
Village/Town	46	14.2
The longest lived geographical region		
Aegean Region	20	6.3
Mediterranean Region	22	7.0
Black Sea Region	7	2.2
Marmara Region	2	0.6
Central Anatolia Region	265	83.9

Of the nurses, 91.5% thought traditional practices were important but 8.5% thought that such practices were unimportant to prevent/resolve health-related problems. The most common first three practices that the nurses implemented to prevent puerperal fever included fortieth-day baths (44.3%), praying (37.3%), and not staying home alone (28.2%). In order to increase breast milk supply, their practices involved consuming molasses/halva/sweet food items (42.4%), consuming crashed wheat pilaf/kisir (traditional

crashed wheat salad)/lentils (38.6%) and consuming onions (29.4%), in the order of frequency (Table 2).

Table 2. *Traditional practices that nurses implemented for themselves during their own postpartum period. (n:316)*

Traditional practices	Yes n	%	No n	%
Practices to prevent puerperal fever				
Taking a fortieth-day bath	140	44.3	176	55.7
Praying	118	37.3	198	62.7
Not staying home alone	89	28.2	227	71.8
Placing a copy of Koran in puerperal women's room	73	23.1	243	76.9
Tying a red scarf or ribbon on the head of the woman	71	22.5	245	77.5
Avoiding attending a funeral	47	14.9	269	85.1
Not allowing two puerperal women to visit each other	41	13	275	87
A menstruating woman's avoiding visiting a puerperal woman	34	10.8	282	89.2
Leaving a sharp tool like a sickle or a knife in puerperal women's room	26	8.2	290	91.8
Practices to increase breast milk supply				
Consuming molasses, halva, and sweet food items	134	42.4	182	57.6
Consuming crashed wheat pilaf/kısır (traditional crashed wheat salad)/lentil	122	38.6	194	61.4
Consuming onion	93	29.4	223	70.6
Drinking puerperal woman sherbet (a type of sweet drink prepared specifically for the sake of a puerperal woman)	86	27.2	230	72.8
Consuming quince compote	68	21.5	248	78.5
Other traditional practices Puerperal women's avoiding having sex for 40 days	245	77.5	71	22.5
Puerperant women's celebrating the 40th day of delivery	148	46.8	168	53.2
Wrapping puerperant women's abdomen	126	39.9	190	60.1
Avoiding doing housework	61	19.3	255	80.7
Avoiding leaving the house for 40 days	59	18.7	257	81.3
Traditional practices implemented to prevent/resolve health-related problems	289	91.5	27	8.5

When the nurses were asked about what they would initially do in any health-related problem, 67.7% stated that they presented to a health institution, 27.8% stated that they tried to solve it using certain traditional practices that they knew, and 4.4% stated that they tried to cure it on their own.

4. DISCUSSION

Every culture has their own beliefs and practices. A nursing care practice that ostracizes cultural characteristics negatively influences patients' sense of trust in and cooperation with nurses. Nurses should be mindful of cultural differences, so that people who have influenced their lives according to cultural values and spiritual beliefs can be supported with high quality and professional nursing care. In order to do that, first of all, nurses should be aware of their own cultural values and beliefs. Otherwise, they will tend to ignore cultural characteristics and orientations of people receiving care by making decisions according to the values and norms of their (the nurses') own culture in their decisions when providing care.

The average age of the 316 nurses involved in the study was 35.9 ± 7.05. It can be said that the nurses were in their mid-adulthood. The most important function of the idea of self in mid-adulthood, according to Erikson's theory of Stages of Psychosocial Development, is productivity and creativity, especially in technical and artistic fields (10). Accordingly, given their ages, it can be said that the nurses had matured in terms of professional knowledge and experience and were at a stage where they could transfer such knowledge and experience to patient care.

The nurses' opinions about traditional practices implemented to prevent/resolve health-related problems showed that 91.5% thought such practices were important and 8.5% thought that they were unimportant. Similarly, Kaewsarn, Moyle, and Creedy (8) reported that almost half of nurses (48.92%) cared about traditional practices implemented during the postpartum period. In another study, Karakuş, Babadağ, Abay, Akyar, and Çelik (11) reported that nurses were aware of the importance of cultural differences in health care. Similarly, Yalçıner and Çam (12) reported that 43.1% of nurses considered non-harmful traditional practices favorably. It can be said that nurses were mindful of traditional practices.

Culture influences every aspect of human life. Such practices can be implemented even in the most important parts of women's lives and when they are very sensitive, like in the postpartum period. It has been reported in many studies that mothers carry out different practices during the postpartum period and attach great importance to such practices to protect their health and the health of their babies (13, 14, 15). Particularly important for transcultural treatment in this context is customs, beliefs and values of nurses themselves. In this study, the nurses reported their own traditional practices that they performed during the postpartum period. Among them, the most common first three implemented by the nurses to prevent puerperal fever included fortieth-day baths (44.3%), praying (37.3%), and not staying home alone (28.2%). Among the practices that were carried out

to increase breast milk supply, consuming molasses/halva/sweet food items (42.4%), consuming crashed wheat pilaf/kisir (traditional crashed wheat salad)/lentils (38.6%) and consuming onions (29.4%) were prominent. Similarly, the idea that "the baby and woman who have not completed forty days after childbirth are not left alone and not taken out of the house for forty days" (64.1%) were among the practices aimed at preventing women's puerperal fever in a study conducted in Karaman, Turkey (16). In the study of Kaewsarn et al. (8), nurses stated that there should be a balanced diet to maintain milk supply during the postpartum period. In that study, the nurses stated that people should consume fish (98.9%), eggs (98.7%), buffalo meat (20%), vegetables (97.6%), red pepper (chili pepper, 54.9%), and durian (a tropical fruit, 62.9%). In the study by Tien (17), nurses and mothers stated that they believed postpartum traditional practices are a universal phenomenon, and traditional practices are effective in regaining physical health.

5. CONCLUSION

It was found that there were nurses who thought that traditional practices during the postpartum period were important, and they implemented such practices personally. Nurses need to be conscious of their own attitudes towards traditional practices, appreciate transcultural care and deliver services in this way. In this context, it is recommended to incorporate transcultural nursing courses into undergraduate education. In addition to raising nurses' awareness of transcultural care, their cultural competence should be supported by in-service training programs after graduation.

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Clinical and Experimental Health Sciences

The Effects of Cyclosporine and Tacrolimus on Gingiva and Alveolar Bone of Rats

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ABSTRACT

Objective: Cyclosporine A (CsA) and tacrolimus (Tac) are immunosuppressive drugs which is frequently used in organ transplantation. CsA can cause various side effects including gingival overgrowth (GO) and osteopenia. Tac has similar side effects to CsA but with different incidences. The aim of the present study was to evaluate and compare the effects of CsA and Tac on GO and alveolar bone resorption in rats.

Methods: Sixty mature male rats were randomly and equally allocated into six groups, as follows: Control-I, Control-II, CsA-I, CsA-II, Tac-I and Tac-II. The Control-I and Control-II groups received, subcutaneously, 1 ml/kg 0.9% NaCl, while the CsA-I and CsA-II groups received 10 mg/kg CsA daily, and the Tac-I and Tac-II groups 1.5 mg/kg Tac daily. The Control-I, CsA-I and Tac-I groups were sacrificed on the 16th day and other groups on the 31st day. Histological and histomorphometric analysis of the buccal gingiva and tartrate-resistant acid phosphatase (TRAP) enzyme histochemistry of the alveolar bone were performed in the right mandibular segment of each animal.

Results: GO was significantly greater in the groups administered CsA compared to the other groups ($P<0.05$). The gingival parameters in the Tac groups were quite similar to those in the control group ($P>0.05$). CsA caused a significant increase in TRAP positivity ($P<0.05$), while Tac had no significant effect on TRAP ($P>0.05$).

Conclusion: Our results showed that Tac does not seem to cause GO and alveolar bone resorption. However, the deleterious side effects of Tac on the gingival tissues of rats may be time-related.

Keywords: Bone Resorption, Cyclosporine A, Gingival Overgrowth, Tacrolimus, Tartrate-Resistant Acid Phosphatase.

1. INTRODUCTION

Gingival overgrowth (GO) has many etiologies, but has often been associated with the systemic administration of certain medications, particularly anticonvulsants, calcium channel blockers, and immunosuppressants (1). Immunosuppressive drugs cause selective inhibition or suppression on various components of the immune system. Cyclosporine A (CsA), which is an immunosuppressive agent, is a T lymphocyte suppressor used to restrain rejection in organ transplants. Although it is a unique selective immunosuppressant drug, CsA has a number of side effects, such as nephrotoxicity, neurotoxicity, diabetes, osteopenia, and GO (2). As a result of the difficulties associated with the emergence of CsA side effects, tacrolimus (Tac) was introduced as a less toxic but more potent calcineurin inhibitor (3). Both CsA and Tac show their immunosuppressive activity by inhibiting the calcineurin pathway. CsA is still considered to be the most effective immunosuppressive drug currently in use (4).

Tac has been shown to have similar side effects to CsA but with different incidences (2). Both drugs were found to have similar incidences of nephrotoxicity (5). Tac has a less acute rejection rate and better allograft survival rate (5). However, it is more associated with diabetes mellitus and neurotoxicity after transplantation (5). On the other hand, complications such as hyperlipidemia, hypertension and hirsutism with Tac are less common (5). Similarly, although there are many studies showing various degrees of GO due to CsA use (6), it has been suggested that the use of Tac does not cause GO (7), or causes less GO than CsA, and is less severe when it causes GO (8,9). There are also studies showing that GO spontaneously decreases with the replacement of CsA with Tac in patients with GO caused by CsA (10).

Osteopenia is a significant complication of organ transplantation. Conflicting evidence has been presented on the interference of calcineurin inhibitors with the bone metabolism. While some studies have shown that Tac causes

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an increase in alveolar bone formation by decreasing the number of osteoclasts (11), in contrast, it has also been reported that by increasing the number of osteoclasts, Tac increases bone resorption but does not affect bone formation (12). CsA, on the other hand, has been shown to increase bone formation and bone resorption, causing high-turnover bone loss (12). Kanda et al. also found bone mineral density after CsA to be significantly lower than after Tac (12). It was reported that there was an increase in bone volume and a decrease in the number of osteoclasts in rats following the replacement of CsA with Tac (13). Similarly, it has been demonstrated in experimental periodontitis that Tac reduces the severity of periodontitis (14).

The most effective treatment for the patients with drug-induced gingival overgrowth is to replace the drug with another medication that has fewer side effects. Treatment plan is primarily performed in consultation with the patient's physician by considering the systemic condition of the patient. In recent years, Tac has been recognized as a noteworthy alternative to CsA in patients with gingival overgrowth. However, the studies suggesting that both drugs have possible effects on bone metabolism raise concerns about the negative effects of the drug choice or replacement on alveolar bone.

Tartrate-resistant acid phosphatase (TRAP) has been established as a reliable, specific and sensitive histochemical marker of bone resorption in that it is an enzyme synthesized and secreted by bone-resorbing cells, osteoclasts (12, 13, 15). Osteoclasts can be stained for TRAP as a means of assessing the number of osteoclasts in addition to their activity. TRAP levels have been shown to be elevated in the serum of patients with bone diseases and the amount of secreted TRAP significantly correlated with the number of osteoclasts (12, 13, 15).

The effects and mechanisms of action of CsA and Tac on bone metabolism are still unclear. Knowing the possible effects of these calcineurin inhibitors on periodontal tissues may improve the effectiveness of periodontal treatment and the quality of life of patients using these drugs. Therefore, the purpose of the present study focused on evaluating and comparing the effects of CsA and Tac on GO and bone metabolism. In this study, standardized histomorphometric variables were used together with TRAP activity as a histochemical marker in histological sections.

2. METHODS

2.1. Animals and Experimental Design

Sixty mature (4 months old), male Sprague-Dawley rats weighing between 195-205 g were used in this study. The animals were obtained from the Experimental Medicine Research and Application Centre of Selcuk University. The preparation of the animals was performed by their spending a habituation period of one week in the same center prior to the experiment. The animals were housed in plastic cages with 5 animals in each, in standard conditions (Humidity 50% ± 10 %, room temperature 20 ± 1 °C in 12 hours night / 12 hours daytime period) without any restriction on food and water during the study. All protocols and animal care were carried out in compliance with guidelines determined by the Experimental Medicine Application and Research Center Ethics Committee (Approval no: 2008/35).

The animals were randomly separated into six groups and the animals of each group were treated as presented in the Table 1. The drug doses used in this study were based on the literature (16,17).

Table 1. *Study groups.*

Groups	Treatments
Control-I (n=10)	1 ml/kg 0.9% NaCl was subcutaneously administered daily for 15 days
Control-II (n=10)	1 ml/kg 0.9% NaCl was subcutaneously administered daily for 30 days
CsA-I (n=10)	10 mg/kg CsA was subcutaneously administered daily for 15 days
CsA-II (n=10)	10 mg/kg CsA was subcutaneously administered daily for 30 days
Tac-I (n=10)	1.5 mg/kg Tac was subcutaneously administered daily for 15 days
Tac-II (n=10)	1.5 mg/kg Tac was subcutaneously administered daily for 30 days

n: Number, NaCl: Sodium Chloride, CsA: Cyclosporine (Sandimmune Neoral; Novartis Pharma, East Hanover, NJ, USA), Tac: Tacrolimus (Prograf; Eczacibasi Pharmaceutical Marketing Inc., Kerry, Ireland).

The weight of the rats was measured, and the dose of the drug was adjusted at the beginning of the experiment. The animals were weighed, and the doses were readjusted daily according to body weight daily. The weights were measured again at the end of the experiment, and the animals were euthanized with a pentobarbital overdose (100 mg/kg intraperitoneal) (Nembutal;100 mg/mL,Abbott Laboratories,Chicago, IL) on the 16th and 31st days. Histological and histomorphometric analyses were performed.

2.2. Histological Procedures

The right mandibular segment of each animal was dissected from the surrounding soft tissues and fixed in buffered formal saline (0.1 M, pH 7.4) for 48 hours. Then, the samples were decalcified in 10% ethylene diamine tetra acetic acid (EDTA;Titriplex,Merck Darmstadt,Germany) for 3 months at 4 °C. The decalcification of the samples was confirmed radiographically.

The decalcified tissue samples were processed by routine histological procedures and immersed in paraffin blocks as described below. After decalcification was completed, the samples were washed overnight under running water, the samples were then transferred to the tissue monitoring device and were passed once through 80° and 90°alcohols, three times through 96° alcohols; three times through isopropyl alcohol; twice through xylol and twice through

hot paraffin respectively and subsequently blocked. The blocks were sectioned transversally through the first molar teeth level with rotary microtome (SM 2000R;Leica microsystems,Heidelberg,Germany). From each tissue sample, 6 tissue sections at 6 µm thick were taken on poly-L-lysine coated glass slides and dried overnight in the oven at 37°C. Tissue sections were rehydrated by deparaffinization in the xylene series followed by a reduced concentration of ethyl alcohol and then transferred to deionized distilled water. Three of the sections from each tissue sample were stained with Crossmon's three chrome stain (18). The specimens were covered with cover glass using synthetic resin.

2.3. Histomorphometric Analysis

All specimens were evaluated under a light microscope (Nikon Eclipse E400;Nikon,Tokyo,Japan) with digital imaging system. Selected microscopic images were recorded and processed using image-analyzing software (BS 200 PRO;BAB Image Analyzing Systems, Ankara, Turkey). Histomorphometric analysis was performed to quantify the amounts of the tissue types mentioned above by an examiner who was blind to the experimental design (İ.Ç.). In these specimens, the following linear measurements of the gingiva were determined by the modification of the histomorphometric methods described previously (Figure 1) (19,20):

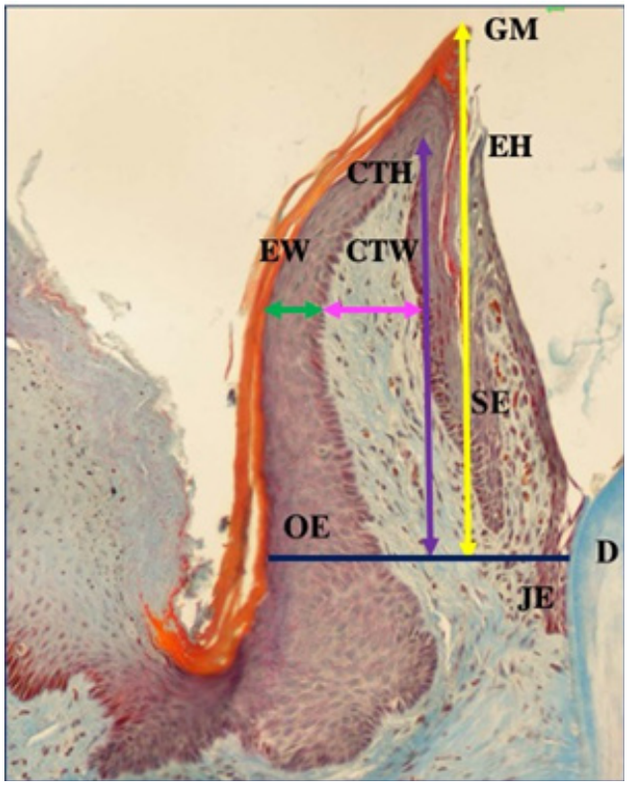

Figure 1. *Measurements on the buccal gingiva of right mandibular molars (Crossmon's three chrome stain). GM: Gingival Margin, EH: Oral Epithelium Height (Yellow arrow), EW: Oral Epithelium Width (Green arrow), CTH: Connective Tissue Height (Purple arrow), CTW: Connective Tissue Width (Pink arrow), OE: Oral Epithelium, SE: Sulcular Epithelium, JE: Junctional Epithelium, D: Dentin.*

Oral Epithelium Height (EH): The distance between the gingival margin and the most coronal cell of the junctional epithelium.

Oral Epithelium Width (EW): The distance between the outer epithelial surface and oral epithelium-connective tissue interface; measured at the coronal, middle and apical part of the free gingiva, with average of these measurements then calculated.

Connective Tissue Height (CTH): The distance between the most coronal point of the connective tissue and the most coronal cell of the junctional epithelium.

Connective Tissue Width (CTW): The distance between the oral epithelium-connective tissue interface and sulcular epithelium – connective tissue interface; measured at the coronal, middle and apical part of the connective tissue, with the average of these measurements then calculated.

2.4. TRAP Histochemistry

In the remaining 3 sections of each tissue sample, TRAP staining was performed by the method described previously (21). Briefly, the sections were deparaffinized, rehydrated and incubated in incubating solution (pH 5) at 37°C for 45 minutes. The solution contained naphthol AS-BI phosphate (Sigma;St. Louis, MO, USA) dissolved in an acetate buffer (0.2M, pH 5) as a substrate, 50 mM tartaric acid (Sigma;St. Louis, MO, USA) as an acid phosphatase blocking agent and fast-Red Violet LB diazonium salt (Sigma;St. Louis, MO, USA) as a chromogen. At the end of the TRAP reaction, the sections were stained with 1% methyl green prepared in 0.2 M acetate buffer (pH 5.2) for cell nuclei. The specimens were covered with cover glass by using Kaiser's gelatin. TRAP-positive areas were determined by a digital image analysis system (BS 200 PRO;BAB Image Analyzing Systems, Ankara, Turkey). From the data obtained, the TRAP-positive area ratio (TRAP-positive area/total image area X 100 = TRAP-positive area percentage in total image area) was calculated in the unit tissue area ($1.23X10^8$ μm^2). TRAP-positive regions in 10 different areas of each specimen were determined in a unit tissue area and expressed as a percentage (%) of the unit area.

2.5. Statistical Analysis

The sample size calculated by R program (version 3.6.2) was 10 animals per group (power=80%). A statistical analysis using package program (SPSS Inc.,Chicago, IL, USA) version 17 software was performed for the statistical analysis of the obtained numerical data. The data showed normal distribution; differences within and between the groups were compared by one-way analysis of variance (ANOVA) and CsA-I and CsA-II groups were compared by dependent two samples t-test. The significance level was α=0.05.

3. RESULTS

3.1. Clinical Findings

Any unexpected clinical and systemic changes attributable to CsA and Tac were not observed in any of the animals during the experiment. All CsA-administered rats presented GO after 15 and 30 days of treatment. There were no significant differences (P>0.05) in the body weight between the groups at the baseline and the 16th day of the experiment (Table 2). However, at the 31st day of the study, the mean body weight of the CsA – administered group was significantly (P<0.05) lower than those of the other groups.

Table 2. *The mean body weights (g) of the groups.*

	Control	CsA	Tac
Baseline (Mean±SD)	196.23 ± 17.04 (n=20)	194.75 ± 14.04 (n=20)	202.93 ± 12.88 (n=20)
16th day (Mean±SD)	193.93 ± 30.22 (n=10)	206.62 ± 13.57 (n=10)	193.32 ± 15.46 (n=10)
31st day (Mean±SD)	201.38 ± 12.28 (n=10)	161.36 ± 14.44*,† (n=10)	201.30 ± 20.49 (n=10)

n: Number, CsA: Cyclosporine, Tac: Tacrolimus, SD: Standart Deviation.
* Significantly different from the control group (P<0.05).
† Significantly different from the Tac group (P<0.05).
P<0.05 was considered statistically significant.

3.2. Histological and Histomorphometrical Findings

In all specimens, enamel was completely decalcified and disappeared; thus, a definite enamel space was seen. Severe epithelial hyperplasia with mononuclear cell infiltration was observed in both CsA-I and CsA-II groups. Vascularization was also highly developed in the connective tissue. In some of the specimens, erosion and detachment of both JE and SE were seen, and the gingival sulcus was filled with bacterial plaque (Figure 2A-2B).

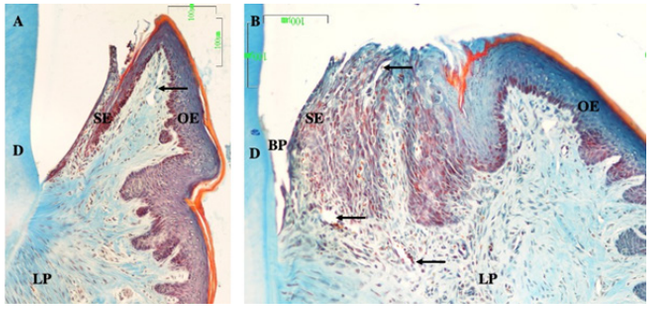

Figure 2. *Sections from the buccal gingiva (Crossmon's three chrome stain). (A) CsA-I group. (B) CsA-II group. OE: Oral Epithelium, SE: Sulcular Epithelium, LP: Lamina Propria, D: Dentin, BP: Bacterial Plaque, Black Arrows: Vascularization.*

Structural changes in both the epithelium and connective tissues of the Tac-I and Tac-II groups were generally quite mild. Mild mononuclear cell infiltration with increased vascularity in both epithelium and lamina propria was observed. Bacterial plaque in the gingival sulcus was seen (Figure 3A-3B).

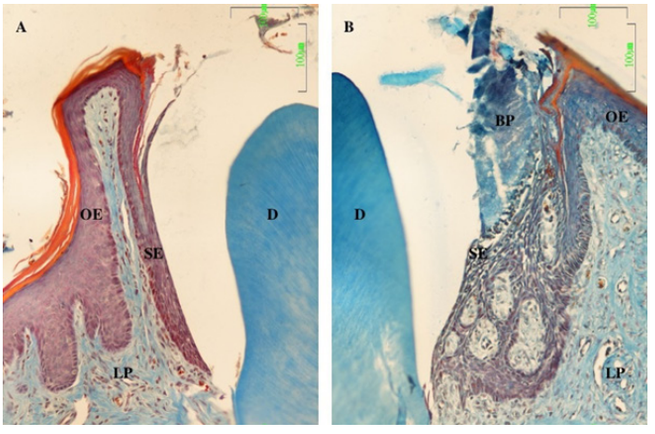

Figure 3. *Sections from the buccal gingiva (Crossmon's three chrome stain). (A) Tac-I group. (B) Tac-II group. OE: Oral Epithelium, SE: Sulcular Epithelium, LP: Lamina Propria, D: Dentin, BP: Bacterial Plaque.*

Oral epithelium (OE), sulcular epithelium (SE) and junctional epithelium (JE) were normal in structure in both Control-I and Control-II groups. Mild mononuclear cell infiltration in the lamina propria (LP) was seen. Any detachment in JE, cellular debris and epithelial erosion was not observed. There were no apparent histological differences between Control-I and Control-II groups (Figure 4A-4B).

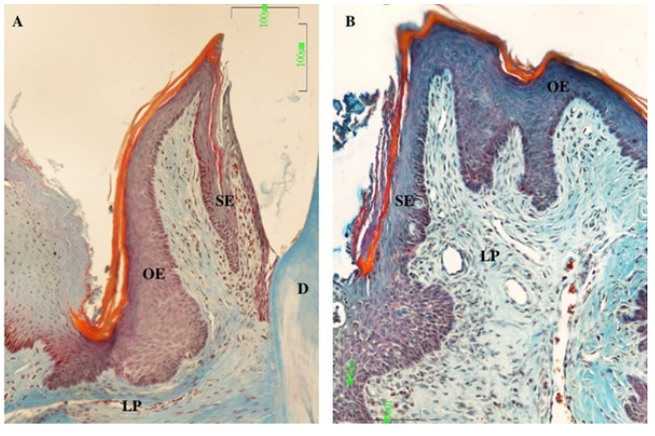

Figure 4. *Sections from the buccal gingiva (Crossmon's three chrome stain). (A) Control-I group. (B) Control-II group.OE: Oral Epithelium, SE: Sulcular Epithelium, LP: Lamina Propria, D: Dentin.*

3.3. Gingival Histomorphometry

The histomorphometric measurements of the gingiva confirmed the histological findings. Table 3 indicates the histomorphometric measurements of the gingiva on the 16th and 31st days.

The 16-day EH, EW, and CTW values in the CsA group were significantly higher than the other groups (P<0.05). However, no significant difference was observed between the groups when the 16-day CTH value was examined (P>0.05). The Tac-I group had similar EH, EW, CTH, and CTW values to those of the Control-I group at the 16th day of the experiment (P>0.05).

Table 3. *Histomorphometric measurements of the gingiva on the 16th day and on the 31st day.*

16th day				31st day			
Measurements (mm)	Control-I (n=10)	CsA-I (n=10)	Tac-I (n=10)	**Measurements (mm)**	Control-II (n=10)	CsA-II (n=10)	Tac-II (n=10)
EH (Mean±SD)	56.45 ± 0.65	59.26 ± 2.19*,†	56.92 ± 0.85	**EH (Mean±SD)**	56.74 ± 0.36	125.82 ± 10.31‡,§,‖	58.61 ± 1.20
EW (Mean±SD)	49.66 ± 1.30	53.99±1.80*,†	49.92 ± 1.17	**EW (Mean±SD)**	49.77±0.84	114.96±2.77‡,§,‖	49.97 ± 1.05
CTH (Mean±SD)	307.88 ± 1.56	311.49 ± 5.75	307.96 ± 2.52	**CTH (Mean±SD)**	307.98 ± 3.02	640.13 ± 6.88‡,§,‖	308.62 ± 2.82
CTW (Mean±SD)	94.61 ± 0.77	100.03 ± 3.41*,†	94.86 ± 2.60	**CTW (Mean±SD)**	94.84 ± 1.60	204.91 ± 16.73‡,§,‖	98.36 ± 2.90

*n: Number, CsA: Cyclosporine, Tac: Tacrolimus, SD: Standart Deviation, EH: Oral Epithelium Height, EW: Oral Epithelium Width, CTH: Connective Tissue Height, CTW: Connective Tissue Width. * Significantly different from the Control-I group (P<0.05); † Significantly different from the Tac-I group (P<0.05).*

‡ Significantly different from the Control-II group (P<0.05); § Significantly different from the Tac-II group (P<0.05).; ‖ Significantly different from the CsA-I group (P<0.05); ¶ P<0.05 was considered statistically significant.

The 31-day EH, EW, CTH, and CTW values in the CsA group were significantly higher than in the other groups (*P*<0.05). The Tac-II group had similar EH, EW, CTH, and CTW values to those of the Control-II group at the 31st day of the experiment (*P*>0.05). However, there were similar linear measurements in all dimensions in the Tac and Control groups at all periods of the experiment (*P*>0.05).

3.4. TRAP Histochemistry

TRAP-positivity was observed as a dark red reaction product in the cytoplasm of osteoclasts located on the surface of the bone trabeculae (Figure 5A-C). This reaction product was not found in the other cells of the bone tissue and the connective tissue. In the CsA treated groups, alveolar bone trabeculae were relatively narrower than in the other groups.

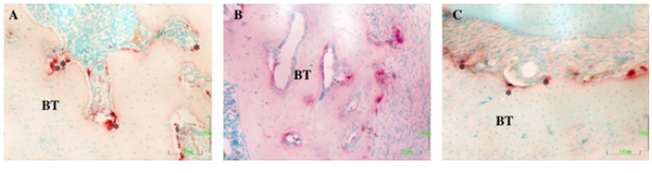

Figure 5. *Sections from the alveolar bone. (A) CsA-II group. (B) Tac-II group. (C) Control-II group.*
*BT: Bone Trabecula, *: TRAP positive osteoclastic cells on the trabecula.*

The 16-day and 31-day TRAP-positivity values of the groups are shown in Table 4. No significant difference was found between the 16-day TRAP-positivity values of the groups (*P*=0.05). However, on the 31st day, the TRAP-positivity values of the CsA group were significantly higher than those of the other groups (*P*<0.05). No significant difference was found between 16 and 31 days in the Tac and the control groups in terms of TRAP-positivity (*P*>0.05). Although TRAP-positivity values in the CsA group at 31 days were higher than those of the 16 days, no significant difference was found (*P*=0.05).

Table 4. *The mean percentage (%) of TRAP-positivity.*

	Control-I (n=10)	**CsA-I (n=10)**	**Tac-I (n=10)**
16th day (Mean±SD)	0.27 ± 0.08	0.44 ± 0.24	0.26 ± 0.08
	Control-II (n=10)	**CsA-II (n=10)**	**Tac-II (n=10)**
31st day (Mean±SD)	0.26 ± 0.07	0.66 ± 0.15*,†	0.26 ± 0.08

TRAP: Tartrate Resistant Acid Phosphatase, n: Number, CsA: Cyclosporine, Tac: Tacrolimus, SD: Standart Deviation.
** Significantly different from the Control-II group (P<0.05).*
† Significantly different from the Tac-II group (P<0.05).
¶ P<0.05 was considered statistically significant.

4. DISCUSSION

In patients using calcineurin inhibitors as immunosuppressive agents to prevent organ transplant rejection, the occurrence of osteopenia has been reported as a common complication (2). However, in these patients, osteopenia has frequently been attributed to the use of glucocorticoids, which often accompany the treatment regimen (22). On the other hand, the results of very few studies using calcineurin inhibitors alone without the use of glucocorticoids are contradictory and the effects on the alveolar bone of both drugs are still unclear (11,14), although Tac has been shown to cause GO less frequently or less severely than CsA (8). Therefore, the purpose of our study is to reveal and to compare the effects of both drugs on the gingiva and alveolar bone. Moreover, revealing the efficacy of these drugs, particularly on the alveolar bone, may be useful in developing new approaches in the prevention and treatment of periodontal diseases in the future.

The major problem in human studies regarding the mechanism of action of immunosuppressants is the inhomogeneity of variables such as genetic predisposition, transplanted organs, age, duration and dose of treatment (5,23). Since the patients taking the immunosuppressants use a number of concomitant drugs, the effect of each drug individually may not be fully revealed. In our study, an experimental rat model was chosen to overcome these difficulties. Furthermore, quantitative histological evaluations have been

shown to be among the best methods of showing the effect of drugs on tissue (24). Our study presents novelty with the histopathological evaluation of TRAP levels. Although there are animal studies evaluating the effects of both CsA and Tac on the alveolar bone, TRAP levels were evaluated in serum but no histopathological evaluation was made (12,13,23).

CsA and Tac have been administered by different methods when using drug-induced GO models in animals. It has been reported that different degrees of absorption occur in perioral administration and the serum level of the drug administered perorally is not sufficient to provide immunosuppression (25). In intraperitoneal administration, CsA has been shown to have negative side effects associated with high concentrations (25). Subcutaneous administration in male rats was chosen in our study in order to obtain a more consistent cycle. The risk and severity of drug-related GO tend to be higher in men (26). In an animal study (26), male rats were found to be more prone to nifedipine-related GO than were females. Although the serum levels of the drugs used in the present study were not measured, the doses of both drugs have previously been shown to provide sufficient and constant levels in serum to produce immunosuppression in rats (16,17,25).

In the present study, GO was prominent on the 16th and 31st days following the subcutaneous administration of CsA 10 mg/kg/day. GO related to CsA is a well-established phenomenon in the literature (9,27,28). In our study, gingival measurements in all dimensions were greater in the groups administered CsA compared to the other groups, and this finding is in accordance with previous studies (5,13,29).

There is limited information in the literature about the effect of Tac on GO. Costa et al. (9) reported lower prevalence and severity of GO for Tac than CsA and other authors suggested that Tac did not cause GO (5,13,29). In accordance with these studies, the groups administered Tac did not develop statistically significant GO in our study. In addition, the gingival parameters measured in the Tac groups were quite similar to those in the control group on both the 16th and 31st days (P>0.05). Nassar et al. (30) reported that Tac did not cause GO over 120 days of drug use, whereas Tac-induced GO started from the 180th day and continued through to the 240th day of the experiment. They suggested that Tac-induced GO in rats may be time-related. This report supports our findings that Tac has no GO effect in short term use. In the study of Prabhu et al (4), which has a similar design to our study, the GO in the Tac group in rats on the 16th and 31st days was lower than that of the CsA group, in accordance with our study. However, the dose of CsA administered in their study was 30 mg/kg/day and both drugs were given to the rats via gavage.

In accordance with previous studies, in our study CsA caused a significant increase in TRAP positivity, which is a bone resorption parameter. However, in our study, Tac had no significant effect on TRAP. Consistent with the results of our study, in the study of Spolidorio et al. (13), in addition to marked gingival growth due to CsA on the 60th and 120th days, bone resorption, serum TRAP levels and the osteoclast count were significantly higher than in the other groups. In our study, TRAP-positivity was found to be significantly higher in the CsA-treated group than in the control and Tac groups. In both studies, no difference was found between the Tac and control groups in terms of TRAP levels. These results show that Tac does not cause significant bone resorption. However, it should be emphasized that studies examining the impact of Tac on bone metabolism are still contradictory. In other studies that showed an increase in serum TRAP levels, it has been found that Tac increases bone resorption and causes osteopenia (12,23). The variety of parameters such as the age and weight of the animals, the nature of the bone, the method of evaluation, the duration and dose of the drug in these studies seems to give rise to different results.

The findings of this study have to be seen in light of some limitations. One of the study's limitation is the small sample size of the rats. Though the sample size meets the adequacy criterion, authors believe that taking a large sample in each group might have improved the results of the study as well as the generalizability of the study. The data from our study should be used to design larger confirmatory studies. The second limitation of our study is the difficulty in adapting the results of our study, which is an animal experiment model, to clinical applications in humans. We should be careful in interpreting and drawing conclusions based on data obtained from animals due to genetic and environmental divergence. The last limitation of our study is the lack of the long-term drug-administered groups. The effects of both calcineurin inhibitors on GO and bone metabolism depend on the dose and duration of administration. Further studies are needed in order to understand the effects of CsA and Tac on GO and bone metabolism.

5. CONCLUSION

In conclusion, within the limitations of our study, Tac does not cause GO and alveolar bone resorption. Using Tac for a longer period of time may cause gingival overgrowth, which reveals the importance of the duration of the treatment in terms of its side effects. We suggest that Tac may be an alternative to CsA to prevent gingival overgrowth and alveolar bone destruction, given the side effects of CsA.

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Clinical and Experimental Health Sciences

Pragmatic Language Disorders Resulting from Semantic Degradation in Patients with Alzheimer's Disease

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ABSTRACT

Objective: The aim of this study is to create an inventory of pragmatic language disorders specific to Alzheimer's disease (AD), to illustrate them by case examples, to determine the severity of disorders according to the stages of Alzheimer's, and to specify the impact of patients' demographic characteristics on the pragmatic disorders experienced by them.

Methods: The study adopted a descriptive research design. The sample was selected using the stratified sampling method. Interviews were conducted with the patients using the free association technique. The feedbacks from the participants were collected as audio recordings and transcribed using the SALT program. The findings were analysed and compared with the control group data, and the conclusion was drawn from the results obtained.

Results: In the course of study 19 types of pragmatic language disorders of AD patients were identified. The differences between the pragmatic disorders detected at various stages of the disease were illustrated in detail using case examples, and the effect of the demographic variables on the disorders was determined.

Conclusion: As a result of the research, pragmatic language disorders resulting from semantic degradation experienced by AD patients were identified. It was found out that the early stage of AD is characterised by mild pragmatic disorders, which tend to get more distinct at the middle stage and even more severe at the late stage. In addition, it was determined that the demographic characteristics of patients have an impact on the severity of pragmatic language disorders.

Keywords: Dementia, Alzheimer's disease, semantic degradation, pragmatic language disorders.

1. INTRODUCTION

The American Psychiatric Association describes dementia as being a complex of mental and behavioural disorders, comprising one or more executive dysfunctions such as aphasia, apraxia, and agnosia, and exhibiting clinical features such as memory impairment (1,2).

The most common type of dementia is Alzheimer's disease (AD), corresponding to about 60% of cases (3,4). AD, characterized by cognitive dysfunctions, is a progressive neurodegenerative disease (5). The most prominent feature of AD is forgetfulness observed from the very beginning of the disease (6). Neuropathological changes in AD include senile plaques formed by deposits of diffuse extracellular amyloid, intracellular neurofibrillary tangles, reactive microgliosis and neuron-synapse losses (7,8).

Post-mortem macroscopic examination of the brains of individuals with AD reveals such neuropathological features as cortical atrophy and enlarged ventricles and sulci (9). In the late stages of AD the degeneration spreads from temporal association cortex to the parietal cortex, and from there to the frontal cortex and eventually to other areas of the neocortex (10). In the prodromal phase patients with mild cognitive disorders usually have no functional impairment, however since neurodegeneration affects the large-dimensional neurocognitive network of episodic memory, the patient has a progressive memory impairment that can be detected by neuropsychological methods (11).

Language disorders occurring in AD patients are closely related to the impairment of such functions as memory, attention and abstraction, and they show themselves at an early, middle or late stage depending on the course of the disease. These linguistic disorders also reveal extremely important findings in terms of diagnosing clinical subtypes of dementia (12,13). In the early stages of the disease, individuals usually have fluent speech. Articulation disorders, breakdown of the syntactic structure of language as well as auditory processing disorders and difficulties when reading

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out loud do not fully manifest themselves at this stage (14). Symptoms related to language disorders in the early stages of AD include difficulties with object and action naming, word recalling and finding the correct word. The middle stage is characterised by patients not being able to syllabify and find the appropriate words during communication. This situation shows the loss of conceptual basic perception and abstract information in patients. In the late stages of the disease, the impairment in language functions becomes more severe (6,15-18).

In the early stages of AD, pragmatic language disorders are not much evident. However, as the disease progresses, the symptoms get much more severe and in the last stages of the disease result in the patient's complete loss of the linguistic communication with the outside world (19). The deterioration of the pragmatic component of language in different stages of the disease is closely related to the impairment of explicit memory, which includes episodic and semantic memory, and the loss of the awareness of the distinctive semantic features such as the features and functions of concepts in communication (20,21). As the disease progresses, disconnected speech is observed alongside with the decline in the ability of patients to choose the correct words and use them according to the context (22). Based on these findings, pragmatic language disorders occurring in AD can be said to be the result of semantic memory destruction caused by temporal lobe atrophy experienced by the patient (23-26).

In the light of the facts mentioned above, our research aims at creating a profile of pragmatic language disorders specific to AD, making an inventory of these disorders and illustrating them by case examples, determining the severity of disorders according to the stages of AD, and specifying the impact of patients' demographic characteristics on the pragmatic disorders experienced by them.

2. METHODS

The sample was selected using the 'stratified sampling' method that involves the division of a population into smaller subgroups. After the group that constitutes the population of the study was stratified, the participants were selected from each stratum using a simple random non-proportional stratified sampling method. The study was carried out on 20 patients possessing different demographic characteristics, diagnosed with early, middle and late stages of AD, and staying in the AD Department of one of the elderly care centres in Istanbul, and a control group of 20 healthy aging elderly participants with similar demographic characteristics. The study adopted a descriptive research design. The selection and exclusion criteria of the sample group included having been diagnosed with early, middle or late stage of AD, being in the age range of at least 65 and at most 95, not having undergone language and speech therapy before, not having severe intelligibility and hearing problems. Control group selection and exclusion criteria are as follows: having similar demographic characteristics with the case group, not having any mental problems, not having language and speech disorders, not having undergone language and speech therapy.

Ethical approval was obtained from the Hamidiye Scientific Research Ethical Committee of University of Health Sciences (Approval number: 20/380). After participants and staff members were informed about the research design and any other related issues, question sets related to 'professions, clothes, household items, seasons and food' to be used in the interview were created. Interviews were conducted with the patients using free association technique in order to obtain natural verbal feedback from them. In addition, pictures containing visuals related to the question sets were shown to the patients and the answers of the participants were collected in the form of audio recordings. The audio recordings were transcribed using the 'Systematic Analysis of Language Transcripts (SALT)' program without adding or removing anything. After analysing the obtained written texts, an inventory of pragmatic language disorders caused by semantic degradation was created and the differences between these disorders according to the stages and demographic characteristics of the patients were illustrated by case examples.

3. RESULTS

Pragmatic language disorders caused by semantic degradation experienced by AD patients, which were detected within the scope of the study, were as follows:

3.1. Inability to Understand and Use Abstract Language

1st stage AD patient T.S. said, "İçi sizi, içi beni, içi beni dışı sizi yakıyor" (tries to reproduce the saying "Dışı seni, içi beni yakar" – "Good from far, far from good"). 2nd stage AD patient P.S. said, "Oğlumun, çocukları severler, gülü seversin, oğlum, gülü, başına katlanırsın" (tries to reproduce the proverb "Gülü seven dikenine katlanır" – "There's no rose without a thorn"). When told, "I guess you've grown cold towards such people," 3rd stage AD patient Y.E.A said, "hmmm, I haven't, if I'm cold, I'll put on this".

3.2. Inability to Make up Long Sentences

When asked, "Do you have children, if any, can you talk about them?" 1st stage AD patient S.S. responded, "Yes, I have children, of course I have". When asked what she was going to do that day, 2nd stage AD patient G.H. responded, "I'm here today. Here". When asked, "What did you do in the garden, how was your day?" 3rd stage AD patient F.Ç. said, "Today? It was good, good".

3.3. Repetitions

Perseveration

When asked about her hometown, 1st stage AD patient Z.T. answered, "Erzurum, Erzurum, Erzurum, are you from

Erzurum?" 2nd stage AD patient A.S. said, "Yaşar Nuri Öztürk, professor, professor, professor of theology theology". When asked, "Did you eat? Are you hungry?" 3rd stage AD patient L.H. replied, "eat, I ate, I ate, eat, yes".

Echolalia

When asked "It feels like it's summer, isn't it?" 1st stage AD patient B.B. answered, "It feels like summer, it feels like summer". When asked, "Are you fifty years old?" 2nd stage AD patient G.H replied, "Fifty, fifty, are you fifty, you fifty". When asked, "Where were you born?" 3rd stage AD patient F.Ç. responded, "Were born, were born, were born, were born".

3.4. Inability to Follow a Thread of Conversation

When asked, "This cat is very nice, is it yours?" 1st stage AD patient S.S. said, "Yes, this cat is very nice, I can speak English, yes I did good translations". When asked, "What's the weather like now?" 2nd stage AD patient A.E. replied "Right now I don't stay there". When asked, "What is there in the room?" 3rd stage AD patient F.Ç. said, "They are not mine, this is hotel, hotel".

3.5. Lesser Tendency for Clustering Behaviour

When asked, "What things are brown?" 1st stage AD patient S.S. answered, "A tree", when asked to add anything else, she said, "A tree, a table". When asked, "What other professions are there other than the doctor related to health?" 2nd stage AD patient V.Y. answered, "There is a doctor, there is a nurse, there are those who wear white clothes, in the hospital". When asked, "So what other animals are there in the village?" 3rd stage AD patient F.Ç. responded, "There are sheep, there are animals, running, there are sheep".

3.6. Being Aware of Having Made a Mistake but Not Being Able to Correct It

When asked, "Do you like listening to music?" 1st stage AD patient S.S. said, "Yes, I do. Sorry, I don't like so much". When asked if he was married 2nd stage AD patient F.M.N. said that he wasn't. However, when the interviewer noticed that his records said that he was married, the patient replied, "No, no, yes I'm married". When asked, "Do you have a notebook?" 3rd stage AD patient E.İ. said, "Here is it, I've brought it from above". After being reminded that it was not his notebook, he still said, "No, no, I've just brought it, I've bought it from inside, I've brought it".

3.7. Inability to Grasp the Main Idea of the Conversation

When asked to describe her childhood home, 1st stage AD patient A.Ö. said, "I say, they graduate from their universities. They are not married, that is they are single". When asked if he had any close friends, 2nd stage AD patient V.Y. answered, "I came from there, set off but it took a long time". When asked what her favourite food was, 3rd stage AD patient F.Ç. replied, "I came today today, I'll go here tomorrow. To Paşabahçe".

3.8. Inability to Start a Conversation

After the interview was finished, 1st stage AD patient T.S. asked, "Do you have any other questions?" 2nd stage AD patient E.D. said, "There are red flowers, do you know what their names are?" Patients at the 3rd stage didn't make any attempts to initiate a conversation.

3.9. Inability to Understand the Question Asked

When asked, "Are you in pain?" 1st stage AD patient A.Ö. replied, "They don't give any, look here is the hospital, we stay here but they didn't give any". When asked if she read books, 2nd stage AD patient G.H. responded, "If I had a job related to it, I would speak English brilliantly today, but mine was different". When asked how many children she had, 3rd stage AD patient F.Ç. answered, "I was born in thirty-seven, I'm over eighty".

3.10. Lack of Use of Respectful Language

While 1st stage AD patient T.S. used respectful language when saying, "My deceased husband was a very kind gentleman, he was a retired teacher" and 2nd stage AD patient P.S. used words like "You're welcome" and "Thank you", patients at the 3rd stage weren't found out to use respectful language.

3.11. Frequent Use of the Word "Şey" ("Thing", "Um")

1st stage AD patient T.S. said, "İnönü did um, um, that is, he criticized that he did not enter the war, he said yes, we were hungry, but we didn't lose our fathers". 2nd stage AD patient G.H. said, "Because since um, that is since 12 years old she has experienced great um, difficulty". 3rd stage AD patient F.Ç. said, "I studied only at primary um, um".

3.12. Periphrasis

When asked, "Where does this animal live?" 1st stage AD patient A.Ö. responded, "They have their place. They also have a house. Where they stay, they have a house apart from home". When asked what her job was, 2nd stage AD patient G.H. said, "I do different kind of things, when they ask something I answer, when it is wrong, I correct it, this kind of job you see". When asked if she knew any other neighbourhoods or districts in Istanbul, 3rd stage AD patient F.Ç. said, "It was in Istanbul. The place where our aunt used to live".

3.13. Paraphasia

Semantic Paraphasia

When asked, "So what do you eat the soup with?" 1st stage AD patient A.A. answered, "With fork". When asked if he had an umbrella, 2nd stage AD patient F.M.N. replied, "Umbrella, it is used in summer, umbrella then". When asked, "(by pointing

the window) What is the name of this?" 3rd stage AD patient S.M. answered, "Door, let's open the door, let the air in".

Neologistic Paraphasia

When asked, "What did you use in the field?" 1st stage AD patient Z.T. answered, "These are agricultural *biği* chemicals". When asked, "In which season do we wear warm things?" 2nd stage AD patient G.H. replied, "There is more *assulu* in winter". When asked, "What do we write in the notebook with?" 3rd stage AD patient S.M. said, "With *yeesin*".

3.14. Omitting Words and Predicates in Sentences

When asked, "Do you like reading?" 1st stage AD patient T.S. answered, "I … hmm… every book I can get here. When they come to visit the patients, I even …". 2nd stage AD patient A.E. said, "there was a patient, I would … him, I would examine him". When asked if she liked to watch movies, patient at the 3rd stage of AD F.Ç. answered, "Very much, I wat…, movies, I wat…" (tries to say the verb "seyretmek" – "watch").

3.15. Inability to Answer the Question Properly

When asked, "So what kind of objects are there in the garden?" 1st stage AD patient B.B. answered, "Well that's enough for me, I don't need anything else. I'm not fond of luxury". When asked if she was married, 2nd stage AD patient G.H. replied, "My daughter has 2 children, a son and a daughter, they all went to America". When asked, "Do you know the capital city of Germany?" 3rd stage AD patient E.İ. said, "I do not speak German, I went there for the first time, I worked alone, I came back but I did not learn it."

3.16. Speaking out of Context

When asked, "Where did you live before?" 1st stage AD patient T.S. answered, "I actually used to live in Ankara. I'm from Izmir, though. My son is a doctor here. I was ill. In 2015 my hip bone was broken. I've had a lot of surgery. After the operation, my children hired a caregiver for me. I lost my wife in 2003, it has been sixteen years". When asked, "Who do you live with here, alone? Or with your wife?" 2nd stage AD patient E.D. replied, "I hate fighting with my wife. We shout at each other, then quickly calm down". When asked, "What would you plant in your field in the village?" 3rd stage AD patient Y.K. said, "Cucumber, tomato, pepper. My mom died. My brother died. My sister died. It's not easy, it's very difficult. May God give no one so much pain, that is, death causes much pain. It never comes out of you again. That's how loneliness is".

3.17. Inability to Provide Information and Explanations

No disorder of this kind was observed in 1st stage AD patients participating in the study. When asked, "Why do you think winters are not so cold anymore, especially in Istanbul?" 2nd stage AD patient A.E. replied, "Yes, it is, yeah so the weather is not so much anymore, but it's not cold". When asked to describe her profession, 3rd stage AD patient F.Ç. answered, "Washing like this all the time, doing um like this, my dear".

3.18. Inappropriate and Incorrect Use of Subjects and Personal Endings

No disorder of this kind was observed in 1st stage AD patients participating in the study. 2nd stage AD patient V.Y. said, "Ayna varım, büyük bir aynam" (tried to say, "I have a mirror, a big mirror," but used first-person singular instead of third-person singular). 3rd stage AD patient F.Ç. said "Allaha şükür. Onu hiçbir şeye sıkılmadı bu zamana kadar" (tries to say "Thanks God. I haven't had any problems until now" but used passive voice with direct object and wrong subject).

3.19. Inability to Explain the Working Principles of Tools and Equipment

No disorder of this kind was observed in 1st stage AD patients participating in the study. When asked, "How do you think this clock works?" 2nd stage AD patient P.S., answered, "This shows what time is it, there with these hands". When asked, "How do we write on the notebook with this pen?" 3rd stage AD patient S.M. replied, "This is what does it in a book or a notebook, a pen, now whatever is there of course".

4. DISCUSSION

AD is a progressive neurodegenerative disease, characterized by semantic degradation caused by the aggressive course of cortical atrophy. This degradation results in the impairment of patients' pragmatic functions, representing the most complex component of language. Literature review shows that there are few studies in the field of language and speech therapy in Turkey, especially those dealing with pragmatic language disorders. In order to fill this gap, it is crucial to identify pragmatic language disorders caused by semantic degradation, as recent studies reveal that some types of dementia can be reversed by early diagnosis (27). Since one of the early symptoms of the disease is the deterioration in the ability to use language, this study is important in terms of detecting the disease at an early stage and allowing to start the medical intervention much earlier.

As a result of the study, a significant difference was observed in pragmatic language skills of AD patients compared to the control group. After analysing the transcribed texts, a 19-item inventory of pragmatic disorders resulting from semantic degradation experienced by AD patients was developed. The inventory includes such disorders as inability to understand and use abstract language, inability to make up long sentences, repetitions (perseveration and echolalia), inability to follow a thread of conversation, showing lesser tendency for clustering behaviour, being aware of having made a mistake but not being able to correct it, inability to grasp the main idea of the conversation, inability to start a conversation, inability to understand the question asked, lack

of respectful language usage, frequent use of the word "şey", periphrasis, semantic and neologistic paraphasia, omitting words and predicates in sentences, inability to answer the question properly, speaking out of context, inability to provide information and explanations, inappropriate and incorrect use of subjects and personal endings, and inability to explain the working principles of tools and equipment.

The above-mentioned disorders were found out to differ according to the stages of AD and the demographic characteristics of the patients. It was determined that the early stage of AD is characterised by mild pragmatic disorders, which tend to get more distinct at the middle stage and even more severe at the late stage. In addition, the evidence from this study suggests that patients which have a higher level of education and a daily reading habit and which communicate more with other individuals display lower levels of pragmatic disorders than other patients at the same stage of AD.

The results obtained are consistent with the findings of previous studies. For example, Cuerva et al. examined pragmatic abilities in thirty-four subjects with probable AD and came to the conclusion that AD subjects displayed significantly more severe pragmatic deficits than controls (28). Amanzio et al., Papagno, Rassiga et al., Papagno et al. reported that comprehension of non-literal language in AD patients decreased over time (29-32). Leyhe et al. and Chapman et al. found that AD patients experienced significant difficulty with interpretation of proverbs (33,34). Mentis et al. discussed discourse deficits in AD patients, such as problems with topic management during casual conversational interaction (35). Carlomagno et al. found that AD patients produced confounding and irrelevant information during the communication task (36). Welland et al. reported poorer overall comprehension of narratives in subjects with early-stage and middle-stage AD (37).

Limitations of the Study

The findings of this study have to be seen in light of some limitations. The primary limitation to the generalization of the results is a small sample size. However, the results of this study provide valuable insight about the types of pragmatic language disorders in AD patients.

5. CONCLUSION

The present study confirmed previous findings and contributed additional evidence that suggests that unlike healthy aging elderly people, adults with AD suffer from pragmatic language impairment. It revealed a broad spectrum of pragmatic disorders in AD patients, which were classified into 19 categories. It was determined that the demographic characteristics of the patients as well as their reading habits and quantity of communication have an impact on the severity of the pragmatic language disorders.

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Clinical and Experimental Health Sciences

The Assessment of the Abrasiveness for Resin Composite Finishing and Polishing Systems

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ABSTRACT

Objective: This study was aimed to assess the abrasiveness of 4 composite finishing and polishing systems, on 2 nano-hybrid composite materials.

Methods: Fourty samples were prepared using Tetric EvoCeram BulkFill and IPS Empress Direct composites (Ivoclar Vivadent, Schaan, Lichtenstein). Each group was divided into 4 subgroups (Sof-Lex Disc, 3M, MN, USA; Enhance/Pogo, Dentsply, Konstanz, Germany; OptraGloss, Ivoclar Vivadent; Twist Dia, Kuraray, Tokyo, Japan). Finishing and polishing systems were performed at one side, for 30 s regarding each step. Initial (t0) and final (t1) thicknesses were measured with a micrometer (ME-DI-MIC-25-50-LD Digital External Micrometer, Machine DRO, Hoddesdon, UK). Two-way Anova test and Tukey HSD were performed for multiple comparisons, according to the t1-t0 values. Deem significance was set at p<0,05.

Results: IPS Empress Direct composite presented significantly a greater level of abrasion (52.85 ± 42.26) than Tetric Evo Ceram BulkFill (p<0.001). Significantly a greater level of abrasiveness was observed for Sof-Lex Disc system (91.25 ± 47.22) among all finishing and polishing materials (p<0.001). There was no significant differences in abrasiveness, between Enhance/Pogo – Optragloss (p=0.859), Enhance/Pogo – Twist Dia (p=0.891), and Twist Dia – Optragloss (p=0.440).

Conclusion: Both the type of composite and the finishing and polishing material were considered effective factors for abrasion. The greatest level of abrasiveness was observed for Sof-Lex Disc system (91 µm on average). The abrasiveness for 2-step systems was similar and ranged between 24–36 µm on average. IPS Empress Direct presented a greater level of abrasion on equal terms of finishing and polishing.

Keywords: Abrasiveness, level of abrasion, composite, finishing, polishing.

1. INTRODUCTION

The quality of finishing and polishing procedures is directly related to the longevity of a composite restoration. Accordingly, manufacturers have introduced numerous systems for composite finishing and polishing procedures. *Finishing* is defined as gross contouring or reduction to obtain the required restoration morphology while *polishing* refers to the reduction in roughness and scratches typically created by the finishing instruments (1). Proper finishing and polishing procedures in direct composite restorations are necessary for long-lasting, esthetic result. Lack of these procedures may lead to tactile perception by the patient and plaque accumulation, thereby gingival irritation, staining, and secondary caries lesions (2-4). Previously, 0.2 µ surface roughness was reported as the threshold value to avoid bacterial accumulation (5). Also, it was shown that mechanical properties have a positive correlation with wear resistance, both can be decreased by unpolished restorations (6, 7).

Finishing and polishing procedures are material – and technique-sensitive. The filler content of resin-based composites and the type of finishing and polishing systems used to influence the surface roughness and staining of restoration (1). Whereas, it was reported that the difference in polishability between composite materials is more significant compared to the difference between polishing systems (4). Also, the composite materials polished with finishing systems of the same manufacturer presented less surface roughness and staining, previously (8). Higher surface gloss can be maintained if the operator spends more time in finishing and polishing procedures (4). Contouring and re-shaping of the final restoration are generally performed with diamond or tungsten carbide burs and a more regular surface was reported for tungsten carbide burs compared to the diamond burs (9). However, some operators use polishing systems for this step (4).

Different shapes of finishing and polishing materials have been introduced to provide an effective application for different

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anatomical forms of restorations. These shapes include flame-shaped, points, cups, flexible discs, lenses, brushes, wheels, and spiral wheels in different sizes (4). In addition, they can be made of various materials, such as rubber, silicone, polyurethane, and rubber. To enhance the polishing effect, diamond and aluminum oxide particles are generally embedded in the material (5). Most recently, materials for both composite and ceramic surface polishing were also introduced.

The press-on force is another important parameter influencing the effectiveness while using the finishing and polishing materials (4). Some manufacturers (i.e., Kenda and Shofu) recommend operators to use a specific press-on force, ≤2 N (4, 10). However, it is difficult for the operator to adjust the exact force during the clinical application. Many previous studies have used one-dimensional force, however, the direction of the applied force to the surface is also important (4). Krejci *et al.* used 2.5 N one-dimensional press-on force to evaluate abrasive bristles *in vitro* but didn't describe how the force was stabilized (6). The shape of the polishing material as well as the inclination of the surface to be polished are the parameters influencing the press-on force. In this respect, large flames and cups were reported to conduct greater forces compared to small flames and lenses (4). Heintze *et al.* presented a clinically simulated procedure using a 3D force sensor for evaluating the press-on forces for the first time *in vitro* (4). Each operator has a specific idea of the applied force when using a polishing instrument with a dental handpiece, yet it seems to be quite inaccurate.

There is a lack of knowledge regarding the level of abrasiveness of the finishing and polishing materials in literature. The level of abrasion depends on the press-on force, the type of the polishing material, and the material to be polished. Heintze *et al*. reported that higher forces result in either increase or decrease in the quality of surface polishing, depending on the material being polished (10). They concluded fine particle hybrid composites are press-on force-sensitive, while microfilled composites are not. Accordingly, a greater level of surface material removal, as well as a higher heat generation on the surface can be caused by higher press-on forces (4, 9). Moreover, it may also result in alterations in the optical properties of the restoration, as the width of the covering composite material changes. Therefore, it would be useful for the operator to know the average level of material removal from the surface during finishing and polishing procedures in clinical daily practice.

The aim of this *in vitro* was to evaluate the abrasiveness of various composite polishing systems on equal terms. The h_1 hypotheses were that; [1] the type of composite polishing system influences the level of abrasion, [2] the type of resin composite influences the level of abrasion.

2. METHODS

2.1. Preparation and Distribution of the Specimens

Two nano-hybrid resin composite materials, Tetric EvoCeram BulkFill (A1 body shade, Ivoclar Vivadent, Schaan, Lichtenstein) and IPS Empress Direct (A1 enamel shade, Ivoclar Vivadent, Schaan, Lichtenstein) were used for the preparation of the composite samples (Table 1). A total of 80 disc-shaped samples of 4 mm in diameter and 2 mm in thickness were prepared using silicon molds. Resin composites were condensed into the silicon mold in two layers and mylar strips were placed over the top and the bottom surfaces to avoid oxygen inhibition layer formation (11-13). Excessive material was extruded by condensing the mold in between two glass slides. Polymerization of the samples was performed using a LED curing unit (Valo Grand, Ultradent Products, USA) at irradiation of 1000 mW/cm^2 for 40 s on each side. The light intensity was monitored with a radiometer during the preparation of the specimens (13). Each specimen was notched at two edges 180° apart (single notch at one edge, double notch at the opposite edge) to maintain consistent orientation during the polishing procedures (14). Then the specimens were immersed in water at a constant 37 °C for 24 hours using a dental incubator (9, 11, 13, 15).

Table 1. *Contents and Manufacturers of Resin Composite Materials Finisging and Polishing Systems.*

		Type	Shade	Content	Manufacturer
Resin Composite	Tetric Evo Ceram Bulk Fill	Nano-hybrid	A1 body	Dimethacrylate, barium aluminum silicate glass (0.4 µm and 0.7 µm), ytterbium trifluoride (200 nm), spherical mixed oxide (160 nm), prepolymers (17 % wt), ivocerin light initiator. 80 % wt, 61 % vol, and 17 % isofillers	Ivoclar Vivadent, Schaan, Lichtenstein
	IPS Empress Direct	Nano-hybrid	A1 enamel	Dimethacrylate, barium aluminum fluorosilicate glass (0.7 µm), barium glass, spherical mixed oxide (150 nm), ytterbium trifluoride (100 nm), silicone dioxide (0.04–3 µm, mean 0.55 µm). 78.1 % wt	Ivoclar Vivadent, Schaan, Lichtenstein
Polishing System	Sof-Lex Disc			4-step aluminum oxide embedded flexible disc system. Coarse (55 µm), medium (40 µm), fine (24 µm), and super fine (8 µm).	3M, St Paul, MN, USA
	Enhance/Pogo			2-step aluminum oxide and diamond embedded rubber cup system. Enhance (40 µm), Pogo (7 µm).	Dentsply Sirona, Konstanz, Germany
	OptraGloss			2-step diamond embedded cup and spiral wheel system for both composite and ceramic polishing. Cup and spiral wheel.	Ivoclar Vivadent, Schaan, Lichtenstein
	Twist Dia			2-step diamond embedded spiral wheel system. Pre-polisher (14 µm), high-shine polisher (10 µm).	Kuraray Noritake, Tokyo, Japan

The initial evaluation of thickness (t_0) for each sample was performed for 3 times by a single operator for each sample using an industrial type screw-type digital micrometer (0.001 mm) with 25-50 mm measuring range (ME-DI-MIC-25-50-LD Digital External Micrometer 25-50mm, Machine DRO, The Allendale Group Ltd., Hoddesdon, UK; Figure 1). This device was used as the control method for monitoring the quantitative dental hard tissue loss, previously (16, 17).

Figure 1. *Digital Contact-Type Micrometer*

2.2. Finishing and Polishing Protocol

The resin composite groups were divided into 4 polishing material subgroups randomly (n=10 for each subgroup). Sof-Lex Disc (3M, St. Paul, MN, USA), Enhance/Pogo (Dentsply Sirona, Konstanz, Germany), OptraGloss (Ivoclar Vivadent, Shaan, Lichtenstein), and Twist Dia (Kuraray Noritake, Tokyo, Japan) were used for the finishing and polishing procedures (Table 1). For each specimen, one side was selected and marked for the finishing and polishing (9). The selected surfaces were roughened with 600 and 800 grit sandpapers (Carbimet, Special Silicone Carbide Grinding Paper, IL, USA), respectively to generate standardized initial roughness for the surfaces (12, 18).

A preliminary study was undergone regarding the calibration of press-on force and micrometer measurements with two blind female operators using another 20 samples. A latch-type slow speed handpiece was used with the polishing materials attached (11). Also, both observers measured the thicknesses of 20 samples using the micrometer, before and after the abrasion procedures. After achieving a perfect interclass correlation for both measurement periods (0.999 and 1.000; Table 1), the real polishing procedures were initiated. Operator 1 was selected as the single operator to perform the surface roughening and the finishing and polishing procedures.

All samples were treated with the 4 different finishing and polishing systems (Twist Dia, Sof-Lex Disc, Enhance/Pogo, and OptraGloss) at 10.000 rpm, in dry conditions, by the same operator [Figure 2 (A–D)]. Each material in the systems was used for 30 s in the present study (19). The specimens were rotated (a quarter turn for every 5 s) during the finishing and polishing procedures to equalize the surface contacts. The application was performed in various directions to the whole specimen surface for 30 s. The specimens were rinsed and dried between steps to remove the polishing debris. Also, the finishing and polishing materials were renewed for each composite specimen (19).

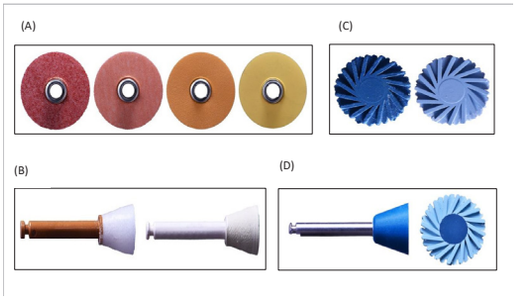

Figure 2 *(A – D). The Polishing Systems Used in the Study. (A) Sof-Lex Disc, (B) Enhance & Pogo, (C) Twist Dia, (D) OptraGloss.*

The four-step Sof-Lex Disc system includes 4 aluminum oxide (Al_2O_3) embedded discs and each was used for 30 s on both sides at dry conditions (14, 20). The discs including thick to thin grains (55 µm, 40 µm, 24 µm, and 8 µm) were used respectively for each specimen (11). The two-step Enhance/Pogo system includes two Al_2O_3 and diamond embedded silicon cups (11) and each was used for 30 s on both sides at dry conditions. Enhance cups with 40 µm grains were used first and followed by Pogo cups with 7 µm grains (13). The two-step Twist Dia system includes two diamond-embedded spiral wheels and each was used for 30 s on both sides at dry conditions. The dark blue pre-polisher wheel including 14 µm grains was used first and followed by the light blue high-shine polisher wheel including 10 µm grains (12, 21). The two-step OptraGloss system includes one diamond-embeded cup and one diamond-embedded spiral wheel. Each was used for 30 s on both sides at dry conditions. The dark blue cup was used first and followed by the light blue spiral wheel.

The specimens were cleaned from debris and the final evaluation of thickness (t_1) was performed by the same operator 3 times for each sample using the digital micrometer.

2.3. Statistical Analysis

Data were analyzed using IBM SPSS V23 software. The normality of data for the composites and the finishing and polishing materials was observed with the Shapiro Wilk test. The correlation between the two operators regarding the polishing procedures and the reliability of the calculations of the two observers were observed with ICC. The two-way Anova test was used for the evaluation of abrasion level according to the composites and polishing materials. Multiple comparisons were evaluated with Tukey HSD. Standard deviations were presented as average ± S.D. Deem significance was set at p<0,05.

3. RESULTS

A perfect, positive correlation was observed between the two blinded observers for both observation periods (p<0.001 for each; Table 2). Therefore, the average values of the measurements of observer 1 were taken into consideration for the statistical analyses.

Table 2. *ICC Results (Correlation between the two blind observers)*

Measurement Period	ICC (%95CI)	p
Before abrasion	0.999 (0.999-1.000)	<0.001
After abrasion	1.000 (1.000-1.000)	<0.001

Both the type of composite and the finishing and polishing material, were considered effective factors for abrasion (p=0.014, p<0.001, respectively). Moreover, polishing material was found a more effective factor than composite. However, composite – polishing material combination was not considered an effective factor on abrasion (p=0.533).

The average abrasiveness observed for the Sof-Lex Disc system for 120 s of application, was 91.25 µm, whereas it was 24–36 µm for Enhance/Pogo, Optragloss, and Twist Dia for 60 s of application (Table 3).

Table 3. *Descriptive Statistics and Multiple Comparisons Regarding Composites and Polishing Materials. The Level of Abrasion was Defined as µm.*

Polishing Material	Composite		Total
	Tetric Evo Ceram Bulk Fill	IPS Empress Direct	
Enhance/Pogo	24.10 ± 13.45^{x}	36.20 ± 13.05^{x}	30.15 ± 14.32^{a}
SoftLex Disc	77.30 ± 38.40^{x}	105.20 ± 52.92^{x}	91.25 ± 47.22^{b}
Optragloss	29.50 ± 11.72^{x}	43.70 ± 20.68^{x}	36.60 ± 17.91^{a}
Twist Dia	22.30 ± 6.60^{x}	26.30 ± 10.47^{x}	24.30 ± 8.76^{a}
Total	38.30 ± 30.84^{A}	52.85 ± 42.26^{B}	

A-B: No significant difference was found between the composites with the same letter; a-b: No significant difference was found between the finishing and polishing systems with the same letter; x: No significant difference was found for the composite and finishing and polishing system interactions with the same letter.

In terms of composite materials, IPS Empress Direct (52.85 ± 42.26) presented significantly a greater level of abrasion than Tetric Evo Ceram Bulk Fill (38.30 ± 30.84) (p<0.001). In terms of finishing and polishing materials, Sof-Lex Disc (91.25 ± 47.22) presented a significantly greater level of abrasion among all (p<0.001) (Table 3). There was no significant differences between Enhance/Pogo – Optragloss (p=0.859), Enhance/Pogo – Twist Dia (p=0.891), and Twist Dia – Optragloss (p=0.440) (Table 3). The combination of Sof-Lex Disc with IPS Empress Direct showed the highest level of abrasion (105.20 ± 52.92), whereas the combination of Twist Dia with Tetric Evo Ceram Bulk Fill showed the lowest (22.30 ± 6.60) (Table 3).

4. DISCUSSION

The abrasiveness of the finishing and polishing materials is very important, as the objective in composite restorations is to obtain the maximum surface smoothness with minimum surface material loss, clinically, especially when performing the additive layering technique rather than the subtractive technique (22, 23). Accordingly, several previous studies have observed the effectiveness of composite polishing systems on surface smoothness or color stability (5-9, 12, 13, 20, 24-26). However, there is a lack in the studies regarding the evaluation of the level of abrasiveness of these materials. The method used to monitor the quantitative abrasiveness of finishing and polishing systems in the present study was not common. But, monitoring with the contact type digital micrometer, was previously used *in vitro* and *in vivo*, for evaluating bruxism-related incisal hard tissue loss quantitatively, as the control method (16, 17).

The type of the polishing material was reported to influence the final surface roughness, however, the influence for the type of composite material is controversial (26, 27). With regard to our results, the level of abrasion also varied among the composite finishing and polishing systems. Also, the level of abrasion varied among the composite types. Therefore, the h_1 hypotheses were accepted. However, the finishing and polishing material was considered a more effective factor influencing the level of abrasion compared to the composite type.

Current composite polishing systems in the market include only a single step or up to 4 steps with various grit sizes (11, 20, 27, 28). Moreover, some of these systems include only polishing materials with only fine grits, whereas, some include both finishing and polishing materials with fine and coarse grits. The systems including only composite polishing materials might also be combined with another material that can be used for the finishing procedure. Therefore, these should be taken into consideration for the comparison of the effectiveness as well as the abrasiveness of these systems. It has been shown that single-step polishing systems can be as effective as multi-step techniques, according to the finishing quality before the polishing (9, 20, 26). Fine diamond burs, tungsten carbide burs, Arcansas burs, or rough polishing discs can be used as additional finishing materials to smoothen the composite surface (9, 29). A greater level of abrasiveness was reported for the finishing materials than the polishing materials (9). All the composite polishing systems in the present study included finishing and polishing steps to obtain a fair evaluation. According to the the literature, the polishing time for even the same polishing system may vary from 5 to 40 seconds (10). Whereas, only 5 s was reported to be enough for the greatest improvement on surface roughness, clinically, depending on the press-on force, type and shape of the finishing and polishing material, and also type of the resin composite (10). In this study, all systems were used at 10.000 rpm (4) and dry conditions according to the instructions of the manufacturers. As the surface roughness, as well as the abrasiveness, are time-dependent (10), each step in the systems was used equally for 30 s to evaluate the total abrasive effect of each step of the system and also to achieve a standardized and maximum surface smoothness.

The effectiveness in the surface smoothness and the level of abrasiveness might not be directly proportional every time and sometimes might even be inversely proportional. Regarding the polishing material, the flexibility of the material and the hardness and grain size of the abrasive particles influence the polishing quality, as well as the level of abrasiveness (26,

29, 30). The grain size of the abrasive particles should be harder than the filler particles of the material for an effective finishing and polishing procedure (25, 29, 30). Otherwise, the polishing material removes the organic matrix from the surface and the filler particles will remain as protrusions, open to staining (27). Therefore, synthetic rubber, silicon carbide, aluminum oxide (Al_2O_3), or diamond particles were generally used as the abrasive particles in many composite finishing and polishing systems (14, 29, 31). Recently, a new two-step diamond-embedded polishing system Optragloss, including both finishing and polishing materials, was introduced with the claim of effectiveness for polishing of both resin composite and ceramic restorations, clinically. It might be interpreted that, this system includes abrasive particles harder than the hardness of ceramic materials, which might increase the level of abrasion for resin composite materials. In this study, one Al_2O_3 embedded, one Al_2O_3 and diamond embedded, and two diamond-embedded finishing and polishing systems were used to evaluate the level of abrasiveness on resin composites. According to the results, significantly the greatest level of abrasion was observed for the Al_2O_3 embedded Sof-Lex Disc system ($p<0.001$; Table 3). In terms of the surface smoothness, the previous gold standard considered Sof-Lex Discs system (20, 25, 31), had probably a disadvantage regarding the level of abrasiveness, due to the containing of a 55 µm grit size disc. Also, the number of steps, as well as the total application time for the Sof-Lex Disc system, were two-times longer (4 steps / total of 120 s) than the other systems (2 steps/total of 60 s), which might have influenced the outcome. Therefore, it might be interpreted that, the abrasiveness of a finishing and polishing system was grit size and also finishing and polishing step dependent. Accordingly, it might be better to decide the number of steps to use in a finishing and polishing system, according to the smoothness of the restoration surface rather than the instructions for use. To reduce the level of abrasiveness, after evaluating the level of surface smoothness of the restoration, it might be better to use the 4-step Sof-Lex Disc system as a 3-step system, by extracting the coarse disc (55 µm), as some researchers did previously (11, 19).

Regarding the results, an unexpected outcome was about the 2-step composite and ceramic polishing system, the Optragloss. Although the observed abrasiveness of OptraGloss system (36.60 ± 17.9) was higher than the Enhance/Pogo system (30.15 ± 14.32), and followed by the Twist Dia system (24.30 ± 8.76), there was no significant difference among these polishing systems ($p<0.05$; Table 3 and 5). Marigo *et al*. reported that the type of the abrasive particles is an effective factor for the surface gloss (31). Unlike the number of steps, the harder abrasive particles in Optragloss did not significantly affect the level of abrasion. However, although it was not statistically significant, there was a quantitatively higher level of abrasiveness for OptraGloss, compared to the Enhance/Pogo and Twist Dia (Table 3). This difference might be because of the use of the high grain, dark blue, diamond embedded cup with greater abrasive particle hardness, which was suggested for the polishing of zirconium oxide (ZrO_2) and lithium disilicate glass-ceramic (LS_2) materials according to the manufacturer's instructions (29, 30). Moreover, the cup shape might have an affect to enhance the abrasiveness, in agreement with Heintze *et al.* (4). But, without using the cup with coarse grit, only the light blue spiral wheel with fine grit can not be enough for both finishing and polishing procedures of resin composites in this system. Therefore, in the present study, both cup and spiral wheel in OptraGloss were used as a two-step finishing and polishing system. Nevertheless, the abrasiveness was not different compared to Enhance/Pogo ($p=0.859$) and Twist Dia ($p=0.440$) systems.

The quantitatively greater level of abrasiveness for Enhance/Pogo compared to Twist Dia, might be because of the differences in the abrasive particle type and size in these systems (Table 3) (26). Enhance/Pogo contains both the Al_2O_3 (40 µm) and diamond (7 µm) abrasive particles (11), whereas Twist Dia only includes diamond (14 µm and 10 µm) particles (12), which might explain the greater abrasiveness of Enhance/Pogo for equal application times (26). Also, the spiral wheel shape of Twist Dia polishing materials might have reduced the press-on force, in agreement with Heintze *et al*. (4), and thereby, reduced the level of abrasiveness. According to Heintze et al. (4), other than press-on force advantage, the spiral wheels might have a good advantage for clinical application on curved dental surfaces. The shape might also effect the greater abrasiveness of the Sof-Lex Disc system in the present study. In accordance with Heintze *et al.* (4), the shape of the polishing system was considered an influencive factor for the effectiveness, in various researches, previously (10, 26, 28). Sof-Lex Disc system included flat flexible discs, while other systems included rubber cups and/or flexible spiral wheels, which were reported to act as more pressure absorbers compared to the elastic paper discs (4, 26, 28). The discs and spiral wheels generally bend and counteract the increase in pressure while performing, whereas they act more rigidly while polishing the cups (10). However, regarding our results, this pressure absorbance factor might have not been as effective as the finishing and polishing step factor to inhibit the greater level of abrasiveness of the discs. Because a greater level of abrasion was observed for the Sof-Lex Disc system among all. Additionally, the material surfaces were flat in this *in vitro* study, and considering the round dental surfaces, the abrasiveness of the disc-shaped materials might be much higher, clinically (26, 31).

The spiral wheels such as Twist Dia and Sof Lex Spiral (3M, St. Paul, MN, USA) were considered as effective as the 4-step Sof-Lex Disc system, regarding the color stability of resin composites, with a shorter polishing time advantage, recently (26). However, only 3-4 % of the dental practitioners in the US were reported to prefer spiral-shaped materials (4). Accordingly, the spiral shaped polishing materials with shorter application time, low level of abrasiveness, and good adaptation on curved dental surfaces might be preferred in daily clinical practice confidently.

Regarding the resin composite materials used, significantly a greater level of abrasion was detected for IPS Empress Direct

(52.85 ± 42.26) compared to Tetric Evo Ceram Bulk Fill (38.30 ± 30.84) ($p<0.001$; Table 3). Both of the resin-based materials used in this study were nano-hybrid composites with a similar organic matrix, whereas the filler contents were not the same (Table 1). The surface micro-morphology of resin composites following the finishing and polishing procedures was reported to be influenced by the size, amount, and hardness of the filler particles, previously (26, 30). The filler ratio of IPS Empress Direct (78.1% wt) and Tetric EvoCream Bulk Fill (80% wt) materials was close, therefore the 1.9% wt difference can not be the only reason of Tetric EvoCream Bulk Fill be more resistant to abrasion, concerning our results (Table 1). However, the prepolymers (17% wt) in Tetric EvoCeram Bulk Fill which increase the strength and reduce the volume shrinkage (15), are not included in IPS Empress Direct enamel shades. Also, IPS Empress Direct enamel shades do not contain additional coarse (0.7 µm) barium glass fillers, unlikely which Tetric EvoCeram contains to increase the strength (15). Although the coarse barium glass fillers were reported to cause increased surface roughness previously (15), in terms of the level of abrasion, it might act as an advantage. The lack of these two fillers might be the reason for the greater level of abrasion for IPS Empress Direct in our study. Additionally, a photo-initiator system (Ivocerin – a dibenzoyl germanium compound) in Tetric EvoCeram Bulk Fill might contribute to the abrasion resistance by enhancing the depth of cure as well as the degree of conversion (Table 1) (32). In a previous study, the surface properties were considered statistically similar for IPS Empress Direct enamel and Tetric EvoCeram Bulk Fill composites, after toothbrush abrasion (33). This result might be interpreted that, the level of abrasion for both composites were similar. Opposingly, according to our results, the level of abrasion was higher for IPS Empress Direct enamel. Also, the combination of the most abrasive considered 4-step Sof-Lex Disc system with IPS Empress Direct composite presented the greatest level of abrasion. On the contrary, the combination of the least abrasive considered two-step Twist Dia with Tetric Evo Ceram Bulk Fill presented the lowest level of abrasion (Table 3).

Standardization in the press-on force has been an important topic for the *in vitro* studies about polishing materials. Antonson *et al.* reported no statistical difference among male and female operators for polishing previously (11), whereas Heintze *et al.* considered female dentists using lower press-on force than male dentists and the average moderate hand pressure as 2 N, more recently (4). In this study, to calibrate the press-on force and micrometer measurements during the finishing and polishing procedures, a preliminary study was undergone by two blind female operators, on 20 other samples. Micrometer calibration was achieved by measuring the thicknesses of the 20 samples three times, before and after abrasion procedures. The average values were considered for the anlayses. Also, a perfect interclass correlation was observed for both measurement periods (0.999 and 1.000; Table 1), therefore the real polishing procedures were initiated with operator 1.

In the present study, the assessment of the effectiveness of dental polishing systems was generally tested *in vitro* on flat specimen surfaces, using dental handpieces, with a defined rotation speed and a predefined polishing time (4). However, the polishing procedure is a dynamic task, clinically (4). Especially for the occlusal surfaces, as the material moves on curved tooth surfaces, the press on force also fluctuates depending on the angle of the curve and the shape and hardness of the material (4, 10). Therefore, the conditions of *in vitro* studies might not simulate the clinical conditions. It might be better to monitor the press-on force while performing abrasion procedures for further studies. Also in the present study, the finishing and polishing systems were used including all the steps to compare the total effects of the systems. However, reducing the number of steps may alter the outcome clinically. Moreover, more proven abrasion monitoring methods such as optic profilometer, AFM, and SEM should be used for further studies to crosscheck the outcomes. Also, resin composites in different brands and types, and finishing and polishing materials in different brands and shapes might influence the level of abrasiveness.

5. CONCLUSIONS

Within the limits of this study, both types of composite and finishing and polishing material were considered effective factors for surface abrasion. The 4-step Sof-Lex Disc system presented the greatest level of abrasiveness (91 µm on average) among all, for 120 seconds of application. The abrasiveness of Enhance/Pogo, Optragloss, and Twist Dia was similar and ranged between 24 – 36 µm on average, for 60 seconds of application. IPS Empress Direct presented a greater level of abrasion than Tetric Evo Ceram Bulk Fill regarding finishing and polishing procedures on equal terms.

Conflict of Interest

The manuscript has been read and approved by all the authors. No potential conflict of interest was reported by any of the authors in this study.

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Clinical and Experimental Health Sciences

Can Hypo-osmotic Swelling Test (Host) Improve Pregnancy Outcomes in Unexplained Iinfertility Patients with Normal Semen Parameters Undergoing ICSI –Frozen Embryo Transfer Cycles?

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ABSTRACT

Objective: The objective of this study is to compare the pregnancy outcomes of the couples who underwent Hypo-Osmotıc Swelling Test (HOST) as a sperm selection method in Intracytoplasmic sperm injection (ICSI) – Frozen embryo transfer (ET) cycles and those who did not.

Methods: ICSI – Frozen ET cycles, employing HOST as a sperm selection method were assigned to the Study Group; whereas those not employing HOST were included in the Control Group. Both study and control groups were divided into two subgroups according to the age of the women; those between the 25-35 years old and those between 36-40. The study and the control group included 509 and 1304 patients; respectively. Patients between 25-40 years old, who received Invitro fertilization (IVF) treatment for the first time, had good quality (grade A) blastocyst embryo on the 5th day, had normal semen parameters and HOST scores of b, c, and d were included in the study.

Results: Pregnancy outcomes were comparable between cycles using HOST and not using HOST in 25-35 years group. However, cycles employing HOST showed significantly higher pregnancy rate (p = 0.023), clinical pregnancy rate (p = 0.005), and live birth rate (p = 0.045) as compared to cycles not using HOST, in the 36-40 years group.

Conclusion: With normal semen parameters, the use of HOST in ICSI-Frozen ET cycles does not increase live birth rates in women aged 25-35, while it increases the rate of live births in women aged 36-40.

Keywords: Hypo-Osmotic Swelling Test, Infertility, Pregnancy Outcomes

1. INTRODUCTION

In the area of contemporary assisted reproductive Technologies (ART), the most commonly preferred technique to help infertile couples conceive is the intracytoplasmic sperm injection (ICSI), through which an oocyte is fertilized by a single spermatozoon injection. Although the diagnostic criteria used to define male factor infertility fail to predict under-fertilization in assisted reproductive technology (ART) with excellent accuracy studies, they support the safety and efficacy of ICSI for treating a variety of male factor conditions. (1-3)

The impact of the quality of oocyte and spermatozoon on subsequent fertilization potential and embryo development is undisputed. Sperm selection techniques for Invitro fertilization (IVF) aim to isolate sperm cells that are characterized by a high fertilization potential and can later result in a successful pregnancy. Conventional semen analysis is an essential investigative tool in the evaluation of the male fertility; however the predictive value of this test on reproductive outcomes with ART remains poor (2). Therefore, the need to develop new markers of sperm DNA integrity and the importance of sperm DNA integrity in human fertility is increasingly recognized, and more advanced methods are used to address specific and complex infertility cases to achieve higher live birth rates (4-6).

Intracytoplasmic sperm injection (ICSI) was originally developed as an adjunct to in IVF for couples with severe male infertility, but is now also used in clinical practice in couples with mild male or even unexplained infertility. In the ICSI technique, a spermatozoon is mechanically injected into an oocyte to ensure fertilization. The only sperm selection criteria for ICSI are morphology and mobility as observed under the microscope (7), it has been shown to have significant false-negative rates and sperm cannot predict chromatin integrity (8). In fact, up to 11% of men with a normal semen analysis have a visible sperm chromatin fragmentation (SCF), which can affect 5% of men with semen parameters above the 50th percentile (9,10). For this reason, advanced sperm screening techniques before ICSI attract more attention due to the disappearance of the natural selection process (11).

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Numerous sperm selection methods have been proposed to reduce the possibility of fertilization by DNA-damaged sperm. The hypo-osmotic swelling test (HOST) was originally developed as a diagnostic sperm test to assess the functional integrity of the sperm plasma membrane, as it plays an integral role in sperm capacitation, acrosome reaction, and attachment to the oocyte surface. Water (fluid) passes through the sperm membrane and causes swelling in the tail of living sperm (12) HOST has been proposed as a simple, safe, low-cost and reliable method for determining viable and intact spermatozoa (13) and is currently used as a reliable indicator of sperm quality in clinical practice (14-17). Upon spermatozoa's exposure to the hypoosmotic environment, different tail patterns, labeled from "a" to "g" can be observed based on the World Health Organization (WHO) criteria (15).

In this context, HOST has been used in conjunction with ICSI to improve fertilization and pregnancy outcomes in men with severe astheno-zoospermia (18). In ICSI cycles using the HOST method, sperm cells are incubated in a hypo-osmotic solution at 37oC. HOST positive spermatozoa (coiled tails) are then selected and washed. When spermatozoa were selected by HOST before ICSI, the absence of total sperm motility, higher fertilization and implantation rates, and better quality embryos were reported, although they were not statistically significant (19-20).

Objectives

In this study, we aimed to investigate the effect of HOST as a sperm selection method on the reproductive results of couples with normal semen parameters in ICSI – Frozen embryo transfer (ET) cycles.

2. METHODS

This retrospective study included 1813 cycles of IVF with ICSI performed at the Istanbul Sisli Kolan International Hospital IVF Unit and Istanbul IVF Center IVF Unit from March 2014 to May 2019. The data of this eligible cycles was obtained by searching for all 24382 IVF cycles that have been performed during this time. Study was approved by the local ethic committee of Bandirma Onyedi Eylul University (08 May, 2020; 2020-23).

2.1. Patient Selection

Patients who underwent HOST as a sperm selection method in ICSI-Frozen ET cycles have been included in the study group, whereas patients without HOST in the control group. Both study and control groups were divided into two subgroups according to the age of the women; those between the 25-35 years old and those between 36-40. The study and the control groups included 509 and 1304 patients, respectively. Of the 509 patients in the study group, 356 were between the ages of 25-35, and 153 were 36-40. 905 of 1304 patients in the control group were between the ages of 25-35 and 399 of them were 36-40. Inclusion criteria were as follows; patients between 25-40 years old who underwent their first IVF treatment cycles, couples with normal semen parameters and HOST scores of b, c, and d and the cycles with good quality (grade A) 5th day-blastocyst embryo.

All infertile couples were evaluated to detect any endocrine, chronic inflammatory, infectious, anatomical, and chromosomal abnormalities. Endocrine and metabolic evaluation and tests for diabetes, thyroid diseases, hypopituitarism, hyperprolactinemia, luteal insufficiency, and hyperandrogenism were also made. Transvaginal ultrasound was performed to evaluate pelvic anatomy. Also, rheumatoid factor, C-reactive protein, phospholipids, and cardiolipin (Ig M and IgG) antibody levels were evaluated. All patients underwent hysterosalpingography (HSG) for tubal patency or any uterine anomaly evaluation. The karyotypes were studied to detect chromosomal abnormalities. All patients in the study had semen analysis.

Exclusion criteria from the study; patients undergoing fresh embryo transfer, patients with endocrine, chronic inflammatory, infectious, anatomical or chromosomal abnormalities, patients with bilateral or unilateral hydrosalpinx and/or structural anomalies in the uterus, patients who have previously received IVF treatment, those under the age of 25 and above 40 years of age, patients do not have good quality (grade A) blastocyst embryo on the 5th day, patients who have undergone or need Preimplantation Genetic Screening-Assay / Next Generation Sequencing (PGT-A / NGS), patients who had not received ICSI, patients without HOST score b, c and d and patients with subnormal semen parameters.

2.2. The HOST Procedure

As stated in the WHO 2010 criteria, semen samples were prepared and applied for the HOST procedure. 30 minutes after each sample was taken, they incubated at 35 °C for complete liquefaction. Each sample was evaluated as stated in WHO 2010 criteria, and samples were washed with Multipurpose Handling Medium-Complete (MHM-C) with Gentamicin (Irvine). Then the washed semen sample of each patient was kept at 37 °C for 5 minutes in 150 mOsm hypoosmotic swelling solutions (Multipurpose Handling Medium diluted with the same amount of purified sterile H_20 solution). Scoring was performed from "a" to "g" according to the tail shapes formed as a result of tail swellings of sperm. Sperm's response to hypoosmotic stress, scored as grade "a" if lack of tail swelling and grade "b" to "g" according to various degrees of swelling at the distal end of the tail flagellum, was scored (15). In this study, ICSI was applied with sperms that have b, c, and d scores.

2.3. ICSI-ET Procedure

Controlled ovarian stimulation (COS) was performed with recombinant follicle-stimulating hormone (FSH) (Gonal-F; Merck Serono, Italy) or human menopausal gonadotropin (hMG) (Menopur 75 IU SC/IM, Ferring, USA), with starting doses

ranging from 225 to 375 IU/day, based on the patients' age and ovarian reserve tests, in a GnRH antagonist protocol. A GnRH antagonist, cetrorelix 0.25 mg, (Cetrotide; Merck Serono, Italy) was introduced when a leading follicle achieved 12-13 mm. Final oocyte maturation was induced with 5000 units of IM/SC hCG (Choriomon 5000 IU, IBSA, Switzerland) and/or 0.2 mg of triptorelin (Gonapeptyl daily; Ferring Pharmaceuticals, Saint-Prex, Switzerland) when at least two follicles reached a diameter of 18 mm. Oocyte retrieval was performed 35-36 h after the trigger.

When the oocyte retrieval was completed, the oocytes were placed into the Continuous Single Culture-NX Complete Medium (CSCM – NXC-IRVINE SCIENTIFIC) and incubated in a Miri Benchtop incubator (ESCO) until 38-40th hour of hCG administration. Than ICSI was performed after this procedure. After the ICSI procedure, all oocytes were transferred into the Continuous Single Culture-NX Complete Medium with 10% global protein, and their development was followed until the 5th day. All embryos were cryo-preserved, by vitrification on the 5th day of development, as part of a freeze-all strategy adopted by the IVF Units involved in this study.

Only good quality (Grade A) 5th-day blastocyst embryos were transferred. Embryos were classified as described by the embryo evaluation criteria proposed by ESHRE/ALPHA consensus (21).

Luteal-phase support consisted of 4 mg of oral estradiol valerate (Estrofem tablet, Nova Nordisk, Denmark), 90 mg of vaginal progesterone (Crinone 8% gel, Merck Serono, England) per day and 50 mg of intramuscular (IM) progesterone (Progestan ampoule, Koçak Farma, Turkey) per day. The estrogen treatment was ceased if a positive pregnancy test was obtained, whereas vaginal and IM progesterone regimen continued until the 12th gestational week.

A positive pregnancy was defined as a serum β-hCG level >5 mIU/ml 12 days after embryo transfer. Biochemical pregnancy was described as a serum β-hCG level of 5-40 mIU/ml 16 days following embryo transfer. Clinical pregnancy was defined as a visualization of a gestational sac and/or a vital embryo through transvaginal sonography, 4 weeks after embryo transfer. Delivery of a viable infant of 22 weeks or more was considered as live birth, while deliveries below 22 gestational weeks were defined as abortus.

Statistical analysis

In this study, statistical analysis was performed using the NCSS (Number Cruncher Statistical System) 2007 statistical software (Utah, USA) package program. Descriptive statistical methods, independent t-test in the comparison of two groups with normal distribution, the Mann-Whitney U test in the comparison of two groups without normal distribution, and the Chi-square test in the comparison of categorical variables were used. The results were evaluated as statistically significant if $p < 0.05$.

3. RESULTS

A total of 509 patients underwent HOST, as a sperm selection method. Among couples who underwent HOST, 356 (19.63%) were between 25-35 and 153 (8.43%) were between 36-40 years of age. A total of 1304 patients were not exposed to HOST; 905 (49.91%) and 399 (22.00%) were between 25-35 and between 36-40 of age, respectively. There was no statistically significant difference between the groups in terms of mean ages of women and men (p = 0.553 and 0.696, respectively); Body Mass Index (BMI) (p = 0.532); infertility duration (p = 0.254); antral follicle count on the 3rd day of menstruation, Follicular Stimulating Hormone (FSH) and Estradiol (E_2) values (p = 0.446; 0.600 and 0.128, respectively); duration of the stimulation (p = 0.266); number of the retrieved oocytes, mature oocyte and fertilized oocyte counts (p = 0.336; 0.372 and 0.391; respectively). Clinical and demographic characteristics of the patients are demonstrated in Table 1.

Table 1. *Clinical and Demographic Features of the Patients*

Clinical features	Whole group n=1813	Study Group n=509		Control Group n=1304		P*
		25-35 Age n=356	36-40 age n=153	25-35 age n=905	36-40 age n=399	
Female Age, y	33.38±4.47	30.4±4.51	37.83±2.51	30.81±4.25	37.36±1.56	0.553
Male Age, y	36.44±5.52	36.17±5.69	36.58±5.23	36.47±5.81	36.74±5.37	0.696
BMI	23.84±3.99	23.86±4.37	23.24±4.15	23.81±4.12	23.83±3.97	0.532
Infertility duration, y	5.35±3.63	4.91±3.01	5.83±4.19	4.11±3.81	5.30±4.64	0.254
D_3 AFC, n	8.23±3,45	9.07±2.41	7.25±4.28	9.43±2.73	7.17±4.39	0.446
D_3 FSH, mIU/mL	8.05±3.56	8.03±3.44	8.21±4.29	8.08±3.73	8.25±4.14	0.600
D_3 LH, mIU/mL	8.79±4.22	9±4.49	8.54±3.93	9±4.26	8.44±4.01	0.452
D_3 E_2, pg/mL	49.29±27.67	54.37±32.86	43.62±19.21	54.58±32.18	43.03±19.52	0.128
Stimulation Day, d	10.74±2.15	10.64±1.62	10.86±2.63	10.23±1.76	10.13±2.91	0.266
Number of Oocytes Collected, n	11.16±6.78	11.65±7.23	9.77±6.09	11.91±7.12	9.34±6.61	0.336
Mature Oocytes, n	8.83±5.89	9.91±6.37	7.88±5.29	9.89±6.49	7.76±5.43	0.372
Fertilized Oocytes, n	7.16±5.21	8.59±5.99	6.32±4.35	8.53 ±6.14	6.21±4.12	0.391

**: Pearson's Chi-Square , D_3: Third day of the menstrual cycle, AFC: Number of antral follicles < 8mm, FSH: Follicular Stimulating Hormone, LH: Luteinzan Hormone, E_2:Estradiol BMI: Body Mass Index*

Table 2. *Pregnancy outcomes of study and control groups by age*

	Whole group n=1813	Study Group 25-35 Age n=356	Control Group 25-35 age n=905	P+	Study Group 36-40 age n=153	Control Group 36-40 age n=399	P+
Pregnancy result, n (%)	1230 (67.84)	254 (72.19)	637 (70.3)	0.210	101 (66)	238 (59.64)	*0.023*
Biochemical pregnancy, n (%)	65 (3.58)	13 (3.65)	32 (3.53)	0.152	5 (3.26)	15 (3.75)	0.414
Ectopic pregnancy, n (%)	15 (0.82)	4 (1.12)	6 (0.66)	0.422	1 (0.65)	4 (1.00)	0.602
Clinical pregnancy, n (%)	1150 (6.34)	237 (66.5)	599 (66.18)	0.305	95 (62.09)	219 (54.88)	*0.005*
Abortion, n (%)	237 (13.07)	42 (11.79)	111 (12.26)	0.208	20 (13.07)	64 (16.04)	0.850
Live birth, n (%)	913 (50.36)	195 (54.77)	488 (53.92)	0.383	75 (49.01)	155 (38.84)	*0.045*

+: Chi-square Test, p < 0.05

Of 1813 female patients participating in the study, 1230 (67.84%) resulted with positive pregnancy tests, 65 (3.58%) with biochemical pregnancy, 15 (0.82%) with ectopic pregnancy, 1150 (6.34%) with clinical pregnancy, 237 (13.07%) with abortion and 913 (50.36%) with live birth.

When groups were sub-divided based on age, patients aged 25-35 years with and without HOST the groups were comparable in terms of pregnancy (p = 0.210), biochemical pregnancy (p = 0.152), ectopic pregnancy (p = 0.422), clinical pregnancy (p = 0.305), abortion (p = 0.208) and live birth (p = 0.383) rates. Patients aged 36-40 years with and without HOST, there was no significant difference in the rates of biochemical pregnancy (p = 0.414), ectopic pregnancy (p = 0.602) and abortion (p = 0.850); however, rates of pregnancy, clinical pregnancy, and live birth were significantly higher in couples having undergone HOST procedure (p= 0.023, 0.005 and 0.045; respectively). Reproductive outcomes of the patients are shown in Table 2.

4. DISCUSSION

In this study, we showed that the sperm selection by the HOST method in frozen-thawed ICSI cycles increased the rates of positive pregnancy test, clinical pregnancy, and live birth in 36-40 years aged women group, while the rates of ectopic pregnancy and abortion did not alter. However, the results of our study reveal that sperm selection with the HOST method in women aged 25-35 years does not make any difference in the ICSI results, as compared to the control group. The quality of selected sperm for ICSI is thought to be one of the determining factors for the success of assisted reproductive therapy (22). Given the potential of ICSI to overcome severe male infertility, the use of DNA damaged or apoptotic sperms with normal appearance and motility in ICSI may have a negative effect on fertilization and embryo development (23). Therefore, it has been proposed to select sperms not only according to morphology and vitality but also on the basis of functionality, since DNA damaged or apoptotic sperms reduce the chance of fertilizing oocyte (9,10).

Morphological sperm features are most commonly used methods for selecting sperms to fertilize the oocytes in ICSI cycles. In this study, the HOST technique, selecting live immotile sperms, was employed. This technique is not only used for the selection of immotile sperm but also is one of the most common tests to evaluate the structural and functional integrity of the plasma membrane, which is critical for the fertilization process. It evaluates the ability of the sperm plasma membrane to pass water in the hypo-osmotic state, thereby inducing tail swelling and stretching of the plasma membrane (14-24). In the HOST evaluation, the classification varies from “a” to “g” in 7 different ways according to the tail folding of sperm tails (14,25).

It has been stated that Sodium/ Potassium (Na^+/ K^+) andSodium/Hydrogen (Na^+/H^+) pump in the sperm membrane cause tail swelling by reaction under hypotonic conditions. In sperms with intact membranes, the functional activity of these pumps is minimal in tail swelling, and in the sperms with impaired Na^+/K^+ pump, a complete swelling called HOST grade “g” is observed (13,26).

Stanger et al. show that it is possible to the selection of sperms with robust DNA based on the degree of the HOST (15). Based on the current results, fertilization of “g” class sperms that contain damaged DNA can be avoided through the HOST rating. This selection may be more useful for severe male infertility cases where the percentage of sperm with damaged DNA is higher (8,27). According to these results, Stanger et al. show that sperm percentage with DNA fragmentation is higher in some HOST degrees (13). For this reason, it is recommended to avoid using “g” grade sperm in ICSI and, where possible, use “d” followed by “c” and “b” grade sperm (28). This is why, in our study, we used the sperms with HOST grade “b”, “c” and “d” in the ICSI procedure. In this study, the HOST method was assessed to evaluate the impact of sperm selection in unexplained infertile couples undergoing frozen-thawed ET-ICSI cycles.

Recently, defects in the functional integrity of the sperm membrane, which can be detected with the HOST test, have been shown to increase the rate of implantation failure or spontaneous miscarriage rather than fertilization failure (29). Moreover, ICSI was proposed as an effective therapy

for infertility related to subnormal HOST scores, although, poor morphology did not adversely affect the outcome. Remarkably, significant correlations were observed between the percentage of HOST positive sperm and fertilization, implantation, and pregnancy rates (30).

In our study, we compared the results of frozen-thawed ICSI cycles between those who were and were not treated with HOST in a patient population that was categorized by age, unlike the other studies conducted so far. While our study results indicate that there is no significant difference in pregnancy outcomes among patients aged 25-35 with and without the HOST, it also shows a significantly higher pregnancy outcome, clinical pregnancy, live birth rates after the administration of HOST in women between the ages of 36-40. On the other hand, there is no statistically significant difference in biochemical pregnancy, ectopic pregnancy, and abortion rates in both groups.

Unlike other studies, in our study, it was seen that HOST, which is used as a sperm selection method, created more successful pregnancy rates in elderly population (36-40 years old). Sperm DNA damage is seen less, not seen at all or sperm morphology and motility are better in young patients could be the main reason. Based on the results of previous and current studies, sperm selection based on HOST patterns has been shown to improve sperm quality including chromatin integrity, a low level of apoptosis, and sperm morphology (28). The significantly improved implantation and chemical pregnancy rates, and insignificantly improved clinical pregnancy rate were most likely to be due to the quality of sperm selected by the HOST procedure. Of note, previous literature on IVF couples has also observed significant correlations between the percentage of HOST positive sperm with fertilization, implantation and pregnancy rates (30).

We are aware that this study has some limitations. Principally, its retrospective design makes the study prone to the biases inherent to any retrospective data. On the other hand, the inclusion of freeze-all cycles makes it difficult to generalize the results to the fresh-transfer IVF population. Moreover, since the possible contribution of sperm selection to the success of ART has already been established for male-factor infertility, the necessity of a sperm selection technique in an unexplained infertility population, rather than a male-factor population, is a debatable issue.

5. CONCLUSION

Based on the results of the present study, we suggest that the use of HOST technique in normo-zoospermic men increases the live birth rate in frozen-thawed ICSI-ET cycles in 36-40 aged women group, but not in 25-35 aged group. It also increases the rates of pregnancy and clinical pregnancy in 36-40 years group. Thus, HOST can be recommended as a sperm selection method in ICSI cycles of unexplained infertile couples, where the female age exceeds 36. The HOST method in IVF treatments can be considered as a main way to standardized sperm selection procedure for ICSI.

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Clinical and Experimental Health Sciences

Investigation of Average Values of Prolidase, Adenozin Deaminase, Glutathione S-Transferase and Glutathione Reductase Enzymes in Pancreas Cancers

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ABSTRACT

Objective: The purpose of this study is to determine the relationship between enzymatic antioxidants such as glutathione reductase and glutathione s-transferase and prolidase and adenosine deaminase in patients diagnosed with pancreatic cancer.

Methods: Prolidase, adenosine deaminase, glutathione s-transferase and glutathione reductase activities were determined spectrophotometrically in blood sera collected from patients and healthy control subjects included in the study.

Results: In patients with pancreatic cancer, the mean value of glutathione reductase and glutathione s-transferase enzymes decreased, while the mean value of prolidase, and adenosine deaminase, enzyme activities increased ($p < 0.05$).

Conclusion: In this study, in which prolidase, enzyme activity was first measured in pancreatic cancer, high prolidase, activity can be evaluated as a factor that increases the risk of cancer. Prolidase, adenosine deaminase, glutathione reductase and glutathione s-transferase enzyme activities may play an important role in the etiopathogenesis of pancreatic cancer.

Keywords: Adenosine deaminase, cancer, glutathione reductase, glutathione s-transferase, pancreatic cancer

1. INTRODUCTION

In cancer deaths, pancreatic cancer is in 4th place after lung, colorectal and breast cancer. Ductal adenocarcinoma accounts for approximately 85-90% of pancreatic cancers(1). Pancreatic adenocarcinoma is approximately 1.5 times more common in men than in women (2). The incidence of pancreatic cancer is increasing gradually in all developing countries (3). Especially of this rise is thought to be changes in diet and environmental factors in western societies. These causes make pancreatic cancer an important health problem (4). Diagnosis of pancreatic cancer; laboratory examinations and imaging methods and by pathological examinations are determined. The most important problem in diagnosis: none of the diagnostic methods cannot be detect cases smaller than 2 cm with high sensitivity and specificity. Most of the pancreatic carcinomas are seen in the head of the organ (73.2%) and the other part is in the trunk and tail. While the tumor gives early symptoms at the beginning of the pancreas, Tumors located distally give symptoms very late, and physical examination findings appear only after spreading too much (5 – 6). It was stated that the lesions in the head were mostly 5 cm in diameter, while of the lesions in the trunk and tail were mostly 10 cm in diameter (7). Also, pancreatic cancer has been identified to be more common at advanced ages (8). When the tumor is in the head part of the pancreas, it presses on the collector and patients most times apply to the clinic with the complaint of jaundice. Among the symptoms of pancreatic cancer exist with jaundice, abdominal pain, darkened urine, light-colored stool, weight loss, itching, slimming, and anorexia. In patients with pancreatic cancer has been reported that the risk increases in those who are fed with obesity, high-calorie diet, animal fats and red meat but the risk decreases in those who feed on fruits and vegetables (9).

Prolidase (Pro) (E.C.3.4.13.9) plays a role in the catabolism of proteins containing procollogen, collagen and proline or hydroxyproline in the cell. (10). In the work done have been reported that prolidase plays an important role in physiological and pathological processes such as embryonic development, wound healing, inflammation, carcinogenesis, angiogenesis, cell migration and cell differentiation (11 – 12).

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Adenosine deaminase (ADA) (E.C.3.5.4.4) is an enzyme that catalyzes hydrolytic deamination of adenosine to inosine and of deoxyadenosine to deoxycinosis. (13 – 14). In the studies conducted, it has determined that ADA is very common in all tissues of mammals. The organs where ADA is found most respectively; cerebral cortex, liver, kidney, thymus, spleen and lymph nodules. It is stated that a large part of ADA is present in the cytoplasm of the cells and a small part in the nucleus. It has found that lymphocytes are 10 times more than erythrocytes (15, 16, 17).

Glutathione reductase (GR) (E.C. 1.6.4.2) has an indirect but important task in terms of preventing oxidative damage in the cell by helping to maintain the amount of intracellular glutathione (GSH). Together with the glutathione peroxidase enzyme, glutathione is responsible for lowering the level of harmful hydrogen peroxide in the cell (18). Glutathione reductase inhibitors are applied in the treatment of cancer and malaria (19).

The glutathione s-transferase (GST) (E.C.2.5.1.18) enzyme has been found to be quite common in some organisms. Also GST enzyme different anti-cancer drugs such as chlorambusil, melphalan, cyclophosphamide and mitoxanthene, hormones, hydrocarbons and ethacrinic acid-like endogenous metabolites which diuretic drug, By adding it with GSH, it makes it more easily soluble in water and facilitates its excretion through urine and bile. Also, GST detoxifies harmful ends that occur in lipid and DNA in the presence of oxygen, the last metabolic products of DNA hydroperoxides, alkenol and endogenous electrophilic compounds (20).

The purpose of this study is is to determine the relationship between enzymatic antioxidants such as glutathione reductase (GR) and glutathione s-transferase (GST) and prolidase (PRO) and adenosine deaminase (ADA) in patients diagnosed with pancreatic cancer.

2. METHODS

This non-prospective study was performed according to the modified World Helsinki Declaration. After the receiving of the ethics committee of Van Regional Training and Research Hospital of Health Sciences University (S.B.Ü) dated 13 September 2018 and numbered 13, started to work. This study was done out in the Biochemistry laboratory of the Chemistry Department of the Faculty of Science of the University. The study population is formed from individuals in total of 20 patients with pancreatic cancer and 20 non-cancerous healthy controls, changing ages between 44-75 years, who were diagnosed and followed up in the Van Regional Training and Research Hospital of S.B.Ü. Biochemical parameters; determined with serum samples. Activities of PRO, ADA, GST and GR were determined from the serums separated by centrifugation of the blood samples taken from the patients included in the study.

2.1. Taking samples

Venous blood samples in accordance with the 3 ml method taken from healthy and sick individuals selected as subjects in the study were centrifuged at 5000 rpm / min for approximately 5 minutes and then the serums were separated. Serums were stored at – 80 degree in until examined.

2.2. Biochemical analysis

Determination of prolidase activity (PRO)

Prolidase activity was performed according to the method of appointment proposed by Myara et al. (1982). Then absorbances were read at 515 nm. (21)

Determination of adenosine deaminase activity (ADA)

Adenosine deaminase activity was performed according to the method of appointment proposed by Giustı [1974]. Absorbances of samples and sample blind tubes against pure water at 628 nm were read (22).

Determination of glutathione reductase (GR) and glutathione-s-transferase (GST) activity activity

Glutathione reductase activity was performed according to the method of appointment proposed by Goldberg and Spooner (1983). 100 µl of pure water and 900 µl of daily buffer were placed in the blind tube. 900 µl of daily buffer and 100 µl of serum were added to the sample tube and the tubes were vortexed. Tubes were incubated at 37˚C for 10 minutes. Absorbances were read against the blind at 340 nm at 0 and 5 minutes (23).

Glutathione-s-transferase (GST) activity was performed according to the method of appointment proposed by Mannervik et al. (1981).

2.3. Statistical Analysis

The descriptive statistics for the features mentioned were expressed as mean and standard Deviation. T-Test was used in the comparison of binary groups providing the condition of normal distribution. On the other hand, the statistics of Mann Whitney U test was used when the condition of normal distribution was not provided. Statistical significance level was taken as $p < 0.05$ in calculations and SPSS statistical software was used for calculations.

3. RESULTS

Activities for GR, PRO, ADA and GST are showened in Table 1. When Table 1 is examined, the difference between patient and control group averages was found as statistically significant for GR, PRO, ADA and GST ($p<0.05$).

Average enzyme values for GR and GST are given in figure 1. When Figure 1 is examined, the average enzyme values for GR and GST in the patient group were found to be quite low compared to the control group ($p <0.05$).

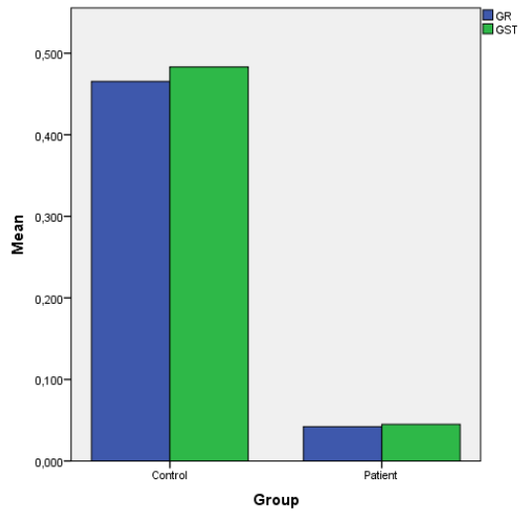

Figure 1. *Average enzyme values for GR and GST in control and patient groups*

Average enzyme values for prolidase and ADA are given in Figure 2. When Figure 2 is examined, the average enzyme values for Prolidase and ADA in the patient group were found to be significantly higher than the control group (p <0.05).

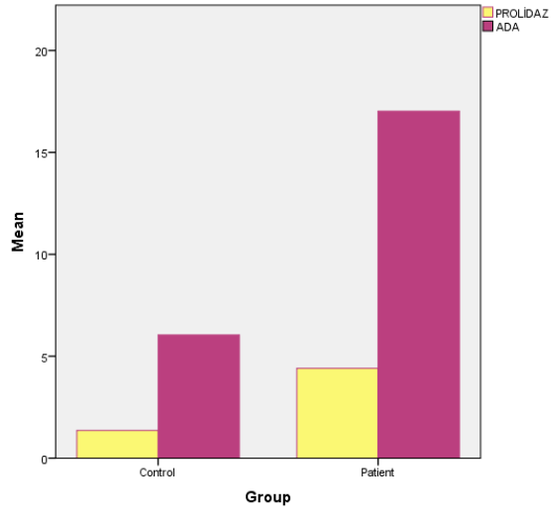

Figure 2. *Average enzyme values for prolidase and ADA in control and patient groups*

4. DISCUSSION

The high prevalence of pancreatic tumors, high level mortality, and surgical resection being still the only cure method make it important to know from the beginning the course of the disease without delay (25).

There are many studies examining the change of enzyme activities in cancerous cells or tissues. Made studies on ADA is the key enzyme of purine metabolism.Its general feature is to detach an amine from adenosine and convert it into inosine irreversibly. Many studies have been conducted on ADA enzyme in different types of cancer. ADA serum activity values were found to be particularly high in lymphoid tissues (26). When compared to normal people in the literature datas,It has been reported that an increase or decrease in activity occurs in cancer patients due to the new regulation of ADA enzyme. In one study, there was no change in the total activity of ADA in some types of cancer. In another study, it was found that DNA-enzyme activity is of great importance in terms of reflecting the cancer cell's form of enzymatic change. This situation has been observed to attract the attention of researchers especially in terms of cancer-enzyme relationship (27, 28, 29, 30).In the literature studies conducted, ADA has found to be increased in tuberculosis (tbc) pleurisy, tbc pericarditis, tbc meningitis, malignancies, parapneumonic fluids and, in addition, collagen tissue disease related in pleural fluid samples (31,32). However, serum ADA studies are still limited.In literature datas, serum ADA activity has been reported to increase in typoid fever, infectious mononucleosis, liver diseases, acute leukemia, brucellosis, pneumonia, rheumatoid arthritis and malignancies (33,34). Change of ADA activity in cancer cells or tissues, In addition to understanding this metabolism, it has been stated that it can assist the clinician in diagnosing the disease, following the treatment or evaluating the prognosis. Total ADA enzyme levels; high performance liquid chromatography can be determined by enzymatic or colorimetric methods. The measurement of ammonia released by the conversion of adenosine to inosine is one of the simplest methods (35). In this study, serum ADA activity was found to be significantly higher in patient group levels than in the healthy control group (p<0.05) (Table1). However, serum ADA studies are still limited.

Table 1. *Descriptive statistics and Comparison results*

	Group	n	Mean±Std. Deviation	p
GR (U/L)	Control	20	0.465±0.112	0.001
	Patient	20	0.042±0.020	
PRO (U/L)	Control	20	1.356±0.203	0.001
	Patient	20	4.409±0.722	
ADA (U/L)	Control	20	6.043±0.135	0.001
	Patient	20	17.023±5.390	
GST (U/L)	Control	20	0.483±0.051	0.001
	Patient	20	0.045±0.032	

As a result in this study, the high ADA activity in the patient group can be considered as a factor that increases the risk of cancer.

GR is a dimer composed of 2 subunits that convert oxidized glutathione into reduced form. Each subunit contains 3 structural areas: NADPH binding area, FAD binding area and interface area. Electrons are often transferred from NADPH to FAD during the reduction reaction of glutathione. It is then transferred to the oxidized glutathione by transferring it to the disulfide bridge between the two cysteines in the subunits. It is then transferred to the oxidized glutathione by transferring it to the disulfide bridge between the two cysteines in the subunits. More studies are needed to determine whether it is useful in preventing or treating GR pancreatic cancer (36). GR is the homodimeric enzyme which on duty involved in the regeneration of glutathione. It is also

important in selenium metabolism (37). In a study conducted by Navarro et al. when mice born with tumors were compared with the control group, there was no significant difference in GR enzyme activity (38). In the study conducted by Tisdale et al., GR activities were found to be high in patients with solid tumors (39). By Yavuz et al. In the study performed which on patients with skin cancer, GR activity was found to be low in accordance with the literature (40). In the another study done, it was found that glutathione reductase activity decreased in diabetes (41). In our study, serum GR activity patient group levels were lower than the healthy control group ($p<0.05$) (Table 1). Consequently, low GR activity in the blood in this study can be considered as a factor that increases the risk of cancer.

GST is an antioxidant which molecular weights are 20,000-25,000 dalton and each subunit consists of 200-240 amino acids. It is applied for the first time by Boyland et al in the rat liver (42). The GST enzyme catalyzes the conjugation of glutathione with toxic metabolites, leading to detoxification of toxic metabolites. GST plays an important role in antioxidant defense system and protective system which is in the fight against many diseases in humans (43). In the study done, it was found that antioxidant GST activities were lower in liver cancer patients compared to control patients (44). In the another study done, antioxidant enzyme activities such as GST were found low in cancer patients (45). In a study conducted by Turan et al., GST activity was found to be low in patients with abortion compared to healthy control groups (46). In our study found that serum GST activity patient group levels were lower than the healthy control group (Figure 1). Consequently, low of GST activity in the blood in this study can be considered as a factor that increases the risk of cancer.

PROis a hydrolase specific to dipeptides with proline (pro) or hydroxyproline (Hyp) at the C terminal. This enzyme plays an important role in collagen and procollogen destruction because it contains abundant (25% Pro and Hyp) in the structure of the collagen (47). Proline takes place in the central nervous system in general (48). In this study, serum pro activity patient group levels were higher than the healthy control group ($p <0.05$) (Table 1). High prolidase activity in the blood can be considered as a factor that increases the risk of cancer.

5. CONCLUSION

As a result, prolidase, adenosine deaminase, glutathione reductase and glutathione s-transferase enzyme activities may play an important role in the etiopathogenesis of pancreatic cancer.

In this study we have done, ADA, GR, GST and Prolidase enzyme activities were measured for the first time in pancreatic cancer. Therefore, we believe that it will make an important contribution to the literature.

* This study was presented as abstract at the International Medical and Health Sciences Research Congress (UTSAK) held at Bandırma University on 11-14 July 2019. page:93

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Clinical and Experimental Health Sciences

Preconception Risk Factors and Preconception Care Practices in a Hospital Based Turkish Sample

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ABSTRACT

Objective: The aim of the study was to evaluate the preconception risk factors that may adversely affect pregnancy outcomes, and preconception care practices.

Methods: A descriptive study was completed with 359 women. The data were collected with a questionnaire that was drawn up by the researchers.

Results: Findings demonstrated that preconception risk factors were advanced age (20.6%), smoking (23.1%), existence of a chronic illness (23.6%) and being overweight (26.7%). Applied to a health institution to receive preconception care was 12.3 %. The most common preconception care practices were the use of folic acid (45.4%) and applying to the doctor for reorganization of the treatment for chronic illness (41.2%).

Conclusion: The data showed that women had preconceptional risk factors and did not receive adequate preconceptional care. Women need to be provided with awareness on preconception risk factors. Policies should be developed to increase the frequency of women receiving preconception care.

Keywords: Preconception care, preconception risk factors, health behavior, pregnancy.

1. INTRODUCTION

The care provided to couples prior to pregnancy with the aim of reducing maternal and fetal mortality and morbidity is referred to as preconception care. Preconception care (PCC) involves screening for risks and providing treatment at an early stage as well as offering couple's education and counseling to promote the health of women and their children. In recent years, it has been noted that antenatal care by itself is not sufficient in promoting mother-child health and in this context; the importance of preconception care has been emphasized (1-3).

Organizations such as World Health Organization (WHO), Centers for Disease Control and Prevention (CDC) and *American College of Obstetricians and Gynecologists* (ACOG) have reported that all couples in the preconception period must be assessed by health professionals and that women who are smokers/drinkers, women who have a chronic disease (e.g., diabetes, hypertension, hypothyroidism, epilepsy), those who have been infected with Rubella, Hepatitis-B, etc. or who have a genetic condition, folic acid or nutritional deficiency, are overweight or obese must be considered as being at risk in terms of maternal and fetal morbidity and mortality (1-3). It has been asserted that women in the risk group in particular should receive PCC as an essential requirement for the protection of maternal and fetal wellbeing (2,4). For example, the incidence of neural tube defects such as spine bifida and anencephaly declines in women who start taking folic acid at least 1 month prior to their pregnancy (1,3,4). Similarly, keeping blood sugar at normal levels in the preconception (PC) period is reported to reduce maternal morbidity, spontaneous abortion, fetal malformation, fetal macrosomia and neonatal morbidity (1-4). Other PCC practices to protect and promote maternal and fetal health include assessments as to healthy diet, physical exercise, weight control, quitting smoking and the use of alcohol, the diagnosis and treatment of chronic diseases, identifying genetic conditions, preventing exposure to occupational and environmental agents, avoiding the use of no prescribed medications, immunization, screening for and preventing infectious diseases, breast examinations, dental examinations and cervical evaluation (1,2,3,5). In a globalizing world, knowing the PCC practices specific to different cultures can be guiding and beneficial on creating countries' policies

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for PCC practices. In Turkey, in the few studies that have focused this matter, it has been observed that these have looked into the maternal and fetal outcomes of obesity, advanced age and smoking (6-8) and the assessment of the prevalence of taking folic acid (9). To the best of our knowledge, the present study is the first to evaluate PC risk factors and PCC care practices in Turkey. In consequence of the study, it is aimed to remark PCC, to determine PCC practices and to contribute to national and international literature. The results obtained from the study are thought to contribute to cross-cultural PCC practices. The aim of the study was to evaluate the PC risk factors that may adversely affect pregnancy outcomes, and PCC practices.

We searched answers to the following questions in this study:

What is the prevalence of PC risk factors for adverse pregnancy outcomes?

What is the prevalence of PCC practices?

2. METHODS

2.1. Design

This descriptive study was conducted over the period 15 May 2017 – 30 August 2017, at the Antenatal Care Polyclinic of Health Sciences University, Zeynep Kamil Women's and Children's Diseases Training and Research Hospital, located in the district of Üsküdar in the province of Istanbul.

2.2. Participants

The sample size was calculated to be 291 using a sample calculation formula in universe-unknown situations (a type of error 0.05, the prevalence of PCC practices 5%, d=0.01). In our study, convenience sampling method was used. A total of 385 pregnant women presenting to the antenatal polyclinic during the mentioned period and carrying the inclusion criteria stated below were taken into the study. Twenty-six pregnant women withdrew from the study because they did not wish to answer some of the questions. The study was concluded with 359 participants.

Inclusion criteria

Pregnant women who consented to participate over the age of 18 and had applied for the first antenatal care visit of their current pregnancy were accepted into the study.

2.3. Data Collection

The data were collected with a questionnaire that was drawn up by the researchers and this form was filled out in a face-to-face interview. The participants were interviewed in a room which in antenatal polyclinic. The questionnaire was completed in approximately 10 minutes.

The questionnaire

The questionnaire consists of 3 sections. The first section contained 6 structured questions designed to evaluate the sociodemographic characteristics (age, educational status, and employment status) of participants, the number of pregnancies experienced and the status of planned pregnancy. In the second section, the queries (26 structured) pertained to the woman's PC risk factors (e.g., use of cigarettes and alcohol, obesity, genetic diseases, chronic diseases, consanguineous marriage, use of drugs without a prescription and obstetric history). Pre-pregnancy body mass index (BMI) was calculated by dividing the weight reported by the woman (kg) by the square of the measured height (m). The third section of the form contained 24 structured questions on the participating woman's about PCC practices (an evaluation in terms of the use of folic acid, quitting smoking and intake of alcohol, use of multivitamins, weight control, regulating treatment of chronic disease, regular exercise frequency, checking fasting blood glucose, whole blood count, dental examination, having a Pap smear in the last 5 years, inoculations and infectious diseases, etc.).

2.4. Analysis of the data

Since the data will be presented as frequency, the analyzes were made using Microsoft Office Excel program. In the statistical analysis of the study data we used percentages and mean values.

Ethical considerations

During the planning stage of the study, the permission of the Ethics Committee of the hospital was obtained (Protocol Number:125 Date: 07.2015). After written and oral explanations, informed consent forms were collected from those wishing to participate in the study.

3. RESULTS

The mean age of the women in our study was 29.4 ± 5.7 years. The average duration of marriage was 65.2±58.6 months and the average number of pregnancies experienced was 2.16 ± 1.3. 28.4% were university graduates and 66.3% had wanted pregnancies (Table 1).

Table 1. *The characteristics of study participants (n=359)*

Characteristics	X±SD	
Age (years)	29.4 ± 5.7	
Duration of marriage (months)	65.2 ± 58.6	
Number of pregnancies	2.16 ± 1.3	
	n	**%**
Women's education		
Middle school	140	39
High school	117	32.6
University degree or above	102	28.4
Women employment status		
Working	124	34.5
Not working	235	65.5
Planned pregnancy		
Yes	238	66.3
No	121	33.7

A look at the preconception risk factors of the women in the study showed that 20.6% were 35 years of age or over, 23.1% smoked, 23.6% had a chronic disease, 16.4% were in consanguineous marriages, 13.1% were obese (Body Mass Index [BMI] ≥ 30) and 26.7% overweight (BMI ≥25-29.9). Of the multigravidae, 36.1% had experienced at least one miscarriage, 13% had had a stillbirth and 27.4% had delivered prematurely (<37th gestational week). Among the women, 4.2% and 2.5% of their spouses had some form of genetic disease (Table 2).

Table 2. *The preconception risk factors of the women*

Variables	n	%
Age Years ≥35	74	20.6
Cigarette Smoking	83	23.1
Alcohol Consumption	14	3.9
Consanguineous marriage	59	16.4
Body Mass Index (BMI) (kg/m^2)		
Low (<18.5)	21	5.8
Normal BMI (18.5-24.9)	195	54.8
Overweight ≥25-29.9)	96	26.7
Obese (≥30)	47	13.1
Presence of Hereditary Disease in Women		
Yes	15	4.2
No	307	85.5
Unknown	37	10.3
Presence of Hereditary Disease in Partner		
Yes	9	2.5
No	317	88.3
Unknown	33	9.2
Presence of any Chronic Disease	85	23.6
Hypertension	57	15.9
Hypothyroidism	10	2.8
Diabetes	5	1.4
Asthma	4	1.1
Epilepsy	3	0.8
Gastrointestinal diseases	1	0.3
Rheumatic diseases	2	0.6
Cervical Problem	17	4.7
Prescription Drug Use (disease specific)	46	12.8
Non-prescription drug use	12	3.3
Total	**359**	**100**
Bad Obstetric History	**n**	**%**
Spontaneous Abortion	75	36.1
Premature Birth (Before Gestational Age 37. Week)	57	27.4
Immature Birth (Gestational Age 20-24.Week)	15	7.2
Low Birth Weight Baby Birth (< 2500 Gr)	18	8.7
Stillbirth	27	13
Termination of Pregnancy Due to Anomaly	14	6.7
Birth of Baby with Anomaly (Sipifida, Cleft Palate, Etc.)	10	4.8
Eclampsia / Preeclampsia	24	11.5
Gestational Diabetes	6	2.9
Total*	**208**	**100**
* Answers from multigravida women.		

A total of 217 women (60.4%) study said that they had previously heard of PCC. Out of these women, 34.5% said they heard about PCC from healthcare providers, 30.1% from social media channels and 9.7% from their friends.

When the women's PCC practices were reviewed, it was found that only 12.3% had applied to a health institution to receive PCC.

Among the participants, the use of folic acid was 45.4%, applying to the doctor to regulate a chronic disease was carried out by 41.2% of the women while 44.6% had a complete blood count assessment, 22.8% were tested for fasting blood glucose, 89.4% had had a Pap smear test in the last 5 years, 54.2% had quit smoking, 78.5% had quit drinking, 36.8% increased their intake of nuts, 24.2% preferred to eat organic foods, a diet to have normal weight %14 and 14.2% exercised (Table 3).

Table 3. *Women's preconception care practices*

Variables	n	%
Applied to a Health Institution to Receive Preconception Care	44	12.3
Folic Acid supplementation	163	45.4
Consumption of at Least Five Servings of Vegetables / Fruits Per Day	39	10.9
Increase in the Consumption of Nuts	132	36.8
Multivitamin supplementation	51	14.2
Consuming at Least Three Servings of Milk and Milk Products Per Day	72	22.1
Regular Exercise (150 Minute Per Week)	51	14.2
Avoid Exposure to Radiation and Chemical Agents	126	35.1
Avoid contact with animals	46	12.8
Avoid contact with sick people	57	15.9
Consumed Organic Food	87	24.2
Not to Eat or Drink Raw Animal Products	65	18.1
Avoid Non-Prescription Drug Use	12	3.3
Fasting Blood Glucose Assesment	82	22.8
Complete Blood Count Assesment	160	44.6
Dental checkups (yearly)	44	12.3
Pap smear test in the last 5 years	321	89.4
Hepatitis B Vaccination	10	2.7
Tetanus Vaccination	30	8.3
Rubella (IgG) Vaccination	3	0.8
Total	**359**	**100**
Applied a modified diet to achieve normal weight standard *Only among low, overweight, and obese pregnants (n=164)*	23	14
Applied to reorganization of the treatment of chronic disease *Only among pregnants who have chronic diseases (n=85)*	35	41.2
Avoid Cigarette Smoking *Only among smoking pregnants (n=83)*	45	54.2
Avoid Alcohol Consumption *Only among pregnants using alcohol (n=14)*	11	78.5

In the PC period, 24.2% – 31.5% of the participants had been tested for Hepatitis-B, Chlamydia, Human Papilloma Virus (HPV), Gonorrhea, Syphilis, Herpes Simplex Virus (HSV) and Toxoplasmosis (Figure 1).

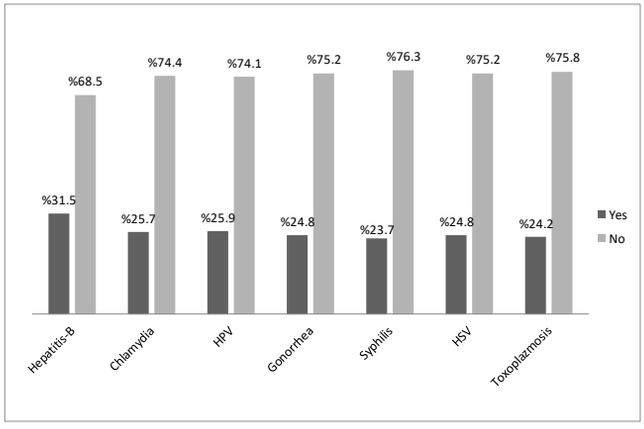

Figure 1. *Test status of participants for infectious diseases*

4. DISCUSSION

The findings have indicated that women carry preconception risks such as advanced age, being overweight or obese, being smokers, having a chronic disease, having an adverse obstetric history and that preconception care is not receiving adequate.

It has been emphasized, especially in developed countries, that regulating prenatal and neonatal health, preventing adolescent and unwanted pregnancies, averting miscarriages and abortions are among the benefits of PCC and that attention could be focused on this service (3,4,10). Although the number of women who had heard of the concept of PCC was higher than what has been reported in studies conducted in other countries (11), the percentage of women applying to health institutions to receive PCC was either lower than in some other studies (12,13), or similar (14). This suggests that the sociocultural characteristics of women in other countries, their more adequate knowledge of this matter and the health policies of the countries in question may have been the reasons behind the variation in results (15).

It is important that determine the presence of risk factors that may cause adverse obstetric outcomes (4,5). We found the rates of spontaneous abortion, premature childbirth, abnormal birth and stillbirth in our study to be higher than both the average in Turkey (16) and what has been reported by Agricola et al. (2014) (17). In Turkey, where the fertility rate is 2.26 % and 25.9 % of births are the result of unwanted pregnancies, 14% of pregnancies end in spontaneous abortion, 4.7% in voluntary abortion and 0.9% in stillbirth (16). The higher rate we found in our study compared to the country in general may perhaps be explained by the fact that the hospital in which the research was conducted is a tertiary medical institution that particularly responds to the monitoring and treatment of referred pregnancy cases at high risk. Our findings are important in terms of pointing to women's need for PCC.

In this study a significant percentage of the participants were in consanguineous marriages. Couples who are in consanguineous marriages should be evaluated in terms of genetic diseases in the PC period (1). Most of the women in the study reported that they did not know whether either their husbands or they had any genetic disorder.

The percentage of women of advanced ages in our study was lower than in other studies (12). Advanced age (≥35) also brings with it an increased risk of experiencing chronic health conditions. Anemia, hypertension, diabetes, hypothyroidism issues and other chronic conditions increase maternal and fetal mortality and morbidity risks (8,18).

In particular, iron deficiency anemia, which is a condition commonly found in developing countries due to poor dietary habits, may result in maternal mortality and cause physical and cognitive developmental disorders in the child (3). It was reported in a study conducted in Turkey that the incidence of gestational hypertension increased in women with hemoglobin levels of ≤9 g/dL in the first trimester (19). Women diagnosed with anemia n the PC period should be prescribed iron supplements. Our study indicated that close to half of our participants had blood tests during PC and we found that this rate was consistent with the results of other studies (20).

Related to diabetes, the risk of congenital malformations, spontaneous abortion and premature childbirth risks can increase (5). It is important during PC that women have their fasting glucose levels checked and if high, regulating glucose levels will reduce the risks. It was determined that only one-fourth of the participants had their fasting blood glucose levels checked during PC. The reason the rate of women having complete blood tests and fasting glucose tests was higher in our study than the rate of women applying for preconception care may be related to the fact that the family health centers in Turkey are vigilant in conducting complete blood, fasting blood glucose and similar tests in the monitoring processes.

The percentage of women with chronic conditions in our study was higher than in other studies (12,17) and the most common chronic disease noted was hypertension. On the other hand, since it was seen that only close to half of the women were under the treatment of a doctor during PC, it can be surmised that women are not adequately awareness about their condition.

Women should routinely undergo dental checkups (yearly) and Pap smear tests (every 5 years) during PC (21). It is known that dental maladies and reproductive system infections can cause miscarriage (22). The percentage of our participants having dental checkups was lower than that reported in another study (23) while the percentage of those having a Pap smear test was similar to the findings of Agricola et al. (2014) (17) but higher than reported in the study by Ignaszak-Kaus et al. (2018) (20). The reason the rate of having a Pap

smear test was high in our study can be associated with the fact that the Pap smear test is a routine part of screening programs in Turkey.

Overweight and obesity increase the risk of birth defects, neural tube defects, miscarriage, preeclampsia, gestational diabetes and macrosomia (3,4,7,24,25). The percentage of women in our study who were overweight (BMI) or obese was similar to rates reported in some studies (15, 23), but lower than in others (12,17). The difference in these rates may have resulted from the difference in the dietary habits and lifestyles of the women in the studies conducted in various countries.

Women in the PC period should be encouraged to follow diets followed up under the supervision of a dietician and to perform regular exercise in order to attain their normal weight (3). It has been reported that losing 10% of one's weight during PC and regularly exercising decreases the risk of miscarriage (5,7). In our study, however, it was seen that very few overweight or obese women followed a diet for weight control or exercised regularly. Our finding suggests that women do not know about the adverse effects of overweight and obesity on maternal and fetal health. The low rate of exercising in PC period in the study is consistent with the finding in another study (24,26).

Smoking during pregnancy can lead to low birth weight and the use of alcohol can result in birth defects and fetal alcohol syndrome (27). In Turkey, 13.1% of women are smokers (28). The rate of smokers among the women in preconception in our study is similar to those reported in other research (6,17). PC alcohol intake rates however are considerably low. While our study indicated that the quitting rate of women smokers in the PC period was similar to other studies (6,13,14,17), we found that this rate, was lower than that reported by Anderson et al. (2006) (23), was still not at the desired rate of 100%, The difference in smoking cessation rates during PC may be related to the degree of adequate or inadequate knowledge about this matter among the women in the countries where the studies were conducted. Research shows that education provided during PC significantly reduces the smoking rate (17,20).

The rate of taking folic acid in our study is consistent with the rates reported by Stephenson et al. (2014) (13), Ignaszak-Kaus et al. (2018) (20), Anderson et al. (2006) (23); On the other hand, this rate was higher than the rates reported by Baykan et al. (2011) (9), Mastroiacovo et al. (2014) (12) and Luton et al. (2014) (14), but still not at the desired level (100%). Although only a few of the women in our study applied to a health institution to receive PCC, it was observed that close to half had started taking folic acid, possibly as a continuation of their habit from previous pregnancies. It was seen that women were more likely to take folic acid after receiving prenatal education (17, 20, 29).

Folic acid can also be obtained through diet. Eating fruits, vegetables and dried nuts and fruits can reduce foliate deficiency. The participants in our study were eating at least five portions of fruit and vegetables during PC, which is lower than reported in other studies (23). At the same time, it was interesting to observe that the women increased their consumption of dried nuts and fruits. This finding can be related to the belief prevalent in the Turkish population that eating dried nuts and fruits will increase the chance of becoming pregnant. This superstitious habit may however be considered a positive PCC practice because of the vitamins, minerals and foliate intake that it provides.

The women in PC in our study were considerably lacking in the habit of taking multivitamins and consuming milk and milk products. The rate of multivitamin use was lower than in other studies (15,23), which may be a result of the fact that social security in Turkey does not cover multivitamins.

Exposure to teratogenic factors in PC may lead to fetal anomalies and miscarriage (5). Some of the women in the study avoided exposure to radiation and chemical agents in the PC period, tried not to be in contact with animals and sick people, consumed organic food, were careful not to eat or drink raw animal products and only a few took no prescribed medications. Although these results were not at the desired level, the data still indicates an awareness of these matters on the part of the women. The fact that the women were making positive changes in their dietary style during PC and preparing themselves for pregnancy may have something to do with the widespread broadcasts now available in the country's media on nutritional tips to follow during pregnancy.

The inadequacy in the rate of inoculations against Hepatitis-B and Tetanus reveals a lack of awareness about these diseases (17).

Screening for infections, treatment if any infection is detected, or immunization is imperative during the period of PC (1, 2, 5, 27, 30). Of the participants in our study, 65.8%-75.8% had not been evaluated for infections such as Hepatitis-B, Chlamydia, HPV, Gonorrhea, HSV, Toxoplasmosis or Rubella; this can be explained by the fact that these women had not applied to a doctor to received PCC. It was observed that a study by Ignaszak-Kaus et al. (2018) (20) revealed a similar rate of women failing to be tested for Toxoplasmosis and Rubella among those that were not receiving PCC.

Limitations

Our findings are only valid for the study sample and cannot be generalized to the country. Since no validity and reliability studies have been made of any measuring instrument that assesses PCC, data on the PCC practices in our study were obtained with a questionnaire that was drawn up by the researchers. This is one of the limitations of our study. It would be recommended that a standard questionnaire be devised in future for use in assessing PCC practices.

5. CONCLUSION

The results of our study led us to conclude that many women are at risk during the PC period but that only very few apply to a health institution for PCC and PCC practices are inadequate. Consequently, it can be said that PCC is an important need in Turkey. Although there have been major developments in prenatal care in Turkey, standard PCC guidelines have yet to be put into force. The Ministry of Health needs to devise strategies that will ensure that women apply to health institutions to receive preconception care. Healthcare professionals should be trained in raising women's awareness about this matter and a PCC protocol should be drawn up. Public awareness should also be promoted about the significance of proper planning and preparation for pregnancy (31). Increasing the frequency of PCC may contribute to our country's reaching its sustainable development goals (3). Besides, the results we acquired are important in terms of revealing that one-third of women obtain information about PCC from their social media accounts. This situation presents the necessity of using social media accounts about PCC practices that are prepared by healthcare professionals in order to inform women who do not want to apply to the health institutions.

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Clinical and Experimental Health Sciences

Comparison of the Effect of Surface Conditioning Methods on the Bond Strength of Different Zirconia Reinforced Lithium Silicate and Hybrid Ceramics to Resin Cement

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ABSTRACT

Objective: The objective of this study is to investigate the effect of surface treatment techniques on the shear bond strength (SBS) of resin cement bonded to CAD / CAM materials.

Methods: The zirconia-reinforced lithium silicate, Vita Suprinity (VS) and Celtra Duo (CD), and hybrid ceramics, Vita Enamic (VE) and Nacera Hybrid (NH), were used. Eighty specimens from each material were fabricated following the manufacturer's instructions and separated into 8 groups according to surface treatments. These were; K (control, no treatments), H (hydrofluoric acid), HS (H+ Silane S), A (abraded with 50-micron alumina particles A), AS (A+ S), C (abraded with 30-micron Cojet sand C), CS (C+S), S. The mean surface roughness (SR) of the specimens was evaluated. Surface treated specimens were cemented to the resin cement (Panavia F 2.0) for testing the adhesion using the shear bond strength (SBS) test. Mean SR and SBS were evaluated by 2-way ANOVA with the material type and surface treatments techniques as the independent factors.

Results: A and AS groups were observed to have the highest SR values. Both hybrid ceramics VE and NH showed the highest SR values among surface treatments. The highest SBS values were found usually on the H and HS treated surfaces. The highest values were observed on the CD material in the HS group (18.01MPa) and followed by the VE material (16.25 MPa) in the CS group. For CD and VS materials, adhesive and cohesive failures were found; and for VE and NH materials, adhesive and mixed cohesive failures were observed.

Conclusion: The surface treatment showed a significant effect on SR and SBS values. Although the SR values of the materials are high in the A and AS group, the highest SBS values were observed on H and HS treated surfaces.

Keywords: Shear Bond Strength, Surface Roughness, Hybrid Ceramic, Zirconia Reinforced Lithium Silicate Ceramic.

1. INTRODUCTION

Ceramics and resin-based composites are two different types of dental materials (1). Ceramics have good mechanical and optical properties and excellent biocompatibility due to their chemical stability (2). New ceramic materials in dentistry are increasing as stronger and tougher materials are developed with contemporary manufacturing techniques (3, 4). These include monolithic zirconia, zirconia reinforced lithium silicate ceramics and hybrid ceramics (3, 5, 6). Monolithic restorations have significant advantages such as decreased manufacturing time, improved cost effectiveness and elimination of the interface between the core and veneer materials (7, 8). Recently various monolithic glass ceramic materials also come into use currently with CAD/CAM systems for the application of fixed prosthesis (5, 9). This new zirconia reinforced lithium silicate glass ceramics are enriched lithium silicate glass ceramics (10% by weight) and combine the favorable material properties of zirconia (ZrO_2) and glass ceramic. The zirconia particles were added to reinforce the ceramic structure. (9, 10, 11, 12).

Hybrid ceramics introduced to the market to achieve a material with elastic modulus comparable to dentin have a number of advantages, including less crack propagation and better fracture resistance than few CAD / CAM systems (1, 6, 11, 13, 14, 15). Hybrid ceramics are composites of nanofiller and resins (6, 11, 16, 17). These materials composed of an organic polymer matrix reinforced by inorganic filler particles consist of porcelain glasses and ceramics (6).

The fracture resistance of ceramic materials can also be reinforced by the properties of the support materials or the bond strength. It was described that well-cemented specimens were generally more fracture resistant (13). For long term success, adhesion to a ceramic material is the one of the most important properties to evaluate the bond durability (14, 19). Another key factor for the clinical success of fixed prosthesis is the cementation procedure (20, 21). Luting cements and agents link prosthetic restorations with the supporting tooth structure and interfacial surface defects (13, 19, 20, 21). Retention loss

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is the second reason why traditional fixed prostheses fail (21). Usually, ceramic restorations are pretreated physically or chemically, but are more likely made by a combination of both methods (22). The strength of the adhesion between the ceramic and the bonding agent determines the clinical success of a ceramic restoration. Also, clinical success partially depends on the adhesion techniques controlled by the surface treatments used (23). Various conditioning methods for ceramic surface pretreatment such as roughening the surface with a diamond bur, sandblasting with alumina or silica-coated alumina oxide particles, chemical etching with hydrofluoric acid (HF) are recommended to increase adhesion (4, 20, 23)

Acid abrasion resistant ceramics require some special surface treatment to optimize bonding to the resin-based composite. The most common surface treatments for this purpose are airborne particle abrasion and silica coating. (22). Air particle abrasion is also used to increase the roughness of the ceramic. Surface roughness (SR) allows interlocking between ceramic and resin cement. (24, 25). Ceramics with high glass content form a micro mechanical retention surface as a result of the effect of HF, and these ceramics are called acid-sensitive (12). During HF etching, some parts of the silicate ceramic surface are removed and a surface roughness occurs (4, 22). Application of silane coating agent is a chemical approach to bonding to ceramic and provides a chemical connection between ceramic and resin composite (4, 12, 22). These agents can create chemical connections between the inorganic phase of the ceramic and the organic phase of the resin (26, 27).

Fracture resistance of the ceramic-resin adhesion is controlled by the microstructure and surface treatment (28). Mechanical laboratory tests can be used to show material selection and clinical recommendations for resin bonding to ceramics. (4, 19). Various methods can be used for the assessment of the bond strength: 3-point bending, the tensile and micro tensile and the shear and micro shear tests (4, 19, 28). The most common method is the shear bond strength (SBS) test (4, 17, 28, 29). The advantages of the shear bond strength (SBS) test performed by applying parallel force to the binding interface are easy specimen preparation and simple test protocol. (14, 16, 17, 19, 30, 31). Nevertheless, non-uniform stress distribution in the bonding surface and polymerization shrinkage of resin cement are not considered in this technique (28, 29, 30).

The objective of this study is to evaluate the effect of different surface treatments on surface roughness and shear bond strength of resin cement bonded to different ceramic materials. The null hypothesis in this study is that surface roughness and SBS are not affected by material variety and surface treatment technique.

2. METHODS

Two zirconia reinforced lithium silicate ceramics, Vita Suprinity (VS) and Celtra Duo (CD) and two hybrid ceramics, Vita Enamic (VE) and Nacera Hybrid (NH) were selected for the study. The materials, their manufacturers and compositions used in this study are shown in Table 1. All specimens (10 x 10 x 1 mm) in this study were prepared from prefabricated blocks. 320 specimens were separated into 8 subgroups (n = 10) for various surface treatments to be applied. The schematic diagram of the experimental groups is shown in Figure 1.

Table 1. *Composition of the materials tested in this study.*

Material	Brand	Manufacturer	Lot No	Composition
Zirconia-reinforced Lithium Silicate	Celtra Duo **CD**	Sirona Dentsply, Milford, De, USA	16000579	SiO_2, P_2O_5, Al_2O_3, Li_2O, ZnO_2, Tb_4O_7, ZrO_2, CeO_2, pigments
Zirconia-reinforced Lithium Silicate	Vita **VS** Suprinity	Vita Zahnfabrick, Bad Säckingen, Germany	59841	ZrO_2, SiO_2, Li_2O, La_2O_3, P_2O_5, K_2O, Al_2O_3, La_2O_3, CeO_2, pigments
Hybrid Ceramic	Vita **VE** Enamic	Vita Zahnfabrik, Bad Säckingen, Germany	63460	SiO_2, Al_2O_3, Na_2O, K_2O, B_2O_3, CaO, TiO_2, UDMA, TEGDMA
Hybrid Ceramic	Nacera **NH** Hybrid	Doceram Medical Ceramics Gmbh, Dortmund, Germany	230516	50% Nano-Glass, 50% Polymer-Matrix
Hydrofluoric Acid	IPS Ceramic Etching Gel	Ivoclar Vivadent, Schaan, Lichtenstein	W31655	<%5 Hydrofluoric Acid
Aluminium Oxide Sand	Korox	Bego, Bremen, Germany	14361781112	%99.6 Al_2O_3 (50µm)
Cojet Sand	Cojet Sand	3M ESPE, St. Paul, USA	654604	30 µm silica coated sand
Silane Coupling Agent	Monobond N Silane	Ivoclar Vivadent, Schaan, Lichtenstein	W90335	Alcohol based silane metacrylate, Phosphoric Acid Methacrylate, Sulfur Methacrylate Solution
Dual Cure Resin Cement	Panavia F 2.0	Kuraray Medical Inc., Okayama, Japan	B70150	Paste A: MDP, hydrophobic aromatic and aliphatic photoiniator, dibenzoyl peroxide dimethacrylate, hydrophilic dimetacrylate, silanized silica, silanized colloidal silica, camphorquinone, catalysts, initiators
			AR0034	Paste B: Hydrophobic aromatic and aliphatic dimethacrylate, silanized barium glass, sodium fluoride, catalysts, initiators, color pigments.

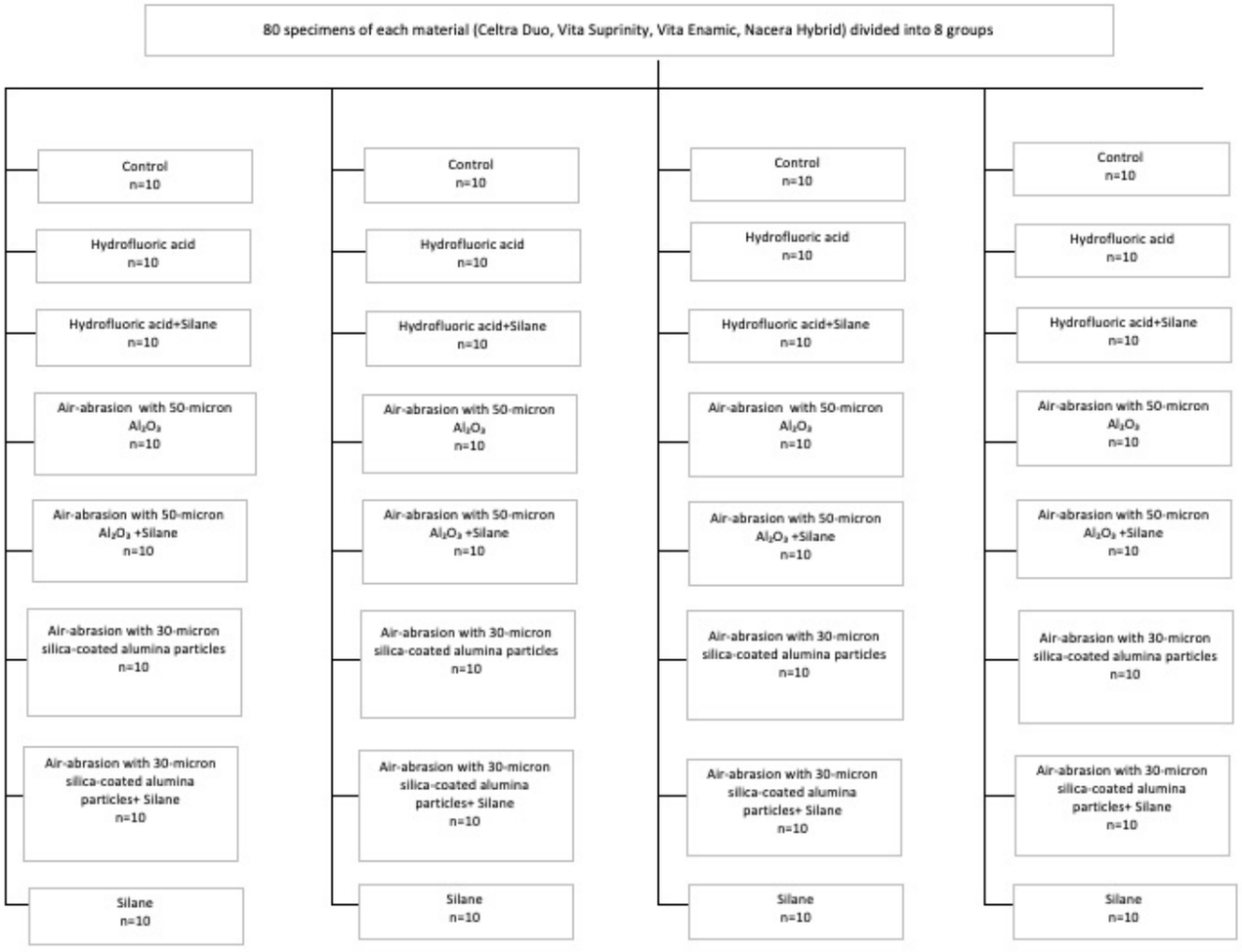

Figure 1. *Schematic diagram of experimental groups.*

All specimens were put into acrylic resin blocks and then polished under water cooling to obtain standardized surfaces. The specimens were separated into 8 groups according to the used surface treatments.

K: No treatment (control)

H: %5 Hydrofluoric acid application for 20 seconds

HS: %5 HF acid for 20 seconds **+** silane application for 60 seconds.

A: Air-abrasion with 50-micron Al_2O_3 at 2-5 bar pressure.

AS: Air-abrasion with 50-micron particles of alumina Al_2O_3 at 2.5 bar pressure **+** silane application for 60 seconds.

C: Air-abrasion with 30-micron silica-coated alumina particles with 2.5 bar pressure.

CS: Air-abrasion with 30-micron silica-coated alumina particles with 2.5 bar pressure **+** silane application for 60 seconds.

S: Silane application for 60 seconds.

All specimens were cleaned with ethanol and distilled water for 10 minutes in an ultrasonic cleaner after all surface treatments. A surface roughness (SR) profile was determined for each group using a profilometer (Mahr Surf M 300c, Mahr Gmbh, Germany). Three readings were taken from the surface of the specimens and a mean value was calculated.

After SR measurements, a dual-cure resin cement (Panavia F 2.0, Kuraray Medical Inc, Japan) was packed onto specimen surfaces using a mold which was 3 mm in diameter and 2 mm in depth cylindrical. Layers were added incrementally and cured using a light-curing unit (BA Optima 10 Boses 20, BA International Ltd. England). The application of cement in the specimen is shown in Figure 2. Then all specimens were kept in 37°C distilled water for 24 hours.

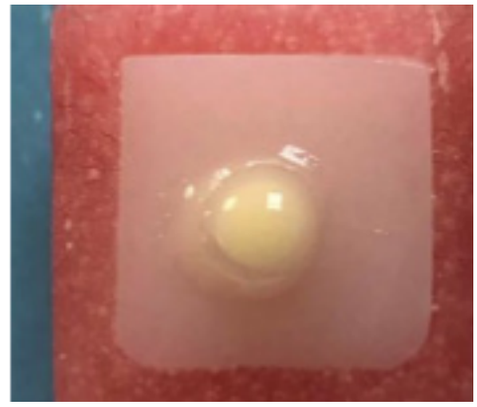

Figure 2. *The application of dual-cure resin cement on the specimen.*

The SBS was determined with a universal testing machine (Lloyd Instruments, Ametek Inc. Florida USA). SBS test with specimens is shown in Figure 3. The specimens were loaded at a crosshead speed of 0.5 mm/min. The maximum load (P) was measured when the resin cement was separated from the specimen. The SBS was measured from the formula below:

Figure 3. *The specimen under the SBS test in the universal testing machine.*

SBS (in MPa): P x 9.8 / r^2 x π,

where is the maximum load (in kg F) and r is the radius (in mm) of the resin cement.

After the SBS test, the interface of the specimens was analyzed using a loupe (Loupe opt-on Orange Dental, Biberach Germany) at 2.5 mm magnification. The fracture modes were classified as follows:

Type 1: Adhesive (between the surface of the both materials),

Type 2: Cohesive (within the ceramic material),

Type 3: Cohesive (failure within the material and resin cement) failure.

Statistical analyses were applied to the surface roughness and SBS values. Mean surface roughness and SBS results analyzed 2-way ANOVA with the material type and surface treatments as the independent variables. Multiple comparisons were made by Tukey's and Tamhane's tests. Statistical significance was set at the 0.05 probability level. The correlation between SR and SBS results was investigated using Pearson correlation and chi-squared analysis.

3. RESULTS

3.1. Surface Roughness

Multiple comparisons of the mean SR values of the materials used in this study and surface treatment methods were made with Tukey's and Tamhane's test.

Table 2. *Mean and standart deviation (SD) of the surface roughness (Ra) values for the materials used in this study.*

Materials	Surface Treatments	Ra Values			One-Way ANOVA	
		n	Mean	SD	F	p
CD	K	10	0.19 ^{d}	0.06	116.58	**0.001**
	H	10	0.35 ^{c}	0.08		
	HS	10	0.37 ^{c}	0.11		
	A	10	1.65 ^{a}	0.26		
	AS	10	1.45 ^{a,e}	0.34		
	C	10	1.15 ^{b,e}	0.11		
	CS	10	0.96 ^{b}	0.14		
	S	10	0.18 ^{d}	0.04		
VS	K	10	0.18 ^{c}	0.05	125.152	**0.001**
	H	10	0.2 ^{c}	0.07		
	HS	10	0.15 ^{c,d}	0.07		
	A	10	1.5 ^{a}	0.31		
	AS	10	1.39 ^{a}	0.29		
	C	10	0.92 ^{b}	0.13		
	CS	10	0.95 ^{b}	0.1		
	S	10	0.09 ^{d}	0.03		
VE	K	10	0.18 ^{d}	0.04	170.055	**0.001**
	H	10	0.39 ^{c}	0.05		
	HS	10	0.37 ^{c}	0.04		
	A	10	1.82 ^{a}	0.19		
	AS	10	1.79 ^{a,e}	0.38		
	C	10	1.21 ^{b}	0.17		
	CS	10	1.31 ^{b,e}	0.13		
	S	10	0.18 ^{d}	0.06		
NH	K	10	0.23 ^{c}	0.08	384.525	**0.001**
	H	10	0.22 ^{c}	0.07		
	HS	10	0.19 ^{c}	0.04		
	A	10	2.18 ^{a}	0.24		
	AS	10	1.96 ^{a}	0.2		
	C	10	1.43 ^{b}	0.11		
	CS	10	1.34 ^{b}	0.18		
	S	10	0.21 ^{c}	0.05		

**Tukey HSD test, Tamhane's test. There is no statistically significant difference between the mean Ra values of the groups with common lowercase letters (p> 0.05)*

The mean SR values of the materials used and surface treatments are presented in Table 2. The SR was affected significantly differently from the treatments for all materials, and the effect of surface treatment methods was evaluated for each material. Within all materials, the highest SR values were observed in the A and then AS group and the value difference between the two groups was not significant (p>0.05). The Mean values of A groups were; 1.65±0.26 MPa for CD, 1.5±0.31 MPa for VS, 1.82±0.19 MPa for VE, 2.18±0.24 MPa for NH. The mean values of AS groups were; 1.45±0.34 MPa for CD, 1.39±0.29 MPa for VS, 1.79±0.38 MPa for VE, 1.96±0.2 MPa for NH. Then, C and CS groups significantly followed these two groups. The lowest Ra values were found generally in K and S groups for all materials. Among the surface treatment groups, the highest Ra values were observed in the A group on NH material, in the C group on the VE material, and in AS and CS groups on NH and VE materials. Then, the lowest Ra values were obtained in H and HS groups in NH and VS materials.

3.2. Shear Bond Strength

Multiple comparisons of the mean SBS values and surface treatment methods were made with Tukey's tests. The mean shear bond strength test values of the materials used and surface treatments are presented in Table 3. The SBS test values were significantly affected by surface treatment methods for all materials and the effect of the treatments was evaluated for each material. Within all the materials used, the highest SBS test values were observed in H and HS groups on CD, VS, NH materials and in the CS group on the VE material (16.25±5.83 MPa). CD material mean values are; 11.58±2.53 MPa for H group, 18.01±4.07 MPa for HS group. VS material mean values are; 18.84±4.37 MPa for H group, 11.60±3.09 MPa for HS group. NH material mean values are; 12.81±4.03 MPa for H group, 12.44±3.43 MPa for HS group. The lowest SBS values were generally found in the control group. Among the surface treatment groups, the highest SBS values were observed in C and CS groups on the VE material, and in A and AS groups on VE and VS materials. The lowest SBS test value was found in the K group at the CD material.

After the SBS test, the interface of the fracture specimens was analyzed and the fracture mode was classified as presented in Table 4. The failure type on the surfaces of all used materials differed according the material type and the surface treatments. Among the tested materials, when all surface treatments were evaluated, the Type 1 highest adhesive failure was observed in NH and then CD material, Type 2 cohesive failure was seen in VS and then CD materials and Type 3 cohesive failure was primarily seen in VE material. Type 3 cohesive failure was not observed in CD and VS materials. Among the surface treatments, when all tested materials were evaluated, the highest Type 1 adhesive failure was observed in K and S treatment groups, Type 2 cohesive failure was seen in CS and then HS groups and Type 3 cohesive failure was observed primarily in HS treatment group. Type 3 cohesive failure was not observed in K and S groups.

Table 3. *Mean and standart deviation (SD) of the Shear Bond Strength (SBS) (MPa) values of the materials used.*

Materials	Surface Treatments	SBS Values			One-Way ANOVA	
		n	Mean	SD	F	p
CD	K	10	2.45 ^{e}	1.56	33.924	**0.001**
	H	10	11.58 ^{b,d}	2.53		
	HS	10	18.01 ^{a}	4.07		
	A	10	6.81 ^{c}	2.66		
	AS	10	8.55 ^{c,d}	3.27		
	C	10	5.37 ^{c}	1.68		
	CS	10	5.37 ^{c}	2.64		
	S	10	5.36 ^{c}	1.74		
VS	K	10	3.43 ^{c,d}	1.97	11.709	**0.001**
	H	10	12.84 ^{a}	4.37		
	HS	10	11.6 ^{a}	3.09		
	A	10	8.7 ^{a,b}	3.04		
	AS	10	7.15 ^{b,c}	4.15		
	C	10	5.62 ^{b,c}	2.31		
	CS	10	5.99 ^{b,d}	2.54		
	S	10	4.3 ^{c,d}	2.6		
VE	K	10	8.87 ^{b}	5.25	2.461	**0.025**
	H	10	13.17 ^{a,b}	1.9		
	HS	10	14.5 ^{a,b}	3.33		
	A	10	12.65 ^{a,b}	5.22		
	AS	10	11.25 ^{a,b}	4.64		
	C	10	13.99 ^{a,b}	4.69		
	CS	10	16.25 ^{a}	5.83		
	S	10	10.59 ^{a,b}	5.82		
NH	K	10	5.53 ^{b}	1.37	7.506	**0.001**
	H	10	12.81 ^{a}	4.03		
	HS	10	12.44 ^{a}	3.43		
	A	10	5.76 ^{b}	2.08		
	AS	10	8.24 ^{a,b}	3.3		
	C	10	8.23 ^{a,b}	2.41		
	CS	10	8.26 ^{a,b}	3.64		
	S	10	8.69 ^{a,b}	3.49		

**Tukey HSD test, there is no statistically significant difference between the mean SBS values of the groups with common lowercase letters (p>0.05).*

Table 4. *Failure modes of the experimental groups*

		FAILURE MODE								Chi Square Test	
		Type 1		Type 2		Type 3		Total			
		n	%	n	%	N	%	n	%	Chi Square	p
Materials	CD	51	26.29	29	29.9	0	0	80	25	94.296	**0.001**
	VS	47	24.23	33	34.02	0	0	80	25		
	VE	43	22.16	9	9.28	28	96.55	80	25		
	NH	53	27.32	26	26.8	1	3.45	80	25		
	Total	194	100	97	100	29	100	320	100		
Surface Treatments	K	38	19.59	2	2.06	0	0	40	12.5	*	**0.001**
	H	27	13.92	12	12.37	1	3.45	40	12.5		
	HS	12	6.19	20	20.62	8	27.59	40	12.5		
	A	25	12.89	12	12.37	3	10.34	40	12.5		
	AS	20	10.31	15	15.46	5	17.24	40	12.5		
	C	21	10.82	13	13.4	6	20.69	40	12.5		
	CS	13	6.7	21	21.65	6	20.69	40	12.5		
	S	38	19.59	2	2.06	0	0	40	12.5		
	Total	194	100	97	100	29	100	320	100		

**Chi-Square Analysis, Chi-square analysis was performed with the Monte Carlo Simulation since 20% of the expected value in cells is less than 5.*

4. DISCUSSION

This in vitro study evaluated the effect of different surface treatments on the SR and SBS of resin cement to/on? different CAD/CAM ceramic materials and demonstrated that the surface treatment methods have an influence on SR and SBS test values of the materials used and that these surface treatment methods significantly affected the results of this study. Consequently, the results of this study reject both null hypotheses.

Lithium-silicate based glass ceramics and hybrid ceramics have been recently used as materials for CAD/CAM techniques (5, 6). The newest generation glass ceramics VS and CD contains 10%wt. highly dispersed zirconia (9, 11). One of the two hybrid ceramics used in this study is a ceramic network consisting of approximately 14% resin embedded in 86% of a ceramic network VE material (15, 21, 26, 33). Another new CAD/CAM hybrid ceramic is the NH material for permanent restorations and contains 50% nano-glass and 50% polymer-matrix. This new hybrid ceramic has been introduced for manufacturing partial crowns, veneers and up to 3 units bridges (34).

To evaluate the adhesion of resin cement, tensile and micro tensile bond strength, pull and push tests are the other test methods. Sano et al. created the micro tensile bond strength test in order to eliminate the non-uniform stress distribution within the adhesive zone (35). However, the micro tensile bond strength test method is difficult to conduct, time consuming and highly technique sensitive because of the specimen preparation (28). The SBS test is simple and reliable. Hu et al. compared the difference between the two SBS tests for resin composite cements and concluded that the shear test is reliable to assess differences in bonding performance as long as shearing occurs at the interface with no fracture of the substrate (29). Therefore, the SBS test was used in the present study.

Achieving a chemical adhesion at the cement/ceramic interface may be essential for successful full bonds. Cement selection is a precondition for ensuring effective bond strength to indirect restorations. It has been found that bond strength is more effective when using dual-cured resin cement in indirect restorations (32). In the present study, only one resin cement was used to ensure standardization.

Various surface treatment techniques are preferred depending on the characteristics of the material (32, 37). Elsaka SE has evaluated and confirmed the effect of surface treatments applied to CAD / CAM materials on micro tensile bond strength to resin cement (32). Similar results have also been reported for glass ceramics (26). Also, Kim et al. stated that the bonding strength varies between different types of materials even when implementing the same surface treatment method (24). In this study, different surface treatments were applied to different CAD/CAM material surfaces and SR and SBS values of the treated surfaces were evaluated. An important requirement for the clinically successful function of ceramic indirect restorations is adequate adhesion between the ceramic and tooth structure and the surface treatment prior to cementation could enhance the bond strength (38). Common physical surface treatment methods are roughening with a diamond bur, airborne particle abrasion with alumina or silica and etching with hydrofluoric acid (HF) (4). During HF etching, parts of the silicate ceramic surface are etched and result in the surface roughness. The HF etching time is important for adequate mechanical retention (4, 20). Della Bona et al. suggested that etching mechanisms change according to the type of the etchant and etching time and the ceramic microstructure and composition (39). In another study, Menees et al. found that HF etching for 20 seconds in concentrations varying from 5% and 9.5% is enough for etching. (40). In another study, Sato et al. concluded that etching with HF acid for 20 and 40 seconds was equally effective in producing stable resin bonding to a

zirconia reinforced lithium silicate ceramic (12). Therefore, 5% HF acid was applied for 20 seconds in the present study.

Airborne abrasion using alumina or silica particles is commonly recommended for luting resin composites to CAD/CAM blocks (4, 21, 25). The air abrasion system ensures air-particle abrasion with different particle sizes ranging from 30 to 250 micron between the ceramic and cement (41, 42). Generally, sand blasting pressure is recommended as 0.1-0.2 MPa. However, this pressure is lower than the pressure commonly used for ceramic restorations (25). In the present study, the surfaces were sandblasted in the air abrasion groups at 2.5 bars. The SR of the material was evaluated with a surface profilometer. In this study, Ra, which is the mean value of all absolute distances of the linear roughness profile, was used (43).

Regarding the influence of surface treatments between the four CAD/CAM materials, the A and AS groups produced significantly higher Ra values compared to the others and followed by the C and CS groups significantly. Untreated group K and S surfaces showed generally the lowest roughness values. In the present study, NH material showed the highest Ra values in A and AS groups followed by VE materials. Then, among the treated surfaces, the lowest values were observed in H and HS groups. Both NH and VE materials are hybrid ceramics and have different microstructures. The moduli of elasticity of NH and VE materials are 9.9 GPa and 30.0 GPa according to the manufacturer's information (34, 44). The composition of the NH new hybrid ceramic material matrix consists of 50% nano glass and 50% polymer matrix. According to the manufacturer's information, 100% silanized glass is permanently integrated into the polymer matrix (34). VE is based on a polymer-infiltrated ceramic network material that consists of a dominant network (86 wt.%) reinforced by an acrylic polymer network (14%). The two networks penetrate each other completely (45). This could possibly be attributed to the different compositions of these two hybrid ceramics with different filler contents, which have an impact on the much higher SR values. According to the SBS test results for the different tested materials, the H and HS chemical conditioning groups produced the highest bond strength values contrary to the SR test results.

Although the SR of the materials is high in A and AS groups in the present study, generally the highest SBS values were observed on H and HS treated surfaces. The lowest SR values in H and HS groups were found in VE and CS materials, but also the highest SBS values.

According the SBS results, H and HS treated surfaces produced the highest bond strength and the highest values were observed on the CD material (18.01±4.07 MPa) in the H group and followed by the VE material (16.25±5.83 MPa) in the CS treatment group. Both ceramics are etchable ceramics. Then, these materials were followed by the VE material (14.5±3.33 MPa) in the HS group, VS material (12.84±4.37 MPa) in the H group and NH material (12.81±4.03 MPa) in H and (12.44±3.43) HS groups. As surface treatments, Frankenberger et al. suggested using HF acid for the VE material and also lithium disilicate ceramics. (46). In another study, Aboushelib et al. investigated the effect of surface treatments of two types of lithium disilicate ceramics on the micro tensile bond strength to a resin adhesive and found that the highest strength values were observed significantly in the CD material (34 MPa), which were also used and found in the present study (10). Also, they concluded that bond strength to lithium disilicate ceramics depends on proper surface treatment and on the chemical composition of the glass ceramics. Their bond strength methodology was not exactly the same as we used in this study, there was no micro tensile bond strength, but we used the SBS test. So, direct comparisons are not applicable. Sato et al. evaluated the effect of surface conditioning of the zirconia reinforced lithium silicate ceramic and resin cement on the micro tensile bond strength and observed that the silica coating was not efficient and etching with hydrofluoric acid for 20 seconds was effective for the stable resin bonding (12). In another study, Al-Thagaafi et al. (47) investigated the effect of surface conditioning protocols on the VS zirconia reinforced lithium silicate ceramic material with micro tensile bond strength and found that the bond strength of VS was 31.2 MPa in the HS treatment group and also has the highest bond strength values in sandblasting with Cojet sand. Pneumans et al. and Elsaka et al. investigated the micro tensile bonding performance of different glass ceramics and resin cement (11, 32). Pneumans et al. used H acid etching (%5) and silane combination as the surface treatment and they found that the best pretreatment for C (41.5) and VE (46.3) materials included etching with HF acid and observed that an application of S did not have any effect on the bond strength values (11). In contrast to the study of Pneumans et al., we observed the highest SBS values for the CD material in the HS (18.01 MPa) group compared to the H group (11.58 MPa). Elsaka et al. found the highest SBS value for the VE material (27.4 MPa) (32). The HS group showed higher values of bond strength compared to other treated surfaces, and the specimens including cohesive failure failed in a mixed mode. In this study, among all tested materials, the failure mode for the VE material was found between all tested materials the highest percentage of mixed cohesive failure. For CD and VS glass ceramics were observed more adhesive and cohesive mixed failures. Another published investigation measured the micro bond strength values of VE and CD materials and found 20.2 and 26.9 MPa (46). Both values are very close to the results of the present study in the HS group. Various in vitro studies established that H acid etching in combination with the use of silane is the finest surface treatment for lithium disilicate glass ceramics and the zirconia reinforced lithium silicate ceramics (11, 48, 49). According to the results of this study, as surface roughness increased through mechanical surface treatment as A or C, air-particle abrasion had less impact on the SBS test than chemical conditioning.

Concerning the mechanical bond strength, the present study used the SBS method to investigate the bond strength between different glass ceramic materials and resin cement. Hu et al. (29) evaluated and compared the adhesion of

different-cement combinations with the SBS test The VS material (21.6 MPa) they found in the glass-based ceramic groups revealed significantly higher values than the VE material (14.7 MPa), and they also observed that on etched surfaces, VE exhibited primarily cohesive failures and the VS material exhibited primarily adhesive failures. According to the results of this study, considering all surface treatments, while adhesive and cohesive failures were found in the VS material, adhesive and primarily cohesive failures were observed in the VE material. This result was in accordance with the results of Hu et al and Elsaka et al. (29. 32). Also, similarly, some studies investigated the effect of the SBS test on hybrid ceramics (14, 30). Gungor et al. concluded that SBS was affected by surface treatments and found strength values for the VE material in HS treatment groups as 17.91 MPa (30).

Rohr et al. observed the highest SBS values for the VE material as 11.5 MPa and Schwenter et al. as 19.9 MPa. Similar results were obtained in the present study, which was in agreement with previous studies (14, 16, 20, 29, 30). In the present study, the highest SBS value with the VE material was determined in the CS group as 16.25±5.83 MPa, not in the HS group. VE with CS treatment showed comparable bond strength to HS. This result is in agreement with previous studies (26, 32). In the study by Campos et al., C treatment group also resulted in the highest bond on the VE material before aging, but micro tensile bond strength values decreased significantly after aging (26). According to the study of Elsaka et al., for the groups etched with H and HS , the SR was lower than A, AS treatments, but the higher bond strength on the non-aged group for the VE material was found in the HS group and were comparable with the AS group (32).

Between the surface treatment groups, most of the specimens in the HS group showed mixed and primarily cohesive failures according to the present study and also the failure mode may also change with different tested material types. (32). The adhesive type of failure is typically associated with low bond strength values. Thus, mixed and cohesive failure modes are clinically preferable to total adhesive failure (50). Therefore, this finding is valuable data on the performance of the ceramic-resin bond where the resin cement is chemically bonded to the substrate material (20). Several studies reported mean SBS values between 15-25 MPa among the glass ceramic and resin for clinical applications, which is in agreement with the present SBS values data (14, 16, 20, 29, 30).

In this study, a single type of resin cement and silane coupling agent were used to ensure standardization. However, the sort of luting agent is the main determinant in the adhesion of dental materials.

Another limitation of the study is that thermal cycling was not included. Specimens in water at 37 C^0 were only short-term storage. Future in vitro studies should be conducted to investigate other factors such as different resin cement. Silane coupling agents and different test methodology should involve aging conditions together with the use of thermocycling to provide a closer simulation of clinical situations.

5. CONCLUSION

With the limitations of this in vitro study, these conclusions can be emphasized:

In the present study, surfaces with A and AS treated groups increased the SR for all tested ceramics and are significantly followed by the C and CS surface treated groups.

Among all ceramic materials, the highest SBS values were observed in the HS group on the CD material and in the CS group on the VE material and in H and HS surface treatment groups on the VS and NH materials. The failure mode for CD and VS and NH materials was found to be the highest percentage adhesive and cohesive failures, however, adhesive and mixed cohesive failure was primarily observed for the VE material.

3. The higher SR will not always provide a higher bond strength value. SBS test results depend on the effect of surface treatments on the bond strength of the tested materials to resin cement.

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Conflicts of interest

The authors declare that they have no conflict of interest

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Clinical and Experimental Health Sciences

Microleakage and Marginal Integrity of Direct and Indirect Composite Resin Restorations in MOD Cavities After Thermo-Mechanical Loading

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ABSTRACT

Objective: The aim of this in vitro study is to compare the microleakage of mesial-occlusal-distal (MOD) composite resin restorations made by using CAD/CAM block and methacrylate/ormocer-based direct resin composites after thermo-mechanical loading.

Methods: Standard 40 noncarious human third mandibular molars were selected for the study. Standardized MOD (3x4x2mm) cavities were prepared on the mesial and distal sides. The gingival margin was placed above the cementoenamel junction (CEJ) on the mesial side and below the CEJ on the distal side. The prepared samples were divided into three experimental groups [indirect group-GrandioBlock (GB), direct-methacrylate group-TetricN-Ceram+TetricN-Flow (T+TF), direct-ormocer group-Admira Fusion+Admira Fusion Flow (A+AF)] and control group [direct-methacrylate group-GrandioSo+GrandioSoFlow (G+GF)] (n=10). After finishing restorations samples were subjected to 50 N to 240.000 thermo-mechanical cycles (5-55°C, for 60 sec) and kept in 0.2% methylene blue. Samples sectioned longitudinally in the mesiodistal direction with a precision cutting device were examined under stereomicroscope at X8 and X25 and microleakage values were scored. In the evaluation of the data, descriptive statistical methods as well as the chi-square test was used for the comparison of qualitative data.

Results: No significant difference was found among the coronal and gingival-enamel microleakage distributions of the groups ($p>0.05$). A statistically significant difference was observed among the gingival-cementum microleakage distributions of the groups ($p=0.003$). The distribution of gingival-cement microleakage with the no dye penetration score in the T+TF group was found to be statistically significantly lower than the G+GF and GB groups ($p = 0.010$, $p = 0.001$).

Conclusion: Under the limitation of this in vitro study; restoring MOD cavities using different matrix structures of the composites could not eliminate the leakage at the gingival seat under CEJ.

Keywords: CAD/CAM, chewing simulator, microleakage, ormocer, resin composite.

1. INTRODUCTION

In today's dentistry practice, resin composites are among the most preferred materials in the treatment of posterior teeth. Resin-based composite materials, which are developed day by day, exhibit acceptable aesthetic, physical, and mechanical properties (1-3). Composite materials have many advantages, as well as disadvantages. One of the most important of these disadvantages is polymerization shrinkage and the resulting microleakage. When the polymerization shrinkage exceeds the bonding strength between the restorative material and dental tissues; micro-leakage, plaque accumulation, post-operative sensitivity, bacterial penetration, pulpal inflammation, secondary caries, and fractures in the connective surface areas may occur due to the formation of micro-gaps between the restoration and dental tissue (1,2). Polymerization shrinkage varies depending on the adhesive system used and the method of application, the intensity and mode of the light device used, the use of composite technology with ceramic technology, and the use of a flowable composite or liner in the cavity (4). Flowable composite resins are used in restorative dentistry applications to prevent polymerization shrinkage and to create a stress-breaking barrier under conventional composites. The ease of application and viscosity of flowable composites expand the indication of flowable composites in practical applications (5).

With the advances in the filling, matrix structure, and application techniques of composite resins, it is aimed to make more successful restorations. Ormocers are organically modified ceramic materials with high biocompatibility and less polymerization shrinkage. Unlike traditional polymers, the first produced ormocers; are obtained by adding monomers such as bisphenol-A (Bis-GMA),

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glycyldimethacrylate, hydroxylethyl methacrylate (HEMA), triethylene glycol dimethacrylate (TEGDMA) and urethane dimethacrylate (UDMA) and various inorganic fillers to the main structure consisting of Si-O-Si network consisting of inorganic-organic copolymers. The filler content consists of special glass, ceramic, and a high amount of silica (6). Innovative modifications of ormocer-based composites have been developed over time.

With the indirect application of composite restorations, ideal occlusal morphology, ideal approximal contact, ideal polished surface, and reduction in polymerization shrinkage, can be obtained (7,8). However, incompatibility in inlay restorations can often be observed in the gingival margins (9). It can be thought that there is more microleakage in the gingival margin than the occlusal margin, depending on the problems that occur during impression and laboratory procedures. This problem can be eliminated with CAD/CAM systems. Due to the indirect application, the residual monomer amount decreases, thus properties such as aesthetics, optics, color stability, homogeneity, and fluorescence are obtained. It is thought that polymerization shrinkage in the application of indirect restorations will be limited to the adhesive cement and thus minimized (9-12).

Thermo-mechanical chewing simulators have been developed to mimic the stresses that occur in contact with the against tooth during chewing and to evaluate the effects of intraoral temperature changes and mechanical conditions on restorations (13). It is thought that the results obtained by comparing restorative materials with different thermal and mechanical properties will guide the selection of restorative materials in clinical applications.

This study was planned due to the limited literature data comparing the indirect restorative material Grandio Block with methacrylate and ormocer-based composite materials in terms of microleakage. The following null hypotheses were tested; 1) Composite restoration technique (direct vs. indirect) will not affect the microleakage values of the restorations. 2) Different types of matrix structure (ormocer vs. methacrylate) will not affect the microleakage values of the restorations.

2. METHODS

This study was approved by the ethic committee of Marmara University, Faculty of Dentistry in Istanbul, Turkey (Protocol number 2019-286).

The number of samples was determined based on power analysis. The minimum sample size required to detect a significance difference using this test should be at least 10 in each group, (60 in total), considering type I error (alfa) of 0.05, power (1-beta) of 0.99, and effect size of 1.623.

2.1. Providence of Samples for Preparation

In our study, 40 extracted sound mandibular molar teeth with similar dimensions were used. The teeth extracted within 6 months that provide these criteria were kept in an isotonic saline solution containing 0.1% thymol until the experimental stage. The residues on the teeth were cleaned with an ultrasonic device. A rubber bur and fluoride-free paste were then used to remove stains and debris. For preparation, the teeth were fixed in the pools of the chewing simulator using self-cure acrylic resin (Imicryl, Konya, Turkey).

2.2. Preparation of the Samples

According to the restoration method standard MOD cavities were prepared by a single researcher with round and inversely tapered diamond burs (Adia, Turkey) on all teeth. Standard MOD cavities preparations were approximately 3.0 mm in width buccolingually, 2.0 mm in axial depth, and 4.0 mm in gingival depth (Figure 1). The samples were randomly divided into 4 groups (n = 10) (Table 1). In the preparation of thirty molar teeth to be restored with the direct method, the cavity wall was prepared parallel to each other, with the width of the gingival cavity greater than the occlusal cavity width. A periodontal probe was used for millimetric measurement of cavity borders. In the preparation of ten molar teeth to be restored with indirect restorations, round corners were created within the cavity at an angle of 6-8° between the cavity base and the side walls in accordance with the entrance path of the restoration.

Table 1. *Materials and Equipment Used in Indirect and Direct Restorations of Samples*

Indirect Restorations			
	Composite	**Contents**	**Adhesive system**
1	**Grandio Block (Voco, Cuxhaven, Germany)** Nano-ceramic hybrid block	86% w/w inorganic fillers in a polymer matrix-14% UDMA + DMA	**Bifix QM** Dual-cure **(Voco, Cuxhaven, Germany)** Bis-GMA, HEMA, Benzoyl peroxide, high Fluoride amin **Futura Bond DC** Universal resin-based adhesive **(Voco, Cuxhaven, Germany)** Bis-GMA, HEMA, Ethanol, Acidic adhesive monomer
Direct Restorations (Conventional Composite + Flowable Composite)			
	Composite	**Contents**	**Adhesive system**
2	**GrandioSo (Voco, Cuxhaven, Germany)** Nano-hybrid composite	Bis-GMA, TEGDMA, Bis-EMA Glass ceramic and Silica-nanoparticles Filler (% w/w): 89	**Futurabond U** Universal HEMA, Bis-GMA, HEDMA, Acidic adhesive monomer, UDMA, Catalyst, Silica nanoparticle, Ethanol
	GrandioSo Flow (Voco, Cuxhaven, Germany) Flowable nano-hybrid composite	Bis-GMA, TEGDMA, HEDMA, Glass ceramic, Silicon dioxide Filler (% w/w): 81	
3	**Admira Fusion (Voco, Cuxhaven, Germany)** Nano-hybrid ormocer-based composite	Aromatic and Aliphatic dimethacrylates, Methacrylate-functionalized polysiloxane, Ba-Al-glass, Pyrogenic SiO_2 Filler (% w/w): 84	
	Admira Fusion Flow (Voco, Cuxhaven, Germany) Flowable nano-hybrid ormocer-based composite	Filler (% w/w): 74	
4	**Tetric N-Ceram (Ivoclar Vivadent, Schann, Liechtenstein)** Nano-hybrid composite	Bis-GMA, UDMA, Ba glass,Ytterbium trifluoride, Mixed oxide Filler (% w/w): 80	**Tetric N-Bond** Universal Phosphoric acid acrylate, HEMA, Bis-GMA, UDMA, Ethanol
	Tetric N-Flow (Ivoclar Vivadent, Schann, Liechtenstein) Flowable nano-hybrid composite	Bis-GMA, UDMA, TEGDMA, Bis-EMA, Barium glass, Ytterbium trifluoride, Mixed oxide, Silicon dioxide Filler (% w/w): 63.8	
Light device		**Wavelength**	**Light intensity**
Valo Cordless (Ultradent, ABD) 3. Generation		395-480 nm	Standard mode: 1000 mW / cm^2 High power mode: 1400 mW / cm^2 Extra power mode: 3200 mW / cm^2

Bis-GMA: Bisphenol A-glycidyl methacrylate, Bis-EMA: Ethoxylated Bisphenol-A-Dimethacrylate, DMA: Dimethylacetamide, HEDMA: Hydroethyl dimethacrylate, HEMA: Hydroethylmethacrylate, TEGDMA: Triethylene glycol dimethacrylate, UDMA: Urethane dimethacrylate

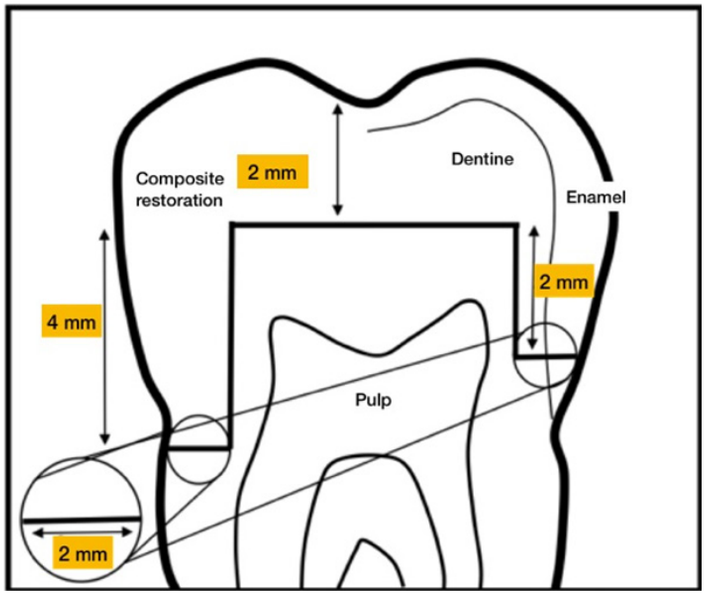

Figure 1. *Measurements of Standard MOD Cavities*

2.3. Indirect and Direct Composite Resin Restorations Procedure

Indirect restorations were performed by using the CAD/CAM system (Sirona, Bensheim, Germany). After scanning the cavity margins of the teeth with the CEREC Omnicam camera, the restoration design was completed on the virtual model with the data obtained. Grandio blocks were placed in the processing unit (inLab MC X5) and processed according to the design. The materials (Table 1) and application methods used in the construction of indirect (Figure 2) and direct restorations (Figure 3) are described in Table 2.

Table 2. *Indirect and Direct Composite Resin Restoration Procedure*

	Restorative material	Acid	Adhesive system	Polisher
Indirect Restorations	**Grandio Block(GB)**	Restoration surface: **Porcelain Etch** (9% HF) 120 sec Enamel surface: **Vococid** (35% H_3PO_4) Selective etch 20 sec	**Ceramic Bond** was applied to the restoration surface for 60 sec and waited and dried with air. **Futurabond DC** was applied to both enamel-dentin and restoration surface for 20 sec. The indirect restorations were luted with **Bifix QM Dual-cure**, and polymerized with Valo Cordless LED for 20 sec.	**Dimanto** (VOCO, Germany)
	Restorative material	**Acid**	**Adhesive system**	**Polisher**
Direct Restorations	**GrandioSo(G)** 2+2+1 mm layers **GrandioSo Flow(GF)** 1mm layer-on the gingival seat	Enamel surface: **Vococid** (35% H_3PO_4) Selective etch 20 sec	**Futurabond U** was applied to the enamel and dentine surface for 20 sec and it was polymerized with Valo Cordless for 10 sec.	**Dimanto** (VOCO, Germany)
	Admira Fusion(A) 2+2+1 mm layers **Admira Fusion Flow(AF)** 1mm layer-on the gingival seat	Enamel surface: **Vococid** (35% H_3PO_4) Selective etch 20 sec	**Futurabond U** was applied to the enamel and dentine surface for 20 sec and it was polymerized with Valo Cordless for 10 sec.	**Dimanto** (VOCO, Germany)
	Tetric N-Ceram(T) 2+2+1 mm layers **Tetric N-Flow(TF)** 1mm layer-on the gingival seat	Enamel surface: **N-Etch** (37% H_3PO_4) Selective etch 20 sec	**Tetric N-Bond** was applied to the enamel and dentine surface for 20 sec and it was polymerized with Valo Cordless for 10 sec.	**OptraPol** (Ivoclar Vivadent, Liechtenstein)

HF: Hydrofluoric acid, H_3PO_4: Orthophosphoric acid

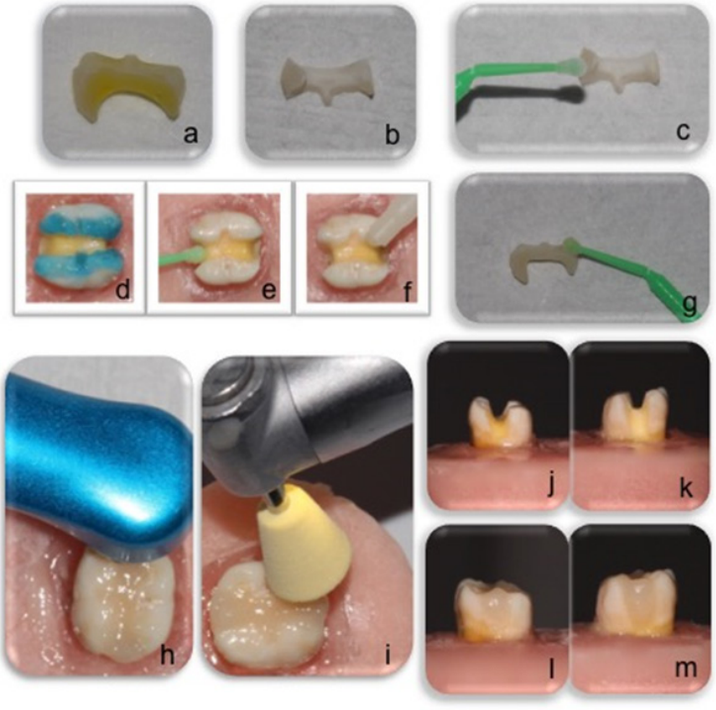

Figure 2. *Indirect Composite Resin Restoration Procedure* ***a.*** *Etching the Restoration Surfaces with Hydrofluoric Acid,* ***b.*** *Restoration Surface After Etching,* ***c.*** *Silane Application,* ***d.*** *Selective Etching of the Enamel Surface,* ***e.*** *Bond Application on Enamel and Dentine Surfaces,* ***f.*** *Adhesive Resin Cement Application on Enamel and Dentine Surfaces,* ***g.*** *Bond Application on Restoration Surfaces,* ***h.*** *Luting the Restoration to the Cavity with Adhesive Resin Cement and Polymerization,* ***i.*** *Finishing and Polishing,* ***j-k.*** *Cavity Preparation of Indirect Restorations,* ***l-m.*** *Cavities Restored by Indirect Method.*

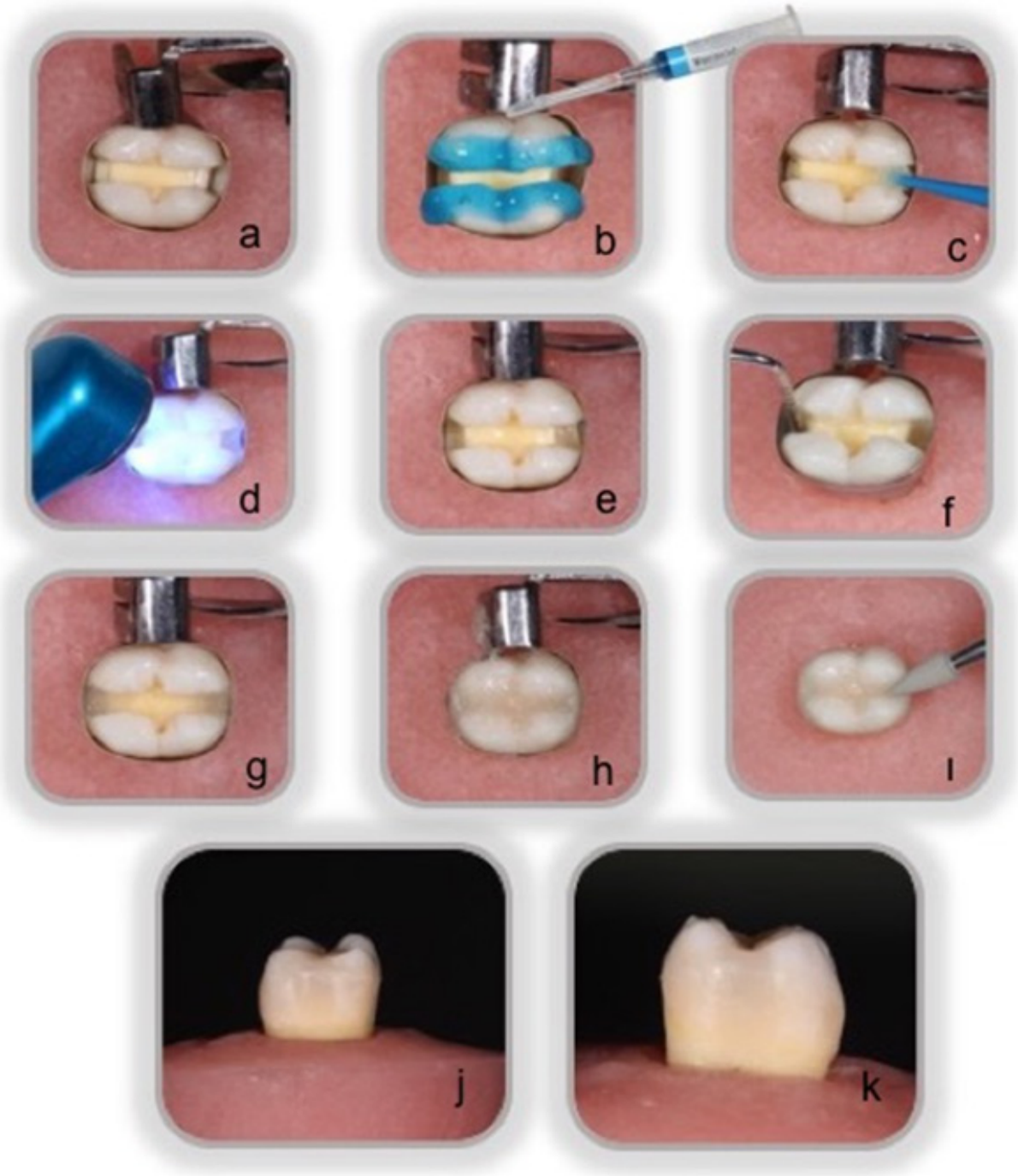

Figure 3. *Direct Composite Resin Restoration Procedure* ***a.*** *Cavity Preparation of Direct Restorations,* ***b.*** *Selective Etching of the Enamel Surface,* ***c.*** *Bond Application on Enamel and Dentine Surfaces,* ***d.*** *Polymerization,* ***e.*** *1 mm Flowable Composite Application on the Gingival Seat,* ***f.*** *Measuring Material Thickness with a Periodontal Probe,* ***g-h.*** *Restoration of the Cavity Using the Incremental Technique,* ***i.*** *Finishing and Polishing,* ***j-k.*** *Cavities Restored by Direct Method.*

2.4. Thermo-Mechanical Loading

The samples were subjected to thermomechanical fatigue using chewing simulator (Willytec SD Mechatronic GmbH CS-4.4 Professional Line, Feldkirchen-Westerham, Germany) (Figure 4). Thermo-mechanical loading was applied during cyclic loading to the restorations with a maximum occlusal load of 50 N at 1.7 Hz. For simulating to standardized conditions steel balls of 6 mm in diameter acted as antagonists. 1-year clinical service stimulation was aimed with 240,000 loading cycles (13, 14). At the same time, thermal cycles were applied to the samples with a heated-cooled thermal cycle system controlled by PLCs included in the chewing simulator (5°C to 55°C every 60 sec).

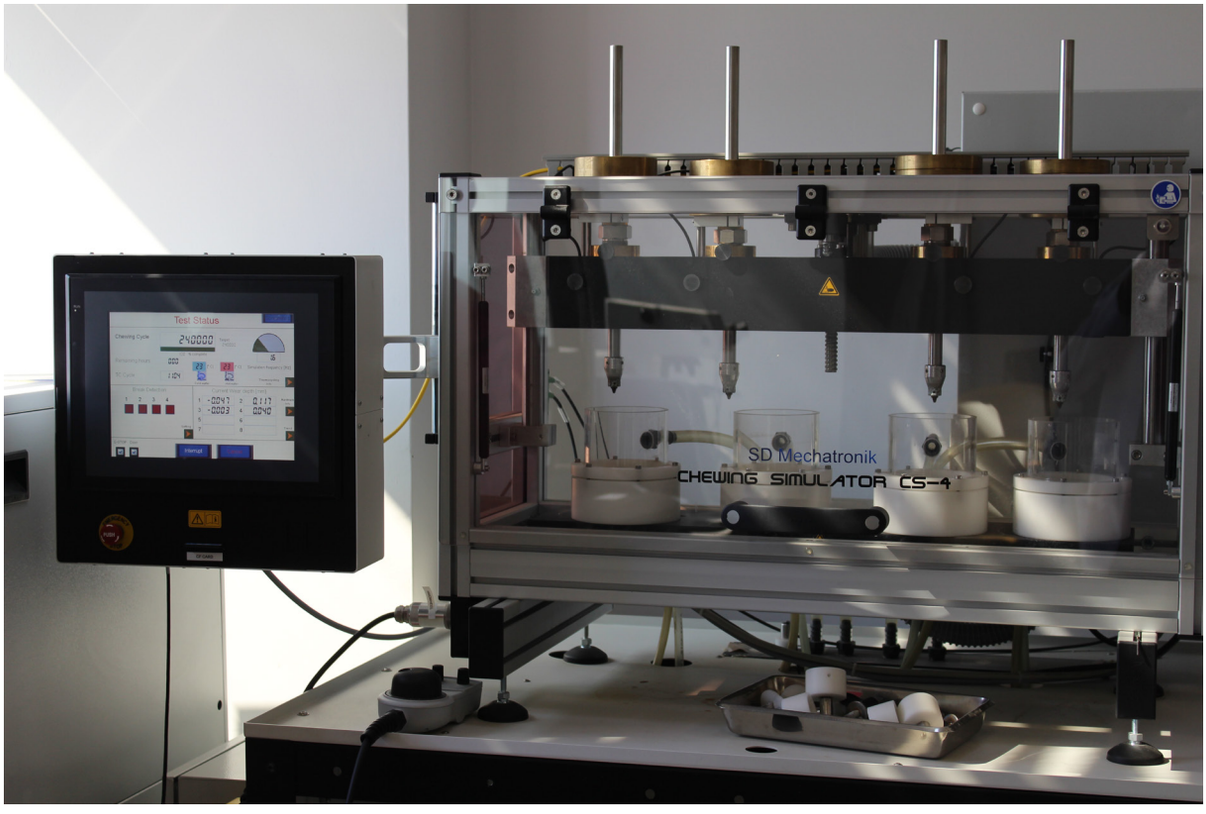

Figure 4. *Chewing Simulator*

2.5. Evaluation of Microleakage and Marginal Adaptation

After thermo-mechanical loading, all surfaces of the teeth samples were coated with nail polish except the restoration areas. Samples were kept in 0.2% methylene blue solution for 24 hours. The teeth were sectioned longitudinally in mesio-distal direction with a precision cutting device (IsoMet 1000, Buehler, USA). Coronal and gingival margin microleakage were scored under X8 and X25 magnifications using a light-stereomicroscope (Leica MZ 75, Germany) (Table 3) (15). The samples that were coated with gold/palladium (20%/80%) using Emitech SC7620 Sputter Coater were examined with Fei Sirion at 10 kV. The images of the samples examined by scanning electron microscopy under X120, X500, X5000 magnification were recorded.

Table 3. *Scale Used to Evaluate Dye Penetration*

Scoring for dye penetration for marginal microleakage on the cervical wall		Scoring for dye penetration for marginal microleakage on the occlusal wall	
0.	No dye penetration	0.	No dye penetration
1.	Dye penetration into half extension of the cervical wall.	1.	Dye penetration into half extension.
2.	Dye penetration into more than half or complete extension of the cervical wall.	2.	Dye penetration more than half.
3.	Dye penetration into the cervical and axial walls towards the pulp.	3.	Dye penetration into the pulpal wall.

2.6. Statistical Analysis

Statistical analyzes in this study were performed using the NCSS (Number Cruncher Statistical System) 2007 Statistical Software (Utah, USA) package program. In the evaluation of the data, descriptive statistical methods (frequency and percentage distributions) as well as the chi-square test was used for the comparison of qualitative data. The results were evaluated at the significance level of $p<0.05$.

3. RESULTS

3.1. Microleakage Analysis

The images obtained under X8 and X25 magnifications of samples with a gingival dye penetration score of 0 (Figure 5.a), 1 (Figure 5.b), 3 (Figure 5.c), and a coronal dye penetration score of 0 (Figure 5.b) were included.

No statistically significant difference was found among the coronal microleakage values of the G+GF, A+AF, GB, and T+TF groups ($p=0.074$). There was no statistically significant difference among the gingival-enamel microleakage values of the G+GF, A+AF, GB, and T+TF groups ($p=0.249$). A statistically significant difference was found among the gingival-cementum microleakage values of the G+GF, A+AF, GB, and T+TF groups ($p=0.003$) (Table 4).

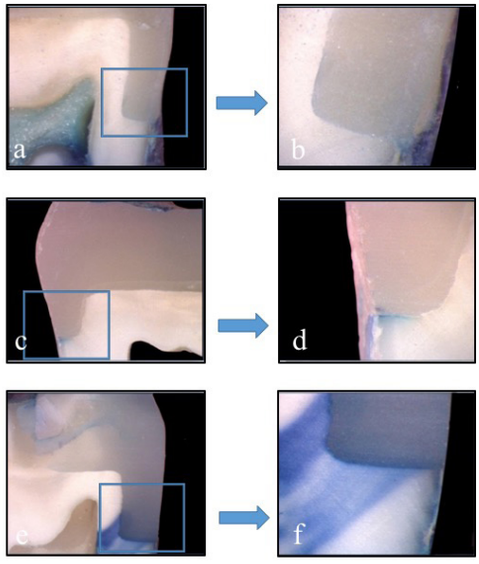

Figure 5. *Dye Penetration According to Gingival and Coronal Score* ***a.*** *Dye Penetration Gingival Score 0 (X8),* ***b.*** *The Image of the Area Marked with a Rectangular Shape in Figure a, Recorded under X25 Magnification.* ***c.*** *Dye Penetration Gingival Score 1 and Dye Penetration Coronal Score 0 (X8),* ***d.*** *The Image of the Area Marked with a Rectangular Shape in Figure c, Recorded under X25 Magnification.* ***e.*** *Dye Penetration Gingival Score 3 (X8),* ***f.*** *The Image of the Area Marked with a Rectangular Shape in Figure e, Recorded under X25 Magnification.*

Table 4. *Evaluation of Microleakage Scores According to Groups*

		G+GF N (%)	A+AF N (%)	GB N (%)	T+TF N (%)	p
Coronal microleakage	No dye penetration	1 0 (100)	9 (90)	5 (55.56)	8 (80)	0.074
	Dye penetration into half extension	0 (0)	1 (10)	4 (44.44)	2 (20)	
Gingival-enamel Microleakage	No dye penetration	7 (70)	7 (70)	5 (55.56)	4 (40)	0.249
	Dye penetration into half extension of the cervical wall	3 (30)	2 (20)	2 (22.2)	5 (50)	
	Dye penetration into more than half or complete extension of the cervical wall	0 (0)	1 (10)	0 (0)	1 (10)	
	Dye penetration into the cervical and axial walls towards the pulp	0 (0)	0 (0)	2 (22.22)	0 (0)	
Gingival-cementum Microleakage	No dye penetration	6 (60)	3 (30)	5 (55.56)	0 (0)	**0.003**
	Dye penetration into half extension of the cervical wall	3 (30)	3 (30)	1 (11.11)	5 (50)	
	Dye penetration into more than half or complete extension of the cervical wall	1 (10)	4 (40)	0 (0)	5 (50)	
	Dye penetration into the cervical and axial walls towards the pulp	0 (0)	0 (0)	3 (33.33)	0 (0)	

A+AF:Admira Fusion+Admira Fusion Flow, G+GF:GrandioSo+GrandioSo Flow, GB:GrandioBlock, T+TF:Tetric N-Ceram+Tetric N-Flow

Among the T+TF, G+GF, and GB groups, the distributions of gingival-cement microleakage no dye penetration were statistically significantly lower in the T+TF group (p=0.010, p=0.001). The gingival-cementum microleakage score 3 distributions of the GB group were found to be statistically significantly higher than the A+AF group (p=0.037). No statistically significant difference was found among the gingival-cementum microleakage distributions of the other groups (p>0.05) (Table 5).

Table 5. *Comparison of Microleakage Values According to Groups*

	Coronal Microleakage	Gingival-enamel Microleakage	Gingival-cementum Microleakage
G+GF /A+AF	0.304	0.549	0.246
G+GF / GB	0.051	0.288	0.168
G+GF / T+TF	0.136	0.313	**0.010**
A+AF / GB	0.140	0.349	**0.037**
A+AF / T+TF	0.531	0.701	0.164
GB / T+TF	0.252	0.226	**0.001**

A+AF:Admira Fusion+Admira Fusion Flow, G+GF:GrandioSo+GrandioSo Flow, GB:GrandioBlock, T+TF:Tetric N-Ceram+Tetric N-Flow

3.2. SEM Images

In our study in which two samples of each group were evaluated with SEM, the gap formation observed in the SEM evaluation of the GB group occurred between both dentine-cement material, and the block-cement material (Figure 6.a). According to the result obtained from SEM evaluations, gap formation between dentine and adhesive layer was observed in T+TF and A+AF groups (Figure 6.b and c). Gap formation observed in the sample taken from the G+GF group was less common (Figure 6.d).

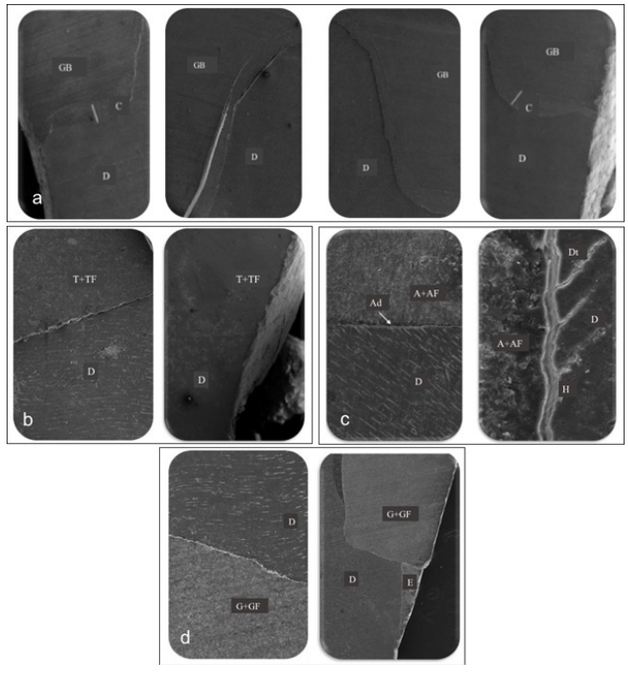

Figure 6. *SEM Images* ***a.*** *GB X120 and X500 SEM Image (D:Dentine and C:Cementum),* ***b.*** *T+TF X120 and X500 SEM Image (D:Dentine),* ***c.*** *A+AF X500 and X5000 SEM Image (D:Dentine, Ad:Adhesive, H:Hybrid Layer and Dt:Dentine Tubules),* ***d.*** *G+GF X120 and X500 SEM Image (D:Dentine and E:Enamel)*

4. DISCUSSION

Disadvantages of composites such as polymerization shrinkage, shrinkage stress, insufficient cavity adaptation, and microleakage have led to new pursuits in the development of composite materials. Ormocer-based composites with differences in the chemical structures have been produced to prevent clinical failure and to extend the survival of the restoration (16).

It is aimed to make restorations with low polymerization shrinkage, high abrasion resistance, and biocompatibility by increasing the amount of silicon in the filler content in composites that are ormocer-based and produced by modifying the organic phase. The specific oligomers of ormocer materials can be obtained by hydrolyzing and densifying the silane molecules used to functionalize the surface of fillers in conventional resin composites (6). If the oligomers have suitable viscosity and hydrophilicity, they can form the entire resin phase if the filler allows particle loading, thus replacing Bis-GMA, TEGDMA, and other conventional dimethacrylates (17).

In our study, no statistically significant difference was found between the coronal and gingival-enamel microleakage values of the ormocer-based nano-hybrid composite and other composite groups. In cavities that ended beyond the cementoenamel junction, the A+AF group has a lower gingival-cementum microleakage score compared to the T+TF and GB groups.

There are studies comparing ormocer-based composites with different restorative materials in terms of microleakage. In the study of Garapati et al., class II cavities were restored with nanofill composite (Filtek supreme), ormocer-based composite (Admira), and micro-hybrid composite (P60) were compared and no significant difference was found between the groups (18). Hodobet et al., in their study, compared the marginal adaptation of the restoration to the cavity with SEM in class II cavities restored with ormocer (Admira Fusion), nanocomposite (Premise), micro-hybrid composite (Gradia Direct). It was found that there were no significant differences between the materials used in both dentine and cementum (19). Kalra et al., compared the microleakage values after thermal cycle in class I restorations of ormocer-based (Admira) and hybrid composites (TPH Spectrum) using ormocer-based adhesive and universal 5th generation adhesive. The low dye penetration scores were obtained in the restoration of the ormocer-based composite with ormocer-based adhesive. However, no statistically significant difference was found (20). This finding is consistent with the studies by Fleming et al., Hodobet et al., and Garapati et al., which did report no significant difference in dye penetration among different materials (18,21).

In a study by Politi et al., compared the microleakage values after the thermo-mechanical cycle of class II restorations using ormocer-based composite (Admira Fusion) and methacrylate-based composite (Tetric EvoCeram), the ormocer group has lower microleakage values compared to the methacrylate group (22). In the study of Yazıcı et al., after thermo-mechanical loading, there is no statistical difference between occlusal and gingival microleakage scores in all restorative material groups. It is noteworthy that there is no occlusal and gingival micro-leakage in the class v cavity group restoring with ormocer-based composite. This is attributed to the fact that ormocer has less polymerization shrinkage due to its organic resin structure (23).

In our study, the higher number of samples with no dye penetration in the G+GF group compared to the A+AF group was associated with the high percentage of filler content of GF causing less polymerization shrinkage. The different results obtained from the studies can be explained by the different methods followed in the study. While the aging method with the thermal cycle is frequently used in the studies performed, aging with the thermo-mechanical cycle, which is thought to simulate the oral environment was preferred in our study.

Restorations in the oral environment are exposed to thermal changes and different pH values with the intake of food and liquids at various temperatures during the day. Thermal changes can result in gaps and microleakage due to the inconsistency in the thermal expansion coefficient between the restorative material and dental tissue and the stress it creates (13). Vertical occlusal loads that occur between the opposing teeth during the chewing of food cause the stresses that occur by transmitting to the occlusal surfaces of the teeth to spread to all occlusal surfaces. All these occlusal loads affect the long-term success of the restorations by mechanically destroying the bonds at the adhesive interface. For this reason, aging tests such as thermal cycle and mechanical loading are used to imitate the oral environment in vitro studies where materials are evaluated (13,16). In our study, 1-year clinical aging was aimed at applying mechanical loading at 240,000 cycles with 50 N force (24).

One of the most important features aimed in successful restorations is to provide ideal marginal adaptation to prevent clinical consequences such as microleakage, marginal discoloration, secondary caries, and sensitivity. Despite the ongoing development of resin composites, the marginal leakage encountered may be related to insufficient bonding between the adhesive material and tooth structures such as cementum and dentine layer or non-prism enamel tissue. Numerous studies have shown that the restorative material does not provide good marginal adaptation in the restoration of cavities terminating below the cementoenamel junction, compared to restorations that end in enamel, and that low marginal closure leads to an increase in gingival microleakage (16,25,26). Bonding of resin with enamel is mainly micro-mechanical and is based on obtaining a high energy roughened surface that can be wetted with low viscosity adhesive agents for resin tag formation. Surface preparation in dentin tissue is important for forming a hybrid layer where a hydrophilic monomer can penetrate and attached with the exposed collagen to provide micro-mechanical connection (27). Dentin tissue, which has low mineral content compared to enamel, has a complex structure rich in organic molecules.

Increased microleakage values in the area under the CEJ were associated with larger diameter and a great number of dentinal tubules compared to the occlusal wall (28).

In our study, microleakage values were compared in cavities ending in cementum and enamel tissues and no statistically significant difference was found. When the scores are examined, microleakage values increased for all composite groups in cavities ending under the cementoenamel junction.

Based on the results of the studies conducted, low-viscosity composite applications are recommended in order to reduce the microleakage that may occur in this area (29,30). In class II cavities, it was aimed to increase marginal adaptation and marginal sealing, decrease dentin sensitivity and create a stress-breaking layer with the application of flowable resin composites in deep, hard-to-reach areas below the CEJ (29). In the restorations of the teeth divided into groups in this study, flowable composites were used as liner materials. Ormocer-based and methacrylate-based composites were preferred as flowable composite materials.

In our study, the number of samples with gingival-cementum no dye penetration score was found to be statistically significantly lower in the T+TF group than in the G+GF and GB groups. The gingival-cementum microleakage scores were higher in the T+TF group compared to the G+GF group. In the study where both groups have nano-hybrid composite properties, different leakage values can be explained with different filler ratios, the size of the filler particles, the monomer composition with organic content, and two different ethanol-based adhesive agents used in adhesion. According to the results we obtained from our study; the second null hypothesis was partially rejected.

Increasing the inorganic content of composites and adding pre-polymerized resin fillers (organic fillers) restricts polymerization shrinkage by reducing the amount of monomer. This can also increase the elastic modulus of the material and lead to high shrinkage stress (31). Polymerization shrinkage stresses are affected by the composition, filler content, elastic modulus, and viscosity of the resin composite and these properties can compensate for the stresses generated during polymerization. As a reflection of these properties, the degree of polymerization conversion and polymerization depth influence the stress formation by affecting the quality of the bond at the interface of the restorations (32,33).

There is a correlation between the shrinkage stress values of composites and internal adaptation (34, 35). While a high polymerization rate can be observed in the upper layer of the composite materials applied to the cavity and the surfaces connected to the outer walls of the cavity close to the light source, a low polymerization rate can be achieved in the inner and pulpal walls. As a result of polymerization shrinkage, stress flow between these areas and gaps in the marginal surface may occur (35,36). Inadequate adaptation with the dentin surface of the material is an indication of the increased potential for gap formation and microleakage (37).

Because CAD / CAM blocks can be produced under controlled conditions, their physical and optical properties are higher than traditional indirect restorations. Marginal integrity, cavity preparation design, and cementation are factors that determine the long-term clinical success of indirect restorations (9).

Different parameters can affect the adaptation of CAD/CAM inlay/onlay restorations. The type of processing device, the design of the restoration, its interior angles, and groove areas are influential on the adaptation of the restoration to the cavity. Preparation of the cavity and its complex geometry is important for the accuracy of intraoral scanning (38,39).

For indirect composite restorations, polymerization shrinkage is limited to the adhesive cement material. It has been shown that adhesive cement thickness has a statistically significant effect on marginal adaptation of CAD/CAM restorations. As the cement thickness decreased, the marginal fit increased (40,41).

In the study of Qian et al., where marginal adaptation and marginal gaps were evaluated under stereomicroscope, samples were restored with CAD/CAM blocks (Enamic, Lava Ultimate) and lab composite (Ceramage). Digital intraoral impression and CAD/CAM systems have not shown superior accuracy in obtaining hybrid ceramic inlays compared to conventional technique. All of the overall mean marginal gaps of inlay restorations made with hybrid ceramics were obtained within the clinically acceptable range (42).

Grandio block was preferred in our study due to the limited literature on nano-hybrid ceramic CAD/CAM blocks.

In the study of Bortolotto et al., the marginal adaptation of CEREC ceramic inlays, CEREC composite inlays, and direct composite restorations in proximal slot cavities was evaluated using scanning electron microscopy. It is concluded that the marginal adaptation of indirect restorations made of both composite and ceramic is better than direct composite restorations (43).

In our study, no significant difference was found between the coronal and gingival-enamel microleakage values of restorations made with CAD/CAM blocks and G+GF group direct restorations.

When the gingival-cementum microleakage values of GB and A+AF groups are compared, the fact that the GB group does not have lower microleakage scores. It can be attributed to the fact that the block is not included in the software program used, and the data was entered by selecting the same size but the different block to transfer it to the processing device. This situation is thought to negatively affect the adaptation of the restoration to the cavity and shows the importance of the design program and the processing device. So first null hypothesis was partially rejected.

The limitations of our in-vitro study, in which the microleakage scores were compared by aging the restorations with a chewing simulator, are the lack of factors such as saliva, patient's diet, and oral hygiene habits that affect the natural

conditions in the oral cavity. Further limiting factor may be steel antagonist ball used instead of human tooth as antagonist in chewing simulator.

5. CONCLUSIONS

When the data we obtained within the limitations of this study are evaluated, we can reach the following results:

1. Different application techniques and materials used in the present study, could not completely eliminate the microleakage observed at the tooth-restoration interfaces.
2. A higher microleakage value was obtained in the restorations of the prepared MOD cavities ending in cementum compared to the restorations ending in enamel.
3. Microleakage values in indirect restorations obtained with CAD/CAM block showed similar results with direct restorations.

Under the conditions of this study, the use of conventional nanocomposite in the direct restoration of MOD cavities has shown the least microleakage.

Today, limited information about the content and structure of ormocer materials can be reached. The limited number of clinical and in vitro studies carried out requires more studies in order to reach clear information about the clinical longevity and success rate of the ormocers.

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Conflict of Interests

The authors do not have any financial interest in the companies whose materials are included in this article.

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Clinical and Experimental Health Sciences

Which Polishing Method is Effective for Coffee Stains? – An in Vitro Study of Surface Roughness and Color Change

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ABSTRACT

Objective: To assess the effects of three different polishing protocols on the surface roughness and color change of the enamel and compare the results with the enamel specimens exposed to coffee.

Methods: Seventy-two bovine enamel specimens were randomly divided into two groups-Group I: only polishing, Group II: immersion in coffee solution and polishing–which were then subdivided into three groups according to polishing procedures as follows: polishing with rubber cup and Pumice Flour (PF), polishing with rubber cup and Prophy Paste (PP), polishing with Air Abrasion (AA). Surface roughness (Ra) and tooth color were assessed using a surface profilometer and a digital spectrophotometer. The color change was determined by the CIE L*a*b* system. One specimen from each group was also examined by SEM. Statistical analyses were performed by GraphPad software. Kruskal-Wallis and Friedman tests were used for multiple comparisons between-groups and in-groups, respectively.

Results: At baseline measurements, no significant differences were found among groups in terms of roughness and color values ($p>0.05$). In Group I, surface roughness values and color change were similar after polishing ($p=0.393$, $p=0.093$, respectively). In Group II, post-polishing Ra values were significantly increased in all groups ($p<0.05$) and the highest ΔE value was detected in PP group.

Conclusion: Following coffee immersion, enamel surfaces become rougher in all polishing protocols and the roughest surface was in PF group. In all study groups visible clinical success was achieved in terms of color; therefore, dental clinicians should prefer PP in clinical practice due to the less abrasive and sufficient color change properties.

Keywords: surface roughness, color change, polishing protocols, enamel

1. INTRODUCTION

Clinicians remove plaque, calculus and stain from tooth surfaces by scaling, cleaning and polishing (1). On the other hand, the mechanical method most frequently used by individuals to control plaque accumulation is tooth brushing. However, it cannot completely and effectively remove all dental plaques, especially when not done regularly. In modern societies, people's desire to have clean teeth is increasing day by day, and many people apply to dentists once in 3-6 months for a professional dental cleaning (2).

The common two methods that dentists use for oral prophylaxis are rubber cup and air-polishing. The rubber cup procedure is the application of some agents to the tooth surfaces with a rotating rubber cup or rotating bristle brushes. One of the most commonly used agents during prophylaxis procedures is pumice-water mixture applied to the tooth surface with the help of brushes and rubber cups attached to rotating tools. As an alternative to this agent, commercial prophylaxis pastes have been frequently used by dentists in recent years (3). In air-polishing procedure, air and water pressure are mixed with an abrasive powder, so the remaining external stains are removed. Some studies have suggested that this method is more effective, useful and requires less chair time than polishing procedures with rubber cups (4, 5).

Although enamel tissue shows a clinically smooth surface, there are some microscopically detected structures on its surface. Polishing methods have been suggested to be clinically safe. However, they can cause scratches on the enamel surface or create rough surfaces, which can result in faster deposition of biofilm products. Some studies reported

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no morphological changes (6, 7), while others reported only minimal changes in the enamel surface (8, 9).

Due to the accumulation of plaque and surface stains, the external discoloration is closely related to hygiene, smoking habits and diet. Some studies have shown the coloring effect of staining solutions consumed frequently, such as tea and coffee (10, 11). Coffee is one of the most frequently consumed and colored drinks in daily life. Moreover, the reason for the coloring effect of coffee is shown to have a dark color and an acidic pH value (11). Enamel, the outermost layer of teeth, is open to attack, so staining of the enamel can cause demineralization and erosion (12, 13). According to coffee manufacturers, the consumption of a mug of coffee takes an average of 15 minutes, and a coffee consumer consumes 2 cups of coffee three times a day. Therefore, keeping the samples 24 hours in coffee corresponds to monthly coffee consumption in vitro studies (10).

One of the important goals of today's modern esthetic dentistry is to ensure the continuity of dental esthetics by preserving the natural tooth color (14). Each individual's natural tooth color is unique and is affected by various factors. Some external stains can be partially or completely removed by brushing teeth with toothpaste or professional prophylaxis (15). Moreover, there are both positive and negative aspects of every treatment. The most common problems faced by dentists with polishing methods in clinical routine are that patients may have a feeling of roughness in their teeth after the procedure or that unwanted coloring is frequently repeated following previous polishing treatment.

In the light of all this information, the purpose of this in vitro study was to assess the effect of three different polishing protocols – pumice flour (PF), prophy paste (PP) and air abrasion (AA) – on the surface roughness and color change of the enamel and compare the results with the enamel specimens exposed to coffee solution followed by polishing protocols. The tested null hypotheses were as follows: [1] there would be no difference between the tested polishing systems in terms of the effect on enamel surface roughness and color change [2] different polishing systems would have no influence on the roughness of the enamel surface and the color change after exposure to coffee.

2. MATERIALS AND METHODS

2.1. Specimen Preparation

A total of thirty-six sound bovine incisors were stored at 100% moisture containing 10% formalin before usage. Calculus and soft tissue deposits were cleaned using a hand scaler. The teeth were sectioned buccolingually using a water-cooled diamond cutting disc (n = 72), and then all teeth were mounted on a self-hardening acrylic resin (Meliodent, Heraeus/Kulzer, Hanau, Germany) block with the buccal surface exposed. The sample surfaces were first grounded with 600-grit and then 1000-grit silicon carbide papers under running water for 10 s on a polishing machine (LabPol 21, Struers, Ballerup, Denmark) and kept in deionized water at 37 ℃. Using a power of 80%, the sample calculation indicated the need for approximately 12 teeth for each group in order to determine a difference of 25% among the study groups.

2.2. Groups and Applications

The color and surface roughness (Ra) of all teeth were assessed at baseline prior to the polishing procedures using a surface profilometer (Perthometer, M1 Mahr, Göttingen, Germany) and a spectrophotometer (VITA Easyshade, VITA Zahnfabrik, Bad Sackingen, Germany), respectively. Then, the teeth were categorized into two groups having 36 teeth in each. The specimens were distributed to the groups paying attention to the L *, a * and b * initial parameters. While Group I was only subjected to polishing procedures, Group II was immersed in coffee solution (Nescafé Classic, Nestlé, Vevey, Switzerland) and then polished. These groups were also subdivided into three groups according to polishing procedures as follows (n=12):

Group PF**:** The samples were polished for 15 s with a rubber cup and pumice flour (Isler Dental; Ankara, Turkey) attached to the low-speed contra-angle handpiece in a circular motion. The rpm value applied for speed was a steady slow pace of 2500 rpm.

Group PP**:** The samples were polished for 15 s with a rubber cup and polishing paste (Deepak Products, Inc.; Keystone Europe LLC, Netherlands) attached to the low-speed contra-angle handpiece in a circular motion. The rpm value applied for speed was a steady slow pace of 2500 rpm.

Group AA**:** The samples were polished for 15 s with an air polisher (Prophy-Tech; Benlioglu Dental Inc., Ankara, Turkey) using sodium bicarbonate powder. Air setting 20 psi. The tip of the air polisher was set at a 90° angle to the tooth surface when the distance was held constant at 6 mm.

In practice, all polishing procedures were performed by the same operator.

2.3. Coffee Immersion

The coffee solution was prepared by pouring 15 g of coffee powder (Nescafe ® Classic, Nestle SA, Vevey, Switzerland) into 500 mL of boiling distilled water. After the solution has been stirred for 10 minutes, it was filtered through filter paper. The immersion time was 48 hours.

2.4. Measurement of Surface Roughness

The average surface roughness (Ra; µm) was measured with a Surface Profilometer using a tracing length of 1.25 mm and a cutoff of 0.25 mm to maximize filtration surface waviness, and a measuring speed of 0.5 mm/s. In each specimen, measurements were made three times in different directions and at different locations by turning it around. The roughness values were recorded by taking the average of the obtained values. The performance of the device was controlled by

using a calibration block after each specimen. Baseline measurements were recorded for all samples before they were divided into groups. For Group I, surface roughness measurements were recorded as post-polishing; for Group II, Ra was recorded as post-immersion and post-polishing.

2.5. Measurement of Color Values

Color values were recorded in sequence using a digital spectrophotometer. Following baseline measurements; for Group I, color value measurements were recorded as post-polishing; for Group II, color value measurements were recorded as post-immersion and post-polishing. The spectrophotometer measured the tooth color based on the CIEL*a*b* color space system, which allows the color to be determined in three-dimensional space.

The color difference (ΔE) between the color coordinates was calculated by applying the formula $\Delta E=[(\Delta L)^2 + (\Delta a)^2 + (\Delta b)^2]^{½}$. Three measurements were taken with the spectrophotometer at the center of each sample. So, the instrument automatically averaged three readings for each sample, which were then used for overall data analysis. The device was also calibrated before each measurement.

2.6. *Scanning Electron Microscopic Analysis*

One representative specimen from each group was prepared for SEM evaluation. For the decontamination of the samples, a soaking procedure was performed in 10% neutral buffered formalin solution for 8 hours. The specimens were fixed on metal stubs and were then gold-sputtered (one cycle of 120 s) under a vacuum atmosphere in a sputtering device (MED 010, Balzers Union, Balzers, Liechtenstein). The surfaces were examined by scanning electron microscopy (Tescan GAIA 3) to examine the effect of polishing systems.

2.7. *Statistical Analysis*

Statistical analyses were performed by GraphPad Prism 8.2.1 for Windows (GraphPad Software, San Diego, California). In addition to the descriptive analysis, data were analyzed using non-parametric tests, alpha=0.05. Multiple comparisons between-groups and in-groups were performed using Kruskal-Wallis and Friedman tests, respectively. For pairwise comparisons, Wilcoxon matched pairs signed rank test was used in – groups and Mann Whitney-U test was used in between – groups.

3. RESULTS

3.1. Surface Roughness

At baseline measurements, no significant differences were found among treatment groups in terms of roughness in both Group I and II (p=0.836, p=0.530, respectively). Medians (min-max) of surface roughness values are presented in Table 1 for Group I and in Table 2 for Group II.

Table 1. *Comparison of the Surface Roughness Within and Among Different Polishing Protocols at baseline and Post-polishing in Group I.*

Subgroups	Baseline Ra	Post-polishing Ra	p
	Median (min-max)	Median (min-max)	
Pumice flour	0.232 (0.146 – 0.442)	0.192 (0.156 – 0.246)	0 .016*
Prophy paste	0.211 (0.115 – 0.280)	0.204 (0.128 – 0.266)	0.102
Air abrasion	0.213 (0.140 – 0.448)	0.189 (0.137 – 0.299)	0.176
p	0.836	0.393	

** significantly different from baseline (p<0.05).*

Table 2. *Comparison of the Surface Roughness Within and Among Different Polishing Protocols at Baseline, Post-Immersion and Post-Polishing in Group II.*

Subgroups	Baseline Ra	Post-immersion Ra	Post-polishing Ra	p
	Median (min-max)	Median (min-max)	Median (min-max)	
Pumice flour	0.226 (0.145 – 0.341)	0.213 (0.145 – 0.371)	0.439[a] (0.199 – 0.808)	0.000*
Prophy paste	0.208 (0.156 – 0.274)	0.212 (0.155 – 0.256)	0.329[a] (0.188 – 0.567)	0.013*
Air abrasion	0.214 (0.140 – 0.321)	0.192[a] (0.155 – 0.187)	0.241[A] (0.133 – 0.667)	0.004*
p	0.530	0.131	0.002*	

*BL: Baseline, AIM: After immersion. * a significant difference (p<0.05). [a] significantly different from other groups in each row, and [A] significantly different from other groups in each column (p<0.05).*

In Group I, Ra values were diminished after polishing for 15 seconds with PF, PP and AA; however, only significant difference was detected in PF group (p=0.016). Intergroup comparison of Ra values showed no statistically significant difference (p=0.393). In Group II, surface roughness values were similar after coffee immersion (Table 2). When 15 sec polishing were performed, surface roughness values were significantly different when compared to baseline in PF, PP and AA groups (p<0.05, Table 2). The Kruskal-Wallis test exhibited significant difference for intergroup roughness comparison (p=0.002). When pairwise comparisons were evaluated, Group AA showed significantly lower values when compared to PF (p=0.0007); and when compared to PP (p=0.012). On the other hand, Group PF and PP showed similar values (p>0.05).

3.2. Color stability

At baseline measurements, no significant differences were found among PF, PP and AA in terms of color values in both Group I and II (p>0.05). Table 3 exhibits the medians (min-max) of the color change for Group I and II.

In Group I, no statistically significant difference was detected between PF, PP and AA in terms of color change after polishing (p=0.093). In Group II, statistically significant differences were

detected between treatment modalities in both comparisons of baseline – after immersion (p=0.009) and after immersion – after polishing (p=0.003) (Table 3). In Group II, the highest median ΔE value was detected in PP group, demonstrating more color change. Representative SEM images of enamel surfaces for each group are shown in Figure 1.

Table 3. *Comparison of the Color Change Values Within and Among Different Polishing Protocols for Group I and II.*

Subgroups	Group I	Subgroups	Group II		p
	Baseline-Post polishing ΔE		Baseline-After immersion ΔE	After immersion-Post polishing ΔE	
	Median (min-max)		Median (min-max)	(min-max)	
Pumice flour	6.898 (1.980 – 18.77)	Pumice flour	24.23 (9.414 – 50.39)	6.352^{A} (1.552 – 10.66)	0.037*
Prophy paste	5.522 (2.602 – 9.032)	Prophy paste	30.99 (21.12 – 50.69)	19.11^{B} (3.775 – 50.84)	0.001*
Air abrasion	8.343 (2.022 – 13.75)	Air abrasion	25.51 (9.696 – 45.23)	4.953^{A} (1.136 – 11.66)	0.003*
p	0.093	p	0.091	0.002*	

** a significant difference (p<0.05), and different superscript upper case letters indicate significant differences for Group II (p<0.05)*

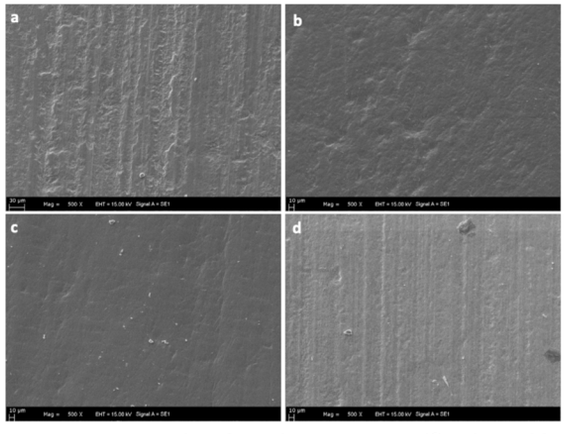

Figure 1. *Representative SEM images, magnification=500x: (a) untouched enamel; (b) enamel surface polished with pumice flour; (c) enamel surface polished with prophy paste; (d) enamel surface polished with air abrasion*

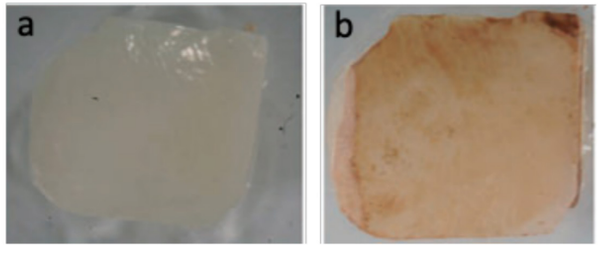

Figure 2. *Representative images of specimens at baseline (a) and after immersion (b)*

4. DISCUSSION

The main purpose of polishing, which is an integral part of clinical practice, is to remove the plaque and stains on the enamel surface to provide a surface as smooth as possible. It has been reported that scaling alone is not sufficient to reduce the surface roughness, but can be achieved by polishing afterwards (16). Moreover, there is a widespread debate about whether the tooth surface should be polished or not. Some studies suggested that polishing removes plaque and reduces bacterial colonization, resulting in a smooth tooth surface (17, 18). The results of the present study revealed alteration of the enamel surface with all the prophylactic methods applied. This outcome was assessed through an evaluation of the surface roughness and a scanning electron microscopy examination. On the other hand, the first null hypothesis that there would be no difference between the tested polishing systems in terms of the effect on enamel surface roughness and color change has to be accepted. Following the polishing procedure, no statistically significant difference was detected between PF, PP and AA in terms of surface roughness and color change.

Even though polishing with rubber cup and paste is the most common method, air-powder polishing devices are also becoming popular. It is believed that surfaces that rubber cup cannot reach are achieved in this way, but their actual effectiveness in smoothing the enamel surface remains controversial (19). In a study conducted by Galloway and Pashley (20), they concluded that air-polishing devices have sufficient stain removal ability. Still, their abrasive effect on enamel was not as much as applying pumice flour with a rubber cup. On the other hand, several studies (9, 21, 22) reported that air-polishing increased the surface roughness. It has been suggested that this may be due to the shape of the sodium bicarbonate powder particle and the high-pressure during application.

Sodium bicarbonate has a particle area of approximately 0.037496353 mm^2/74 mcm and the Mohs' scale hardness number of 2.5, which is low in comparison to pumice [6–7], and as well as enamel [5–6]. The shape of sodium bicarbonate particles has been shown to have irregular and sharp edges (23), eroding the particles more and causing roughness on the tooth surface. It has been previously shown that increasing pressure causes more wear and roughness, leading to tooth surface loss (24). Air polisher is typically used with an air setting of 80 psi, while the pressure for bristle brush and rubber cup application is approximately 20 psi (25). Therefore, it can be interpreted that the air-polishing device should be used carefully.

According to the findings of the present study, polishing procedures reduced the surface roughness in all samples of Group I; however, no statistically significant difference was detected among PF, PP and AA (p=0.393). Moreover, only polishing with rubber cup and pumice flour for 15 seconds significantly affected the enamel surface roughness. In a scanning electron microscopy (SEM) study, the authors evaluated the efficiency of 3 different polishing methods

on enamel and cementum (26). According to their results, polishing with a rubber cup and polishing paste was more effective than polishing with a bristle brush or air polisher in obtaining a smooth enamel surface. The difference in roughness findings of polishing systems in the literature may be related to different value ranges for application time, speed and application pressure. For example, while the rpm value applied for speed in various studies ranged from 1000 rpm to 5826 rpm, the application time varied from 5 seconds to 60 seconds and the application pressure could be used between 150 g and 450 g (27-29).

In the present study, a coffee solution was used as a coloring agent because it is a frequently consumed beverage in daily life, with reference to previous studies that created artificial coloring (14, 30, 31). Pigmentation of teeth with coffee or other beverages could cause some alterations to enamel and dentin tissues. The substances responsible for causing tooth stains in coffee solution are known as tannins which are polyphenol structures such as tannic acid, gallic acid, catechins and leucoanthocyanins. In an in vitro study conducted by Singh and Aggarwal (32), they found that coffee could change the opalescence color of teeth. On the other hand, coffee has the potential to cause erosion, but its mechanism is not fully understood (33, 34). However, it can be assumed that coffee deposition can cause fine abrasive effects on teeth by changing the enamel composition. Erosion is a progressive localized loss of major element components of enamel by the effect of acid or chelation (13). In agreement with the literature, following coffee immersion, the difference among groups was statistically significant for both parameters. Therefore, the second null hypothesis that different polishing systems would have no influence on the roughness of the enamel surface and the color change after exposure to coffee has to be rejected.

In general, coffee has been shown to contain a pH around 5.8 (35). Moreover, decalcification that can occur on the enamel surface is mainly associated with erosion caused by acidity. Manno et al. evaluated enamel staining by coffee using spectroscopy and scanning electron microscopy and reported that coffee caused a loss in calcium and phosphates, the main elements of hydroxyapatite (36). Moreover, it has been reported that the change in the color of teeth is due to the high concentration of metals contained in coffee. In another SEM study, the effects of soft drinks such as coffee on etched and sealed enamel were investigated (37). The authors stated that demineralization occurs when etched regions of the enamel are exposed to coffee. According to our findings, the roughness values of specimens did not differ significantly after immersion in coffee solution. This result of the study may be due to the fact that the immersion time in coffee coincides with the 2-months coffee consumption and a possible erosion did not make a significant difference in roughness device measurements. On the other hand, after immersion and 15 sec polishing, Ra values for all groups significantly increased. It is noteworthy that the roughness values of the samples subjected to only the polishing procedure decreased, while the roughness values of the samples immersed in coffee solution increased after polishing. As mentioned in the above studies, the abrasive potential of the polishing procedures may have arisen, possibly because coffee made the enamel surfaces more vulnerable to damage. Therefore, clinicians may need to pay attention to factors such as handpiece speed or pressure in the polishing process of patients who consume too much coffee.

The result of this study indicated that all the tested polishing systems were effective on removing stains from the teeth surfaces as they all showed ΔE values above 3.3, which is accepted as the threshold value for a clinically significant color change (38). There are different methods to detect color; moreover, the most preferred one in clinical practice is visual color selection. On the other hand, visual color selection does not provide reliable results for scientific research because of various factors such as the experience of the person who makes the determination, ambient light and lighting, the wall color of the room. In order to detect tooth color and discoloration, spectrophotometers are mostly preferred for scientific research, so that in the present study, the color measurements obtained with the spectrophotometer were evaluated based on the International Commission of Illumination (CIE) color system.

In Group I, ΔE values ranged from 3.4 to 18.7 following polishing and no statistically significant difference was observed among groups in terms of color change. Based on this finding, the following comment can be made that all three polishing methods tested could clean superficial stains at a noticeable level. Camboni and others (39) compared the tooth surface following air-polishing and rubber cup polishing with several different pastes using SEM analysis. They reported that air-polishing was able to clean more deeply without any damage to the enamel compared to polishing pastes with rubber cup. In agreement with this study, the surface roughness values of specimens exposed to air-polishing were lower than other groups, for both groups (Group I and II) of this study. On the other hand, polishing with rubber cup and prophy paste following coffee immersion showed higher color change compared to other polishing protocols. This interesting result may be related to the fact that the rougher surface of the enamel which was subjected to immersion and polishing with rubber cup and pumice flour, may be associated with a minimal surface loss and may have caused more reflection of the dentin color. Therefore, prophy paste may have been the method that removed coffee stains better than other tested polishing methods.

In the present study, bovine teeth were preferred because of the larger flat areas that could accommodate the tip of the profilometer and spectrophotometer handpiece. Moreover, bovine teeth are used routinely as an alternative to human teeth in in vitro studies (40, 41). Like other in vitro studies, clinical difficulties arising from the oral environment could not be mimicked exactly and is one of the limitations of the study. Especially saliva, which is a natural part of the oral environment and may buffer the possible erosive effect of

coffee, was not used in the study. Therefore, these results need to be supported by more studies.

5. CONCLUSION

According to the results of the present study, one can suggest that the statistically significant smoothest surface was achieved after polishing with rubber cup and PF for 15 sec; however, after coffee immersion teeth surfaces were more prone to erosion and became rough in all polishing protocols and the roughest surface was in PF group. In all study groups visible clinical success was achieved in terms of color; therefore, dental clinicians should prefer PP in clinical practice due to the less abrasive and sufficient color change properties.

Disclosure Statement

The authors do not have any financial interest in the companies whose materials are included in this article.

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Conflict of Interest

The authors declare that they have no conflict of interest.

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Clinical and Experimental Health Sciences

Knowledge and Management of Pediatricians About Children's Oral Health

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ABSTRACT

Objective: This study aims to analyze the knowledge level of pediatricians in Turkey regarding dentistry, oral-dental health, some common oral diseases and to evaluate their approach to their patients from a dental point of view.

Methods: A total of 260 pediatricians responded to a 26-question electronic survey about their personal information and knowledge about children's oral health. The data obtained were analyzed using the t test, Anova and chi-square tests.

Results: The survey was answered by 260 pediatricians. The mean pediatricians' knowledge score was 9.55±2.85 (min-max: 3 to 22) and the median score was nine. The number of physicians who didn't know that cariogenic microorganisms can be transmitted from mother to baby was 161 (62%). It was determined that the pediatricians chose the option "No idea" about protective and preventive applications such as fissure sealants (66.1%), topical fluoride applications (53.4%), space maintainer/child prosthesis (67.3%) and hence they don't have sufficient information.

Conclusion: Lack of information and training seems to limit the role of pediatricians in children's oral and dental health. It should be ensured that there are stronger cooperation and communication between pediatric dentists and pediatricians.

Keywords: Preventive Dentistry, Oral Health, Pediatricians, Dental Care for Children, Pediatric Dentistry.

1. INTRODUCTION

Oral health is an integral part of children's overall health. Dental caries is considered the most common childhood disease with significant consequences. It has been reported to be five times more than asthma and seven times more than high fever (1).

Dental caries is an infectious disease caused by cariogenic bacteria, diet, and host sensitivity (2). These types of oral diseases can be prevented and controlled through training provided for parents. In the United States of America (USA), dental caries is observed on the primary teeth of approximately 31% to 53% of children between the ages of 2 and 8 (3), and it affects 75% of children by the age of 15 (4). The studies conducted in Turkey have reported even higher rates of dental caries. In studies performed on preschool children, the presence of dental caries was reported in 74.1% of children between the ages of 3 to 6 and 84.9% of children between the ages of 5 to 9 years (5,6).

Especially in developing countries, it is reported that the incidence of dental caries has increased 5-10 times due to socioeconomic reasons, diet and insufficient or inappropriate oral hygiene (7). In developed western countries such as Finland, Norway, and Germany, the prevalence of caries in children and young individuals was shown to have decreased rapidly in the 1970s and 1980s (8). This decrease was attributed to various factors such as the use of fluoride-containing toothpaste, changes in sugar consumption, increased socioeconomic level, dentistry services becoming widespread, application of basic protective and preventive treatments, increased awareness of personal oral hygiene practice (8).

As healthcare professionals responsible for the overall health of children, pediatricians often face dental caries-related morbidity. Since pediatricians are the first healthcare professionals to see children, they also have a unique position in identifying and directing diseases related to oral and dental health (9). Evidence in the literature indicates that parents systematically consult pediatricians, regarding dental queries during the first year of their children's life, when the frequency of visits to the pediatrician and pediatric dentist

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is examined, regardless of the nature of the service sought (public or private) (10). The development of dental caries can be prevented if pediatricians detect dental caries and raise awareness of families about preventive measures (11).

This study aims to analyze the knowledge level of pediatricians in Turkey regarding dentistry, oral and dental health, and some common oral and dental diseases, and to evaluate their approach to their patients from a dental point of view.

2. METHODS

The study was approved by the Non-Interventional Clinical Research Ethics Committee of Inonu University (Protocol: 2020/573). This study is random demographic research that evaluated pediatricians' oral and dental health knowledge, their attitudes towards oral health and nutrition during infant controls and their approach to certain oral pathologies. The study was explained to the children's parents, whose intraoral photographs were used in the questionnaire and the article, and the informed consent form was signed.

The questionnaire was kept short so that the length of the survey was not negatively reflected in the answers of the respondents, and it was prepared as 26 questions on Google forms. While creating questions, five pediatricians, one public health specialist, and five pediatric dentists were consulted, and the recommendations of the physicians were reflected in the questionnaire items.

The study population was accessed by using case sharing platforms that pediatricians frequently use. A message which contained a participation link and a short text describing the study was sent to pediatricians who were members of these platforms.

The questions are given in Tables 1, 2, 3, 4 together with the findings. The correct answers are marked with an ** sign.

The sample of this study was determined by power analysis. According to the calculations made using the G * power 3.1 program; The sample size was determined as minimum 252 with 0.25 effect size, 0.05 margin of error, 0.95 confidence level, and 0.95 universe representation power (12).

The analysis of the data included in the study was made with the SPSS (Statistical Program in Social Sciences) 25 program. In the study, quantitative data were presented in "Mean ± Standard deviation", and qualitative data were presented in numbers and percentages. Whether the data included in the study conformed to the normal distribution was checked with the Kolmogorov Smirnov Test. The significance level (p) was taken as 0.05 for the comparison tests. Since the data showed normal distribution, the significance test (t test) and the ANOVA test were used for the difference between the two averages. The Duncan multiple comparison (post-hoc) test was used to determine the groups with differences in the ANOVA test, as variance homogeneity was provided. In addition, qualitative data calculated by chi-square test.

3. RESULTS

The survey was sent to 1830 pediatricians across the country through message, 260 of them answered the survey, and the participation rate was calculated as 14.2%. Survey questions and answers are given in Tables 1, 2, 3, 4.

The pediatricians' mean knowledge score about oral health was 9.55±2.85 and the median score was nine (min-max: 3 to 22). A statistically significant difference was found between male and female according to the total scores of the participants included in the study ($p < 0.05$, Table 5). A statistically significant difference was found between the age and working year groups according to the total scores of the participants included in the study ($p < 0.05$, Table 5). Duncan Multiple Comparisons test was conducted to see which groups differed for both variables, since variance homogeneity condition was provided. For working years; A statistically significant difference was found between 0-5 years, 5-10 years and 15 years and above in terms of scores ($p < 0.05$), but there was no difference between the other groups ($p < 0.05$, Table 5).

Table 1. *Pediatrician's demographic informations*

Gender Value*	
Female	56% (n=146)
Male	44% (n=114)
Average of age	35.7± 6,3
Years of professional experience	
0-5	49.6% (n=129)
5-10	23.8% (n=62)
10-15	16.2% (n=42)
15 and over	10.4% (n=27)

**Values are evaluated as percent (%). n = number of people.*

Pediatricians correctly answered the eruption time of the first permanent molar with 42.3%, by choosing six years of age. The oral cavity of an eight-year-old girl was photographed upon taking the consent of the parents, and the photo was attached to the questionnaire (Figure 1). The participants were asked to identify the first permanent molar among the numbered teeth in Figure 1. 35% of the physicians answered this question correctly (Figure 1). There was no significant difference in the rate of correct answers to these two questions by gender (p=0.561, p=0,693, Table 6).

When pediatricians were asked how often they encountered patients with an ectopic eruption of permanent lower incisors as in Figure 2; 4% stated that they met it once a week, 14% said once a month, 40% once a year and 42% answered that they had never met any. 76.5% of the physicians thought that this situation may cause crowding

and 85.3% of them thought that orthodontic treatment might be necessary.

While 48.8% of the physicians who participated in the survey correctly diagnosed primary herpetic gingivostomatitis (PHG) in the photograph, in the next question, 64.5% found it appropriate to prescribe oral antibiotics for treating this disease. A significant relationship was found between medical experience and the ability to treat PHG (p=0.270). 46.4% of physicians with 15 or more experience treated PHG correctly (Table 7).

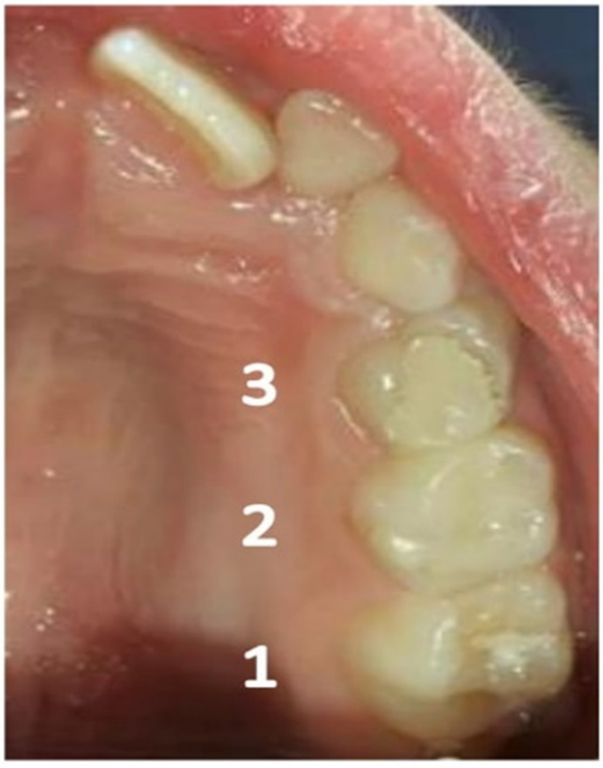

Figure 1. *The intraoral photograph of an eight-year-old girl. The participants were asked to identify the first permanent molar among the numbered teeth.*

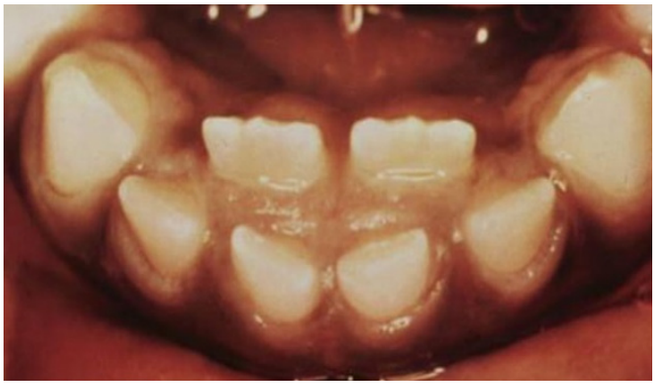

Figure 2. *The intraoral photograph of a six-year-old girl with an ectopic eruption of permanent lower incisors. Praticipants were asked "How often they encountered patients with an ectopic eruption and may this situation may cause crowding and orthodontic treatment be necessary?".*

When asked about the treatment approach to the patient with lodge abscess caused by teeth, the rate of those who responded that the patient should be treated with combined antibiotic IM/IV (aerob + anaerobe) in hospital conditions was 77%. 20% preferred to prescribe a combined oral antibiotic and refer the patient to the dentist.

Table 2. *Questions and answers about oral examination of 0-1 years old children*

	Value*	
When do you recommend the first dental examination?		
With the first tooth eruption **	27% (n=70)	
After the age of 1	26.6% (n=69)	
After the age of 2	27.3% (n=71)	
I don't recommend in routine/ I forget	19.3% (n=50)	
How often do you recommend routine dentist control to your patients?		
Every 6 months **	30.4% (n= 79)	
Once a year	38.5% (n=100)	
When there is a problem	21.2% (n=55)	
I do not recommend in routine/ I forget	10% (n=26)	
When to start brushing teeth?		
With the first tooth eruption **	40.8% (n=106)	
12. month	16.5% (n=43)	
18. month	13.8% (n=36)	
24. month	28.8% (n=75)	
When to start using toothpaste?		
1 age	13.8% (n=36)	
2 age	45% (n=117)	
3 age	26.2% (n=68)	
4 age	15% (n=39)	
What is your opinion about the natal/neonatal tooth?You can mark more than one option.		
Absolutely tooth must be extraction.	40% (n=104)	
No tooth should be extracted if it is not mobile and there is no risk of swallowing **	48.1% (n=125)	
If the tooth is mobile and there is a risk of swallowing, the tooth should be extracted after the 10th day of birth. **	42.3% (n=110)	%21.5**
Absolutely tooth must not be extraction.	0.4% (n=1)	

**Values are evaluated as percent (%). n = number of people. ** The correct answers are marked with an ** sign.*

Table 3. *Questions and answers about pediatricians' approach to preventive applications and caries protection*

	Definitely Yes	No Idea	Definitely No
Does cariogenic microorganisms(s. mutans) can pass from mother to baby?	99**	111	50
Do you think that long-term and overnight breastfeeding causes caries?	110**	44	106
Do you think the use of feeding bottles (milk, baby formula, sugary drinks etc.) causes caries?	247**	9	4
Can malocclusion occur in a 3-year-old child who uses feding bottle or a pacifier?	240**	13	7
Would you recommend applying fluorid gel or fluorine varnish?	121**	77	62
Would you recommend fissure sealant applications?	73**	172	15
Would you recommend space maintainer / child prosthesis applications?	85**	164	11
Should caries on primary teeth be treated?	175**	53	32
When you detect caries, do you refer it to the dentist?	247**	10	3

** Values are evaluated as the number of people. ** The correct answers are marked with an ** sign.*

Table 4. *Questions and answers about the knowledge of tooth eruption and tooth anatomy*

	Value*
How many months should the child be so that we can diagnose"delayed tooth eruption" in a child?	
12 month	21.2% (n=55)
15 month	39.2%(n=102)
18 month**	34.2% (n=89)
24 month	5.3% (n=14)
When does the permanent 1. molar tooth usually erupt in children?	
6 age**	42.3%(n=110)
7 age	31.9% (n=83)
8 age	14.6% (n=38)
9 age	11.1% (n=29)
Which is permanent 1. molar tooth? (Figure 1).	
1**	35% (n=91)
2	16.1% (n=42)
3	48.8%(n=127)

Values are evaluated as percent (%). n = number of people. The correct answers are marked with an ** sign.*

Table 5. *Comparison of groups of variables based on total scores*

Variables	Grup	Avg ± sd	Test Value	p Value
Gender	Female	9.82 ± 2.7	2.032[a]	0.043*
	Male	9.12 ± 2.8		
Age	25-30	8.8 ± 2.44	0.236[b]	<0.001*
	31-36	8.9 ± 2.6		
	37-42	10.41 ± 2.49		
	43 and over	10.82 ± 3.33		
Experience	0-5	2.7 ± 0.24	7.079[b]	<0.001*
	5-10	2.45 ± 0.32		
	10-15	2.39 ± 0.37		
	15 and over	3.28 ± 0.63		

*Avg; average, sd; standard deviation, a; The significance test (t-test) value of the difference between the two means, b; ANOVA test F Value, *p<0.05 There is a statistically significant difference between the groups.*

Table 6. *Relationship of pediatricians' knowledge of permanent 1. molar teeth with gender*

Q	Incorrect		Correct		P value
	Male (n/%)	Female (n/%)	Male(n/%)	Female(n/%)	
Identify the first permanent molar among the numbered teeth	72 / 62.8%	97 / 66.0%	42 / 37.1%	50 / 34.0%	.561
Eruption time of the first permanent molar	67 / 59.3%	83 / 56.8%	46 / 40.7%	63 / 43.2%	.693

**p>0.05, There is not a statistically significant difference between the groups.*

Table 7. *Distribution of PHG treatment responses according to professional experience*

Experience (Year)	PHG Treatment					
	False		True		Total	
	n	%	n	%	n	%
0-5	106	82.2%	23	17.8%	129	100.0%
5-10	47	77.0%	14	23.0%	61	100.0%
10-15	31	73.8%	11	26.2%	42	100.0%
>15	15	53.6%	13	46.4%	28	100.0%
Total	199	76.5%	61	23.4%	260	100.0%

[*]p=0.27, p<0.05 There is a statistically significant difference between the groups.

4. DISCUSSION

This survey was conducted to evaluate pediatricians' attitudes and practices regarding oral health through the data obtained from a random sampling in Turkey. Furthermore, it was aimed to create awareness about oral health in pediatricians and to emphasize the importance of oral health in basic medical education.

Based on the knowledge of 260 pediatricians, the average correct answer score of the 22 questions is less than 50%. A statistically significant difference was found between genders according to the total scores of the participants included in the study ($p < 0.05$, Table 5). In the study of Sezer et al. (2), while the correct answer score of female was 50% higher than male, there was no relationship between years of experience and correct answer score. In the study of Indira et al. (17), the group with more than 10 years of medical experience had a higher score for correct answers. In the current study, the mean knowledge score of pediatricians with 15 years and more experience were significantly higher than the other groups ($p < 0.05$, Table 5).

While 38% of the participants reported that the bacteria that cause caries can pass from mother to baby, 42.6% of the pediatricians had no idea about this condition. Cariogenic microorganisms (*S. mutans*) transmits from mother to baby from mouth to mouth (13). According to the "Caries Assessment Tool-CAT" developed by the American Academy of Pediatric Dentistry (AAPD), the presence of active caries in the mother is a reason for the child to be included in the high-risk group for caries (14). Early acquisition of *S. mutans* is an important risk factor for early childhood caries (ECC) and future caries experiences (15). The risk of developing caries increases when *S. mutans* is acquired at an early age, which can be partially prevented by other factors such as good oral hygiene and a non-cariogenic diet (16).

In many studies comparing the cariogenicity of cow's milk with that of breast milk, it was found that breast milk contains a high concentration of lactose with lower mineral and protein content. When breast milk was compared with cow's milk kept for the same period, the decrease in pH level in mother's milk was higher, which was considered to be effective in the development of smooth surface caries (17). Current literature has demonstrated the risk of ECC is increased in children who are breastfed and/or sleep at the breast for a long time (14). 40.7% of the participants think that breast milk will not cause caries. Breastfeeding should not be in the form of the baby sucking milk while lying next to the mother at any time and sleeping with milk in her mouth. Instead, breastfeeding should be at regular intervals, with the mother holding her baby in her lap in a sitting position. This form of breastfeeding also reduces the risk of ECC (17).

Bottle-feeding is not the only reason for ECC, it is an important risk factor when combined with poor oral hygiene (14). In their study, Indira et al. reported that 75% of pediatricians knew that "ECC occur in bottle-fed children" (17). In this survey, 95% of the pediatricians stated that if the baby drinks 'milk, formula or any beverage containing sweetener' with a bottle, it will cause ECC. It was observed that pediatricians in Turkey are knowledgeable on this subject and achieved the highest rate of correct answers among all questions.

While AAPD previously suggested that the first dental examination should be done around 36 months, in the current treatment guidelines it is now recommended that it should be performed in the 12th month. With this new view, there has been a consensus on AAPD oral health guidelines which recommend that the first dental examination should be made at the latest in the 12th month or when the first tooth erupts (18). Wagner et al. (19) reported that 63% of the pediatricians in Germany who participated in the research said the first dental examination should be done after the age of 2. While the study, conducted in Canada by Prakash et al. (20), reported that 55.6% of the participants believed that the first dental examination should be done after 2-3 years of age. In this study, 27% answered with the eruption of the first tooth, 26.6% after the age of 1, and 27.3% after the age of 2. According to the studies in the literature, although the pediatricians in Turkey are more knowledgeable, still the rate of correct answers in this question is not satisfactory

Acquiring the habit of oral hygiene starts at an early age. AAPD, EAPD, and IAPD have reported that as soon as the first tooth erupts, parents should start brushing the baby's teeth with soft toothbrushes or finger brushes suitable for the age of the baby (21). In this study, the rate of pediatricians who recommended brushing with the eruption of the first tooth was 40.8%, while Murthy and Mohandas (22) reported this rate as 33.3% in their study.

In this study, 45% of pediatricians indicated that the first toothpaste should be used at the age of two. To prevent ECC, it is recommended in EAPD's 2019 guideline to use toothpaste as small as a grain of rice for children with ages between six months to two years and the toothpaste use of a size of a pea is recommended for children after two years of age (23).

Fluoride applications are extremely important in preventing caries development. While 46.5% of pediatricians recommend applying fluoride gel or fluoride varnish, 29.6% of them abstained by saying that "No idea", and 23.8% did not recommend fluoride application thinking that they were harmful. It was reported in the studies conducted that blood, urinary values, and tissue accumulation measurements after topical fluoride application was not at a harmful level (24). It is important to pay attention to the concentrations of the agents used, the use of suction, the preference of fluoride varnish in younger age groups, and the frequency of topical application and the daily fluoride intake by the child should be evaluated (23). Many studies on caries conducted to date have shown that the occlusal surfaces are susceptible to caries due to pits and fissures arising from their anatomical structures. While Murthy and Mohandas (22) reported in their study that 84% of the pediatricians stated that fluoride and fissure sealants would prevent the development of caries, 66.1% of the pediatricians participating in this study had no idea about

fissure sealant application. And also, a study conducted in Turkey by Akyildiz et al., had found a similar rate, which was 66% (25). The serious lack of knowledge of pediatricians in Turkey about preventive practices may be due to the fact that they do not take part in medical education. Moreover, the absence of a follow-up system in which dentists and medical physicians will be in constant communication may have caused this lack of information.

Appliances made to prevent the closure of the gap created by the early lost tooth by neighboring teeth are called "space maintainer". The use of space maintainers is essential to prevent tooth crowding and orthodontic anomalies that may arise (26). It was seen that 67.3% of pediatricians did not know about the space maintainer/child prosthesis applications.

The number of pediatricians who advocated that caries in primary teeth should be treated (67.3%), and the number of physicians who directed their patients to dentists when they detected caries (95%) was quite high in this study. Dental caries which start in the first years of life increase the risk of caries development in the future. Deep caries can cause the development of pain, abscess and extraoral swelling. Most importantly, infected primary teeth can create defects on the successor permanent teeth, such as enamel opacities, hypoplasias and developmental disorders (27).

After consulting with pediatricians, a question was added about the natal/neonatal tooth, which pediatricians stated that they frequently encountered during neonatal examinations. 40% of physicians think that these teeth should definitely be extracted. According to the literature, it is reported that approximately 90% of the natal/neonatal teeth are primary teeth, and only 10% of them are supernumerary teeth (extra teeth) (28). For this reason, if the natal tooth does not prevent the child from sucking the mother and is asymptomatic, its extraction is not necessary and it is kept under control in the mouth (28). Extraction is indicated if the tooth is extremely mobile, holds weakly in the mouth, and there is a risk of aspiration (28).

Thirty-nine percent (39.2%) of the physicians answered the delayed tooth eruption as 15 months. The eruption of primary teeth can be delayed until the 12th and even up to 14th months as a genetic feature. Children with no tooth eruption until the 14th month should be investigated in terms of systemic and nutritional disorders such as hypothyroidism, cleidocranial dysostosis, Down syndrome, hypopituitarism, progeria, Albright's Hereditary Osteodystrophy, incontinentia pigmenti, and rickets. Local causes such as small skull base, hyperdontia, ankylosis of primary teeth may also be the cause of delayed tooth eruption. Numerical anomalies of teeth such as anodontia and hypodontia can also be observed in some children (29). If no genetic or systemic problem in the child is detected after analysis and if the tooth still does not erupt after 15 months, the control should be conducted by dentists via x-ray.

For the patient in Figure 2, 76.5% of pediatricians stated that there would be crowding and 85.3% thought that orthodontic treatment would be required. The first physicians whom the patients should refer to for this condition are the dentists. The reason for the addition of these questions was that pediatricians frequently consulted with pediatric dentists on this issue and the number of patients referred by pediatricians to the dentists was therefore high. The eruption of permanent lower incisors from the lingual of the primary incisors is one of the leading eruption problems observed in this region. This condition is observed in one in ten children. In most cases, with the development of the root of the permanent tooth, the effect of the tongue, and the growth and development of the alveolar crest, the lower permanent incisor teeth are automatically positioned normally on the dental arch over time (30).

The perioral and oral cavity photograph of a male patient with primary herpetic gingivostomatitis (PHG) was added to the questionnaire after obtaining consent from the parents. Pediatricians were asked two different questions as to what their diagnosis and treatment would be for this patient. While 48.8% of the physicians made the diagnosis correctly, 64.5% stated that they would prescribe antibiotics and mouth wash for the patient with primary herpetic gingivostomatitis, which is a viral disease, and refer him/her to the dentist. Besides, pediatricians with 15 years of experience and above gave a significantly higher number of correct answers compared to those with less experience ($p < 0.05$, Table 7). In the treatment of PHG, it is aimed to prevent the further spread of the infection by the healing of the lesions with palliative interventions, adequate fluid supply, and nutrition. Topical anesthetics and coating agents provide pain relief and aid nutrition. Early diagnosis is required for specific treatment with antiviral (acyclovir) (31).

5. CONCLUSION

The fact that a small portion of the pediatricians correctly answered information-based questions shows that physicians need oral and dental health training. Lack of information and education seems to limit the role of pediatricians in children's oral and dental health. These results indicate that post-specialist training and courses for pediatricians covering oral and dental health may be beneficial in Turkey. Adding it to the 'medicine core education program' or to the relevant specialist trainings will make future generations more conscious about oral and dental health. Furthermore, the inclusion of dentistry-related content in scientific journals and books for pediatricians can increase awareness on the subject. Cooperation between pediatric dentists and pediatricians is very important; it should be ensured that the communication between them is stronger.

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Clinical and Experimental Health Sciences

Digital Game Addiction and Lifestyle Behaviors in Turkish Adolescents

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ABSTRACT

Objective: Digital game addiction is a concern that threatens public health around the world, especially in adolescents. This study was conducted to determine the relationship between digital game addiction and lifestyle behaviors in adolescents.

Methods: The research was carried out in from three high schools offering different types of education in Maltepe district between March and April 2017. Data were collected by using the Introductory Information Form, Game Addiction Scale for Adolescents and Adolescent Lifestyle Profile Scale. Data were evaluated in computer environment. Descriptive data were shown with numbers, percentages and means. The relationship between game addiction and independent variables was evaluated by chi-square test, Mann-Whitney U test, Pearson Correlation Analysis and Logistic Regression Analysis.

Results: 22.4% of adolescents were determined to be addicted to digital games. The mean scores of health responsibility, nutrition, interpersonal relationships and stress management of adolescents who had game addiction were significantly lower than the adolescents without game addiction. Digital game addiction rates were significantly higher in boys, vocational high school students, ninth grade students, and in those who described that their family had low income, that they had very poor relations with their families/friends, that they had very poor living conditions and that they were generally unhappy.

Conclusions: It was determined that game addiction negatively affected adolescents' lifestyle behaviors, and there was a negative, low to moderately significant correlation between interpersonal relationships and stress management and game addiction.

Keywords: Digital game addiction, lifestyle behaviors, adolescents

1. INTRODUCTION

Today, computers and internet, which provide convenience in many areas of life, are also frequently used for games and entertainment in adolescents. Some aspects of digital games such as providing communication, realizing the dreams that people cannot realize in real life, experiencing a sense of winning and success make games more attractive for adolescents (1). Also, adolescents find it easier to engage with others in an imaginary world of games than face-to-face communication, and they want to gain respect and reputation among other players, driving them to prefer digital games. Thus, adolescents fulfill their needs to realize themselves using digital games (2).

It has been reported that playing digital games is normal unless it is done in excess, and that games even have positive effects such as emotional relief/relaxation and improved leisure time utilization and problem-solving skills (3, 4). However, excessive and uncontrolled gaming has created the term game addiction and the resulting problems have caused serious concerns all over the world (5). Lemmens et al. (6) defined Digital Game Addiction (DGA) as "excessive and compulsive use of computer or video games and the player's inability to control excessive use, even though it causes social and/or emotional problems."

In the literature, game addiction is also referred to as "Game Disorder", "Online Game Addiction" and "Online Gaming Disorder". Although the definitions may differ, they basically describe gaming and the accompanying problems. In addition, it was stated that "Internet Addiction" could be related to game addiction (7). It is also noteworthy that in the third research supplement of the Diagnostic and Statistical Manual of Mental Disorders-5 (DSM-5) developed by the American Psychiatric Association, game addiction was listed under the title of personality disorders and addressed to as "recommended for further research" (8).

All individuals who play games may experience addiction as a part of the normal process. However, as a result of

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developmental changes in the brain and intense emotional and social stress during adolescence, adolescents are more vulnerable in behavior control and susceptible to addiction (5). Research has shown that male adolescents aged 10-19 are at a higher risk of game addiction than other age groups and girls (9,10).

Many studies have shown that DGA was associated with many negative lifestyle behaviors such as unhealthy nutrition behaviors, sedentary life, problems in interpersonal relationships, sleep problems, low life satisfaction, avoiding responsibilities and ineffective coping with stress (11-15). In addition, it has been reported to cause a variety of psychiatric disorders including attention deficit, hyperactivity, impulse control disorders, high levels of anxiety, depression, violence tendency and suicidal ideation (16-19).

In the international prevalence studies conducted on online game addiction, it has been found that game addiction ranged from 0.3% to 50% (10,14, 20-22). Especially in China, Korea and Taiwan, problematic online gaming behaviors have been reported to become a serious public health problem (10, 22). The establishment of specialized treatment centers in Southeast Asia, the United States and Europe reflects the seriousness of the situation (10).

Although there are no prevalence indicators at the national level in Turkey, Irmak and Erdoğan (23) found the ratio of addicted players as 28.8%, Baysak et al. (24) as 11.1% and Göldağ (25) as 22.6% in their studies.

Physical inactivity, unhealthy diet, stress, cigarette-alcohol-substance addiction, digital addictions, not taking responsibility for health, and negative interpersonal relationships are the biggest threats to adolescents' health. These behaviors have important lifelong consequences (26-28). All kinds of addictions and game addiction constitute a risk for healthy lifestyle behaviors. The fact that adolescents who spend most of their time with playing games inactively avoid all kinds of responsibilities can also lead to avoiding health responsibilities and adopting negative behaviors (29).

Although research on digital game addiction is rapidly increasing, there is limited research examining digital game addiction and lifestyle behaviors together in adolescents who are at greater risk than others in terms of engaging in risky behaviors and developing addiction (10). In order to determine the current situation; there is a need for descriptive studies with valid and reliable measurement tools. The aim of this study is to determine digital game addiction and lifestyle behaviors in adolescents.

In this research, the answers to the following questions were sought:

- What are the digital game addiction rates of adolescents?
- What are the total scores and subscale scores of adolescents from the Game Addiction Scale for Adolescents (GASA) and Adolescent Lifestyle Profile Scale (ALPS)?
- Is there any difference between ALPS subscale scores of adolescents with and without digital game addiction?
- What are the socio-demographic characteristics of adolescents that increase the risk of game addiction?
- Is there a difference between the socio-demographic characteristics of adolescents and game addiction?

2. METHODS

2.1. Population and Sample

The population of the study consists of students from three high schools offering different types of education in Maltepe district between March and April 2017. These high schools are vocational technical high schools (n=1954), an anatolian high school (n=1317) and a health high school (n=350) attended by a total of 3621 adolescents. In the study; sample selection was not made, it was aimed to reach the whole population. The study was completed with 2001 students (55.2% of the population), who were at the school on the data collection days and completed the data collection forms completely. The inclusion criteria of the study were lack of communication barriers, volunteering, obtaining parental consent and completing the data collection forms completely.

2.2. Variables

Dependent variables: The mean scores obtained from the health responsibility, physical activity, nutrition, interpersonal relationships and stress management subscales of the ALPS were the dependent variables of the study.

Independent variables: Digital game addiction and socio-demographic characteristics including age, gender, height, weight, parents' educational level and profession, socioeconomic level, whether the adolescent worked outside the school, etc. and family relationships, friend relationships, life satisfaction, tendency to violence, coping with stress and mood were independent variables of the study.

2.3. Data Collection Tools

Data were collected by using the Introductory Information Form, Game Addiction Scale for Adolescents (GASA) and Adolescent Lifestyle Profile Scale (ALPS).

Introductory information form: Developed by the researchers based on the relevant literature, the form consists of 31 closed-ended questions covering school characteristics, familial characteristics, interpersonal relationships, disease and health perception, and Body Mass Index (BMI) measurements of adolescents (28, 30, 31).

Body mass index (BMI): BMI was calculated by measuring the height and weight of the students and dividing the weight in kilograms to square meters (kg/m^2). In this study, using the BMI percentile curves of Turkish children developed

by Neyzi et al. (32), those with percentile below 5% were defined as "underweight", 5-85 percentile as "normal", between 85-95 percentile as "overweight" and above 95 percentile as "obese".

Game addiction scale for adolescents (GASA): GASA was developed by Lemmens, Valkenburg and Peter (6) to determine problematic game behaviors of adolescents between the ages of 12-18 years. The adaptation to Turkish language and validity and reliability study was conducted by Ilgaz (32). The Cronbach's Alpha value for the total reliability coefficient of the adapted scale was found to be 0.92, and in this study, it was 0.94. The Cronbach's Alpha value for the subscales of the adapted scale was found to be between 0.62-0.85, and it was between 0.70 and 0.87 in this study. The scale consists of seven subscales, namely: salience $_{(1)}$, tolerance $_{(2)}$, mood modification $_{(3)}$, withdrawal $_{(4)}$, relapse $_{(5)}$, conflict $_{(6)}$ and problems $_{(7)}$. The scale is a 5-point Likert-type (1-Never, 2 – Rarely, 3 – Sometimes, 4 – Frequently, 5 – Very often). The highest score to be taken from the scale is 105 and the lowest score is 21. Higher scores indicate greater game addiction. As described by Charlton and Danforth (33) and Baysak et al. (24) monothetic vs polythetic diagnoses are used to determine game addiction. In this study, monothetic diagnosis was used for digital game addiction. According to the monothetic diagnosis, if the person scores 3 (sometimes) and above 3 in 21 items, he / she is considered addicted. In polythetic diagnosis, if he scores 3 (sometimes) and above 3 for at least 12 items, he / she is defined as a game addict. Those who scored 63 points and above from the GASA in monothetic diagnosis were digital game addicts.

***Adolescent lifestyle profile scale (ALPS)*:** The Adolescent Lifestyle Profile is a version of Health Promotion Lifestyle Profile II developed for adolescents based on the Health Promotion Model. The reliability and validity study of the scale was conducted by Hendricks, Murdaugh and Pender (34). Adaptation to the Turkish language and validity and reliability study of the scale was conducted by Ardıç (35) and Cronbach's Alpha coefficients were found to be 0.87 for the total scale and 0.58 to 0.77 of the subscales. The scale has seven subscales that can be used independently of each other. There is no cut-off point in the scale consisting of 40 items of four-point likert type. Higher scores indicate improved positive health behavior (35). The subscales are health responsibility, physical activity, nutrition, positive life perspective, stress management and spiritual health. Five subscales were used in this study, excluding the positive life perspective and spiritual health subscales. The Cronbach's Alpha coefficients of the five subscales used in this study ranged from 0.50 to 0.81.

2.4. Data Collection

The data was collected between March and April 2017 by visiting the schools two days a week and using a questionnaire based on self-reporting which lasted 25 minutes on average. The questionnaires were given during the lessons when the students could complete them. Before collecting data from the population, a pilot study was conducted with a different group of 15 students to test the comprehensibility of the data collection forms.

2.5. Statistical Analysis

Data were evaluated in computer environment. Descriptive data were shown with numbers, percentages and means. The relationship between GASA game addiction and independent variables was evaluated by chi-square test, Mann-Whitney U test, Pearson Correlation Analysis and Logistic Regression Analysis. Statistical significance was set at $p < 0.05$.

2.6. Ethical considerations

Written permission was obtained from the Istanbul Provincial Directorate of National Education, the school administration to conduct the research. At the same time, written consent was obtained from the students and their parents to participate in the study. In order to use the GASA and ALPS in this study, permission was obtained by e-mail from the authors who adapted the Turkish version. Ethical permission was obtained from the Ethics Committee of the Institute of Health Sciences (09.10.2017-193) of a university.

3. RESULTS

The mean age of the study sample was 16.5 ± 1.0 years (min=14, max=19). 58.1% of the adolescents were between 14-16 years, 4.9% of them were between 17-19 years of age. 33.4% of the adolescents were girls, 56.2% were vocational technical high school students and 31% were studying in 10th grade, and 57.5% had 1-2 siblings. The mean body weight of the students was 63.27 ± 12.7 kg, average height was 171.43 ± 16.4 cm, mean BMI was 21.48 ± 3.42 and 5.6% of them were obese according to their percentiles. The average monthly income of 29.5% of the families was between 1501-2500 TL (Table 1).

Adolescents scored 48.64 ± 19.83 points on average on the Game Addiction Scale. The highest score (mean=8.46 ± 3.77) from the subscales was from the mood modification subscale, while the lowest score was from the problems subscale (mean=5.97 ±3.07). The highest score from the subscales of the Adolescent Lifestyle Profile Scale was from the interpersonal relationships subscale (mean=14.98 ± 3.39) while and the lowest score was from the health responsibility subscale (mean=10.50 ± 2.38) (Table 2).

The scores of adolescents from the ALPS subscales were compared by whether the adolescent had game addiction and the results are provided in Table 3. Accordingly, there was a significant difference between game addiction and health responsibility (Z=3.416; p=.001), nutrition (Z=2.071; p=.038), interpersonal relationships (Z=4.585; p=.000) and stress management (Z=3.936; p=.000) subscales. The mean scores of the adolescents with game addiction were lower (Table 3).

22.4% of the adolescents (n=449) were considered to have game addiction with a score of 63 or higher from GASA. The addiction ratios of the adolescents were compared with independent variables and the results are shown in Table 2. Boys (χ^2=64.89; p=.000), vocational high school students (χ^2=20.82; p=.000), ninth grade students (χ^2=13.13; p=.004), those with the lowest family income (χ^2=16.32; p=.003), those who described that they had very poor relations with their families (χ^2=32.42; p=.000) and friends (χ^2=12.99; p=.005) and those who described that they had very poor living conditions (χ^2=17.80; p=.000) had higher addiction rates than the others (Table 4).

Table 1. *Socio-demographic characteristics of adolescents who participated in the study (n=2001)*

Variables		Mean (SD)	
Age (mean ± SD)		16.5 ±1.07 years	
		n	**%**
Age groups	14-16 age	1163	58.1
	17-19 age	838	41.9
Gender	Female	668	33.4
	Male	1333	66.6
School type	Technical High School	1124	56.2
	Health High School	207	10.3
	Anatolian High School	670	33.5
Grade	Grade 9	531	26.5
	Grade 10	620	31.0
	Grade 11	613	30.7
	Grade 12	237	11.8
Number of Siblings	1-2 siblings	1150	57.5
	3 – siblings	462	23.1
	4 and over	247	12.3
	None	142	7.1
BMI Percentiles	Under weight (<5. Perc.)	301	15.1
	Normal (5-85 Perc.)	1443	72.1
	Overweight (85 – 95 perc.)	144	7.2
	Obese (>95 perc.)	112	5.6
Family Income	500-1000 TL	83	4.2
	1001-1500 TL	345	17.2
	1501-2500 TL	590	29.5
	2501-3500 TL	467	23.3
	3501 and over	516	25.8

SD= Standard Deviation, BMI= Body Mass Index

A moderately negative statistically significant correlation was found between the Problems sub-dimension of GASA and the stress management sub-dimension of ALPS (r=-. 520; p=.000). Either there was no correlation, or a very low level of significant correlation was found between the other sub-dimensions of the two scales (Table 5).

When independent variables associated with game dependence were subjected to logistic regression analysis, it was found that the risk of developing game addiction was 2.75 times higher for male adolescents than female adolescents, 0.76 times higher for 12th grade students, 0.82 times higher for those with a family income of 500-1000 TL and below, 1.48 times higher for those who described that they had very poor relations with the family, 1.34 times higher for those who described that they had very poor relations with the friends, 0.78 times higher for those who experienced sleep problems, 0.62 times higher for those who resort to violence, 1.58 times higher for those who do not have a healthy lifestyle, and 0.50 times higher for those who played digital games (p <0.05) (Table 6).

Table 2. *Distribution of total and sub-dimension mean scores of Game Addiction Scale for Adolescents and Adolescent Lifestyle Profile Scale*

Scales		Median	Mean (std.)	Min-max.
GASA Total Score		46.00	48.64 (19.83)	21-105
Game Addiction Scale for Adolescents	Salience	7.00	7.78 (3.80)	3-15
	Tolerance	7.00	7.41 (3.84)	3-15
	Mood Modification	8.00	8.46 (3.77)	3-15
	Withdrawal	7.00	6.79 (3.23)	3-15
	Relapse	5.00	6.07 (3.48)	3-15
	Conflict	5.00	6.14 (3.34)	3-15
	Problems	5.00	5.97 (3.07)	3-15
Adolescent Lifestyle Profile Scale	Health Responsibility	10.00	10.50(2.38)	5 – 20
	Physical Activity	14.00	14.85 (4.38)	6-24
	Nutrition	14.00	14.61 (3.39)	6-24
	Interpersonal Relationships	15.00	14.98 (3.39)	5-20
	Stress Management	14.00	13.76 (3.32)	5-20

GASA: Game Addiction Scale for Adolescents

***Table 3. Distribution** of the mean scores of the subscale scores of adolescents with and without game addiction*

Sub dimensions of ALPS	GASA						Statistics	
	GASA Not Addicted (n=1552)			GASA Addicted (n=449)				
	Median	25. – 75. quarter	Mean (std.)	Median	25. – 75. quarter	Mean. (std.)	Z	P
Health Responsibility	10.00	9 – 12	10.58 (2.32)	10.00	8-12	10.22 (2.54)	**3.416**	**.001**
Physical Activity	15.00	12-18	14.93 (4.31)	14.00	11-18	14.57 (4.60)	1.434	.151
Nutrition	14.00	12-17	14.70 (3.33)	14.00	12-17	14.28 (3.59)	**2.071**	**.038**
Interpersonal Relationships	15.00	13-18	15.19 (3.22)	14.00	12-17	14.25 (3.68)	**4.585**	**.000**
Stress Management	14.00	12-16	13.89 (3.31)	13.00	11-16	13.18 (3.33)	**3.936**	**.000**

Z=Mann-Whitney U test

ALPS: Adolescent Lifestyle Profile Scale; GASA: Game Addiction Scale for Adolescents

***Table 4. Comparison** of socio-demographic characteristics and game addiction of adolescents*

Variables		According to GASA Monothetic format				Statistics	
		Not Addicted (n=1552)		Addicted (n=449)			
		n	%	n	%	χ 2	p
Gender	Female	589	88.2	79	11.8	**64.89**	**.00**
	Male	963	72.2	370	27.8		
School Type	Technical High School	832	74.0	292	26.0	**20.82**	**.00**
	Health High School	178	86.0	29	14.0		
	Anatolian High School	542	80.9	128	19.1		
Grade	Grade 9	387	72.9	144	27.1	**13.13**	**.00**
	Grade 10	486	78.4	134	21.6		
	Grade 11	500	81.6	113	18.4		
	Grade 12	179	75.5	58	24.5		
Family Income	500-1000 TL	59	71.1	24	28.9	**16.32**	**.00**
	1001-1500 TL	270	78.3	75	21.7		
	1501-2500 TL	462	78.3	128	21.7		
	2501-3500 TL	386	82.7	81	17.3		
	3501 and over	375	72.7	141	27.3		
Family Relationships	Very good	778	82.7	163	17.3	**32.42**	**.00**
	Good	698	74.1	244	25.9		
	Bad	59	64.8	32	35.2		
	Very Bad	17	63.0	10	37.0		
Friend Relationships	Very good	735	78.8	198	21.2	**12.99**	**.00**
	Good	756	77.9	215	22.1		
	Bad	41	64.1	23	35.9		
	Very Bad	20	60.6	13	39.4		
Living conditions	Very good	426	80.2	105	19.8	**17.80**	**.00**
	Good	1018	78.1	286	21.9		
	Bad	90	66.2	46	33.8		
	Very Bad	18	60.0	12	40.0		
Are you generally happy?	Yes	754	80.6	181	19.4	**17.13**	**.00**
	No	240	69.8	104	30.2		
	Sometimes	558	77.3	167	22.7		

χ^2=Pearson Chi-Square; GASA: Game Addiction Scale for Adolescents; TL: Turkish Lira

Table 5. *Correlation between subdimensions of Game Addiction Scale for Adolescents and Adolescent Lifestyle Profile Scale*

GASA Subdimensions	ALPS Subdimensions				
	Health Responsibility	Physical Activity	Nutrition	Interpersonal Relationships	Stress Management
	r (p)	r (p)	r (p)	r (p)	r (p)
Salience	-.022 (.320)	.016 (.477)	.003 (.883)	**-.120 (.000)**	-.033 (.136)
Tolerence	-.026 (.247)	.009 (.673)	.007 (.749)	**-.154 (.000)**	**-.078 (.000)**
Mood Modification	-.016 (.473)	.025 (.268)	-.003 (.898)	-.049 (.029)	-.032 (.151)
Withdrawal	-.020 (.364)	-.030 (.123)	-.029 (.193)	**-.129 (.000)**	**-.107 (.000)**
Relapse	-.031 (.161)	-.013 (.563)	-.034 (.125)	**-.174 (.000)**	**-.115 (.000)**
Conflict	-.052 (.020)	-.028 (.213)	-.035 (.122)	**-.162 (.000)**	**-.132 (.000)**
Problems	-.041 (.065)	-.005 (.814)	-.026 (.239)	**-.139 (.000)**	**-.520 (.000)**

Table 6. *Logistic regression analysis of independent variables with game addiction*

Variables		B	Exp(B)	Sig.	95% CI
Gender	Female Male	1.01	2.75	**0.00**	2.00–3.79
School type	Anatolian High School Health High School Technical High School	0.14	1.15	0.33	0.87-1.56
Grade	Grade 9 Grade 10 Grade 11 Grade 12	0.27	0.76	**0.02**	0.51-1.12
Family income	500-1000 TL 1001-1500 TL 1501-2500 TL 2501-3500 TL 3501 TL and over	0.18	0.82	**0.00**	0.45-1.49
Family relationships	Very Good Good Bad Very Bad	0.39	1.48	**0.01**	0.58-3.79
Friend relationships;	Very Good Good Bad Very Bad	0.28	1.34	**0.03**	0.55-3.28
Sleep problems	No Yes	0.24	0.78	**0.04**	0.57-1.06
Enjoying life	Yes Sometimes No	0.14	1.15	0.47	0.78-1.69
Healthy Lifestyle	No Yes	0.45	1.58	**0.00**	1.22-2.04
Resort to violence	No Yes	0.47	0.62	**0.00**	0.45-0.86
Playing digital games in free time	No Yes	0.68	0.50	**0.00**	0.39-0.64

4. DISCUSSION

In this study, which was conducted to determine the digital game addiction and lifestyle behaviors of adolescents, it was found that approximately one fourth of the adolescents were addicted to digital games. Among the sub-scales of GASA, the highest score was obtained from the mood changing subscale, and the lowest score was obtained from the problems subscale. Adolescents got the highest score from the interpersonal relationships subscale, and the lowest score from the health responsibility subscale from the ALPS. Game addicted adolescents; average scores for health responsibility, nutrition, interpersonal relationships, and stress management were lower than non-game addicts. Digital game addiction rates of males, vocational high school students, ninth grade students, those with low family income, those who stated that their relations with their family and friends were very weak, and those who stated that they were generally unhappy were found to be higher than the others.

In this study, it was found that adolescents who are addicted to digital games assume less health responsibility than adolescents who are not addicted to digital games. It is stated in the literature that adolescents who spend most of their time with playing games may inactively avoid all kinds of responsibilities including health responsibility and adopt negative behaviors (29). In their research, Stockdale and Coyne (36) found that individuals with game addiction had poorer health than those without game addiction.

In this study, it was determined that adolescents with digital game addiction ate unhealthy food. The mean score of the adolescents with game addiction was lower. In parallel with our study findings, there are studies showing that problematic gaming and technology-related addictions are associated with poor nutrition habits (11,37). In this study, it was determined that game addicted adolescents got lower scores in ALPS interpersonal relations dimension. It has been reported that excessive game play isolates people and decreases their level of socialization (27). It was reported that symptoms of problematic gaming and social media use

negatively affects adolescents' life satisfaction, and that symptoms of problematic gaming had a negative effect on their perceived social competence (38).

In this study, adolescents with game addiction had lower scores from the stress management subscale of ALPS than those without game addiction. Saquib et al. (39) found a strong and significant correlation between game addiction and stress and stated that individuals with game addiction were at 4.7 times higher risk than those without game addiction. Mentzoni et al. (14) found that people with psychological health problems were more prone to game addiction. There are studies showing that adolescents use online games as a tool to deal with stress (21,37). The results showing that games provide emotional relief and relaxation also support this finding (3). These findings suggest that adolescents play digital games to cope with stress or that their stress increases as they play.

This research found that 27.8% of male adolescents and 11.8% of female adolescents were addicted to digital games. In addition, according to logistic regression analysis, it was found that males had a 2.75 times higher risk of being dependent. This finding is in line with the findings of previous studies (14, 37). In the study of Wittek et al. (40), it was found that males were 2.9 times more likely to have game addiction than females. In a study, higher activity and functional link was found in the mesocorticolimbic system that controls brain pleasure mechanisms and behaviors in male compared to female subjects with game addiction (41). However, the addictive potential of the game types preferred by men may be higher. It is also thought that this finding may be due to the fact that most of the games are prepared by men for men (19).

In this study, it was seen that 28.9% of those with low family income were high and 27.3% of those with high family income had digital game addiction and their addiction rates were higher than other income groups. In addition, analysis has shown that having a low income increases the risk of game addiction. In the literature, it is stated that families with low income have lower education level. Families with low levels of education may not know the negative effects of game addiction and strategies to protect adolescents from game addiction (42). On the other hand, it is stated in the literature that adolescents with high income level play more online games to spend time and for social interaction. It is also mentioned that children of families with higher incomes can easily access digital gaming means, which may increase game addiction (25). The high level of addiction of adolescents in both low and high income families suggested that game addiction was not only affected by family income. Therefore, awareness of parents and adolescents should be raised regarding game addiction in both settings.

Adolescents with poor family and friends relationships were found to have a higher risk of game addiction. The results of the study by Choi et al. (43) showed that adolescents play online games to spend time and engage in social interaction. Lenhart (44) in his study; reported that 72% of teens play online games every day and that these teens have poor friendships in daily life. In the study of Bonnaire and Phan (45), adolescents who have poor family relationships and conflict with their families experienced problematic gaming and online gaming disorders significantly more than others. In addition, Han et al. (46) reported in their study that harmony within the family may be important in controlling problematic gaming. In line with these findings, it can be concluded that both poor family and friend relationships lead adolescents to game addiction and that game addiction affects family and friend relationships negatively.

In this study, digital game addiction was found to be higher in adolescents with sleep problems. It has been reported that in adolescence, 7.5 hours of sleep for girls and 8.5 hours for boys are necessary for a healthy life (28). It has been reported that game addiction disrupts normal sleep patterns of adolescents and generally causes less sleep, longer time to fall asleep and more interruptions during sleep (13, 47). There are studies showing that time and duration of sleep are affected by digital game addiction (14, 28, 39). Results of other studies also show that game addiction is associated with sleep problems (10, 48).

5. CONCLUSIONS

The results showed that game addiction negatively affects healthy lifestyle of adolescents. It should be noted that male gender, vocational high school students, adolescents with low family income and those with poor relationships with family/friend constitutes risky groups. The inclusion of efforts to improve stress management, family and friendship relations and to develop communication skills and good nutrition, sleep, and healthy lifestyle behaviors to prevent and reduce game addiction can increase the effectiveness of the initiatives.

Conflict of Interest

There are no conflicts of interest in connection with this paper.

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Clinical and Experimental Health Sciences

Preclinical Medical Students' Awareness About Disabled Friendly Campus

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ABSTRACT

Objective: The "Disabled Friendly Campus" is relatively new consept in the world. In this study we aimed to evaluate the awareness of preclinical medical students about the Disabled Friendly Campus.

Methods: Cross-sectional study was conducted at a public university's Faculty of Medicine Campus. In our study, 362 students were included and the data were obtained between March and June 2019. A questionnaire was prepared in the light of the literature. In the first part of the questionnaire, socio-demographic features were questioned; In the second part of the questionnaire there were 13 questions about the arrangements required for a disabled person on a campus. Answer options such as 1= I don't agree, 2= I have no idea and 3= I agree. The score varied between 13-39, and as the total score obtained increases, it was assumed that the awareness of Disabled Friendly Campus will increase.

Results: In our study 3.3% (n = 12) of the participants had any disability, and 18.2% (n = 66) had a disabled person in their family. A statistically significant difference was observed between the participants' disabled friendly campus awareness scores according to their gender, class, their participation in an activity related to disabled people and whether they found their campuses suitable for disabled people.

Conclusion: It can be suggested that the questionnaire, which is assumed to evaluate the awareness of preclinical medical students on Disabled Friendly Campus, can be made into a scale with high validity and reliability.

Keywords: Students, Medical Faculty, Disabilities.

1. INTRODUCTION

Disability is an unfavorable situation that prevents or limits an individual from performing the activities that are expected to be done according to age, gender, social and cultural status as a result of an injury or disability. Disability causes both the disabled individual and the person responsible for their care to be affected physically, emotionally and socially, and therefore to be exposed to various problems (1). The problems of people with disabilities are a global human rights problem and it is known that disabled people have problems in terms of social integration in our country (2).

According to World Health Organization (WHO), it is observed that approximately 10% of the world's population is disabled and this rate reaches 15% in some countries (3). In our country, according to the data of Turkey Statistical Institute, 12% of our population is composed of people with disabilities. Accordingly, it is understood that approximately 8.5 million disabled people live in our country (4).

Universities are institutions that direct the future of countries, train various professionals who have an important place in the society, enable entrepreneurial individuals to emerge, and aim to make these individuals useful to the society in every sense. University education broadens individuals' horizons, paves the way for new ideas and plays an active role in shaping the future (5). The settlements that describe the university areas are called "campus" in general definition. Students spend most of their time in campus areas while studying at the university. Campuses are a living environment. All the educational, physical and social needs of the students should be met in a campus area. It should be one of the main features of a campus to access common areas for disabled students and to be able to use it with non-disabled individuals. The disabled individual will only feel more normal and comfortable under these conditions (6).

As suggested by Brown (1995) and Olkin (2002), disability should be perceived as a social structure in which the problems arising from disability are focused on the inability of the environment to adapt to the needs of the disabled rather than a defect within individuals by nature (7). Nevertheless, negative attitudes and limited physical access are typical obstacles that prevent people with disabilities from fulfilling

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their desired roles in society. The awareness of disability perceived from the cultural and social paradigm is a step towards removing these social and environmental barriers to ensure the full social, physical and spiritual participation of persons with disabilities in society (8).

Wilson and Lieberman (2000) stated the main benefits of reaching disability awareness as follows; Acceptance of disabled people by others, increase in socialization experienced by disabled people, improvement of living standards of disabled people and enabling disabled people to live independently (9).

In our country, the provision of tools and equipment to facilitate the education life of disabled university students in the 15th article of the Law on the Disabled People and the Amendment of Some Laws and Decree Laws that entered into force in 2005 (Law No: 5378 Date of Adoption: 01.07.2005) Establishment of Disabled Counseling and Coordination Center to work on issues such as preparing special course materials, education, research and accommodation suitable for the disabled (10).

It is important to change the attitudes towards disabled people in a positive way for their full and effective participation in the society. Universities are one of the places where this change will take place (11). Physicians are the individuals who encounter disabled individuals most frequently and have high awareness. For this reason, first of all, it is necessary to investigate how medical faculty students evaluate disability for change.

This study was conducted to evaluate the awareness of preclinical medical faculty students about Disabled Friendly Campus.

2. METHODS

2.1. Ethical Statement

Prior to the study, Ethics Committee Approval and research permit were obtained from the Marmara University Ethics Committee with 09.2019.480 protocol number on the 3rd May 2019 and the people who constituted the sample size of the research were asked to participate in the study after being informed about the research and permits. Our study was conducted according to the Declaration of Helsinki and written informed consent was obtained from all participants.

2.2. Study Population

This cross-sectional study was carried out at a Public University, Anatolian side in Istanbul province in Turkey. Time period of the research was March-June 2019. The total population of our study consists of 610 preclinical medical students. The sampling calculation was made with the unlikely quota sampling method. It is aimed to reach minimum 354 people by accepting alpha error level 5%, sample power 80% and design effect 1.5. Each class was accepted as a cluster and it was planned to take participants from each cluster according to the number of students (proportional to the population). In all of participants, 127 students from 1st grade students, 116 students from 2nd grade students and 119 from 3rd grade students were reached. A total of 362 students participated in our study. Inclusion criteria were preclinical medical students who study at the concerned public university and individuals who gave informed consent.

2.3. Study Tool: The Questionnaire

The students were given questionnaires before the practical lecture hour on campus, and filled in under observation. A questionnaire was applied to the participants to measure their awareness about the Disabled Friendly Campus. In the first part of the questionnaire, the socio-demographic characteristics of the students have been questioned. In the continuation of the questionnaire, whether or not he/she had a disabled friend up to now, the kind of disability the friend had; whether he/she has helped any individual with a disability to date and how he/she has assisted. Furthermore, it has been questioned whether or not he/she participated in a disabled-related activity and if so, what kind of activity he/she attended. In the second part of the questionnaire, there were 13 questions of Likert-type group questions. In the Likert group questions (having 3 options), the participants were asked about the arrangements that should be in a campus for individuals with disabilities; Answer options were 1= I don't agree, 2= I have no idea and 3= I agree. The score that a person will get from these questions varied between 13-39, and as the total score obtained increases, the awareness of students about the disabled friendly campus were assumed to be increasing as well.

2.4. Statistical Analysis

Descriptive data in the study were presented with mean values and standard deviation values and frequency tables. Percentage and frequency distributions of the answers given to each question were calculated. For the statistical analysis of the data, the Chi-Square test was used to compare the classified data, and the Mann-Whitney U test and Kruskal Wallis variance analysis were used to compare continuous variables that did not fit the normal distribution. The suitability of variables to normal distribution was examined using visual (histogram) and analytical methods (Kolmogorov-Smirnov/Shapiro-Wilk). In this study, $p<0.05$ was considered as statistically significant.

3. RESULTS

Sociodemographic characteristics of the participants are given in Table 1. The mean age of respondents was 20.56 (±1.28) years, with a range of 18-27 years. Among these participants 51.9% are females and 48.1% are males. In our study 35.1% of the participants are 1st grade, 32% are 2nd grade, 32.9% are 3rd grade students. Among all participants

96.7% reported not to have any disabilities; 81.8% of them reported not to have any family member with a disability.

Table 1. *Sociodemographic characteristics of the participants*

		n	%
Gender	Female	188	51.9
	Male	174	48.1
Grade	1st grade	127	35.1
	2nd grade	116	32.0
	3rd grade	119	32.9
Disability Situation Of Participants	No	350	96.7
	Yes	12	3.3
Being A Disabled Person In The Family	No	296	81.8
	Yes	66	18.2
	Total	362	100

Among participants in the study 0.6% (n=2) self-reported to have a visually or auditory disability, 0.3% (n=1) to have an orthopedic disability, 1.1% (n=4) to have a mental disability (Attention deficit, autism, etc.), 0.6% (n=2) to have a chronic illness (Diabetes, Celiac, Thalassemia, Epilepsy etc.) and 0.8% (n=3) to have other kind of unspecified disability. Of the individuals who participated in our study 0.3% (n=1) had a speech disability disorder in their family, 1.7% (n=6) had a visually or auditory disability in their family, 1.7% (n=6) had an orthopedic disability in their family, 2.3% (n=8) had mental disability in their family (Attention deficit, autism, etc.), 10.2% (n=37) had a chronic illness (Diabetes, Celiac, Thalassemia, Epilepsy etc.) in their family, and 2.2% (n=8) had other kind of unspecified disability in their family (Table 2).

Table 2. *Distribution of participants by disability category*

		n	%
Distribution Of Participants By Disability Category	None	350	96.7
	Speech Disability	0	.0
	Visually or Auditory Disability	2	.6
	Orthopedic Disability	1	.3
	Mental Disability (Attention Deficit, Autism, Etc.)	4	1.1
	Chronic Illness (Diabetes, Celiac, Thalassemia, Epilepsy Etc.)	2	.6
	Others	3	.8
Distribution Of Family Members Of The Participants By Disability Category	None	296	81.8
	Speech Disability	1	0.3
	Visually or Auditory Disability	6	1.7
	Orthopedic Disability	6	1.7
	Mental Disability (Attention Deficit, Autism, Etc.)	8	2.3
	Chronic Illness (Diabetes, Celiac, Thalassemia, Epilepsy Etc.)	37	10.2
	Others	8	2.2

Among 12 participants who self-reported to have some kind of disability in our study, 3 of them stated that they did not receive help for their disability, 2 of them used glasses, 1 of them used hearing aids, 1 of them used sign language, and 5 of them went to the psychiatrist and used medication. When the ways of getting help of the disabled individuals in their family, 45 of them stated that they did not receive help, 15 of them received medical help, 3 of them used assistive devices, 1 of them received special training and 4 of them received psychiatric help.

When the participants' status of having helped any disabled individual up to now and having participated in a disability-related activity to date were examined, 102 of them stated that they helped at least one disabled individual up to now and 32 of them stated that they participated in an activity related to disability. When the type of the activity attended by the participants was examined, one of them stated that he/she talked at a discussion section, 25 of them participated in the sign language learning activity, two performed a book translation/outloudreading activity, and one participated in a club related to disability.

When the ways of helping friends with a language and speech disability were examined, 4 out of 10 participants stated that they helped their friends mostly with sign language; 5 of them stated that they helped socially by establishing close friendships and 1 of them stated that they guided him to get support.

Of the 28 people who stated that they helped their visual or hearing-impaired friends, 12 of them were helpful in finding directions, 8 of them helped in homework, 5 of them helped socially by establishing friendships, 3 of them learned sign language, 1 of them contributed to the production of 'we walk technology'.

Of the 20 people who stated that they helped their orthopedically disabled friend, 18 of them stated that they helped him/her in their transportation or in carrying goods, and 2 of them stated that they supported him/her by providing moral support and motivation.

Of the 57 people who stated that they helped their mentally disabled friends, 24 of them stated that they made friends and socially supported him/her, 17 of them stated that they provided psychological support, 11 of them helped in their lessons, and 5 of them stated that they provided guidance.

Of the 35 people who stated that they helped their friend with a chronic illness, 18 of them stated that they gave psychological support, 15 of them stated that they supported him/her to get medical help, and 2 of them stated that he helped in his/her lessons.

When the participants were asked about the shortcomings they noticed in their own campuses, 32% stated problems related to transportation, 48.8% stated problems related to physical conditions (such as elevators, ramps, toilets, lecture halls, lecture materials), 1.3% stated problems related to proper diet, and 50% did not have an opinion on this issue.

When asked about the participants' suggestions about their own campuses, they stated that there should be regulations for course materials (such as books for the visually impaired, written videos for the hearing impaired) , transportation conditions (such as on-campus bus) ,physical conditions (such as automatic door, toilets, disabled elevator), appropriate diet (vegan, gluten-free), and should have sign language

interpreters, should inform people and staff , and need to organize training on this subject.

The distribution of the answers given by the participants to the awareness questions about the disabled friendly campus is given in Table 3.

Table 3. *Distribution of the answers given to the awareness questions about the disabled friendly campus*

		n	%
1. Every university must have a disabled student representative.	1)I don't agree	11	3,04
	2)I have no idea	25	6,91
	3)I agree	326	90,06
2. Students with disabilities should be included in the decision process for adaptations to be made for them on campus.	1)I don't agree	7	1,93
	2)I have no idea	16	4,42
	3)I agree	339	93,65
3. The physical environment of universities should be arranged in a way that disabled students can also benefit.	1)I don't agree	4	1,10
	2)I have no idea	10	2,76
	3)I agree	348	96,13
4. The academic environment of universities should be arranged in a way that disabled students can also benefit.	1)I don't agree	6	1,66
	2)I have no idea	9	2,49
	3)I agree	347	95,86
5. Separate living areas should not be created for disabled students, dormitory, laboratory, classroom, library, toilet, etc. should be made available to everyone.	1)I don't agree	22	6,08
	2)I have no idea	26	7,18
	3)I agree	314	86,74
6. Teachers must also have sufficient knowledge in the field of disability in order to enable the disabled student in the classroom to follow the lesson.	1)I don't agree	10	2,76
	2)I have no idea	31	8,56
	3)I agree	32	88,67
7. Course materials should be delivered to disabled students in a way that they can use.	1)I don't agree	8	2,21
	2)I have no idea	14	3,87
	3)I agree	340	93,92
8. Various software and hardware should be provided for disabled students to continue their education equally.	1)I don't agree	10	2,76
	2)I have no idea	12	3,31
	3)I agree	340	93,92
9. There should be some special diet food in the cafeteria, canteen.	1)I don't agree	11	3,04
	2)I have no idea	24	6,63
	3)I agree	327	90,33
10. There should be a shuttle buses on the campus that disabled students can also ride.	1)I don't agree	11	3,04
	2)I have no idea	23	6,35
	3)I agree	328	90,61
11. Each campus must have an accessible resource office that can convert printed course materials into accessible formats.	1)I don't agree	6	1,66
	2)I have no idea	27	7,46
	3)I agree	329	90,88
12. The disabled friendly campus unit of the school should inform the instructors about the course and exam adaptations that students with disabilities may need.	1)I don't agree	7	1,93
	2)I have no idea	25	6,91
	3)I agree	330	91,16
13. School administrative staff should also be informed in line with the needs of students with disabilities.	1)I don't agree	8	2,21
	2)I have no idea	19	5,25
	3)I agree	335	92,54

When we compared the total scores of the participants from the questionnaire regarding the awareness questions according to their socio-demographic characteristics in Table 4, the main findings were as the following: women (37.94 ± 3.36) compared to men (37.25 ± 3.93) ($p < 0.05$), those who participated in a disabled – related activity (38.66 ± 1.60) and those who did not participate (37.51± 3.78) ($p < 0.05$); and also 1st graders (37.31 ± 3.75) getting statistically significantly lower scores than the 2nd (37.98 ± 3.22) and 3rd (37.56 ± 3.95) grades ($p < 0.05$).

Table 4. *Comparison of participants' total scores on awareness questions according to their socio-demographic characteristics, having a disabled friend and participating in an disabled related activity*

		n	Mean	Sd.	p
Gender	Women	188	37.94	3.36	0.005
	Men	174	37.25	3.93	
Class	1st grade	127	37.31	3.75	0.003
	2nd grade	116	37.98	3.22	
	3rd grade	119	37.56	3.95	
Disability status of the participant	Yes	12	37.33	3.82	0.806
	No	350	37.62	3.66	
Disability in the family of the participant	Yes	66	38.00	2.30	0.543
	No	296	37.52	3.89	
Having a disabled friend	Yes	261	37.60	3.64	0.775
	No	101	37.64	3.73	
Availability of the participant to assist a disabled person	Yes	102	37.58	4.01	0.760
	No	260	37.62	3.52	
Participant's status of participating in an activity related to persons with disabilities	Yes	32	38.66	1.60	0.004
	No	330	37.51	3.78	
Situation of the participant to see his / her campus suitable for people with disabilities	Yes	72	35.78	6.24	<0.001
	No	290	38.07	2.47	

No statistically significant differences were observed between the participants' status of being disabled, having a disabled family member, having a disabled friend, having helped a disabled person up to now and their average awareness scores ($p > 0.05$).

When the socio-demographic characteristics of the participants were compared with having helped a disabled individual up to now, it was found that those with a disabled friend (38.7%) were statistically significantly more helpful than those without a disabled friend (1.0 %) ($p < 0.05$).

No statistically significant difference was found between helping any disabled individuals up to now and gender, class, disability status of the participants, and the disability status of the family of the participant ($p > 0.05$).

When the participants' attending a disabled – related activity was examined according to the socio-demographic characteristics, it was found that the 1st graders (3.9%), the 2nd graders (12.1%) and the 3rd grades (10.9%) were statistically significantly less involved ($p < 0.05$).

No statistically significant difference was found between participating in a disabled – related activity up to now and with gender, disability status of the participants, the disability status of the family of the participant and having a disabled friend ($p> 0.05$).

No statistically significant difference was found between seeing their own campus suitable for disabled individuals and with gender, class, disability status of the participants, the disability status of the family of the participant and having a disabled friend ($p> 0.05$).

4. DISCUSSION

Universities are institutions that shape the future of a community and enable the students to become beneficial to society. There is no doubt that individuals with disabilities have the right to receive education in the field they wish and to benefit from other opportunities offered by universities, just like their peers without disabilities. The society we live in, will be complete with the establishment of institutions that include the disabled, making environmental arrangements that help them to maintain their independent lives, and equal access to educational Opportunities (12). This is possible by accepting and valuing people with physical, emotional, cultural and mental disabilities as others (13). Awareness as a factor that is affected by all these processes is seen as a concept that needs to be focused on and researched (14).

In our study, a statistically significant difference was found between male and female participants in terms of awareness scores. According to a study conducted at Kırıkkale University Faculty of Health Sciences on the attitudes of university students towards disabled individuals, there was a statistically significant difference between male and females in terms of scale scores (1). In the study conducted by Altıparmak et al. a statistically significant difference was observed when scores and gender were compared.

According to a study conducted at the Malaysian university, it was found that there is no relationship between gender and disability awareness level (15).

In our study, consistent with the literature, it was found that 1st graders got statistically significantly lower scores than the 2nd and 3rd grades (1, 16).

In our study, no significant difference was found between the scale scores of the participants, and the status of having a disabled person in their family.

According to a study conducted in China, it has been observed that the prejudice levels of individuals with a disabled relative are lower than those who do not have a disabled relative(17). In addition, it has been stated that being in contact or in contact with disabled individuals makes attitudes towards disabled people more positive.

In our study, when asked about the shortcomings that the participants noticed in their own campuses, almost half of them stated that there were physical conditions and then they stated problems related to transportation problems and proper diet. Similarly, according to a study conducted at Ege University, 64.6% of the disabled individuals when asked about their transportation stated that they could easily leave their homes, while 35.4% answered no to the question. When the users who answered "No" were asked about the reasons why they could not get out of their homes easily, 23.1% of the users emphasized the physical conditions such as the lack of a ramp on the edge of the stairs, and the 20.0% of the users that the entrance width of the building was inadequate (18). These results might show us that there are deficiencies in transportation and physical conditions for people with disabilities and more regulation is needed.

When we compared the total scores of the participants in our study obtained from the questionnaire regarding the awareness questions according to their socio-demographic characteristics, it was found that those who participated in a disabled-related activity got statistically significantly higher scores than those who did not. According to the research of participating in the awareness education for the disabled in the USA, it is shown that there is an improvement in the feelings and thoughts about the attitudes towards the disabled in those who have completed the education (19).

It is important to have an understanding and knowledge of how disability perceptions and human rights can be implemented. One way to do this would be to raise awareness of the barriers and opportunities that exist in the environment for different people with disabilities (20).

The work of health professionals is directly influenced by somatopsychological attitudes. Expectations from the disabled, healthcare professionals and society play an important role in disability adaptation. Since our study was conducted with the students of a health-related department, a high level of awareness is expected. Tracking students longitudinally throughout their education and professional business life will also collect information on how the awareness of disabled people will change or not (21). We think that future research should include a more robust sample size.

The strengths of this study are that there is no previous study on this subject in the literature, so we think that our study will make significant contributions to the literature. In addition, in recent years, disadvantaged individuals are encouraged to be brought into our universities in our country and in the world. In this sense, universities are rewarded, especially in our country. Our study is also a study that emerged as a result of the efforts in this field at our University.

Limitations

If we look at the limitations of our study, first of all, having done it in a limited population of preclinical medical school students may not reflect all medical faculty students. They may not have wanted to talk about their disability or the disabled individuals in their family, as disability can be a problem for this age group and they fear stigmatization. As it is a cross-sectional study, people with disabilities may not have been there at the time of data collection or may not have attended school that day. As the strength of our study, the fact that the study was conducted in a health-related section may have led to higher awareness**.**

5. CONCLUSION

This is a pioneering study in the field of research, and it has been carried out to ensure solidarity and awareness for all individuals, especially those with disabilities in campus life. During the literature review, it was observed that similar studies, especially measuring awareness, were very limited. With this study, it was thought that even just applying a questionnaire, an awareness could be raised on the campus and a health-enhancing step could be taken. Conducting more comprehensive and larger-scale studies on this subject will provide an opportunity for the establishment of the disabled friendly campus concept, and for all individuals to be in more cooperation and solidarity with individuals with disabilities.This pilot study enabled the researchers to plan to develop scales for measuring Disabled Friendly Campus awareness.

Ethics Committee Approval: Marmara University Clinical Research Ethics Committee granted approval for this study (date: 3/05/2019, number: 19.2019.480).

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Clinical and Experimental Health Sciences

Breastfeeding in Turkey: A Systematic Review

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ABSTRACT

Objective: This study was carried out to systematically review the studies conducted on breastfeeding in Turkey and to provide information on the breastfeeding status.

Methods: This study is a systematic review and conducted by examining 47 studies carried out in Turkey between January 2008-December 2018 and published in national and international journals. The methodological quality of the studies was examined according to the evaluation criteria of the Joanna Briggs Institute Critical Appraisal Checklist for Studies Reporting Prevalence Data. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses checklist was used while reporting the review.

Results: According to the obtained study results, it was determined that the time of breastfeeding initiation and the mean duration of breastfeeding were in quite a wide range. Among breastfeeding-related factors, maternal age, education, employment status, the number of living children, the type of birth, preterm birth, receiving professional support on breastfeeding, early postnatal breastfeeding, and giving complementary feeding or formula were frequently listed. The most common reason for starting complementary feeding or was determined to be the idea that breast milk was insufficient.

Conclusion: No common language and unity of definition were observed in the studies reviewed. The studies were conducted in different samples. It is thought that the systematization of studies on breastfeeding will be scientifically useful for determining the current situation, determining the scope of future studies, and making the necessary arrangements.

Keywords: Breastfeeding, Breast milk, Turkey, Systematic review

1. INTRODUCTION

The World Health Organization (WHO) states that breastfeeding is the most effective way to provide infants with nutrients they need for growth and development (1). The World Health Organization and the United Nations International Children's Emergency Fund (UNICEF) recommend that mothers should start to breastfeed their infants within the first hour after birth (2,3).

Furthermore, it is recommended that mothers should maintain exclusive breastfeeding in the first 6 months without giving any food or drinks including water. It is also recommended to maintain breastfeeding for their infants at night and during day time at frequencies their infants want, not to use by not using a feeding bottle or a pacifier. After the 6th month of infants, it is recommended to continue breastfeeding until at least 2 years of age or older, provided that breastfeeding is accompanied by appropriate complementary feeding (2,3).

Breastfeeding has many benefits for the infant. While providing the emotional and cognitive development of infants, it also protects them against infections and strengthens the immune system. Moreover, it protects against otitis media, gastroenteritis, necrotizing enterocolitis, sudden infant death syndrome, atopic skin diseases, respiratory tract and urinary tract infections, bacterial meningitis, allergic diseases, acute and chronic diseases such as obesity, diabetes, celiac disease, and childhood leukemia, and accelerates the healing process. Research also shows that very early skin-to-skin contact and suckling may have physical and emotional benefits (1-5).

The Turkey Demographic and Health Survey (TDHS, 2018) defines not giving children anything other than breast milk, in other words, feeding children only with breast milk as

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"Exclusive breastfeeding." According to the survey, only 41% of children younger than 6 months were exclusively breastfed. Exclusive breastfeeding rate decreases rapidly with age. While the rate of exclusive breastfeeding in 0-1 months old infants is 59%, this rate decreases in 2-3 months and 4-5 months old infants to 45% and 14% respectively (2,6).

There are many sociodemographic, obstetric, and breastfeeding-related factors that affect mothers' exclusive breastfeeding. Sociodemographic factors include maternal age, educational status, employment status, economic status, family type, environmental factors, hospital conditions where birth will take place, and cultural factors (7-9). Obstetric factors include age of gestation, parity and number of living children, and type of birth (10-13). Breastfeeding-related factors include counseling on breastfeeding received by mother during pregnancy, self-confidence in breastfeeding, mother's attitude toward breastfeeding and healthcare professionals' attitude toward breastfeeding, thinking that breast milk is insufficient, unwillingness to breastfeed, giving formula in hospital, and use of a pacifier (7-10,14-16).

This systematic review was carried out to systematically review studies conducted on breastfeeding in Turkey and to provide information on breastfeeding status, and the time of breastfeeding initiation, breastfeeding duration, factors affecting breastfeeding, and reasons for starting complementary feeding were determined.

2. METHODS

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist was used in preparation of systematic review protocol and writing of article (17,18). This checklist has a Turkish text (19).

2.1. Search

Literature review was conducted by performing retrospective screening of publications on subject through search engines by using internet access network of Istanbul University-Cerrahpaşa. Literature review was performed using various combinations of keywords of breastfeeding, breast milk, and Turkey in Turkish and English. It was performed using search engines of Electronic databases, Google Scholar, Medline, CINAHL, Embase, Cochrane Library, ULAKBİM, and Türk Tıp Dizi. In order to reach current research data, studies published in a period of 10 years (January 2008-December 2018) were included in study.

2.2. Study selection

Research articles to be included in study were determined by a consensus of two researchers. Discrepancies that occurred between researchers in meantime, whether an article should be included in the study or not, were resolved by reaching a consensus as a result of review by a third researcher.

2.3. Eligibility criteria

Studies conducted in Turkey and published in national/international refereed journals between January 2008-December 2018, with sample containing healthy mothers and infants, with original and quantitative characteristics, and full text of which could be reached were included in research. Repeated publications were eliminated during selection. Unpublished theses on subject, books/book chapters, reviews, qualitative studies, experimental studies, oral or poster papers presented at congresses, and studies data of which were not collected in Turkey and not having sample group of healthy infants and children were not included in study (Figure 1).

2.4. Protocol and registration

Titles and abstracts of all studies determined by electronic search were examined by two researchers independently of each other in terms of eligibility criteria. One researcher evaluated methodological quality of articles that met eligibility criteria according to the Joanna Briggs Institute (JBI) Critical Appraisal Checklist for Studies Reporting Prevalence Data (20). Evaluations made were checked by another researcher.

2.5. Data collection process

A pre-designed form was used independently by two researchers for data collection. With this form, years of publication of studies, their types, characteristics of sample group, place of study data collection, definition of questionnaire and scales used, time of breastfeeding initiation, duration of breastfeeding, breastfeeding-related factors, and reasons for starting complementary feeding were descriptively summarized by two researchers in an Excel table. This summarized information was checked by another researcher. In contradictory cases, three researchers reached a consensus.

2.6. Research Questions:

1. What is the time of breastfeeding initiation?
2. What is the duration exclusively breastfeeding?
3. What is the total duration of breastfeeding?
4. What are the factors related to breastfeeding?
5. What are the reasons for starting complementary feeding?

2.7. Data items

After literature review, 1755 studies were reached on subject in electronic environment at first stage. After removal of repeated publications, 858 studies were evaluated. Study titles and abstracts were examined, and 718 studies were excluded from study. Full text of 140 studies was reached and

analyzed. Accordingly, 93 studies that did not meet inclusion criteria were excluded. Systematic review data were collected by examining 47 studies. Details of article selection process are presented in Figure 1.

2.8. Data Analysis

Due to the fact that data obtained from examined studies were not homogenous, a meta-analysis could not be performed. Quantitative data on the time of breastfeeding initiation and duration of breastfeeding in studies were given as minimum and maximum values considering all studies. Methodological quality of studies was evaluated by the JBI Critical Appraisal Checklist for Studies Reporting Prevalence Data. In this evaluation system, quality of studies is determined by scoring between 1 and 9. Mean score of 47 studies examined was determined to be 6.58±1.0.

3. RESULTS

Results of review will be evaluated under two separate headings:

3.1. Results of study characteristics are as follows

1. Publication years and types of studies
2. Characteristics of sample group
3. Place of study data collection
4. Questionnaire and scales used in studies

3.2. Results of breastfeeding are as follows

1. Results on the time of breastfeeding initiation
2. Results on the duration of exclusively breastfeeding and total breastfeeding
3. Results on breastfeeding-related factors
4. Results on the reasons for starting complementary feeding

3.3. Results of study characteristics

3.3.1. Publication years and types of studies

Upon examining number of studies by years, highest number of publications on subject (eight publications) was in 2018, followed by 2012 with seven publications. In 2013 and 2017, there were six publications in each of years. There were five publications in 2008, four publications in 2010 and 2015, three publications in 2009, and two publications in 2014. Besides, in 2011 and 2016, there was only one publication in each of years. Of the 47 studies examined, 41 studies were determined to be descriptive-cross-sectional (4,21-60) three studies were retrospective (7,61,62), three studies were prospective (63-65) follow-up studies.

3.3.2. Characteristics of Sample Group

Upon examining sample number of reviewed studies, it was observed that studies were conducted with 51 people at least (58) and with 3038 people at most (26). Age range of children of mothers included in study varied and was determined to cover groups of neonates (7,34,39,43,45,50,51,58,63), 0-3 months (30,42), 0-6 months (22,27,41,47,53,56,64,65), 0-12 months (4,23,24,28,29,54,61,62), 0-18 months (32,44), 0-24 months (25,33,35-37,46,48,49,52,55,57,59,60), and 0-36 months (26,31). In other studies, children in 0-5 age range (21,38,40) were studied in different time periods.

3.3.3. Place of Study Data Collection

Places where reviewed studies were conducted and data were collected vary. Of studies, 16 were performed in primary health care centers (4,23,24,26,29,32,37,38,41,44,47,49,52,54,55,57), 22 were performed in polyclinics for healthy children and other polyclinics of hospitals (7,21,22,27,28,30,31,33-36,39,40,42,46,48,50,56,59,61,62,65), seven were conducted in postnatal wards of hospitals (43,45,51,53,58,63,64), and two studies were community-based (25,60) (Table 1).

3.4. Questionnaire and Scales Used in Study

Questionnaires used in most of studies (7,21,23-33,35-41,44-49,51-57,60-62,64,65) are non-standardized questionnaires prepared by researchers based on literature review on subject.

In only nine of examined studies (4,22,34,42,43,50,58,59,63), scale was used. The Breastfeeding Attitude Assessment Scale was used in two studies (22,34), the Breastfeeding Diagnostic Scale (LATCH) (43,50,58) was used in three studies, the BSES-SF (42,59) was used in two studies, and a scale not related to breastfeeding (the Brief Symptom Inventory) and helping to evaluate mothers' psychopathologies was used in two studies (4,63) (Table 1).

3.5. Results of breastfeeding

3.5.1. The time of breastfeeding initiation

The times of breastfeeding initiation vary in studies reviewed. Accordingly, the time of breastfeeding initiation was indicated to be in the first 30 minutes in 17 studies (4,26,34-36,39,41,44,45,47,48,51,52,54-56,58), in the first hour in 19 studies (22-26,29,30,32,34,35,38,39,41,43,44,47,55,57,65), and after the first hour in 19 studies (22,24,26,32,34,35,38,39,41,44,47,48,50-52,54,55,63,65), and the time of breastfeeding initiation was not questioned in 17 studies (7,21,27,28,31,33,37,40,42,46,49,53,59-62,64). Rates of breastfeeding initiation in the first 30 min, first one hour, and after the first hour in studies are presented in Table 2.

Table 1. *Characteristics of the studies reviewed*

Author and Year of Publication	Aim of the Study	Sample Size Age Range	Place of the Study	Type of the Study	Form Used in the Study
Can et al. (2008)[21]	To evaluate the characteristics of children and families in Istanbul province	374 people (9 months-5 years)	Pediatric Polyclinic	Descriptive-Cross-sectional	Questionnaire
Gölbaşı and Koç (2008)[22]	To determine the effect of breastfeeding behaviors in the first 6 months postpartum and attitudes toward breastfeeding during pregnancy of women in Ankara province on their breastfeeding behaviors	90 people (0-6 months)	Pregnant women polyclinic and by telephone in the postpartum period	Descriptive-Cross-sectional	Questionnaire and Breastfeeding Attitude Assessment Scale
Ünalan et al. (2008)[23]	To examine which variables affect mothers' start to complementary feedings in a health care institution in Istanbul province.	358 people (0-12 months)	Family Health Center	Descriptive-Cross-sectional	Questionnaire
Yıldız et al. (2008)[24]	To determine the breastfeeding status of mothers with 0-11-month-old infants in Ankara province and the affecting factors	121 people (0-11 months)	Family Health Center	Descriptive-Cross-sectional	Questionnaire
Yeşildal et al. (2008)[25]	To evaluate breastfeeding practices by using standard breastfeeding indicators in Düzce province and determine the reasons for the early cessation of breastfeeding in 0-24-month-old children in Turkey	158 people 0-24 months	Community	Cross-sectional	Questionnaire
Gün et al. (2009)[26]	To determine the breastfeeding and feeding status of 0-36-month-old children in Kayseri province	3038 people (0-36 months)	Family Health Center	Descriptive-Cross-sectional	Questionnaire
Kondolot et al. (2009)[27]	To evaluate the rates of exclusive breastfeeding in the first six months of healthy infants in Ankara province and the affecting factors	302 people (3-24 weeks)	Pediatric Polyclinic	Descriptive-Cross-sectional	Questionnaire
Örün et al. (2009)[63]	To investigate the effects of the psychopathologies and sociodemographic characteristics of mothers in Ankara province on breastfeeding within 1-1.5 months postpartum	657 people (1-1.5 months)	Postpartum service	Longitudinal (Prospective)	Brief Symptom Inventory and Questionnaire
Çınar et al. (2010)[28]	To determine the effect of mother and infant sleeping in the same room on breastfeeding in Sakarya province	254 people (0-12 months)	Pediatric Polyclinic	Descriptive-Cross-sectional	Questionnaire
Dolgun and Yüksel (2010)[29]	To assess the implementation of a breastfeeding education program for women against the backdrop of the relevant policies adopted by the country of Turkey in Istanbul province.	801 people (0-12 months)	Mother and Child Care and Family Planning Center	Descriptive-Cross-sectional	Questionnaire
Gökdemirel et al. (2010)[64]	It was intended to promote mothers to exclusively breastfeed their infants for the first six months by preventing the possible flourishing problems of breast and breastfeeding in the early period just after the birth with the help of counseling and support in Istanbul province.	101 people 0-6 months	Postpartum service	Longitudinal (Prospective)	Questionnaire
İnce et al. (2010)[30]	To investigate the reflection of breastfeeding counseling training on practice by asking mothers, who applied to the Healthy Child Polyclinics of two university hospitals in Ankara and Kayseri, about the status of receiving breastfeeding counseling	285 people 15-90 days	Healthy Child Polyclinic	Descriptive-Cross-sectional	Questionnaire
Bolat et al. (2011)[65]	To examine the effects of the factors affecting the time of breastfeeding initiation on exclusive breastfeeding in the sixth month in Istanbul province	246 people (0-6 months)	Pediatric Polyclinic	Descriptive, Prospective, Longitudinal	Questionnaire
Akova et al. (2012)[31]	To determine the effect of breast milk intake on child development in infants aged 0-36 months in Istanbul province	100 people (0-36 months)	Pediatric Polyclinic	Descriptive-Cross-sectional	Questionnaire
Araz (2012)[7]	To investigate sociodemographic factors that may influence the initiation of breastfeeding on the 15th day in the neonatal period in Gaziantep province	121 people (15 days)	Pediatric Polyclinic	Retrospective	Questionnaire

Çatak et al. (2012)[32]	To determine the breastfeeding status and feeding pattern of mothers in Burdur province	1080 people (0-18 months)	Family Health Center	Descriptive-Cross-sectional	Questionnaire
Çeçe and Yenal (2012)[33]	To determine factors affecting the duration of breastfeeding of working mothers in Izmir province	120 people (12-24 months)	Pediatric Polyclinic and Family Health Center	Descriptive-Cross-sectional	Questionnaire
Kepekçi et al. (2012)[61]	To examine mothers who apply to a breastfeeding counseling unit in Istanbul province and their infants	90 people (2-300 days)	Breastfeeding Counseling Unit	Retrospective	Questionnaire
Yiğitbaş et al. (2012)[34]	To determine the behaviors and attitudes of mothers with regard to breastfeeding in Trabzon province	405 people Neonates	Postpartum service and Pediatric polyclinic	Descriptive-Cross-sectional	Breastfeeding Attitude Assessment Scale and Questionnaire
Sökücü and Aslan (2012)[62]	To determine the effects of the employment status on breastfeeding among breastfeeding mothers in Cyprus	380 people (6-12 months)	Pediatric polyclinic	Retrospective	Questionnaire
Beşbenli et al. (2013)[35]	To investigate the information and practices related to breast milk and nutritional supplements of mothers living in Istanbul province and included in three different socioeconomic groups	202 people (6-24 months)	Pediatric polyclinic	Descriptive-Cross-sectional	Questionnaire
Bülbül and Kılınçkaya (2013)[36]	To investigate the breast milk intake and breastfeeding status of infants in Kırıkkale province	94 people (0-2 years)	Pediatric polyclinic	Descriptive-Cross-sectional	Questionnaire
Sabbağ (2013)[37]	To compare the behaviors of mothers with 0-24-month-old infants in urban and rural areas in Adıyaman province in child nutrition	103 people (0-24 months)	Family Health Center	Descriptive-Cross-sectional	Questionnaire
Şahin et al. (2013)[38]	To determine the problems faced by mothers during breastfeeding and risk factors affecting breastfeeding in Kayseri province	500 people (24–60 months)	Family Health Center	Descriptive-Cross-sectional	Questionnaire
Yenal et al. (2013)[39]	To investigate the relationship between the breastfeeding self-efficacy perception and breastfeeding success of mothers in the postnatal period in Izmir province	220 people (Neonates)	Pediatric polyclinic	Descriptive-Cross-sectional	Questionnaire
Şencan et al. (2013)[40]	To investigate factors affecting the duration of breastfeeding in Ankara province	2-4 years	Pediatric polyclinic	Descriptive-Cross-sectional	Questionnaire
Sivri et al. (2014)[41]	To determine the duration and causes of the transition to complementary feeding among mothers with 0-6-month-old infants in Konya province	220 people (0-6 months)	Family Health Center	Descriptive-Cross-sectional	Questionnaire
Çınar et al. (2014)[42]	To determine breastfeeding self-efficacy and factors affecting it among mothers during the 0-3-month period in Sakarya province	152 people 0-3 months	Pediatric polyclinic and Family Health Center	Descriptive-Cross-sectional	Questionnaire Breastfeeding Self-Efficacy Scale-Short Form / BSES-SF
Bostancı and İnal (2015)[43]	To determine the level of knowledge about breastfeeding and breastfeeding status of mothers who gave birth in a private hospital in Istanbul province	150 people (Neonates)	Postpartum service	Descriptive-Cross-sectional	Breastfeeding Diagnostic Measurement Tool (LATCH) and Questionnaire
Dinç et al. (2015)[44]	To determine traditional practices with regard to breastfeeding and breast milk of mothers with 6-18-month-old infants in Çanakkale province	212 people (6-18 months)	Family Health Center	Descriptive-Cross-sectional	Questionnaire
Demirtaş (2015)[45]	To describe the informative, practical and emotional support received by multiparous mothers in the early postnatal period from nurses in Ankara province	278 people Neonates	Postpartum service	Descriptive-Cross-sectional	Questionnaire

Erkuran et al. (2015)[46]	To determine the frequency of exclusive breastfeeding and to examine the affecting factors among infants applying to a pediatric polyclinic in Ankara province	603 people 6-24 months	Pediatric polyclinic	Descriptive-Cross-sectional	Questionnaire
Karadağ et al. (2016)[47]	To determine breastfeeding characteristics of mothers with infants younger than 6 months in Bursa province	186 people (0-6 months)	Family Health Center	Descriptive-Cross-sectional	Questionnaire
Çalık et al. (2017)[48]	To determine breastfeeding practices and affecting factors of mothers with 6-24-month-old infants in Trabzon province	401 people (6-24 months)	Pediatric polyclinic	Descriptive-Cross-sectional	Questionnaire
Gümüştakım et al. (2017)[49]	To evaluate the nutritional habits of 0-2-year-old children and their mothers' levels of knowledge about nutrition in 5 different provinces (Sakarya, Hatay, Karaman, Ordu, Rize)	250 people (0-2 years)	Family Health Center	Descriptive-Cross-sectional	Questionnaire
İnce et al. (2017)[50]	To evaluate breastfeeding self-efficacy and characteristics affecting breastfeeding success of mothers in Izmir province	91 people (Neonates)	Pediatric polyclinic	Descriptive-Cross-sectional	Breastfeeding Self-Efficacy Scale-Short Form, Breastfeeding Diagnostic and Assessment Scale (LATCH) and Questionnaire
Koç et al. (2017)[51]	To evaluate the knowledge, opinions, and attitudes of mothers in Erzurum province with regard to breastfeeding coaching	275 people (Neonates)	Postpartum service	Descriptive-Cross-sectional	Questionnaire
Şahin and Özyurt (2017)[52]	To evaluate the breastfeeding status and nutritional habits of 0-24-month-old infants in Manisa province	140 people (0-24 months)	Family Health Center	Descriptive-Cross-sectional	Questionnaire
Yılmaz et al. (2017)[53]	To determine the time of the first breastfeeding, the rates of exclusive breastfeeding in the first six months of life, and factors affecting the feeding practices of infants of mothers, who gave birth in a baby-friendly hospital in Ankara province	350 people 0-6 months	Postpartum service and by telephone after 6 months	Descriptive-Cross-sectional	Questionnaire
Canbay (2018)[54]	To examine the ways of feeding of infants born by cesarean section in Aydın province in the first six months	152 people (7-12 months)	Family Health Center	Descriptive-Cross-sectional	Questionnaire
Derin and Erdoğan (2018)[55]	To determine breastfeeding practices of mothers with 0-24-month-old infants in Muş province	508 people (0-24 months)	Family Health Center	Descriptive-Cross-sectional	Questionnaire
Kırıcı and Görak (2018)[56]	To evaluate the nutritional status and affecting factors of mothers with 0-6-month-old infants in Karaman province	200 people (0-6 months)	Pediatric polyclinic	Descriptive-Cross-sectional	Questionnaire
Göl (2018)[57]	To evaluate the effect of the status of receiving prenatal care on breastfeeding behaviors of mothers with 0-24-month-old infants who apply to family health centers in Çankırı province	141 people 0-24 months	Family Health Center	Descriptive-Cross-sectional	Questionnaire
Keloğlan et al. (2018)[58]	To investigate factors affecting the breastfeeding status of postpartum mothers in Amasya province	51 people neonates	Postpartum service	Descriptive-Cross-sectional	LATCH
Küçükkaya et al. (2018)[59]	To investigate the relationship between breastfeeding self-efficacy and the time of transition to supplementary feeding of mothers in Edirne province	282 people 0-2 years	Pediatric polyclinic	Descriptive-Cross-sectional	Questionnaire Breastfeeding Self-Efficacy Scale
Salcan et al. (2018)[60]	To investigate the frequency of exclusive breastfeeding during the first six months and factors affecting this in infants born in 2016 in Erzincan province	635 people 0-2 years	Family practice Community	Descriptive-Cross-sectional	Questionnaire
Yüzügüllü et al. (2018)[4]	To investigate sociodemographic characteristics and psychopathological characteristics of mothers living in Adana province and to investigate the effects of these characteristics on the status of exclusive breastfeeding in the first six months	284 people 6-12 months	Family Health Center	Descriptive-Cross-sectional	Questionnaire Symptom Check List (SCL-90-R)

3.5.2. Duration of breastfeeding, exclusively breastfeeding and total breastfeeding

In studies examined, mean duration of breastfeeding was (7,26,29,31-33,38-41,44,52,53,59,60) minimum 3.45 months and maximum 17.7 months, the time of starting complementary feeding (24,29,31,38,53,58,59) was minimum 2.04 months on average and maximum 6 months, and ratio of exclusive breastfeeding in the first 6 months (4,21,26,29,38,46,48,52,53,57-60,64) was minimum 8.7% and maximum 67.1%. In 23 studies, duration of exclusive breastfeeding was not indicated (Table 3).

3.5.3. Breastfeeding-related factors

Upon examining breastfeeding-related factors in study, it was determined that maternal age (46,48,58,59), educational level (4,25,33,34,48,52,53,55,59,60), employment status (4,34,40,48,60,62,63), and economic status (33,38,63) were frequently effective in terms of demographic variables; parity and number of living children (29,30,33,38,39,58,59,63,65), type of birth (22,23,25,29,30,38,52,53,57) and preterm birth (23,27,36,59,64,65) were frequently effective in terms of obstetric variables; and status of receiving information on breastfeeding (4,29,42,48,53,57,60,65), having breastfeeding experience (22,42,50,58), early postnatal breastfeeding (4,38,55,58,59,65), giving complementary feeding or formula (23,25,46,55,59,60), and use of a pacifier or a feeding bottle were frequently effective in terms of breastfeeding-related variables (23,27,53,60) (Table 4).

In studies examined, it was determined that an increase in number of children, having a vaginal birth, having received education on breastfeeding, and initiating early postnatal breastfeeding affected breastfeeding positively. Advanced maternal age, high educational level, working mother, good economic status, preterm birth, giving complementary feeding or formula, and use of a pacifier or feeding bottle were observed to have adverse effects on breastfeeding.

3.5.4. Reasons for starting complementary feeding

Upon examining reasons for starting complementary feeding in examined studies, the most common reasons were determined as insufficient breast milk or cessation of breastfeeding (4,25,29,32,40,41,44,45,46,48,53,55,60), the fact that infant does not suck (25,32,37,44,45,48), and mother's thinking that child has grown up and it is time to wean (4,41,44,53,60). The other reasons were determined to be mother's and infant's disease (25,44), experiencing a breastfeeding problem (45), starting to work (4), getting used to a feeding bottle (44), and low self-efficacy (58). In the other 32 studies (7,21-24,26-28,30,31,33-36,38,39,42,43,47,49-52,54,56,57,59,61-65), no data on this variable could be found (Table 5).

Table 2. *The times of breastfeeding initiation*

Breastfeeding Times	The Number of Studies	Minimum-Maximum
The first 30 minutes	17 studies[4,26,34-36,39,41,44,45,47,48,51,52,54-56,58]	12.4% – 93.7%
The first 1 hour	19 studies[22-26,29,30,32,34,35,38,39,41,43,44,47,55,57,65]	9.9% – 92.4%
After 1 hour	19 studies[22,24,26,32,34,35,38,39,41,44,47,48,50-52,54,55,63,65]	12% – 100%
Not specified	17 studies[7,21,27,28,31,33,37,40,42,46,49,53,59,60-62,64]	Non applicable

Table 3. *Data on the duration of breastfeeding**

	The Number of Studies	Min-Max (Mean)
The Mean Duration of Breastfeeding	15 studies[7,26,29,31-33,38-41,44,52,53,59,60]	3.45 – 17.7 months
The Time of Starting Complementary Feeding	7 studies[24,29,31,52,53,58,59]	2.04-6 months
		Min – Max (%)
Exclusive Breastfeeding in the First 6 Months	14 studies[4,21,26,29,38,46,48,52,53,57-60,64]	8.7-67.1
The duration of exclusive breastfeeding was not specified	23 studies[7,22-24,28,30,31,33,34,36,37,39,41-45,51,54-56,62,63]	Non applicable

**In one study, there may be more than one data on the duration of breastfeeding.*

Table 4. *Breastfeeding-related factors*

Sociodemographic	Obstetric	Breastfeeding
Maternal age[46,48,58,59]	Parity/number of living children[29,30,33,37,38,58,59,63,65]	Receiving professional support on breastfeeding by the mother[4,29,42,48,53,57,60,65]
Mother's educational level[4,25,33,34,48,52,53,55,59,60]	Type of birth[22,23,25,29,30,38,52,53,57]	The status of breastfeeding the previous infant / Having a positive breastfeeding experience[22,42,50,58]
Employment status[4,34,40,48,60,62,63]	Premature birth/ Premature infant[23,27,36,59,64,65]	First breastfeeding time/ Early postnatal breastfeeding[4,38,55,58,59,65]
Economic status[33,38,63]	Willing pregnancy[22,53,63]	Giving complementary feeding/formula[23,25,46,55,59,60]
Living in rural/urban areas[25,59]	The frequency of pregnant follow-up[48]	The use of a pacifier/feeding bottle[23,27,53,60]
Family type[48]	Birth weight[38]	The concern about insufficient milk secretion[38]
Smoking[63]	Infant's gender[25,33]	The number of daily breastfeeding[38]
Medical problems[22,46]		Weak sucking reflex[22]
		The frequency of breastfeeding[55]
		The suitability of breastfeeding conditions at work[33]
		Breast problem[38,58]
		The status of exclusive breastfeeding[50]
		Postnatal stay of the infant in the neonatal unit[22]
		The status of taking colostrum[55,58]
		The status of receiving social support[33,53]
		Sharing the same room with the infant[40,59]

Table 5. *The reasons for starting complementary feeding***

	The Number of Studies
The thought that breast milk is insufficient	13 studies[4,25,29,32,40,41,44-46,48,53,55,60]
The fact that the infant does not suck	6 studies[25,32,37,44,45,48]
Thinking that the child has grown up or the time to wean from breast has come	5 studies[4,41,44,53,60]
Disease of the mother or infant	2 studies[25,44]
Experiencing a breastfeeding problem	1 study[45]
Starting to work	1 study[4]
Getting used to a feeding bottle	1 study[44]
Low self-efficacy	1 study[58]
Studies without data on this subject	32 studies[7,21-24,26-28,30,31,33-36,38,39,42,43,47,49-52,54,56,57,59,61-65]

***There may be more than one reason in one study.*

4. DISCUSSION

The present study was carried out to systematically review studies conducted on breastfeeding in Turkey and to provide information on breastfeeding status, and the time of breastfeeding initiation and duration of breastfeeding. Factors affecting breastfeeding, and reasons for starting complementary feeding in Turkey were also determined within scope of study.

International organizations recommend that mothers should start breastfeeding their infants within the first hour after birth because it is important to support initiation of breastfeeding within the first hour in terms of maternal and neonatal health. Among studies evaluated within scope of this systematic review, ratios of breastfeeding initiation in the first hour are quite different from each other, and there is no consistency between studies. Similarly, in literature, Silva et al. (2018) (9), Smith et al. (2015) (66), and Kushwaha et al. (2018) (67) indicate different ratios in their studies in terms of ratios of breastfeeding initiation in the first hour. This can be interpreted as the fact that ratios of breastfeeding initiation in the first hour can be affected by many factors, and this can be due to different sample groups for each study. The fact that reasons for not breastfeeding within the first hour were included in very few studies in this review led to conclusion that this subject should be investigated in future studies. Determining factors that increase and decrease initiation of breastfeeding within the first hour may contribute to increasing breastfeeding within the first hour.

The most important characteristic of the first years of life is rapid growth and development. During this period, infant should be breastfed and receive breast milk sufficiently. In Turkey, 41% of infants younger than 6 months are exclusively breastfed. These results are similar to world data (40%). However, it is observed that ratio of exclusively breastfed infants rapidly decreases from the first month and decreases to 14% in 4-5-month-old infants (2,6). This shows that reasons for the rapid regression of breastfeeding in the early period should be investigated, and effective solutions should be put forward. Mean duration of breastfeeding varies among studies in this review. It was determined that goal of exclusive breastfeeding in the first six months and breastfeeding until two years of age could not be mostly achieved in Turkey. It is observed that in studies by Bai et al. (2015) (68), Cox et al. (2015) (69), and Nelson et al. (2018) (13), these goals could not be achieved, similarly to result of present study. This can be considered as an indication that goal of exclusive breastfeeding in the first six months and breastfeeding until two years of age could not be reached despite the long-term strategies to support breastfeeding worldwide. These results suggest that strategies and practices for initiating and sustaining breastfeeding should be reviewed and studies should be carried out to determine difficulties in practice.

Within scope of current systematic review, it was detected that breastfeeding is affected by many factors in studies examined. In this section, breastfeeding-related variables in publications examined within scope of review were discussed under demographic, obstetric, and breastfeeding-related sub-headings.

Maternal age was among variables affecting breastfeeding in the current review. Breastfeeding was observed to be negatively affected with increasing maternal age. In literature, there are studies supporting the fact that advanced maternal age affects breastfeeding negatively (13), not supporting this fact (66), and indicating that they are not related (10,14,70). In this review and in literature, it is still not possible to reach a conclusion about age and breastfeeding. It is thought that further studies are needed.

Educational level is another variable that affects breastfeeding. According to result of this review, it was determined that breastfeeding was adversely affected as educational level increased. In literature, there are studies supporting the fact that increase in educational level affects breastfeeding adversely (10,11), not supporting this fact (66,70), and stating that they are not related (14). Effect of educational level on breastfeeding has not been revealed yet. However, this variable should be evaluated together with employment status, not alone because women with high educational level are usually active in working life. In other words, it can be thought that educational level affects breastfeeding indirectly, not directly. Research on this subject is needed.

In this review, it was detected that breastfeeding status of working mothers was negatively affected. In literature, there are studies supporting negative effect of employment status on breastfeeding (15,66,69,71) and indicating that they are not related (14). However, no study that did not support this result was encountered. This suggests that working mothers need strategies to help them continue breastfeeding. Also economic status was identified as an other variable that affects breastfeeding in the present study.

Breastfeeding was observed to be adversely affected as the income increased. This can be interpreted as the fact that ease of accessing formula by individuals with good economic status may affect breastfeeding adversely. In literature, there are studies supporting negative effect of increase in economic status on breastfeeding (11,72), not supporting this (70) and stating that they are not related (14). It is thought that more studies on effect of economic status are needed.

Among reviewed publications, breastfeeding status in rural and urban areas was included only in two studies. While the duration of breastfeeding was found to be longer in the rural area in comparison with urban area in one of them, it was observed that complementary feeding was given earlier in rural area in the other study. No data on this variable were found in literature. There is a need for further studies on this subject.

Smoking emerged as a factor affecting breastfeeding in one of publications examined in this review. Upon reviewing literature, there are studies stating that smoking affects breastfeeding adversely (13,69,70,73). It is observed that breastfeeding is negatively affected by a replaceable factor, such as smoking. Therefore, it is thought that quitting smoking during pregnancy will contribute positively to breastfeeding.

Two of publications reported that medical reasons of mother and infant affected breastfeeding adversely in the current review. In literature, there are studies indicating that medical reasons of mother and infant affect breastfeeding adversely (66) and indicating that they are not related (70). There is a need for more studies to reach a conclusion with regard to this variable. Also, no data on body mass index (BMI) and breastfeeding were found in any of publications in the present review. However, there are studies in literature supporting the fact that obesity affects breastfeeding adversely in relation to this variable (13,69,73) and indicating that it does not affect breastfeeding (66). It is thought that developing strategies to reduce prenatal BMI will affect breastfeeding positively and will not have a negative effect.

Parity and number of living children is one of the most common obstetric variables related to breastfeeding in this review. Increase in parity and number of living children was observed to affect breastfeeding positively. There are studies in literature supporting the fact that increase in number of children affects breastfeeding positively (10,13,73). This situation suggests that primiparous mothers should be supported more.

Type of birth is another variable most frequently associated with breastfeeding in this review. Breastfeeding was determined to be positively affected in vaginal delivery group. In study conducted by Kronborg et al. (2018) (10) in Denmark,

durations of exclusive breastfeeding and breastfeeding were found to be longer in non-cesarean mothers. Result obtained by Kronborg et al. (2018) (10) and result of this review are similar to each other. Supporting vaginal delivery can be recommended as a variable that affects breastfeeding positively. However, it was determined that preterm birth affected breastfeeding negatively in the present review. In literature, there are studies that support (10) and do not support this result (66). Difference between this review and study by Smith et al. (2015) (66) may be due to the fact that studies were conducted in different countries.

In this review, a willing pregnancy was included in three publications as a variable that affects breastfeeding. No data on positive or negative effects of it on breastfeeding were found in these publications. Furthermore, no data on this variable were found in literature. Data on gender of infant were found in two publications in the current review. In one of these publications, it was determined that male infants were breastfed longer. In study conducted in Denmark, Kronborg et al. (2018) (10) found that gender was not related to duration of breastfeeding. In study carried out by Stough et al. (2018) (70) in the USA, no relationship between infant's gender and breastfeeding was found.

Receiving professional support on breastfeeding is one of the most common variables that affect breastfeeding in this review. Receiving education on breastfeeding was determined to affect breastfeeding positively. In literature, there are studies supporting this result (10,14,15,73). Achieving a similar result with literature revealed necessity of providing professional support on breastfeeding to women. In addition, it was determined that having breastfeeding experience affected breastfeeding positively in the present review. In literature, there are studies supporting this result (10,68). This suggests that primiparous women and women without previous breastfeeding experience should be supported.

Early breastfeeding in postpartum is another variable that is prominent in publications examined in this review. Early breastfeeding in postpartum was found to affect breastfeeding positively. In study conducted in the USA, Perrine et al. (2012) (73) reported that initiating breastfeeding within the first hour had a positive effect on breastfeeding. The early initiation of breastfeeding is thought to be a factor that affects breastfeeding positively. Recommendations of the WHO and UNICEF are also in line with this.

In this review, it was determined that giving complementary feeding or formula affected breastfeeding adversely. There are studies in literature supporting this result (10,11,15,73,74). These results suggest that effective counseling should be provided in postpartum period and it should be ensured that mothers exclusively breastfeed and complementary feeding or formula is not given in hospital. Moreover, in publications examined in this review, use of a pacifier or feeding bottle is another variable that affects breastfeeding. The use of a pacifier or feeding bottle was found to affect breastfeeding adversely. Bottle-feeding is common in Turkey. According to the TDHS 2018 data, 53% of all 0-23-month-old children are fed with a feeding bottle (6). In literature, there are studies stating that use of a feeding bottle affects breastfeeding (9,73). Mothers should be informed about adverse effects of use of a feeding bottle on breastfeeding.

In publications examined in the current review, variables such as the concern of insufficient milk secretion, daily number of breastfeeding sessions, poor sucking reflex, breastfeeding frequency, suitability of breastfeeding conditions at work, experiencing breast problems, status of exclusive breastfeeding, status of taking colostrum, status of infant's staying in postpartum neonatal unit, receiving social support, father's breastfeeding support, and sharing same room with infant were reported as rare factors affecting breastfeeding. There is a need for more studies on positive or negative effects of all these variables on breastfeeding.

The most common reason for starting complementary feeding in this review was stated as insufficiency/cessation of breastfeeding/absence of breast milk. In literature, there are studies supporting this result (15,75). Mothers' concerns about whether their milk is sufficient or not should be eliminated, and they should be informed on this subject. Therefore, it is thought that rates of starting complementary feeding in the early period will decrease, if there is no need for it (except for indications). Moreover, non-sucking of infant was among reasons for starting complementary feeding in current review. It is striking that there are no data on this variable upon reviewing literature. This variable is based on statements of mothers. It is necessary to investigate whether this subjective evaluation made by mothers is related to objective data (appropriate position, etc.), to determine and solve problem. Thinking that child has grown up or the time to wean from breast has come is another variable among reasons for starting complementary feeding in this review. However, when reviewed studies are examined, age ranges of infants (min: 0 months, max: 24 months) differ. Therefore, no clear data on the month when complementary feeding was started could be obtained. Thinking that the time to wean from breast has come and starting complementary feeding are parallel to result of the prospective study by Susiloretni et al. (2019) (75) in which mothers and her infants were followed up for 26 months. In addition, in this review, diseases of mother and infant was indicated as reason for starting complementary feeding in two studies. In literature, there are studies supporting the fact that this variable is among reasons for starting complementary feeding (15,74). In this case, breastfeeding should be supported more by health care professionals in presence of medical reasons.

Experiencing a breastfeeding problem was stated as reason for starting complementary feeding only in one study in this review. In literature, there are studies supporting idea that this variable is among reasons for starting complementary feeding (14,15,74). It is thought that elimination and prevention of breastfeeding problems will positively affect breastfeeding of infant. Getting used to a feeding bottle was indicated as reason for starting complementary feeding in

only one study in this review. WHO does not recommend using a bottle to support breastfeeding (2,3).

Starting to work was indicated as reason for stopping breastfeeding in only one study in the current review. Present study is parallel to study by O'conner et al. (2018) (74) in terms of this variable. Mothers who breastfeed need necessary arrangements to maintain breastfeeding when they start to work. Low self-efficacy was among reasons for stopping breastfeeding in only one study in this review. Sun et al. (2017) (15) found in their study that women with lower self-efficacy quitted breastfeeding more frequently. We think that more studies are required on this subject and women's self-efficacy on breastfeeding should be increased.

In literature, desire for breastfeeding (15,74), confidence in breastfeeding and mother-friendly hospital practices, lack of mother's plan on exclusive breastfeeding (14), and low postpartum support (74) were found to be associated with weaning from breast. It was determined that all these variables were not indicated as reasons in studies examined in current review. There is a need for future studies to investigate these variables.

Limitations

This systematic review has some limitations. These are as follows:

The use of different and non-standard data collection forms in studies reviewed, experiencing difficulties with interpretation of data on breastfeeding (the time of breastfeeding initiation, the duration of breastfeeding, etc.),

- The inclusion of only publications the full text of which could be reached,
- Different sample sizes and the heterogeneous structure of age groups,
- The fact that most of study data are based on personal statements.

Still, the fact that most of the studies included the time of breastfeeding initiation, duration of breastfeeding, breastfeeding-related factors, and reasons for starting complementary feeding made a significant contribution in terms of creating an idea about the status of breastfeeding in Turkey.

5. CONCLUSION

This systematic review was reported using the PRISMA checklist (http://www.prisma-statement.org/) in order to systematically review studies conducted on breastfeeding in Turkey and to provide information on breastfeeding status. At the end of this reporting, it was determined that studies conducted on breastfeeding in our country had common goals, but there was no unity of language and definition. Studies were conducted with different time intervals, sample sizes, and age ranges. Despite these difficulties, results show important conclusions about national breastfeeding status.

The time to start breastfeeding can be stated as half an hour in 17 studies and 1 hour in 19 studies. In studies examined, mean duration of breastfeeding was minimum 3.45 months and maximum 17.7 months. And ratio of exclusive breastfeeding in the first 6 months was minimum 8.7% and maximum 67.1%. It was determined that ratio of initiating breastfeeding and mean duration of breastfeeding varied significantly in our country and breastfeeding was mostly influenced by educational level of mother. The most common reason for starting complementary feeding was found to be thought that breast milk was insufficient.

Ethical approval

Not applicable. As this paper presents findings of an integrative literature review of published articles ethical approval was not required.

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Conflicts of interest

The authors have no conflicts of interest to declare.

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Clinical and Experimental Health Sciences

Common Variable Immunodeficiency at Adult Age

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ABSTRACT

Common Variable Immunodeficiency (CVID) is a heterogeneous group of diseases progressing with recurrent infections. This disease should be considered in cases experiencing recurrent lung infection, otitis media, rhinosinusitis, and urinary tract infection. Since it is generally seen in the childhood age group, the diagnosis in adults may be delayed. A Common Variable Immunodeficiency case, which was followed up in our clinic and characterized by recurrent upper respiratory tract infection and pneumonia, was presented to raise awareness on this issue. CVID should be kept in mind in patients who are admitted to outpatient clinics with recurrent infections, who do not respond despite appropriate treatments, and who develop complications.

Keywords: Adult, Common Variable Immunodeficiency, Infection, Pneumonia

1. INTRODUCTION

Common Variable Immunodeficiency (CVID) is a heterogeneous group of diseases progressing with recurrent infections [1]. It usually gives clinical symptoms within the first 20 years. It is prevalent in 10 years of age in childhood and 30-40 years in adults. The gender distribution is equal. It is one of the most common immune deficiencies, and although genetic mutations have been identified, its formation mechanism is not fully known. Since patients are examined in different departments with different clinical presentations, diagnosis is often delayed. This disease should be considered in cases presenting with a recurrent lung infection, otitis media, rhinosinusitis, and urinary tract infection. The prevalence of the disease in our country is unknown. There is a lack of epidemiological data in this disease group due to the lack of awareness and knowledge of appropriate diagnostic methods.

In order to increase awareness on this issue, we present a late-diagnosed immunodeficiency case.

2. CASE

A 55-year-old male patient was admitted to the emergency department with cough, sputum, and fever complaints. Upon observation of consolidations, including air bronchogram and pleural effusion on computed lung tomography, the patient was hospitalized with a preliminary diagnosis of pneumonia (Figure 1). In his history, it was learned that he was under follow-up in another health facility for asthma, and he had been using inhaler treatment for five years and had no history of smoking. It was also learned that the patient had had otitis media several times in the last year with similar complaints and was hospitalized three times with a pneumonia diagnosis. When the previous radiological imagings were examined, displacement-like consolidations were observed. In order to identify the etiology, diagnostic thoracentesis and bronchoscopy procedures were performed. The procedure results ended up as consistent with benign cytology. The immunodeficiency pre-diagnosis was considered for the patient who had a history of frequent hospitalizations after eliminating the presence of malignancy. Serum immunoglobulins were low (IgG <108 mg/dL, IgA<5 mg/dL, IgM<5 mg/dL, anti-HIV: negative), other laboratory parameters were normal, the 23-serotype pneumococcal vaccine was administered, and there was no significant increase in pneumococcal antibody level after six weeks. The patient was diagnosed with common variable immunodeficiency (CVID), and intravenous immunoglobulin (IVIG) treatment was initiated. The patient is now under the follow-up of our Allergy and Immunology clinic.

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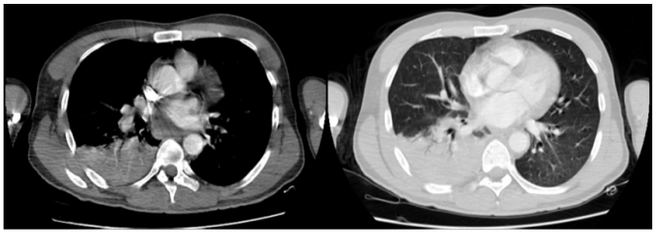

Figure 1. *Computed tomography image shows consolidations including air bronchogram in the sections of mediastinum and parenchyma.*

3. DISCUSSION

Common Variable Immune Deficiency (CVID) is characterized by a deficiency in immunoglobulin synthesis due to impaired B cell proliferation. CVID is the roof for a large group of diseases that includes a variety of genetic disorders. It is the most common primary immunodeficiency condition in adults. The highest CVID prevalence was 40.2% of all primary immunodeficiency (PID) patients in the United States, while the lowest rates were in the Middle East countries at 2.6% and Africa at only 1.3% [2]. However, it is known as the most common form of PID in the Caucasian population [3].

In various studies, the average age of onset of the disease is around 33 years in women and 28 in men [1, 4]. Considering these studies, our patient was diagnosed at a more advanced age. The oldest patient reported in the literature is a 73-year-old female patient who was described in the study of Ardeniz et al.

The disease has been named 'variable' because of emerging with different presentations. Susceptibility to infection is the most common clinical finding in these patients. Infections such as sinusitis, pharyngitis, otitis, and especially pneumonia caused by encapsulated bacteria such as streptococcus pneumonia, staphylococcus aureus, Haemophilus influenza are common. Although rare, severe infections such as giardia diarrhea, sepsis, empyema, osteomyelitis, meningitis, septic arthritis can be seen. Our patient also had common sinopulmonary infections. Due to this clinical range and the fact that clinicians are not aware of this disease, the average diagnosis time reaches 6-7 years. Our patient applied to the hospital and outpatient clinic many times with asthma and pneumonia diagnosis in the last one year.

The disease may be accompanied by a sarcoidosis-like reaction with diffuse granulomas in the lung, spleen, and lymph nodes or autoimmune diseases with a rate of 25% [5]. Autoimmune diseases such as hemolytic anemia, pernicious anemia, splenomegaly, primary biliary cirrhosis, uveitis, and psoriasis can also be seen frequently in the CVID clinic. Once again, the risk of malignancy, especially lymphomas, has increased in this disease, compared to the normal population [3]. Extranodal involvement is common, especially in non-Hodgkin lymphoma.

The most common lung complication of CVID is the increased risk of pneumonia. Bronchiectasis and interstitial lung disease are two major lung complications that occur after recurrent and severe lung infections [2]. Our patient had recurring pneumonia with a displacing characteristic. There was bronchiectasis development (Figure 2); however, there was no interstitial involvement.

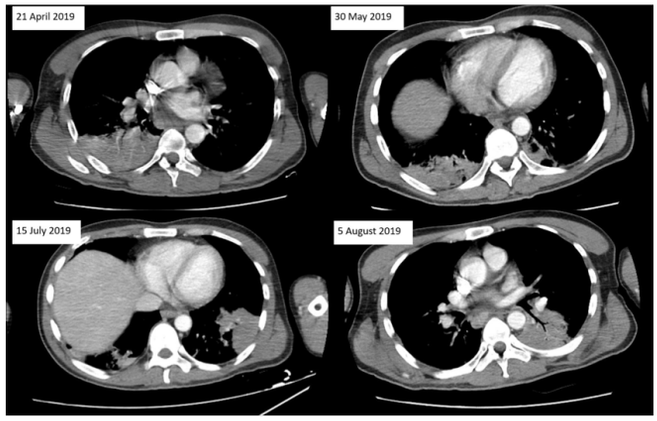

Figure 2. *Computed tomography sections taken at different dates Show pneumonia in different localizations.*

Diagnosis is made by demonstrating low serum immunoglobulin (Ig) A, G, M levels, and the absence or decrease of antibody production with laboratory tests. If the IgG level is below 150 mg/dl, there is no need for additional tests. However, if the IgG is at the level of 400-600 mg/dl or if there is only a slight decrease in Ig A levels, additional tests are required. The lack of reaction to vaccines in patients should also be alarming for CVID, as it would suggest a decreased antibody response. Other diseases that may cause low immunoglobulin should be considered. In our case, the IgG level was below 108, and there was no antibody response to the pneumococcal vaccine.

In the treatment of CVID, 400-600 mg/kg intravenous immunoglobulin (IVIG) is recommended once a month. Apart from this, appropriate management and treatment of infections and complications should be accomplished. In our case, IVIG was initiated after appropriate antibiotic treatment for lung infection.

4. CONCLUSION

CVID should be kept in mind in patients who are admitted to outpatient clinics with recurrent infections, who do not respond despite appropriate treatments, and who develop complications.

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