Clinical and Experimental Health Sciences

Contents

RESEARCH ARTICLES

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The Effects of Dressing up Preterm Infants After Tub Bathing on Moisture Loss: A Randomized Controlled Trial

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ABSTRACT

Objective: The skin of the preterm newborn plays an important role in adapting the newborn to the environment after birth. This was designed as a randomised controlled experimental trial in order to determine the effect of dressing after tub bathing on loss of skin moisture in healthy preterm infants.

Methods: The population of the study consisted of the infants who were born between 33,0-36,6 weeks of gestation. Skin moisture (forehead, abdomen, back, arm, leg) and body temperature measurements of the infants before bathing, immediately after bathing, and 10, 20, 30, and 60th minutes after bathing were assessed.

Results: It was determined that while the moisture was kept and increased in the experimental group, moisture loss occurred in the control group. The infants in both groups had heat loss after the bathing.

Conclusion: It was determined that the skin moisture and body temperature of the experimental group infants were affected positively.

Keywords: Infant; bathing; temperature; moisture; skin.

1. INTRODUCTION

Maintaining fluid and electrolyte balance in the first days after birth is very difficult particularly in preterm and low-birth-weight infants. Hidden fluid losses occur as a result of mucous membranes and the evaporation of water from the skin (1).

The characteristics of the skin, the largest organ in the body of preterm infants cause greater fluid loss than term infants. Structure of stratum corneum (SC) is the most important factor in preserving skin moisture and integrity in preterm infants (2). Preterm infants have thinner skin than term infants, their body surface area to body weight ratio is high, their subcutaneous fat tissues are not fully developed, their brown fat tissue is low, their glycogen storage are low, and their stratum corneum layer is thin (3). This causes more transepidermal water loss (TEWL) in preterm infants (2,4-6).

Bathing causes evaporative and transepidermal water loss in infants (4-6). Skin moisture forms a barrier for the infant. Inadequate skin barrier is risky for skin permeability and infant can be exposed to fluid losses, electrolyte imbalance, thermoregulatory impairment, infection, and delayed skin development (1,7).

It is stated in the studies that within the first 10 minutes after the bathing, significant decreases occur in the body temperature of the infant and the clothes dressed right after the bathing get moistened and can cause rapid heat loss due to evaporation after bathing (8,9).

2. METHODS

2.1. Design and setting

This study was conducted to determine the effect of dressing after tub bathing on loss of skin moisture in healthy preterm infants.

This study was conducted a randomised controlled experimental trial (Figure 1). The randomisation was determined by entering the total number of cases into the program in URL address of https://www.randomizer.org. Before entering the sample size data into the program, it was assumed that the set 1 would represent control group including the infants who were dressed after bathing (DAB) and the set 2 would represent experimental group including the infants who were swaddled after bathing (SAB).

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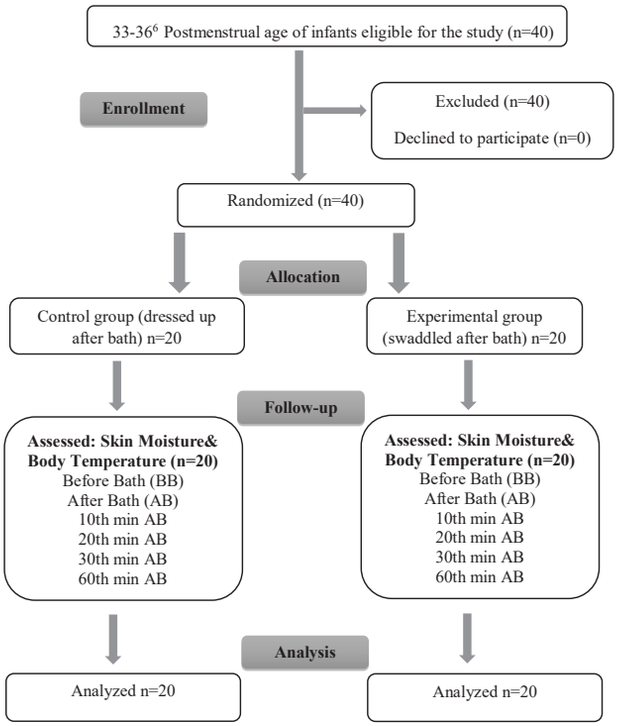

Figure 1. *CONSORT Flow Diagram of Randomized Controlled Trial*

2.2. Sample

The population of the study consisted of the preterm infants having postmenstrual ages of 33^{0}-36^{+6} weeks who met the inclusion criteria in NICU.

Before starting the study, written ethics committee approval and institutional permission were obtained from Medical Research Evaluation Board of Acibadem University and Acibadem Health Institutions (2013-509). The legal representatives of all infants were informed about aim, design, and duration of the study and how data would be used by using "Informed Consent Form" and their consents were obtained.

In order to determine the sample size, a priori power analysis was performed by using G*Power (v3.1.7) program. The sample size was calculated by considering the study entitled "The effect of duration of the first bath on body temperature of the infant" conducted by Varda and Behnke (2000); the effect size was found to be 1.89 when measurements taken at 10^{th} minute before and after the bathing were evaluated in both groups.

When the power of the study was requested to be (1-β) 0.80; it was determined to include 30 cases, including 15 homogeneous ones in both groups, in the sample group. By taking possible case losses into consideration, a total of 40 preterm infants were planned to be included in the study.

The inclusion criteria for the sample group:

Preterm infants whose parents were voluntary to participate in the study,

Those who were considered as healthy by the physician,

Those who had stable physiological condition,

Those who had no congenital abnormality and underwent no surgical procedure,

Those who had a postmenstrual age of 33^{0}-36^{+6}.

The data of the study were collected at NICU of a private hospital in Istanbul between November 2013 and December 2015. In this unit, every infant is bathed before discharge, and the mothers are synchronously trained about infant bathing.

2.3. Measurements

The data collection form including the study application steps as a check list was prepared by the researchers in order to record the data of the study and perform the same bathing steps in every infant by guiding the researcher during the study. The form was sent to 14 pediatric nurses professionals and the form was revised in accordance with their suggestions.

The data collection form involved;

Descriptive information about the infant and family,

A check list containing room temperature, room humidity, air movement, depth and temperature of bath water, and duration of bathing to control the environmental factors,

A check list to control the materials to be used during and after the bathing,

A table for recording skin moisture and body temperature recorded based on the time intervals determined before and after the bathing.

A calibrated General Electric Carescape B650 model monitor was used to measure oxygen saturation and heart rate; a calibrated Welch Allyn digital axillary thermometer was used to measure body temperature, a calibrated TFA DOSTMANN TFA 30.5002 model thermometer and moisture meter was used to control the room temperature and mositure; and Arzum bebbe AR 857 model bath thermometer was used to measure water temperature before the bathing.

The "DMM-Digital Moisture Monitor For Skin" was used to measure skin moisture loss of infants. This device developed especially for precise measurement was preferred since it can show the moisture amount only through touching without giving any harm on the skin, is wireless, and has a wide measuring range (it can measure the moisture amount of the skin from 0% to 99.9%).

All infants were dressed with 100% cotton, identical standard baby clothes of the hospital and thin baby blanket and infant-specific gel skin cleanser with neutral pH used by the hospital as a standard in all infants during the bathing were used.

Bathing was performed in the bathroom unit equipped with standard materials including care materials, bathtub, thermostatic battery, and drying and dressing sections.

2.4. Procedure

Each of the infants included in the study was healthy and their physiological condition was stable. The physiological condition of all infants was monitored for 24 hours before the bathing and the bathing was applied after the neonatolog stated that they were healthy and stable. The infants in both groups were bathed one hour after breastfeeding.

In the data collection process, two different dressing methods were applied to the infants included in the study. In the unit where the study was conducted, the infants are dried and dressed immediately after they are routinely bathed. For this reason, the control group of the study consisted of the infants dried and dressed immediately after the bathing (n=20) (Figure 2). The infants included in the experimental group were dried after the bathing and fastened the diaper by putting a cap on their heads. These infants were not dressed but they were swaddled with a double – layered blanket (Figure 3), they were taken onto the open crib, and they were dressed 10 minutes later (n=20).

Figure 2. *Dressing of control group newborn infants after bath*

Figure 3. *Swaddled experimental group newborn infants after bath*

Step 1: Before the Bathing (BB)

Before the data collection, legal representatives of the infants were informed by using the informed consent and voluntary ones were included in the study.

Variables were controlled. Environmental variables (room temperature: 26-27^{0}C ; humidity: 40-60%; Temperature of bath water: 38 ^{0}C) in both experimental and control groups were adjusted in the same way. By keeping the door closed in the room where the infants were bathed, the heat loss induced by airflow and convection was minimised.

After measuring and recording body temperature, oxygen saturation, pulse, and the skin moisture from forehead, abdomen, back, arm, and leg regions before the bathing for the infants of both groups, the infants were disconnected from the monitor. They were swaddled in blanket.

Step 2: The Bathing

Duration of bathing in both groups was less than 5 minutes and bathing performed by the researcher. All infants were slowly placed into the bathtub as swaddled with a thin 100% cotton blanket. Their head was supported by practitioner only under shoulders in the way to keep the head up.

Step 3: After the Bathing

After the bathing, all infants were immediately dried with towels and the wet towels were removed from them. They were diapered, put a cap on their head. After this step, experimental group infants were swaddled and control groups were dressed. Skin moisture (forehead, abdomen, back, arm, leg) and body temperature measurements of the

infants before bathing, immediately after bathing, and 10, 20, 30, and 60th minutes after bathing were recorded.

2.5. Statistical analysis

The NCSS (Number Cruncher Statistical System) 2007 (Kaysville, Utah, USA) programme was used for statistical analysis while evaluating the results obtained from the study. The results were evaluated at confidence interval of 95% and significance level of p<0.05.

3. RESULTS

No statistically significant difference was found between the groups in terms of gender, gestational age at birth, postmenstrual age, APGAR score (1st min. and 5th min.), physical characteristics at birth and before the bathing (body weight, height, head circumference), physiological characteristics before the bathing (body temperature, heart rate, O_2 saturation), and duration of bathing (Table 1; p>0.05).

Table 1. *Infants' Descriptive Characteristics and Comparison of their Descriptive Characteristics based on the Groups (N=40)*

Descriptive Characteristics		Experimental		Control		Test	P
		n	%	n	%		
Gender	Female	9	45,0	6	30,0	χ^2 = 0,427	*0,514
	Male	11	55,0	14	70,0		
		Mean± SD		Mean± SD			
Gestational Age At Birth (week,day)		32,51±2,54		31,71±3,66		t=0,803	†0,427
Postmenstrual Age (Week)		35,16±1,06		35,22±1,05		t=-0,194	†0,847
APGAR score (1st min.)		6,95±2,16		7,28±2,27		Z=-0,903	‡0,367
APGAR score (5th min.)		8,80±1,54		9,00±1,19		Z=-0,279	‡0,780
At Birth	Weight (g)	1862,00±498,33		1786,25±681,88		t=0,401	†0,691
	Height (cm)	42,44±4,03		41,33±4,69		t=0,803	†0,427
	Head Circumference (cm)	29,95±2,38		30,28±4,69		t=-0,276	†0,784
Before Bath (BB)	Weight (g)	2029,50±379,32		1990,50±469,28		t=0,289	†0,774
	Height (cm)	43,95±4,05		43,55±3,00		t=0,355	†0,725
	Head Circumference (cm)	30,83±2,21		31,95±3,35		t=-1,253	†0,218
	Body Temperature (°C)	36,76±0,35		36,66±0,39		t=0,850	†0,400
	Heart Rate (/min.)	143,45±18,94		137,65±16,85		t=1,023	†0,313
	O_2 Saturation (SPO_2 %)	96,95±2,84		98,15±2,76		Z=-1,827	‡ 0,068
Duration of Bathing Time (min.)		4,05±0,95		4,20±0,62		Z=-0,321	‡0,748

**Yates Continuity Correction Test † Student-t Test ‡ Mann Whitney U Test*

When the groups were compared in terms of moisture averages according to before and after bathing, no statistically significant difference was found between the groups (Table 2; p>0.05).

Table 2. *Comparison of skin moisture measurement averages of body regions (forehead, abdomen, back, arm, leg) according to different dressing applications (N=40)*

Measurement time		Skin Moisture Measurement (%)									
		Forehead		Abdomen		Back		Arm		Leg	
		Exp	Control	Exp	Control	Exp.	Control	Exp	Control	Exp.	Control
BB	Mean± SD	31,36±4,86	31,98±5,60	33,93±3,56	35,05±4,87	31,79±2,18	34,01±6,52	30,33±4,71	32,14±4,31	29,23±3,87	30,73±2,91
	Test †p	-0,374 **0,710**		-0,827 **0,413**		-1,448 **0,156**		-1,273 **0,211**		-1,392 **0,172**	
After Bath (AB)	Mean± SD	35,84±4,39	34,86±6,22	36,67±5,28	35,93±5,21	34,12±4,58	34,99±4,82	34,35±6,33	32,78±3,17	32,65±3,80	33,93±5,03
	Test †p	0,573 **0,57**		0,443 **0,66**		-0,585 **0,562**		0,992 **0,328**		-0,912 **0,368**	
10thmin	Mean± SD	31,28±4,69	31,94±3,91	34,08±4,84	32,92±2,83	31,38±3,09	32,40±1,95	30,26±3,95	31,03±3,35	29,73±2,17	31,07±3,22
	Test †p	-0,483 **0,632**		0,930 **0,358**		-1,254 **0,217**		-0,669 **0,507**		-1,542 **0,131**	
20thmin	Mean± SD	32,69±4,93	31,95±3,26	32,10±4,81	32,03±2,68	31,95±2,14	32,38±2,75	30,72±2,64	28,74±3,45	28,36±3,89	29,44±3,06
	Test †p	0,560 **0,579**		0,053 **0,958**		-0,552 **0,584**		2,045 **0,048****		-0,976 **0,335**	
30thmin	Mean± SD	31,14±2,17	30,91±4,14	32,31±4,98	32,24±2,43	31,82±1,59	32,32±2,68	28,61±3,34	29,70±4,14	28,42±4,30	29,57±3,54
	Test †p	0,220 **0,827**		0,052 **0,958**		**-0,717** **0,478**		-0,917 **0,365**		-0,924 **0,361**	
60thmin	Mean± SD	32,42±5,52	31,69±4,26	33,09±4,99	31,67±2,17	31,18±1,76	31,72±3,44	28,76±3,13	30,24±2,20	29,58±3,51	29,64±3,01
	Test †p	0,471 **0,64**		1,161 **0,256**		-0,624 **0,536**		-1,730 **0,092**		-0,063 **0,95**	

*† Student-t Test **p<0,01*

When moisture values in the arm region of the infants and the variation difference of moisture values were compared between the groups, a statistically significant difference was observed only at 20th minute in terms of moisture averages (Table 2; p<0.05) and the variation differences (Table 3; p<0.05).

Table 3. *Comparison of moisture variation difference values of body regions (forehead, abdomen, back, arm, leg) of the infants according to different dressing applications (N=40)*

Measurement time		Skin Moisture Measurement (%)									
		Forehead		Abdomen		Back		Arm		Leg	
		Exp	Control	Exp	Control	Exp.	Control	Exp.	Control	Exp.	Control
BB-AB	Difference	4,48±4,46	2,88±6,21	2,74±5,21	0,89±4,38	2,34±4,25	0,98±7,75	4,02±8,00	0,64±4,55	3,42±4,94	3,20±3,53
	§p	**0,004****	0,777	0,449	1,000	0,357	1,000	0,552	1,000	0,089	**0,010***
	Test	-0,933		-1,216		-0,685		-1,645		-0,162	
	†p	**0,357**		**0,232**		**0,497**		**0,11**		**0,872**	
BB-10thmin	Difference	-0,08±4,62	-0,04±5,10	0,15±5,56	-2,13±3,66	-0,41±3,01	-1,61±6,66	-0,07±5,92	-1,11±6,70	0,50±4,26	0,34±3,25
	§p	1,000	1,000	1,000	0,261	1,000	1,000	1,000	1,000	1,000	1,000
	Test	0,026		-1,532		-0,735		-0,520		-0,138	
	†p	**0,979**		**0,134**		**0,467**		**0,606**		**0,891**	
BB-20thmin	Difference	1,33±5,95	-0,04±5,53	-1,84±4,50	-3,02±4,48	0,16±2,13	-1,64±6,49	0,40±5,13	-3,41±6,01	-0,87±4,11	-1,29±3,11
	§p	1,000	1,000	1,000	0,108	1,000	1,000	1,000	0,306	1,000	1,000
	Test	-0,749		-0,831		-1,175		-2,148		-0,368	
	†p	**0,459**		**0,411**		**0,247**		**0,038****		**0,715**	
BB-30thmin	Difference	-0,22±4,23	-1,07±7,87	-1,63±4,76	-2,81±4,10	0,03±2,36	-1,70±6,06	-1,72±4,49	-2,44±5,86	-0,81±1,16	-3,90±2,58
	§p	1,000	1,000	1,000	0,097	1,000	1,000	1,000	1,000	1,000	0,882
	Test	-0,425		-0,840		-1,187		-0,439		-0,340	
	†p	**0,673**		**0,406**		**0,243**		**0,663**		**0,736**	
BB-60thmin	Difference	1,06±5,96	-0,30±6,38	-0,85±5,64	-3,37±4,17	-0,61±1,97	-2,29±6,09	-1,57±4,49	-1,90±4,31	0,35±4,40	-1,09±3,21
	§p	1,000	1,000	1,000	**0,028***	1,000	1,000	1,000	0,952	1,000	1,000
	Test	-0,694		-1,611		-1,177		-0,241		-1,182	
	†p	**0,492**		**0,115**		**0,247**		**0,811**		**0,244**	

*†Student-t Test §Bonferroni Test **p<0,01*

There was no statistically significant difference between the groups in terms of whole body moisture averages as well as the variation difference of whole body moisture values (Table 4; p>0.05).

Table 4. *Comparison of all body skin moisture measurement averages and moisture variation difference values of the infants according to different dressing applications (N=40)*

Measurement time	Skin Moisture Measurement (%)		Test	†p
	Experimental Mean± SD	Control Mean± SD		
BB	31,33±2,55	32,78±3,56	-1,487	**0,145**
AB	34,72±3,53	34,50±4,02	0,188	**0,852**
10thmin	31,34±2,76	31,87±1,89	-0,705	**0,485**
20thmin	31,16±2,44	30,91±1,77	0,380	**0,706**
30thmin	30,46±2,34	30,95±2,34	-0,660	**0,513**
60thmin	31,00±2,46	30,99±2,05	0,017	**0,986**
Test	14,311	6,557		
‖p	**0,001****	**0,002****		
BB-AB	3,40±3,20	1,72±4,19	-1,426	**0,162**
§p	**0,002****	1,000		
BB-10thmin	0,02±2,10	-0,91±3,30	-1,062	**0,295**
§p	1,000	1,000		
BB-20thmin	-0,16±2,17	-1,88±3,17	-1,991	**0,054**
§p	1,000	0,239		
BB-30thmin	-0,87±2,02	-1,83±3,69	-1,027	**0,311**
§p	1,000	0,580		
BB-10thmin	-0,32±2,61	-1,79±2,92	-1,679	**0,101**
§p	1,000	0,194		

*†Student-t Test ‖ Repeated Measure Anova Test § Bonferroni Test **p<0,01*

It was found that there was no statistically significant difference between the groups in terms of the mean body temperatures and body temperature variation differences evaluated due to measurement times (Table 5; p>0.05).

Table 5. *Comparison of body temperature averages and body temperature variation difference values of the infants according to different dressing applications (N=40)*

Measurement time	Body Temperature (°C)		Test	†p
	Experimental Mean± SD	Control Mean± SD		
BB	36,78±0,36	36,68±0,39	0,885	**0,382**
AB	36,50±0,42	36,47±0,35	0,244	**0,809**
10thmin	36,53±0,35	36,50±0,36	0,270	**0,789**
20thmin	36,66±0,26	36,49±0,33	1,812	**0,078**
30thmin	36,60±0,31	36,59±0,35	0,143	**0,887**
60thmin	36,77±0,27	36,63±0,39	1,313	**0,197**
Test	3,005	2,485		
‖p	**0,045***	**0,079**		
BB-AB	-0,29±0,47	-0,21±0,36	0,571	**0,572**
§p	0,203	0,240		
BB-10thmin	-0,25±0,32	-0,18±0,38	0,671	**0,506**
§p	**0,038***	0,821		
BB-20thmin	-0,12±0,35	-0,19±0,32	-0,613	**0,544**
§p	1,000	0,296		
BB-30thmin	-0,18±0,49	-0,09±0,44	0,614	**0,543**
§p	1,000	1,000		
BB-10thmin	-0,02±0,40	-0,05±0,43	-0,266	**0,792**
§p	1,000	1,000		

*†Student-t Test ‖ Repeated Measure Anova Test § Bonferroni Test *p<0,05*

4. DISCUSSION

There are numerous studies and guidelines on creation of appropriate conditions and methods within the scope of skin care practices of infants, protection and strengthening of skin barrier, prevention of TEWL and hypothermia (5,10-15) in order to bring risks under control and thus prevent complications (2,16). In addition, Blume-Peytavi et al., have reported that there is a need for further researches with high evidence level (17). In accordance with literature (18) 33.0-36.6 week-old preterm infants with low hypothermia risk were included in the study (Tablo 1).

It is reported in the literature that bathing affects physiological characteristics (5,9,17,19-23) and thus physiological condition of infants should be stable before bathing (2,19). It was determined that the infants included in the study had physiological characteristics similar to those stated in the literature (23,24) and there was no harm for bathing (Table 1).

In the study conducted by Kim and Park on term infants, they reported that duration of bathing was approximately 3 minutes (24). Bathing duration of the infants included in the study was limited as similar to the duration stated in the literature (2) One of the strengths of the data is that duration of bathing in both groups is similar both to the literature and between the groups (Table 1).

In the moisture evaluation made for each region before the bathing, it was found that the highest moisture value was observed in abdomen region in both experimental and control groups; whereas, the lowest moisture value was observed in leg region in both groups. This result was remarkable in terms of reliability of the data (Table 2). In a study investigating the effect of radiant heater on TEWL and skin hydration and comparing 31.6 week-old preterm infants having an average weight of 1588 g with those receiving care in the incubator, it was reported that there was no statistically significant difference in the other regions except for abdomen region in terms of stratum corneum hydration (18). When the results of the present study were compared with results of Maayan-Metzger et al.'s study, similarly it was observed that moisture level of abdomen was higher than the other body regions.

It was determined in a study comparing two bathing methods in healthy term infants that those bathed using a wetted washcloth twice a week had the highest TEWL in the hip region compared to those bathed normally and the highest SC hydration was obtained from abdomen and forehead (21). In the present study, it was found that while the highest moisture value was obtained in abdomen region, the lowest moisture value was obtained in the leg region before the bathing. This result is similar to Garcia Bartels et al.,'s study, and supports that there is more hydration in the abdomen region.

When the infants' body moisture average differences before and after the bathing were compared, it was observed that the moisture values increased in both groups and the difference in the experimental group was higher than the control group. However, the increase difference in the moisture level was not statistically significant. This increase in body moisture average within the first 10 minutes after bathing was associated with the fact that the body got wet during the bathing, thus, the skin got moisturized by absorbing the water and the highest evaporation occurred within the first 10 minutes after the bathing (Table 3).

The fact that there were the increase in the experimental group and moisture loss in the control group regarding the difference of the whole body moisture average at 10th minute after bathing (Table 4) was not statistically significant; however it was determined that the skin moisture of the infants from the experimental group dressed after being swaddled with the blanket for ten minutes after the bathing increased; whereas, the skin moisture of the control group decreased.

In the present study, it was determined as a result of within-group measurements that the whole body moisture condition changed significantly in both groups until 60th minute after the bathing (Table 4). When examining the differences between the measurements, it was observed that moisture decreased mostly at 30th minute in the experimental group and at 20th minute in the control group. Additionally, while maximum decrease difference in the control group was –-1.88±3.17, the decrease difference was – 0.87±2.02 in the

experimental group (Table 3). In accordance with all these data, it was thought that the intervention of swaddling with the blanket for 10 minutes after the bathing was affected the skin moisture positively even though this was not statistically significant.

It was determined that the infants lost heat after bath in both groups (Table 5). Body temperature values right after the bath and at 10th minute showed a similar decrease in both groups. The experimental group almost reached their pre-bath body temperature at 60th minute; whereas, control group did not reach the pre-bath body temperature at 60th minute.

In the study conducted by Edraki et al., to investigate the effect of swaddle bathing and traditional bathing methods on crying duration and body temperature in preterm infants, they determined that body temperature of the group dressed right after the swaddle bathing, was 36.50°C before the bathing and 36.42 °C at 10th minute after the bathing, and the variation difference between values obtained before the bathing and at 10th minute after the bathing was – 0.09 °C. The results supported that the body temperature decreased during and after the bathing, which was similar to the present study (Table 5) (25).

It was also reported in the study by Kim and Park that the body temperature decreased immediately after the bathing and the group dressed with a cap reached to the pre-bath body temperature within 90 minutes and the group without a cap reached this value within 180 minutes (24). In another study, it was stated that when the time of preterm infants to return to the body temperature after the bathing was examined, the body temperature of only 43% of the infants reached to 36.5°C within 60 minutes and 70% of them reached to the same temperature within 120 minutes (26). Based on these results, it was observed that putting a cap on infants has an effect on time of return to body temperature. Similar to the results of these studies (24,26) in the present study, it was determined that the group dressed, worn with a new cap and swaddled in double – layered blanket for 10 minutes after the bathing almost reached the pre-bath body temperature at 60th minute; whereas, the control group dressed immediately after the bathing did not reach to the pre-bath body temperature at 60th minute, yet (Table 5). As a result, dressing infants after being dried, put a cap on, and swaddled with blanket for 10 minutes after the bathing and then by changing their cap is a method helping to maintain body temperature and ensure the thermal stability in a shorter time among infants.

5. CONCLUSION

There was no statistically significant difference between the effects of dressing immediately after tub bathing and dressing after drying and swaddling with a blanket for ten minutes after the bathing on skin moisture loss and body temperature.

However, stable and increased moisture in the experimental group and moisture loss in control group in the variation change occurring in the whole body moisture at 10th minute showed that the application caused less skin moisture loss. This was not statistically significant between the groups, which suggested that the result was associated with the small sample size. The data obtained about the body temperature within the scope of the study showed that the body temperature of infants decreased in both dressing applications after the bathing. However, it was observed that the body temperature of the infants dressed at the 10th minute after the bathing got closer to the pre-bath value at 60th minute compared to the infants dressed right after the bathing.

In accordance with all these data, it was determined that the skin moisture and body temperature of the infants in experimental group were affected positively even though this was not statistically significant.

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Clinical and Experimental Health Sciences

Investigation of the Relationship Between Nurses' Burnout and Psychological Resilience Levels

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ABSTRACT

Objective: This descriptive and correlational study was performed to determine the relationship between resilience and burnout levels of nurses working in psychiatry clinics.

Methods: The population of this correlational study comprised 70 nurses, 55 of which constituted the study sampling between February and May in 2018. Research data was collected by means of "Personal Information Form", "Psychological Resilience Scale/PRS" and "Maslach Burnout Scale/MBS".

Results: "Devotion" subscale of PRS showed a strong statistically significant inverse relationship with "Emotional Burnout" subscale of MBS ($r=-0.707$; $p=0.000$) albeit a moderate statistically significant inverse relationship noted with both "Desensitization" and "Personal Success" subscales of MBS ($p<0.05$).

Conclusion: The results of this study may help nurse managers and hospital administrators to have a better understanding of nurses' burnout and resilience levels. Future studies on the determination of compassion fatigue, which is an expression of empathy fatigue against nurses in psychiatric clinics and particularly Community Mental Health Services, are highly recommended.

Keywords: Burnout, Psychiatric Nursing, Resilience.

1. INTRODUCTION

Resilience is the ability of an individual to successfully overcome and adapt to adverse conditions. Although it is defined as a talent and a psychological quality, resilience has a number of features such as contribution to the maintenance of healthy development and coping capacity with a negative situation (1,2). Masten et.al. (1990), while defining the concept of resilience have touched on three basic features (1). The first basic resilience; people who live in negative conditions and who have high risk have a personal ability to survive in difficult conditions and to overcome difficulties. The second basic resilience; expresses the ability of the people with difficult and stressful life to adapt quickly with the experiences they have gained under these negative conditions. The third resilience; refers to psychological concussion at times like losing a loved one, accidents and natural disasters (1). The ability to cope with such difficult situations and get rid of the effects of trauma are considered within the third group.

Despite difficult working conditions, psychiatric and mental health nurses' ability to carry on their professional clinical skills, cope with challenging situations and retain their empathic and willing states are realized thru their resilience (2-4). Thus, resilience is reported to be a key factor in job satisfaction, depression and burnout in nurses and especially in nurses who work at psychiatric and mental health services (3-5).

Burnout experience leads to job dissatisfaction, prevention of professionalism, patient dissatisfaction, reduced nurse productivity, low quality of life and low quality of care (6-9). Meanwhile, studies assert that burnout contributes to the problem of nurse scarcity (10). The effect of burnout not only is limited to the nurses experiencing it but also filters thru their patients, institutions, affiliated society, family and friends (11).

According to the relevant literature, in the event of an encounter with an unforeseen stressful situation, nurses reported improved resilience by the adoption of protective factors (personal, social, professional) (12,13). Furthermore, resilience welcomes the adoption of skills

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such as self-confidence, autonomy, coping, adaptation and creating motivational life force (14-19). Accordingly, positive amelioration is observed in personal and professional outcomes, job and life satisfaction, and development of professional nursing skills while staff turnover, sense of burnout and depression decrease (14, 15, 20, 21).

Nurses are the most risky group among the health care professionals in terms of stressors arising from the work environment. Nurses often experience work stress, are exposed to psychological violence in the workplace, and suffer from secondary traumatic stress and burnout. The problems experienced by the nurses negatively affect the physical, mental and social health of the nurses. Mental distress decreases the efficiency of nurses, as a result of which both patient quality of care and institutions are adversely affected. The concepts of coping skills, social support and resilience come into prominence in the protection and strengthening of mental health of nurses (12,15,18). It is vital to determine the level of resilience especially in nursing and take preventive actions before burnout takes place. The literature review yielded no studies that focused on both the resilience and burnout concepts featuring psychiatric nurses/nurses work in psychiatric clinics. For these reasons, it is the aim of our study to determine the relationship between resilience and burnout levels of nurses working in psychiatry clinics.

The research questions:

What are the sociodemographic characteristics of nurses?

What are the sociodemographic characteristics that affect the resilience level of nurses works in psychiatric clinics?

What are the sociodemographic characteristics that affect the burnout level of nurses works in psychiatric clinics?

Is there any relationship between resilience and burnout levels of nurses works in psychiatric clinics?

2. METHODS

Study design

This research was designed as a descriptive and correlational study.

Settings and participant

This study was carried out in Bolu İzzet Baysal Mental Health and Diseases Training and Research Hospital. The data was collected between February and May in 2018. The population of this study comprised 70 nurses who work in a mental health and diseases education and research hospital. Sampling method was not used in the study, it is aimed to reach the whole population. Reasons about maternity leave, military service, annual leave the study sampling was carried out by selecting 55 nurses that accepted to participate in the study and filled out the data collection forms completely.

Data Collection

The research data collection was carried out by means of self-report methods such as survey and scales, namely, “Personal Information Form”, “Psychological Resilience Scale” and “Maslach Burnout Scale”.

Personal information form: This form was developed by researchers. It solicits information such as age, work experience, education level, perception of job satisfaction level, monthly night shift frequency and staffing status, all of which relate to occupational burnout (7, 20)

Psychological resilience scale (PRS): Psychological resilience scale was developed by Terzi (2016) to determine resilience level, consists of 21 items and three sub-dimensions indicating the beliefs of the individual about himself/herself and his/her life (22). The psychological resilience scale is a 5-point Likert-type scale scored between 0-4 and items of the scale are marked as (0) strongly disagree, (1) disagree, (2) neutral, (3) agree, (4) strongly agree. Psychological resilience scale includes direct expressions and reverse expressions, and items 2 and 15 are scored in reverse direction. Exploratory and confirmatory factor analyses were administrated in order to determine the construct validity of the scale, and it was found out that the scale consisted of 21 items and three sub-dimensions. These dimensions were called Self-Commitment (PRS-SC), Control (PRS-C) and Challenging (PRS-CH) in the light of literature. General resilience score is obtained after scoring three sub-dimensions separately. While high scores of scale indicate that resilience reduces, low scores refer that resilience increases.

Maslach burnout scale (MBS): MBS, developed by Maslach and Jackson in 1981 to determine the level of burnout of individuals, consists of 22 items and 3 subdimensions (emotional burnout, desensitization, personal success). MBS was set on a 5-point Likert scale, in the order of (0) never, (1) seldom, (2) sometimes, (3) frequently and (4) always. In detail, MBS is calculated by the sum of scores for 22 items spanned across 3 subdimensions, namely, emotional burnout (items 1, 2, 3, 6, 8, 13, 14, 16, 20), desensitization (items 5, 10, 11, 15, 22) and personal success (items 4, 7, 9, 12, 17, 18, 19, 21). Higher scores in “Emotional Burnout” and “Desensitization” subscales and a lower score in “Personal Success” subscale are clear indications of a high level of burnout. “Emotional Burnout” represents the individual stress dimension of burnout and imply a diminution of an individual’s emotional and physical resources. “Desensitization” represents the inter-personal dimension of burnout that includes negative, rigid attitudes towards patients and unresponsiveness to work. On the other hand, low level of “Personal Success” refers to an individual’s negative self-assessment tendency.

Ethical Consideration

Permission to conduct the study was granted by the Abant İzzet Baysal University Human Research Ethics Committee (No: 2018/23), which serves as the institutional review board for clinical research. All participants completed the approved

informed consent procedures and were assured that they had the right to refuse to participate in the study.

Statistical Analysis

Statistical data analyses were carried out using SPSS. Frequency tables and descriptive statistics were utilized to interpret the findings. Student t tests, the One way ANOVA test and Tukey HSD, Tamhane tests were used for comparison of the groups. For determining correlation between Pearson's and Spearman correlation was deployed. The correlation between levels PRS and MBS subscales were analyzed using Pearson's and Spearman correlation analysis. $p<0.05$ was considered statistically significant.

3. RESULTS

The Socio-demographic Characteristics of Nurses

The mean age of sample population was 36.47 ± 7.76 (years). 72.7% of the participants were women, 63.6% were married and 52.7% had bachelor's degree. 65.5% of the participants had 6 years or more work experience in the psychiatric clinic and 54.5% had a total of 16 years or more work experience (Table 1).

Research Findings of PRS Sub-dimensions According to Sociodemographic Characteristics

There was a statistically significant difference between PRS total scores and "Challenge" subscale scores with respect to nurse age ($t=2.647;p=0.011$; $t=2.128;p=0.038$). "Challenge" subscale score and total scale score of 35 years old and younger nurses were statistically significantly higher than that of 36 years old or older nurses (Table 2).

"Control" subdimension scores of PRS with respect to gender showed a statistically significant difference ($t=-2.246$; $p=0.029$). As such, "Control" subdimension score of male nurses were statistically significantly higher (Table 2).

"Devotion" subscale scores versus total PRS scores with respect to the affiliated psychiatry department yielded statistically significant differences ($\chi2=7.836;p=0.020$; $\chi2=6.445;p=0.040$).

Table 1. The Socio-demographic Characteristics of Nurses

Variable (N=55)	n	%
Age ($\bar{x}$ ± ss. 36,47±7,76 (years**)**		
35 years-old and below	22	40.0
36 years-old and above	33	60.0
Gender		
Female	40	72.7
Male	15	27.3
Marital Status		
Married	35	63.6
Single	20	36.4
Number of Children		
1 child	6	17.1
2 children and more	29	82.9
Education Level		
Health Vocational High School	8	14.6
Bachelor's Degree	13	23.6
Graduate Degree	29	52.7
Post-Graduate Degree	5	9.1
Work Experience		
5 years or less	10	18.3
6-10 years	7	12.7
11-15 years	8	14.5
16 years or more	30	54.5
Work Experience in Psychiatry		
5 years and below	19	34.5
6 years and above	36	65.5
Department of Psychiatry		
Services	39	70.9
Polyclinic	9	16.4
Community Mental Health Services (CMHS)	7	12.7
Night Shifting Status		
Yes	45	81.8
No	10	18.2
Night Shift Frequency		
Once a month	11	24.5
2-3 times a month	5	11.1
4-5 times a month	15	33.3
6 times and above a month	14	31.1
Staffing Status		
On-Contract	7	12.7
Permanent	48	87.3
Job Satisfaction Level		
Moderate	23	41.8
High	32	58.2

Table 2. Comparison of PRS and MBS with respect to Research Findings

Variable (N=55)		n	PRS				MBS		
			Devotion	*Control*	*Challenge*	*TOTAL*	*Emotional Burnout*	*Desensitization*	*Personal Success*
Age	35 years old and more	22	20,41±3,80	19,5 [14,0-25,0]	22,95±2,80	62,50±8,16	12,14±5,46	5,00±3,92	7,80±3,65
	36 years old and less	33	19,85±3,27	17,0 [13,0-21,0]	20,58±3,54	58,00±7,35	13,18±5,97	4,72±3,58	10,76±4,32
	Statistical Analysis*		t=0,584	Z=-1,889	t=2,647	t=2,128	t=-0,658	t=0,267	t=-0,074
	Possibility		p=0,562	p=0,059	**p=0,011**	**p=0,038**	p=0,514	p=0,791	p=0,941
Gender	Female	40	19,73±3,43	17,73±2,57	21,5 [14,0-28,0]	59,15±7,78	12,95±5,95	4,53±3,49	11,28±4,39
	Male	15	21,00±3,51	19,47±2,53	21,0 [8,0-27,0]	61,53±8,32	12,26±5,31	5,67±4,17	9,47±4,31
	Statistical Analysis*		t=-1,220	t=-2,246	Z=-0,086	t=-0,993	t=0,390	t=-1,024	t=-1,368
	Possibility		p=0,228	**p=0,029**	p=0,932	p=0,325	p=0,698	p=0,311	p=0,177
Psychiatry Department	Services [1]	39	20,0 [14,0-26,0]	18,0 [13,0-25,0]	22,0 [8,0-28,0]	60,0 [42,0-78,0]	12,95±5,40	4,0 [0,0-16,0]	10,46±4,58
	Polyclinic [2]	9	22,0 [19,0-25,0]	19,0 [14,0-21,0]	22,0 [18,0-27,0]	62,0 [53,0-72,0]	7,33±3,81	2,0 [0,0-8,0]	9,33±3,87
	CMHS [3]	7	17,0 [15,0-20,0]	16,0 [13,0-21,0]	20,0 [16,0-27,0]	50,0 [49,0-68,0]	18,71±2,63	6,0 [2,0-9,0]	14,43±1,51
	Statistical Analysis*		χ^2=7,836	χ^2=4,315	χ^2=3,445	χ^2=6,445	F=10,557	χ^2=4,634	F=2,925
	Possibility		**p=0,020**	p=0,116	p=0,179	**p=0,040**	**p=0,000**	p=0,099	p=0,063
			[2-3]			**[2-3]**	**[1-2,3] [2-3]**		
Work Experience	5 years and more[1]	10	18,90±3,25	18,00±2,71	22,0 [20,0-27,0]	59,60±6,11	14,70±5,74	6,80±4,29	12,10±3,14
	6-10 years[2]	7	22,57±3,46	19,29±3,45	23,0 [19,0-27,0]	65,14±9,44	7,42±4,54	2,00±1,53	9,00±6,63
	11-15 years[3]	8	20,25±4,68	19,38±3,34	21,0 [16,0-28,0]	60,62±11,09	12,37±5,50	3,75±3,15	9,00±5,04
	16 years and more [4]	30	19,83±3,05	17,70±2,18	21,0 [8,0-27,0]	58,40±6,94	13,47±5,56	5,13±3,61	11,23±3,91
	Statistical Analysis*		F=1,712	F=1,308	χ^2=3,799	F=1,436	F=2,810	F=2,902	F=1,241
	Possibility		p=0,176	p=0,282	p=0,284	p=0,243	**p=0,049**	**p=0,044**	p=0,305
							[1-2]	**[1-2]**	
Night Shift Frequency	Once a month	11	20,00±3,52	18,09±3,21	22,18±3,54	60,27±9,29	19,0 [4,0-23,0]	5,64±4,13	13,0 [1,0-16,0]
	2-3 times a month	5	16,80±2,59	16,20±2,59	18,60±2,88	51,60±4,83	18,0 [8,0-23,0]	4,80±1,30	13,0 [8,0-17,0]
	4-5 times a month	15	19,27±3,59	18,60±2,20	21,53±1,73	59,40±5,78	15,0 [9,0-21,0]	6,13±3,94	11,0 [3,0-19,0]
	6 times and more	14	21,28±3,03	18,93±2,70	21,29±4,91	61,50±8,79	10,0 [0,0-18,0]	3,64±3,30	10,0 [2,0-21,0]
	Statistical Analysis*		F=2,445	F=1,375	F=1,220	F=2,108	χ^2=8,911	F=1,258	χ^2=2,482
	Possibility		p=0,078	p=0,264	p=0,315	p=0,114	**p=0,030**	p=0,302	p=0,479
							[1-4]		
Job Satisfaction Level	Moderate	23	18,83±3,26	18,0 [13,0-23,0]	21,0 [8,0-28,0]	58,30±8,33	16,0 [4,0-23,0]	6,04±3,43	11,0 [2,0-17,0]
	High	32	20,97±3,38	18,0 [14,0-25,0]	22,0 [14,0-27,0]	60,88±7,58	11,0 [0,0-23,0]	3,97±3,67	10,0 [1,0-21,0]
	Statistical Analysis*		t=-2,353	Z=-0,448	Z=-0,026	t=-1,191	Z=-2,936	t=2,125	Z=-1,602
	Possibility		**p=0,022**	p=0,654	p=0,646	p=0,239	**p=0,003**	**p=0,038**	p=0,109

*PRS: resilience scale; MBS: Maslach burnout scale * [a] Kruskal-Wallis H, [b] Indepedent Sample-t, [c] ANOVA, [d] Mann-Whitney U*

"Emotional Burnout" subscale of MBS with respect to the affiliated psychiatric clinic showed a statistically significant difference (F=10.557;p=0.000).

Another statistically significant difference in MBS was determined between "Emotional Burnout" subscale scores of nurses with respect to monthly night shift frequency (χ2=8.911;p=0.030).

A statistically significant difference in MBS was determined in terms of "Emotional Burnout" and "Desensitization" subscale scores with respect to nurses' perception of job satisfaction level (Z=-2.936;p=0.003; t=2.125;p=0.038).

The Correlation Between PRS and MBS Subscales

"Devotion" subscale of PRS showed a strong statistically significant inverse relationship with "Emotional Burnout" subscale of MBS (r=-0.707; p=0.000) albeit a moderate statistically significant inverse relationship noted with both "Desensitization" and "Personal Success" subscales of MBS (p<0.05) (Table 3).

Table 3. *The Correlation Between PRS and MBS Subscales*

Correlation* (N=55)			MBS		
			Emotional Burnout	Desensitization	Personal Success
PRS	Devotion	r	-0,707	-0,558	-0,625
		p	**0,000**	**0,000**	**0,000**
	Control	r	-0,287	-0,228	-0,416
		p	**0,034**	0,095	**0,002**
	Challenge	r	-0,299	-0,103	-0,305
		p	**0,027**	0,456	**0,023**
	Total	r	-0,542	-0,351	-0,567
		p	**0,000**	**0,009**	**0,000**

*PRS: resilience scale; MBS: Maslach burnout scale *Pearson and Spearman*

4. DISCUSSION

Ability of nurses working in psychiatric and mental health services in utilizing professional clinical skills for patient care despite difficult working conditions is a matter of presenting coping skills in the event of a challenging situation and retaining eagerness and empathetic thinking all of which

are explained by resilience (2-4). In addition, resilience is regarded as an important factor related to job satisfaction, burnout and depression in mental health nursing (3-5). One of the main objectives of this study was to determine the resilience levels of nurses working in psychiatric and mental health services. Nurses often experience stressful life events in their work environment that led them to indirect traumatization. In particular, indirect trauma is of great importance to mental health and psychiatric nurses working with patients that feel stigmatized by society, have trouble in expressing themselves or have a history of traumatic life.

The factors were scrutinized, namely, depression, burnout, self-esteem and resilient personality trait in relation to resilience level of nurses, and concluded that nurses with higher resilience reported lesser depression, emotional burnout and desensitization (4). It was examined that the burnout and resilience levels of nurses working in military hospitals and reported an inverse correlation in between (11). The research findings concur with the above-mentioned literature. In our study, both "Psychological resilience scale – challenge" subscale and total PRS scores of nurses aged 35 and under were statistically significantly higher than that of nurses aged 36 and older (t=2.647;p=0.011; t=2.128;p=0.038). In contrast to our research findings, researchers such as Tekin (2011) whom studied nurses serving in military hospitals and Güngörmüş et al. (2015) whom studied at nursing students found no relationship between age and resilience. Discrepancy between this study and the literature can be related to several factors that impede resilience such as prolonged close interactions with patients and their relatives, caring patients with chronic psychiatric diseases, experiencing empathy fatigue, and vice versa.

In this study, the subscale scores pertinent to MBS were determined as low level, respectively. Low burnout scores in our study may be associated with various factors such as research sampling which consisted only nurses from psychiatric clinics or stressor perception differences were present among the nurses as to what may cause burnout.

It is determined that the nurses with 5 years and below work experience compared to the nurses with 6-10 years of work experience had scored higher in "Emotional Burnout" and "Desensitization" subscales. Parallel to our finding, it was reported high burnout and desensitization levels in nurses with meager work experience in a different study (23).

In our study, nurses taking six or more night shifts per month had lower emotional burnout level than the nurses taking only one night shift per month. Taking night shifts is common in many professions, especially in health care services. These can lead to emotional burnout due to physical fatigue and thus feeling of separation from home and family. Surprisingly, this research showed statistically significant inverse relationship between night shift and emotional burnout. This discrepancy is most likely caused by the fact that interaction between nurse and patient relatives are more frequent in the daytime than it is during the shift hours, which builds up emotional burnout in the psychiatric nurses over time.

In this study, nurses with high job satisfaction perception had lower emotional burnout and desensitization than the nurses with moderate job satisfaction perception. In fact, with respect to "Devotion" subscale, nurses with high job satisfaction perception presented higher resilience compared to the nurses with moderate job satisfaction. Tekin (11) identified total working hours and job satisfaction as the occupational attributes of nursing affecting resilience. The working environment factor has direct impact on the peace and success of the people, which is in concurrence with the results of our study. In a different study with the participation of 454 nurses and disclosed an evidence of a positive relationship between intention to stay at work and nurses' job satisfaction, psychological strength and stress resilience (24). Conclusively, it is tought that nurses may feel emotionally worn-out, desensitized and led to a decrease in their personal success. Conversely, willful working and higher job satisfaction have positive impact on the level of resilience unlike burnout.

Nurses working in outpatient clinics had the lowest emotional burnout among others working in the services and community mental health services (CHMS). Additionally, nurses working in CHMS had the highest emotional burnout levels. As an ancillary explanation for this phenomenon, nurses in outpatient clinics, unlike the ones in services or CHMS, do not take the responsibility of patient and patient care but rather attend interviews with the company of a physician. In a study, aimed at investigating the underlying reasons of psychological stress in burnout from a nurse standpoint, problems in communication with doctors (57%), patient relatives (52%), nursing management (49%) and lastly patients (40%) were enumerated in a descending order of magnitude (25). Another study, having reported "lack of respect" as the leading source of stress in nursing, enumerated an array of subordinate factors such as complaints of patients and their families, attitudes of patients under the influence of alcohol and pace of work, accountable for increased emotional burnout among nursing staff (26). Working in the services and CHMS, unlike outpatient clinics, requires constant interaction with patients and their families. In particular, having had difficulty to cope with patients with acute or chronic psychiatric illnesses, those nurses are prone to higher emotional burnout in tandem with work experience. In addition, working in the services demands high-level professional skill, teamworking and 24-hour servicing competence. Hence, it becomes inevitable to experience various work environment stresses and emotional burnout build-up over time. The presence of a higher emotional burnout level within CHMS nurses due to care of chronic psychiatric patients, suggests a difference in stress perceptions between nurses in the services and CHMS. The CHMS nurses furnish continuous training and consultancy services to both patients and their relatives while seeking a wide range of multidisciplinary input such as from psychologists, doctors, social workers, public education trainers and vice versa. On the other hand, as endorsed under CHSM nursing job description, CHSM nurses are required

to fulfill responsibilities related to primary and tertiary protection in addition to secondary care. Eventually, this situation may form a basis for emotional burnout of CHSM nurses. Moreover, contrary to the patient group receiving treatment in the services, CHSM patients have to establish long-term interaction with the nurses following their discharge. Thus, CHSM nurses, having identified themselves with the feelings of patients experiencing internalized stigma, unemployment, disease difficulties and vice versa, will eventually suffer from empathy fatigue and emotional burnout. In fact, the evaluation of CHSM nurses for resilience yielded a lower resilience level with respect to dedication.

The total PRS scores are negatively associated with the total MBS scores and MBS subscale scores. Each individual perceives the stressor at different levels. These differences in perception of occupational stress are inversely related to burnout.

Burnout levels of nurses who exposed to more occupational stress were also found to be higher (27). Difficulty of caring patients suffering from a trauma or a natural disaster and being exposed to several patient sysmptoms during psychiatric patient care in mental health nursing such as patient stigmatization, isolation, guilt and disease, and incidents of violence, often lead to burnout, job dissatisfaction and depression amongst nurses (3,5,12).

5. CONCLUSION

Resilience of nurses in psychiatry clinics vary by factors such as age, gender, job satisfaction and affiliated department, whereas burnout vary by factors such as affiliated department, work experience, night shift frequency and job satisfaction. The findings of this study can enrich our knowledge of the role of resilience in influencing nurse burnout at a correlational context. The results of this study show us the resilience of nurses vary by factors such as age, gender, affiliated department and perception of job-satisfaction level, whilst their burnout rate vary by factors such as affiliated department, work hours, night shift frequency and job-satisfaction level

Nurse leaders as well as policymakers should take the initiative to launch courses, seminars, conferences, panels, workshops and structured training programs aimed at improving personal skills in the workplaces.

Although the significance of resilience is clear, a better understanding is needed of which factors affect a nurse's level of resilience and burnout and how resilience can best be improved and burnout level can be decreased. For this to happen, a more explicit definition of which resilience at nurses involves should be formulated and applied in a consistent manner. This will allow better theoretical models to be developed and evaluated.

All data were obtained from only in work in nurses one hospital. All data were based on the personal declaration of the nurses.

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Clinical and Experimental Health Sciences

Update on the Evaluation of the Anti-Obesity Effect of Green Tea (Camellia sinensis)

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ABSTRACT

Objective: Obesity is a worldwide rising risk factor for numerous incommunicable illnesses. The most common interventions have been ineffective from a public health perspective. Green tea (Camellia sinensis) seems to be an effective well-known alternative but there is a need to see the most updated and reliable information on the matter. The study aimed to verify how effective is green tea as reductor of human body mass index (BMI).

Methods: This meta-analysis reviewed recent controlled randomized trials on the effect of catechin and caffeine in the BMI of adult male and female subjects. The analysis did not include studies including alternative therapies or drugs potentially affecting BMI. The studies presented the quantity of catechin and caffeine (mg). Body mass index and waist circumference were measured before and after the interventions. The trials lasted two to eight months, depending on the study designs.

Results and Conclusion: Five studies met the criteria for the current analysis. In one study, the subjects took oral capsules of green tea extract (379mg). Overall, daily doses of catechin varied from 208-1200mg, and caffeine from undetectable levels to 480mg (the tea products were either enriched, capsules or canned with known levels). All showed reduction in body weight, the average BMI reduction was 0.68 kg/m2, and waist circumference was 1,5cm. There was a direct relationship between the concentration of catechin and reduction of BMI, but the BMI appeared to drop to a certain threshold of "optimal" weight, close to values considered as normal weight by the World Health Organization (WHO). There were few cases suggesting abdominal discomfort, but there they did not require additional treatment or hospitalization. Green tea consistently showed ability to reduce weight to a less risky level for health. Yet, it is now necessary to develop dose-response models for its active compounds and clarify the dynamics of the dosage over time. Furthermore, green tea is perhaps more effective in synergy with well-known methods to maintain or reduce weight, such as balanced diets or physical exercise.

Keywords: Green tea, obesity, catechin, caffeine, body mass index, waist circumference

1. INTRODUCTION

Obesity occurs when calorie intake is higher than energy expenditure, resulting in excessive lipid accumulation in the adipose tissue, and it is well-known as an increasingly prevalent medical condition (1). It is a major risk factor for several cardiovascular diseases, diabetes, pulmonary illnesses, certain types of cancer and osteoarthritis (2). In 2016, the World Health Organization (WHO) estimated that over 1.9 billion adults (> 18-year old) were overweight from which more than 650 million were obese, 39% of men and 40% of women were overweight and 13% of the world population (11% of men and 15% of women) were obese (3). In 2018, Piche *et al.* (4) published more recent estimates as 30% of men and 35% of women obese worldwide. According to them, it has doubled in more than 70 countries since 1980. In Mozambique, the prevalence of obesity in adults is 7,2% (5).

Despite of several interventions to combat reduce the prevalence of obesity through promotion of healthier lifestyle, medication, surgical interventions, physical activity and low-calorie diets, results have not been satisfactory and their effects do not last for long, and sometimes patients face adverse effects of such therapies (2, 6-8). Thus, it is crucial to search for effective, easy to use, tolerable and economic alternatives. Recently, natural phytotherapeutic supplements are drawing attention, and green tea (from *Camellia sinensis*) is the most widely used (9-11).

Green tea's anti-obesity properties is associated to its relatively high content of catechins, antioxidants consisting

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of (–)-epicatechin (EC), (–)-epicatechin-3-gallate (ECG), (–)-epigallo-catechin (EGC), and (–)-epigallocatechin-3-gallate (EGCG) (12). According to Kao *et al.* (13), EGCG was capable of reducing up to 29% of body weight of rats within one week, when injected in the peritoneum. The authors added that such effect is due to EGCG's molecular inhibition of fatty acid synthase. Catechins also inhibit a-amylase and lipase, interfere with emulsification, digestion, and fungal solubilization of lipids (14, 15). Akhlaghi and Kohanmoo (15) summarized the same information and added other possible mechanisms at which catechins can affect weight loss, including: (a) appetite control, perhaps by inhibiting ghrelin, (b) interaction with intestinal bacteria, resulting in its breakdown into bioavailable components with potential anti-obesity effects, and (c) increasing the population of colonic bacteria and selecting species capable of affecting converting lipids into short-chain fatty acids. Though clinical evidence supports green tea's anti-obesity effects, there are some contradictions and inconclusive findings. Furthermore, optimal intake is yet to be understood (16).

Considering the importance of obesity and the lack of effective, safe and long-lasting strategies to control it, the current study was performed on green tea, since it is inexpensive and easy to use, with minimal collateral effects. Thus, it aims to investigate how green tea affects weight loss in overweight and obese subjects.

2. METHODS

The study comprised a meta-review of randomized controlled clinical studies about the impact of green tea on weight loss in overweight and obese patients. The participants were healthy male and female subjects, at least 18 years old. They were overweight (> 25 kg/m^2) or obese (> 30 kg/m^2) according to standards by the WHO standards for BMI and waist circumference (which ideally should be within 85-95cm in healthy individuals) (17, 18). The current analysis did not include studies in which participants used other medicines potentially affecting body weight. They used exclusively green tea or its extract. Were excluded studies in which the chemical composition of the tea was not specified or it was mixed with other ingredients.

All studies considered provided, to their control groups, a placebo or a smaller dose of great tea in relation to the experimental group. Studies where patients performed physical exercise were excluded. All experiments lasted at least two months and the studies were all performed during the last ten years.

Initially, 30 studies seemed potentially relevant. However, 11 were excluded because they were *per si* literature reviews. Then, 9 were excluded because they had been performed over 10 years before. Three were excluded because they used other types of intervention together with green tea, and 2 more were excluded because they did not presented measurements of both BMI and waist circumference. Finally, 5 articles matched all criteria for this study and they were analyzed (Table 1). It was also necessary to perform an analysis of covariance (ANOVA, a = 0.05) in Jamovi (Version 0.9.5.13, Jamovi, Project, Amsterdam, Netherlands) (19) to determine if the weight loss in female and male subjects were significantly different and linear regression to visualize the relationship between catechin consumption and body loss. The latter analysis was not performed for waist circumference and caffeine because of some inconsistencies.

Table 1. *Demographic characteristics of the subjects analyzed.*

Authors	Intervention and control	Sample size	Number of randomized participants	Number of participants in the end of the study	Participants in the end of the study (%)	Female/male ratio	Average age (sd)
Suliburska *et al.* (26)	I1: green tea C1: placebo	I1: 23 C1: 23	I1: 23 C1: 23	I1: 23 C1: 23	I1: 100% C1: 100%	I1: 1:1 C1: 1:1	I1: 49 (9) C1: 52 (8)
Wang *et al.* (21)	I2: green tea C2: placebo	I2: 205 C2: 205	I2: 192 C2: 192	I2: 182 C2: 182	I2: 95% C2: 95%	I2: 3:1 C2: 3:1	I2: 37 (9) C2: 37 (9)
Brown *et al.* (23)	I3: green tea C3: placebo	I3:67 C3:70	I3: 64 C3: 64	I3: 64 C3: 64	I3: 100% C3: 100%	I3: 0:1 C3: 0:1	I3: 50 (5.5) C3: 49 (5.5)
Nabi *et al.* (20)	I4: green tea C4: placebo	I4: 41 C4: 41	I4: 29 C4: 29	I4: 29 C4: 29	I4: 100% C4: 100%	I4: 2:1 C4: 2:1	I4: 46 (6.4) C4: 48 (7.58)
Sone *et al.* (27)	I5: green tea C5: placebo	I5: 30 C5: 30	I5: 25 C5: 26	I5: 25 C5: 26	I5: 100% C5: 100%	I5: 2:1 C5: 2:1	I5: 43 (14.8) C5: 48 (12.4)

C: control; I: intervention; sd: standard deviation

3. RESULTS and DISCUSSION

All authors consulted presented reduction of the average BMI, particularly Nabi *et al.* (20), likely because they used higher daily levels of catechins (1200mg) and caffeine (480mg; see Table 2), resulting in an average IMC reduction of 3.1 kg/m2 (Table 3). The overall average BMI reduction was 0.68 kg/m2. It is worthwhile mentioning Wang *et al.* (21), who divided the intervention group in three subgroups, IG1, IG2 and IG3, the order representing an increased concentration of catechin and caffeine. The subgroup IG3 did not present significant weight reduction, and the average BMI actually appeared to increase slightly. This might have been due to well-known limitations of BMI itself as a measure of BMI, as

it for instance misrepresents the state of body fat content in several circumstances, especially because of the muscular mass (22). For instance, the same individuals showed final values of waist circumference value inversely proportional to the amount of catechin consumed daily, though waist circumference is still to be discussed in detail. In all studies, the placebo did not present considerable BMI decline. Three studies presented considerable differences between the intervention groups and the placebos, especially the study by Brown *et al.* (23) where intervention took longer (8 months) if compared to the others (≤ 3 months). Thus, it seems safe to assume that consumption of green tea affected BMI. Auvichayapat *et al.* (9) found similar results in Thailand, Matsuyama *et al.* (24) in Japanese children, and Jurgens *et al.* (16) in another meta-analysis.

It is important to know if green tea had a similar effect in both female and male subjects, because the demographic differences between the studies might have affected the results. The ANOVA test in Table 4 does not show significant differences between the results assuming the different ratios between male and female subjects (p = 0.472).

Table 2. *Description of the interventions used in the selected studies.*

Authors	Intervention group (s) (delivery method, frequency, total doses/ day)	Catechin content per intervention group	Caffeine content per intervention group	Control group (delivery method, frequency, total doses/day)	Duration	Other interventions for weight loss	Co-medication	Co-morbidity
Suliburska *et al.* (26)	1 oral capsule (379mg) of green tea extract, daily (morning)	208mg (daily)	No caffeine detected	1 oral capsule (379mg) of placebo extract, daily (morning)	I1: 3 months C1: 3 months	No	No	No
Wang *et al.* (21) **	1 cup (250 ml) green tea daily in 3 intervention groups (GI*)	GI1 – 458mg GI2 – 468mg GI3 – 886mg	GI1 – 104mg GI2 – 126mg GT3 – 198mg	1 cup of placebo with 30mg of catechin and 10mg of caffeine	I2: 3 months C2: 3 months	No	No	No
Brown *et al.* (23)	1 oral capsule (530mg) of green tea, 2x/day	404mg per capsule	<1%	1 placebo capsule 2x/ day	I3: 8 months C3: 8 months	No	No	No
Nabi *et al.* (20)*	1 glass (150ml) of green tea 2x/day	1200mg	480mg	1 glass (150ml) of placebo 2x/day	I4: 3 months C4: 3 months	No	No	No
Sone *et al.* (27) **	1 glass (500ml) of green tea daily	400mg	105mg	1 glass (500ml) of placebo containing 100mg of catechins daily	I5: 2 months C5: 2 months	No	No	No

*GI – intervention group; * Catechin and caffeine information from the label; ** Tea with catechin and caffeine extracted, and then enriched with these compounds.*

Table 3. *Results of the analyzes.*

Authors	BMI (kg/m2)		Waist circumference (cm)		% of patients with adverse effects
	Baseline	Results after intervention	Baseline	Results after intervention	
Suliburska *et al.* (26)	I1: 32.07 ± 2.41 C1: 33.45 ± 2.65	I1: 31.71 ± 2.29 ↓ C1: 33.36 ± 2.66 ↓	I1: 101.78 ± 6.42 C1: 104.98 ± 6.53	I1: 101.15 ± 6.42 ↓ C1: 105.02 ± 6.10 ↑	No
Wang *et al.* (21)	GI1 – 27.1 ± 2 GI2 – 27.2 ± 3 GI3 – 26.8 ± 2 C2 – 26.8 ± 2	GI1 – 26.8 ± 2.0 ↓ GI2 – 26.8 ± 2.4 ↓ GI3 – 26.9 ± 2.5 ↑ C2 – 26.3 ± 2.2 ↓	GI1 – 96.1 ± 5.8 GI2 – 95.9 ± 7.0 GI3 – 95.5 ± 6.0 C2 – 94.5 ± 6.0	GI1 – 95.0 ± 6.2 ↓ GI2 – 94.6 ± 7.0 ↓ GI3 – 93.6 ± 7.0 ↓ C2 – 94.3 ± 5.8↓	No
Brown *et al.* (23)	I3: 31.7 C3: 31.4	I3: 31.5 ↓ C3: 31.6 ↑	N/A	N/A	I3: 58% C3: 66%
Nabi *et al.* (20)	I4: 29.95 ± 1.79 C4: 29.69 ± 2.01	I4: 26.86 ± 2.59 ↓ C4: 27.07 ± 2.22 ↓	I4: 87.77 ± 6.06 C4: 86.94 ± 8.8	I4: 83.91 ± 6.13 ↓ C4: 85.23 ± 7.8 ↓	Non-specified (there were few cases of abdominal discomfort)
Sone *et al.* (27)	I5: 24.6 ± 4.3 C5: 24.5 ± 4.2	I5: 24.0 ± 4.1 ↓ C5: 24.1 ± 3.9 ↓	I5: 85.0 ± 12.7 C5: 85.7 ± 4.2	I5: 82.7 ± 12.2 ↓ C5: 83.9 ± 11.4 ↓	No

N/A: Not applicable

Table 4. *ANOVA of average BMI reduction between the groups with distinct ratios female/male*

	Sum of Squares	*df*	Mean Square	*F*	*p*
Ratio female/male	3.57	3	1.19	1.09	0.472
Residuals	3.27	3	1.09		

df: degrees of freedom

Figure 1 shows a direct relationship between daily catechin intake and reduction of BMI (Pearson's coefficient = 0.67). However, it is important to bear in mind that these interventions had different duration and that might have impacted the final outcome. Yet, since the Pearson's coefficient shows an acceptable correlation between the daily intake and BMI loss, it is possible that green tea induces weight loss to a certain threshold at which BMI maintains steady. Brown *et al.* (23) conducted their study through eight months but there is no information on the gradual weight loss during this period and it makes difficult to know if such threshold exists through their observations. Since the impact of green tea on BMI has already been demonstrated, further analysis should be longitudinal to clarify the dynamics of weight loss over time.

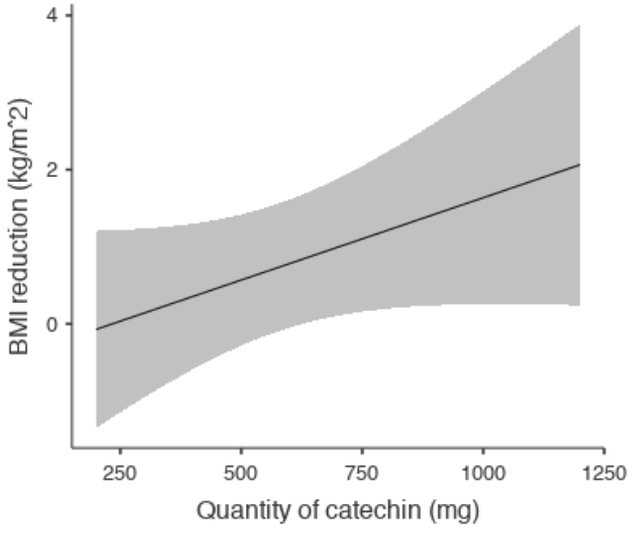

Figure 1. *Relationship between daily intake of catechin and BMI loss. The shade represents 95% confidence interval. The negative values of the vertical axis represent weight gain.*

Results were not considerably different regarding waist circumference. Nabi *et al.* (20) again indicated the most pronounced reduction (3.86cm), certainly because the patients received higher daily doses of catechins and caffeine. The average reduction for all studies (in which it was measured) was 1,5cm. Wang *et al.* (21) did not find increased concentration of green tea to be directly proportional to reduction of waist circumference, but, the final outcome (the final size) was proportional to the concentration. It sustains the previous conclusion that there is a threshold at which green tea exerts its weight reducing effects, depending on particular variables still to be considered (possibly genetic, physiological or morphological, lifestyle, environmental, etc.). It is equally important to observe that most subjects Wang *et al.* (21) studied were not obese but rather overweight, and considering the standard deviations, very few were likely obese in comparison to the entire sample. Thus, perhaps tea only reduced the body fat into an "optimal" range. There is no agreement about such value, as it depends on several factors, but WHO Expert Consultation (18) showed that risk for cardiovascular disease increases considerably when the circumference is within the range 85-95cm. Thus, the results show that the mixture of catechins and caffeine in green tea is beneficial for the reduction of waist circumference. Hursel *et al.* (25) made similar observations through another meta-analysis and this reinforces the idea of green tea as regulator of human BMI.

Regarding adverse effects, Brown *et al.* (23) and Nabi *et al.* (20) reported few cases in which patients reported slight abdominal discomfort. However, such effects did not require hospitalization or any special treatment. Furthermore, there is no evidence indicating that green was the sole cause, or the cause at all, of the adverse effects.

4. CONCLUSION

The current study suggests that green tea can be a reliable alternative to treating overweight or obese patients, since it was effective, well-tolerated, with no significant adverse effects. However, there is a need to expand the study, explore it for longer periods and longitudinally, to find out how green tea extract functions over time and determine the doses or adequate posology for the treatment of obesity. The method can be coupled with other treatments such as diets and physical exercise. Larger samples might further improve the results.

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Clinical and Experimental Health Sciences

Evaluation of Drug-Related Problems in a Pediatric Bone Marrow Transplantation Unit Identified by a Clinical Pharmacist in-training in a 7-Month Period

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ABSTRACT

Objective: This cross sectional study was performed to demonstrate the importance of clinical pharmacists' participation in pediatric hematopoietic stem cell transplantation patient management with regards to the detection, prevention, and management of drug-related problems.

Methods: The study was carried out from 1st October 2015 to 1st May 2016 in a pediatric bone marrow transplantation unit of a tertiary care hospital. The inpatients and outpatients between 0 to 18 years of age were included and the patients were monitored and evaluated for drug-related problems (interactions, side effects, preparation, and administration). A clinical pharmacist-in-training made recommendations to the physicians and the nurses on the problems that were identified.

Results: Twenty inpatients and twenty-two outpatients were monitored during the study. In total, 245 problems were identified in the inpatients, 37.14 % of which were drug-related; 33 % of the drug-related problems were the side effects of cyclosporine. Eleven recommendations on drug-related problems were made to the physicians and six of them were for the problems identified in the inpatient services with regards to drug dosing and administration. Five recommendations regarding total parenteral nutrition, drug incompatibility, drug administration from the feeding tube, and drug side effects were made to the nurses. Twenty-nine information on the dosing, side effects, incompatibilities, administration, and preparation of the drugs, were given by the pharmacist to the physicians and the nurses.

Conclusion: Clinical pharmacists' participation will improve the detection and the management of drug-related problems in pediatric hematopoietic stem cell transplantation units in Turkey.

1. INTRODUCTION

Hematopoietic Stem Cell Transplantation (HSCT) is currently a common medical practice in the world; it is performed on > 40,000 patients annually as reported in European Blood and Marrow Transplantation Registry (1). HSCT procedure involves several stages consisting of the administration of highly toxic preparative regimens (chemotherapy and/or radiotherapy), intravenous (IV) infusion of hematopoietic stem cells, administration of prophylactic and supportive medications for the prevention of side effects, and administration of medications for the treatment /management of complications (2-4). The use of polypharmacy for prophylaxis and treatment may lead to adverse effects and drug interactions (5,6). Because of the pharmacokinetic differences in the childhood and adulthood stages, it is necessary to be more careful in monitoring adverse and side effects in pediatrics (7).

The exponential increase in HSCT activities has led to the inclusion of pharmacists in HSCT practice throughout the world. Clinical pharmacists have become critical members of HSCT teams for the last 10 years (6). The presence of a clinical pharmacist in the HSCT team is an approach aimed at improving the quality of care, through their contribution to detection, prevention and management of drug-related problems (DRPs) (8,9). The involvement of a dedicated pharmacist is particularly important in pediatric HSCT practice because children are highly prone to the side effects of drugs due to pharmacokinetics reasons (10). Many transplantation units in developed countries have pharmacy staff in their multidisciplinary teams who routinely attend clinical rounds and are actively involved in the management of DRPs and in decision making. However, this has not become a standard practice in most of the units in the developing countries including Turkey. The involvement of a clinical pharmacist in a HSCT team has become a requirement in the recent editions of the Joint Accreditation Committee of International Society for Cellular Therapy-European Group for Blood and Marrow Transplantation/The Foundation for the Accreditation of Cellular Therapy standards, and this is expected to play a role in generalizing this practice for all HSCT Units (11).

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HSCT activities have risen sharply in Turkey since 2010 and approximately 3500 transplantations are performed annually with one-fourth of those in children (12). In pediatric practice, due to the heterogeneity of diagnoses, transplantation practice necessitates an age and diagnosis specific approach in the management of patients, including the choice and the administration of medications. Therefore, there is a need for the active involvement of pharmacists in pediatric practice, particularly in centers performing transplantation in complicated patients with primary immunodeficiency, inborn errors of metabolism, or systemic problems.

The present pilot study was performed to investigate the role of a clinical pharmacist-in-training in the detection and the identification of DRPs in pediatric HSCT patients in a given period, and to assess the impact of this practice on patient management, with regards to the sharing of information by the clinical team members.

2. METHODS

This study was carried out from 1st October 2015 and 1st May 2016 in a tertiary care hospital's pediatric bone marrow transplantation unit, as a prospective observational study. A written informed consent was obtained from the patients or their parents and the study was ethically approved by the Hacettepe University Ethics Committee of Non-Interventional Clinical Investigations (GO 15 / 596-04, dated 21.10.2015). Inpatients and outpatients between 0 to 18 years of age were included in the study. Patients who did not want to take part in the study and those who had a short-term hospitalization period of drug administration were not included in the study.

The pharmacist was a graduate student (Masters) in the clinical pharmacy program. The treatment of the inpatients was prospectively monitored. The pharmacist attended the physicians' visits in the inpatient service between 9 am and 12 am, 4 days a week. The outpatients, using at least one drug, were followed up with face-to-face interviews conducted by the pharmacist once a week. Patient information was collected daily, through chart review.

The assumed DRPs were identified, and the side effects were observed. Pharmaceutical Care Network Europe defines a drug related problem as "an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes". Drug related problems in this study were identified according to above mentioned definition. To distinguish disease and drug related side effect, suspected drug was stopped or the dose was decreased and the given symptom was evaluated again. If the symptom disappeared or was relieved, it was accepted as drug related. Drug orders were evaluated with regards to supportive therapy doses, the duration of treatment, and drug interactions in accordance with current guidelines and publications. The blood levels of narrow therapeutic index drugs were monitored and evaluated. The recommendations of the pharmacist with regards to dose adjustment, drug interactions, and the alteration of drug administration times were negotiated verbally with the physicians. For the evaluation of side effects, pharmacokinetic information and drug interactions, Micromedex Solutions®, Medscape® and UpToDate® online sources were used.

IBM SPSS version 23 program was used for the statistical analysis of the data in the study. The distribution of the data was calculated through descriptive statistics.

3. RESULTS

During the study period, the pharmacist monitored 20 inpatients and 22 outpatients (median ages = 8, ranges = 0.6-17 and 2-17 years, respectively). All the patients received transplants from family donors, except one autologous. A total of 177 patients visited the HSCT outpatient clinic and only 56 of them were receiving more than one medication in the study period. These patients visited the outpatient clinic at least once after HSCT. The pharmacist interviewed only 22 outpatients (10 of them were inpatients, and they were included after they were discharged once during the study period).

The demographic data of the patients are summarized in Table 1. In the majority of the inpatients, the primary diseases were acute lymphoblastic leukemia (ALL), thalassemia major and Fanconi anemia; and in the outpatients, the primary diseases were thalassemia major, ALL and Wiskott-Aldrich syndrome, respectively.

Table 1. *Demographic data of inpatients and outpatients*

		Inpatients (n = 20)	Outpatients (n = 22)
		n (%)	n (%)
Gender	Female	4 (20.0)	8 (36.4)
	Male	16 (80.0)	14 (63.6)
	Total	20 (100)	22 (100)
Disease	ALL	5 (25.0)	4 (18.2)
	Thalassemia majör	3 (15.0)	8 (36.4)
	WAS	2 (10.0)	2 (9.1)
	Fanconi anemia	3 (15.0)	1 (4.5)
	Other diseases*	7 (35.0)	7 (31.8)
Transplantation Type	Allogeneic	19 (95.0)	22 (100)
	Autologous	1 (5.0)	-
Stem cell source	Peripheral stem cell	4 (20.0)	2 (9.1)
	Bone marrow	16 (80.0)	20 (90.9)
Donor	Sibling	13 (65.0)	18 (81.8)
	Non-sibling but family member	7 (35.0)	4 (18.2)
Preparative regimen	Myeloablative	16 (80.0)	19 (86.4)
	Reduced intensity	4 (20.0)	3 (13.6)

ALL: Acute lymphoblastic leukemia, WAS: Wiskott Aldrich Syndrome. Sibling donor means patient's sister or brother, Non-sibling but family members (haploidentical): mother, father, aunt, and cousin. Other diseases: there was one inpatient for each disease-osteopetrosis, neuroblastoma, congenital neutropenia, adrenoleukodistrophy, lipopolysaccharide-responsive beige-like anchor gene defect-immunodeficiency, and juvenile myelomonocytic leukemia. There was one outpatient for each disease-osteopetrosis, immunodeficiency due to osteopetrosis, adenosine deaminase enzyme deficiency, aplastic anemia, acute myeloid leukemia, congenital neutropenia, and myelodysplastic syndrome*

A total of 245 problems were encountered in the inpatients. The most common problems were; low-grade fever (fever between 37.5° C and 38.3° C), neutropenic fever, nausea, vomiting, and diarrhea, which were observed in nearly all the patients. The problems are summarized in Table 2. Of the problems, 91 were DRPs. The DRPs are summarized in Table 3. The majority (33 %) of the side effects was associated with cyclosporine. Furthermore, most of the detected side effects could not have been prevented because they were associated with essential HSCT drugs which could not have been withdrawn. Cyclosporine, methotrexate, and caspofungin-related side effects such as hypertension, dyslipidemia, and hyperglycemia were managed by the adjustment of drug doses. After the detection of the side effects related to the above mentioned drugs by the pharmacist, the physicians were informed and the necessary adjustments on drug dosages were made with the consensus of the pharmacist and the physicians.

Table 2. *Distribution of problems.*

Problems	Number (n)	Percentage (%)
Nausea	15	6.1
Vomiting	13	5.3
Diarrhea	13	5.3
Low grade fever	11	4.5
Neutropenic fever	8	3.3
Increase in CMV copy	8	3.3
Chronic GVHD	8	3.3
Cytopenia	5	2.0
Others	73	29.8
Drug-related problems	91	37.1
Total	245	100

CMV: Cytomegalovirus, GVHD: Graft versus Host Disease. Others: Acute GVHD, bacterial catheter colonization, Engraftment Syndrome, hypotension, tachycardia, bradycardia, hypothyroidis, electrolyte imbalance, catheter infection, convulsion, pancreatitis, cellulite, cough, weight loss, stomachache, epigastric pain, headache, hyperemia, bacterial colonization in urine culture, CMV retinitis, hypotermia, refractory thrombocytopenia, dysphagia, hemolysis, gastrointestinal bleeding, cortical blindness, respiratory arrest, angioedema, feeding problem.

Sixteen consultations were given to the physicians. They included those on side effects (25 %), dosing and administration (25 %), drug blood levels (12.5 %) and others (12.5 %).

In total, six recommendations were made to the physicians for the problems identified in the inpatients with regards to drug dosing and administration. One recommendation was about changing the dosage schedule of interacting medicines, three recommendations were about reducing the dose, one recommendation was about converting 'thrice daily dosing' of amikacin to 'single daily dosing', and one recommendation was about switching to another formulation. Except one, which was about dose reduction, all the recommendations were accepted by the physicians.

Table 3. *Distribution of drug-related problems.*

Problems	Number (n)	Percentage (%)
Preparative regimen related mucositis (stage 1-2-3-4)	43	47.2
Cyclosporine induced triglyceride and cholesterol levels elevation	7	7.7
Chemotherapy or cyclosporine induced hypertension	18	19.8
Steroid induced hyperglycaemia	4	4.4
Cyclosporine-caspofungin interaction induced increase in liver transaminases	3	3.3
Methotrexate induced increase in liver transaminases	2	2.2
Cyclosporine induced posterior reversible encephalopathy syndrome	2	2.2
Intravenous immunoglobulin related fever and rash	2	2.2
Others	10	11.0
Total	91	100

Others: There was one patient for each problem; renal dysfunction after foscarnet administration, etoposide related hyponatremia, etoposide related hypokalemia, fever after Anti-thymocyte globulin administration, high dose administration of tacrolimus, foscarnet related nausea, foscarnet related vomiting, azacitidine related diarrhea, azacitidine related weight loss and regimen related hemorrhagic cystitis.

Five recommendations were made with regards to the outpatients; two of them were about dissolving the drug in apple juice to aid swallowing, two were about changing the administration times of interacting drugs, and the last recommendation was about addition of a new drug for an untreated indication. Except the addition of a new drug, all the recommendations were accepted by the physicians. At outpatients, the problems observed directly by pharmacist was evaluated so the other problems such as diarrhea, vomiting, etc. could not be assessed in the limited interview time.

A total of five recommendations were made to the nurses. Two of the recommendations were about the preparation of the drugs, one was about preventing the precipitation in the total parenteral nutrition (TPN) tract, one was about drug administration through an enteral feeding tube, and the last recommendation was about the prevention of side effects. The total 13 consultations given to the nurses were about drug-drug incompatibilities (46.2 %), drug preparation and administration (30.7 %), and TPN-drug incompatibility and drug administration time (23.1 %). Necessary actions were taken by the nurses.

4. DISCUSSION

In the literature, there are several studies showing clinical pharmacists' impact, especially on the detection of medication errors, prevention of drug-drug interactions and development of supportive treatment for adverse reactions in pediatric HSCT units. Nevertheless, in Turkey, including the department where this study was conducted, clinical pharmacists are not routinely involved in these activities.

In the present study, we investigated the role of a clinical pharmacist-in training in the detection and the prevention of DRPs in pediatric HSCT patients in Turkey for the first time. We evaluated the complications encountered during the transplantation period and the problems caused by the drugs. Furthermore, we recorded the outcomes of the recommendations of the pharmacist on the HSCT activities. Before the clinical pharmacist's participation, the whole process of the HSCT was being monitored by only the physicians and the nurses, wasting their limited resources and time for DRPs.

The most common DRPs identified were mucositis, dyslipidemia, hypertension, and hyperglycemia.

Oral mucositis develops in 75–85 % of patients who undergo a myeloablative preparation regimen (13,14). In a meta-analysis, 79 % of the patients receiving the myeloablative regimen and 71 % of the patients receiving non-myeloablative regimens had severe mucositis (grade 2, 3, 4) according to the World Health Organization and the National Cancer Institute (NCI) toxicity criteria (15). In our study, all the patients had grade 1 mucositis (according to NCI-Common Toxicity Criteria version 2.0). Grade 4 mucositis (mucositis requiring TPN) was seen in 30 % of 20 patients. In our study, the rate of grade 1 mucositis was similar to those of other studies; however, the rate of severe mucositis was lower than that of other studies owing to the effective preventive and supportive treatments for mucositis in our unit.

Dyslipidemia is a late-onset post-transplantation problem associated with factors such as obesity, genetic lipid disorders, primary disease, transplantation, and its complications, TPN, use of cyclosporine, chronic graft versus host disease (GVHD), and individual condition and other diseases. Dyslipidemia observed in the early post-transplantation period is associated with calcineurin inhibitors (16,17). In a study conducted by Mehdizadeh et al. (18), 95 % of adult patients using cyclosporine had dyslipidemia. In our study, we found that 35 % of the patients on cyclosporine developed dyslipidemia. There was a decrease in the basal levels of triglyceride and cholesterol when the dose of cyclosporine was reduced; hence, we inferred that dyslipidemia was associated with cyclosporine in our patients.

Hypertension, a result of preparative regimens and immunosuppresants, is frequently observed in pediatric patients. It has been demonstrated that cyclosporine, one of the causes of hypertension, significantly increases blood pressure in studies in comparison with placebo (19). In Kishi and his colleagues' study (20), cyclosporine dose needed to be reduced in 64 % of adult patients because of the incidence of hypertension. In the present study, almost all the patients had elevated blood pressure (>140/90 mmHg) at least once during the study. The exact cause of hypertension has not been clearly elicited, but it has been considered as a side effect of calcineurin inhibitors and preparative regimens including total body irradiation. In this study, unlike the other studies, cyclosporine dose was not modified, but hypertension was managed with antihypertensive treatment.

Calcineurin inhibitors and corticosteroids are important drugs used in the prophylaxis and treatment of GVHD through immunosuppression. However, as a result of long-term use of steroids, side effects such as hyperglycemia and prolonged hospitalization are observed in patients (21). In Fuji and colleagues' study (22), 64 % of patients' fasting blood glucose values were higher than 126 mg/dl. In the present study, 14 patients (70 %) had a higher fasting blood glucose level than 126 mg/dl, and hyperglycemia (> 200 mg/dl) was observed in four patients due to a long-term use of steroid. The results showed that steroid and calcineurin inhibitors should be used carefully, and patients' blood glucose levels should be monitored regularly in terms of the other factors that might influence the blood glucose levels, such as TPN.

The studies carried out in more developed HSCT units showed that collaborations between pharmacists and physicians increased the quality and efficiency of the patients' care. The establishment of a system, in which physicians and pharmacists negoitate on DRPs, will positively affect the health outcomes of the patients and also alleviate the workload of the physicians (23). In our study, DRPs were generally known as the side effects of drugs, and they were checked by considering the patient's individual response in the treatment process. Nonetheless, the adverse effects occurred due to the essential drugs (immunosuppressants) for HSCT, and these drugs could not be withdrawn. Compared to the in this study the number of recommendations made by the pharmacist for the detected errors was very few. Most of the recommendations were about the regulation of drug administration times of interacting drugs. A good documentation of the HSCT treatment process in our unit such as the lists of the calculated doses of the drugs per kilogram for each patient, contributed to the reduction of medication errors. Also, the presence of experienced physicians and nurses in the team had a positive impact on the treatment outcomes.

In the outpatients as well as in the inpatients, the regulation of the administration times of different drugs causing pharmacokinetic interactions when given at the same time, and suggestions such as the mixing of drugs with apple juice for patients who had difficulty in swallowing were the interventions made by the pharmacist.

In one of the studies conducted in the pediatric HSCT units, clinical pharmacists' involvement had significant contribution to the development of the protocols for the prevention of adverse effects and drug interactions through the adjustment of drug doses and the selection of appropriate supportive treatments (such as pain management and mucositis prevention) for complications (6). During the seven-month period of our study, consultancy on different issues was provided by the pharmacist to the physicians. The majority of the consultations were about side effects, dose adjustment, and information on unexpected symptoms in the patients. The rates of consultation and intervention on drug dose adjustment and drug side effects in this study were similar to those in the literature (24-26).

Drug administration errors are common problems (19–27 %) and have negative consequences for patients. Particularly, the preparation and the administration of IV drugs involve more than one step, thus, giving room for mistakes (27). Ghaleb et al. (28) reported that, errors in drug administration and the wrong infusion of IV drugs were the most common problems in pediatric patients. In this study, when the pharmacist's consultations with the nurses were evaluated, we found that the majority of the problems originated from drug incompatibilities and difficulties in drug preparation processes. In our study, nurses needed pharmacist's support mostly in the same fields as reported in the literature. One of the recommendations made was the preparation of cyclosporine infusion not only with dextrose, but also with saline. This suggestion hastened the preparation of cyclosporine infusion.

5. CONCLUSION

This study, being the first to evaluate a clinical pharmacist's role in the pediatric HSCT unit in Turkey, can be a guide for other HSCT units in our country. However, the seven-month study period, and the small number of participating patients were considered as limiting factors. In order to demonstrate a clinical pharmacist's role more effectively, a larger number of patients will be required.

The administration of cytotoxic drugs at high doses, a high probability of complications, and the use of a large number of high-cost drugs necessitate the care of a multidisciplinary team during the long and complex process of HSCT therapy. As HSCT team members, clinical pharmacists can evaluate all clinical findings related to drugs, they can check doses, identify drug interactions, prevent side effects, and provide recommendation for drug preparation and administration. Therefore, the support of a clinical pharmacist to physicians and nurses will help to prevent possible DRPs, and generally improve the success of HSCT.

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Clinical and Experimental Health Sciences

Does Kinesiophobia Effect One Day Physical Activity Behaviour and Functionality of Young People with Ankylosing Spondylitis?

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ABSTRACT

Objective: The aim of this study was to investigate the relationship between kinesiophobia, physical activity behaviour and functionality in patients with ankylosing spondylitis (AS).

Methods: This study included 57 participants (mean age, 30.8 ± 5.19 years) in 2 groups of AS and healthy controls. One day physical activity behaviour was evaluated with tri-axial accelerometer. Tri-axial accelerometer was recorded physical activity domains and intensities for 24 hours. Participants completed clinical questionnaires assessing pain, kinesophobia, disease activity, and functionality. Kinesiophobia and pain were quantified by the Tampa Scale for Kinesiophobia and Short-Form McGill Pain Questionnaire. Function and disease activity were rated by using the Bath Ankylosing Spondylitis Functional Index, and Bath Ankylosing Spondylitis Disease Activity Score.

Results: There was no correlation between kinesiophobia and one day physical activity behaviour in AS patients group. There was a negative correlation between high physical activity level and disease activity($p<0.05$, r:-.519) and there was a negative correlation between high and moderate physical activity levels, and functionality ($p <0.05$, r:-.555 r:-395, respectively).

Conclusion: According to the results of this study showed that; there was a relationship between disease activity, functionality, and one day physical activity behaviour. On the other hand, there was not any relation between pain intensity, kinesophobia and data obtained from accelerometer. Further studies with larger sample size and longer time periods should be carried out to reveal physical activity behaviours and its related factors in AS patients who will survive with this disease for years.

Keywords: ankylosing spondylitis, disease activity, functionality, kinesophobia, physical activity

1. INTRODUCTION

AS is a rheumatic disease characterized by inflammation, pain, and stiffness especially in the spinal column and sacroiliac joints (1,2). The disease is prevalent between the ages of 20 and 30 which is an important period in lifespan for career stages and performing physically active life (3).

AS restrains individual's physical capacity and results in reduced participation in physical activity in their daily living due to restricted respiratory functions, pain, limitation of joints and spinal motions (4). Since it is well known that participation in regular physical activity can prevent chronic systemic diseases and improve musculoskeletal health, it is important to encourage AS patients to avoid getting into this vicious cycle (limited physical activity due to symptoms and exacerbated symptoms due to limited physical activity) (5). Therefore, it is a prerequisite to examine the factors that cause physical activity limitation, especially in adult AS patients who will survive with this disease for years.

Recently, some factors that influence physical activity have been identified by few researches (6-8). Disease activity, pain, depression, flexibility and respiratory functions are some of them. But there are few studies investigating the kinesiophobia which is defined by Kori et al,'a fear of movement resulting from a feeling of vulnerability to painful injury or reinjury' (9, 10). It is assumed to be pain-related experiences, combined with kinesiophobia, may be more disabling than pain itself.

Functionality in daily living is an other crucial factor to maintain qualified life especially in young ages. Mobility restrictions of spine and pain are one of the limiting factors for functionality. Nas et al. have revealed this relation in AS (11). But, we have not known yet if kinesiophobia affects the physical activity behaviour and functionality in AS patients.

We suggest that it is important to identify the physical activity behaviour of patients with AS at young ages, firstly. Secondly,

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factors relating with AS that cause limitations in physical activity and functionallity should be revealed to be able to overcome these obstacles. Therefore, the aim of the study was to investigate the relationship between kinesiophobia with physical activity behaviour and functionality in young patients with AS.

2. METHODS

2.1. Study design and recruitment

The study was designed as a cross-sectional observational. It was carried out between December 2015 and May 2016, with patients who were diagnosed as AS, in rheumatology clinic, in Istanbul University-Cerrahpasa, Cerrahpasa Faculty of Medicine Hospital. Forty-two AS patients were screened for possible inclusion criteria whereas thirty AS patients agreed to participate in the study and twenty-seven age-matched healthy people were included into the control group. Patients with AS were recruited from a register of patients fulfilling the Newyork Classification Criteria, diagnosed by a rheumatologist at Istanbul University-Cerrahpasa, Cerrahpasa Faculty of Medicine Hospital, Istanbul. Eight patients withdrew from the assessment and four did not attend the accelerometer assessment, leaving a total of 30 patients who completed the study (Fig 1). Controls were recruited from the healthy hospital staff member with age matched AS patients. Participants in control group did not report any pain complaint.

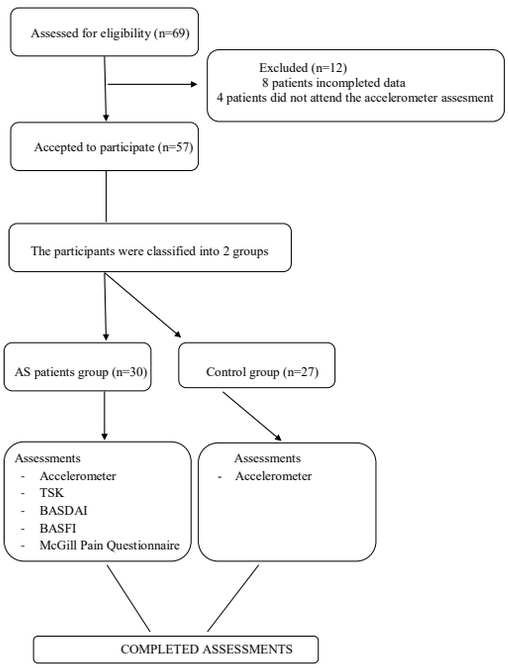

Figure 1. *Design of the study*

To participate in the study, subjects should have been between 20-40 years old, should have had the absence of lower extremity involvement, should have agree to participate in the study, and sign an informed consent form. The exclusion criteria were having the cognitive disorder, the neurological deficit in lower limbs, visual, auditory, vestibular problems that could affect the independent walk. AS patients continued similar medical treatment in their routine.

Each participant who completed a recruitment screening received written and verbal explanations of the procedures to be applied. They were all asked to participate on a voluntary basis. The project observed the principles outlined in the Declaration of Helsinki of 2013, and the study protocol was approved by the Human Research Ethics Committee of Marmara University (Institutional Review Board No: 30.11.2015-4).

2.2. Assessment

The evaluation was comprised of questionnaires parts and accelerometer measurements. The characteristics of participants (age, gender, weight, height, employment, education, regularly exercise habit) were questioned by the *Socio-Demographic Data Form.* Participants were asked to complete the questionnaires, which assessed disease activity, functionality, kinesophobia, pain intensity. Physical activity level was assessed with triaxial accelerometer. Tampa Scale for Kinesiophobia (TSK) was used to measure kinesiophobia scores. The pain was evaluated with Kısa Form-McGill Pain Questionnaire (SF-MPQ), disease activity was evaluated with Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), functionality was evaluated with Bath Ankylosing Spondylitis Functional Index (BASFI). All measurements were performedby the same physiotherapist for 2 groups.

2.3. Physical activity measurement

The one day physical activity behaviour was assessed according to the results of the triaxial accelerometer device manufactured by Maastricht University in the Netherlands (MOX). Accelerometer was recorded for 24 hours for each case, from 08:00 am until the next morning 8:00 am.

Records were uploaded to the computer program and the data was saved. A day was chosen when he/she continued any daily activities except Sunday, and he/she was moved in the middle of his/her pants belt. Participants measured minute by minute accelerations (expressed as counts) in the anteroposterior, mediolateral, and longitudinal axes of the trunk. Total sedentary time (sitting/reaching), total standing time, total light physical activity time, total moderate physical activity time, total high physical activity time were recorded (minutes per day) (12).

2.4. Disease-related variables

TSK consists of the 17 items that are rated using a 4-point Likert scale whereby 1 = strongly disagree and 4 = strongly agree. The total kinesophobia score is the sum of responses to all 17 items. The total score ranges from 17 to 68 points, with higher scores indicating the presence of kinesophobia.

The TSK is a reliable and valid instrument for the assessment of kinesophobia in the Turkish population (13).

Pain severity and localization of the cases were evaluated according to the results of SF-MPQ. It consists of 15 descriptive adjectives for the pain sensation, which are self-rated by the patient (range from 0-3 points (from none to severe). The total score is the sum of the intensity values of words chosen for sensory, effective and total descriptors. The SF-MPQ includes a pain intensity measure indicated by the visual analog scale (VAS) (14). The SF-MPQ is a valid construct within the Turkish culture (15).

BASDAI was used for an assessment of the disease activity. Six questions were asked. Fatigue, pain, discomfort, swelling was questioned in the first five questions.In the sixth question, the patient described their "morning stiffness". The patients scored between 0 and 10, with 0 indicating no and 10 indicating very severe. The total BASDAI score was calculated by the average of the scores obtained from the fifth and sixth questions and the sum of all the items and dividing them by 5. ((1+2+3+4+(5+6/2))/5). The BASDAI is a valid construct within the Turkish culture (16).

BASFI consists of the 10 items that are rated by using a 10 cm visual analog scale whereby 0 = easy and 10 = not possible, for each activity. The score is sum of all the items and dividing them by 10. Higher scores indicate less functionality. The Turkish version of the BASFI has been shown to be a valid and reliable scale for the assessment of functional status (17).

2.5. Statistical analysis

The SPSS version 21.0 for Windows was used to evaluate data and analyze descriptive statistics (frequency, mean, SD). Statistical analysis was performed at a 95% confidence level, and the *statistical significance* level was set as 0.05. In the present study, conformity to normal distribution was analyzed using the Shapiro–Wilks test. Descriptive statistics were used for demographic variables. Independent sample t-test (parametric test) and Mann Whitney U test (nonparametric test) were used to analyze the continuous variables. Intercorrelations between the one day physical activity behaviour, pain, kinesophobia, disease activity and functionality parameters were analyzed using by Spearman correlation analysis (specifically, r= 0.5-1.0 was large; r= 0.30-0.49 was medium, and r= 0.1-0.29 was small).

3. RESULTS

The comparisons of the demographic and clinical characteristics of the groups are shown in Table 1. No significant differences were found between the groups in regards to the demographic characteristic (age, weight, height, BMI, employment, regularly exercise habits parameters) (p> 0,05). The TSK score average was 46.56 (± 5.41), the McGill pain questionnaire score average was 24.76 (± 6.91), the BASDAI total score average was 5.64 (± 1.30), and the BASFI total score average was 3.78 of the AS patients group (Table 1). AS group's kinesiophobia levels and disease activities were found to be high. At the same time, functionality were found to be low.

Table 1. *Demographic and disease-specific variables*

	AS (n=30)	Controls (n=27)	p[a]
Demographic			
Age (years)	32.6±5.04	28.9±4.73	0.06
Female sex (n/%)	15 (50%)	21(77.7%)	0.03
Weight (kg)	67.3±9.53	64.1±13.4	0.29
Height (cm)	167±8.54	166±7.30	0.63
BMI (kg/m^2)	23.9±2.69	23±3.95	0.28
Employment (n/%)	20 (66.7%)	17 (62.9%)	0.77
Education≥12 years (n/%)	14 (46.7%)	25 (92.5%)	0.001
Regulary exercise habits (n/%)	4(13.3%)	3(11.1%)	0,79
Disease characteristics			
Because of AS, applying to Physiotherapy and Rehabilitation Units	1(3%)	N/A	
BASDAI	5.64±1.3	N/A	
BASFI	3.78±1.91	N/A	
McGill Pain Score	24.76±6.91	N/A	
TAMPA Kinesophobia Score	46.56±5.41	N/A	

BMI:Body Mass Index, AS: Ankylosing Spondylitis, BASDAI Bath Ankylosing Spondylitis Disease Activity Index, BASFI Bath Ankylosing Spondylitis Functional Index, N/A: not assessed, number of participants (%) and Mean (standard deviation), unless otherwise stated.p[a] Independent-samples t-test

Moderate level physical activity time was lower in AS group than controls (p<0.05) while there was no statistically significant difference in other domains of physical activity (total sedentary, standing, light and highlevel physical activity time) (Table 2).

Table 2. *Daily physical activity behaviour in different domains, in patients with AS and controls*

	AS (n=30)	Controls (n=30)	t[a]	p[a]
Domains (minutes)	Mean±SD	Mean±SD		
Sedantery	786.7±404.5	1045.7±408.2	-2.4	**0.02***
Standing	377.9±175.2	379.2±198.7	-0.02	0.97
Moderate	64.2±45.4	91.1±52.8	-2.07	**0.04***
Domains (minutes)	Mean±SD	Mean±SD	**z**[b]	**p**[b]
Light	9.46±5.1	13.9±16.4	-0.32	0.97
High	2.70±7.86	5.66±13.2	-1.43	0.15

SD:Standart Deviation, min:minimum, max:maximum. [a]Independent-samples t-test, [b]Mann Whitney U Test

Disease activity was found to be correlated with total high level physical activity time (r: – .519, p<0.05). As the BASDAI total score increased, the severity of physical activity decreased. Therefore, functionality was found to be correlated with total moderate and high level physical activity time (p <0.05, r: – .555 r: – .395, respectively) (Table 3). When the BASFI total

score decreased, total moderate and high physical activity time increased.

On the other hand, no correlation was found with kinesiophobia, pain and one day physical activity behaviour (p> 0.05) (Table 3).

Table 3. *Comparison between results of accelerometer and TAMPA Kinesophobia Score, McGill Pain Score, BASDAI, BASFI*

Variables (AS) (n=30)	TAMPA Kinesiophobia Score	McGill Pain Score	BASDAI	BASFI
Sedentary	rh_o – .109 p .567	-.035 .855	-.206 .275	-.185 .327
Standing	rh_o – .018 p .925	-.205 .278	-.078 .680	-.115 .546
Light	rh_o .142 p .454	-.026 .893	.029 .878	-.187 .321
Moderate	rh_o .027 p .888	-.057 .765	-,113 .551	-.395* **.031**
High	rh_o – .307 p ,099	-.254 .176	-.519** **.003**	-.555** **.001**

BASDAI Bath Ankylosing Spondylitis Disease Activity Index, BASFI Bath Ankylosing, Spondylitis Functional Index, Spearman Correlations Test.

4. DISCUSSION

Current study examine the presence of kinesiophobia and its correlation with physical activity behaviour in patients with AS. On the basis of the our study's results, it is worthwhile to note that 96.7% AS patients in the current study had high kinesiophobia levels. Moderate level physical activity time was lower in AS group than controls. AS groups' disease activities were found to be high. There was no correlation with kinesophobia, pain and physical activity behaviour. However, there was a negative correlation between disease activity and total high level physical activity time. In addition, there was a negative correlation between functionality and total moderate and high level physical activity time, too.

Interestingly, our results showed that physical activity levels of AS patients aged 20-40 years were not affected by high kinesophobia and pain intensities. Most of the studies investigating kinesiophobia were carried out on musculoskeletal disorders and some of them involved ankylosing spondylitis, Sjögren's syndrome, fibromyalgia, osteoarthritis(specially knee) among rheumatical diseases (10, 18, 19, 20). Er G. et al, investigated relation between kinesophobia and respiratory functions in AS (20-70 years). Their study did not find a significant relationship between TSK values and respirotary functions and endurance (21). Swinnen et al, reported that TSK-11 is a promising and valid tool to assess fearful beliefs in relation to activity limitations in axial spondyloarthropathy (22). In recent study Oskay et al, examine the level of kinesiophobia and its correlation with some clinical variables in patients with AS (mean age 37.6±10 years) (10). They found that, AS patients had high kinesiophobia level (≥37) and there was a correlation between kinesiophobia and physical function (assesed by BASFI), but kinesiophobia was not correlated with disease activity or mobility levels. In the current study, AS group's kinesiophobia levels was found to be high but there was no correlation between kinesiophobia and one day physical activity behaviour. However, kinesophobia affects the motivation of activity negatively (23). On the other hand, in a study published in 2016, Felicio et al. found that the pain which caused disability was not associated with a kinesiophobia in lowback pain (24).

One of the most common symptoms of AS is the pain. Fongen et al. indicated that the majority of patients had more obstacles than controls while performing physical function, these were pain-related disorders such as fatigue, stiffness, and disability. They reported that the pain and disease activity could be reduced physical activity level (25). In a study, avoidance of activity was also correlated with pain and depressionon patients with chronic pain (26). However, kinesiophobia was correlated neither with pain nor with physical activity in our study, suggesting that kinesiophobia in patients with AS was not a direct obstacle because of their young ages. Even so, this potential relationship should be investigated by further studies with greater sample size.

Moderate level physical activity time was lower in AS group than controlsand AS group spent less sedentary time in a day compared to controls while there was no statistically significant difference in other domains of physical activity (total standing, light and high physical activity time) in both groups. In a recent study showed that patients with AS had similar total physical activity, compared with controls, but may avoid in higher intensities of physical activity (25). In another study, Swinnen et al. used a limb containing two axial accelerometers and thermal sensors to evaluate physical activity, between 40 adult with spondyloarthropathies (mean age 44 ± 10 years) and 40 healthy controls. There was no significant difference between sedentary, light and moderate physical activity levels among the groups (27). Plasqui et al. compared the physical activity levels of 25 AS patients with 25 healthy adult controls (mean age 48 ± 11) using a triaxial accelerometer, and they found no significant difference in measured parameters between groups (2). Arends et al. used a uniaxial accelerometer to evaluate daily physical activity levels in patients with AS(mean age 44 years) and reported that their study had the limitations because their tool only provided single-axial motion recordings (23). The accelerometer which we used in our study (MOX) was Tri-Axis Digital Accelerometer. Three axial movements' accelerations, anteroposterior, mediolateral and vertical, can be recorded (28). The one of the possible explanation of nonsignificant difference in one day physical activity levels between healthy and AS groups in our study could be the characateristics of control group as being sedentary since their total sitting time was higher than AS group.

Another significant results of our study was the association of one day physical activity behaviour and disease related-variables(disease activity, functionality). As the total score of BASDAI increased, total high physical activity time decreased paralel with previous studies. Arends et al. showed that

high levels of physical activity were associated with low disease activity (23). Brophy et al. reported that people with moderate and low disease activity had a high level of physical activity (7). Fongen et al. compared the physical activity levels between healthy controls and AS patients (mean age 51.5 years with high disease activity and low disease activity), using the International Physical Activity Questionnaire-Long Form and found similar results (6).

In this study, we found that functionality was correlated with total moderate and high physical activity time in consistent with previous studies. O'Dwyer et al. found that there was a significant relationship between total physical activity score and BASFI scores (8). A high level of physical activity was found to be associated with good functionality by Brophy et al (7). In another study showed that, AS patients with reduced time spent in moderate and high physical activity levels had lower functionality (25).

The present study has some limitations that should be adresssed. Most importantly, the sample size was small and the medication was ongoing. Patients' physical activity could be assessed for another day, so that hartworne effect could be prevented. Included controls could have led to selection bias based on physical activity behaviours. Individuals who have different jobs characteristics should be included to avoid sedentary behaviours in control groups for the further studies investigating physical activity behaviour of AS patients.

5. CONCLUSION

In conclusion, regardless of disease activity and pain which are common symptoms in AS, kinesiophobia was present even the population was consisted of AS patients. One day physical activity monitoring in AS patients showed that they have tendency to spend time with sitting and lying, similar with healthy controls. They did not differ from controls by means of light and high level physical activity time. However, the moderate level physical activity time in AS group was considerably lower compared to healthy control group.

Kinesiophobia did not influence time spending physically active in AS patients. Further studies with larger sample size and longer time periods should be carried out to reveal physical activity behaviours and its related factors in AS patients who will survive with this disease for years.

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Clinical and Experimental Health Sciences

The Effect of Endocrinological Parameters on Sleep Quality, Life Quality, Depression and Anxiety Levels in Pregnancy

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ABSTRACT

Objectives: Examining the relation between sleep quality, quality of life, depression and anxiety levels with some endocrinological parameters in pregnancy.

Methods: The oral glucose loading test and thyroid function test results of the pregnant women who were in the 24-29th weeks of pregnancy were used in the study. Non-pregnant women, who were matched with the study group in terms of sociodemographic data, were also included in the study as the healthy control group. All participant completed a standardized sociodemographic data collection form and the following scales; Beck Depression Inventory (BDI), Beck Anxiety Inventory (BAI), Pittsburg Sleep Quality Scale (PDCA), Quality of Life Scale (SF-36).

Results: No significant differences were detected between the sociodemographic data of the participants except for the educational status and living area. As a result, statistically significant differences were detected between the "sleep latency" (p=0.016), "usual sleep activity" (p=0.004), "sleep disorder" (p=0.000) subcomponents compared to the control group. For SF-36, on the other hand, the results of the pregnant group in "physical function" (p=0.000), "physical role limitation" (p=0.002) and "pain" (p=0.000) sub-dimensions were worse than the control group. The Thyroid Stimulating Hormone (TSH) value was positively correlated with "sleep time" (r=0.233); the "fasting blood glucose" was positively correlated with "pain" sub-dimensions (r=0.497); and the "physical function" sub-dimension was negatively correlated (r=-0.192).

Conclusion: Our data suggest that the depression and anxiety scores of the pregnant women were high, and life and sleep quality was impaired in certain sub-dimensions.

Keywords: Pregnancy, depression, anxiety, quality of life, quality of sleep.

1.INTRODUCTION

The term "life quality" is used as a unifying concept, which consists of numerous areas like personal development, self-acceptance, autonomy, purpose in life, positive social relations, the order of the living environment, and psychological and physical health (1, 2). The life quality of the individual may be affected by general health and social relations, personal beliefs and relations with his/her environment (3). Sleep which has an effect on the quality of life of the person is one of the basic and indispensable daily life activities, which influences the emotional status, general health and health perception of an individual, and is a physiological need for all humans. Sleep quality is affected by environmental factors like lifestyle, business life, social and economic status, and general health status (4).

Pregnancy is a transition period with significant physical and emotional changes (5). These changes, which occur even in healthy pregnant women, affect both the quality of life and sleep quality of the pregnant women and affect the health of both mother and baby (6,7). In the light of the developments in mental health field, it was reported that psychiatric problems were common during pregnancy in the last 3 decades. Among the major ones of these problems, there are depressive disorder and anxiety disorder (8-11). The psychiatric symptoms that appear during pregnancy are attributed to hormonal and physical changes, and therefore, may go undetected. The psychiatric difficulties faced by the mother who is expecting her baby may cause negative effects on the physical and psychological development of the fetus. Also, a pregnant woman cannot prepare herself for role of a mother, life quality decreases, and conflicts may appear within the family (12). There are many studies in which the anxiety and depression levels of pregnant women are evaluated in the literature (12-15). However, studies that examine the quality of life, sleep quality, depression and anxiety levels are limited (16-20).

The aim of this study was to investigate the effect of endocrinological parameters on sleep quality, quality of life, depression and anxiety levels in pregnant women. Our first hypothesis in our study is that endocrinological parameters might be related with sleep and quality of life in pregnant

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women. Our second hypothesis is that endocrinological results and anxiety and depression levels might be correlated. Our final hypothesis is that the anxiety and depression levels of pregnant women may increase, and sleep quality and quality of life may be impaired independently from endocrinological functions. In the light of these hypotheses that are related to each other, it is considered that although there are no additional diseases, the rate of psychiatric symptoms (like anxiety and depressive symptoms) of pregnant women may increase, which might affect life and sleep quality scores. It was also hypothesized that the deterioration in one or more fields in endocrinological functions might cause more risks for psychiatric diseases. When considered from this viewpoint, having a good regulation in eating, drinking, physical activity and sleep, and psychosocial support are very important in terms of both the pregnancy period and the development of the baby.

2. METHODS

2.1. Ethical procedure

Approval was received for this study from Tokat Gaziosmanpaşa University Hospital, Non-Interventional Local Ethics Board and was carried out in line with the Helsinki Declaration.

2.2. Inclusion and exclusion criteria

The study was conducted Gaziosmanpaşa University Hospital between 05.03.2018 and 05.10.2018 as a case-control study. Pregnant women who volunteered, who were literate, able to give written informed consent and fill in the forms, and who did not have a history of psychiatric treatment, chronic renal failure, chronic liver disease, heart disease, diabetes mellitus and any known thyroid disease were included in the study. Approximately 300 randomly selected pregnant women who were at the 24-29 weeks of pregnancy were interviewed, informed about the study, and referred to the psychiatry outpatient clinic. However, only 164 pregnant women among these visited the psychiatrist, and were evaluated by the same psychiatrist. Forty-five of these pregnant women could not be included in the study; because of 13 women refused to participate in the study, 11 women did not fill in the forms and 21 women did not meet the criteria for inclusion in the trial. No data were collected from 136 women who did not come to the psychiatry outpatient clinic. The healthy control group participants was randomly selected from among women who were examined in the psychiatry outpatient clinic, and who did not have a disease to meet the criteria for diagnosis of mental health, and those who could be matched in terms of sociodemographic data like age, marital status, working status, and educational status. For this group, approximately 85 women were evaluated; however, 60 women met the inclusion criteria.

2.3. Data collection tools

The serum free T_4 (sT_4), Thyroid Stimulating Hormone (TSH), fasting blood sugar and glucose values after 75 gr glucose loading test were evaluated in the pregnant group. In addition, the Sociodemographic Data Form, Beck Depression Scale (BDS), Beck Anxiety Scale (BAS), Pittsburg Sleep Quality Scale (PSQS), Life Quality Scale (SF-36) were applied to all participants. The Socio-Demographic Data Form was applied during the interviews by psychiatrist and the other forms were filled in by the participants while they were waiting for the laboratory test results.

Sociodemographic Data Form: It was prepared in line with the clinical experience and the data obtained from the sources that were reviewed by considering the purpose of the study. It includes demographic data like age, marital status, educational status, living area, working status and economic status; and questions on clinical evaluation like the pregnancy week and whether or not the participant received psychiatric treatment before or during the study.

Beck Depression Scale (BDS): This is a self-report consisting of 21 items, and is used to determine the depression risk and to measure the level and severity of depressive symptoms. Each item is scored between 0 and 3; and the total score is between 0 and 63. As the score becomes higher, this means that the person is experiencing higher depression (21,22).

Beck Anxiety Scale (BAS): This consists of a total of 21 questions, and is used to measure the severity and level of anxiety symptoms. Each item is scored between 0 and 3. As the score becomes higher, this means that the person is experiencing more anxiety. The highest score possible is 63 (23,24).

Pittsburg Sleep Quality Scale (PSQS): This scale was developed by Buysse et al. (25); and is a self-report scale evaluating the sleep quality within the last 1 month. It consists of 19 questions and 7 components. It consists of “subjective sleep quality”, “sleep latency”, “sleep duration”, “usual sleep activity”, “sleep disorder”, “sleep drug use” and “daytime function disorder” components. The scores of the 7 components and the total score are calculated. The total score being ≤ 5 shows “good sleep quality”, > 5 shows “bad sleep quality” (26).

Life Quality Scale (SF-36): This is a self-report scale, which consists of eight sub-titles each having a total of 2-10 questions. The scale consists of “general health”, “physical function”, “physical role limitation”, “emotional role limitation”, “social function”, “pain”, “vitality/energy” and “mental health” sub-dimensions. Scoring varies between 0-100 for each sub-dimension. Low score means bad health status (27,28).

2.4. Statistical analyses

Descriptive analyses were made to collect data on general characteristics of the participants. The data on continuous variables are given as mean ± standard deviation; and the data on categorical variables are given as *n* (%). The qualitative variables of the study were the demographic data like age, educational status, socioeconomic status, and psychiatric treatment history, whether there was additional medical disease, and if there was, what the diagnosis was. The Cross-Table and Chi-Square Tests were made use of to evaluate the relations between the qualitative variables.

The quantitative variables were the scores that obtained obtained from the applied scales and thyroid functions, fasting glucose values and glucose values measured after glucose loading test. The reference range of our hospital for laboratory parameters were; TSH: 0.27-4.6 uIU/ml; sT4: 0.93-1.7 uIU/ml; fasting blood glucose: 70-110 mg/dl. For the 1st hour:180 mg/dl; for 2 st hour:153 mg/dl. When the relations between the quantitative variables were evaluated, the Significance of the Difference Between Two Averages Test, One-Way Variance Analysis, and Pearson correlation coefficient were made use of. The scores obtained from the scales were calculated as the dependent variables, and the scores that were obtained from the laboratory parameters were calculated as the independent variables. When the *p* values were calculated less than 0.05, they were considered to be statistically significant. The SPSS for Windows 19

weeks of the pregnant women ranged between 24 and 29 weeks. The average age of the pregnant group was 25.55±5.14 (17-38); and the average age of the healthy control group was 22.55±1.60 (19-26). One participant was single in both groups. No significant differences were detected between the sociodemographic data of the participants except for the educational status and living area. None of the participants had psychiatric treatment history and additional medical disease before or during Software (Statistical Package for Social Sciences for Windows 19) was employed in the calculations.

3. RESULTS

A total of 119 pregnant women were included in the study, and 60 women were included as the healthy control group. The pregnancy the study period. The families of the participants did not receive any psychiatric treatment (Table 1).

Table 1. *Sociodemographic characteristics of the participants.*

	Pregnant Group N=119	Control Group N=60	p
Marital status (Married/single)	% 99.2/0.8	% 97.5/2.5	0.972
Living area			
City center	46.2	62.5	0.038
Village	53.8	37.5	
Educational status			
Primary school graduate	2.5	5.0	0.025
High school graduate	68.1	37.5	
University graduate	29.4	57.5	
Working status			
Regular/full-time job	8.4	5.0	0.280
Irregular/part-time job	5.0	7.5	
Housewife	86.6	87.5	
Socioeconomic status			
Low	22.7	5.0	0.228
Moderate	69.7	85.0	
High	7.6	10.0	

None of the participants had received psychiatric treatment and additional medical diseases. Chi-square test was used. Values are presented as percentage (%) in the table.

In the results of the participants that were analyzed with the Significance of the Difference Between Two Averages Test, it was determined that both BDS and BAS scores of the pregnant group were higher at a statistical level compared to the healthy control group (the *p* values were calculated as 0.000; 0.004, respectively). For PSQS, on the other hand, statistically significant differences were detected between "sleep latency", "usual sleep activity", "sleep disorder" sub-components and the total score (*p* values were calculated as 0.016; 0.004; 0.000; 0.003, respectively). For SF-36, the results of the pregnant group were worse than the control group in "physical function", "physical role limitation" and "pain" sub-dimensions (*p* values were 0.000; 0.002; 0.000, respectively) (Table 2).

Table 2. *Distribution of quantitative variables according to the groups*

Scale Applied	Control Group N=60 (mean ± SD)	Pregnant Group N=119 (mean ± SD)	P value
TSH		1.8±0.94	
sT4		1.13±0.23	
Fasting glucose		88.19±15.82	
75 gr glucose loading		123.59±32.89	
Beck Depression Scale	5.68±4.57	8.19±6.19*	0.000
Beck Anxiety Scale	9.10±9.11	11.45±8.82*	0.004
Pittsburg Sleep Quality Scale	0.98±0.70	0.98±0.75	1.000
Subjective sleep quality	0.93±0.83	1.13±0.94*	0.016
Sleep latency	0.23±0.48	0.42±0.78	0.805
Sleep duration	0.18±0.38	0.58±0.79*	0.004
Decreased sleep activity	1.03±0.62	1.50±0.76*	0.000
Sleep disorder	0.13±0.40	0.08±0.36	0.262
Sleep drug	0.85±0.92	0.76±0.83	0.817
Daytime function loss	6.60±1.30	5.40±2.87	0.003
Total score			
Life quality scale			
Physical function	85.62±28.49	53.40±24.69*	0.000
Physical role limitation	68.75±38.71	47.73±36.63*	0.002
Emotional role limitation	60.40±43.31	51.99±37.63	0.199
Vitality	49.38±19.59	54.71±20.65	0.240
Mental health	58.95±18.75	61.22±19.36	0.095
Social function	71.37±23.36	68.77±22.13	0.063
Pain	73.62±18.62	55.06±20.94*	0.000
General health	60.13±18.66	57.44±18.33	0.204

*Mean±SD= Mean±Standard deviation. The Significance of the Difference Between Two Averages Test was used. * P<0.05*

The Pearson Correlation Analysis results of the scales that were applied in the present study are presented in the tables (Table 3 and Table 4). Although BDS and SF-36 were negatively correlated; certain sub-dimensions of PSQS were positively correlated and sleep quality worsened as depression scores increased. Similarly, BAS and PSQS were positively correlated and SF-36 was negatively correlated. In our results, some sub-dimensions of PSQS and SF-36 were shown to be negatively correlated (Table 3, 4).

Table 3. *Life quality and sleep quality Pearson Correlation Analysis results*

SF-36	Pittsburg Sleep Quality Scale (R value)							
	PSQS-1	PSQS-2	PSQS-3	PSQS-4	PSQS-5	PSQS-6	PSQS-7	PSQS – Total
Physical function	-.146	-.099	-.131	-.148	-.131	-.039	-.021	-.174
Physical role Limitation	-.277*	-.157	.064	-.047	-.300*	.111	-.224*	-.255*
Emotional role limitation	-.155	-.100	-.041	-.039	-.361*	-.075	-.003	-.202*
Vitality	-.269*	-.202	-.103	-.167	-.359*	-.140	-.233*	-.381*
Mental health	-.200*	-.244*	-.172	-.179*	-.299*	-.022	-.242*	-.345*
Social function	-.277*	-.212*	-.079	-.181*	-.483*	-.023	-.323*	-.420*
Pain	-.013	-.023	-.062	.039	.042	-.022	-.094	-.034
General Health	.053	-.184*	-.040	-.152	-.324*	-.122	-.155	-.252*

SF-36: Life Quality Scale; PSQS: Pittsburg Sleep Quality Scale ; 1:"subjective sleep quality"; 2: "sleep latency"; 3: "sleep duration"; 4:"usual sleep activity"; 5:"sleep disorder"; 6:sleep drug take";7: daytime function disorder". ***Pearson correlation analysis results, the values in the table are "r" values. * P<0.05.***

Table 4. *Relation of Beck Depression Scale and Beck Anxiety Scale scores with sleep and life quality*

	Beck Depression Scale		Beck Anxiety Scale	
	R value	P value	R value	P value
Pittsburg sleep quality scale				
PSQS-1	0.296*	0.001	0.181*	0.049
PSQS-2	0.266*	0.004	0.197*	0.032
PSQS-3	0.248*	0.007	0.161	0.081
PSQS-4	0.269	0.003	0.237*	0.009
PSQS-5	0.315*	0.000	0.409*	0.000
PSQS-6	0.107	0.246	-0.071	0.443
PSQS-7	0.178	0.052	0.219*	0.017
PSQS-total	0.451*	0.000	0.378*	0.000
Life quality scale				
Physical function	-0.226*	0.013	-0.302*	0.001
Physical role limitation	-0.303*	0.001	-0.379*	0.000
Emotional role limitation	-0.374*	0.000	-0.413*	0.000
Vitality	-0.498*	0.000	-0.464*	0.000
Mental health	-0.514*	0.000	-0.363*	0.000
Social function	-0.388*	0.000	-0.492*	0.000
Pain	0.034	0.712	-0.035	0.707
General health	-0.356*	0.000	-0.350*	0.000

*PSQS: Pittsburg Sleep Quality Scale ; 1:"subjective sleep quality"; 2: "sleep latency"; 3: "sleep duration"; 4:"usual sleep activity"; 5:"sleep disorder"; 6:sleep drug take";7: "daytime function disorder". Pearson correlation analysis results; * P<0.05.*

The TSH values of only one participant were higher (0.84%) than the normal range (4.850 uIU/ml), the sT4 value of all participants was within the normal range. The fasting blood sugar values of 10 participants (8.40%) were higher than the normal range. It was determined that the blood glucose levels of 24 participants in the first hour after 75 gr glucose loading were higher than the expected values. However, it was also determined that these values decreased to the normal limits at the second and third hours in all pregnant women. The values of the other pregnant women were within normal limits. The TSH value, which is one of the thyroid functions, showed a positive correlation with sleep duration (r:0.233). Although the fasting blood sugar values and the SF-36 "physical function" sub-dimension were negatively correlated (r:-.0.192), the "pain" sub-dimension was positively correlated (r:0.497) (Table 5).

4. DISCUSSION

In our study, in which the relations between sleep and life quality of pregnant women and endocrinological functions were investigated, it was determined that there were deteriorations in the sleep and life quality scores of pregnant women in certain sub-dimensions. In addition to this, it was

Table 5. *The correlation of thyroid function and blood sugar values with anxiety-deppressive scores and sleep-life quality*

	Pittsburg Sleep Quality Scale							Life Quality Scale							BAS	BDS
	1	2	3	4	5	6	7	1	2	3	4	5	6	7		
TSH	.061	.131	-.092	.030	.025	-.050	-.010	-.013	.018	.015	.101	.018	.011	-.032	-079	-.001
sT_4	-.030	.019	233*	.085	.011	.073	.028	.080	.083	.037	.049	.039	.054	-.074	.001	-.022
FBS	.109	.087	-.116	-.058	-.156	-.101	.032	-192	-.144	-.030	-.137	-.013	-.143	.497*	.034	.095
75 gr GLT	.031	-.005	-.034	.127	.047	.047	.098	-.045	-.091	.040	-.075	.146	.108	.335*	.000	-.017

PSQS: Pittsburg Sleep Quality Scale ; 1:"subjective sleep quality"; 2: "sleep latency"; 3: "sleep duration"; 4:"usual sleep activity" 5:"sleep disorder"; 6:"sleep drug take";7: "daytime function disorder"

Life Quality scale; 1: "Physical function"; 2: "Physical role limitation"; 3: "Emotional role limitation"; 4:"Vitality"; 5: "Mental health"; 6: "Social function"; 7: "Pain"

sT4 : free thyroxin, TSH: thyroid stimulant hormone; FBS: Fasting blood sugar; 75 gr GLT: 75 gr glucose loading test.

*Pearson correlation analysis results, the values in the table are "r" values. * P<0.05*

also determined that the depression and anxiety scores of the pregnant group were higher than the Control Group.

Psychiatric symptoms may go undetected with the effect of hormonal and physical changes during pregnancy. In the literature, in previous studies that were conducted in the last 20 years, depressive disorder and anxiety disorder, which are among psychiatric diseases during pregnancy, rank the first (8-16). It was even shown in some studies that depression and anxiety levels of pregnant women could be interrelated with demographic characteristics like age, marital status, education level, socioeconomic status and residence (13,14). In our results, no correlations were detected between the depression scale, anxiety scale scores and sociodemographic data. No significant relations were detected between depression and anxiety levels and any endocrinological parameters in our study. Depression scores and anxiety scores, on the other hand, showed positive correlation with each other, which is consistent with the literature (9-11,13-16). It was seen that depression levels increased in a pregnant woman if she had high anxiety levels, and also, anxiety levels increased in a pregnant woman if she had high depression levels.

In terms of sleep quality, a deterioration was detected between the "sleep latency", "usual sleep activity", "sleep disorder" sub-components and total scores, compared to the controls. In studies conducted on the sleep quality of women, it was shown that many young women experienced sleep disorder (17,18). When the literature is examined, it is seen that many studies show that sleep quality is impaired in pregnant women. This situation was attributed to many factors like weight gain during pregnancy, insufficient physical activity, fetal growth, pain, cramps and hormonal changes (19,20,29,30). In our results, no significant relations were detected between fasting blood sugar, glucose loading values and PSQS sub-dimensions or total scores. In the literature, it was shown in a study that sleep quality was worse in pregnant women who had higher fasting glucose levels. In the same study the hemoglobin A1c values were measured and it was determined that the sleep quality of pregnant women who had high hemoglobin A1c was worse (29). In another retrospective study, it was reported that the blood sugar values of pregnant women who had impaired sleep quality and low sleep periods were more likely to be higher (31). Although no positive and significant relations were detected between PSQS and blood sugar values in our results, it was determined that "sleep duration", "usual sleep activity" and "taking sleep drugs" sub-dimensions were negatively related in the correlation analyses results. In terms of thyroid functions, only sT4 values and "sleep duration" were found to be interrelated. In our results, none of the subdimensions and total scores of PSQS were found to be interrelated with sociodemographic data. In some studies in the literature, it was found that as age furthered, and as education level decreased, sleep quality scores were found to be worsened in unplanned pregnancies and in patients who had other diseases that accompanied pregnancy (16).

The pregnant women received lower scores than control group in almost all sub-dimensions in our results. In other words, non-pregnant people had poor life quality in all sub-dimensions. But statistically significant scores were detected in "physical function", "physical role limitation" and "pain" sub-dimensions. A great number of studies were conducted in the past using different life quality scales in pregnant women. In another study with SF-36, the quality of life scores in areas other than "mental health" and "pain" sub-dimensions was calculated as low. The quality of life scores in participants who had diseases that accompanied pregnancy, who had high number of total pregnancies, high number of children and high number of individuals living in the family were found to be poorer (16). In another study that was conducted by examining PUBMED and COCHRANE references, it was determined that the quality of life was impaired in general although there were no objective measurement tools for the quality of life in pregnant women. Meanwhile, it was determined that pregnant women showed more depressive symptoms in psychiatric terms (32). In a study that evaluated quality of life with the Nottingham Health Profile, it was determined that physical activities of pregnant women were negatively related to their life quality (33). In our results, a negative relation was determined in all parameters except life quality "pain" sub-dimension and anxiety and depression levels were. In other words, it was determined that as the scores of depression and anxiety increased, the quality of life scores became impaired. In a study in which SF-36 was used on two different groups of pregnant women with and without depression, it was found that the pregnant women had poor life quality scores. It was determined that the life qualities and especially "mental health", "vitality" and "social function" sub-dimensions of pregnant women who are diagnosed with depressive disorder were much worse (34). Sleep quality and life quality were found to be inversely related in many fields. It was observed that as the life quality, "physical role limitation", "physical role limitation", "emotional role limitation", "vitality", "mental health", "social function" and "general health" became impaired, d-so did the sleep quality. It was reported in many studies in the literature that as sleep quality deteriorated, life quality became also impaired (16, 34-36). In our result, no significant relations were detected between thyroid functions and any of the subdimensions of life quality. The fasting blood sugar values were related negatively with "physical function", and positively with "pain" sub-dimension.

In a study investigating the life and sleep quality scores of pregnant women with high risks (pregnant women diagnosed with diabetes and hypertension), it was determined that sleep and life quality were impaired (35). In a study that was conducted on life quality and problem-solving skills of diabetes patients, no relations were detected between blood sugar and hemoglobin A1c levels and life quality. It was observed in the same study that there was a negative relation between the functional problem-solving styles of diabetics and HbA1c (37). In another study that was conducted in diabetic patients, no relations were detected

between blood sugar levels and quality of life. However; demographic characteristics like education level, economic status and duration of diabetes had significant correlations with life quality (38). In our results, no relations were detected between sociodemographic data and life quality scores.

Our results must be evaluated by considering some limitations. The first one of the limitations is that the sample size was relatively small. Also, the study was conducted with the scales that were filled by the participants themselves; and the pregnant women in a single trimester period were evaluated. These limitations avoid that our findings are generalized. Further studies are required to examine more pregnant women in larger sampling groups who are at different gestational periods with larger laboratory parameters.

As a result; our first hypothesis in our study was that endocrinological results might be related with sleep and quality of life in pregnant women. However, we did not find any relationship between thyroid functions and quality of life in the results we obtained. In terms of sleep quality, it was determined that only the “sleep time” was associated with thyroid functions. In terms of blood sugar values, although a relation was not detected with sleep quality, it was determined that there was a positive correlation between “physical function” sub-dimension, and a negative correlation with “pain” sub-dimension. Our second hypothesis was that endocrinological results could have relations with anxiety and depression levels. However, our results did not confirm this hypothesis. It was determined that there were no relations between depression and anxiety levels and blood parameters. Our last hypothesis was that the anxiety and depression levels of pregnant women might increase and sleep quality and quality of life may be impaired independently from endocrinological functions. Our results confirmed this hypothesis. It was determined that the depression and anxiety scores of pregnant women were high, and sleep and quality of life were impaired in certain subcomponents. It was considered that sleep and life quality might be impaired with the changing hormonal values, weight, eating and physical activity in pregnancy. When many pregnant women are considered from this point of view, it becomes obvious that they must be collaborates with multiple disciplines like gynecologist and obstetrician, dieticians, psychiatrists to have a more comfortable and healthy pregnancy.

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Clinical and Experimental Health Sciences

Treatment Adherence Levels and Factors Affecting Adherence in Patients Receiving Osteoporosis Treatment

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ABSTRACT

Objective: Treatment adherence is regarded as an important factor in achieving optimal outcomes across many disease states. The purpose of this study was to evaluate the adherence of osteoporosis patients and determinate the factors affecting adherence.

Methods: A total number of 150 patients with osteoporosis were included in the study. Demographic data, anthropometric measurements and laboratory results of the patients were recorded. In addition, the survey questions including patients' marital status, education levels, income status, smoking and alcohol consumption habits, exercise levels, dietary habits, fracture histories, menopausal ages, treatments they received, medication side effects and treatment adherences were asked by a face-to-face interview method.

Results: The mean age of the 150 patients included in the study was 65.6±9.8 years. Ninety-four percent of the patients were female. Patients who received osteoporosis treatment with oral agents had poorer adherence to treatment than patients receiving subcutaneous or intravenous agents (p=0.003). Other factors had no effect on adherence.

Conclusion: Treatment adherence, which is one of the concepts related to the principles of rational drug use, is an important part of treatment success. The choice of agents administered subcutaneously or intravenously in the treatment of osteoporosis will result in better adherence with treatment than oral agents.

Keywords: Osteoporosis, adherence, bisphosphonate

1. INTRODUCTION

Adherence to therapy means that the patient obeys to the rules of treatment and is also active involved in this process. Rational drug use rules begin with diagnosis and prescription. It goes on with patient education and continuing with the drug. Rational drug therapy means therapy with appropriate dosage in appropriate form also in the appropriate range with appropriate intervals. Adherence is determined whether the patient uses the medicaments in direction of recommendations of the physician. If there is a problem in the name of adherence there cannot be told about therapy success (1).

Osteoporosis is a disease that can be seen in every part of the society and every age, and it has to be considered from physical, psychological and economic aspects. When addressed in terms of gender, 80% is more common in women. This is why it is generally evaluated as a health problem for women (2-4). The deterioration of the bone structure in addition to low bone mass in osteoporosis causes morbidity and mortality by preparing the ground for fracture formation. Osteoporosis due to prolonged life span is defined as a bone disease, which is seen in elderly individuals, and due to its multifactorial, insidious course, and long treatment duration, and chronic course, early diagnosis and treatment yields successful results (5-7). Currently, classification of osteoporosis as primary or secondary due to the etiology is a widely accepted classification, although a wide range of various classifications. Primary osteoporosis can be age-related (senile) or idiopathic, with no known disease or event that can cause osteoporosis. Osteoporosis is defined as secondary osteoporosis if it develops due to diseases such as malign, endocrine, rheumatologic, digestive or respiratory diseases. Inactivity, smoking, alcohol consumption and drug use are also considered as causes of secondary osteoporosis (8).

If pharmacological treatment of osteoporosis is carried out within the framework of rational drug use principles in a cost-effective manner and in a convenient way of current scientific towards, it is possible to achieve multi-faceted benefits by preventing both fracture formation and disease progression. In our study, we aimed to determine the level

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of adherence of our patients to osteoporosis treatment and also the affecting factors.

2. METHODS

Study population

The study was designed as a descriptive, cross-sectional, survey study. The study was carried out on face-to-face interviews with 150 patients, who consecutively attended our Internal Disease and Endocrinology outpatient clinics at our hospital from September to November in the last year. Patients who had been diagnosed with osteoporosis and had been receiving osteoporosis treatment already were included in the study. Exclusion criteria included patients with any history of chronic renal failure, malabsorption syndrome, liver and biliary system diseases, active infection, cancer, chronic inflammatory diseases involving the skeletal system, advanced heart failure, and permanent immobility. In the data collection form, forms of fracture, nutrition habits of milk and dairy products, drugs used for osteoporosis, forms of osteoporosis drugs (oral, intravenous, subcutaneous), application frequency and duration, application methods (intermittent or continuous) were recorded as well as socio-demographic information. Concomitant diseases and drug use policies for these diseases were questioned. Patients were re-interviewed 3 months later and patients were reevaluated for drug side effects and drug interactions. At the same time, patients' treatment adherence (leaving the treatment in place, forgotten treatment) was assessed. Written informed consent was obtained from all of the patients prior to the inclusion into the study. Our study complies with the 1964 World Health Organization Declaration of Helsinki and the World Psychiatric Association, Good Clinical Practices and Good Laboratory Practice Rules. Dumlupınar University Faculty of Medicine, Clinical Research Ethics Committee approved the study protocol (Approval number is 2017-11/3).

Statistical analysis

The data obtained in the study were analyzed using the Statistical Program for Social Sciences (SPSS) version 22.0 (SPSS Inc., Chicago, IL, USA). Normal distribution of continuous variables was evaluated by Kolmogorov-Smirnov and Shapiro-Wilk tests. For parametric tests, continuous variables are expressed in mean ± standard deviation, while for non-parametric tests, data are expressed in median and interquartile range (25^{th} and 75^{th} percentiles). Differences between groups were compared using Student's t test for normally distributed data. Categorical parameters were analyzed using Chi-square test. A p value of <0.05 was considered statistically significant.

3. RESULTS

Sociodemographic characteristics of the patients, exercise habits, levels of attention to nutrition, cigarette and alcohol consumption habits are shown in Table 1. The age of the participating patients ranged from 42 to 88 years and the mean age was 65.6±9.8 years. The 93.3% of the patients in the study group constituted of female individuals. Patients had a fracture of 41 variable fractures, of which 26 were vertebrae and 6 were hip fractures.

Table 1. *Sociodemographic characteristics of the study groups*

	n=150
Age, year	65.6±9.8
Female gender, n (%)	140 (93.3%)
Marital status, n (%)	
Married	111 (74.0%)
Single	1 (0.7%)
Divorced/Widowed	38 (25.3%)
Educational status, n (%)	
Illiterate	46 (30.7%)
Primary school graduate	89 (59.3%)
Secondary school graduate	5 (3.3%)
High school graduate	8 (5.3%)
University graduate	2 (1.3%)
Income status (monthly, Turkish Liras), n (%)	
Less than 1000	19 (12.7%)
1000-1500	87 (58.0%)
1500-2500	36 (24.0%)
2500-3500	5 (3.3%)
3500-5000	2 (1.3%)
More than 5000	1 (0.7%)
Bone fracture, n (%)	41 (27.3%)
Vertebra	26
Hip	6
Wrist	4
Arm	2
Ankle	1
Knee	1
Hand	1
T score hip	-1.84±1.11
T score L1-L4 vertebra	-3.13±0.52
T score femur neck	-2.08±0.98
Exercise, n (%)	62 (41.3%)
Less than 3 times per week	29
3 times weekly	16
More than 3 times weekly	17
Paying attention for nutrition, n (%)	79 (52.7%)
Milk and dairy products	77
Soup prepared with bones	1
Honey	1
Smoker, n (%)	15 (10.0%)
Alcohol consumption, n (%)	0 (0%)
Height, cm	156.1±6.7
Weight, kg	68.2±11.8
Body mass index, kg/m^2	28.0±4.7
Menopause age, year	45.4±7.2
Vitamin D level (ng/ml)	25 (19-36)

The majority of drugs used for the treatment of osteoporosis were drugs in the bisphosphonate group (n=123, 82%) (Figure 1).

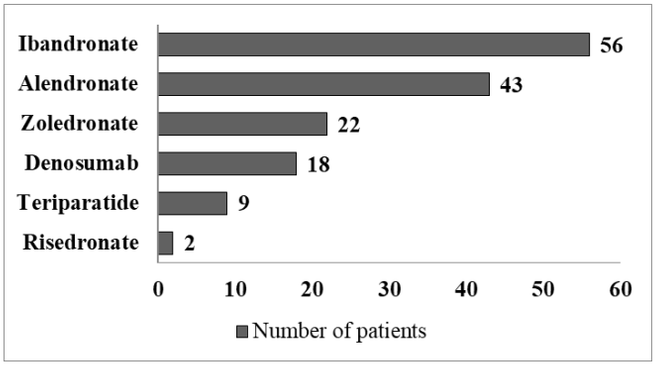

Figure 1. *Drugs used in the treatment of osteoporosis.*

Ninety-one (60.7%) of the patients treated with osteoporosis were receiving oral medications, while 32 patients (21.3%) used their drugs via the intravenous route and 27 patients (18%) via the subcutaneous route. When we examined the conditions of the patients who forgot their treatment, 20 of the 34 patients who forgot their treatment were using oral medication for osteoporosis. The rate of forgetting treatment of patients using oral medication was significantly higher than those using intravenous or subcutaneous administration (p=0.003). When we examine the relationship between the drug use form and the break period; we have found that 61 patients were on breaks for treatment and 41 patients who made breaks most frequently used oral medications (p=0.359).

One of the indicators of the adherence behavior is the usage of medicaments in accordance to the instruction rules. Among the patients who received their osteoporosis treatment via the oral route; all the 91 patients were taking their drug appropriately in the morning, but 12 of them was using the drug falsely after breakfast.

The waiting period ranged from 10 to 120 minutes after taking the medicine, while 78 patients were waiting and 13 patients were not waiting. After taking the medication, 70 patients stated that they were standing upright, while 21 patients were not standing upright.

Thirty five patients (23.3%) reported side effects due to drug treatment. The most common side effect was dyspepsia. Other common side effects were; dysphagia, nausea, vomiting and headache. Seventy four patients (49.3%) were on medication for gastrointestinal system (GIS) side effects. The drugs used are shown in Table 2. No significant drug interaction was observed in the patients.

Table 2. *Drugs used for the gastrointestinal system side effects*

Drugs	n=74
Lansoprazole	49
Esomeprazole	8
Rabeprazole	7
Pantoprazole	7
Nizatidine	1
Famotidine	1
Sodium alginate + sodium bicarbonate + calcium carbonate	1

When the measures taken by osteoporosis patients in their homes against falls were examined, only 24 patients (16%) took measures. The measures that had been taken were; take measures to prevent carpet slipping (13 patients), not going to high stairs (8 patients), using a walking stick or walker (2 patients), and lifting mats in the house (1 patient).

Family support for any disease is important. When we examined the marital status of the patients in our study group, 111 (74%) patients were married, 1 (0.7%) were single, and 38 (25.3%) were divorced or widows. Family support was available in 132 (88%) of the study patients. When we examine the cases of patients with family support who discontinue treatment and forget treatment; we observed that 54 out of 61 patients who had discontinued treatment had family support (p = 0.870). We also found that 32 out of 34 patients who forgot the treatment had family support (p=0.342). Although there was a positive family support in the patients in our study group, there was a drug adherence problem.

The average age of our study group is 65.6±9.8 years; we can say it as an elderly population group. Therefore most of the patients have comorbidities and were taking multiple medications. The most common diseases in patients are hypertension, diabetes mellitus and hyperlipidemia (Table 3). Patients receiving polypharmacy (3 or more drugs) were significantly elder than patients who did not receive polypharmacy (67.50±9.01 years versus 62.47±10.43 years respectively, p=0.003). Forgetting rate of osteoporosis medicaments were similar among patients receiving polypharmacy and above them who did not receive polypharmacy treatment (20% to 18% respectively, p=0.476). Treatment break rates of patients receiving polypharmacy were similar to those who did not (p=0.086). There were 34 patients who forgot the treatment, and the mean age was similar to the mean age of the patients who did not forget the treatment (65.2±9.8 years versus 65.4±9.8 years respectively, p=0.922). All 34 patients who forgot their treatment were female when the gender relation was examined. There was no difference between treatment forgetting and patients' income status (p=0.464), also no difference between treatment forgetting and educational status could be observed (p=0.922). There were 61 patients who made breaks in the treatment and the mean age was similar to the mean age of the patients who did not interrupt their treatment (67.2±9.3 years versus 64.5±10.0 years respectively, p=0.101). When the gender relationship with the therapy intervention was examined, 59 of 61 patients were female and there was no difference in terms of gender (p=0.168). There were no differences between the treatment interventions and the income status of the patients (p=0.901) and education status (p=0.220).

Six percent of the patients who were treated with osteoporosis were using also herbal support products or had Hijama treatment as complementary medicine.

4. DISCUSSION

Drug adherence rates for chronic diseases range from 50% to 60%. Values below this ratio are considered as low treatment adherence. Among the factors leading to this are the asymptomatic course of the disease and the high incidence of side effects due to treatment (9). Osteoporosis is an insidious illness. There are various side effects of the drugs used for its treatment. In our study, the incidence of side effects related to drugs used in the treatment of osteoporosis was found to be 23.3% and the treatment interruption rate was 40%. Our patients can be considered as to have some drug adherence problems.

Osteoporosis is a sneaky and preventable disease seen in both sexes, but is more common among women. With increasing age, the incidence of osteoporosis is also increasing. The incidence of osteoporosis is higher in women, especially in postmenopausal period (3). According to prevalence studies, the prevalence of osteoporosis in our country was found to be 7.5% in males older than 50 years and 12.9% in females (2-4). When we look at the sex and age distribution of our study group, we can say that the average age is 65 years and the majority is female patients. Behavioral changes and lifestyle changes can change the course of the disease positively by identifying early risk factors for osteoporosis (10). Smoking, sedentary lifestyles, not to consume regular milk and dairy products are some of the risky habits for osteoporosis. Smoking is an important risk factor for osteoporosis and fracture formation. The relationship between smoking and osteoporosis is due to the harmful effects of nicotine in majority (11). Fortunately, smoking rates of our patients were low.

One important issue in preventing osteoporosis is regularly exercising (12). In a study conducted by Yağmur Y, 96.2% of the women did not exercise regularly, although a large proportion of them had adequate knowledge of osteoporosis (13). In another study has been shown that 51.2% of the patients did never exercise (14). Although the rate of exercising in our study group is low, it can be considered as good if compared with the data of previous studies. According to the Framingham study, consumption of milk and dairy products is associated with increased hip bone density, but not with spinal cord density and fracture development (10). It is known that women do not consume enough milk and dairy products during adolescence and adulthood. Patients' habits not to consume milk and dairy products were found to be 47.3%. The low consumption of milk and dairy products in women in our society is among the factors that prepare the osteoporosis background (10). Hyperthyroidism, diabetes, rheumatoid arthritis, chronic obstructive pulmonary disease, asthma, some renal diseases, malabsorption syndrome and chronic diarrhea are the causes of the development of secondary osteoporosis (15). A lot of our patients had also concomitant diseases that may also contribute to the development of osteoporosis.

Long-term use is required for effective treatment with bisphosphonates. Bisphosphonates have forms that are applied on a daily, weekly, monthly or annual basis. However, investigations show that 70% of daily drug users and 60% of weekly drug users terminate treatment before the end of one year of treatment (16). In other words, as the usage period is more frequent, there is a bigger adherence problem. In our study group, the bisphosphonate group included patients receiving their medications daily, weekly, monthly, every six months and once a year. When we examine the drug forms (oral, intravenous, subcutaneous) of our patients using bisphosphonates, we can say that treatment forgetting and treatment interruption are seen most frequently in patients taking oral medications. Of the patients using oral bisphosphonate, 41 were using bisphosphonates orally once a week and 50 patients once per month.

Side effects that occur in patients using bisphosphonates in the clinic are often seen as GIS complaints. The incidence of side effects related to the use of bisphosphonates in our study was 23.3%. Side effects were mainly stomach pain, swallowing difficulty, nausea, vomiting and headache. Proton pump inhibitors (PPI) are preferred to prevent and treat the development of GIS-mediated side effects. Among the causes of secondary osteoporosis are also mentioned the use of drugs. PPI can also be mentioned as one of these drugs. PPI's, produced as benzimidazole derivatives, act by reducing the release of gastric acid. In recent years, research has been published on the effects of PPI on calcium malabsorption and on the development of osteoporosis and fracture formation. It is stated that fractures developed due to the use of PPI are most commonly in the hip and spine, and the dose and duration are important, and it is stated that only one year of use is sufficient for the development of osteoporosis (17). In our study, we found that 24 of 71 patients who had used PPI for GIS complaints had a history of fracture. The most common observed fracture was vertebra fractures (n=14).

There are different opinions in the literature regarding the relationship between treatment adherence and education level. In an adherence study for calcium and vitamin D treatment, it is reported that the education level of incompatible patients is low, whereas in another study there is no relation between education level and drug adherence (18, 19). The 59.3% of our study group had only education at primary education level. We have observed that drug adherence is lower among less educated patients and, the rate of intermittent breaks of treatment dramatically decreases as education level increases. Forgetting of the treatment was much lower among the more educated group. According to our study results, we can say that drug adherence is high in educated osteoporosis patients, while drug adherence is lower in low educated patients.

Altered physiology in elderly individuals may lead to some problems related to drug use and adherence. The use of multiple medicines in elderly people leads to the frequent occurrence of increased side effects, in particular the problem of forgetting the treatment, and the interruption of treatment (20). All of these problems are present in our study group and are similar to previous studies.

In studies related to adherence, it is pointed out that family support affects the treatment positively. There are opinions that the level of adherence is low in individuals living alone (21). Most of the patients in our study had family support, but the drug adherence problem was also observed in individuals with family support. In long-term treatments, drug adherence was found to be related to the developmental level of the countries also. In developed countries, adherence to the drug was observed in half of the population, while lower levels were found in less developed countries (22). Cramer et al. reported an annual treatment adherence rate to the drug was 26% to 70% in osteoporosis (23). Solomon et al. and Penning et al. reported an adherence rate of 50% (24, 25). According to our data, drug adherence rate is moderate in our study population.

5. CONCLUSION

In conclusion, the factors that affect adherence to the treatment of osteoporosis in our study were interrupting the drug treatment, forgetting to take the medication, disregarding to obey to medication instructions (not taking the pill on fasting, not standing up after taking the drug) and multiple drug use. This was especially observed in patients receiving oral bisphosphonates. 49.3% of the patients, nearly the half of patients were on medication for GIS side effects of oral bisphosphonates, which itself causes osteoporosis. This is also increases the treatment costs and brings also another additive drug. Our suggestions for solutions to the drug adherence in the directions of rational drug use is intelligent planning of osteoporosis treatment, implementation and follow-up of osteoporosis treatment, efforts for patient trainings, strengthening patient-doctor communication and raising awareness of osteoporosis.

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Clinical and Experimental Health Sciences

Maternal Anxiety Associated with Newborn Screening

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ABSTRACT

Objective: In this study, it was aimed to determine the anxiety levels of mothers associated with newborn hearing screening test and heel prick blood sampling.

Methods: A randomized controlled trial of 112 mothers who applied for newborn screening in a public hospital were conducted. The mothers were divided into two groups depending on their baby's assigned group; hearing screening test group (HST group) or heel prick blood sampling group (HBS group). The study was completed with a total of 101 participants. Parental Information Form, Subjective Units of Distress Scale (SUDS), State-Trait Anxiety Inventory (STAI-S, STAI-T) were used in data collection. Data analysis were performed by using descriptive statistics, Mann-Whitney U test, Kruskal Wallis test, Independent groups t test, Pearson and Spearman correlation.

Results: In the HST and HBS groups, the score median of the SUDS was 5,0 (IQR: 4,0-7,0) and 5,0 (IQR: 4,0-7,0), the score average of the STAI-S was 39,8±6,7 and 41,3±7,6, and the score average of the STAI-T was 42,5±7,1 and 41,4±6,5, respectively. There were significant relationships between the mothers' scores of the SUDS, STAI-S and STAI-T.

Conclusion: The mothers' anxiety associated with hearing screening test and heel prick blood sampling were higher than Spielberger's female population. There was no difference between the anxiety of the mothers according to whether the screening test is interventional. In order to avoid problems associated with parental anxiety, it may be advisable to investigate appropriate methods to reduce the anxiety of mothers.

Keywords: Anxiety, newborn screening, parenting

1. INTRODUCTION

In Turkey, the prevalence of phenylketonuria is 1 in 3000-4000 neonates, the prevalence of congenital hypothyroidism is 1 in 4000 neonates, the prevalence of cystic fibrosis is 1 in 3000 neonates (1), and the prevalence of profound biotinidase deficiency is 1 in 14866 neonates (2,3). The screening of these congenital metabolic diseases is carried out by pricking the baby's heel and drawing a few drops of blood onto a piece of absorbent paper (1,4). The prevalence of congenital hearing loss is 1-3 in 1000 neonates (5-7). Neonatal hearing screening is performed using otoacoustic emission (OAE) and auditory brainstem response (ABR) tests (6-9). With screening studies, approximately 4500 children per a year can be protected from the results of existing diseases, and disability can be prevented (9). However, medical practices are perceived as painful practices by mothers (10). Especially, interventional practices such as neonatal heel prick blood sampling can cause anxiety in mothers, because it is painful (1).

There is possible that each individual can feel anxiety in different densities. Especially before and/or during diagnosis and treatment procedures, parents can experience anxiety intensively. High anxiety levels can prevent families to understand the statements about the child correctly, interpret the facts realistically, make appropriate decisions, participate in the child's care and use appropriate coping methods (11). At the same time, it can slow down the working speed of health professionals and prevent to perform procedure correctly, appropriately and adequately.

2. MATERIAL AND METHODS

2.1. Design and Participants

This study was a randomized controlled trial. The population of the study consisted of newborns' mothers who applied for routine diagnosis procedures in the neonatal hearing screening unit and the baby room of the obstetrics and gynecology unit of a public hospital. The required sample size power analysis results, in total, including at least

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90 individuals were determined. In this case, 80% of the power test is expected to be obtained. The sample of the study consisted of 112 mothers who applied for the neonatal screening between July and December 2018, who agreed to participate in the study, were communicated easily and whose babies were performed the procedure for the first time. The mothers were divided into two groups depending on their baby's assigned group; hearing screening test group (HST group) or heel prick blood sampling group (HBS group). The study was completed with a total of 101 participants (Figure 1).

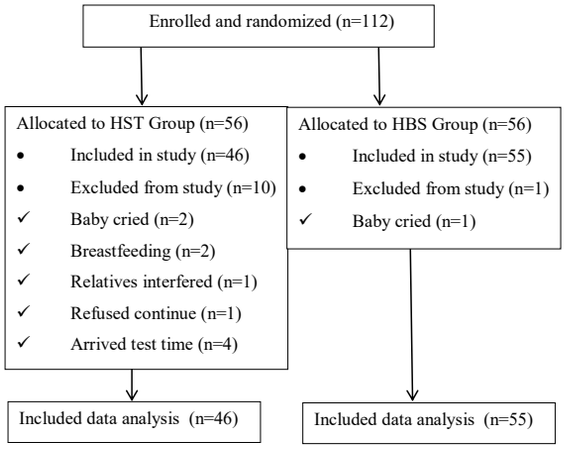

Figure 1. *Flow chart for selection of study participants*

2.2 Data Collection

Data were collected by face-to-face interview method by the researcher. The mothers apply to the Hearing Screening Department for their newborns' hearing screening test before/after discharge and apply to the Baby Room for their newborns' heel prick blood sampling before discharge. Data were filled in by the mothers in the waiting area while waiting for the tests. During the study, the babies were cared by the mothers' relatives. An interview lasted about 15-20 minutes. The mothers were divided into two groups, and data were taken from the same mother only once. Parental Information Form, Subjective Units of Distress Scale, STAI State-Trait Anxiety Inventory were used in data collection.

2.2.1. Parental information form: Based on the literature, there are 10 questions about the mothers' descriptive characteristics in the questionnaire prepared by the researchers.

2.2.2. Subjective units of distress scale (SUDS): SUDS is a subjective measure involving a person's own subjective assessment of his/her current mood (12, 13, 14, 15). The person scores of his/her discomfort in this scale between 0-10. The scale is composed of 0 (no discomfort at all) to 10 (unbearable discomfort) (12, 13, 16, 17).

2.2.3. State-trait anxiety inventory (STAI): In this study, the state – trait anxiety scale which was developed by Spielberger et al. in 1970 and was adapted by Oner and Le Compte in 1977 was used. The scale consists of state and trait anxiety subscales. The reliability coefficients determined by the alpha correlations of the scale ranges from 0,94 to 0,96 for the state anxiety scale and 0,83 to 0,87 for the trait anxiety scale. In Turkish adaptation of the scale, the reliability coefficients are between 0,42 and 0,85 for the state anxiety scale and 0,34 to 0,72 for the trait anxiety scale (18). In our study, reliability coefficients were determined as 0,72 for state anxiety subscale and as 0,71 for trait anxiety subscale. While the State Anxiety Scale aims to determine how the individual feels himself / herself at a certain time and under certain conditions, the Trait Anxiety Scale determines how the individual feels himself / herself independent of the circumstances and conditions. Both subscales are four-point likert type scales consisting of 20 items. The total score that can be taken from each of the state-trait anxiety subscales is between 20 and 80. The high score from the scales shows the high level of anxiety and the low score shows the low level of anxiety (18).

2.3. Statistical Analysis

Data were analyzed by using the IBM Statistical Package for social Sciences v20 (SPSS Inc., Chicago, IL, USA). Statistical significance was accepted as $p < 0,05$. Descriptive statistics (the frequency, percentage distribution, arithmetic mean and median) were used for the assessment of the obtained data. Normality of the distributions were tested with Shapiro-Wilk test. Independent groups t test and Pearson correlation were used for normally distributed variables, and Mann-Whitney U test, Kruskal Wallis test and Spearman correlation were used for non-normally distributed variables. As a result of univariate analyzes, we could not find any meaningfulness to lead us to multivariate analysis.

2.4. Ethical Consideration

For the implementation of the study, the necessary permission was obtained from Abant Izzet Baysal University Clinical Research and Ethics Committee (desion no: 2018/98) and Bolu Provincial Health Directorate. Participation in the study was conducted on a voluntary basis. After the information was given to the participants about the research, their written and verbal consent were taken.

3. RESULTS

The age of the mothers who participated in the study ranged from 19 to 42 years. The average age of the mothers in the HST group and the HBS group were 29,1 ± 5,6 years and 27,0 ± 4,7 years, respectively. The median age of the newborns was 2,0 (IQR: 2,0-3,0) days in the HST group and 2,0 (IQR: 1,0-2,0) days in the HBS group (Table 1).

The majority of mothers were high school graduates; 37% of the HST group and 40% of the HBS group. All participants were married and had social security insurance or maternity insurance. A percentage of 69,6 of the HST group and 72,7%

of the HBS group were non-working, and 52,2% of the HST group and 65,5% of the HBS group evaluated their income status as middle (Table 1).

A percentage of 78,3 of the HST group and 87,3% of the HBS group reported that they wanted the pregnancy. 56,5% of the HST group and 61,8% of the HBS group delivered by cesarean section. %56,5 of the HST group had a female baby and %50,9 of the HBS group had a male baby. 45,7% of the HST group and %45,5 of the HBS group gave birth to their second baby. 76,1% of the HST group and 89,1% of the HBS group reported that they delivered at term (Table 1).

Table 1. *Participant characteristics*

Characteristics	Study Groups			
	HST Group		HBS Group	
	n	%	n	%
Age (years)				
19-30	31	67,4	44	80,0
31-42	15	32,6	11	20,0
x̄± sd (Min-Max)	29,1±5,6 (19-42)		27,0±4,7 (19-39)	
Newborn's age (days) Median (IQR)	2,0 (2,0-3,0)		2,0 (1,0-2,0)	
Educational status				
Literate	0	0	2	3,6
Primary school	6	13,0	6	10,9
Secondary school	13	28,3	14	25,5
High school	17	37,0	22	40,0
University	10	21,7	11	20,0
Working status				
Working	14	30,4	15	27,3
Non-working	32	69,6	40	72,7
Income level				
Good	22	47,8	19	34,5
Middle	24	52,2	36	65,5
Pregnancy intention				
Intended	36	78,3	48	87,3
Unintended	10	21,7	7	12,7
Delivery method				
Vaginal	20	43,5	21	38,2
Cesarean	26	56,5	34	61,8
Newborn's gender				
Female	26	56,5	27	49,1
Male	20	43,5	28	50,9
Newborn's birth order				
1	18	39,1	21	38,2
2	21	45,7	25	45,5
3	7	15,2	7	12,7
4	0	0	2	3,6
Gestational age				
Term	35	76,1	49	89,1
Preterm	5	10,9	2	3,6
Postterm	6	13,0	4	7,3

x̄: Average, sd: Standart deviation, Min: Minimum, Max: Maximum

When the anxiety scores of the participants were considered, both of the study groups' SUDS score median was 5,0 (IQR:4,0-7,0). In the HST and HBS groups, the score average of the STAI-S was 39,8±6,7 and 41,3±7,6 and the score average of the STAI-T was 42,5±7,1 and 41,4±6,5, respectively (Table 2).

Table 2. *Participant anxiety scores*

	Study Groups	
Anxiety scores	HST Group	HBS Group
SUDS Median (IQR)	5,0 (4,0-7,0)	5,0 (4,0-7,0)
STAI-S x̄± sd (Min-Max)	39,8±6,7 (30-53)	41,3±7,6 (28-58)
STAI-T x̄± sd (Min-Max)	42,5±7,1 (31-58)	41,4±6,5 (29-57)

x̄: Average, sd: Standart deviation
Min: Minimum, Max: Maximum

In the HBS group, the median of the STAI-S score was significantly higher in mothers with cesarean delivery (Median: 45,0; IQR: 37,0-50,0) than in mothers with vaginal delivery (Median: 37,0; IQR: 34,0-43,0) (p=0,02), and the median of the STAI-T score was significantly higher in mothers with unintended pregnancy (Median: 47,0; IQR: 41,0-52,5) than in mothers with intended pregnancy (Median: 40,0; IQR: 36,5-46,0) (p=0,03) (Table 3).

In the HST group, there was a moderate positive correlation between the SUDS and the STAI-S scores (r = 0,63, p<0,05), a weak positive correlation between the SUDS and the STAI-T scores (r = 0,37, p<0,05), and a moderate positive correlation between the STAI-S and the STAI-T scores (r = 0,40, p<0,05). There was a weak positive correlation between the birth order of the newborns and the STAI-S scores (r= 0,37, p<0,05) (Table 4).

In the HBS group, there was a weak positive correlation between the SUDS and the STAI-S scores (r= 0,35, p<0,05) and a weak positive correlation between the STAI-S and the STAI-T scores (r=0,31, p<0,05). There was a moderate positive correlation between the birth order of the newborn and the mother's age (r= 0,50; p<0,05) (Table 4).

Table 3. *Anxiety scores according to the participant characteristics*

Participant Characteristics	Anxiety Scales					
	SUDS		STAI-S		STAI-T	
	HST (N=46)	HBS (N=55)	HST (N=46)	HBS (N=55)	HST (N=46)	HBS (N=55)
	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)
Age						
19-30	5 (5-7,5)	5 (4-7)	40,0 (34,0-46,0)	38,5 (35,0-46,5)	43,0 (38,0-48,0)	40,5 (36,5-46,0)
31-42	4 (3,5-7)	5 (4-6,5)	39,0 (34,5-42,0)	44,0 (37,0-48,0)	41,0 (35,5-47,0)	42,0 (38,0-47,0)
p	0,25[a]	0,53[a]	0,58[a]	0,45[a]	0,38[a]	0,44[a]
Educational status						
Literate	-	7,5 (5-10)	-	47,5 (43,0-53,0)	-	49,5 (47,0-52,0)
Primary school	6,5 (5-7)	5,5 (5-8)	44,0 (32,0-47,0)	39,0 (34,0-44,0)	45,0 (38,0-51,0)	41,5 (40,0-46,0)
Secondary school	5 (4-6)	5 (4-6)	33,0 (31,0-41,0)	39,5 (36,0-46,0)	42,0 (38,0-53,0)	41,0 (35,0-46,0)
High school	5 (4-7)	5 (4-7)	40,0 (35,0-48,0)	41,5 (34,0-48,0)	43,0 (33,0-48,0)	39,5 (36,0-44,0)
University	5,5 (3-7)	5 (4,5-7,5)	40,0 (38,0-43,0)	39,0 (36,5-46,5)	41,5 (39,0-43,0)	41,0 (38,0-47,5)
p	0,73[b]	0,64[b]	0,21[b]	0,73[b]	0,74[b]	0,34[b]
Working status						
Working	5 (3-7)	5 (4-6,5)	38,5 (35,0-41,0)	44,0 (35,5-46,5)	39,0 (35,0-42,0)	38,0 (37,0-41,5)
Non-working	5,5 (4,5-7)	5 (4-7)	40,5 (33,5-47,0)	40,0 (35,0-47,0)	43,0 (38,5-50,5)	42,0 (37,0-46,5)
p	0,13[a]	0,63[a]	0,34[a]	0,92[a]	0,06[a]	0,14[a]
Income level						
Good	5,5 (5-7)	5 (4-6,5)	41,0 (38,0-46,0)	44,0 (34,0-46,0)	42,0 (36,0-49,0)	41,0 (37,0-42,5)
Middle	5 (3,5-7)	5 (4-7)	37,0 (31,5-44,5)	40,0 (37,0-49,0)	42,5 (37,5-48,0)	42,0 (37,0-48,0)
p	0,26[a]	0,90[a]	0,11[a]	0,36[a]	0,93[a]	0,40[a]
Pregnancy intention						
Intended	5 (4,5-7,5)	5 (4-6,5)	40,5 (35,0-46,5)	39,0 (35,0-46,5)	43,0 (37,5-48,5)	40,0 (36,5-46,0)
Unintended	4,5 (3-6)	5 (4,5-7,5)	36,0 (32,0-41,0)	43,0 (40,5-47,0)	39,0 (33,0-42,0)	47,0 (41,0-52,5)
p	0,10[a]	0,66[a]	0,09[a]	0,47[a]	0,14[a]	**0,03**[a]
Delivery method						
Vaginal	5 (5-8)	5 (3-6)	38,5 (32,0-46,0)	37,0 (34,0-43,0)	43,0 (39,0-50,5)	41,0 (36,0-46,0)
Cesarean	5 (3-7)	5 (4-7)	40,0 (36,0-46,0)	45,0 (37,0-50,0)	42,0 (36,0-48,0)	42,0 (37,0-46,0)
p	0,20[a]	0,32[a]	0,38[a]	**0,02**[a]	0,36[a]	0,53[a]
Newborn's gender						
Female	5,5 (4-8)	5 (4-6)	41,0 (33,0-47,0)	39,0 (37,0-46,0)	43,5 (38,0-48,0)	40,0 (35,5-46,0)
Male	5 (3,5-7)	5 (5-7)	39,0 (35,0-41,5)	43,0 (34,0-47,5)	42,0 (35,5-46,0)	41,5 (37,5-48,0)
p	0,29[a]	0,35[a]	0,41[a]	0,72[a]	0,51[a]	0,34[a]
Newborn's birth order						
1	5,5 (4-7)	5 (5-7)	41,0 (38,0-45,0)	41,0 (37,0-47,0)	41,5 (37,0-50,0)	39,0 (36,0-42,0)
2	5 (5-8)	5 (4-6)	35,0 (31,0-47,0)	39,0 (35,0-46,0)	44,0 (38,0-49,0)	41,0 (38,0-46,0)
3	5 (3,5-6)	6 (5-7)	39,0 (35,0-45,0)	39,0 (31,5-46,5)	42,0 (34,5-42,5)	47,0 (36,0-48,5)
4	-	6 (4-8)	-	50,0 (44,0-56,0)	-	42,0 (41,0-43,0)
p	0,58[b]	0,52[b]	0,35[b]	0,50[b]	0,39[b]	0,61[b]
Gestational age						
Term	5 (4-7)	5 (4-6)	40,0 (34,5-45,0)	43,0 (35,0-46,0)	42,0 (36,5-46,5)	42,0 (38,0-46,0)
Preterm	7 (6-8)	8,5 (8-9)	47,0 (46,0-47,0)	49,5 (48,0-51,0)	48,0 (45,0-48,0)	42,5 (37,0-48,0)
Postterm	5 (4-7)	4,5 (3,5-6)	37,0 (32,0-40,0)	37,5 (33,5-39,5)	41,0 (39,0-47,0)	37,0 (36,0-45,0)
p	0,29[b]	0,97[b]	0,21[b]	0,12[b]	0,65[b]	0,78[b]

a=Mann Whitney U test, b= Kruskal-Wallis test

Table 4. *Comparison of anxiety scores of the study groups*

Anxiety scores	Study groups	N (101)	Median (IQR) / x̄±sd	p
SUDS	HST	46	5,0 (4,0-7,0)	0,98[a]
	HBS	55	5,0 (4,0-7,0)	
STAI-S	HST	46	39,83±6,7	0,28[b]
	HBS	55	41,36±7,6	
STAI-T	HST	46	42,50±7,1	0,42[b]
	HBS	55	41,40±6,5	

a= Mann Whitney U test, b= Independent samples t-test

When the anxiety score averages of the HBS and HST groups were compared, there was no significant differences between the groups; SUDS (p=0,98), STAI-S (p=0,28), STAI-T (p=0,42) (Table 5).

Table 5. *The study groups and correlations*

		HST Group		HBS Group		
		STAI-S	STAI-T	STAI-S	STAI-T	Mother's age
SUDS	r	0,634*	0,377*	0,355**		
	p	0,000	0,010	0,008		
	n	46	46	55		
STAI-S	r		0,402*		0,315*	
	p		0,006		0,019	
	n		46		55	
Newborn's birth order	r	0,379**				0,505**
	p	0,009				0,000
	n	46				55

**r= Pearson's correlation coefficient, **r= Spearman's correlation coefficient*

4. DISCUSSION

According to the Turkish Statistical Institute's data (2018), the average age of the mothers who gave birth in 2017 was 28,7 years (19). The average age of the mothers who participated to study was 29,1 years in the HST group and 27 years in the HBS group (Table 1). Study results were similar to the average of Turkey.

It is recommended that all newborns should be screened with an appropriate hearing screening method (OAE and / or ABR) in the first month of their lives in order to obtain early diagnosis and appropriate prevention (20, 21). The median age of the newborns was 2 (IQR: 2,0-3,0) days in the HST group (Table 1). Hearing screening of newborns of our study group was performed in accordance with the recommendation of the literature. The median age of the newborns was 2 (IQR: 1,0-2,0) days in the HBS group (Table 1). Although it is recommended that the heel prick blood sample should be taken within 48-72 hours postnatally, blood samples are taken "at the last moment before leaving hospital" in order to reach more babies and to be diagnosed early (22).

A percentage of 37 of the HST group and 40% of the HBS group were the high school graduates, and 21,7% of the HST group and 20% of the HBS group were university graduates (Table 1). In Turkey, schooling rate for women are 83,4% for high school, and 47,4% for university (23). Our study population has lower educational status compared to Turkey's average. The mothers may not have benefited from educational opportunities sufficiently because they lived in rural areas.

Turkey employment rate for women is 28,9% (24). The minority of our study population was working (Table 1), that was similar to Turkey's average. It was seen that the mothers did not take part in business life enough. All mothers in the study groups evaluated their income status as good / medium level (Table 1), and they were generally satisfied with their income status.

The majority of mothers reported that they wanted the pregnancy. More than half of the participants delivered by cesarean section (Table 1). In Turkey, cesarean delivery rate in all deliveries in 2016 was 53,1% (25). The ideal cesarean section rate should be 10-15% in all deliveries (26). However, according to 2014-2017 data, Turkey has the highest rate of cesarean delivery among OECD countries (27). Our research results are in line with the average of Turkey.

In Turkey, the total fertility rate for 2018 was 1,99 (19). Almost all of the mothers delivered at term and gave birth to their first or second baby (Table 1). Research results are similar to the average of Turkey.

In the postpartum period; although maternal age (28, 29), socioeconomic status (29, 30), educational status (28, 30), unplanned pregnancy (30), delivery method (31, 32, 33), parity status (33) and gestational age (33, 34) have been reported to be affected the anxiety levels of mothers, there are inconsistent results in the literature (35). In current study; maternal age, educational and working status, income level, gestational age, gender of the baby and birth order of the baby did not significantly affect the anxiety levels of mothers. However, in the HBS group, it was found that the state anxiety was significantly higher in mothers with cesarean delivery than in mothers with vaginal delivery, and the trait anxiety was significantly higher in mothers with unintended pregnancies than in mothers with intended pregnancies ($p<0,05$) (Table 3). Some studies reported that an important part of mothers who delivered by cesarean section had high levels of anxiety before and after delivery (31, 35), women who experienced psychological distress during pregnancy more likely delivered cesarean section and their psychological distress tended to continue after childbirth (35). In another study reported that the state anxiety score was higher in mothers with unintended pregnancy than in mothers with intended pregnancy (36).

The SUDS score medians of the HST and the HBS groups were with 5,0 (IQR: 4,0-7,0) out of 10. Spielberger reported that the STAI-S score average of the women was 35,2 (37). In this study, the average STAI-S score was 39,8 in the HST group and 41,3 in the HBS group (Table 2). The state anxiety score average of mothers was higher than the state anxiety score average of Spielberger's female population. This situation may be due to the fact that mothers did not have enough information about the procedures. In a study that investigated the state anxiety levels of parents regarding to magnetic resonance imaging

under anesthesia; the average state anxiety scores were 39 in the group who was detailed information, and were 43,6 in the group who was provided information about only the risks of anesthesia (38). In another study that examined parental anxiety before and after surgery; the average state anxiety scores of the mothers were 50,02 before the operation, and were 40,68 after the operation (39). In a study that examined the anxiety levels of the parents whose children would undergo surgical procedures, the average score of the state anxiety of the parents ranged from 38 to 47,5 (40). In another study that evaluated the anxiety states of mothers of children with obstructive sleep apnea; it was reported that mothers' anxiety levels increased according to the severity of the disease (41).

In a study that examined the effects of positive newborn screening results on families; it was reported that uncertainty caused anxiety, and while the uncertainty was increasing, families' anxiety was also increasing (42). Parental anxiety increases as the risk and unknownness of the procedure is increased. Additionaly, stressful life events are a risk factor for anxiety (35), neonatal screening tests are also stressful events for mothers and may cause anxiety. The mothers may concern about the screening test itself as well as the result of the test, and the process after the positive test result. Especially, unknownness is increased anxiety (43). In a study found that pregnant women experienced anxiety because of unknownness during the prenatal screening test (44). Although the difference was not significant, the HBS group mothers had higher anxiety than the HST group (Table 4). Heel prick blood sampling may have increased anxiety because it is an interventional procedure.

Spielberger reported that the STAI-T score average of the women was 34,8 (37). In a study that examined parental anxiety before surgery; the trait anxiety score average of the mothers was 38,47 (39). In another study that examined the anxiety levels of the parents who would undergo surgical procedures to their children, the trait anxiety score average of the parents ranged from 33 to 35 (40). In this study, the STAI-T score average was 42,5 in the HST group and 41,4 in the HBS group (Table 2). The trait anxiety score average of mothers was higher than the trait anxiety score average of Spielberger's female population. There was no statistically significant difference between the groups ($p>0,05$) (Table 4).

There was a moderate positive correlation between the SUDS scores and the STAI-S scores in the HST group ($r = 0,63$) and a weak positive correlation between the SUDS scores and the STAI-S scores in the HBS group ($r = 0,35$) ($p<0,05$) (Table 5). These findings showed that, as anxiety levels of mothers related to the procedures increase their subjective evaluations scores increased, as well as state anxiety scores. At the same time these results showed that the SUDS can measure the state anxiety.

In the HST group, there was a weak positive correlation between the SUDS scores and the STAI-T scores, and also a moderate positive correlation between the STAI-S scores and the STAI-T scores.

There was a weak positive correlation between the STAI-S scores and the STAI-T scores in the HBS group (Table 5). These results showed that the trait anxiety affects the state anxiety. In a study that investigated parents' anxiety levels, a moderate positive correlation was found between the STAI-S and the STAI-T (45). It is reported that an another study, adolescents with higher trait anxiety may have higher state anxiety at induction of anesthesia (46). According to another study, high trait anxiety in children and parents are predictive of elevated levels of perioperative anxiety (47). Similarly, to these studies, the current study was found that, mothers with high trait anxiety had high anxiety about the procedure, and at the same time there was a relationship between their state and trait anxiety.

There was a weak positive correlation between the birth order of the baby and the STAI-S scores of the mothers, in the HST group ($p<0,05$) (Table 5). In this study it was determined that, as the number of children increased, the mothers' anxiety about the procedure have also increased. In particular, during the procedure, if the baby moves/cries or does not sleep, it can cause the procedure time to pass, and the mothers can wait a long time. These situations may increase the level of anxiety in mothers. The mothers may have lived similar negative situations at their previous child or may have witnessed in other newborns similar situations while waiting for their procedure time.

There was a moderate positive correlation between the birth order of the baby and mother age, in the HBS group ($p<0,05$) (Table 5). It is usual that, as mother age increases, mothers can have more children.

5. CONCLUSION

Newborn screening tests increase the anxiety levels of mothers. Increased of maternal anxiety can adversely affect mothers' capacities to properly understand the explanations and referrals, and adaptation to screening procedure. On the other hand, health professionals may experience problems caused by anxiety of mothers during screening procedure. This situation may cause newborn screening can not be performed at a desired level and repeated practices and time wasting. It may be advisable to provide adequate, clear and comprehensible information on newborn screening tests to avoid problems with anxiety of the mothers. Additionally, appropriate methods to reduce anxiety may be identified and implemented.

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Clinical and Experimental Health Sciences

Usability of Mobile Health Application for Individuals with Type 2 Diabetes Mellitus and Clinicians

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ABSTRACT

Objective: Usability of technological devices is an important and relevant construct as mobile technologies are increasingly used to deliver healthcare products. Most accessible devices are smartphone and smartwatch but information on their usability is scarce. The aim of this study is to compare the usability of smartphone and smartwatch devices in delivering an exercise platform to individuals with Type 2 Diabetes Mellitus (T2DM) among two focus groups: individuals with T2DM and clinicians.

Methods: A total of 40 individuals with T2DM (focus group 1) and 20 clinicians (focus group 2) were recruited to use the platforms one week. Each focus group was randomly divided into: smartphone and smartwatch groups. Each participant was provided with a practice trial for a week before data collection. Usability of both devices was measured with System Usability Scale (SUS). Student t-test was used to compare the total and subscale scores of SUS between two devices in each focus group.

Results: In focus group 1 and 2, the mean total scores of SUS were slightly higher in smartphone group (88,75 $\pm$ 9,34 and 86,75 $\pm$ 8,68) than smartwatch group (87,87 $\pm$ 7.56 and 82,35 $\pm$ 6,59) respectively. When compared to individual items, three items were statistically significant in focus group 1 and one in focus group 2 ($p \leq 0.05$).

Conclusion: This study demonstrates a high usability (SUS score>80,8) for both smartphone and smartwatch devices in individuals with T2DM and clinicians. When compared between devices for two groups, exercise platform delivered through smartphone performed better on usability than smartwatch for both individuals with T2DM and clinicians.

Keywords: Type 2 Diabetes Mellitus, Mobile Health, Smartphone, Technology

1. INTRODUCTION

Type 2 Diabetes Mellitus (T2DM) is one of the most prevalent chronic health conditions around the world and costs large burden to the health care system particularly for the middle-income countries with already constrained resources [1]. The main goal of management for individuals with T2DM is to maintain blood glucose levels within normal limits through optimal use of medications combined with physical activity (PA) [2]. PA is an important aspect in achieving optimal glycemic control. The extent to which a person participates in PA is directly influenced by his or her preferences that are under self-control [3]. However, approximately 60% of individuals with T2DM fail to meet the PA guidelines [4], which are, at least 150 minutes of moderate to vigorous aerobic exercise and at least 2 sessions per week of resistance exercise [3]. Currently, there are several technological choices at disposal to these population so as to meet the PA guidelines [5].

There are many technological devices commercially available to help individuals with T2DM to meet the PA guidelines and maintain good health [6]. Exercise applications are most commonly delivered through mobile devices such as smartphone and smartwatch [7]. Smartphone applications typically allow an individual to monitor his/her PA level by providing real-time feedback and also generate a personalized exercise program tailored to individual needs [8]. Smartwatch applications additionally can monitor some physiological parameters such as heart rate and blood pressure through sensors [5]. Given these qualifications, smartphone and smartwatch have been shown to be efficacious to improve PA levels and reduce sedentary behaviour in individuals with T2DM [6-8]. However, in order to maximize the benefits from these devices, it is critical to ensure that the people use all the features of these technologies on regular basis and for sustained duration of time.

While there are several studies that have evaluated the clinical efficacy of the mobile applications in T2DM [9], there are a very few studies that have reported any information about the usability and acceptability of mobile applications

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[10]. Furthermore, around 95% studies that involve use of smartphone for health applications lack any information on usability [11]. Of the remaining, even fewer studies have obtained feedback from the users but missed information or feedback from the clinicians [12]. Only one study has investigated the usability of smartwatch applications in self management for individuals with T2DM [13]. Existing studies on smartwatch usability was only patient based and was not custom applications [14].

From users' perspective, usability of these applications includes efficiency, effectiveness, and satisfaction so as to achieve a specified goal [15, 16]. Usability is considered an essential aspect in the development process for an application [17] [18] as it facilitates the extent to which these applications will be adopted by an individual [19]. Usability reports are also used to guide the upgrades in these applications [20]. Moreover, a usability analysis of these applications will meet the needs of the users and experts and will create applications that could be used in future research in PA and health promotion [21].

While smartphones and smartwatches are reported to be widely used to monitor and improve PA in T2DM, there continue to be a gap in the literature on the comparative effectiveness of these devices in terms of their usability [22]. Brooke's usability definition used [23] in this study refers to whether users complete a task using the applications, to see the level of resource consumed in performing a task and to understand user reactions to use of the applications. Furthermore, to assess usability from a clinicians' perspective can provide insights into redesign of the application and its content validity. Therefore, this study is an important contribution to the body of knowledge on usability of exercise platforms for individuals with T2DM.

The global aim of this project is to contribute evidence towards the barriers and facilitators of technology adoption to maintain PA in T2DM. The specific objective is to compare usability of smartphone and smartwatch devices in delivering an exercise platform to individuals with T2DM in two focus groups (individuals with T2DM and clinicians)

2. METHODS

2.1. Design

The study is a cross section analysis of data obtained from RCT designed to test comparative effectiveness of exercise intervention delivered through smartphone and smartwatch for glycemic control in individuals with T2DM. Other exploratory outcomes included usability of these devices in delivering the interventions. The current study is to analysis and present the findings of usability of these devices. The trial was carried out at the Fatih Sultan Mehmet Hospital Diabetes and Obesity Center in Istanbul, Turkey. The assessments were carried out between January and February 2018. The ethical approval for the study was obtained from Marmara University Clinical Research Ethics Committee, Istanbul, Turkey.

2.2. Participants

Participants were included in focus group 1 if they were 1) diagnosed with T2DM 2) at between the age of 18 to 65 years old and 3) free from any diagnosis of cognitive impairments, neurological and orthopedic disorders. Focus group 2 included if they 1) were physiotherapists with minimum master degree, 2) possessed at least 3 years of clinical experience in either public or private settings and have been currently working with patient with T2DM. All participants provided a written informed consent prior to their participation. Data on a total of all the 40 individuals with T2DM and 20 physiotherapists as clinicians was available.

2.3. Randomization

40 individuals with T2DM (focus group 1) and 20 physiotherapists (focus group 2) were randomly assigned (1:1 ratio) into two groups (smartphone and smartwatch) such that the groups were matched for age, sex, and education.

2.4. Measures

System Usability Scale (SUS) was one of the exploratory outcomes in the trial [24]. SUS is a 10 item self-report questionnaire to measure usability of software and hardware products. Each item is scored on a 5-point Likert scale from 1 (strongly disagree) to 5 (strongly agree). Of the 10 items, item no. 1, 3, 5, 7 and 9 are positively worded (higher score represents strongly agree) and item no. 2, 4, 6, 8 and 10 are negatively worded (higher score represents strongly disagree). SUS is validated in Turkish language [25] and widely used to obtain users' [24] and clinicians' [26] perception on technology. To calculate total score for odd numbered items, the individual item score is subtracted from 5 which is the maximum possible score on each item. These scores are added to obtain a total subscale score for odd numbered items. For even numbered items, individual scores are subtracted from 1 which is the minimum score possible for each item. These scores are added to get subscale score for even numbered items. The total score for SUS is a sum of subscale score for odd and even numbered items multiplied by 2.5. The standardized score ranges from 0 to 100 where 100 represents higher usability [26].

2.5. Procedures

Diabetex online exercise platform (DIABETEX; www.diabetex.com) has been developed by research team at Department of Physiotherapy and Rehabilitation, Marmara University that can be delivered either via a smartphone or smartwatch. Diabetex is an online platform that includes exercise types and parameters. It allows clinicians to monitor exercise performance and modify his/her exercise program accordingly. There is possibility for the clinicians to send push notification to patients based on their performance and progress. The exercise platform is compatible with both Android and IOS version. Figure 1 shows two images for

each of devices displaying the exercise platform. The devices provide an individually tailored exercise plan and has capacity to track as well as provide feedback. At the onset when the devices were given to the participants, they received training session for approximately 45 minutes. The session included practice with a full set of the exercise sessions as prescribed for individual. The participants than took the devices home for a week to test and use all features of the platform. They were required to complete at least 3 exercise sessions during that period. After a week individuals with Type 2DM and clinicians completed SUS online.

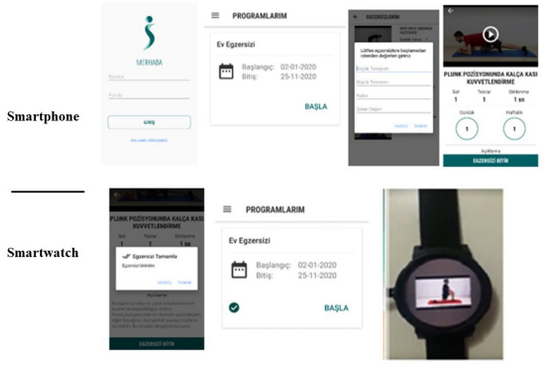

Figure 1: *Screenshots of Diabatex Exercise Platform Delivered through Smartphone and Smartwatch*

2.6. Statistical analysis

Each item was tested for normality using Kolmogorov-Smirnov test. The Student t-test was performed for each item between the two groups. The critical cut-off value for statistically significance was set at p≤0.05 [27] . Statistical analysis was carried out with IBM SPSS Statistics, version 22.0 (IBM Corporation, Armonk, New York, USA).

3. RESULTS

The characteristics of individuals with T2DM and clinicians are shown in Table 1. The variables of age, education, and diagnosis for individuals with T2DM only, are shown as mean and SD. Mean is an inaccurate reflection of personal scores when the response categories are ordinal in nature. Therefore, median values for each of the 10 item on SUS are shown in Table 2. In focus group 1, the mean (SD) total score on SUS were 88,75 (9,34) for smartphone group and 87,87 (7,56) for smartwatch group. In focus group 2, these results were 86,75 (8,68) for smartphone group and 82,35 (6,59) for smartwatch group. Figure 2 shows the graphical representation of the mean scores for focus group 1, while figure 3 demonstrates for focus group 2. In focus group 1, three items revealed statistically significant differences between two groups including item #3 (I thought this app was easy to use), #4 (I think that I would need assistance to be able to use this app) and #10 (I needed to learn a lot of things before I could get going with this app). In all three items, the usability of smartphone was expressed as better than smartwatch. In focus group 2, only differences were in item #10 between the groups where smartphone revealed a better score than smartwatch.

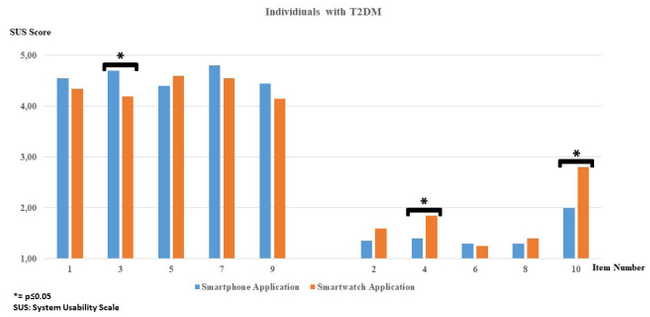

Figure 2: *The mean scores of each item for individuals with T2DM*

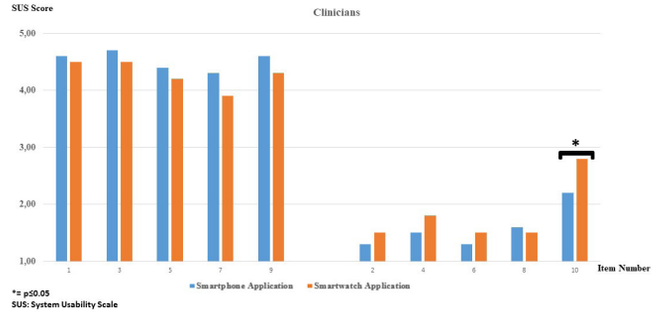

Figure 3: *The mean scores of each item for clinicians*

Table 1: *Demographic characterictics of the individuals with T2DM and clinicians*

Characteristics of the individuals with T2DM	**Smartphone application** Mean (SD) / N	**Smartwatch application** Mean (SD) / N
Age (years)	46,1 (8,9)	46,1 (8,8)
Diagnosis (years)	9,5 (3,1)	9,9 (2,8)
Education		
Graduate	2	2
Bachelor	7	8
High school	6	5
Secondary School	5	5
Mobile phone (operating system)		
Android	12	20
IOS	8	–
Characteristics of the clinicians		
Age (years)	37,3 (12,3)	38,9 (12,1)
Education		
Doctoral degree	6	6
Master degreee	4	4
Mobile phone (operating system)		
Android	7	10
IOS	3	–

SD: Standard Deviation

Table 2: *Comparison of SUS scores between smartphone v/s smartwatch for individuals with T2DM and clinicians*

Groups SUS score Item score	Individuals with T2DM			Clinicians		
	SP Median (min-max)	SW Median (min-max)	p*	SP Median (min-max)	SW Median (min-max)	p*
Items of SUS (higher score represents strongly agree)						
I think that I would like to use this app frequently. (item #1)	5 (3-5)	5 (2-5)	0,31	5 (1-5)	(1-5)5	0,36
I thought this app was easy to use. (item #3)	5 (3-5)	4 (2-5)	**0,01***	5 (1-5)	5 (1-5)	0,56
I found the various functions in this app were well integrated. (item #5)	5 (2-5)	5 (2-5)	0,08	4 (1-5)	4 (1-5)	0,20
I would imagine that most people would learn to use this app very quickly. (item #7)	5 (2-5)	5 (2-5)	0,10	4 (1-5)	4 (1-5)	0,57
I felt very confident using this app. (item #9)	5 (2-5)	4 (1-5)	0,19	5 (1-5)	4 (1-5)	0,07
Items of SUS (higher score represents strongly disagree)						
I found this app unnecessarily complex. (item #2)	1 (1-5)	1 (1-5)	0,06	1 (1-5)	1 (1-5)	0,29
I think that I would need assistance to be able to use this app. (item #4)	1 (1-5)	2 (1-5)	**0,01***	1 (1-5)	1 (1-5)	0,71
I thought there was too much inconsistency in this app. (item #6)	1 (1-5)	1 (1-5)	0,44	1 (1-5)	1 (1-5)	0,56
I found this app very cumber some awkward to use. (item #8)	1 (1-5)	1 (1-5)	0,18	1 (1-5)	1 (1-5)	0,63
I needed to learn a lot of things before I could get going with this app. (item #10)	2 (1-5)	3 (1-5)	**0,01***	2 (1-5)	3 (1-5)	**0,03***
Total score mean (SD)	**88,75 (9,34)**	**87,87 (7,56)**	**0,21**	**86,75 (8,68)**	**82,35 (6,59)**	**0,27**

** p ≤0.05 app: application, SD: Standard Deviation, SP:Smartphone, SUS: System Usability Scale, SW:Smartwatch*

4. DISCUSSION

The aims of this study was to understand the usability of Diabetex exercise platform on smartphone and smartwatch in individuals with T2DM and clinician. Moreover, objective of this research was to compare usability of Diabetex exercise platform designed for individuals with T2DM to provide exercise and physical activity tracking on smartphone and smartwatch devices. This study has demonstrated an excellent usability (SUS SCORE>80,8) [28] for Diabetex when delivered using smartphone and smartwatch devices in individuals with T2DM and clinicians. The comparison of two devices for the usage of platform showed that Diabetex exercise platform when presented through smartphone showed better usability than smartwatch for both individuals with T2DM and clinicians. The analysis of individual items revealed that for the individuals with T2DM these differences was due to technical support provided to use smartwatch that was not offered for smartphone. The participant also needed assistance to use smartwatch than smartphone and took longer time to learn all features of smartwatch than smartphone. Clinicians reported same statement with patient which to learn a lot of things before this application in smartwatch to compare with smartphone.

The results of this study demonstrated that participants encountered some difficulties to use the smartwatch that is due to the advance technically features of smartwatch in comparison to smartphone. Technical problems that battery technology as well as cultural barriers are emphasized in other study that evaluated smartwatch devices used for rehabilitation [29]. In another qualitative studies that included evaluation of wearable technology for women with breast cancer showed negative preference for uptake of technology for physical activity [30]. The participant in this study did not report any negative preference for Diabetex exercise platform. In fact, the participants reported satisfaction with two delivery methods that they can choose.

Usability problems are appraised as a feature that can lead mobile health to failure and inclusion of clinicians in development process has not been so common [31]. This research team who developed our application was included software engineers, clinicians and patients.

According to recent report, more than half of mobile device users had downloaded one or more mobile health apps but approximately half of those users do not use the applications [32]. This study show that usability of diabetes smartphone applications has limited user compatibility. In another study about mobile applications developed for T2DM, there was limited information on about usability of the mobile devices [33]. A review about mobile exercise health application stated technical problems and application malfunctions. Moreover, most applications developed are usually peer reviewed by professionals or clinicians [34]. Up to now, there are fewer number of studies that focus on usability for delivery of health services using mobile technologies such as smartphone [35] or wearable [36] technology. This study focused on difference in usability of these devices on perception individuals with T2DM as well as clinicians.

5. CONCLUSION

The current study showed that Diabetex exercise platform was seen excellent usability by individuals with T2DM and clinicians. Furthermore, usability of Diabetex exercise platform when delivered through smartphone has higher acceptability than delivered through smartwatch. An understanding of usability smartphone and smartwatch for

exercise application in individuals with T2DM and clinician will shed light on mobile app developers. The findings of this study have greater future implications in delivery of exercise interventions.

Limitations

The study was secondary analysis of data and was not designed to test the usability as the main outcome. There was lack of guidelines on the duration to get familiar with the online platform before administering SUS. The team thought one week would suffice as an acceptable time frame for people to be familiar with the platform. There was lack of data on the frequency of platform usage for individuals with T2DM.

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Clinical and Experimental Health Sciences

Evaluation of the Relationship Between the Patient Safety Culture and Medical Error Attitudes of the Pediatric Nurses

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ABSTRACT

Objective: This study was conducted descriptively so as to determine the relationship between the patient security culture and medical error attitudes of the nurses.

Methods: The population of the study was conducted between 10 August and 25 August 2017 that the data were collected in the hospitals in the eastern Turkey of 82 nurses working in children's services. The sampling selection method was not used in this study, but 68 nurses that were accessed between the dates and that accepted to participate in the study voluntarily were included in the sampling of the study. "Descriptive Information Form" in which the socio-demographic information of the nurses is assessed, "Patient Security Culture Scale (PSCS)" and "Scale of Attitudes towards Medical Errors (SAME)" were used as data collection tools in the study.

Results: Nurses received an average score of 3.71±0.27 from PSCS, and an average score of 3.02±0.44 from SAME. A significant relationship was determined between the education status of the nurses and their PSCS total score ($p<0.05$). As a result of the correlation analysis it was determined that there was a positively significant relationship between the PSCS score and SAME scores of the nurses, and as their PSCS scores increased, their SAME scored increased aswell.

Conclusion: Evaluation of the current status by conducting regular measurements in regard to patient security in institutions and should be make improvements accordingly. Also, nurses should take responsibility in patient safety and improvement of patient safety culture should be the main priority of the institutions.

Keywords: Patient Safety, Medical Error, Pediatric, Nurses

1. INTRODUCTION

The patient safety culture should be established in order to ensure patient safety in health institutions (1). The patient safety culture is defined as the transparency in error reports and a systematic approach for preventing medical errors and honesty (2). The patient safety culture is a multidisciplinary structure that combines information and communication technologies (3). It also contains value judgments, beliefs and rules on what is important in the organization and how to act about patient safety (4,5). The Institute of Medicine (IOM) which is known as the most influential body to guide medical practice in the United States, defines patient safety as the prevention of harm to patients. It has been reported that this is possible with a care system that is based on a safety culture that includes health care workers, institutions and patients and prevents errors and takes lessons from the errors (6). Turkey National Patient Safety Foundation defines patient safety as the prevention of medical service related errors and the elimination or reduction of the damages caused by these errors (7, 8).

According to the latest report published by the National Medical Institute in the United States in 2000, 44,000-98,000 people die due to medical errors in US hospitals every yeary. This figure reveals the importance of errors in health sector (9). The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) defines the concept of medical error as a harm to the patient as a result of an appropriate and unethical behavior by a healthcare professional and inadequacy and negligence in occupational applications (10). Similarly, the applications which elongate increase the length of stay of patients, deteriorate patients' health, harm of patients or lead to death due to lack of knowledge, inexperience, lack of interest or the technology, are considered as medical errors (11). The issue of medical errors is a growing problem in health. In a study, it was found that the ratio of those who believed that a medical error was 34% in the United States, 30% in Canada, 27% in Australia, 23% in Germany and 22% in the UK (12).

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The pediatric patient safety is a dynamic and complex subject as a result of the physiological and developmental characteristics of children. The growth and development are very fast during the first years of life and the maturation continues at a slow pace throughout the late childhood. This situation increases the risk of error due to children's cognitive and physical development. On the other hand, children, especially the children who are small and can not communicate verbally, are dependent on adults to meet their health needs. These differences are more influential in higher number of application errors in children than that in adults (13,14). Clinical differences should be taken into consideration for patient safety. Pediatric clinics need more effort in patient safety. Hospital environment is different from the familier environment of infants and children. It is a danger for health of them and a threat that prevents them from their normal environment and functions for a certain period of time. Therefore, a safe and positively influential physical environment is known to affect the infant and child physically, mentally and socially; it also shorten the process of recovery and hospital stay (15,16). Malpractice in nursing is impairment of patients due to tyhe lack standard application during nursing care. It is very important that pediatric nurses know the conditions that increase the risk of malpractice and take the necessary precautions in order to prevent to harm pediatric patients and their families and to protect themselves against the law. For reducing the risk of malpractice, pediatric nurses should keep away from administering a drug that they do not know well; they should consult a reliable source about this drug and negotiate with the physician (13).

The main condition for preventing medical errors and providing safe health care, is the establishment of the patient safety culture in health care institutions (17). The patient safety culture requires that all healthcare staff have the responsibility of patient safety culture in terms of the reporting of the factors that threaten patients and staff' safety and medical errors. It also requires the maintenance of the diagnosis, treatment and care services without causing harm to patients (18,19). In this context, it is very important to determine nurses in pediatric clinics have a tendency to medical error in which subjects. It is very important to detect medical errors at the right time before they cause serious harm to human health, to reveal their causes and to develop suggestions for their solution. For this purpose, determining the attitudes of the nurses who spend a long time with the patients and take care of them, towards the medical errors, especially towards the reporting of errors enable the necessary arrangements for the safe care. In this respect, the study was planned to determine the patient safety culture and medical error attitudes of pediatric nurses.

2. METHODS

2.1. Study design

This study was carried out as a cross-sectional, descriptive relational survey to determine the relationship between the pediatric nurses' patient safety culture and medical error attitudes. Relational survey model was used because it was desired to be described as it was without changing the situation. Relational survey models are research models which aim to determine the existence and/or degree of interchange between two or more variables.

2.2. Setting

The population of the study was conducted between the dates 10 August and 25 August 2017 that the data were collected in the hospitals in the eastern Turkey of 82 nurses working in children's services.

2.3. Sample

The universe of the study consisted of 82 nurses working in pediatric clinics in the hospitals in the eastern provinces of Turkey at the time the study. The sample selection method was not used in the study; 68 nurses who were reached at the the time of the study and who accepted to participate in the study were included in the sample of the study. The data were collected by using the Introductory Information Form, Patient Safety Culture Scale (PSCS) and Scale of Attitudes towards Medical Errors (SAME).

2.4. Research Questions

- Is there a relationship between patient safety culture and medical error attitudes of pediatric nurses?
- Is there a relationship between sociodemographic, work-related characteristics and medical errors and patient safety culture and medical error attitudes?

2.5. Instruments

2.5.1. Descriptive Information Form: A twenty item questionnaire form which was prepared by the researchers was used to collect the data. This form included the questions about demographic data, professional knowledge, patient safety and medical errors.

2.5.2. Scale of Attitudes Towards Medical Errors (SAME): It is a 16-item scale which was developed by Gülec and Intepeler to determine the attitudes of health care professionals' attitudes towards medical errors. The Scale of Attitudes Towards Medical Errors is a 5-point Likert-type scale. It consists of three sub-dimensions as medical error perception (1st and 2nd items), medical error attitude (3. 8. 10. 11. 12. 13. and 14. items) and the causes of medical errors. It's scoring is (1) I strongly disagree, (2) I disagree, (3) I am

neutral, (4) I agree and (5) I totally agree. Two items in the scale (item 10th and 13th) are scored in reverse. In scoring, the score from the whole scale is taken; the scale score is obtained by dividing the raw score by the number of items in the scale. In the sub-dimension score calculation, the total sub-dimension score is calculated; the sub-dimension is divided by the number of items; the score is rated between 1-5. The cut-off point of the scale has been determined as 3. The medical error attitudes of health care professionals who have a score less than 3 points on the scale are considered to be negative, while medical error attitudes of health care professionals who score 3 or higher are considered as positive. A negative attitude means that health care professionals are less aware of the importance of medical errors and medical error reporting. The positive attitude shows that health care professionals' awareness about the importance of medical error and error reporting is high. The scoring and assessment of the whole scale is accepted for all sub-dimensions of the scale in the same way. In the study of Güleç and İntepeler (20), the Cronbach's alpha reliability coefficient of the Attitude Scale for Medical Errors was found as 0.75. Cronbach's alpha coefficient ranged from r = .73 to .86 in this study.

2.5.3. Patient Safety Culture Scale (PSCS): For the assessment of the patient safety culture, the PSCS was developed by Türkmen et al. The validity-reliability study of this scale was conducted in the nursing group, it consists of 51 items. The PCS consists of 5 sub-dimensions as management and leadership (17 items), staff behavior (14 items), unexpected events and error reporting (5 items), staff training (7 items) and care environment (8 items). The PSCS is a 4-point likert type measurement tool. The effectiveness of patient safety practices is evaluated based on the scores ranging from "1 Strongly disagree", 2 "Disagree", "3 Agree" to "4 Strongly agree". In the analysis of the score on the scale, the increase in the mean score up to 4 shows positive patient safety culture and the decrease to 1 indicates the presence of negative patient safety culture. Turkmen et al.(21) found that the Cronbach's alpha reliability coefficient was found to be 0.97 for the whole scale and 0.83-0.92 for the sub-dimensions. In this study, the Cronbach's Alpha reliability coefficient of the scale was found as 0.97 while the coefficient of the sub-dimensions ranged between 0.85 and 0.94.

2.6. Ethical Statement

The ethical committe approval and required permissions were obtained from the Ibrahim Cecen University Ethics Committee (No: 95531838-050.99) and the Provincial Health Directorate and the institutions. The purpose of the study was explained to the nurses and information was given about their right to withdraw their consent at any time. After the verbal permissions of the participants were obtained, the questionnaire form was applied. The principles of the Declaration of Helsinki were agreed before the forms were applied.

2.7. Data Collection

The verbal permissions of the nurses were obtained after the explanation of the aim of the study to them. After that, the forms were applied to the nurses who accepted to participate in the study with face to face interview method by the researchers in the nurse room. It took approximately 10-15 minutes.

2.8. Statistical Analysis

The analyzes were performed with Windows Statistical Package for Social Sciences (SPSS) 21.0. The normality of the data was evaluated by using Shapiro-Wilk test. Data was not normally distributed. The descriptive statistical methods such as number, percentage, mean and standard deviation were used in the analysis of the data while Kruskal Wallis Test and Mann Whitney U test were used for the comparison of SAME and PSCS scores of the groups. Pearson's correlation coefficient was used for the analysis of the relationship analysis between age, occupational experience, working time in pediatric service and SAME, PSCS scores. The results were evaluated at 95% confidence interval and $p<0.05$ was considered as statistically significanct.

3. RESULTS

83.8% of the nurses included in the study were female; 48.5% of them had an undergraduate education 50.0% of them were single; 50% of them worked shifts. The mean age of the nurses was 26.88±4.87; their mean time of professional experience was 6.01±4.04 years; 75% of them enjoyed their profession. 36.8% of the nurses in the study had previously encountered a medical error; 19.1% of them stated that they made a medical mistake during their career. 45.6% of the nurses believed that the cause of medical error is high workload/low number of staff; 48.5% of them thought that the most common drug administration error was wrong dose (Table 1).

In Table 2, the mean scores of the pediatric nurses on the whole SAME and PSCS and on the subdimensions of them were given. The mean score of the nurses on the whole SAME was 3.02±0.44. Their mean score on the Medical Error Perception sub-dimension was 1.96±0.48; their mean score on the Medical Error Attitude sub-dimension was 3.53±0.73; their mean score on the Medical Error Causes sub-dimension was 3.59±0.58. The mean score of the nurses on the whole PSCS scale was 2.71±0.27. Their mean score on the Management and Leadership sub-dimension was 2.60±0.45; their mean score on the Staff Behavior sub-dimension was 2.77±0.43; their mean score on the Unexpected Case and Error Reporting sub-dimension was 3.02±0.77; their mean score on the Employee Training sub-dimension was 2.58±0.68; their mean score on the Care Environment sub-dimension was 2.60±0.48.

Table 1. Distributions of nurses'sociodemographic, work-relatedcharacteristicsandmedicalerrors

CHARACTERISTICS	N	%
Age		
19-25	32	47.1
26-32	30	44.1
33-39	6	8.8
Gender		
Female	57	83.8
Male	11	16.2
Education Level		
High School	18	26.5
Associate Degree	13	19.1
Undergraduate	33	48.5
Postgraduate	4	5.9
Marital Status		
Single	34	50.0
Married	34	50.0
Child bearing Status		
Yes	11	16.2
No	57	83.8
Working Type		
Full Time, On Days	34	50.0
Shift	34	50.0
Occupational Enjoyment		
I enjoy	51	75.0
I don't enjoy	5	7.4
Neutral	12	17.6
Have you ever encountered a medical error?		
Yes	25	36.8
No	43	63.2
If yes, who made the medical error?		
Nurse	19	76.00
Physician	6	24.00
What is the cause of medical errors according to you?		
High work load/low number of staff	31	45.6
New staff /Poor practice	8	11.8
Loading non-tasking jobs	11	16.2
Stress/Fatigue /Exhaustion/Busy schedule	18	26.5
Have you ever made any medical errors in your career?		
Yes	13	19.1
No	55	80.9
The most common drug administration error which you encountered		
Wrong administration way	10	14.7
Wrong administration time	11	16.2
Wrong patient	4	5.9
Wrong dose	33	48.5
Wrong medication	10	14.7
Causes of patients falling at your service		
Physical and consciousness state of the patient	6	5.9
Not using the bed edge bars	39	57.4
Wet floors	6	5.9
Carelessness of staff	8	11.8
Having no companion	9	13.2
Total	68	100.0
Age (Mean±SD)	26.88±4.87	(min=19, max=39)
Length of Professional Experience (Mean±SD)	6.01±4.04	(min=1, max=20)
Working Years in Pediatric Service (Mean±SD)	4.25±2.73	(min=1, max=11)
Total Weekly Working Hours (Mean±SD)	53.10±15.59	(min=40, max=72)
Daily Number of Patients (Mean±SD)	21.00±17.42	(min=2, max=30)

N= number, SD= standard deviation

Table 2. *The Pediatric Nurses' Mean Scores on the SAME and PSCS (N=68)*

	Minimum	Maximum	Mean	Standart Deviation
SAME Total Score	0.94	4.57	3.02	0.44
Medical Error Perception	0.25	3.00	1.96	0.48
Medical ErrorAttitude	1.43	7.86	3.53	0.73
Medical Error Causes	1.14	4.86	3.59	0.58
PSCS Total Score	1.82	3.49	2.71	0.27
Management and Leadership	1.71	3.71	2.60	0.45
Staff Behavior	1.78	4.11	2.77	0.43
Unexpected Case and Reporting Error	1.00	4.10	3.02	0.77
Staff Training	1.00	4.00	2.58	0.68
Care Environment	1.33	3.83	2.60	0.48

In Table 3, the relationship between the scores of the pediatric nurses on the whole SAME and PSCS were analyzed. As a result of the correlation analysis, a significant relationship weak and positive correlation was found between the mean score of the nurses on the SAME scale and their mean score on the PSCS scale (r=0.326; p=0.007). As the scores of the nurses on the whole SAME increased, their scores on the whole PSCS increased.

Table 3. *Pearsoncorrelationcoefficientbetweenthepediatricnurses' scores on thewhole PSCS andSAME (N=68)*

	PatientSafetyCultureScale (PSCS)	
	r	p-Value
Scale of AttitudesTowardsMedicalErrors (SAME)	+0.326	0.007

In the correlation analysis, there was no significant relationship between the mean age of the nurses, their length of professional experience, their working years in pediatric service, their total weekly working hours and their mean scores on the PSCS and SAME (p>0.05). However, a significant relationship weak and negative correlation was found between the mean daily number of patients of the nurses and their mean scores on the PSCS and SAME (p<0.05). As the daily number of patients of the nurses increased, their scores on the PSCS and SAME decreased (p<0.05). As a result of the analyzes (Kruskal Wallis Test and Mann Whitney U test), a significant relationship was found between the education status of nurses and their scores the PSCS (p<0.05), but there was no significant relationship in terms of the total SAME score. No significant relationship was found between the marital status of the nurses, their occupational enjoyment, working type, the status of making a medical error and their scores on the SAME and PSCS (p>0.05). (Table 4).

Table 4. *Pearson correlation coefficient between the pediatric nurses' scores on thewhole PSCS andSAMEscales(N=68)*

	PSCS		SAME	
	r	p-Value	R	p-Value
Age (Mean±SD)	-0.026	0.835	-0.060	0.629
Length of Professional Experience (Mean±SD)	-0.235	0.273	-0.245	0.044
WorkingYears in Pediatric Service (Mean±SD)	-0.194	0.113	-0.209	0.352
Total WeeklyWorkingHours (Mean±SD)	+0.135	0.273	+0.094	0.446
Daily Number of Patients (Mean±SD)	-0.314	**0.009**	-0.365	**0.002**
	PSCS		**SAME**	
	Mean±SD	**test and p**	**Mean±SD**	**test and p**
Education Level				
High School	2.50±0.20	KW=9.72	2.97±0.56	KW=0.88
AssociateDegree	2.65±0.34	p<0.05	2.99±0.37	p>0.05
Undergraduate	2.70±0.29		3.04±0.14	
Postgraduate	2.76± 0.25		3.14± 0.24	
MaritalStatus				
Single	2.69±0.53	MWU=397.50	2.97±0.23	MWU=550.50
Married	2.73± 0.33	p>0.05	3.08± 0.31	p>0.05
WorkingType				
Full Time	2.65±0.26	MWU=546.00	2.96±0.47	MWU= 422.00
On DaysShift	2.77±0.27	p>0.05	3.09±0.40	p>0.05
OccupationalEnjoyment	2.73±0.28	KW=1.57	3.04±0.48	KW=7.03 p>0.05
I enjoy	2.64±0.21	p>0.05	2.88±0.47	
I don'tenjoy	2.66±0.26		3.02±0.21	
Neutral				
Haveyou ever madeanymedical errors in yourcareer?				
Yes	2.51±0.44	MWU= 230.00	2.88±0.74	MWU= 181.00
No	2.76± 0.19	p>0.05	3.06± 0.34	p>0.05

SD= standard deviation

4. DISCUSSION

The development of safety culture in healthcare is an important component of the prevention or minimisation of medical errors. In this study which was conducted to determine the relationship between pediatric nurses' patient safety culture and their medical error attitudes, the mean score of the nurses on the whole SAME was determined as 3.02±0.44. In the study of Gök(22) which investigated the relationship between the pediatric nurses status for reporting medical errors and their attitudes towards medical errors, the mean score of the nurses on the SAME was 3.48±0.51. This finding is similar to our finding. Since the mean score of the nurses on the SAME was higher than 3, it can be suggested that their attitudes towards medical errors are generally positive.

In this study, it was found that 36.8% of the pediatric nurses encountered a medical error while 19.1% of them had previously made a drug administration error. The most common type of drug administration error encountered by the nurses was determined as wrong dose (48.5%). When the literature was searched, it was seen that the rates of encountering medical errors by nurses varied but the types and causes of medical errors were similar. In a study of Gök (22), 40.8% of the pediatric nurses reported more than one drug administration error in their clinics in a year. Ersun et al.(23) found that 61% of the pediatric nurses encountered medical errors; 48.5% of them witnessed the errors of their colleagues; the most common medical error (57.8%) was drug administration errors. It was also determined that 27.7% of the nurses had previously made a drug administration error while the most common type of drug administration error was the wrong dose (67.8%). In a study of Mayo and Duncan (24)it was found that 46.5% of 983 nurses made drug administration errors. In the study of Özkan et al. (25) the medical error rate was found as 35.5%. The rate of witnessing the errors of the nurses was determined as 10.4% in a study of Özata and Altunkan (26). According to the study of Glaheb et al. (27) the error rate was 27.6% . Young et al. (28) reported that the rate of drug administration errors was 28.2%. In a study of Çırpı et al. (5), it was found that the drug administration errors was on the first place among the errors encountered by nurses with the ratio of 57.0%. In a study of Madegovda et al.(29), the drug administration errors were found to be related to wrong dose (16.7%), wrong medication (10.0%), wrong time (9.2%) and wrong patient (7.5%), respectively.

In this study, 45.6% of the pediatric nurses stated that the cause of medical errors was the high workload/low number of staff. In this study, it was observed that the scores of the nurses on the SAME and PSCS decreased when the daily number of patients of them increased. In their study conducted with the pediatric nurses, Lan et al. (30) reported that the most important cause of drug administration errors (67.4%) was low number of nurses. In their study, Sears et al.(31) analyzed 372 drug administration error reports of the pediatric nurses. According to their findings, the main three reasons for drug administration errors were high workload, distraction and ineffective communication. You et al.(32) reported that low number of nurses in each shift and the administration of similar named or labeled drugs were the main causes of drug administration errors. Parry et al. (33) reported that nurse to patient ratio was a factor in drug administration errors in their systematic review Chang and Mark (34)determined that the number of drug errors decreased when the number of the nurses in the services increased. In a Turkish study of Gök (22), it was determined that the main causes of the pediatric nurses' drug administration errors were the number of patients per nurse (92.7%) and workload (91.1%). In the SAME, they also reported that high number of patients (81.1%) and the long daily working hours (83.8%) increase the number of medical errors. Özkan et al.(35) reported that the main reason of the errors was the workload of pediatric

nurses. In the study of Törüner and Uysal(36)which was conducted with 119 pediatric nurses, it was determined that the long working hours (68.1%) and the number of patients per nurse (58.8%) were the main causes of drug administration errors. According to the study conducted by Özata and Altunkan(26) high workload, low number of the nurses were the leading causes of medical errors.In the study of Ateş (37) nurses reported that the main causes of drug administration errors were high number of patients per nurse, long working hours, the lack of pediatric forms of drugs and fatigue. According to the studies in Turkey and in other countries, drug administration errors originated from the system. It is very important to detect medical errors at the right time before they cause serious harm to human health, to reveal their causes and to develop suggestions for their solution. The arrangements for the prevention of errors should be aimed at both reducing the workload of nurses and effective planning of the number of patients per nurse. For this purpose, determining the attitudes of the nurses who spend a long time with the patients and take care of them, towards the medical errors, especially towards the reporting of errors enable the necessary arrangements for the safe care (20,22).

In this study, the mean score of the nurses on the PSCS was 2.71±0.27. The mean score nearly 4 shows a positive patient safety culture. In this study, it could be considered that the perception of patient safety culture wass slightly above the medium level. In the study of Rızalar et al.(38)the mean score of the nurses on the PSCS was 2.64±0.43. In the study of Ertürk et al.(39) the mean score of the nurses on the PSCS was 2.81±0.40.Karaca and Arslan(40) found that the mean score of the nurses on the PSCS was 3.00±0.539.In a study of Özdemir (41) in which another patient safety culture scale was used and the mean score ranged between 1 and 5, the mean score of patient safety culture was found to be 3.40±0.70. In the studies of Dursun et al.(19) and Erdağı and Özer (42) patient safety perception was found to be above the middle level.These studies support the results of our study and the nurses' perception levels about patient safety culture were above the middle level. In the study, the perception level about patient safety was not very good, therefore it showed the necessity to make improvements.

When the scores on the sub-dimensions of the PSCS were analyzed, it was found that the nurses had the highest score on the Unexpected Event and Error Reporting subdimension (3.02±0.77) while they had the lowest score on the Staff Training subdimension (2.58±0.68). In the study conducted by Türk et al. (43), the highest score on the patient safety dimension was reported on the Event and Error Reporting subdimension (2.4±0.735) in accordance with our study. According to this, it is possible to suggest that the nurses had the necessary sensitivity about the incident and error reporting; the nurses exhibited adequate attitudes and behaviors. Rızalar et al.(38)found that the scores of the nurses on the staff training subdimension were generally low (2.59±0.73). In the study of Erdağı and Özer(42) the lowest mean score of the nurses was on the staff training subdimension of the PSCS (2.45±0.61). Our study findings were similar to the findings of these studies. One of the most emphasized areas within the framework of the quality studies is the training of employees. Therefore, low level of staff training is not an expected condition. It is considered that providing training to staffs of institutions to improve the safety culture in institutions is an important step in terms of the functionality of the culture.

5. CONCLUSION

In a conclusion, it was found that the attitudes of the nurses about medical errors (3.02±0.44) were generally positive; their patient safety culture perception (2.71±0.27) was slightly above the medium level. A significant relationship was found between the attitudes of nurses about medical errors and patient safety culture. In this study, the error rate of pediatric nurses in pediatric clinic were found to be 19.1% while their rates of witnessing an error rate was found as 36.8%. For the pediatric nurses, it is considered that these rates should be further reduced and error tendency should be much lower. For this reason, importance should be given to orientation and in-service training programs and safe communication issues related to the drug administrations and pediatric dose drug calculations taking into account the development and physical characteristics of pediatric patients in order to eliminate or minimize the medical errors. Reporting of errors and events, improvement of care environments, adequate number of nurses, regulation of working hours and appointment of specialized nurses provide benefit. Adding the subject of patient safety to the curriculum of nursing education and raising the awareness of patients about patient safety are beneficial. In addition, the number of studies for analyzing nurses' attitudes about medical errors and patient safety culture should be increased. The information obtained about the nurses' attitudes about medical errors and their patient safety culture was based on their statements; no observation could be made about this. The results can be only generalized to the nurses in the study group.

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Clinical and Experimental Health Sciences

Prevalence and Characteristics of Soft Tissue Calcifications in Cbct Images of Mandibular Region

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ABSTRACT

Objectives: The goal of the study is to evaluate the prevalence and characteristics of soft tissue calcifications (STCs) detected in the mandibular region in CBCT images.

Methods: 242 (150 female, 92 male) mandibula CBCT images were evaluated in this study. Prevalence, anatomical location, pattern (bilateral or unilateral), size (mm), number (single or multiple), age (<35, 35-50, >50) and gender tendency were recorded. Images were evaluated in the axial, coronal and 3D reformated images. The Chi-square test was used to test for differences of the STC groups and the percentage values.

Results: 88 patients (36.4%) had at least one STC in the mandibular region. The mean age of the patients with STC was 58.3±11.06 years. No gender predilection was stated in terms of the presence of STC. STC was higher in patients over 50 years than the other age groups (p=0.00). Most of the STCs were unilateral, above 3mm in size, single and located in the lingual aspect of the mandible.

Conclusion: It is of vital importance for clinicians to know characteristics of STCs and to detect STCs in early stages especially those concerning systemic conditions and to prevent life-threatening consequences.

Keywords: Cone Beam Computed Tomography; Mandible; Soft Tissue Calcification; Prevalence

1. INTRODUCTION

Soft tissue calcifications (STCs) in the maxillofacial area are uncommon and generally, correspond to radiographic findings in routine radiographic examinations. STC is classified as idiopathic, dystrophic, or metastatic. Dystrophic calcification occurs in degenerating, diseased, and dead tissue despite normal serum calcium and phosphate levels. In contrast, metastatic calcification is the process by which normal undamaged tissues are calcified by means of a hypercalcemic condition like what occurs in hyperparathyroidism (1).

In the diagnosis to determine the exact location of STC is one of the primary challenges. Due to the presence of ghost images, panoramic radiographs remain incapable in the diagnosis of STC (2). In addition, STCs located in the head and neck area are positioned adjacent to each other and estimation of the true position is very difficult in conventional imaging (3).

In recent years, cone beam computed tomography (CBCT) has become more widely used in dentomaxillofacial imaging. CBCT provides three-dimensional images and supplies sagittal, coronal, and axial images plus their multiplanar transformation (4). According to the guidelines of the American Academy of Oral and Maxillofacial Radiology, CBCT images constitute a valuable tool for determining the location of STCs (5).

The goal of this retrospective study is to evaluate the prevalence of STC in the mandibular region of a Turkish subpopulation by using CBCT images and to detect their anatomical location, pattern, size, number and age/gender tendency.

2. MATERIALS and METHODS

The study was approved by the X University Ethical Committee (approval number 2018/15) and conducted according to the principles described in the Declaration of Helsinki, including all amendments and revisions. This retrospective study assessed the soft tissue calcification in the mandibular region of 242 patients consisting of 92 male and 150 female (from 12 to 76 years) with the mean age of 46.42 years. CBCT data

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of patients who recruited to in X University, Dentistry Faculty for several reasons were retrospectively evaluated. The CBCT images were obtained using the I-CAT 3D Imaging System (Imaging Sciences International, Hatfield, PA, USA) with the following parameters: 5 mA, 120kVp, 16x13 cm FOV. Images were evaluated in the axial, coronal and 3D reformated images. Images were evaluated according to presence, anatomical location, pattern (bilateral or unilateral), size (mm), number (single or multiple), age (<35, 35-50, >50) and gender tendency. The anatomical location of STCs in relation to mandibular bone were categorized into six regions (Figure 1) as follows; Regions A and F, which comprised the vestibular aspect of the mandible, extending from the lower first premolars to the edge of the scan (distally); regions B and E, which comprised the lingual aspect of the mandible, extending from the lower first premolars to the edge of the scan (distally); region C, which comprised the lingual aspect of the anterior teeth, from canine to canine; region D, which comprised the vestibular aspect of the anterior teeth, from canine to canine. All measurements were done twice by one observer (S.B.).The SPSS 25© software (SPSS Inc., IBM Company Headquarters, Chicago, IL) was used for storing and analyzing data. The significance level value was set at 0.05. The Chi-square test was used to test for differences of the STC groups and the percentage values.

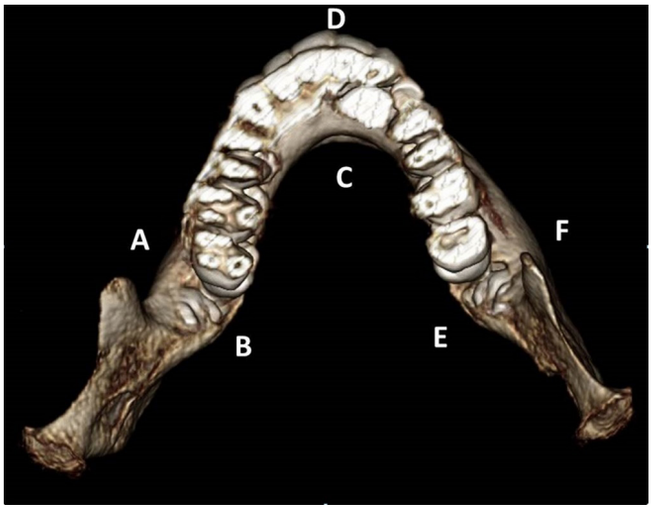

Figure 1. *Schematic illustration of the location of the STC in the CBCT axial image.*

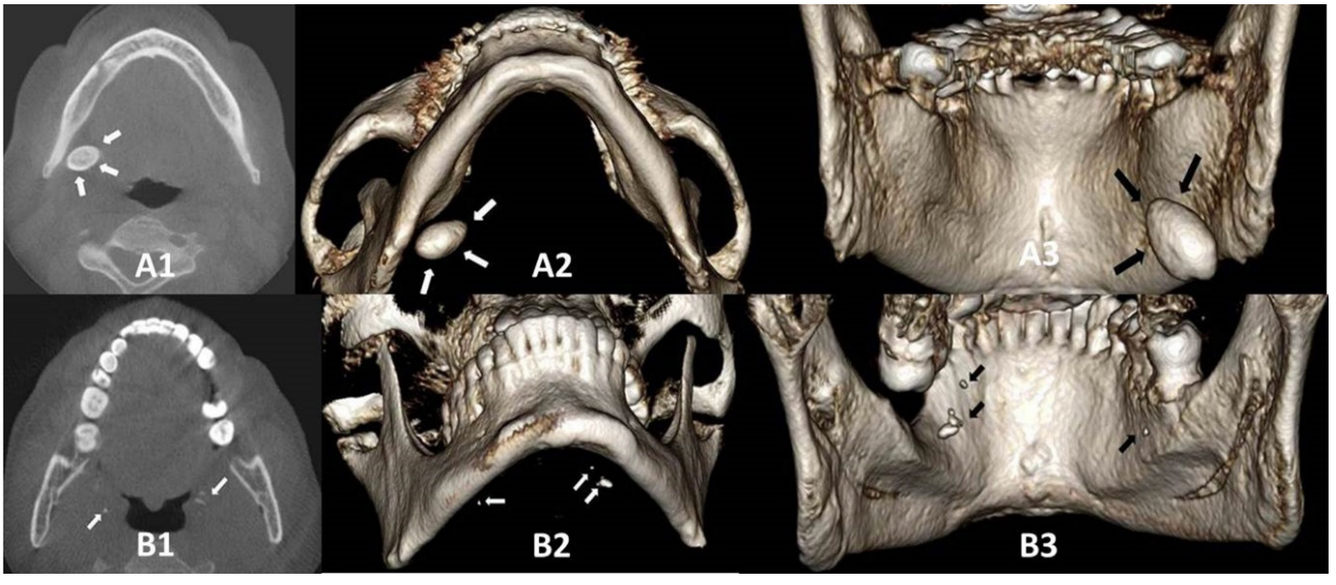

Figure 2. *STC samples are shown with arrows: A1, B1 (coronal CBCT image); A2, B2 (base of mandible's 3D reconstructed image); A3, B3 (inside of the mandible's 3D reconstructed image)*

3. RESULTS

The overall prevalence of STC was 36.4% in the studied population. The mean age of patients with STC was 58.3±11.06 with the age ranging between 21 and 67 years. According to anatomical location, STCs were the most located in the lingual aspect of the mandible whereas the least located in the lingual aspect of the anterior teeth with statistical significance (p=0.035). When we evaluated STCs in terms of pattern, unilaterality was observed higher among STCs (p=0.000). Assessment according to the size of STC showed that above 3 mm was the most observed size (p=0.000). Multiple STCs were fewer than single STCs with statistical significance (p=0.015) (Table 1). There was no statistically significant relationship between gender and the presence of the STC as demonstrated in Table 2 (p=0.671). Age was stated statistically related to STC (p=0.000).STC was observed higher in patients over 50 years than the other age groups (Table 3).

Table 1. *Anatomical location, pattern, size distribution and the number of the STCs.*

	Anatomical Location				Pattern		Size (mm)			Number	
STC	a/f	b/e	c	d	Bilateral	Unilateral	<=1	1<size<3	>=3	Single	Multiple
n	26	35	3	24	27	61	28	25	35	55	33
%	29.54	39.77	3.40	27.27	30.68	69.32	31.82	28.41	39.77	62.50	37.50

Table 2. *Correlation between gender and the presence of the STCs.*

Soft Tissue Calcifications						
Gender	n (%)	Absent n (%)	Present n (%)	Odds Ratio	%95CI	p
Male	92 (38.02)	57 (61.96)	35 (38.04)	0.89	(0.52-1.524)	0.671
Female	150 (61.98)	97 (67.67)	53 (35.33)			
Total	242 (100)	154 (63.63)	88 (36.37)			

Table 3: *Correlation between age and the presence of the STCs.*

Soft Tissue Calcifications						
Age	n (%)	Absent n (%)	Present n (%)	Odds Ratio	%95CI	p
<35	57(23.55)	49(31.82)	8(38.04)			
35-50	103(42.56)	62(40.26)	41(35.33)	4.05	(1.74-9.43)	**0.000***
>50	82 (33.88)	43(27.92)	39(42.56)	5.56	(2.34-13.18)	
Total	242 (100)	154(63.63)	88(36.37)			

4. DISCUSSION

It is worth mentioning that there is a considerable variation in the prevalence of STC among various studies. The prevalence may be influenced by differences in age, studied populations and sample size. In addition, the evaluation method has great importance in the diagnosis of STCs: indeed, three-dimensional imaging modalities have shown greater efficiency than conventional radiography in the detection of these conditions (6).

In the current study, the prevalence of STC was found at 36.4%. Age was found to be significantly related to STC whereas gender was stated unrelated. Most of the STCs were unilateral, above 3 mm in size, single and located in the lingual aspect of the mandible.

The presence of STC in some tissues may be associated with the presence of a systemic condition and represent a sign of more potentially threatening consequences. It is therefore reasonable that dental practitioners to enhance their comprehension of the anatomy of the head and neck structures and potential sites of calcification (1).

da Silva Nunes et al. (2) found STC prevalence as 15% in CBCT images of the mandible and predominantly at the posterior region of the mandible with no relation to gender and age. Icöz and Akgünlü (7) assessed 4263 panoramic radiographs for the presence of STC and estimated only 6.4 % STC in the whole study population. Difference between the current study in terms of incidence may be attributed to radiological examination methods used in the studies. But in line with our study, the authors also stated that the prevalence of calcifications increased with age. Contrary to current results, the authors also detected more calcification in women than male counterparts. This relationship was stated due to a decline in the estrogen level after menopause, which affects the lipoprotein metabolism by preventing the formation of atheromatous plaques and its reduced levels may increase the prevalence (8). The limited sample size of patients to reach statistical difference between gender groups may be the limitation of the current study.

Missias et al. (6) evaluated the prevalence of STCs using CBCT images with various fields of view (FOV) including both maxilla and mandible, maxilla only and mandible only. Of the studied samples, STC was observed in 62.6% with the highest prevalence in both maxilla and mandible (76.8%) and the least prevalence in maxilla only (57.2%). The authors found no association between STCs and patients' gender or age.

Khojastepour et al. (3) found the prevalence of STC as 25.9 % in the mandibular region with the mean age 51.7 years. STCs were higher in the male population and predominantly detected in the posterior region of the mandible. The prevalence of STC increased with age and most of them were smaller than 3 mm. In the current study, in contrast with Khojastepour et al. the rate of incidence was higher (36.4%), the mean age of patients with STC was higher, no gender predilection was stated and most of the STCs were higher than 3 mm.

In a study by Garay et al. (9) 3028 dental panoramic radiographs were examined in terms of STC in the mandibular

angle area. They stated a total of 79 calcifications (2.61%) in 75 individuals which increases with age. Also, a large number of the calcifications found were small, of low density and unilateral.

The other limitation of this study is the retrospective nature that makes it impossible to clinically examine, to reach patients' entire history and to accurately diagnose the patients. So we prefer not to classify calcifications themselves. We also have not compared our results with the studies those reporting the incidence of various STCs such as tonsilloliths, sialoliths.

5. CONCLUSION

In the current study, a considerable amount of STC was detected in the mandibular region especially in the older age group. Considering these finding it is essential for the practitioner to have detailed knowledge regarding these entities.

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Clinical and Experimental Health Sciences

Comparison of the Accuracy and Time Efficiency of Two Different digital Impressions of Single Tooth Implant Treatments

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ABSTRACT

Objective: Over the last decades, techniques and materials have evolved with the improvement in digital technology. Computer-aided impressions have been transforming the dental implant field with these developments. The aim of this in vivo study was to compare the accuracy and time efficiency between two intraoral scanning systems in single tooth implant treatment.

Methods: 10 patients with single tooth bone level implant (Straumann, Basel, Switzerland) received one conventional impression with polyvinyl siloxane and three scans with 2 different intra-oral scanners (CEREC AC Omnicam and Straumann CARES IOS). The time required for the impressions was measured at this stage. The casts obtained from conventional impressions were scanned as the master model to evaluate accuracy. Digital impression files were analyzed using a software (Geomagic Control). Independent Samples Test was performed for trueness and precision. One-way ANOVA was executed for time efficiency. Least significant difference test for post hoc comparison was conducted ($p<0.05$).

Results: The differences between the two systems regarding trueness and precision were not statistically significant ($P>0.05$), but a statistically significant difference was found in the time efficiency ($P<0.05$). CEREC AC showed the lowest mean values in time measures.

Conclusions: There was no difference regarding accuracy in comparison between CEREC AC Omnicam and CARES. CEREC AC Omnicam was found to be superior in terms of time efficiency in comparison to CARES and conventional impressions.

Keywords: Intraoral digital scanning, Implant impression, Accuracy, CAD/CAM

1. INTRODUCTION

Impressions have been used since the end of eighteenth century in the dental field, and still very essential in the practice of dentistry. Throughout the past two centuries, making dental impressions have greatly evolved, including compound, molded wax, synthetic rubbers and reversible and irreversible hydrocolloids. The 20th century showed outstanding advances in technology, and digital impressions came about in the 1980's for use in dentistry. In the decades following till recently, digital impression techniques have been evolving and their uses still broadening. Digital impressions and 3D models used widely in the application of dental field and dental specialties. Uses of digital models for prosthodontics contain analysis of occlusion, appliance design and production, treatment simulation and treatment effects (1).

The main reason digital impression technology has not been fully integrated into modern dentistry is the endurance of conventional impression techniques. These methods include hydrocolloid and elastomeric materials, such as alginate, polyether, and polyvinyl siloxane. The advantage of these materials is that they are well accepted, accurate and are generally inexpensive. However, these methods have been reported as unpleasant and not favored by the patients (2).

Additionally, these conventional impression techniques require stocking of raw materials and inventory as well as storage space for the stone casts. Digital impressions and the 3-dimensional models have huge advantages over plaster models and elastomeric materials, including more efficient storage and retrieval, superior durability, increased diagnostic versatility, decreased processing time and easier transferability (3).

The most familiar conventional impression materials in implant treatments are polyvinyl siloxane (PVS) and polyether (PE). These materials show great dimensional accuracy and have been successfully used in prosthodontics for years (4,5). PVS is one of the commonly used impression materials

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in the field of dentistry; it is proved to guarantee accurate impression of the oral cavity (6-8).

The popularity of digital impression techniques has been increasing in dentistry fields due to the supported evidence of their accuracy (9). Since the advent of 3-dimensional scanning in dentistry, several dental and prosthodontics companies have started making digital scanners and comprehensive software analysis programs that supply many functions. These functions can ease procedures that were traditionally performed using physical models such as dental analysis, occlusal setups, and treatment predictions. The digital software innovates new procedures that were not presented with plaster casts, such as allowing visualization of tooth movements, the ability to overlay models and treatment outcomes (10).

There is a changing market of scanners available due to variety of intra-oral scanning systems. Digital scanners differ in acquisition techniques as well as in the unit's weight, speed and size. Digital scanners have different methods for the acquisition of intraoral impression, these methods are triangulation, parallel confocal, active wave front sampling, accordion fringe interferometry and three-dimensional in-motion video (11).

The 3D implant position can be captured digitally with an intra-oral optical scanner. One of the advantageous of intraoral optical scanner is that they can be used chairside for immediate digitization (12-14). Afterwards, the scanning data are saved as standard tessellation language (STL) files and can be used for digitalization and manufacturing of customized abutments and supra-structures with novel restorative materials (15).

Accuracy consists of trueness and precision (ISO 5725-1). Precision refers to how repeated scans match each other, thus the scanner with higher precision indicates a more repeatable and regular scan. Trueness indicates how different are the scanned measurement from the actual dimensions of the scanned structures (Fig 1). Therefore, the scanner with high trueness means that the scanner provides a matching or close result to the real dimensions of the scanned structure (16).

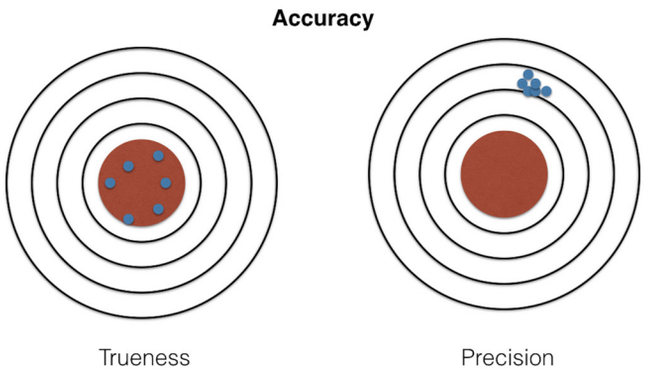

Figure 1. *Truness and presicion*

Accuracy is a prime aspect in function and aesthetics of indirect restorations. The fit of implant-supported dental restorations has been debated comprehensively in the literature. In contrast to natural teeth, osseointegrated implants cannot compensate for minor inaccuracies of the prostheses, as they are practically immobile. Their sensory discrimination is more limited than for teeth (17, 18).

The clinical time associated with chair-side digital scanning systems mostly plays significant role in the adaptation of this new technology. These days a few information concerning the learning curve and efficiency of the digital scanning techniques is presented and specific technologies in particular (13,15).

The aim of this in vivo study is to compare the accuracy (trueness, precision) of a powder-free, continuous imaging impression system (CEREC AC Omnicam) and Multi-scan Imaging system with powder coating (Straumann CARES IOS) to determine the more accurate system and to compare the differences in time (impression time) required to create clinically acceptable impressions using material-based (polyvinyl siloxane [PVS]) monophasic impression with two chairside digital scanning systems (CEREC AC Omnicam and Straumann CARES IOS).

The null hypothesis was (1) because of requiring a layer of powder, the inhomogeneous powder thickness may affect the accuracy comparing with powder free system (2). There will be no difference in the time required to perform clinically acceptable impressions using material-based (polyvinyl siloxane [PVS]) monophasic method and chairside digital scanning techniques.

2. METHODS

This project was approved by the Ethics Committee of Marmara University in Istanbul, Turkey (Application No:2017-99). All of the volunteers recruited for the study accepted to sign the consent form.

Patients selected for the study were volunteers who applied to Marmara University with missing single posterior tooth and treated with a bone level implant (Straumann, Basel, Switzerland). Inclusion criteria were patients with good oral hygiene, no temporomandibular joint disease, aged at least eighteen years**,** intact hard and soft tissues around the implant area. Exclusion criteria were patients with advanced periodontitis affecting gingival recession.

Two intraoral scanning systems were evaluated in the study: CEREC AC Omnicam (Sirona Dental Systems, Sirona, Bensheim, Germany); Straumann CARES IOS (Straumann Cares Intraoral Scanner, Straumann, Basel, Switzerland). The study was conducted with 10 patients, each with osseintegrated single tooth bone level implant placed in posterior region and already had their healing caps were placed. After peri-implant hard and soft tissues were healed, every patient was received 1 conventional impression and 3

repeated scans with each system of CEREC AC Omnicam and Straumann CARES IOS (Fig 2).

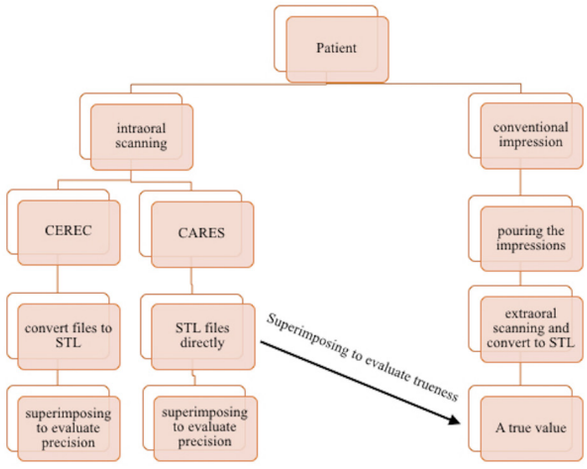

Figure 2. *Workflow of the study*

Manufacturer's guidelines were followed in the scan process. Saliva was removed, and vestibule mucosa were pulled by cheek and lip retractor. The camera of the scanner was aimed towards the scanned area. The camera tip was 5-10 millimeters away from the tooth or the scan body. The camera head was slid over the scanned area in a single direction gently to capture data. This process was then repeated two times, thus every patient had three digital impressions for each jaw for each system (Fig 3). To standardize the procedure, all scans were made by one dentist.

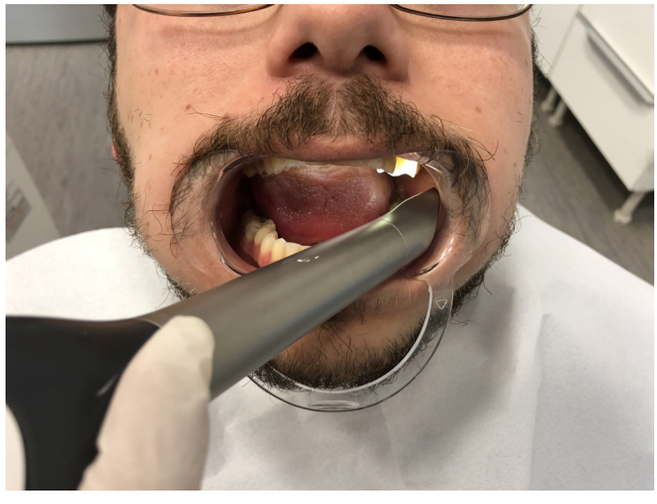

Figure 3. *Digital scanning with CEREC AC Omnicam*

A scan body (Straumann Bone Level RC) for Cares and (Sirona Dental Systems) for CEREC AC Omnicam was used to digitally transfer the implant position. During the conduction of digital scanning, some difficulties were countered while acquiring data in the interproximal margins, it was challenged to bring within the focal distance of the wand tip.

All the digital casts obtained with CEREC scanners were processed using CEREC SW 4.4.4 software to convert STL files. The STL file format was compatible with and able to be imported into most 3D model processing software.

Additionally, CARES scanner works in camera image impression and requires a powder coating on the scanned surfaces. Because of this, the teeth and the scan body in the quadrant were coated with a thin layer of titanium dioxide powder (Dentaco scan liquid, Essen – Germany) before scanning with CARES. In all cases, the opaque layer was renewed before each new scan (Fig 4).

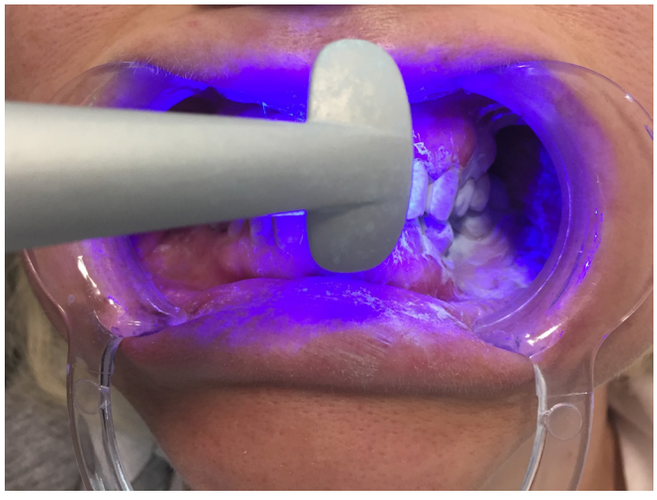

Figure 4. *Digital scanning with Straumann CARES IOS (Powder was apllied)*

Patients' conventional impressions were obtained right after the completion of intraoral digital scanning. Conventional impressions were made with PVS (Elite HD+, Zhermack SpA, Italy) using impression analog RC (Straumann Implant Level, Closed tray impression post – with guide screw and cap-, Straumann, Basel, Switzerland). Standard perforated metal stock trays (ASA Permalock; ASA Dental) were used to make PVS impressions. No tray adhesive was applied. Manufacturers' guidelines were followed in handling of the PVS materials.

The following acceptance criteria were used in of both impression methods: (1) accurate imprint of implants, (2) absence of voids on the surfaces, (3) proper reproduction of vestibule around peri-implant tissue. The impressions which did not meet the criteria were retaken for conventional impression or rescan for the digital impressions.

The time required for conventional and digital impressions was measured at this stage. Assessment of time efficiency was exercised after calculating the mean of required time results of every method.

Conventional impressions were disinfected for 10 minutes (Impresept; 3M ESPE, Seefeld, Germany) and suitable analog was seated over the impression post, afterwards

the impression was poured with scannable Type IV dental stone (Vel-Mix™ Die Stone, California, USA). The impression trays were removed from the stone cast after 60 minutes according to manufacturers' guidelines, and the stone casts were stored at room temperature and humidity.

Each cast was digitized once by an optical lab scanner (3Shape D700 scanner, Copenhagen, Denmark) to obtain the STL file format and considered as reference models (Fig 5).

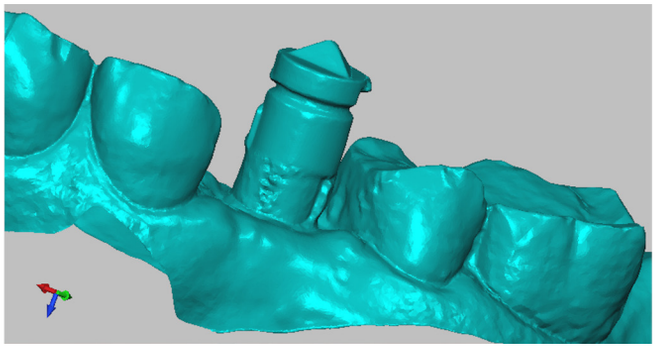

Figure 5. *STL model of impression*

All STL datasets were imported into the analyzing software (Geomagic Control; Geomagic**,** Morrisville, USA) and the STL data from each test group were pre-superimposed using CAD software (Geomagic Control; Geomagic**,** Morrisville, USA). To ensure an accurate superimposition, the models were trimmed to field of interest (the area of the implant, the adjacent teeth and about 1 mm of attached gingiva). Therefore, all irrelevant areas were eliminated manually to ensure precise superimposition and equal boundaries of all digital models (scan bodies were trimmed because of the difference in size between the systems). The trimmed models were imported into Geomagic Control again for overall compare.

For the 3D analysis, the digital models of the conventional group and 2 different intraoral scanned data group were superimposed by using the best-fit tool. Color maps to show the differences between two aligned models and deviation information were set to 20 color segments. The maximum and minimum critical values were set to ±50 µm. With these settings, 3D analysis results were derived, and color maps were derived as qualitative results (Fig 6).

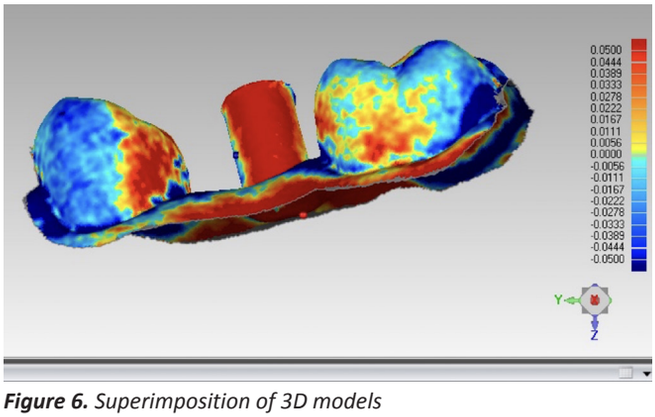

Figure 6. *Superimposition of 3D models*

Accuracy analysis

Trueness is defined as the deviation between digital impression (from each system) and a conventional impression (true value) of the same patient. Precision is defined as deviation between repeated digital scanning models obtained from the same patient with the same scanner. Following the 3D compare of every pairs, deviation information expressed as mean absolute deviation (average positive deviation + average negative deviation/ 2) accounting for trueness and standard deviation accounting for precision. The mean deviations for each patient were calculated.

Time efficiency

For execution time, all scanner systems were switched on and entered essential information of the case, performed the scan and processed the scan data. Next, it was allowed to a 2-minute intermission to cool down the scanner units before starting the next scanning.

The effective work time was calculated as the sum of the actual impression taking, we did not include the time needed for preparation of the IOS software, time spent powdering the dentition, entering appropriate scan modes, insertion of the scan-body, removal of the scan-body and positioning of the patient. Scan time for digital impressions began with activation of the scan wand.

As for the conventional impression-taking procedure we didn't include the time spent assembling the dispensing gun, applying adhesive to the tray if needed, Insertion and removal of the transfer post, disinfectant appliance and positioning the patient. Impression time for PVS impressions began with application of light body to the abutment tooth.

Time efficiency were independently recorded in minutes/ seconds (m/s) for both methods using a stopwatch. The number of required rescans and/ or impression retakes was documented and added for calculation if needed. No effect was identified for the randomized order of treatment starting with digital or conventional workflow.

For statistical analyses, one period was determined: intraoral time including scans of the scan body. For efficiency outcomes, the mean and standard deviation was calculated for each timed portion of the study. Measured time is recorded as min:sec and all data are presented as mean ± SD. Comparison of mean working time including retakes/rescans.

Statistical analysis

Statistical analysis was performed with SPSS statistic software (version 21.0, SPSS Inc., Chicago, Illinois, United States). For each group classification, the mean value, the standard deviation (SD), the minimum and the maximum was calculated. For analyzing two dimensional deviations, Independent Samples Test was performed (for trueness and precision). And for analyzing three dimensional deviations, one-way ANOVA was executed (for time efficiency). LSD (least significant difference) test for post hoc comparison was conducted. The statistical significance was set at ($p < 0.05$).

3. RESULTS

Trueness

After the models were imported to Geomagic Control software, the superimpositions were performed. In the terms of trueness of the digital systems, the lowest deviation respectively for the CEREC AC Omnicam and CARES group was 0.645 µm and 0.549 µm. The highest deviation respectively for the CEREC AC and CARES group was 1.294 µm and 1.188 µm. The mean (±standard) deviations were: 0.9627±0.1446 µm for CEREC AC Omnicam and 0.9167±0.17264 µm for CARES (Table 1).

The Independent Samples Test was performed after the descriptive analysis to determine whether there are any statistically significant differences among study groups. Independent Samples Test result is shown in table 4. According to Independent Samples Test, differences in trueness between CEREC AC Omnicam and CARES did not differ significantly (P>0,05) (Table2).

Table 1. *Descriptive statistics of trueness groups*

		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean	
						Lower Bound	Upper Bound
average positive deviation	cerec	10	0,992	0,132	0,044	0,891	1,093
	cares	10	0,930	0,169	0,056	0,801	1,060
	Total	20	0,961	0,150	0,035	0,886	1,036
average negative deviation	cerec	10	0,934	0,190	0,063	0,788	1,079
	cares	10	0,903	0,197	0,066	0,752	1,055
	Total	20	0,918	0,189	0,044	0,825	1,012
c-d mean	cerec	10	0,963	0,145	0,048	0,852	1,074
	cares	10	0,917	0,173	0,058	0,784	1,049
	Total	20	0,940	0,156	0,037	0,862	1,018

Table 2. *Independent Samples Test result to determine trueness*

Independent Samples Test										
		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	t	df	Sig (2-tailed)	Mean Difference	Std.Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
average positive deviation	Equal variances assumed	0,699	0,415	0,864	16	0,400 *	0,062	0,071	-0,090	0,213
	Equal variances not assumed			0,864	15,095	0,401	0,062	0,071	-0,090	0,214
average negative deviation	Equal variances assumed	0,112	0,742	0,332	16	0,744 *	0,030	0,091	-0,163	0,224
	Equal variances not assumed			0,332	15,976	0,744	0,030	0,091	-0,163	0,224
c-d mean	Equal variances assumed	0,38	0,546	0,613	16	0,549 *	0,046	0,075	-0,113	0,205
	Equal variances not assumed			0,613	15,524	0,549	0,046	0,075	-0,114	0,206

**. The mean difference is significant at the 0.05 level.*

Precision

After the models were imported to Geomagic Control software, the superimpositions were done. In the terms of precision of the digital systems, the lowest deviation respectively for the CEREC AC and CARES group was 0.054 µm and 0.048 µm. The highest deviation respectively for the CEREC AC and CARES group was 0.235 µm and 0.215 µm. Table 7 gives the mean values and their standard deviation for each parameter after superimposition. The measurement results (mean ±standard deviation) for precision were: 0.1222±0.0479 µm for CEREC AC Omnicam, 0.1040±0.0417 µm for CARES (Table 3).

The Independent Samples Test was performed after the descriptive analysis to determine whether there are any statistically significant differences among study groups. Independent Samples Test result is shown in table 4. According to Independent Samples Test, differences in precision between CEREC AC Omnicam and CARES was not significantly important (P>0.05).

On the basis of the results of this in vivo study, there was no difference regarding accuracy (trueness and precision) in comparison between CEREC AC Omnicam and CARES for the impression of single tooth implant.

Table 3. *Descriptive statistics of precision groups*

		N	Mean	Std. Deviation	Std. Error	95%Confidence Interval for Mean	
						Lower Bound	Upper Bound
superimposition 1-2	cerec	10	0,112620	0,0467570	0,0147859	0,079172	0,146068
	cares	10	0,096670	0,0299303	0,0094648	0,075259	0,118081
	Total	20	0,104645	0,0390750	0,0087374	0,086357	0,122933
superimposition 1-3	cerec	10	0,131890	0,0669412	0,0211687	0,084003	0,179777
	cares	10	0,111470	0,0461100	0,0145813	0,078485	0,144455
	Total	20	0,121680	0,0569165	0,0127269	0,095042	0,148318
c-d mean	cerec	10	0,122255	0,0479711	0,0151698	0,087939	0,156571
	cares	10	0,104070	0,0346684	0,0109631	0,079270	0,128870
	Total	20	0,113163	0,0417899	0,0093445	0,093604	0,132721

Table 4. *Independent Samples Test result to determine precision*

		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
superimposition 1-2	Equal variances assumed	1,516	0,234	0,909	18	0,376 *	0,0159500	0,0175557	-0,0209332	0,0528332
	Equal variances not assumed			0,909	15,315	0,378	0,0159500	0,0175557	-0,0214022	0,0533022
superimposition 1-3	Equal variances assumed	3,530	0,077	0,794	18	0,437 *	0,0204200	0,0257046	-0,0335833	0,0744233
	Equal variances not assumed			0,794	15,971	0,439	0,0204200	0,0257046	-0,0340793	0,0749193
c-d mean	Equal variances assumed	1,190	0,290	0,972	18	0,344 *	0,0181850	0,0187166	-0,0211372	0,0575072
	Equal variances not assumed			0,972	16,386	0,345	0,0181850	0,0187166	-0,0214166	0,0577866

**. The mean difference is significant at the 0.05 level.*

Time efficiency

The efficiency of impression techniques was evaluated by measuring working time in minutes/seconds (m/s) and numerical variables of interest were descriptively analyzed with sample means and standard deviations (SD). The best result was seen respectively in group CEREC AC Omnicam with 3.02 min, conventional 4.55 min and CARES 5.00 min. The longest time was seen respectively in group conventional 6.60 min, CARES 6.45 min and CEREC 4.54 min.

Table 5 gives the mean values and their standard deviation, as well as the minimum, median, maximum and 95 % confidence interval for each parameter. The measurement results (mean ±standard deviation) for time efficiency were: 3.619±0.4597 m/s for CEREC AC Omnicam, 5.368±0.2590 m/s for CARES, 5.402±0.7068 m/s for conventional.

Table 5. *Descriptive statistics of time efficiency groups*

	Number	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean	
					Lower Bound	Upper Bound
cerec	10	3,6190	0,45975	0,14538	3,2901	3,9479
cares	10	5,3680	0,25909	0,08193	5,1827	5,5533
conventional	10	5,4020	0,70684	0,22352	4,8964	5,9076
Total	30	4,7963	0,97910	0,17876	4,4307	5,1619

The one-way analysis of variance (ANOVA) test was performed after the descriptive analysis to determine whether there are any statistically significant differences among study groups. ANOVA test result is shown in Table 6. According to ANOVA, variations in time efficiency between CEREC AC Omnicam, CARES and conventional techniques differ significantly (P<0.05).

Table 6. *ANOVA test results to determine time efficiency*

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	20,797	2	10,399	40,092	.000
Within Groups	7,003	27	,259		
Total	27,800	29			

To determine differences among the study groups LSD (least significant difference) test for post hoc comparison was performed. To detect the different group least significant difference LSD test was done, LSD results are detailed in Table 7. The LSD test results showed significant difference among the study groups according to statistical significance (p<0.05), and accordingly it indicates that CEREC AC Omnicam group (3.619±0.4597 m/s) was significantly more time efficient than CARES group (5.368±0.2590 m/s) and conventional group (5.402±0.7068 m/s). There were no significant differences between CARES and conventional impressions in the same manner.

According to the results of the present in vivo study, CEREC AC Omnicam was found to be superior regarding time efficiency in comparison with CARES and conventional approaches and might accelerate the work flow of making impressions.

Table 7. *LSD test results on study groups*

Multiple Comparisons						
(I) group	(J) group	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
cerec	cares	-1,74900*	,22776	.000	-2,3137	-1,1843
	conventional	-1,78300*	,22776	.000	-2,3477	-1,2183
cares	cerec	1,74900*	,22776	.000	1,1843	2,3137
	conventional	-,03400	,22776	,988	-,5987	,5307
conventional	cerec	1,78300*	,22776	,000	1,2183	2,3477
	cares	,03400	,22776	,988	-,5307	,5987

**. The mean difference is significant at the 0.05 level.*

4. DISCUSSION

The null hypothesis was (1) due to the requirement of layer of powder, the inhomogeneous powder thickness may affect the accuracy comparing with powder free system (2). There will be no difference in the time required to perform clinically acceptable impressions using material-based (polyvinyl siloxane) and chairside digital scanning techniques.

According to results of the present study, the null hypothesis (1) was rejected, no significant differences were found between the two scanning systems regarding both trueness and precision (2). The 2nd null hypothesis was rejected, a significant deference (p < 0,05) were found in the time efficiency, CEREC AC Omnicam showed the lowest mean deviation and consequently more time efficient than CARES and conventional impressions. No significant differences were found between CARES and the conventional method regarding the time efficiency.

In the present study PVS impression material was used as golden standard to obtain STL files of conventional impressions (6,7). The deficiencies reported with elastomeric impression materials were technique sensitivity, patient discomfort, dimensional changes, dental stone and disinfection agent's distortion (19).

There are several studies related to patient outcomes for digital implant impressions with those for conventional implant impressions (10). These clinical studies showed consistent findings with an overall patients' preference significantly in favor of the intraoral optical scanner, rather than the conventional method regarding the capturing of the three-dimensional implant position. Moreover, one pilot study assessed the operators' perceptions when comparing conventional and digital impressions in a standardized setting for single-implant crowns (20). Study participants were performing both methods on a phantom model. In this study, the digital systems were higher acceptance than the conventional impressions as the other studies (10,21).

Accuracy of digital impressions can also be affected by scan-body related factors (22). Characteristics of the scan bodies could be another source of errors. Shorter and less visible scan bodies can negatively influence the accuracy. It was recommended that longer scan bodies should be used with deep-placed implants. One of the studies included in the systematic review used longer scan bodies, which could also contribute to better measured accuracy. Sharp angles of the scan bodies could negatively influence scan accuracy (5). To ensure the standardization, same scan-bodies recommended by the systems were used in the present study.

Spraying of the scan bodies with powder is still needed for some of the intra-oral scanners to reduce the reflections and

aid the stitching of the images. Clinically, a slight powder layer might be also used as an indicator for moisture, and powdering could potentially influence the accuracy of scanning through homogeneity and thickness of spray. It was reported that experienced clinicians achieved greater homogeneity and thinner coatings. Therefore, it is recommended to use only light dusting on the surfaces to be scanned (23). In the present study, the powdering did not affect the results of the accuracy.

There are few clinical studies concerning digital implant impressions that are currently available. Partially quadrant-like intraoral optical scans and CAD/CAM technology revealed a reduced treatment method (4). Additionally, the need for chairside modifications, such as secondary grinding and polishing, can be decreased, or may not even be required, within a complete digitized procedure using monolithic restorations. This increases the time efficiency and may also minimize the threat of cracks and chipping as an outcome of the absence of veneered ceramics (12). In this study, the measurement results (mean ±standard deviation) for trueness were: 0.9627±0.1446 µm for CEREC AC Omnicam, 0.91678±0.17264 µm for CARES, while the measurement results (mean ±standard deviation) for precision were: 0.1222±0.0479 µm for CEREC AC Omnicam, 0.1040±0.0417 µm for CARES. In the terms of accuracy (trueness and precision) there was no significant differences between two systems.

Lee and Gallucci (20) assessed the efficiency of digital and conventional impressions of single-implant reconstructions models. The mean fully treatment time was 24.42 min for the conventional method and 12.29 min for the digital method. The researchers incorporated the preparation time and procedure durations for retakes or rescans in their calculation. According to this in vivo study, one sextant was scanned from each patient to examine the difference in time efficiency (impression taking time only) between the digital and conventional techniques. In another study, the time in making impression of 50 single implants were recorded as 12.13 min for conventional (open tray, polyether), while CEREC AC Omnicam required only 6.39 min although complete arch scanning was performed.[24] In the present study, the results (mean ±standard deviation) for time efficiency were: 3.619±0.4597 m/s for CEREC AC Omnicam, 5.368±0.2590 m/s for CARES, 5.402±0.7068 m/s for conventional, thus the CEREC AC Omnicam were more time efficient than the CARES and conventional approaches.

In comparing the chairside time required to complete each type of impression, the CARES digital impression required significantly more time than the other two impression groups. The CEREC AC Omnicam impressions had the shortest median time. It should be noted that these measurements include only the time spent making the impression, and do not take into consideration the time required to disinfect and process any of the impressions.

The limitations of the present study were the scanning a single implant. There are more studies needed to evaluate multiple implants and wider scanning surface in the terms of time efficiency.

5. CONCLUSION

Within the limitation of this in vivo study, both of the intraoral scanning systems were capable to give sextant impression of single tooth implant with clinically satisfying accuracy (trueness and precision), there were differences between the digital and conventional methods regarding impression taking time, CEREC AC Omnicam was more time efficient than CARES and the conventional way.

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