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The Seasonal Variations of Energy Expenditure and Physical Activity in Turkish Older Adults

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ABSTRACT

Objective: Regular physical activities contributes to better health outcomes in all stages of life. Older adults may have altered levels of exercise at different times of the year.

Methods: Community-dwelling older adults (≥ 65 years of age) in Ankara, is the capital city of Turkey were recruited prospectively. Physical activity status and the resting metabolic rate were assessed every three months (May, August, November, and February).

Results: Overall, 31 individuals were analyzed (mean age women: 73.9 ± 7.0 years, men: 75.5 ± 5.7 years; women: 65.0%). The level of physical activity was highest in autumn (44.0 ± 41.0 min) and summer (41.0 ± 48.0 min) but lowest in winter (24.0 ± 19.0 min) ($p < 0.05$). The ratio of performing regular daily exercise was highest in summer (25.8%), which decreased significantly in winter (9.7%). No statistically significant changes were noted in the total daily energy expenditure and resting metabolic energy expenditure across four seasons.

Conclusion: Although some increases were observed in autumn and summer, the level of physical activity in older adults was low in all seasons. However, daily energy expenditure remained constant. The study suggests that there is a need for improvement in lifestyle behaviors of Turkish older adults to increase health-related quality of life and also to prevent adverse outcomes.

Keywords: Older adults, Seasonal changes, Physical activity, Resting metabolic energy expenditure.

1. INTRODUCTION

People worldwide are living longer, and the world's population aged 60 years and older is increasing (1,2). According to the World Health Organization, between 2015 and 2050, the proportion of the world's population over 60 years will nearly double from 12% to 22% (2). Therefore, improvement of health and quality of life are critical, particularly for the aged individuals (1). Regular physical activity and exercise have been shown to improve not only the physical and mental health but also the quality of life in older adults (3).

Seasonal variations are among the critical environmental factors that have strong influences on duration and frequency of physical activities at certain times of year (4,5). Studies have shown that the level of physical activity is dependent on winds, rainfall, and altered humidity (6). In general, older adults are more physically active in summer and spring, but they slowdown in winter mainly because of extreme cold, slippery ground and shorter daytime (7). While evaluation of physical activity in older adults needs consideration of seasonal changes, lifestyle habits including eating and doing exercise in the old age may be dependent also on adulthood

behaviors, cultural infrastructure, and financial situation. Thus, information collected from a population may not be valid for another. The present study aimed to assess the level of daily exercise and energy expenditure in a group of Turkish older adults. First hypothesis of this study is; Physical activity level and energy expenditure of older adults can be affected by seasonal changes. Other hypothesis of this study is; Turkish older adults should be more active in spring and summer, but more inactive in winter.

2. METHODS

In this single-center, prospective, non-interventional study, we enrolled subjects aged 65 years or older living in the capital city Ankara, Turkey. Inclusion criteria were; having sufficient cognitive and functional skills to adapt the study procedures, residing in the same region at least for three years, and signing the informed consent. Exclusion criteria were being bedridden, having memory and speech disorders, cancer, traumatic disease, arthritis, arm injury, or neuromuscular disorders. All participants underwent cognitive testing by the mini mental state examination test (8).

The ethics committee of Gülhane Military Medical Academy, Turkey, approved the study protocol (13/1648.4-1242) and all participants gave written, informed consent.

The data were collected between May 15, 2013, and November 30, 2014, and planned four periods of observation; spring (May), summer (August), autumn (November) and winter (February) in this study. Basic characteristics were recorded using a questionnaire. At each season, the level of physical activity and energy expenditure were measured for three consecutive days, one of which was a weekend day. Participants were specifically informed about remaining on their routine and doing no additional physical exercise before or during the time of data collection.

The average frequency of regular exercise and physical activity (no less than 30 minutes per session) were recorded using a scale which included the following choices: none, once a week, twice a week, three times a week, and daily. Resting metabolic rate (RMR) is the total number of energy consumption when your body is completely at rest, was measured with a desktop metabolic monitor (*Fitmate Pro, Cosmed, Italy*) in the summer and winter (9). Physical activity status was determined using the armband (*Sensewear armband, BodyMedia Inc., ABD*) which is a validated, objective method to assess the physical activity (5,10). Duration of lying down (h), duration of physical activity (min), total energy expenditure (kcal/day), number of steps and average METs values through the three days were taken with the armband, and average values were calculated. METs values that show exercise intensity were classified as light (< 3.0 MET), moderate (3.0–5.9 MET) and vigorous (> 6.0 MET) (11).

Continuous variables were presented as the mean and standard deviation. Categorical data were presented as the absolute number and percentage of the total. Non-normal distribution was tested by the Shapiro-Wilk test. Seasonal changes in numerical values were calculated by the Friedman test and Wilcoxon Rank test. The differences in qualitative data on different seasons were tested by the Cochran’s Q test, and McNemar test. Statistical significance was accepted at p<0.05. All analyses were performed using SPSS (PASW) 23.0 software (SPSS Inc, Chicago, Illinois).

3. RESULTS

Forty-three individuals initially were enrolled but two of them died during the study, and another ten withdrew consent. Among the 31 subjects analyzed, 20 (65%) were women, and mean age was 73.9±7.0 years old for women and 75.5±5.7 years old for men.

According to the physical activity questionnaire, 48.4% of the participants had regular exercise in summer, 41.9% in autumn, and 35.5% in both spring and winter. All of the participants doing regular exercise preferred walking to other types of physical activity. The frequency of performing regular physical activity in winter, spring, summer, and autumn was 54.5%, 63.6%, 81.8% and 72.7%, respectively among men; and 25.0%, 20.0%, 30.0% and 25.0%, respectively among

women. We found no statistically significant difference in regular physical activity across seasons in both men and women. The percentages of did exercise twice a week, were found highest (22.6%) in whole group, also only 9.7% exercised in winter. Exercise frequency increased in summer and autumn (25.8% and 19.4%, respectively). In summer, the frequency of daily physical activity increased in women, but it was not statistically significant. In winter, 18.2% percent of men had daily physical activity, which increased to 54.6% in summer and to 45.5% in autumn. Seasonal changes in exercise frequency were more prominent among men by this was also not significant (p>0.05) (Table 1).

Table 1. Exercise frequency according to season in older adults

Exercise frequency	Winter		Spring		Summer		Autumn	
Men (n=11)	n (%)		n (%)		n (%)		n (%)	
Daily	2	18.2	3	27.3	6	54.6	5	45.5
1/w	-	-	-	-	-	-	-	-
2/w	3	27.3	2	18.2	1	9.0	1	9.0
3/w	1	9.0	2	18.2	2	18.2	2	18.2
None	5	45.5	4	36.3	2	18.2	3	27.3
Women (n=20)								
Daily	1	5.0	1	5.0	2	10.0	1	5.0
1/w	-	-	-	-	-	-	1	5.0
2/w	4	20.0	2	10.0	2	10.0	2	10.0
3/w	-	-	1	5.0	2	10.0	1	5.0
None	15	75.0	16	80.0	14	70.0	15	75.0
Total (n=31)								
Daily	3	9.7	4	12.9	8	25.8	6	19.4
1/w	-	-	-	-	-	-	1	3.2
2/w	7	22.6	4	12.9	3	9.7	3	9.7
3/w	1	3.2	3	9.7	4	12.9	3	9.7
None	20	64.5	20	64.5	16	51.6	18	58.1

Mean duration of exercise across seasons is presented in Table 2. Men had more than 25 min longer daily exercise in summer than spring. Among women, the duration of exercise decreased in winter (28.0±4.5 min/day) and increased in summer (42.5±24.0 min/day). The duration of exercise increased in summer in both men and women. The duration of daily exercise in the total sample was 42.7±20.4 min in winter and 43.6±14.2 min in spring, which increased to 60.0±40.1 min in summer and decreased to 46.2±17.8 min in autumn. None of these comparisons were significant statistically (p>0.05) (Table 2).

Table 2. Seasonal exercise duration of older adults have a regular exercise period (min)

Exercise duration	Winter	Spring	Summer	Autumn	p
	Mean±SD	Mean±SD	Mean ±SD	Mean ±SD	
Men (n=11)	55.0±20.5	47.1±13.5	71.7±45.5	50.6±19.5	0.392
Women (n=20)	28.0±4.5	37.5±15.0	42.5±24.0	39.0±13.4	0.392
Total (n=31)	42.7±20.4	43.6±14.2	60.0±40.1	46.2±17.8	0.330

*Wilcoxon Signed Ranks Test was used.

Total daily energy expenditure and the duration of physical activity are presented in Table 3. According to the armband data, the duration of physical activity was higher in summer and autumn compared to other seasons, and it was significantly lower in winter ($p < 0.05$). Mean daily step count in summer (4851 ± 3708) was significantly higher than in winter (3685 ± 2534) ($p < 0.05$). Changes in the duration of seasonal physical activity and steps count were statistically significant by gender ($p > 0.05$). Total daily energy expenditure showed

alterations depending on the variations in the duration of physical activity. Mean daily energy expenditure was higher in summer (2228 ± 380 kcal/day) and autumn (2187 ± 351 kcal/day), respectively, and lowest in winter (2120 ± 361 kcal/day). However, changes in daily energy expenditure were not statistically significant ($p > 0.05$). Seasonal changes in the duration of resting and METs values were not significant in both genders ($p > 0.05$). There were also no significant differences in RMR (kcal/day) across seasons ($p > 0.05$) (Table 3).

Table 3. Energy expenditure, physical activity status and duration of exercise in older adults according to season from armband database

Energy expenditure and physical activity	Winter	Spring	Summer	Autumn	p
	Mean±SD	Mean±SD	Mean±SD	Mean±SD	
Men (n=11)					
Lying down duration (h)	7.7±2.3	8.0±1.3	8.1±1.8	8.1±2.2	0.938
Physical activity duration (min)	32.0±23.0	48.0±53.0	61.0±68.0	68.0±57.0	0.138
Total Energy Expenditure (kcal/day)	2224±350	2228±336	2358±391	2380±469	0.301
Step Count	3816±2303	4406±3751	6013±5293	5144±3888	0.200
Average METs	1.1±0.1	1.2±0.2	1.2±0.3	1.2±0.2	0.464
Women (n=20)	Winter	Spring	Summer	Autumn	p
Lying down duration (h)	8.3±1.6	8.1±2.3	8.0±1.5	7.8±1.7	0.423
Physical activity duration (min)	19.0±16.0	34.0±50.0	31.0±28.0	30.0±21.0	0.117
Total Energy Expenditure (kcal/day)	2062±363	2153±410	2094±296	2145±303	0.884
Step Count	3613±2708	3364±1630	4212±2399	3975±2029	0.068
Average METs	1.1±0.2	1.3±0.6	1.1±0.2	1.2±0.2	0.125
Total (n=31)	Winter	Spring	Summer	Autumn	p
Lying down duration (h)	8.1±1.8	8.1±2.0	8.0±1.6	7.9±1.8	0.433
Physical activity duration (min)	24.0±19.0 ^a	39.0±51.0 ^a	41.0±48.0 ^b	44.0±41.0 ^{a,b}	0.011*
Total Energy Expenditure (kcal/day)	2120±361	2179±381	2187±351	2228±380	0.459
Step Count	3685±2534 ^a	3734±2575 ^a	4851±3708 ^b	4390±2823 ^b	0.008*
Average METs	1.1±0.2	1.3±0.5	1.2±0.2	1.2±0.2	0.095

a,b,c Values within row with different superscripts are significantly different, ($p < 0.05$) Wilcoxon Signed Ranks Test.

4. DISCUSSION

Physical inactivity is the fourth most important cause of mortality in the world and is assumed to be responsible for the death of 3.2 million people annually. Regular mild physical activity (walking, cycling, etc.) has favorable influences on the health status of older adults (3,12). It is well-known that older people who are physically active have lower morbidity and mortality rates than inactive older people. Nevertheless, regular physical activity decreases progressively with age (13). The negative consequences of physical inactivity and sedentary behavior, such as prolonged sitting, among older people are also well established. Inactive lifestyle has been associated with mortality, decreased quality of life, and increased risk of chronic diseases such as cardiovascular disease, type 2 diabetes, obesity, cancer and depression (14-17).

In this study, seasonal variations in the level of physical activity and energy expenditure were examined. Although

less is known in older adults, studies in adult populations have shown that climate or seasonal changes have profound effects on the basal metabolic rate, such that individuals living in mild climates have lower BMR (basal metabolic rate) than those who live in cold climates to maintain body size and composition (18-20). In an adult group, a 7°C decrease in ambient temperature caused a reduction in body temperature, development of tremors and an increase in RMR by 11.5% (21). A marked decline in temperature and subsequent cold exposure increases the energy required to restore tissue temperature. In older adults, a relatively larger body fat percentage protects the individual against the adverse effects of cold (22, 23). The study on indigenous and nonindigenous circumpolar groups of North America and Siberia has shown that the ecology and genetics of thyroid function may regulate metabolic rates (24). In this study, RMR energy expenditure changes were not significant statistically across seasons in both men and women. This finding was

different from the literature because older adults did not generally leave the house in winter to protect themselves from the cold/rainy weather, slippery ground, or in summer to avoid the sun and hot weather. Accordingly, Umemiya et al. reported that the use of air-conditioners might have favorable influences on RMR (25). Also, Kashiwazaki has shown that RMR may not be affected by the seasons when the body core temperature is preserved (26). On the other hand, body size, age, and gender have a significant effect on RMR. (27). Older adults we studied were unlikely affected by seasonal temperature changes, and therefore their RMR's remained unaltered during the year.

Seasonal changes are one of the most critical environmental factors that affect the frequency and duration of physical activity (4,6). In the spring or summer, older adults increase their house/garden activities, but they have reduced the level of physical activity in the wintertime. Previously, the level of physical activity of retired older persons was found more likely to be affected by the seasonal changes (7). In this study, 35.5% of the older adults exercised in the winter and spring and 48.4% exercised in summer and 41.9% exercised in autumn. Also, exercise preferences of all older adults were walking, probably because they found it more comfortable, safe and economical. Although performing regular exercise increased in summer and spring, the changes were not statistically significant. The ratio of older adults who had regular daily exercise was 27.3% in winter and 53.3% in summer (Table 1). Although these changes were not statistically significant, the numbers indicate the need for suitable places for older adults to do indoor exercise activities in cold periods of the year.

Step count was measured by motion sensors such as pedometers and accelerometers which are objective and reliable ways to assess the physical activity level even in older adults (28). In a Canadian study, the number of steps per day increased from 4901±2464 in winter to 5659±2611 in summer (15%) (29). In another study, physical activity status of women between 51 and 86 years of age was determined with pedometers, and the mean walking distance was 17.5±13.2 km in summer and 13.7±8.7 km in winter (30). In this study, the number of steps taken by the older people was not similar in all seasons and increased in summer and decreased in winter significantly. Our findings are in line with the result of other studies which reported that the frequency of physical activity decreased in cold and wet months and increased in hot and sunny periods such as summer and spring. METs values of older adults were lower than 3 in all seasons, indicating an overall mild intensity physical activity level throughout the year. When seasonal differences were evaluated, older adults' physical activity status were not adequate in all seasons even though the level of physical activity increased in summer. Moreover, seasonal changes on METs values were not statistically significant, probably because the participants limited their outdoor activities even under the best environmental conditions to prevent falls and related injuries at all seasons.

The present study allows compression of the duration of physical activity obtained by the armband and questionnaire. According to self-reports, the mean duration of exercise increased in summer (Table 2). However, according to armband readings, the duration of physical activity markedly declined in winter (Table 3). Overall, self-reported duration of physical activity was different from the armband data except for autumn. This finding supports the use of objective methods to assess the correct level of physical activity in older individuals.

In conclusion, it was found that seasonal variations affect to the frequency and duration of physical activity in a sample of older adults. However, RMR remained similar across four seasons in the same population. The results suggest that older adults need to be encouraged to increase the time of being physically active in cold and wet weather conditions like winter and autumn. Also, as a public health recommendation, it is essential to include some modifications in the environment of older adults during the winter, such as preference appropriate clothing or maintaining well-ventilated indoor activities to maintain physical activity.

Most important limitation of this study is absence of ambience temperatures (home temperature etc.) measurement that older adults exposed to more than outside temperature.

Conflict of interest

The authors do not have any conflict of interest to disclose.

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The Association between Quality of Perioperative Nursing Care and Comfort among Neurosurgery Patients

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ABSTRACT

Objective: This study was carried out in an effort to find out how surgical hospital patients perceived the quality of perioperative care they received at an operating department and to determine its association with comfort level.

Methods: This cross-sectional study was conducted between March and July 2016 at the neurosurgery clinic of a Training and Research Hospital. A random sample of patients (n =175) who were conscious and oriented, did not stay in the intensive care unit following the surgery, had been hospitalized for at least one night and were on their first postoperative day were included.

Results: A significant positive and weak correlation was found between the quality of perioperative nursing care and perianesthesia comfort levels ($r=0.264$, $p<0.01$).

Conclusion: These study findings showed that perianesthesia comfort was affected by the quality of perioperative nursing care.

Keywords: Comfort, quality, neurosurgery patients, perioperative care.

1. INTRODUCTION

The concept of quality in healthcare is complex and multidimensional, therefore, difficult to define and assess. Healthcare quality measures have traditionally focused on structure and outcome indicators, such as morbidity, mortality and hospitalization, as well as aspects defined entirely through professional healthcare perspectives (1). When healthcare professionals define quality, there tends to be less focus is on what service users feel is important and patients' views are not explicitly considered (2). Since patients tend to assess healthcare quality according to responsiveness to their specific needs, healthcare professionals tend to define quality in terms of the attributes and results of care, the perspectives of each party are valuable and both perspectives must be considered when assessing healthcare (3).

Despite increasing awareness of the patient perspective in quality of care, patients' experiences are currently not routinely measured in neurosurgery patients or in perioperative settings. The large numbers of operations performed daily makes the care provided at operating departments an important aspect of modern healthcare. To improve quality of care, the factors that adversely affect satisfaction and experience must be identified (4). Patients

are generally very satisfied with their surgical nursing care (5,6), but not all quality standards are always met. In physical care, quality consists of staff competence, efficient pain management and success in the surgical operation (7). In this regard, there have been reports of some problems with pain management, postoperative nausea and vomiting, particularly within operating departments (5,7).

Holistic comfort is also a desirable outcome of nursing care in the perianesthesia setting. Moreover, it is an umbrella term under which the discomforts that patients experience as a result of surgery or procedures can be placed. These discomforts are many and include pain, nausea, anxiety, and hypothermia (8). Kolcaba has defined comfort as "the immediate state of being strengthened through having the human needs for relief, ease, and transcendence met in 4 contexts of experience including physical, psychospiritual, sociocultural, and environmental" (9-12). The terms "relief", "ease", and "transcendence" are derived from the above dictionary definitions plus a review of the professional literatures in medicine, theology, ergonomics, psychology, and nursing (9,10). "Relief" is the state of having a severe discomfort mitigated or alleviated (e.g, a patient with nausea

obtains relief from ondansetron). “Ease” is the absence of specific discomforts. To experience ease a patient does not have to have a previous discomfort, although the nurse may be aware of predispositions to specific discomforts (e.g, the tendency for shortness of breath in a patient with chronic obstructive pulmonary disease). “Transcendence” is the ability to “rise above” discomforts when they cannot be eradicated or avoided (e.g, the patient feels motivated to ambulate although (s)he knows it will exacerbate pain) (8,9).

Briefly, comfort is an important criterion for initial, ongoing, and discharge assessment and management of the perianesthesia patient. Perianesthesia nurses are patient advocates who provide care to every age group and are committed to the safety and comfort of perianesthesia patients (13).

The specific aims of this study were to determine:

1. How do neurosurgery patients perceive the quality of perioperative care they received at an operating department?
2. Is there any relationship between the quality of perioperative care and perianesthesia comfort level?

2. METHODS

2.1. Design and Sample

A descriptive cross-sectional correlational design was used to identify the quality of perioperative care patients received at an operating department and to examine its relationship with perianesthesia comfort level. This study was conducted between March and July 2016 in the neurosurgery clinic of a Training and Research Hospital in the northeast region of Turkey. The inclusion criteria consisted a random sample of patients who were conscious and oriented, did not stay in the intensive care unit following the surgery, had been hospitalized for at least one night and were on their first postoperative day. The sample was restricted to adult patients who were capable of completing the questionnaire without help and returned to their own wards after their recovery period at the department. Patients requiring intensive care after surgery, as well as those who were unconscious, confused or very tired were excluded from the study. The G POWER 3.1 (Heinrich-Heine University of Dusseldorf, Germany) computer program was used to calculate the sample size. A sample size of 175 was calculated based on adding a 10% attrition rate for a power of 0.80, at significance level of 0.05.

2.2. Instruments

The data for the study were collected using the Good Perioperative Nursing Care Scale (GPNCS) and Perianesthesia Comfort Questionnaire (PCQ). The GPNCS, which was developed by Leinonen and Leino-Kilpi (6) and whose validity and reliability in a Turkish setting was tested by Dönmez and Özbayır (14), was used to measure the quality of perioperative nursing care. The GPNCS is a 34-item tool

for measuring the quality of perioperative nursing care. The scale has six subscales: physical care, giving information, support, respect, personnel characteristics, environment and nursing process. The instrument is a Likert type scale (0–5). The responses are given as five points for ‘I completely agree’ to one point for ‘I completely disagree’. A score of 0 was given for ‘I can’t evaluate this aspect’ and a score of 3 was marked for ‘I neither agree nor disagree, not different, I don’t have any idea’ (it does not matter). As a result of expert opinion and construct-language validity, study items that were similar to each other were removed, and the scale was revised to 32 items to prevent repetition (6,14).

PCQ is developed by Kolcaba (13). The validity and reliability of the questionnaire to test its use on the Turkish population was conducted by Ustundag and Eti Aslan and the Cronbach’s alpha value was found to be 0.83 (15). The questionnaire includes 24 items questioning the self-understanding and feelings of a patient that reflect the general thoughts about pre – and post-operative periods. The questionnaire is scored using a 6-point Likert scale (1= strongly disagree to 6= strongly agree). The total possible score that can be obtained from the scale is a minimum of 24 and a maximum of 144. The total score obtained is divided by the number of scale statements, the mean score is then calculated, and the result is expressed in the range of 1-6. A low score indicates a poor level of comfort and a high score indicates a good level comfort (15).

2.3. Data Collection

After obtaining the necessary permissions, data collection tools were completed by patients. Patients were briefly informed by the researchers about the purpose and methods of the study. Patients completed the forms within approximately 20 to 25 minutes.

2.4. Ethical Considerations

The study was approved by the Ethics Committee (Approval Date: 29.02.2016, Approval Number: 49715540/050.01.04) and conducted according to the ethics guidelines established in the Declaration of Helsinki. Written consent was obtained from patients who agreed to enroll in the study. All participants were informed about the purpose and design of the study.

2.5. Statistical Analysis

Statistical analysis was performed using SPSS Statistics software for Microsoft Windows XP (Version 21.0, SPSS Inc., Chicago, IL). Demographic and clinical characteristics of participants were described using frequency distributions for categorical variables and means/standard deviations (median, min-max) for continuous variables. To make a comparison of the means of the variables, the Pearson Correlation test was used. A p-value below 0.05 was considered to indicate a statistically significant difference.

3. RESULTS

A total of 183 potential participants were assessed; 175 were deemed eligible, consented to participate, and completed the survey. Eight patients were not eligible because they were very tired and experiencing intense pain. Table 1 shows the participants' demographic characteristics. The patients' mean age was 55 years with a standard deviation 11.4 years; 70.9% were female. Of the participants, 78.3% were married, 48.6% graduated from primary school, 69.7% were housewives. General anesthesia was the most common type of sedation (90.9%); surgery was primarily performed in the afternoon (40%). An elective neurosurgery was performed in the study (93.9%).

Table 1. Demographic Characteristics of Patients (n=175)

Age (Mean±SD)	55.24±11.47 (range: 24-79)	
	n	%
Gender		
Female	124	70.9
Male	51	29.1
Marital status		
Single	38	21.7
Married	137	78.3
Level of education		
Literate	69	39.5
Primary school	85	48.6
Secondary school	15	8.6
High school	4	2.3
University	2	1.1
Profession		
Housewife	122	69.7
Self-employed	13	7.4
Worker	5	2.9
Retired	22	12.6
Farmer	13	7.4
Type of surgery		
Elective	164	93.9
Urgent	11	6.3
Premedication		
Yes	70	40.0
No	104	60.0
Type of anesthesia		
General anesthesia	159	90.9
Local anesthesia	16	9.1
Arrival at operating department		
Morning	60	34.3
Midday	30	17.1
Afternoon	70	40.0
Evening	15	8.6

SD: standard deviation

The mean score of the GPNCS was 113.08±21.45, and their mean sub-scale scores were 38.6±7.1 for physical care, 15.6±5.6 for giving information, 10.3±4.2 for support, 11.3±2.9 for respect, 14.6±4.5 for personnel characteristics, 15.3±4.2 for environment, and 7.1±2.0 for nursing process. The participants' total PCQ mean score was 4.27±0.58 (Table 2). Items from each questionnaire with the highest mean are listed in Table 3.

Table 2. Mean Scores for GPNCS and PCQ Sub-scales

	Mean±SD	Minimum	Maximum
Physical care	38.6±7.1	4	50
Giving information	15.6±5.6	1	25
Support	10.3±4.2	0	19
Respect	11.3±2.9	0	15
Personnel characteristics	14.6±4.5	0	20
Environment	15.3±4.2	0	20
Nursing process	7.1±2.0	1	10
Total GPNCS	113.0±21.4	25	152
Total PCQ	4.2±0.5	2	5

GPNCS: Good Perioperative Nursing Care Scale; PCQ: Perianesthesia Comfort Questionnaire; SD: standard deviation

Table 3. Items with the Highest Mean per Questionnaire

Item	Mean±SD
Good Perioperative Nursing Care Scale	
I think my operation/treatment was well performed	4.27±0.86
I think my anesthesia (general or regional anesthesia) was well performed	4.21±0.98
Staff in the operating department were professional	4.18±1.07
Perianesthesia Comfort Questionnaire	
My family/friends helped me to cope	5.48±1.09
My sense of self-respect was not preserved	5.29±1.19
The noises were disturbing	5.10±1.31

SD: standard deviation

A significant positive and weak correlation was found between the GPNCS scores and PCQ scores ($r=0.264$, $p<0.01$) (Table 4). It was found that perianesthesia comfort levels of participants increased if the scores of the quality of perioperative nursing care were higher in the study. Statistical analysis showed that there was a significant correlation between the scores of GPNCS sub-scales including physical care, giving information, respect, personnel characteristics, environment, nursing process and PCQ scores ($p<0.05$), while no significant correlation was found between sub-scale "support" score and PCQ scores ($p>0.05$) (Table 4).

Table 4. Correlation between the GPNCS and the PCQ Scores of Patients

GPNCS	PCQ	
	r	p
Physical care	0.235**	0.002
Giving information	0.156*	0.039
Support	0.105	0.168
Respect	0.173*	0.022
Personnel characteristics	0.162*	0.032
Environment	0.245**	0.001
Nursing process	0.183*	0.015
Total GPNCS	0.264**	0.000

GPNCS: Good Perioperative Nursing Care Scale; PCQ: Perianesthesia Comfort Questionnaire; *Correlation is significant at the 0.05 level (2-tailed); **Correlation is significant at the 0.01 level (2-tailed)

4. DISCUSSION

The aim of this study was to explore the quality of perioperative care patients received at an operating department and to examine its relationship with perianesthesia comfort level. Having to undergo surgery can be a major life event (16). During this period, patients reported both satisfaction and dissatisfaction with their quality of care (7,17). Patients are in a vulnerable situation and dependent on hospital staff during the perioperative period (18). Surgical patients may also have difficulty expressing their care needs (19). Therefore, it is important that surgical patients be given the opportunity to evaluate the care they receive and to express their own needs to further develop the quality of perioperative care.

This study showed that the overall patient perception regarding quality of perioperative nursing care was moderately good, with a score of 113.0 ± 21.4 . The study finding was consistent with those of the previous studies examining patients' perceptions regarding quality of care (20-22). In a study by Hertel-Joergensen et al. quality of perioperative nursing care scores of orthopedic patients were found to be 146.6 ± 14.0 (23). At another study, Dönmez et al. reported that quality of perioperative nursing care scores of surgical patients were 128.2 ± 1.2 (14). The scores of neurosurgery patients in the current study were lower than those of the surgical patients' reported by the aforementioned researchers. Patients' perceptions are needed to achieve unique insights into what works and what does not work in healthcare, so researchers that identify patients' perspectives on quality of healthcare are needed (23).

Neurosurgery patients reported higher scores for the items "I think my operation/treatment was well performed", "I think my anesthesia (general or regional anesthesia) was well performed", and "Staff in the operating department were professional" in the perioperative nursing care scale. These items were under the factor, 'Physical Care' which included 10 items. This finding was consistent with an earlier study by Forsberg et al., where the authors reported that the majority of patients rated it as important that their surgery (95.1%) and anesthesia (96.9%) were performed in the best way, and 97.0% were satisfied with the surgery and anesthesia procedures (16). Similarly, Leinonen et al. indicated that patients had high ratings for setting up the surgical position, performing the anesthesia and operation, and staff skills in the recovery room in the area of physical activities (17). It was particularly encouraging to see that physical care received the highest score; after all, that plays a key role in the work of all operating departments.

Patients also scored higher on "My family/friends helped me to cope", "My sense of self-respect was not preserved", and "The noises were disturbing" in the comfort questionnaire. Factors in the environment that detract from patients' comfort are cold, noise, chaos, endless bright lights, bad odors, lack of privacy, and uncomfortable stretchers, chairs, and beds (8). When nurses are unable to provide a peaceful, health-producing environment, they may be able to help patients transcend less than ideal settings. However, nurses

should make conscious efforts to decrease noise, lights, and interrupted sleep to facilitate a peaceful environment (13).

Comfort is a positive outcome that has been linked to successful engagement in health seeking behaviors and is an important indicator to measure for perianesthesia nursing care and research (8,24). Findings of this study revealed that there was a direct and significant relationship between comfort and quality of perioperative nursing care in the perioperative period. Patients who reported more comfort also had more quality of perioperative nursing care. In other words, this study showed that there was a reciprocal relationship between comfort and quality of perioperative nursing care, which was consistent with the Comfort Theory (25). However, there has been no research examining its relationship with quality of perioperative nursing care among surgical patients. Nurses should implement a variety of interventions to meet comfort needs, and assess patients' comfort levels and quality of perioperative nursing care during perioperative period. The holistic, interrelated, and individualized nature of comfort needs is better understood when nurses mentally place their patients' needs within the cells on the grid. This approach makes it easier for nurses to identify and implement comfort interventions targeted to meet perioperative needs (8, 13).

Limitations

Although this study is the first research comparing the quality of perioperative nursing care and perianesthesia comfort level of neurosurgery patients, our findings have several limitations. This study is limited by its single-center design and the exclusive use of neurosurgery patients, which may weaken the strength of generalizations. Despite the inclusion of patients of differing ages, gender, material status, and conditions (acute or chronic) who received both elective and acute surgery, our findings may not apply to other groups, such as cardiovascular or other surgical patients. Using self-administration and leaving patients alone while answering the questionnaire may have increased their willingness to disclose sensitive information and reduced social desirability bias (25).

5. CONCLUSION

This study concluded that perianesthesia comfort was affected by the quality of perioperative nursing care. After surgery and anesthesia, nurses are the patients' first links with normalcy. Nurses are coaches in perianesthesia settings, assuring patients that they can recover, are safe, are protected from harm, and are capable to create and participate in their treatment plan (13). Perianesthesia nurses may address the patient's fears regarding the procedure and the anesthesia with information/education, compassion, and reassurance. Nurses may also facilitate a productive educational environment for recovery and rehabilitation. Future studies may be conducted to explore and compare patients' and

their nurses' perceptions of the quality of perioperative care and to identify possible differences in these perceptions.

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Lean Approach to Processes Regarding Nursing Activities at Hospital: Evaluation of Nurses' Views

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ABSTRACT

Objective: The study was planned to evaluate views of the nurses about lean approach to processes related to nursing activities.

Methods: The descriptive study was conducted with 178 (71.2%) nurses selected from a total of 250 nurses working at six public hospitals in Artvin Province. The data were collected with a survey consisting of questions regarding the nurses demographic features and their views about lean approach to nursing activities at hospitals and then analyzed with percentages and chi-square tests.

Results: In the study, 46.1% of nurses stated that the unit where they worked needed lean approach partly. The nurses with graduate degree supported this view more ($p=0.034$). These nurses stated that the activities to receive belongings of patients during patient admission (21.3%), to fill in patient discharge form during discharging process (16.4%), to perform the hygienic and other care applications of the patients and to record them on the nurse observation form of daily nursing activities (11.1%) were unnecessary. In addition, they explained that activities to shave patients before operation (9.4%) and to enter physicians' orders by nurses into the system in laboratory process (13.5 %) and to in monitoring process (20.8%); to send all patient files to the pharmacy with the personnel for drug/device supply in pharmacy process (14.3%), were unnecessary.

Conclusion: The unnecessary nursing activities were defined in the nursing processes regarding patient admission and discharge processes, daily nursing workflow, operating room processes and laboratory, monitoring, blood centre, pharmacy processes. It is recommended that these processes identified may provide lean approach by eliminating them.

Keywords: Nursing, hospital, lean management, lean approach.

1. INTRODUCTION

Today, health institutions need to regulate their organizational structures and management methods in order to continue their activities in national and international arena and survive in an increasingly competitive environment (1,2). One of these regulations is lean management, which is one of the current and contemporary management approaches that are used in institutions (3-5).

Lean management includes the elimination of waste and the delivery of the product/service to the customer in the fastest way with minimum downtime by focusing on the concept of value in the production process of products or services (5-7). In other words, to be lean is to be purify from everything that is not really needed. Moreover, it means getting more with less human effort, less equipment, less time and less space (2,8).

By reducing costs and increasing the capacities, the lean approach/management enables developing and facilitating the activities in health institutions. It encourages and empowers employees to develop themselves avocationally (9,10). It shortens business processes, improves patient flow, increases patient safety and satisfaction (2,8,11). It also eliminates waiting times, repetitive activities, errors and unnecessary activities (12-15). The Institute for Health Improvement (IHI) has also reported that the lean approach has led to 45%-75% increase in productivity, 25%-55% decrease in costs, 50%-90% decrease in faults, 60%-90% decrease in stock and 50%-90% decrease in waiting times (16). In a study carried out in a Canadian hospital, it was found that the lean approach led to a 20% increase in hospital efficiency (17).

Lean management is also an important approach in terms of nursing services which are an integral part of health services.

Because the activities containing nursing services include complex procedures, repetitive processes and procedures, long work periods. However, as nurses are inexperienced in lean approaches, they cannot focus on patient care which is their main duty (11). In this direction, in some studies conducted with the nursing group on lean management, it was determined that the activities in nursing services needed lean applications (12,18,19) and 50% of all American hospitals carried out some kind of continuous improvement activities involving lean techniques (18). In addition to this, in a study conducted by the American Society of Quality in 77 hospitals, it was found that 53% of the employees used a form of lean, 42% of them used one of the lean tools and 4% of them used purely lean approach (20). While there is a limited number of studies on lean management in nursing services in the international arena, could not found any study carried out in Turkey. There are only two studies carried out by the Ministry of Health on lean management in two pilot hospitals in Bolu and Kahramanmaraş provinces in Turkey. However, these studies are general hospital management rather than nursing services. Therefore, raising awareness about the effects of the lean management system on nursing services and evaluating the processes to be leaned based on the views of nurses will contribute to the effectiveness and increase the efficiency of a large part of health services (11). In this direction, the study was carried out to evaluate the views of nurses about the lean of the processes related to nursing activities in wards and units.

2. METHODS

2.1. Participants and Samples

The population of this descriptive study consists of 250 nurses working in six public hospitals in a province of Blacksea Region of Turkey. In this research, the whole population was tried to be reached by not selecting a sample. The study was conducted with 178 (71.2%) volunteers who participated in the study and who were not on leave during the study period. The limitation of this study is that it is conducted only with the opinions of nurses working in six public hospitals of Artvin province.

2.2. Research Instruments and Procedures

Data were collected by "Information Form" and "Nursing Services Business Process Survey". Ethical permission for the study was obtained from the Faculty of Medicine Scientific Research Ethics Committee, Karadeniz Technical University (No: 2016-191, Date: 23.01.2017).

2.3. Information Form

It consists of nine questions; seven questions related to the age, gender, marital and educational status of the nurses, position, working year in the hospital and ward-unit, also two questions including information about the concept of lean hospital and the need for lean approach of the ward/unit.

2.4. Questionnaire of Nursing Services Business Processes

It was prepared by the researchers in line with the Quality Standards in Health-Hospital in order to define unnecessary activities by defining nursing business processes (21). In addition, one day nursing functions were observed by the researcher working in the hospital where the study was conducted in six different wards selected from special units such as internal medicine, surgery, emergency and intensive care, operating room for the identification of business processes, and arranged in the light of group meetings with hospital managers. The questionnaire was prepared by creating a standard work schedule within the scope of standardized work including the patient admission and discharge, daily nursing workflow, operating room processes, laboratory, monitoring centre, blood centre, pharmacy nursing activities. (Table 3). Activities related to the processes were evaluated by the nurses under the options of 'being done, not being done' and 'necessary, unnecessary, rarely necessary'.

2.5. Data Collection Method

The relevant forms were distributed to the participants and they were given one week to complete the forms. One week later, the forms were collected by the researcher.

2.6. Statistical Analysis

The data on the demographic characteristics of nurses, their activities in nursing services, whether nurses were performing in their clinics or if they found it necessary, were analyzed with percentage and average tests. In addition, chi-square test was used to compare the demographic characteristics of nurses, their knowledge status and views on lean approach.

3. RESULTS

42.7% of the nurses are 31-40 years old, 92.7% are women, 79.8% are married and 46.1% have bachelor's degree and master degree education. 64% of the nurses did not have knowledge of the lean hospital approach and 46.1% stated that the unit they work in need of partial lean approach (Table 1).

Nurses with bachelor's/master degree education supported the need for leanness of the unit in which they work more than the nurses with a vocational high school and associate degree ($\chi^2=10.426$; $p=0.034<0.05$) (Table 2).

Table 1. Distribution of demographic characteristics of nurses and their views on lean hospital concept and knowledge status (n=178)

Distribution of Demographic Characteristics of Nurses		n	%
Age	20-30 age	59	33.1
	31-40 age	76	42.7
	40 years and older	43	24.2
Gender	Woman	165	92.7
	Man	13	7.3
Marital Status	Married	142	79.8
	Single	36	20.2
Educational Background	Health Vocational High School	33	18.5
	Associate Degree	63	35.4
	Bachelor\Master Degree	82	46.1
Position	Nurse	166	93.3
	Executive Nurse	12	6.7
Working Year in Hospital	1-5 year	91	51.1
	6-10 year	35	19.7
	11-15 year	14	7.9
	16-20 year	23	12.9
	20 years later	15	8.4
Working Year in Ward/Unit	1-5 year	120	67.0
	6-10 year	33	18.0
	10 years later	25	14.0
	Total	178	100.0
Opinions and Information Status of Nurses		n	%
Knowledge of Lean Hospital Concept	Yes	64	36.0
	No	114	64.0
Lean approach need of the ward/unit	Yes	53	29.8
	No	43	24.2
	Partly	82	46.1
	Total	178	100.0

Table 2. Comparison of opinions and knowledge status of lean hospital concepts according to education of nurses

Demographic Characteristic	Having knowledge about the concept of lean hospital				The situation of the unit in need of lean approach					
	Yes		No		Yes		No		Partly	
Educational Background										
Health Vocational High School	10	30.3	23	69.7	9	27.3	13	39.4	11	33.3
Associate Degree	18	28.6	45	71.4	20	31.7	18	28.6	25	39.7
Bachelor\Master Degree	36	43.9	46	56.1	24	29.3	12	14.6	46	56.1
χ^2 and p value	$\chi^2 = 4.198$ p=0.123				$\chi^2 = 10.426$ p=0.034					

When the nursing activities in the work flow process are evaluated, 74.6-99.4% of the nurses stated that the 31-item admission and discharge activities were performed in wards/units and 49.4%-98.6% found these activities necessary. 21.3% of the nurses mentioned it is unnecessary to receive the patient's valuables and record them, 16.4% to record all the data related to the pre-assessment to the nursing plan by the nurse, 15.9% to submit a copy to the patient/patient relative by filling out the discharge and training form (Table 3).

In the daily work flow process, 87%–99.4% of the nurses consisted of 58 items daily nursing activities were performed in wards/units and 77.4% – 100% found these activities necessary. 11.1% of the nurses found it unnecessary to perform the hygienic and other care applications of the patients and to record them on the

nurse observation form, 10.9% of the nurses found it unnecessary for the nurse on the day shift to prepare drugs and devices for evening treatments, 10% of the nurses found it unnecessary to prepare nursing observation forms for use the next day (Table 3).

In the process of patient who will go to surgery and come, 88.1% – 100% of the nurses stated that they did the related activities consisting of 21 items in the wards/units and 82.7%-95.9% found these activities necessary. 9.4% of the nurses found it unnecessary to shave and provide shave control of the surgical site. 7.8% of the nurses found it unnecessary to take the patient from the operating room by a nurse and helper staff. Besides, 7.5% of the nurses found it unnecessary to deliver the patient to the operating room accompanied by the nurse with the necessary forms. (Table 3).

Table 3. Nurses processes including nursing activities and their views on necessity of activities

NURSING ACTIVITIES	Necessary		Unnecessary		Rarely Necessary	
	n	%	n	%	n	%
PATIENT ADMISSION AND DISCHARGE PROCESS						
Activities Related to Patient Admission Process						
Introduces himself to the patient	53	65.4	8	9.9	19	23.5
Patient and patient relatives are directed to the patient room	60	89.6	3	4.5	4	6.0
Explain the room presentation and usage for the patient's adaptation to the room	55	78.6	7	10.0	8	11.4
Department unit is introduced to the patient	50	70.4	7	9.9	13	18.3
The patient is introduced to the medical team in the ward	42	49.4	18	21.2	22	25.9
Relatives of the patient are informed about telephone, food, visitor, companion, hotel, parking facilities	50	71.4	9	12.9	10	14.3
The patient's valuables are received and recorded	44	58.7	16	21.3	13	17.3
The patient's drugs are delivered and recorded with the expiry date and quantity	51	78.5	9	13.8	3	4.6
If the patient cannot meet his / her needs, he / she is helped to wear his / her clothes and taken to the patient bed.	41	62.1	7	10.6	17	25.8
All patients admitted to the ward are pre-evaluated within 4 hours.	58	92.1	1	1.6	3	4.8
The patient's life signs are taken and recorded.	54	93.1	1	1.7	2	3.4
Pre-evaluation form of the patient is completed	51	87.9	2	3.4	4	6.9
NRS2002 form is completed	35	71.4	4	8.2	8	16.3
In adults, itaki falls risk form is completed	48	81.4	3	5.1	5	8.5
In children, harizmi falls risk form is completed	48	80.0	3	5.0	7	11.7
Patient-specific risk assessments (nutritional risk assessment, pressure sore risk assessment, etc.) are performed in the department.	52	81.2	2	3.1	9	14.1
Risk assessment form is signed by the patient's relatives	49	77.8	9	14.3	4	6.3
All information and results of this preliminary assessment are recorded in the nursing care plan	50	74.6	11	16.4	4	6.0
According to the preliminary assessment, the patient's needs and problems are identified and a patient-specific care plan is prepared.	57	80.3	8	11.3	4	5.6
Patient treatments are arranged according to the treatment plan of the physician	68	98.6	0	0.0	1	1.4
The necessary procedures are performed for routine tests requested by the physician (blood collection, x-ray etc.)	63	98.4	1	1.6	0	0.0
Informed consent is given to the relatives of the patients before the applications, and informed consent form is signed by obtaining verbal consent.	59	84.3	7	10.0	3	4.3
Patients' relatives are informed about their right to refuse or terminate treatment, the consequences of their decisions and responsibilities.	61	89.7	1	1.5	4	5.9
Information's are recorded and signed by the patient's relatives and physician with a general informed consent form.	50	87.7	2	3.5	3	5.3
Other treatments and follow-ups that are appropriate to the request of the physician are made and recorded.	56	96.6	1	1.7	0	0.0
Activities Related to Discharge Process						
The patient's file, all information and documents of the patient are collected.	43	93.5	1	2.2	2	4.3
The files of the patients who will be discharged will be delivered to the secretary.	49	90.7	2	3.7	1	1.9
The patient is given discharge training and recorded on the patient training form.	49	79.0	4	6.5	7	11.3
The patient is discharged and the training form is completed and a copy is delivered to the patient-patient's relative.	42	66.7	10	15.9	9	14.3

The patient is assisted in preparing for discharge.	39	60.0	8	12.3	17	26.2
The patient's delivered goods, drugs; prescription information is delivered to the patient.	52	86.7	3	5.0	4	6.7
ACTIVITIES RELATED TO DAILY WORKFLOW PROCESS						
During the shift change, the ward is delivered between the nurses: ward order, life signs devices, narcotic drugs and notebook, heat and humidity charts, patient and nurse rooms and order, information about missing drug and consumables is exchanged.	60	98.4	0	0.0	1	1.6
After the delivery of the ward, the delivery of the patient is done by visiting the patient rooms in order: general status of the patient, the follow-up of the received and resistance, consultation status, the things to be done during the day of imaging centre and laboratory centre, drug applications	59	98.3	1	1.7	0	0.0
Preparing, applying and recording the treatments at 08.00 am hours: the treatments prepared for this shift from the previous day and added to the nurse observation sheet are written on the drug cards, which are specific to the patient.	54	93.1	4	6.9	0	0.0
These papers are glued onto syringes and serums.	53	93.0	3	5.3	1	1.8
Drugs are removed from the cupboards which are special for the patients and put on the table. 08.00 am treatment or medicines are prepared.	50	100	0	0.0	0	0.0
Prepared drugs with patient identification information are placed on the treatment cart according to the room numbers.	43	91.5	1	2.1	2	4.3
Patients are treated in the patient's room at 08.00 am.	40	95.2	0	0.0	2	4.8
The treatments are recorded on the nurse observation form.	53	100	0	0.0	0	0.0
Blood glucose measurements of patients are made.	51	86.4	2	3.4	6	10.2
If the blood sugar abnormal condition is notified to the physician.	60	98.4	0	0.0	1	1.6
Insulin is taken from the refrigerator in the nurse's room and administered to the patient.	60	98.4	0	0.0	1	1.6
The life signs of the patients are taken and recorded on the nurse observation form.	58	96.7	1	1.7	1	1.7
Patient visits are made with physicians.	56	96.6	2	3.4	0	0.0
The process related to laboratories is carried out.	56	96.6	1	1.7	1	1.7
The process for monitoring centres is performed.	51	92.7	2	3.6	2	3.6
The blood centre process is carried out	52	96.3	1	1.9	1	1.9
The process for the patients who will undergo surgery is performed.	45	91.8	3	6.1	1	2.0
The process for patients who will come from surgery is performed	49	94.2	2	3.8	1	1.9
The process for patients to be discharged is performed.	51	92.7	2	3.6	1	1.8
Cleaning of the service rooms and patient order is provided.	51	98.1	1	1.9	0	0.0
Patients with special conditions are admitted to private rooms.	49	89.1	3	5.5	2	3.6
If there is a patient admission process is initiated.	49	92.5	3	5.7	1	1.9
Care plans for the needs and problems of the patients are prepared and evaluated after the patient visit and evaluation of the nurses at each shift change.	51	85.0	5	8.3	4	6.7
If there is a change in the patient's nutritional, pressure sores, fall risk score or the general condition of the patient with an interval of eight hours, the services are re-evaluated and the care plan is rearranged according to the results.	48	77.4	2	3.2	11	17.7
Other treatments and follow-up are made according to the request of the physician and the results are recorded on the nurse observation form.	46	90.2	3	5.9	2	3.9
According to the daily drug regulations of physicians, drug and consumables process is carried out from pharmacy.	48	88.9	4	7.4	2	3.7
Hygienic and other care practices of the patients are made and recorded on the nurse observation form.	42	77.8	6	11.1	5	9.3
Lunch is provided in accordance with diets and help the patient who cannot eat.	47	83.9	1	1.8	8	14.3

12.00 am o'clock treatments are prepared and applied.	46	90.2	2	3.9	3	5.9
Life signs are taken at 12.00 am.	47	92.2	1	2.0	3	5.9
At 14.00, treatments are prepared and applied.	44	89.8	2	4.1	3	6.1
Nurse observation forms are prepared for use the next day.	42	84.0	5	10.0	3	6.0
Treatments are prepared at 04.00 pm.	41	85.4	3	6.2	4	8.3
The necessary devices and drugs are put on a tray for evening shift treatments for the nurse who will come to the evening watch.	36	78.3	5	10.9	5	10.9
Service is arranged before the delivery of the guard.	49	94.2	1	1.9	2	3.8
Treatments are applied at 04.00 pm.	45	95.7	0	0.0	2	4.3
Service and patient delivery is made to the nurse who comes to the night shift.	42	95.5	1	2.3	1	2.3
Blood glucose is measured and insulin is given at 05.00 pm.	40	85.1	1	2.1	6	12.8
It is ensured that dinner is served in accordance with diets and the patient who is unable to eat is assisted.	37	80.4	1	2.2	8	17.4
Physicians who come to visit at the end of the working hours are made one's rounds.	49	94.2	1	1.9	2	3.8
The treatment changes of the physicians are recorded on the nurse observation forms prepared for the same day and the next day.	51	94.4	2	3.7	1	1.9
The treatment trays prepared by the day nurses are taken to the medicine room and the drugs are prepared.	44	95.7	1	2.2	1	2.2
Treatments are made at 08.00 pm.	46	93.9	1	2.0	2	4.1
After treatment at 08.00 pm, signs of life are taken.	47	97.9	0	0.0	1	2.1
Blood glucose is measured and patients are given insulin.	44	89.8	0	0.0	5	10.2
Treatments are made at 00.00.	44	93.6	1	2.1	2	4.3
Treatments are made at 02.00. am	44	84.6	3	5.8	5	9.6
Blood tests to be taken at 05.00 am are entered into the laboratory module.	49	94.2	1	1.9	2	3.8
Lab glues barcodes to tubes.	49	87.5	3	5.4	3	5.4
Groups the tubes by room number and leaves them on the table.	40	88.9	3	6.7	2	4.4
The patient's blood is collected by verifying the patient's identity and the blood is sent to the laboratory.	50	96.2	1	1.9	1	1.9
Blood glucose is measured and patients are given insulin.	44	89.8	0	0.0	5	10.2
If there is a dying patient, the physician is notified and the dying patient care process is initiated.	53	93.0	1	1.8	2	3.5
Treatments are prepared and applied at 06.00 am.	48	92.3	1	1.9	3	5.8
After treatment, life signs are taken at 06.00 am.	50	96.2	0	0.0	2	3.8
Nurse observation forms are distributed to the patients.	38	86.4	3	6.8	3	6.8
It is ensured that breakfast is served in accordance with diets and the patient who is unable to eat is assisted.	44	88.0	2	4.0	4	8.0
Records the seizure in the seizure book.	53	94.6	2	3.6	1	1.8
OPERATING ROOM PROCESSES						
Activities Related to Patients Going to Surgery						
Relatives of the patients are informed about the operation and anaesthesia process.	42	93.3	2	4.4	1	2.2

Pre-op patient evaluation form is completed.	46	93.9	2	4.1	1	2.0
General / Regional Anaesthesia Informed Consent Form for surgical intervention is signed by the patient / his / her relatives and physician.	46	93.9	2	4.1	1	2.0
Preoperative blood components are requested from the blood unit, and after preparing the blood unit, it is taken to the service for the patient.	44	88.0	4	8.0	2	4.0
Pre-routine routine assays are completed and checked (laboratory tests, radiology tests, EKG etc.)	44	93.6	2	4.3	1	2.1
The patient's clothes, metal items, if any, the denture is removed and dressed in a patient scrub.	47	95.9	1	2.0	1	2.0
If necessary, shaving or shaving of the operation area is provided.	45	84.9	5	9.4	3	5.7
Patient delivery form and safe surgical checklist are filled in before the patient leaves the clinic.	48	90.6	2	3.8	2	3.8
The patient is delivered to the operating room with the necessary forms under the supervision of a nurse.	47	88.7	4	7.5	2	3.8
Pre-operative, patient preparation and delivery of the patient to the operating room is performed by the nurse who performs the transfer of authentication.	47	92.2	3	5.9	1	2.0
Activities Related to Patients Coming from Surgery						
The nurse and assistant personnel go to the operating room to pick up the patient from the operating room.	46	90.2	4	7.8	1	2.0
The anaesthesia technician and operating room nurse informs the ward nurse of the about the type of anaesthesia, the unusual conditions during the operation, the drugs used, the drains, catheters, catheters and the general condition of the patient.	50	100	0	0.0	0	0.0
The nurse verifies the patient's identity.	45	100	0	0.0	0	0.0
It is checked whether all forms of the patient are completed and signed completely, and the nurse receives the patient with the fields in the related forms completed.	43	95.6	1	2.2	1	2.2
The patient is taken to the room in the ward unit accompanied by nurses and service personnel.	43	93.5	1	2.2	2	4.3
Upon admission to the ward, life signs are monitored until the patient's condition is stable.	43	89.6	1	2.1	4	8.3
The physician is informed in case of changes in the patient's condition and follow-up results.	45	95.7	0	0.0	2	4.3
The postoperative treatment plan ordered by the physician is applied by the nurse and the effects and side effects of the drug are monitored.	45	95.7	0	0.0	2	4.3
All treatment, follow-up and care records of the patient are recorded on the nurse observation form.	44	95.7	0	0.0	2	4.3
The relatives of the patients are informed about the postoperative nutrition, mobilization, analgesic application times and all the procedures to be performed.	45	91.8	2	4.1	2	4.1
Visitor restrictions are made.	43	82.7	2	3.8	7	13.5
SUPPORT SERVICES						
Activities Related to Laboratories						
Laboratory requests requested by the physician are entered into the system by the nurse.	43	82.7	7	13.5	2	3.8
Blood and other assay samples to be taken are entered into the laboratory module by the nurse.	44	86.3	6	11.8	1	2.0

The barcode is pressed by the nurse and attached to the tubes.	46	92.0	3	6.0	1	2.0
Blood and other test samples are taken from the patient by the nurse.	50	98.0	1	2.0	-	-
The samples taken with the personnel are sent to the laboratories.	50	94.3	2	3.8	1	1.9
Activities Related to Monitoring Centres						
The physician is called to find out the type of X-ray, MR and CTs requested by the physician. After the type and purpose of the diagnosis is learned, the nurse enters the system.	40	75.5	11	20.8	2	3.8
The imaging center is called and the appointment time is taken.	44	88.0	4	8.0	2	4.0
When the appointment time approaches, the patient is sent to the centre accompanied by the staff. If necessary, the nurse accompanies the patient.	43	86.0	5	10.0	2	4.0
After the patient comes from the centers, he is taken to bed and the treatment is started.	45	93.8	3	6.2	0	0.0
Blood Center Activities						
The laboratory is searched for the presence of the desired blood components.	48	92.3	3	5.8	1	1.9
The blood product ordered by the physician is entered into the system from the blood centre and requested by telephone.	51	98.1	0	0.0	1	1.9
She takes blood from the patient for a cross match.	51	98.1	0	0.0	1	1.9
The cross blood and filled blood components are sent to the blood unit by personnel.	54	96.4	1	1.8	1	1.8
Consent form for blood transfusion is explained and signed to the patient and put in the patient file.	54	98.2	0	0.0	1	1.8
By searching the blood unit of the laboratory, it is learned whether the blood components are prepared or not.	47	94.0	1	2.0	2	4.0
When the blood components are ready, they are brought to the service with the personnel.	49	92.5	3	5.7	1	1.9
Pharmacy Activities						
The drug of all patients is entered into the pharmacy module according to the daily physician's request.	49	94.2	2	3.8	1	1.9
Request is made from the system for consumables.	48	92.3	2	3.8	2	3.8
All patient files are sent to the pharmacy with service personnel for the supply of drugs / devices.	45	80.4	8	14.3	3	5.4
After the medicines and consumables are prepared within 3 or 4 st, the nurse and staff go to the pharmacy and the nurse receives the medicines in return for signature.	46	79.3	6	10.3	4	6.9
Incoming medicines are taken out of patients' special bags and placed in special cupboards for patients.	54	91.5	2	3.4	2	3.4
The nurse in charge of high-risk drugs receives from the pharmacy.	54	93.1	2	3.4	2	3.4
If there is any new drug missing on the change of request, new drug is entered into the system by the nurse.	50	96.2	1	1.9	1	1.9
Pharmacy officer is called and interviewed who is a attending doctor.	48	90.6	3	5.7	2	3.8
After the pharmacist arrives at the pharmacy and prepares the drug, staff and medicines are taken.	48	94.1	1	2.0	2	3.9
If the pharmacist cannot come, if the drug is available in a different ward, the nurse will contact the on-call nurse of that ward and have the drug taken by the staff.	42	93.3	2	4.4	1	2.2
The medicine taken from the other ward is supplied from the pharmacy and delivered to this ward the next day.	45	90.0	2	4.0	3	6.0
If the requested drug is not in the pharmacy stock, a physician is called and an external prescription is provided.	47	94.0	2	4.0	1	2.0
Ward consumables are requested weekly.	47	95.9	1	2.0	1	2.0
Weekly consumables are taken from the pharmacy and placed in the warehouse according to the warehouse order.	44	93.6	2	4.3	1	2.1

In the processes related to support services; laboratories, monitoring and blood centre, hospital pharmacy, 91% – 99.4% of the nurses stated that these activities, which consist of 30 items, were performed in the wards/units and 75.5%–98.2% found these activities necessary. However, 20.8% of the nurses found it unnecessary to call the physician to find out the type of X-ray, magnetic resonance, computerized tomography requested by physician and to enter the physician's request by the nurse into the module after learning the type and purpose of the diagnosis. Moreover, 14.3% of the nurses found it unnecessary to send all patient files to the pharmacy with the personnel for drug/device supply; 13.5% of the nurses found it unnecessary to enter the physician's laboratory requests and 11.8% of nurses found it unnecessary to enter blood and other assay samples into the laboratory module by the nurse (Table 3).

4. DISCUSSION

In this study, when the activities about the nursing work processes related to lean management were evaluated, it was determined that the majority of nurses did not have knowledge about the concept of lean hospital. The reason for this is that concept of lean is the new handling issues in the health services in Turkey and there is a limited number of studies.

In our study, regarding the need for lean approach, almost half of the nurses stated that the unit they work with needs to be partially lean. This may be due to the fact that the researchers informed the nurses before the data collection phase or that the nurses with undergraduate education supported this opinion more than the other nurses. Because in recent years these new approaches have been included in nursing bachelor's level programs.

When the views of nurses regarding the work processes related to patient admission and discharge, daily work flow, operating rooms and support services such as, laboratories, monitoring centre, blood centre and hospital pharmacy were evaluated, the majority of the nurses stated that most or all of the activities mentioned in this process were applied in the wards/units where they were located and that they found these activities necessary. In this direction, it was suggested that the majority of nurses perceived each task as self-assigned, were not clear about their duties or roles, or that job descriptions were not prepared for nursing roles. Therefore, it can be said that they cannot distinguish between necessary and unnecessary activities and also feel the responsibility of performing every task in order to prevent disruption of the work and to prevent the patients from being victims.

When the activities related to the patient admission process are evaluated, it is noteworthy that one out of four nurses rarely find it necessary to introduce themselves and the health care team to the patient and to assist the patient who is unable to meet his or her needs to wear and taking into the bed. According to the Nursing Regulations, taking

the patient's history and orientation, helping to dress and undress the patient are among the nursing activities to be applied by the nursing decision (22). Therefore, this may be due to the fact that nurses do not know their job descriptions, do not care about the orientation of the patient to the ward, or are expected these activities, which have their own roles, from their patient's relatives.

During the patient admission process, one out of five nurses found it unnecessary to receive and record the patient's valuables, and one out of six nurses found it unnecessary to record the data in the care plan after evaluating the patient. This is due to the fact that these procedures are not seen as a priority procedure in special units such as emergency room, intensive care unit, operating room. In addition, although it is still performed in many clinics, it may be caused by the fact that in many public hospitals, hospitalization of valuable items should be handed over to the patient's relatives and it is stated that no responsibility will be taken. In addition, the preparation of a patient care plan after evaluation of the patient is one of the basic roles of nurses (22) and this approach should be performed by nurses in every unit of the hospital. However, the function of delivering and receiving the patient's belongings can be assigned to a custody unit or responsible personnel to handle these tasks. Thus, the nursing process can be leaned.

In the discharge process, only one quarter of the nurses stated that they rarely helped to prepare the patient during discharge, while one out of eight found this procedure unnecessary. In addition, one of the six nurses found it unnecessary to complete the discharge training form and to deliver a copy to the patient's relatives. Actually, discharging is an attempt made with the decision of nurse and physician (22). But, it takes a lot of time for the nurse to prepare the patient for discharge. However, it can be more useful to transfer the nurse's collection of the patient's belongings to the helper staff or the hotel services personnel. Besides, in the literature, it is mention that it would be useful the nurse devotes her/his time to patient education (23).

In the daily workflow process, one in ten nurses found it unnecessary for the patients to perform daily care practices and record them on the nurse observation form, for the morning shift nurse to prepare medicines and devices for evening shift treatments and to prepare nurse observation forms for use the next day. In the regulation, helping to feed the patient by mouth, feeding with spoon/glass, improving the quality of life, giving care and helping to meet physiological needs are the primary duties of the nurse (22–25). Although, the care needs of the patients are the duties of the nurses (24), it may be considered unnecessary because some of the patients meet these needs by themselves or their relatives. Nurses prepare drugs and devices in advance for the next shift, but this increases the workload of nurses and wastes time. Furthermore, this approach, which is not suitable for patient safety requires re-control of drugs and devices. Observation forms can be made available through the system and can be used at any time. In support of

our study findings, another study, it was stated that the undisclosed waste in daily work is 35%. (26). Kurutkan et al. (2014) has attributed the high amount of waste to inconsistencies in health services, unreliable delivery systems and unnecessary interruptions in their study (26). In Atkinson's study, the process time was reduced by 60% by eliminated 14 unnecessary steps with lean application (27, 28). Another study, supported by the Robert Wood Johnson Foundation, found that nurses were able to answer call bells, spend less time, and identify patient problems more quickly with improved workflow (29). According to Güteryüz, in the study of Wadhwa and Wadhwa, method cards were prepared and ensured that each work was performed in a standard way, so wastes and activities that did not create value were eliminated. Moreover, balance was achieved by using a single piece flow system. Thus, the number of patients waiting due to paperwork was reduced (27).

In the processes that the patient will go to the operation and come from operation, respectively, one out of eleven the nurses and one out of thirteenth of the nurses found it unnecessary to shave and to control of shaving at the pre-operative area and to deliver the patient to the operating room accompanied by the nurse. The reason why nurses find these procedures unnecessary may be due to their work in internal clinics or specialized units such as emergency, and intensive care units, or due to differences between wards/units and hospital policies. In addition, the shaving of the patients who will have an operation can be done by the hospital's barber. Therefore, this procedure can be excluded from the process and only the shaving control can be performed by the nurses or this duty can be transfer to a helper staff as specified in the Nursing Regulation (22).

In the process of laboratory and imaging centres, one out of eight nurses found it unnecessary to enter the physician's laboratory requests, blood and other assay samples into the system by the nurse. One fifth of the nurses found it unnecessary to call the physician to learn the type and purpose of imaging procedures such as x-ray and tomography, and then to enter the system by the nurse and one-tenth of the nurses found it unnecessary to send the patient to the imaging centres in a presence of nurses and staff. In the nursing regulation, the duty of the nurse regarding the laboratory process is not to enter the physician's request into the system (22). However, in this study, the nurses perform the requests for diagnostic procedures as if they were their own activities, not only the laboratory but also the physician's procedure, although these are physicians' duties. However, these procedures, which do not add value to nursing services and increase the workload, should be eliminated from the process.

In the pharmacy processes, approximately one out of seven of the nurses found it unnecessary to send all patient files to the pharmacy with the staff for the supply of drug/ devices, going to the pharmacy after the preparation of drug and consumables by the nurse and staff and to receiving them in return for signature by the nurse. In this context,

information systems and technology products can be utilized in order to reduce the workload of the nurses related to the pharmacy. For example, a PYXIS system integrated with the hospital information system ensures over-dispatch of drugs and return of unused medicines in clinics / units through automation, eliminating waste of drugs and eliminating unnecessary activities such as unnecessary transport, stock and unnecessary movement. In addition, the lean approach can be achieved in pharmacy processes by using process mapping technique. In a study conducted in a university hospital, the physician prepared the treatment plan digitally according to the process map of the pharmacy, the drugs coming to the pharmacy module were prepared on a patient basis, the drugs delivered to the clinic by the pharmacy staff, thus the mistakes for the patient safety were prevented and the burden of the cheaf nurse was reduced (30).

5. CONCLUSION

As a result, in this study which was defined the processes involving nursing activities, it was found that nurses were not aware of the lean approach and did not use it adequately in nursing care process. It was found that nurses thought some activities unnecessary although they were within the scope of their duties, authorities and responsibilities. However, it was determined that the nurses performed some activities and thought them necessary even though they were not covered by their duties. Eliminating unnecessary activities thanks to the lean approach it can be ensured that nurses can devote their time and energy to patient care and education.

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Determining Individual Workload Perceptions and Malpractice Tendencies Among Operating Room Nurses

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ABSTRACT

Objective: To determine the workload perceptions and malpractice tendency of nurses working in the operating room.

Methods: A descriptive, cross-sectional study was conducted with 92 operating room nurses from 3 provinces of Turkey. The data were analyzed by using the numbers, percentages, the Mann-Whitney U test and the Kruskal Wallis test.

Results: The mean age of the nurses was 35.19±6.11; 50% of the nurses had operating room working duration of 1-5 years, and 78.3% of the nurses had weekly working hours more than 40 hours. A total of 33.7% of the nurses stated that they came across with one malpractice case. The mean "Individual Workload Perception Scale(IWPS)" score of the participants was 98.82±9.39, and the mean "Malpractice Tendency Scale(MTS)" score was 225.59±12.75. There was a statistically significant difference between the communication subscale mean scores of the participants on the MTS according to their time in the profession. There were statistically significant differences between the gender of the participants and the overall IWPS mean score, the managerial support subscale mean score, and the workload subscale score. Statistically significant differences were detected between the working time of the nurses and the managerial support subscale and the workload subscale scores. Significant differences were detected in the participants' mean scores on the intention to stay at work subscale of the IWPS according to the operating room working time of the participants.

Conclusion: Teamwork and effective communication in the operating room are two critical factors in ensuring patient safety. Eventually, approaches to be developed to foresee and prevent malpractice in operating rooms may ensure a safe perioperative process. The job descriptions of the operating room nurses should be reviewed. Training should be planned to strengthen team communication. Patient safety culture should be expanded in the health care team through monitoring and work flow charts.

Keywords: Operating Room, Nurse, Malpractice, Workload.

1. INTRODUCTION

Operating rooms are high-risk areas for malpractice due to factors such as their complex structure, the intensive working environment and having to function with insufficient personnel, a high workload, and stress (1-3). In the United States, it was determined that 12.5% of the 1100 malpractice cases in the courts between 1995 and 2001 were brought during or after operations (4). Malpractice in operating rooms include wrong side surgery, forgetting a foreign body, transfusion errors, falls, hospital infections, medication errors, surgical burns, faulty anesthesia, and sharp object injuries (5,6). Malpractice in an operating room causes serious injury, organ loss, prolonged hospital stay, and can even result in mortality (7, 8). Reasons for malpractice in operating rooms include urgency of the intervention, unusual physical characteristics of the patient, inadequate patient consent, time pressure, working with multiple surgeons, and simultaneous interventions to the same patient. Moreover, poor communication, the inexperience of healthcare

workers, distraction, the importance personnel attribute to their jobs, their physical and/or psychological problems, and the physical environment (many risky devices, multiple complicated procedures) are also important causes of malpractice. Stress, an intensive work schedule, insufficient rest, lack of managerial support, not feeling safe, confusion in job descriptions, high expectations, organizational problems, fatigue, long hours or shift work, and sleeplessness are also important factors (9). In addition to these, a shortage of nurses leads to an increase in individual workloads. Under such conditions, malpractice, which is in fact preventable, becomes unavoidable (5, 8, 10). To understand the causes of malpractice and to prevent performance that leads to legal, ethical, and financial consequences in addition to medical repercussions, is the most important aspect of ensuring patient safety. Operating room nurses have a significant role in ensuring and maintaining patient safety (9, 11). Determining the workload perceptions of nurses and

their tendencies toward malpractice will help to identify the sources of malpractice in the operating room and to create more efficient working conditions for both the patient and the employee. In this way, approaches to be developed to foresee and prevent malpractice in operating rooms may ensure a safe perioperative process.

This study was performed to determine the workload perceptions and malpractice tendencies of nurses working in operating rooms.

2. METHODS

This was a descriptive and cross-sectional study. Three hospitals located in three different regions of Turkey were included. The inclusion criteria was: to be working in the operating room for at least a year. A total of 118 operating room nurses were working at these hospitals. The goal was to reach all of the nurses; however, due to various reasons (sick leaves, on leave status, refusal to participate), the study ultimately involved 92 nurses. To conduct this study, permission was obtained from the local ethics committee (Mehmet Akif Ersoy University Non-Invasive Clinical Researches Assessment Commission-GO 2017/96) and the institution, and written and verbal consent was obtained from the nurses who accepted participating in the research.

2.1. Measurements

Data collection tools were a Personal Data Form, the Individual Workload Perception Scale (IWPS), and the Malpractice Tendency Scale (MTS). The Individual Data Form, developed by the investigators on the basis of the relevant literature, (9, 12, 13) included 12 questions on descriptive features (age, sex, education status, working time in the nursing profession, working time in an operating room, weekly workload, and previous encounters with malpractice).

Individual Workload Perception Scale: Cox (2007). developed the Individual Workload Perception Scale (14). The validity and reliability study of the Turkish version of the Revised Individual Workload Scale was performed by Ozyurek & Kilic (2017). The Cronbach alpha coefficient of the scale was found to be 0.923. This Likert-type 5-point scale consists of 29 items and is scored as "1=none", "2=minimal", "3=moderate", "4=very", and "5=full". The scale consists of five subscales. Peer support comprises items 1-6, unit support comprises items 7-12, manager support corresponds to items 13-20, workload to items 21-24, and intention to stay at work comprises items 25-29. The mean score from each of the IWPS items is minimum 1 and maximum 5. A higher total score reflects a positive workload perception and general nurse satisfaction (15). In our study, the Cronbach alpha coefficient was 0.735.

Malpractice Tendency Scale: Ozata & Altunkan (2010) developed the Malpractice Tendency Scale to measure the malpractice tendency of health care personnel (nurse, midwife, paramedic) directly caring for patients and tested its validity and reliability (16). This scale's 5 subscales consist of drug and transfusion practices (18 items), prevention of infections (12 items), prevention of falls (5 items), patient

monitoring and material safety (9 items) and communication (5 items). There are 49 items included in the scale, and a 5-point Likert type rating is used to respond to the items as "1-never, 2-very rarely, 3-sometimes, 4-usually, and 5-always". The lowest possible score was 49, and the highest possible score was 245. A higher score from the scale reflects a low malpractice tendency, and a lower score reflects a high malpractice tendency for nurses (17). The Cronbach alpha coefficient of the scale was found to be 0.95 (16). In our study, the Cronbach alpha coefficient was found to be 0.88.

2.2. Data Collection and Analysis

The study data were collected with face-to-face interviews between June 2017 and January 2018. The time for filling the data collection forms is about 10-15 minutes. The data were analyzed using the Statistical Package for Social Sciences (SPSS) 23. The Shapiro-Wilk tests were used to determine whether the data obtained were normally distributed. Numbers, percentages, the Mann-Whitney U test and the Kruskal Wallis test were used to evaluate the data. The level of significance was set at ≤ 0.05 for all the tests performed.

3. RESULTS

The mean age of the nurses who participated in this study was 35.19 ± 6.11 years, and 80.4% (n=74) were females. A total of 50% (n=46) of the participants were faculty graduates, 65.2% (n=60) had been working for a period of 11 years or more, 50% had worked in an operating room for a period of 1-5 years, and 78.3% (n=72) worked for more than 40 hours a week; 33.7% of the nurses (n=31) previously encountered a malpractice case.

The mean Malpractice Tendency Scale score of the participants was 225.59 ± 12.75 , and the mean Individual Workload Perception Scale score was 98.82 ± 9.39 . The minimum, maximum and mean values of the subscales of the two scales are given in Table 1.

Table 1. The Distribution of the Mean Scores from the Malpractice Tendency Scale and Individual Workload Perception Scale of the Operating Room Nurses (N=92)

	Min.	Max.	(X \pm SD)
Malpractice Tendency	191	243	225.59\pm12.75
Drug and Transfusion Applications	76	90	85.80 \pm 3.66
Prevention of Infections	45	60	53.86 \pm 3.76
Prevention of Falls	15	25	21.65 \pm 2.39
Patient Monitoring and Material Safety	30	45	38.60 \pm 3.65
Communication	15	25	22.80 \pm 2.81
Individual Workload Perception	75	116	98.82\pm9.39
Manager Support	9	30	22.45 \pm 5.29
Peer Support	8	29	22.10 \pm 2.76
Unit Support	24	30	26.65 \pm 1.20
Intention to Stay at Work	4	17	15.58 \pm 1.81
Workload	8	19	12.02 \pm 2.85

No significant differences could be found between the mean total and subscale scores of the nurses who participated in the study and the variables of gender, weekly working hours, and encounters with malpractice ($p>0.05$). There was a significant difference in the communication subscale mean score on the Malpractice Tendency Scale of the nurses according to educational status ($p<0.05$). The communication

subscale mean score of high school graduates was higher. There was a statistically significant difference between the communication subscale mean scores of the participants on the Malpractice Tendency Scale according to their time in the profession ($p<0.05$). Those who worked for 11 years or more in the profession had higher mean scores in the communication subscale (Table 2).

Table 2. Comparison of the mean malpractice tendency scores for several independent variables (N=92)

Variable	Drug and Transfusion Practices	Prevention of Infections	Prevention of Falls	Patient Monitoring and Material Safety	Communication	Malpractice Trend Total
Gender						
Female	85.81±3.71	53.72±3.72	21.51±2.22	38.72±3.57	22.75±2.85	222.54±10.76
Male	85.77±3.57	54.44±3.98	22.22±3.00	38.11±4.05	23.00±2.74	223.55±13.91
p*	0.90	0.40	0.14	0.42	0.64	0.42
U**	654.00	582.50	518.50	586.00	621.00	584.50
Education						
High School	86.39±3.05	54.06±3.65	21.58±2.58	38.10±4.19	23.58±2.15	223.73±11.07
Faculty	85.21±4.14	53.67±3.91	21.71±2.21	39.10±2.99	22.02±3.18	221.73±11.69
p*	0.26	0.70	0.90	0.30	0.005	0.34
U**	915.50	1010.00	1042.50	928.50	717.50	938.00
Working time in the profession						
1-5 years	85.68±3.66	53.93±4.15	20.56±2.30	38.37±3.15	20.81±4.26	219.37±10.37
6-10 years	85.43±4.21	54.12±2.65	22.31±1.77	38.37±2.65	22.12±2.41	222.37±10.90
11 years and above	85.93±3.56	53.78±3.96	21.76±2.49	38.73±4.03	23.51±2.10	223.73±11.73
p	0.97	0.99	0.08	0.86	0.007	0.18
KW***	0.05	0.02	4.86	0.28	9.87	3.39
Working time in operating room						
1-5 years	86.58±3.33	54.06±3.51	21.76±2.46	39.06±3.44	22.36±3.22	223.84±10.40
6-10 years	85.40±3.77	53.93±3.30	21.86±2.03	38.60±3.73	23.40±2.26	223.20±10.94
11 years and above	84.83±3.92	53.54±4.38	21.38±2.49	37.93±3.93	23.16±2.35	220.87±12.96
p	0.89	0.92	0.65	0.58	0.40	0.80
KW***	4.84	0.15	0.84	1.07	1.81	0.44
Weekly working hours						
40 hours or lower	84.85±5.12	52.50±4.62	22.50±2.50	39.20±4.39	22.65±2.83	221.00±17.39
Above 40 hours	86.06±3.14	54.25±3.43	21.41±2.33	38.44±3.44	22.84±2.83	223.02±9.18
p*	0.72	0.13	0.08	0.40	0.86	0.77
U**	683.00	563.50	541.00	632.50	703.00	689.50
Malpractice encounters						
None	85.98±3.58	53.96±3.51	21.49±2.39	38.90±3.52	22.49±2.99	222.83±10.70
Once or more	85.45±3.84	53.67±4.28	21.96±2.41	38.03±3.90	23.41±2.36	222.54±12.76
p*	0.43	0.95	0.44	0.30	0.11	0.58
U**	852.50	938.50	853.50	822.00	765.00	879.00

* p: ($p<0.05$); **U: the Mann-Whitney U Test; *** KW: the Kruskal-Wallis Test

No statistically significant difference could be found between the overall and subscale mean scores on the Individual Workload Perception Scale and education status or malpractice encounters ($p>0.05$). There were statistically significant differences between the gender of the participants and the overall Individual Workload Perception Scale mean score, the managerial support subscale mean score, and the workload subscale score ($p<0.05$). Female participants were found to have higher levels of individual workload performance. Statistically significant differences were detected between the working time of the nurses and the managerial support subscale and the workload subscale scores ($p<0.05$). Nurses who worked

for five years or less in the profession were detected to have a lower level of individual workload perception. Significant differences were detected in the participants' mean scores on the intention to stay at work subscale of the Individual Workload Performance Scale according to the operating room working time of the participants ($p<0.05$). Nurses who worked for 11 years or more were less eager to stay in their current jobs. There was a statistically significant difference in the Workload Subscale of the individual workload perception scale according to the weekly working hours of the nurses ($p<0.05$). Employees whose weekly working hours were 40 hours or more had higher workload perceptions (Table 3).

Table 3. The Comparison of the mean individual workload scale scores according to independent variables (N=92)

Variables	Manager Support	Peer Support	Unit Support	Intention to Stay at Work	Workload	Individual Workload Total
Gender						
Female	21.50±5.29	22.02±2.78	26.64±1.17	15.48±1.92	11.67±2.91	97.33±9.37
Male	26.38±3.01	22.44±2.74	26.66±1.37	16.00±1.23	13.44±2.12	104.94±6.79
p*	0.001	0.33	0.74	0.43	0.01	0.001
U**	297.50	571.00	634.50	589.00	428.50	325.50
Education						
High School	21.89±5.12	21.78±3.18	26.47±1.24	15.47±2.21	11.58±2.67	97.21±10.00
Faculty	23.02±5.44	22.43±2.26	26.82±1.16	15.69±1.31	12.45±2.99	100.43±8.55
p*	0.21	0.59	0.07	0.97	0.08	0.06
U**	898.00	991.50	839.50	1054.00	836.50	819.00
Working time						
1-5 years	25.31±3.85	22.06±2.26	26.75±1.12	15.81±0.75	13.43±1.78	103.37±5.87
6-10 years	20.12±5.80	22.12±4.39	26.93±1.06	15.81±1.22	10.43±3.05	95.43±11.24
11 years and above	22.31±5.20	22.11±2.36	26.55±1.26	15.46±2.12	12.06±2.85	98.51±9.29
p*	0.01	0.94	0.55	0.99	0.01	0.06
KW***	8.09	0.12	1.16	0.01	8.97	5,60
Operating room working time						
1-5 years	21.89±5.73	21.69±2.76	26.54±1.14	15.50±1.22	11.67±2.51	97.30±8.82
6-10 years	24.33±4.22	22.13±3,09	27.13±0.99	15.33±2.16	11.66±2.58	100.60±9.13
11 years and above	22.38±4.99	22.70±2.58	26.58±1.36	15.83±2.33	12.70±3.37	100.22±10.24
p*	0.35	0.54	0.25	0.03	0.08	0.20
KW***	2.07	1.20	2.69	6.48	4.84	3.16
Weekly working hours						
40 hours and below	24.15±4.77	21.95±1.31	26.75±0.71	15.15±1.59	13.55±2.16	101.55±7.45
Above 40 hours	21.98±5.36	22.15±3.05	26.62±1.31	15.70±1.86	11.59±2.89	98.06±9.77
p*	0.07	0.44	0.68	0.07	0.01	0.16
U**	531.50	642.50	678.50	536.50	453.00	573.50
Malpractice encounters						
Once or more	22.27±5.21	21.75±2.83	26.60±1.25	15.36±2.12	11.91±2.72	97.91±9.27
None	22.80±5.50	22.80±2.53	26.74±1.12	16.03±0.83	12.22±3.13	100.61±9.52
p*	0.57	0.45	0.55	0.14	0.46	0.21
U**	877.50	858.50	877.00	774.00	858.50	797.00

* p: ($p < 0.05$); **U: The Mann-Whitney U Test; *** KW: The Kruskal-Wallis Test

4. DISCUSSION

In our study, the Malpractice Tendency Scale mean score of the nurses was 225.59 ± 12.75 . Because the highest possible score in the Malpractice Tendency Scale is 245, it can be said that the tendency of the participating nurses toward malpractice was low. Similar to our study, malpractice tendencies in nurses were low in other studies (12, 13, 17). This may be due to the continuous in-service training nurses receive and the success of the protocols developed by the Ministry of Health in the effort to prevent malpractice in accordance with quality standards. In our study, the dimensions in which operating room nurses were more likely to lean toward malpractice included patient monitorization and materials safety, fall prevention, and the prevention of infections. The dimension of patient monitorization and materials safety reflects malpractice tendencies in the auditing of all equipment and materials and in monitoring patients. The highest possible score on this scale is 45; the

nurses in our study scored 38.60 points. The highest possible score in the fall prevention subscale is 25; the mean score of the nurses in our study was 21.65. The infection subscale reflects malpractice tendencies regarding the use of aseptic techniques in the care of patients and in nursing practices. The nurses in this study displayed a mean score of 53 while the highest possible score is 60. In another study, nurses displayed the highest mean subscale scores on the prevention of infection and communication subscales and the lowest mean scores on the patient monitorization and the material and equipment safety subscales (18). The shortage of nurses working in operating rooms leads to obliging scrub nurses to additionally perform the duties of circulating nurses during surgeries. This causes an increased tendency toward malpractice in the domain of patient and materials safety. Although the scores in our study were not very low, the desired outcome in terms of decreasing the number of infections and falls was to obtain the highest mean scores in this dimension. In particular, the responsibilities of nurses

increase in all the aspects of patient safety when a patient inevitably lies unconscious under anesthesia in the operating room. Studies show that most nurses have encountered cases of medical error (18, 19, 20). In our study, only 33.7% of the nurses had not encountered a case of medical error. According to the Safety Reporting System Statistics and Analysis Report of the Ministry of Health, 74,383 cases of malpractice were reported in 2016 (21). Also, among all professional groups, nurses were the group making the most frequent errors. The reasons cited for this have been the fact that nurses constitute the majority of healthcare professionals, they take active roles in all healthcare procedures, and their level of awareness for error reporting is high (17). In our study, the mean score of the operating room nurses who were high school graduates was higher on the communication subscale of the Malpractice Tendency Scale. The communication subscale evaluates communications with peers and other disciplines. It is emphasized that the leading cause of cases of malpractice in operating rooms is a lack of communication (18, 22). Among the participants, those who had worked for 11 years or more had higher mean scores on the communication subscale. This indicates that communication skills improve as the number of working years increase and also means that malpractice due to lack of communication is preventable. Ugur, et al. (2011) included all healthcare workers in the operating room in their study and reported that 37.7% of malpractice cases were due to mistakes in communication and data flow. Studies have shown that tendencies toward malpractice diminished as the number of working years increased. Our study is in parallel with these findings (13, 23). The overall mean score on the Individual Workload Perception Scale was 98.82 ± 9.39 . While the highest possible score in the scale is 145, the score found in the study indicated that workload perceptions of the nurses were at a moderate level, meaning that the level of satisfaction was not very high. Among the subscales of the Individual Workload Perception scale, the mean Unit Support subscale score was higher than in the other dimensions. The Unit Support subscale reflects the satisfaction of employees regarding the provision of required materials and service support. This result suggests that using the appropriate materials may be effective in reducing the number of malpractice cases. It is also reported in the literature that technical factors (insufficient automation, insufficient or defective devices, lack of support and integration) are among the causes of malpractice (21). The intention to stay at work subscale is the combination of the other dimensions and reflects the intention of employees to stay at their current jobs for the next year. It was determined in our study that the intention to stay at work subscale mean scores of the nurses who had worked 11 years or more were higher. Higher mean scores indicate a higher level of intent to stay in the current job. This result may be due to the fact that experienced operating room nurses occupy positions of competence that require higher levels of responsibility and therefore they are more likely to take more satisfaction out of their jobs. In another study that investigated the individual workload perceptions of healthcare employees, it was

reported that the employees received the lowest scores from the intention to stay at work dimension (24). In addition, the more the number of years' nurses worked, the more there was an increase in their professional satisfaction and professional quality of life. On the other hand, it was seen that the mean scores on the managerial support, peer support and direct workload subscales were lower, pointing to more negative perceptions. Managerial support is essential in operating room nursing, and it is especially important for inexperienced nurses. Operating rooms are open to conflict due to the complexities of having multiple disciplines work together and the necessity for highly technical skills (25, 26). Under these circumstances, enlisting the support of nurse supervisors is important for establishing and maintaining a well-working team and preventing incidents of malpractice (27, 28). In the study conducted by Ciftcioglu et al. (2018), the highest results were in the peer support, managerial support, and workload subscales (24). Similar studies have also demonstrated that the highest subscale scores appear on the peer support subscale (14). Another study found that the highest scoring subscale of the Individual Workload Perception Scale was the managerial support subscale (23). The direct workload subscale reflects the effect of the workload on employees and is affected by factors such as expectations, resource sufficiency, sufficient number of competent personnel, and fair distribution of duties (14). All of these factors are necessary for the effective conduct of healthcare services (2). Many factors may be responsible for the fact that the mean workload subscale score was lower than in the other subscales in our study. One of these is the long working hours. In our study, the direct workload perception scores of the group that was working 40 hours or more were higher. In another study, it was reported that it was the higher number of night shifts nurses worked that was the cause of the increase in the perceptions of workload in the direct workload subscale (23). According to the regulations of the International Labor Organization (ILO) on the working hours of healthcare workers, the recommendation is a 40-hour working week for nurses (29, 30). Although the number of hours is officially defined by law, nurses usually work more than what has been stipulated. Working shifts and long working hours are reported to cause stress, fatigue, diminished performance and professional satisfaction, and higher workload perceptions, all of which increases the risk of malpractice (7, 16). Also in our study, there was a significant difference found between the workload subscale and years spent in the profession; satisfaction was higher in nurses who had been working for 5 years or less. This was found to be due to the support supervisors offer young nurses starting to work in the operating rooms. This hypothesis is also supported by the fact that the managerial support subscale mean score was the highest in this young age group. There were significant differences in terms of the gender variable in the managerial support, direct workload, and the overall Individual Workload Perception Scale; it was determined that male participants had higher mean scores. Ozyer, (2016) also found higher scores in the peer support subscale in male nurses (23). Ciftcioglu, et al. (2018) could not detect any

differences in the overall and subscale scores of the Individual Workload Performance Scale according to the gender variable (24). We think that the difference in our study was due to the fewer number of male participants in our study.

5. CONCLUSION

In conclusion, we found that operating room nurses perceived their workloads to be at high levels. This perception was related to many factors such as long working hours, communication, materials support, and support from peers and managers. Trying to improve the working conditions of nurses working in operating rooms in which malpractice can cause grave consequences is a priority if possible cases of malpractice are to be prevented. In addition, effective communication within the team should be established to achieve safety in healthcare in the operating room, and all operating room team members should develop and adopt an institutional culture of patient safety. In particular, support offered to new nurses in the operating room by their seniors, improving technical and environmental conditions, and up-to-date in-service training may be recommended to develop the culture of patient safety in the institution and to reduce malpractice in the operating rooms.

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The Effects of Cord Clamping Time and Early Skin-to-Skin Contact on Maternal Birth Satisfaction in Term Infants

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ABSTRACT

Objective: Meeting the expectations of mothers during labor is defined as birth satisfaction. Evaluation of women's perception of satisfaction at birth is an important quality criterion in the evaluation of services. This study aims to determine the effect of cord clamping time and early skin contact on maternal birth satisfaction.

Methods: Randomized controlled experimental study. The study data were collected between June and December 2018, from a total of 80 participants.

Results: Case group was applied late cord clamping and skin contact, control group was applied routine care. The first breastfeeding time was 11.20 ± 5.16 min. for the case group and 44.55 ± 18.03 min. for the control group ($p < 0.001$). Neonatal blood glucose levels within the first 15 minutes were 91.23 ± 20.61 mg/dL for the case group and 83.13 ± 14.17 mg/dL for the control group ($p = 0.044$). Hemoglobin levels of the newborn 24 hours after birth were 18.90 ± 1.58 g/dL for the case group and 18.13 ± 1.78 g/dL for the control group ($p = 0.042$). The difference between the before and after birth hemoglobin-hematocrit values of the mothers was not statistically significant ($p = 0.327$ for Hgb; $p = 0.238$ for Htc). Postpartum satisfaction levels of the mothers were found to be 106.28 ± 9.52 for the case group and 99.93 ± 13.17 for the control group; mothers at the case group had higher postpartum satisfaction levels ($p = 0.016$).

Conclusion: Late cord clamping and early skin contact in newborn positively affect the first breastfeeding time, hemoglobin, hematocrit and blood sugar levels of newborns and can be considered as an important factor that increases mothers' satisfaction independent of many variables.

Keywords: Newborn, late cord clamping, skin to skin contact, maternal birth satisfaction.

1. INTRODUCTION

The World Health Organization (WHO) recommends 1-3 minutes postpartum as the cord clamping time for all non-asphyxial newborns that do not require resuscitation (1). According to the routine approach in Turkey, it is considered appropriate to keep the umbilical cord at the baby-perineum level (30-45 sec) due to the risk of polycythemia and hyperbilirubinemia.

The mother and the baby should not be separated from each other within the first two hours after birth and should spend this time in skin contact with each other. Weighing, measuring, dressing, performing the first examination, etc., which requires separation from the mother. procedures should be performed at the end of the monitoring period in the delivery room, after two or three hours. Immediate skin to skin contact (SSC) after birth was associated with stable body temperature, stable blood glucose level, less crying, less respiratory distress, earlier and more effective sucking, and longer breastfeeding time (2).

Meeting the expectations of mothers during labor is defined as birth satisfaction. Every woman's expectation from birth is different and each woman's satisfaction varies according to different characteristics. Evaluation of women's perception of satisfaction at birth is an important quality criterion in the evaluation of services. Increasing the quality of maternity services and reducing the cost per patient has become a health policy adopted by all countries of the world (3,4).

Giving birth is an important experience in women's life. A traumatic birth experience may pose a risk to problems such as post-partum depression, post-traumatic stress disorder, sexual dysfunction, Cesarean section, inadequate maternal attachment and infant neglect (5-7).

Demographic characteristics of the mother, mode of delivery, planning of delivery, hospital environment and facilities, attitudes and behaviors of health personnel, and the effects of various factors such as prenatal education have been

evaluated in the studies conducted on birth satisfaction and results vary (8-14).

The effects of Early Cord Clamping (ECC) and early skin-to-skin contact (SSC) are popular research topics in recent years, but there are not any studies being conducted on the effects of these on maternal satisfaction. In this respect, this research would contribute to the literature. The aim of this study is to determine the effects of ECC and early SSC on maternal birth satisfaction in term infants.

2. METHODS

This is a randomized controlled experimental study conducted to determine the effects of cord clamping time and early skin contact on maternal birth satisfaction in term infants. The table of random numbers was used in line with the simple random sampling method.

A total of 80 mothers and infants were included in the study, 40 in the control group and 40 in the case group. In the mothers included in the case group, the umbilical cord was cut after waiting for 1-3 minutes (mean 2 minutes) according to WHO recommendations and the newborn was laid naked in the mother's chest for the first 15 minutes. During the procedure, the baby's back was wrapped with a heated cover and the headgear was dressed. First breastfeeding and skin contact was provided. Measurements of height, weight, and head circumference, and administration of vitamin K and Hepatitis B vaccine were performed after the completion of skin-to-skin contact. Data were collected in the first 15 minutes, during the SSC. In the control group, the umbilical cord was cut within 30 seconds after the baby was born in accordance with routine hospital practices, and the routine care of the newborn was performed under a radiant heater.

2.1. Participants

The study data were collected between May 2018 and December 2018 from pregnant women who met the inclusion criteria and accepted to be involved in the study. The study sample consisted of 901 pregnant women who admitted to the state hospital for labor and delivery in the previous year. The power of the study was targeted to be 80% and $\alpha=0.05$, and the sample size was calculated. In the study, type I error was limited to 0.05 and type II error rate was limited to 0.20. Under these conditions, the minimum number of subjects required for each group was determined to be 37 in order to find a significant difference of 5.00 units between the two groups. The study was completed with 80 mothers (Consort Diagram: Appendix 1).

The inclusion criteria consisted of 'primiparous and multiparous mothers aged 18-38 years without any risk during pregnancy and postpartum' and 'healthy term babies born at term (38-42

weeks) and 2500-4000 g, with Apgar score above 7, with no need for resuscitation and any congenital anomalies'.

2.2. Data Collections and Tools

General Information Form, Maternal and Newborn Data Form, and Birth Satisfaction Scale (BSS) were used for data collection. General Information Form includes questions regarding the socio-demographic characteristics of the participants such as age, gender, marital status, education level, occupation, and number of children. Maternal and Newborn Data Form includes questions such as the mother and the baby's vital signs in the first 24 hours after the birth, the first breastfeeding time, and the Apgar score (Appendix 2).

BSS was developed by Caroline Hollins Martin and Valerie Fleming in 2011 to assess women's perceptions of birth (15). Validity and reliability were not made in the first form. Martin et al. revised the scale in 2014 and did a validity and reliability study, and reported the Cronbach's alpha value as 0.79 (16). Cetin et al. (2015) performed the validity and reliability study of the first version of the scale in Turkish Language (3). It is a 5-point Likert type scale and scored as follows: Strongly agree: 5, Agree: 4, Undecided: 3, Disagree: 2, Strongly disagree: 1. Items 4, 8, 12, 15, 16, 17, 19, 20, 21, 23, 25, 29 are scored in reverse. The scale has 30 items and the score can vary between 30-150 points, and the higher the score, the higher the satisfaction with birth. Cronbach's alpha value of the scale was 0.79 in this study.

The following measuring devices were used: Acon Mission Hb & Hct Meter, Seca 834 Digital Baby Scale, Clever chek TD-4231 Blood Glucose Meter

2.3. Data Analysis

In order to test the normality of data distribution, the skewness and kurtosis values were between -1.5 and +1.5 and the data were found to be reliable. The internal consistency coefficient (the Cronbach's alpha value) of the scale was 0.79. 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, one-way ANOVA analysis was used for comparison of more than two groups with normal distribution, and the non-parametric Kruskal-Wallis H test was used for comparison of more than two groups that were non-normally distributed.

2.4. Ethical Considerations

Approval was received from the Marmara University Faculty of Medicine Clinical Research Ethics Committee on April 6, 2018, with the protocol code 09.2018.274. Verbal and written informed consent was obtained from women who agreed to participate in the study. Permission to use the scale was obtained.

3. RESULTS

In the study, the mean \pm standard deviation (SD) age of the mothers was found to be 27.70 ± 5.50 in the case group and 26.67 ± 4.98 in the control group. There was no statistically significant difference between the case and control groups in terms of age, education, income level, working status, presence and number of children, family type, presence of chronic disease (diagnosed during pregnancy), Rh incompatibility, number of pregnancies, and gestational week ($p > 0.05$). The demographic characteristics of the two groups were similar.

In Table 1, according to the time of postnatal first breastfeeding the difference between the case group (11.20

± 5.16 min) and the control group (44.55 ± 18.03 min) was statistically significant ($p < 0.001$). The difference between systolic blood pressure values of the case group mothers (99.00 ± 8.41 mmHg) and the control group mothers (104.25 ± 10.83 mmHg) was statistically significant ($p = 0.018$). At the 60th minute and the 24th hour postpartum measurements, the difference between the pulse rate of the case group and the control group was statistically significant ($p = 0.046$ and $p < 0.001$, relatively). The difference between the before and after birth hemoglobin (Hgb) and hematocrit (Htc) values of the mothers was not statistically significant ($p = 0.327$ and $p = 0.238$, respectively).

Table 1. Comparison of Vital Signs and Blood Values of Mothers

Time of Measurement	Variables	Mean \pm SD		T	Sd	p
		Study Group n=40	Control Group n=40			
Postpartum	Time of first breastfeeding (min)	11.20 \pm 5.16	44.55 \pm 18.03	-11.245	45.36	0.000
Postpartum within the first 15 minutes	Systolic BP(mmHg)	99.00 \pm 8.41	104.25 \pm 10.83	-2.421	78	0.018
	Diastolic BP(mmHg)	63.00 \pm 8.23	64.75 \pm 9.87	-0.861	78	0.392
	Pulse Rate	79.83 \pm 7.54	80.68 \pm 5.75	-0.567	78	0.572
60 th minute of postpartum	Systolic BP(mmHg)	101.00 \pm 7.44	103.25 \pm 10.71	-1.091	69.52	0.279
	Diastolic BP(mmHg)	65.25 \pm 8.16	63.75 \pm 9.25	0.769	78	0.444
	Pulse Rate/dk	81.08 \pm 6.78	84.88 \pm 9.00	-2.031	69.76	0.046
24 hours after birth	Systolic BP(mmHg)	101.10 \pm 9.15	97.15 \pm 16.05	1.352	78	0.180
	Diastolic BP(mmHg)	63.00 \pm 6.26	61.70 \pm 9.19	0.739	68.81	0.462
	Pulse rate/dk	79.43 \pm 6.85	86.38 \pm 8.95	-3.902	78	0.000
Difference in Hgb and Htc levels before and after birth	Hgb (g/dL)	1.02 \pm 1.07	0.79 \pm 0.79	0.993	39	.327
	Hct (%)	3.97 \pm 5.51	2.42 \pm 5.54	1.197	39	.238

BP: Blood pressure; Hgb:Hemoglobin Htc:Hematocrit

In Table 2, blood glucose values of newborns measured at the first 15th minute after delivery were found to be 91.23 ± 20.61 mg/dL for the case group and 83.13 ± 14.17 mg/dL for the control group. The difference between the groups was statistically significant in favor of the case group. The difference between SpO₂ values, Hgb and Htc values measured in the newborns at the 24th hour postnatal period was statistically significant in favor of the case group ($p < 0.05$).

In Table 3, maternal BSS scores were 106.28 ± 9.52 in the case group and 99.93 ± 13.17 in the control group, and the difference between the groups was statistically significant ($p = 0.016$).

The correlation between birth satisfaction score and age, education, working status, presence of child, and family type was found to be statistically insignificant. The increased income status in the control group and the prenatal education satisfaction level in the case group were found to significantly correlate with birth satisfaction score.

Table 2. Comparison of Vital Signs and Blood Values of Newborns

Time of measurement	Variables	Mean±SD		T	P
		Study Group n=40	Control Ggroup n=40		
Postpartum within the first 15 minutes	APGAR first min.	9.00±0.00	8.93±0.27	1.778	0.083
	APGAR 5 th min.	10.00±0.00	9.93±0.27	1.778	0.083
	SpO2	94.58±8.97	94.98±6.85	-0.224	0.823
	Pulse Rate/dk	135.50±13.16	139.38±7.41	-1.622	0.109
	Body Temperature/ °C	36.65±0.29	36.57±0.21	1.541	0.127
	Blood Sugar(mg/dL)	91.23±20.61	83.13±14.17	2.049	0.044*
	Hemoglobin(g/dL)	20.31±1.33	19.93±1.53	1.172	0.245
	Hematocrit (%)	59.73±3.88	58.70±4.45	1.098	0.275
	Body weight(g)	3406.75±354.23	3289.75±480.77	1.239	0.219
24 hours after birth	Body weight(g)	3237.25±349.16	3131.75±472.67	1.135	0.260
	SpO2	97.30±1.07	96.08±1.89	3.575	0.001*
	Pulse rate/dk	128.63±11.25	125.38±9.45	1.399	0.166
	Weight loss(g)	162.70±63.19	158.00±54.64	0.356	0.723
	Blood sugar(mg/dL)	81.45±9.43	80.20±14.06	0.467	0.642
	Hemoglobin(g/dL)	18.90±1.58	18.13±1.78	2.067	0.042*
	Hematocrit (%)	55.65±4.63	53.30±5.14	2.148	0.035*

SpO2:Blood Oxygen Saturation

Table 3. Comparison of birth satisfaction levels of mothers in the case and the control groups

Mean±SD		T	Sd	P
Experimental Group (n=40)	Control Group (n=40)			
106.28±9.52	99.93±13.17	2.471	70.99	0.016

4. DISCUSSION

No statistically significant difference was found between the case and the control groups in terms of age, education, income, working status, presence and number of children, family type, chronic disease (diagnosed during pregnancy), Rh incompatibility, number of pregnancies, and gestation week ($p>0.05$). The demographic characteristics of both groups were similar and the groups were homogeneously distributed.

In the study, the time to start breastfeeding was significantly earlier in the case group ($p<0.001$). Continuous skin contact until the time of first breastfeeding facilitates breastfeeding and helps the baby gain a better suction technique from the very beginning (2). WHO recommends SSC with the mother during the first hour after birth to prevent hypothermia and to promote breastfeeding in newborns without complications (1).

Similar to the results of the study, in the studies conducted to determine the effect of post-partum early term baby skin contact on breastfeeding; early SSC was reported to have a positive effect on first breastfeeding time and breastfeeding success (17-22).

When the life signs of postpartum mothers were evaluated; control group mothers' systolic blood pressure in the first 15 minutes, and the heart rate after one hour and 24 hours was found to increase significantly. When stress physiology

is examined, it is stated that there is an increase in heart rate, blood pressure and respiration rate during stress and these values are regulated when coping with stress (23). In this respect, it can be said that the skin contact applied in the early postpartum period facilitates mothers' coping with birth stress. In parallel with the study, with SSC, a reduction in stress responses such as systolic blood pressure and cortisol levels has been reported in preterm infant fathers (24).

The differences between prenatal and postnatal maternal Hgb and Hct levels were not statistically significant. Similarly, in various studies, no differences were found in Hgb and Htc levels of mothers with Late Cord Clamping (LCC) and it was reported that LCC was not associated with postpartum hemorrhage (25,26). In this respect, it can be said that the cord clamping time has no negative effect on postpartum hemorrhage.

Hypoglycemia is frequently observed in healthy newborns as a result of the metabolic adaptation process in the first postpartum hours. Therefore, it is recommended that all babies should be breastfed for the first 30 minutes in the postpartum period (27). SSC at birth also facilitates immediate breastfeeding (18,19,21). In the study, blood glucose levels of the newborns who were treated with SSC at the first hour were found to be significantly higher. In studies examining various parameters of neonatal SSC administered at birth, it was reported that blood glucose levels were significantly safe (22,28).

LCC is recommended by the WHO. In evidence-based studies, it has been emphasized that LCC increases hemoglobin and hematocrit levels and therefore has hematological advantages (25,26,29-33). Similarly, Htc and Hgb values were significantly higher in the experimental group newborns at the 24th hour postpartum.

Evaluation of satisfaction perception of women at birth is an important criterion in the evaluation of health care. Childbirth is an important experience in women's life, the level of satisfaction in this process is considered important for maternal-newborn health and positive family relationships (5,8,34). As a result of traumatic birth experience in women; post-partum depression, post-traumatic stress disorder may cause problems such as sexual dysfunction, cesarean section, insufficient maternal attachment, and neglect of infants (5-7,35).

In the study, birth satisfaction levels of case group mothers were found to be higher ($p < 0.05$). When mothers' BSS scores were analyzed in terms of demographic characteristics, the relationship between BSS and age, education, working status, presence of child and family type was found to be statistically insignificant. According to the studies, the significance of the factors affecting birth satisfaction varies (4,8,9,11-14).

Limitations: Newborn blood sugar could not be measured at the 6th hour because it was not in hospital routines.

5. CONCLUSION

LCC and early skin contact in newborn positively affect the first breastfeeding time, hemoglobin, hematocrit, and blood sugar

levels of newborns. It can be said that mothers' satisfaction with birth is affected by too many components, but providing LCC and SSC provides significant efficacy independent of other factors. LCC and early SSC are important factors that increase maternal satisfaction regardless of age, education, working status, and presence of children. We can also say that birth satisfaction is an important factor for strategies to improve perinatal care

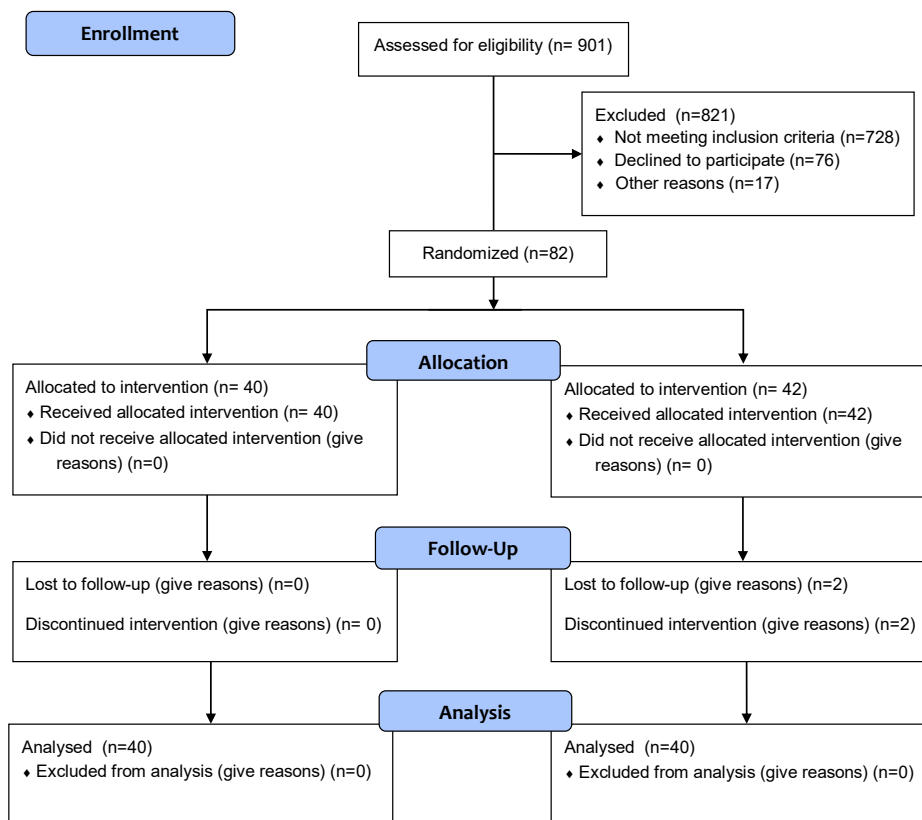
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Appendix 1. CONSORT Flow Diagram






Appendix 2. Data collection planning

	Mothers	Newborns
	Time of first breastfeeding time	
Post-partum first 15 minute	Blood pressure Pulse rate	APGAR (1-5min) SpO ₂ Pulse rate Body temperature Blood sugar Hemoglobin Hemotocrit
Postpartum 60 th minute	Blood pressure Pulse rate	Body weight
Postpartum 6 th hour	Hemoglobin Hemotocrit Bleeding control	Newborn blood sugar could not be measured at the 6 th hour because it was not in hospital routines
Postpartum 24 th hour	Blood pressure Pulse rate Birth satisfaction scale	Body weight Spo2 Pulse rate Blood sugar Hemoglobin Hemotocrit

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The Epidemiology of Students Injuries in a Private Primary School in Turkey from 2012 to 2018

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ABSTRACT

Objective: The aim of this study is to identify the occurrence frequency of school injuries, and to report where, when, and why they occur most.

Methods: This retrospective descriptive study includes students aged between 6 and 11 years and is composed of 7042 school injury records. The school was chosen by the purposive sampling method since there was a school nurse working at school. The school injury records were formed by all injury records kept by the school nurse. The data were evaluated using descriptive statistics.

Results: The study results showed that most of the school injuries occurred during the fall period (60.1%) and at break times (38.6%). As for the causes of the injuries, 13.3% of them were environmental, while 86.7% were behavioral. The floor on where most of the injuries occurred was rubber floor (53.6%) and the area where most of the injuries occurred was playground-garden (64%). The factor most frequently causing the injuries was hit collision, and the activity causing most of the injuries was running. The most frequently affected part of the body was head-neck-forehead-chin. The most common type of injury was tenderness and redness.

Conclusion: With this study, it is seen that the rate of injury among students is high. Most of the school injuries occurred during the break times and mealtimes. Most of the causes of injuries were behavioral. These epidemiological data would be a guide for studies on prevention of injuries.

Keywords: Wounds and injuries, epidemiology, schools, nursing.

1. INTRODUCTION

Injury is defined as intentional or unintentional damage to the body. These injuries generally include drowning, poisoning, falling, burning, violence, assault, self-harm and war (1,2). School injuries are unintentional injuries. As environments preparing children for life, schools also present some environmental risks. Risk factors for childhood injuries are related to factors such as locomotor skills, individual attention and control, emotional stress, psychological problems, physical activity, susceptibility to accident, problematic risk-taking behaviors, socio-economic and family factors, communication with schoolmates (3). Other than the risk factors related to child and family, the most common causes of injury among school-age children are male gender, physical condition of the school, school administration and wrong policies (1,3).

A study from Turkey investigating the risk factors that caused the injury showed that 53.6% of the risks stem from the child himself/herself, 37.5% from another child, 5.4% from school uncertainty and lack of control, and 3.6% from the school's environmental factors (4). In another study, most of the risk factors have arisen from the child himself/herself, the

irregularity and lack of control at school and the insufficient environmental factors at school (5).

School injuries are considered a major cause of death and disability among children in Europe and are an important public health problem around the world (2). The rate of school injuries varies by countries and regions. The rate of school injuries in global studies ranges from 5% to 54% (6-8). In the studies conducted in Turkey, this ratio is between 9% and 55.4% (4,9,10).

Injuries experienced by children can lead to permanent disability, physical problems and psychological problems both for them and their families. In addition, family and country economy are adversely affected by the medical costs resulting from these problems and the cessation of productivity (11,12).

It is essential for health professionals to identify the causes of school injuries to take measures against these negative consequences. Causes of school injuries can be attributed to students' individual characteristics (aggressive

behavior, loco-motor skills, physical activity, student profiles, susceptibility to injury, socio-economic and familial factors, interaction with school friends) and environmental characteristics of schools (ecological characteristics, dangerous activities, sports activities, playground) (3). Kılınc reported that 18.9% of the school children had at least one injury at school (13).

Areas where school injuries most commonly occur are the road to and from school, the classroom environment, gym, garden, corridor, cafeteria and canteen (1,8,13). The most dangerous areas where students experience injuries are gyms and school gardens (3). About four million children and adolescents aged 10 to 17 around the world are injured at school, and more than 1 million of them are injured while doing sports every year (14). The activities that most commonly lead to sports injuries are football, basketball, and volleyball, respectively (13).

In general, risks should be recognized to take adequate measures for injuries. Preventing school injuries is a key role for school nurses. It is school nurse's responsibility to identify risk factors by assessing the characteristics of the child, family and school environment. School nurses, who are responsible for the health of children, can test the benefits of safety measures in their research, and instill the awareness of preventing accidents to those who regulate the laws. They can take the advocacy role in the formation of legal regulations on accident prevention and attract the public's attention with their research. In addition, they can promote prevention and control of injuries by providing training and improving environmental protection strategies (3, 15).

Another important group that should be sensitive in taking necessary precautions against the risks of injuries is the school administration (1,15,16). In addition to a school administration taking all necessary measures with the required planning and arrangement, it is very important that children have the necessary knowledge and health belief to protect themselves from injuries (15,17,18). Parents also play a critical role in this regard because behaviors of parents before or after injuries are of importance in reducing the risk of injuries caused by the school environment and protecting children from injuries (1,16).

We believe that the findings of this study will guide school administrations, school nurses, teachers, students and parents by identifying the risk factors that lead to school injuries and answering questions 'when, where and during which activity the injuries occur' and 'what efforts are made after the injury'. The aim of this study is to identify the frequency of occurrence of school injuries, and to report where, when and why they occur most.

2. METHODS

2.1. Study Design and Participants

This retrospective descriptive study examined the epidemiology of school injuries occurred between September

2012 and June 2018. The study consisted of all the injury records of first, second, third and fourth grade students who were injured at a private school in Istanbul during this period. The school was chosen by the purposive sampling method since there was a school nurse working at school. The school injury records were formed by 7042 injury records kept by the school nurse.

There was a school nurse in the campus where the research was conducted and the nurse was working at the infirmary serving 350 students and 120 employees. In the school where the research was carried out, students were organized to use playgrounds so that each level could take a break at different hours. The school had two playgrounds (500 m²) in common areas, one large garden (500 m²) and two gyms (one indoor-one open).

The socio-economic conditions of the students enrolled in the school were quite good and their parents' education level was high. The institution and accessibility of the researcher were taken into consideration in the selection of the school where the research was conducted.

2.2. Data Collection Tools and Procedures

Data was obtained from the forms filed by the school nurse. The 'School Injury Form' was created by Gür and tested at a two-week preliminary study and finalized with the necessary arrangements; the preliminary study was conducted on 50 primary school students in 2004 (19). This form can easily be filled in for any student injured by the school nurse. The form filled in for each injured student was stored by the school nurse in the school injury file.

Since the data was entered by the nurse and regularly checked, no missing data was detected. Data was entered into the data set by the researchers within a period of 2 weeks. The number of responses of each item might vary. The questions included 'when and where the student had the injury at school, the type of injury, the injured body area, and the activities that caused the injury'. The students were categorized by characteristics such as gender, injury time at school, and injury type. Information about the injury-causing activity, area of the injury, time of occurrence, type of injury, and the post-injury intervention was obtained for each student.

2.3. Data Analysis

Data was evaluated by IBM Predictive Analytics Software (PASW) Statistical Product and Service Solutions (SPSS, Chicago, IL, USA) version 22. The data analysis utilized frequency, percentage, mean \pm standard deviation for the epidemiology of school injuries.

2.4. Ethical Consideration

This study was ethically approved by TR Pamukkale University Non-Invasive Clinical Research Ethics Committee (10.07.2018-14). The records of the study were used with

the written permission of the school administration and the school nurse.

3. RESULTS

A total of 7042 school injury records were examined. The mean age of 7042 students who had an injury at school was 8.36 ± 1.26 (min= 6; max= 11). 60.4% of the students were boys and 39.6% were girls (Table 1). There were also recurrent records of students among these injury records.

Table 1. Sociodemographic Characteristics and Injury Records (n=7042)

Characteristics		n	%
Gender	Boy	4253	60.4
	Girl	2789	39.6
Age	6	326	4.6
	7	1737	24.7
	8	1895	26.9
	9	1483	21.1
	10	1352	19.2
	11	249	3.5

By years, school injuries were most frequently seen between 2012 and 2013 (Figure 1). School injuries most frequently occurred during break times, meal time, lunch break and leisure time (77.1%). It was found that most of the injuries occurred in the fall term, in December and between the hours 12:01 and 14:00 (Table 2).

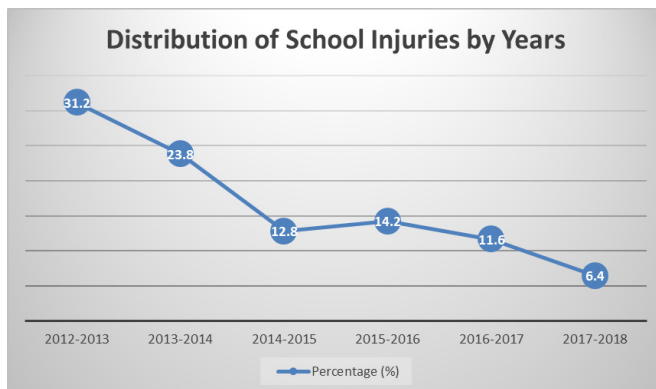


Figure 1. Distribution of School Injuries by Years (n=7042)

As for the causes of the injuries, 13.3% of them were environmental while 86.7% were behavioral. The factor causing most of the injuries was hit-collision (46.8%), and the activity causing most of the injuries was running (40.5%). The floor on where most of the injuries occurred was rubber floor and the area where most of the injuries occurred was playground-garden (Table 3).

The most frequently affected part of the body was head-neck-forehead-chin (31.4%) (Figure 2). The most common type of injury was tenderness (99.7%) and redness (19.0%) (Figure 3).

19.3% of the students were subjected to activity restriction after the injuries, and only 0.7% of them were absent from the school. All the students at the school were given first aid by the school nurse, families of 53.6% were informed, and 0.3% of them were referred to a healthcare clinics/hospital after the injuries.

Table 2. School Injuries by Periods, Times and Hour Intervals (n=7042)

		n	%
Term	Fall	4230	60.1
	Spring	2812	39.9
Month	September	686	9.7
	October	827	11.7
	November	908	12.9
	December	943	13.4
	January	608	8.6
	February	521	7.4
	March	898	12.8
	April	794	11.3
	May	472	6.7
Hours	Between 08.00-10.00	692	9.8
	Between 10.01-12.00	1981	28.1
	Between 12.01-14.00	2721	38.6
	Between 14.01-16.00	1648	23.4

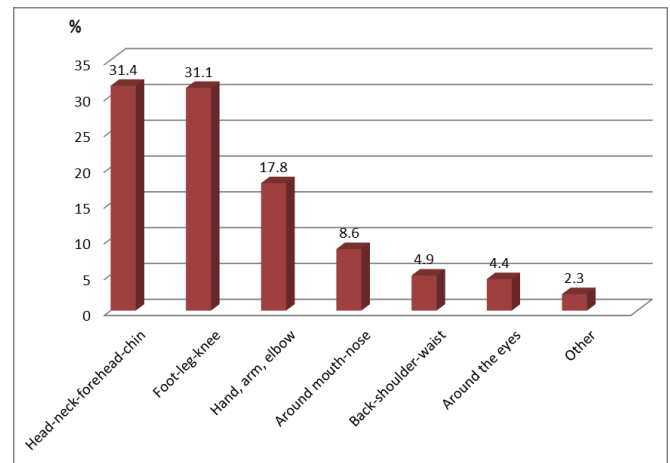


Figure 2. Body areas affected with school injury (n=7042)

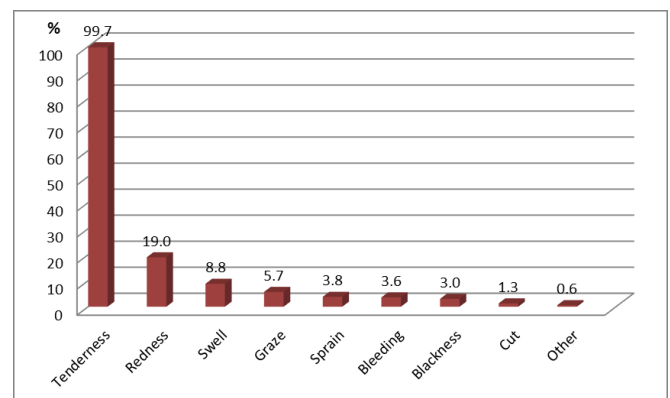


Figure 3. Types of injuries and symptoms caused by school injury (n=7042)

Table 3. Factors and Activities Causing School Injuries (n=7042)

		n	%
Cause of injury	Environmental	937	13.3
	Behavioral	6105	86.7
Factor causing the injury	Collision-hit-strike	3294	46.8
	Falling	2316	32.9
	Injury with a tool/object	962	13.7
	Sprain	246	3.5
	Getting stuck – jamming	183	2.6
	Animal bite – scratching	24	0.3
	Heat – electricity	17	0.2
Sports injuries	Running	2850	40.5
	Pushing around	2214	31.4
	Walking	578	8.2
	Football	465	6.6
	Volleyball	359	5.1
	Sitting	246	3.5
	Basketball	171	2.4
	Slipping	72	1.0
	Jumping	50	0.7
Riding on a swing	37	0.5	
Floor of injury	Tartan (rubber) floor	3777	53.6
	Asphalt-concrete-tile-ceramic	2409	34.2
	Carpet-rug-mat	660	9.4
	Gravel-sand-grass-soil	187	2.7
	Slippery floor-frosted-wet	9	0.1
Area of injury	Garden-playground-park	4505	64.0
	Classroom-library-events	1490	21.2
	Gym	447	6.3
	Corridor-stairs	440	6.2
	Cafeteria-canteen	70	1.0
	Toilet	41	.6
	School service-school premises	37	.5
	Lab	12	.2

4. DISCUSSION

Our study showed that boys had more injuries than the girls. In the literature, it was also observed that boys more frequently had injuries than girls (6,9,10,13). The fact that boys had injuries more frequently than girls might be due to riskier behaviors of boys, their stronger physical activity levels and aggressive structures, and harsher behaviors and understanding of game between boys as well as the cultural structures in which parents and society have different expectations from the male character. Therefore, it is thought

that the rate of injuries experienced by boys is higher as they are more prone to risky behaviors (10,20).

When individual factors affecting school, injuries were examined; the age factor was found to be important (3,10,21). In our study, the age range that students experienced injury most frequently was between the ages of seven and nine. Cognitive and behavioral skills of school children are immature (their physical condition is weak and prone to clumsiness). Elementary school children are curious, investigative and unaware of the dangers, creating a high risk of injuries (8,3,19).

In our study, school injuries decreased compared to years. Information was obtained from the school nurse about the reason for this situation. Accordingly, the reason for this situation was the training provided by the school nurse to prevent injuries. In addition, it is thought that this might have been affected by the improvement of the school's physical security structure. Researches in the literature also indicate that providing education and increasing school security reduces injuries (3,15,18).

It was observed that most of the school injuries occurred during break times, lunch break-meal time or leisure time. Other studies in the literature determined that most of the injuries occur during the break times (8,10,13,21). Break times are among the periods in which children rush up and down the stairs when going to the canteen and push each other around in and outside school, that is, they are at their most active time. It is thought that the increase in injuries is caused by their desire to get out of classrooms where they are kept under control and most of their behaviors are restricted and to act more uncontrollably when the bell for the break time rings. As in other studies (10,21), it is thought in this study that the reason why most of the school injuries were observed in December and at noon might have been the increased incidents of slipping during snow and rainfall in winter and noon being the most energetic time for children.

School injuries can be caused by the students' own behaviors as well as by the unsafe school environment (3). This study found that 13.3% of the causes of injuries were environmental while 86.7% were behavioral. Akçay and Yıldırım observed that 3.6% of the injuries were due to environmental factors while Gevrek Akar found a rate of 17.3% (4,5). Although student behaviors are highly effective in the occurrence of injuries, the risks of school safety need to be minimized.

It was observed in our study that the factors causing most of the school injuries were hit-collision, falling, and injury by a device while the activities causing the most school injuries were running, pushing around, walking, football and volleyball. In other studies, on school injuries (5,8-10,13), falling, collision, running, walking, and playing football, volleyball and basketball were among the factors and activities that cause injuries. The reason for this finding might be the fact that children act carelessly and without protecting themselves during physical education classes, break times and leisure times and do sports without protecting themselves,

warming up and wearing protective equipment. To prevent injuries, it is necessary that students are told not to prefer slippery shoes and run on slippery surfaces in the school and school administration put warning signs near slippery floors, and to prevent sports injuries, training and counseling should be provided about warming up and wearing protective equipment (kneepads, elbow pads, etc.) before doing sports.

As for the floor and area of injuries, most of the injuries occurred on tartan (rubber) floor which was followed by asphalt-concrete-tile floor whereas most of the injuries occurred in garden-playground, classroom, gym and corridors-stairs. It is thought that injuries were more frequent in areas such as playgrounds, gardens, corridors and stairs where students are the most active; this finding is in line with those of other studies (5,8-10,13). However, in our study, the reason why the floor where most of the injuries occurred on was tartan (a two-layer, water-permeable, granular, flexible sports floor made of rubber) is that garden and sports areas of the school where the was conducted were tartan-covered. As explored by national and international studies, since the most used building materials in and outside the school are concrete and asphalt, these hard floors cannot absorb the fall-related impact and can lead to severe symptoms as a result of injury (22-24). It should be ensured through the cooperation with school administration to cover school gardens and playgrounds with rubber-content materials to prevent these severe injuries.

In our study, head-neck-forehead-chin body region was affected the most after the students' injury. Then, the extremities (foot-leg-knee, hand, arm, elbow) were affected. In the study of Gür, in primary school students, it was determined that the head and extremities were affected the most (19). In the study of Eraslan and Aycan, research results are in line with our study results (10). Students' being constantly in motion and fall and collision while running, sliding, jumping, doing sports and climbing is the most common cause of head injuries. According to our study, the extremities are the most injured area of the body. This is thought to be due to the individuals protecting their vital organs with the help of extremities during injury (13,19).

In our study, most frequently tenderness, redness, swelling and graze occurred as the types of injuries. In Özkan's work, the most common types of injuries were graze, swelling and bruising (25). In the study of Gür, swelling, tenderness and graze were observed the most (19). In the study of Eraslan and Aycan, hurt, sprain, bruising, swelling and graze occurred the most (10). The leading reason for this is that the causes of injury are mostly falling, crashing, and sports-related (19).

Our study showed that all the students who had a school injury were given first aid by the school nurse, only 0.3% of them were referred to the health institution, and 0.7% were absent from the school. In other studies, the rate of referral to health institutions varied between 7.5 and 35.2% (5,10,13). The reason can be associated with the high rate of referral of students to hospital and the low rate of first aid. Şengel and Gür observed that all of the students were given

first aid by the school nurse after the injury, only 1.9% of the students applied to the infirmary due to injury in the last two years, and only 1.9% were absent from the school (21). Akçay and Yıldırım reported that the first intervention was performed to the students by their teachers (64.3%) and the school health personnel (8.9%), and 37.5% of the students went to the hospital/visited a physician after the injury (4). In the study of Ayaz, 92.7% of the primary school teachers stated that school nurses were required at school (26). These findings indicate that students are mostly referred to health institutions and students' absenteeism is increased in schools that do not employ school nurses. It was also shown in international studies that nurses are effective and needed to prevent school injuries (27,28).

School administration, teachers, parents, and most importantly, school nurses play a key role in this matter. The duties and powers of school health nursing were published in the Official Gazette on 19 April 2011 (29). In this regulation, "School Health Nursing" falls within the scope of Public Health Nursing and have several roles. The article "he/she cooperates with students, families, school administrations and educators in improving the prevention of injuries and safety precautions" sets one of the school nurse's duties, powers and responsibilities. In this context, school nurses should develop intervention programs with existing research evidence and cooperation with school administration to create a safe school environment. Such intervention programs based on models that provide behavioral change such as health belief model can contribute to their effectiveness (18,30-33).

In this context, establishing a safe school environment through employment of school health nurses who are effective in protecting, improving and maintaining students' health, preventing injuries and injuries, giving first aid to students who have had an injury are required for the continuation of a healthy society.

Limitations

The main limitation of the present study is the limitation of generalizability of the results due to results from only one private school. The institution and accessibility of the researcher were taken into consideration in the selection of the school where the research was conducted. The school was chosen by the purposive sampling method since it is a school nurse at school.

5. CONCLUSION

Our study found out that boys had injuries more frequently, most of the injuries occurred during break times and lunch times, were caused by behavioral problems and as a result of hit, and the activity which caused the most of injuries was running. It was determined that the injuries in the school were mostly experienced on rubber ground and that they were mostly in playgrounds and gardens. After the accidents, the head and extremity areas of the students

were injured the most. The most common injury after the accident is tenderness, redness, swelling and graze. School nurses made first aid interventions for all injured students. Thus, unnecessary referrals to healthcare institutions were prevented.

It is accordingly recommended that school nurses who can provide extensive school healthcare service are employed in every school to create safe schools; non-slippery, rubber floors which dampens the fall impact are used to minimize environmental risk factors in all schools. In addition, more extensive epidemiological studies for school injuries are recommended.

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Conflict of Interest

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Validity and Reliability of the Exercise Health Belief Model Scale

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ABSTRACT

Objective: The aim of this study was to investigate the validity and reliability of the Turkish version of the Exercise Health Belief Model Scale (EHBMS).

Methods: This methodological study was conducted in 2018-2019 academic year with students from two universities located in east and west provinces of Turkey (n= 743). The sociodemographic data and those from the EHBMS scale were collected. This five-point likert-type scale consists of 32 items and five factors. Construct and content validities were used to evaluate the validity of the scale, and its reliability was investigated with item-total correlation, internal consistency and test-retest method.

Results: The content validity index (CVI) of the scale was 0.98. While the Cronbach Alpha coefficient of the scale was 0.87, the alpha values of the factors were as following: 0.87 for general health value, 0.76 for beliefs about the vulnerability of not exercising, 0.87 for beliefs about the severity of not exercising, 0.87 for beliefs that exercising can reduce threats, and 0.77 for beliefs that the benefits exceed the costs of exercising. The test-retest correlation value was 0.88 ($p<0.05$) for the whole scale. The model fit indices of the five-factor structure of the scale were found to be good.

Conclusion: The Turkish version of the Exercise Health Belief Model Scale was found to be a valid and reliable scale.

Keywords: Exercise, Health Belief Model, Reliability, Scale, Validity

1. INTRODUCTION

Modern technology has dramatically reduced the habits of people to move. Cars have reduced our need to walk, and machines that do heavy work for us have taken their place in daily life. In addition, devices such as televisions and computers cause us to remain inactive for long periods of time. Research shows that even the most inactive people can gain significant health benefits when they perform light exercises, such as short walks, on a regular basis (1). Exercise programs planned on scientific basis have become a necessity of our daily life (2).

Although the positive effects of physical activity and exercise on health are widely known, the physical activity level of the majority of people worldwide is low (3). According to the latest data from the World Health Organization (WHO), one in four adults (1.4 billion people) worldwide does not follow physical activity recommendations that reduce common chronic diseases and increase health and well-being (4). Physical activity is an important indicator of a healthy life. Considering the clinical, psychological and social benefits,

physical activity is found to be the most important factor contributing to healthy aging (5). In line with both the physiological and psychological benefits of physical activity, encouraging participation in physical activity is amongst the priorities of promoting public health in many developed countries (6).

Health behaviors include all actions related to health protection and health promotion. Many theories and models related to behavior change have been developed (7) and using these models plays an important role in nursing as these models guide health behaviors and indicate possible interventions that might be needed (8, 9). Since the early 1950s, the Health Belief Model (HBM) is one of the most widely used models in health-related behavior research, both to explain the change and maintenance of health-related behaviors and as a guiding framework for initiatives towards health behavior (10). The model explains the indicators of the use of preventive health behaviors (11, 12). According to this model, the individual's desire to participate in physical

activities depends on his/her perception of how beneficial or harmful his/her current health behavior is (13, 14).

In addition to being very beneficial for the health of young people, physical activity in this population becomes a habit and leads to long-term benefits. On the larger scale, it positively influences both the individual and the community health. Therefore, assessment of the persistence level of physical activity in different stages of life is useful for planning future interventions (15). In programs aiming to increase physical activity in adults, using a valid and reliable health belief model scale will be useful in planning, evaluating, and implementing effective programs.

In this regard, there is no measurement tool based on health belief model in Turkey. Hence, the aim of the present study is to translate and adapt the Exercise Health Belief Model Scale (EHBMS) developed by Esparza et al. (2017) into Turkish and to investigate its reliability and validity.

2. METHODS

This methodological study was conducted with 743 undergraduate students from two universities in 2019. Inclusion criteria were being a university student and volunteering to participate and exclusion criteria were not wanting to participate in the study and filling in the data collection forms incompletely.

2.1. Data Collection

Using self-report method, all the data were collected using descriptive information form and EHBMS. The test was repeated 4 weeks later with 100 students. *Descriptive information forms* were created by the researcher, this form consists of 11 questions regarding age, gender, place of residence, financial status, health status, place of residence of the family, etc.

2.1.1. Exercise Health Belief Model Scale (EHBMS):

Developed by Esparza et al. (2017), this 5-point Likert-type scale consists of 32 items. For items 1 to 26, the response options are as following: "1. Not at all", "2. A little", "3. More or less", "4. Quite a bit", and "5. A lot". For items 27 to 32, the response options are: "1. I don't believe", "2. Maybe, but it's unlikely", "3. I believe it's likely", "4. I believe it's very likely", and "5. I believe, I'm sure of it". The scale consists of 5 factors and there is no reverse item. The highest and lowest score on the scale is 160 and 32, respectively. Higher scores indicate higher level of exercise health belief (16).

Cronbach Alpha coefficients of the five factors in the original scale are as following: 0.84 for general health value, 0.67 for beliefs about the vulnerability of not exercising, 0.90 for beliefs about the severity of not exercising, 0.85 for beliefs that exercising can reduce threats, and 0.75 for beliefs that the benefits exceed the costs of exercising.

2.2. Translation Process

As the first step, a linguist and a professor with good command of English translated the original scale from English to Turkish. The translation was reviewed and edited by the researchers, and the Turkish version of the scale was translated back to English by two different linguists (17). The back-translated scale was sent to the developer, Esparza, for evaluation and compliance approval.

2.3. Validity and Reliability

The validity of the scale was tested in terms of construct and content validity. After the translation, ten academician nurses were asked for their opinions regarding scale validity. Both qualitative and quantitative data were obtained from the experts. Quantitatively, the experts were asked to evaluate and score the relevance and intelligibility of each scale item on a range of 1 to 4. Qualitatively, they were asked to submit their written opinions about the scale items. Construct validity was assessed using confirmatory factor analysis. The reliability of the scale was tested using internal consistency, item-total correlation and time invariance methods.

2.4. Data Analyze

SPSS Statistics 22.0 and Lisrel 8.80 programs were used to analyze the data. Descriptive statistics were used to analyze sample characteristics. Content validity of the scale was assessed using the Content Validity Index (CVI) as proposed by Lynn (1986) (18).

CVI was calculated for each of the scale items as well as the whole scale. For each item, the CVI was calculated by dividing the number of the experts who scored the item as 3 or 4 to the total number of the experts. The arithmetic mean of CVIs of all items was recorded as the CVI of the entire scale. Test-retest reliability was examined using Pearson correlation analysis. Internal consistency was evaluated using Pearson correlation (item-total correlation) and Cronbach α . Confirmatory factor analysis was performed for construct validity. Multiple confirmatory indices were used for Confirmatory Factor Analysis. Fit indices $>.95$ for Goodness of Fit Index (GFI), Adjusted Goodness of Fit Index (AGFI), Comparative Fit Index (CFI), Non-Normed Fit Index (NNFI) and Root Mean Square Residual (RMR); and fit indices $<.05$ for Root Mean Square Error of Approximation (RMSEA) and Standardized Root Mean Square Residual (SRMR) indicate perfect fit. However, for the RMSEA and SRMR, $<.08$ indicates good fit. Furthermore, although χ^2/df value is preferred to be ≤ 2 , the model is still considered acceptable if this value is less than 5 (19, 20).

2.5. Strengths and Weaknesses of the Research

This scale is a scale developed based on health belief model. Adaptation to Turkish is the strength of this study.

3. RESULTS

79.8% of the students participated in the study were females, 51% were residing in dormitories, 84.9% had moderate financial status, 75.5% had no sports facilities in their university, 58.7% had no access to suitable areas to do sports in their neighborhood, 71.3% were coming from families with no major interest in sports, 88.3% had no illnesses, 50.5% were in good health, and 42.5% were living in city centers (Table 1).

Table 1. Sociodemographic characteristics of the participants

	n	%
Gender		
Male	150	20.2
Female	593	79.8
Place of Residence		
With Family	268	36.1
Student House	96	12.9
Dormitory	379	51
Financial Status		
Low	89	12
Moderate	631	84.9
High	23	3.1
Are there any sports facilities in your university?		
Yes	182	24.5
No	561	75.5
In your neighborhood, are there any areas where you can do sports?		
Yes	307	41.3
No	436	58.7
Are any of your family members interested in sports?		
Yes	213	28.7
No	530	71.3
Do you have any illnesses?		
Yes	87	11.7
No	656	88.3
Health Status		
Good	375	50.5
Moderate	360	48.5
Poor	8	1
Family Place of Residence		
City Center	316	42.5
Suburbs	282	38
Countryside	34	4.6
Village	111	14.9

0.87 for general health value, 0.76 for beliefs about the vulnerability of not exercising, 0.87 for beliefs about the severity of not exercising, 0.87 for beliefs that exercising can reduce threats, and 0.77 for beliefs that the benefits exceed the costs of exercising.

3.1. Reliability

The Cronbach Alpha coefficient was found to be 0.87 for the entire scale. Cronbach Alpha coefficients of the five factors of the scale were as following: 0.87 for general health value, 0.76 for beliefs about the vulnerability of not exercising, 0.87 for beliefs about the severity of not exercising, 0.87 for beliefs that exercising can reduce threats, and 0.77 for beliefs that the benefits exceed the costs of exercising. The factors of the scale items and item-total score correlations were between 0.23-0.88 and were statistically significant ($p < .001$) (Table 2). The test-retest reliability correlation value of EHBMS was found to be 0.88.

3.2. Validity

Content validity; considering the experts' opinions regarding the relevance and intelligibility of the scale items, the CVI of the items was found to be between 0.90 and 1, and the CVI of the entire scale was 98%.

Construct validity; was assessed using confirmatory factor analysis. The result of confirmatory factor analysis revealed that although chi-square value ($\chi^2 = 2577.21$, $df = 454$, $p = .00$) was significant, chi-square/degree of freedom ($\chi^2/df = 5.6$) was higher than expected. Goodness of fit values were CFI = .93; NNFI = .93; SRMR = .066; and RMSEA = .079 (Table 3) (21).

Table 3. Confirmatory factor analysis fit indices

Fit Indices	Definition *	Results
X2 / Degree of Freedom	Below 5 = moderate fit Below 3 = perfect fit	2577.21/ 454=5.6
P value	$P < .05$ = no fit $p > .05$ = perfect fit	0.000
Goodness of Fit Index (GFI)	Above .90 = good fit Above .95 = perfect fit	0.82
Adjusted Goodness of Fit Index (AGFI)	Above .90 = good fit Above .95 = perfect fit	0.79
Comparative Fit Index (CFI)	Above .90 = good fit Above .95 = perfect fit	0.93
Non-Normed Fit Index (NNFI)	Above .90 = good fit Above .95 = perfect fit	0.93
Root Mean Square Residual (RMR)	Below .10 = weak fit Below .08 = good fit Below .05 = perfect fit	0.058
Standardized Root Mean Square Residual (SRMR)	Below .10 = weak fit Below .08 = good fit Below .05 = perfect fit	0.066
Root Mean Square Error of Approximation (RMSEA)	Below .10 = weak fit Below .08 = good fit Below .05 = perfect fit	0.079

Table 2. Psychometric properties of exercise health belief model scale

Sub-scales	Scale Items	X	Ss	r	r ₁	CFL	α
General health value	1. How much are you interested in your health?	3.50	0.90	0.30	0.75	78	
	2. How much do you think about your health?	3.65	0.92	0.29	0.83	88	.87
	3. How much do you care about your health?	3.81	0.96	0.32	0.80	80	
	4. How much important do you think it is to pay attention to your health?	4.25	0.90	0.30	0.54	48	
Beliefs about the vulnerability of not exercising	5. How much serious is it to suffer from high blood pressure?	4.55	0.76	0.37	0.54	40	
	6. How much serious is it to have diabetes?	4.61	0.73	0.42	0.66	47	
	7. How much serious is it to suffer heart attack?	4.79	0.58	0.43	0.68	47	.76
	8. How much serious is it to suffer heart a stroke?	4.83	0.55	0.48	0.66	48	
	9. How much serious is it to get cancer?	4.79	0.60	0.42	0.56	43	
	10. How much serious is it to get weight?	3.75	1.04	0.31	0.22	23	
Beliefs about the severity of not exercising	11. How much do you think exercise will help you to prevent being a patient with high blood pressure?	4.13	0.87	0.45	0.55	49	
	12. How much do you think exercise will help to prevent (or control) diabetes?	4.04	0.90	0.50	0.60	54	
	13. How much exercise do you think will help to prevent heart attack?	4.24	0.84	0.53	0.65	56	
	14. How much exercise do you think will help to prevent strokes?	4.02	0.96	0.39	0.52	51	
	15. How much exercise do you think will help to prevent cancer?	3.81	1.09	0.47	0.60	64	.87
	16. How much exercise do you think will help to prevent gaining weight	4.46	0.83	0.52	0.59	56	
	17. How much do you think exercise will help you to have better health?	4.48	0.78	0.63	0.68	62	
	18. How much exercise do you think will help to have a better quality of life	4.43	0.83	0.63	0.65	64	
	19. How much do you think exercise will help to live longer?	4.17	0.97	0.51	0.55	65	
	20. How much do you think exercise will help to appear better?	4.29	0.91	0.59	0.53	61	
Beliefs that exercising can reduce threats	21. Is it worth [to spend time and to deal with laziness] to make efforts to exercise to prevent diseases in the future?	4.23	0.83	0.60	0.65	61	
	22. Is it worth the to make effort [to spend time and dealing with laziness] to exercise for a better health?	4.30	0.83	0.61	0.71	67	
	23. Is it worth the to make effort [to spend time and to deal with laziness] to exercise for a better quality of life?	4.29	0.81	0.64	0.76	69	.87
	24. Is it worth the to make effort [to spend time and to deal with laziness] to exercise to live longer??	4.02	1.00	0.54	0.71	76	
	25. Is it worth the to make effort [to spend time and dealing with sloth] to try to appear better?	4.14	0.93	0.54	0.65	66	
	26. Even if exercising is difficult, it is worth doing to prevent diseases in the future.	4.26	0.88	0.51	0.61	58	
Beliefs that the benefits exceed the costs of exercising	27. Do you think you can be a high blood pressure?	2.53	0.98	0.17	0.58	77	
	28. Do you think you can be a diabetes?	2.63	1.03	0.24	0.64	85	
	29. Do you think you can have a heart attack?	2.84	1.05	0.15	0.57	65	.77
	30. Do you think you can have a stroke?	2.51	1.01	0.17	0.58	64	
	31. Do you think you might have cancer?	2.74	1.13	0.14	0.56	64	
	32. Do you think you can get weight?	3.22	1.27	0.22	0.27	38	

X = Mean ; Ss = Standart Deviation; CFL = Confirmatory Factor Loadings; a = Cronbach's Alpha, r = Item Total Scale Score Correlation; r₁ = Item Sub-Scale Score Correlation

4. DISCUSSION

According to this study, it can be concluded that the Turkish version of the Exercise Health Belief Model Scale is an appropriate, valid and reliable scale for adults. The first step of scale adaptation studies in different cultures is the translation of the scale from the original language to the target language (22). In the present study, the back-translation of the Turkish version of EHBMS was sent to the developer of the scale, Esparza, who evaluated and approved the translated scale.

Reliability, which is one of the essential characteristics of any scale, expresses the accuracy, consistency and stability of the scale. This feature indicates that the tool collects data correctly and is repeatable (23-25). The reliability of the data collection tool can be tested via considering its invariance with respect to time, its compatibility between independent observers and its internal consistency (24, 26).

Internal consistency is the reliability that determines whether all aspects of the scale are capable of measuring the desired parameter. Cronbach alpha coefficient less than 0.40 indicates that the scale is not reliable, $0.40 \leq \alpha < 0.60$ indicates low reliability, $0.60 \leq \alpha < 0.80$ indicates fair reliability, and $0.80 \leq \alpha < 1.00$ indicates high reliability (24, 25-27).

Cronbach Alpha coefficient of the original scale was similar to that of the translated version of scale.

The test-retest method is performed to ensure consistent results in repeated measurements at regular intervals and to evaluate the scale's invariance over time (28).

In the present study, the test-retest correlation value was 0.88 ($p < 0.05$), indicating that there was a strong correlation between the two measurements at different times and that the scale was invariance over time.

Validity determines the degree to which a measuring instrument measures "what", "how much", and "how accurately" (24). Although there are different methods to evaluate the validity of a scale, content validity and factor analysis are among the most commonly used methods (29).

Content validity is used to evaluate to what extent the scale and each item in the scale measure the target correctly. Any CVI value above 0.80 ensures the content validity of the scale (24, 30). According to this study, the CVI of EHBMS was 0.98 indicating that the content validity criterion was met and was consistent with the literature (24, 30-32).

The construct validity evaluates the extent to which the tool fulfills its purpose in measuring the target, and the extent to which it can accurately perform the measurement (19, 24). The most commonly used method for construct validity is factor analysis (24). which is a statistical technique to assess whether all items in the scale can be collected under different subscales (24). Factor analysis can be performed in two different methods: Explanatory factor analysis, which is recommended for scale development studies, and confirmatory factor analysis, which is recommended for scale

translation/adaptation studies (33). Confirmatory factor analysis was performed in this study.

"Goodness of fit statistics" performed in confirmatory factor analysis should be at desired levels (24). It is also recommended that the loads between the subscales and the items should be at least 30 and above. In our study, it was found that the loads between the items and their subscales were above 30 except for the items 10 and 32. Eliminating these two items did not cause any change in the goodness of fit indices and Cronbach Alpha values of the scale. Since it is recommended that items that do not change reliability and support the scale should not be excluded from the scale (34), these two items were preserved in the translated version.

Confirmatory factor analysis of the Turkish version of EHBMS was compared with the five-factor model of the original scale, and the chi-square value ($\chi^2 = 2577.21$, $df = 454$, $p = .00$) was found to be significant; yet the chi-square/degree of freedom (χ^2/df) was found to be 5.6. Although χ^2/df value is preferred to be ≤ 2 , the model is considered acceptable in cases where this value is less than 5 (19, 33, 35). The literature reports that chi-square value increases as the sample size increases (19). So, it can be said that the high chi-square value of the current study was due to the sample size ($n = 743$). Other goodness of fit values were: CFI = .93; NNFI = .93; SRMR = .66; and RMSEA = .79. Based on these results, goodness of fit values confirmed that the scale validates five different factors at an acceptable level.

5. CONCLUSION

The validity and reliability of the Turkish version of the Exercise Health Belief Model Scale are quite good. The scale can be used to evaluate exercise-oriented health beliefs and behaviors in Turkish-speaking adults.

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Identifying Genital Hygiene Behaviours of Pregnant Women in Rural and Urban Regions: A Cross-Sectional Study

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ABSTRACT

Objective: The research was done to identify the genital hygiene behaviors pregnant women in rural and urban regions.

Methods: This research was done in analytical cross-sectional design at a maternity and children hospital in Aegean Region between April 15-October 2019. 278 pregnant women, who applied for follow-up and accepted to participate in the research, were included in the research. The data were collected through personal information form and Genital Hygiene Behavior Inventory. Descriptive statistics, chi-square test, Mann Whitney U test and Kruskal Wallis test were used in data analysis. Significance was accepted as $p < 0.05$.

Results: It was identified that 26.9% of pregnant women in rural regions were primary school graduate and 44.4% were secondary school graduate. It was found that 32.4% of pregnant women living in urban regions were high school graduate and 31.2% had bachelor's degree. A statistically significant relationship was identified between educational status and genital hygiene behaviors of pregnant women ($p < 0.05$). Depending on their living places, Genital Hygiene Behavior Inventory mean score was calculated as 77.98 ± 12.19 those living in rural regions and 81.29 ± 11.22 for those living in urban regions. It was found that Genital Hygiene Behavior Inventory levels of pregnant women living in urban regions was higher than those living in rural regions at a statistically significant level ($p < 0.05$).

Conclusion: It was identified that living place, educational status, employment status, age status and marriage year affected genital hygiene behavior. It is suggested that health professionals provide genital hygiene training to the pregnant women living in rural regions and with a low level of income through protective and preventive approach.

Keywords: Pregnancy, Genital Hygiene, Rural, Urban, Reproductive health.

1. INTRODUCTION

Genital hygiene behaviors are self-care practices that individuals gain through their belief, ways of healthy life and hygiene habits. These practices differ among individuals. This difference stem from individuals' different life styles, culture and socio-economic features. Genital hygiene behaviors, like all hygiene behaviors, should converted into a form of behavior and should be provided individuals as a learned behavior (1,2).

It is known that women are more prone to genital infections in comparison with men due to their anatomy. Genital hygiene behavior at an undesired level can generally lead to diseases which abnormal vaginal discharge, malodor and genital infections cause (3-5). Most women have problems about genital infections, are open to reservoirs and become more sensitive due to pregnancy. Urinary tract infections and vaginal infections occur more often because of the physical and mental changes especially experienced in pregnancy. It is seen that these infections cause negative pregnancy results

like preterm labor, recurrent abortus and abortion based on abortus (6-8). In general terms; activities like using flexible and bleeding underclothes, changing underclothes daily, changing sanitary pads frequently, doing perineal cleaning top-down, keeping perineal area dry, avoiding from vaginal douching and washing hands before and after using the toilet are accepted as positive hygiene behaviors (9-13).

It is important to identify the genital hygiene habits of pregnant women throughout pregnancy in terms of determining those needing consultancy about genital hygiene habits and getting genital infections under control. The studies carried out in Turkey about genital hygiene behaviors are at a limited level and it was identified that as the education and income level increase, positive reproductive health attitudes increase (14,15). As genital hygiene behaviors are shaped depending on different environmental factors, socioeconomic status and cultural factors, identifying genital hygiene behaviors of pregnant women living in rural and urban regions. Therefore,

the research aimed to identify genital hygiene behaviors of pregnant women in rural and urban regions. In line with this aim, answers are sought for the questions below: "What is the genital hygiene behavior level of pregnant women in rural and urban regions?" and "What are the factors affecting genital hygiene behaviors of pregnant women in rural and urban regions?"

2. METHODS

2.1. Type, place and time of the study

The analytical cross-sectional research was carried out at maternity policlinics of a maternity and children hospital in Aegean Region between April 15-October 2019.

2.2. Participants

The research population included pregnant women applying to Ministry of Health Aydın Maternity and Children Hospital Maternity Policlinics for follow-up. This hospital was chosen due to the fact that it is convenient for the research purpose and all the pregnant women living in the rural and urban areas apply to it. Therefore, it was aimed to identify the difference between living place and genital hygiene behaviors. The number of pregnant women included in the research sample was identified as 239 at least through sampling method for unknown universe. In case of a loss, 275 pregnant women were invited to participate in the research. Selection of research sampling was done in accordance with the simple random numbers table. The participants were identified through random sampling method and all pregnant women, who were suitable to the research criteria and accepted to participate in the study, were taken into the scope of the study. When a randomly selected pregnant woman did not meet the criteria, the next pregnant woman was included in the study.

Four pregnant women did not accept to participate in the study and two pregnant women were excluded as they were illiterate. Six pregnant women were not taken in the scope of study totally. The pregnant women who were suitable to the research criteria were invited to the research in order. In terms of living place, 108 pregnant women were living in rural regions and 170 women were residing in urban regions. The study was completed with 278 pregnant women. The pregnant women residing in a village were allocated as rural and those living in a town or city were assigned to urban group. The data gathered from the rural and urban regions were evaluated and reported (Figure 1). The pregnant women, who were over 18, could understand Turkish, could speak, read and write in Turkish, were primary school graduate at least, did not have any psychological problem which could prevent filling the question form and were willing to participate in the study, were included in the study. Those, who had a psychological problem and did not fill the form completely, were excluded from the study.

2.3. Data Collection Tools

The data collection process started with the pregnant women taken into the study scope in accordance with the number of sampling. The pregnant women were filled the "Personal Information Form" and "Genital Hygiene Behavior Inventory". Those, who came to a state hospital in Aegean Region of Turkey for follow up, were informed about the research and were invited to participate in the research. The data were collected through questionnaire form and face-to-face interview technic. Filling the questionnaire form took around 10-15 minutes.

2.3.1. Personal Information Form

It included 22 questions. It was prepared by the researchers for the purpose of collecting data about socio-demographic, obstetrical and gynecological features of pregnant women based on the literature (9-12).

2.3.2. Genital Hygiene Behavior Inventory (GHBI)

It is a four point Likert inventory consisting of 27 questions. The validity and reliability of the inventory was done by Ege and Eryilmaz (16). 1 point was given for the response "never", 2 points were given for the response "sometimes", 3 points were given for the response "usually" and 4 points were given for the response "always" in positive questions. Negative questions (numbered 17, 26 and 27) were graded reversely. The lowest score which can be gained is 27 and the highest score is 108 from GHBI. The score received from GHBI shows the level of genital hygiene behavior and as the total score increases, the genital hygiene behaviors reach to the desired level. It has single dimension and includes questions about practices of general hygiene, menstrual hygiene, toilet hygiene and genital hygiene. Its Cronbach's Alpha coefficient was $\alpha:0.86$. It was calculated as $\alpha:0.78$ in this research.

2.4. Data Analysis

Kolmogorow-Smirnov test, Shapiro-Wilk test, descriptive analysis, Mann Whitney U test and Kruskal Wallis test were used in data analysis. Statistical significance level was accepted as $p<0.05$ in the research.

2.5. Ethical Dimension of the Research

Informed consent was received from the participant pregnant women by informing them about the research before starting to collect data. Ethical principles, including "the principle of privacy and privacy protection" with the statement that their data would be kept secret and "the principle of respect for autonomy" with the inclusion of people who were volunteer to participate in the research, were performed. Records about volunteers' identities were protected based on the related legislation provisions in a manner that would respect to private life and confidentiality rules. Helsinki declaration was honoured throughout the research. Ethics

committee approval with the protocol number 2019/017 was received from Aydın Adnan Menderes University

Faculty of Health Sciences Noninvasive Chairmanship (Number:92340882-050.04.04./22405).

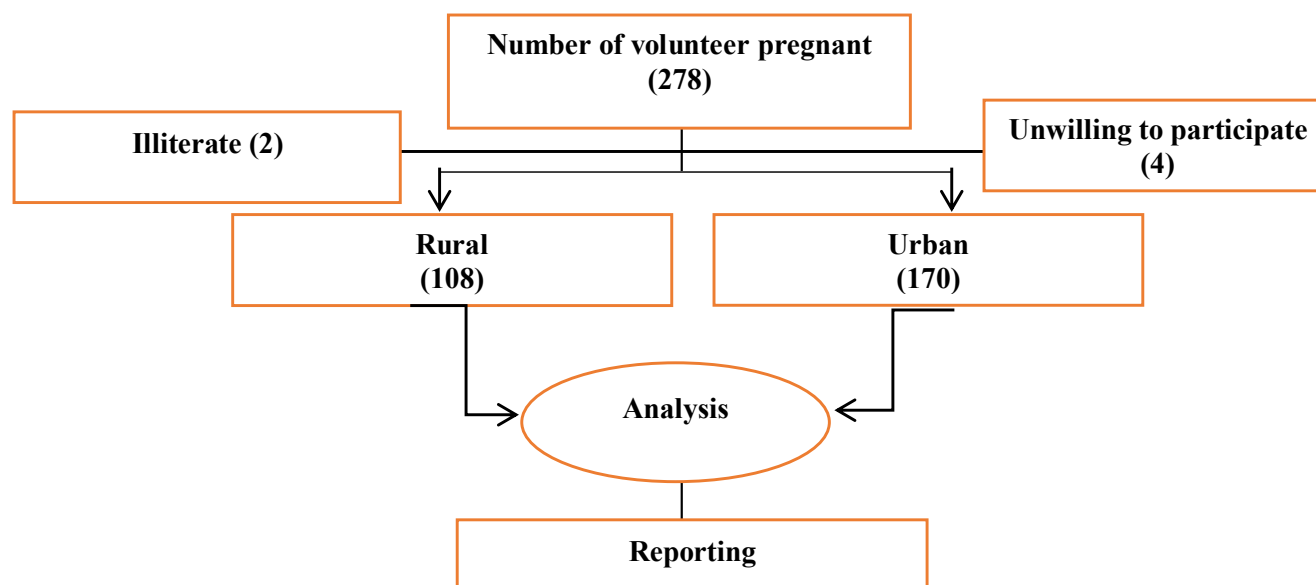


Figure 1. The process of research

3. RESULTS

It was identified that while 26.9% of pregnant women in rural regions were primary school graduate and 44.4% were secondary school graduate, 32.4% of pregnant women in urban regions were high school graduate and 31.2% had a bachelor's degree. A statistically significant relationship was found between education status and genital hygiene behaviors of pregnant women ($p < 0.05$). 12% of pregnant women residing in rural regions and 28.2% of those residing in urban regions stated that they had an income-generating work. A statistically significant relationship between working status and genital hygiene behaviors of pregnant women was found ($p < 0.05$). Age average of pregnant women living in rural regions was 26.06 ± 5.83 (17-41) and that of those living in urban regions was 27.86 ± 5.27 (18-40). A statistically significant relationship between age and genital hygiene behaviors of pregnant women was identified ($p < 0.05$). Average marriage year of pregnant women in rural regions was 4.96 ± 4.48 (1-25) and those in urban regions had an average marriage year of 5.79 ± 4.76 (1-22). Average marriage

years of pregnant women created a difference in their genital hygiene behaviors ($p < 0.05$; Table 1).

When obstetric features of pregnant women were examined, it was identified that 93.5% of all pregnant women became pregnant willingly, and 67.6% of pregnant women in rural regions and 80% of those in urban regions had planned pregnancy. It was calculated that average pregnancy of pregnant women was 32.59 ± 7.37 (8-41) in rural regions and 33.45 ± 6.02 (6-40) in urban regions. Obstetric features of pregnant women in both regions were similar and it was found that there was not a statistically significant relationship between their obstetric features and genital hygiene behaviors ($p > 0.05$; Table 2).

In accordance with the living places of pregnant women in study, when their GHBI mean scores were examined, it was calculated that all pregnant women had 79.83 ± 12.28 , those in rural regions had 77.06 ± 13.16 and those in urban regions had 81.59 ± 11.39 in GHBI mean scores. It was identified that GHBI mean scores of pregnant women in urban regions were significantly higher than those living in rural regions ($p < 0.05$; Table 3).

Table 1. Comparison of genital hygiene behaviors of pregnant women in accordance with individual features

Individual features (n=278)	Rural (n=108)	Urban (n=170)	GHBI $\bar{X}\pm SD$	Test and p	
	n(%)	n(%)			
Educational status					
Primary school	29(26.9)	30(17.6)	78.16±11.53	KW=4.656 p=0.003*	
Secondary school	48(44.4)	32(18.8)	77.20±12.54		
High school	21(19.4)	55(32.4)	80.69±11.79		
University	10(9.3)	53(31.2)	84.25±9.38		
Working status					
Yes	13(12.0)	48(28.2)	83.00±9.53	z=-1.996 p=0.046**	
No	95(88.0)	122(71.8)	79.12±12.12		
Profession type					
Worker	5(38.5)	21(43.8)	83.80±9.70	KW=0.375 p=0.689	
Officer	3(23.1)	9(18.8)	81.70±10.29		
Self-employment	5(38.5)	18(37.5)	84.10±8.80		
Health coverage					
Available	72(66.7)	143(84.1)	80.41±11.18	z=-1.262 p=0.208	
Unavailable	36(33.3)	27(15.9)	78.22±13.38		
Income status					
Lower income than expenditure	44(40.7)	60(35.3)	79.86±11.73	KW=0.564 p=0.570	
Balanced income and expenditure	40(37.0)	90(52.9)	80.49±11.57		
Higher income than expenditure	24(22.2)	20(11.8)	78.23±12.34		
Living place (the longest period of time)					
City	8(7.4)	89(52.4)	82.00±10.69	KW=2.451 p=0.088	
Town	25(23.1)	76(44.7)	79.64±11.11		
Village	75(69.4)	5(2.9)	78.01±13.17		
Genital discharge status					
Transparent	49(45.4)	74(43.5)	80.08±11.24	KW=6.853 p=0.652	
White	17(15.7)	32(18.8)	81.92±13.39		
Smelly, transparent	8(7.4)	11(6.5)	78.42±10.80		
Smelly, itchy, white	9(8.3)	4(2.4)	75.62±12.51		
Smelly, yellow	7(6.5)	13(7.6)	78.60±10.96		
Yellow, itchy	4(3.7)	9(5.3)	79.62±11.10		
Transparent, itchy	5(4.6)	3(1.8)	77.63±11.33		
Smelly, yellow and painful	3(2.8)	1(0.6)	83.25±14.31		
Smelly, white, painful	4(3.7)	6(3.6)	79.63±10.74		
Smelly, yellow, itchy	2(1.8)	17(10.0)	80.78±10.33		
Status of having infection					
Yes	24(23.1)	46(27.9)	82.56±10.20	z=-0.468 p=0.640	
No	84(77.8)	124(72.9)	80.82±11.58		
Mean scores					
	$\bar{X}\pm SD$	Min.-Max.	$\bar{X}\pm SD$	Min.-Max.	$\bar{X}\pm SD$
	n(%)		n(%)		
Age of pregnant women	26.06±5.83	18-41	27.86±5.27	18-40	79.91±11.75
18-25	55(32.4)		54(50.0)		77.77±12.49
26 and higher	115(67.6)		54(50.0)		81.37±10.98
Marriage year	4.96±4.48	1-25	5.79±4.76	1-22	79.99±11.72
1-10	23(71.9)		55(32.4)		80.65±9.89
11 and higher	9(28.1)		115(67.6)		82.00±8.43

%Percentage, $\bar{X}\pm SD$ Mean±standard deviation, nNumber, KWKruskal Wallis Test, ZMann Whitney U Test, pSignificance level, GHBIGenital Hygiene Behavior Inventory,

Table 2. Comparison of pregnant women's genital hygiene behaviors in terms of their obstetric features

Features (n=278)	Rural (n=108) n(%)	Urban (n=170) n(%)	GHBI $\bar{X}\pm SD$	Test and p
Status of willingness for pregnancy				
I wanted.	101(93.5)	159(93.5)	9.94±11.71	z=0.355
I did not want.	7(6.5)	11(6.5)	79.53±12.32	p=0.723
Status of pregnancy plan				
Planned	73(67.6)	136(80.0)	79.97±12.05	z=-1.424
Unplanned	35(32.4)	34(20.0)	79.73±10.80	p=0.156
Mean scores	$\bar{X}\pm SD$ n(%)	Min.-Max. n(%)	$\bar{X}\pm SD$ n(%)	Min.-Max. $\bar{X}\pm SD$
Pregnancy number	2.26±1.34 1-8	2.27±1.42 1-7	80.00±11.76	KW=0.644
1	39(36.1)	71(41.8)	80.79±11.03	p=0.725
2-3	51(47.2)	67(38.4)	82.55±10.61	
4 and more	18(16.7)	32(18.8)	77.02±12.97	
Delivery number	1.55±0.98 0-5	1.78±1.04 0-5	79.35±12.41	z=-0.533
1	38(55.9)	48(52.2)	77.14±12.53	p=0.594
2 and more	27(39.7)	39(42.4)	79.87±13.52	
Number of children	1.52±0.89 0-5	1.74±1.04 0-5	79.54±11.67	z=-1.042
1	34(58.6)	43(50.0)	82.42±9.92	p=0.297
2 and more	24(41.4)	43(50.0)	78.67±13.67	
Miscarriage number	1.33±0.96 0-5	1.33±0.69 1-4	79.82±10.38	z=-0.297
1	15(62.5)	25(75.8)	79.43±10.77	p=0.767
2 and more	9(37.5)	8(24.2)	80.76±9.66	
Number of death	0.56±0.53 0-1	1.00±0.00 1-1	79.79±11.88	z=-0.869
Available	5(4.6)	6(3.5)	83.00±8.66	p=0.385
Unavailable	103(95.4)	164(96.5)	79.66±11.99	
Number of abortion	1.47±1.30 0-1	1.34±0.77 0-4	81.39±10.76	z=-0.275
1	6(50.0)	21(72.4)	79.78±15.19	p=0.783
2 and more	6(50.0)	8(27.6)	82.79±7.52	
Pregnancy week	32.59±7.37 8-41	33.45±6.02 6-40	79.96±11.69	
The first follow-up	1.47±0.88 1-6	1.05±0.43 1-6	79.91±11.72	

%Percentage, $\bar{X}\pm SD$ Mean±standard deviation, nNumber, KWKruskal Wallis Test, ZMann Whitney U Test, pSignificance level, GHBIGenital Hygiene Behavior Inventory

Table 3. Comparison of GHBI mean scores of women in research sample in terms of rural and urban regions

Regions (n=278)	Pregnant women n(%)	GHBI $\bar{X}\pm SD$	Test and p
Rural	108(38.85)	77.06±13.16	z=-2.864
Urban	170(61.15)	81.59±11.39	p=0.004*
Total	278(100)	79.83±12.28	

%Percentage, $\bar{X}\pm SD$ Mean±standard deviation, nNumber, ZMann Whitney U Test, pSignificance level, GHBIGenital Hygiene Behavior Inventory

4. DISCUSSION

In our research, it was identified that pregnant women, who had an education level at high school and university, genital hygiene behaviors were significantly higher at those having higher levels of education. Similarly, in the study carried out by Ilgaz et al. (17), it was seen that women in urban regions with better socio-demographic conditions showed more positive genital hygiene behaviors. In another study, it was identified that educational status affected genital hygiene behavior in consistency with our study (18). Likewise, in

a study carried out in Cameroon, it was found that socio-demographic features and genital hygiene habits influenced prevalence of bacterial vaginal infections (19). Accordingly, it can be inferred that pregnant women with low level of education are privileged in terms of genital hygiene training.

In this study, it was identified that pregnant women resided mostly in urban regions and working status affected genital hygiene behaviors positively. Similarly, in the study of Şahin Orak and Canuygur (20), it was found that working women had better genital hygiene behaviors in comparison with those who did not work. Çankaya and Ege (21) identified that women who were sexually active and worked had more positive genital hygiene habits than those who did not work. In accordance with these findings, it is thought that working pregnant women reach knowledge about healthy life style and health services more easily due to their economic freedom. In this regard, pregnant women, who have difficulty in reaching health services, and their training requirements should be identified.

In the current research, it was identified that pregnant women, living in rural and urban regions with higher ages, had significantly higher levels of genital hygiene behaviors in a similar way. In the research done by Masha et al. (22), it was found that age factor was correlated with genital hygiene behaviors. In another study carried out in southeastern Turkey, it was identified that genital hygiene behaviors and age factor affected vaginal infections in women who were seasonal agricultural workers (23). Similarly, in a study where genital hygiene behaviors of girls at adolescence period were investigated, majority of the participants stated that they did not have knowledge about genital hygiene behaviors, and erroneous genital hygiene behaviors were identified (24). According to these results, it is thought that especially young individuals living in rural regions should be privileged in terms of gaining positive behaviors on genital hygiene.

In our research, it was stated that pregnant women living in rural regions were mostly at the first ten years of their marriage and there was a relationship between marriage year and genital hygiene behaviors. In the research of Çankaya and Ege (21), it was calculated that married women had marriage year averages of higher than fifteen years and was found that women, who had genital infection diagnosis, had more negative genital hygiene behaviors. In a similar study, among pregnant women, residing close to two different family health centers, it was stated that those residing in rural regions had earlier first marriage ages than those in urban regions and it was found that those living in urban regions had more positive genital hygiene behaviors (17). In this sense, these results make us think that newly-wed individuals should be informed about genital hygiene behaviors.

In our research, it was identified that pregnant women living in urban regions had more positive genital hygiene behaviors in comparison with those living in rural regions and the difference between genital hygiene mean scores were statistically significant. In the research of Thakur et al. (25), it was determined that women living in rural regions had a weaker level of genital hygiene behaviors. In another study done in eastern Turkey, it was found that women mostly did the practice of vaginal douching and this affected women's health negatively (26). On the other hand, it was seen that women with negative genital hygiene behaviors were more prone to urinary tract infections, genital ulceration, bacterial vaginal infections and cervical cancers (8,20,22,25). In another study carried out systematically, prevalence of vaginal infections at a high rate was noteworthy in pregnant women living in low and middle income countries (27). It is seen that living place of pregnant women is affective on their genital hygiene behaviors and prenatal trainings specific to living places of pregnant women should be planned.

5. CONCLUSION

It was seen that living places of pregnant women influenced their genital hygiene. Pregnant women living in urban regions had more positive genital hygiene behaviors when compared with those living in rural regions. In line with

these findings, supporting pregnant women living in rural regions by informing them about healthy life behaviors like genital hygiene behaviors gains importance due to their socio-demographic features. Thus, health trainings about genital hygiene behaviors should be a part of school curricula and training programs of health institutions. Additionally, it should be provided that midwives and nurses working at health care areas primarily take charge in active practices more effectively, which can increase awareness levels of pregnant women living in rural areas.

Limitations of the Research

The findings gained from this research represent pregnant women applying to the hospital for follow-up. Additionally, the research data is limited to the responses of participant pregnant women.

Conflict of interest: There is no conflict of interest among the authors to declare.

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Effect of Midwifery Students' Negative Clinical Experiences on Their Emotional Labor Behaviors

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ABSTRACT

Objectives: Emotional labor is the effort type that organizations expect from their employees or the effort that the individual makes based on his/her mood. Negative clinical experiences in the workplace may have long-term influence on emotional labor behavior. Aim of this study was carried out to determine the effect of midwifery students' negative experiences in clinical practices on their emotional labor behaviors.

Methods: The study is a mixed-methods study. Thematic analysis and descriptive was used. The study was conducted from November to December 2018 with 370 midwifery students in Istanbul. The relevant data were collected via a "Descriptive Information Form" and Emotional Labor Behavior Scale of Nurses (ELBS).

Results: The mean age of the students recruited for the research is 21.57 ± 1.51 . Eighty-five percent of students ($n=314$) were identified to have at least one negative clinical experience, which decreased their motivations to be a midwife. "Healthcare professional's behaviors towards pregnant women during childbirth" rank first (48.1%) among these negative experiences. A little more than the half of the students (51%) react to these negative experiences by "staying away from the setting." It was identified that ELBS total score mean of students were 96.52 ± 11.92 and also that as students' fear to vaginal birth management increased, their ELBS scores decreased ($p=0,00$, $r=-0,22$). It is determined that clinical negative experiences do not affect students' emotional labor behavior ($p>0,05$).

Conclusion: The factor affecting a large part of students' motivation to be midwife negatively is the healthcare professional's negative behaviors towards pregnant women and students. Within this context, it must be attempted to make healthcare personnel behave in a more humanistic and professional way towards women and students. Therefore, midwifery education programs should be planned and written about the qualifications that students should be knowledgeable and equipped to understand the emotional needs of women.

Keywords: Student midwives, clinical negative experience, emotional labor behavior.

1. INTRODUCTION

The "emotion", a feeling special to that one individual, is reflected on the person who takes the service from the employees. One of the most important concepts about healthcare quality in the field is the emotional labor, which means the effort to have the relevant facial and physical appearance and presence of the service-giver (1,2). The employee has to manage her/his emotions to show the desired behavior during the service process (3,4). The service-giver needs to suppress some of his/her emotions and evoke some others just to make the service-taker feel comfortable, provide relevant social norms and reflect the emotions expected from him/her (5,6). The concept of emotional labor was first used by Arlie Hochschild in 1983 (4). The concept of emotional labor is increasingly being discussed (1-4).

Throughout the literature, emotional labor concept is grouped under three different dimensions as superficial

behavior, deep behavior and sincere behaviors. Superficial behavior occurs when the employee pretends to feel what he/she does not feel the way expected from him/her at that very moment (1,2). Individuals show some positive emotions to the service-taker through controlling their momentary negative emotions and hide their own authentic emotions (3,4). Deep behavior comes when the employee not only behaves like he/she feels the way expected or desired from her/him but also internalizes and handle that emotion (5,7). Sincere behaviors means that what the individual feels corresponds to what he/she shows. Shortly, the individual does not make an extra effort to direct his/her emotions while behaving in an sincere behaviors way (6,7). Midwives/midwifery students offer one-to-one care containing emotional labor to women during their childbirth, the most important event for many women.

Midwifery requires constant one-to-one communication, which affects emotional labor. Therefore, midwifery students need to handle their own emotions in birth clinics. Especially, in the intrapartum period, when women undergo an emotional and physical change, midwives have an active role. For an intrapartum period to end in a healthy way, midwives/midwifery students have to handle both their own and the woman's emotions. The midwives who cannot handle their own emotions in a good way may exhibit negative behaviors (8-10). This affects the quality of the care offered by midwives and midwifery students negatively and also may result in stress, decrease in motivation, intention to quit the job and burnout (11).

In this context, this study was planned to be conducted descriptively to identify the relationship between negative clinical experiences of senior midwifery students and their emotional labor behaviors and affecting factors.

2. METHODS

2.1. Research type: The study is a mixed-methods study. Thematic analysis and descriptive was used. In this study consists of the senior midwifery students in the universities of Istanbul who accepted to participate in this study in between November-December 2018. No sample was selected and all students who accepted to participate in this study were recruited for this research. After the approval of the ethics committee, separate permission was obtained from each university. Appointments were made for students of each university to fill out the questionnaires outside the class hours. The researchers went to universities at specified appointment times. The researchers invited students to research by giving information about the research in the classroom. Students were provided to fill out questionnaires on a voluntary basis. A total of 465 students in senior grade of their undergraduate midwifery students were present in Istanbul on that date. Four hundred five volunteer students (88%) joined and filled the questionnaires but missing forms were excluded and the research was completed with 370 students (80%).

2.2. Data collection tools: The data were collected via Descriptive Information Form and Emotional Labor Behavior Scale for Nurses.

2.3. Descriptive Information Form: The General Information Form is based on examples in the literature and comprises queries on the participants' socio-demographic features (age, education, etc.) and clinical experiences of participants. Besides, students' fear to vaginal birth management was assessed using Visual Analog Scale (VAS). In this VAS assessment, participants were asked to mark the density of their fear emotions on a vertical line of 10 centimeter and then the marked point was measured with the help of a ruler. In this VAS assessment, childbirth fear scoring was as such: "I have no fear to vaginal birth management: 0 point" and "I am so afraid vaginal birth management: 10 points." The content of vaginal birth management fear was asked in an open-ended way. And the most negative experience that students underwent in the clinical setting, which decreased

their motivations to be midwives, was asked in an open-ended way, either.

2.4. Emotional Labor Behavior Scale for Nurses (ELBS): Developed by Degirmenci-Oz and Baykal (2018), this scale consists of 24 items being 5-point Likert scale type. Responses to the expressions in the scale were graded as such: "I absolutely do not agree-1 point", "I do not agree-2 points", "I am indecisive-3 points", "I agree-4 points" and "I totally agree-5 points". The scale consists of 3 subscale including "Superficial behavior subscale" (Items from 1 to 6), "Deep behavior subscale" (Items from 7 to 19) and "Sincere behavior subscale (Items from 20 to 24). Deep behavior is that employees should be able to really feel the emotion that they need to reflect at that moment by organizing their emotions and behave accordingly. Superficial behavior is that employees simply change their behavior and act as though they do not actually feel that way. However, sincere behaviors comes when the employees act spontaneously and the way how he/she genuinely feels. When the scores from the scale are assessed, total score from each sub-scale is divided into item number in this sub-scale and the arithmetical mean is taken. As per this calculation, sub-scale score mean in each sub-scale varies between "1" and "5". As the mean score in sub-scale comes close to "1", emotional labor behavior decreases and as it comes close to "5", the very same behavior increases (12). In this study, Cronbach alpha value of Emotional Labor Behavior was determined as .90.

2.5. Data collection: After obtaining written permission from universities, data were collected in senior students' classes on their appropriate days and hours. These students were invited to participate in the study and asked to fill the forms on a voluntary basis.

2.6. Ethics of the study: A relevant approval was obtained from Marmara University Health Sciences Faculty Non-Invasive Ethics Committee (19th October 2018, 30) to conduct this study. Afterwards, written permission was obtained from 3 state and 6 foundation universities with midwifery bachelor programs in Istanbul with the approval of ethics committee to be able to carry out this study.

2.7. Analysis of data: Statistical analyses of the data were conducted using PSAS Statistics 21.0. After assessing individual traits of the students, mean±standard deviation, number and percent distributions were found. While comparing individual traits and ELBS scores, Student t test was used. $p < 0,05$ was accepted as the statistical significance value. Students' expressions for negative clinical experiences were written on text document and then deciphered. Inductive qualitative content analysis was used to create themes in the analysis of students' clinical negative experiences (13). With this analysis method, both the apparent content obtained from the expressions of the participants and the content underlying the verbal expressions were analyzed with the interpretation of the researcher. The content of the text formed by students' answers were open-coded (determination of the expressions with similar meanings) and after specified expressions were

named, they were coded. It is composed of three themes named in the meaning of the code.

3. RESULTS

It was determined that age mean of the students that were recruited was 21.57 ± 1.51 and 97.3% of them ($n=360$) were single, 50.5% of them ($n= 187$) lived with their families and 76.8% of them ($n=284$) were attending to a state university. It was also established that 11.6% of midwifery students ($n=43$) did not want to work as midwives after graduation. It was determined that 28.9% ($n = 107$) of the students had at least one traumatic experience and 17.6% ($n = 65$) of them experienced violence at least once. It was found that 20% ($n = 74$) of the students included in the study perceived the delivery room as a dangerous place. And it was also detected that a great portion of the recruited students (84.9%, $n=314$) had at least one negative clinical experience, which decreased their motivations to be midwives. Three main themes were identified when negative experiences that caused decrease in the motivations of midwifery students to work as midwives in a clinical setting were evaluated.

Three main themes and the codes that make up the themes are as follows;

1-Negative attitudes of healthcare professional towards pregnant women during childbirth (48.1%, $n=178$): 1.1.Unprofessional approaches of obstetricians and midwives to pregnant women (physical or verbal violence against pregnant women during childbirth, ill-treatment, rude behaviors, non-emphatic attitudes and desensitization), 1.2.Failure to provide adequate care to pregnant women (none of the methods for coping with the pain are performed, absence of appropriate clinical setting in the hospital), 1.3.Unnecessary routine interventions (unnecessary episiotomy, induction without indications, constant Nonstress Test and movement restriction, restriction of nourishment and oral fluid intake during the labor, rush during the childbirth, episiotomy without anesthesia and its repair, detachment of mother and the child immediately after the childbirth), 1.4.Giving no information about the practices and no explanations about the risks and benefits of the waiting attempt, 1.5.Giving no importance to privacy, 1.6.Leaving the women alone often during the childbirth.

2-Negative attitudes of healthcare personnel towards students (21.9%, $n=81$): 2.1.Insults, despises and overlooking behaviors of obstetricians and midwives against students, 2.2.Unsupportive and non-educatory attitudes of midwives, no permission for a student who follows a pregnant to manage that woman's childbirth, no permission for any practice and no answers to students' questions, 2.3.Non-compatibility between theory and practice, 2.4.Tasks in some other clinicals than gynecology clinics, 2.5.Unsupportive attitudes of school teachers in the clinical setting, inadequate clinical training.

3-Reasons stemming from childbirth room and its setting (14.9%, $n=55$): 3.1.The rush of the childbirth room,

3.2.Dystocia, 3.3.Complications during the childbirth, 3.4.Babies with anomalies, 3.5.Mother and child deaths.

It was determined that the most frequent reaction of the students after the negative experience of the students during in clinics was to move away from clinical setting (50.8%, $n=188$) (Table 1). ELBS total score mean of students was determined to be 96.52 ± 11.92 (min:52, max:120) while their item score mean (total score/item number) was found to be $4,02 \pm 0,49$ (Table-2). It was found that ELBS scores of the students unsatisfied with midwifery education were significantly lower ($p<0,05$) (Table-3). It was also determined that ELBS score mean was not affected by negative experience, type of experience or the kind of reaction ($p>0,05$) (Table-4). Additionally, it was determined that fear to vaginal birth management of the students corresponded to "the fear of hurting mother and the baby" and ELBS scores decreased ($p=0,000$, $r=-0,22$) as the fear of childbirth increased.

Table 1. The students characteristics ($n= 370$)

Characteristics		n	%
Satisfied with midwifery education	Yes	336	90.8
	No	34	9.2
Wish to work as midwives after graduation	Yes	327	88.4
	No	43	11,6
History of trauma	No	263	71,1
	Yes	107	28,9
History of domestic violence	No	305	82,4
	Yes	65	17,6
Witnessed incidents of traumatic childbirth (for example bleeding, low apgar score and other complications)	No	131	35.4
	Yes	239	64.6
Negative clinical experience	Yes	314	84,9
	No	56	15,1
Negative experiences that caused decrease in the motivations of midwifery students to work as midwives	Negative attitudes of healthcare professional towards pregnant women during childbirth	178	48,1
	Negative attitudes of healthcare personnel towards students	81	21,9
	Reasons stemming from childbirth room and its setting	55	14,9
Reaction of the students after the negative experience	Move away from clinical setting	188	50,8
	Fear	184	49,7
	Cry	104	28,1
	Anger	88	23,8
	Physiological responses such as palpitations and nausea	67	18,1

Table 2. Emotional Labor Behavior Scale of Nurses mean scores of students (n= 370)

Scale	Total Mean \pm SD (Min-Max)	Item Mean \pm SD (Min-Max)
The total scale	96,52 \pm 11,92 (52-120)	4,02 \pm 0,49 (2,17-5)
Superficial behavior subscale	23,81 \pm 3,33 (9-30)	3,96 \pm 0,55 (1,50-5)
Deep behavior subscale	51,95 \pm 7,33 (25-65)	3,99 \pm 0,56 (1,92-5)
Sincere behavior subscale	20,67 \pm 3,25 (8-25)	4,13 \pm 0,65 (1,60-5)

Table 3. Comparison of the characteristics of students with Emotional Labor Behavior Scale of Nurses score (n= 370)

Characteristics		n	%	Mean \pm SD	p
Satisfied with midwifery education	Yes	336	90,8	96,98 \pm 11,58	0,023* t=2,277
	No	34	9,2	92,11 \pm 14,35	
Wish to work as midwives after graduation	Yes	327	88,4	96,72 \pm 11,70	0,38* t=0,86
	No	43	11,6	95,04 \pm 13,53	
History of trauma	Yes	107	28,9	97,40 \pm 12,80	0,36* t=0,902
	No	263	71,1	96,16 \pm 11,54	
History of domestic violence	Yes	65	17,6	96,40 \pm 14,14	0,92* t=0,089
	No	305	82,4	96,55 \pm 11,42	
Witnessed incidents of traumatic childbirth	Yes	239	64,6	96,94 \pm 11,25	0,36* t=-0,903
	No	131	35,4	95,75 \pm 13,11	

*Student t-test

Table 4. Comparison of the negative clinical experience of students with Emotional Labor Behavior Scale score (n= 370)

Characteristics		n	%	Mean \pm SD	p	
Negative clinical experience	Yes	314	84,9	96,61 \pm 11,78	0,72* t=-0,352	
	No	56	15,1	96,00 \pm 12,82		
Negative experiences that caused decrease in the motivations of midwifery students to work as midwives	Negative attitudes of healthcare professional towards pregnant women during childbirth	Yes	178	48,1	96,36 \pm 12,38	0,80* t=0,249
		No	192	51,9	96,67 \pm 11,51	
	Negative attitudes of healthcare personnel towards students	Yes	81	21,9	96,23 \pm 11,33	0,80* t=0,246
		No	289	78,1	96,60 \pm 12,10	
	Reasons stemming from childbirth room and its setting	Yes	55	14,9	97,98 \pm 10,48	0,32* t=-0,981
		No	315	85,1	96,26 \pm 12,16	
Reaction of the students after the negative experience	Move away from clinical setting	Yes	188	50,8	96,92 \pm 11,12	0,52* t=-0,641
		No	182	49,2	96,12 \pm 12,72	
	Fear	Yes	184	49,7	96,96 \pm 11,84	0,48* t=-0,694
		No	186	50,3	96,09 \pm 12,03	
	Cry	Yes	104	28,1	97,98 \pm 11,50	0,14* t=-1,452
		No	266	71,9	95,96 \pm 12,06	
	Anger	Yes	88	23,8	96,29 \pm 12,78	0,83* t=0,209
		No	282	76,2	96,60 \pm 11,66	
	Physiological responses such as palpitations and nausea	Yes	67	18,1	96,66 \pm 13,27	0,91* t=-0,105
		No	303	81,9	96,49 \pm 11,63	

*Student t-test

4. DISCUSSION

It is certainly remarkable that 85% of the students recruited for this study had negative clinical experiences that decreased their motivations to be midwives and what made these experiences were predominantly negative attitudes of healthcare personnel towards pregnant women and students themselves. ELBS total score mean of students was determined to be 96.52 \pm 11.92 and ELBS scores of the students unsatisfied with midwifery education were significantly lower ($p < 0,05$). When the literature was reviewed, it was determined that 96% of midwifery students faced with serious ill-treatment

and disrespectful behaviors during clinical practices similar to our research findings (14). Frequent physical and verbal abuse and even inhumane and extremely disrespectful attitudes in childbirth rooms were also witnessed as per the literature (15,16). Doşler et al. (2014) states that 83% of midwifery students expose to mobbing in the clinical setting, an extremely high rate, while Malwela et al. (2016) specifies that professional midwives have negative behaviors towards students and act involuntarily when it comes to teach anything. In a qualitative study conducted with midwifery undergraduates, it is stated that when the women they offer

care become disappointed or hurt, the students begin feeling what the women feel in a parallel and silent way and also feel themselves stressful, unsuccessful and inadequate (19). The most common reason why healthcare personnel in childbirth clinics act negatively towards women and midwifery students is their high levels of exhaustion (20,21). In this context, it is of great importance for them to behave more humanely and professionally towards women and students. When this is achieved and settled, traumatization of both pregnant women and midwifery students can be avoided. According to Spiby et al. (2018) midwifery students were asked to give immediate feedback following their experiences not to be traumatized by possible negative experiences in the clinical setting and it was specified that when the students were supported later on, their learning outcomes came positive. And it is also considered really important that if mental health of the students are to be sustained, their supervisors must support and follow them closely after possible negative experiences in the clinical setting.

Midwifery as a profession requires sincere and empathy. As to the studies in the literature, when delivering women evaluate their own process as negative, their accompanying midwifery students may have more trouble and responsibility and their possibility of evaluating the birth as negative increases (19,23). Cohen et al. (2017) states that mistaken attempts and birth complications affect the midwives negatively. On this basis, Pezaro et al. (2017) states that midwifery students experience serious psychological problems in their workplaces while Christensen (2018) specifies that mistaken medical practices, regardless of their seriousness or the harm inflicted on the patient, have an important mental and emotional cost and affect many students in a negative way. Hence, this study has similarly put forth that witnessing a complication decreases the motivation to be a midwife. Negative experiences of midwifery students in the clinical setting may cause them to take a quick dislike to their profession and decrease their sense of belonging. That is why these negative experiences may be minimized. In this study, mean score of emotional labor behavior of students who are not satisfied with their midwifery education and do not want to work as midwife after graduation were identified to be lower. Moreover, reported in the literature that tells us that when midwives are not prepared professionally and supported adequately during these practices, their self-confidence decrease and when they are not satisfied with their professional life and think of themselves as unable to give qualified care to delivering women and their families, they quit their jobs (27-29). Therefore, midwifery education programs should be planned and written about the qualifications that students should be knowledgeable and equipped to understand the emotional needs of women. This perspective may increase the satisfaction of both service-taker and service-giver.

In this study, it was identified that midwifery students had the highest score for sincere behaviors amongst ELBS sub-scale scores. This finding is similar to the finding of another study conducted with midwife and nurses in Turkey (30,31). It is expected that midwifery students exhibit more sincere

behaviors towards women they give care in accordance with the nature of their profession. Midwifery by its definition requires so much emotional labor. The literature, which talks about the masculine and feminine aspects of emotional labor, focuses on attention, sympathy and harmony from female employees in the service sector; states that male employees are expected to behave towards intimidation, authoritarianism, and oppression (31,32).

It was also observed that as the fear of midwifery students' fear to vaginal birth management increased, their emotional labor behavior scores decrease. According to Dahlen and Caplice (2014), the reasons underlying midwives' fear to vaginal birth management can be listed as such: the fear of hurting the baby, perceived inability to manage the labour process, the fear of hurting the mother, the fear of harming oneself and some other individual fears. While Schroder et al. (2016) states that majority of midwives and obstetricians experiences a great deal of stress, Toohill et al. (2019) specifies that 8% of midwives have a great degree of fear to vaginal birth management. Additionally, Leinweber et al. (2017) reports that midwives may react with four times more fear while accompanying the childbirth where disrespectful or bad expressions are used. It is considered more beneficial to direct a midwife with a fear to vaginal birth management to a caesarean one since he/she can make a mistaken decision under the influence of that fear. The fear of midwives affect the childbirth process and the pregnant woman in a negative way (37). Any practice of student on a healthy/unhealthy individual is a great source of stress for both the student and the individual at stake. That the clinical practices of midwifery students happen in highly stressful places like childbirth room inevitably affect the emotional labor behaviors of students due to their dense feelings of fear.

In another study on fear it is stated that, by contrast with this study, the fear of midwives is not about childbirth but system and being tracked or examined (38). Likewise, Dahlen and Caplice (2014) specified that midwives had a dense fear of being tracked and criticized and they also included such factors as lack of support, pressures from any possible lawsuits, judgments, kind of oppressions, questioning and regulatory bodies. However, in this study, the fear of midwifery students is founded to be related to hurting the mother and baby rather than being sued. Moreover, it is remarkable that the problem here is not to make no intervention, which is quite against the nature of the birth but to focus negatively on necessary invasive attempts (e.g: implementations about episiotomy). It is also understood that the midwifery students have not developed any kind of consciousness for certain cases that will create so many concerns and thus felt no responsibility (no fear for being sued etc.).

5. CONCLUSION

That 85% of students recruited for the research have had at least one negative clinical experience leading decrease in their motivations to be a midwife is a quite high rate. One of the underlying reasons that reduce their motivations to work

as midwife in clinical settings is “healthcare professional’s negative behavior towards pregnant women and students during the labour”, which can be avoided. It is considered that certain interventions must be made to decrease such negative behaviors of healthcare professional and also students must be supported by their educators. The students must be supported professionally when they have to cope with such experiences. Thus, students will be able to give more emotional labor and more motivated and empathic care. It is determined that clinical negative experiences do not affect students’ emotional labor behavior. The concept of emotional labor has gained a value increasing with each passing day when its individual and organizational effects are considered. In addition, further work should be done to identify other factors affecting emotional labor behaviors between midwives and other healthcare professionals.

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Conflict of Interest

The authors declare that they have no conflict of interest.


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Does Total Rotation Range of Motion Asymmetry Have an Effect on Shoulder Isometric Muscle Strength in Young Swimmers?

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ABSTRACT

Objective: The total rotational range of motion (TRROM) difference in right-left side shoulder glenohumeral joint and muscle strength imbalance in the dominant-nondominant side have been reported to be associated with injury in swimmers. The purpose of this study was to investigate the shoulder isometric muscle strength of young swimmers with and without TRROM asymmetry.

Methods: Assessments of passive TRROM were measured with a goniometer. Hand-held dynamometry was used for the shoulder isometric muscle strength measurements in young swimmers. Thirty-two female swimmers (age: 11.1±1.5 years; body weight: 39.8±9.6 kg) and 42 male swimmers (age: 10.9±1.6 years; body weight 38.1±8.3 kg) were divided into two groups according to TRROM asymmetry in glenohumeral joint.

Results: Isometric strength of shoulder muscles (flexion, extension, external rotation (ER), internal rotation (IR), Flexion: Extension and External rotation: Internal rotation) were similar between the groups with TRROM asymmetry (n=30) and without TRROM asymmetry (n=44) in both dominant and non-dominant sides (p>0.05). Additionally, while external rotation: internal rotation of dominant side was greater in female (p=0.04), other isometric muscle strength and ratio were similar in both gender (p>0.05).

Conclusions: TRROM asymmetry is one of the many factors affecting muscle strength in overhead sports (basketball, volleyball) but it is not effective in these ages range in the swimming.

Keywords: Asymmetry; muscle strength imbalance; overhead athlete; swim

1. INTRODUCTION

Swimming is one of the sports performed in water that provides physical development in the most perfect way where gravity is almost zero and all muscles work in harmony (1). The swimming sport requires the upper extremity muscle strength to push the body through the water and advanced rapidly. Although swimming provides a symmetrical and balanced development of body muscles, factors such as internal rotation (IR) and external rotation (ER) muscle strength imbalance, shoulder flexibility, total rotational range of motion (TRROM) asymmetry, previous injury history, incorrect technique of swim, and overuse were found to be associated with shoulder pain and injury (2). Shoulder pain is the most common injury (up to 41%) in young swimmers, which may result in poor performance and misses of training (2, 3).

TRROM asymmetry is described as the difference in the TRROM of the right and left shoulder (IR plus ER) greater than 10° (4-6). It has been reported in previous studies that the difference in TRROM between the right and left shoulder is related to injury (7, 8). Wilk et al. reported that the risk of

injury in upper extremity athletes with a shoulder right and left TRROM asymmetry higher than 5° is 2.5 times greater (9). These asymmetries in ROM were attributed to changes in bone morphology because of participation in sports in athletes in the process of musculoskeletal development in the humeral head and glenoid (10, 11). Repeated torsional swimming stroke over the humeral head leads to further retroversion of the humeral head. This retroversion position affects TRROM by increasing ER (12). Similarly, young swimmers use the shoulders approximately 11.000 times in a week in the overhead position during swim stroke (13).

Training involving multiple repetitive overhead activities may cause muscle strength imbalance, which has been associated with shoulder injury and pain (2). Especially when freestyle swimming training is dominant; shoulder makes continuous repetitive movements in the direction of shoulder, IR, adduction and extension (EX) and these muscles are expected to strengthen further. IR and adduction muscle strength have been declared to be increased in studies, but studies on flexion (FL) and EX strength are

inconsistent (13, 14). McLaine et al. reported that the low EX muscle strength may be associated with a shoulder injury (15). A strong selective increase in shoulder muscle groups that produces the strength required to swim can cause muscle imbalances over time (16). In the literature, there are studies examining the profiles of shoulder muscle strength (FL, EX, ER, IR) and muscle strength ratios (FL: EX, ER: IR) in the studies investigated in swimmers (14, 17, 18). However, these muscle strengths and ratios are different and inconsistent. While there are studies reported as ER: IR ratio 2: 3 in master and college-level swimmers, there are studies that report this ratio as 1: 1 (14, 17, 18). The current study was to investigate these muscle strengths and ratios in young swimmers.

Studies examining shoulder rotation movements, strength and mobility in swimmers have been conducted in a larger age range. Muscle strength imbalance and TRROM asymmetry in swimmers were examined separately (14, 15). Nevertheless, there is no study in the literature on whether or not TRROM asymmetry affects isometric shoulder muscle strength in young swimmers. Therefore, the purpose of current study was to investigate the shoulder isometric muscle strength of young swimmers with and without TRROM asymmetry. The authors hypothesized that shoulder isometric muscle strength is lower with TRROM asymmetry than without TRROM asymmetry in young swimmers.

2. METHODS

When starting the research, the G * Power (G * Power Ver. 3.0.10, Franz Faul, Universität Kiel, Germany) program was used to determine the strength of the study and it was deemed appropriate to include at least 74 people with 85% power ratio. Signed informed consents were obtained from all swimmers and their parents before the data collection and the study was approved by the Hacettepe University Non-Invasive Clinical Research Ethics Committee (GO 19/876).

Participants

This cross-sectional observational study was designed for young swimmers aged 8-12 years (32 females; 42 males) who had at least six hours of swimming and 2 hours of dry-land training per week without shoulder pain. All of the athletes were level 2 according to the Tanner stage, and none of them were in the pubertal period. All athletes were referred to study by the swimming club's team coaches. An information meeting was organized for coaches, swimmers, and their parents before the assessments. Swimmers who did feel shoulder pain for the last 2 months, history of shoulder and neck surgery or shoulder dislocation were not included in this study. Before the assessments, all participants completed a questionnaire which includes demographic information (hand dominance, swimming experience, etc.).

2.1. Range of Motion Measurement

Assessments of passive TRROM were measured with a goniometer (Model 12-1000, Fabrication Enterprises, Inc: White Plains, New York). The two-measurer method with scapular stabilization which among the other GH rotation measurements to have the best reliability was used (19). For assessments, athletes were positioned supine with the shoulder 90° abduction with the elbow at 90° FL (Figure 1 a, b). While one examiner stabilized scapula with pressure to the anterior aspect, the other examiner rotated internally and externally until end-feel was felt (20). All TRROM measurements were performed after 5 minutes warm-up. Each test was performed three times for consistency by the same therapist on the same day.

2.2. Muscle Strength Measurement

Hand-held dynamometry (HHD) (Model-01165, Lafayette Instrument Company, Lafayette IN, USA) was used for the shoulder isometric muscle strength measurements in young swimmers. HHD is a valid and reliable tool for assessing isometric muscle strength of the shoulder in swimmers (21). For every athlete, strength measurements were applied after TRROM assessments and each swimmer included in the study was informed verbally about the technique of the isometric shoulder strength test application before starting the test. Athletes were positioned supine on the table. FL and EX isometric muscle strength were measured at 140° abduction of shoulder in the scapular plane with the elbow elongate because this position is functionally for swim when hand entry and early pull-through phase (3). For measurements isometric muscle strength of shoulder IR and ER at 90° abduction of the arm position with the elbow at 90° FL was chosen because this position is functionally appropriate to the mid-pull-through and recovery phases of the swim. To ensure correct movement, athletes were asked to be performed submaximal contraction against the hand of examiner before measurements. Muscle strength was measured without manual stabilization of the shoulder because this position has shown excellent intra-rater reliability in supine to the upper extremity or trunk (22). After the shoulder position was completed, the HHD was placed on the anterior and posterior side of the distal (ulnar styloid process) of the forearm. After completing the shoulder movement position determined for the test, athletes were asked to maintain the maximum isometric contraction for 5 seconds. The tests were performed 3 times and the averages were recorded. In addition, 30 seconds of rest was given between each test and tests were performed bilaterally. During the test, the dynamometer was pushed into the patient's arm without movement in the joint to overcome the maximum muscle strength and verbal encouragement was provided during the test (break test) (4). Because there were different sized swimmers in the study, the average maximum contraction strength (Newtons) was standardized based on body weight to compare shoulder muscle strength

(3). ER: IR and FL: EX ratios were calculated for each swimmer from the standardized values and were reported.

According to many studies conducted in overhead athletes in the literature, and measurement error associated with standard goniometry, a 10° cut-off value was chosen considering bone morphology (5-7). Swimmers were divided into two groups according to TRROM asymmetry.

2.3. Statistical Analysis

SPSS 23.0 software program (IBM SPSS Statistics version 23.0, IBM Corp. Armonk, New York, ABD) was used for the statistical analyses. It was determined whether the variables were normally distributed by Kolmogorov-Smirnov / Shapiro-Wilks analytical methods and visual methods (histograms and probability plots). Independent samples t-test was used to compare the data (in terms of TRROM asymmetry and gender) groups because all strength variables were distributed normally. Paired samples t-test was used to

compare the data (dominant and non-dominant side isometric muscle strength) dependent variables in females and males. The significance level was determined as $p < 0.05$.

3. RESULTS

Thirty-two female and 42 male swimmers between 9-12 years old (female: 11.1 ± 1.5 years and male: 10.9 ± 1.6 years; mean body weight 39.8 ± 9.6 kg and 38.1 ± 8.3 kg, respectively) were included in the present study. All swimmers had an average of 6.4 hours (6-9 hours) practice per week. Two swimmers were excluded from the study according to shoulder pain during the tests.

Thirty swimmers of 74 (40.5%) had TRROM ($19.3^{\circ} \pm 6.7^{\circ}$) asymmetry in GH joint. Isometric shoulder muscle strength measures were distributed normally and there was no difference in isometric muscle strength between with TRROM asymmetry ($n=30$) and without TRROM asymmetry ($n=44$) groups ($p > 0.05$) (Table 1).

Table 1. Comparison of isometric shoulder muscle strength in swimmers with and without TRROM asymmetry

	Dominant			Nondominant		
	TRROM asymmetry	without TRROM asymmetry	p	TRROM asymmetry	without TRROM asymmetry	p
FL	12.66 \pm 3.51	13.23 \pm 3.18	0.471	11.42 \pm 3.24	12.36 \pm 2.73	0.182
EX	11.03 \pm 1.81	11.13 \pm 1.91	0.833	9.80 \pm 1.81	10.24 \pm 1.99	0.342
IR	15.40 \pm 3.04	15.64 \pm 2.99	0.739	13.70 \pm 3.44	14.91 \pm 2.80	0.702
ER	15.28 \pm 2.58	16.50 \pm 3.05	0.077	13.39 \pm 2.90	14.27 \pm 3.02	0.213
FL: EX	1.14 \pm 0.29	1.19 \pm 0.25	0.537	1.17 \pm 0.29	1.22 \pm 0.26	0.409
ER: IR	0.99 \pm 0.12	1.07 \pm 0.18	0.102	0.97 \pm 0.20	0.96 \pm 0.15	0.352

FL, flexion; EX, extension; IR, internal rotation; ER, external rotation; TRROM, total rotational range of motion.

There were a similar muscle strengths between dominant and non-dominant sides in both genders ($p > 0.05$). ER: IR ratio significantly higher in females than males ($p < 0.05$). Unilateral shoulder muscle strengths were stronger in the dominant

side than non-dominant side in both gender ($p < 0.001$). Unilateral muscle strength (ER: IR, FL: EX) ratios were similar in both gender ($p > 0.05$) (Table 2).

Table 2. Mean isometric shoulder strength and mean strength ratios for females and males.

	Dominant			Nondominant		
	Females	Males	p	Females	Males	p
FL	12.15 \pm 2.82 ^{abd}	13.66 \pm 3.53 ^{abd}	0.052	11.45 \pm 2.23 ^{abd}	12.38 \pm 3.39 ^{abd}	0.183
EX	10.97 \pm 1.89 ^{abd}	11.18 \pm 1.85 ^{abd}	0.634	10.01 \pm 1.89 ^{abd}	10.01 \pm 1.96 ^{abd}	0.830
IR	14.79 \pm 2.69 ^{acd}	16.12 \pm 3.11 ^{acd}	0.059	13.95 \pm 2.74 ^{acd}	14.78 \pm 3.35 ^{acd}	0.258
ER	16.25 \pm 3.17 ^{acd}	15.81 \pm 2.73 ^{acd}	0.526	13.66 \pm 2.69 ^{acd}	14.11 \pm 3.21 ^{acd}	0.524
FL: EX	1.11 \pm 0.20	1.23 \pm 0.30	0.054	1.16 \pm 0.20	1.23 \pm 0.31	0.224
ER: IR	1.10 \pm 0.16	0.99 \pm 0.15	0.004*	0.99 \pm 0.18	0.96 \pm 0.17	0.486

*, $p < 0.05$; significant difference between: ^a, males or females for each test $p < 0.001$; ^b, flexion or extension strength $p < 0.001$; ^c, internal or external rotation strength $p < 0.001$; ^d, dominant and non-dominant sides $p < 0.05$.

4. DISCUSSION

This is the first study to compare isometric shoulder muscle strength according to TRROM asymmetry in young swimmers aged between 8-12 years old. The main result of the current study indicated that TRROM asymmetry was not effective on shoulder isometric muscle strength in young swimmers. Additionally, there was no significant relationship between TRROM asymmetry ($>10^\circ$) in the GH joint and shoulder mobility.

Asymmetry in TRROM of the GH joint in dominant upper extremity in comparison to non-dominant upper extremity has been associated to shoulder injury in overhead athletes (7, 8). In addition, Wilk et al. (9) stated that 5° TRROM asymmetry leads to a 2.5 times greater possibility of upper extremity injury. Furthermore, Ellenbecker et al. (5) found that the right-left shoulder TRROM asymmetry in junior tennis athletes were $7-9^\circ$, also reported that (4) a 5° TRROM difference in high school and professional baseball athletes. Reeser et al. (23) reported that the right-left shoulder ROM asymmetry in volleyball players was 11° . In addition, 5° asymmetry in overhead athletes is recommended to be accepted as pathological (6). Sprague et al. (24) accepted a 10° threshold asymmetry for athletes performing overhead activity (baseball, swimming, volleyball) to allow for degree of measurement errors. Therefore, in the present study, 10° TRROM asymmetry in GH joint was considered as a cut-off value in accordance with significant differences in previous studies. Due to young swimmers were participated in this study, we considered the amount of rotation associated with bone morphological changes in the overhead athlete, unlike other studies.

Upper extremity muscle strength is one of the most important factors to be successful in swimming. However, repetitive stresses or other factors may cause an imbalance in shoulder muscle strength. It was stated that the reason for this imbalance may be caused by ROM differences in the GH joint (25, 26). The current study showed that there was no statistically significant difference in all isometric shoulder muscle strength between groups with and without TRROM asymmetry. This means that TRROM asymmetry has no effect on shoulder muscle strength in young swimmers. Although swimming sport is an overhead activity, continuous repetitive movement patterns are performed bilaterally, unlike other sports (volleyball, basketball) might be the main reason for this result. On the other hand, Güney et al. (26) reported that shoulder IR and ER muscle strengths were lower in volleyball and basketball athletes with TRROM asymmetry than athletes without TRROM asymmetry. The authors also stated that the increase in range of motion of the ER, which is specific to the sports performed may reveal this result.

Although it is discussed in the literature whether ER:IR ratio is the most suitable measurement technique for shoulder stability in overhead athletes, in previous studies, ER: IR ratio was shown as a risk factor for a shoulder injury in athletes performing an overhead activity (3, 13). In addition, the ER: IR ratio > 0.66 suggests the possibility of injury in overhead

athletes (27). Furthermore, the ER: IR muscle strength ratio of the swimmers at college and masters level was reported to be approximately 2:3 (17). However, Magnusson et al. (28) stated this ratio as 1: 1 for swimmers at college and masters levels. ER: IR ratios were approximately 1:1 in both groups in this study. McLaine et al. (15) reported lower extension muscle strength associated with the injury. IR muscle strength is expected to be greater than antagonists in swimmers (13). Opstoel et al. (18) stated that children between the ages of 9 and 11 did not show any physical characteristics specific to the sport and the most important reason for this was the hours spent on the sport. Ericsson has specified the 10000 hours rule for the sport-specific characteristic (29). The reason for this similarity in the current study is maybe that the swimmers of this age have different style of swimming in each training session and the lack of specialization yet.

Contrary to the literature (14, 28), there was no statistically significant difference in isometric shoulder muscle strength between males and females, except for the dominant arm ER: IR ratio. The main reason for this result might be the immaturity of our sample accompanying with no technical specialization.

The results of studies involving higher age groups in the literature have shown that muscle strengths are similar between dominant and non-dominant sides due to the bilateral nature of swimming (14, 17, 28). In contrast to the literature, shoulder muscle strengths were found to be higher on the dominant side in females and males in our study. This result, which is contrary to the bilateral characteristics of swimming, may be due to the fact that swimmers at this young age cannot perform parameters such as arm stroke and breathing during swimming completely symmetrically yet.

Muscle strength ratios are important to follow muscle imbalance around the joint (17, 30). In the present study, the FL: EX ratios were similar in females and males. It is important to assess FL: EX ratio in elevation position as a functional position in swimming and may be useful in monitoring muscle imbalance in this age group. Additionally, our results of IR and ER strength are difficult to compare with other studies on young swimmers because athletes in these studies were not normalized to body weight and were evaluated with different protocols like isokinetic dynamometers (13, 16). In the literature, a study in which hand dynamometer was used and calculate muscle strength according to body weight; shoulder muscle strength (FL, EX, ER, IR) was found to be greater in males than females, but strength ratios (FL: EX, ER: IR) were reported to be similar (14). The difference between the current study and McLaine's study is the age difference. His study had more swimming experiences because the age range in the study was 14-20 years. In studies which included a larger age range (mean 16 years old), in females the ER: IR ratio was 0.91, the FL: EX ratio was 0.93, while males ER: IR ratio was 0.86, the FL: EX ratio was 0.86 (14, 16). Differently, ratios in the current study are higher than these studies. This

may be due to the body's adaptation to the training as the age grows and the increase in EX and IR muscle strength.

The primary limitation of current study is that age range (8-12 years) includes a long period and 4 years is an important growth period for individuals at this age. However, it was important for the result that there was no age difference between the groups.

5. CONCLUSION

Shoulder muscle strengths and ratios were similar in both groups separated according to TRROM asymmetry. The strength and ROM evaluations contributed to the clinical data for the evaluation of swimmers. It will also shed light on coaches to consider these shortcomings when designing their training programs. The results of this study are an example of swimmers in these ages (8-12 years old). To avoid asymmetry and injury at older ages (elite, master level), the results of this study may be essential. Therefore, prospective studies are needed to show how TRROM asymmetry affects isometric shoulder muscle strengths (FL, EX, IR, ER) and ratios (FL:EX, ER:IR) in older (elite, college, master level) swimmers.

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Awareness of Human Papillomavirus Vaccine Among Dental Students

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ABSTRACT

Objective: More recently, HPV infection has been portrayed as a vital risk factor for head and neck squamous cell carcinoma (HNSCC). Dentistry students need comprehensive information about HPV to provide accurate advice to their patients. The aim of this study is 4th and 5th grade students' awareness about HPV vaccination.

Methods: A questionnaire consisting of 7 questions was applied to 226 students (102 4th grade and 126 5th grades), who were studying at Marmara University Faculty of Dentistry. In this survey, students' knowledge level and awareness were examined.

Results: In our study 75 (33.1%) of the participants were male and 151 (66.8%) were female. The rates of agreement of 4th grade students (96.1%) with the proposition "It is important that oral health professionals play an active role in the general medical condition of their patients." were statistically significantly lower than the 5th grade students (97.6%) ($p: 0.010$; $p < 0.05$). A statistically significant difference between grades in terms of participation rates in the statement "I got my HPV vaccine / I am thinking of getting it". The rate of participation of 5th grade (%38.7) students in this statement was significantly lower than 4th grades (%45.1) ($p: 0.019$; $p < 0.05$) and significantly higher in women (47.7%) than in men (29.3%) ($p = 0.005$; $p < 0.05$).

Conclusion: Comprehensive training and motivation for improving dentistry students awareness against HPV vaccine will also improve knowledge and attitudes of the dental students on HPV induced oral cancer.

1. INTRODUCTION

Oral cavity cancers are the seventh most frequently existing cancer and, in terms of mortality, the ninth fatal by cancer region in the world as portrayed by World Cancer Report 2014 (1-7). Human papillomavirus (HPV) leads to approximately 72% of male and 63% of female oropharyngeal cancers (8). It has been reported that HPV is responsible for 91% of anal cancers, 75% of vaginal cancers and 60% of oropharyngeal cancers in the United States (9). While oral cancer rates are growing overall, HPV-related oral cancer is rising undoubtedly and requires a prevention attempts focused on HPV (10).

For the etiology of oropharyngeal cancer, various studies have portrayed HPV as a factor (10-15). It has been reported that, 24 types of HPV, 1, 2, 3, 4, 6, 7, 10, 11, 13, 16, 18, 30, 31, 32, 33, 35, 45, 52, 55, 57, 59, 69, 72, and 73, have been related with benign and 12 types, 2, 3, 6, 11, 13, 16, 18, 31, 33, 35, 52, and 57, with malignant lesions in the oral cavity (16,17).

The recently introduced two HPV vaccines, bivalent and quadrivalent types, for HPV infection is active against subtypes of HPV which are related to genital warts, cervical

cancer, and cancers including oropharyngeal cancer. Evidence shows the possibility that HPV vaccination may be effective in decreasing the incidence of oral cancer, however, the assessment of HPV vaccination for oral cancer prevention is still debatable (18). The results of a study that was conducted in Belgium in order to evaluate awareness of students about HPV infection showed that, 95% of medical students were aware of HPV and 92% were aware of vaccinations and immunity against HPV, while only 46% knew that HPV could cause anogenital cancer (19). In a study by Lorenzo et al. (20), a survey was handed out to 240 dental students, of which 158 returned it. Most of the students described not been vaccinated against HPV ($n = 81$, 51.3%) and admitted that HPV infection was related to oropharyngeal cancer (75%).

Dentists play a crucial role in examination of the oral cavity to determine potential malignant lesions. As a result of our literature review, it has been found that there is not enough information and awareness about HPV vaccination related oropharyngeal squamous cell carcinoma among dentistry students in Turkey. The aim of this study is to evaluate

awareness of 4th and 5th grade students of Marmara University Faculty of Dentistry about HPV vaccination.

2. METHODS

This study was conducted at Marmara University Faculty of Dentistry, Istanbul, Turkey. A self-administered survey was applied to 226 students (102 4th grade and 124 5th grade). Students' awareness were examined in a questionnaire consisting of 7 questions. The questions in the questionnaire were made without any names by specifying only the classes. All students from fourth and fifth year were invited to participate. Participation in the survey was anonymous, and voluntary.

2.1. Statistical Analysis

IBM SPSS Statistics 22.0 (IBM SPSS, Turkey) program is used for statistical analysis. Chi-square test and Fisher Freeman Halton test was used to compare descriptive statistics (mean, standard deviation, frequency) as well as qualitative data. Significance was assessed at $p < 0.05$ level.

2.2. Ethical Approval

The study protocol of the study was approved by Marmara University School of Medicine Non-Interventional Clinical Research Ethics Committee with protocol number 09.2019.658.

3. RESULTS

The study was conducted on a total of 226 students, of which 75 (33.1%) were male and 151 (66.8%) were female. The mean age of the students was 23.15 ± 1.33 years. 102 (45.1%) of the students were 4th grade, 124 (54.9%) were 5th grades.

According to gender, there was no statistically significant difference between the rates of participation in the statements "It is important that oral health professionals play an active role in the general medical condition of their patients", "HPV vaccine can promote earlier or more risky sexual behavior in adolescent patients", "I'm sure most patients will get it if I recommend getting an HPV vaccine", "It is the responsibility of oral health professionals to recommend HPV vaccine" and "I feel knowledgeable enough to discuss the HPV vaccine with patients and parents." ($p > 0.05$). There is no statistically significant difference between the rates of recommending HPV vaccine to male patients according to gender ($p > 0.05$). The rates of participation in the statement "I got my HPV vaccine / I am thinking of getting it." is significantly higher in women (47.7%) than in men (29.3%) ($p = 0.005$; $p < 0.05$) (Table 1).

There was a statistically significant difference between the classes in terms of participation rates in the statement "It is important that oral health professionals play an active

role in the general medical condition of their patients." The rate of participation of fourth grade (96.1%) students in this proposition was significantly lower than 5th grade (97.6%) students ($p = 0.010$; $p < 0.05$).

Table 1. Assessment of HPV vaccination according to gender

		Male	Female	Total	p
It is important that oral health professionals play an active role in the general medical condition of their patients.	I agree	72 (96%)	147 (97.4%)	219 (96.9%)	0,822*
	I do not agree	1 (1.3%)	2 (1.3%)	3 (1.3%)	
	No idea	2 (2.7%)	2 (1.3%)	4 (1.8%)	
HPV vaccine can promote earlier or more risky sexual behavior in adolescent patients.	I agree	5 (6.7%)	22 (14.6%)	27 (11.9%)	0,105**
	I do not agree	51 (68%)	83 (55%)	134 (59.3%)	
	No idea	19 (25.3%)	46 (30.5%)	65 (28.8%)	
I'm sure most patients will get it if I recommend getting the HPV vaccine.	I agree	21 (28%)	36 (23.8%)	57 (25.2%)	0,659**
	I do not agree	35 (46.7%)	80 (53%)	115 (50.9%)	
	No idea	19 (25.3%)	35 (23.2%)	54 (23.9%)	
It is the responsibility of oral healthcare professionals to recommend the HPV vaccine.	I agree	47 (62.7%)	71 (47%)	118 (52.2%)	0,085**
	I do not agree	11 (14.7%)	32 (21.2%)	43 (19%)	
	No idea	17 (22.7%)	48 (31.8%)	65 (28.8%)	
I feel well informed enough to discuss the HPV vaccine with patients and parents.	I agree	19 (25.3%)	29 (19.2%)	48 (21.2%)	0,417**
	I do not agree	44 (58.7%)	89 (58.9%)	133 (58.8%)	
	No idea	12 (16%)	33 (21.9%)	45 (19.9%)	
I got my HPV vaccine / I am thinking of getting it.	Yes	22 (29.3%)	72 (47.7%)	94 (41.6%)	0,005**
	No	34 (45.3%)	38 (25.2%)	72 (31.9%)	
	No idea	19 (25.3%)	41 (27.2%)	60 (26.5%)	
Would you recommend HPV vaccine to male patients?	Yes	45 (60%)	82 (54.3%)	127 (56.2%)	0,256**
	No	1 (1.3%)	9 (6%)	10 (4.4%)	
	No idea	29 (38.7%)	60 (39.7%)	89 (39.4%)	

*Fisher Freeman Halton Test; **Chi-square test.

There was no statistically significant difference between 4th and 5th grade students in terms of participation rates in the statement "HPV vaccine can promote earlier or more risky sexual behavior in adolescent patients", "I'm sure most patients will get it if I recommend getting the HPV vaccine", "It is the responsibility of oral healthcare professionals to

recommend the HPV vaccine”, “I feel well informed enough to discuss the HPV vaccine with patients and parents” and “Would you recommend HPV vaccine to male patients?” ($p > 0.05$).

Moreover a statistically significant difference between grades in terms of participation rates in the statement “I got my HPV vaccine / I am thinking of getting it”. The rate of participation of 5th grade (38.7%) students in this statement was significantly lower than 4th grades (45.1%) ($p = 0.019$; $p < 0.05$) (Table 2).

Table 2. Assessment of HPV-related cancer knowledge and HPV vaccination according to grade levels

		4 th grade	5 th grade	Total	p
It is important that oral health professionals play an active role in the general medical condition of their patients.	I agree	98 (96.1%)	121 (97.6%)	219 (96.9%)	0.010*
	I do not agree	0 (0%)	3 (2.4%)	3 (1.3%)	
	No idea	4 (3.9%)	0 (0%)	4 (1.8%)	
HPV vaccine can promote earlier or more risky sexual behavior in adolescent patients.	I agree	13 (12.7%)	14 (11.3%)	27 (11.9%)	0.945**
	I do not agree	60 (58.8%)	74 (59.7%)	134 (59.3%)	
	No idea	29 (28.4%)	36 (29%)	65 (28.8%)	
I'm sure most patients will get it if I recommend getting the HPV vaccine.	I agree	26 (25.5%)	31 (25%)	57 (25.2%)	0.467**
	I do not agree	48 (47.1%)	67 (54%)	115 (50.9%)	
	No idea	28 (27.5%)	26 (21%)	54 (23.9%)	
It is the responsibility of oral healthcare professionals to recommend the HPV vaccine.	I agree	49 (48%)	69 (55.6%)	118 (52.2%)	0.370**
	I do not agree	19 (18.6%)	24 (19.4%)	43 (19%)	
	No idea	34 (33.3%)	31 (25%)	65 (28.8%)	
I feel well informed enough to discuss the HPV vaccine with patients and parents.	I agree	24 (23.5%)	24 (19.4%)	48 (21.2%)	0.744**
	I do not agree	58 (56.9%)	75 (60.5%)	133 (58.8%)	
	No idea	20 (19.6%)	25 (20.2%)	45 (19.9%)	
I got my HPV vaccine / I am thinking of getting it.	Yes	46 (45.1%)	48 (38.7%)	94 (41.6%)	0.019**
	No	23 (22.5%)	49 (39.5%)	72 (31.9%)	
	No idea	33 (32.4%)	27 (21.8%)	60 (26.5%)	
Would you recommend HPV vaccine to male patients?	Yes	54 (52.9%)	73 (58.9%)	127 (56.2%)	0.498**
	No	6 (5.9%)	4 (3.2%)	10 (4.4%)	
	No idea	42 (41.2%)	47 (37.9%)	89 (39.4%)	

*Fisher Freeman Halton Test; **Chi-square test.

4. DISCUSSION

Oral cancer is commonly classified as head and neck cancer, and globally, head and neck squamous cell carcinoma (HNSCC) is the sixth to ninth most common malignancy (18,21). The main risk factors for head and neck cancers are increasing age, smoking and alcohol consumption (22-24). Recently, HPV infection has been portrayed as a vital risk factor for HNSCC and the majority (82%) of HPV-positive HNSCCs are due to HPV-16 infection (25).

The current HPV vaccination approach for cervical cancer prevents development of some oral squamous cell cancer, as broadly defined, counting some anogenital carcinoma, such as anal, penile, and vulvar cancers. The Gardasil vaccine for strains 6,11,18,16 of HPV and Cervarix for strains 16 and 18 was introduced and are recommended for prevention of HPV infection in 11-12 years old individuals (26). The prophylactic HPV vaccines may reduce oropharyngeal cancer incidence by protecting against HPV-16 and HPV-18 infection (27).

Dentists should be involved in improvement of knowledge and healthy attitudes of vaccination to prevent HPV infections and oral cancer associated with HPV (18,28). Lorenzo-Pouso et al. (20) assessed 158 dental students for their knowledge of HPV and the study composed of 89 preclinical students (56.3%) and 69 clinical students (43.7%). They found that 48.7% of students declared to be vaccinated against HPV and that 57.7% of female students and 27.7% of male students reported to be vaccinated. Hashemipour et al. (9) conducted questionnaire on 290 medical and dental students to evaluate awareness of medical and dental students about the infection and vaccination of the human papilloma virus. In their study, 39.9% of respondents were not familiar with the HPV vaccine and 62.1% tended to be vaccinated. Rajiah et al. (29) assessed the influence of final year dental students' knowledge and attitude for human papillomavirus infection of cervical cancer on willingness to pay for vaccination. They reported that dental students' knowledge on HPV and cancer has no affect on their attitude towards HPV vaccines yet about 90% of students would be vaccinated if sufficient information was available. The results also revealed that female students have more knowledge than their males.

In our study the rates of participation in the statement “I got my HPV vaccine / I am thinking of getting it.” is significantly higher in women (47.7%) than in men in our study (29.3%) ($p = 0.005$; $p < 0.05$).

Poelman et al. (30) evaluated knowledge of HPV and oral cancer among dentistry students and they showed in their study that one third of the female students were vaccinated against HPV. It is also reported that Dutch dental students thought dentists should discuss this subject with their patients, which suggests students are ready to discuss the HPV vaccine with their patients. However, in our study there was a statistically significant difference between the classes in terms of participation rates in the statement “It is important that oral health professionals play an active role in the general medical condition of their patients”. The

rate of participation of fourth grade (96.1%) students in this proposition was significantly lower than 5th grade (97.6%) students ($p=0.010$; $p<0.05$).

5. CONCLUSION

In conclusion, early detection of oral cancer dentists play a vital role which would conclude in a favorable outcome for the patients. Future dentists are willing to take part in prevention of HPV-related oral cancer. Therefore, screening for oral cancer and education about HPV vaccination should be essential elements of the dental curriculum.

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Comparison of the Effects of Three Different Methods in Reducing Primary Postpartum Hemorrhage

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ABSTRACT

Objective: The aim of this study was to determine the effects of three different methods in reducing primary postpartum hemorrhage.

Methods: The study was carried out in Istanbul/Turkey with 150 people at a maternity hospital. The participants were assigned to the external circular fundus massage (ECFM) (n=50), external bimanual fundus compression (EBFC) (n=50) and control (C) (n=50) groups with the simple randomization method. The women in the experiment groups of external circular fundus massage or external bimanual uterus fundus compression received intervention for one hour in the postpartum period. At the 6th postpartum hour, the hemogram values and total lochia amount of all women were measured.

Results: The mean \pm standard deviation (SD) age of the women was 24.77 ± 4.40 years, 63.3% were having their first birth, and 47.3% gained weight between 11 and 16 kg in their pregnancy. There was no significant difference between the groups in terms of the mean \pm SD Hb at the 6th postpartum hour (ECFM group = 11.5 ± 1.1 ; EBFC Group = 11.7 ± 3.6 ; C group = 11.4 ± 1.0 g/dL, F = 0.371, p = 0.691). In comparison to the ECFM and C groups, the 2nd postpartum hour visual analog scale (VAS) score of the EBFC group was found to be significantly lower (p < 0.05).

Conclusion: The hemoglobin and thrombocyte levels at the 6th postpartum hour were higher in the EBFC group in comparison to the other groups, while the hematocrit value decreased more. Since EBFC is effective in reducing postpartum pain, it is recommended to be applied especially to women with postpartum pain.

Keywords: Hemoglobin, delivery, postpartum hemorrhage, randomized controlled, uterus massage

1. INTRODUCTION

Postpartum hemorrhage (PPH) is defined as blood loss over 500 mL in vaginal delivery and over 1000 mL in post-cesarean delivery. Primary postpartum hemorrhage occurs within the first 24 hours (early), and the bleeding that occurs after 24 hours is called secondary (late) postpartum hemorrhage. Primary postpartum hemorrhages occur in 4-6% of births, and hemorrhagic shock and sudden death develop when bleeding is not controlled. One-half of maternal deaths occur due to bleeding in the first 24 hours postpartum (1-4).

The World Health Organization (WHO) reported that, in 2015, an estimated 303,000 maternal deaths were occurring worldwide (5). In Turkey, according to the Health Statistics Yearbook 2018 News Bulletin, in 2017, the maternal mortality rate was reported as 14.6 per 100,000 live births (6). Primary postpartum hemorrhages usually occur as a result of uterine atony, placenta retention and delivery (vagina and cervix) due to laceration. The most important cause of primary postpartum hemorrhage is uterine atony (75-90%) (2,7).

In the postpartum period, various pharmacological and non-pharmacological interventions are performed to achieve uterine contraction and prevent bleeding. One of the routine non-drug interventions is external uterine massage. Uterine massage reduces the amount of postpartum hemorrhage by stimulating prostaglandin release and contraction of the uterus. In a study, it was stated that uterine massage reduces blood loss and uterotonic requirement. External uterus fundus massage may be applied in various ways (external circular fundus massage-ECFM and external bimanual fundus compression-EBFC) (8-10).

Although it is stated that uterine massage increases contractions and accelerates uterine involution and prevents atony, there are limited and conflicting studies in the literature showing the effectiveness of massage. The aim of this study was to determine the effects of three different methods in reducing primary postpartum hemorrhage.

2. METHODS

2.1. Study Design

This study was planned as a single-blind, randomized controlled trial (Figure 1). After the research was planned, a power analysis was performed using the G * Power 3.1 program. According to the results obtained from the research, as a result of the standard deviation obtained from the postpartum Hb mean, the mean difference was 0.90, the degree of freedom (df) was 2, the effect size was calculated as 0.3, and it was observed that 90% power was obtained on the $\alpha=0.05$ level (11,12). A total of 224 persons were included in the study considering data losses. However, the study was completed with 150 person, including 50 in each group. The eligibility criteria for the participants in this study are shown in Table 1.

Table 1. Eligibility Criteria for Participants

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> • Age range: 18-40 • Gestation: 37-41 • Nulliparous or multiparous • Intrapartum hemoglobin value of at least 11 g/dL (Center for Disease Control=CDC recommendation) • Fetus in cephalic presentation • Single healthy fetus • Vaginal delivery • Estimated fetal weight: 2500-4000 gr. 	<ul style="list-style-type: none"> • Those with any medical or obstetric complication (coagulation defect, placenta previa, etc.) • Developing any postpartum complications • Those whose babies were transferred to the newborn unit • Cesarean births • Cervical tear cases • Those who cannot collect their pads • Women without postpartum 6th-hour hemogram results • Those who were administered postpartum analgesics and additional uterotonics • Women who did not volunteer for participation in the study.

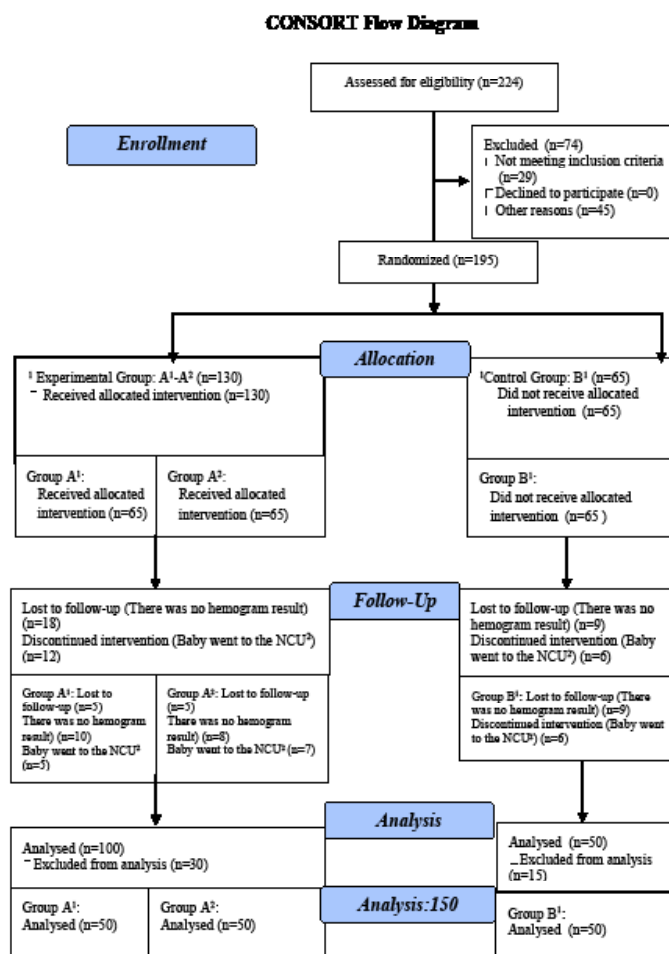


Figure 1. CONSORT Flow Diagram of Randomized Controlled Trial
¹Experimental Group A1- A2 and Control Group B1 and comparator arms
²Newborn care unit

2.2. Settings and Participants

The study was conducted in Istanbul, Turkey with women at a maternity hospital between February and November 2015. The hospital where the research was conducted has a capacity of 352 beds. At this hospital, approximately 7321 deliveries, 4303 vaginal deliveries and 3018 caesarean section deliveries occur annually. Randomization was performed using a computer. Envelopes containing the randomization results were kept closed in the delivery room. Block randomization was used to equilibrate the groups (13). The consort flow diagram of the research is shown in Figure 1.

2.3. Data Collection Tools

Participant diagnostic information form: All forms used in the study were prepared by the researcher using the literature (5,9,14). This form included the socio-demographic and obstetric characteristics of the participants and questions about the second stage of labor (episiotomy, the way the placenta is removed, the baby's weight, etc.).

Postpartum information form: The vital signs of the participants, the pad used, the lochia clot status, the urination status and the time the newborn was breastfed were recorded (at the end of the 1st-2nd-6th postpartum hours). Venous blood (intrapartum and postpartum at the 6th hour) was also taken for the hemogram sample.

Standard pad: A standard sterile pad (weighed in a digital weighing instrument) was given to each woman at the delivery desk. All pads used at the end of the second postpartum hour were weighed. At the end of the second hour, the women were given standard sterile pads weighed to the extent that they could be used for at least 6 hours postpartum (at least 4 pads) and a pouch to collect the pads. At the end of the postpartum 6 hours, all used pads were weighed. The total weight of bleeding was recorded by subtracting the final total weight from the initial total weight.

Bed protector: A standard bed protector (weighed on a digital weighing instrument) used by the clinic was placed on the bed sheet. At the end of the postpartum second hour, the bed protector was weighed (pre-weighed) and the total amount of lochia was recorded. Bleeding controls were performed at the end of the second hour. In the following hours, the women did not need a mattress protector.

Sensitive scale (digital): A digital precision scale (Dikomsanfec digital weighing instrument (<https://www.orsa.gen.tr/FEC>) was used for weighing the pads. These instruments were being calibrated every 6 months.

2.4. Data Collection

The participant diagnostic information forms were filled in by the face-to-face interview method. The delivery processes of the women participating in the study were monitored. Immediately after the placenta was out and episiotomy or

laceration repair was completed, the woman was given a pre-weighed pad and bed protector.

Postpartum information forms were filled at the postpartum clinic. The women's vital signs (at the 1st-2nd-6th postpartum hours) were measured by the researcher. The postpartum pain levels (at the 1st-2nd-6th postpartum hours) were evaluated by the Visual Analog Scale (VAS) and recorded.

2.5. Intervention

The experiment 1 group was applied external uterine massage at the end of the first postpartum hour. The experiment 2 group was applied external bimanual fundus compression at the end of the first postpartum hour.

External Circular Fundus Massage (ECFM): At the end of the first postpartum hour, the women were administered ECFM by the researcher in one hour, for 60-second durations repeated every 15 minutes. During the massage, a gentle circular rubbing motion was performed gently down the fundus uteri with one hand, while the lower uterus was supported on the level of the symphysis pubis with the other hand.

External Bimanual Fundus Compression (EBFC): At the end of the first postpartum hour, the women were administered EBFC by the researcher in one hour, for 60-second durations repeated every 15 minutes. During the massage, the fundus uteri was gently pressed down with one hand, the lower part of the uterus was supported on the symphysis pubis level with the other hand, and the fundus was compressed between the two hands. Care was taken not to disturb the woman in both massages.

Care was taken not to impair the comfort of the woman during the massage application. After each massage, pad control was performed and evaluated in terms of lochia clots. The perineum was also evaluated in terms of edema, redness and hematoma. The control group received no intervention other than routine care and follow-up. Venous blood was collected at the 2nd and 6th prepartum and postpartum hours for hemogram measurements from all women in the three groups. All pads and bed protectors used by the woman (previously weighed) were weighed again with a digital weighing device at the end of the 2nd and 6th hours. According to the clinical protocol, 20 units of oxytocin in 500 cc 5% dextrose fluid were routinely given to all women giving vaginal delivery (5,15).

2.6. Ethical Considerations

In order to conduct the research, first of all, ethical approval from the hospital's ethics committee (the decision of the ethics committee of the Zeynep Kamil Training and Research Hospital of the Health Sciences University (date 02/06/2015/ No:7) and the permission of the institution were obtained. Before starting the study, written consent was obtained from the participants who agreed to participate in the study. It was declared that the ethical principles of the 1975 Declaration of Helsinki would be followed.

2.7. Statistical Analysis

The data obtained in the study were analyzed using the Statistical Package for the Social Sciences (SPSS) demo program. The qualitative categorical data were analyzed by Chi-squared test, the normally distributed continuous data were analyzed by One-Way ANOVA and t-test. Additionally, descriptive statistics (mean, standard deviation, frequency and percentage) were calculated. The results were evaluated in a 95% confidence interval and on a <0.05 significance level (16).

3. RESULTS

The individual and obstetric characteristics of the participants in each group were similar and are shown in Table 2.

Table 2. Individual and Obstetric Characteristics of the Women

Characteristics	ECFM group (n=50)	EBFC group (n=50)	Cgroup (n=50)	χ ² / p value
Age (years)				
18-24	28 (56.0)	25 (50.0)	29 (58.0)	1.770
25-30	16 (32.0)	20 (40.0)	14 (28.0)	0.787
>31	6 (12.0)	5 (10.0)	7 (14.0)	
Education				
Primary school	20 (40.0)	16 (32.0)	21 (42.0)	1.793
Secondary/ high school	25 (50.0)	26 (52.0)	22 (44.0)	0.774
University	5 (10.0)	8 (16.0)	7 (14.0)	
Number of pregnancies				
One	32 (64.0)	27 (54.0)	27 (54.0)	1.363
Two-four	18 (36.0)	23 (46.0)	23 (46.0)	0.506
Number of births				
Nulliparous	38 (76.0)	28 (56.0)	29 (58.0)	5.225
Primiparous	12 (24.0)	22 (44.0)	21 (42.0)	0.073
Gestational week				
37-39	15 (30.0)	16 (32.0)	21 (42.0)	1.825
40-41	35 (70.0)	34 (68.0)	29 (58.0)	0.422
Total weight gain during pregnancy				
5-10	18 (36.0)	9 (18.0)	14 (28.6)	5.870
11-16	22 (44.0)	28 (56.0)	21 (42.0)	0.273
17 and over	10 (20.0)	13 (26.0)	15 (30.6)	
Episiotomy				
Applied	45 (90.0)	42 (84.0)	39 (78.0)	2.679
Not applied	5 (10.0)	8 (16.0)	11 (22.0)	0.285
Birth weight of newborn (g)				
2500 – 3000	7 (14.0)	14 (28.0)	12 (24.0)	3.741
3001 – 3499	30 (60.0)	27 (54.0)	25 (50.0)	0.442
3500-4000	13 (26.0)	9 (18.0)	13 (26.0)	

ECFM: external circular fundus massage; EBFC: external bimanual fundus compression; C: control

In the study, there was no difference between the groups in terms of prepartum and postpartum Hb values being 11-12 g/dL or > 12.1 g/dL (Table 3).

There was no difference between the groups in terms of the prepartum and postpartum Htc values of the groups being below 34.0% or >34.1%.

There was no difference between the groups in terms of the prepartum postpartum Plt values being below ≤150 K /mm³ or > 151 K/mm³ (Table 3).

Table 3. Comparison of Hemogram and Lochia Values of Groups

Variables		ECFM group (n=50)	EBFC group (n=50)	C group (n=50)	Total (n=150)	χ ² /p value n (%)
		n (%)	n (%)	n (%)	n (%)	
Prepartum Hb	11-12	21(42.0)	20 (40.0)	22 (44.0)	63 (42.0)	0.164
	>12.1	29 (58.0)	30 (60.0)	28 (56.0)	87 (58.0)	0.921
Postpartum 6 th hour Hb	11-12	30 (60.0)	39 (78.0)	36 (72.0)	105 (70.0)	4.000
	>12.1	20 (40.0)	11 (22.0)	14 (28.0)	45 (30.0)	0.135
Prepartum Htc	≤34.0	1 (2.0)	4 (8.0)	6 (12.0)	11 (7.3)	3.728
	>34.1	49 (98.0)	46 (92.0)	44 (88.0)	139 (92.7)	0.155
Postpartum 6 th hour Htc	≤34.0	23 (46.0)	26 (52.0)	25 (50.0)	74 (49.3)	0.373
	>34.1	27 (54.0)	24 (48.0)	25 (50.0)	76 (50.7)	0.830
Prepartum Plt	≤150	10 (20.0)	7 (14.0)	5 (10.0)	22 (14.7)	2.024
	>151	40 (80.0)	43 (86.0)	45 (90.0)	128 (85.3)	0.363
Postpartum 6 th hour Plt	≤150	8 (16.0)	5 (10.0)	4 (8.0)	17 (11.3)	1.725
	>151	42 (84.0)	45 (90.0)	46 (92.0)	133 (88.7)	0.422
Postpartum 6 th hour total lochia (g)	<100	44 (88.0)	46 (92.0)	44 (88.0)	134 (89.3)	0.560
	≥100	6 (12.0)	4 (8.0)	6 (12.0)	16 (10.7)	0.756

ECFM: external circular fundus massage; EBFC: external bimanual fundus compression; C: control

There was no statistically significant difference between the groups in terms of the amount of lochia at the 6th postpartum hour being <100 g or 100 g (p> 0.05) (Table 3).

In the study, the mean ± SD prepartum Hb of the groups (12.4±0.9; 12.3±0.8; 12.4±0.9, respectively) and the mean 6th postpartum hour Hb (respectively: 11.5±1.1; 11.7±3.6; 11.4±1.0) values were compared, and no difference was observed between the groups in terms of the mean Hb values (p> 0.05) (Table 4).

The mean ± SD prepartum Htc values of the groups (37.7±2.7; 37.6±2.8; 37.5±2.8, respectively) and the mean 6th postpartum hour Htc (respectively: 34.6±3.0; 34.1± 2.8; 34.3 ± 2.8) values were compared, and the difference between the groups in terms of the mean Htc values was not significant (p> 0.05) (Table 4).

In the study, the mean ± SD prepartum Plt of the groups (respectively: 212.4±67.7; 230.4±60.4; 216.0±46.6) and the mean ± SD 6th postpartum hour Plt (215.1±58.7; 227.3±55.4; 218.9±47.7, respectively) values were compared, and there was no significant difference between the groups in terms of the mean Plt values (p> 0.05) (Table 4).

The mean 6th postpartum hour lochia amount (g) values of the groups (respectively: 110.7±48.3; 108.1±43.7; 111.9±63.9) were compared, and there was no significant difference between the groups in terms of the amount of lochia (p> 0.05) (Table 4).

In the study, the mean \pm SD 2nd postpartum hour VAS scores of the groups (respectively: 1.7 ± 1.7 ; 0.6 ± 1.1 ; 1.4 ± 1.9) were compared, and a statistically significant difference was found between the groups in terms of the mean VAS scores ($p < 0.05$) (Table 4). There was no significant difference between the groups in terms of the other hourly VAS mean scores.

Table 4. Comparison of Hemogram Values, Amount of Lochia and VAS Score of the Groups

Variables	TCFM group (n=50)	TBFC group (n=50)	C group (n=50)	F/ p value
	Mean \pm SD (Min-Max)	Mean \pm SD (Min-Max)	Mean \pm SD (Min-Max)	
Prepartum Hb	12.4 \pm 0.9 (11.0-14.5)	12.3 \pm 0.8 (11.0-15.0)	12.4 \pm 0.9 (11.0-14.6)	0.098 0.907
Postpartum 6 th hour Hb	11.5 \pm 1.1 (7.8-13.6)	11.7 \pm 3.6 (9.1-36.2)	11.4 \pm 1.0 (9.3-13.8)	0.371 0.691
Prepartum Htc	37.7 \pm 2.7 (33.7-43.3)	37.6 \pm 2.8 (32.4-47.2)	37.5 \pm 2.8 (32.3-43.5)	0.112 0.894
Postpartum 6 th hour Htc	34.6 \pm 3.0 (28.4-41.3)	34.1 \pm 2.8 (27.0-41.2)	34.3 \pm 2.8 (27.0-40.4)	0.408 0.666
Prepartum Plt	212.4 \pm 67.7 (101.0-387.0)	230.4 \pm 60.4 (100.0-364.0)	216.0 \pm 46.6 (121.0-301.0)	1.300 0.276
Postpartum 6 th hour Plt	215.1 \pm 58.7 (111.0-400.0)	227.3 \pm 55.4 (88.0-345.0)	218.9 \pm 47.7 (116.0-319.0)	0.666 0.515
Postpartum 6 th hour total lochia (gr)	110.7 \pm 48.3 (41.0-250.0)	108.1 \pm 43.7 (30.0-237.0)	111.9 \pm 63.9 (12.0-368.0)	0.066 0.936
Postpartum 2 th hour VAS	1.7 \pm 1.7 (0.0-7.0)	0.6 \pm 1.1 (0.0-4.0)	1.4 \pm 1.9 (0.08.0)	5.834 0.004

ECFM: external circular fundus massage; EBFC: external bimanual fundus compression; C: control; VAS: visual analog scale; SD: standard deviation

As a result of further analysis, the postpartum VAS score of the EBFC group was found to be significantly lower in comparison to the ECFM group ($t = 3.645$, $p < 0.05$). Compared to the control group, the postpartum VAS score of the EBFC group was significantly lower ($t = 2.443$, $p < 0.05$). No excessive bleeding or atony occurred in any of the groups.

4. DISCUSSION

Different strategies have been published in the literature to prevent PPH. Active management of the third stage of labor consists of a group of interventions, such as administration of prophylactic oxytocin after birth and uterine massage (2,5,17). Blood loss at birth affects the hemogram levels. The degree of postpartum blood loss can be determined by measuring hemogram values and the amount of lochia (18,19).

In the study, there was no difference between the groups in terms of the prepartum and postpartum Hb values being 11-12 g/dL or > 12.1 g/dL (Table 3). Hofmeyr et al. concluded that application of postpartum uterus massage reduces the bleeding rate by 80% (9). In another study, no difference was found between the groups in terms of the hemoglobin value with and without uterine massage, while the mean blood

loss in the massage group was found to be lower (8). In the study by Chen et al., one group received uterine massage together with oxytocin, the other group received only uterine massage, and no difference was found between the groups in terms of blood loss in the first 2 hours after delivery (20). In another study, intramuscular oxytocin, continuous uterine massage and both methods together were applied, and uterine massage was reported to be less effective than oxytocin in reducing postpartum hemorrhage (21). Chantrapitak compared lower uterine segment compression and non-compression applied groups, and lower blood loss was found in the women who were administered lower uterine segment compression (14). In another study, a group that was administered active management at the third stage of labor and a group that received active management + massage were compared, and it was reported that blood loss was reduced in the women who received active management + massage (22,23). The differences in the results of studies are thought to be due to the use of additional medication and non-drug methods to prevent bleeding, application of episiotomy and removal of the placenta by active traction.

There was no difference between the groups in terms of the prepartum and postpartum Htc values of the groups being below $\leq 34.0\%$ or $> 34.1\%$ (Table 3). Yazıcıoğlu et al. compared groups with and without manual compression of the uterine isthmus after the placenta emerged during elective caesarean section and found that the Htc value was lower in patients who did not undergo intervention on the first postpartum day (12). Chantrapitak et al. reported no significant difference between the Htc values of the group where massage was applied and the group where it was not applied (8). It was stated in the literature that both analgesic and anxiolytic effects of massage stimulate oxytocin release (23,24,25). In this study, it was observed that the massage applied to the women in the EBFC group had a relaxing effect. There was no significant difference between the groups in terms of the prepartum and postpartum Plt values being below ≤ 150 K / mm^3 or > 151 K/ mm^3 (Table 3). In the study by Chantrapitak et al., in terms of the postpartum thrombocyte values, there was no significant difference between the groups receiving and not receiving massage (8). Platelets are an important parameter in monitoring postpartum hemorrhage and determining treatment efficacy. Additionally, while Hb and Htc values decrease at the onset of bleeding, an increase in platelet values is thought to be a sign of healthy hemostasis physiology.

No statistically significant difference was found between the groups in terms of the amount of lochia at the 6th postpartum hour (g) (Table 3). Abdel-Aleem et al. arrived at significant results showing that uterine massage performed at the third stage of labor reduces hemorrhage in 30 minutes and 60 minutes (21). However, in this study, no difference was found between the uterine massage groups and the control group in terms of the amount of lochia. Uterine massage is not recommended for women who have been administered prophylactic oxytocin (5).

In the study, the mean postpartum 2nd-hour VAS scores of the groups (respectively: 1.7 ± 1.7 ; 0.6 ± 1.1 ; 1.4 ± 1.9) were compared, and a statistically significant difference was found between the groups in terms of the mean VAS scores (Table 4). Ramasamy and Suzan found that fundal massage and alternative leg raising exercise reduced postpartum pain. Since the pressing/compression of the uterus is applied with EBFC, the effect of the woman lying prone was achieved, and the postpartum pain was reduced (26). In this study, the EBFC massage reduced the postpartum pain of the women.

Limitations of Research

This research is limited to the hospital where the data were collected. So, it is not generalizable to the entire country.

5. CONCLUSION

As a result of this study in which the effects of external uterine massages was discussed, the women in the group treated with EBFC had higher postpartum 6th-hour Hb and Plt mean values in comparison to the other groups, while their mean Htc was found to be lower. The postpartum 2nd-hour VAS mean scores of the women in the group that received EBFC were significantly lower than the other groups.

Consequently, in order to reduce postpartum hemorrhage, the importance of early breastfeeding, early mobilization and frequent bladder emptying should be explained to women. External uterine fundus massages should not be applied routinely, but external uterine massages should be applied until pharmacological treatments are initiated in the atonic uterus. It is recommended to apply EBFC massage to women who have pain in the postpartum period.

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Experiences of Women in Turkey on Using Complementary and Alternative Medicine Methods Against the Symptoms of Menopause: A Descriptive Study

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ABSTRACT

Objective: The purpose of this study was to determine the efficiency of Complementary and Alternative Medicine (CAM) applications that women have been using against the symptoms of menopause.

Methods: The research was conducted in descriptive design with the women between the ages of 45 and 60 (n=629). A “Questionnaire Form” and “Menopause Rating Scale (MRS)” were used in data collection process.

Results: It was determined that women, who were aged 55 and over, were married, had at least 5-year education, and had chronic diseases such as diabetes and hypertension and had treatment for her diseases, obtained higher scores than the total of MRS and sub-dimensions of the scale at a statistically significant level ($p<0.05$); 52% of the sample stated that they benefited at least one of CAM methods to cope with menopausal complaints. The most commonly used methods were determined to be praying/worship (33.2%), massage (19.2%) and phytotherapy (14.8%) respectively.

Conclusion: An increase in menopausal complaints were observed in various sub-dimensions of the used scale for those who benefited from praying/worship, massage applications and vitamin/mineral supplements while a decrease in menopausal complaints and an increase in life standards were observed for those who applied hydrotherapy, chiropractic, cup therapy, reflexology and osteopathy methods.

Keywords: Woman, menopause, menopause symptoms, complementary and alternative medicine

1. INTRODUCTION

According to the definition of World Health Organization (WHO), the menopause is the permanent stop of menstruation as a result of losing the ovary activity (1). A woman, is diagnosed with menopause if she has had amenorrhea (no menses) condition for 12 months (1,2). Symptoms commonly associated with menopause are experienced in the late reproductive years before observable changes in menstrual cycles (2). Certain hormonal, physical and emotional changes are observed in some women starting (premenopause) from nearly four-five years before the menopause and the mentioned changes increase in menopausal period due to the decrease in estrogen hormone. Vasomotor, atrophic and psychological changes are the problems that are experienced in short terms and cardiovascular diseases and osteoporosis are the problems for the long term (1). Almost 40% of the women in their menopausal period request medical support for the management of menopausal symptoms including hot flashes, night sweating, vaginal dryness and sleep disorders (3).

Hormone therapy is the most effective therapy for menopausal hot flashes. Women with certain medical conditions (such as breast cancer, liver disease, or a history of blood clots) shouldn't use hormone therapy (4). Results of the WHO highlighted multiple concerns regarding the use of estrogen and progestin products in the treatment of menopausal symptoms. Treatment with prescription hormones has been associated with significant adverse effects such as coronary events, deep vein thromboembolisms, stroke, and breast cancer. There has been a resulting increased use and seeking of Complementary and Alternative Medicine (CAM) (5).

Complementary and alternative treatment terms refer to different concepts. If a non-mainstream practice is used together with conventional medicine, it's considered “complementary”. If a non-mainstream practice is used in place of conventional medicine, it's considered “alternative”. Most complementary health approaches fall into one of two subgroups-natural products or mind and body practices.

Natural products group includes a variety of products, such as herbs, vitamins and minerals and probiotics. Mind and body practices group includes yoga, chiropractic and osteopathic manipulation, meditation, and massage therapy, acupuncture, relaxation techniques, tai chi, qi gong, healing touch, hypnotherapy and movement therapies (4).

Many natural products have been studied for menopause symptoms. Non-hormonal medicines and methods are also used to treat menopausal symptoms (4). These therapies are increasingly popular among women seeking alternatives to treatment with estrogen for managing menopausal symptoms (3). In 2013, the U.S. Food and Drug Administration (FDA) approved a non-hormonal treatment for hot flashes and a treatment for vaginal symptoms associated with menopause. Phytoestrogens appear to be safe for short-term use. Because phytoestrogen supplements may have effects like those of the hormone estrogen, they may not be safe for women who shouldn't take estrogen. Some of mind and body practices for menopause symptoms might help to relieve symptoms or make them less bothersome (4).

Women, who look for alternative treatments to cope with the menopause symptoms, generally prefer treatment methods that are in compliance with their cultural background. Acupuncture, yoga, relaxation poses, manipulation techniques, meditation, exercise, homeopathy, traditional Chinese teas, natural estrogen sources, diet, vitamins and minerals are among these methods (5,6). Studies in literature show that 42% of women in USA benefit from CAM methods. Women particularly prefer herbal teas and massage for stress management (7,8). Likewise, use of CAM has increased in Turkey day by day and the rate of use is stated as between 36.0% and 70.0% (9).

In the view of the information presented above, this study was conducted with the purpose of determining the species of complementary and alternative medicine methods used against the symptoms of menopause and their effect on severity of symptoms and on women's quality of life.

The specific study questions were:

1. What is the frequency of using CAM methods by menopausal women?
2. Do CAM methods used by women affect menopausal symptoms?

2. METHODS

2.1. Study Design

The research was conducted descriptive design between January 15 and March 15, 2016 in University of Usak, Faculty of Medicine, Education and Research Hospital, Department of Gynecology. The research population was composed of women between the ages of 45 and 60, who applied to the department of gynecology because of menopausal complaints. The minimum sample size required in the study was determined with the help of power analysis. All

calculations in the power analysis to determine the a priori required minimum sample size G-Power 3.1.9.2. was carried out through the program. In the study, the required minimum sample size was calculated to be at least 620 in total with 5% first type error, 0.10 Cohen standardized effect size, double-sided hypothesis and 90% working power. The study sample was composed of 629 women who accepted to participate in the study, had no communication deficiency, mental disorders, did not menstruate for at least one year and applied to the department of gynecology between the stated dates with menopausal complaints. Local ethic committee approval was obtained from the mentioned institute for the study (25/01/2016-E.2697).

2.2. Measures

A questionnaire form, which was composed of 29 questions and created by the study researchers, was used for data collection and Menopause Rating Scale (MRS) was used for menopausal complaints' evaluation. Women who agreed to participate in the interview and consented in written format to take part in the research were taken to a private room where they would respond to survey questions. The questionnaire and scale were applied by the researchers in face-to-face interviews with women, who accepted to participate in the research and applied to the department for their menopausal complaints as fitting the above stated criteria, by visiting the related department in their convenient days.

The questionnaire form was prepared to investigate the participants' socio-demographic characteristics, obstetric characteristics, health conditions, habits, menopausal histories, and their status of using complementary and alternative medicine applications (3,5,6,8).

MRS was firstly developed in German language to measure the severity of menopause symptoms and their effects on life quality, in 1992 by Schneider, Heinemann et al. International versions, reliability and validity of the scale was made in 2003 by Schneider, Heinemann et al., Turkish form's reliability and validity was made by Gürkan (2005) (10,11). MRS is composed of 11 items for menopausal complaints. 0: none, 1: mild, 2: moderate, 3: severe, 4: very severe are options to choose from in each items. Minimal score that can be taken from the scale is 0 while the maximum is 44. Likert type scale has three dimensions as somatic (items 1, 2, 3 and 11), psychological (items 4, 5, 6 and 7) and urogenital complaints (items 8, 9 and 10). The increase of total score in the scale shows that the severity of complaints increases and this condition affects life standards negatively. Inner consistency co-efficient of the whole scale was found as 0.84 (11). Cronbach alpha value for this research was determined as 0.81.

2.3. Data analysis

Data analysis for this research was conducted in SPSS (Statistical Package for Social Sciences) 21.0 package program. Number, percentage distribution, t test and one-way Anova tests were used in data analysis. Comparisons

were considered as significant if respective *p* values were found below 0.05 as the result of the statistical analyses.

3. RESULTS

Average \pm standard deviation (SD) age of the participant women was found as 53.69 ± 4.40 (min:45-max:60), majority (81.7%) of them were married and more than half (61.5%) had primary school and below education levels, 80.3% of them did not work, 73.8% of them had nearly equivalent income for their expenses, 81.7% of them had nuclear family and majority of them lived in the city center.

According to the results, average \pm SD Body Mass Index (BMI) of the women were 27.99 ± 4.29 and 73.9% of them were considered as overweight. They had a chronic disease and, 35.6% of them had hypertension, 34.3% of them had diabetes, 22.4% of them had osteoporosis, 13.8% of them had psychological issues, 11.6% of them had musculoskeletal, 11.0% of them had cardiovascular diseases, and 72.8% of them regularly used medicine for their chronic diseases respectively. Majority of women, who participated in the study, stated that they did not smoke (88.1%) and did not exercise regularly (84.7%).

In the analysis of socio-demographic factors that affected women's menopausal complaints, those participants who were aged over 55 had statistically significant high scores from the total of scale, those who were married and had at least 5-year education had statistically significant high scores from urogenital sub-dimension of the scale, those who had a chronic disease such as diabetes and hypertension and had treatment for these diseases had statistically significant high scores from total of the scale and its sub-dimensions, those who did not make exercises regularly had statistically significant high scores from only urogenital sub-dimension of the scale ($p < 0.05$, Table 1).

Average \pm SD number of pregnancy of women, who participated to the study, was determined as 3.41 ± 1.62 (min:0-max:11) and average \pm SD number of children they had was found as 2.81 ± 1.26 (min:0-max:10). It was determined that 87.8% of them entered to menopause period naturally and the rest of them (12.2% of them) entered the menopause period with surgical ways; and average \pm SD menopausal period was 6.42 ± 4.90 (min:1-max:27) years. All of them stated that they were supported by their husbands, children, relatives and friends while coping with menopausal complaints however they received the highest support from their husbands (31.2%). 9.9% of the participants stated that they had medical treatments during their menopause periods while 52% of them used

one of the CAM methods to cope with their menopausal complaints.

In the analysis of factors that affected menopause symptoms in terms of obstetric-gynecological and menopausal characteristics; women who entered the menopause naturally had significantly higher scores from only urogenital sub-dimension of the scale compared to those who entered to menopause with surgical ways and women who did not receive medical treatment in their menopause periods had significantly high scores from psychological and urogenital sub-dimensions and the total of the scale ($p < 0.05$). Additionally, women who used one of the CAM methods (e.g. phytotherapy, reflexology, massage, and etc.) received higher scores in somatic and urogenital sub-dimensions and the total of the scale ($p < 0.05$, Table 2).

Maximal score for the MRS is 44. According to the analyses, participants received mean \pm SD, 18.90 ± 8.15 scores from the total of the scale and 7.79 ± 3.60 (min:0-max:16), 7.29 ± 3.46 (min:0-max:16), 3.82 ± 2.67 (min:0-max:12) scores from somatic complaints, psychological complaints and urogenital complaints sub-dimensions, respectively (Table 3).

Women who participated in this research was asked to state which CAM they used to cope with their menopausal complaints. For the most commonly used to least commonly used methods, women stated that 33.2% of them used praying/worship, 19.2% of them used massage technics, 14.8% of them applied phytotherapy, 9.2% of them took vitamin/mineral supplements, 8.9% of them made breathe exercises, 8.6% of them received psychotherapy treatment, 8.4% of them used hydrotherapy, 7.3% of them used chiropractic, 5.2% of them used aromatherapy technics, 4.6% of them benefited from cup therapy, 4.0% of them used reflexology and 3.8% of them used osteopathy method. Majority of women (56.2%) stated that they used these methods to treat menopausal complaints while 27.1% of them stated that they used these methods to support the medical treatments related to their complaints.

According to the findings, women, who used praying/worship as a CAM for their menopausal complaints, had significantly high scores from all sub-dimensions of the scale except from psychological sub-dimension, those who used only massage method had high scores from only urogenital sub-dimension and those who did not use the methodology of taking vitamin/mineral supplements had high scores only from psychological sub-dimension ($p < 0.05$, Table 4). On the other hand, women who used hydrotherapy, chiropractic, cup therapy, reflexology and osteopathy methods had significantly lower scores from all sub-dimensions of the scale except from urogenital sub-dimension compared to those who did not use the mentioned methods ($p < 0.05$, Table 4).

Table 1. Comparison of Score Averages of Menopause Symptoms Rating Scale Sub-Dimensions According to Participants' Characteristics (n=629)

Characteristics	Menopause Rating Scale			
	Somatic Subscale	Psychological Subscale	Urogenital Subscale	MRS Total
Age (years)				
<50 (n= 177)	7.32 ± 3,60	6.86 ± 3,39	3.44 ± 2,43	17.63 ± 7.73
51 – 55 (n= 212)	7.92 ± 3,69	7.38 ± 3,60	3.96 ± 2,73	19.27 ± 8.40
> 55 (n= 240)	8.02 ± 3,49	7.52 ± 3,37	3.97 ± 2,76	19.52 ± 8.02
<i>p</i> **	0.118	0.138	0.084	0.046
Marital status				
Married (n=514)	7.78 ± 3,54	7.31 ± 3.50	3.96 ± 2.71	19.06 ± 8.16
Single/widow (n=115)	7.80 ± 3,86	7.20 ± 3.31	3.20 ± 2.37	18.21 ± 8.10
<i>p</i> *	0.956	0.774	0.005	0.315
Education level (years)				
Illiterate (n= 51)	8.07 ± 3.50	7.19 ± 3.84	2.82 ± 2.43	18.09 ± 7.71
<5 (n=387)	7.69 ± 3.75	7.29 ± 3.62	3.78 ± 2.67	18.74 ± 8.60
>5 (n=191)	7.91 ± 3.32	7.37 ± 3.01	4.16 ± 2.67	19.46 ± 7.29
<i>p</i> *	0.656	0.914	0.005	0.464
Working status				
Yes (n= 124)	7.38 ± 3.65	7.21 ± 3.15	3.93 ± 2.73	18.54 ± 8.12
No (n=505)	7.89 ± 3.58	7.31 ± 3.54	3.79 ± 2.65	19.00 ± 8.16
<i>p</i> *	0.163	0.789	0.608	0.574
Income status				
High income (n=108)	8.07 ± 3.14	7.51 ± 3.50	4.06 ± 2.73	19.65 ± 7.58
Balanced income (n=521)	7.73 ± 3.68	7.24 ± 3.46	3.77 ± 2.65	18.75 ± 8.26
<i>p</i> *	0.371	0.457	0.306	0.295
BMI group				
Normal (n=164)	7.58 ± 3.51	7.31 ± 3.53	3.98 ± 2.84	18.88 ± 8.67
Over weight (n=465)	7.86 ± 3.63	7.28 ± 3.44	3.76 ± 2.60	18.91 ± 7.97
<i>p</i> *	0.394	0.937	0.385	0.963
Chronic health problems				
Yes (n: 504)	8.08 ± 3.39	7.56 ± 3.43	4.07 ± 2.65	19.72 ± 7.83
No (n: 125)	6.60 ± 4.13	6.19 ± 3.39	2.82 ± 2.48	15.62 ± 8.63
<i>p</i> *	0.000	0.000	0.000	0.000
Regular medicine use				
Yes (n=458)	8.14 ± 3.41	7.65 ± 3.43	4.08 ± 2.62	19.88 ± 7.79
No (n=171)	6.85 ± 3.91	6.30 ± 3.38	3.14 ± 2.67	16.30 ± 8.53
<i>p</i> *	0.000	0.000	0.000	0.000
Smoking cigarette				
Yes (n=75)	7.85 ± 3.70	7.69 ± 3.42	3.60 ± 2.97	19.14 ± 8.58
No (n=554)	7.78 ± 3.59	7.23 ± 3.47	3.85 ± 2.62	18.87 ± 8.10
<i>p</i> *	0.875	0.286	0.437	0.789
Regularly doing exercise				
Yes (n=96)	7.63 ± 4.01	7.63 ± 3.78	3.12 ± 2.36	18.09 ± 8.65
No (n=533)	7.81 ± 3.52	7.23 ± 3.40	3.95 ± 2.70	19.00 ± 8.06
<i>p</i> *	0.674	0.329	0.002	0.503

*p**: Student's *t*-test; *P***: One Way-Anova test; BMI: body mass index.

Table 2. Comparison of Score Averages of Menopause Symptoms Rating Scale Sub-Dimensions According to Participants' Obstetric-Gynecological and Menopausal Characteristics (n=629)

Characteristics	Menopause Rating Scale			
	Somatic Subscale	Psychological Subscale	Urogenital Subscale	MRS Total
Number of pregnancies				
≤3 (n=367)	7.84 ± 3.63	7.45 ± 3.38	3.93 ± 2.77	19.23 ± 8.28
>3 (n=262)	7.71 ± 3.56	7.06 ± 3.57	3.67 ± 3.51	18.45 ± 7.95
<i>P</i> *	0.663	0.157	0.228	0.237
Number of births				
≤2 (n=291)	7.82 ± 3.59	7.40 ± 3.25	4.00 ± 2.79	19.23 ± 8.14
>2 (n=338)	7.76 ± 3.61	7.19 ± 3.63	3.67 ± 2.55	18.63 ± 8.16
<i>P</i> *	0.831	0.445	0.123	0.355
Gynecological operation status				
Yes (n=147)	8.01 ± 3.78	7.67 ± 3.41	3.59 ± 2.69	19.27 ± 8.06
No (n=482)	7.72 ± 3.54	7.17 ± 3.47	3.89 ± 2.66	18.79 ± 8.18
<i>P</i> *	0.394	0.128	0.227	0.531
Menopause type				
Naturally menopause (n=552)	7.87 ± 3.56	7.26 ± 3.47	3.39 ± 2.69	19.10 ± 8.16
Surgical menopause (n=77)	7.20 ± 3.83	7.45 ± 3.39	2.83 ± 2.30	17.49 ± 7.97
<i>P</i> *	0.129	0.662	0.000	0.104
Menopause duration (years)				
≤5 (n=335)	7.88 ± 3.65	7.32 ± 3.52	3.88 ± 2.59	19.10 ± 8.35
6-10 years (n=170)	7.49 ± 3.64	7.18 ± 3.47	3.98 ± 2.63	18.65 ± 8.11
>10 (n=124)	7.93 ± 3.40	7.34 ± 3.32	3.43 ± 2.88	18.71 ± 7.68
<i>P</i> **	0.449	0.888	0.181	0.808
Medical treatment for menopause				
Yes (n=62)	7.08 ± 2.91	6.30 ± 3.35	3.27 ± 2.20	16.66 ± 6.61
No (n=567)	7.86 ± 3.66	7.40 ± 3.46	3.88 ± 2.71	19.15 ± 8.27
<i>P</i> *	0.056	0.018	0.046	0.007
Using CAM applications				
Yes (n=327)	8.18 ± 3.25	7.41 ± 3.26	4.16 ± 2.75	19.76 ± 7.54
No (n=302)	7.36 ± 3.90	7.15 ± 3.67	3.45 ± 2.52	17.98 ± 8.68
<i>P</i> *	0.005	0.344	0.001	0.006

*P**: Student's *t*-test; *P*** : One Way-Anova test; CAM: complementary and alternative medicine

Table 3. Distribution of participants according to Menopause Rating Scale*

Subscale MRS	n	%	mean±SD
Somatic Subscale			
Hot flushes/night sweating	604	96.0	2.66±1.12
Tachycardia	392	62.3	1.29±1.27
Sleeping problems	516	82.0	1.87±1.19
Joint and muscular discomfort	517	82.2	1.95±1.26
Psychological Subscale			
Depressive mood	540	85.9	1.80±1.09
Irritability	564	89.7	2.07±1.19
Anxiety	476	75.7	1.59±1.18
Physical and mental exhaustion	529	84.1	1.81±1.17
Urogenital Subscale			
Sexual problems	352	56.0	1.08±1.13
Urinary problems	462	73.4	1.45±1.13
Vaginal dryness	415	66.0	1.28±1.13

MRS: Menopause Rating Scale; SD: standard deviation; *participants stated more than 1 symptoms.

Table 4. Comparison of Score Averages of Menopause Symptoms Rating Scale Sub-Dimensions According to CAM Methods that Participants Used for Their Menopause Symptoms (n=629)

CAM Methods	Menopause Rating Scale			
	Somatic Subscale	Psychological Subscale	Urogenital Subscale	MRS Total
Praying/worship				
Yes (n=209)	8.40 ± 3.24	7.63 ± 3.24	4.49 ± 2.78	20.52 ± 7.44
No (n=420)	7.48 ± 3.73	7.12 ± 3.56	3.49 ± 3.55	18.10 ± 8.37
<i>P</i>	0.002	0.074	0.000	0.000
Massage				
Yes (n=120)	8.25 ± 2.93	6.90 ± 3.33	4.48 ± 2.61	19.64 ± 7.34
No (n=509)	7.68 ± 3.73	7.38 ± 3.49	3.66 ± 2.66	18.73 ± 8.33
<i>P</i>	0.074	0.177	0.003	0.238
Phytotherapy				
Yes (n=93)	7.34 ± 3.27	7.12 ± 3.53	3.73 ± 2.77	18.20 ± 8.17
No (n=546)	7.86 ± 3.65	7.32 ± 3.45	3.84 ± 2.65	19.03 ± 8.15
<i>P</i>	0.194	0.623	0.714	0.367
Vitamin/mineral supplements				
Yes (n=58)	7.44 ± 1.99	6.03 ± 2.62	4.29 ± 2.09	17.77 ± 5.46
No (n=571)	7.82 ± 3.72	7.42 ± 3.51	3.77 ± 2.72	19.02 ± 8.37
<i>P</i>	0.217	0.000	0.087	0.122
Breathing exercises				
Yes (n=56)	7.23 ± 2.91	6.51 ± 3.30	3.85 ± 2.58	17.60 ± 7.20
No (n=573)	7.84 ± 3.66	7.36 ± 3.47	3.82 ± 2.68	19.03 ± 8.23
<i>P</i>	0.147	0.080	0.925	0.211
Psychotherapy				
Yes (n=55)	7.72 ± 3.11	7.31 ± 3.42	3.29 ± 2.45	18.33 ± 7.29
No (n=586)	7.79 ± 3.64	7.29 ± 3.47	3.87 ± 2.68	18.96 ± 8.23
<i>P</i>	0.859	0.961	0.128	0.588
Hydrotherapy				
Yes (n=53)	6.69 ± 2.39	6.16 ± 2.98	3.33 ± 2.32	16.47 ± 5.94
No (n=576)	7.86 ± 3.68	7.39 ± 3.49	3.89 ± 2.69	19.13 ± 8.29
<i>P</i>	0.001	0.014	0.121	0.004
Chiropractic				
Yes (n=46)	6.60 ± 2.09	5.43 ± 3.20	3.50 ± 2.29	15.54 ± 6.13
No (n=583)	7.88 ± 3.68	7.43 ± 3.44	3.85 ± 2.69	19.17 ± 8.23
<i>P</i>	0.000	0.000	0.392	0.004
Aromatherapy				
Yes (n=33)	7.66 ± 2.89	6.36 ± 3.56	3.90 ± 2.42	17.93 ± 7.04
No (n=596)	7.79 ± 3.63	7.34 ± 3.45	3.82 ± 2.68	18.96 ± 8.21
<i>P</i>	0.803	0.114	0.853	0.483
Cup therapy				
Yes (n=29)	6.75 ± 2.01	5.58 ± 3.23	3.41 ± 2.04	15.75 ± 5.91
No (n=600)	7.84 ± 3.65	7.37 ± 3.45	3.87 ± 2.69	19.06 ± 8.22
<i>P</i>	0.011	0.007	0.283	0.007
Reflexology				
Yes (n=25)	6.68 ± 2.24	5.32 ± 3.32	3.76 ± 2.27	15.76 ± 6.08
No (n=604)	7.83 ± 3.64	7.37 ± 3.45	3.82 ± 2.68	19.03 ± 8.20
<i>P</i>	0.022	0.006	0.901	0.049
Osteopathy				
Yes (n=24)	6.79 ± 2.20	4.79 ± 3.18	3.95 ± 2.69	15.54 ± 6.53
No (n=605)	7.83 ± 3.64	7.39 ± 3.44	3.81 ± 2.67	19.04 ± 8.18
<i>P</i>	0.037	0.000	0.804	0.039

P: Student's *t*-test; CAM: complementary and alternative medicine; MRS: Menopause Rating Scale

4. DISCUSSION

The study depended on the data regarding species of complementary and alternative medicine methods used against the symptoms of menopause and their effect on severity of symptoms and on women's quality of life.

In our study, the number of women, who naturally entered the menopause period and used CAM, was higher. Peng et al. (12), determined that use of CAM was in low rates among women who had hysterectomy or oophorectomy. In the related study, women, who had more severe somatic and urogenital symptoms, were those who entered to menopause naturally. Use of CAM methods can be analyzed according to the ways that they enter the menopause period.

Women in our study preferred CAM more than medical treatments to cope with menopause symptoms. Use of CAM methods to reduce the severity of menopause symptoms was common among these women (13-15). In the study that CAM methods were found to be commonly used among women, these methods were considered as more secure than Hormone Replacement Therapy (14). The factors of preferring CAM methods are attributed to the fact that they are easily reachable, their applications are economic and there are the effects of socio-cultural characteristics. In this sense, the reasons for using CAM methods can be researched.

In this study, 96% of women stated that they had hot flush/night sweating symptoms. Hot flush, which is caused by vasomotor inconsistency, is the most common symptom of climacterics (16-18). Almost 75% of perimenopausal or postmenopausal women in west societies have hot flushes (16). It was found in literature that physical exercise and consumption of soya products were effective on reducing vasomotor related complaints (19). Use of non-prescribed creams involving progesterone in USA and Canada has been steadily increased. This cream is made of soya beans and wild sweat potato, and is equivalent to endogen progesterone. This preparation is promoted in many radio and TV programs and in websites to be used in various doses, forms and by adding different elements. Many producers recommend creams with progesterone as a supplement to daily diet (20). In the study of Gartoulla et al. (2015), the prevalence of use of CAMs for vasomotor symptoms was 13.22% (21).

Hot flushes can cause insomnia, sleep disorders, thus they many cause cognitive and effective disorders (22). Decrease in estrogen levels in menopause can cause sleep disorders by decreasing the serotonin metabolism that has an important role on regular sleep routine (23). In a study of Olivera et al. (24), 32 passive and therapeutic treatment massage sessions were applied as twice per week to the patients, who had sleep disorders and did not have a medical treatment. The patients were evaluated following the 6th and 32nd sessions and a significant difference was observed between the massage treatments and the decrease in sleep symptoms in the group to which the therapeutic massage was applied (24). In our study, the frequency of sleep disorder incidents was found to be 82%. However, a significant relationship between

massage treatment and somatic symptoms could not be found. In the analysis of research findings, chronic diseases were observed to be a significant factor which caused sleep disorders. Additionally, details of massage treatments may be questioned, therefore, further studies must be conducted in this area. It is important that nurses inform women about treatment alternatives to cope with sleep disorders.

Significant relationship between physical activity, the use of phytotherapy and menopause symptoms could not be found in our study. This result could be attributed to the limited number of participants, who made regular physical activities (n=96) and used phytotherapy method (n=93). Exercise is an important factor to cope with osteoporosis, to prevent cardiovascular health, and to prevent and improve social and psychological well-being (23,25). Moreover, in the analysis of the findings of our study, it was observed that 72.8% of participants took medicine regularly. In this condition, an exercise program that is unique and convenient to individuals' conditions should be recommended in supervision of an expert. Low level of phytotherapy usage could be attributed to the worry that the use of medicine and herbal products together might cause toxic effects on the participants who had medical treatment due to chronic diseases.

Praying/worship was the most commonly preferred method to cope with menopause symptoms in this study. Despite this conclusion, any positive effects of praying/worship on a menopause symptom severity could not be found (i.e. praying/worship did not decrease severity of any menopause symptoms). In a study, herbal treatments, diet, exercise and massage were found to be the most commonly used CAM methods (26). In a study of Buhling et al. (27), change in life style was found to be the most effective CAM while phytoestrogen treatment was found as the weakest method. According to the study of Peng et al. (28), yoga/meditation was commonly used among women who entered the menopause period naturally and had hysterectomy, on the other hand the method of taking vitamins and herbal medicine was the most commonly used one among women whose ages ranged from 59 to 64. In another study, dietary treatments and taking herbal medicine were found as the most commonly used methods, which were followed by applying physical methods (29). Accordingly, various methods are preferred to cope with menopausal symptoms. These methods vary depending on the differences such as cultural characteristics and personal/social factors. In a study of social and cultural factors' effects on the use of CAM, van der Sluijs et al. (30) stated that differences in the use of the CAM methods were caused by the reachability of CAM methods, education level of women and their occupational status. In another related study, it was presented that German gynecologists generally had positive experiences with CAM in their patient's treatments (31). Another reason of benefiting from CAM methods was attributed to the fact that their side effects were fewer and in lower severity than medical treatments.

It was determined in our study that hydrotherapy, chiropractic, cup treatment, reflexology and osteopathy

among the methods that were preferred to cope with menopause symptoms were effective on decreasing the severity of especially somatic and psychological complaints and taking vitamin and mineral supplements was effective on decreasing the severity of psychological complaints.

Limitations

This study cannot be generalized to all menopausal women, since this study was conducted only with women who applied to Usak Faculty of Medicine Education and Research Hospital Department of Gynecology.

5. CONCLUSION

In direction of the conducted studies, it could be said that patients use CAM methods to cope with especially somatic and psychological symptoms and this is effective on their life qualities. Today, many CAM methods have become a part of modern medicine and has been increasingly used among women who have to cope with menopause symptoms. Therefore, health professionals have been facing the women who use CAM methods or women who would like to learn about these methods. Health professionals should have evidence based and sufficient level of knowledge and experiences about menopause symptoms and CAM methods. It is important that a nurse, as being a health professional, knows CAM methods that can be used in the management of menopause symptoms and inform doctors about this subject, in terms of increasing the effectiveness of the service that is given to patients. Nurses have many opportunities.

Special training programs about menopause period can be organized for women and can be promoted in press, internet and media, so that effective use of methods can be maintained by creating awareness about women's getting professional help from expert health professionals instead of their acquaintances.

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Knowledge, Attitude and Clinical Decision-Making Abilities of Pediatric Nurses Regarding Pain Management

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ABSTRACT

Objective: The aim of this study was to describe knowledge, attitude and clinical decision-making abilities of pediatric nurses regarding pain management, and to find the factors that affect them.

Methods: In this descriptive and analytical study, the participants consisted of 131 pediatric nurses who were employed in pediatric clinics of a university hospital and a state hospital in Manisa, Turkey. Data were collected by using the Nurse Description Form, the Questionnaire on Nurses' Attitudes and Knowledge About Pain, and the Clinical Decision Making Questionnaire.

Results: In the study, the mean (standard deviation) score of knowledge and attitude of pediatric nurses in pain management and patients with pain was 7.32 (7.00), and the scores of 45% of them were at an intermediate level. It was found that while variables such as age, occupation and years of working experience did not affect the total mean score of knowledge and attitude of pediatric nurses in pain management, educational background and the unit at which they worked affected it. Moreover, most of the pediatric nurses had sufficient information regarding pain diagnosis; 61.1% of them observed patients' behavior while diagnosing the severity of pain, and 65.6% of them used a pain diagnosis scale to measure patients' pain.

Conclusion: As a result of the study, it was found that pediatric nurses had an intermediate level of knowledge and behavior regarding pain management and had sufficient knowledge about pain diagnosis and management.

Keywords: Attitude, clinical decision-making, knowledge, pain, pediatric nursing

1. INTRODUCTION

The concept of pain, which is considered not only a symptom of a certain disease but also an independent phenomenon, is defined as the fifth vital sign by the American Pain Society (APS). Pain is expressed as a concept which affects every age group, is individual and whose interpretation is subjective and universal (1,2). Pain is an important factor in children's lives and is usually experienced for the first time during childhood. The American Academy of Pediatrics (AAP) and the APS suggest that pain and stress should be eased and minimized even in minor interventions like establishing vascular access (3-5).

Neurobiological development, age, previous experience of pain, learning status, gender, culture, personality structure, emotional state (fear, anxiety, depression), reactions of family members and healthcare professionals, and socio-cultural factors have an effect on pain perception. Particularly, the most important factor in children's pain perception and in their reaction to pain is their age. Children in different age groups have different pain perceptions and reactions (6,7).

In pain management, pharmacological (anesthetics, analgesics and drugs) and non-pharmacological methods (such as position, giving a baby a pacifier, kangaroo care, massage, breastfeeding, reducing environmental stimuli, sucrose, music, guided imagery, hypnosis, breathing techniques and relactation, blowing up a balloon and coughing) are used (6,8,9). Prevention and management of pain in children increase child's tolerance towards pain in subsequent applications (7). It is indicated that the effects of children's previous pain experiences continue into adulthood, and this may cause an increased reaction to pain and the avoidance of subsequent medical operations (10). It is important to diagnose children's pain correctly and timely for effective pain management (8). A multidisciplinary team approach is necessary to achieve success in pain management in children. A nurse is an important member of this team; a nurse's taking an active role in pain management starts with assessment and treatment of pain, choosing suitable interventions and planning caring (8,11).

The most important difference that separates nurses from other team members in pain management is that they spend a long time with the patient, learn about the patient's

previous pain experiences and methods of overcoming pain, and make use of this information if necessary. They also apply planned treatment, and observe the effects and results of the treatment (6,12,13). Previous studies have shown that nurses' decisions in pain management and pain problems are more influenced by their own attitudes towards pain and their misperceptions of pain than by diagnosing patients' current conditions (11,14). This study aims to determine the knowledge, attitude and clinical decision-making abilities of Turkish pediatric nurses regarding pain management, and to find the factors affecting them.

2. METHODS

2.1. Study Design and Participants

This study had a descriptive and analytical design and the study population included 170 pediatric nurses who were employed in pediatric clinics of a university hospital and a state hospital in Manisa, Turkey. No sampling method was used in the study and all the nurses (n=131) were contacted within working hours and who accepted to take part in the research between these dates were included in the study. Of the nurses 77% were contacted. The nurses who declined to take part in the research (n=19), who were on leave (n=12), or had a sick leave (n=8) were excluded.

2.2. Data Collection

Data was obtained by face-to-face interviews using the questionnaire forms, namely "Nurse Description Form", "Questionnaire on Nurses' Knowledge and Attitudes about Pain" and "Questionnaire on Clinical Decision-Making About Pain". The data collection forms were filled out by the nurses themselves. The completion of the data collection forms took 15 to 20 minutes.

2.2.1. Questionnaires

2.2.1.1. Nurse Description Form

This form includes 5 questions about the nurses' age, educational background, place of work, position/duty and years of work. This measure was prepared by the researchers.

2.2.1.2. Questionnaire on Nurses' Knowledge and Attitude About Pain

This questionnaire was formed on the basis of studies conducted to analyse the knowledge and attitude of nurses about pain management and patients with pain (15,16). This questionnaire form was prepared by Özer et al. (11) and comprised of 16 True/False questions. Every 'True' response scored 1 point and every 'False' response scored 0 points. The lowest possible score on the questionnaire was 0, and the highest was 16. The highest score shows that a nurse's knowledge and attitude about pain is at the top level.

2.2.1.3. Questionnaire on Clinical Decision-Making About Pain

The Questionnaire on Clinical Decision-Making About Pain was formed by McCaffery and Ferrell (15) with the aim of determining nurses' clinical decision-making status about pain, and it were adapted to Turkish by Özer et al. (11). This questionnaire consists of 14 questions answered as 'Yes / No'.

2.3. Statistical Analyses

The findings were analysed using frequency [number (percentage)] distribution, mean, Kruskal-Wallis and Chi-Square tests. Descriptive statistics in the form of frequency and percentage were used to summarize nurses' descriptive features analyzing their answers given to the 'Questionnaire on Nurses' Knowledge and Attitude About Pain' and distribution of nurses' average knowledge and attitude scores about pain management. Kruskal-Wallis test was used to compare nurses' descriptive features (age, educational background, place of work, position/duty, years of work) and their total mean scores of knowledge and attitude about pain management. Mann Whitney U test was used for determining the group causing the differentiation. In addition, Chi-square test was used to analyze the distribution of pediatric nurses by their use of a pain scale and their recording of pain according to the unit where they worked. Data were analyzed with the Statistical Package for the Social Sciences (SPSS Statistics for Windows, Version 23.0, IBM Corp., Armonk, NY). All the *p*-values that were <0.05 were considered to be statistically significant.

2.4. Ethical Considerations

For this study, approval was obtained from the Ethical Committee of Celal Bayar University Medical Faculty (Date/IRB No: 25.03.2015/ 20.478.486-148). The survey was conducted in accordance with the Helsinki Declaration criteria. Written permissions from the institutions where the study would be conducted were taken. Before the data collection process, the participants were informed about the study and written informed consent was obtained from all subjects who agreed to participate in the study.

3. RESULTS

3.1. Findings About Descriptive Characteristics of Pediatric Nurses

Ages of 131 pediatric nurses participating in the study varied from 19 to 52 years, with a mean of 29.96 ± 6.47 years, and their professional experience varied from 1 to 20 years, with a mean of 7.37 ± 5.54 years. Of the pediatric nurses who took part in the research, 55.7% were between the ages of 21 and 30, 69.5% of them had a Bachelor's Degree. It has been determined that 40.5% of the nurses were working in the Pediatric Unit, 55% of them were working as a Clinical Nurse and 38.9% of them had professional experience between 6-10 years (Table 1).

Table 1. Descriptive characteristics of pediatric nurses (n=131)

Characteristics		n	%
Age	Less than 21 years	4	3.1
	21-30 years	73	55.7
	31-40 years	48	36.6
	41-50 years	5	3.8
	More than 50 years	1	0.8
Education	Health Vocational High School	14	10.7
	Associate Degree	14	10.7
	Bachelor's Degree	91	69.5
	Master's Degree	12	9.2
Place of Work	Pediatric Unit	53	40.5
	Pediatric Surgery Unit	14	10.7
	Neonatal Intensive Care Unit	17	35.9
	Pediatric Emergency Unit	47	13.0
Position/Duty	Clinical Nurse	72	55.0
	Intensive Care Nurse	43	32.8
	Executive Nurse	7	5.3
	Outpatient Clinic Nurse	9	6.9
Years of Work	Less than 5 years	45	34.4
	6-10 years	51	38.9
	11-15 years	20	15.3
	More than 15 years	15	11.5

3.2. Findings on Pediatric Nurses' Knowledge and Attitude Scores in Pain Management

When examining the responses of pediatric nurses to the 'Questionnaire on Knowledge and Attitude About Pain', it was determined that the questions with most frequent correct answers were the 10th, 14th and 5th questions, and the questions with most frequent wrong answers were the 13th, 16th and 9th questions (Table 2).

When the responses given to these questions were evaluated (with a total possible score of 16), it was found that the knowledge and attitude scores of 45.0% of the pediatric nurses about pain management and patients with pain was at a mid-level (Table 3).

When the nurses were asked the question 'How much do you trust yourself about the accuracy of the questions answered in the Knowledge and Attitude About Pain Questionnaire?', 61.8% of the nurses marked number 4 and 29.8% marked number 3 on a scale where 1 stood for 'I don't trust myself' and 5 stood for 'I trust myself'. It was found in the research

that the average self-reliance score for all the nurses was 3.74±0.60 (min=2, max=5).

Table 2. Answers given by pediatric nurses to the questionnaire on knowledge and attitude about pain*

Questions and answer key on the questionnaire form	True answer		False answer	
	n	%	n	%
1. Observed changes in vital signs are important indicators to diagnose that a patient has intense pain. (F)	40	30.5	91	69.5
2. Pain level should be evaluated by healthcare personnel, not by the patient himself. (F)	89	67.9	42	32.1
3. A patient can sleep in spite of intense or mid-level pain. (T)	64	48.9	67	51.1
4. If the patient's attention can be drawn in another direction, it means the patient does not have as high a pain level as s/he has stated. (F)	66	50.4	65	49.6
5. Before a pain relief method is applied, the patient should be encouraged to endure to pain as much as possible. (F)	92	70.2	39	29.8
6. If a patient's pain eases with placebo (sterile water injection), the pain is not real. (F)	40	30.5	91	69.5
7. Because the neurological system in children under two years of age is not completely developed, their pain sensitivity is low and their experience of pain is limited. (F)	67	51.1	64	48.9
8. Aspirin and other NSAID agents are not affective for chronic pain that stems from metastasis (F)	40	30.5	91	69.5
9. Non-pharmacological treatments (for example heat application, music) are very effective for mid-level pain, but are not effective for serious pains. (F)	33	25.2	98	74.8
10. Respiratory depression rarely emerges in patients who have been taking opioids for a long time (for months). (T)	109	83.2	22	16.8
11. Single analgesic agents should be used in a patient in pain rather than a combination of drugs. (F)	59	45.0	72	55.0
12. Sedative drugs are effective in reducing pain. (F)	37	28.2	94	71.8
13. Opioids should not be given to reduce pain to patients with a history of substance abuse, because these patients are at higher risk of repetitive addiction. (F)	31	23.7	100	76.3
14. The pain stated by children under the age of eleven should not be trusted. Nurses should trust parents about the pain level of the child. (F)	98	74.8	33	25.2
15. It should be recommended to a patient that non-pharmacological methods should be used alone, not with pain medications. (F)	62	47.3	69	52.7
16. Hot and cold applications should only be applied to the painful area to be effective. (F)	33	25.2	98	74.8

*Percentages in Table 2 are valid for the nurses who answered the questions. NSAID: non-steroidal anti-inflammatory

Table 3. Average pain management knowledge and attitude scores of the pediatric nurses (n=131)

Pain management knowledge and attitude scores	n	%
Low Level (1-5 points)	47	35.9
Mid-Level (6-10 points)	59	45.0
High Level (11 points and above)	25	19.1

The pediatric nurses taking part in the research were asked different questions to determine their clinical decision-making status. To the question 'which criteria do you use most while diagnosing the pain level of the patient?' 78.6% of the nurses answered 'I observe the patient's behavior', but 31.3% answered 'I ask the patient how much pain she/he feels'. Most of the nurses (65.6%) indicated that they used a pain scale when measuring patient's pain, and when they were asked whether they recorded their evaluations and diagnosis of the patient's pain, most of them (87.8%) said they did. All the nurses (100%) who indicated they recorded evaluations and diagnosis said that they recorded them on a nursing observation scale. The nurses taking part in the research reported that paracetamol (46.6%), Non-Steroid Anti-Inflammatory Drugs (25.2%), narcotics (20.6%) and anesthetic analgesics (7.6%) were the most widely used drugs in their clinics. Most of the nurses (87.8%) stated that when giving medications which were ordered as 'in case of need', they gave the medication as they were ordered. 56.5% of the nurses in the research reported that they had not been asked for a non-pharmacological method of pain relief for patients in pediatric clinics but 36.6% reported that they had been asked for 'cold application' and 26.7% reported that they had been asked for 'hot application'. Almost all of the pediatric nurses (99.2%) reported that they get into contact with the patient's doctor about pain, and many of them (77.1%) said that they reported changes in a patient's pain status. When asked 'Do you face any obstacles or problems in reducing or eliminating a patient's pain?', 58% of the nurses who participated in the research reported that they did, and they said that 29% of these problems were related to the 'patients' or their family's knowledge', 27.5% were related to 'doctors co-operation' and 23.7% were related to 'time'. To the question 'In which situations do you have to make a decision about a patient's pain?' 74.0% of the nurses answered 'identifying the patient's pain intensity', 55% answered 'identifying a patient's pain' and 26.7% answered 'when medication is to be given to a patient'. When pediatric nurses were asked to place in order the professional/ethical dilemmas that they faced while stopping the patient's pain from the most important to the least important (1-9), 48.9% of them stated that anxiety about respiratory depression was the most important dilemma for them, and 29.8% stated that

conflict with the patient or the patient's family was the least important dilemma that they faced. When the nurses were asked at the end of the questionnaire to rank the first three issues about which they needed information related to pain management, they placed pain diagnosis in the first place (62.6%), pharmacological pain management in the second place (35.9%), and non-pharmacological treatments in the third place (32.8%).

3.3. Correlation Between Pediatric Nurses' Descriptive Characteristics and Their Total Mean Scores on Knowledge and Attitude About Pain Management

When nurses' characteristics and their total mean scores on knowledge and attitude about pain management were compared, a statistically significant relationship was found between the education of the nurses, the unit where they worked and their total mean scores on knowledge and attitude about pain (respectively: Chi-Square=17.092, $p=0.001$, and Chi-Square=15.100, $p=0.002$) (Table 4). It was also found that the mean scores for knowledge and attitude about pain were higher for nurses who had a Master's Degree and worked at the Neonatal Intensive Care Unit (NICU). However, no statistically significant relationship was found between the ages, duties or years of work of the nurses and their total mean scores on knowledge and attitude about pain (respectively: Chi-Square=7.949, $p=0.093$; Chi-Square=4.913, $p=0.178$, and Chi-Square=6.114, $p=0.106$). However, the total mean scores for knowledge and attitude of nurses who were in the 21-30 age group, who were working as Intensive Care Nurses and who had 6-10 years of working experience were higher than those of others (Table 4).

When considering the distribution of the units where pediatric nurses worked according to whether they used a pain scale to measure the patient's pain, it was found that 34.8% of the nurses using a pain scale worked in the Pediatric Units and 30.9% of them worked at the NICU. In the Chi-Square analysis it was found that there was a statistically significant difference between the groups (X^2 : 14.695, $p=0.002$) (Table 5).

When considering the distribution of the units where the pediatric nurses who were included in the research worked according to whether they recorded evaluations and diagnosis about pain, it was found that 46.5% of the nurses who recorded pain worked in the Pediatric Unit, and 41.3% of them worked at the NICU. A statistically significant difference was found according to the Chi-Square analysis between the nurses' recording patients' pain and the units where they worked (X^2 : 33.706, $p=0.000$) (Table 5).

Table 4. Distribution of scores of knowledge and attitude about pain according to descriptive characteristics

Descriptive characteristics	n	Pain Knowledge and Attitude Score		X ²	p
		X	SD		
Age groups	Less than 21 years	4	4.50±2.08	7.949	p=0.093*
	21-30 years	73	7.86±3.21		
	31-40 years	48	7.00±3.19		
	41-50 years	5	5.40±1.51		
	More than 50 years	1	5.00±0.00		
Education levels	Health Vocational High School ^a	14	4.57±1.55	17.092	p=0.001* b=c=d>a**
	Associate Degree ^b	14	6.92±3.31		
	Bachelor's Degree ^c	91	7.53±3.06		
	Master's Degree ^d	12	9.41±3.62		
Place of work	Pediatric Unit ^a	53	7.52±2.83	15.100	p=0.002* a=b>c**
	Pediatric Surgery Unit ^b	14	7.07±2.40		
	Pediatric Emergency Unit ^c	17	4.58±2.23		
	Neonatal Intensive Care Unit ^d	47	8.17±3.58		
Position/Duty	Clinical Nurse	72	6.84±2.97	4.913	p=0.178*
	Intensive Care Nurse	43	8.34±3.52		
	Executive Nurse	7	7.14±3.33		
	Outpatient Clinic Nurse	9	6.44±2.35		
Years of work	Less than 5 years	45	7.42±3.51	6.114	p=0.106*
	6-10 years	51	7.86±3.02		
	11-15 years	20	7.05±3.21		
	More than 15 years	15	5.60±2.19		

*Kruskal-Wallis test, **Mann-Whitney U test; X ± SD: mean ± standard deviation

Table 5: Distribution of pediatric nurses by their use of a pain scale and their recording of pain according to the unit where they worked

	Pediatric Unit	Pediatric Surgery Unit	Pediatric Emergency Unit	Neonatal Intensive Care Unit	X ²	p
Pain Scale						
Using ^a	34.8 (42)%	9.2 (8)%	11.2 (5)%	30.9 (31)%	14.695	0.002* a>b
Not Using ^b	18.2 (11)%	4.8 (6)%	5.8 (12)%	16.1 (16)%		
Recording of Pain						
Recording ^a	46.5 (51)%	12.3 (11)%	14.9 (8)%	41.3 (45)%	33.706	0.000* a>b
Not Recording ^b	6.5 (2)%	1.7 (3)%	2.1 (9)%	5.7 (2)%		

*Pearson chi-square test

4. DISCUSSION

A life free of pain is the right of every child, and stopping the pain of children and improving their quality of life are the basic aims of nursing care (17). The quality of pain

management is related to the knowledge, attitude and decision-making abilities of health care team members who carry out pain treatment (6,12,18). Spending a longer time with patients provides an opportunity for nurses to observe a child's pain closely. However, whether nurses have the necessary knowledge, attitude and abilities to fulfill this role still remains unclear (4,5,19).

In this study, in which pediatric nurses' knowledge, attitude and clinical decision-making abilities were studied, 69.5% of the nurses stated that 'in diagnosing the patient's intense pain, observed changes in vital signs are important indicators'. In a study by Demir et al. (13), it was found that the correct response rate to this question of nurses who worked at internal and surgical units was 7.2%, but in research by Özer et al. (11) it was 8.5%. The results and findings of the research were found to be quite low when compared with the results (88.4%) of the research by McCaffery et al. (16).

Until the 1980s it was popular wisdom that in neonates, cortical functions, which play an important role in the interpretation and memory of painful experiences, were not fully developed (8,20,21). Studies since that time have shown that a neonate can perceive and remember pain well, and feel pain from intrauterine life onwards (8). In the present study it was found that the response rate of correct answers to the question 'because the neurological system isn't completely developed in children under two years of age, pain sensitivity is low and pain experience is limited' was 48.9%. These results were higher than the results (19.0%) of research by Demir et al. (13), but they are lower than the results (61.3%) of research by Özer et al. (11).

While evaluating pain it is important to choose the correct measurement tool according to an infant's features and the type of the pain to be evaluated (22,23). In our study 65.6% of the nurses said they used a pain scale to measure the patient's pain. Nimbalkar et. al. (24) stated that they needed pain scales for assessing a neonate's pain (50%). Demir et al. (13) reported that 66.7% of nurses did not use a scale to measure pain, and the proportion reported by Ay and Ecevit (25) was 67.7%, and by Özer et al. (11) 74.5%. Abdalrahim et al. (26) also stated that 95.7% of nurses did not use a scale to evaluate the patient's pain in the post-operative period. Efe et al. (9) also stated that one-half of the nurses (49.5%) did not have knowledge about pain scales in pediatric surgical units. The main goals of nursing care are to relieve the pain of children and improve the quality of life. Pain diagnosis and control requires a team work. The nurse is one of the most important members of this team. The most important difference that distinguishes the nurse from other health care team members in pain management is that the nurses spend longer time with the patients and have the opportunity to monitor the child's pain more closely (4,5,17,19). However, in our study and other studies, it was found that the necessary knowledge, attitude and clinical decisions-making abilities of pediatric nurses in fulfilling this role were not at the desired level. When the results are considered in general, it is seen that the rate of pain scale use is quite low. In the results of the

statistical evaluation, a statistically significant difference was found between the use of a pain scale and the units where the nurses worked in favour of the Pediatric Unit and the NICU (χ^2 : 14.695, $p=0.002$). This result is thought to be related to high level of knowledge and skills of Pediatric Unit and NICU nurses in using pain scales and objective evaluation of pain. According to the results obtained from the study, the mean scores on knowledge and attitude about pain management of most of the pediatric nurses were at mid-level (45%), but a large number of pediatric nurses were at low-level (35.9%). The results of the study resemble the results of Demir et al. (13), Özer et al. (11), McMillan et al. (14) and Nimbalkar et al. (24). It is thought that these results stem from nurses not having sufficient knowledge of pain physiology, and of the pharmacological and non-pharmacological management of pain. According to the statistical analysis results, there was a statistically significant relation between the nurses' educational background and the unit where they worked and their mean scores on knowledge and attitude about pain in favour of the nurses who had a Master's Degree and who worked at the NICU.

It was seen that the results of previous studies about nurses' recording of pain were different from one another. The rate of nurses' recording of pain in work by Demir et al. (13) was 88.9%, and in a study by Özer et al (11) it was 71.5%. In a study of nurses' care of patients in the post-operative period by Abdalrahim et al. (26), it was seen that there was no data on pain in the records of 35% of nurses. In our study, it was seen that the rate of recording by pediatric nurses was 87.8%. It was found in the statistical evaluation that there was a statistically significant difference between the nurses' recording of pain and the units where they worked in favour of the Pediatric Unit (46.5%) and the NICU (41.3%). The lowest recording rate was in the Pediatric Surgery Unit (12.3%). This was interpreted as being because nurses take post-operative pain experience as normal so they don't see the need to use a pain scale, and therefore the rate of recording is low.

This is supported by studies showing that in pain management, especially in pediatric patient groups, non-pharmacological methods are used in addition to pharmacological methods (8,9). In our study it was found that non-pharmacological methods were used by pediatric nurses at a rate of 56.5%. In the study by Demir et al. (13), it was found that 40% of nurses used non-pharmacological methods. In the study by Ay and Ecevit (25), it was found that nurses informed patients more frequently about medicines, observing the side effects of treatment and following up the vital signs and the effects of the illness and the medicine; and they seldom preferred non-pharmacological methods such as teaching, applying relaxation techniques and massaging. It was thought that nurses and doctors preferred pharmacological methods because they were easy to apply and showed their effects quickly. This opinion is supported by studies (27).

In the literature review, it was seen that nurses are inadequate in pain diagnosis and pain management, critical decision-making, choosing analgesics and knowledge of

medicines (11,28,29). In the present study it was found that when pediatric nurses were asked to rank the three most important issues that they needed to know concerning pain management, they stated 'pain diagnosis, pharmacological pain management and non-pharmacological treatments'. With its developing scientific knowledge content, nursing is in a position to solve the professional and ethical problems specific to its working area. In our study, when pediatric nurses were asked to order the professional and ethical dilemmas that they faced while stopping the pain of a patient from the most important one to the least important one, they stated that the anxiety they faced with regard to respiratory depression was the most important dilemma (48.9%), and conflict with the patient and the family of the patient was the least important one (29.8%). In the study by Demir et al. (13), the most important professional and ethical dilemma that nurses faced was overdosing and addiction; in a study by Karakaya (30) it was fear of patients becoming addicted. In the light of these findings, it is important for hospital administrators to start in-service training programmes on pain diagnosis, pharmacological management of pain and non-pharmacological treatments for pain, and the choice of a suitable pain scale for child age groups and clinical diagnosis, and it is also important to maintain these programmes.

Study Limitations

The study data was collected from a sample of pediatric nurses who were employed at pediatric clinics of a university hospital and a state hospital in Manisa, Turkey. These two hospitals have different opportunities, and different patient and staff profiles. In this research, nurses with a bachelor's and master's degree level of education mostly worked at the university hospital, while the nurses with a health vocational high school and associate degree level of education mostly worked at the state hospital. Therefore, the findings represent only this population and cannot not be generalized to all pediatric nurses.

6. CONCLUSION

As a result of the study, it was found that pediatric nurses had a mid-level of knowledge and behavior score related to pain management and had sufficient knowledge about pain diagnosis and management. However, it was found that the necessary knowledge, attitude and clinical decisions-making abilities of pediatric nurses for pain management were not at the desired level.

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Is Standard Urine Bag or Urofix? Which is More Useful in Surgical Nursing Care? Accuracy of Urine Output Monitoring

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ABSTRACT

Objective: The aim of this study is to evaluate and compare the accuracy of urine output measurement performed by standard urine bags and urofix.

Methods: This is a prospective study conducted at a 22-bed urology unit. Urine volume was measured either by a standard urine bag or urofix, verified by scaled container measurements in patients dressed with urinary catheter and expected to stay with it for 24 hours or more. In total, 1048 measurements were obtained for 131 patients.

Results: The difference between median, maximum and minimum values of urine volumes from the scaled container and nurse's forecast was evaluated for each of 4 measurements. When the urine volume was measured with the standard urine bag, the average volume was 550 cc in the first measurement while it was 300 cc with urofix. Mean values for the second, third and fourth measurements with standard urine bag and urofix were as follows respectively; 590 cc and 335 cc, 500 cc and 300 cc, 600 cc and 300 cc. The difference was statistically significant in all measurements ($p < 0.001$).

Conclusion: In this study, urofix was the most reliable method for measuring urine output and fluid management. Furthermore, if the patient has a standard urine bag, it is recommended to confirm the urine output with a scaled container.

Keywords: Urine levels, urine bag, urofix, fluid management

1. INTRODUCTION

Accurate fluid management in patients admitted to the surgical units is still one of the most challenging and important tasks for the surgical team. Intravenous (IV) fluid therapy is given to managing fluid volume shortage/excess, fluid losses, or electrolyte and acid-base imbalances (1). Fluid and electrolyte disorders are seen as the most common clinical problem in the perioperative period. According to the current National Institute for Health and Care Excellence (NICE) guide; The use of "R 5R", which includes "resuscitation, routine care, replacement, redistribution and reassessment" is recommended for parenteral fluid treatments (2).

Surgery can impair fluid and electrolyte balance. These failures may occur in hormonal systems such as hypovolemia, hypotension, renin-angiotensin-aldosterone system and vasopressin and tubular damage. For this reason, influid and electrolyte disorders, diagnosis, fluid management and treatment approaches should be carefully evaluated(3).

While fluid and electrolyte disturbances affect the prognosis significantly, maintenance of balance stands as the main challenge in care and treatment of all patients. Previous perioperative death reports have suggested that most of the serious postoperative morbidity and mortality cases are attributed to fluid imbalance. Therefore, to increase awareness and disseminate good practice among medical and nursing staff training in fluid management is recommended (4). The administration of fluid to restore intravascular volume is a main stay of therapy in preventing Acute Kidney Injury (AKI), although the optimal amount of fluid therapy is unclear. Lopes et al. (5) demonstrated that intraoperative fluid boluses titrated in accordance with the variation in arterial pulse pressure improve postoperative outcomes. Therefore, fluid and electrolyte balance, which entails a careful and perfect practice, mostly means the vital section of patient care for the nursing care. A urine output supports the clinical picture of a patient instable condition;

therefore, patient fluid input and urine output should be monitored (5). The accuracy of fluid input and urine output records is critical for detecting and preventing hypovolemia, evaluating the amount of fluid and electrolyte requirement in perioperative period (6). Thus, standard urine bag, urofix and scaled containers are important materials. Differences between those materials prevent proper monitoring of urine output leading to an obstacle in detecting hypovolemia, acute renal failure or fluid and electrolyte disturbances and acute therapeutic interventions. In perioperative care, fluid treatment is usually provided by electronic tools such as pump devices and the amount of fluid taken is accurately recorded. However, the volume of urine, which is the main component of the fluid output, is measured on an hourly basis and is manually determined and recorded based on the visual assessment of nurses from urofix or urine bags (7). It is important to be a good observer, follow up the patient in a correct and timely manner, and recognize the patients' reactions to the fluid electrolyte imbalance for the nurses giving continuous patient care for 24 hours in order to provide good quality nursing care and to obtain positive patient outcomes (8).

In this study, we aimed to evaluate and compare the accuracy of urine output measurement performed by standard urine bags and urofix.

2. METHODS

2.1 Clinical Setting and Patients

After the acknowledgement by the local ethical committee (Tekirdag Namik Kemal University Non-Invasive Clinical Studies Ethical Board, 2013/57), 131 urology patients who were hospitalized between April and June 2013 and monitored for urine output in University Health and Practice Center enrolled in our study. Patients were included in the sample population if they were older than 18 years old, were hospitalized for at least 24 hours, got urine follow-up, and volunteered to participate in the study. This study is a prospective study conducted at a 22 beds urological unit. Totally 131 urology patients were divided at random into two groups, standard urine bag (n=68) and Urofix (n=63) groups. Overall, accuracy was assessed by comparing each method with the scaled container. A nurse measured urine output four times a day with standard urine bag, urofix and scaled container. Maximum, minimum and median values for these measurements were calculated. In patients with an urinary catheter and who were expected stay for 24 hours or more, urine volume was measured either by a standard urine bag or by urofix, verified by scaled container measurements. In total, 1048 measurements were obtained for 131 patients (Figure 1).

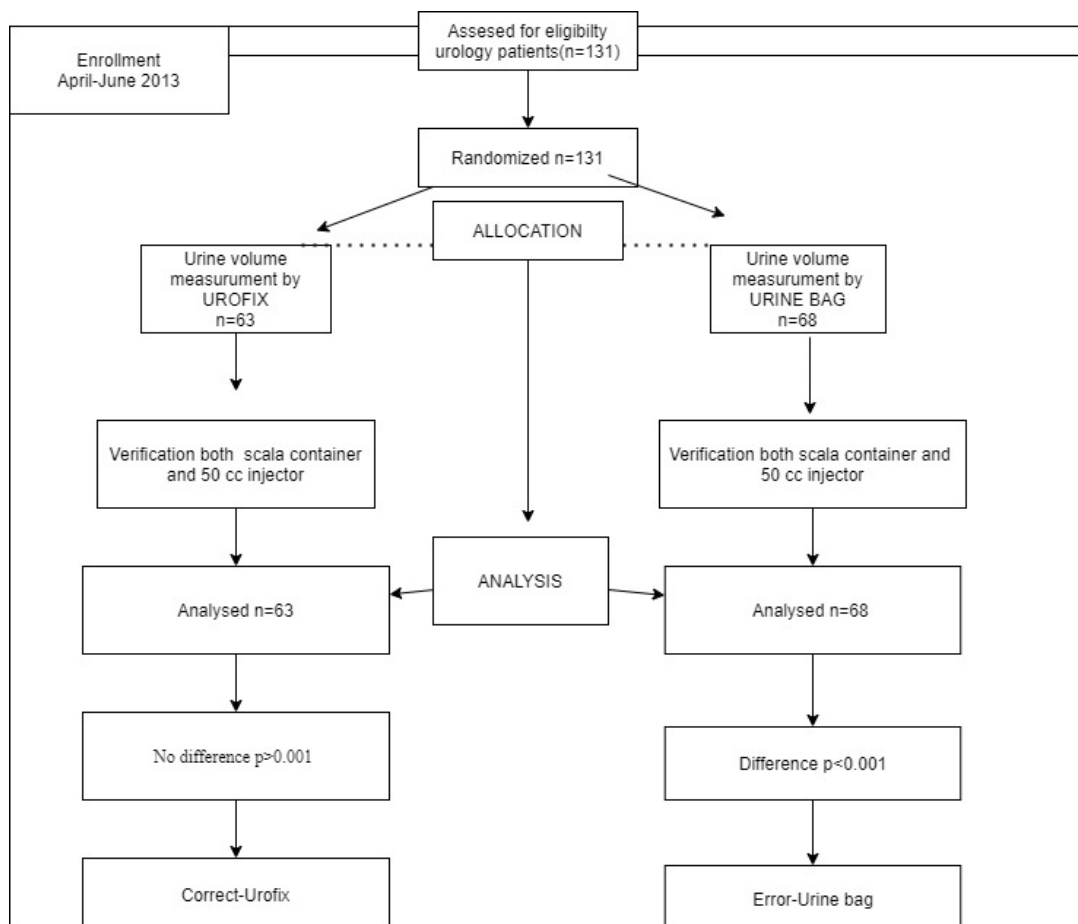


Figure 1. Flow Chart of Research

2.2 Urine Output Monitoring:

Urine output (UO) data of hospitalized patients was gathered via standard 2000 mL urine bag, hourly urine bag (urofix) and scaled container. Monitoring of UO was performed via standard urine bag and urofix, and was measured using a scaled container; and the accuracy of the methods were estimated according to the measurements done by the scaled container. Urine output was monitored four times a day with 6 hours intervals, for the patients who were expected to stay for at least 24 hours at the urological unit. The total number of UO data were same for all patients. Evaluation for comparison of three methods was done by 16 nurses. These nurses had been trained for measurements standardization. All nurses were educated for measuring urine output from urine bag and urofix.

When the nurses were asked about the feasibility of the scaled container, it was considered to be better in two aspects:

1. Urofix measurements confirmed the results obtained with scaled container
2. No need to measure with a scaled container once more.

Additionally, the accuracy of the three measurements was evaluated via 50 cc injectors and equivalence of the amount measured by the scaled container and urofix was confirmed by injectors in each sample.

2.3 Statistical Analysis

While evaluating the findings of the study, all analyses were conducted by institutional statistics program. The convenience of data with normal distribution was assessed with the Shapiro-Wilk test and variance homogeneity was evaluated by using the Levene test. For comparison of two independent groups, the Independent-Samples T test was used. The twicely repeated analysis of the dependent variables was done by using Wilcoxon Signed Ranks Test with Monte Carlo simulation technique. To compare categorized data with each other Pearson Chi-Square and Fisher Exact tests were used again with Monte Carlo simulation technique.

Quantitative data are shown in the tables by mean \pm SD (standard deviation) and median (minimum-maximum) values. Categorized data are shown by n (number) and % (percentage) values. Data were evaluated in 95% confidence level and a p-value smaller than 0.05 was considered significant.

3. RESULTS

A total of 131 urology patients were randomized to standard urine bag (n=68) and urofix (n=63) groups. Overall accuracy was assessed comparing each method with the scaled container. A nurse evaluated the urine collected in the standard urine bag verified by scaled container measurements. In the same way, urofix measured urine volume was evaluated with a scaled container and verified. The results showed that the difference between median values of urine volumes of the scaled container and the standard urine bag, was statistically

significant in all measurements ($p < 0.001$). But there was no statistically significant difference between the urofix and scaled container measurements ($p > 0.001$) (Table 1).

The difference between median urine volumes from the scaled container and the nurse's forecast (visual estimate) from standard urine bag was evaluated for each of the 4 measurements. In the first measurement the urine volume was measured as 550 cc with the standard urine bag, and as 300 cc with the scaled container. In the second measurement, it was measured as 590 cc with the standard urine bag, and as 335 cc with the scaled container. In the third measurement, it was measured as 500 cc with the standard urine bag, and as 300 cc with the scaled container. In the fourth measurement, it was measured as 600 cc with the standard urine bag, and as 300 cc with the scaled container. However, when the urine volume was evaluated with the urofix and the scaled container, it was found that there was no difference in the measurements ($p > 0.05$) (Table 1) (Figure 2).

Table 1. Comparison of urine median, maximum and minimum values of urine volumes obtained by the scaled container and nurse's forecast with urine bag and urofix in 4 measurements.

	Scaled Container	Nurse's forecast	P Value
	Median (Max.-Min.)	Median (Max.-Min.)	
1. Measurement			
Urine Bag (n:68)	300 (1000 – 50)	550 (2100 – 100)	<0,001
Urofix (n:63)	350 (850 – 100)	350 (850 – 100)	1
2. Measurement			
Urine Bag (n:68)	335 (800 – 50)	590 (1550 – 100)	<0,001
Urofix (n:63)	350 (750 – 100)	350 (750 – 100)	1
3. Measurement			
Urine Bag (n:68)	300 (1200 – 50)	500 (2000 – 100)	<0,001
Urofix (n:63)	350 (850 – 225)	350 (850 – 225)	1
4. Measurement			
Urine Bag (n:68)	300 (1560 – 50)	600 (2000 – 100)	<0,001
Urofix (n:63)	400 (850 – 175)	400 (850 – 175)	1

Wilcoxon Signed Ranks Test (Monte Carlo)

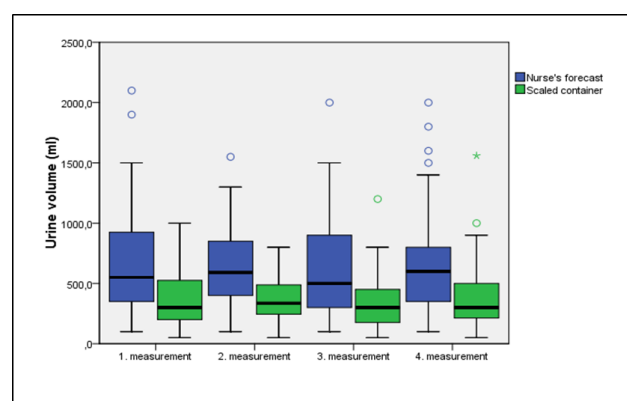


Figure 2. Comparison of urine volume results by the scaled container and nurse's forecast (urine bag) in 4 measurements

4. DISCUSSION

Normal fluid balance is impaired by surgery, so proper and adequate fluid management should be part of the management of a patient. Monitoring fluid balance is dynamic and requirements should be calculated perioperatively. The correct assessment of hydration status in critically ill patients is still complex. Fluid and electrolyte disturbances significantly affect prognosis, while maintaining the balance is the main challenge in the care and treatment of all patients. Perioperative haemodynamic optimization using goal-directed fluid therapy (GDFT) has been correlated with improved postoperative outcomes following moderate to major risk surgeries (1,9). Urine output is a vital sign for patients. Careful monitoring of UO could lead to a better fluid management. Thus, UO is the main parameter which provides an early alert to impending kidney/organ failure consistently used by medical staff in an already complex care environment (10).

In our study, it was once again determined that monitoring urine output was very important. In the follow-up, the lines on the standard urine bag did not reflect the actual amount of urine by the nurse observation. In the standard urine bag, 550 cc urine output was considered. When the nurse evaluated the lines on the standard urine bag, the patient's urine output was recorded excessively and in fact the patient had less urine output. A statistically significant difference was found between them ($p < 0.001$) (Table 1, Figure 2). These measurement errors also indicate that patients may receive incorrect fluid therapy and fluid management. The measurement by urofix was accurate when verified by scaled container measurement.

Currently, the nurse measures the urine output manually hourly or every 4/6 times a day (11). These tasks must be performed for each patient admitted to the critical care unit 24 times a day, 365 days a year (4). In the hospital setting, patient fluid input is carefully recorded and mostly administered by electronic devices, such as volumetric and syringe infusion pumps. In this same setting, urine volume, the main component of the patient's fluid output, is measured intermittently (on an hourly basis) relying on nurses' visual assessment obtained from urine meters and collection bags. Nowadays the estimated amount of urine is calculated by the simple manual devices. This methods of urine collection demands constant nursing management and handling. Hersch et al. (7) determined that when the amount of urine is measured by the observation of the urine bag, a deviation of urine output was over 130 cc per hour, which is a parallel result with our study.

The measurement of urine with a scaled container or urofix will provide a more accurate calculation of the urine output than the standard urine bag. This error is considerably smaller than the error committed when taking visual measurements, and those committed by other devices proposed to measure urine output (7,12). In fact, interval of once every hour currently employed for UO establishes a compromise between avoiding risk states for the patient and

doesn't cause an excessive burden on the nursing staff (7). Sometimes the nurses can not properly close the container valve; thus part of the urine produced during one hour leaks into the plastic bag and is not measured. When this happens, the urine overflows from the graduated container and falls directly into the plastic bag, without being measured.

Our study was carried out in a urologic surgery clinic. It is undeniable that perioperative maintenance is a hardly important issue for the patients. Fluid and electrolyte balance is the fundamental of perioperative and especially postoperative maintenance. In this sense, fluid intake and urine output measurement play the starring role while it predicts any possible imbalance and provides response control for intravenous treatments in case. Therefore, it is recommended to use a scaled container or urofix for the measurement of urine output in order to ensure correct fluid management for the patient.

Limitations of The Study

The sample population included only patients in the wards, further research is recommended to be done in the intensive care units. Besides, the sample populations of this study includes only urology patients. Studies that include other patient populations are also recommended.

5. CONCLUSION

In conclusion, the instruments for urine output measurement is important for the accurate monitoring of urine output. Urofix is more accurate than the standard urine drainage bag in measurement of urine output. Therefore, usage of urofix provides better monitoring of urine output, which is vital for providing electrolyte-fluid balance in surgical patients. Urofix may also relieve the nurses' labour, and should be encouraged for clinical studies.

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The Frequency of and Contributing Factors to the Psychological Abuse of Older People in Nursing Homes in Turkey

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ABSTRACT

Objective: This study investigated the frequency of the psychological abuse of older people in nursing homes and contributing factors.

Methods: The population for this methodological and descriptive study was 161 elderly individuals living in two nursing homes in Istanbul. The data were collected using Barthel's Index, the Standardized Mini Mental Test (SMMT) and the Elders' Psychological Abuse Scale (EPAS). The scale's reliability was tested using the Kuder–Richardson Formula 20 (KR–20) and test–retest analysis. Its validity was tested using the Content Validity Index (CVI) and concurrent validity. The frequency of abuse is presented using numbers, percentages, and means. The relationship between the independent variables and abuse was evaluated using the t-test and Kruskal–Wallis variance analysis.

Results: The participants' mean age was 73.5 years (42.2% were older than 80 years); 44.7% were female. The mean scores were 5.57 ± 4.12 on the EPAS and 89.13 ± 17.13 on Barthel's Index. The KR-20 reliability coefficient for the scale was 0.80. The test–retest reliability was 0.97; $p=0.000$, and the content validity index was 90%. Of the participants, 14.3% were exposed to psychological abuse. Individuals with high dependency and low levels of income, education and mental capacity were exposed to psychological abuse more frequently ($p < 0.05$).

Conclusion: The Turkish version of the originally English EPAS is reliable and valid.

Keywords: Psychological abuse, older people, nursing homes, scale

1. INTRODUCTION

Abuse is a preventable social problem that leaves physical, psychological, and social scars on elderly individuals. According to the World Health Organization (WHO), elder abuse is defined as 'a single, or repeated act, or lack of appropriate action, occurring within any relationship where there is an expectation of trust which causes harm or distress to an older person' (1). The global prevalence of elder abuse in the community setting is 15.7%, or approximately one in six older adults (2). Abuse takes on many different forms that include physical, sexual, emotional, and financial abuse as well as neglect. Abuse is often observed in co-occurrence with other adverse situations. When older people become dependent or semi-dependent upon another for their care, they may become defenseless in the face of physical, psychological, emotional, sexual, and, economic abuse and neglect (3,4).

Studies conducted in Turkey have found that the rate of physical abuse among elderly individuals ranged between 4.2% and 25.7% whereas the rate of psychological abuse was between 5.9% and 40.5% (4–7). In various but limited number of studies conducted in Turkey on this matter, rates have been reported as being between 2.1%–33% for economic exploitation, between 0.4%–9% for sexual abuse, and

between 7.6%–8.2% for neglect of older individuals (6,8,9). It has been determined that older individuals are more likely to be victims of psychological abuse (40.5%) and economic exploitation (33%) (5,8). An Australian study determined the rate of physical abuse as 30% and the rate of psychological abuse as 55% (10). A literature review reported the rates of psychological abuse in the US and Thailand as ranging between 1.1% and 41.18% (11). Another research prevalence for abuse reported by older residents were highest for psychological abuse (33.4%), and were somewhat lower for physical (14.1%), financial (13.8%), and sexual abuse (1.9%) and neglect (11.6%) (12).

Although physical abuse is among the types of abuse that can easily be detected, acts of neglect and psychological abuse cannot be as readily spotted. Psychological abuse is single or repetitive inappropriate behavior that psychologically harms elderly individuals when in a relationship with the expectancy of trust (13). Verbal assault, humiliation, threats, embarrassment, criticism, frightening, calling names, and pushing away are examples of psychological abuse (5,14). Psychological abuse has negative effects on an elderly individual's self-esteem, dignity, decision-making processes, and general well-being (15).

Abuse of elderly individuals is usually observed in at-home or long-stay nursing homes and generally meted out by close relatives or caring staff and caregivers (11,16). Psychological abuse is often difficult to detect because it is usually kept hidden. In particular, health professionals cannot easily detect the psychological abuse of elderly individuals (16,17). Psychological abuse cannot be identified through concrete behavioral criteria and direct questioning alone. Instead, direct questioning, inspecting for signs of abuse, and assessing risk factors of abuse must be used together (18).

A review of the literature shows that most studies focus on physical abuse of elderly individuals (5-8,14). However, recent literature indicates that psychological abuse is particularly common among elderly individuals, suggesting that more studies are needed (2,5). Valid and reliable measurement tools that make a multidimensional assessment of psychological abuse are required for these studies. Currently, there are no valid and reliable measurement tools that can be used for assessing psychological abuse (19).

In a scan of the literature, it was found that Wang et al. (2017) developed and used the 'Elders' Psychological Abuse Scale (EPAS)' to evaluate cases of psychological abuse of older individuals (2,20). The instrument contains 32 items that have yes or no responses and since it can be administered in 10 minutes, it is a user-friendly scale. EPAS is single-dimensional, having no factor construct but three different approaches set up for its administration. The scale is made up of questions regarding psychological abuse directed towards the older individual, healthcare providers and the older individual's caregivers. The questions are addressed directly to the older individual (Q1-Q7), to healthcare personnel for their active observations (Q8-Q13), and to the individual's caregivers (Q14 – Q32). A response of 'yes' indicates the presence of abuse and is scored as '1', while a response of 'no' is scored as '0'. The individual's total psychological abuse score is the sum of the statements receiving a positive response and a high score indicates a high potential for psychological abuse. The cut-off point of the scale has been determined as 10 (17,20).

Nurses have the opportunity to evaluate elderly individuals in their living environments (e.g., homes, nursing homes, primary health care centers, and hospitals). Thus, they play an important role in detecting and intervening in cases where elderly individuals are abused (21,22). This study aims to determine the frequency of psychological abuse in elderly individuals at nursing homes and the factors that contribute to this. The Elders' Psychological Abuse Scale was adapted to the Turkish language and culture to determine the frequency of psychological abuse.

2. METHODS

2.1 Design

This methodological and descriptive study was conducted between December 2014 and April 2015. It was carried out in two nursing homes in Istanbul, Turkey, which are qualified

as Elderly Care and Rehabilitation Centers. Both centers are staffed with healthcare professionals 24 hours a day. In nursing home A, there were 279 elderly individuals and 110 elderly individuals resided in nursing home B.

2.2 Participants

In total, 389 individuals in two nursing homes formed the population of the study, with 161 individuals (nursing home A = 120, nursing home B = 41) meeting the sample inclusion criteria. The inclusion criteria were as follows: age \geq 65 years, Standardized Mini Mental Test (SMMT) score to be 19 and above, having no communication disability, being partially dependent on a caregiver, and agreeing to participate in the study

2.3 Ethical Considerations

The researcher obtained written permission from Wang to adapt the scale into Turkish, from the Ethical Board of Marmara University Institute of Health Sciences (protocol code: 09.2014.0270 – 70737436-050.06.04; date: 12/18/2014), as well as from the nursing homes. Elderly individuals and their caregivers provided written consent.

2.4 Data Collection Tools

The dependent variable of the study is the EPAS score. The independent variables of the study are the Modified Barthel's Index score; the SMMT score; and sociodemographic variables, including age, gender, education level, marital status, and income level.

Study data were collected using a sociodemographic characteristics description form, SMMT, Modified Barthel's Index and EPAS. The researchers created a sociodemographic characteristics description form to inquire about the individuals' sociodemographic characteristics. It included 11 closed-ended questions.

SMMT was adapted to the Turkish culture by Gungen et al. (23). The test includes five main sections: orientation, recording memory, attention and calculation, recollection, and language. It has 11 items, and a full score of 30. Scores of 24–30 indicate a normal mental state; scores of 18–23 indicate mild dementia; scores of 12–17 indicate moderate dementia; and scores of \leq 12 indicate severe dementia (23).

The Modified Barthel's Index was adapted to the Turkish culture by Kuçukdeveci et al. The index assesses how dependent on others the individual is in all the parameters of carrying out the activities of daily life. These activities are categories under 10 sub-headings: eating, bathing, self-care, dressing, bladder control, bowel control, use of the toilet, transferring between chair/bed, mobility, use of stairs. Scale scores of between 0 and 20; 21 and 61; 62 and 90; and 91 and 100 correspond to the states of being 'totally dependent', 'semi-dependent', 'moderately dependent', and 'totally independent', respectively (24).

EPAS was created by Wang et al. It includes 32 items. Items 1–7 are directly addressed to elderly participants, items 8–13 are completed by the researcher based on observation, and items 14–32 are marked as 'yes' or 'no' by the researcher based on the responses provided by the caregivers. The cut-off score for the scale is 10. Scores >10 indicate that the elderly individual is being psychologically abused (17).

Study data were collected from elderly individuals and their caregivers during face-to-face interviews and by observation. The observers first received training and were then asked to make observations about the responses given to EPAS statements 8-13. These observations involved notice of: facial expressions of dissatisfaction toward the caregiver, no response to an alert about health problems, verbal description of the abusive situation, privacy not respected, irrelevant answers to questions or unresponsive, unexplained problems with verbal expression or language. The scale items were guidelines for the observers. In this study, two separate researchers worked at two different nursing homes using the same measuring tool but since the evaluations were made only of the older adults at the nursing homes at which the researchers worked, inter-rater reliability could not be tested.

Data were collected again from 39 individuals and their caregivers 2 weeks later to ensure test-retest reliability.

2.5 Adaptation Process of the Elders' Psychological Abuse Scale (the EPAS)

The EPAS was translated from English into Turkish and back translated from Turkish into English (25). Three academics in nursing compared the original to the translated scales. The academics focused on term equivalence, clarity, and cultural adaptation. The researcher took their opinions into account when revising the scale.

The researcher also conducted a pilot study with 10 participants. The purpose of the pilot study was to evaluate the items' clarity and suitability, decide on the duration, and determine the reliability and readability of the tool for a Turkish sample. The tool was determined to be explicit, readable, reliable, and understandable for Turkish participants.

The reliability of the scale was tested using KR–20 and test-retest analysis (n = 39), which demonstrated its unchanging quality over time.

The validity of the scale was evaluated in terms of content validity, hypothesis testing and confirmatory factor analysis. Content validity was analyzed with the Content Validity Index (CVI). The CVI was the chosen method of assessment so that the opinions of the experts could be verified and both language and cultural equivalence and content validity could be evaluated. The experts rated each item on a scale of 1-4 such that a score of 1 meant that the statement was not appropriate in terms of language, culture and content, 2 meant that the statement would have to be made relevant in terms of language, culture and content, 3 indicated that the statement was appropriate in terms of language, culture and content but small revisions would have to be made, 4

indicated that the statement was clearly appropriate and relevant in terms of language, culture and content.

For hypothesis testing, Pearson's correlation test was used to assess the correlation between EPAS and SMMT and the Modified Barthel's Index.

2.6 Data Analysis

The study used descriptive statistics, parametric tests (independent group t-test and ANOVA), and non-parametric tests (Mann–Whitney U test and Kruskal–Wallis variance analysis). The Tukey test was used for advanced analyses. The significance level of the study was $p < 0.05$.

3. RESULTS

Of the elderly individuals in the sample, 44.7% were female and 55.3% were male. A large number of these individuals (42.2%) were aged ≥ 80 years, and 72% were widows or widowers. Of the elderly participants, 13.7% perceived their income as sufficient whereas 46.6% did not. Two-thirds (67.7%) had between one and three chronic diseases (Table 1).

The mean score of the individuals on SMMT was 23.18 ± 1.67 . Of the individuals, 39.8% had mild dementia and 60.2% had normal mental states. Their mean score on the Barthel's Index was 89.13 ± 17.13 . Of the elderly individuals, 8.1% were semi-dependent, 32.9% were moderately dependent, and 59.0% were totally independent (Table 1).

Table 1. Sociodemographic Characteristics of the Participants (n=161)

Characteristics	n	%	
Gender	Female	72	44.7
	Male	89	55.3
Age Group	65–69	39	24.2
	70–74	33	20.5
	75–79	21	13.0
	80 and older	68	42.2
Education Level	Illiterate	37	23.0
	Middle school	73	45.3
	High school	33	20.5
Marital Status	Higher education	18	11.2
	Married	9	5.6
	Single	36	22.4
Economic Level	Widow/widower	116	72.0
	Very high	22	13.7
	High	64	39.8
Chronic Diseases	Low	75	46.6
	No	45	28.0
	1–3	109	67.7
Barthel's Index Score	4 or more	7	4.3
	Semi-dependent (21–61)	13	8.1
	Moderately dependent (62–90)	53	32.9
	Totally independent (91–100)	95	59.0
Standardized Mini Mental Test Score	Mild dementia	64	39.75
	Normal	97	60.25

3.1 Findings Related to the Validity and Reliability of the EPAS

Ten experts in this study area evaluated the understandability and scope of the scale items used in the study and determined that the CVI value was 0.90. The test of hypothesis showed that the value of correlation (r) between SMMT and EPAS scores was -0.174 (p <0.02). The value of correlation (r) between Barthel's Index and EPAS scores was -0.255 (p <0.00). The KR-20 value, which was calculated to check for internal consistency of the scale, was determined to be 0.80.

The scale was re-administered to 39 of the elderly participants 2 weeks after the implementation for the purpose of testing the unchanging quality of the scale over time. The test-retest analysis showed that there was a highly significant correlation between the mean scores on the scale (r = 0.97; p=0.00).

The confirmatory factor analysis (CFA) values obtained from the goodness of fit indexes are estimated. The correlation coefficients on the scale varied between 0.10 – 0.74. When CFA was estimated it was found that X²/sd=2.09. Goodness of fit indexes are NNFI=0.46, CFI=0.61, GFI=0.71, AGFI=0.67, IFI=0.62, TLI=0.58, RMR=0.01, RMSEA=0.83. Following modification indices suggestions, error covariances between items 19 and 28, 22 and 31, 34 and 44, as well as 44 and 45 were added.

3.2 Frequency of Elderly Individuals' Being Exposed to Psychological Abuse

EPAS scores of the elderly individuals in the sample ranged between 0 and 22, with 14.3% (n=23) obtaining scores higher than 10, the cut-off score of the scale (Table 2). The mean score on EPAS was 5.57 ± 4.12.

Table 2. Individual Exposure to Psychological Abuse Based on EPAS Scores

Exposure to abuse	n	%
Yes (0–10)	138	85.7
No (11–24)	23	14.3

Nearly half of the elderly individuals (44.7%) stated that they were 'left alone involuntarily'. Researchers observed that 20.5% of elderly individuals showed a facial expression of dissatisfaction toward the caregiver. According to the caregivers, 54% elderly individuals were 'emotionally confused, dispirited, and anxious' (Table 3).

There were significant differences between EPAS scores and gender (t=3.22, p=0.002), education level (kwx² = 12.93; p=0.005), and income level (kwx² = 26.86; p=0.00) (Table 4). The study found that the women residents, individuals with lower education levels, and those who had low incomes were more often exposed to abuse.

There was a statistically significant difference between dependency levels determined with Barthel's Index and those

determined with EPAS mean scores (kwx² = 22.65; p=0.000). The group that created this difference was the group with total independence (p <0.05).

According to the SMMT score, there was a significant difference between individuals who had mild dementia and those with a normal mental state in terms of their EPAS scores (t=3.44; p=0.001). Individuals with mild dementia were more frequently exposed to psychological abuse (Table 4).

Table 3. Frequency of Individuals Who Answered 'Yes' to All EPAS Items (n=161)

	No	Scale items	n	%
Questions asked to elderly individuals	1	Left alone involuntarily	72	44.7
	6	Poor sleep for unknown reasons	66	41.0
	4	Dependent on others economically	44	27.3
	3	Angry at caregiver	36	22.4
	5	Expectation to see relatives unfulfilled	26	16.1
	2	Personal belongings used without permission	15	9.3
	7	Unable to make own decisions	11	6.8
Researcher observations	10	Facial expression of dissatisfaction toward caregiver	33	20.5
	8	No response to alert for health problems	24	14.9
	13	Verbal description of abuse situation	9	5.6
	12	Privacy not respected	8	5.0
	9	Irrelevant answers to questions or unresponsive	6	3.7
Questions asked to the caregivers	11	Unexplained problems with verbal expression or language	3	1.9
	15	Emotionally confused, dispirited, and anxious	87	54.0
	16	Isolation and withdrawal from social activities and unwillingness to talk with others	86	53.4
	29	Dissatisfied with current conditions	63	39.1
	21	Unexplained irritability	43	26.7
	24	Unreasonably inflexible viewpoint	37	23.0
	23	Eating difficulties	33	20.5
	14	Nightmares	29	18.0
	17	Unnecessary suspicions and ideation of being harmed	22	13.7
	20	Fear of specific persons or events	20	12.4
	22	Low self-esteem	19	11.8
	30	Unreasonable demands	19	11.8
	18	Feelings of shame, powerlessness, and loss of dignity	18	11.2
	26	Pleasure in blaming others	18	11.2
	32	Sudden loss of trust in an acquaintance	13	8.1
25	Unexplained ideation of harm and murder of others	10	6.2	
31	Timidity and fearfulness	9	5.6	
27	Taking of improper medication for unknown reasons	8	5.0	
28	Excessive dependence on caregiver	7	4.3	
19	Destroyed own belongings	2	1.2	

Table 4. Comparison of Mean EPAS Scores between Different Levels of Independent Variables

Variables	Mean EPAS Scores		Statistics	
	Mean	SD	t/ kwx ²	p
Sex			t = 3.22	0.002
Female	6.69	4.82		
Male	4.65	3.18		
Educational Level			kwx ² = 12.93	0.002
No school education (illiterate)	*6.83	4.63		
Middle school	5.17	3.75		
High school	6.30	4.18		
Higher education	*3.16	3.14		
Income Level			kwx ² = 26.86	0.000
Very high	*2.54	1.62		
High	4.59	2.85		
Low	*7.28	4.74		
Barthel's Index Score			kwx ² = 22.65	0.000
Semi-dependent (n = 13)	7.58	2.77		
Moderately dependent(n = 53)	6.83	4.37		
Totally independent (n = 95)	*4.54	3.81		
Standardized Mini Mental Test Score			t = 3.44	0.001
Mild dementia (n = 64)	6.44	4.44		
Normal (n = 97)	4.23	3.15		

*The group that created the difference based on the Tukey test; SD: standard deviation

4. DISCUSSION

A valid and reliable measurement tool was required for assessing psychological abuse. Therefore, EPAS, developed by Wang et al., (17) was adapted to the Turkish language and culture.

As a result of the adaptation of the scale to Turkish, CVI proved that there was a 90% consistency among the experts, and the criteria for content validity were met. The CVI of the original scale was 92%, and there was a high similarity between the original and translated scales (17). The study concluded that the linguistic structure of the scale was understandable and that the content was suitable.

The test for concurrent validity that was administered for construct validity evaluated the direction and level of correlations that had been anticipated before using the correlation analysis based on sources and observation (25). As in the study by Wang et al., (17) a negative weak correlation was found between SMMT, Barthel's Index, mean scores, and EPAS (p <0.001). However, these findings also showed that the scale was valid according to concurrent validity. Parametric and non-parametric tests also showed that there was a significant difference between the individuals' exposure to psychological abuse and dependence levels and mental capacities (p <0.01). These results confirm the hypothesis that those who are semi-dependent and those who have mild dementia are exposed to more psychological abuse, and this is a statistically significant result.

Reliability refers to the consistency of an assessment tool (25,26). Because items on this scale had two options (yes and no) and assessed one structure, internal consistency was assessed using the KR-20 formula. This type of reliability will be increased when the characteristics assessed by the test items are similar to the behaviors they measure. If the K-20 formula is used for information tests comprising a small number of items (e.g., 10-15 items), small values such as 0.50 will also be accepted as reliable. The value of reliability increases in direct proportion with the number of items on the test (20). The KR-20 value of the original scale, which included 32 items, was 0.82 and that of the adapted scale used in this study was 0.80 (18). The internal consistency of the scale was high.

Test-retest analysis was performed to assess the quality of consistency of the test over time. It is recommended that there should be at least 2 weeks between the first and second assessments (4 weeks at most) and the test should be administered to at least 30 individuals (26). The researchers did not check the test-retest correlations of the original scale. In this study, the test-retest correlation was significantly high, and it was very clear that there was consistency over time (p <0.001).

When confirmatory factor analysis indicates that X²/df <3, this points to an excellent model fit (27,28). Accordingly then, it can be accepted that scale displaying this quality fit the model at a high level.

In the review of the DFA goodness of fit indexes, it is accepted that a value of <0.08 in RMSEA and a value of >0.80 or >0.95 in NFI indicates a good fit. A value of >0.95 in TLI, of 0.90 and, according to some research, of >0.95 in CFI indicates a good fit. Other indications of good fit are an IFI value of 0.90 and over, of over 0.90 in GFI and over 0.90 in AGFI. Although PNFI and PGFI do not have definitive limits, a minimum value of 0.50, and a value of 0.90 in RFI indicate a good fit (26,29). RMR value is sensitive to the scale and is not considered an indication in assessing good fit (29).

According to these goodness of fit values, it was decided that the scale was under good model fit values. This result was associated with the fact that it was below 10 people per scale item proposed for scale adaptation studies.

Of the participants, 14.3% achieved a score of ≥10 on EPAS, which indicates exposure to psychological abuse. Wang et al. (17) reported that 22.6% participants and Acharya et al. (15) reported that 33% participants were exposed to psychological abuse. The difference may be attributable to the sociocultural differences between the countries.

Mean scores on EPAS were 5.57 ± 17.13 in this study, 6.32 ± 4.59 in the study by Wang et al. (17), and 6.92 ± 4.57 in the study by Acharya et al. (15). These mean scores were different but close to each other.

Risk factors related to the individual, the environment and to caregivers are involved in the abuse of older adults. Being of an advanced age, a woman, dependency on others for

carrying out activities of daily living, failing mental capacity, a low level of education, chronic diseases, social isolation, poverty, alcohol or substance addiction can be cited as risk factors related to the individual. Living in a nursing home, a shortage of nursing home personnel, limited resources, living in isolation from the community are among the environmental risk factors. Other risk factors relate to caregivers who are themselves victims of abuse, poorly educated, alcohol and substance users, or afflicted with a psychological disorder (30).

In this study, female participants, participants with low levels of income and education, those with mild dementia, and semi-dependent participants were exposed to psychological abuse to a greater extent than the other participants. Consistent with this finding, Acharya et al. (15) found that gender, income level, education level, dependency level, and mental capacity affected psychological abuse. In addition, Wang et al. also reported that elderly individuals with low-income levels were exposed to psychological abuse to a greater extent than others (20). These similar findings show that gender, educational level, income, and physical and mental capacity affect the risk of psychological abuse in elderly individuals.

In the study by Wang et al, there was a statistically significant difference between EPAS mean scores and chronic disease status (20). On the other hand, this study found no significant difference in this regard ($p > 0.05$). This difference may also be related to other characteristics of the individuals with chronic diseases (such as gender, dependency level, and disease management capacity).

The literature indicates that psychological abuse is difficult to recognize. It cannot be detected by merely engaging in directly questioning elderly individuals or those around them (18). Cohen stipulated that different occupational groups (e.g., elderly care personnel, physicians, and nurses) should be involved in the evaluation process, a holistic approach should be adopted, and culturally appropriate measurement tools should be used for identifying abuse of elderly individuals (18). EPAS, as adapted to Turkish language and culture, provides an opportunity for multidimensional assessment and diagnosis of psychological abuse among elderly individuals. It enables researchers to diagnose emotional abuse by directly asking elderly individuals questions (for example, "Are your personal belongings being used without your permission?") and includes the researchers' observations (for example, 'facial expression of dissatisfaction towards the caregiver'), and the caregivers' opinions (for example, 'nightmares'). EPAS is easily administered because it has a yes/no question format and can be completed in 10 minutes (18).

Certain interventions may provide an opportunity to prevent psychological abuse in nursing homes. The first of these might be adopting a policy of hiring nursing home personnel after evaluating these individuals for characteristics (having a history of suffering from violence, low educational level, psychological issues, alcohol and substance addiction, etc.) that may constitute a risk for abuse. Another precaution

that can be taken is to ensure that healthcare personnel working at nursing homes (doctors, nurses, social workers, etc.) and other employees (dietitians, cleaning personnel, personal support providers, etc.) are provided with an in-house program of education on the prevention of abuse and interventions that can be implemented. Additionally, the number of personnel hired per nursing home resident should be consistent with recommendations (31). Finally, it is of vital importance that older individuals are screened (through physical examinations, observations, interviews, the use of assessment tools such as EPAS, etc.) in order to achieve early detection of psychological abuse and that in the event of a determination of psychological abuse, these individuals are provided with early treatment and rehabilitation (30).

5. CONCLUSION

This study found that the Turkish version of EPAS, which was created in English by Wang et. al. (17) was reliable and valid. This scale will help in detecting elderly individuals at risk of psychological abuse. However, in order to improve the exploratory factor analysis results, it can be suggested that the scale be applied to a larger elderly sample group.

Of the participants, 14.3% were exposed to psychological abuse. The factors that increase the frequency of psychological abuse included female gender, low income and education levels, being semi-dependent, and having mild dementia. Therefore, it is recommended that these groups be monitored more closely using EPAS for signs of psychological abuse.

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Fracture Resistance of Lithium Disilicate, Indirect Resin Composite and Zirconia By Using Dual Cure Resin Cements

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ABSTRACT

Objective: The aim of the study was to examine the fracture resistance of lithium disilicate, indirect resin composite and zirconia by using dual cure resin cements.

Methods: Three groups of 180 samples (n= 60) of E-max, zirconia and indirect resin composite materials (10mm diameter and 1 mm thickness). Discs were fabricated and cemented with three dual curing resin cements. Aging treatment was then applied to the discs by using thermal cycle machine (at 5°C to 55°C/dwell time: 20s), 10000 cycles for 168 hours' 7 days. Fracture tests were performed to the sample discs using piston on three balls test to determine the biaxial flexure strength of the 180 discs of the three materials. The results were analysed by using one-way analysis of variance (ANOVA) and t-test.

Results: Statistically significant difference was found between control groups (before cementation and thermal cycle) and both group B (after cementation before thermal cycle) and group C (after cementation and thermal cycle) in all materials (P<0.05). Comparing Zirconia, Gradia and E-max all control groups showed statistically significant difference and Zirconia was showed greater flexural resistance against other materials. In addition, all materials also showed statistically significant difference in Variolink/Multilink cemented Group B and C. In Nexus cemented Group B and C statistically significant difference was found only Zirconia material. Similar to control group results, Zirconia material was showed greater flexural resistance values with both cements in Group B and C.

Conclusion: There is a difference between flexural strength of the three materials, Zirconia has a better flexural strength when compared to lithium disilicate and indirect resin composite.

Keywords: Zirconia, lithium disilicate, indirect resin composite, fracture resistance, thermal cycle

1. INTRODUCTION

Fracture resistance is the most essential factor for the survival of a dental restoration (1). The strength and aging of intraoral restorations are associated with the achievement of three parameters; strength, fit and esthetic (1,2). An important characteristic of dental materials is fracture resistance as it depends on material resistance to crack from its internal defects (3). Such cracks may lead to microscopic fractures of the restoration margins and/ or the bulk fracture of the filling (4). According to Juntavee and Millstein (5) many ceramic materials have a critical strain fracture ranging from 0.05 to 0.2%, thus to improve the strength of ceramics, the flexural modulus should be amended. Batchelor (6) found that strength and modulus of elasticity improves with the increase of the proportion of the crystalline phase after addition of the crystalline grains of high strength and elasticity. Moreover, latest arguments about dental ceramics stated that the presence of residual stresses influence the strength of dental ceramics (7). Ceramic materials are known for

their good aesthetic, excellent fracture resistance, bonding durability and simplified fabrication techniques using CAD/CAM, therefore, there is a growing interest in them (8). Lithium disilicate glass ceramic is one of the glass ceramic materials that has improved in performance in the last years; it is known for its high flexural strength and appealing translucency (9). In addition, Nawafleh (10) investigated the impact of core/veneer thickness ratio on the fracture strength of lithium disilicate crowns. According to this study results revealed that lithium disilicate had higher fracture resistance and more capable to survive. Additionally, Johansson et al (11) compared fracture resistance of monolithic zirconia and monolithic lithium disilicate (IPS E-max press) after thermal cycle and found zirconia has higher flexural strength (1000 MPa) than lithium disilicate (400 MPa). Besides, Guazzato et al. found that among a type of materials; zirconia offers enhanced mechanical properties when compared to other ceramic materials. However, it has been demonstrated that

flexural strength of zirconia decreases when subjected to such aging treatments and thermal cycle (12-15).

The most popular aesthetic restorative material used in prosthetic restorations are porcelain fused to metal (PFM); zirconia, lithium disilicate and indirect resin composite as they are thought to have excellent mechanical properties. Thus, they have been widely used by clinician because of their excellent aesthetic properties. Fracture resistance of lithium disilicate, Indirect resin composite and zirconia has been intensively studied. However, there is lack of research comparing the materials that which is better in terms of strength and colour maintenance. Thus, this study aimed to examine the fracture resistance of lithium disilicate (E-max), Indirect resin composite and zirconia by using dual cure resin cements. The null hypothesis was that there is no difference of flexural strength between the materials.

2. METHODS

2.1. Preparing the samples

Three groups of 180 samples (n= 60) (10mm diameter, 1 mm thickness) (16-19) of E-max, zirconia and indirect resin composite materials (Table.1). The specimens were randomly divided into three experimental groups; Group A (control groups; before cementation and thermal cycle, before cementation after thermal cycle), Group B (after cementation before thermal cycle), Group C (after cementation and thermal cycle).

Table 1. Materials and groups

Groups	Materials	Working methods
Group A: total (n=60) Control group (no cementation)	E-Max (n=20) Zirconia (n=20) Gradia (n=20)	Control group no thermal cycle+ fracture (n=30) Thermal cycle Control group fracture (n=30)
Group B: total (n=60) Divided into: Variolink N + Multilink N auto-mix (n=30) Nexus3 (n=30)	E-Max (n=20) Zirconia (n=20) Gradia (n=20)	Cementation + fracture + no thermal cycle.
Group C: total (n=60) Divided into: Variolink N + Multilink auto-mix (n=30) Nexus3 (n=30)	E-Max (n=20) Zirconia (n=20) Gradia (n=20)	Cementation+ thermal cycle + fracture.

For the E-max fabrication lost-wax and heat-pressed techniques (IPS E-max press Programat EP3000 press furnace, Ivoclar Vivadent, Schaan, Liechtenstein) was used for one shade of a lithium disilicate glass-ceramic material (IPS e-max Press HT and LT, A1 shade, n=60/each; Ivoclar Vivadent, Schaan, Liechtenstein). All samples were fabricated at 10 mm diameter and 1 mm thickness by using the CAD/CAM Ceramill Motion2 (Amann Girrbach, Koblach, Austria)

with 5-axis technology wet-grinding and dry-milling in one compact unit (figure 1). In order to achieve the accurate dimension of the wax block as shown in every sample takes 10 min milling. After that wax was removed from the CAD/CAM machine and attached to a special sprue ring.

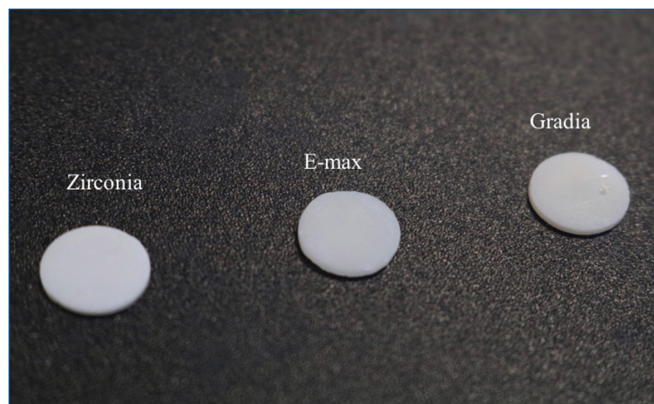


Figure 1. Final shape of the disc materials (Zirconia, E-max and Gradia)

Later on, investment powder 100g (Maruvest investment, Cerampress, Megadental, Germany) was poured and mixed with water using vacuum mixing unit (Renfert, Hilzingen, Germany) then placed inside 850°C furnace (burn-out furnace, Renfert Magma, Hilzingen, Germany) for 45 minutes. After furnace, it was ready for Programat EP3000 press furnace. After pressing the ring was separated using sandblasting unit (Renfert, Hilzingen, Germany) then removed the sprues using a diamond disc (Horico, Berlin, Germany). Then the disc was removed by using airborne particle abrasion unit (Toptec-Bego, Bremen, Germany) with 50-mm glass beads at a pressure of 4 to 2 bars. The level of the pressure was decreased when it became closer to the ceramic material's surface. Both surfaces of the specimens were successively wet-ground to the desired dimensions with 220-, 320-, 500-, 600-, and 800-grade silicon carbide papers mounted on a surface grinder and polisher machine (MetaServ Grinder-Polisher; Buehler UK, Coventry, UK). The final step was to clean and wash the specimens under water. These are the steps of creating E-max samples to reach the accurate dimension required which is 10 mm diameter and 1mm thick.

Zirkonzahn (Zirkonzahn, der Ahr, Gais, Italy) translucent blank was used for 60 fabricated samples of zirconia. The zirconia was manufactured in the CAD/CAM Ceramill Motion2 (Amann Girrbach, Koblach, Austria) with 5-axis technology wet-grinding and dry-milling in one compact unit by using CAD/CAM software and inserted the samples of 10mm diameter and 1mm thickness, after that the CAD/CAM milling machine started to mill the specimen for 10 minutes for each sample. After milling the specimen, a low speed hand piece (NSK ultimate xl, Shimohinata, Japan) was used with a fine bur to remove the disc from the blank. After that, using a rubber finishing bur to soften the edges of the disc and scrubbed with a small brush. Then immersed the disc inside

A1 water-based (Zirkonzahn, der Ahr, Gais, Italy) colour liquid to achieve the desired A1 shade discs and placed them into the sand until dried. The zirconia specimens were sintered at 1500°C after they were made.

For indirect resin composite fabrication 60 samples of Gradia (GC Europe N.V: Leuven, Belgium) were manufactured into A1 shade by filling a metal ring of 10mm diameter and 1mm thick by using a tube of indirect resin composite Gradia manufactured from (GC Europe N.V, Leuven, Belgium). After filling the metal ring by the composite, the material was pressed between two glass slides and fixed with an elastic band, then was stapled with a stapler machine for 15 minutes to achieve the accurate dimension. After that it was inserted inside the light-cured machine (Lumamat100, Ivoclar Vivadent AG, Schaan, Liechtenstein) for 12 minutes to polymerise the discs.

2.2. Cementation

Before cementing the materials one surface of the disc was sandblasted by a suitable sandblasting unit with alumina sand from a distance of 10 mm for 15 seconds each (Renfert, Hilzingen, Germany, 30 µm, 0.28MP). These steps were applied with different types of pressure according to the bonds manufacture. The three materials were then cemented with Dual Cured Resin Cements: Variolink N Resin Cement System Base (shade "0" transparent), and catalyst "0" transparent shade (Ivoclar Vivadent AG, Schaan, Liechtenstein). Multilink N transparent shade (Ivoclar Vivadent AG, Schaan, Liechtenstein) and Nexus Third Generation NX 3 – Nexus3 "clear" shade (SDS Kerr, California, USA).

Cementation was prepared using Mylar strip technique" (20). The Mylar strip was placed over a glass slab and two adhesive tape strips (4M) were placed over the Mylar strip to act as spacer to ensure the standard thickness for all cements and prevent it from moving.

The Resin Cement Variolink N, Base and catalyst "0" transparent shade, respectively: was used for Gradia samples by first painting the samples with a special brush from the Variolink N kit with Monobond N and waited for one minute then mixed the (shade "0" transparent) base and catalyst together on a mixing paper pad with a spatula then applied on the disc by using a plastic instrument and placed on the glass slab. Additionally, the same procedure has been done for the E-max samples but first used hydrofluoric acid on each disc before applying the Monobond N. Multilink N transparent shade was used only for Zirconia by applying Monobond N with a special brush from the Multilink N kit. A dual-cured cement (base/catalyst) and a single-syringe with small tube on each disc were then placed on the glass slab.

Nexus Third Generation NX 3 – Nexus3 "Clear" shade was used for all materials (E-max, Zirconia and Gradia) by using a special brush from the kit to apply the Optibond XTR then waited for one minute before auto-mix. After that a

dual-cured cement (single-syringe base/catalyst) was applied to the disc then placed on the glass slab.

All disk-shaped specimens were placed over the glass slab to create a Resin Cement layer with approximately 100µm thick underneath the ceramic disc (20). After that light cured device was applied for 1 minute for every sample of each material (Bluephase N; Ivoclar Vivadent AG, Schaan, Liechtenstein) to achieve optimum polymerization for each disc.

2.3. Thermal cycle

Thermocycling with temperature switching from (5°C to 55°C/dwell time: 20s (SD Mechatronik Thermocycler, Julabu, Germany) was performed; 10000 cycles for 168 hours (7 days) (21, 22). After thermocycling, the specimens were washed in water and dried in absorbent paper before fracture resistance test was made.

2.4. Fracture resistance testing (Biaxial flexure test)

All samples were individually mounted on a computer controlled universal testing machine (Shimadzu, Japan) with a loadcell of 5kN and data was recorded using computer software (Shimadzu Software). The test was done by compressive mode of load using a metallic rod with a flat end tip (1.4mm radius) as recommended in ISO 6872. This metallic rod is attached to the upper movable compartment of testing machine traveling at cross – head speed of 1mm/min. The lower immobile base was fixed with screws. The piston on three balls test was used to determine the biaxial flexure strength of the 180 discs (10mm diameter 1mm thick) of the three materials. The disc specimens were supported on three steel balls (2.38mm diameter) positioned 120 distances between each other on a circle (7.44-mm radius). The force was applied to the middle of the specimen. The recorded fracture load in (N) was then inserted into the following equation to give the flexural strength value in (MPa):

$$S = -0.2387 P(X - Y)/d^2$$

S is the flexure strength in (MPa), P is the total load-causing fracture in (N), and d is the specimen thickness at the fracture origin. X and Y were determined as follows

$$X = (1 + \nu) \ln (r_2 / r_3)^2 + [(1 - \nu)/2](r_2/r_3)^2$$

$$Y = (1 + \nu)[1 + \ln(r_1/r_3)^2] + (1 - \nu)(r_1/r_3)^2$$

The equation translated in as r_1 is the radius of the support Circle in (mm), r_2 is the radius of the loaded area or the tip of the piston in (mm), and r_3 is the radius of the specimen in (mm) and (ν) is Poisson's ratio and it is noticed to be changed from material to another (figure 2). According to lithium disilicate Poisson's ratio is (0.23) (23), (0.342) for Zirconia according to material market instructions and for Gradia we assumed (0.31) (24).

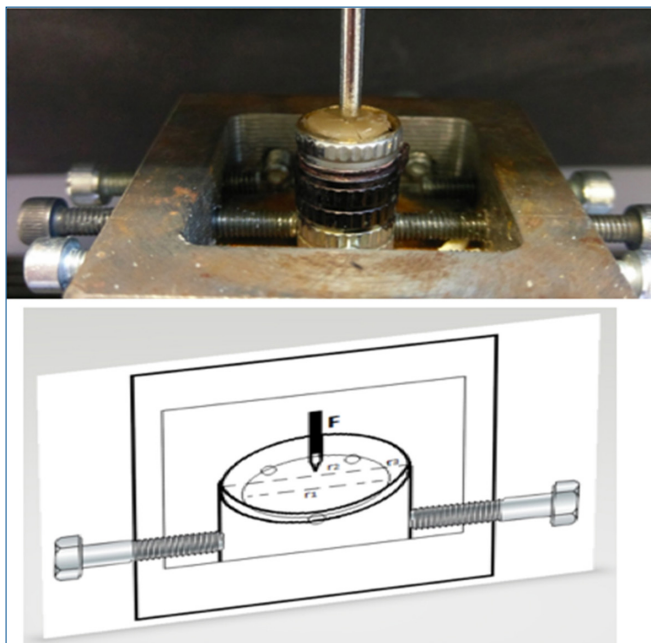


Figure 2. Fracture resistance test

2.5. Statistical analysis

Descriptive statistics and inferential statistical techniques were used for data analysis using SPSS (SPSS 23.00, SPSS Inc., Chicago, IL, USA). Statistical significance difference between the variables was analysed using t-test and analysis of

variance and One-way ANOVA (post hoc) followed by Tukey at significance level of $P < 0.05$.

3. RESULTS

Table 2 illustrates the descriptive statistics of the flexural strength results of the three materials E-max, Zirconia and Gradia. One-way ANOVA (post hoc test) was used to examine the difference of flexural strength between materials according to the cements used and the difference between groups (A, B, and C). For instance, the difference between E-max Variolink control group A and E-max Variolink group B, and the difference between Variolink group B and Variolink group C etc (Table 3). The study results showed a statistical significant difference between the groups and material used in most of the variables. For instance, there was a significant difference between E-max control group (before cementation and thermal cycle) and Variolink Group B (after cementation before thermal cycle) ($P = 0.000$) and also a difference between control group and Variolink Group C (after thermal cycle) ($P = 0.020$). One-way ANOVA was also used to examine the difference between flexural strength of the three materials among all the groups. According to the study results presented in Table 4 there is statistical significance difference between the majority of the variables. Independent sample t-test determined the effect of thermal cycle on the flexural strength of each material. The results indicated no significant difference between control group A before thermal cycle and control group A after thermal cycle in all materials (E-max $P = 1.000$), (Zirconia $P = 0.076$) and (Gradia $P = 0.917$).

Table 2. Flexural strength results of the three materials E-max, Zirconia and Gradia

S	E-max (n=60)						Zirconia (n=60)				Gradia (n=60)							
	A Group (n=20)		B Group (n=20)		C Group (n=20)		A Group (n=20)		B Group (n=20)		C Group (n=20)		A Group (n=20)		B Group (n=20)		C Group (n=20)	
	C	CT	V	N	V	N	C	CT	M	N	M	N	C	CT	V	N	V	N
S1	163.8	163.5	513.5	212	197.2	284	582.5	607.3	864.4	1094.4	741.3	904.3	110	86.6	457.7	407.3	273	389
S2	172.9	155.9	642.9	185	448	240.8	659.5	753.4	1007.7	1007.6	753.9	958.8	95.9	81	261	435.3	143.6	367.8
S3	152.5	185.2	367.6	335.6	157.3	193.3	713.9	718.3	943.7	947.8	917.8	890.2	87	65.8	297.3	223.9	132.7	149
S4	169.4	204.4	446.5	348.4	232.7	183.8	703.9	667.2	896.2	935.4	879.2	600.2	117.4	72.4	297.6	296.2	154.8	172.1
S5	150.6	120.4	346.2	294.8	140.4	284.8	735.4	558.2	1014.8	1028.4	899.4	984.6	108.7	107.7	244.3	314.6	262.2	248.9
S6	200.0	134.6	457.6	209.7	216.2	141.5	816.9	614.3	1009.6	942.9	863.5	859	94.3	81.2	199.6	306.4	187.6	159.2
S7	155.4	140.6	582.6	222.3	366	141.9	660.3	715.3	854	855.5	745.5	910.3	105.3	63.7	161.6	159.8	98.7	138.2
S8	166.2	130.3	519.7	555.1	226.4	310.9	680.8	482.9	941.6	1050.5	996.3	1002.7	100.5	88.5	108.9	399	129.3	107.8
S9	179.7	168.9	358	399.5	226.9	221.8	708.9	407.4	1075.9	882.2	970.6	1013.1	87	74.4	244.1	407.3	132.7	319.1
S10	173.1	178.5	566.9	260.1	477.3	395	738.1	537.6	757.7	1014	849.5	535.4	88.6	76.4	203.9	199.5	240.8	264.7
Mean	168.4	158.2	480.2	302.3	268.8	239.8	700	606.2	936.6	975.9	861.7	865.9	99.5	79.8	247.6	314.9	175.5	231.6

S: Sample; C: Control group before thermal cycle; CT: Control after thermal cycle; V: Variolink cement; N: Nexus cement

Table 3. The difference of flexural strength between materials according to the cements

Material			Difference of mean	P value	95% Confidence Interval	
					Lower limit	Upper limit
E-max	Control	Variolink Group B	-311.79000*	.000	-395.1812	-228.3988
		Variolink Group C	-100.48000*	.020	-183.8712	-17.0888
	Variolink Group B	Control	311.79000*	.000	228.3988	395.1812
		Variolink Group C	211.31000*	.000	127.9188	294.7012
	Control	Nexus Group B	-133.89000*	.001	-207.8151	-59.9649
		Nexus Group C	-71.42000	.058	-145.3451	2.5051
	Nexus Group B	Control	133.89000*	.001	59.9649	207.8151
		Nexus Group C	62.47000	.094	-11.4551	136.3951
	Control after thermal cycle (CAT)	Variolink Group B	-321.92000*	.000	-406.1601	-237.6799
		Variolink Group C	-110.61000*	.012	-194.8501	-26.3699
	Control after thermal cycle (CAT)	Nexus Group B	-144.02000*	.001	-218.9014	-69.1386
		Nexus Group C	-81.55000*	.034	-156.4314	-6.6686
Zirconia	Control	Multilink Group B	-236.54000*	.000	-313.5809	-159.4991
		Multilink Group C	-161.68000*	.000	-238.7209	-84.6391
	Multilink Group B	Control	236.54000*	.000	159.4991	313.5809
		Multilink Group C	74.86000	.056	-2.1809	151.9009
	Control	Nexus Group B	-275.85000*	.000	-377.7059	-173.9941
		Nexus Group C	-165.84000*	.002	-267.6959	-63.9841
	Nexus Group B	Control	275.85000*	.000	173.9941	377.7059
		Nexus Group C	110.01000*	.035	8.1541	211.8659
	Control after thermal cycle (CAT)	Multilink Group B	-330.37000*	.000	-421.7789	-238.9611
		Multilink Group C	-255.51000*	.000	-346.9189	-164.1011
	Control after thermal cycle (CAT)	Nexus Group B	-369.68000*	.000	-482.7945	-256.5655
		Nexus Group C	-259.67000*	.000	-372.7845	-146.5555
Gradia	Control	Variolink Group B	-148.13000*	.000	-208.2132	-88.0468
		Variolink Group C	-76.07000*	.015	-136.1532	-15.9868
	Variolink Group B	Control	148.13000*	.000	88.0468	208.2132
		Variolink Group C	72.06000*	.021	11.9768	132.1432
	Control	Nexus Group B	-215.46000*	.000	-289.9173	-141.0027
		Nexus Group C	-132.11000*	.001	-206.5673	-57.6527
	Nexus Group B	Control	215.46000*	.000	141.0027	289.9173
		Nexus Group C	83.35000*	.030	8.8927	157.8073
	Control after thermal cycle (CAT)	Variolink Group B	-167.83000*	.000	-228.0255	-107.6345
		Variolink Group C	-95.77000*	.003	-155.9655	-35.5745
	Control after thermal cycle (CAT)	Nexus Group B	-235.16000*	.000	-309.7080	-160.6120
		Nexus Group C	-151.81000*	.000	-226.3580	-77.2620

Table 4. The difference between flexural strength of the three materials among all groups

			Difference of mean	P value	95% Confidence Interval	
					Lower limit	Upper limit
Control group Group A	E-max	Zirconia	-531.66000*	.000	-565.6306	-497.6894
		Gradia	68.89000*	.000	34.9194	102.8606
	Zirconia	E-max	531.66000*	.000	497.6894	565.6306
		Gradia	600.55000*	.000	566.5794	634.5206
Control group after thermal Group A	E-max	Zirconia	-447.96000*	.000	-509.0345	-386.8855
		Gradia	78.46000*	.014	17.3855	139.5345
	Zirconia	E-max	447.96000*	.000	386.8855	509.0345
		Gradia	526.42000*	.000	465.3455	587.4945
Variolink/ Multilink Group B	E-max	Zirconia	-456.4100	.000	-564.41610	-348.403898
		Gradia	232.55000	.000	124.543898	340.556102
	Zirconia	E-max	456.41000	.000	348.403898	564.416102
		Gradia	688.96000	.000	580.953898	796.966102
Variolink/ Multilink Group C	E-max	Zirconia	-592.8600	.000	-696.50465	-489.215343
		Gradia	93.30000	.084	-10.344657	196.944657
	Zirconia	E-max	592.860000	.000	489.215343	696.504657
		Gradia	686.160000	.000	582.515343	789.804657
Nexus Group B	E-max	Zirconia	-673.6200	.000	-780.66878	-566.571217
		Gradia	-12.68000	.954	-119.72878	94.368783
	Zirconia	E-max	673.62000	.000	566.571217	780.668783
		Gradia	660.94000	.000	553.891217	767.988783
Nexus Group C	E-max	Zirconia	-626.0800	.000	-760.54135	-491.618650
		Gradia	8.20000	.987	-126.26135	142.661350
	Zirconia	E-max	626.08000	.000	491.618650	760.541350
		Gradia	634.28000	.000	499.818650	768.741350

4. DISCUSSION

This study includes an examination of three esthetic materials, which are considered the most popular esthetic materials used in the field of dentistry. The materials include Lithium disilicate, Indirect Resin Composite and Zirconia. Aging process was applied on the materials using thermal cycle machine (10,000 cycles), this is equivalent to one year of clinical service of composite (25). The current study determined the difference of flexural strength between the materials (Zirconia, E-max and Gradia). According to the results shown in Table 3 there was a statistically significance difference between all the variables. However, there was no significant difference between E-max Nexus group B (after cementation, before thermal cycle) and E-max Nexus group C (cementation with thermal cycle) ($P=0.094$). The reason for this could be that the Nexus cement was better at maintaining the strength of the material even after thermal cycling. According to Lambade et al (26) Nexus NX3 had the highest value of shear bond strength and Variolink II had the lowest. Moreover, the results showed a significant difference between E-max control group (before cementation and thermal cycle) and Variolink Group B (after cementation, before thermal cycle), a difference between control group and Variolink Group C (after thermal cycle) and the difference between Groups B and C ($P<0.050$) mean difference (-311.79000; - 100.48000; 211.31000*). Group B (after cementation before thermal cycle) showed the highest mean values when compared to group A and C. However, this study determined the effect of thermal cycle on the flexural strength of each material. According to the study results, there was no statistically significant difference between control group A before thermal cycle and control group A after thermal cycle in all materials ($P<0.05$). Porto et al (27) evaluated the effect of thermal cycling process on four ceramic materials and unlike the current study they found that thermal cycle had a significant impact on the toughness of all materials. In addition, according to Shafter et al (28) also found that thermocycling has an impact on the flexural strength of different materials, however, their study found no significant difference between the impact of thermal cycle and water soaking. Moresi et al (29) similarly found that flexural strength significantly decreased after thermal cycling protocols in all composites materials tested. In the current study it was also demonstrated that in most samples there is a difference between control and cemented discs (groups B and C) (Table 3). This indicates that factors such as the material, type of cement and heat exposure all have an impact on the aging and the flexural strength of teeth. Li et al (30) compared the differences in flexural strength and compressive strength between different resin-modified luting glass cements that are commonly used in clinics. According to their study, all cements had an impact on the flexural strength on the ceramic, chemical cure cements had a superior flexural strength. Moreover, Francncscantonio et al (31) evaluated the effects of curing mode and viscosity on the biaxial flexural strength (FS) and modulus (FM) of dual resin cements. Their study found that the use of different cements

with different viscosities has an impact on the biomechanical behaviour of luting materials. Besides, insignificance difference between the groups that was revealed in current study was more apparent in group B. This again indicates that not exposing the teeth to heat will lengthen its age. Prakki et al (32) found that the non-cemented groups had a lower fracture loads compared to the cemented groups. On the other hand, Scherrer et al (33) found that treating ceramics with resin cements smoothed its sharpness and roughness which makes it more prone to fracture.

In addition, the current study results also detected a significant difference between the materials in nearly all variable in groups A, B and C (Table 4). Therefore, the null hypothesis has been rejected. It was clearly shown in the results presented in Table 4 that Zirconia has a better flexural strength in all the groups followed by E-max and then Gradia. Jihad et al (34) similarly found that Zirconia materials showed superior biaxial flexural strength values than the lithium disilicate glass ceramics. According to Piconi and Maccauro (35) Zirconia is strongly dependent on its grain size, thus, it cannot be easily transformed. Johansson et al (36) also found higher strength for the zirconia crowns compared to lithium disilicate crowns when undergone the thermal cycle machine. In relation to Gradia, there is lack of studies on the flexural strength difference between Gradia (indirect composite) and Zirconia. Most studies assessed the difference between indirect and direct composite. For instance, Borba et al (37) evaluated the flexural strength and hardness of direct and indirect composites. According to their study results direct composite showed higher mean value than the indirect composites. Similarly, Cesar et al (38) found that the flexural strength of direct composite (Z100) was much higher than indirect composite materials (Artglass, Belleglass, Sculpture and Targis). Nevertheless, the current study found insignificance difference was between E-max and Gradia (Variolink group C), E-max and Zirconia (Nexus group B) and E-max and Gradia (Nexus group C) with ($P>0.05$). This may be due that fact that Nexus NX3 has a higher value of shear bond strength than Variolink as mentioned earlier (25). Thus, the Nexus balanced between E-max and Gradia, whilst Zirconia remained with the highest strength.

5. CONCLUSION

Within the limitations of this study the following conclusions may be drawn:

- i) There is a difference between flexural strength of the three materials, Zirconia has a better flexural strength when compared to E-max and Gradia.
- ii) Different types of cement could have an impact on the flexural strength of ceramic materials.

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Usage and Results of Levosimendan in Ischemic Mitral Valve Surgery

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ABSTRACT

Objective: Large number of comprehensive studies has been carried out on levosimendan. There are many studies on its use, especially in cardiac dysfunction, ischemic cardiac surgery, and heart transplantation surgery. But, there are limited number of studies regarding its use in mitral valve interventions and ischemic mitral dysfunction combined with coronary artery by-pass surgery (CABG). We aimed to investigate the efficacy of levosimendan usage on patients undergone combined coronary artery by-pass grafting and mitral valve surgery because of ischemic mitral dysfunction.

Methods: Subsequent patients, who have undergone concurrent CABG and mitral valve repair surgery by a single surgery team, were retrospectively examined. 36 patients were divided into 2 groups; Group 1 (levosimendan therapy group, n=15) and Group 2 (n=21).

Results: There was no statistically significant difference between the groups in terms of preoperative characteristics, echocardiographic data of the patients and preoperative medication. Inotrope therapy was required for 12 patients in Group 1, which was statistically higher than Group 2 (n=5, p=0.001). Moreover, IABP following LCOS utilized six and two patients in group 1 and 2 with a statistically significant difference (p=0.03), respectively.

Conclusion: We recommend using levosimendan on selected patients for its several beneficial effects. However, we do not satisfied with the treatment because the pathology of all patients was not related to ischemia, more to the alteration of ventricle anatomy with deterioration of diameters.

Keywords: Levosimendan, ischemic, mitral valve, mitral repair

1. INTRODUCTION

With its combined inotropic and vasodilatory effect, levosimendan having gradually increasing use shows positive effects in treatment of cardiac failure and ventricle dysfunction (1). This medication binds to troponin-C depending on the calcium concentration, improves the myocardial contractility by increasing the calcium-sensitivity of myofilaments, and ensures the peripheral and coronary vasodilation by opening the ATP-sensitive potassium channels (2,3). Thus, both of preload and afterload decrease, coronary blood circulation increases, and anti-ischemic effect appears. Besides that, especially in ischemic cardiac diseases, it plays important role from the aspect of cardiac protection by increasing preoperative and postoperative cardiac output through preoperative myocardial preconditioning.

Large number of comprehensive studies has been carried out on levosimendan. There are many studies on its use, especially in cardiac dysfunction, ischemic cardiac surgery,

and heart transplantation surgery. In these studies, they emphasize that levosimendan using before cardiac surgery effected ventricular function positively. But, there are limited number of studies regarding its use in mitral valve interventions and ischemic mitral dysfunction combined with coronary artery by-pass surgery (CABG). However, studies investigating the efficacy of levosimendan for ventricular function in patients with ischemic mitral regurgitation are limited. In this regard, we aimed to investigate the effect of preoperative levosimendan administration on ventricular function in patients with ischemic mitral regurgitation. Hence, we aimed to investigate the use of levosimendan on patients undergone combined coronary artery by-pass grafting and mitral repair surgery due to coronary cardiac disease and ischemic mitral dysfunction.

2. MATERIAL AND METHODS

Subsequent patients, who have undergone concurrent CABG and mitral valve repair surgery by a single surgery team, were retrospectively examined. This study was reviewed and approved by the Kartal Kosuyolu Higher Specialization Research and Training Hospital Ethics Committee for Non-Invasive Clinical Research (Reg. No: 2020.2/08-293). The inclusion criteria were coronary artery disease, severe left ventricle dysfunction and moderate left ventricle dysfunction having increased ventricle diameter, and on-pump CABG and mitral repair surgery; whereas, exclusion criteria were previous cardiac surgery, tricuspid non-valve pathologies, renal and liver dysfunction, preoperative intubation, emergency cardiac surgery interventions and valve replacement requirements. 16 patients having these characteristics were excluded from the study. 36 patients were divided into 2 groups; patients with low ventricular function, enlarged ventricular diameter and levosimendan retrospectively were identified as group 1. Group 1 (levosimendan therapy group, n=15) and patients with the same characteristics and no levosimendan were identified as group 2. Group 2 (n=21). Preoperative characteristics of patients were summarized in Table 1 (Table 1). Each patient was examined echocardiographically prior to operation (Table 2).

Table 1. Preoperative demographic characteristics of patients.

	Group 1 (n=15)	Group 2 (n=21)	P value
Age (years)	57.3±12	62.8±7.8	0.1
Male	11 (73%)	14 (66%)	0.6
Weight (kg)	66.86±14.35	73.42±14.53	0.3
Height (cm)	161.7±10.6	160.1±8.7	0.6
BSA (m ²)	1.73±0.2	1.8±0.2	0.3
COPD	2(13%)	3 (14%)	0.6
Diabetes	9 (60%)	7 (33%)	0.11
Unstable angina	1 (7%)	3 (14%)	0.47
Euroscore	7.91±6.50	11.88±5.08	0.6

BSA: body surface area; COPD: Chronic Obstructive Pulmonary Disease

The patients in Group 1 were taken into intensive care unit 24 hours before the surgical intervention, and levosimendan therapy was initiated preoperatively (200 mcg/kg) under the control of heart rate, arterial blood pressure, central venous pressure and pulse oximeter with hourly urine analysis. Moreover, the treatment was continued during the operation following to postoperative 24 hours.

Table 2. Preoperative echocardiographic evaluation of the patients

	Group 1 (n=15)	Group 2 (n=21)	P value
PAP (mmHg)	65.18±32.51	51.75±13.40	0.11
LVEDD (cm)	4.8±0.7	4.25±0.85	0.06
LVEDD (cm)	6.11±0.72	5.73±0.70	0.13
LEDV (ml/m ²)	185.43±55.90	174.62±51.41	0.67
LESV (ml/m ²)	112.65±39.06	87.75±43.29	0.21
LA (cm)	4.56±1.19	4.62±0.72	0.62
Posterior wall (cm)	0.97±0.21	1.05±0.12	0.19
IVS (cm)	0.99±0.20	1.08±0.13	0.12
LVEF (%)	34.80±6.96	34.76±6.22	0.58
MI (grade)			
3/4	7 (47%)	9 (43%)	
4/4	8 (53%)	12 (57%)	
TI (grade)			
2/4	3 (20%)	4 (19%)	
3/4	2 (13%)	0	
4/4	1 (6%)	1 (5%)	

IVS: interventricular septum; LA: left atrium; LEDV: left ventricular end-diastolic volume; LESV: left ventricular end-systolic volume; LVEDD: left ventricular end diastolic diameter; LVEF: left ventricular ejection fraction; LVEDD: left ventricular end systolic diameter; MI: mitral insufficiency, PAP: pulmonary artery pressure; TI: tricuspid insufficiency

2.1. Operation-Surgical Method

All of the patients were intubated under general anesthesia (fentanyl 5mcg/kg, midazolam 0.1mg/kg, vecuronium bromide 0.15 mg/kg, and propofol 1mg/kg). Inhaled sevoflurane with fentanyl and propofol infusions (1mg/kg/hour) were implemented.

Standard aortic arterial and bi-caval venous cannulation was utilized for cardiopulmonary by-pass (CPB). Myocardial protection with mild hypothermia was achieved via intermittent antegrade cardioplegia, whereas continuous retrograde cardioplegia was also preferred in some patients. Following the cross-clamp, distal anastomoses, mitral valve repair and proximal anastomoses were performed respectively. Ring annuloplasty is the common method for all patients undergoing repair.

Preoperative basal creatinine level higher than 50% and/or anuria was considered to be renal, suddenly-developing stroke or temporary ischemic attack to be neurological, respiratory dysfunction and repetitive mechanic ventilation need to be respiratory; any tachycardia, bradycardia, atrial and ventricular dysrhythmias to be arrhythmia and hemorrhage ≥500ml at 1st postoperative hour, ≥400ml at 2nd postoperative hour, and ≥300ml at 3rd postoperative hour were considered to be hemorrhagic complications. Patients having systolic arterial pressure of <80 mmHg, diastolic arterial pressure of <50 mmHg and not responding to liquid replacement treatment were given inotropic therapy. Hypotension, high central venous pressure, tachycardia, sweating, oliguria, and severe ventricular dysfunction in echocardiographic examination were considered as low

cardiac output syndrome, in whom intraaortic balloon pump (IABP) support was applied.

2.2. Statistical Analysis

Statistical analyses were performed using Statistical Package for the Social Sciences (SPSS software Version 15.0, IBM Analytics, New York, USA). The normal distribution of variables was examined using visual (histogram and probability graphs) and analytical methods (Kolmogorov-Smirnov/Shapiro-Wilk tests). Descriptive analyses were performed using frequency tables for categorical variables, and mean and standard deviation for normally-distributed variables. Median and interquartile ranges were used for non-normally distributed variables. Independent sample t-test was used for normally distributed variables; whereas, Mann-Whitney U test for non-normally distributed variables, and Pearson Chi-Square test for categorical variables between two groups. The Paired t-test and Wilcoxon test were utilized for dependent groups. $p < 0.05$ was considered statistically significant.

3. RESULTS

There was no statistically significant difference between the groups in terms of preoperative characteristics, echocardiographic data of the patients (Tables 1 and 2) and preoperative medication (Table 3).

Table 3. Preoperative medication management

	Group 1 (n=15)	Group 2 (n=21)	P value
Nitrates	12 (80%)	18 (86%)	0.65
ACE inh/ARB	9 (60%)	9 (43%)	0.31
Beta Blockers	5 (33%)	3 (14%)	0.17
Diuretics	7 (47%)	5 (24%)	0.15

ACE inh: angiotensin converting enzyme inhibitor; ARB: angiotensin receptor blocker

Given the intraoperative data, the levels of hypothermia were similar in both groups ($p=0.85$). In addition, there was no statistically significant difference regarding CPB and cross-clamp time ($p=0.34$ and 0.06 , respectively). Continuous retrograde cardioplegia was added to 29 patients (80%) with no statistical difference in terms of cardioplegia strategies. Left internal mammary artery (LIMA) was the choice of left anterior descending (LAD) anastomoses; vein graft was used for other graft anastomoses. Furthermore, various reconstruction methods, such as Alfieri procedure ($n=2$), McCune plasty ($n=2$), neochorda implantation ($n=1$) and posterior leaflet plication ($n=12$), were employed for repairing in addition to ring annuloplasty performed to all patients. Additional Tricuspid valve repair was employed for 5 patients in Group 1 and 6 patients in Group 2, whereas there was no statistically significant difference between the groups (Table 4).

Table 4. Operative values of the patients

	Group 1 (n=15)	Group 2 (n=21)	P value
Hypothermia ($^{\circ}\text{C}$)	31.56 \pm 1.66	31.35 \pm 2.98	0.85
ACC time (min)	89.20 \pm 25.27	100.61 \pm 34.95	0.06
CPB time (min)	132.86 \pm 33.09	143.80 \pm 34.38	0.34
Retrograde cardioplegia	10 (67%)	19 (90%)	0.07
Number of grafts			
1	6 (40%)	7 (33%)	
2	7 (47%)	9 (43%)	
3	2 (13%)	5 (24%)	
Concomitant tricuspid reconstruction	6 (40%)	5 (24%)	0.46

ACC: aortic cross clamping; CPB: cardiopulmonary bypass.

Given the postoperative data of patients, as a neurological complication, temporary ischemic attack was observed in one patient (Group 1). The renal problems were observed in seven patients (four in Group 1 and three patients in Group 2, $p=0.35$) with temporary hemodialysis in two and hemofiltration in one. Renal replacement treatment was utilized for the rest of the patients. There was no statistically significant difference between the groups in these findings. Respiratory complications were observed in one patient in Group 1 and seven patients in Group 2; hence, there was statistically significant difference between groups ($p=0.05$). Postoperative arrhythmia was observed in nine patients in Group 1 and 11 patients in Group 2 ($p=0.2$). Atrial fibrillation needed medication, temporary AV block and nodal rhythm was observed in five, four and two patients, respectively. Permanent pacing was required in only one patient. There was no statistically significant difference between the groups in these findings. Vasopressor and inotropic use were present in 6 and 11 patients in group 1 and 5 and 12 patients in group 2, respectively, and there was no statistical difference between vasopressor and inotropic use between groups. Looking at the use of IABP; the use of IABP was observed in 6 patients in group 1 and in 2 patients in group 2 and the difference between the groups was statistically significant ($p:0.03$). Revision for postoperative bleeding was observed in one patient in Group 1. Hospital mortality was seen in two patients of group 1 (Table 5). Longer duration of ventilation and hospitalization in ICU were observed in group 1 when compared to group 2. ($p=0.01$ and $p=0.003$). However, there was no statistically significant difference ($p=0.11$) regarding hospital stay (Table 6).

There was no statistically significant difference in terms of echocardiographic data in two groups. Residual mitral regurgitation was observed in two patients in Group 1 and in three patients in Group 2 without statistically difference (Table 7).

Decrease in left ventricular systolic and diastolic end diameters and diastolic end volumes were seen in group 1, even though there was no statistically difference comparing pre – and post-operative echocardiographic data. Moreover, increase in posterior wall thickness was significant ($p=0.04$). Reduction in pulmonary artery pressure was observed (Table 8).

Table 5. Postoperative adverse events

Complications	Group 1 (n=15) (n, %)	Group 2 (n=21) (n, %)	P value
Neurologic	1 (7)	0 (0)	0.23
Respiratory	4 (26)	2 (9)	0.17
Renal	4 (27)	3 (14)	0.35
Arrhythmia	9 (60)	11 (52)	0.2
Inotropic support	7 (46)	4 (19)	0.15
Vasopressor support	10 (66)	7 (33)	0.12
IABP support	6 (40)	2 (9)	0.03*
Hemorrhage	1 (7)	0 (0)	0.23
Infection	2 (13)	0 (0)	0.08
Mortality	2 (13)	0 (0)	0.08

IABP: intraaortic balloon pump

Table 6. The duration of ventilation, ICU and hospital stay

	Group 1 (n:15)	Group 2 (n:21)	P value
Duration of ventilation (hour)	43.13±38.76	24.66±36.38	0.01*
Length of ICU (day)	8.60±5.97	4.19±2.82	0.003*
Length of hospitalization (day)	13.72±5.60	12.52±6.17	0.11

ICU: Intensive care unit

Table 7. Postoperative echocardiographic evaluation of the patients

	Group 1 (n=15)	Group 2 (n=21)	P value
LVESD (cm)	4.50±0.55	4.27±0.88	0.57
LVEDD (cm)	5.75±0.44	5.52±0.72	0.48
LEDV (ml/m ²)	168±36.09	142.78±47.09	0.4
LESV (ml/m ²)	94.36±31.54	88.14±39.01	0.8
LA (cm)	4.66±0.62	4.68±0.73	0.89
Posterior wall (cm)	1.10±0.10	1.04±0.10	0.30
IVS (cm)	1.10±0.15	1.11±0.15	0.83
LVEF (%)	36.87±7.98	39.47±7.05	0.48
MI (grade)			
2/4	2 (5%)	3 (8%)	0.9

IVS: interventricular septum; LA: left atrium; LEDV: left ventricular end-diastolic volume; LESV: left ventricular end-systolic volume; LVEDD: left ventricular end diastolic diameter; LVEF: left ventricular ejection fraction; LVESD: left ventricular end systolic diameter; MI: mitral insufficiency

Table 8. Pre – and post-operative echocardiographic comparison in patients who received levosimendan

	Preoperative TTE	Postoperative TTE	P value
LVEF (%)	34.80±6.96	36.87±7.98	0.28
LVESD (cm)	4.8±0.7	4.50±0.55	0.07
LVEDD (cm)	6.11±0.72	5.75±0.44	0.11
LA (cm)	4.56±1.19	4.66±0.62	0.24
IVS (cm)	0.99±0.20	1.10±0.15	0.1
Posterior wall (cm)	0.97±0.21	1.10±0.1	0.04*
PAP (mmHg)	65.18±32.51	55.0±32.01	0.14
LESV (ml/m ²)	112.65±39.06	94.36±31.54	0.18
LEDV (ml/m ²)	185.43±55.90	168±36.09	0.1

IVS: interventricular septum, LA: left atrium, LEDV: left ventricular end-diastolic volume, LESV: left ventricular end-systolic volume, LVEDD: left ventricular end diastolic diameter, LVEF: left ventricular ejection fraction, LVESD: left ventricular end systolic diameter, PAP: pulmonary artery pressure, TTE: Trans-thoracic echocardiography

4. DISCUSSION

Levosimendan is a positive inotropic and calcium-sensitizer agent supporting diastolic function of the heart (4). Moreover, showing effects on ATP-sensitive potassium channels on the mitochondria, it preconditions the myocardium against ischemia and has a protective mechanism against the ischemia reperfusion damage (5). Without disturbing the energy balance of the heart, it creates positive inotropic effects. It also increases the myocardial contractility and cardiac output without increasing the oxygen demand of myocardia (6). Short-term infusion of levosimendan allows lower level of damage on dysfunctional myocardia and creates the preconditioning effect (7,8). Besides, it has effects on improving the cardiac index and mean arterial pressure and decreasing the pulmonary capillary wedge pressure (6-9). In our study, even if the results are not statistically significant, reduction was observed both in left ventricle systolic/diastolic end diameters and volumes. There was also a statistically significant increase in left ventricular posterior wall thickness. Moreover, an improvement was observed in pulmonary arterial pressures, which have been high during preoperative period.

In current guidelines, levosimendan referred as Class 2A from inotropic aspect that having proof level C (10), is used in various stages of cardiac surgery. In many reports, levosimendan is used in weaning from CPB or in postoperative period, and even before the surgery (8). We preferred to initiate 24 hours before the surgery, and then continued for 24 hours after the operation.

However, in some studies, the half-life of levosimendan was reported to be one hour but that of the active metabolite to be approx. 80 hours and, for this reason, the effect continues in early period even if the treatment was stopped (6,11).

One of the issues emphasizing on levosimendan is whether it is inducing higher doses of inotropic agents. And, yet, there is still much controversy between the studies on this topic.

It was asserted in some of the studies, in which it decreases the use of inotrope, meanwhile the others have been reported with a reduction in the high-dose inotrope (11,12). On the contrary, some has reported an increasing effect of inotrope and vasopressin usage (9). In our study, the increase in the use of additional inotropes was not statistically significant in patients using levosimendan. As a matter of fact, it is obvious to use vasopressor agents due to the hypotensive effect of levosimendan. On the other hand, according to guidelines, it is recommended to not use it unless it is combined with inotrope and vasopressor agents in patients either with hypotension (systolic blood pressure of <85 mmHg) or in cardiogenic shock (10). However, the use of vasopressor in the group receiving levosimendan for the prevention of possible hypotension effect in our study, however, was not statistically significant. Kolseth et al. determined that the prophylactic use of levosimendan in patients with reduced left ventricular ejection fraction (LVEF) has no superiority over the catecholamines (13).

Even though levosimendan is said to have been reduced IABP initiation in some studies (11), we observed an increase in group 1, astonishingly as not expected. Another remarkable issue is the effects on ventilation and the length of intensive care unit (ICU) and hospital stay. There are some studies depicting the reduction in all parameters, and some are not (7-9,12). There was no statistically significant difference between the groups in the duration of hospital stay in our study. Although there is a statistically significant difference in intensive care unit stay in the levosimendan group, we do not think it is clinically significant. Because patients receiving levosimendan were admitted to intensive care for drug usage preoperatively. Adverse effects, such as nausea, vomiting, hypotension, can be seen with the higher doses (9). However, Lahtinen et al. came up with a decrease hemorrhage with levosimendan after valve surgery (14). In our study, there was no statistically significant difference between the groups in terms of postoperative complications.

Regarding the effect of levosimendan on mortality, the common opinion showed no effect on mortality and morbidity (8,13). In our study, mortality was observed in two patients, whom were in group 1, due to the sepsis. Besides, parallel to publications, there was no difference between groups in terms of early mortality. During the last decade, Alvarez and colleagues brought different dimension and they claimed that proven beneficial effects of levosimendan should not be considered due to the lack of larger sample sizes. And, they said that it is controversial to clarify the increased survival with levosimendan in the absence of randomized studies (15).

5. CONCLUSION

The use of levosimendan in cardiac surgery provides many beneficial effects. We conclude that levosimendan has a significant positive effect on cardiac function and ventricular diameters for ischemic mitral valve patients, even if it is not statistically significant. In addition, we do not see any harmful effects. However, since we can not see very great superiority as expected, we think that it will be more beneficial to use it in selected patients from the point of view of cost effectiveness. Finally, since the studies on these groups of patients undergoing combined surgery are limited, larger scale studies are needed.

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Colorimetric Assessment of Surface Sealants for Discoloration of a Nanofilled Resin Composite

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ABSTRACT

Objective: This *in vitro* study was aimed to assess the effect of different surface sealants on discoloration of a nonfilled resin-based composite quantitatively, using a colorimeter.

Methods: 40 specimens were prepared using nanofilled resin composite, Filtek Universal Restorative (A2 shade, 3M, USA). Specimens were polymerized from both sides, polished using polishing discs (SofLex, 3M, USA) and divided by test groups (n = 10 for each), regarding the sealant used; Permaseal (Ultradent Products, USA), Biscover LV (Bisco, USA), Optiglaze Clear (GC Corp., Japan) and control group. Samples were discolored for 144 hours in coffee solution, and color measurements were performed using colorimeter (ShadeStar, Dentsply Sirona, USA). Nominal color codes of specimens regarding Vita Classical Shade Guide, were converted to corresponding numerical values. Level of color change after sealant application (Δ Vita1) and after discoloration (Δ Vita2) were calculated. Shapiro Wilk and Kruskal Wallis tests were used for statistical analyses.

Results: Color changes in Permaseal, Optiglaze and control groups were significant ($p < 0.001$) compared to Biscover, for Δ Vita1 scores. Remarkable level of darkening was observed for all groups, for Δ Vita2 scores. Permaseal revealed significantly the highest level of darkening, among all ($p < 0.001$), but no difference with control group. Optiglaze showed significantly lower level of darkening compared to the control group ($p < 0.001$), whereas no difference with Biscover ($p \geq 0.05$). Biscover group showed similar level of darkening with Optiglaze and control groups ($p \geq 0.05$).

Conclusion: Permaseal sealant presented significantly the highest discoloration, whereas Biscover and Optiglaze sealants presented similar and lower. Colorimeter might be determined as repeatable method for measuring discoloration *in vitro*.

Keywords: Sealant, Biscover, Optiglaze, Permaseal, discoloration, nanocomposite

Clinical relevance statement:

Discoloration of resin-based composite restorations may cause esthetic problems clinically, in long-term clinical. The use of surface sealants might be a supporting procedure for maintaining the color stability of composite restorations. In this study, the effect of various surface sealants with a nanofilled composite was assessed *in vitro*, regarding corresponding coffee discoloration for 6 months.

1. INTRODUCTION

Resin-based composite (RBC) materials have been preferred frequently for direct anterior restorations, with the increasing expectations in esthetics (1). Accordingly, surface characteristics of the RBC restoration plays a key role in long-term esthetic outcome. Polishing capacity of the composite

material, surface hardness and surface roughness are the important factors influencing the the color stability (2). Resin matrix absorbs water to compensate polymerization shrinkage (1,2). Unreacted free monomers may develop due to the insufficient polymerization rate and may increase solubility of the resin, microleakage and thereby potentially discoloration as a result of decrease in mechanical properties (2). Etiology of discoloration may be related to internal and external factors. Discoloration is not only related to to the polymerization level, but also the inorganic filler content of the material and deficiencies in polishing procedures (3,4). Type, shape, size, and amount of the inorganic filler particles may alter the physical properties of the RBC material. Also effective polishing using proper polishing materials is essential to achieve a smooth restoration surface, thereby, inhibiting the plaque accumulation and the caries process (5). Whereas, patient related factors (i.e., systemic diseases,

oral hygiene, diet, and smoking habits) may also influence the long-term color stability of RBC restorations.

Surface sealants are resin-based materials developed to maintain the color stability of the RBC restorations in long-term. The low-viscosity structure led these materials to cover the surface of restorations by penetrating through microporosities. Aim of surface sealants is to cover the surface permanently as a thin film layer, reduce the water absorption of the material, and thereby maintaining the color stability (1,6,7). Previous studies regarding the effectiveness of surface sealants have been controversial. Some researchers suggested the application, whereas some reported no meaning in application (6-8). There are a few surface sealants of different brands available in the market currently and each have individual application protocols.

Various diagnostic techniques have been used to evaluate the color stability of RBCs. Colorimeters, spectrophotometers, and recently cross-polarization dental photography are quantitative techniques which were mentioned previously in literature for the color assessment (9).

Quantitative scoring of color change have frequently been performed according to Commission Internationale de l'Eclairage (CIE) color universe (9-11), which includes mainly two color coordinate systems, $L^* a^* b^*$ and $L^* C^* h^*$. Color is expressed by three parameters in $L^* a^* b^*$ coordinate system. L^* refers to brightness between black (0) and white (100), a^* refers to color from red (+ a^*) to yellow (- a^*), b^* refers to the color from yellow (+ b^*) to blue (- b^*).^{9,10} $L^* c^* h^*$ coordinate system was reported to be more compatible with human eye regarding the color perception. L^* refers to luminance, C^* refers to chroma, and h^* refers to hue (10). In addition, another color system, CIEDE2000 (ΔE_{00}), was introduced to improve the performance of gray and blue colors, recently (12). However, controversial results are available in literature, regarding the sensitivity of CIEDE2000 system (11,12).

The objective of this *in vitro* study was to assess the effect of different surface sealants on discoloration of a contemporary nonfilled RBC quantitatively, using a colorimeter. The null (H_0) hypothesis was determined as follows; the use of surface sealants had no effect on the level of discoloration of nanofilled composites.

2. METHODS

A novel nanofilled RBC, Filtek Universal Restorative (3M, MN, USA) was used in this study. A total of 40 disc-shaped specimens of A2 shade were prepared. Disc molds of 12 mm in diameter and 2 mm thickness were used for the preparation. A polywave LED unit (Valo Grand, Ultradent Products, USA) with 12 mm tip in diameter was used for polymerization of the samples. The curing unit was calibrated with a radiometer before each cure. The specimens were polymerized from both sides for 20 s, an irradiance of 1000 mw / cm². Surface abrasions were performed for 20 s on both surfaces, using 600 grit silicone carbide (SiC) abrasion papers (30 μ m abrasive particle size), for initial surface standardization. A

new abrasion paper was used per specimen. Following the preparation, the specimens were kept in distilled water for one day, at room temperature.

Three different resin-based surface sealant agents were used in this study; Permaseal (Ultradent Products, USA), Biscover LV (Bisco, USA), Optiglaze Color Clear (GC Corp., Japan). The specimens were divided into 4 groups (i.e., Permaseal group (n = 10); Biscover group (n = 10); Optiglaze group (n = 10), and control group (n = 10). All specimens including the control group were polished from both sides, using Sof-Lex polishing discs (3M, St. Paul, MN, USA) in four different grains (i.e., thick, 80 μ ; medium, 40 μ ; fine, 24 μ ; ultrafine, 8 μ). New discs were used per specimen for 30 s, under dry conditions, at 10000 rpm and the surfaces of the specimens were gently cleaned from debris before changing the disc.

Surface sealants were applied on polished surfaces of the specimens. No surface sealant agent was applied to the specimens in control group. The sealant agents were used according to the individual manufacturers' instructions. Polymerization of the sealants were also performed using the same LED unit at an irradiance of 1000 mW/cm². The contents and composition of the composite material and the sealant agents were resented in Table 1.

Phosphoric acid was used on sample surfaces prior to the application of Biscover LV and Permaseal sealants according to the manufacturers' instructions, to clean the surface of resin composite.

Regarding Permaseal application, 37 % phosphoric acid was applied on polished surfaces for 20 s, the sealant was applied on both sides, dried with slight air for 5 s, and then polymerized for 20 s from both sides.

Regarding Biscover LV application, 37 % phosphoric acid was applied on polished surfaces for 30 s, the sealant was applied on both sides, slightly refined with air, and then polymerized for 20 s from both sides.

Regarding Optiglaze Color Clear application, composite primer and sealant agent were applied on both sides, respectively. The surfaces were polymerized for 20 s from both sides.

Following the sealant application on polished surfaces, all specimens were slightly cleaned from debris with continuous water and stored in distilled water for a day. Then the samples were immersed in staining solution, inside an incubator, at constant room temperature for 144 hours, which corresponds to 6 months of coffee consumption (13,14). The staining solution was prepared by dissolving 20 gr of coffee (Nescafe Gold, Nestle SA, Switzerland) in 250 ml of 100 °C boiling water (14), and was renewed daily. At the end of discoloration procedure, the specimens were rinsed and gently dried.

The color of the specimens was measured using a clinical type colorimeter (ShadeStar, Dentsply Sirona, USA) with Vita Shade Guide mode. Colorimeter was calibrated before each measurement using the calibration unit on individual stand

of the device. Specimens were gently dried using a tissue paper before the color measurements. The Vita Classic shade of each specimen was collected for the baseline (T_1), after sealant application (T_2) and after discoloration procedure (T_3). The collected nominal color codes from B1 to D4 were converted to numerical values of 1 – 16, in accordance to the Vita Classic Shade Guide Scale. The level of potential color change for each specimen after sealant application was assessed by calculating the difference between $T_2 - T_1$

($\Delta Vita_1$). The level of discoloration was assessed by calculating the difference between $T_3 - T_2$ ($\Delta Vita_2$).

Statistical analysis was performed using IBM SPSS V23 software. The normality of the data was investigated by using Shapiro Wilk test. Comparisons between the groups were investigated by using Kruskal Wallis test and the results of the analysis were presented as medium (min-max). 'p' value of .05 was deemed significant.

Table 1. Compositions, type and manufacturers of the resin composites and the surface sealants tested in this study.

Resin-based material	Shade	Filler	Composition	Manufacturer
Filtek Universal Restorative	A2 enamel	Nanofilled	Matrix: Bis-GMA, UDMA, TEGDMA, PEGDMA, Bis-EMA Filler: Silica filler (20nm), zirconia filler (4-11nm), zirconia/silica cluster filler. 0,6 – 10 microns particle size. 78.5 wt%, 63.5 vol%	3M, St. Paul, MN, USA
Permaseal	-	Unfilled	BIS-GMA 60%, TEGDMA 40%, 1-dimethylaminoethyl metacrylate <3%	Ultradent Products, South Jordan, UT, USA
Biscover LV	-	Unfilled	Dipentaerythritol penta-acrylate esters and ethanol	Bisco Inc., Schaumburg, IL, USA
Optiglaze Color Clear	-	Nanofilled	Methyl-methacrylate (30-40%), Silica filler(10%), Multifunctional acrylate(50-60%), diphenyl(2,4,6-trimethylbenzoyl)-phosphine oxide(less than 5%), Photoinitiator	GC Corp., Tokyo, Japan

Bis-EMA=ethoxylated bisphenol-A dimethacrylate; Bis-GMA=bisphenol-glycidyl methacrylate; TEGDMA=triethyleneglycol dimethacrylate; UDMA=urethane dimethacrylate; PEGDMA=polyethylene glycol dimethacrylate.

*The data regarding the compositions of the RBCs were obtained from the manufacturers of the composites.

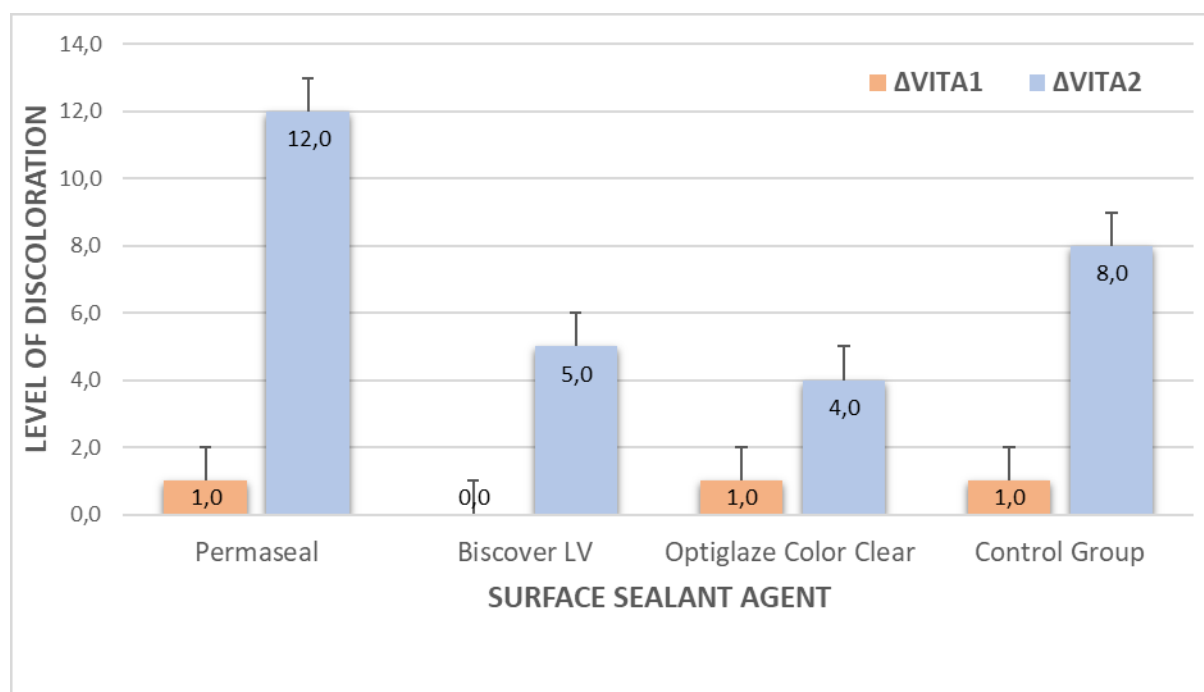


Figure 1. The level of discoloration for surface sealant agents, regarding $\Delta Vita_1$ and $\Delta Vita_2$ scores.

3. RESULTS

A good intra-observer agreement was obtained regarding the kappa values of 0.92 and 0.94. Initial color of the specimens were ranged between B2 to D2, and no significant changes in color were observed for Biscover group at T_1 , T_2 , and T_3 , in terms of $\Delta Vita_1$ scores. However, significant color changes were observed for the specimens in Permaseal, Optiglaze and control groups compared to Biscover group ($p < 0.001$). Level of color changes in Permaseal, Optiglaze and control groups were only 1 unit, and statistically similar ($p \geq 0.05$; Table 2).

Table 2. Comparisons between the surface sealant agents, regarding VITA1 and $\Delta Vita_2$ scores

	$\Delta Vita_1$	$\Delta Vita_2$
Permaseal	1 (0 – 1) ^a	12 (8 – 13) ^c
Biscover LV	0 (0 – 1) ^b	5 (4 – 5) ^{ab}
Optiglaze Color Clear	1 (0 – 1) ^a	4 (2 – 5) ^b
Control Group	1 (0 – 1) ^a	8 (7 – 8) ^{ac}
p^*	<0.001	<0.001

*a-c: There is no difference between the groups with the same letter, for each column.

Remarkable level of darkening in color was observed for all specimens after coffee discoloration for 144 hours, in terms of $\Delta Vita_2$ scores (Graphic 1). Permaseal group revealed significantly the highest level of darkening, among others ($p < 0.001$), but no significant difference was observed with control group ($p \geq 0.05$). Optiglaze group showed significantly lower level of darkening than control group ($p < 0.001$), whereas no significant difference was observed with Biscover ($p \geq 0.05$). Biscover and control groups revealed statistically similar level of discolorations ($p \geq 0.05$; Table 2).

4. DISCUSSION

The null hypothesis (H_0) was rejected, because the surface covering agents have affected the level of discoloration of the composite material used.

Flexible aluminum oxide discs were used for polishing in this study, which were considered gold standard materials for obtaining the highest surface smoothness on composite surface (15-18). It was aimed to obtain the optimum surface standardization by using the polishing system in four grains, and also to increase the accuracy of color measurements by eliminating the microgap formations on surfaces (14,19).

Coffee was used as staining solution in this study to simulate daily routine *in vitro*, with regards to the previously reported high effectiveness in discoloration of RBCs, because of the yellow colorants (19,20). The absorption and adsorption of colorants through the organic phase was described as staining mechanism of the coffee (20) and high discoloration of resins was reported after storage in coffee for two days

period, previously (21). It was determined as the most effective agent for discoloration of RBCs (22). Mundim *et al.* (20) reported 15 days of storage in coffee simulated the 1 year consumption. Rajkumar *et al.* (14) reported 15 min as the average consumption time of a cup of coffee and 3,2 cups per day. With regards to the previous results, the specimens were kept in coffee solution at room temperature for 144 hours, corresponding to the consumption of 6 months (14,21).

A contemporary nanofilled RBC was used in this study for all sealant groups. Less color change was reported to be expected for nanofilled composites, because of presenting smoother surfaces with less stains, as a result of smaller filler size (16,22-24). The inorganic filler content is silica, zirconia and silica/zirconia cluster fillers with 78,5 wt % and 63,5 vol % (Table 1). Also triethyleneglycol dimethacrylate (TEGDMA) has enhancing effect in degree of polymerization, elastic modulus, and surface hardness (18,24,25), and urethane dimethacrylate (UDMA) has lower rate of water absorption (14,17). Regarding our results, these resins and hard filler particles in high concentration might have influenced the resistance to discoloration of the specimens. Whereas, only a single RBC was used in total and thereby resin composite was not an effective factor on color change for this study.

Repeatability of colorimeter measurements were confirmed by obtaining good intra-observer agreement ($k = 0.92$ and 0.94). All surface sealants were polymerized for 40 s in our study, therefore curing time might not be considered an effective factor. Although all specimens were produced using A2 shade of Filtek Universal Restorative (3M), the measured colors were B2 or D2, which were 2 and 1 unit(s) different, respectively, according to the Vita Classic Shade Guide Scale. However, as the statistical analyses were performed according to the color differences ($\Delta Vita$ scores), standardization in color initially was not mandatory for this study.

Regarding the $\Delta Vita_1$ scores, all groups showed significant color changes after surface sealant application except Biscover group, which showed only one unit of discoloration, according to the Vita Classic Shade Guide Scale (Table 2). The surface gloss obtained after surface polishing might be responsible for this slight color change, as light reflections might create deceiving effect on surface during the color assessment (10). However, no color change was observed for Biscover group which might be interpreted that, Biscover sealant might have prevented the unwilling reflection effect of polishing, whereas Permaseal and Optiglaze sealants could not. Therefore, with regards to our results, surface polishing as well as surface gloss might be considered effecting factors on digital color measurement of RBCs.

Regarding the $\Delta Vita_2$ scores, the specimens in all groups were discolored significantly after coffee discoloration for 144 hours (Graphic 1). Coffee was considered an effective agent on discoloration of nanofilled RBC, supporting the previous results (23). The specimens in Permaseal group [12 (8 – 13)^c] and control group [8 (7 – 8)^{ac}] statistically discolored similarly, however, Permaseal showed a greater

level of discoloration mathematically (Table 1). Permaseal also showed the greatest level of discoloration among other sealants. Permaseal contains bisphenol-glycidyl methacrylate (Bis-GMA) resin and more staining potential was reported for the RBCs including (Bis-GMA) resin than UDMA, previously (14,17). Furthermore, hydrophilic TEGDMA resin might have also increased the water uptake of the Bis-GMA based Permaseal (25) and thereby, both factors potentially affected the greater staining in coffee solution (26).

In the present study, the specimens in Optiglaze [4 (2 – 5)^b] and Biscover [5 (4 – 5)^{ab}] groups showed similar and the lowest level of discolorations mathematically (Graphic 1). The color stability of the specimens in Optiglaze group was significantly better than control group. In addition, Biscover group showed similar level of discoloration with Optiglaze and control groups (Table 2). With regards to these results, Optiglaze might have revealed a slightly better performance compared to Biscover, although no significant difference was determined between. Thus, our study agreed the results of Sahin et al. (26), who reported Biscover less stain resistant than Optiglaze. On the contrary, our results have conflicted the previous results of that, Optiglaze could cause increase staining because of debonding of nanofillers from resin matrix and thereby, forming void formations on the surface (17,27). However, positive effects of nanofillers on prevention of discoloration were also reported (23).

In this study, all surface sealants were applied on well-polished resin composite surfaces, which might have caused debonding problems during discoloration process (28). This perspective should be considered for further studies. Only one type of resin composite and staining solution were used which might also be interpreted as a limitation of this study. Also, clinical factors such as occlusal relations, the effect of saliva, diet, and toothbrushing, should be taken into consideration. Therefore, the conclusions of this study should be verified with further clinical trials.

5. CONCLUSION

Within the limitations of this in vitro study, the experimented surface sealants might be considered effective on discoloration of the nanofilled composite, in terms of coffee discoloration for six months. Specimens with Permaseal sealant showed the highest discoloration, significantly. Specimens with Biscover LV and Optiglaze Color Clear sealants showed similar and lower level of discolorations. Colorimeter might be determined as a repeatable method for measuring the level of discoloration in vitro. The conclusions of this study should be verified with different staining solutions, RBCs and further clinical trials.

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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Color Stability of Flowable Composites in Different Viscosities

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ABSTRACT

Objective: This *in vitro* study was aimed to evaluate the color stability of resin-based composite materials in different viscosities immersed in various colorant solutions.

Methods: 250 composite samples of A2 shades were prepared using two high-viscosity flowable composites (G-aenial Injectable, GC, Tokyo, Japan; Estelite Super Low Flow, Tokuyama Dental, Japan A2 shade), a bulk-fill flowable composite (Filtek Bulk-Fill, 3M, USA), a low-viscosity flowable composite (Filtek Ultimate Flowable, 3M, USA), and a packable composite (Filtek Ultimate, 3M, USA). Samples were polymerized and polished from both sides with a LED curing unit (Valo Grand, Ultradent, Switzerland) and polishing discs (SofLex, 3M, USA). Then divided by test groups (n=10 for each) regarding colorant solutions; coke (CocaCola Company, USA), tea (Yellow Label, Lipton, Rize, Turkey), coffee (Nescafe Classic; Nestle, Switzerland), red wine (Doluca, Öküzgözü, Doluca, Istanbul, Turkey), and physiologic saline as the control solution. Samples were discolored for 144 hours with solutions in an incubator at 37°C, and repolished after discoloration. Color measurements were performed using a clinical spectrophotometer (EasyShade IV, Vita, Germany) and a colorimeter (ShadeStar, Dentsply Sirona, USA). Two-way Anova test and Tukey HSD test were used for statistical analyses.

Results: Composite material and colorant solution were considered effective factors for influencing the color change, regarding after discoloration scores ($p<0.001$, $p<0.001$, respectively). In addition, colorant solution was found more effective than the type of composite. Filtek Ultimate Flowable presented significantly the highest level of color change among others ($p<0.001$), for both 'after discoloration ($5,34 \pm 3,78b$)' and 'after repolishing ($3,93 \pm 2,23b$)' periods. No significant difference in color change was found between Gaenial Injectable, Estelite Super Low Flow, Filtek Bulk Fill Flowable, and Filtek Ultimate, and all showed imperceptible color changes ($\Delta E^* < 3.7$). Red wine solution showed significantly the highest level of color change ($8,00 \pm 2,08d$) among other colorant solutions ($p<0.001$), and followed by coffee ($4,59 \pm 1,52c$), tea ($3,38 \pm 1,21b$), and coke ($1,58 \pm 0,99a$), respectively. A strong relation was found between the spectrophotometer and colorimeter measurements.

Conclusion: Viscosity was considered an effective factor for discoloration of RBCs. Color stability of high viscosity flowable composite materials were found to be good and similar to packable composite. Samples immersed in red wine showed the greatest level of discoloration and followed by coffee, tea, and coke. The repolishing procedure was considered effective for reversing back the surface discoloration of composite materials.

Keywords: Discoloration, repolishing, flowable composite, viscosity, color stability

1. INTRODUCTION

Resin-based composites (RBCs) are frequently preferred in dental clinical practice with regards to multiple advantages such as improved optical and mechanical properties, color stability, ease of repair, and single visit treatment option (1). However, there are many studies indicating these materials are susceptible for color change in long-term use (2,3). Color stability of resin composite materials may vary depending on the surface roughness, which is directly related to the finishing and polishing procedures (4,5). Restorations with smoother surfaces result in fewer leakage, less microbial dental plaque build-up, less gingival irritation in the gums, fewer caries, and therefore less discoloration (6). Minimum surface roughness

was reported when using transparent mylar strips without finishing and polishing protocols (7), however, composite restorations may not generally be finished in this way in clinical conditions and need finishing and polishing to remove the outer weak polymerized and softer surface. An accurate and effective finishing and polishing protocol with proper materials are essential for maintaining the color stability of a RBC restoration (8).

Recently, many manufacturers have presented RBC materials with various filler content and viscosity for clinical use. There is a proven relationship between the inorganic filler

type, shape, and proportion as well as the surface hardness, abrasion resistance, and polishability with viscosity, regarding the resin-based composites (5). Previously, it has been reported that the restorations performed with the resins with low polishability, featured low surface gloss clinically in long-term, and the polishability varied among the resin type (5). In terms of polishability, generally microhybrid resin composites (filler particle size ranging from 0.04 to 2 μm) were considered as more disadvantageous compared to the nano-hybrid and nano-filled resin composites filler (filler particle size ranging from 0.005 to 0.01 μm) (9,10). However, some researchers determined that the micro-hybrid and nano-hybrid composite materials do not differ significantly in terms of surface hardness and polishability, as well as the color stability (11).

It is a fact that RBCs change color in time due to internal and external factors (8). Internal discolorations may include only dentin tissue, enamel tissue, or both tissues at the same time, whereas, external discolorations include only the enamel. Internal discoloration is related to the structure of tooth and is formed in deeper layers as a result of the physicochemical reactions occurring in the restoration by the contact to a coloring agent (6,12). External discolorations may occur depending on some factors such as deterioration of restoration surfaces, improper finishing and polishing processes, the effect of coloring agents in beverages, smoking, poor oral hygiene, or dietary habits (12,13). Accordingly, the manufacturers have developed advanced finishing and polishing materials to maintain the discoloration potential of

the RBCs. Recently, there are various finishing and polishing systems in the market for polishing RBC restorations. Metal, rubber, or silicon-based polishing materials can be found in different size, shape and structure with various abrasive particles. Contemporary polishing materials are in disc or spiral wheel shape and include diamond and/or aluminum oxide surface coating (8,14).

This *in vitro* study is aimed to assess the color stability of five RBC materials in different viscosity (a packable, a bulk-fill flowable, two high-viscosity flowable, and a low-viscosity flowable) after discoloration in five different colorant solutions.

The h_1 hypotheses of the study are considered as follows: (1) the viscosity, which is influenced by the particle size and content of the material, is an influencing factor for discoloration of RBCs, (2) The discoloration of the resin composites was affected by the type of colorant solution.

2. MATERIALS AND METHODS

2.1. Preparation and Distribution of the Samples

In this study, five different resin-based composites in different viscosities were used: Gaenial Injectable Flow, A2 shade (GC, Tokyo, Japan); Filtek Ultimate, A2 Body shade (3M, USA); Filtek Bulk-Fill Flowable, A2 shade (3M, USA); Estelite Universal Flow Super Low, A2 shade (Tokuyama Dental, Japan); Filtek Ultimate Flowable, A2 shade (3M, USA) (Table 1).

Table 1. Type, content and manufacturer of resin composites used in the study

Material	Code	Type	Content	Manufacturer
G-aenial Injectable Flow	GIF	Nano-hybrid	The resin matrix: UDMA, Bis-MEPP, TEGDMA, pigment, photoinitiator The filler: 69 wt %, 50 vol %; Silicon dioxide, strontium glass (10-200 nm).	GC Corp., Tokyo, Japan
Filtek Ultimate	FU	Nano-filled	The resin matrix: Bis-GMA, UDMA, TEGDMA, Bis-EMA The filler: 78.5 wt %, 63.3 vol % Silica / zirconium (0.6-10 μm), zirconium particles (4-11 nm).	3M, St. Paul, MN, USA
Filtek Bulk-Fill Flowable	FBF	Nano-filled	The resin matrix: UDMA, Bis-GMA, Bis-EMA, Proacrylate resins, TEGDMA The filler: 64.5 wt %, 42.5 vol % YBF3 fillers (0.1-5.0 μm), zirconium silica particles (0.01-3.5 μm).	3M, St. Paul, MN, USA
Estelite Universal Super Low Flow	ESLF	Nano-hybrid	The resin matrix: Bis-GMA, Bis-MPEPP, TEGDMA, UDMA The filler: 70% wt, 56% vol Supra-nano spherical filler (200nm silicon and zirconium).	Tokuyama Dental Co., Tokyo, Japan
Filtek Ultimate Flowable	FUF	Nano-filled	The resin matrix BIS-GMA, TEGDMA, EDMA, benzotriazole, diphenyl iodonium hexafluorophosphate, dimethacrylate, ytterbium fluoride The filler: 65 wt %, 46 vol % Silica (75 nm), zirconium (5-10 nm), silane treated ceramic and silica.	3M, St. Paul, MN, USA

Bis-GMA: bisphenol A diglycidil dimethacrylate, Bis-EMA: bisphenol A glycol methacrylate ethoxylated, TEGDMA: triethylene glycol dimethacrylate, UDMA: urethane dimethacrylate, HEMA: hydroxyethyl methacrylate, EDMA: ethylene glycodimethacrylate, Bis-MPEPP: 2,2-bis[4-methacryloxy polyethoxy]phenyl]propane

On top of a glass, the selected resin composite was placed in a rubber mold in 2 mm thickness and 8 mm in width and covered with a transparent mylar strip and another glass at the top. Excessive composites were removed slightly and light finger pressure was applied on top of the glass while polymerizing. The polymerization was performed from both sides of the samples, using a LED curing unit (Valo Grand, Ultradent, Switzerland) for 20 s per surface, at irradiation of 1000 mW/cm². All samples were stored in distilled water for a day. Then both surfaces of the samples were roughened to ensure surface standardization before initial color measurements. Coarse grain (50-90 µm) aluminum oxide coated polishing discs (SofLex Discs, 3M, USA) were used without water cooling at 5000 rpm for the surface standardization. A new disk was used for each sample for 20 s per side by a single operator. The roughened surfaces were cleaned from debris continuous water and kept in distilled water at room temperature for 1 day before polishing.

A total of 250 composite samples of five different composite group (n=50 for each group) were prepared. Each group was divided into five sub-groups of four different colorant solutions and a control group (n=10 for each sub-group).

2.2. Polishing Protocol

Previously accepted gold standard surface polishing material for RBCs, SofLex discs were used for the polishing of the samples (15). All standardized pre-roughened samples were polished from both sides using medium grain (10-40 µm), fine grain (3-9 µm), and superfine grain (1-7 µm) aluminum oxide discs, respectively. The discs were used by a single operator without water cooling at 5000 rpm for 20 s per side. The discs were renewed for each sample.

All samples were repolished again after the discoloration was completed and the records were obtained. Medium grain (10-40 µm), fine grain (3-9 µm), and superfine grain (1-7 µm) aluminum oxide discs were used respectively for repolishing protocol.

2.3. Discoloration Protocol

Following obtaining the initial color records, the samples were divided into five sub-groups for the immersion in the coloration solutions. The solutions were: coke (CocaCola Company, USA), tea (Yellow Label, Lipton, Rize, Turkey), coffee (Nescafe Classic; Nestle, Switzerland), red wine (Doluca, Öküzgözü, Doluca, Istanbul, Turkey), and physiological solution (Table 2).

An incubator (Cultura Incubator, Ivoclar Vivadent, Lichtenstein) was used to set the temperature at a constant 37°C for all solutions, to simulate human body temperature (16). The samples in coke group (n = 10) were immersed in 50 ml CocaCola for 144 h with daily solution renewal (17). The samples in tea group (n = 10) were immersed in tea for 144 h with daily solution renewal (16). The tea solution was prepared by immersion of a teabag in 50 ml of boiling water

for 5 m. The samples in coffee group (n = 10) were immersed in coffee for 144 h with daily solution renewal. The coffee solution was prepared by dissolving 3 g of coffee in 50 ml of boiling water (16,17). The samples in wine group (n = 10) were immersed in 50 ml of red wine for 144 h (16,17). The samples in the control group were kept in 50 ml physiological solution for 144 h. All the samples were cleaned from debris and all solutions were renewed daily (17). It was reported that 144 h of immersion *in vitro* corresponded to about 6 months of immersion in colorant drinks *in vivo*, previously(16,17).

Table 2. Type, content, manufacturer, and pH of staining solutions used in the study

Solution	Brand	Manufacturer	pH
Coke	CocaCola	The CocaCola Company, FL, USA	2.52
Tea	Yellow Label	Lipton, Rize, Turkey	6.50
Coffee	Nescafe Classic	Nestle, Vevey, Switzerland	4.50
Red Wine	Doluca Öküzgözü	Doluca, Istanbul, Turkey	3.50
Control Solution	Physiologic Saline	-	5.50

2.4. Evaluation and Statistical Analysis

Color measurements were performed in three different periods [i.e., before discoloration (T₁), after discoloration (T₂), and after repolishing (T₃)] for each sample. T₁ assessment was considered the initial record of the samples after polishing procedures. Before each measurement, the samples were slightly cleaned from debris with continuous water and dried. The color measurements were performed using a clinical contact type spectrophotometer device (EasyShade 4, Vita, Germany) and a clinical contact type colorimeter device (ShadeStar, Dentsply Sirona; USA) by a single experienced researcher on a gray background (CIE L* = 94.48, a* = -0.16, and b* = -0.21). Before the measurements, both devices were calibrated with individual calibration stands. The tip of the devices was located in contact, perpendicular to the middle of the sample surfaces.

Surface color of the samples was assessed regarding the E* and Vita* values, both generated from CIE L*c*h* color coordinates. E* values and Vita* values for each sample were obtained for T₁, T₂, and T₃ periods. Previously, various ΔE* cutpoint values were reported for evaluating the level of color change such as; ≥ 2 (18), ≥ 2.6 (19), ≥ 3.3 (20), ≥ 3.7 (21,22) for perceptibility, and ΔE* < 2 (18), < 5.5 (19), and < 6.8 (22) for acceptability. In this study, respective cutpoints for ΔE* scores were considered ≥ 3.7 and < 5.5 for perceptibility and acceptability levels of color change. Level of color changes (ΔE* scores) was assessed by calculating the differences between T₂ - T₁ (ΔE₁), T₃ - T₂ (ΔE₂), and T₃ - T₁ (ΔE₃). ΔE₁ represents the level of discoloration after immersion in staining solution, ΔE₂ represents the level of brightening after repolishing, and ΔE₃ represents the level of color matching/mismatching of repolished samples with the initial scores.

Besides, recorded Vita* color codes from B1 to D4 were converted to numerical values of 1 – 16, in accordance with Vita Classic Shade Guide Scale. Δ Vita* scores were assessed to evaluate the correlation between the two color measurement techniques. Δ Vita* scores were assessed by calculating the differences between $T_2 - T_1$ (Δ Vita₁), $T_3 - T_2$ (Δ Vita₂), and $T_3 - T_1$ (Δ Vita₃).

The data were analyzed using IBM SPSS V23 software. The ΔE^* values in each measurement period according to the composites and the colorants were analyzed using Two-way Anova test. The significant differences were investigated using Tukey HSD test of multiple comparisons. The correlation between the Vita* and ΔE^* scores were investigated with Kappa test statistics. The \pm standard deviations were presented and 'p' value of .05 was deemed significant.

3. RESULTS

Composite material and colorant solution were considered effective factors for influencing the color change, regarding ΔE_1 ($p < 0.001$, $p < 0.001$), ΔE_2 ($p < 0.001$, $p < 0.001$), and ΔE_3 ($p = 0.009$, $p < 0.001$) scores, respectively. Additionally, the type of discoloration solution was found more effective than composite material type for all evaluation periods (Table 3).

Table 3. Univariate test statistics of composite and solution factors.

Factor	ΔE_1		ΔE_2		ΔE_3	
	F	p	F	p	F	p
Composite	27.308	<0.001	12.724	<0.001	3.596	0.009
Colorant Solution	252.212	<0.001	80.098	<0.001	52.684	<0.001
Composite*						
Colorant Solution	4.983	<0.001	2.656	0.002	2.793	0.001

F: Univariate test statistics

According to ΔE_1 scores, FUF composite presented significantly the greatest level of color change ($5,34 \pm 3,78^b$) among other composite materials, regardless of the solution type ($p < 0.001$), which was perceptible (≥ 3.7) but acceptable (< 5.5). In addition, there was no significant difference in color change between the scores of GIF ($3,40 \pm 2,52^a$), ESLF ($3,21 \pm 1,99^a$), FBF ($3,18 \pm 2,65^a$), and FU ($3,37 \pm 2,61^a$) composites and all were not perceptible (≤ 3.7 ; Table 4). Regardless of the composite type, samples in red wine solution showed significantly the highest level of color change ($p < 0.001$; $8,00 \pm 2,08^d$) among other solutions, which was not acceptable (> 5.5). The level of color change for coffee group ($4,59 \pm 1,52^c$) was also significantly different and perceptible, but acceptable. Although tea group presented

significantly a greater level of color change ($3,38 \pm 1,21^b$) compared to water and coke groups ($p < 0.001$), these three solutions showed imperceptible color changes. In terms of composite*solution interactions, combinations of red wine with all composites presented not acceptable color changes (≥ 5.5). Moreover, coffee combination with FUF presented not acceptable color change. Red wine combination with FUF ($11,32 \pm 1,38^a$) presented significantly the greatest level of color change ($p < 0.001$). All combinations with water and coke presented an imperceptible level of color changes. The interactions of tea with all the composites also showed an imperceptible level of color changes, except with FUF ($4,94 \pm 0,39^{cDE}$) which was perceptible but acceptable (Table 4).

According to ΔE_2 scores, all composites presented imperceptible ΔE^* levels regardless of the solution type, except FUF ($3,93 \pm 2,23^b$), which was also significantly different ($p < 0.001$). Regardless of the composite type, samples in both red wine ($4,36 \pm 1,29^c$) and coffee ($4,38 \pm 1,36^c$) solutions showed significantly higher and perceptible ΔE^* levels ($p < 0.001$; Table 4). ΔE^* levels for water, coke, and tea groups was all imperceptible. In terms of composite*solution interactions, all red wine combinations except with ESLF and combinations of FUF with tea and coffee presented statistically similar, perceptible ΔE^* levels ($p > 0.05$), which were also significantly higher than the other combinations ($p < 0.001$).

According to ΔE_3 scores, all composite materials presented imperceptible ΔE^* levels (≤ 3.7), regardless of the solution type. Also, the samples in all solutions presented imperceptible ΔE^* levels, regardless of the composite type, except red wine group ($3,77 \pm 1,90^c$), which was perceptible. In terms of composite*solution interactions, the combination of FUF composite with red wine showed significantly the highest ΔE^* level among all ($p < 0.001$), which was the only perceptible value ($6,26 \pm 1,7^a$; Table 4).

Distribution of the scores of 0 – other scores for Δ Vita* and $< 3.7 - \geq 3.7$ scores for ΔE^* were analyzed, regarding the perceptible and imperceptible scores for both methods. A very good correlation was found between the ΔE^* and Δ Vita* scores for all the evaluation periods ($p < 0.001$ for each period; Table 5).

Table 5. Correlation between ΔE^* and Δ Vita* scores.

Evaluation Period	Kappa	p
$T_2 - T_1$	0.984	<0.001
$T_3 - T_2$	0.920	<0.001
$T_3 - T_1$	0.968	<0.001

The accordance of distribution of the scores of 0 – other scores for Δ Vita* and $< 3.7 - \geq 3.7$ scores for ΔE^*

Table 4. Multiple comparisons between composite materials, discoloration solutions, and evaluation periods.

ΔE^*	Solution	GIF	ESLF	FBF	FUF	FU	Total
ΔE_1	Water	0.42 ± 0.27 ^I	0.78 ± 0.54 ^I	1.24 ± 0.30 ^{HI}	1.62 ± 0.34 ^{GHI}	0.74 ± 0.27 ^I	0.96 ± 0.54 ^a
	Coke	1.66 ± 0.25 ^{GHI}	2.18 ± 0.40 ^{GHI}	0.44 ± 0.26 ^I	1.92 ± 1.78 ^{GHI}	1.70 ± 0.38 ^{GHI}	1.58 ± 0.99 ^a
	Tea	3.04 ± 1.06 ^{EF}	3.36 ± 0.75 ^{EF}	3.32 ± 1.36 ^{EF}	4.94 ± 0.39 ^{CDE}	2.24 ± 0.52 ^{FGHI}	3.38 ± 1.21 ^b
	Coffee	4.58 ± 0.41 ^{DE}	3.58 ± 0.89 ^{EF}	3.56 ± 1.58 ^{EF}	6.9 ± 0.84 ^{BC}	4.32 ± 0.62 ^{DEF}	4.59 ± 1.52 ^c
	Wine	7.30 ± 0.91 ^B	6.16 ± 1.48 ^{BCD}	7.36 ± 1.29 ^B	11.32 ± 1.38 ^A	7.84 ± 0.3 ^B	8.00 ± 2.08 ^d
	Total	3.40 ± 2.52 ^a	3.21 ± 1.99 ^a	3.18 ± 2.65 ^a	5.34 ± 3.78 ^b	3.37 ± 2.61 ^a	
ΔE_2	Water	0.50 ± 0.32 ^H	0.74 ± 0.21 ^{GH}	0.84 ± 0.35 ^{GH}	0.7 ± 0.43 ^{GH}	1.02 ± 0.43 ^{FGH}	0.76 ± 0.37 ^a
	Coke	0.96 ± 0.42 ^{FGH}	1.38 ± 1.21 ^{EF}	0.94 ± 0.5 ^{FGH}	2.46 ± 0.57 ^{DEF}	0.58 ± 0.26 ^H	1.26 ± 0.91 ^a
	Tea	2.84 ± 1.32 ^{BCDE}	2.72 ± 1.42 ^{CDE}	3.1 ± 1.68 ^{BCDE}	4.9 ± 1.03 ^{ABC}	1.32 ± 0.68 ^{EF}	2.98 ± 1.65 ^b
	Coffee	4.00 ± 0.24 ^{BCD}	3.40 ± 1.02 ^{BCDE}	3.7 ± 1.17 ^{BCD}	6.54 ± 0.58 ^A	4.24 ± 0.74 ^{BCD}	4.38 ± 1.36 ^c
	Wine	4.38 ± 0.81 ^{ABCD}	3.32 ± 1.75 ^{BCDE}	4.44 ± 1.22 ^{ABCD}	5.06 ± 0.98 ^{AB}	4.58 ± 1.32 ^{ABCD}	4.36 ± 1.29 ^c
	Total	2.54 ± 1.74 ^a	2.31 ± 1.57 ^a	2.6 ± 1.8 ^a	3.93 ± 2.23 ^b	2.35 ± 1.88 ^a	
ΔE_3	Water	0.72 ± 0.15 ^{EF}	0.96 ± 0.9 ^{DEF}	1.08 ± 0.98 ^{DEF}	1.0 ± 0.72 ^{DEF}	1.2 ± 0.98 ^{CDEF}	0.99 ± 0.76 ^{ab}
	Coke	0.7 ± 0.39 ^{EF}	1.64 ± 0.96 ^{BCDEF}	0.98 ± 0.54 ^{DEF}	1.42 ± 1.04 ^{BCDEF}	1.6 ± 0.5 ^{BCDEF}	1.27 ± 0.77 ^a
	Tea	0.32 ± 0.19 ^F	0.92 ± 1.29 ^{DEF}	0.3 ± 0.29 ^F	0.58 ± 0.26 ^F	1.48 ± 0.97 ^{BCDEF}	0.72 ± 0.82 ^{ab}
	Coffee	0.58 ± 0.28 ^F	0.34 ± 0.19 ^F	0.58 ± 0.33 ^F	0.56 ± 0.22 ^F	0.48 ± 0.36 ^F	0.51 ± 0.27 ^b
	Wine	2.96 ± 1.63 ^{BCD}	2.84 ± 1.69 ^{BCDE}	3.52 ± 1.16 ^B	6.26 ± 1.7 ^A	3.26 ± 1.38 ^{BC}	3.77 ± 1.90 ^c
	Total	1.06 ± 1.21 ^a	1.34 ± 1.35 ^{ab}	1.29 ± 1.36 ^{ab}	1.96 ± 2.38 ^b	1.6 ± 1.25 ^{ab}	

a-c: No differences between the composites/solutions with the same letter for each evaluation period.

4. DISCUSSION

According to the results, viscosity was considered an effective factor for discoloration of RBCs and discoloration of the materials was affected by the type of colorant solution. Therefore, both h_1 hypotheses were accepted.

The immersion period was set for 144 hours at 37 °C with regards to the previously reported methodology. 144 hours of immersion *in vitro* corresponded to about 6 months of immersion in colorant drinks *in vivo* (16,17). A clinical contact type spectrophotometer and a colorimeter were used for the assessments, which were the most commonly accepted color change monitoring devices in the literature (19,21,23,24). In addition, no color change ($\Delta E^* = 0$) should be detected after immersion to colorant agent to obtain complete color stability for a material, which is almost impossible (25). Thus, acceptability and perceptibility terms are important to scale the level of color change. However, there is still no consensus for the cut points of perceptibility and acceptability of color change. O'Brien et al. (18) reported that, values of ≤ 2 were clinically acceptable. Ragain and Johnston (26) considered ≤ 2.7 , and Douglas et al. (19) considered ≤ 1.7 acceptable. Tuncer et al. (20) and Vichi et al. (10) mentioned ≥ 3.3 , whereas Celik et al. (23) and Kim and Lee (21) reported ≥ 3.7 as perceptible. Respective, values of $\geq 3.7 / \leq 6.8$ and $\geq 2.6 / \leq 5.5$ by Johnston and Kao (27) and Douglas et al. (19) were considered perceptible and acceptable cut points. In the present study, recent and the most frequently preferred

values of 3.7 and 5.5 were considered cut points for perceptibility and acceptability of color change, respectively.

A major disadvantage of RBC materials is the color change in long-term, clinically (17). The level of discoloration may vary among the quality of isolation, quality of polymerization, the effectiveness of polishing material, type of composite material, and also the type of staining solution/diet. This study has investigated two of these influencing factors, the type of RBC, and the colorant solution.

4.1. Assessment according to the type of composite

Composition, filler size, weight, volume, thickness, polymerization quality, and polishing quality parameters were reported to be effective factors on microhardness and color stability of resin composites, previously (28). In this *in vitro* study, all samples were prepared in uniform 2 mm in thickness and polymerized using the same LED curing unit for 20 s, to maintain the standardization.

The level of discoloration for composites varies among the brand and content of the material (30). Clinical application of early generation flowable composites were restricted previously, because of their low mechanical properties (30). Water plays a role as a transporter for pigments to the resin matrix and accordingly, Dietschi et al. showed that level of discoloration is directly related to the water sorption rate (31). In addition, filler particles do not absorb water, therefore, the water sorption rate is also filler content dependent. RBCs

with a lower amount of inorganic fillers (i.e., early generation flowable composites) presented weaker bond strength between the resin matrix and filler particles, resulting in greater water uptake, which may allow stain penetration and discoloration of the material (32). In addition, water sorption and hygroscopic expansion were considered positively correlated (33). Thus, some researchers reported that flowable composites can relieve internal polymerization shrinkage stress and provide similar marginal adaptation and clinical stability with regular viscosity composites (33,34).

Composites used in this study were nanofilled (FU, FBF, and FUF) and nanohybrid (GIF and ESLF) RBCs in different viscosities. The introduction of nanotechnology to flowable composites provided the combination of strength, polishability, gloss retention, wear resistance, and translucency or opacity of a conventional composite with elasticity, adaptation, and better handling of flowable composites (30,32,35). Smoother restoration surfaces were provided using composites with a lower particle size as a result of better distribution within the resin matrix, previously (17). Accordingly, polymerization shrinkage was also minimized by almost 20% (35). In addition, a systematic review and meta-analysis study suggested new generation, nanofiller-included flowable composites with enhanced mechanical and physical properties, to be suitable for minimally invasive posterior restorations (20,36). Another systematic review and meta-analysis study also reported good marginal adaptation, thereby lower marginal discoloration for low viscosity flowable composites for 3-year clinical follow-ups (33). According to our results, a regular viscosity composite, FUF presented significantly the highest level of color change ($5,34 \pm 3,78^b$) among others, regardless of the solution type (ΔE_1 period, Table 4). This result might be related to the lower amount of inorganic fillers (65% wt. and 46% vol.) of FUF composite than FU, GIF, and ESLS composites. Although FBF composite has the lowest amount of fillers (64.5% wt. and 42% vol.), the amount of color change for FUF was greater than FBF. A stain-resistant co-monomer urethane dimethacrylate (UDMA) was determined to have a lower rate of water absorption, thereby enhancing the color stability of the resin-based material (16). Thus, UDMA in FU, GIF, ESLS, and also FBF composites might be responsible for this result, as it is only absent in FUF composite (Table 1). All composites except FUF, presented similar and imperceptible discolorations in our study, although there are slight differences in filler amounts (Table 1). Therefore, two high viscosity flowable composites (GIF and ESLS), a bulk fill composite (FBF), and a packable composite (FU) presented statistically similar amount of color changes. This result is consistent with the previous results of Szesz et al. (33) and Rosales-Leal et al. (34), in which viscosity was not found effective for the retention and discoloration rates. According to Sideridou et al. (37), triethylene glycol dimethacrylate (TEGDMA) has the highest water sorption capability, followed by diglycidyl ether dimethacrylate (BisGMA) and by UDMA. All composite materials include TEGDMA in this study, therefore this co-monomer might not be an effective factor in color change. However, all composite materials include

Bis-GMA except GIF composite. But also this exception did not provide a significant difference in color change.

4.2. Assessment according to the type of colorant solution

In the present study the control group, physiological solution did not cause significant color changes with $\Delta E < 1.0$ even after 144 h of immersion. With regard to previous studies, the level of discoloration for RBCs varies among the colorant agents. Bagheri et al. (38) and Barutcugil and Yildiz (16) mentioned coffee as one of the most effective colorant solutions for RBCs. Zajkani et al. (39) reported a greater color change in coffee and tea compared to coke and orange juice. Our results showed that the level of color change for coffee solution ($4,59 \pm 1,52^c$) was below red wine, but above other solutions (Table 3). It was considered perceptible (≥ 3.7), but also acceptable (≥ 5.5). Absorption and penetration of yellow colorants into the organic phase may be the explanation of the discoloration mechanism by coffee (17). Llena et al. (40) used red wine, coffee, cola, and distilled water as colorant solutions for discoloration of two different nanohybrids, two different ormocers, and one compomer for four weeks. Discoloration in all beverages was considered above clinically acceptable limits. Discoloration by red wine was considered greater than coffee, and followed by cola. Ardu et al. (29) reported greater color change was caused by red wine and followed by coffee, tea, orange juice, and cola. Also, Barutcugil and Yildiz (16) considered red wine the most effective colorant, followed by coffee. Inconsistent with the results of Llena et al. (40), Ardu et al. (29), and Barutcugil and Yildiz (16), red wine solution presented significantly the greatest level of color change ($8,00 \pm 2,08^d$) among other solutions in our study, regardless of the composite type (Table 3). Also, the combination of red wine with any composite presented unacceptable color change (≥ 5.5) and FUF composite was significantly the most affected one ($11,32 \pm 1,38^a$). Tannins in red wine might be the reason for the greater discoloration rate, as having a strong discoloration capacity (17). Also, in accordance with the results of Ardu et al. (29) and Zajkani et al. (39) tea group presented a significantly greater level of color change ($3,38 \pm 1,21^b$) compared to water and coke groups, but lower level of color change than red wine and coffee groups. It was considered imperceptible (≤ 3.7). Opposing to our results, Ceci et al. (17) mentioned greater discoloration for coffee than red wine, previously. Whereas, they immersed the samples in cola solution before immersion in red wine and coffee, which might influence the final result. In addition, phosphoric acid including drink, coke, was not considered a strong colorant agent for composites (17,40). However, there are several researches mentioning acidic drinks effective for the alterations in surface smoothness of the RBCs and consequently for extrinsic discoloration (17). Although exposure to acidic or alcoholic drinks was determined to be effective in color change clinically, that can only be simulated with thermocycle procedure *in vitro* (41). However in the present study, thermocycle procedure was not undergone, therefore, it is impossible to observe the effect of acidity for coke (pH: 2.52), red wine (pH:3.50), and also coffee (pH: 4.50) (Table 2).

In this study, the effectiveness of repolishing after discoloration was also assessed. Polishing materials used were flexible aluminum oxide (Al_2O_3) discs, which were previously reported as gold standard polishing system for RBC materials (41). Red wine, coffee, and tea stains are both external and internal discolorations and because of the penetration of staining materials into the organic phase, only partial reverse in color was reported previously by repolishing (42). With regards to our results, a partial recovery was detected in color, which is inconsistent with the results of Villalta *et al.* (42) All composites and colorant combinations presented color changes in different levels, after repolishing. In addition, a greater level of color change was detected for the samples which had discolored more (Table 4, ΔE_2 scores). The color of all samples did not exactly reverse back to the baseline colors, but the differences (ΔE_3 scores) were all not perceptible (< 3.7), except the samples of FU and red wine combination group ($6,26 \pm 1,7^A$; Table 4). Therefore, it might be interpreted that, the discoloration of the majority of the samples was reversed back, therefore repolishing procedure might be considered as an effective procedure for reversing the discoloration of RBCs back.

A crosscheck between spectrophotometry and colorimetry measurements was performed. In terms of perceptible color changes, a positive and very good correlation was found between ΔE^* values and $\Delta Vita^*$ values in this study, for all the evaluation periods (Table 5).

This study has also some limitations. As previously reported, the type of adhesive system may also play a role in restoration discoloration (17). This *in vitro* study is lacking some clinical information regarding this. The color stability of RBCs depends on the filler type, size, and concentration, as well as the type and concentration of initiators, inhibitors and activators, minor pigments, and unreacted carbon bonds (24). The color stability of the materials tested in this study might have also been influenced by these factors. In addition, different results might have been found with different brands and different shades of RBCs as well as different brands of polishing materials (16,43).

5. CONCLUSIONS

Within the limitations of this study, viscosity was considered an effective factor for discoloration of RBCs, and color stability of new generation high viscosity flowable composites were found to be good and similar to the packable composite. Composite samples in red wine presented the greatest level of discoloration and followed by coffee, tea, coke, and physiological solution. Repolishing procedure was considered effective for reversing the surface discoloration of RBCs back.

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.

Clinical relevance statement

Surface discoloration of resin composite restorations may cause esthetic problems clinically. Bewaring of colorant solutions may inhibit the level of discoloration. Also, the repolishing procedure may have a discoloration reversing effect for the discolored restoration surfaces. The present study assessed the effectiveness of different colorant solutions and repolishing on the color stability of composite samples, while the color stability of new generation high viscosity flowable composites were also evaluated.

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Is Depression Associated with the Risk of Cardiovascular Disease or Vice Versa?

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ABSTRACT

The comorbidity between cardiovascular disease (CVD) and depression has been observed for many years. Several biological and behavioral hypotheses have been proposed to explain this comorbidity. However, the underlying common mechanisms are still unclear. Evidence suggests a bidirectional relationship between depression and CVD. Inflammation has been implicated in the etiology of both depression and CVD. In this review, we aim to increase awareness for CVD and depression comorbidity and provide some insights about the possible role of inflammation.

Keywords: major depression; cardiovascular disease; inflammation; *hs*-CRP

1. INTRODUCTION

Major depressive disorder (MDD) is one of the most common psychiatric disorders and a leading cause of disability worldwide which is characterized by depressed mood, anhedonia, impaired cognitive, motor, and physiological functions, feeling of worthlessness or excessive or inappropriate guilt, and recurrent thoughts of death (1). The specifiers of MDD according to DSM-5 (Diagnostic and Statistical Manual of Mental Disorders 5th Edition) are severity, anxious distress, mixed features, melancholic features, psychotic features, peripartum onset, seasonal pattern (2). When the depressive symptoms do not meet the criteria for MDD, it is called subthreshold depression (3). Subthreshold depression has a considerable impact on the quality of life of patients and may be considered as a risk indicator of MDD (4).

Despite advances in neuroscience research, the pathophysiology of MDD has not been elucidated. The results of tremendous amount of research are consistent with a multifactorial etiology. Some of the suggested pathophysiological mechanisms are biological amine hypothesis, genetic and environmental factors, increased inflammation, the hypothalamic-pituitary-adrenal (HPA) axis abnormalities, decreased neurogenesis, and neuroplasticity (5).

Depression is associated with a significantly increased risk of cardiovascular morbidity and mortality (6). Cardiovascular diseases (CVD) and MDD are among the leading health problems worldwide (7, 8). It is known that CVD and MDD are the two most common causes of disability in high-income

countries and are expected to become so for countries of all income levels by 2030 (9). A recent population-based cohort study demonstrated that depression was associated with incident CVD, myocardial infarction, non-cardiovascular death, and all-cause mortality in economically diverse settings, especially in urban areas (10). Approximately 35-40% of patients with CVD report depressive symptoms and depressive individuals have a 1.5 times higher risk of developing CVD than non-depressed controls (11). Many large-scale prospective studies have shown that MDD and even subthreshold depressive symptoms are an independent risk factor for CVD (9, 12-14). Standardized depression screening strategies should be provided in patients with CVD because early identification and optimal management of depression might improve health outcomes for these patients (15).

2. DEPRESSION AS A RISK FACTOR FOR CVD

The comorbidity between CVD and depression has been observed for many years, and studies argue that this relationship is bidirectional (16). In 1967, Wynn stated the relationship between unwarranted emotional stress and ischemic heart disease (17). The relationship between depression and CVD has been studied since the 1980s. In a cohort study included individuals with no history of ischemic heart disease or other serious medical illnesses at

baseline, depressed affect and hopelessness were related to increased risk of fatal and nonfatal ischemic heart disease (18). The INTERHEART study conducted in 52 countries found that current smoking, raised Apolipoprotein B/Apolipoprotein A1 ratio, history of diabetes, hypertension, and psychosocial factors (depression, perceived stress, and life events) were the strongest risk factors for myocardial infarction (19). The Framingham Study reported a direct association between depressive symptoms and all-cause mortality over 6 years of follow-up (20). A study assessed the prevalence of depression in patients with acute myocardial infarction (AMI) found that 19.8% of the patients were diagnosed with MDD according to the structured interview, and 31.1% of these patients were found to have clinically significant depressive symptoms according to the Beck Depression Inventory (21). AMI is associated with a previous hospitalization for depression and this association cannot be explained by confounding from known risk factors for AMI (22). In a ten-year follow-up study conducted with the clinically depressed patients and their matched community controls found that depressed patients had almost two-thirds higher risk for physical illness, including cardiac problems compared to controls (23).

The Whitehall II study also stated that depression and increased resting heart rate are independent risk factors for death from all causes (24). In particular, anhedonia symptom of depression is the most strongly associated with cardiac events and mortality after AMI and the risk of CVD increased by 2.5 times in the year after the onset of MDD episode (25). A meta-analysis included prospective cohort studies evaluating the association between depression and the risk of CVD demonstrated that the depressed participants had an increased risk of 30% for CVD (26). Also, this association remained significant after the results were adjusted for the potential confounding factors. Furthermore, a study included young people who had a parent with depression but no personal history of depressive illness, found that the participants with a family history of depression had higher cardiovascular risk compared to healthy controls (27).

In 2014, the American Heart Association (AHA) announced that despite the heterogeneity of published studies depression is an independent risk factor for negative outcomes in patients with acute coronary syndrome (13).

3. THE POSSIBLE ROLE OF INFLAMMATION IN COMORBIDITY

The relationship between CVD and depression can be evaluated in three ways: First; these two conditions are comorbid, second; depression increases the risk of CVD or vice versa. Third; depression is an important indicator of poor prognosis in patients with CVD (28).

While the comorbidity between CVD and depression is well known, the underlying common mechanisms are still unclear. Several biological and behavioral hypotheses have been established including altered autonomic

nervous system activity, low heart-rate variability, elevated catecholamine levels, endothelial dysfunction, platelet dysfunction, increased inflammatory activity, sedentary behavior, smoking, poor adherence to medication and diet (9, 16, 29) (Figure 1). In recent years, the studies focused on the role of the immune system in the etiology of MDD and have shown increased pro-inflammatory cytokines in MDD (30-32). Similarly, the role of inflammation in CVD has attracted considerable attention and it has been determined that systemic inflammation has an important role in the development, progression, and prognosis of CVD (33).

Atherosclerosis is not considered as a simple “lipid deposition disease” anymore. For the past few decades, it has been known that atherosclerosis is a lipid-driven disease characterized by low-grade chronic inflammation of the arterial wall (34). Targeting of inflammatory processes might be beneficial in attenuating myocardial and arterial injury, reducing disease progression, and promoting healing (35).

Atheromatous plaque development, plaque rupture, and thrombus formation are the main components of this process. Deposition of low-density lipoprotein (LDL) particles in the sub-endothelial layer activates inflammation, causing the attraction of monocytes to atherosclerotic plaque and transformation of monocytes into tissue macrophages (36,37). Macrophages transform into foam cells by phagocytosing lipoprotein particles (36), foam cells maintain inflammation and destabilize the extracellular matrix and endothelial layer (38). As a result of inflammation, pro-coagulant factors are stimulated, and it also increases the production of plasminogen activator inhibitor 1 (PAI1), one of the main endogenous inhibitors of thrombus and fibrin (39). In this vicious cycle of inflammation, extracellular matrix destruction, and expansive remodeling gradually increase plaque growth and eventually cause acute plaque rupture and acute coronary syndrome (39). C-reactive protein (CRP), fibrinogen, tumor necrosis factor-alpha (TNF- α), interleukin-1 (IL-1), interleukin-6 (IL-6), interleukin-7 (IL-7), and interleukin-8 (IL-8) levels are high in myocardial infarction or unstable angina (29, 40). Chronic low-grade inflammation is a known risk factor for diabetes and cardiovascular disease, which is highly comorbid with depression (41).

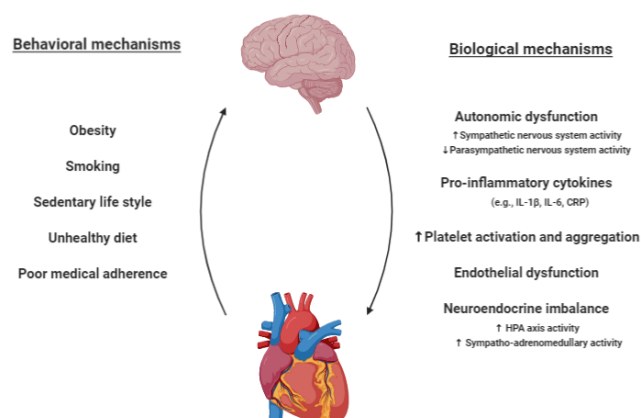


Figure 1. Biological and behavioural mechanisms linking depression and CVD

The CANTOS study addressed the inflammatory hypothesis in a large cohort of CVD patients, comparing the anti-IL-1 β human monoclonal antibody, canakinumab, and placebo (42). Canakinumab provided a 15% decrease in major cardiovascular events, regardless of LDL levels. However, in another study where inflammation was targeted with low-dose methotrexate, no decrease in IL-1 β , IL-6, and CRP levels was observed with treatment (43). Anakinra treatment, an IL-1 receptor antagonist, reduced high-sensitivity CRP (*hs*-CRP) levels in patients with acute MI (44).

The accumulating data suggest that cytokines contribute to the pathophysiology of both MDD and CVD, and inflammation is one of the underlying mechanisms in this comorbidity (16, 29, 45, 46).

In 2013, the inflammasome hypothesis of depression and related comorbid systemic diseases has been suggested as a linking pathway by Iwata et al. (47). The Nod-like receptor protein 3 (NLRP3) pathway has been evaluated in the pathogenesis of both MDD and CVD; however, the possible *bridge* role of NLRP3 in this comorbidity has not been investigated so far (48).

A 20-year cohort study assessed the cardiac events associated with depression and its interaction with hypertension, diabetes, dyslipidemia (49). As a result they stated that the association between depression and a cardiac event cannot be explained by the effects of these other cardiovascular risk factors.

Psychosocial stress is frequently addressed in both CVD and depression. Chronic stress alters the balance in the autonomic nervous system, causes sympathetic system dominance, and decreased vagal tone (29). Decreased vagal tone contributes to a pro-inflammatory status (29). Stress hormones and certain pro-inflammatory substances are released from macrophages and microglia and tryptophan upregulates rate-limiting enzymes in the metabolic pathway. This enzymatic upregulation stimulates the kynurenine pathway and results in the formation of neurotoxic metabolites. Inflammation is already observed in cardiac, cardiovascular, and cerebrovascular pathologies regardless of the presence of depression. Inflammation is closely related to endothelial dysfunction, which is important in atherosclerosis (29).

In recent years, studies have shown that anti-inflammatory treatment strategies including non-steroidal anti-inflammatory drugs (NSAIDs), cytokine inhibitors, statins are beneficial in improving symptoms in both CVD and depression (50).

4. THE POSSIBLE USE OF HS-CRP IN COMORBID DEPRESSION AND CVD

C-reactive protein (CRP) is a member of the pentraxin family, it is released by hepatocytes largely in response to IL-6 and other inflammatory cytokines (51). It increases within 4-6 hours after acute tissue damage or inflammation, the half-life is 19 hours and returns to normal levels within days (52).

The normal CRP level in healthy people is below 3 mg / L. While CRP is between 3-10 mg / L in low-grade inflammation, the levels above 10 mg / L are generally associated with underlying infection, malignancy, or inflammatory disease (53).

While CRP analyzes can detect above 3 mg / L levels, *hs*-CRP can detect values as low as 0.1 mg / L (53). *hs*-CRP has been studied for CVD for many years and is considered an important marker for cardiovascular risk assessment and treatment decision. Thus, The American Heart Association and the Center for Disease Control and Prevention have recommended the measurement of *hs*-CRP for screening cardiovascular risk. According to this recommendation, *hs*-CRP <1 mg / L is associated with low risk, 1-3 mg / L moderate risk and > 3 mg / L high risk (54). CRP is not only a predictive marker but also plays a role in the development of the lesion with its pro-inflammatory and pro-atherogenic effects by activating the complement system through complement C1q and contributes to the destabilization of the fibrotic layer of atheroma and plaque rupture by stimulating the matrix metalloproteinase-1 (MMP-1) by macrophages (52).

A meta-analysis conducted in 2009 showed that IL-1, IL-6, and CRP levels are elevated in patients with depression (55). In a follow-up study with 1 794 participants, it was observed that there is a strong relationship between depression and IL-6, CRP, and soluble intercellular adhesion molecule 1 and they predict CVD disease development (56). It is thought that inflammation and depression are risk factors in terms of CVD and *hs*-CRP has a role in the pathophysiology of CVD and depression, although sometimes inconsistent results have been found in studies. *hs*-CRP is an important inflammatory marker while discussing CVD and depression comorbidity with its common use in cardiology clinics and its increasing importance in psychiatric diseases. A large-scale study demonstrated that psychological stress and depression are associated with increased CRP levels and that higher CRP levels were associated with hospitalization for depression (57).

A prospective study showed that higher CRP levels did not predict depressive episodes; however, it emphasized that higher CRP levels were observed with recurrent depressive episodes (58). A study conducted with 6005 people in Finland, found that Beck Depression Inventory (BDI) scores were correlated with high CRP levels in both men and women (59). In a study examining the relationship between risk factors and inflammatory markers in cardiovascular diseases, in the presence of a diagnosis of depression, *hs*-CRP and IL-6 levels were found to be significantly higher than in patients without a diagnosis of depression (60). A large-scale study showed that depression and anxiety disorders scores were correlated with *hs*-CRP levels, and this relationship was more pronounced in men (61).

After the results were adjusted for other risk factors, such as age, obesity, smoking, body mass index, lipid profile, this relationship remained significant in men but not in women. According to a recent meta-analysis, the prevalence of

low-grade inflammation (CRP >3 mg/L) in depression is 27%, the prevalence of elevated CRP (>1 mg/L) in depression is 58% (62). Also, higher levels of CRP at baseline are associated with an increased risk of depression in subsequent follow-ups (62). Also, the recent studies found that CRP levels showed a significant decrease with antidepressants (63, 64). However, some other meta-analysis has demonstrated no significant effects of antidepressants on CRP levels (65).

5. CONCLUSION

Despite the growing amount of literature on the CVD and depression comorbidity, more studies are needed to understand the underlying mechanisms. This is important for screening, early identification, and treatment of comorbid CVD and depression. Also, the initiatives should aim at improving health outcomes in those with CVD and / or depression. hs-CRP, as a well-known biomarker in the cardiology practice, holds promise as a psychiatric biomarker as well. hs-CRP might be useful for identifying the risk groups.

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Cemento-Ossifying Fibroma: Clinical, Radiological, and Histopathological Findings

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ABSTRACT

Cemento-ossifying fibroma, which is considered a benign mesenchymal odontogenic tumour of the jaws, is a type of fibro-osseous lesion characterized by slow growth and proliferation of fibrous cellular stroma containing osteoid, bone or cementum-like tissue. The aim of this study was to report a case of cemento-ossifying fibroma in the mandible with clinical, radiological, and histopathological findings and surgical treatment. A 37-year-old woman was admitted to our clinic with the complaint of gradually growing painless swelling in the right mandibular premolar area. Intra-oral examination revealed a bony hard and non-tender mass with intact overlying mucosa on the buccal and lingual aspects of the mandibular right premolar teeth. Periapical, panoramic, and cone beam computed tomography images revealed the presence of a multilocular hypodense lesion with bicortical destruction and expansion in the relevant area. Excisional biopsy of the lesion was performed and histopathological examination exhibited the definite diagnosis of cemento-ossifying fibroma. Clinical, radiological, and histopathological examination should be considered in the diagnosis and treatment planning of cemento-ossifying fibroma.

Keywords: Cemento-ossifying fibroma, fibro-osseous lesion, cone beam computed tomography

1. INTRODUCTION

Cemento-ossifying fibroma, derived from the periodontal ligament mesenchymal blast cells and capable of forming fibrous cellular tissue, osteoid, bone, cementum-like tissue, or a combination of such elements, is a benign mesenchymal odontogenic tumour of the jaws (1, 2).

Cemento-ossifying fibroma has been a puzzling and unclear term for many years (3). In 1971, the cemento-ossifying fibroma was first classified by the World Health Organization (WHO) under lesions containing cementum, including fibrous dysplasia, ossifying fibroma, and cementifying fibroma (4). According to the second classification of WHO in 1992, benign fibro-osseous lesions in the oral and maxillofacial region were grouped as osteogenic neoplasms and non-neoplastic bone lesions, separate cementifying fibroma and ossifying fibroma lesions were gathered under a single entity of "cemento-ossifying fibroma" because they showed different histological variants of the same type of lesion and belonged to the former category (5). Based on the WHO classification in 2005, the term "cemento-ossifying fibroma" was shortened to ossifying fibroma due to the fact that cementum-like material of odontogenic origin was found

unexpectedly in fibromas located in the extragnathic regions, and the fact that cementum and bone were actually the same tissue that could be differentiated only by their relationship to tooth roots (3, 6). In addition, three ossifying fibroma forms (classical, psammomatoid juvenile, and trabecular juvenile) were distinguished (3, 7).

Recently, in 2017, the term "cemento-ossifying fibroma" was deemed to appropriately describe a benign mesenchymal odontogenic tumour specific to the tooth-bearing regions of the jaws (7). Cemento-ossifying fibromas can be classified as the central type arising from the periodontal ligament adjacent to the root apex and the peripheral type occurring exclusively in the soft tissues of the tooth-bearing regions (8).

The aetiology of cemento-ossifying fibroma remains obscure, but odontogenic, developmental, and traumatic factors have been proposed as predisposing factors due to stimulation of the periodontal ligament to produce and accumulate cementum and osteoid material (1, 8, 9).

The aim of this study is to report a case of cemento-ossifying fibroma in the mandible accompanied by clinical, radiological, and histopathological findings and surgical treatment.

2. CASE PRESENTATION

A 37-year-old woman, complaining of progressive painless swelling in the right mandibular premolar region for 1 year, was admitted to the Department of Oral and Maxillofacial Radiology, Faculty of Dentistry, Marmara University, Istanbul, Turkey. Her medical and dental histories were non-contributory.

Extra-oral examination revealed no facial asymmetry. There was no erythema, elevated local temperature, or palpable regional lymph nodes showing no evidence of inflammation.

In intra-oral examination, a bony hard and non-tender mass with intact overlying mucosa on buccal and lingual aspects of mandibular right premolars was observed (Figure 1a and b). The associated teeth were non-vital and mandibular right second premolar was mobile.

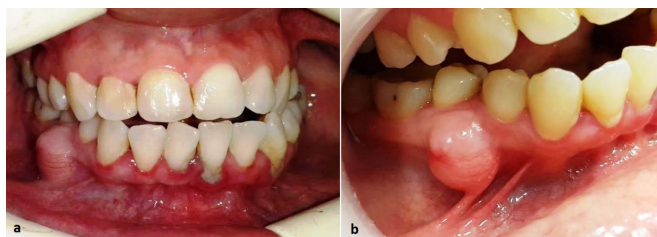


Figure 1a, b. Pre-operative intra-oral clinical view of the lesion.

The periapical radiograph and orthopantomogram (OPTG) demonstrated a multilocular radiolucent mass with well-defined borders and a sclerotic rim in the interradicular region of the mandibular right first and second premolars, and displacement of the second premolar. The coronal, sagittal, and axial plane cone beam computed tomography (CBCT) images revealed the presence of a well-defined hypodense lesion of approximately 9x14x8 mm with bicortical destruction and expansion without any cortical perforation in the area of interest. In addition, the continuity of the mandibular nerve within the lesion was disrupted (Figure 2a, b, and c).



Figure 2a, b, c. Pre-operative periapical, OPTG, and CBCT (coronal, sagittal, axial planes, and 3D reconstruction) images of the lesion.

Excisional biopsy of the lesion in conjunction with extraction of the mandibular right second premolar was performed under local anaesthesia. For the surgical exposure of the lesion, a crestal incision was performed to raise a full-thickness mucoperiosteal flap. Osteotomy was performed at clear margins of the bone with round and fissure burs under saline irrigation. Care was taken to protect the inferior alveolar nerve. Using proper osteotomes the lesion was excised totally as one piece. The lesion, which was macroscopically a lobular, elastic, and solid fibrotic mass attached to the root of mandibular right second premolar, could easily be separated from the periosteum. Since the lesion did not cause perforation in either the buccal or the lingual cortical bone plates and the periosteum was preserved, no graft material was used and the defect was left to heal like a routine extraction socket. The flap was sutured and primary closure was obtained. 500 mg penicillin, 275 mg naproxen sodium, and 0.1% chlorhexidine rinse two times a day were prescribed and continued for a week (Figure 3a, b, and c).



Figure 3a, b, c. Incision and exposure of the lesion during surgical procedure, and the excised mass.

In the microscopic examination, hematoxylin and eosin (H&E) stained sections demonstrated well-demarcated, cellular fibroblastic stroma containing changeable amount of mineralized areas, osteoid, immature bone, and spherical cementum-like tissues confirming the diagnosis of cemento-ossifying fibroma (Figure 4a and b).

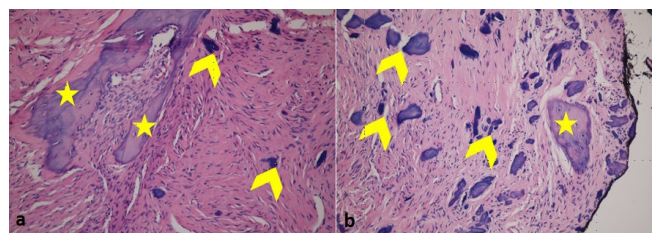


Figure 4a, b. Mineralized areas, immature bone trabeculae (*), and small, spherical cementum-like structures (↗) (H&Ex200).

Post-operatively, the area recovered uneventfully. No recurrence was detected clinically and radiologically at the 1-year follow-up (Figure 5a and b).

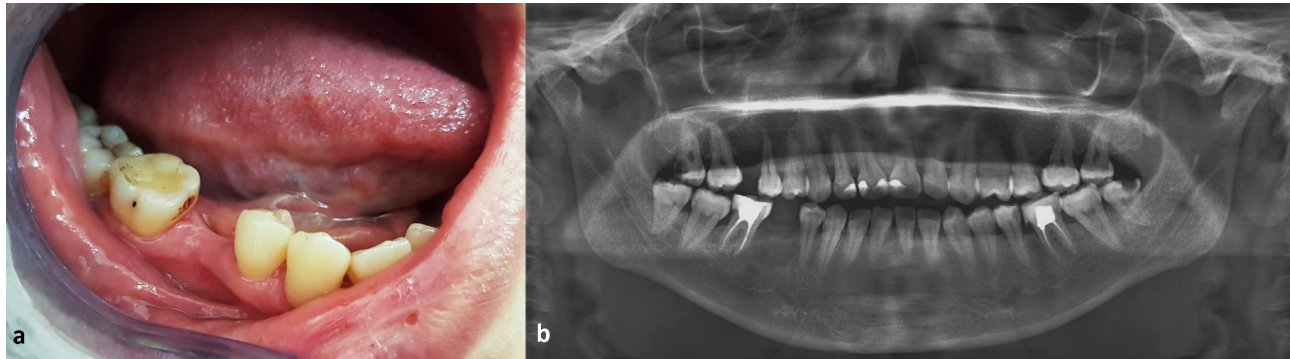


Figure 5a, b. Post-operative 1-year follow-up intra-oral clinical view and OPTG image.

3. DISCUSSION

Cemento-ossifying fibroma is a rare benign odontogenic neoplasm characterized by replacement of normal bone with fibrous tissue (2, 10, 11). Although it has been reported to occur in children, adolescents, and elderly adults, it is most commonly diagnosed in the second to fourth decades of life (12, 13). Women are affected more often than men with a female-to-male ratio of up to 5:1 (2, 10, 14, 15).

Cemento-ossifying fibroma has a predilection for the premolar-molar region of the mandible and is usually small in size (16). However, the maxilla and paranasal sinuses may be involved and the lesion may gradually become large in these areas as there is more space for expansion (12, 17).

Clinically, cemento-ossifying fibroma usually presents as a slow-growing and asymptomatic intra-bony mass but it may cause facial asymmetry or bone fracture when it becomes large in size (1, 2, 11). Although teeth in proximity with the lesion usually preserve their vitality, pain or paraesthesia may occur if pressure is exerted on a neighbouring nerve (11). It is mostly solitary, but rarely may present as multiple synchronous lesions which are isolated or a component of hyperparathyroidism-jaw tumour syndrome (7, 18).

The radiological features of cemento-ossifying fibroma reveal a well-defined mostly unilocular or in minority of cases multilocular radiolucency with or without radiopaque foci associated with the degree of calcification (1, 18). In the initial phase, cemento-ossifying fibroma manifests as a radiolucent lesion with the absence of internal radiopacity. With the increasing tumour maturity, radiopaque masses which may coalesce to form a large radiopaque focus surrounded by radiolucent border emerge (9). There are three distinct patterns of radiographic margins, which are defined lesion without sclerotic border (40%), defined lesion with sclerotic border (45%), and lesion with ill-defined border implying a fast growing tumour (15%) (11, 19). A particular diagnostic radiographic hallmark is the centrifugal growth pattern instead of a linear one, and therefore the lesions grow uniformly in all directions and present as a round tumour mass (9, 11, 19). Cemento-ossifying fibroma may lead to root resorption, divergence or mobility of the adjacent tooth (9, 19). Additionally, buccal and lingual bone

expansion unaccompanied by cortical perforation may be detected (1, 11, 12).

Fibrous dysplasia, cemento-osseous dysplasia, giant cell granuloma, calcifying odontogenic cyst (Gorlin cyst), calcifying epithelial odontogenic tumour (Pindborg tumour), adenomatoid odontogenic tumour, and osteogenic sarcoma should be regarded in radiological differential diagnosis. Fibrous dysplasia has a characteristic “ground glass” appearance and blending margin with the surrounding bone. However, cemento-ossifying fibroma is consistently well-defined and discriminated from the circumscribing bone. Cemento-osseous dysplasia demonstrates broad sclerotic borders and is multifocal opposed to cemento-ossifying fibroma. Giant cell granuloma, which is more common in the mandible affecting the earlier age groups, shows a slightly granular pattern of fine calcification with poorly-defined internal septa and causes displacement or resorption of tooth roots. Gorlin cysts, Pindborg tumours, and adenomatoid odontogenic tumours are frequently involved with impacted teeth. On condition that they are not associated with impacted teeth, the definitive diagnosis is based on histological appearance. The well-defined border of the cemento-ossifying fibroma facilitates the differentiation from osteogenic sarcoma which presents cortical bone destruction and invasion into the surrounding soft tissues and periodontal ligament space (8, 9, 13, 19, 20).

Histologically, cemento-ossifying fibroma is composed of well-vascularized fibrocellular tissue capable of forming immature bone trabeculae and cementoid (10, 12, 14, 15). The bone trabeculae are variable in size and often show a combination of woven and lamellar pattern. Bone usually demonstrates peripheral osteoid and osteoblastic rimming. The cementoids are basophilic spherical bodies representing peripheral brush border that blend into adjacent connective tissue and also have a smooth contour with cells (16, 20, 21). Nevertheless, cementum and immature bone trabeculae may also be seen in other fibro-osseous lesions such as fibrous dysplasia and cemento-osseous dysplasia, so this appearance is not specific for cemento-ossifying fibroma (10, 14, 22). On the grounds of this, a correlation of clinical, radiological, and histopathological findings is required for a definite diagnosis.

Enucleation with curettage is the treatment of choice for small lesions, and surgical resection and reconstructive surgery are indicated for larger lesions (16, 17, 20, 21). Enucleation is unchallenging because it is a clearly defined lesion that easily detaches from the surrounding bone. This is the most important clinical and per-operative feature for differentiation from fibrous dysplasia. Radiotherapy has been confirmed to be ineffective and contraindicated due to its inductive effect for malignant transformation (12). The prognosis of cemento-ossifying fibroma is favourable and recurrence, reported as high as 12%, is unusual (13, 15-18, 21). The recurrence rate of maxillary cemento-ossifying fibromas is higher in comparison to mandibular ones as a consequence of further complicated surgical removal and larger size at the time of diagnosis (8, 20).

Our case was a 37-year-old female patient who presented with an asymptomatic slow-growing mass in the mandibular premolar-molar region. Radiographic examination revealed a well-defined, multilocular lesion with a sclerotic border. The early stage lesion manifested as radiolucency without internal radiopacity. Furthermore, expansion and destruction of the buccal and lingual cortices were detected without any cortical perforation. Histopathological findings were similar to the characteristics of cemento-ossifying fibroma. Because the lesion was small in size, treatment was performed by enucleation and no recurrence was observed in the 1-year follow-up.

4. CONCLUSION

Clinical, radiological, and histopathological examination should be implemented in the diagnosis and treatment planning of cemento-ossifying fibroma. Asymptomatic benign fibro-osseous lesions may lead to problems such as complicated surgical procedures, post-operative complaints, or prosthetic needs as a result of extraction of teeth associated with the lesion. In conclusion, patients should be instructed not only about the importance of early detection of the lesion, but also the necessity of routine periodic check-ups for avoidance of recurrence or future complications after treatment.

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