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Kapak resmi: Prof. Dr. Erkmen Böke (1939-2014):

İzmir'de 1939 yılında doğdu. 1962 yılında Ankara Üniversitesi Tıp Fakültesi'ni bitirdi. 1970 yılında Almanya Heidelberg Üniversitesi'nden Genel Cerrahi uzmanlığını aldı. Türkiye'ye döndükten sonra Hacettepe Üniversitesi'nde 1970 yılında Genel Cerrahi Uzmanı, 1973 yılında da Göğüs ve Kalp-Damar Cerrahisi Uzmanlığını aldı. Aynı üniversitede 1976 yılında Doçentliğe, 1982 yılında da Profesörlüğe atandı. 1982-1988 yılları arasında Hacettepe Üniversitesi Hastaneleri Başhekimliği görevinde bulundu. Almanca ve İngilizce bilen Prof. Dr. Böke, evli ve iki çocuk babasıdır.

Resim çalışmalarına 2003 yılından beri yoğun olarak devam etmiş olan Prof. Dr. Böke, ilk iki yağlıboya kişisel resim sergisini Hacettepe Üniversitesi Ahmet Göğüş Sanat Galerisi'nde 2005 ve 2007 yıllarında, üçüncü kişisel sergisini Arslan İskender Sayek Evi'nde "Fusun'un Çiçekleri" adıyla ve dördüncü sergisini de 2011 yılında Ankara Elele Sanat Galerisi'nde açmıştır. Prof. Dr. Erkmen Böke, yedi karma sergiye katılmıştır.

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Cover image: Prof. Dr. Erkmen Böke (1939-2014):

He was born in Izmir in 1939. He graduated from Ankara University Faculty of Medicine in 1962. In 1970, he received his General Surgery specialty from Heidelberg University, Germany. After returning to Turkey, General Surgeon at Hacettepe University in 1970, also in 1973, took/finished the Thoracic and Cardiovascular Surgery Specialty. He was appointed Associate Professor in 1976 and Professor in 1982 at the same university. Between 1982-1988, he worked as the Chief Physician of Hacettepe University Hospitals. Speaking German and English, Prof. Dr. Böke is married and has two children.

Prof. Dr. Böke opened his first two personal oil painting exhibitions at Hacettepe University Ahmet GÖĞÜŞ Art Gallery in 2005 and 2007, the third one at the Arsuz İskender Sayek House under the name "Flowers of FÜSUN" and the fourth one at the Ankara Elele Art Gallery in 2011. Prof. Dr. Erkmen Böke participated in seven group exhibitions.

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Effect of the Pandemic on the Turnaround Time Intervals in the Public Health Laboratory

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ABSTRACT

Introduction: Turnaround time is one of the most important signs of a laboratory service which many clinicians use to evaluate the quality of the laboratory. Pandemic has enlightened the importance of laboratory medicine in healthcare organizations. Each step in total testing process can be affected by errors essential in laboratory medicine. Our study aims to evaluate the impact of the COVID-19 pandemic on turnaround time.

Material and Methods: We evaluated turnaround time periods of the routine biochemistry, immunoassay, hematology, hemoglobinopathies, HbA1c and blood-typing. In our study, intra-laboratory turnaround time, which is starting from sample acceptance time to results' verification time is determined. Defined turnaround time duration for all type of analytes are 1440 min. Time intervals in study as listed; Group 1 (pre-pandemic stage), Group 2 (pandemic stage), and Group 3 (post-pandemic stage). Frequency of samples with a TAT exceeded the laboratory's cutoff time interval was determined and compared within groups.

Results: The percentage of exceeded turnaround time of all analytes, except blood typing, hematology and HbA1c in the Group 1 are significantly lower than other groups. With regards to comparing Group 2 and Group 3, percentage of exceeded turnaround times of HbA1c and hematology samples in the Group 3 are found significantly lower than the Group 2

Discussion: Turnaround time can be evaluated as a benchmark of the laboratory performance. Workload of the laboratories should be taken into consideration is specific situations, like pandemic.

Keywords: Laboratory Quality, Turnaround Time, Pandemic

Halk Sağlığı Laboratuvarında Test İstem Sonuç Süre Aralıklarına Pandeminin Etkisi

ÖZET

Giriş: Test istem sonuç süresi, laboratuvar kalitesini değerlendirme amaçlı, çoğu klinisyenin kullandığı önemli bir parametredir. Pandemi dönemi, sağlık hizmeti organizasyonlarında laboratuvar tıbbının önemini bir kez daha göstermiştir. Toplam test sürecindeki her bir basamak, laboratuvar tıbbında önemli olan hatalardan etkilenebilmektedir. Çalışmamızın amacı test istem sonuç süresine COVID-19 pandemisinin etkisini göstermektir.

Materyal ve Metot: Rutin biyokimya, immünassay, hematoloji, hemoglobinopati değerlendirmesi, HbA1c ve kan gruplama parametrelerindeki test istem sonuç süresi değerlendirilmiştir. Çalışmamızda, örneğin kabul zamanı ile sonuçların onaylanma süresi arasındaki fark olarak da bilinen, laboratuvar içi test istem sonuç süresi kullanılmıştır. Laboratuvarımızda belirlenen test istem sonuç süresi, 1440 dk'dır. Çalışma grubundaki zaman aralıkları; Grup 1 (Pandemi öncesi dönem), Grup 2 (Pandemi dönemi) ve Grup 3 (Pandemi sonrası dönem) olarak gruplandırılmıştır. Laboratuvarın belirlediği test istem sonuç süresini aşan örneklerin sıklığı belirlenmiş ve gruplar arası karşılaştırması yapılmıştır.

Sonuçlar: Grup 1'deki Kan grubu, hematoloji ve HbA1c analizleri dışındaki diğer analizlerdeki test istem sonuç süresini aşan numune sıklıkları, diğer gruplara göre daha düşüktür. Grup 2 ve Grup 3 karşılaştırıldığında, HbA1c ve hematoloji örneklerindeki test istem sonuç süresi aşma sıklığı, Grup 3'de anlamlı düzeyde düşüktür.

Tartışma: Test istem sonuç süresi, laboratuvar performansının bir belirteci olarak değerlendirilebilir. Laboratuvarların iş yükü, pandemi gibi spesifik durumlarda göz önünde bulundurulmalıdır.

Anahtar Kelimeler: Laboratuvar Kalitesi, Test istem sonuç süresi, Pandemi

Clinical laboratories have a classically limited analytical and technical quality discussion, focusing on imprecision and inaccuracy goals (1). At the same time, clinicians evaluate the “quality of the laboratory” for rapid, reliable, and efficient service delivered at a low cost (2). To illustrate this, timeliness is one of the essential features prepared for evaluation as one of the crucial quality steps.

Turnaround time (TAT) is one of the most important signs of a laboratory service which many clinicians use to evaluate the quality of the laboratory (3). The definition of TAT can be varied by test, priority, or population-based. According to Lundberg, who assessed the total-testing cycle, it is necessary to achieve the following steps to perform a laboratory test: ordering, collection, identification, transportation, preparation, analysis, reporting, interpretation, and action (4). Due to the limitations of controlling all the steps mentioned above, most laboratories evaluate TAT through their intra-laboratory activities.

Coronavirus disease (COVID-19) is caused by severe acute respiratory coronavirus type 2 (SARS-CoV-2), firstly reported in China, and World Health Organization (WHO) declared SARS-CoV-2 a pandemic in March 2020 (5). In Turkey, the first case was announced on the 11th of March, 2020, and numerous precautions, including an outdoor mask mandate, school closures, transportation restrictions, contact tracing, and lockdowns (weekdays and weekends). In line with the decisions taken by the Presidential Cabinet Meeting on 21st June 2021, a circular was issued outlining the start of a gradual normalization period, which started as of 1st July 2021 (6).

Pandemic has enlightened the importance of laboratory medicine in healthcare organizations. Each step in the total testing process can be affected by errors essential in laboratory medicine. Our study aims to evaluate the impact of the COVID-19 pandemic on the turnaround time based on pre-pandemic, during a pandemic, and post-pandemic periods.

MATERIAL AND METHODS

Definition of TAT

In our study, we used intra-laboratory TAT, starting from the sample acceptance time to the results verification time.

Study Design

Our study has a retrospective design. In the Mardin Public Health Laboratory, samples ordered from family physicians in Mardin are analyzed. Mardin is a city in the Southeastern Part of Turkey; its population in 2021 was 862757. Samples ordered from the city center of Mardin are performed within the day shift. However, samples collected from the districts of Mardin are performed within the night shift. Our laboratory is closed on the weekends. Our defined TAT duration for all type of analytes are 1440 min (one-day).

We evaluated TAT periods of the routine biochemistry (Abbott Architect c8000, Abbott, Abbott Park, Illinois, USA), immunoassay (Abbott Architect i2000SR, Abbott, Abbott Park, Illinois, USA), full-blood count (Sysmex XN1000, Sysmex Corporation, Japan, Sysmex XT1000, Sysmex Corporation, Japan) hemoglobinopathies (Arkray, ADAMS HA-8180V, Minnesota, USA), HbA1c (Abbott Architect c8000, Abbott, Abbott Park, Illinois, USA), blood-typing (Ortho Vision, France)

The laboratory staff was assigned into three groups: a day shift (08:00-17:00) on workdays (Monday, Tuesday, Wednesday, Thursday, and Friday) who are responsible for routine biochemistry, immunoassays, and HbA1c; a day shift (08:00-17:00) of workdays which are accountable for hemoglobinopathies, blood-typing, hematology and a night shift (17:00-24:00) of workdays which are responsible for all types of analyzers.

The Time interval of the study is divided into three groups: Group 1 (pre-pandemic stage), Group 2 (pandemic stage), and Group 3 (post-pandemic stage) are stated time intervals from March 2018 to January 2019; from July 2020 to May 2021 and from July 2021 to May 2022, respectively.

A number of patients found positive for COVID-19 in Mardin were taken from Mardin Local Health Authority.

The samples were grouped in terms of panel and sample receipt day and time via VENTURA ALIS, the laboratory information system. Results verification times of samples were also retrieved from the system. The time interval between sample acceptance and result verification was considered the TAT.

Samples that were rejected and misidentified specimens were not included in the study. Samples without acceptance time were also excluded.

Statistical Analysis

Statistical analyses were performed MedCalc® Statistical Software version 20.009 (MedCalc Software Ltd, Ostend, Belgium; <https://www.medcalc.org>; 2021) and GraphPad Prism version 8.0.0 for Windows, GraphPad Software, San Diego, California USA, www.graphpad.com”.

After the frequency of samples with a TAT exceeded the laboratory’s cutoff time interval was determined, the proportion of these samples to all samples of all groups was compared with a chi-square test. $p < 0,05$ was considered statistically significant.

The study procedure was based on the Helsinki Declaration and confirmed by the local ethics board (2022/147).

RESULTS

Mean TAT of all groups are shown in Figure 1.

The number of total samples and number of samples that exceeded the defined TATs are given in Table 1.

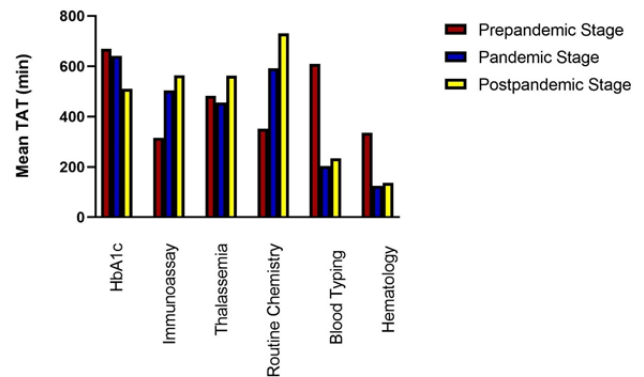


Figure 1. Mean TAT of All Groups

Table 1. The Number of Total Samples and Number of Samples that Exceeded the Defined TATs

		Samples that Exceeded TAT	Total Samples	p*
HbA1c	Prepandemic Stage	1017	19810	<0,001
	Pandemic Stage	1812	24085	
	Postpandemic Stage	2535	39520	
Immunoassay	Prepandemic Stage	582	62399	<0,001
	Pandemic Stage	4052	72074	
	Postpandemic Stage	4855	88696	
Thalassemia	Prepandemic Stage	555	14983	<0,001
	Pandemic Stage	1137	15046	
	Postpandemic Stage	1290	16789	
Routine Chemistry	Prepandemic Stage	578	53472	<0,001
	Pandemic Stage	5946	77759	
	Postpandemic Stage	7089	93686	
Blood Typing	Prepandemic Stage	1990	28024	<0,001
	Pandemic Stage	670	31001	
	Postpandemic Stage	877	38038	
Hematology	Prepandemic Stage	1166	61829	<0,001
	Pandemic Stage	1377	78115	
	Postpandemic Stage	1233	95757	

* Evaluated by Chi-Square Test

According to Table 1,

The percentage of exceeded TAT of HbA1c samples in the pre-pandemic stage are found significantly lower than pandemic and post-pandemic stages ($p < 0,001$).

The percentage of exceeded TAT of immunoassay samples in the pre-pandemic stage are found significantly lower than pandemic and post-pandemic stages ($p < 0,001$).

The percentage of exceeded TAT of thalassemia samples in the pre-pandemic stage are found significantly lower than pandemic and post-pandemic stages ($p < 0,001$).

The percentage of exceeded TAT of routine chemistry samples in the pre-pandemic stage are found significantly lower than pandemic and post-pandemic stages ($p < 0,001$).

The percentage of exceeded TAT of blood typing samples in the pre-pandemic stage are found significantly higher than pandemic and post-pandemic stages ($p < 0,001$).

The percentage of exceeded TAT of hematology samples in the post-pandemic stage are found significantly lower than pandemic and pre-pandemic stages ($p < 0,001$).

The percentage of exceeded TAT of HbA1c samples in the post-pandemic stage are found significantly lower than pandemic stage ($p < 0,001$).

The percentage of exceeded TAT of hematology samples in the post-pandemic stage are found significantly lower than pandemic stage ($p < 0,001$).

There is no difference between the percentage of exceeded TAT of immunoassay samples between pandemic and post-pandemic stage ($p:0,19$).

There is no difference between the percentage of exceeded TAT of thalassemia samples between pandemic and post-pandemic stage ($p:0,67$).

There is no difference between the percentage of exceeded TAT of routine chemistry samples between pandemic and post-pandemic stage ($p:0,39$).

There is no difference between the percentage of exceeded TAT of blood typing samples between pandemic and post-pandemic stage ($p:0,20$).

Comparisons of the proportion of the samples which are exceeded the TAT among groups are shown in Figure 2.

Comparison of the COVID-19 cases and percentage of samples that exceeded TAT are shown in Figure 3.

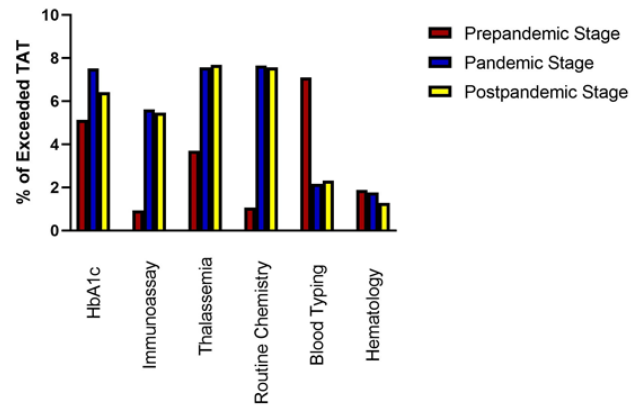


Figure 2. Comparisons of the Proportion of the Samples which are Exceeded the TAT Among Groups

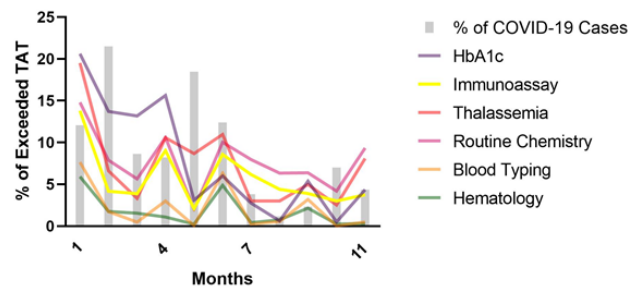


Figure 3. Comparison of the COVID-19 Cases and Percentage of Samples that Exceeded TAT

DISCUSSION

TAT still looks as an important parameter for evaluating the quality of the laboratory. Definition of TAT may vary. It can be related with the type of laboratory (emergency, central and/or public health), the population served (7). In Turkey, samples that ordered from family health medicine clinics are evaluated. As it mentioned, preanalytical stage is the most common problems that affected on prolonged TAT (8). Preanalytical errors are also hard to solve in the public health laboratory for some reasons such as transportation among suburbs, ineffective centrifugation etc.

Our study has two hypotheses. First hypothesis is there was no significant difference in percentage of samples with exceeded-TAT in prepandemic, pandemic and post-pandemic stage.

As it shown in Table 1, percentage of samples with exceeded-TAT in pre-pandemic stage was significantly lower than pandemic and post-pandemic stage. Difference in number of samples may be the possible explanation for this result. There was growing number of samples in pandemic and post-pandemic stage, compared to pre-pandemic stage.

Second hypothesis is there was a significant difference in percentage of samples with exceeded-TAT in pandemic and postpandemic stage.

However, in our study, there were no differences between the percentage of exceeded TAT in pandemic and post-pandemic stage for routine biochemistry, thalassemia, blood typing. As mentioned before, samples from family health clinics are performed in the public health laboratory. Therefore, this may be reason for this result.

In the literature, there are some reports which are evaluated TAT in laboratories. However, these articles are interested in emergency laboratories, especially (9, 10). Because of the differences among the laboratories, it is hard to compare the TAT's of the laboratories.

The COVID-19 pandemic has been affected all parts of the world and also still behave as a threat for both laboratories and health care systems. Because of the high number of COVID-19 cases, laboratory staff's workload had been higher, therefore test process and also TAT is prone to the errors the high workload of the laboratory staff, and the enhanced pressure, the laboratory test process is sensitive to errors (11).

In the literature, there are some articles which evaluate for the affect of pandemic on the total testing process (12, 13). However, our study is the first to evaluate the impact of the pandemic on the turn around time at a public health laboratory in Turkey. However, testing for COVID-19 in our city did not performed by our laboratory; as a result of this, our study did not evaluate the possible higher workload of our laboratory and staff. This is the main disadvantage of our study. Further studies may be helpful to enlighten this issue.

As a result, TAT can be evaluated as a benchmark of the laboratory performance. Workload of the laboratories should be taken into consideration is specific situations, like pandemic.

DECLARATIONS

Funding

None

Conflicts of Interest/Competing Interests

None

Ethics Committee Approval

Our study was approved by the Local Ethics Committee of Ordu University Faculty of Medicine (protocol ID: 2022/147).

Availability of Data

Available upon request.

Authors' Contributions

Murat Cihan conceived and designed the analysis. Muhammed Fevzi Kılınçkaya collected the data, performed the analysis and wrote the paper.

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Electroencephalography and Neuroimaging Markers of Poor Prognosis in Hypoxic-Ischemic Brain Injury

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ABSTRACT

Purpose: Hypoxic-ischemic brain injury (HIBI) can cause coma. Several factors may affect the outcome after HIBI and prediction of the prognosis is challenging in clinical practice. Magnetic Resonance Imaging (MRI) and Electroencephalography (EEG) are two reliable tools to predict the possible outcome after brain damage. We aimed to test the utility of MRI and EEG in predicting the outcome by exploring specific lesion and electrophysiological patterns.

Method: Patients admitted to the intensive care unit (ICU) due to hypoxic-ischemic brain injury between January 2017 and March 2020 were retrospectively reviewed. Patients over 18 years of age with a history of cardiac arrest or respiratory problems leading to hypoxic-ischemic brain injury were included in the study. Glasgow Coma Score (GCS) was used as a clinical measure for the level of consciousness. All patients had a Glasgow Coma Score (GCS) of <8 and had both MRI and EEG investigations. Patients were classified as having Poor Outcome (PO) and Good Outcome (GO). Poor outcome defines either death or lack of recovery in consciousness (GCS<8). MRI findings that could lead to a coma state were classified as "MRI-positive", otherwise were classified as "MRI-negative". Modified Hockaday Scale was used for grading of EEG.

Results: Nineteen patients with HIBI were included. In the MRI-positive group, 87.5% of the patients had poor outcome whereas the remaining 12.5% had good outcome. In the MRI-negative group, 45.5% of the patients had poor outcome whereas the remaining 54.5% had good outcome. According to the Modified Hockaday EEG Grading System, 91% of the patients with a score of Grade 4 and above had poor outcome whereas only the remaining 9% had good outcome.

Conclusion: Although MRI is a valuable clinical marker, EEG seems to be more reliable for predicting prognosis in HIBI. The modified Hockaday scale can be useful for determining the cut-off points for the prediction of poor prognosis.

Keywords: Hypoxia-ischemia, Brain, coma, magnetic resonance imaging, electroencephalography, prognostic factors

Hipoksik-İskemik Beyin Hasarında Kötü Prognozun Elektroensefaloogram ve Nöro-görüntüleme Belirteçleri ÖZET

Amaç: Hipoksik-iskemik beyin hasarı komaya neden olabilir. Çeşitli faktörler bu hasar sonrası prognozu etkilemekte olup; prognozu tahmin etmek klinisyeni zorlayan bir süreçtir. Manyetik Rezonans Görüntüleme (MRG) ve Elektroensefaloogram (EEG), beyin hasarı sonrasında olası prognozu tahmin etmede kullanılan iki güvenilir yöntemdir. Çalışmamızda MRG ve EEG yöntemlerinde spesifik lezyon ve elektrofizyolojik paternleri araştırarak prognoz tahminlerini test etmeyi amaçladık.

Yöntem: Ocak 2017 ile Mart 2020 tarihleri arasında hipoksik beyin hasarı sebebi ile yoğun bakım ünitesinde (YBÜ) izlenmiş olan hastalar retrospektif olarak taranmıştır. 18 yaş üzeri, kardiyak arrest veya solunumsal problemler sebebi ile hipoksik iskemik beyin hasarı gelişen hastalar çalışmaya dahil edilmiştir. Glasgow Koma Skalası (GKS) bilinç durumu için kullanılmış olup, çalışmaya dahil edilen tüm hastalarda GKS<8'dir ve her hastanın MRG ve EEG'leri mevcuttur. Hastalar kötü ve iyi prognozlu olarak iki gruba ayrılmıştır. Kötü prognoz ölüm veya şuurun toparlamamasını (GKS<8) tanımlamaktadır. Koma tablosunu açıklayacak MRG bulguları olanlar "MR-pozitif", olmayanlar "MR-negatif" olarak sınıflandırılmışlardır. EEG sınıflaması modifiye Hockaday ölçeğine göre yapılmıştır.

Sonuç: Toplamda on dokuz hasta çalışmaya dahil edilmiş olup; MR-pozitif grupta hastaların %87.5'i kötü prognoz gösterirken sadece %12.5'i iyi prognoz göstermiştir. MR-negatif grupta ise hastaların %45.5'i kötü prognoz gösterirken %54.5'i iyi prognoz göstermiştir. EEG sınıflaması Modifiye Hockaday ölçeğine göre 4 ve üzeri olan hastaların %91'i kötü prognoz gösterirken sadece %9 hastada iyi prognoz gözlenmiştir.

Yorum: Pozitif MRG bulguları EEG kadar hassasiyete sahip olmayıp; EEG daha kesin prognoz tahmin etmede yardımcı olmaktadır. Hockaday ölçeği, kötü prognoz tahmininde eşik değerleri belirlemede yararlı gözükmemektedir.

Anahtar Kelimeler: Hipoksik-iskemi, Beyin, koma, manyetik rezonans görüntüleme, elektroensefalografi, prognostic faktörler

Severe brain damage caused by lesions to the brainstem reticular formation, large hemispheric areas, or widespread bilateral hemispheric areas may cause coma. Coma is a state of consciousness characterized by continuous absence of eye-opening (unwakefulness), and any spontaneous or stimulus-induced arousal or voluntary behavioral responses (unresponsiveness) (1).

Hypoxic-ischemic brain injury (HIBI) is one of the most common causes of coma. Hypoxia may lead to brain damage due to a reduction of oxygen supply or utilization. Low oxygen pressure and low hemoglobin levels are frequent causes of hypoxia. On the other hand, ischemia is caused by a reduction of blood flow which may lead to both decreased oxygen delivery and tissue damage (2,3). Cardiac arrest and respiratory failure may lead to HIBI (4). Patients with a prolonged stay at the intensive care unit (ICU) may require additional interventional and surgical procedures such as central venous catheterization and tracheostomy. Both procedures are essential for the continuation of hemodynamic, metabolic, and respiratory support. However, these procedures may lead to significant complications including emphysema, infection, bleeding, hematoma, tracheal injury, trachea esophageal fistula, pneumothorax, arrhythmias, cardiac arrest, arterio-venous fistula, embolism, etc (5,6).

Several factors may affect the outcome after HIBI including the duration and the severity of hypoxemia, accompanying small vessel diseases, and cerebral vascular diseases (2). Nevertheless, predicting the prognosis of coma caused by hypoxic-ischemic brain injury (HIBI) is extremely challenging in neurological intensive care practice. Predicting the prognosis of comatose patients is vital for the clinician before critical decisions are made in the management of HIBI. Magnetic Resonance Imaging (MRI) and Electroencephalography (EEG) are two reliable tools for investigating the magnitude of brain damage and predicting the probable prognosis. Recent studies showed promising results for the utility of MRI and EEG in predicting the prognosis of patients with HIBI (7-10).

MRI provides information about the localization (i.e. focal or diffuse) and the nature (i.e. hypoxic, ischemic, or hemorrhagic) of the brain lesions. Diffusion-Weighted Imaging (DWI) and apparent diffusion coefficient (ADC) are two MRI modalities that provide information about the hemodynamic changes and neuronal damage even in the early stages of HIBI. T2 weighted and fluid-attenuated inversion recovery (FLAIR) sequences are expected

to be normal in the early stages of acute ischemia (2). DWI is used to get a more accurate result in the detection of acute ischemic lesions, which are seen in stroke and HIBI patients within 6 hours. Moreover, it is superior to computerized tomography and conventional MRI (11). ADC increases the precision in the estimation of disease severity (12,13). However the sensitivity and specificity of DWI in post-cardiac arrest patients are inconsistent between studies (14-17).

EEG detects the natural electrical activity of the brain and it is widely used to assess the level of consciousness and to predict the prognosis after HIBI (18,19). In the early period after hypoxic damage, EEG may show electrical silence while the patient is in a deep coma which may be followed by a gradual evolution of specific rhythms reflecting neuronal functionality. It should be kept in mind that confounders such as sepsis, medications, and metabolic derangements may have influence on EEG (2). Continuous patterns of EEG such as normal or diffusely slowed rhythms were found to be predictors of good outcome; whereas suppression and burst-suppression patterns were found to be highly specific for poor prognosis. On the other hand, the sensitivity of these EEG parameters was low (20-22). Therefore, using EEG may increase the specificity in predicting outcomes in HIBI-related comatose patients, however additional modalities such as ADC and DWI imaging are necessary to increase the sensitivity.

In this study, we aimed to test the utility of MRI and EEG in predicting the outcome of patients with HIBI. Therefore, we will explore specific lesion and electrophysiological patterns that may guide clinicians in the prediction of prognosis in HIBI.

METHOD

In this study, medical reports of the patients admitted to the intensive care unit (ICU) and referred to the neurology clinic because of suspected hypoxic-ischemic brain injury between January 2017 and March 2020 were reviewed, retrospectively. Patients over 18 years of age with a history of cardiac arrest or respiratory problems leading to hypoxic-ischemic brain injury were included in the study. Glasgow Coma Score (GCS) was used as a practical measure for the level of consciousness which ranges between 3 (deep coma) and 15 (full consciousness). Patients receive scores for an eye-opening response as an indicator of wakefulness (1-4), for a verbal response as an indicator of language comprehension and orientation (1-5), and for motor response to a verbal command or painful stimuli

(1-6) (23). All patients included in our study were with a Glasgow Coma Score (GCS) of <8.

All patients had both MRI and EEG investigations completed and consulted by a neurology specialist during their admission to the ICU and were classified into two groups; Poor Outcome (PO) and Good Outcome (GO). Poor outcome defines either death or lack of recovery in consciousness. A cut-off value of 8 or above for GCS was used as an indicator of recovery of consciousness as those patients are more likely to be extubated and discharged from ICU. Two patients were transferred to other ICU units without reaching a Glasgow Coma Score of 8, and they were accepted as having a poor outcome.

MRI sequences were obtained using a Siemens 3T (Skyra, head coil 32 channel) scanner. Diffusion-weighted imaging (DWI), apparent diffusion coefficient (ADC) maps, and perfusion-weighted imaging were used to detect signal changes associated with acute ischemic changes and/or hypoxia. High-intensity signals on DWI and low-intensity signals on ADC sequences in the acute phase have been described as signal changes associated with hypoxic brain damage (24). Changes due to hypoperfusion were detected by arterial spin labeling (ASL) MR perfusion sequence. Ascending reticular activating system (ARAS) connects thalamic and subthalamic nuclei to the reticular intermediary grey substance of the spinal cord. Bilateral damage of ARAS leads to alteration of consciousness, even with very small lesions. Damage to the brainstem also can lead to coma (25). Patients having MRI findings in these sequences that could lead to a coma state by disturbing ARAS were classified as "MRI-positive", otherwise were classified as "MRI-negative". Please see Figure 1 for representative MRI findings in the MRI-positive group.

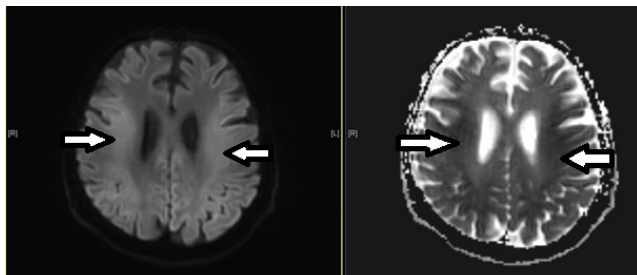


Figure 1: MRI IMAGES

a) Diffuse hypoxia, hyperintense in the DWI (left) and hypointense in the ADC (right) sequence (white arrows)

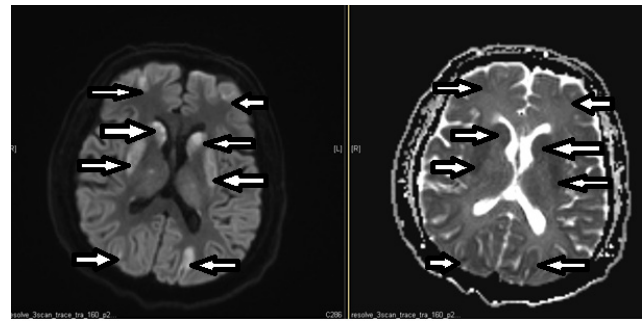


Figure 1: MRI IMAGES

b) Ischemic findings at anterior and posterior watershed zones and basal ganglia; hyperintense in the DWI (left) and hypointense in the ADC (right) sequence (White arrows)

EEG was recorded using a Neurosoft Neuron-Spectrum-4/P® 21 channel EEG System. All EEG recordings were obtained at least 24 hours after cessation of any sedation. Silver and silver chloride (Ag/AgCl) electrodes were used and placed according to the international 10-20 system (26). The duration of EEG recordings ranged between 20 to 30 minutes. The EEGs were analysed in Double banana montage with a high frequency filter setting of 35 Hz and low frequency filter setting of 0.5 Hz and sweep speed set at 30 mm/s.

All the EEGs were reviewed by two experienced neurologists M.S and M.E.T. using a Neurosoft Neuron-Spectrum-4/P® software. Modified Hockaday Scale was used for grading of EEG (27,28). According to this grading system Grade 1 defines dominant alpha activity, with or without theta or delta activity; Grade 2 defines dominant theta or delta rhythm, with detectable alpha activity; Grade 3 defines dominant theta or delta rhythm without any detectable alpha activity; Grade 4a defines low voltage delta activity with the possibility of short interval isoelectric intervals; Grade 4b defines monomorphic and nonreactant alpha activity; Grade 4c defines periodic generalized activity with a very low background voltage; and Grade 5 defines flat to isoelectric voltage (Table 1). Any epileptiform activity was also noted. Finally, EEG readers were blind to the clinical outcome. Please see Figure 2 for representative EEG findings used for Modified Hockaday Grading system.

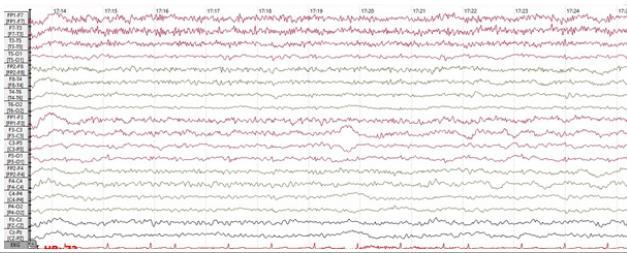


Figure 2: EEG images
a) Grade 1: Dominant alpha activity, with or without theta or delta activity

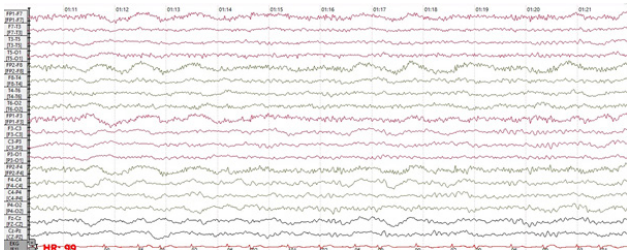


Figure 2: EEG images
b) Grade 2: Dominant theta or delta rhythm, with detectable alpha activity

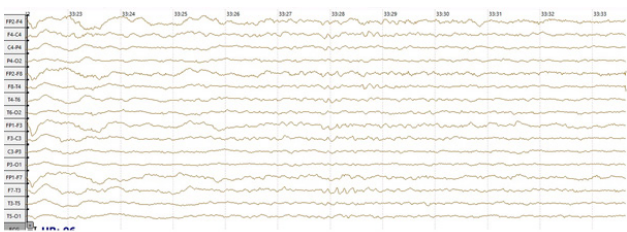


Figure 2: EEG images
c) Grade 3: Dominant theta or delta rhythm without any detectable alpha activity

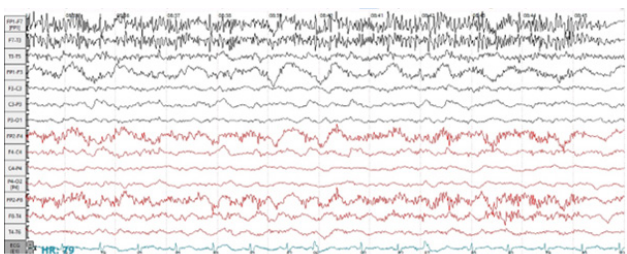


Figure 2: EEG images
d) Grade 4(a): Low voltage delta activity

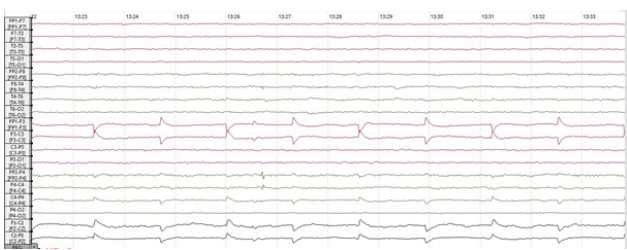


Figure 2: EEG images
e) Grade 5: Flat to isoelectric voltage

Table 1: Modified Hockaday Grading Scale

Grade	Description
1	Dominant rhythm is alpha with or without theta or delta rhythm activity
2	Dominant rhythm is theta and/or delta with detectable alpha rhythm
3	Dominant rhythm is theta and/or delta without detectable alpha rhythm
4a	Low voltage delta rhythm activity. There may be short periods of isoelectric activity
4b	Dominant rhythm is monomorphic and non-reactive alpha activity
4c	Periodic generalized activity on low voltage background rhythm.
5	Isoelectric activity

RESULTS

Nineteen patients (8 female and 11 male) were evaluated with a mean age of 72±10 years (56-90 years). The mean ages of female and male groups were equivalent (71.37±8.6 years for the female group and 72.81±10.7 years for the male group) (p=0.75). Cardiac arrest was the reason for admission to ICU in 4 patients and the remaining patients were admitted due to respiratory distress caused by several etiologies such as pneumonia, exacerbation of bronchitis, and sepsis. Sixteen patients were intubated on the admission day, two of them were intubated on the 4th and one of the patients was intubated on the 6th day of admission. The mean intubation-extubation period of the patients who recovered was 14,6±13,41 days (5-44 days). MRI scans were obtained between 1st to the 27th days of admission (Mean 6,89±6,31 days).

The MRI-negative group consisted of 11 patients who had no detectable perfusion abnormalities or hypoxic damage. The admission-to-brain scan period in the MRI-negative group ranged from 1 to 13 days (Mean 6,25±4,89 days).

On the other hand, 8 patients were grouped as MRI-positive. Two patients had a hypoxic brain injury, watershed hypoperfusion was detected in five patients, and one patient had both hypoxic brain injury and watershed hypoperfusion. Admission-to-brain scan period in the MRI-positive group ranged from 1 to 27 days (Mean 7,36±7,37 days). Admission-to-brain scan period did not differ between MRI-negative and MRI-positive groups (p=0,93).

In the poor-outcome (PO) group, the admission-to-brain scan period ranged between 1 to 12 days (Mean $5,28 \pm 9,4$ days) in patients with positive MRI, whereas the admission-to-brain scan period ranged between 1 to 27 days (Mean $9,4 \pm 10,73$ days) in patients with negative MRI. MRI-positive and MRI-negative subgroups of the PO group did not differ significantly in the admission-to-brain scan period ($p=0,68$). Table 2 shows the demographic and clinical characteristics of each patient.

The admission-to-EEG period ranged from 1 to 28 days of admission (Mean $7,21 \pm 6,85$). EEGs were graded according to the modified Hockaday scale and more than 50% of the patients had a grade of at least 4 (Table 3).

Only 36.8% of the patients with a Glasgow score of ≥ 8 showed good prognosis and were discharged from ICU. In the MRI-positive group (with hypoxia or hypoperfusion), 87.5% of the patients had poor outcome whereas the remaining 12.5% had good outcome. In the MRI-negative group, 45.5% of the patients had poor outcome whereas the remaining 54.5% had good outcome. Table 4 shows the sensitivity and specificity of positive MRI and EEG findings.

Grade	N of patients	Outcome
1	1	Good (1)
2	3	Good (2) Poor (1)
3	4	Good (3) Poor (1)
4a	3	Poor (3)
4b	0	N/A
4c	1	Poor (1)
5	7	Good (1) Poor (6)

Diagnostic Procedure	Poor Outcome (%)	Good Outcome (%)	Sensitivity (CI 95%)	Specificity (CI 95%)
MRI- Positive (regardless of EEG)	87.5	12.5	58,3 (0.28-0.83)	85,71 (0.42-0.99)
EEG grade 3,4 or 5 (regardless of MRI)	73.3	26.6	91,66 (0.59-0.99)	42,85 (0.11-0.79)
EEG grade 4 or 5 (regardless of MRI)	91	9	83,3 (0.50-0.97)	85,71 (0.42-0.99)
MRI-positive with EEG grade 3,4 or 5	100	0	50 (0.22-0.77)	100 (0.56-1)
MRI-positive with EEG grade 4 or 5	100	0	50 (0.22-0.77)	100 (0.56-1)

Patient No	Gender	Age (years)	HIBI Etiology	Admission-to-Intubation (days)	Admission-to-Brain Scan (days)	MRI Finding	Admission-to-EEG (days)	EEG Grade	Outcome
1	Male	70	Respiratory distress	1	6	Negative	7	2	Good
2	Female	56	Cardiac arrest	1	11	Negative	2	3	Good
3	Male	61	Cardiac arrest	1	1	Positive	2	5	Poor
4	Male	71	Cardiac arrest	1	2	Positive	5	5	Poor
5	Female	79	Respiratory distress	6	6	Negative	1	3	Good
6	Male	90	Cardiac arrest	1	2	Positive	1	5	Poor
7	Male	68	Respiratory distress	1	3	Positive	13	5	Poor
8	Female	80	Respiratory distress	1	4	Negative	4	5	Good
9	Male	79	Cardiac arrest	1	12	Negative	17	5	Poor
10	Female	78	Cardiac arrest	1	1	Negative	1	4a	Poor
11	Female	63	Respiratory distress	1	27	Negative	28	4a	Poor
12	Female	73	Cardiac arrest	1	7	Positive	10	4c	Poor
13	Male	61	Respiratory distress	1	2	Negative	4	5	Poor
14	Female	67	Respiratory distress	1	2	Negative	2	3	Good
15	Female	75	Respiratory distress	4	10	Positive	8	4a	Poor
16	Male	63	Respiratory distress	1	5	Negative	5	2	Good
17	Male	84	Cardiac arrest	1	5	Negative	4	3	Poor
18	Male	88	Respiratory distress	4	12	Positive	12	2	Poor
19	Male	66	Respiratory distress	1	13	Positive	11	1	Good

DISCUSSION

In this study, we aimed to test the utility of EEG and MRI in predicting the prognosis of HIBI patients. Since the DWI modality is sensitive to cortical changes after hypoxemia, MRI can provide valuable information about the prognosis in HIBI (29-31). Grey matter in the brain is much more vulnerable to ischemia and hypoxia because it is metabolically more active than white matter. It requires high amounts of oxygen and glucose supply for its large number of synapses. Glutamate excitotoxicity caused by HIBI also gives severe damage to grey matter since it contains most of the dendrites where postsynaptic glutamate receptors are located. Basal ganglia, thalamus, cerebral cortex, cerebellum, and hippocampus are the most frequently affected sites due to hypoxia (2,14,15,32-36).

MRI findings may change as the time passes after the onset of HIBI. The sequence of these changes was characterized as brain swelling, cortical laminar necrosis, hyperintense signal in the basal ganglia, delayed white matter degeneration, and atrophy (37). However it is recently shown that different patterns of MRI findings can be seen at varying intervals. Due to this variability, a uniform sequence of MRI change after HIBI is unlikely (2). Poor prognosis is associated with early abnormal findings in DWI and the use of ADC increases the precision of poor outcome if a severe reduction in the whole brain is evident (2,19,29).

A recent meta-analysis on the prediction of outcome by using MRI scans showed a range of the sensitivity as 59% to 62% (95% CI); and a range of specificity as 94% to 96% (95% CI). This heterogeneity in the sensitivity and specificity was considered to be associated with the timing of the MRI scan after hypoxemia and the inconsistencies in the MRI criteria which were accepted as positive indicators (38).

In the current study, patients were classified as MRI-positive if the DWI and the ADC modalities showed findings of hypoxic injury and/or the perfusion-weighted imaging showed hypoperfusion which could lead to a coma state based on the size and location of lesions. The sensitivity and specificity of positive MRI in our study were 58.3% (95% CI 0.28-0.83) and 85.71% (95% CI 0.42-0.99), respectively. Although the sample size of the present study is small; the sensitivity of MRI was between the ranges reported in the previous studies.

The timing of the MRI scan after the onset of hypoxia may affect the appearance of typical signs. Therefore, we also

calculated the admission-to-brain scan period (days) and there was no statistical significance between the timing of the pathological and normal MRI scans. We also calculated the admission-to-brain scan period (days) in patients with poor prognosis with pathological versus normal MRI findings and no significant difference was detected.

EEG is another tool that can be used to assess the level of consciousness and to help clinicians predict the prognosis in comatose patients. Several EEG patterns have been associated with poor prognosis such as suppression or suppression-burst pattern, unresponsive rhythms, and periodic patterns including periodic lateralized, bilateral, or synchronous epileptiform activities (10). It was reported that periodic patterns and EEG grades 4 and 5 according to the modified Hockaday Scale are significantly associated with poor outcomes (2). In a recent study, the sensitivity of EEG was found to be highest within 24 hours of the event, and data obtained from 5 centers revealed that the average sensitivity and specificity of poor outcomes were 0.47 (CI 95% 0.42-0.51) and 1 (CI 95% 0.99-1) respectively, if the EEG was performed within 12 hours after cardiac arrest.

When the EEG was performed 12 hours after cardiac arrest, the prediction of a good outcome was reported to have a sensitivity of 50% (CI 95% 0.46-0.55) and a specificity of 91% (CI 95% 0.88-0.93). Generalized suppression or synchronous pattern with 50% suppression were accepted as predictors of poor outcome and the presence of a continuous pattern (delta, theta, and alpha) was accepted as a predictor of good outcome (31).

In our study, EEG was not performed on every patient within 24 hours. That is mainly because the patients were under pharmacological sedation and neurology consultation was required when the patients were unable to gain consciousness after the cessation of anesthetic substances. EEG was performed on the patients at a mean time of 7.21 ± 6.85 days. We classified the EEGs according to the modified Hockaday scale and took two separate cut-off points, grade 3 and grade 4, to see the specificity and sensitivity of the prediction of poor prognosis. No detectable alpha rhythm is present in grades 3 and higher. Therefore, we chose grade 3 and grade 4 as cut-off points. We found that if the EEG pattern was grade 3 or above, the sensitivity was 91.66% (CI 95% 0.59-0.99) and the specificity was 42.85% (CI 95% 0.11-0.79). On the other hand, if the EEG pattern was grade 4 or above, the sensitivity was 83.33% (CI 95% 0.50-0.97) and the specificity was 85,71% (CI 95%

0.42-0.99). Although our sample size is relatively small, it may be concluded that EEG patterns compatible with the modified Hockaday grade 3 and above have more sensitivity but less specificity compared to the previous studies. Whereas, if grade 4 or above is accepted as a predictor, the specificity comes closer to the previous studies with higher sensitivity.

One of our patients showed good prognosis despite being classified as Grade 5 on Modified Hockaday Scale. That may be because the EEG was performed within 24-48 hours after cessation of sedation, a time frame which may not be sufficient to wash-out the sedative substances from blood circulation that might have confounded the EEG. No control EEG was performed because she had gained consciousness in the following 48 hours. Thus, a follow-up EEG may be necessary if a suppression pattern is present after the cessation of anesthetics, particularly in elderly patients.

The specificity for prediction of poor prognosis increases significantly (100%; CI 95% 0.56-1) when positive MRI findings accompany EEG patterns at or above grade 3. The specificity is also 100% when positive MRI findings are accompanied by EEG patterns at or above grade 4. On the other hand, the sensitivity in both conditions decreases to 50% (CI 95% 0.22-0.77). That is mainly because the sensitivity of positive MRI findings is low.

In conclusion, we recommend that positive MRI findings, hypoxia or hypoperfusion, are not as sensitive as EEG findings. EEG must also be performed on the patients, suffering from hypoxia, to make a more precise prediction. EEG grading according to the modified Hockaday scale seems to be useful for determining the cut-off points for the prediction of poor prognosis. If the cut-off point is Grade 3 or above, the sensitivity is higher, but specificity is significantly lower than a cut-off point of Grade 4.

We believe that the present study contributes to the literature by showing the significance and efficiency of EEG to determine the prognosis in HIBI patients, which is still a challenge in neurology practice. This approach will guide neurologists and intensive care specialists in decision making for specific treatments and interventions (i.e. tracheostomy) based on the patients' prognosis.

Our study has several limitations including a small sample size and the lack of a healthy control group. On the other hand, we showed the significance of EEG along with MRI

scans in the prediction of poor prognosis. Studies focusing on EEG patterns with larger sample sizes may help develop new methods to increase the accuracy of prediction of the prognosis in comatose patients with HIBI.

DECLARATIONS

Funding

We declare no funding for the present study.

Conflicts of Interests

We declare no conflict of interest.

Ethics Approval

The present study has the approval of the local ethical committee, ATADEK 2021-03/04.

Availability of Data and Material

Not applicable.

Authors' Contributions

Both authors contributed in the design, data collection, data analysis and writing of the present study.

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Covid-19: A retrospective Study About The Challenges for ERCP

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ABSTRACT

INTRODUCTION: We aimed to investigate the effects of Covid-19 on Endoscopic retrograde cholangiopancreatography (ERCP) and to investigate what should be considered in the next possible epidemic situations.

METHODS: In our study, patients who applied to Trakya University School of Medicine, Department of General Surgery for ERCP (Endoscopic retrograde cholangiopancreatography) between March 2019 and March 2021 were evaluated, retrospectively. Percentages, mean, standard deviation, median and interquartile range were used as the descriptive statistics. Mann-Whitney U test was used for the variants which are contrary to the normal distribution range in the comparison of two groups. The relations between qualitative variants were studied by the Pearson Chi-Square test and Fisher's Exact Chi-Square test. Significant value was determined as 0.05 for all statistical analyses.

RESULTS: Prior to COVID-19, ERCP indications were in the order of stone (90.1%), stent removal (8%) and tumor (1.1%), while in the period of COVID-19, the ranking changed to stone (73.8%), tumor (13.7%), and stent removal (12.4%). The diagnostic use of ERCP has been greatly reduced (from 0.7% to 0.0%). No perforation was detected in both periods, there was no bleeding, but a small increase (4.7% to 5.9%) was found in pancreatitis in the COVID-19 period. In the pre-COVID-19 period, stones were detected in 46.2% of the patients and all of them were successfully removed, but during the COVID-19 period, stones were detected in 50.6% of the patients and the stones could not be removed in 1.3% of the patients.

DISCUSSION AND CONCLUSION: It was observed that the number of ERCPs decreased due to the delay in admissions to the hospital and the fear of coming to the hospital during the Covid-19 epidemic period, and the number of malignancies diagnosed with ERCP increased in this process. In such epidemic periods, more scheduled health services will provide better results for both patients and health personnel.

Keywords: Endoscopic Retrograd Cholangiopancreaticography, Choledoch, Covid, Gall stone, Mechanic icterus

Covid-19: ERCP'de Karşılaşılan Zorluklar Hakkında Bir Retrospektif Çalışma

ÖZET

GİRİŞ ve AMAÇ: Covid-19'un Endoskopik Retrograd Kolanjiyopankreatikografi (ERCP) üzerindeki etkilerini araştırmayı ve bundan sonraki olası salgın durumlarında nelere dikkat edilmesi gerektiğini araştırmayı amaçladık.

YÖNTEM ve GEREÇLER: Çalışmamızda Mart 2019-Mart 2021 tarihleri arasında Trakya Üniversitesi Tıp Fakültesi Genel Cerrahi Anabilim Dalı'na ERCP (Endoskopik retrograd kolanjiyopankreatografi) için başvuran hastalar geriye dönük olarak değerlendirildi. Tanımlayıcı istatistikler olarak yüzdeler, ortalama, standart sapma, ortanca ve çeyrekler arası aralık kullanıldı. İki grubun karşılaştırılmasında normal dağılım göstermeyen değişkenler için Mann-Whitney U testi kullanıldı. Nitel değişkenlerin gruplar arası karşılaştırmaları için Pearson Ki-Kare testi ve Fisher's Exact ki-kare testi ile incelenmiştir. Tüm istatistiksel analizler için anlamlı değer 0.05 olarak belirlendi.

BULGULAR: COVID-19 öncesi ERCP endikasyonları taş (%90.1), stent (%8) ve tümör (%1.1) iken, COVID-19 döneminde sıralama taş (%73.8), tümör (%13.7) ve stent (%12.4) olarak değişti. ERCP'nin tanınal kullanımı büyük ölçüde azaltıldı (%0,7'den %0,0'a). Her iki dönemde de perforasyon saptanmadı, kanama olmadı ancak COVID-19 döneminde pankreatitte küçük bir artış (%4,7 ile %5,9) bulundu. COVID-19 öncesi dönemde hastaların %46,2'sinde taş tespit edildi ve tamamı başarıyla çıkarıldı, ancak COVID-19 döneminde hastaların %50,6'sında taş tespit edildi ve hastaların %1,3'ünde taşlar çıkarılamadı.

TARTIŞMA ve SONUÇ: Covid-19 salgını döneminde hastaneye başvuruların gecikmesi ve hastaneye gelme korkusu nedeniyle ERCP sayısının azaldığı ve bu süreçte ERCP tanısı konan malignite sayısının arttığı gözlemlendi. Böyle salgın dönemlerinde daha planlı sağlık hizmetleri hem hastalar hem de sağlık personeli için daha iyi sonuçlar sağlayacaktır.

Anahtar Kelimeler: Endoskopik kolanjiyopankreatikografi, Safra yolu, Covid, Safra taşı, Tıkanma sarılığı

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Endoscopic retrograde cholangiopancreatography (ERCP) is a procedure that uses synchronous radiology and endoscopy in the diagnosis and treatment of gallbladder, pancreatic and upper gastrointestinal system diseases (1, 2, 3). When it was introduced in the 1970s, being able to treat pancreaticobiliary diseases without making an incision in the patient and being able to view the channels unhindered created a stir (2, 3, 4, 5). ERCP has started to be used more therapeutically in the 1990s with the emergence of magnetic resonance cholangiopancreatography (MRCP) and similar non-surgical methods, as well as its usage for diagnostic purposes in distinguishing surgical and medical jaundice and in the diagnosis of late-onset advanced pancreatic cancer (2, 3, 4, 5, 6). It is still performed today as a therapeutic procedure, as stated in the guidelines of the American Society of Gastrointestinal Endoscopy (3).

In addition to all these comprehensive therapeutic and diagnostic benefits, it is risky to usage in some patients due to the potential for complications (7). In fact, with more therapeutic use, the complication rate in these ERCPs was also found to be higher (2). There are many complications post-ERCP such as pancreatitis, perforation, infections such as cholangitis or cholecystitis, and hemorrhage (4, 7, 8). Although cholangitis and cholecystitis are less common, the perforation rate was higher (8). Although the mortality rate post ERCP varies according to its purpose, it was found to be higher in ERCP performed for therapeutic purposes (8).

Covid-19 severe acute respiratory syndrome is an infectious disease caused by the coronavirus 2 (SARS-CoV-2), which was declared a global pandemic by WHO in March 2019 (9, 10, 11, 12). Although it presents with symptoms such as fever, myalgia, shortness of breath, and cough, it can also progress asymptotically (9, 11). They can be transmitted by respiratory droplets or faecal-oral, and they can also remain for a long time on surfaces contaminated with stool and endoscopic biopsy specimens (9, 10). Healthcare workers are more vulnerable than the general population due to their high level of contagiousness, transmission routes, and long-term survival (9, 11, 13).

During the pandemic period, a consensus could not be reached in critical and urgent procedures, but new procedures were published by adding infection prevention measures in order to avoid support and ethical dilemmas (11, 14). In these guidelines, the operating area of the health system, the length of stay in the hospital, the care

potential of the hospital and the duration of the operation; there are many items such as age and other existing diseases such as diabetes (14).

Appointments and non-urgent procedures were postponed by following the instructions, and the number of endoscopic procedures decreased (12, 13, 14). It was observed that the postponing process increased the number of deaths and workload due to postponement after the pandemic (12, 13, 14). Simultaneously, patients were afraid of leaving home and coming to the hospital during the pandemic, and due to late admission and restrictive policies, diseases were detected in late stages (11, 12).

It is unclear how the accumulated workload and postponed operations will be performed and how patients are affected because we have limited data on these (13, 14).

In this study, we aimed to reveal the difficulties and results of the ERCP procedure during the Covid-19 pandemic, compare it with other studies and contribute to the literature.

MATERIAL AND METHOD

Ethics

This study was approved by the Scientific Research Ethics Committee of Trakya University School of Medicine (Protocol Code: TÜTF-GOBAEK 2022/146).

Patients

This study was approved by the Ethics Committee of the Trakya University, Edirne, Turkey, and written informed consent was obtained from each participant in accordance with the institutional guidelines. Between March 10, 2019 and March 10, 2021, 427 consecutive patients who underwent ERCP were retrospectively recruited from the Trakya University, Edirne, Turkey.

Inclusion Criteria

The predefined inclusion criteria were as follows: (1) undergoing ERCP. (2) Being older than 18. The predefined exclusion criteria were as follows: (1) having a pre-ercp anesthetic complication. (2) Being younger than 18.

Statistical Analysis

Shapiro-Wilk test used for test of normality. Mann-Whitney U test was used for the variants which are not fit to normal distribution in the comparison of two groups. The relations between qualitative variants were studied by the the Pearson Chi-Square test and Fisher's exact test.

When necessary assumptions were met, Phi and Cramer V tests were used to compare qualitative variables. Median and quarter values has been given for the quantitative variants and percentage and frequency rates were given for the qualitative variants as descriptive statistic evaluation. Significant value was determined as $p \leq 0.05$ for the all statistical analysis. All statistical analyses were performed by the using of Statistical Package for the Social Sciences (SPSS), version 22.0 (IBM®, Chicago, USA) statistical software program.

RESULTS

In our study, we evaluated 427 patients, and the rate of female patients (%64) was found to be higher than the rate of male patients(%36) (Figure 1). No statistical difference was found in the comparison of the pre- and post-Covid groups in terms of age ($p=0,501$) (Table 1).

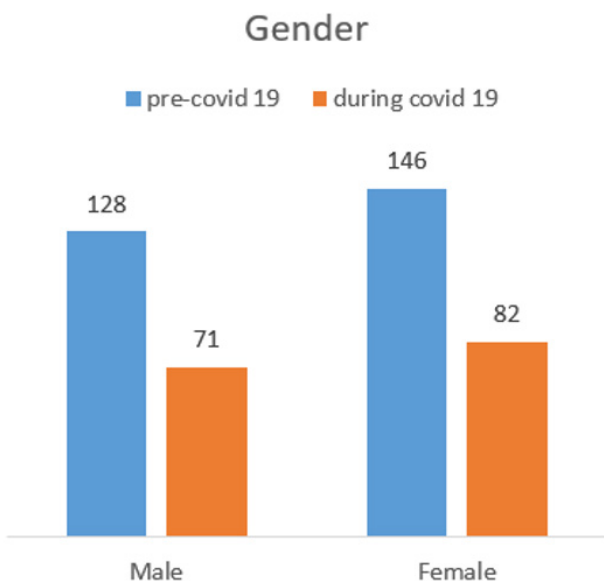


Figure 1. Gender

	Group		p
	Pre-covid 19	During covid 19	
N	274	153	0.501
Median	67	66	
IQR	18.8	20	
Minimum	20	30	
Maximum	93	88	
SD	14.9	14.5	

*IQR: Interquartile Range
SD: Standart Deviation*

We observed a significant decrease in the drainage success and quality of the ERCP technique ($p=0,03$)(Table 3). We did not find a significant difference in terms of the development of complications ($p=0.776$). We observed that the rate of diagnosis of choledocholithiasis decreased (17%) but the rate of diagnosis of malignancy increased (%17,6). In the order of ERCP indications in the COVID19 period, while stone, stent, tumor in the pre-COVID19 period, this situation changed to stone, tumor, stent (Figure 2). We observed that while all stones were successfully removed before COVID19, the rate of stones that could not be removed in the period of COVID-19 increased to 1.3% (Table 2).

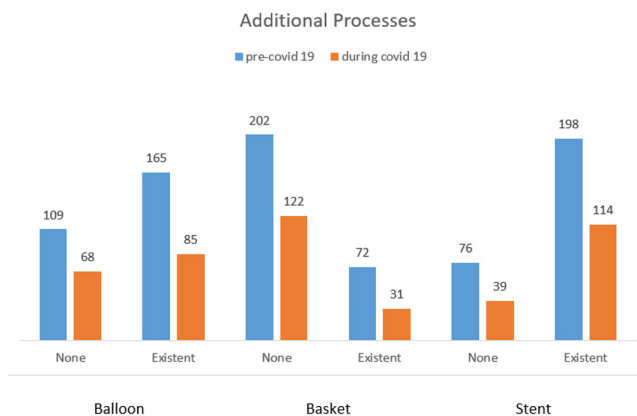


Figure 2. Additional Processes

Table 2: Comparison of p values of indication, stone, pathology, complications and diagnosis between covid 19 periods

		Group		p (Phi or Cramer's V)
		Pre-covid 19	During covid 19	
Indication	Stone	90.1 %	73.8 %	< 0.001 (0.282)
	Tumor	1.1 %	13.7 %	
	Diagnostic	0.7 %	0.0 %	
	Stent removal	8.0 %	12.4 %	
Stone	None	53.8 %	49.4 %	0.129
	Stone removal	46.2 %	49.4 %	
	No stone removal	0.0 %	1.3 %	
Pathology	None	96.7 %	94.1 %	0.200
	Adenocarcinoma	3.3 %	5.9 %	
	Neuroendocrine tumor	0.0 %	0.0 %	
	Gastrointestinal tumor	0.0 %	0.0 %	
Complications	None	94.9 %	94.1 %	0.776
	Pancreatitis	4.7 %	5.9 %	
	Perforation	0.4 %	0.0 %	
Diagnosis	Choledocholithiasis	96.7%	79.1%	< 0.001 (0.287)
	Malignancy	3.3%	20.9%	

No difference was detected in the additional procedures, except for a significant decrease in the number of stents (Figure 3). We observed that the decrease in drainage success (98.8% to 95.6%) was parallel to the increase in the diverticulum (12.4% to 18.3%) (Table 3).

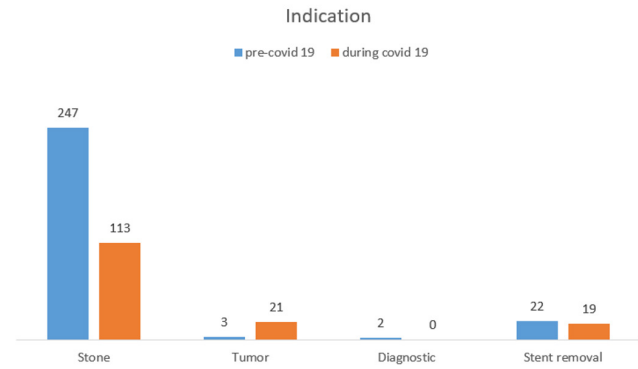


Figure 3. Indication

	Group				p (Phi or Cramer's V)
	Pre-covid 19		During covid 19		
	none	existent	none	existent	
Drainage	1.2%	98.8%	4.4%	95.6%	0.039
Additional Processes	21.5%	78.5%	23.5%	76.5%	0.816
Balloon	39.8%	60.2%	44.4%	55.6%	0.464
Basket	73.7%	26.3%	79.7%	20.3%	0.141
Stent	51.8%	48.2%	79.1%	20.9%	< 0.001 (0.269)
Diverticulum	87.6%	12.4%	81.7%	18.3%	0.098

DISCUSSION

Endoscopic retrograde cholangiopancreatography (ERCP) is a procedure used in the diagnosis and treatment of pancreaticobiliary system diseases. It is a life-saving procedure in the treatment of obstructions caused by biliary system stones and malignancies, acute pancreatitis and biliary sepsis (15).

The success of the ERCP procedure varies according to the endoscopist's experience, case, indication and techniques used. Also some undesired outcomes may occur due to the complications such as bleeding perforation pancreatitis and cholangitis (11).

During the Covid-19 pandemic, which has turned into a global health crisis, complicative situations due to delay in applying to the hospital and from being unable to reach the diagnosis due to the limitation in working conditions in all diseases appear as a major problem (14).

Some countries changed the pattern of endoscopies and reduced the number of endoscopy during and after the lockdown (16, 17). In the study of Kim et al, They present to the mean ages were 73, 72 and 66 in 2018, 2019 and 2020 respectively. In addition, the dominant gender was woman in 2018, comparison of that, it was man in 2020. They argue that older people do not consult to a doctor until complications become serious for fear of leaving home and going into quarantine, so the mean age in 2020 is lower than in other years (18). Another research indicates that 18 ERCP procedures done in 16 patients between 15 March and 1 July 2020 and the vast majority were male, with an average age of 65 (13).

In our study, we found that while the median age was 67 in the pre-Covid period, it was 66 in the covid period, in line with the literature. Again, as in other articles in the literature, the rate of women in our study was found to be higher than men in both pre-Covid and Covid periods.

They assert the number of procedures in 2020 decreased than 2018 and 2019. So it is fact that covid-19 significantly reduced the number of ERCP but no difference was observed in indications (18).

According to our retrospective study, we found a major decrease in the number of patients by 44% (from 274 to 123) in the period of COVID-19 compared to the pre-COVID-19 period.

The most common uses of ERCP are stone disease, malignancy, bile duct obstruction manifested by jaundice as well acute procedures such as acute pancreatitis or cholangitis (12). According to some studies, 3 most common indications for ERCP are bile duct stones, abdominal pain and distal tumors. Furthermore, following by these jaundice, fever, biliary duct stricture, kolangitis (12, 13, 18, 19, 20).

Prior to Covid 19, ERCP indications were in the order of stone (90.1%), stent removal (8%) and tumor (1.1%), whereas during the COVID19 period, the ranking changed to stone (73.8%), tumor (13.7%) and stent removal (12.4%). The diagnostic use of ERCP has been greatly reduced

(from 0.7% to 0.0%). A significant change was found between the two periods in terms of indication percentages.

When specific endoscopic procedures are compared between 2019 and 2020, not an important difference is found. Balloon trawl, stent deployment or both were the most frequently used techniques in both years and not common techniques were use of a basket and lithotripter (12).

In our study, no significant difference was found between the two periods in the number of patients who underwent specific endoscopic procedures (78.5% to 76.5%). While no significant difference was found in balloon trawl and basket between the two periods, there was a significant decrease in stent deployment in the post-covid 19 period (27.3%, $p=0.001$).

To another study remarks, there were not differences between 2018, 2019, 2020 . Moreover, endoscopic retrograde biliary drainage (ERBD) was the first on the list of the ERCP procedures and followed by bile duct stone removal ,endoscopic sphincterotomy (EST) and endoscopic nasobiliary drainage (ENBD) (18).

In the pre-Covid19 period, stones were detected in 46.2% of the patients and all of them were successfully removed, whereas during the COVID19 period, stones were detected in 50.6% of the patients and unfortunately, the stones could not be removed in 1.3% of the patients. There was a slight decrease in success, which was thought to be due to the delay of patients in applying to the clinic, the operator's performing ERCP under difficult conditions, or the localization and size of the stone.

In addition, cannulation made successfully in all patients, as well guide-wire assisted cannulation was the first choice followed by double-guidewire and contrast-guided technique. Additionally covid 19 patients and the others in term of cannulation methods were not different from each other (13).

In our study, no significant difference was found in terms of cannulation techniques in the period before and during COVID19. The increase in the number of patients with diverticulum during the COVID19 period was also reflected in the success of cannulation and reduced the probability of success. It is thought that the increase in the number of patients who applied repeatedly during the COVID19 period may also be related to the decrease in the success of cannulation in this period.

We searched the study about the complications that occur in patients with covid-19 and without. It is indicated, there was a decreased of success and Covid-19 was the only risk factor for that which it is the low possibility but there is no significant differences in terms of complications (12, 13). To their opinion, it will continue that quality of ERCP and success during COVID-19 like before (12).

Donato G et al, investigated 804 patients. 23 of 804 patients had post ERCP acute pancreatitis, 16 of 804 patients had bleeding, 14 of 804 patients had cholangitis/ cholecystitis and 4 of 804 patients had perforation but none of these turn to critical situation. There is no death because of ERCP but 3 of 804 patient died due to COVID-19 (19).

The European Society of Gastrointestinal Endoscopy (ESGE) has given priority to emergency procedures and has suggested some changes in endoscopies for situations requiring urgent intervention (14). Among these measures, the patient's position change during the endoscopy, ventilation in the area to be applied to the endoscopy, and the use of personal protective equipment by the staff and the patient are (9, 10, 14). According to the ESGE directive, personal protective equipment was evaluated as gloves, mask (N95, FFP2), apron, goggles and hairnet (9, 10). These equipments can create reluctance in the operator due to their bulky structure as well as their protectiveness and indirectly cause a decrease in ERCP success (13).

There was no significant change in the number of complications before and during COVID19. In both periods, no perforation was detected, there was no bleeding, but a small increase (4.7% to 5.9%) was found in pancreatitis in the covid 19 period. As in all diseases, the number of hospital admissions decreased during the COVID19 period, but despite some uncomfortable conditions (wearing protective equipment and the stress of the pandemic period), it did not change the quality of the procedure and the occurrence of complications. In addition, one of our patients died after ERCP performed before COVID19, not because of ERCP, but because of fulminant cholangiopepsis.

We think that this delay in diagnosis is caused by the fear of COVID19 in patients, delaying admission to the clinic, and delaying cases that are not considered urgent, and that the health system is more affected by this. We attribute the increase in tumor incidence to the decrease in the use of ERCP for diagnosis and screening. We think that the comfort of protective equipment should be increased and the operator will be less affected by the conditions under appropriate conditions.

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Ethical Approval

This study was approved by the hospital's institutional review board.

Conflicts of Interest

All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. The authors have no independent disclosures or conflicts of interest.

Contributors

IEC: concept, design, literature search, data acquisition, data analysis, statistical analysis, manuscript preparation, manuscript editing and manuscript review; MYK: data acquisition, data analysis, manuscript review, SNC: literature search, data acquisition, data analysis; MNY: data analysis, statistical analysis, manuscript preparation; DA: manuscript preparation, manuscript editing and manuscript review.

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How should Travel-Related Malaria Management in Emergency Departments of Non-endemic Countries? Single-center Study

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ABSTRACT

Purpose: Advancements in air travel enabled an increase in traveling to malaria-endemic countries such as those in sub-Saharan Africa. An increase in the incidence of imported malaria accompanied these advancements. This study aims to summarize how malaria patients who have imported the disease into non-endemic countries present to the emergency departments and to enlighten physicians in emergency departments by providing suggestions for practical approaches to handling such situations.

Methods: This study was conducted retrospectively in a university hospital, from January 1, 2014 to March 1, 2022. Eight years of emergency department records of patients who were examined in the emergency department with a suspected, or definitive diagnosis of malaria were included in the study. Epidemiological and clinical characteristics were evaluated.

Results: 892 patients were admitted to the emergency department with suspicion of malaria. Thirty of these patients were diagnosed with malaria, and 846 of the 892 patients were members of airline cabin crews. 94.3% (n=798) of the cabin crew did not use prophylactic medication for malaria. The mean age of the patients was 33.2±8.5. Twenty-five patients were diagnosed via peripheral blood smears, and the remaining three patients were diagnosed with polymerase chain reaction (PCR). Rapid diagnostic tests were positive in 26 out of 28 patients.

Conclusion: The risk of acquiring malaria is still high despite short-term visits and airport-limited stays. Travel history should be routinely asked of patients with fever by emergency physicians. Education of people traveling to malaria-endemic countries, including cabin crew, regarding malaria prophylaxis and protective measures to prevent mosquito bites plays a crucial role in preventing malaria.

Keywords: Malaria; Import Malaria; Emergency Department; Cabin Crew; Infection

Endemik Olmayan Ülkelerin Acil Servislerinde Seyahate Bağlı Sıtma Yönetimi Nasıl Olmalı? Tek Merkezli Çalışma

ÖZET

Amaç: Hava yolu ulaşımındaki gelişmeler ve artış, sıtmanın endemik olduğu Afrika ülkelerine olan seyahatlerinde artmasını sağladı. Bu gelişmelerle birlikte ithal sıtma vakalarının da dünya genelinde artmasına sebep oldu. Bu çalışma, hastalığı endemik olmayan ülkelere ithal eden sıtma hastalarının acil servislere nasıl geldiklerini özetlemeyi ve bu tür durumlara başa çıkmak için pratik yaklaşımlar için önerilerde bulunarak acil servislerdeki hekimleri aydınlatmayı amaçlamaktadır.

Yöntemler: Bu çalışma 1 Ocak 2014-1 Mart 2022 tarihleri arasında bir üniversite hastanesi kayıtları incelenerek retrospektif olarak yürütülmüştür. Acil serviste sıtma şüphesi veya kesin tanısı ile başvuran hastaların yedi yıllık acil servis kayıtları çalışmaya dahil edilerek, epidemiyolojik ve klinik özellikler değerlendirildi. Sıtma tanısı alan hastalara tekrar ulaşılarak anket düzenlendi.

Bulgular: 892 hastanın acil serviste sıtma ön tanısıyla değerlendirildiği tespit edildi. Bu hastaların 30'u sıtma teşhisi aldı ve 892 hastanın 846'sı havayolu kabin ekibi üyesiydi. 28 hasta ithal sıtma tanısı aldı. Kabin ekibinin %94,3'ünün (n = 798) sıtma için koruyucu ilaç kullanmadığı saptandı. Hastaların yaş ortalaması 33,2±8,5 idi. Yirmi beş hastaya periferik kan yayması, kalan üç hastaya PCR ile tanı konuldu. 28 hastanın 26'sında hızlı tanı testleri pozitif.

Sonuç: Kısa süreli ziyaretlere ve havaalanında sınırlı kalışlara rağmen sıtmaya yakalanma riski hala yüksektir. Acil hekimleri tarafından ateş şikayeti olan hastalara rutin olarak seyahat öyküsü sorulmalıdır. Kabin ekibi de dahil olmak üzere sıtmanın endemik olduğu ülkelere seyahat eden kişilerin sıtma profilaksisi ve sivrisinek ısırıklarını önlemeye yönelik koruyucu önlemler alması, sıtmayı önlemede çok önemli bir rol oynamaktadır.

Anahtar Kelimeler: Sıtma; İthal Sıtma; Acil Servis; Kabin Ekibi; Enfeksiyon

The number of people who travel to Africa has increased enormously in recent years, and travel-acquired infections have also increased (1). Malaria is one of the most critical infections among these. Authorities estimate that around 229 million cases were present in 2019 in 87 malaria-endemic countries (2). Malaria is an infectious disease with high mortality and is caused by Plasmodium parasites. It is endemic in many countries throughout the world and threatens approximately 40% of their populations (3). People most at risk for malaria infection and malaria-related death are those traveling to Sub-Saharan African Countries (4). Prophylaxis and protective measures are of great importance and included in the World Health Organization's 2030 goals (5).

The malaria cases that are imported into non-endemic countries are frequently associated with delayed diagnosis and treatment and are thus accompanied by increased mortality rates (6). These cases also cause the rates of drug resistance to rise and have an overall negative effect on the long-term goals for eradicating this disease (7). Therefore, malaria prophylaxis should be initiated for people who travel to high-risk malaria-endemic countries, and measures need to be taken to avoid mosquito bites (8). However, people who are staying in the malaria-endemic countries for short-term periods without getting started on malaria prophylaxis constitute a severe problem. This is a particularly important issue among the members of airline cabin crews, who represent a clear example of short-term visitors who make multiple visits to malaria-endemic countries and do not initiate the malaria prophylaxis before traveling.

The number of infections acquired during international travels that arise in different settings may vary throughout the world. People who visit endemic countries for a short time and become infected with malaria may present to the emergency department (ED) with nonspecific symptoms. Most emergency physicians rarely encounter such diseases; therefore, malaria may not be among the preliminary diagnoses of emergency physicians. Any delay in recognizing or treating a possible malaria infection may increase both morbidity and mortality rates (9).

This study aims to summarize how malaria patients who have imported the disease into non-endemic countries present to the EDs and to inform physicians in EDs by providing suggestions for practical approaches to handling such situations. The second goal of the study is to investigate the prophylaxis statuses of patients and the reasons

why they do not get the prophylactic treatments in cases where this was not initiated.

METHODS

This study was conducted retrospectively in a university hospital, from January 1, 2014 to March 1, 2022. This study was approved by Acibadem Mehmet Ali Aydinlar University Medical Research Evaluation Committee (ATADEK) (Decision number: 2020-12/2). The University hospital is not a primary referral center for tropical diseases but because it is located close to an international airport and may be more frequently visited by airline cabin crews, airport personnel, and travelers. Eight years of ED records of patients who were examined in the ED with a suspected, or definitive diagnosis of malaria were included in the study. From an epidemiologic perspective, the ages of the patients were recorded, along with their genders, occupations, primary complaints, the countries they had visited, the duration of their visits, their statuses regarding prophylaxis usage, and any previous malaria diagnoses. The lengths of time between their returns to the countries and the beginning of symptoms, the symptoms they had when they were admitted to the ED, and the duration of the time when their symptoms began to when they applied to our clinic were also evaluated. Any histories of mosquito bites, ongoing fevers, and accompanying symptoms such as nausea, vomiting, diarrhea, jaundice, or muscle pain were recorded. Findings from physical examinations including hepatomegaly and splenomegaly were also noted. Laboratory examination results were collected for parasitic loads, leukocytes, hemoglobin, thrombocytes, lactate dehydrogenase, aspartate transaminase, alanine transaminase, total and direct bilirubin, urea, creatinine, C-reactive protein, and international normalized ratios. Also, rapid diagnostic tests, blood smears, and polymerase chain reactions test results were noted. Clinical features regarding treatment were recorded using the hospital's electronic medical system. Telephone numbers were obtained from the hospital records of the patients diagnosed with malaria, and the patients were called. An explanation was given about the study, and verbal consent was obtained from those who agreed to participate in the study, 6 questions were asked; 1- Before you got malaria, did you know about malaria disease while traveling to a risky area? 2- Did you take any precautions (using chemical-topical repellent; wearing long pants, socks, and long-sleeved shirts; staying indoors) to protect yourself from malaria disease while traveling to the risky area? 3- Did you use any prophylaxis? if you did not take any prophylaxis, what is the reason? 4- When the

symptoms started? did you think you might have malaria? 5-When you applied to the emergency service, did the triage nurse or doctor question whether you went to a risky area from malaria? 6- After receiving treatment for malaria, did you go to the risk area for malaria again? If you went, did you take any precautions to protect yourself from malaria? Approval for the study was obtained from the university's ethics committee, to which the university hospital is linked.

Data were analyzed using IBM SPSS version 18 for Windows. Descriptive statistics were used to determine the frequencies and percentages for biodemographic variables. The median Malaria Mortality Score (MMS) was used as the measure of the severities of the disease

RESULTS

It was determined that 892 patients had been admitted to the ED with suspicion of malaria in a 8-year period. Flowchart 1 is shown in Figure 1. Thirty of these patients were diagnosed with malaria, and 846 of the 892 patients were members of airline cabin crews. A full 94.3% (n = 798) of the cabin crew members did not use prophylactic medication for malaria. In addition, malaria prophylaxis had not been initiated in any of our patients before or during their travel. 30 people diagnosed with malaria were identified. As we aimed to evaluate imported malaria, we included 28 patients in the study. The other two patients lived in South Africa.

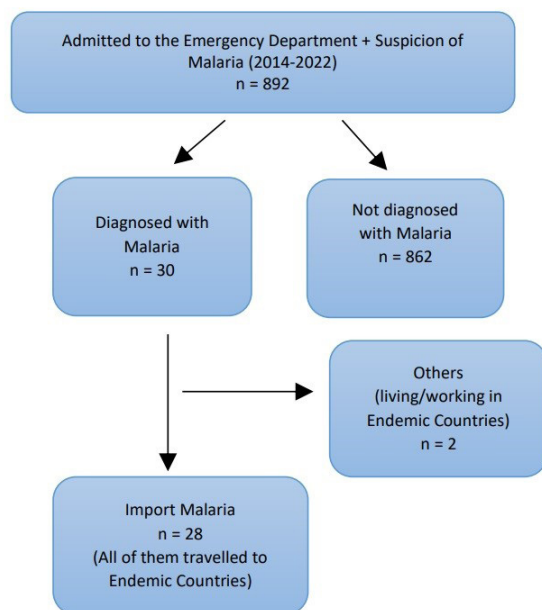


Figure 1. Flowchart of Study Population

Table 1 presents the general characteristics of those who were diagnosed with malaria. The mean age of these patients was 33.2 ± 8.5 (24-48), with 17 male patients and 11 female patients. All infected patients had a history of visiting Sub-Saharan Africa. The mean duration of their layover in Africa was 2.3 ± 1.6 (1-8) days; the mean delay before the onset of their symptoms after return from travel was 9.0 ± 6.0 (0-35) days, and the mean symptom duration before presentation to the ED was 3.6 ± 2.0 (1-10) days.

All 28 malaria patients had fever, 22 reported accompanying chills, and 21 mentioned sweating. Sixteen had nausea and/or vomiting, and eight reported diarrhea. In addition, 21 patients had histories of mosquito bites. Splenomegaly was detected in 17 patients, hepatomegaly in 15, and jaundice in six. Nine patients had signs of central nervous system involvement. Table 1 presents the laboratory parameters of the patients at the time of their applications. Among the 28 patients, 25 were diagnosed through peripheral blood smears and the remaining three patients were diagnosed through PCR. Rapid diagnostic tests were positive in 26 out of the 28 patients; 27 patients were determined to be infected with *Plasmodium Falciparum* and one patient with *Plasmodium Ovale*. In addition, 13 patients had parasitic loads of over 5% and seven had over 10%. In terms of treatment, 20 patients were given artemether-lumefantrine, five received artemether-lumefantrine and primaquine, and three patients who were critically ill were given artemether-lumefantrine following intravenous artesunate. The mean duration of the hospitalizations of the patients was 6.1 ± 4.5 (3-18) days. Nine patients received a transfusion of red blood cells or platelets, and 27 were discharged after treatment completion. One patient, who had a 20% parasitic load, died during their hospitalization. Three patients experienced recurrence during the two-month follow-up.

All patients diagnosed with malaria were called by phone and a 6-question survey was conducted except one patient. The one patient, that we couldn't reach was deceased. In this survey, all of the participants express that they had information on malaria before their visit to the malaria-endemic country. The survey questions and results are in Table 2.

	Frequency (n)	Percentage (%)
Gender		
Male	17	60.7
Female	11	39.3
Symptoms		
Jaundice	7	25
Fever	28	100
Diarrhea	8	28.5
Nausea/vomiting	16	57.1
Neurological	9	32.1
History of a mosquito bite	21	75
Splenomegaly	17	60.7
Hepatomegaly	15	53.5
	Median \pm SD	
Time to treatment	7.18 \pm 6.7 days	
Age	33.2 \pm 8.5 years	
Duration of travel	2.3 \pm 1.6 days	
Beginning of the symptoms	3.6 \pm 2.0 days	
Laboratory Parameters		
Leucocyte (mm ³)	5228 \pm 3210	
Hemoglobin (gr/dL)	13.0 \pm 2.2	
Thrombocyte (mm ³)	83935 \pm 68432	
ALT (U/L)	76.82 \pm 54.5	
AST (U/L)	72.61 \pm 50	
Total bilirubin (mg/dL)	1.95 \pm 2.18	
Direct bilirubin (mg/dL)	1.19 \pm 1.49	
Creatinine (mg/dL)	1.20 \pm 1.24	
Lactate Dehydrogenase (U/L)	497 \pm 579	
C-Reactive Protein (mg/dL)	10.5 \pm 8.0	
International Normalized Ratio (INR)	1.97 \pm 0.2	

DISCUSSION

United States emergency physicians rarely encounter internationally acquired travel illnesses in emergency departments (9). However, malaria is one of the more frequent of these. Symptoms of malaria are nonspecific, and few have abnormal physical findings. The most common of these is fever, which our study supports (10). However, fever is a general symptom and could represent non-malarial infections. The symptom of fever in the setting of travel, even with layovers of short duration was key to prompting suspicion of malaria in our cohort.

The questions	Yes (n)	No (n)
1- Before you got malaria, did you know about malaria disease while traveling to a risky area?	27	0
2- When the symptoms started, did you think you might have malaria?	5	22
3- When you applied to the emergency service, did the triage nurse or doctor question whether you went to a risky area from malaria?	20	7
4- After receiving treatment for malaria, did you go to the risk area for malaria again?	24	3
-If you went, did you take any precautions to protect yourself from malaria?	9	15
5- Did you take any precautions to protect yourself from malaria disease while traveling to the risky area?	8	19
6- Did you use any prophylaxis?	0	27
-Reasons for not using prophylaxis	n	%
•In spite of short trips to risky areas, they had never been sick. So they feel safe without using prophylaxis.	19	70.3
•They closely follow their health condition and symptoms, they apply to the health institution quickly in case of any problem	4	14.8
•They are concerned about the side effects of drugs	3	11.1
•For allergic reasons	1	3.7

In our study, some cases in which the patient may have had no fever and therefore not suspected of malaria. This could have resulted in undiagnosed cases that were not selected for study, leading to selection bias. Emergency physicians or triage nurses should inquire about whether patients have been to endemic areas for malaria in emergency departments. This raises the following question: Which countries are at risk from malaria disease? Figure 2 shows countries with indigenous cases and their status from 2000 to 2019 (2). Any patient with a travel history to any of the countries in Figure 2 should be investigated as a potential malaria case.

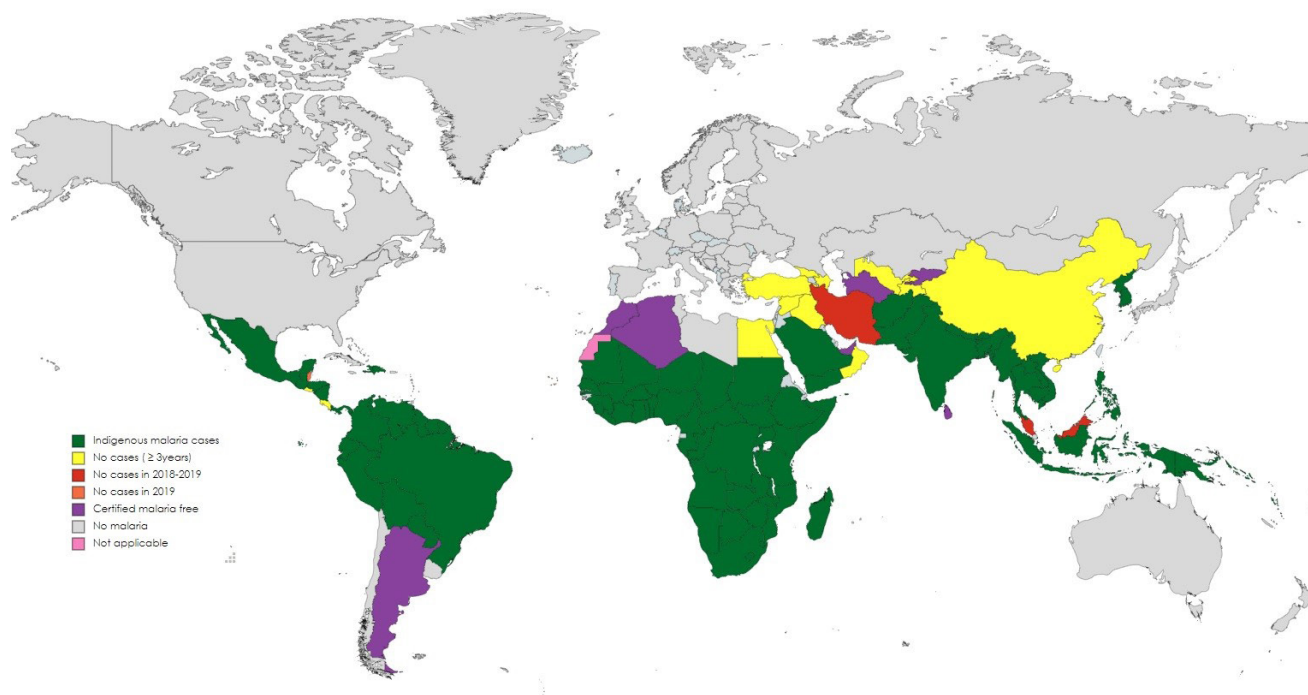


Figure 2. World Map; Countries with indigenous cases and their status

Although malaria is mostly deemed preventable for those traveling from non-endemic to endemic countries, numerous studies have reported that if prophylaxis is not initiated or there is reduced compliance to the recommended dosage, malaria is commonly encountered in this group (11). Travel has become more frequent to endemic areas, and as indicated in our study, even exposure of 2-3 days is enough to contract malaria.

This short duration layover may be incorrectly perceived as safe, since 82.8% (798/846) of cabin crews did not have prophylaxis, and of these, 3.5% (28/798) became infected. Of the 28 infected cases, none were prophylaxed (12,13). Travel timing reported local resistance, and drug side effects should guide physicians in chemoprophylaxis selections for malaria. Table 3 summarizes the drugs recommended by the Centers for Disease Control and Prevention (CDC) for malaria prophylaxis and gives a review for each drug (14).

Table 3. Prophylactic Regimens for Malaria and Special Considerations by CDC (Centers for Disease Control and Prevention)

	Dosing	Pregnancy	Special Considerations
Primaquine	- Daily dosing - 1–2 days before through 7 days after	Contraindicated	- Used in areas where <i>P. vivax</i> is seen intensely - Not used in G6PD deficiency
Chloroquine	- Weekly dosing - 1–2 weeks before through 4 weeks after	Trustworthy for pregnant	- Many areas with resistance
Doxycycline	- Daily dosing - 1–2 days before through 4 weeks after	Likely safe but second line	- Inexpensive - Photosensitivity
Atovaquone-proguanil	- Daily dosing - 1–2 days before through 7 days after	Contraindicated	- More expensive
Tafenoquine	- Daily dosing for 3 days before travel and transitions to weekly through 1 week after return	Contraindicated	- Not used in G6PD deficiency
Mefloquine	- Weekly dosing - 2 weeks before to 4 weeks after	Trustworthy for pregnant	- Not recommended for seizures, psychiatric disorders, cardiac dysfunctions

There is a definite association between international air travel to malaria-endemic countries and the possibility of contracting the disease. Overall, the degree of endemicity in the region of travel, period of stay, the health status of the person during travel, precautions taken, and the person's behavior determine the risk (15,16). It is estimated that for aircraft cabin crews, the contagion rate of malaria is 0.5 per 1,000 people per night in malaria-endemic countries (13). Although our patients had traveled to malaria-endemic countries, malaria prophylaxis was not initiated in any of them. Prophylaxis has been neglected because of some reasons, most of the patients (70%) stated that they travel to the malaria-endemic country and do not use prophylactic medication because they are not sick. Other patients answered that they keep track of their symptoms closely and did not take prophylactic medication because they were concerned about the adverse effects. They had tried to protect themselves from mosquito bites. The literature cites cabin crews may mitigate the risk of mosquito bites and thus malaria, by wearing long-sleeves shirts and pants, using bed netting, and by minimizing night-time outdoor activities (13,17). However, 28 of our malaria patients had no prophylaxis, suggesting that prophylaxis may be important for cabin crews even for short layovers in endemic countries. Unfortunately, in the current study, 21 of the patients (75%) recalled being bitten by a mosquito.

Fatal malaria cases among members of cabin crews have been reported, and even non-lethal cases have resulted in a significant loss in the workforce (13). We were informed that the deceased patient, a 34-year-old female cabin crew member, spent two days in Africa at the airport hotel. It was found that most of our patients had stayed in malaria-endemic countries for only two or three days. These cases show that the risk is still high for short-term travels. Our study identified two important clues in suspecting patients having malaria: it only requires 2-3 days exposure in an endemic area to acquire malaria, and a delay of symptom onset of 9 days after return from travel is common in patients presenting to the ED (18,19). Before her death, our deceased patient reported that she had returned from Africa 40 days ago. Her symptoms had started 15 days before application to our clinic, and she had received non-specific treatment for an upper airway infection at another hospital. However, she applied to our clinic because of persistent fever and fatigue despite the treatment. Her parasitic load in the peripheral blood smear was detected to be 20%. Delayed diagnosis of imported malaria cases is a common occurrence, emphasized in a meta-analysis by Tatem et al (7). In addition to contributing to global eradication plans, scrutinizing imported malaria cases in non-endemic countries could decrease

complications and mortality rates by increasing the awareness level of clinicians, which can prevent these cases from being overlooked.

Treatment depends on four main factors, which are as follows: the *Plasmodium* species by which the patient was infected; the patient's symptoms and clinical severity; the sensitivity of the *Plasmodium* species in the geographical region where infection occurs to anti-malarial drugs; and previous use of antimalarials, including those taken for malaria chemoprophylaxis. The CDC recommends that a blood smear be performed if the patient has a fever and has traveled to a risky area for malaria in the last 2 months or is clinically suspected of having malaria. If a blood smear is negative, repeat blood smears should be conducted every 12–24 hours (a total of three times). If the blood smear is positive, the instructions in flowchart 2 should be followed (Figure 3) (20). Malaria treatment usually takes 3–7 days. Most of the patients in our study received only artemether-lumefantrine; four received artemether-lumefantrine and primaquine, one received quinine and primaquine, and three patients received artemether-lumefantrine following intravenous artesunate. The utilization of the anti-malarial medication artesunate in conjunction with exchange transfusion demonstrated efficacy and safety in patients suffering from severe malaria and neurological complications (21). An exchange blood transfusion and artesunate treatment were applied to two malaria patients. One patient was deceased. The obvious difference between the deceased patient and the others was that she was diagnosed approximately 40 days later.

When patients present to the ED with fever, it is prudent for emergency physicians or triage nurses to ask about their travel history in the prior two months. Or if the patient presents to the ED with a history of recent travel it is prudent to ask about fevers, chills or night sweats. When there is suspicion of malaria, then testing should be considered regardless of the duration of their endemic exposure or whether a mosquito bite has been observed. Blood smears, rapid diagnostic testing (antigen), or polymerase chain reaction testing are commonly used to make malaria diagnoses in suspected cases (9). Rapid diagnostic tests for malaria represent a fast, cheap, simple, and field-deployable way to accurately identify a malarial infection at the point of care, and these tests are especially useful in low-resource and rural settings. Blood smears were the most widely used method to confirm the entity of *Plasmodium* parasites until the appearance of malaria rapid diagnostic tests; they are still useful and reliable. Polymerase chain reaction assays can determine low parasitemia and have great analytical performance, but they are costly and impractical for use (22).

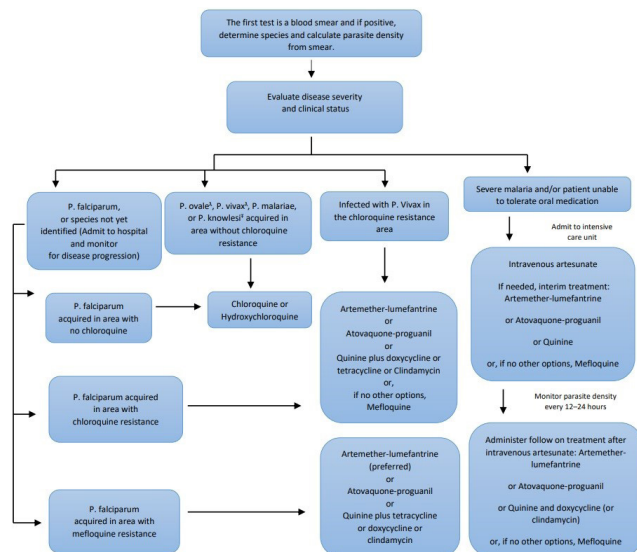


Figure 3. Algorithm for Treatment of Malaria[‡]

Footnotes:

[‡] Algorithm for treatment not for children and pregnant women

[†] If species later identified *P. knowlesi* admit to hospital and monitor for disease progression.

^λ If species later identified as *P. vivax* or *P. ovale*, add primaquine if not G6PD deficient by quantitative testing. Tafenoquine can only be used if chloroquine or hydroxychloroquine used for acute infection.

Limitations

There are some limitations in the current study. The fact that the study is single-centered is one of them. Since the university hospital where the study was conducted is a hospital close to the airport, airline employees may have applied more frequently. Although the number of patients examined with a prediagnosis of malaria is sufficient, the low number of patients diagnosed with malaria is low.

CONCLUSION

Traveled malaria-endemic country, fever and mosquito bite are factors that should raise emergency physician suspicion of malaria. Blood smears, rapid diagnostic testing (antigen), or polymerase chain reaction testing are commonly available to confirm the diagnosis. Unprophylaxed cabin crews who have even one or two days duration layover in endemic areas may be at risk for acquiring malaria. Although wearing long-sleeved shirts and pants, using bed netting, and minimizing night-time outdoor activities may mitigate the risk of acquiring the condition, prophylaxis may be especially important.

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Does Most Watched YouTube Videos Related to Carpal Tunnel Syndrome Provide Sufficient Information?

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ABSTRACT

Purpose: The aim of this study was to evaluate the quality of the most watched YouTube videos regarding the diagnosis and treatment of Carpal Tunnel Syndrome.

Methods: The first fifty most watched videos for search term “Carpal Tunnel Syndrome” on YouTube, meeting inclusion criteria are included and evaluated by two researchers with DISCERN, JAMA and Carpal Tunnel Syndrome Informational Assessment (CTSIA) scores, under the groups of physicians, health channels and other sources.

Results: There were statistically significant positive correlation between scoring systems, including CTSIA. No statistically significant correlation was found between video source and number of views, and between video source and view rate. There was a relation between video source and DISCERN, JAMA, and CTSIA scores which was statistically significant ($p<0.05$). The videos uploaded by doctors and health channels had higher DISCERN scores than other sources ($p=0.025$ and 0.024 , respectively), the videos uploaded by health channels had higher JAMA scores than other sources ($p=0.013$), and the videos uploaded by doctors had higher CTSIA scores than other sources.

Conclusion: Informational quality of videos about CTS is insufficient, even for physician videos although these are better than other sources. There is a clear need for guidelines and scoring systems for online medical information videos since internet is accepted and used as the ultimate information source.

Keywords: carpal tunnel syndrome, YouTube, patient education, medical informational video

Karpal Tünel Sendromu ile İlgili En Çok Seyredilen YouTube Videoları Yeterli Bilgi Sağlıyor mu?

ÖZET

Amaç: Bu çalışmanın amacı, Karpal Tünel Sendromu (KTS) tanı ve tedavisi ile ilgili en çok izlenen YouTube videolarının kalitesini değerlendirmektir.

Yöntemler: YouTube’da “Karpal Tünel Sendromu” arama terimi için dahil edilme kriterlerini karşılayan en çok izlenen ilk elli video dahil edilmiş ve DISCERN, JAMA ve Karpal Tünel Sendromu Bilgilendirme Değerlendirmesi (CTSIA) puanları iki araştırmacı tarafından, hekimler, sağlık kanalları ve diğer kaynaklar yönünden değerlendirilmiştir.

Bulgular: CTSIA’da dahil olmak üzere skorlama sistemleri arasında istatistiksel olarak anlamlı pozitif korelasyon vardı. Video kaynağı ile görüntüleme sayısı arasında ve video kaynağı ile görüntüleme oranı arasında istatistiksel olarak anlamlı bir ilişki bulunmadı. Video kaynağı ile DISCERN, JAMA ve CTSIA puanları arasında istatistiksel olarak anlamlı bir ilişki vardı ($p<0.05$). Doktorlar ve sağlık kanalları tarafından yüklenen videolar, diğer kaynaklara göre daha yüksek DISCERN puanlarına sahipti (sırasıyla $p=0.025$ ve 0.024). Sağlık kanalları tarafından yüklenen videolar diğer kaynaklara göre daha yüksek JAMA ($p=0.013$) ve doktorlar tarafından yüklenen videolar diğer kaynaklardan daha yüksek CTSIA puanlarına sahipti.

Sonuç: Diğer kaynaklardan daha iyi olmasına rağmen KTS ile ilgili videoların bilgi kalitesi hekim videoları için bile yetersizdir. İnternet, nihai bilgi kaynağı olarak kabul edildiğinden ve kullanıldığından, çevrimiçi tıbbi bilgi videoları için kılavuzlara ve puanlama sistemlerine açık bir ihtiyaç vardır.

Anahtar kelimeler Karpal tünel sendromu, YouTube, hasta eğitimi, tıbbi bilgilendirme videosu

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Carpal Tunnel Syndrome (CTS) is entrapment of median nerve at wrist level and the most frequent compressive focal mononeuropathy. CTS affects approximately 3-12% of adult population (1). Symptoms may worsen during nighttime and include numbness in first three fingers, pain and thenar atrophy. Common risk factors for CTS are repetitive overuse, obesity, diabetes mellitus, pregnancy but most of the cases remains idiopathic. Diagnosis is based on physical examination, radiological assessment (ultrasonography, magnetic resonance imaging) and electrophysiological studies. Treatment options are patient education, conservative treatment (non-steroidal anti-inflammatory drugs, splinting), local injections and physiotherapy for early to mild disease and surgical (open or endoscopic) release for severe disease.

Today internet is highly accepted as the ultimate information source and almost all patients with opportunity to reach the internet, checks out their options and conditions online as a second opinion. In this manner YouTube is one of the first addresses that patients visit, with 122 million daily active users and more than 1 billion videos watched every day (2). This tendency raised a concern about the quality and accuracy of the medical informational videos hosted by YouTube since it is not a peer-reviewed platform (3). Recent studies conducted to evaluate the information quality on YouTube videos regarding CTS concluded that the information quality of these videos are low and lack of essential information such as complications and other treatment modalities (4,5). Another recent study by Goyal et al. (6) focused on the potential of YouTube videos about CTS to reinforce misconceptions. The authors identified a notable number of statements that may reinforce unhealthy misconceptions and they stated that more popular videos might mistakenly be assumed by patients that the information in these videos is more accurate and these videos are less likely to reinforce potential misconceptions.

Popularity of a video on YouTube depends on several parameters and calculated by an algorithm, but since these parameters include concerns other than medical issues popularity can be a misleading factor. Although above-mentioned studies evaluated CTS videos on YouTube, their methodology was similar and included the first 50 or 60 relevant videos. A recent study by Mert and Bozgeyik (4) stated that useful and quality videos are in the background in terms of the number of views and likes and that videos with low quality are viewed more. To the best of our knowledge there is no study that evaluated the content quality of the most watched (highest number of views) videos related to CTS. The aim of this study was to

evaluate the quality of the most watched YouTube videos regarding the diagnosis and treatment of CTS.

MATERIAL and METHODS

Videos available on YouTube on 09 January 2021 were searched using the keyword "Carpal Tunnel Syndrome" without changing default search options by using a web browser with cleared cache. The first 100 most watched videos were evaluated. Non-English, advertising content, less than 1 minute and longer than 20 minutes were excluded from the study. The fifty most watched videos meeting the appropriate criteria were included in the study.

The number of views, the time since the upload date, the number of views, the number of likes and the number of dislikes were recorded. Video strength index (VSI) values ($(\text{likes} / \text{dislikes} - \text{dislikes}) * 100$) were calculated to determine video popularity. Video length (sec), video source and video content were also noted.

The videos were watched separately by 2 orthopedic surgeons and evaluated independently according to the DISCERN, Journal of the American Medical Association (JAMA) and a novel scoring system, Carpal Tunnel Syndrome Information Assessment (CTSIA) which was designed by the authors. There were no statistically significant differences between the two authors in terms of the DISCERN, JAMA, and CTSIA scores (Table 1). In the event of a disagreement between the authors, reevaluations were performed until a consensus was reached. The authors of this study then made a final evaluation using the DISCERN, JAMA, and CTSIA scoring systems for further statistical analysis.

Table 1. Pearson Correlation Analysis of Author's Scores According to Video Quality Assessment Tools

	DISCERN Author1	DISCERN Author2
DISCERN Author1	1	r=0.9687
DISCERN Author2	p<0.001*	1
	JAMA Author1	JAMA Author2
JAMA Author1	1	r=0.369
JAMA Author2	p=0.008*	1
	CTSIA Author1	CTSIA Author2
CTSIA Author1	1	r=0.9578
CTSIA Author2	p<0.001*	1

r: correlation coefficient, p: significance, *: significant

The DISCERN scoring system has 3 sections, with a total of 16 questions. These 3 sections include: 8 questions for the reliability assessment of information, 7 questions about treatment information, and 1 question to evaluate the general quality of information (Table 2). The JAMA scoring system consists of 4 criteria (Authorship, Attribution, Disclosure, Currency) with 1 point for each, with a maximum score of 4 points. The lowest quality information is 1 point and highest quality information is 4 points according to JAMA scoring system (Table 3). CTSIA is a novel scoring system consists of 7 sections (definition and pathoanatomy, risk factors and associated conditions, signs and symptoms, diagnosis, nonoperative treatment, operative treatment and complications) and the overall CTSIA score ranges between 0 and 10 (Table 4). CTSIA scores indicate low quality between 0 and 2.5 points, moderate quality between 2.6 and 5 points, high quality between 5.1 and 7.5 points, and very high quality between 7.6 and 10 points.

The relation between several parameters were statistically studied including: 1. Number of views and DISCERN, JAMA, and CTSIA scores, 2. View rate and DISCERN, JAMA, and CTSIA scores, 3. VSI rate and DISCERN, JAMA, and CTSIA scores, 4. VSI and view rate, 5. Video source and number of views, 6. Video source and view rate, 7. Video source and VSI, 8. Video source and DISCERN, JAMA, and CTSIA scores, and 9. Video length and DISCERN, JAMA, and CTSIA scores.

Descriptive data was used to define variables. Pearson's correlation coefficient was calculated to evaluate the relation between normally distributed continuous variables. As the parameters did not show normal distribution, the Kruskal-Wallis test was used in intergroup comparisons, and the Mann-Whitney U test (with Bonferroni's correction) in the identification of the group that caused the difference. The statistically significant level was set at 0.05, and the statistical analysis was performed with IBM SPSS Statistics 21.0.

Table 2. DISCERN Scoring System						
DISCERN Scoring System						
		No	Partially		Yes	
		1	2	3	4	5
Section-1: Is the publication reliable?						
1	Are the aims clear?					
2	Does it achieve its aims?					
3	Is it relevant?					
4	Is it clear what sources of information were used to compile the publication (other than the author or producer)?					
5	Is it clear when the information used or reported in the publication was produced?					
6	Is it balanced and unbiased?					
7	Does it provide details of additional sources of support and information?					
8	Does it refer to areas of uncertainty?					
Section-2: How good is the quality of information on treatment choices?						
9	Does it describe how each treatment works?					
10	Does it describe the benefits of each treatment?					
11	Does it describe the risks of each treatment?					
12	Does it describe what would happen if no treatment is used?					
13	Does it describe how the treatment choices affect overall quality of life?					
14	Is it clear that there may be more than one possible treatment choice?					
15	Does it provide support for shared decision-making?					
Section-3: Overall rating of the publication?						
16	Based on the answers to all of the above questions, rate the overall quality of the publication as a source of information about treatment choices.					

Table 3. JAMA (Journal of the American Medical Association) Scoring System	
JAMA Scoring System	
Authorship	Authors and contributors, their affiliations, and relevant credentials should be provided
Attribution	References and sources for all content should be listed clearly, and all relevant copyright information should be noted
Disclosure	Website "ownership" should be prominently and fully disclosed, as should any sponsorship, advertising, underwriting, commercial funding arrangements or support, or potential conflicts of interest
Currency	Dates when content was posted and updated should be indicated

Table 5. Pearson Correlation Analysis of DISCERN, JAMA and CTSIA Scores			
	DISCERN	JAMA	CTSIA
DISCERN	1	r=0.4815 p<0.001*	r=0.8415 p<0.001*
JAMA	-	1	r=0.3747 p=0.007*
<i>r: correlation coefficient, p: significance, *: significant</i>			

Table 4. Carpal Tunnel Syndrome Informational Assessment (CTSIA) Scoring System				
Carpal Tunnel Syndrome Informational Assessment Score				
No	Essential Info	Components	Score	Subtotal Score
1	Definition & Pathoanatomy (Max 2 pts)	Anatomy (0.5 pt)		
		Compression (1 pt)		
		Thickening of Flexor Retinaculum (0.5 pt)		
2	Risk Factor & Associated Conditions (Max 1 pt)	Repetitive Stress (1 pt)		
		Obesity (0.5 pt)		
		Pregnancy (0.5 pt)		
		Underlying Conditions (R.A., mass, etc.)(0.5 pt)		
3	Signs & Symptoms (Max 1 pt)	Numbness (1 pt)		
		Pain (0.5 pt)		
		Thenar Atrophy (0.5 pt)		
4	Diagnosis (Max 1 pt)	EMG(1 pt)		
		Radiologic Imaging (0.5 pt)		
		Physical Tests (0.5 pt)		
5	Non-Operative Treatment (Max 1 pt)	Splint&Rest (0.5 pt)		
		NSAID (0.5 pt)		
		Local Injections (0.5 pt)		
		PTR (0.5 pt)		
6	Operative Treatment (Max 2 pts)	Open Release (2 pt)		
		Endoscopic Decompression (2 pt)		
7	Complications (Max 2 pts)	Recurrence (1 pt)		
		Nerve Injury (1 pt)		
		Infection (0.5 pt)		
		Tendon Injury (0.5 pt)		
			Total Video Score	

RESULTS

The results of this study revealed that majority of the videos (28 videos, 56%) consisted of information about non-surgical treatment options. The remaining 22 videos were as following: Eight videos were about general information regarding CTS (16%), 6 videos were related to operative techniques in CTS surgery (12%), 7 videos were demonstrations of physical examination in CTS (14%), and 1 video was a patient experience after CTS surgery (2%). Of the 50 videos evaluated, 30 (60%) were uploaded by health channels, 8 (16%) were uploaded by physicians, 12 (24%) was uploaded by other sources.

The mean video length was 354.4 seconds (73-952 seconds), the mean number of views was 1609516.8 (187606-57033461), the mean time since the video was uploaded was 2403.1 days (275-4991 days), the mean view rate was 474.4 per day (42.2-11427.2 per day), the mean number of likes was 4743.4 (81-19968), the mean number of dislikes was 226.9 (7-2505), and the mean VSI value was 111.2 (100.7-298). The mean scores for JAMA, DISCERN, and CTSIA were 2.34 (1-4), 29.5 (16-71), and 2.9 (0.5-9), respectively.

Statistical analysis revealed statistically significant positive correlations between DISCERN and CTSIA scores (strong, $r=0.8415$, $p<0.001$), DISCERN and JAMA scores (moderate, $r=0.4815$, $p<0.001$), and JAMA and CTSIA scores (weak, $r=0.3747$, $p=0.007$) (Table 5).

No statistically significant correlation was found between video source and number of views, and between video source and view rate ($p>0.05$). On the other hand, there was a relation between video source and DISCERN, JAMA, and CTSIA scores which was statistically significant ($p<0.05$). The videos uploaded by doctors and health channels had higher DISCERN scores than other sources ($p=0.025$ and 0.024 , respectively), the videos uploaded by health channels had higher JAMA scores than other sources ($p=0.013$), and finally the videos uploaded by doctors had higher CTSIA scores than other sources ($p=0.045$). In addition, there was also a statistically significant relation between video source and VSI values ($p<0.05$). Videos uploaded by doctor had higher VSI values than other sources ($p=0.016$).

None of the video popularity parameters were found to be correlated with quality evaluation scores. There was no statistically significant correlation between DISCERN, JAMA, and CTSIA scores and number of views, view rates

or VSI values ($p>0.05$). No statistically significant correlation was found between video length and DISCERN, JAMA, and CTSIA scores and video length ($p>0.05$). Although shorter 25 videos had lower DISCERN, JAMA and CTSIA scores than the longer 25 videos, the difference did not reach significance ($p>0.05$). DISCERN score was 28.56 vs. 30.52, JAMA score was 2.28 vs. 2.4, and CTSIA score was 2.6 vs. 3.3 for shorter vs. longer videos.

DISCUSSION

This study revealed that the most watched YouTube videos related to CTS are insufficient in quality in terms of DISCERN, JAMA and CTSIA scores. Although numerous studies evaluated the content quality of medical information of YouTube videos, almost all of these studies used the inclusion criteria of relevancy used by YouTube search engine and included the first 50-60 videos (7-9). The studies aimed to determine the information quality of YouTube videos on CTS were also designed in same methodology (4-6,10). Since these studies were conducted to evaluate the misinformation potential of these medical videos among viewers, we believe that the amount of distribution of misleading information is much more concerning than the relevancy issue. To reach this aim, the authors of this study included the first 50 most watched videos regarding CTS with an approximately 1.6 million mean number of views.

Of the 50 most watched videos only 16% were provided by physicians. The content quality of videos presented by physicians were higher regarding the mean DISCERN (37.6, 29.8, and 23.3 for physicians, health channels, and other sources, respectively), JAMA (2.5, 2.46, and 1.91 for physicians, health channels, and other sources, respectively), and CTSIA (4.25, 2.296, and 2.04 for physicians, health channels, and other sources, respectively) scores. Additionally, the difference was statistically significant for DISCERN (doctors and health channels had higher scores than other sources), JAMA (health channels had higher scores than other sources), and CTSIA scores (doctors had higher scores than other sources) ($p<0.05$). A recent study about CTS and several other studies on YouTube videos about medical topics revealed that physician videos are high in content quality, yet low in popularity (10-12). This might be the reason of relatively fewer number of physician videos in present study since the most watched videos focused on CTS were included. Adversely, DISCERN scores for medical centers found to be higher than other sources in a study by Ozdemir et al. (5), while there was no correlation between sources and quality scores in another (4).

Results of this study showed no relation between video source and number of views, and between video source and view rate ($p>0.05$). A study by Koller et al. (13) demonstrated that there was a negative correlation between physician videos and view rates. Both these findings are quite concerning because number of views and view rates seem to be independent from and/or negatively affected by the video source and the content quality. The viewer may be exposed to irrelevant or misleading information even in the most watched 50 videos about CTS. On the other hand, there was a statistically significant relation between video source and VSI values ($p<0.05$). Videos provided by physicians had higher VSI values than other sources. The higher interaction rates of physician videos may be a consequence of patients' need for seeking medical information from a health-care professional. Although patients' access to medical information is an advantage in terms of awareness, it has many disadvantages. Poor-quality health information may lead to false expectations, doctor-patient conflicts and cause mistrust (14,15). This underlines the importance of videos provided by physicians for patient information purposes.

Eight videos (16%) out of 50 were about general information on CTS. Most of the videos (56%) were about non-surgical treatment options. Despite, only 6 of all videos (12%) were about operative treatment. Radonjic et al. (10) reported that there were fewer non-surgical treatment videos in their study while the authors' used relevancy as an inclusion criteria. YouTube is a search platform for patients seeking an alternative way of treatment and may be used a tool to avoid surgery. Since our study included the most watched videos related to CTS, the relatively high number of non-surgical treatment videos might be interpreted as the reflection of this patient behavior.

The number of views for shorter 25 videos were noticeably higher than the longer 25 videos (2.77 million vs. 448117). Considering the data in the literature, it was found that the videos with animation content and shorter duration were more liked and watched (16). Additionally, the view rate was also considerably higher for the shorter videos (629.86 vs. 319.65). Although shorter videos had higher mean VSI values (117.13 vs. 105.35) the difference did not reach statistical significance ($p>0.05$). Moreover, all quality assessment scores were lower for shorter videos. These findings indicate that videos with shorter durations have higher popularity among watchers but lack of content quality. Therefore, the ideal patient information videos on medical issues should be planned thoroughly

to cover all essential information but should be shorter in duration.

This study had some limitations. This study included videos in English language and limited to available videos on the search date. Additionally, we used an unvalidated tool, namely CTSIA score to evaluate content quality. There are also studies in the literature using unvalidated assessment tools (6,10,16) since this is a relatively new research area and there are no common or validated tools to use for evaluating the content quality of online medical videos. Although CTSIA is an unvalidated scoring system statistical analysis revealed that there was significant positive correlation with DISCERN scores. This correlation indicates that standardization of video assessment tools may be beneficial in producing high quality patient information videos.

CONCLUSION

The information quality of videos on YouTube related to CTS is insufficient even in the most watched videos. The videos provided by physicians is higher in informationally scores, yet lower in numbers. Physicians should be aware of the low-quality content in YouTube videos in order to guide patients to ideal sources of information and to avoid potential conflicts. Accepting the online platforms as the ultimate source of information in the modern world, the need for thorough and standardized scoring systems for producing patient information videos is undeniable.

DECLARATIONS

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The authors declared that this study received no financial support.

Conflicts of Interest

No conflict of interest was declared by the authors.

Ethics Approval

This study is a retrospective online database cohort study and no human/animal individuals are subjected, therefore is out of scope of ethical board reviews.

Availability of Data and Material

The authors confirm that the data supporting the findings of this study are available within the article [and/or] its supplementary materials.

Authors' Contributions

All authors contributed to the design and implementation of the research, to the analysis of the results and to the writing of the manuscript.

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Analyzing Mid-to-Long Term Mortality Rates and Associated Factors of Geriatric Patients with Hip Fractures during the COVID-19 Pandemic: A Single Centre Prospective Study

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ABSTRACT

Objective: Our objective was to evaluate the mid-to-long term mortality rates (with an average of 1-year follow-up) and associated factors of geriatric patients with hip fractures during the COVID-19 pandemic.

Methods: Prospectively followed-up 104 geriatric patients over 65 years old, with hip fractures during the pandemic, 89 of which underwent surgery, were evaluated. A control group of 126 geriatric patients treated for hip fractures before the pandemic was formed. Patient demographics, initial SARS-Cov-2 Reverse Transcriptase PCR test results, fracture type, type of surgery performed, length of stay (LOS) in hospital and early complications were analyzed.

Results: The mid-to-long term mortality rate of geriatric patients with hip fractures treated during the pandemic period was 42.3% whereas the mortality rate of the control group was calculated as 38.9% ($p=0.599$). Patients that were unfit for surgery and patients with positive initial SARS-Cov-2 Reverse Transcriptase PCR test were significantly related with higher mortality ($p<0.001$ for each). Among the geriatric patients with operated hip fractures, the presence of early complications, longer LOS in intensive care units postoperatively, and longer total LOS in the hospital were significantly related with higher mortality ($p=0.017$, $p=0.001$, and $p=0.045$; respectively).

Conclusion: Patients with a positive initial SARS-Cov-2 Reverse Transcriptase PCR test and deemed as unfit for surgery have higher mortality rates. On the other hand, with correct management and separation of COVID and non-COVID patients and medical staff, increased mortality may be avoidable among patients treated surgically. Unfortunately, it may not always be possible to avoid some of the related factors of increased mortality.

Keywords: COVID-19 Pandemic, Geriatric Patients, Hip Fracture, Mortality, Length of Stay

Level of Evidence: Prognostic Level 2

COVID-19 Pandemisi Sırasında Kalça Kırığı Olan Geriatrik Hastaların Orta-Uzun Vadeli Ölüm Oranları ve İlişkili Faktörlerin Analizi: Tek Merkezli Prospektif Çalışma

ÖZET

Amaç: Amacımız, COVID-19 pandemisi sırasında kalça kırığı olan geriatrik hastaların orta-uzun vadeli ölüm oranlarını (ortalama 1 yıllık takip ile) ve ilişkili faktörleri değerlendirmektir.

Yöntemler: Pandemi sırasında kalça kırığı nedeniyle takip edilen 65 yaş üstü 104 geriatrik hasta prospektif olarak izlendi ve 89'u ameliyat edildi. Pandemi öncesi kalça kırığı tedavisi gören 126 geriatrik hastadan oluşan bir kontrol grubu oluşturuldu. Hastaların demografik verileri, ilk SARS-Cov-2 Reverse Transkriptaz PCR testi sonuçları, kırık tipi, gerçekleştirilen ameliyat tipi, hastanede kalış süresi ve erken komplikasyonlar analiz edildi.

Sonuçlar: Pandemi döneminde tedavi edilen kalça kırığı olan geriatrik hastaların orta-uzun dönem mortalite oranı %42,3 iken kontrol grubunun mortalite oranı %38,9 olarak hesaplandı ($p=0,599$). Ameliyat için uygun olmayan hastalar ve ilk SARS-Cov-2 Reverse Transkriptaz PCR testi pozitif olan hastalar ile daha yüksek mortalite oranları arasında anlamlı ilişki tespit edildi (her biri için $p<0,001$). Ameliyatlı kalça kırığı olan geriatrik hastalarda erken komplikasyon varlığı ve ameliyat sonrası yoğun bakımda ve hastanede daha uzun süre kalmak, yüksek mortalite ile anlamlı olarak ilişkiliydi (sırasıyla; $p=0,017$, $p=0,001$ ve $p=0,045$).

Sonuç: İlk SARS-Cov-2 Ters Transkriptaz PCR testi pozitif olan ve ameliyat için uygun olmadığı düşünülen hastalarda ölüm oranları daha yüksektir. Öte yandan, COVID ve COVID olmayan hastaların ve sağlık personelinin doğru yönetimi ve ayrılması ile cerrahi olarak tedavi edilen hastalarda artan mortalite oranları önenebilir. Ne yazık ki, artan mortalite oranıyla ilgili bazı faktörlerden kaçınmak her zaman mümkün olmayabilir.

Anahtar Kelimeler: COVID-19 Pandemisi, Geriatrik Hastalar, Kalça Kırığı, Mortalite, Hastanede Kalış Süresi

With more than 200 million confirmed cases and over 4.3 million associated deaths, the COVID-19 pandemic is an ongoing major health problem worldwide (1). Although all kinds of precautions have been taken, given the density of hospitals and the number of patients, especially in areas with a higher patient burden, some disruptions regarding emergency health services are inevitable. These disruptions affect all segments of society, especially the geriatric population (2,3). Furthermore, the curfews imposed on the geriatric population in our country during last year, due to the lack of preventive vaccines and therapeutic drugs caused the daily physical activity levels, behavioral patterns, and related health conditions of geriatric patients to deteriorate (4).

The COVID-19 pandemic has affected mortality rates among geriatric patients not only by infecting and causing respiratory failures but also by causing secondary infections and increasing length of stay (LOS) in intensive care units (ICUs) (5). There is a prevailing opinion in the literature that the 30-day mortality rate of geriatric hip fractures increased significantly during the COVID-19 pandemic (6-10). Moreover, several studies have concluded that 90-days and 120-days mortality rates have also increased significantly (11-12). On the other hand, some studies in the literature have stated that a significant increase in mortality rates of hip fractures can be prevented with the right precautions (3,13). Furthermore, in a recently published meta-analysis, it was determined that the mortality rates and disease severity of COVID-19 may vary according to the geographical characteristics of the regions (14).

This study evaluated the mid-to-long term mortality rates (with an average of 1-year follow-up) of geriatric patients over 65 years old with hip fractures in our hospital during the COVID-19 pandemic; it also investigated factors affecting these rates.

MATERIALS AND METHODS

After obtaining approval from the ethical committee (E-2-21-13), all consecutive geriatric patients with an age over 65 years, who were admitted to the study hospital—a Level-1 trauma center—with a diagnosis of pertrochanteric or femoral neck fractures between March 2020 and March 2021 were prospectively analyzed. The exclusion criteria were defined as patients with pathological fractures, subtrochanteric fractures, co-existing other fractures,

and periprosthetic fractures. After applying the exclusion criteria, a total of 104 patients were included.

To compare mortality rates, a control group consisting of geriatric patients with hip fractures in 2018 was formed retrospectively. Patients who underwent operations in 2019 were not included because the study aimed to ensure the control group was completely independent of the effects of the pandemic. Thus all the patients in the control group had a COVID-free follow-up period. Using the same exclusion criteria, 126 geriatric patients were included in the control group. The health status of the patients in the control group was evaluated using online public health management systems and calling the phone numbers included in the patients' files.

The follow-up period was determined based on the date of the initial surgery and the period between the operation date and August 2021 was used in the pandemic group. Accordingly, the average mid-to-long term follow-up period was 11.2 months (Range: 5 – 18 months) for the pandemic group. For the control group, the mid-to-long term mortality rate was calculated based on the health status of patients on their 1-year follow-up; which was comparable to the pandemic groups' average follow-up period.

Demographic data, initial SARS-Cov-2 Reverse Transcriptase PCR test result, injury mechanism, fracture type, preferred treatment modality, type of surgery performed, length of stay in the hospital, and early complications were recorded. Injury mechanisms were classified as low- or high-energy injuries. Simple falls and domestic accidents were classified as low-energy injuries while falling from stairs and pedestrian traffic accidents were classified as high-energy injuries.

Surgery is the preferred primary treatment modality for all geriatric hip fractures in our clinic. On the other hand, patients who were hospitalized in the COVID-related inpatient clinics or intensive care units (ICUs) with a positive initial SARS-Cov-2 Reverse Transcriptase PCR test result and died before they could be ready for surgery (9 patients), and patients who refused surgical treatment at the request of their family (6 patients in the pandemic group and 7 patients in the control group) could not be operated and deemed as unfit for surgery. Following the indications stated in the literature, the type of surgery was determined according to the primary surgeon's (ÖD) recommendation and the patient's general condition. Accordingly,

either proximal femoral nailing or hip hemiarthroplasty was applied to the patients (15,16). All patients, regardless of the surgical method, were mobilized with early weight-bearing that they could tolerate on the first postoperative day; also, a physiotherapist oversaw active quadriceps exercises.

Early complications were defined as complications that occurred during the hospitalization period, such as prolonged serous discharge, deep vein thrombosis/pulmonary embolism, and acute respiratory failure.

Statistical analyzes were performed using SPSS 26.0 software. The compliance of the variables to normal distribution was examined by visual (histogram and probability graphs) and analytical (Kolmogorov-Smirnov/Shapiro-Wilk tests) methods. For normally distributed variables, descriptive analyzes were defined using mean and minimum-maximum values. Student's T and Mann-Whitney U Tests were used to compare the means of the groups. Whether there was a difference between the groups in terms of frequencies was compared using the Chi-Square Test. Fisher's Exact Test was used when the observed values did not meet the Chi-Square assumption. The situations where the P-value was below 0.05 were considered statistically significant.

RESULTS

Although the mid-to-long term mortality rates of geriatric patients with hip fractures treated during the pandemic period increased in comparison with the pre-pandemic period (42.3% vs. 38.9%), no significant difference was observed between the two groups ($p=0.599$). Comparison of mortality rates and related factors of pandemic and control groups can be seen in Table 1.

Patients that were deemed as unfit for surgery and patients with positive initial SARS-Cov-2 Reverse Transcriptase PCR test results were significantly related with higher mortality ($p<0.001$ for each). Mortality-associated factors of all admitted geriatric patients with hip fractures can be seen in Table 2.

Among the geriatric patients with operated hip fractures, presence of early complications, longer LOS in ICU postoperatively, and longer total LOS were significantly related with higher mortality in the mid-to-long term ($p=0.017$, $p=0.001$, and $p=0.045$; respectively). Mortality-associated factors of geriatric patients with operated hip fractures can be seen in Table 3.

Two patients (1.9%) from the pandemic group and three patients (2.4%) from the control group had pulmonary embolisms and anticoagulant therapy was started at the therapeutic dose. Four patients in the control group (3.2%) had electrolyte imbalance postoperatively, were treated in line with the recommendations of the internal medicine department. Among the geriatric patients with operated hip fractures ($n=89$), six patients (6.7%) had respiratory complications, such as severe dyspnea, requiring postoperative ICU admissions and 16 patients (18%) had prolonged serous discharge. However, while no respiratory complications were observed in the control group, 11 patients (9.2%) had prolonged serous discharge. No secondary surgery was required in any patient.

Among the patients that were deemed as unfit for surgery in the pandemic group ($n=15$), 14 patients (93.3%) had severe respiratory complications requiring ICU admissions, which resulted in the death of patients.

DISCUSSION

Although few studies are stating the contrary, the prevailing opinion in the literature is that the mortality rate of geriatric patients with hip fractures during the COVID-19 pandemic is higher, especially in the short term (6-10). On the other hand, the number of studies examining the medium- and long-term outcomes and mortality rates of geriatric patients with hip fractures during the pandemic period is relatively lower (11,12). Furthermore, some reports have stated that the mortality rates and disease severity of COVID-19 may vary according to the geographical characteristics of the regions (14). To our knowledge, this is one of the first studies in the literature analyzing the mid-to-long term mortality rate of geriatric patients with hip fractures in our region. Our most important finding was that even though the mortality rate of geriatric patients with hip fractures increased during the pandemic (42.3% vs. 38.9%), it was not statistically significant ($p=0.599$). On the other hand, a significant relationship was found between the positive initial SARS-Cov-2 Reverse Transcriptase PCR test result and mortality rate ($p<0.001$). Among the geriatric patients with operated hip fractures, a significant relationship was found between longer LOS in ICU postoperatively, longer LOS in hospital, and the presence of early complications with mid-to-long term mortality.

		Pandemic Group (N=104)		Control Group (N=126)		P
		Patients (N)	Rate %	Patients (N)	Rate %	
Gender	Female	74	71.2	87	69	0.729
	Male	30	28.8	39	31	
Mean Age (years)		81.3 (65-99 years)		82.4 (65-96 years)		0.301
Follow-up Period (months)		11.2 (5-18 months)		N/A		N/A
Side	Right	60	57.7	71	56.3	0.838
	Left	44	42.3	55	43.7	
Fracture Type	Femoral Neck	48	46.2	59	46.8	0.919
	Pertrochanteric	56	53.8	67	53.2	
Injury Mechanism	Low-Energy	98	94.2	118	93.7	0.855
	High-Energy	6	5.8	8	6.3	
Initial PCR Test	Negative	83	79.8	N/A	N/A	N/A
	Positive	21	20.2			
Preferred Treatment Modality	PFN	18	17.3	29	22.7	0.055
	Hemiarthroplasty	71	68.3	92	71.9	
	Unfit for Surgery	15	14.4	7	5.5	
Mortality	Survivor	60	57.7	77	61.1	0.599
	Non-survivor	44	42.3	49	38.9	

N: number of patients, P: Statistical significance value, N/A: non-applicable, PCR Test: SARS-Cov-2 Reverse Transcriptase PCR Test, PFN: proximal femoral nail.

		Mid-to-long Term Mortality		
		Survivor (N = 60)	Non-survivor (N = 44)	P
Age (years)		80.6 (65-97 years)	82.2 (68-99 years)	0.401
Gender	Female	44 (73.3%)	30 (68.2%)	0.567
	Male	16 (26.7%)	14 (31.8%)	
Initial PCR Result	Negative	57 (95%)	26 (59.1%)	<0.001
	Positive	3 (5%)	18 (40.9%)	
Injury Mechanism	Low-Energy	55 (91.7%)	43 (97.7%)	0.397
	High-Energy	5 (8.3%)	1 (2.3%)	
Fracture Type	FNF	25 (41.7%)	23 (52.3%)	0.284
	PFF	35 (58.3%)	21 (47.7%)	
Treatment Modality	PFN	14 (23.3%)	4 (9.1%)	<0.001
	Hemiarthroplasty	45 (75%)	26 (59.1%)	
	Unfit for Surgery	1 (1.7%)	14 (31.8%)	

N: number of patients, P: Statistical significance value, PCR Test: SARS-Cov-2 Reverse Transcriptase PCR Test, FNF: femoral neck fractures, PFF: pertrochanteric femoral fractures, PFN: proximal femoral nail.

Table 3: Mid-to-long term mortality rate and associated factors of geriatric patients with operated hip fractures

		Mid-to-long Term Mortality		
		Survivor (N = 59)	Non-survivor (N = 30)	P
Age (years)		80.5 (65-97 years)	83.1 (68-99 years)	0.174
Gender	Female	43 (72.9%)	21 (70%)	0.775
	Male	16 (27.1%)	9 (30%)	
Initial PCR Result	Negative	57 (96.6%)	26 (86.7%)	0.174
	Positive	2 (3.4%)	4 (13.3%)	
Injury Mechanism	Low-Energy	54 (91.5%)	30 (100%)	0.163
	High-Energy	5 (8.5%)	0	
Fracture Type	FNF	25 (42.4%)	16 (53.3%)	0.327
	PFF	34 (57.6%)	14 (46.7%)	
Surgery Type	PFN	14 (23.7%)	4 (13.3%)	0.248
	Hemiarthroplasty	45 (76.3%)	26 (86.7%)	
Early Complications	No	48 (81.4%)	17 (56.7%)	0.017
	Yes	11 (18.6%)	13 (43.3%)	
Preop. LOS in Clinic (days)		3.6 (0-17 days)	3.9 (0-10 days)	0.365
Postop. LOS in Clinic (days)		6.8 (2-23 days)	6.3 (0-31 days)	0.110
Preop. LOS in ICU (days)		0.4 (0-7 days)	0.5 (0-15 days)	0.535
Postop. LOS in ICU (days)		0.8 (0-11 days)	3.9 (0-21 days)	0.001
Total LOS (days)		11.4 (4-26 days)	14.6 (2-37 days)	0.045

N: number of patients, P: Statistical significance value, PCR Test: SARS-Cov-2 Reverse Transcriptase PCR Test, FNF: femoral neck fractures, PFF: pertrochanteric femoral fractures, PFN: proximal femoral nail, Preop: Preoperative, Postop: Postoperative, LOS: Length of Stay, ICU: Intensive Care Unit.

Among all admitted geriatric patients with hip fractures treated during the pandemic, positive initial SARS-Cov-2 Reverse Transcriptase PCR test result is significantly related to mid-to-long term mortality rate ($p < 0.001$). Our finding is consistent with the literature. Since coronavirus infection has a mortal course in the geriatric population, the mortality rate of geriatric patients with hip fractures would inevitably increase during the COVID-19 pandemic (3,5-10). In our study, the fact that patients who were deemed as unfit for surgery had a higher mortality rate ($p < 0.001$) is a result rather than a cause. That is, although our preferred treatment modality in geriatric hip fractures is always surgical, as mentioned before, patients who were diagnosed with COVID-19 when they were first admitted to the hospital and died before they could be operated and patients who refused to be operated were categorized as unfit for surgery. On the other hand, positive SARS-Cov-2 Reverse Transcriptase PCR test result did not have an effect on mid-to-long term mortality of geriatric patients undergoing surgery ($p = 0.163$). Furthermore, no difference was found between pandemic and control groups in terms of mid-to-long term mortality rate ($p = 0.599$). These may be due to several different variables. First of all,

all, from the first days of the pandemic, our hospital was divided into two blocks as COVID and non-COVID blocks, with completely different medical staff. This may have limited the exposure of the virus thus preventing the infection to spread during the treatment process. Chiu et al (13) have mentioned a similar application in their study and achieved strict infection control. Ojeda-Thies et al (3) have concluded that hip fracture patients without an initial COVID-19 infection upon admission can be treated safely through a separated and isolated treatment protocol. Unfortunately, it is not possible to prevent exposure completely. Secondly, most of the studies reporting higher mortality rates are conducted in regions with relatively higher deaths per 1 million people. For example, Italy, the country where most of the aforementioned studies were carried out, has 2136 deaths per 1 million people whereas the number of deaths per 1 million people in our country is 656 deaths (17). Factors affecting the rate and frequency of virus spread, such as race, climate, and geographic differences may affect the mortality of geriatric patients (3). Indeed, studies are indicating that the mortality and transmission rate of COVID-19 may differ from region to region (3,14).

Literature has shown that even slight delays in the treatment of geriatric patients with hip fractures will have an increase in mortality (6). On the other hand, it is inevitable to have increased LOS during the COVID-19 pandemic, due to the need to make the general condition of the patient suitable for surgery preoperatively and treat secondary infections or other coronavirus related pathologies postoperatively. Our study has shown that increased LOS in ICU postoperatively and total LOS in the hospital have a significant relationship between mid-to-long term mortality rates ($p=0.001$ and $p=0.045$, respectively). On the other hand, increased preoperative LOS in orthopedics clinics or ICU did not have a relationship with mortality ($p=0.365$ and $p=0.535$, respectively), which is an expected result considering longer preoperative LOS is associated with the stabilization process of patients and making them suitable for surgery. Our findings are consistent with the literature. Sciard et al (18) reported that surgical delay did not have significant importance on mortality in medically unstable patients. Postoperative LOS, on the other hand, is associated with hospital infections, increased risk of virus exposure, prolonged serous discharge, and other hospital-related complications (19). These risks are far greater in ICU admissions.

In our study, a significant relationship between the presence of early complications and mid-to-long term mortality rate ($p=0.017$) was found. Our finding is consistent with the literature. Basques et al (19) have analyzed 8434 patients and have concluded that the presence of early complications such as prolonged serous discharge or venous thromboembolism is associated with an increased 1-year mortality rate.

There are some limitations to our study. First and foremost, a relatively small number of patients were analyzed in our study. Further analyzes with multi-centered larger cohorts may yield different results. Secondly, although our patient group was formed prospectively, the control group was created retrospectively and recorded information on patient files and online public health management systems were mainly used. The third limitation is that only the initial SARS-Cov-2 Reverse Transcriptase PCR test results were analyzed in this study. Patients with clinical findings at the first admission or who were infected during their routine follow-up period were not evaluated as separate groups. Different results can be obtained with studies carried out by performing sub-group analyzes with larger patient populations. Finally, many confounding factors affect mortality rates in geriatric patients, such as comorbidities, physical behavioral patterns, nutrition, or whether or not

to stay in a nursing house. With more comprehensive studies that can consider all confounding factors, all factors affecting mortality can be understood more clearly.

CONCLUSION

In conclusion, there was no significant increase in the mortality rate of geriatric patients with hip fractures in the mid-to-long term during the COVID-19 pandemic compared to the pre-pandemic period in our region. Patients with a positive initial SARS-Cov-2 Reverse Transcriptase PCR test result and deemed as unfit for surgery have higher mortality rates. On the other hand, with correct management and separation of COVID and non-COVID patients and medical staff, increased mortality may be avoidable among patients treated surgically. Unfortunately, it is not always possible to avoid some of the related factors of increased mortality among geriatric patients with hip fractures, such as increased LOS and the presence of early complications.

DECLARATIONS

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Conflicts of Interest

The authors have no conflicts of interest to declare that are relevant to the content of this article.

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Authors' Contributions

ÖD: co-designed the study, conducted data analysis and wrote the manuscript. BG: co-designed the study, data entry, conducted data analysis and wrote the manuscript.

Ethical Approval

This study was approved by the Ministry of Health and the local ethics committee (E-2-21-13).

Consent to Participate

Informed consent was obtained from all individual participants included in the study.

Consent to Publish

All authors agreed with the content and all authors gave explicit consent to submit the study. Patients signed informed consent regarding publishing their data.

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Comparison of Radiological, Functional and Plantar Pressure Disturbance Results of Two Different Surgical Techniques on Syndesmosis Injuries with Malleolus Fractures

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ABSTRACT

Background and objectives: This study compared the clinical and radiological results of three cortex conventional metal screw fixation and EndoButton implant techniques. We applied dynamic pedobarographic analysis to the cases to reveal the effect of the postoperative functional levels on the gait and plantar pressure distribution parameters and to determine the differences between the groups.

Materials and methods: In our retrospective study, 42 patients were evaluated in two groups, divided into metal screw (Group I; n=24) and EndoButton implant technique (Group II; n=18). After the groups were formed, the functional and clinical outcomes of the patients were evaluated and measured prospectively by an investigator blinded to the surgical procedures of the patients clinically and radiologically.

Results: We found the AOFAS score significantly higher in the EndoButton group (p=0.041), while the Weber and Freiburg scores were similar between the two groups (p=0.07 and p=0.49, respectively). When the plantar pressure distribution analyzes of the operated sides were examined, the loading percentages in the forefoot and midfoot were found to be statistically significantly higher in the metallic screw group providing static fixation, while the percentage of lateral heel loading was found to be statistically significantly lower. The medial heel loading percentage was also lower in the screw group, but no statistically significant difference was detected.

Conclusions: We observed that the conventional screw static fixation technique used to repair syndesmosis injuries causes limitation in ankle dorsiflexion, increases the pressure percentages in the forefoot and midfoot, and causes a later return to work/daily life.

Keywords: ankle fracture, syndesmosis outcome, syndesmosis injury

Sindesmoz Yaralanması Eşlik Eden Malleol Kırıklarında Konvansiyonel Vida Tespiti ile Dügme Dikiş İmplant Tekniğinin Klinik, Fonksiyonel ve Plantar Basınç Dağılımı Sonuçlarının Karşılaştırılması

ÖZET

Amaç: Bu çalışmada üç korteks konvansiyonel metal vida tespiti ile EndoButton tekniğinin klinik ve radyolojik sonuçlarının karşılaştırılmasını amaçladık. Olguların cerrahi sonrası fonksiyonel seviyelerinin, yürüyüş ve plantar basınç dağılımı parametrelerine olan etkisinin ortaya konabilmesi ve gruplar arasındaki farkların saptanabilmesi amacıyla, olgulara dinamik pedobarografik analiz uyguladık.

Yöntem: Retrospektif olarak planlanan çalışmamızda 42 hasta, metal vida (Grup I; n=24) ve EndoButton tekniği (Grup II; n=18) olarak ayrılarak iki grup halinde değerlendirildi. Gruplar oluşturulduktan sonra, hastaların cerrahi prosedürlerine kör bir araştırmacı tarafından olguların fonksiyonel ve klinik sonuçlarına ilişkin değerlendirme ve ölçümler prospektif olarak uygulandı.

Bulgular: EndoButton grubunda AOFAS skorunu anlamlı olarak daha yüksek (p=0.041), Weber ve Freiburg skorlarını ise her iki grup arasında benzer bulduk (sırasıyla p=0.07 ve p=0.49). Opere edilen taraflara ait plantar basınç dağılım analizleri incelendiği zaman ise statik tespit sağlayan metalik vida grubunda ayak önu ve ayak ortası yüklenme yüzdeleri istatistiksel anlamlı olarak daha yüksek bulunmuşken, lateral topuk yüklenme yüzdesi istatistiksel olarak anlamlı şekilde daha düşük tespit edildi. Medial topuk yüklenme yüzdesi yine vida grubunda daha düşüktü ancak istatistiksel olarak anlamlı farklılık tespit edilemedi.

Sonuç: Sindesmoz yaralanmalarının tamirinde kullanılan, konvansiyonel vida ile statik tespit tekniğinin ayak bileği dorsifleksiyonunda kısıtlılığına yol açtığı, ayak önu ve ayak ortası basınç yüzdelerini arttırdığı, daha geç işe/günlük hayata dönüş sürelerine neden olduğu gözlenmiştir.

Anahtar kelimeler: ayak bileği kırığı, sindesmoz sonuçları, sindesmotik yaralanma

The syndesmosis is a form of articulation surrounded by connective tissue in the lower part of the tibia and fibula. This joint and the ligaments that make it up are critical to the stability of the ankle. Injuries involving the ligaments in the joint, where the ligaments are torn and joint congruence is impaired, are called syndesmosis injuries (1).

It is common to use “metal screws” or “EndoButton implants” in the surgical treatment of syndesmosis injuries (1,2). As a conventional method in surgical treatment, fixation by metal screws is still in use. Although successful results of this repair method have been reported in the literature (1-4).

The repair method with EndoButton implants is a good alternative because it preserves the physiological movements of the syndesmosis joint (5). The ideal method for syndesmosis repair should allow early joint movement and be sturdy enough to maintain its reduction. Both methods, compared in this study, are used with similar indications, and a consensus could not be reached in terms of clinical and functional results.

This study aimed to compare the clinical, functional, and radiological results of the three cortex metal screw fixation method and the EndoButton implant technique, the two most frequently used surgical methods in the literature in malleolar fractures accompanied by syndesmosis injury.

MATERIALS AND METHODS

Study Design

This is an original research initiative designed as a prospective and double-blind study comparing current results of retrospective cases and 1-year longitudinal results. Informed consent forms were obtained from all of the patients after explaining the details of the study, and the necessary ethical permissions were obtained from the local ethics committee.

Subjects

In this study, 42 cases that meet inclusion criteria were included retrospectively from the archive of our clinic. The patients were treated between January 2017 and January 2018 and underwent surgery and regular follow-up using the methods aimed for comparison in this study. All patients' surgery notes and preoperative and postoperative radiographs were completed, and their surgical procedures were less than 12-months old.

As a surgical repair method, the EndoButton implant technique or three cortex screw fixation was

performed, and patients between the ages of 18-60 that worked actively, who were in the ASA (American Society of Anesthesiologists) I-II-III physical risk group, and that volunteered to participate in the outcome measurement evaluations of the study were included in the study. Patients with a history of previous ankle surgery on the same side, individuals who had had arthrosis of the ankle at the time of injury, those admitted with multiple trauma, patients with visual, auditory, or perceptual pathology, those in the ASA IV-V physical risk group, and anyone who did not volunteer to participate in the evaluations were excluded from the study. The fixation of syndesmosis in 24 cases (12 men and 12 women) was made with three cortex screws, and these cases formed the **Screw Group**. The syndesmosis fixations of 18 cases—6 male and 12 female— were made using the EndoButton technique, and these cases made up the **EndoButton Group**. The 42 cases that formed both groups were called to the clinic by phone for the functional outcome measurements and pedobarographic analyses of the study.

Outcome Measurements

The histories (sex, affected direction, activity levels, time to return to work) and early postoperative period (3rd month) X-ray data of the patients in both groups were collected from the system as baseline measurement values. Then, the post-op 12th-month histories of all cases were gathered by two researchers who were blind to the surgical technique applied to the cases; following this, physical examinations were carried out, and the measurements were taken after the late period (12th month) control X-rays were taken. In order to reveal the functional results of the cases, AOFAS (American Orthopedic Foot and Ankle Society) Weber and Freiburg Scores were applied for the post-op 12th month. Affected extremities were measured with the ankle active and passive range of motion (ROM) and step forward test and subsequently recorded in degrees. Dynamic pedobarographic analyses were performed to obtain the 1-year long-term post-op effects of the two compared surgical methods on gait and plantar pressure distribution (Figure 1).

Radiological Evaluations: TFO (Tibiofibular Overlap), TFCS (Tibiofibular Clear Space), and MCS (Medial Clear Space) values were measured; mortise stability and the presence of arthrosis were evaluated on the standard radiographs of the cases in the form of anterior-posterior, lateral, and mortise radiographs. The measurements taken via the early (3rd month) (MA, UG) and late period 12th month (MA, UG) control radiographs of the cases were made by 2 different researchers, and their arithmetic means were recorded.

Pedobarographic Analysis: In order to obtain sensitive and reliable objective data on pressure distribution alterations in gait from 2 different surgical patient groups, dynamic plantar pressure distribution analysis was performed at the post-op 12th month, and the loading percentages of great toe, other fingers, first metatarsal head, 2nd and 3rd metatarsal head, 4th and 5th metatarsal head, medial arch, lateral arch, medial heel and lateral heel, load response time, maximum load response surface, load response maximum load, terminal stance time, terminal stance maximum surface and terminal stance maximum load values were obtained (Figure 1). The subjects were made comfortable during the test and were informed before about their daily gait patterns. They were allowed to walk until they had adjusted in the testing room. They were then asked to walk at least 3 laps on the platform, and the test values of the gait position that were closest to the ideal were recorded by the system.

For pedobarographic analyses, using the FreeMed brand pedobarography device, which can sample at a frequency over 400Hz, has an 8-meter walking platform, and consists of 24-carat gold-plated rubber sensors embedded in the middle of the platform, patient data were recorded according to date and time and stored in the system with static, dynamic, postural, and visual evaluation through 7 integrated cameras. During the preparation of the data for statistical analysis, the plantar pressure distribution data obtained from the cases were processed and listed as the affected and unaffected side.

Statistical Analysis

Data analysis was performed using the IBM SPSS 24.0 statistical package program. While evaluating the study data, descriptive statistical methods (frequency, percentage, mean, standard deviation) were used in the first stage. In addition, in the comparison of qualitative data and comparisons between groups, statistical differences were evaluated using a T-Test for the dependent groups and a T-Test for the independent groups. The plantar pressure distribution values obtained from the subjects were compared both for in-group affected and unaffected directions and between the groups for the affected and unaffected sides. Comparisons of functional results, active and passive ROM values, and radiological measurements were made only for the 12th month values between the groups. Results were given as mean \pm standard deviation (SD). A p-value of <0.05 was considered to be statistically significant. Values with a probability (P) less than $\alpha = 0.05$ were accepted as significant and showed difference between groups; values with a higher probability were

considered insignificant and demonstrated no difference between groups.

RESULTS

The demographic data of the cases in this study are presented in Table 1 according to the groups. While the mean time to return to work for the patients in Group 1 was 81.25 days, this period was calculated as 52.61 days in Group 2. In the examination of the post-op complications of the cases, it was seen that 22 of 24 cases in Group 1 (8 for pain, 14 at the request of the patient) had a secondary surgery for implant removal. One patient had secondary surgery due to superficial wound infection, and the other remaining patient had secondary surgery due to wound necrosis. It was observed that superficial wound infection developed in 1 of 18 patients in Group 2; none of the patients required secondary surgery. 22 patients (91.6%) in the screw group had implant removal procedure performed. Of these procedures, 33.3% was performed due to ankle pain caused by weight-bearing, and 58.3% was performed at the patients' request. None of the patients in the EndoButton group required a similar procedure to be performed.

The results of the in-group comparison of the postoperative early (3rd month) radiographs and the last (12th month) radiological measurements are presented in Table 2. The radiological data we obtained were compared within and between groups in terms of early and late control measurements. While no statistically significant difference was observed between the early and final control TFCS, TFO, and MCS values in the Screw Group, the early TFO value in the EndoButton group decreased from 8.41 mm, on average, to 7.46 mm, which was the mean value for the final control value; this was statistically significant ($p < 0.05$). Again, in the EndoButton group, the mean value of early MCS showed a statistically significant increase from 3.38 mm to an average of 3.5 mm at the final follow-up ($p < 0.05$). There was no significant change in the TFCS value ($p > 0.05$). When compared between groups, the mean TFO value in the early control was calculated as 8.78 mm in the Screw Group and 8.41 mm in the EndoButton group, and the difference between these values, which was within the normal radiological limits for both groups, was statistically significant ($p < 0.05$). Early MCS values were also found to be within normal values, with an average of 3.77 mm and 3.38 mm, respectively, but the difference between them was statistically significant ($p < 0.05$). When comparing late control radiographs between groups, mean TFCS values were found to be 3.21 mm in the Screw Group, 3.86 mm in the EndoButton group, and the mean MCS values were found to be statistically different as 3.7 mm and 3.5 mm, respectively ($p < 0.05$).

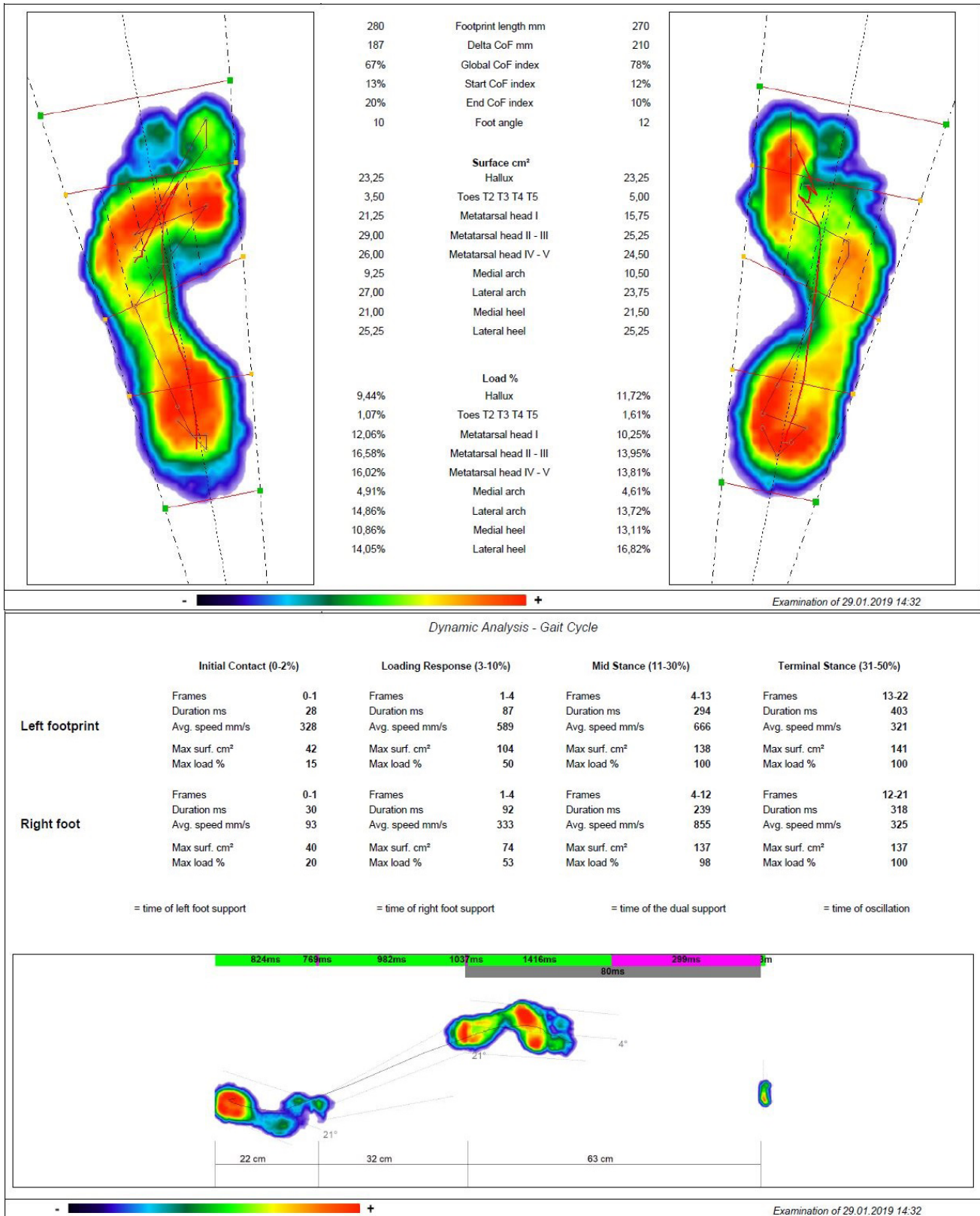


Figure 1. Plantar Pressure Test Results

Table 1. Demographics of Patients

Groups	Sex		Affected Part		Shoe Habit		Activity Habit	
	Female	Male	Right	Left	Soft	Hard	Active	Passive
Screw Group(%) (n=24)	50% (n=12)	50% (n=12)	62.5% (n=15)	37.5% (n=9)	0.83% (n=17)	29.17% (n=7)	83.33% (n=20)	16.67% (n=4)
Endo-Button Group(%) (n=18)	66.67% (n=12)	33.33% (n=6)	33.33% (n=6)	67.67% (n=12)	94.44% (n=17)	5.56% (n=1)	83.33% (n=15)	16.67% (n=3)

Table 2. Radiological Evaluation of Injured Ankles

		Metal screw group (n=24)			EndoButton group (n=18)		
		First evaluation X±SD	Final evaluation X±SD	p	First evaluation X±SD	Final evaluation X±SD	p
Radiological	TFCS (mm)	3.45±1.08	3.21±0.76	0.071	3.48±0.42	3.86±0.32	0.069
	TFO (mm)	8.78±1.59	8.88±2.0	0.271	8.41±0.78	7.76±1.37	0.000*
	MCS (mm)	3.77±1.06	3.70±1.41	0.096	3.38±0.56	3.50±0.93	0.011*
		First evaluation (n)	Final evaluation (n)		First evaluation (n)	Final evaluation (n)	
	Mortise stability (n)	24	23		18	18	
	Arthrosis (n)	0	14		0	4	

*: p<0.05, TFCS:Tibiofibular Clear Space TFO: Tibiofibular Overlap, MCS:Medial Clear Space

The results of the comparison of radiological measurements and ankle ROM results obtained in the early (3rd month) and late (12th month) postoperative period from the cases in the groups are presented in Table 3.

When the non-numerical data were compared, the mortise stability was fully observed in the early radiographs in both groups.

Mortise stability was lost in the final control radiographs in 3 patients in Group 1, and stability was preserved in all patients in Group 2. Arthrosis was not detected in any of the early radiographs. However, when the final control radiographs were examined, it was observed that arthrosis developed in 14 (58%) patients in Group 1 and in 4 (22%) patients in Group 2 (Table 3). The results regarding the comparison of the results of the 12th month functional scoring scales between the groups are shown in Table 4.

Table 3. Intergroup Comparisons of the Data Obtained from the Radiological Evaluation of the Cases, Range of Motion, and Step Forward Tests

		Metal Screw Group (n=24)	EndoButton Group (n=18)	p
Early Control	TFCS (mm)	3.45±1.08	3.48±0.42	0.093
	TFO (mm)	8.78±1.59	8.41±0.78	0.015*
	MCS (mm)	3.77±1.06	3.38±0.56	0.028*
	Mortis stability (+/-)	24 +	18 +	-
	Arthrosis (+/-)	none	none	-
Late Control	TFCS (mm)	3.21±0.76	3.86±0.32	0.000*
	TFO (mm)	8.88±2.0	7.76±1.37	0.079
	MCS (mm)	3.70±1.41	3.50±0.93	0.000*
	Mortis stability (+/-)	23 +	18 +	-
		14 +	4 +	-
Step Forward Test (cm)		1.81	6.83	0.231
Active	Dorsiflexion (°)	3.75±6.12	17.5±7.12	0.460
	Plantarflexion (°)	31.25±9.11	34.17±9.58	0.420
Passive	Dorsiflexion (°)	6.25±6.12	22.5±7.71	0.515
		33.13±8.05	38.33±7.07	0.717

*: p<0.05; TFCS: Tibiofibular Clear Space TFO: Tibiofibular Overlap, MCS: Medial Clear Space.

The results of the comparison of dynamic plantar pressure distribution analysis values and the affected and unaffected sides of the cases are shown in Table 5. In addition, the statistical analysis results of the in-group comparisons of the plantar pressure distribution data of the affected and unaffected sides of the cases in both groups are presented in Table 6. In the Screw Group, a statistically significant increase was observed in the great toe loading percentage of the affected side ($p < 0.05$). In other fingers, the loading percentage was statistically significantly decreased ($p < 0.05$). While the loading percentage of the 1st metatarsal (MT) head was significantly decreased on the affected side ($p < 0.05$), this rate increased significantly at the 4th-5th MT heads ($p < 0.05$). The medial arch loading percentage was found to be significantly increased ($p < 0.05$), and the medial heel loading percentage was found to be significantly decreased ($p < 0.05$). When the data of the affected and unaffected sides of the EndoButton group were compared, it was observed that the loading percentage at the 1st MT head on the affected side was significantly decreased ($p < 0.05$), whereas at the 2nd-3rd MT heads, the loading percentage was significantly increased ($p < 0.05$). The medial arch and lateral arch loading percentage was significantly decreased on the affected side ($p < 0.05$), while the lateral heel loading percentage was significantly increased ($p < 0.05$).

In the comparison of dynamic pedobarographic data of the operated feet of the patients between groups, it was observed that in the Screw Group, great toe, other toes, 1st MT head, 2nd-3rd MT heads, medial arch, and lateral arch loading percentages were higher. All of these differences were statistically significant compared to the EndoButton group ($p < 0.05$). It was found that the mean loading percentages at the 4th-5th MT heads were also higher in the Screw Group; however, this was not statistically significant. The medial heel loading percentage was lower in the Screw Group compared to the other group, but it was not statistically significant. The lateral heel loading percentage, on the other hand, was significantly decreased ($p < 0.05$).

Table 4. Intergroup Comparisons of the Total Scores of the AOFAS, Weber and Freiburg Scales of Groups

	Screw Group (n=24)	Endo-Button Group (n=18)	P
AOFAS	85±13.13	92.33±7.73	0.041*
WEBER	5.88±4.16	2.67±2.63	0.07
FRIEBURG	86,25±11,01	88,50±9,82	0.49

*: $p < 0.05$

DISCUSSION

This study aimed to compare the clinical, functional, and radiological results of the three-cortex screw fixation and the EndoButton technique, which are commonly used procedures in the fixation of concomitant syndesmosis injury in patients with malleolar fractures. Therefore, in this study, the cases that were followed-up for 1 year were divided in 2 groups: the metallic Screw Group and the EndoButton group. Patients were compared according to their histories, physical examination findings and radiological measurements taken from the postoperative early (3rd month), late (12th month) control radiographs, functional scores, and dynamic plantar pressure distribution analysis data. In addition to the parameters already studied on the EndoButton technique's effects on the anatomical reduction of the syndesmosis joint and the preservation of physiological movements, for the first time in the literature, the technique's effects on plantar pressure distribution was also studied.

When the early and late TFCS, TFO and MCS measurement data of the cases were examined in each group, it was seen that these changes remained within normal limits, although they were statistically significant. In both groups, it was observed that all patients had mortise stability in the early control radiographs, but the mortise stability could not be preserved in the final control radiographs of 1 patient in the Screw Group. In the EndoButton group, there was no case exhibiting loss of mortise stability. It is thought that these measurements, which were found to be within normal range, are not clinically significant, even though they are statistically significant. However, the decrease in TFO value and increase in MCS value in the dynamic fixation group show that there is a need for further studies in order to observe whether there is some loosening of the EndoButton.

Arthrosis developed in 14 patients (58%) in the Screw Group and 4 patients (22%) in the EndoButton group in the final follow-up radiographs. These findings and the results of the present study show similarities with the literature (6).

Table 5. Comparison of the Screw and Endo-Button Groups of Dynamic Plantar Pressure Distribution Data of Cases in Affected and Unaffected Sides

	Affected Side			Non-affected Side		
	Screw Group (n=24)	Endo-Button Group (n=18)	p	Screw Group (n=24)	Endo-Button Group (n=18)	p
Great Toe (%)	14.33±6.58	8.24±3.07	0.014*	11.45±5.24	8.45±4.31	0.59
Other Fingers (%)	4.67±5.69	2.78±1.68	0.000*	7.67±7.40	2.60±2.14	0.000*
1st Metatarsal Head (%)	15.91±6.77	6.68±2.34	0.000*	11.41±6.24	8.84±2.55	0.000*
2nd and 3rd Metatarsal Head (%)	24.02±6.81	15.62±2.30	0.000*	22.99±5.17	17.50±4.90	0.867
4th ve 5th Metatarsal Head (%)	17.98±4.15	13.45±3.53	0.368	22.48±7.05	12.41±2.82	0.000*
Medial Arch (%)	10.29±6.97	5.56±1.70	0.002*	6.23±4.03	5.80±2.65	0.287
Lateral Arch (%)	19.92±9.46	14.10±4.15	0.000*	20.73±5.78	14.62±5.40	0.551
Medial Heel (%)	15.75±5.71	16.25±3.54	0.08	21.15±6.08	15.53±2.27	0.000*
Lateral Heel (%)	16.14±10.12	17.13±4.93	0.002*	17.44±8.40	14.27±3.64	0.000*
Load Response Time (ms)	118.88±23.23	152±53.75	0.000*	113±20.09	151.83±44.24	0.001*
Load Response Max. Surface (cm ²)	106.50±28.63	87.83±9.326	0.000*	103.00±14.78	93.83±22.04	0.002*
Load Response Max. Load (%)	60.38±17.85	48±11.067	0.011*	56.25±5.25	45±18.50	0.000*
Terminal Stance Time (ms)	309.13±42.70	380.17±163	0.001*	302.88±68.44	390.83±99.84	0.064
Terminal Stance Max. Surface (cm ²)	125.75±20.78	127±17.72	0.31	125.38±17.54	124.67±8.2	0.006*
Terminal Stance Max. Load (%)	97.63±3.18	95.50±6.051	0.000*	94.50±6.04	99.67±0.76	0.000*

*: p<0.05

Tablo 6. Comparison of Affected and Unaffected Sides of Dynamic Plantar Pressure Distribution Data of Cases in Screw and Endo-Button Groups

	Screw Group (n=24)			Endo-Button Group (n=18)		
	Affected	Non-affected	p	Affected	Non-affected	p
Great Toe (%)	14.33±6.58	11.45±5.24	0.033*	8.24±3.07	8,45±4,31	0,865
Other Fingers (%)	4.67±5.69	7.67±7.40	0.007*	2.78±1.68	2,60±2,14	0,053
1st Metatarsal Head (%)	15.91±6.77	11.41±6.24	0.000*	6.68±2.34	8,84±2,55	0,048*
2nd and 3rd Metatarsal Head (%)	24.02±6.81	22.99±5.17	0.275	15.62±2.30	17,50±4,90	0,002*
4th ve 5th Metatarsal Head (%)	17.98±4.15	22.48±7.05	0.000*	13.45±3.53	12,41±2,82	0,136
Medial Arch (%)	10.29±6.97	6.23±4.03	0.027*	5.56±1.70	5,80±2,65	0.000*
Lateral Arch (%)	19.92±9.46	20.73±5.78	0.599	14.10±4.15	14,62±5,40	0.007*
Medial Heel (%)	15.75±5.71	21.15±6.08	0.009*	16.25±3.54	15,53±2,27	0,381
Lateral Heel (%)	16.14±10.12	17.44±8.40	0.567	17.13±4.93	14,27±3,64	0.000*
Load Response Time (ms)	118.88±23.23	113±20.09	0.116	152.00±53.75	151.83±44.24	0.000*
Load Response Max. Surface (cm ²)	106.50±28.63	103±14.78	0.556	87.83±9.326	93.83±22.04	0.441
Load Response Max. Load (%)	60.38±17.85	56.25±5.25	0.246	48±11.067	45±18.50	0.003*
Terminal Stance Time (ms)	309.13±42.70	302.88±68.44	0.501	380.17±163	390.83±99.84	0.000*
Terminal Stance Max. Surface (cm ²)	125.75±20.78	125.38±17.54	0.912	127±17.72	124.67±8.2	0.000*
Terminal Stance Max. Load (%)	97.63±3.18	94.50±6.04	0.007*	95.50±6.051	99.67±0.76	0.165

*: p<0.05

In the present study, the mean AOFAS score of the EndoButton group was 92.33 and 85 in the Screw Group. It was observed in the literature that EndoButton scores are between 85.57 and 97 and between 75 and 92 in screw fixation groups (7-14). The results in this study are therefore similar to the literature. The AOFAS scores of the EndoButton group are significantly better. In a review by Stiene et al., in which studies carried out in the last 10 years in the literature were reviewed in 2018, 494 patients in 11 studies were evaluated, and when the weighted averages of AOFAS scores between static and dynamic fixation were examined, no statistically significant difference was found despite the fact that the results were higher in favor of the dynamic group ($p > 0.05$) (15).

The in-group comparisons of the dynamic plantar pressure distribution analysis data that were obtained in the present study in terms of the affected and unaffected sides and the differences between the groups on the affected side and the unaffected side were analyzed separately. The decrease in loading percentages under the first metatarsal and medial heel in the surgically operated feet of the patients in the metal screw group, as well as the increase in weight in the 4th and 5th MT heads, along with the pressure distribution analyses on the soles of the feet after the surgical operation, indicate that the foot is positioned towards more supination. Furthermore, the increase in great toe and medial longitudinal arch loading percentage supports this idea. In the foot positioned in supination, the dynamic biomechanics of the subtalar joint and, accordingly, the midtarsal joint will cause rigidity in the foot. It is thought that this situation may cause problems in terms of flexibility and shock absorption of the foot, especially in the forefoot in the future. It was found that the maximum loading percentage of the terminal stance phase increased on the affected side, which was also statistically significant ($p < 0.05$). Terminal stance is the phase in which the extremity ends the stance phase and starts to swing, and studies show that pain or foot pathologies lead to a shortening of the total stance phase time and a reduction in the load in this phase. Considering the prolongation of the stance phase after metal screw fixation in this study's cases, the increase in the foot loading percentage can be considered positive; on the other hand, the increase in loading and time in this period can also cause a decrease in walking speed.

On the surgically operated sides of the cases in the EndoButton group, the decrease in the 1st MT head's medial and lateral arch loading percentage, compared to the unaffected sides, means that the weight shifted

from medial to lateral; however, with the decrease in the percentages in the lateral, the foot was not positioned in complete supination, and a more plantigrade foot was shaped in terms of plantar pressure distribution percentages. In addition, in the cases in this group, the increase in the loading percentage under the 2nd-3rd MT heads compared to the other feet shows that the problem of decreased forefoot flexibility in the screw fixation group did not occur in these cases. Based on these data, it can be said that the present study revealed that the percentages of forefoot and midfoot pressures increased in cases with static fixation compared to cases with dynamic fixation, while the percentages of pressure on the back of the foot decreased. This highlights the necessity for considering the effects of ankle injuries on gait parameters in detail in the selection of surgical technique. In addition, in such approaches, since routine clinical evaluations are not sensitive to the changes that were mentioned, decisions should be made based on the results of evaluation methods that provide more objective data. There is no study in the literature that compares these data.

In the routine practice for syndesmosis injuries with screw fixation, the decision whether or not to remove the syndesmosis screws is made through patient-physician communication. It is explained that both approaches are available in the literature, and the aim is to decide on these approaches together with the patient in line with the positives and negatives of each approach. In addition, conventional screws are removed in the 3rd month in patients who have pain in the ankle due to weight bearing. In the current literature, there is no clear consensus on the necessity of removing conventional screws. In 2 separate studies on this subject, while one group of researchers advocated for the necessity of removing the screws, the other argued that this is not a necessary procedure (16,17).

Limitations of the Study

The fact that this study was conducted with the data obtained from the 1-year follow-up of 2 groups consisting of 42 cases meant that it was not possible to compare the long-term results of the treatment techniques of the related injury. There is a need for broader studies and longer follow-up studies in the literature.

In this study, the radiological measurements and the data that were obtained from the direct radiographs were also compared. Kocadal et al., showed that fibular rotation is seen as a potential problem in cases with screw fixation and that computed tomography is superior to direct

radiography in the post-surgical evaluation (18). Another limitation of the present study is that radiological evaluations were made only on direct radiographs.

CONCLUSION

In addition to physical examination, radiological examinations and clinical scoring, the use of pedographic pressure distribution analysis, which provides objective and measurable data, will be useful in the evaluation of patients. There is a need for reliability and correlation studies on these data that need to be conducted in larger populations, including control groups. In malleolar fractures accompanied by syndesmosis injury, instead of conventional metallic screws that provide static fixation, the EndoButton technique's dynamic fixation seems to be a more rational approach since it allows for an earlier return to work/daily life and physiological movements of the joint; it also does not restrict ankle dorsiflexion and thus does not increase forefoot and midfoot pressure during gait.

DECLARATIONS

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Conflict of Interest

All authors declare that there is no conflict of interest.

Ethical Approval

All protocols for this study were approved by the Ankara Numune Eğitim Araştırma Hastanesi Ethics Committee (Decision No: E-18-2179).

Author Contributions

Concept – YMA, FÖ, UG.; Design – YMA, FÖ.; Supervision – FÖ, NB,.; Resources – YMA, FÖ, NB, İAY, UG.; Materials YMA, İAY, UG.; Data Collection and Processing - YMA, İAY, UG.; Analysis and/or Interpretation – YMA, FÖ, NB, İAY, UG.; Literature Review – YMA, UG.; Writing – YMA, UG.; Critical Review - YMA, FÖ, NB, İAY, UG.

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Retrospective Comparison of Open and Percutaneous Repair Methods in Acute Achilles' Tendon Repair

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ABSTRACT

Purpose: In recent years Achilles' tendon tears are becoming more common. Open and percutaneous repair methods have been described in the surgical treatment of tendon tears. The aim of this study is to determine whether there is a difference between open repair and percutaneous repair.

Methods: Patients who underwent surgical repair due to acute Achilles' tendon full-thickness rupture in our clinic, were included in the study. Open repair was performed for one group of patients and percutaneous repair was performed for the other. At the end of follow-up, clinical scores and complication rates were compared statistically.

Results: Thirty-six patients with a mean age of 46.3 years were included in the study. Nineteen patients were treated with the open method and seventeen patients with the percutaneous method. The mean follow-up period was 27.3 months for both groups. Mean Leppilahti scores were 94.71 in the percutaneous repair group and 90.79 in the open repair group ($p>0.05$). Re-rupture, deep infection and DVT rates were similar ($p>0.05$). Skin necrosis was more common in the open repair group ($p<0.05$). While sural nerve neuropraxia was more common in percutaneous repair ($p<0.05$).

Conclusion: In the surgical treatment of acute Achilles' tendon tears, the percutaneous method should be the first choice with its low complication rate and good clinical results. It is necessary to pay attention to the sural nerve during surgery.

Keywords: Achilles' tendon, percutaneous repair, open repair, sural nerve, skin necrosis

Akut Aşil Tendon Onarımında Açık Ve Perkütan Tamir Yöntemlerinin Retrospektif Karşılaştırılması

ÖZET

Giriş: Son yıllarda spora ilginin artması ve toplumun yaş ortalamasının artması gibi nedenlerden dolayı aşil tendon yırtıkları daha fazla görülmeye başlanmıştır. Aşil tendon yırtıklarının cerrahi tedavisinde açık ve perkütan tamir yöntemleri tanımlanmıştır. biz bu çalışmada açık veya perkütan yöntemle tedavi ettiğimiz hastaların klinik sonuçlarını karşılaştırdık.

Hastalar ve metod: Kliniğimizde akut aşil tendon tam kat yırtığı nedeniyle cerrahi tamir uyguladığımız hastalar çalışmaya dahil edildiler. Bir grup hastaya açık tamir diğerine perkütan tamir uygulanmıştı. Cerrahi sonrası iki grubada benzer rehabilitasyon programı uygulandı. Takip sonunda hastaların klinik değerlendirmeleri Leppilahti skoruna göre yapıldı. Komplikasyonlar not edildi. İki grup arasında istatistiksel değerlendirme yapıldı.

Sonuçlar: Çalışmaya yaş ortalaması 46.3 (27-68) olan 36 hasta dahil edildi. Hastaların 28'i (%77.8) erkek, 8'i (%22.2) kadındı. 19 hasta açık, 17 hasta ise kapalı yöntemle tedavi edilmişti. Ortalama takip süreleri 27.3 (12-60) aydı. İki grup arasında yaş, cinsiyet dağılımları ve takip süreleri arasında istatistiksel anlamlı fark yoktu ($p>0.05$). Perkütan tamirde ortalama Leppilahti skorları açık tamirde 94.71 iken açık tamirde 90.79 idi ($p>0.05$). Cerrahi sürelerin karşılaştırılmasında perkütan tamir daha kısaydı (19.47dk, 47.26dk, $p<0.05$). Tekrar yırtık oranı perkütan tamirde %5.9 iken açık tamirde %5.3 idi ($p>0.05$). Derin enfeksiyon perkütan tamirde görülmedi, açık tamirde %10.5 oranında görüldü ($p>0.05$). Cilt nekrozu perkütan tamirde yok iken açık tamirde %36.8 oranında görüldü ($p<0.05$). sural sinir nöropraksisi açık tamirde görülmez iken perkütan tamirde %35.3 oranında görüldü ($p<0.05$). Derin ven trombozu perkütan tamirde %5.9, açık tamirde %5.3 oranında görüldü ($p>0.05$).

Çıkarımlar: Akut aşil tendon yırtıklarının cerrahi tedavisinde perkütan yöntem düşük komplikasyon oranı ve iyi klinik sonuçlarıyla tedavide ilk seçenek olmalıdır. Cerrahi sırasında sural sinire dikkat etmek gerekmektedir.

Anahtar kelimeler: Aşil tendonu, perkütan tamir, açık tamir, sural sinir, cilt nekrozu.

Interest in sports for a healthy life has recently been increasing. At the same time, society is aging. The Achilles tendon is the most frequently ruptured tendon. More people are expected to have Achilles' tendon injuries over time (1). The Achilles tendon is the thickest tendon in the body. These ruptures usually occur among middle-aged individuals during sporting activities or with sudden movements. Achilles' tendon tears should be treated appropriately because of this tendon's importance in walking (2).

The optimal treatment of Achilles tendon injuries is still controversial. Treatment options can be divided between conservative and surgical methods. With conservative methods, patients can return to daily life with functional physical therapy following immobilization with a cast, splint, or brace (3). The advantage of conservative treatment is the absence of wound problems at the site of surgery and infections that may occur with surgical methods. The disadvantages, especially for young and active individuals, are the risk of re-rupture, weakness due to the retracted muscle, and joint stiffness due to long-term immobilization (4). In addition, the injection of agents that stimulate biological recovery has been described, such as platelet-rich plasma or mesenchymal stem cells. However, there is no scientific evidence that these agents change the course of treatment (5). Open, minimally invasive, and percutaneous methods of surgical treatment have been described (6-8). In the open method, the tendon is repaired by end-to-end sutures (6). In the minimally invasive method, the tear line is opened with a small incision, sutures are passed percutaneously from the proximal and distal ends, and the repair is performed with the help of a special device (7). In percutaneous methods, the tendon is repaired with various suture methods without opening the tear line (8).

Percutaneous repair methods have become particularly popular for preventing skin necrosis and deep infection and for increasing patient comfort. Percutaneous repair methods are also preferred because they do not require the use of additional devices. However, there are concerns regarding the risk of re-rupture and sural nerve neuropraxia related to percutaneous repair (9).

In this study, we compare the results of acute Achilles' tendon tears treated with open and percutaneous methods. Our hypothesis is that percutaneous Achilles tendon repair is a more advantageous method than open repair.

Materials and Methods

After obtaining the approval of the ethics committee (Bakırçay University no: 526-506), patients who had undergone surgery for Achilles' tendon injury were retrospectively reviewed. Only acute repairs (operations performed within the first 36 hours) were included in the study. Patients who underwent repairs in the chronic/subacute period were not included in the study. Pediatric patients and patients who could not be followed clinically were not included in the study.

The diagnosis of Achilles tendon rupture was made by palpation of the Achilles tendon on examination, absence of plantar flexion and inability to walk or limping. Radiologically, ultrasound or MRI was performed for all patients in the course of differential diagnosis and tendinitis and partial tears were excluded (Fig. 1). Surgery was performed for full-thickness tears and tendinous region tears. No surgical intervention was performed for partial musculoskeletal injuries. Patients with Achilles tendon tears after direct incisions with cutting tools, patients with avulsion from the calcaneus attachment site with a bone fragment, and patients with previous surgical scars in that area were not included in the study.

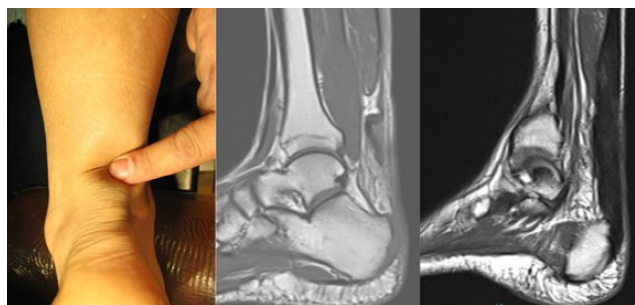


Figure 1: Detection of gap by preoperative palpation. Total tear on preoperative MRI. Healed state of the tendon by MRI control in the 6th month after percutaneous repair.

General or spinal anesthesia was applied for all patients. The prone position was preferred as the surgical position. Antibiotic prophylaxis was administered with 1 g of cefazolin sodium before surgery. Tourniquets were not applied for either the open or the percutaneous method. In the open method, the tear region was opened with an incision in a posterior curve. The body of the tendon was reconstructed with non-absorbable 2-0 Ethicon sutures. Tendon circumference was repaired with 3-0 Prolene sutures. If the plantaris muscle was present, it was augmented

onto the tendon (Fig. 2). In the percutaneous method, six holes were drilled with a total of six #11 scalpels, with two proximal to the tear, two in the tear region, and two distal to the tear. With a long sterile needle, PDS II sutures were applied, with the first suture from the proximal area by drawing eight towards the distal area, and the second suture from the distal in the opposite direction. Sutures were threaded proximally and knotted. Knots were left under the skin (Fig.s 2 and 3). After both repairs, Homan's test was performed passively on the plantar aspect of the ankle. When flexion was observed, the skin was closed. The time between skin incision after anesthesia and skin closure was recorded with the help of anesthesia forms.



Figure 2: Percutaneous repair. Open repair.

After surgery, both patient groups were first treated with a plantar brace. It was followed by an angle-adjustable ankle brace in flexion. At the end of the first week, the brace was adjusted so that the ankle was at 90°. Partial load bearing of 50% was permitted. Sutures were removed in the first week for patients treated by percutaneous method and in the second or third week for the open method. In the fourth week of follow-up, the brace was removed, and weight bearing was recommended as tolerated. Active ankle exercises were also given.

Postoperative clinical control examinations of the patients were performed based on the Leppilahti score at minimum 12 months (10). Skin necrosis, deep infection, neuropraxia in the sural nerve region, re-rupture, and

deep vein conditions such as thrombosis were noted and recorded.

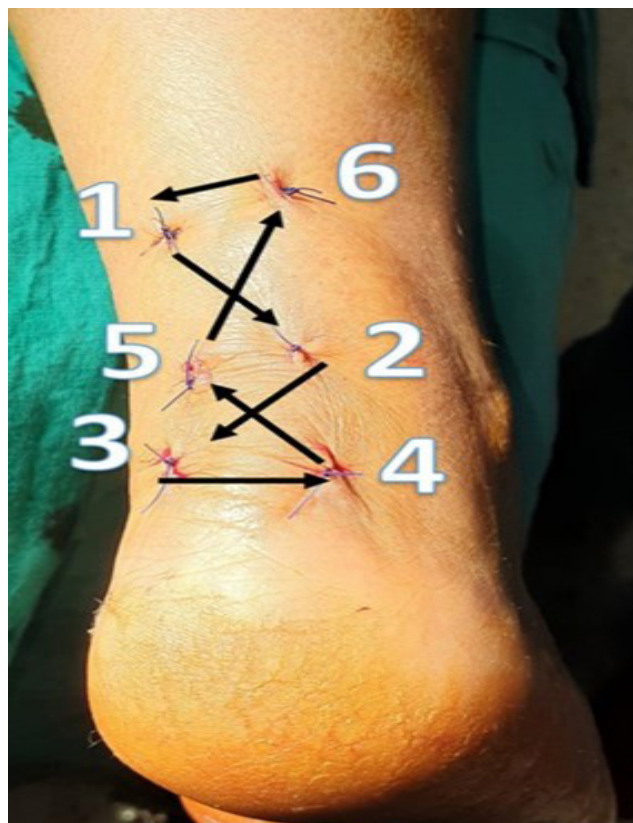


Figure 3: Transition sequence of sutures in percutaneous repair. While going from 1 to 6 for the first suture, two sutures were made in the opposite direction for the second suturing, and these were knotted simultaneously.

SPSS was used for statistical evaluation. The obtained data were entered into Microsoft Excel. Data were listed numerically and categorically. Mean and median values were obtained for numerical data and percentages for categorical data. The Shapiro-Wilk test was used to determine whether the numerical data conformed to normal distribution. Parametric tests were used when normal distribution was confirmed, and nonparametric tests were used when it was not. The chi-square test was used to evaluate categorical data. Fisher's exact test was used when observed values in tables were below 5, while Pearson's chi-square test was used for values greater than five. The significance level was accepted as $p < 0.05$.

Results

A total of 48 patients were identified in the retrospective evaluation. 8 of these patients had chronic tears. Adequate clinical follow-up could not be performed in 4 patients. There were no pediatric patients in our series. Thirty-six patients with a mean age of 46.3 (27-68) years and appropriate clinical follow-up were included in the study. Twenty-eight (77.8%) of the patients were male and 8 (22.2%) were female. Nineteen patients were treated with the open method and seventeen patients with the percutaneous method. The mean follow-up time for both groups was 27.3 (12-60) months. Age, gender, and side distributions were similar between the two groups ($p>0.05$, Table 1). There was no statistically significant difference between follow-up times ($p>0.05$, Table 1).

Mean Leppilahti scores were 94.71 ± 7.800 (80-100) for the percutaneous repair group and 90.79 ± 6.721 (80-100) for the open repair group ($p: 0.129$, $p>0.05$). Percutaneous repair was found to be quicker in the comparison of surgical times (19.47 min vs. 47.26 min, $p<0.001$, $p<0.05$) (Table 2).

In the comparison of complications, the rate of re-rupture was 5.9% (1 patient) with percutaneous repair and 5.3% (1 patient) with open repair ($p: 1.000$, $p>0.05$). Deep infection was not seen in the percutaneous repair group, while it was seen at a rate of 10.5% (2 patients) (fig.4) with open repair ($p: 0.487$, $p>0.05$). Skin necrosis was not observed in the percutaneous repair group, but it was seen at a rate of 36.8% (7 patients) with open repair ($p: 0.008$, $p<0.05$). While sural nerve neuropraxia was not seen with open repair, it was seen at a rate of 35.3% (6 patients) with percutaneous repair ($p: 0.006$, $p<0.05$). Finally, deep vein thrombosis occurred at a rate of 5.9% (1 patient) with percutaneous repair and 5.3% (1 patient) with open repair ($p: 1.000$, $p>0.05$) (Table 2).

		Percutaneous repair		Open repair		p value
Age (years)		47.65	SD: 9,212	45.05	SD: 8,695	0.346*
Gender	male	13	76.5%	15	78.9%	1.000**
	female	4	23.5%	4	21.1%	
Side	Right	8	47.1%	9	47.4%	0.985***
	Left	9	52.9%	10	52.6%	
Follow-up time (months)		30.35	SD:10.839	24.53	SD: 12,642	0.100*

SD: standard deviation, *: Mann-Whitney U test, **: Fisher's exact test, ***: Pearson's chi-square test

		Percutaneous repair		Open repair		p value
Leppilahti score		94.71	SD: 7,800	90.79	SD: 6,721	0.129*
Surgical time (min)		19.47	SD: 2,831	47.26	SD: 3,956	<0.001*
deep infection	yes	0	17.6%	2nd	10.5%	0.487**
	no	17	82.4%	17	89.5%	
skin necrosis	yes	0	0.0%	7	36.8%	0.008**
	no	17	100.0%	12	63.2%	
Re-rupture	yes	1	5.9%	1	5.3%	1.000**
	no	16	94.1%	18	94.7%	
Sural nerve neuropraxia	yes	6	35.3%	0	0.0%	0.006**
	no	11	64.7%	19	% 100	
DVT	yes	1	5.9%	1	5.3%	1.000**
	no	16	94.1%	18	94.7%	

SD: standard deviation, DVT: deep vein thrombosis *: Mann-Whitney U test, **: Fisher's exact test



Figure 4: Superficial skin infection and cellulitis findings. Deep infection and abscess formation.

Discussion

Treatment of Achilles tendon tears is classically either conservative or via surgical open repair. Conservative treatment of Achilles tendon tears may result in weakness, tendon retraction, muscle atrophy, or relapse and open surgery may result in skin problems. For these reasons, surgeons have sought different treatment methods. One of them is the percutaneous method. The percutaneous Achilles tendon repair method was first performed in 1977 by Ma and Griffith (5). In this method, it is aimed to both eliminate skin problems and preserve muscle strength with stable repair. However, the most important problem with the percutaneous method is neuropraxia due to the direct or indirect involvement of the sural nerve, which is close to the Achilles tendon.

In comparative studies of Achilles tendon ruptures treated with open or percutaneous methods, infection rates were found to be lower among patients treated with the open method compared to the percutaneous method (11). Although there were no infections in patients treated with the percutaneous method in their study, Lim et al. found infections in 21% of the patients treated with the open method ($p: 0.01$) (11). In our patient group, these rates were 0.0% and 36.8%, respectively ($p: 0.008$, $p < 0.05$).

Lim et al. found no difference between their two groups in terms of re-tear rates (open repair 3%, percutaneous 6%, $p > 0.05$) or functional scores (11). Karabinas et al. found no

difference between the percutaneous and open methods in terms of clinical scores, return to work, or satisfaction rates (12). Henriquez et al. conducted a functional comparison and concluded that plantar flexion strength, calf diameter, ankle range of motion, and single heel strike results were similar between the two groups (13). Re-rupture rates and functional scores were similar between the two groups in our study, as well ($p: 0.129$). In our study, the rate of re-rupture was 5.9% in the group treated with the percutaneous method, while this rate was 5.3% with the open method ($p: 1.000$).

Percutaneous repair often comes with a higher rate of sural nerve neuropraxia compared to open repair (11,12,14). Although sural nerve neuropraxia was observed at higher rates in previous studies (3% and 18%) (11,12), this rate is seen to be decreasing in more recent studies (6.45%) (14). This is due to advancements of surgical techniques over time and a better understanding of anatomy. In our percutaneous treatment group, we observed sural nerve neuropraxia at a rate of 35%. For all those patients, neuropraxia regressed within 1 month and completely recovered. At the end of the treatment period, sural nerve lesions had decreased to 0%. McGee et al. showed in a cadaver study that needles or sutures do not directly damage the sural nerve and that there may be compression between the tendon sheath and the nerve (15,16). Although the rate of neuropraxia was high among our patients, the permanent damage rate was 0.0%.

Our study is a retrospective study by design. Therefore, randomization and equal distribution of the characteristics of the groups could not be done. In the future, studies with larger numbers of patients and patient groups with longer follow-up periods should be planned.

Conclusion

Percutaneous repair is a method with significant advantages over open repair for acute Achilles' tendon injuries. In particular, fewer wound problems and infections are seen. The surgery time is also shorter. There are no significant differences between functional results and the risk of repeat tears. The disadvantage of the percutaneous method is sural nerve neuropraxia. However, that risk can be minimized by paying attention to anatomical features, and when it does occur, sural nerve neuropraxia is usually temporary. In conclusion, based on the results of this study, percutaneous repair should be the first-choice method for the repair of acute Achilles' tendon ruptures due to low complication rates and good functional outcomes.

DECLARATIONS

Authorship

All authors equally contributed to the design and implementation of the research, to the analysis of the results and to the writing of the manuscript.

Conflict of interest

None

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There is no any financial support for the study.

Data Availability

All data used in the study available upon request from the author.

Ethics Approval

This study was approved by the İzmir Bakırçay University Research Ethics Committee on 02/03/2022 with the decision number 526-506.

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Long-Term Outcomes and Complications of Periprosthetic Fractures of The Proximal Femur: Retrospective Review of 48 Patients

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ABSTRACT

Objectives: Periprosthetic fractures, especially periprosthetic proximal femur fractures, are an increasingly important orthopaedic problem. The aim of this study is to evaluate long-term results, mortality and complications of periprosthetic fractures.

Methods: Patients who had proximal femur periprosthetic fractures were evaluated retrospectively. Patients with Vancouver type B1 and C were treated with plate-screw osteosynthesis and patients with Vancouver type B2 were operated on using revision femoral systems. Follow-up was evaluated by clinical and radiographic, and functional results were assessed by Gos scoring.

Results: Totally 48 patients were evaluated retrospectively. 16 patients (33.3%) were type B1, 18 patients (37.5%) were type B2 and 14 patients (29.2%) were type C. 30 patients (62.5%) with type B1 and C were treated with plate screw osteosynthesis and 18 patients (37.5%) with type B2 treated with revision femoral systems. There was a significant correlation between the surgical method applied and both mortality and preop/postop GOS scoring systems ($p < 0.05$). Complications and/or the need for intensive care were seen in 28 patients (58.3%) only 1 (2.1%) of these was due to iatrogenic. In total, 20 patients (41.7%) from 48 patients could complete the procedure without any problems.

Conclusion: As a result of our study, 58% of patients with periprosthetic femur fractures had complications and need intensive care during the treatment process. Periprosthetic proximal femur fractures, which are generally seen in the elderly population, are injuries with very high complication, mortality and morbidity rates. Therefore, it is recommended that surgeons pay maximum attention during the treatment process.

Level of evidence: Level IV

Keywords: Periprosthetic Femur Fracture; Long-term Results; Glasgow Outcome Scale (GOS); Mortality; Complications

Proksimal Femur Periprostetik Kırıklarının Uzun Dönem Sonuçları ve Komplikasyonları: 48 Hastanın Retrospektif İncelemesi

ÖZET

Amaç: Periprostetik kırıklar, özellikle periprostetik proksimal femur kırıkları, önemli giderek artan ortopedik bir problemdir. Bu çalışmanın amacı, periprostetik femur kırıklarının uzun dönem sonuçlarını, mortalitesini ve komplikasyonlarını değerlendirmektir.

Yöntemler: Proksimal femur periprostetik kırığı olan hastalar retrospektif olarak değerlendirildi. Vancouver tip B1 ve C olan hastalar plak vida osteosentezi ile ameliyat edildi. Vancouver tip B2 olan hastalar ise revizyon femoral sistemler kullanılarak ameliyat edildi. Klinik izlem fizik muayene ve radyografik olarak değerlendirilirken, fonksiyonel sonuçlar Gos skorlaması ile değerlendirildi.

Bulgular: Toplam 48 hasta retrospektif olarak değerlendirildi. 16 hasta (%33,3) tip B1, 18 hasta (%37,5) tip B2 ve 14 hasta (%29,2) tip C idi. Tip B1 ve tip C olan 30 hasta (%62,5) plak vida osteosentezi ile, tip B2 olan 18 hasta (%37,5) ise revizyon femoral sistemler ile tedavi edildi. Uygulanan cerrahi yöntem ile hem mortalite hem de preop/postop GOS skorlama sistemleri arasında anlamlı korelasyon vardı ($p < 0.05$). 28 hastada (%58,3) komplikasyon ve/veya yoğun bakım ihtiyacı görüldü, bunlardan sadece 1 (%2,1) hasta iyatrojenik kaynaklıydı. Toplamda 48 hastadan 20 hasta (%41,7) süreci sorunsuz tamamlayabildi.

Sonuç: Çalışmamız sonucunda periprostetik femur kırığı nedeniyle tedavi edilen hastaların %58'inde komplikasyon görülmüş ve/veya tedavi sürecinde yoğun bakıma ihtiyaç duyulmuştur. Genellikle yaşlı popülasyonda görülen periprostetik femur proksimal kırıkları komplikasyon, mortalite ve morbidite oranı çok yüksek yaralanmalardır. Bu nedenle cerrahların tedavi sürecinde azami dikkat göstermeleri önerilir.

Anahtar Kelimeler: Periprostetik Femur Kırıkları; Uzun Dönem Sonuçlar; Glasgow Sonuç Skorlaması (GOS); Mortalite; Komplikasyonlar

Today, the incidence of periprosthetic femur fractures is increasing steadily. The major factor in this is the increase in both the elderly patient population and the increased number of patients undergoing arthroplasty. (1) Especially, periprosthetic hip fractures are a serious complication. It is stated that the reoperation rate is about 9.5% due to periprosthetic fracture after Total Hip Arthroplasty (THA) and 11% of the 1-year mortality rate after surgically treated periprosthetic hip fracture (2, 3)

Different treatment modalities have been tried in the surgical treatment of periprosthetic fractures after THA. These are locked plate, cerclage cables, bone morphogenetic protein (BMP) together with allograft and revision femoral systems. (4-6) Plate screw osteosynthesis among these treatment methods can be seen as advantageous because it protects the bone tissue. However, revision femoral systems should also be used in case of indication. (7-9). There are not enough studies in the orthopedic literature to evaluate long-term outcomes and non-fracture complications in periprosthetic hip fractures.

The aim of this study is to evaluate patients treated with locking plate and revision femoral systems for periprosthetic fracture in terms of long-term outcomes, mortality, morbidity and complications. In this way, it is aimed to determine the problems that can be seen during the treatment of these fractures and to guide the surgeons.

PATIENTS and METHODS

Forty-eight patients with periprosthetic proximal femur fractures who had at least two years of clinical and radiological follow-up and applied to our clinic between 2012 and 2018 were evaluated retrospectively. Patients with pathological fractures and treated conservatively were excluded from the study. Clinical data of the patients were obtained from the hospital information recording system and radiology images were obtained from clinical radiography and the hospital radiology archive system.

Demographic information of the patients, accompanying injuries, time until surgery and hospital stay were recorded. Comorbid diseases of the patients (Hypertension, Diabetes Mellitus, Heart Failure, Chronic Renal Failure, Alzheimer etc.) were questioned and how many comorbid diseases of each patient were recorded. Perioperative and postoperative complications of the patients (vascular injury, cerebrovascular accident, infection, decubitus wound, etc.) were recorded. All patients were operated on by the same team in the same hospital. The graphs at the

time of arrival of the patients were classified according to the Vancouver classification by evaluating the preoperative history and the status of the femoral stem during the operation. Polyax locking plate system was used for Vancouver type B1 and type C and used revision femoral systems for Vancouver type B2. All patients with locked plates were treated with the Polyax Locked Plating System (Biomet, Warsaw, IN, USA). The Arcos Modular Revision Hip System (Biomet, Inc., Warsaw, Indiana, USA) and the Helios Modular Revision Hip System (Biomet Merck Co., Germany) were used as a revision system. The femoral lateral minimally invasive approach was used as a surgical method for Types B1 and C, and anterolateral approach was applied to the hip for Type B2 fractures. Following removal of the femoral stem, if a cemented stem was present, the cement was cleaned after the femoral extended trochanteric osteotomy and a revision femoral stem was placed. In the uncemented stems, revision stem was inserted without osteotomy following removal of the stem. Postoperative thromboprophylaxis was performed using low molecular weight heparin and/or 300 mg acetylsalicylic acid for 6-8 weeks. All patients were mobilized on the first postoperative day by removing their drains. Quadriceps exercises were initiated. Patients were not given full weight for up to 8 weeks.

The patients were called for control once a year after the 3rd week, 6th week, 3rd month, 6th month, 1st year, 2nd year and after discharge. Patients who underwent plate screw osteosynthesis were evaluated as a union if they did not have weight-bearing pain and three cortex calluses were seen radiologically. If any of the plans had a 10-degree angle on radiographic evaluation, it was considered a malunion. Clinical evaluation was assessed using the Glasgow Outcome Scale (GOS). 1- normal daily activities 2- unassisted moderate activities 3- needing help for daily activities 4- not being able to do daily activities (16-18)

Analysis of the data was done using the IBM SPSS 23.0 statistical package program. Pearson Chi-Square and Fisher's Chi-Square tests were used to comparing qualitative data as well as descriptive statistical methods (frequency, percentage, mean, standard deviation, median, min-max). The normal distribution of the data was evaluated by Kolmogorov-Smirnow and Shapiro-Wilk tests. Independent Samples t-test (t-test in independent groups) and One-Way ANOVA test were used to evaluate quantitative data with normal distribution. Relations between variables were evaluated by the Pearson correlation test. Likelihood (P) Values smaller than $\alpha=0,05$ are significant and there is a difference between groups, with

large values being insignificant and no difference between groups.

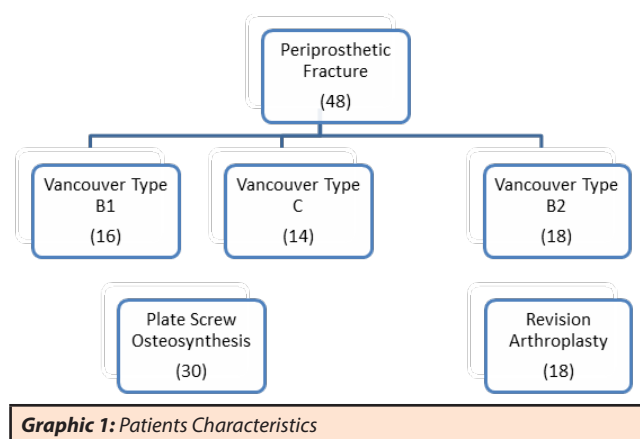
RESULTS

Patient Demographics

A total of 48 patients were included in the study. 26 of the patients were female (54.2%), 22 were male (45.8%) and the mean age of the patients was 70.9 ± 15.4 (range, 43-92). The mean age of patients who underwent plate-screw osteosynthesis was 71.8 (range, 66-92) and the mean age of patients with revision system was 69.4 (range 43-81). The mean follow-up time was 26.1 months (range 0-96 months). There was no statistically significant difference between the groups in terms of age, gender and follow-up time ($p > 0.05$)

Fracture Classification

16 patients (33.3%) were classified as Vancouver type B1, 9 patients (37.5%) were Vancouver type B2, and 14 patients (29.2%) were Vancouver type C when patients were classified according to Vancouver classification. 30 patients (62.5%) with type B1 and C fractures were operated on with plate screw osteosynthesis, and 18 patients (37.5%) with type B2 fractures were operated on using revision femoral systems. (Graphic 1) (Fig. 1-4)



Complications

12 patients (25%) underwent pressure ulcers on hip and heel, despite routine postoperative rehabilitation and mobilization during the hospitalization period. These patients were planned to be followed up by plastic surgery. Superficial infection developed in six patients (12.5%) and the infections resolved with short-term antibiotic treatment. Postoperative embolism developed in the hospital

in 3 patients (6.3%) and the final results were CVS. Two patients had hemiparesis on the operated side and 1 patient had hemiplegia on the non-operated side. Muscle strength was evaluated as 3/5 in two patients and 0/5 in one patient. The treatments of the patients were rearranged by the neurology department. During the operation, femoral artery injury occurred in one patient. The vascular repair was performed by the cardiovascular surgeon in the same session, and the patient's fracture healed completely in the 5th month. (Graphic 2)

Mortality and Scoring

When classified according to GOS, during the preoperative period, GOS 1 in 24 patients (50%), GOS 1 in 10 patients (20.8%), GOS 2 in 14 patients (29.2%), while GOS 1 in 14 patients (29.2%), 14 patients (%) 29.2) GOS 2, 8 patients (16.7%) had GOS 3, 12 patients (25%) had GOS 4. There was a significant correlation between the survival of the patients and the preoperative GOS grading system ($p < 0.05$). All patients with preoperative GOS 3 died within the first 3 years (mean 8 months, range 0-32). 12 of 14 patients with a preoperative GOS value of 3 had a GOS of 4 in the postoperative period, and all these patients died on a mean postoperative 5th month (0-8 months). The mean age of 14 patients was 81.3 (range, 77-92). This rate was higher than the average age of all patients. Of the 14 patients, 3 (6.3%) were treated with the femoral revision system, and 11 (22.9%) were treated with plate-screw osteosynthesis. There was a significant relationship between mortality and surgical method. ($p < 0.05$) (Table 1)



Figure 1: 74 years old female Vancouver Type B2 preoperative graphy



Figure 2: 74 years old female Vancouver Type B2 postoperative 1-year graphy



Figure 4: 81 years old female Vancouver Type B1 postoperative 1-year graphy

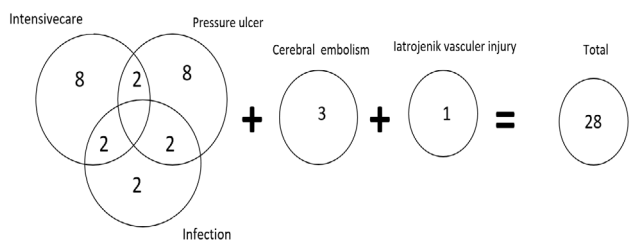


Figure 3: 81 years old female Vancouver Type B1 preoperative graphy

Table 1: Comparison of the operation method and the other parameters

	Plate-screw osteosynthesis (n=30)	Revision systems (n=18)	P value
Mean age	71.8 (66-92)	69.4 (43-81)	0,131 ^a
Mean preop Gos	1.80	1.78	0,140 ^b
Mortality (n)	11	3	0,024^a
Mean postop Gos in patients who died	3.82	4.00	0,364^b

*a:*Fisher's Chi-Square Test, *b:*Pearson Chi-Square Test



Graphic 2: Complications

DISCUSSION

Studies have estimated that until 2030, total and revision hip arthroplasties will increase by 174% and 137%, respectively (10). Periprosthetic femoral fractures are becoming an increasingly common issue for orthopedic surgeons due to the increase in life expectancy in the community and arthroplasty surgeries. New treatment protocols and long-term results are needed to achieve better results in periprosthetic femoral fractures with increased incidence. The most important finding of our study is that the long-term results of periprosthetic fractures are poor regardless of the operations performed, and the complication and mortality rates are very high.

The mortality rates in the first month after periprosthetic fracture are seen to vary between 0.9% and 16% in the literature (2, 11-14). In a study conducted by Berry et al., 1 of 8 patients (12.5%) who underwent Vancouver type B3 periprosthetic fracture after hip arthroplasty and underwent femoral stem revision died within the first week (13). Parvizi et al. reported that 0.9% of 110 periprosthetic fractures in the study died within the first month. (12) McLaughen et al reported 45 patients with periprosthetic femur fractures and reported that 4 patients (8.9%) died in the first month. In the same study, 9 patients reported that they died within the first 3 months. (11). When the long-term mortality rates are considered, it is said that the mortality risk persists in the first 6 months after the surgery and there is a significant decrease after 6 months. Bhattacharyya and colleagues found a mortality rate of 11% at the end of one year when they were followed up with 106 proximal femur periprosthetic fractures in their study. (3) Springer et al. evaluated 134 patients who had periprosthetic femur fractures. Mortality was developed in 11 (8.2%) patients at the end of 2 years (15) In the studies conducted, it is said that the GOS classification is reliable and useful in evaluating functional results in periprosthetic femur fractures (16-18). In the current study, unlike other studies, the issue we found was the relationship between preoperative and postoperative GOS scores and mortality. Of the 14 patients with a preoperative GOS score of 3, 12 of them had a postoperative GOS score of 4, and all of these patients died within 5 months. According to these results, it can be said that the results are worse in fully or partially immobilized patients.

There are also studies showing that mortality may be affected by the surgical procedure performed. Bhattacharyya et al. 106 followed the femur fracture patient for an average of 2.2 years and found that the mortality rate of the

patients who underwent plate-screw osteosynthesis was 33%, whereas the mortality rate was 12% in the patients who underwent surgery with revision system. (3) In another similar study, Langenhan et al. the periprosthetic proximal femur fracture of the plate-screw osteosynthesis and the revision system compared with patients who made the first 6 months mortality plate 30% to 10% higher in the osteosynthesis group (19). In our study, most of the patients who died were surgically treated with plate-screw osteosynthesis (22.9%). Since fracture healing is expected in patients undergoing plate-screw osteosynthesis, their mobilization is more limited compared to patients who have undergone revision femoral system. Restricted mobilization and the resulting decrease in physical capacity can be considered predisposing factors for mortality.

Periprosthetic fractures have been evaluated in terms of post-treatment union and mortality in studies performed, but post-treatment morbidity and complications were almost never emphasized. Since periprosthetic hip fractures are generally seen in a high population in the age group, morbidity and complication rates are high in treatment regardless of surgery. In terms of morbidity, hemodynamic instability was observed in 12 patients (25%) requiring postoperative intensive care. The patients stayed in the intensive care unit for an average of 2.2 days. (range 1-4 days). Bleeding and reduced tolerance to anaesthesia can be seen as a possible causes of this condition. Another important point is the complications that may occur. Although routine postoperative care protocols were applied in the postoperative period, 12 patients (25%) had pressure ulcers in the heel and hip, and 6 (12.5%) had a superficial infection at the wound site. The postop GOS value of the patients with heel pressure ulcers was 3 and above. The mean age of the patients who developed complications was found to be relatively high (47-76 age range). Since the age group is high, microcirculation disorders and prolonged immobilization can be considered the main reason for this situation.

Our study has some limitations. The first of these is that the study is retrospective, and the number of patients is relatively small, although the results of patients with long-term follow-up are. Another limitation is that most of the patients who died did not complete the 2-year clinical and radiological follow-up.

In conclusion, periprosthetic fractures are an orthopaedic question that we have to deal with not only with the surgery but also complications and high mortality rates and its results were seen in the elderly population. Given that we will face more fractures in the future, we need to be more prepared in this regard and we need more and more prospective studies to be able to cope with their complications.

Compliance with Ethical Standards

Conflict of Interest

The authors declare that they have no conflict of interest.

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How Has the COVID-19 Pandemic Revised the Daily Practices of Orthopedics and Traumatology Physicians in Turkey?

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ABSTRACT

Aim: The rapid spread of COVID-19 infection around the world has integrated some precautions and restrictions. In this new period, disruptions and re-prioritizations were experienced in medical practices. The aim of this study is to reveal the changes in the outpatient clinics and surgical services in the practice of Orthopedics and Traumatology in Turkey from the perspective of both residents and specialist physicians with a survey study.

Materials and Methods: In order to evaluate the changes, a survey was prepared which had consisted 42 and 45 questions for residents and specialist working in Turkey, respectively. The survey was published online between December 6, 2020 and January 31, 2021. Data analysis were performed by dividing into 4 subgroups: 1) Demographic information, 2) Changes in internal tasking and working conditions, 3) Variety of services provided and changes in patient applications, 4) Changes in the health care delivery process.

Results: From all over Turkey 62 residents and 230 specialists participated in the survey. 80.4% (185) of the specialists participating in the study and 96.8% (60) of the residents were working in the pandemic hospital. During the pandemic, it was determined that the working hours of physicians were reduced by almost half, and also there was a decrease in the variety and quantity of elective cases. Furthermore, it was observed that the number of applications to emergency services and outpatients clinics decreased during this period. In addition to increased neglected trauma cases, increment of treatment rejection rates are among the observed results.

Conclusion: During the pandemic period, it is observed that there are significant disruptions in orthopedics and traumatology health care delivery and training processes. In the light of experiences, it is crucial to prepare health service action plans for other possible pandemic situations or new waves of COVID-19 due to mutations.

Keywords: Turkey, COVID-19, changes, health care delivery, pandemic

COVID-19 Pandemisi Türkiye'de Ortopedi ve Travmatoloji Hekimlerinin Günlük Uygulamalarını Nasıl Değiştirdi?

ÖZET

Amaç: COVID-19 enfeksiyonunun dünya çapında hızla yayılması, bazı önlemleri ve kısıtlamaları beraberinde getirmiştir. Bu yeni dönemde, tıbbi uygulamalarda aksamalar ve yeniden önceliklendirmeler yaşanmıştır. Bu çalışmanın amacı, Türkiye'de Ortopedi ve Travmatoloji pratiğinde poliklinik ve cerrahi hizmetlerindeki değişimi anket çalışması kullanılarak hem asistan hem de uzman hekimlerin görüşleriyle ortaya koymaktır.

Yöntem: Yaşanan değişiklikleri değerlendirmek için Türkiye'de asistan ve uzman hekimlere sırasıyla 42 ve 45 sorudan oluşan bir anket hazırlandı. Anket, 6 Aralık 2020 ile 31 Ocak 2021 tarihleri arasında çevrimiçi olarak yayımlandı. Veri analizi 4 alt gruba ayrılarak yapıldı: 1) Demografik bilgiler, 2) Hizmet içi görevlendirme ve çalışma koşullarındaki değişiklikler, 3) Sağlanan hizmetlerin çeşitliliği ve hasta uygulamaları, 4) Sağlık hizmeti sunum sürecindeki değişiklikler.

Sonuçlar: Ankete Türkiye'nin her yerinden 62 asistan ve 230 uzman hekim katıldı. Araştırmaya katılan uzmanların %80,4'ü (185) ve asistanların %96,8'i (60) pandemi hastanesinde çalışıyordu. Pandemi sürecinde hekimlerin çalışma saatlerinin neredeyse yarı yarıya azaldığı, elektif vakaların çeşit ve sayısında da azalma olduğu belirlendi. Ayrıca bu dönemde acil servislere ve polikliniklere başvuruların azaldığı gözlemlendi. İhmal edilen travma vakalarının artmasının yanı sıra tedavi reddi oranlarının artması da gözlenen sonuçlar arasındadır.

Çıkarım: Pandemi döneminde ortopedi ve travmatoloji sağlık hizmeti sunum ve eğitim süreçlerinde önemli aksaklıklar olduğu görülmektedir. Deneyimler ışığında, olası diğer pandemi durumları veya mutasyonlar nedeniyle yeni COVID-19 salgın dalgaları için sağlık hizmeti eylem planlarının hazırlanması büyük önem taşımaktadır.

Anahtar Kelimeler: Türkiye, COVID-19, değişiklikler, sağlık hizmeti sunumu, pandemi

With the rapid spread of Sars-CoV-2 infection (COVID-19) around the world, many precautions and restrictions have begun to be taken in public and individual areas. Due to the increasing number of patients with COVID-19, reductions in outpatient services and delays in elective surgeries have begun in many countries, and the concept of “new normal” has been gained (1-6).

In Turkey, especially during the peak periods of the pandemic process, hospitals have almost been turned into COVID-19 care centers. Physicians working in these centers started to work actively in this process, regardless of their specialties. In addition, in order for healthcare professionals to protect their own health, flexible working arrangements were introduced in line with hospital needs, and different application systems were developed outside of routine working hours.

The hypothesis of this study is that the outpatient-clinics and inpatient-clinics in the field of Orthopedics and Traumatology decreased in Turkey in the early period during the COVID-19 pandemic process. The aim of this study is to reveal the changes in the practice of Orthopedics and Traumatology in Turkey with a survey study. In addition, the modifications in the daily practices were also investigated.

Material and Methods

In order to evaluate the changes, a survey that named as “What has the COVID-19 Pandemic revised in Orthopedics and Traumatology Practice?” was prepared. The questionnaire had consisted of 42 and 45 questions for residents and specialist, respectively. The survey was planned to include no patient information in the collected data. Written approval was obtained from the Ministry of Health of the Republic of Turkey due to the study related to the pandemic period. Ethics committee approval was obtained for this study from the Local Ethics Committee (no: 2020/3). The questionnaire was prepared using Google Forms® (<https://docs.google.com/forms>).

A total of 83 questions were divided into 3 groups: Demographic information and professional experience were examined with Part-A (Q:1-5). Part-B (Q:6-45) was customized for specialist, and Part-C (Q:46-83) was for residents. These questions were divided into subgroups: 1) Demographic information, 2) Changes in internal tasking and working conditions, 3) Variety of services provided and changes in patient applications, 4) Changes in the health care delivery process.

The survey was published online on December 6, 2020. It was shared in the e-mail group network of Turkish Orthopedics and Traumatology physicians. Data collection was carried out between 6 December 2020 and 31 January 2021. Participants who could not take an active role in the pandemic process due to personal issues such as health problems were not included in the evaluation.

Results

Sixty-two residents and 230 specialists participated in the survey. Fifty-three of the specialists were in charge of departments. It was seen that the participants were from different geographical region (Figure 1).

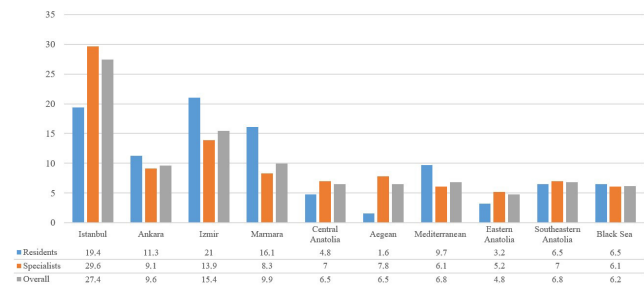


Figure 1. Geographical distribution of participants (%). Istanbul, Ankara and Izmir are not included in their geographical region

In the pandemic hospital, 80.4% (185) of the specialists and 96.8% (60) of the residents were working. During the pandemic, the working hours of residents and specialists were reduced by almost half compared to the pre-pandemic period. The changes in the duties, working conditions and hours of the participants in work areas associated with the COVID-19 are given in Tables 1 and 2 in detail. It was also reported by the participants that the number of monthly night shifts of residents decreased during the pandemic (Figure 2).

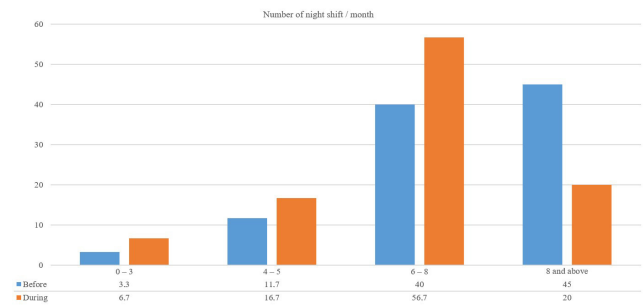


Figure 2. Monthly night shift change graph of residents before and during the pandemic (%)

Table 1. The duties and working conditions of the participants working in the pandemic service units

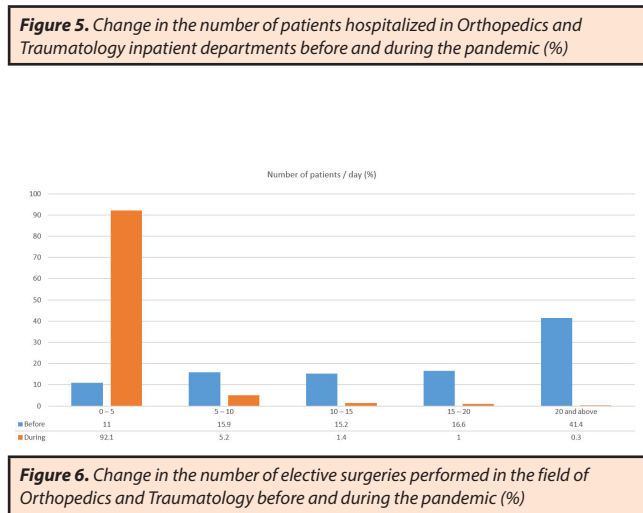
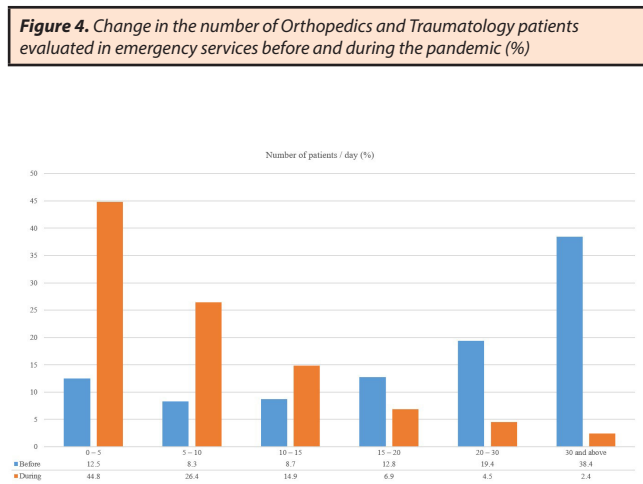
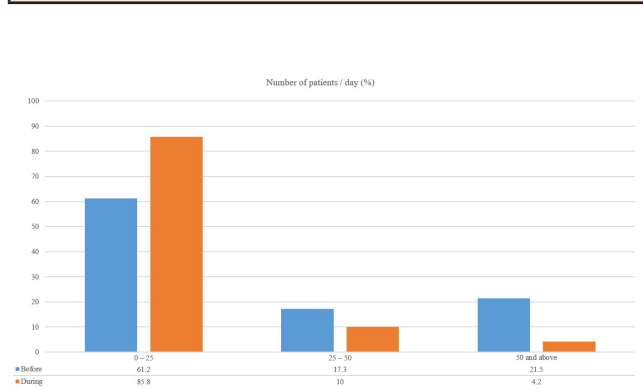
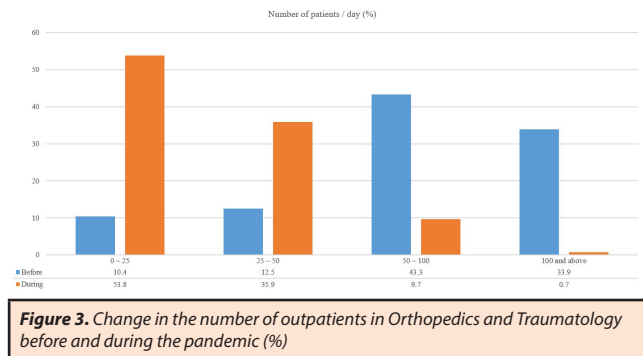
n (%)	Residents (n=60)		Specialists (n=185)	
	Yes	No	Yes	No
Have you worked in the outpatient clinic for COVID-19 suspected patients?	26 (43.3)	34 (56.7)	61 (33.0)	122 (65.9)
Have you worked in the follow-up and treatment unit for patients with COVID-19 infection?	21 (35.1)	38 (63.3)	55 (29.7)	129 (69.7)
Are necessary precautions taken in terms of the risk of contamination in your institution?	47 (78.3)	13 (21.7)	174 (94.1)	11 (5.9)
Was the inpatient service deactivated during the pandemic?	55 (91.7)	5 (8.3)	153 (82.7)	32 (17.3)

Table 2. Comparison of the working hours of the residents and specialists in the hospital before and during the pandemic

hours	Residents				Specialists			
	Before		During		Before		During	
	n	%	n	%	n	%	n	%
0 – 4	0	0.0	9	14.5	4	1.8	107	46.9
4 – 8	1	1.6	32	51.6	68	29.8	93	40.8
8 – 12	34	54.8	19	30.6	153	67.1	24	10.5
12 and above	27	43.5	2	3.2	3	1.3	4	1.8

The changes in the outpatient-clinics, emergency service, inpatient department, elective surgeries, and the variety of surgeries performed in the new working conditions in the early period of the pandemic are given as Figures (Figures 3–7). In the pre-pandemic period, the three most common types of surgery performed by the participants were in trauma (54.7%), arthroplasty (44.2%) and sports injuries (14.9%), while this distribution was trauma (86.8%), arthroplasty (44.8%) and, hand and microsurgery (18.5%) during the pandemic period.

The results of the participants’ considerations regarding the change in emergency services and elective cases following the COVID-19 pandemic are given in Table 3.



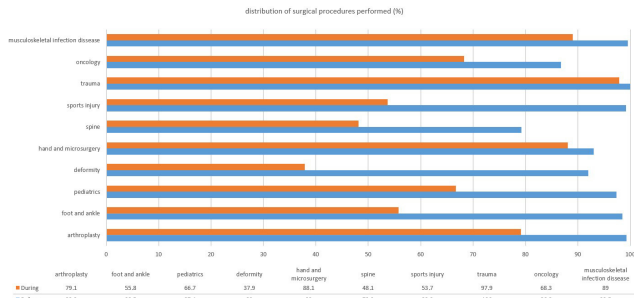


Figure 7. Change in the variety of surgeries performed in institutions in the field of Orthopedics and Traumatology before and during the pandemic (%)

I think that....	Trauma						Elective cases	
	Pediatric		Adult		Elderly		n	%
	n	%	n	%	n	%		
there is an increase in the number of cases	16	5.6	13	4.5	22	7.7	2	0.7
there was no change and the course is similar	64	22.5	54	18.9	91	31.7	8	2.8
there is a decrease in the number of cases	205	71.9	219	76.6	174	60.6	278	96.5

In the early period of the pandemic, the rate of patients refusing suggested treatment and the reason for the decrease in the number of patients who admitted to hospital were reported by the participants (Tables 4 and 5). It was stated by the participants that 67.5% of the patients who did not accept the treatment method did not have a tendency to admission to a private hospital. However, it was stated that traumatized patients' admission was significantly delayed (51% of participants). When the precautions taken during the surgical treatment of patients with COVID-19 are examined it was determined that the participants performed the patients' surgeries in a separate operating room (76.7%), the surgeries were performed with a small number of teams (84.0%), and they used additional personal protective equipments (94.1%).

Table 4. Assessment of treatment withdrawal habits in pandemic conditions

I think that....	discontinuing		refusing with written approval	
	n	%	n	%
there is a change in the rate of increase	127	44.6	97	33.9
it continues in the same way	133	46.7	164	57.3
there is a decrease in treatment rejection rates	19	6.7	18	6.3
I don't know	6	2.1	7	2.4

Table 5. Evaluation of the possible reasons for the decrease in the number of patients during the pandemic in terms of the participants

	n (%)
The risk of transmission of COVID-19 infection due to the lack of isolation	203 (83.1)
The risk of direct transmission from physicians and healthcare workers	135 (48.6)
The curfew implementation	127 (45.7)
Not accepting the idea of delaying treatment as a mistake	113 (40.6)
Inadequate hospital hygiene	47 (16.9)

One of the subjects of this survey was the change in the economic monthly earnings of residents and specialist due to flexible working conditions and decreasing patient admissions. While 52% of the residents stated that there was "no economic change", 57% of the specialists reported that their incomes decreased (Figure 8).

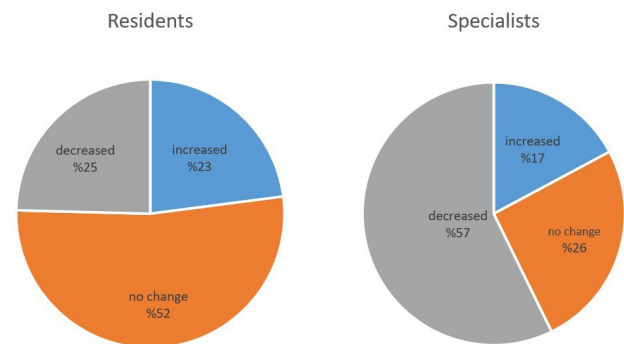


Figure 8. Changing economic earnings in pandemic working conditions

Discussion

Demographic information

The COVID-19 pandemic has brought along some changes in providing and receiving health services in Turkey as well as all over the world. The changes in Orthopedics and Traumatology in the early period of the pandemic were aimed to be enlightened by this survey study. The survey study was carried out with similar proportions of participants from each geographical region of our country. It was observed that the participation from the three metropolitan cities was higher (Istanbul, Ankara and Izmir). In Turkey, 90 educational institutions provide orthopedics and traumatology training. The fact that there were 53 department heads among the participants and that most of the respondents work in these hospitals is crucial in terms of reflecting the results of this survey in Turkey in general.

It has been observed that almost half of the specialist experienced a significant decrease in their salaries in terms of monthly economic earnings in the early period after the changing working conditions with the pandemic. In Turkey, there is a system of salary based on the performance. The decrease in patient applications and in interventional procedures can explain the loss of income. On the other hand, it was observed that there was no significant change in the incomes of residents. Similarly, in the study in which 858 German orthopedic specialists, 26.2% of the participants stated that the compensation for economic loss was sufficient, while 62.8% stated that more financial support should have been provided. It has been determined that the self-employed physicians, who are among the participants, have more economic gain concerns and negative effects than those working in the hospital (7).

Changes in internal tasking and working conditions

It was observed that the majority of the residents and specialists working in pandemic centers did not work in the COVID-19 suspicious patient areas and in the departments where the follow-up and treatment of the infected patients are included. In particular, the fact that 96.8% of the residents participating in the survey work in pandemic centers showed that almost all tertiary care hospitals in Turkey actively worked during the pandemic period. However, it could be said that in the early stages of the pandemic, residents and specialists working in the Orthopedics and Traumatology worked in the background of the pandemic departments. On the other hand, it was reported by most of the participants that the Orthopedics and Traumatology inpatient-clinics were closed and turned into infectious diseases clinics in the institutions where they worked as the course of the pandemic worsened. With various circulars published by the Ministry of Interior,

flexible working arrangements were introduced for public officials. It was aimed to prevent in-hospital contamination to health workers who do not take an active role in the pandemic departments. This supported that the flexible working system could be planned according to the needs and could be an appropriate decision in pandemic situations. Closing the Orthopedics and Traumatology inpatient-clinics and converting them to infection diseases units brought some difficulties in clinical services, but it was a crucial gain in terms of the pandemic. Similar administrations have been shown in a study involving 401 Spanish specialists. It has been reported that 46% of the participants were asked to cooperate in other units or services (8). Likewise, according to the study, in which 102 orthopedic specialists from 19 different European countries participated, it was observed that 49% of specialist in the management of COVID-19. It was also stated that there was not a significant difference between public and private institutions in this working system (51.4% and 44.1%, respectively) (9).

Participants stated that internal measures were taken in terms of high risk of contamination (residents 78.3%, specialists 94.1%). This was a substantial step in the protection of both healthcare workers and patients and also their companions in terms of hospital-acquired contamination. Similarly, Randau et al. (7) reported in their study that the information provided by the government was good (71%) for the participants, while the measures taken were necessary (81.4%) and sufficient (67.9%). Further, Ranuccio et al. (9) in the multinational study, they reported the number of specialists who received training on knowledge and management of COVID-19 as 69 (67.6%), while 15 (65.2%) of 23 specialists who did not receive training were assigned to pandemic clinics.

Working hours of participants varied considerably before and during the pandemic. In the pre-pandemic period, almost all of the residents worked more than 8 hours a day, during the pandemic this time fell to one third. Almost half of the residents stated that they work between 4 and 8 hours. While the majority of specialists worked between 4-12 hours before the pandemic, it was observed that almost half of them worked between 0-4 hours during the pandemic. There has been a significant decrease in working hours with the pandemic. The effect of the flexible working system applied in this decline is undeniable. However, negative effects in the training of Orthopedics and Traumatology due to this decrease should be a separate object to debate. Considering that the current training is 5 years, we think that the educational activities postponed due to the pandemic have serious negative effects, even if they are supported online.

Along with the pandemic, some changes were observed in the number of night shifts of the residents. In the pre-pandemic period, almost half of the residents stated that they had 8 or more night shifts per month, while only 20% of them were on shifts of 8 or more per month during the pandemic. In general, it was determined that during the pandemic, residents were on duty between 4 and 8 times a month. Whether the ward of responsibility is a COVID-19 and/or orthopedic in-patient clinics was not questioned in this survey.

Variety of services provided and changes in patient applications

One of the most crucial points of this study is that it shows the change in orthopedics and traumatology outpatient services. In this period, when the number of infected patients was high, there was a critical decrease in the number of patients who applied to the outpatient-clinics. According participants' observation, while the application rate of 50 and above per day was 77.2% in the pre-pandemic period, this rate decreased to 10.4% during the pandemic. It is obvious that there is a significant decrease in the number of patients. Although not as rigid, parallel decreases were observed in the number of patients admitted to the emergency department with Orthopedics and Traumatology complaints. When the data of other countries are examined, it has been reported that outpatient-clinics have stopped over 90% in a study conducted in 9 different countries (9). In an Italy-based study, it was reported that there was a 59.8% decrease in emergency department admissions involving orthopedics and traumatology compared to the pre-pandemic period. However, geriatric traumas did not decrease, in the general population; it was determined that domestic accidents increased (10).

In the pre-pandemic period, while the average rate of 20 or more inpatients per day in Orthopedics and Traumatology inpatient-clinics was approximately 58%, it was determined that this rate decreased to 6.9% during the pandemic period. Almost half of the participants stated that they are trying to provide orthopedics and traumatology inpatient-clinics with a maximum of 5 beds.

One of the most remarkable changes brought by the pandemic period in the field of orthopedics and traumatology is the decreasing trend in the number of elective surgeries. In general, participants stated that while the rate of elective patient surgeries of 15 or more per week was 58%, this rate decreased to 1.3% during the pandemic. During

pandemic process, 92.1% of those who participated in the survey stated that they could perform a maximum of 5 elective surgeries per week. During the pandemic, decline in elective surgeries were detected in many sub-areas. It is seen that this restructuring has similarly affected other countries (7, 8, 11-13). According to the data obtained in the study, the most serious changes were observed in deformity correction, sports injuries and foot and ankle surgeries with a decrease of approximately 50%. Although a significant numerical decrease was reported in elective surgeries compared to the pre-pandemic period, hand and microsurgery, musculoskeletal infections and arthroplasty surgeries continued to be performed frequently when the proportional changes in the variety of surgeries were examined. In multinational survey studies conducted across Europe, it has been shown that there are serious decreases in elective cases, especially in arthroplasty surgeries (7, 12, 13). Along with the pandemic, such a disruption in elective surgeries will cause or have caused serious problems and severe backlogs after the pandemic. Naturally, the pandemic is a vital priority and such problems are inevitable. Another problem created by the postponement of elective surgeries is that it creates a refractory deficiency in the vocational skills training of residents.

The patient group treated with surgery most frequently before and during the pandemic was caused by trauma. While the rate of centers where trauma surgeries were performed most frequently before the pandemic was approximately 55%, this rate increased to 87% during the pandemic period. In other words, almost only trauma-induced patients were treated surgically during the pandemic period. Although most of the patients who underwent surgical treatment were due to trauma, most of the participants reported that the number of traumatized pediatric and adult patients during the pandemic period decreased by $\frac{3}{4}$ and by $\frac{2}{3}$ in the elderly patient group. Turgut et al. (14) examined trauma cases admitted to a tertiary care hospital between 2018 and 2020. In this study, it was shown that the frequency of fractures decreased one-third with the pandemic, the average age of patients exposed to trauma decreased, and surgical treatments were almost doubled in patients under 16 years of age. Measures such as the general curfew applied in the early period of the COVID-19, and then the curfew and transportation restrictions applied under the age of 18 and over the age of 65, and the restriction of intercity and intra-city traffic density can be considered as the main factors in reducing the number of traumas.

Changes in the health care delivery process

Approximately 45% of the participants stated that the patients did not accept the recommended treatment and 34% stated that they refused treatment with a written approval. The patients refused to receive treatment from the relevant institution due to the pandemic despite all the disadvantages that may occur in the absence of surgery. The participants reported that they thought that patients who refuse treatment or neglected treatment did not tend to go to a private health center or another public hospital that was not a pandemic hospital. Parallel to this, half of the participants stated that delayed diseases and disabilities increased in outpatient-clinics. In a survey of 12000 orthopedic surgeons in India, it was reported that trauma surgeries decreased as well as elective surgeries. It has been concluded that conservative treatments are at the forefront as a reason for this, and revision/reconstruction surgeries are performed more frequently (11).

The most prominent reason for the decrease in the number of patients is the risk of transmission (83%) due to the lack of isolation. The second reason is the risk of direct transmission from physicians and healthcare workers (48%). The curfew implementation and the thought that postponing treatment is not wrong was seen as an effective factor in this decrease at a rate of 40-45%. In the survey conducted at the United Nations, in which the opinions of 360 patients who were planned to have surgery were reflected, it was observed that in places where the pandemic was felt heavy, patients had thoughts of canceling their surgeries, as well as the cancellation procedures were given by surgeons (15).

In this observationally planned study, data and inferences were obtained from the thoughts of the participants. No numerical data were collected from the clinics to which the participants were affiliated. This is the most important limitation of the study.

In conclusion, the number of participants and the fact that most of them work in pandemic hospitals made the results of this observational survey study valuable. During the pandemic period, serious disruptions were experienced in every field in orthopedics and traumatology services. The most crucial result of the decrease in patients, especially in elective diseases, is that there are some delays in the treatment of these patients and accumulation in this group of patients.

During this period, the residents both worked in the pandemic services, and they were interested in the diagnosis, follow-up and treatment of very few patients in Orthopedics and Traumatology. Even if this is an absolute necessity created by the pandemic, it is highly likely that it will cause serious disruptions in the training. In conclusion, it is crucial to prepare health service action plans for other possible pandemic situations or new waves of COVID-19 due to mutations.

DECLARATIONS

Disclosure of Funding and Conflict of Interest

Each of the authors states that there is no funding including pharmaceutical and industry support and conflict of interest about this manuscript.

Ethics Committee Approval

Ethics committee approval was obtained for this study from the Tepecik Training and Research Hospital - Local Ethics Committee (no: 2020/3).

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Tension Band Wiring of Patella Fractures: Mid-Term Radiological and Clinical Results

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ABSTRACT

Objective: To report our radiological and clinical results with a mid-term follow-up on patella fractures treated with tension band wiring (TBW).

Methods: Patients surgically treated with TBW for AO type 34-A1/C1/C2/C3 patella fractures between January 2013 and June 2021 at a level 1 trauma center were included. For radiological evaluation, radiographs obtained at the routine follow-up were analyzed for complications (such as nonunion, malunion, loss of reduction, malreduction, patella baja, elongated patella, implant failure), Insall-Salvati Index (ISI), and Patellar Morphology Ratio (PMR). The Knee Injury and Osteoarthritis Score (KOOS) was utilized for functional evaluation, which includes five subscales: pain, symptoms, activities of daily living (ADL), sports/recreation, and quality of life (QOL). The clinical assessment also included the range of motion (ROM), thigh circumference (TC), and complications such as implant irritation (II).

Results: This study reviewed 42 eligible patients (10 females, 32 males) with a mean age of 42.6 ± 16.1 years and a mean follow-up of 35.4 ± 24.1 months. There were 28 patients (66.7%) with at least one complication (II: 66.7%, flexion deficit: 61.9%, malunion: 40.5%, elongated patella/patella baja: 16.7%). The reoperation rate was high at 69.1% due to the high implant removal rate for II. There were statistically significant differences between injured (I) and uninjured contralateral healthy knees (UI) in terms of mean KOOS subscale scores (symptoms: I: 72.3, UI: 89.8; pain: I: 70.4, UI: 89.4; ADL: I: 72.1, UI: 90; sports: I: 61.4, UI: 84.8; QOL: I: 67.9, UI: 86.2), mean flexion degrees (I: 126.2° , UI: 135.4°), mean ISI (I: 0.9, UI: 1.0), and mean PMR (I: 1.5, UI: 1.4) (all $p < 0.01$). There was no difference in mean extension degrees and TC (all $p > 0.05$). All fractures achieved union.

Conclusion: The mid-term clinical results of patellar fractures treated with TBW were significantly worse than the contralateral healthy knee. Implant irritation, knee flexion deficit, malunion, and patella baja were the significant complications, and efforts should be made to manage these problems. Patellar fractures are susceptible to developing interesting cases of the elongated patella.

Keywords: Patella fracture, Tension band wiring, Radiological and clinical results, Complications, Implant irritation, Flexion deficit, Malunion, Patella baja, Elongated patella, Malreduction, Implant fail.

Patella Kırıklarında Gergi Bandı Tekniği: Orta Dönem Radyolojik ve Klinik Sonuçlar

ÖZET

Amaç: Gergi bandı tekniği (GBT) ile tedavi edilen patella kırıklarının orta dönem takibindeki radyolojik ve klinik sonuçlarımızı bildirmek.

Yöntem: Bu çalışmaya, bir birinci seviye travma merkezinde, Ocak 2013 ile Haziran 2021 arasında, AO tip 34-A1/C1/C2/C3 patella kırıkları nedeniyle GBT ile cerrahi olarak tedavi edilen hastalar dahil edildi. Radyolojik değerlendirme için rutin takipte alınan radyografiler komplikasyonlar (nonunion, malunion, redüksiyon kaybı, malredüksiyon, patella baja, uzamış patella, implant yetmezliği), Insall Salvati İndeksi (ISI) ve Patellar Morfoloji Oranı (PMO) açısından incelendi. Ağrı, semptomlar, günlük yaşam aktiviteleri (GYA), spor/rekreasyon ve yaşam kalitesi (YK) olmak üzere beş alt ölçek içeren Diz İncinme ve Osteoartrit Sonuç Skoru (KOOS) fonksiyonel değerlendirme için kullanıldı. Klinik değerlendirme ayrıca eklem hareket açıklığını (EHA), uyluk çevresi uzunluğunu (UÇU) ve implant irritasyonu (II) gibi komplikasyonları da içeriyordu.

Bulgular: Bu çalışmada, ortalama yaşı 42.6 ± 16.1 yıl ve ortalama takip süresi 35.4 ± 24.1 ay olan 42 uygun hasta (10 kadın, 32 erkek) incelendi. En az bir komplikasyonu olan 28 hasta (%66.7) vardı (II: %66.7, fleksiyon defisiti: %61.9, malunion: %40.5, uzamış patella/patella baja: %16.7). İl kaynaklı yüksek implant çıkarma oranı nedeniyle yeniden ameliyat oranı (%69.1) yüksekti. Opere edilen (O) ve opere edilmeyen kontralateral sağlıklı dizler (S) arasında, ortalama fleksiyon dereceleri (O: 126.2° , S: 135.4°), ortalama ISI (O: 0.9, S: 1.0) ve ortalama PMO (O: 1.5, S: 1.4) ve KOOS alt ölçek puanları (Semptomlar: O: 72.3, S: 89.8; Ağrı: O: 70.4, S: 89.4; GYA: O: 72.1, S: 90; Spor: O: 61.4, S: 84.8; YK: O: 67.9, S: 86.2) açısından istatistiksel olarak anlamlı farklılıklar vardı (tümü $p < 0.01$). Ortalama ekstansiyon dereceleri ve UÇU açısından fark yoktu (tümü $p > 0.05$). Tüm kırıklarda kaynama sağlandı.

Sonuç: GBT ile tedavi edilen patella kırıklarının orta dönem klinik sonuçları, karşı taraf sağlıklı dizden belirgin ölçüde daha kötüydü. Implant irritasyonu, diz fleksiyon defisiti, malunion ve patella baja belirgin komplikasyonlardı ve bu sorunları yönetmek için çaba sarf edilmelidir. Patella kırıkları, uzamış patella kaynaklı ilginç vakaların gelişmesine yatkındır.

Anahtar Kelimeler: Patella kırıkları, Gergi Bandı Tekniği, Radyolojik ve Klinik Sonuçlar, Komplikasyonlar, İmplant İrritasyonu, Fleksiyon defisiti, Malunion, Patella Baja, Uzamış Patella, Malredüksiyon, İmplant Yetmezliği.

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The patella is the largest sesamoid bone in the body and has the thickest articular cartilage, with an average cartilage thickness of 5.5 mm (1). Its functions are to be the pivot point for the knee's extensor mechanism (quadriceps muscle/tendon, patella, patellar tendon) and protect the distal anterior cartilage of the femur against impacts from the knee from the front. It acts as a lever arm by elevating the extensor mechanism from the knee's rotation center and increasing the extensor mechanism's efficiency by 30% (2).

Patella fractures account for 1% of all fractures in adults and occur predominantly in patients between 20 and 50 years, and the incidence has been estimated to be 13.1 per 100,000 person-years (3, 4).

The fractures of the patella cause extensor strength weakness, range of motion restriction, patellofemoral and tibiofemoral arthritis, thus reducing the quality of life (5). The treatment aims to restore the extensor mechanism function, minimize bone loss, ensure the integrity of the articular cartilage, and enable early mobilization (1). Therefore, patella fractures with articular step-off > 2 mm, displacement > 3mm, extensor mechanism disruption, and open fractures are treated by surgical means (6).

The most widely accepted surgical treatment method for displaced patella fractures is tension band wiring (TBW) which converts tension forces into compressive forces across the patella (7). In the classical TBW technique, two K wires are bent proximally and parallel to each other, and a figure of eight bent cerclage wire around them is used (8). For comminuted fractures and distal pole fractures, additional circular cerclage or de-tensioning cerclage (McLaughlin) may be used, respectively (9).

Although union rates of patella fractures are high and favorable radiological outcomes have been reported, the information on the knee range of motion, pain, other symptoms, daily living function, sports/recreation, and knee-related quality of life is limited in the literature (10). Therefore, we aimed to share our relevant radiological and clinical results with a mid-term follow-up on patella fractures treated with TBW.

PATIENTS AND METHODS

Patient Selection

An ethical review board approved this retrospective study (02.06.2022-5-26) which was performed in compliance with the Declaration of Helsinki. Written informed consent was obtained from all patients enrolled in this study.

Patients surgically treated with TBW for AO type 34-A1 (avulsion) and 34-C1 (transverse), C2 (transverse plus second fragment), and C3 (comminuted) patella fractures between January 2013 and June 2021 at our level 1 trauma center were included in this study. Patients had to have had a surgically treated patella fracture, be at least 18 years old, and have had at least a 12-month follow-up period after surgery for the inclusion criteria. Patients with an age under 18 years old (n=1), a conservatively treated patella fracture (n=1), a prior medical condition limiting physical or mental health (n=1), a concomitant brain or spinal cord injury (n=1), ipsilateral/contralateral lower limb fracture, or dislocation (n=1) were excluded. Two patients were lost to follow-up. Hence, the results of forty-two eligible patients were demonstrated in the study.

Surgical Technique

In this level 1 trauma center setting, senior orthopedic surgeons performed more than half of the operations and supervised the senior residents during less than half of the operations. Following a longitudinal midline incision over the patella, the fracture was reduced using reduction clamps. Then, two parallel K wires were inserted longitudinally into the patella, a cerclage was bent in a figure of eight around the K wires, and the cerclage's two ends were curled to secure and tighten the construct (Figure 1). For most of the operations, the K wires were bent proximally and distally. For three cases, the K wires were bent only proximally. The decision regarding where to bend the K wires was up to the surgeon's preference. No objective criteria were used for this process. For comminuted fractures (AO type 34-C3), especially if the fracture was as a "bag of bones", to improve stability, an additional circular cerclage around the patella or additional K wires were used. Surgeons knew that this situation meant sacrificing implant irritation to gain more stability for achieving union, and these patients were acknowledged about this situation after the surgery. Fluoroscopy was used to inspect the reduction, the K wires' position, and the cerclage. Also, if the eventful rupture of the retinaculum was present, it was used to check the intra-articular step-offs.

Follow-up and Rehabilitation

A long leg splint with a full knee extension was applied for two weeks after the operation to allow the wound to heal. On the 15th day, sutures and the splint were removed, and the patient was allowed to bear weight with a hinged knee brace locked at full extension. On the 30th day, the hinged brace was adjusted to allow 90 degrees of flexion. The flexion range was increased by 10 degrees weekly. The hinged knee brace was removed at the end of the second month. Patients were admonished to abide by a home exercise program focused on quadriceps strengthening and knee range of motion (ROM).

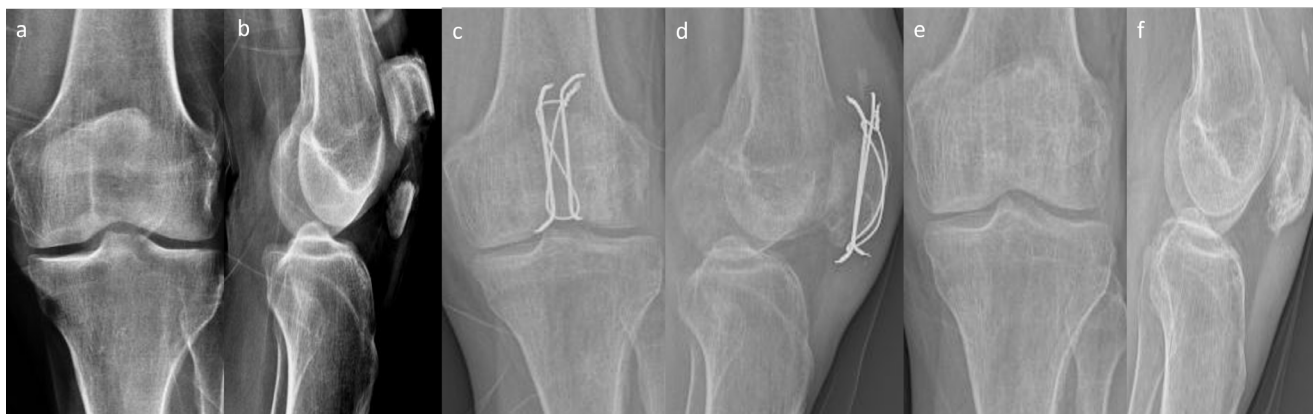


Figure 1. Preoperative anteroposterior (AP) and lateral (L) knee radiographs of a fifty-seven-year-old male patient who sustained an AO-34C1 patella fracture are demonstrated in a and b. Early postoperative and latest (after implant removal) AP and L knee radiographs are shown in c, d, e, and f, respectively.

For follow-up, patients were evaluated postoperatively on the 2nd, 4th, 8th, and 12th weeks and at the 6th and 12th months and then if needed. Implant removal was performed between the 6th and 12th months if the patient demanded it after the bony union. Also, implant removal was advised for some patients if the clinical results were worse than expected by the operating surgeon, who knew the natural course of the recovery period of the fracture with their experience. But even in this situation, the patient made the final decision of the implant removal.

Radiological Evaluation

For radiological evaluation, radiographs obtained at the routine follow-up were analyzed for complications such as nonunion, malunion, loss of reduction, malreduction, patella baja, and implant failure (K wire migration and cerclage stripping off from K wires). A complication was defined as a significant deviation from the normal course of events during surgery or post-operatively by the European Society of Sports Traumatology, Knee Surgery & Arthroscopy (ESSKA) (11).

To be more precise, in our institution, we define an orthopedic complication as any clinical or radiological condition that develops during or after a surgical/non-surgical intervention that adversely affects the patient. Nonunion was defined as less than 80% bridging of the fracture line observed on the lateral knee radiograph (12, 13). Malunion of the patella was defined as a non-anatomical union of the patella with either an elongated patella or an articular step-off of more than 2 mm (Figure 2) or displacement of fragments more than 3 mm. These three malunion conditions were caused by gradual reduction loss or initial malreduction. Insall-Salvati Index (ISI) (patellar tendon length/patellar length) and Patellar Morphology Ratio (PMR) (patellar length/patellar articular surface length) were calculated on lateral knee radiographs with knees at 45° of flexion and superimposed femoral condyles (Figure 3) (14). Patella Baja is defined as an ISI measurement below 0.8 (15). An elongated patella was defined as a PMR measurement above 1.5 according to the Grelsamer classification (Figure 4) (16).



Figure 2. Preoperative (a), early postoperative (b), latest (c) lateral radiographs, and a sagittal CT view (d) of a fifty-nine-year-old patient who sustained an AO-34C3 patella fracture are demonstrated. Note that an articular step-off caused by initial malreduction leading to malunion is presented.

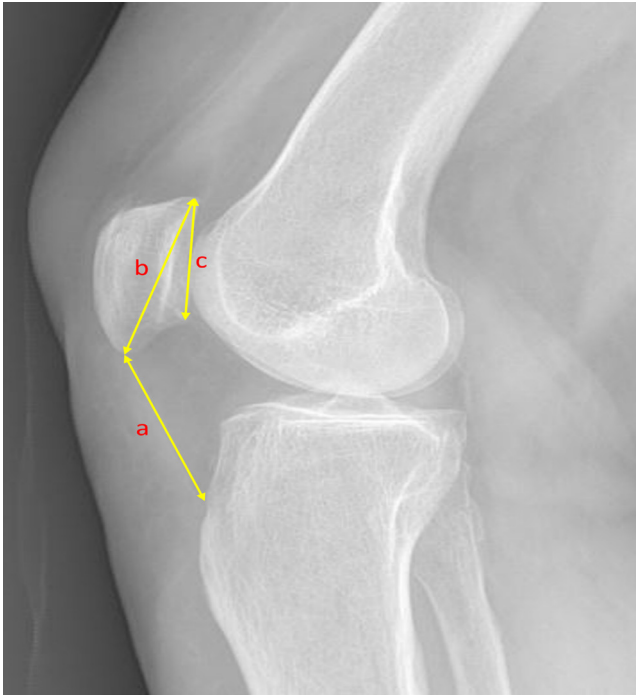


Figure 3. The demonstration of the Insall-Salvati Index (ISI) and the Patellar Morphology Ratio (PMR). For ISI, the length of the patellar tendon (a) is divided by the length of the patella (b). For PMR, the length of the patella (b) is divided by the articular surface length (c).

Clinical Evaluation

The Knee Injury and Osteoarthritis Score (KOOS), a knee-related, self-administered, validated, and widely recognized questionnaire, was used to assess functional status (17). The KOOS includes five subscales: pain, symptoms, daily living activity, sports/recreation, and quality of life. Each subscale was computed as a normalized score ranging from 100 (no symptoms) to 0 (extreme symptoms). Injured and uninjured sides were compared regarding the functional outcomes. A goniometer was used to determine the range of motion of the injured and uninjured knees during active flexion and extension. The flexion and extension deficits were calculated by subtracting the injured side's flexion/extension degrees from the uninjured side. Thigh circumference (TC) was measured from 15 cm above the patella, and the difference of more than 2 cm between injured and uninjured sides was thought to be an indicator of quadriceps muscle atrophy. Complications such as wound complications, infection, implant irritation, TC difference > 2 cm (compared with the contralateral healthy knee), and flexion/extension deficit (compared with the contralateral healthy knee) were evaluated using clinical data. Implant irritation was defined when the patient complained about the skin irritation by prominent hardware during regular follow-up. KOOS, ROM, TC, ISI, and PMR values recorded on the last follow-up visit were demonstrated in this study.



Figure 4. Preoperative coronal and sagittal CT views (a and b), early postoperative AP and Lateral knee radiographs (c and d), lateral knee radiograph before implant removal (e), latest AP and lateral knee radiographs (f and g), and contralateral healthy knee lateral radiograph of a patient with an AO-34C3 patella fracture are demonstrated. Note that there is an elongated patella with patella baja (g) compared to the contralateral healthy knee (h). The reason for this malunion case was initial malreduction.

Statistical Analysis

Descriptive statistical analysis was performed using SPSS 25.0 (SPSS Inc., IBM, NY, USA). Numerical variables were given as means and standard deviations, and categorical variables were provided as frequencies and percentages. Means were compared by using either Student t-test (under the parametric assumption) or Mann-Whitney U test (under violation of the parametric assumption), or Kruskal-Wallis test (under violation of the parametric assumption for more than two groups) in accordance with the Shapiro-Wilk normality test. The P-value was set at a significance level of 0.05.

RESULTS

This study reviewed 42 eligible patients (10 females and 32 males) with a mean age of 42.6 ± 16.1 years and a mean follow-up of 35.4 ± 24.1 months. The main clinical characteristics of the patients were demonstrated in Table 1.

Table 1. Main clinical characteristics of the patients.	
Number of patients	42
Mean age (years)	42.6 ± 16.1
Mean follow-up (months)	35.4 ± 24.1
Gender	
Male	32 (76.2%)
Female	10 (23.8%)
BMI (kg/m ²)	25.3 ± 2.1
Side	
Left	20 (47.6%)
Right	22 (52.4%)
Mechanism of injury	
Fall	37 (88.1%)
Traffic accident	3 (7.1%)
Other	2 (4.8%)
Fracture type (AO classification)	
34-A1	9 (21.4%)
34-C1	16 (38.1%)
34-C2	5 (11.9%)
34-C3	12 (28.6%)
Wound type (Gustillo Anderson)	
Type 1 open	1 (2.4%)
Type 2 open	1 (2.4%)
Closed	40 (95.2%)
ASA classification	
ASA 1	35 (83.3%)
ASA 2	6 (14.3%)
ASA 3	1 (2.4%)
ASA 4	0 (0%)
Hospitalization time (days)	1.7 ± 1.2
Type of anesthesia	
Spinal	39 (92.9%)
General	3 (7.1%)
Mean operation time (min)	40.1 ± 10.4
Mean Union time (weeks)	15.4 ± 5.5
BMI: body mass index, ASA: American Society of Anesthesiologists, AO: Arbeitsgemeinschaft für osteosynthesfragen	

There were statistically significant differences in all KOOS subscales between injured and uninjured knees, especially prominent in the sports/recreation and quality of life scores (all $p < 0.01$). Also, there were statistically significant differences in ROM (flexion), ISI, and PMR results between injured and uninjured knees (all $p < 0.01$). All patients achieved full extension after the TBW surgery. All patients but one had no TC difference between injured and uninjured knees. KOOS, ROM, TC, PMR, and ISI results compared to the uninjured knee were shown in Table 2.

Table 2. KOOS, range of motion, thigh circumference, patellar morphology ratio, and Insall-Salvati Index results in comparison with uninjured knee

	Injured (n = 42) (mean, SD)	Uninjured (n = 42) (mean, SD)	p
KOOS functional results (points)			
Symptoms	72.3 ± 18.8	89.8 ± 13.5	< 0.01
Pain	70.4 ± 20.0	89.4 ± 13.9	< 0.01
ADL	72.1 ± 18.6	90 ± 13.1	< 0.01
Sports/recreation	61.4 ± 24	84.8 ± 19.3	< 0.01
QOL	67.9 ± 19.9	86.2 ± 17.3	< 0.01
Range of motion (°)			
Flexion°	$126.2^\circ \pm 9.4$	$135.4^\circ \pm 6.0$	< 0.01
Extension°	0°	0°	-
Thigh circumference (cm)	49.6 ± 5.9	50.0 ± 5.8	0.77
Patellar Morphology Ratio	1.5 ± 0.2	1.4 ± 0.1	< 0.01
Insall-Salvati Index	0.9 ± 0.2	1.0 ± 0.1	< 0.01
SD: Standart Deviation, °: Degree, KOOS: Knee Injury and Osteoarthritis Outcome Score, ADL: Activities of Daily Living, QOL: Quality of Life, Uninjured: Contralateral healthy knee, p: level of significance.			

Implant irritation, flexion deficit more than 5°, malunion, patella baja, and elongated patella were the major complications. Regarding implant irritation, there were four patient groups: those who had implant irritation and demanded implant removal (II+IR+ group) (25 patients, 59.5%), those who had implant irritation but were satisfied and did not demand implant removal (II+IR- group) (3 patients, 7.1%), those who had no implant irritation and did not demand implant removal (II-IR- group) (10 patients, 23.8%), and those who demanded implant removal even if they did not have implant irritation (II-IR+ group) (4 patients, 9.5%). The study group had no nonunion, infection, or wound complication. Reoperation/refixation was recommended for all patients with malunion in the early postoperative period, especially for patients with malreduction. None of them accepted this proposal because either they were satisfied with their condition or due to the fear of a second surgery, or due to a loss of confidence in the surgeon performing the surgery. All reduction losses were due to implant failure.

K wire migration was seen in two patients, and cerclage stripping off from K wires was seen in the other two patients. All four patients with reduction loss were offered revision surgery, but none accepted this offer. They were satisfied with their condition. Malunion developed in these patients, but nonunion was observed in none of them. Complication profile and reoperation results were demonstrated in Table 3.

Complications	(n, %)
Implant irritation	28 (66.7%)
Malunion	17 (40.5%)
Reduction loss	4 (9.5%)
Malreduction	13 (31%)
Patella Baja	7 (16.7%)
Elongated patella	7 (16.7%)
Flexion deficit more than 5°	26 (61.9%)
Thigh circumference difference > 2 cm	1 (2.4%)
Patients with at least one complication	28 (66.7%)
Reoperation	29 (69.1%)
Implant removal	29 (69.1%)
With implant irritation demanding removal	25 (59.5%)
Without implant irritation demanding removal	4 (9.5%)

According to the KOOS, ROM, TC, PMR, and ISI results, there were no differences between sex, side, or fracture type groups (all $p > 0.05$). The statistically significant results were observed between the patients with and without complications regarding flexion degree and KOOS subscales (all $p \leq 0.01$). There were statistically significant differences in all KOOS subscales and knee flexion degrees between patients with and without malunion (all $p < 0.05$). There were statistically significant differences in all KOOS subscales and knee flexion degrees between patients with and without elongated patella (all $p < 0.05$). There were statistically significant differences in all KOOS subscales between patients with and without flexion loss (all $p < 0.05$). There was a statistically significant difference in flexion degree between patients with and without implant irritation ($p < 0.01$). The comparison of KOOS, ROM, TC, PMR, and ISI results between sex, side, complication, and fracture type groups was given in Table 4.

	Sex (Male vs Female)	Side (Left vs Right)	Complications (Patients with complications vs without complications)	Fracture Type (AO-A1 vs C1 vs C2 vs C3)
KOOS functional results				
Symptoms (points) (mean ± SD vs mean ± SD)	p: 0.15 (74.9 ± 19.1 vs 63.9 ± 15.3)	p: 0.19 (68.3 ± 17.8 vs 75.9 ± 19.2)	p < 0.01 (68.3 ± 17.8 vs 75.9 ± 19.2)	p: 0.17 (71.2 ± 17.7 vs 74.6 ± 20.3 vs 85.7 ± 13.1 vs 64.5 ± 17.4)
Pain (points) (mean ± SD vs mean ± SD)	p: 0.23 (72.8 ± 20.9 vs 62.5 ± 14.9)	p: 0.11 (65.2 ± 19.5 vs 75.0 ± 19.7)	p: 0.01 (61.9 ± 14.8 vs 87.1 ± 18.7)	p: 0.17 (69.1 ± 17.5 vs 73.6 ± 21.2 vs 83.8 ± 14.7 vs 61.2 ± 19.5)
ADL (points) (mean ± SD vs mean ± SD)	p: 0.16 (74.7 ± 19.0 vs 63.6 ± 14.5)	p: 0.22 (68.1 ± 17.1 vs 75.7 ± 19.4)	p < 0.01 (64.3 ± 13.3 vs 87.7 ± 18.0)	p: 0.17 (70.2 ± 17.3 vs 74.2 ± 20.4 vs 85.5 ± 13.2 vs 65.0 ± 16.8)
Sports/recreation (points) (mean ± SD vs mean ± SD)	p: 0.28 (64.0 ± 26.1 vs 53.0 ± 12.7)	p: 0.39 (57.0 ± 22.0 vs 65.4 ± 25.5)	p < 0.01 (50.8 ± 15.4 vs 82.5 ± 24.6)	p: 0.38 (56.6 ± 23.1 vs 63.4 ± 27.0 vs 77.0 ± 22.8 vs 55.8 ± 20.0)
QOL (points) (mean ± SD vs mean ± SD)	p: 0.12 (70.7 ± 21.5 vs 58.7 ± 9.8)	p: 0.13 (62.8 ± 19.4 vs 72.4 ± 19.6)	p: 0.01 (59.5 ± 12.5 vs 84.3 ± 22.0)	p: 0.24 (63.1 ± 17.2 vs 66.7 ± 24.4 vs 82.5 ± 16.7 vs 66.6 ± 15.1)
Range of motion				
Flexion° (mean ± SD vs mean ± SD)	p: 0.09 (127.5 ± 9.6 vs 122.0 ± 7.5)	p: 0.78 (125.7 ± 7.4 vs 126.5 ± 11.0)	p < 0.01 (121.7 ± 7.0 vs 135.0 ± 7.0)	p: 0.11 (123.8 ± 7.4 vs 126.8 ± 10.4 vs 135.0 ± 3.5 vs 123.3 ± 9.3)
Extension° (mean ± SD vs mean ± SD)	-	-	-	-
Thigh circumference (cm) (mean ± SD vs mean ± SD)	p: 0.94 (49.5 ± 5.9 vs 49.8 ± 6.0)	p: 0.32 (48.5 ± 4.8 vs 50.6 ± 6.7)	p: 0.99 (49.7 ± 6.0 vs 49.5 ± 6.0)	p: 0.72 (47.6 ± 5.1 vs 49.6 ± 5.9 vs 50.8 ± 6.9 vs 50.6 ± 6.4)
Patellar morphology ratio (mean ± SD vs mean ± SD)	p: 0.90 (1.45 ± 0.17 vs 1.43 ± 0.13)	p: 0.63 (1.43 ± 0.14 vs 1.47 ± 0.17)	p: 0.89 (1.47 ± 0.19 vs 1.40 ± 0.05)	p: 0.16 (1.47 ± 0.18 vs 1.44 ± 0.12 vs 1.34 ± 0.04 vs 1.48 ± 0.21)
Insall-Salvati Index (mean ± SD vs mean ± SD)	p: 0.99 (0.89 ± 0.19 vs 0.89 ± 0.19)	p: 0.20 (0.91 ± 0.22 vs 0.87 ± 0.15)	p: 0.08 (0.85 ± 0.21 vs 0.97 ± 0.10)	p: 0.41 (0.79 ± 0.25 vs 0.91 ± 0.17 vs 0.93 ± 0.12 vs 0.91 ± 0.16)
KOOS: Knee Injury and Osteoarthritis Outcome Score, ADL: Activities of Daily Living, QOL: Quality of Life, vs: versus, SD: standart derivation, p: level of significance.				

DISCUSSION

The study's most important finding was that considering the mid-term results of patellar fractures treated surgically with TBW, the clinical and radiological results were significantly worse than the contralateral healthy knee, despite all fractures achieving union. These findings were consistent with Lebrun's study (10), which demonstrated 62 points for pain, 65 points for symptoms, 67 points for activities of daily living, 44 points for sports/recreation, and 44 points for the quality of life in KOOS subscale scores with a mid-term follow-up. We attribute these poor results to the subcutaneous location of the patella, the small amount of prepatellar soft tissue covering the anterior compartment of the knee, initial chondral injury, and residual joint incongruity, as previous studies mentioned (18, 19). The second most important finding of the study was implant irritation, knee flexion deficit, malunion, and patella baja were the major complications. The third most important finding of the study was that the patellar fractures were prone to developing elongated patella.

The complication, the reoperation, and the implant irritation rates of TBW surgery for patella fractures vary among studies, but they were reported as high as 75%, 58%, and 48% in the literature, respectively (20). Similarly, the complication and the reoperation rates were high due to the high implant irritation rate (the major complication) in this study. Therefore, with implant irritation a significant problem, it is clear that new fixation methods are needed for patellar fractures.

The second major complication of this cohort was the flexion deficit. There was a flexion deficit (injured knee mean flexion angle: $126.2^\circ \pm 9.4$, healthy knee mean flexion angle: $135.4^\circ \pm 6.0$) of more than 5° in 61.9% of patients treated with TBW compared to the contralateral healthy knee. We attribute this deficit to the decrease in rehabilitation efficiency due to the patients' pain caused by implant irritation. Unsurprisingly, there was a statistically significant difference in flexion degree loss between patients with and without implant irritation ($p < 0.01$). Lin et al. (12), Chiang et al. (20), and Mao et al. (21) reported similar decreased flexion degrees ($136.9^\circ \pm 11.0$, $132.1^\circ \pm 8.5$, and $115.0^\circ \pm 12.8$, respectively) after TBW surgery. There were statistically significant differences in all KOOS subscales between patients with and without flexion loss (all $p < 0.05$). It's evident that the flexion degree affects the

functional outcomes. None of the patients in this cohort had an extension deficit. Thus, we speculate that none of the patients were observed to have an extension deficit because all fractures achieved union.

The third most common complication observed in this study was malunion, with a rate of 40.5%. This is the first study to report malunion of patella fractures after TBW. Malunion was caused by two reasons: initial malreduction or gradual reduction loss. K wire migration and cerclage stripping off from K wires, in short, implant failure caused the aforementioned reduction loss. Malreduction occurred due to failure to achieve anatomic reduction during surgery. This failure was because fluoroscopy was not appropriately used to obtain a true lateral and AP view of the patella, some fractures were multi-fragmented, or the surgeon accepted non-anatomical reduction after trying anatomical reduction many times (intraoperative surgeon exhaustion). There were statistically significant differences in all KOOS subscales and knee flexion degrees between patients with and without malunion (all $p < 0.05$). Therefore, reduction loss/malreduction and the resulting malunion should be avoided.

In terms of KOOS, ROM, TC, PMR, and ISI results, there was no difference between female-male patients, left-right knees, and interestingly AO-A1/C1/C2/C3 fracture types. Besides, there were statistically significant differences between patients with or without complications in KOOS and ROM results. Surprisingly, despite the surgeons in our clinic expecting worse outcomes in comminuted fractures, the results were similar. We think the similar results can be attributed to two reasons: the reduction quality and the occurrence of complications. Given the results, a patient with an anatomically reduced comminuted patella fracture would likely have as good clinical outcomes as a patient with a simple patella fracture unless a complication develops. Here, considering the complication rates, it is necessary to focus on implant irritation as it was the major complication. Despite achieving anatomic reduction is at the hands of surgeons, the reason for implant irritation is unclear. We speculate that the skin-patella distance and the length of the K-wires outside the patella may be important. The assessment of this problem is beyond the scope of this study and requires further studies.

Although there are studies reporting patella baja after patella fracture in the literature, there is no study reporting an elongated patella case. After a patella fracture, the reported Patella Baja rate is up to 43.9% (22, 23). Our rate of patella baja (16.7%) is within this limit. It has also been reported that patella baja does not affect clinical results in the short term (22).

We observed elongated patella for seven (16.7%) of our patients. Of these seven patients, three had AO 34-C3 type fracture, two had AO 34-C1 type fracture, and the other two had AO 34-A1 type fracture. All of the patients with elongated patella also had patella baja. There were statistically significant differences in all KOOS subscales and knee flexion degrees between patients with and without elongated patella/patella baja (all $p < 0.05$). Thus, elongated patella/patella baja should be avoided for patellar fractures. This is the first study reporting elongated patella after patellar fractures. The only research in the literature about elongated patella is reported by Visuri et al. (14). In that study, it is speculated that patients with Osgood-Schlatter disease may exhibit elongated patella, which is thought to result from long-standing tension of the extensor apparatus during the growth spurt. Given the results of our study, patella fractures seemed to be the second reason for the elongated patella.

The major limitations of this study were the retrospective design, the small size of the cohort, the lack of presentation of long-term results, and the use of the contralateral healthy knee as the control group (rather than a different fixation technique such as TBW with cannulated screws, or rather than a different fixation device such as patella plates). Also, more than one surgeon performed the surgeries. The positive aspect of the current study was the presentation of the complications in a detailed manner with radiological and clinical results. Besides, this is the first study to define and address the issues of patellar malunion and elongated patella.

CONCLUSION

The mid-term clinical results of patellar fractures treated with TBW were significantly worse than the contralateral healthy knee. Implant irritation, knee flexion deficit, malunion, and patella baja were the significant complications, and efforts should be made to manage these problems. Patellar fractures are susceptible to developing interesting cases of the elongated patella.

DECLARATIONS

Conflict of Interest

The authors have not declared any conflicts of interest.

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Effect of Treatment Modality on Mobility and Quality of Life in Unstable Intertrochanteric Fractures

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ABSTRACT

Purpose: The aim of the study was to investigate mobility and quality of life in patients who underwent osteosynthesis with proximal femoral nail (PFN), or arthroplasty for unstable intertrochanteric fractures.

Methods: Treatment outcomes of 117 patients (76 Female/41 Male) who were treated with PFN (Group 1, n=66), hemiarthroplasty (Group 2, n=42), or total hip arthroplasty (Group 3, n=9) between 2008 and 2014 were retrospectively evaluated. The mobility of the patients was evaluated with the Palmer and Parker mobility score, and the quality of life was evaluated with the Barthel quality of life index.

Results: The mean ages in the groups were 83.51 (range, 75-97) years, 84.72 (range, 75-109) years, and 83.37 (range, 75-94) years; respectively. The mean follow-up periods were 23.26 (range, 3-43.9) months, 19.24 (range, 3-38) months, and 20.1 (range, 3-40) months; respectively. There was no statistically significant difference between the 3 groups in terms of age and follow-up time (p>0.05). Palmer-Parker mobility scores were 6.23 for Group 1, 3.68 for Group 2, and 4.22 for Group 3. Barthel Indexes were 68.73 for Group 1, 37.75 for Group 2, and 52.77 for Group 3. Group 1 had a statistically significantly higher Palmer-Parker mobility and Barthel Index score than Group 2 and Group 3 (p<0.001).

Conclusion: We concluded that osteosynthesis with PFN was more advantageous than hemiarthroplasty or total hip arthroplasty in terms of mobilization and quality of life in patients who were operated on for unstable intertrochanteric fracture.

Keywords: intertrochanteric fracture, proximal femoral nail, hemiarthroplasty, total arthroplasty, mobility, quality of life

İnstabil İntertrokanterik Kırıklarda Tedavi Yönteminin Mobilite ve Yaşam Kalitesine Etkisi

ÖZET

Amaç: Bu çalışmanın amacı instabil intertrokanterik kırıklarda proksimal femur çivisi (PFN) ile osteosentez veya artroplastik tedavilerinin mobilite ve yaşam kalitesini üzerine etkilerini araştırmaktır.

Yöntem: 2008-2014 yılları arasında PFN (Grup 1, n=66), hemiarthroplastisi (Grup 2, n=42) veya total kalça artroplastisi (Grup 3, n=9) ile tedavi edilen 117 hastanın (76 Kadın/41 Erkek) tedavi sonuçları restrospektif olarak değerlendirildi. Hastaların mobiliteyi Palmer ve Parker mobilite skoru ile, yaşam kaliteleri Barthel yaşam kalitesi indeksi ile değerlendirildi.

Bulgular: Grup 1, Grup 2 ve Grup 3'te ortalama yaşlar sırasıyla 83.51 (aralık, 75-97) yıl, 84.72 (aralık, 75-109) yıl ve 83.37 (aralık, 75-94) yıl idi. Ortalama takip süreleri sırasıyla 23.26 (aralık, 3-43.9) ay, 19.24 (aralık, 3-38) ay ve 20.1 (aralık, 3-40) ay idi. Her 3 grup arasında yaş ve takip süresi açısından istatistiksel anlamlı fark yoktu (p>0.05). Palmer-Parker mobilite skoru Grup 1 için 6.23, Grup 2 için 3.68 ve Grup 3 için 4.22 idi. Barthel indeksi Grup 1 için 68.73, Grup 2 için 37.75 ve Grup 3 için 52.77 idi. Grup 1, Grup 2 ve Grup 3'e kıyasla istatistiksel olarak anlamlı daha yüksek Palmer-Parker skoru ve Barthel indeksi değerine sahip idi (p<0.001).

Sonuç: İnstabil intertrokanterik kırık nedeniyle opere edilen hastalarda PFN ile osteosentezin hemiarthroplastisi ve total kalça artroplastisine göre mobilizasyon ve yaşam kalitesi açısından daha avantajlı olduğu sonucuna varılmıştır.

Anahtar kelimeler: intertrokanterik kırık, proksimal femur çivisi, hemiarthroplastisi, total artroplastisi, mobilite, yaşam kalitesi

The incidence of hip fractures has been increasing in parallel with the aging population. The worldwide incidence was 1.6 million in the years of 2000s, and it is expected to be 2.6 million worldwide by the year 2025 (1, 2). Hip fracture is an important health issue associated with higher mortality, loss of function, and lower quality of life (3, 4). One-year mortality with proximal femoral nail is 24.24%, while it may reach to 60% with hemiarthroplasty (5, 6). On the other hand, regression in mobility due to surgical treatment leads to a lifestyle dependent on the help of others (4, 7). Only half of the patients, who can walk without help before fracture, can maintain an independent life after treatment (8).

The traditional approach, in effect for a long time, includes arthroplasty for collum femoris fractures and osteosynthesis for intertrochanteric fractures in order to provide early mobilization of a patient. Nonetheless, osteosynthesis with proximal femoral nail (PFN) can be applied in treatment of unstable intertrochanteric fractures, or arthroplasty can be applied in severe comminuted fractures with previous symptomatic coxarthrosis or in osteoporotic bones which are not suitable for internal fixation. However, to our knowledge, a limited number of studies compared these two different treatment approaches in terms of mobility and function (9). Unstable intertrochanteric fractures are important due to increasing incidence, obscure ideal treatment options, and significant impairment of return to active life despite treatment. In this study, we performed a functional evaluation of surgical outcome in unstable intertrochanteric fractures, and we tried to provide help to surgeons who experience difficulty during decision making process of ideal treatment.

MATERIALS AND METHODS

In this retrospective study, patients older than 75 years with hip fractures who were admitted to the hospital between April 2008 and March 2014 were analyzed. 117 patients with AO 31A-2.2, 31A-2.3, 31A-3 and Evans-Jensen type 3-4-5 intertrochanteric fracture (Male/Female, 41/76) were included to the study. Exclusion criteria were age below 75 years, pathological fracture, renal osteodystrophy, polytrauma, and less than 3 months follow-up (Table 1).

The mean follow-up of patients was 19.06 (range, 3-43.9) months. Group 1 consisted of 67 patients with an intertrochanteric femoral fracture who were treated by PFN (Proximal Femoral Nail Antirotation Surgical Technique DePuy Synthes); Group 2 consisted of 42 patients who were treated with cemented bipolar hemiarthroplasty

(Echelon Primary Hip System, Smith & Nephew); and Group 3 consisted of 8 patients who were treated by cemented total hip arthroplasty (Echelon Primary Hip System, Smith & Nephew). All surgical procedures were performed in the same center. All patients received low molecular weight heparin during postoperative 4 weeks as prophylaxis for embolism. Preoperative cefazolin prophylaxis (2x 1g) was given half an hour before surgery. All patients underwent preoperative AP hip x-ray imaging; standard AP x-ray imaging of both hips was also performed on the same day after surgery. All patients achieved to sit at bed edge on postoperative 1st day and to walk by the aid of crutches on postoperative 2nd day. Full weight-bearing was permitted on the postoperative 2nd day in arthroplasty patients, and in the postoperative 4th week in PFN patients.

Table 1. Exclusion Criteria

Age below 75 years
Pathological fracture
Renal osteodystrophy
Polytrauma
Less than 3 months follow-up

The mean age in Group 1, Group 2, and Group 3 were 83.51 (range, 75-97) years, 84.72 (range, 75-109) years, and 83.37 (range, 75-94) years; respectively, whereas the mean follow-up periods were 23.26 (range, 3-43.9) months, 19.24 (range, 3-38) months, and 20.1 (range, 3-40) months. The study groups were comparable in terms of age, gender, and follow-up period ($p>0.05$) (Table 2).

Table 2. Characteristics of Patients with Unstable Intertrochanteric Hip Fractures

	Mean age (year)	Follow-up period (month)	Gender
Group 1	83,51 (range, 75-97)	23.26 (range, 3-43.9)	44 F / 23 M
Group 2	84,72 (range, 75-109)	19.24 (range, 3-38)	27 F / 15 M
Group 3	83,37 (range, 75-94)	20.1 (range, 3-40)	5 F / 3 M
P value	$p>0.05$	$p>0.05$	$p>0.05$

Mobility was evaluated by the Palmer-Parker mobility score, and quality of life was evaluated by the Barthel quality of life index (Barthel Index) in the groups (10, 11) (Table 3 and 4). Data were obtained by control visits and phone interviews.

Table 3. Palmer-Parker Mobility Score. Assessment of Mobility After the Treatment. Score is the Total, 0 to 9

Mobility	No difficulty	With an aid	With help from another person	Not at all
Able to get about to house	3	2	1	0
Able to get out of the house	3	2	1	0
Able to go shopping	3	2	1	0

Table 4. The Barthel Index is a Scoring System for Evaluating Mobility, Life Quality and Self-care

Task	With help	Independent
Feeding	5	10
Moving from wheelchair to bed	5-10*	15
Personal toilet (wash, shave, comb)	0	5
Getting on / off toilet	5	10
Bathing	0	5
Walking on level surface	10	15
Ascend, descend stairs	5	10
Dressing	5	10
Controlling bowels	5	10
Controlling bladder	5	10

*5= independent in wheelchair
*10=Either some minimal verbal or physical help is needed in activity

Statistical Analysis

Comparisons among the three groups were performed by One-way ANOVA for variables with normal distribution, and by non-parametric Kruskal Wallis test for variables without normal distribution. Significance level was adjusted to $p < 0.05$. SPSS 22.0.0.0 software was used (IBM, Chicago, IL, USA).

RESULTS

Palmer-Parker mobility scores and Barthel Index were compared among the groups. Palmer-Parker mobility scores were as follows: 6.23 for Group 1, 3.68 for Group 2, and 4.22 for Group 3 (Table 5). In addition, Barthel Indexes were as follows: 68.73 for Group 1, 37.75 for Group 2, and 52.77 for Group 3 (Table 5). PFN group (Group 1) had significantly higher Palmer-Parker mobility and Barthel Index values than groups who underwent cemented bipolar hemiarthroplasty (Group 2) or cemented total hip arthroplasty (Group 3) ($p < 0.001$).

Table 5. Mobility and Quality of Life Scores in Terms of Treatment Modality

	Palmer-Parker Mobility Score	Barthel Index
Group 1	6.23	68.73
Group 2	3.68	37.75
Group 3	4.22	52.77
P value	$P < 0.001$	$P < 0.001$

Furthermore, other factors which affected functionality and quality of life were analyzed. An analysis based on the type of anesthesia revealed that the Palmer-Parker mobility score and Barthel Index were significantly higher in patients who had spinal anesthesia compared to general anesthesia ($p = 0.011$ and $p = 0.009$, respectively). Gender and age were not significant factors in terms of these two scoring systems (for Palmer-Parker mobility score, $p = 0.631$ and $p = 0.16$; for Barthel Index, $p = 0.5$ and $p = 0.72$). When the patients were analyzed according to lower versus higher ASA scores, there was no significant relationship between ASA score and Palmer-Parker mobility score ($p = 0.63$). However, a higher ASA score was found to be related to a lower Barthel Index score ($p = 0.02$).

DISCUSSION

With the prolongation of human life, the clinical importance of hip fractures is increasing. This is because hip fractures are associated with high mortality and morbidity, have a significant adverse effect on mobilization, have high treatment costs and a substantial majority of patients become help-dependent after treatment (4, 12, 13).

Hip fractures include collum femoris fractures, intertrochanteric fractures, subtrochanteric fractures, and femoral head fractures (14). Among these, the most common type is collum femoris fracture and its gold standard treatment approaches have been clearly identified compared to intertrochanteric fractures (14, 15). Intertrochanteric fractures, which are the second most common type, are classified into two groups as stable and unstable fractures according to the Evans-Jensen classification (Figure 1). In this classification, the fracture line starts from the trochanter major and extends to the inferomedial part, but posteromedial cortex, lateral cortex, and trochanter minor are spared and in stable fractures (16). Many clinical studies reported that osteosynthesis is the ideal treatment for stable intertrochanteric fractures (17). Again, according to Evans-Jensen's classification, unstable fractures include loss of lateral cortex unity, comminuted posteromedial cortex, displaced trochanter minor, and reverse oblique fractures with fracture line extending from medial cortex to lateral and distal (16). Osteosynthesis and arthroplasty are treatment choices in unstable intertrochanteric fractures and few studies compared both interventions in terms of patient mobility, return to daily life, and quality of life (17, 18).

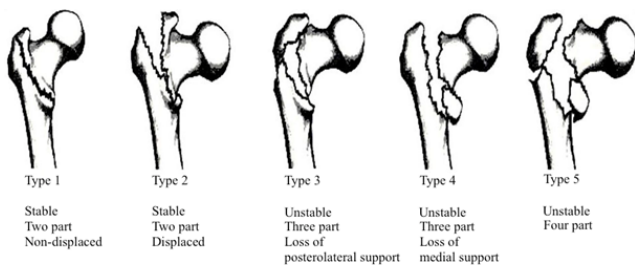


Figure 1. Evans-Jensen Classification

Palmer-Parker compared their own mobility score to mental scoring in order to estimate mortality in patients with a proximal femoral fracture (10). In this mobility scoring system; the patient's ability to perform activities such as mobilization at home, going out of the house, going shopping, and the need for assistance for these activities were taken into account (Table 3). Although they defined the mobility test to be superior to the mental test in predicting 1-year mortality, the mobility test described by Palmer and Parker has been used in many studies in the functional evaluation of hip fracture patients (19, 20).

Barthel Index assesses activities such as feeding, bathing, grooming, dressing, toilet use, transfers (bed to chair and back), and functions of bowels and bladder in addition to patient mobilization (Table 4) (11). Therefore, it is a useful scoring system for the evaluation of a patient's quality of life. Its validity, reliability, and sensitivity have been shown; and its usage has been widely accepted in especially geriatric patient populations (21, 22, 23).

In this study, the Palmer-Parker mobility score and Barthel Index were compared in different surgical approaches. PFN group (Group 1) had a significantly higher Palmer-Parker mobility score and Barthel Index score when compared to cemented hemiarthroplasty group (Group 2) and cemented total hip arthroplasty group (Group 3) ($p < 0.001$) ($p < 0.001$) (Table 5). This finding is in parallel to the findings of Desteli et al., who reported higher mobility scores in osteosynthesis patients (9). They compared functional outcomes of the proximal femoral nail and cementless hemiarthroplasty in the treatment of trochanteric fractures by using the Jensen, Palmer-Parker, and EQ-5D index (9).

On the other hand, to the best of our knowledge, there is no study in the literature comparing the effects of different treatments on quality of life in a similar patient population. Cornwall et al. analyzed functional results of treatment in different types of hip fractures, and they used the Functional Independence Measure (FIM) score (24). Functional scores related to living without help were highest in the patient group of non-displaced femoral fracture and were lowest in the patient group of unstable intertrochanteric fracture (24).

Mariconda et al., in their prospective study, examined the change in daily life activities of patients who were surgically treated for hip fractures. They found no significant mobility difference in terms of fracture type or surgery type (25).

The retrospective design of the study, lack of randomization in unstable fracture subtypes when establishing treatment groups, and a small number of patients in the total hip arthroplasty group may be limiting factors in this study. Nevertheless, we believe that this study is important for current orthopedic practice as it is the first and the only study that evaluated functional level and quality of life together in unstable intertrochanteric fractures

treated by osteosynthesis with proximal femoral nail and arthroplasty. Further prospective studies should be performed in similar patient groups with longer follow-up periods.

CONCLUSION

The findings of this study suggest that osteosynthesis with a proximal femoral nail has superior short to mid-term results in terms of functionality, and quality of life compared to cemented bipolar hemiarthroplasty and cemented total hip arthroplasty treatments in patients with an unstable intertrochanteric fracture.

DECLARATIONS

Funding

None

Conflicts of Interest/Competing Interests

None

Ethics Approval

Our study was approved by the Local Ethics Committee of Istanbul University Faculty of Medicine (protocol ID: 2022/977).

Availability of Data and Material

Available upon request.

Authors' Contributions

GK: conceived and designed the analysis, contributed data and analysis tools, performed the analysis, wrote the paper. YB: conceived and designed the analysis, collected the data. MD: collected the data. GP: conceived and designed the analysis, contributed data and analysis tools. AE: conceived and designed the analysis, contributed data and analysis tools. TK: contributed data and analysis tools. MİB: conceived and designed the analysis. ÖY: conceived and designed the analysis.

Other Declarations

This study was presented as an oral presentation at the 25th National Turkish Orthopedics and Traumatology Congress.

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Metabolic Monitoring of the Patients with Serious Mental Illness (SMI) in a Community Mental Health Center (CMHC) During the COVID-19 Pandemic

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ABSTRACT

Purpose: Metabolic monitoring of patients with serious mental illness (SMI) has been interrupted during the COVID-19 pandemic. Our aim in this study is to compare the metabolic parameters of patients at baseline (before pandemic) and 12 months after the COVID-19 pandemic in a community mental health center (CMHC).

Methods: In this retrospective cohort study, we compared the metabolic parameters such as body mass index (BMI), waist circumference (WC), high-density lipoprotein (HDL), atherogenic index of plasma (AIP) at baseline (before pandemic) and 12 months after pandemic.

Results: BMI ($p<0.001$), WC ($p<0.001$), and HDL levels ($p<0.001$) were significantly higher at month 12 when compared with baseline for both schizophrenia ($n=17$) and bipolar disorder ($n=17$) groups. The prevalence of obesity was significantly higher at month 12 when compared with baseline.

Conclusion: Social restrictions and physical inactivity during COVID-19 pandemic cause deteriorating effect on metabolic parameters. BMI, AIP, WC, and fasting glucose can be used for metabolic monitoring. Common vaccination programs and releasing of social restrictions provided opportunities to assess and intervene metabolic health of patients with SMI. Taken into consideration that obesity cause an increased risk of hospitalization, severe disease, and death due to COVID-19 infection, metabolic monitoring of patients with SMI should be done rigorously.

Keywords: COVID-19, Serious Mental Illness, Community Mental Health Center, Metabolic Monitoring, Physical activity

Bir Toplum Ruh Sağlığı Merkezinde (TRSM) İzlenen Ciddi Ruhsal Hastalığı (CRH) Olan Hastaların COVID-19 Pandemisi Döneminde Metabolik Takibi

ÖZET

Amaç: Ciddi Ruhsal Hastalığı (CRH) olan hastaların metabolik izlemi, COVID-19 pandemisi döneminde ciddi düzeyde aksadı. Bu çalışmadaki amacımız, bir Toplum Ruh Sağlığı Merkezindeki (TRSM) hastaların başlangıçtaki (pandemi öncesi) ve COVID-19 pandemisinden 12 ay sonraki metabolik parametrelerini karşılaştırmaktır.

Yöntemler: Bu retrospektif kohort çalışmada, vücut kitle indeksi (VKİ), bel çevresi (BÇ), yüksek yoğunluklu lipoprotein (HDL), aterosjenik plazma indeksi (API) gibi metabolik parametrelerin başlangıç (pandemi öncesi) ve pandemiden 12 ay sonraki değerlerini karşılaştırdık.

Bulgular: VKİ ($p<0,001$), BÇ ($p<0,001$) ve HDL düzeyleri ($p<0,001$) 12. ayda hem şizofreni ($n=17$) hem de bipolar bozukluk ($n=17$) grupları için başlangıca göre anlamlı olarak daha yüksekti. Obezite prevalansı, 12. ayda başlangıca kıyasla önemli ölçüde daha yüksekti.

Sonuç: COVID-19 pandemisi sırasındaki sosyal kısıtlamalar ve fiziksel hareketsizlik metabolik parametreler üzerinde kötüleştirici etkiye neden olmaktadır. Metabolik izlem için VKİ, API, BÇ ve açlık glukozu kullanılabilir. Yaygın aşılama programları ve sosyal kısıtlamaların azaltılması, CRH tanılı hastaların metabolik sağlığını değerlendirmek ve müdahale etmek için fırsatlar sağladı. Obezitenin COVID-19 enfeksiyonuna bağlı hastaneye yatış, ağır hastalık ve ölüm riskinde artışa neden olduğu göz önüne alındığında, CRH tanılı hastaların metabolik izlemi dikkatle yapılmalıdır.

Anahtar Kelimeler: COVID-19, Ciddi Ruhsal Hastalık, Toplum Ruh Sağlığı Merkezi, Metabolik İzlem, Fiziksel Aktivite

Schizophrenia, bipolar disorder, and other psychotic disorders are chronic and severe mental disorders. Worldwide, they are associated with considerable disability and may affect educational and occupational performance. The life expectancy of severe mental illness (SMI) patients is 8 to 32 years shorter than the general population. This is often due to higher rates of smoking, unhealthy diets, antipsychotic drugs that increase the risk for metabolic syndrome, and preventable physical diseases such as cardiovascular disease and infections (1, 2). Hence, metabolic monitoring of SMI patients in a multidisciplinary approach is critical within psychiatric care. There is clear evidence that old-style mental health hospitals are not effective in the management of metabolic and psychological health of SMI patients. Therefore, a community-based mental health model is being adopted all over the world (3).

After the second half of the twentieth century, psychiatric services in Western Europe underwent serious conceptual and structural transformations. Community-based psychiatric services played a key role as a milestone for modern psychiatric treatments. Institutions such as community mental health centers (CMHCs) have been established to provide services to SMI patients. CMHCs implement the holistic approach, which incorporates both mental health and metabolic monitoring, and collaborate with dietitians, family physicians, cardiologists, and endocrinologists in case of a metabolic problem. Social skills training in CMHCs significantly improves psychopathology, functionality, depression level, insight, and drug compliance of SMI patients (3, 4).

The coronavirus disease 2019 (COVID-19) pandemic, which has been going on for more than a year, has also shaken the metabolic balance of the world with the curfew restrictions it has imposed, along with many other challenges (5). The closure of many workplaces, flexible and home office working resulted in decreased organized physical activity, increase in sedentary lifestyle and screen time with the possibility of stress-induced indulgence in high calorie-dense and sugary foods, resulting in higher susceptibility to weight gain (6). In this study, it was stated that the COVID-19 pandemic caused weight gain in one-half of the respondents in their systematic scoping review, in which they examined 19 out of 396 articles conducted using online self-report surveys. In this review, significant weight gain was reported, associated with a 36.3% to 59.6% increase in total food consumption and a 61.4% to 67.4% decrease in physical activities (6).

SMI patients are at higher risk for metabolic syndrome than the general population (7). COVID-19 is known to exhibit a more severe clinical picture in individuals with metabolic syndrome. Increased metabolic risk due to the physical restrictions of the COVID-19 leads to a vicious circle, and the situation becomes more tragic. SMI patients have more diminished and restricted social networks than the general population (8). Social restrictions during the COVID-19 pandemic have diminished the social network of SMI patients through interrupted general health and CMHC services and curfews. COVID-19 pandemic may decline the size of the social network of SMI patients. Researchers have already sounded the alarm on how the COVID-19 pandemic may affect the mental health of the general population, and more specifically, SMI patients (9). Studies on this group of patients who already experience social, psychological, and physical negative outcomes due to the COVID-19 pandemic are not at the desired level yet. Although it is known that metabolic parameters are regularly recorded in many CMHCs, there is no study comparing the metabolic and functional parameters of SMI patients before and after COVID-19. In this study, we aimed to assess changes in metabolic profiles and functionality of patients with SMI who regularly attend the CMHC, which is interrupted by the COVID-19 pandemic. We hypothesized that during the pandemic, there would be substantial changes in lipid profile, weight, waist circumference, and social functioning in patients with SMI.

MATERIAL AND METHODS

Study Design

This retrospective cohort study was conducted in CMHC of Elazığ Mental Health and Diseases Hospital. Patients diagnosed with schizophrenia and bipolar disorder, according to the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5), were included (10).

Inclusion and Exclusion Criteria

537 SMI patients were recruited from the CMHC of Elazığ Mental Health and Diseases Hospital. We included patients who were > 18 years old, had regular medication, had past (before COVID-19 pandemic) and recent (at the end of the first year of COVID-19 pandemic) blood test results, anthropometric parameters, and psychometric measurements. The patients whose medication schedule and doses are stable at least for the last two years were assessed retrospectively from CMHC records between January 2020 and March 2021. The patients with missing data were excluded from the study. The patients with a known history of diabetes and hypertension before the

COVID-19 pandemic, the patients who were hospitalized at the psychiatry clinic in the last year, were excluded from the study. The patients who had a history of alcohol and drug dependence and who had a history of COVID-19 infection were excluded. The flowchart is shown in Figure 1.

Anthropometric, Metabolic, and Psychometric Measurements

Functionality was assessed by the Global Assessment Scale (GAS) and the Personal and Social Performance Scale (PSP). Changes in psychiatric symptoms were assessed by the Brief Psychiatric Rating Scale (BPRS) (11-14). Variables such as body mass index (BMI), waist circumference, fasting glucose, low-density lipoprotein (LDL), high-density lipoprotein (HDL), triglyceride (TG), and total cholesterol (TC) were evaluated. BMI (kg/m^2) was calculated from weight (measured in light clothing without shoes) and height (measured without shoes). BMI groups defined as underweight ($\text{BMI} < 18.5 \text{ kg}/\text{m}^2$), normal weight ($\text{BMI} 18.5\text{-}24.9 \text{ kg}/\text{m}^2$), class I obesity - overweight ($\text{BMI} 25.0\text{-}29.9 \text{ kg}/\text{m}^2$), class II obesity - obesity ($\text{BMI} 30.0\text{-}39.9 \text{ kg}/\text{m}^2$), class III obesity - extreme obesity ($\text{BMI} > 40 \text{ kg}/\text{m}^2$) (15). Waist circumference (cm) was measured from the midpoint between the lowest rib and iliac crest by using a Gulick II tape measuring tape (16). A total of 5-10 ml of venous blood sample was collected every 6 months for routine metabolic monitoring in CMHC. Peripheral venous blood samples were taken one hour after awakening (8.00 am) and when patients are fasting for 12 hours. Blood samples are analyzed without waiting. Assay parameters were evaluated by medical biochemistry specialist. Atherogenic index of plasma (AIP), which is calculated as the logarithm of plasma triglyceride to HDL ratio, has shown an independent association with cardiovascular risk (17).

Biochemical Analyses

Venous blood samples were obtained from the antecubital vein of patients between 8 and 9 a.m. after at least 12 hours of starvation. The samples were centrifuged within 30 minutes and on the same day (4000 rpm for 10 minutes), centrifugation was followed in the Beckman Coulter AU480 Biochemical Auto-Analyser (Beckman Coulter, Inc.; CA, USA) device at our hospital biochemistry laboratory.

Statistical Analyses

Statistical analysis was performed using Windows SPSS 22.0 (Statistical Package for the Social Sciences Inc.). Descriptive statistics and continuous variables were given as mean \pm standard deviation, and categorical variables were given as frequency and percentage. The Chi-square

test was used to analyze the categorical data. Normal distribution suitability was assessed using the Kolmogorov-Smirnov test. Paired Sample T-test was used to compare the measurements at two time points (baseline and month 12) for metabolic and functioning parameters. The Marginal Homogeneity test was used to compare the change in BMI groups between baseline and month 12. A value of less than 0.05 (p-value) was considered statistically significant.

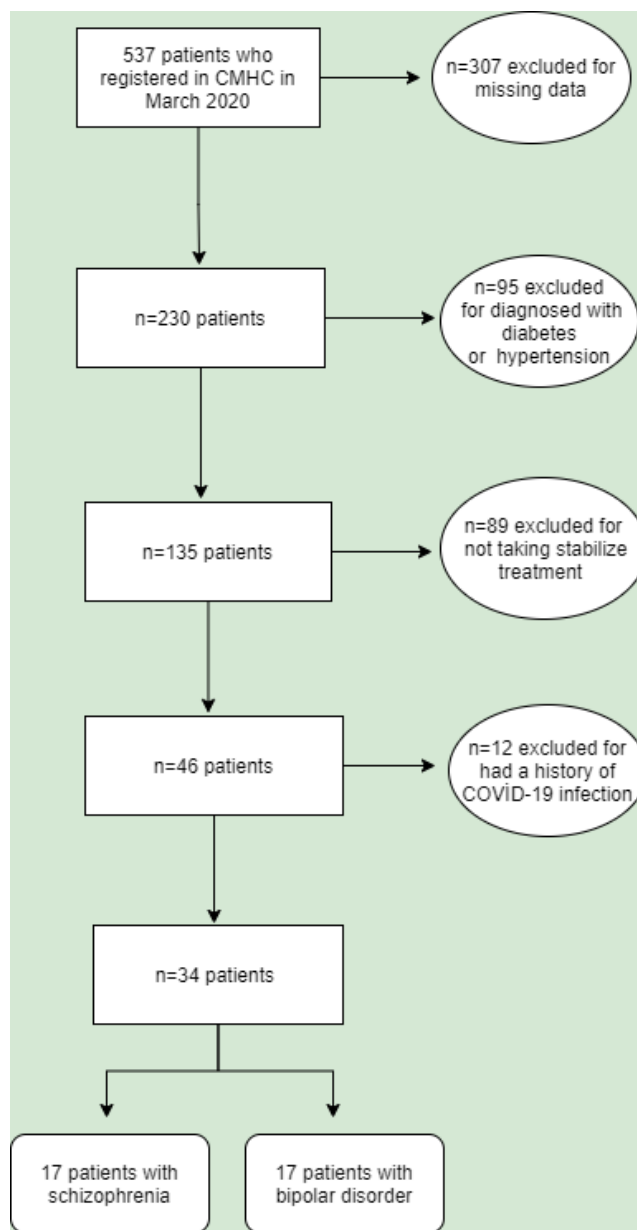


Figure 1. The Flowchart: Selection of Participants

RESULTS

The mean age of participants (n=34) was 42.41±8.25 years (min: 24, max: 58); mean duration of education was 10.32±4.35 years; mean duration of illness was 19.94±7.55 years; mean age at first diagnosis was 22.47±5.36 years; the mean number of hospitalization was 8.91±8.36; the mean number of suicide attempts was 0.41±0.89.

Table 1 shows the comparison of clinical parameters of patients at baseline and month 12. BMI groups of the patients (n=34) at baseline and month 12 are shown in Table 2. Owing to BMI change during one year, six of the patients transited to the higher BMI group (2 patients: normal weight to overweight and 4 patients: overweight to obese). The prevalence of obesity was significantly higher at month 12 when compared with baseline. HDL levels were significantly higher at month 12 when compared with baseline for both smokers and non-smokers.

Parameters	Baseline (n=34) (Mean±SD)	Month 12 (n=34) (Mean±SD)	p value
BMI (kg/m ²)	27.55±4.89	29.21±5.51	<0.001**
Waist Circumference	95.44±12.57	101.52±13.87	<0.001**
Fasting Glucose (mg/dl)	97.9±15.6	96.1±23.5	0.636
HDL (mg/dl)	44.64±13.03	51.08±11.33	<0.001**
LDL (mg/dl)	107.50±29.90	104.82±28.90	0.433
Triglycerides (mg/dl)	164.52±74.21	184.55±103.06	0.185
Total cholesterol (mg/dl)	185.82±39.62	198.32±50.57	0.050
AIP	0.53±0.29	0.51±0.28	0.509
BPRS	14.05±6.46	20.17±9.69	<0.001**
GAS	63.58±12.24	57.97±13.83	<0.001**
PSP	66.55±14.99	58.50±15.29	<0.001**

*p<0.05; **p<0.001; In statistical analysis, Paired Sample T-Test was used; Abbreviations: SD: Standard Deviation; BMI: Body Mass Index; HDL: High-Density Lipoprotein; LDL: Low-Density Lipoprotein; AIP: Atherogenic Index of Plasma; BPRS: Brief Psychiatric Rating Scale; GAS: Global Assessment Scale; PSP: Personal and Social Performance Scale

Clinical parameters of patients with schizophrenia (n=17) were compared between baseline and month 12. BMI (p=0.006), waist circumference (p=0.006), and HDL levels (p=0.006) were significantly higher at month 12 when compared with baseline. Clinical parameters of patients with bipolar disorder (n=17) were compared between baseline and month 12. BMI (p<0.001), waist circumference (p=0.001), and HDL levels (p=0.005) were significantly higher in month 12 compared with baseline.

Table 2. BMI Groups of Patients at Baseline and Month 12

BMI Groups	Baseline (n=34) n (%)	Month 12 (n=34) n (%)	p value
Underweight	1 (%2.9)	1 (%2.9)	0.014*
Normal Weight	10 (%29.41)	8 (%23.52)	
Overweight	13 (%38.23)	11 (%32.35)	
Obese	9 (%26.56)	13 (%38.31)	
Severe Obese	1 (%2.9)	1 (%2.9)	

*p<0.05; In statistical analysis, Marginal Homogeneity test was used; Abbreviations: BMI: Body Mass Index

Patients were divided into two groups as schizophrenia and bipolar disorder as shown in Table 3. The use of a mood stabilizer was significantly higher in bipolar disorder (p<0.001).

The change rates ([Month 12 Value - Baseline Value] / Baseline Value) in clinical and metabolic parameters within one year after the COVID-19 pandemic was compared between schizophrenia and bipolar groups. There was no significant difference between two groups in change rates of BPRS (p=0.709), GAS (p=0.550), PSP (p=0.114) scores, BMI (p=0.224), AIP (p=0.122), LDL (p=0.955), HDL (p=0.426), waist circumference (p=0.375), TC (p=0.206), and TG (p=0.335). The change rates of the clinical and metabolic parameters between baseline and month 12 were compared between employed (n=11) and unemployed (n=23) patients; between married (n=11) and single (n=19); between those who used one or more drugs such as olanzapine, clozapine, quetiapine, and risperidone (n=20) and those who did not use any of these drugs (n=14); between smoking (n=21) and non-smoking (n=13) patients, and no significant difference was found (p>0.05).

DISCUSSION

We found that BMI, waist circumference, and HDL levels significantly increased at the end of the first year of the COVID-19 pandemic when compared with baseline. Our findings showed that at the end of the first year of the COVID-19 pandemic, psychiatric symptoms and functioning deteriorated when compared with baseline. When the schizophrenia and bipolar disorder groups were evaluated separately; BMI, waist circumference, and HDL levels increased in both groups. Change rates of clinical and metabolic parameters in one year after the COVID-19 pandemic were similar between schizophrenia and bipolar disorder groups. We found that employment, marital status, and smoking status did not affect change rates of metabolic and clinical parameters.

Table 3. Comparison of Sociodemographic and Clinical Parameters of Patients with Schizophrenia and Bipolar Disorder

Parameter		Schizophrenia	Bipolar Disorder	p value
Gender	Female	3 (42.9%)	4 (57.1%)	0.671
	Male	14 (51.9%)	13 (48.1%)	
Marital Status	Single	12 (63.2%)	7 (36.8%)	0.209
	Married	4 (36.4%)	7 (63.6%)	
	Widowed	1 (25.0%)	3 (75.0%)	
Living Area	Parent	13 (59.1%)	9 (40.9%)	0.504
	Partner/Child	2 (28.6%)	5 (71.4%)	
	Brother/Sister	1 (50.0%)	1 (50.0%)	
	Alone	1 (33.3%)	2 (66.7%)	
Working Status	Yes	5 (45.5%)	6 (54.5%)	0.714
	No	12 (52.2%)	11 (47.8%)	
Socioeconomic Status	Lower	8 (61.5%)	5 (38.5%)	0.558
	Middle	8 (42.1%)	11 (57.9%)	
	Upper	1 (50.0%)	1 (50.0%)	
Smoking Status	Yes	10 (47.6%)	11 (52.4%)	0.724
	No	7 (53.8%)	6 (46.2%)	
Depot AP Use	Yes	8 (44.4%)	10 (55.6%)	0.492
	No	9 (56.3%)	7 (43.8%)	
Mood Stabilizer Use	Yes	6 (27.3%)	16 (72.7%)	<0.001**
	No	11 (91.7%)	1 (8.3%)	
Oral AP Use	Yes	15 (53.6%)	13 (46.4%)	0.368
	No	2 (33.3%)	4 (66.7%)	
AD Use	Yes	14 (46.7%)	16 (53.3%)	0.287
	No	3 (75.0%)	1 (25.0%)	

**p<0.001; In statistical analysis, Chi-Square Test was used; Abbreviations: AP: Antipsychotic; AD: Antidepressant

The COVID-19 pandemic has caused a more common sedentary lifestyle due to strict rules set by governments. A study showed that 41.8-42.2% of the participants, who exercised regularly before the COVID-19 pandemic, reported a decrease in walking, jogging, and sports during the COVID-19 pandemic (18). According to this study, most of the participants reported an "increase" in watching TV (72.3%), using electronics (82.7%), and logging into social media (81.9%). In another study, which has participants aged 18-35, there was a significant decrease in the physical activities of individuals during the COVID-19 pandemic when compared with before the COVID-19 pandemic, and individuals spent more time on sleep and sedentary activities (19). Besides physical inactivity, unhealthy dietary habits also become more common during the COVID-19 pandemic. A study evaluated the effect of the quarantine during the COVID-19 pandemic on the dietary habits and found that almost half of the respondents (49.4%) ate more than usual, 45.1% increased snacking, and 62.1% cooked at home more often (20). Physical activity and dietary habits have sharply changed in the whole population during the COVID-19 pandemic. SMI patients, who have a greater risk for metabolic problems than the general

population, should be rigorously monitored for metabolic parameters during the COVID-19 pandemic. In our study, we showed that weight gain and abdominal obesity risk of SMI patients increased at the end of the first year of the COVID-19 pandemic. Possible reasons for this increase are thought to be physical inactivity, increasing sedentary lifestyle, and changing dietary habits. Weight gain and abdominal obesity during the COVID-19 pandemic in SMI patients, who have already more metabolic risk than the normal population, may be overlooked due to interruption in the healthcare system. Several studies have shown that obesity is a very important risk factor for hospitalization, severe disease, and death due to COVID-19 infection (21, 22). When taking into consideration the COVID-19 pandemic still goes on, the metabolic health of patients would affect mortality rates due to the COVID-19 infection. COVID-19 vaccination programs provided by health institutions gradually come back to normal. Patients who could not reach to hospital and CMHC during the pandemic may refer after releasing of restrictions. Clinicians should be alert about the deteriorating effects of the COVID-19 pandemic on the weight gain of these patients.

We found a marked deterioration in the general and social functioning levels of SMI patients at the first year of the pandemic when compared with baseline. We found also psychiatric symptoms increased during the first year of the pandemic. These results may be related to social distancing, physical inactivity, difficulty reach to CMHC and hospital during the first year of the pandemic. A study showed that a longer period of social distancing and self-reported history of previous psychiatric disorders were strongly associated with higher severity of psychiatric symptoms (23). Sepúlveda-Loyola et al.'s narrative review including 20.069 individuals from ten descriptive cross-sectional papers demonstrated that the main outcomes of the COVID-19 pandemic were anxiety, depression, and poor sleep quality during the isolation period (24). This situation may lead to the emergence of anxiety and depression problems in addition to their current main psychiatric diagnoses and to worsening of their already poor social functioning. Community-based psychiatric entities such as CMHC help to reduce the social and psychological problems experienced by this patient group (4). Interruption of CMHC services during the pandemic may be related to the decreased social and general functioning of patients.

The most interesting finding in this study is the increased HDL levels detected in patients at the end of the first year of the COVID-19 pandemic when compared with pre-pandemic levels. HDL is synthesized in the liver and intestines and mainly facilitates reverse cholesterol transport, which is a mechanism for removing excess cholesterol from peripheral tissue and delivering them to the liver (25). The long-standing notion that lower HDL levels are directly related to cardiovascular disease has shaken with recent studies. HDL-functionality may have a more important role in atheroprotection than circulating HDL levels (26). In recent studies, there is no clear evidence on the relation of the exercise-HDL level. A study showed that only one meta-analysis showed good quality among 23 meta-analyses on the relation of exercise-HDL levels, the rest had a high risk of bias (27). Research has recently focused on HDL functionality. A study suggested regular and prolonged exercise improves some measures of HDL function (28). Larger studies are needed to determine what dose of exercise needs to provide improvements in HDL levels and function. Taken decreased importance on evaluating the cardiovascular risk of HDL levels when compared with HDL functions, we propose AIP levels instead of HDL levels to assess cardiovascular risk in SMI patients.

AIP is a novel index composed of HDL and triglycerides. AIP, as a biomarker, is an independent risk factor

for coronary artery disease (29). There was no change in AIP levels, which means no increase in cardiovascular risk ratio at the end of the first year of the pandemic. It has been used as an optimal indicator of dyslipidemia and cardiovascular diseases (30). Also, AIP levels use as a predictor of mortality in patients with COVID-19 (31). AIP should be considered when estimating current and future cardiovascular disease risk, along with other traditional risk factors (32). AIP as a predictor for both prognosis of COVID-19 and cardiovascular disease risk may have an important role during the COVID-19 pandemic. As a result, metabolic parameters such as BMI, waist circumference, AIP, fasting glucose should take into consideration for optimal metabolic monitoring of SMI patients.

SMI patients are more vulnerable to infectious diseases due to predisposing metabolic risk factors. Management of abiding by the rules during the pandemic and complying with COVID-19 treatment during infection can be challenging for SMI patients due to lack of insight, insufficient social support. Common vaccination program provides partial renormalization of mental health services. The vaccination status of patients admitted to CMHCs should be followed and hesitation over the vaccination should be dealt with by giving information and correcting the myths about COVID-19 vaccines.

CONCLUSION

Reactivation of mental health services in CMHCs with common vaccination and social distance rules provides an opportunity to detect, assess and intervene with psychosocial and metabolic impacts of the COVID-19 pandemic. Psychiatrists and nurses who work in CHMCs should be alert to the deteriorating effects of the COVID-19 pandemic on metabolic health and keep on metabolic monitoring, which is interrupted during the pandemic. It should be followed whether the COVID-19 vaccine, which is the most effective way to protect against COVID-19 disease, is administered and the hesitation or lack of knowledge of SMI patients in CMHCs about vaccines should be intervened.

The retrospective nature of this study is a significant limitation. There was no objective information about the diet and physical activity habits of the patients during the COVID-19 pandemic. The possible effect of these habits on the results should be investigated in future studies. Although patients using a stable treatment regimen for at least two years were included, the effect of psychotropic drugs on metabolic parameters could not be excluded.

Larger and longitudinal studies are required to assess the effects of the COVID-19 pandemic on metabolic parameters and functioning of CMHCs patients with SMI.

DECLARATIONS

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Conflicts of Interest

The author declares no conflict of interest.

Ethics Approval

All protocols for this study were approved by the Firat University Ethics Committee (Decision No: 2021-07-07).

Authors Contributions

Establishing the main idea and hypothesis of the study: A.B.T. and H.K.; Developing the hypothesis and designing the materials and methods section: A.B.T. and H.K.; Evaluation of data: A.B.T., H.K. and M.H.O.; Writing the introductory part of the article: A.B.T., H.K. and M.H.O.; Writing the conclusion and discussion sections of the article: A.B.T., H.K. and M.H.O.; Writing the draft of the article: A.B.T., H.K. and M.H.O.; Assessing the final version of the article and making necessary corrections: A.B.T., H.K. and M.H.O.

Availability of Data

Available upon request.

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Relationship Between Cognitive Flexibility, Anxiety Sensitivity and Coronaphobia

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ABSTRACT

Objective: In this study, it was aimed to determine relationship two transdiagnostic factors (anxiety sensitivity and cognitive flexibility) between Coronavirus-19 (COVID-19) phobia.

Method: For the study, the forms were sent to social media groups with 4,000 and 3,500 people on social media, and the participants were selected by the simple random sampling method. 280 volunteers who met the inclusion criteria were accepted. Sociodemographic Data Form, Cognitive Flexibility Inventory (CFI), Anxiety Sensitivity Index-3 (ASI-3), COVID-19 Phobia Scale was used to evaluate the volunteers.

Result: 161 male and 101 female volunteers participated in the study. Both sexes have similar characteristics regarding age, marital status, and years of education. In the correlation analyses, positive correlations were found between coronaphobia scale total scores and ASI- physical ($r=.584$), ASI- cognitive ($r=.556$), ASI- social ($r=.524$), ASI-total ($r=.609$), whereas a negative correlation was found between coronaphobia scale total scores and CF-alternatives ($r=-.232$), CF-control ($r=-.375$), CF-total ($r=-.328$). Stepwise regression analysis was applied with ASI and CFI subscales to predict coronaphobia scale scores. According to the results, ASI-physical ($\beta=.287$), ASI-cognitive ($\beta=.178$) positive and CF-control ($\beta=-.148$) negatively predicted coronaphobia total scores significantly ($F(7, 254) = 23,361, p < .01$), with an R^2 of .375

Discussion: Our results were shown that sub-type of transdiagnostic factors were more closely related to coronaphobia and even predicted.

Keywords: coronavirus, anxiety, cognition

“Bilişsel Esneklik, Anksiyete Duyarlılığı ve COVID-19 Fobisi Arasındaki İlişkinin İncelenmesi”

Amaç: Bu çalışmada, Koronavirüs-19 (COVID-19) fobisi ile transdiagnostik faktörler (anksiyete duyarlılığı ve bilişsel esneklik) arasındaki ilişkinin incelenmesi amaçlanmıştır.

Materyal/Method: Araştırma için formlar sosyal medya üzerinden 4.000 ve 3.500 kişilik sosyal medya gruplarına gönderildi. Katılımcılar basit rastgele örnekleme yöntemi ile seçildi, dahil edilme kriterlerini karşılayan 280 gönüllü kabul edildi. Çalışmada Sosyodemografik Veri Formu, Bilişsel Esneklik Envanteri (BEE), Anksiyete Duyarlılık İndeksi-3 (ASI-3), COVID-19 Fobi Ölçeği kullanıldı.

Sonuç: Çalışmaya 161 erkek ve 101 kadın gönüllü katıldı. Her iki cinsiyet de yaş, medeni durum ve eğitim yılı açısından benzer özelliklere sahipti. Korelasyon analizlerinde, koronafobi ölçeği toplam puanları ile ASI-fiziksel ($r=.584$), ASI-bilişsel ($r=.556$), ASI-sosyal ($r=.524$), ASI-toplam ($r=.609$) arasında anlamlı pozitif ilişki, BE-alternatifler ($r=-.232$), BEkontrol ($r=-.375$), BE-toplam ($r=-.328$) arasında anlamlı negatif ilişki bulundu. Yapılan regresyon analizlerine göre, koronafobi puanlarını; ASI-fiziksel ($\beta=.287$), ASI-bilişsel ($\beta=.178$) puanlarının anlamlı pozitif ve BE-kontrol ($\beta=-.148$) puanlarının anlamlı negatif yordadığı saptandı. ($F(7, 254) = 23.361, p < .01$), $R^2:375$

Tartışma: Sonuçlarımız, transdiagnostik faktörlerin bazı alt tiplerinin koronofobi ile daha yakından ilişkili olduğunu, koronafobiyi öngördüğünü gösterdi.

Anahtar kelimeler: koronavirüs, anksiyete, biliş

The coronavirus (COVID-19) pandemic, which broke out in Wuhan, China, and spread rapidly throughout the world, adversely impacted humanity not only physically but also mentally (1,2). While the pandemic is spreading rapidly, it is thought that the physical damage as well as the psychological damage will be substantial, as the virus has the potential to be transmitted easily, there is no known a fully effective treatment and there is a risk of death. (1,3). When the literature is reviewed, it is noticed that outbreaks such as SARS, MERS cause phobic reactions, anxiety, depression, feelings of hopelessness, and hostility, just like natural disasters and wars (4-6). Based on these findings, it is considered that there will be similar outcomes in the COVID-19 pandemic. Considering the processes during and after the COVID-19 pandemic, psychological vulnerability as an important part of developing approaches that can benefit in this area is considered important for taking potential protective measures. As the concern about catching COVID-19 and the processes after it has come to the fore, it is considered crucial to identify psychological risk factors as a part of developing comprehensive approaches in this field to take potential protective measures.

Anxiety sensitivity has been defined as a trait that reflects the tendency to fear the consequences of anxiety. Anxiety sensitivity has been classified into three sub-dimensions: physical, social and cognitive. (7). The concept of anxiety sensitivity was initially considered to be one-dimensional, but as a result of factor analyzes, it was considered as a concept with three sub-dimensions (8). *Physical subtype of anxiety sensitivity*, which is one of these three sub-factors, has been described as being concerned about the consequences of the physical symptoms of anxiety (8). While *cognitive anxiety sensitivity*, which is another sub-factor, has been described as the state of being worried about the loss of cognitive control due to anxiety, the last sub-factor, *social anxiety sensitivity*, has been conceptualized as worrying about the unfavorable social consequences of observing anxiety symptoms by others (8). Previous studies have revealed that anxiety sensitivity is a transdiagnostic factor by associating it with numerous mental illnesses. (9-11). As anxiety sensitivity is openly associated with the assessment of an event and the importance attributed to that status, it has been demonstrated that anxiety sensitivity is a considerable determining factor for increased stress perception (11). Transdiagnostic factors such as anxiety sensitivity are considered to be a key component for elucidating how individuals experience COVID-19-specific fear, anxiety and depression (12). Based on this, it can be suggested that increased anxiety sensitivity might

increase the severity of phobic symptoms associated with COVID-19. In a research, examining the relationship between COVID 19 and anxiety sensitivity, it was determined that high anxiety sensitivity scores were strongly associated with COVID-19 phobia, and particularly the physical sub-dimension of anxiety sensitivity was a significant predictive factor for COVID-19 phobia (12). In a study scrutinizing the predictive factors of COVID-19 anxiety in healthy controls and individuals diagnosed with anxiety disorder in 2020, in both samples, anxiety sensitivity was found to be a significant predictor of COVID-19-related psychiatric diseases, independent of age, sex, chronic diseases, and exposure to COVID-19 (13).

Cognitive flexibility, another transdiagnostic factor, has been described as the ability to adapt thinking to changing environmental conditions (13). Individuals with cognitive flexibility can produce alternative thoughts that are more appropriate for the situation and assess challenging situations as more manageable instead of maladaptive thoughts that cause distress. Cognitive flexibility can also be thought of as a person's capacity to adapt to different situations, to think from multiple angles, or to approach the current problem with different strategies (14). In a crisis such as the outbreak of a life-threatening infectious virus that jeopardizes people's sense of security and well-being, one of the most significant things that could potentially impact the mental well-being of individuals is cognitive flexibility. Cognitive flexibility can be beneficial, particularly when faced with stress that an individual cannot control (15). In the current pandemic environment, which can be considered as an uncontrollable stress factor, cognitive flexibility can play a role as a tool to reframe the understanding of disaster and reconsider behaviors (e.g., hand washing, wearing face masks) that will help reduce their risks. (16,17). The studies analyzing the relationship between cognitive flexibility and COVID-19 phobia are limited. In a study conducted by Kalia et al. in 2020 (18), the relationship between early traumatic experiences, cognitive flexibility, and perceived threat related to COVID-19 was assessed, and it was observed that as cognitive flexibility decreases, the severity of perceived threat related to COVID-19 increases.

In this study, we intended to analyze two basic transdiagnostic factors that might be effective in the emergence of mental problems associated with the COVID-19 pandemic in the Turkish population. For this purpose, we planned to assess the relationship between cognitive flexibility, anxiety sensitivity, and COVID-19 anxiety. The hypotheses of the study;

1. There is a positive correlation between anxiety sensitivity and COVID-19 anxiety.
2. There is a negative correlation between cognitive flexibility and COVID-19 anxiety.

MATERIAL - METHOD

Selection of the Sample Group

For the study, the forms were sent to social media groups with 4,000 and 3,500 people on social media, and the participants were selected by the simple random sampling method. In total, volunteers from a population of 7,500 participated in the study, and an invitation link was sent to the social media groups for the study, along with the information on the research. The participants of the study were informed in detail and it was confirmed whether they volunteered on the first page of the online form. Individuals between the ages of 18-65, who were literate and volunteered to participate were included in the study. Having psychiatric diagnosis and treatment and cognitive disorders (such as mental retardation, dementia) were considered as exclusion criteria. A total of 292 people participated in the study, 12 people were not included in the analyzes due to the shorter than expected questionnaire response time (<5 minutes), and the analyzes were completed with 280 people in this way.

Ethics Committee Approval

Ethics committee approval dated February 17th 2021 and numbered E1-21-1544 was obtained from the Ankara City Hospital Ethics Committee.

Data Collection Tools

Sociodemographic Data Form: It is a form created by researchers that includes sociodemographic characteristics such as age, gender, marital and educational status, occupation, economic status, and clinical data such as psychiatric diagnosis and treatment history, alcohol and substance use history.

Cognitive Flexibility Inventory (CFI): The scale was measures the ability of individuals for generating alternative and compatible ideas in challenging situations (13). This 20-item scale has two subscales: control and alternatives. It is considered that as the score obtained from the scale increases, the cognitive flexibility level of the person increases. The Turkish validity and reliability study of this scale was performed by Gülüm et al., which was developed by Dennis and Vander Wal, was performed by Gülüm et al. (13,19)

Anxiety Sensitivity Index-3 (ASI-3): The scale developed in 2007 evaluates anxiety sensitivity with its dimensions (20). The scale, like the original ASI, consists of 18 items with physical, cognitive, and social sub-dimensions and 6 items in each sub-dimension, and allows a five-point Likert type measurement. The lowest score that can be obtained from the scale is 0, and the highest score is 72. High measure scores on the scale were associated with increased anxiety sensitivity. The Turkish validity and reliability study of the scale was conducted by Mantar et al. (21).

COVID-19 Phobia Scale: The scale developed by Dilbaz et al. (22) in 2020, to assess phobic symptoms related to coronavirus-19. The scale measuring Likert type consists of 22 items. The lowest score that can be obtained from the scale is 22, and the highest score is 110. Based on the factor analysis, it was found that the scale consists of 4 sub-dimensions. These dimensions include anxiety, mood, reassurance/precaution-taking, and avoidance.

Statistical Analysis

Data were analyzed using the software of Statistical Package for Social Sciences (SPSS) version 15.0. Numerical variables were analyzed as a percentage and standard deviation. Correlations between scale scores were analyzed via the Pearson correlation method. Stepwise regression analyzes were carried out to assess the predictors of the COVID-19 phobia scale score. The results were considered significant at $p < 0.05$.

RESULTS

Sociodemographic Characteristics and Scale Scores

While 61.5% (N:161) of the volunteers included in the study were male, 38.5% (101) were female. The marital status, years of education and the scale scores of the participants are given in the related table (Table 1).

The sociodemographic data and scale scores of the volunteers participating in the study were compared in terms of being male and female. Both sexes have similar characteristics regarding age, marital status, and years of education. When the scale scores were compared, it was determined that anxiety sensitivity and coronaphobia scores were similar, whereas there was a significant difference in terms of cognitive flexibility scores (Table 2).

Table 1. Sociodemographic Characteristics and Scale Scores	
Age Mean ± SD	39.5 (± 9.95)
Sex n(%)	
Male	161 (61.5%)
Female	101 (38.5%)
Marital status n(%)	
Married	189 (72.4%)
Single	61 (23.4%)
Other	11 (4.2%)
Years of education Mean ± SD	15.2 (± 2.9)
ASI-physical Mean ± SD	8.42 (± 5.82)
ASI-cognitive Mean ± SD	6.26 (± 5.44)
ASI-social Mean ± SD	8.50 (± 5.49)
ASI-total Mean ± SD	23.18 (± 15.28)
CFI-alternative Mean ± SD	56.31 (± 6.05)
CFI-control Mean ± SD	26.14 (± 5.11)
CFI-total Mean ± SD	82.45 (± 10.13)
COVavoidance Mean ± SD	7.53 (± 1.87)
COVmood Mean ± SD	7.79 (± 2.70)
COVareas Mean ± SD	23.63 (± 5.20)
COVworry Mean ± SD	31.25 (± 9.08)
COVtotal Mean ± SD	70.21 (± 16.58)
<p><i>SD: Standard Deviation, ASI-physical: Anxiety Sensivity Physical, ASI-cognitive: Anxiety Sensivity Cognitive, ASI-social: Anxiety Sensivity Social, AStotal: Anxiety Sensivity total score, CFalternative: Cognitive Flexibility Alternative, CFI-control: Cognitive Flexibility Control, CFI-total: Cognitive Flexibility total score, COVavoidance: COVID-19 Phobia Avoidance, COVmood: COVID-19 Phobia Mood, COVareas: COVID-19 Phobia Areas, COVworry: COVID-19 Phobia Worry, COVtotal: COVID-19 Phobia total score.</i></p>	

Table 2. Sociodemographic Characteristics and Scale Scores Compared in Male And Female			
	Female	Male	P
Your age? Mean ± SD	41 ± 11	39 ± 9	.187
Your marital status? n(%)			.784
Married	71 (70.3%)	119 (73.9%)	
Single	25 (24.8%)	36 (22.4%)	
Other	5 (5.0%)	6 (3.7%)	
Years of education Mean ± SD	15 ± 3	15 ± 3	.489
ASphysical Mean ± SD	8.02 (± 5.16)	8.66 (± 6.19)	.364
AScognitive Mean ± SD	5.89 (± 4.83)	6.48 (± 5.80)	.372
ASsocial Mean ± SD	7.99 (± 4.88)	8.83 (± 5.84)	.212
AStotal Mean ± SD	21.90 (± 13.38)	23.98 (± 16.35)	.286
CFalternative Mean ± SD	55.05 (± 5.55)	57.11 (± 6.24)	.007*
CFcontrol Mean ± SD	24.80 (± 4.92)	26.98 (± 5.06)	.001*
CFtotal Mean ± SD	79.85 (± 9.31)	84.08 (± 10.31)	.001*
Coronaavoidance Mean ± SD	7.70 (± 1.78)	7.42 (± 1.92)	.238
Coronamood Mean ± SD	7.87 (± 2.59)	7.74 (± 2.78)	.701
Coronaareas Mean ± SD	23.68 (± 5.51)	23.60 (± 5.02)	.903
Coronaworry Mean ± SD	30.88 (± 9.30)	31.48 (± 8.96)	.602
Coronatotal Mean ± SD	70.14 (± 17.02)	70.25 (± 16.36)	.959
<p><i>SD: Standard Deviation, ASI-physical: Anxiety Sensivity Physical, ASI-cognitive: Anxiety Sensivity Cognitive, ASI-social: Anxiety Sensivity Social, AStotal: Anxiety Sensivity total score, CFalternative: Cognitive Flexibility Alternative, CFI-control: Cognitive Flexibility Control, CFI-total: Cognitive Flexibility total score, COVavoidance: COVID-19 Phobia Avoidance, COVmood: COVID-19 Phobia Mood, COVareas: COVID-19 Phobia Areas, COVworry: COVID-19 Phobia Worry, COVtotal: COVID-19 Phobia total score. statistical analyzes: two samples t-test</i></p>			

Bivariate correlation analyzes were conducted to determine the correlations between the coronaphobia scale/sub-dimensions measuring the severity of coronavirus anxiety, the anxiety sensitivity index/sub-dimensions measuring transdiagnostic factors, and the cognitive flexibility inventory/sub-dimensions in the volunteers participating in the study.

In the correlation analyses, positive correlations were found between coronaphobia scale total scores and ASI- physical (r=.584), ASI- cognitive (r=.556), ASI- social (r=.524), ASI-total (r=.609), whereas a negative correlation was found between coronaphobia scale total scores and CF-alternatives (r=-.232), CF-control (r=-.375), CF-total (r=-.328). (Table 3)

Stepwise regression analysis was applied with ASI and CFI subscales to predict coronaphobia scale scores. According to the results, ASphysical (β=.287), ASCognitive (β=.178) positive and CFcontrol (β=-.148) negatively predicted coronaphobia total scores significantly {F(7, 254) = 23,361, p < .01}, with an R² of .375 (Table 4).

Table 3. Correlation Analyses Between Coronaphobia Scale and Cognitive Features Scale.

		Cavoidance	Cmood	Careas	Cworry	Ctotal
ASphysical	p	.298**	.579**	.449**	.576**	.584**
	r	.000	.000	.000	.000	.000
ASCognitive	p	.234**	.580**	.434**	.546**	.556**
	r	.000	.000	.000	.000	.000
ASSocial	p	.225**	.504**	.457**	.499**	.524**
	r	.000	.000	.000	.000	.000
AStotal	p	.278**	.608**	.490**	.593**	.609**
	r	.000	.000	.000	.000	.000
CFalter-native	p	-.013	-.176**	-.034	-.105	-.100
	r	.826	.003	.575	.080	.093
CFcontrol	p	-.069	-.366**	-.192**	-.315**	-.302**
	r	.253	.000	.001	.000	.000
CFtotal	p	-.042	-.289**	-.115	-.220**	-.211**
	r	.486	.000	.054	.000	.000

ASphysical: Anxiety Sensivity Physical, ASCognitive: Anxiety Sensivity Cognitive, ASSocial: Anxiety Sensivity Social, AStotal: Anxiety Sensivity total score, CFalter-native: Cognitive Flexibility Alternative, CFcontrol: Cognitive Flexibility Control, CFtotal: Cognitive Flexibility total score, COVavoidance: COVID-19 Phobia Avoidance, COVmood: COVID-19 Phobia Mood, COVareas: COVID-19 Phobia Areas, COVworry: COVID-19 Phobia Worry, COVtotal: COVID-19 Phobia total score, statistical analyses: Pearson correlation test.

Table 4. Regression Analyses Between Coronaphobia Scale and Cognitive Features Scale.

	Adjusted R Square	B	SE	β	t	95%CI (LL / UL) for β	p
	.375						
(Constant)		59,655	9,611		6,207	40.728 / 78.582	.000
Your sex?		.066	1,737	.002	.038	-3.355 / 3.487	.970
Your age?		.099	.084	.059	1,173	-.067 / .265	.242
ASphysical		.818	.247	.287	3,306	.331 / 1.305	.001*
ASCognitive		.544	.268	.178	2,028	.016 / 1.071	.044*
ASSocial		.412	.235	.137	1,754	-.051 / .875	.081
CFalter-native		.095	.177	.035	.539	-.253 / .443	.591
CFcontrol		-.480	.226	-.148	-2,124	-.924 / -.035	.035*

LL: Lower Level, UL: Upper Level, ASI-physical: Anxiety Sensivity Physical, ASI-cognitive: Anxiety Sensivity Cognitive, ASI-social: Anxiety Sensivity Social, AStotal: Anxiety Sensivity total score, CFI alternative: Cognitive Flexibility Alternative, CFI control: Cognitive Flexibility Control, CFI total: Cognitive Flexibility total score, COVavoidance: COVID-19 Phobia Avoidance, COVmood: COVID-19 Phobia Mood, COVareas: COVID-19 Phobia Areas, COVworry: COVID-19 Phobia Worry, COVtotal: COVID-19 Phobia total score, statistical analyses: hierarchical regression analyses *p<.05

DISCUSSION

In this study, it was aimed to investigate the transdiagnostic factors that may be associated with COVID-19 anxiety.

One of the hypotheses of our study was that increased anxiety sensitivity levels were a predictive factor for COVID-19 anxiety. In the analyzes performed, it was found that anxiety sensitivity was a considerable predictor of COVID-19 phobia; however, when the subscales were analyzed, it was noticed that only the physical and cognitive sub-dimensions of anxiety sensitivity were significant predictors of COVID-19 anxiety. Similar to the results of our study, in a study investigating the relationship between COVID-19 anxiety and anxiety sensitivity, it was revealed that there was a significant correlation between these two variables, and the physical sub-dimension of anxiety sensitivity was a significant predictive factor for COVID-19 anxiety (23). In another study conducted in 2020, scrutinizing the relationship between COVID-19 anxiety, anxiety sensitivity, and metacognitions, it was determined that anxiety sensitivity is directly associated with COVID-19 anxiety (24). In a study examining the relationship between COVID-19 anxiety and disgust tendency/sensitivity and anxiety sensitivity, it was found out that all three sub-dimensions of anxiety sensitivity were predictors for COVID-19 anxiety (25).

Owing to the nature of COVID-19, it is a disease in which symptoms of respiratory system diseases can be observed as one of the remarkable causes of mortality. When the studies on the subject are examined, it can be said that high anxiety sensitivity predicts the anxiety about respiratory symptoms. (26).

Considering all these findings, it can be suggested that anxiety sensitivity is a significant predictor for COVID-19 anxiety. The findings of our study support the relevant literature. Unlike previous studies, it was revealed that the cognitive sub-dimension of anxiety sensitivity was a significant predictor for coronaphobia, as well as the physical sub-dimension. Since anxiety sensitivity is associated with the anxiety caused by experiencing its symptoms, it is considered that individuals with increased anxiety sensitivity might be more likely to interpret events catastrophically and may show phobic responses in the face of anxiety-provoking events. Considering all these findings, specific interventions for anxiety sensitivity would be helpful in the treatment of COVID-19 related anxiety. Previous studies indicate that mindfulness-based exercises, meditation, and physical activity could improve symptoms of anxiety and sensitivity (27, 28). There is value in integrating cognitive and behavioral interventions for anxiety sensitivity into treatment when coping with the mental problems associated with COVID-19. Strategies to reduce increased anxiety susceptibility (eg, interoceptive exposure interventions) could be beneficial in lowering the levels of COVID-19-related anxiety.

Another of the hypotheses of the study was that there is a negative relationship between cognitive flexibility and COVID-19 anxiety. In the analyzes made, it was found out that cognitive flexibility was negatively correlated with COVID-19 anxiety, and cognitive flexibility-control sub-dimension was a significant predictor of COVID-19 anxiety. When the literature is reviewed, it is noticed that studies investigating the relationship between COVID-19 and cognitive flexibility are remarkably limited. In a research conducted with dentists in Iran in 2020, the relationship between the cognitive flexibility and perceived threat of COVID-19 was studied. A significant correlation was found between cognitive flexibility and the perceived threat of COVID-19, and the control subscale of cognitive flexibility was found to be an important predictor of COVID-19 anxiety (29). In a study conducted in 2020, the relationship between early traumatic experiences, COVID-19 perceived threat, cognitive flexibility, and anxiety was scrutinized, and a positive correlation was determined between the control sub-dimension of cognitive flexibility and

anxiety (18). Cognitive flexibility is the ability to approach the problem from multiple perspectives and see an alternative solution, without insisting on a single solution when faced with a challenge. The cognitive flexibility control sub-dimension quantifies the tendency of the person to perceive new and challenging situations as controllable (13). It is noteworthy that lower scores on the cognitive flexibility-control scale indicate that the person perceives challenging situations as uncontrollable. In some studies, seeing one's own resources as sufficient to cope with negative events contributes to the evaluation of events as controllable, while thinking that the event cannot be changed independently of one's own actions is associated with evaluating it as uncontrollable.. It is one of the expected results to show phobic symptoms in the face of an unknown and unmanageable situation such as the COVID-19 pandemic.

Up-to-date data on the COVID-19 pandemic reveals that the pandemic causes widespread mental health problems and that psychiatric problems will be of great significance in terms of public health in the forthcoming period. Preventive and curative interventions for COVID-19 related anxiety are an integral part of the struggle against the pandemic. It is thought that it is crucial to consider the transdiagnostic factors that may be related and to make specific interventions when necessary in the treatment of COVID-19 related anxiety.

When interpreting the results of the study, it should be noted that the study has some limitations. Due to the cross-sectional nature of the research, it should be supported by the results of the longitudinal study for determining the causal relationship between the anxiety of COVID-19 and the cognitive factors evaluated. Moreover, study questionnaires consist of self-report scales and thus there may be response bias. It is considered that the findings obtained from this study will be guiding for longitudinal and more comprehensive studies related to COVID-19 anxiety.

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Characteristics of Adolescents Requiring Forensic Assessment Regarding Early Marriage: A Descriptive Study on Clinical Diagnosis and Physical Aggression

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ABSTRACT

Purpose: The aim of this study is to retrospectively evaluate the clinical, sociodemographic, and physical abuse-related factors of adolescents who are referred by the court to child and adolescent psychiatry clinics for early marriage.

Methods: A total of 115 adolescent girls aged over 15 years were included in the study. Sociodemographic information was obtained with the information forms prepared by the interviewer. Participants were also subjected to psychometric evaluation by psychologists and social review by social workers.

Results: Of these children with a mean education year of 5.41 ± 1.7 , 28.7% had a psychiatric diagnosis. The most frequently diagnosed psychiatric disorder was adjustment disorder (12.2%). There was a significant relationship between the duration of the marriage and the age difference between them and having a psychiatric diagnosis. Moreover, there is a significant difference between the age of the spouse and the age difference and physical abuse.

Conclusion: To have comprehensive knowledge of the characteristics of adolescents who are married early can provide insight into the development of systems and policies such as avoiding early marriages protect against various psychosocial stressors that support the development of education, knowledge, and skills of these adolescents.

Keywords: Forensic Assessment, Child and Adolescent Mental Health, Early Marriages

Erken evliliğe ilişkin adli değerlendirme gerektiren ergenlerin özellikleri: Klinik tanı ve fiziksel şiddet üzerine tanımlayıcı bir çalışma

ÖZET

Amaç: Bu çalışmanın amacı erken evlendirilmeleri için çocuk ve ergen psikiyatri kliniklerine mahkeme tarafından yönlendirilen ergenlerin klinik, sosyodemografik ve fiziksel istismar ile ilişkili etmenlerini geriye dönük olarak değerlendirmektir.

Yöntem: Çalışmaya 15 yaş üstü toplam 115 ergen kız çocuğu dahil edilmiştir. Sosyodemografik bilgiler görüşmeciler tarafından hazırlanan bilgi formları ile elde edilmiştir. Katılımcılar ayrıca psikologlar tarafından psikometrik değerlendirmeye ve sosyal hizmet uzmanları tarafından sosyal incelemeye tabi tutulmuştur.

Bulgular: Ortalama eğitim yılı $5,41 \pm 1,7$ olan bu çocukların %28,7'si psikiyatrik tanı almıştır. En sık tanı konulan psikiyatrik bozukluk uyum bozukluğudur (%12,2). Evlilik süreleri ve aralarındaki yaş farkı ile psikiyatrik tanı alma arasında anlamlı bir ilişki vardı. Ayrıca eşin yaşı ve yaş farkı ve fiziksel istismar arasında anlamlı bir fark saptanmıştır.

Sonuç: Erken yaşta evlenen ergenlerin özellikleri hakkında kapsamlı bilgi sahibi olmak, bu ergenlerin eğitim, bilgi ve becerilerinin gelişimini destekleyen, çeşitli psikososyal stres faktörlerine karşı koruma sağlayan erken evliliklerden kaçınma gibi sistem ve politikaların geliştirilmesine ilişkin içgörü sağlayabilir.

Anahtar Kelimeler: Adli Değerlendirme, Çocuk ve Ergen Ruh Sağlığı, Erken Evlilik

The term early marriage refers to the marriage made by individuals under the age of 18 who have not yet completed their mental and physical development. Although this definition covers both genders, it is mostly girls who want or are forced to marry early in the world (1). Although early marriages are observed in every region of the world, it is much more common in underdeveloped or developing countries such as Turkey. Considering the rates of marriage under the age of 18 around the world, early marriages are higher in South-East and Mid-West Africa and South Asian countries, and almost one in two women gets married before the age of 18, while this rate is less than 2% in developed countries (2).

According to UNICEF 2020 report, 15% of females were married by the age of 18 and 2% were married by the age of 15 in our country (3). This rate was not updated in 2021, it was only stated that this rate could be higher for refugees living in the country (4). Although there are legal regulations on early marriage in many countries, the preventive level of these legal regulations remains low due to basic reasons such as poverty, the need to strengthen social ties and beliefs. In favor of these regulations, the rates have seemed to be decreased all over the world, however, a significant proportion of girls are still being married off at a young age. Still, approximately 650 million girls and women alive today were married before their 18th birthday (2).

Although there are restrictions on the age of marriage in the Turkish legal system, it is possible to say that the definition of "early marriage" changes according to the law. The Child Protection Act defines a child as "a person who has not completed the age of 18. Accordingly, those under 18 should be considered as "children" and marriages made before this age as "early marriages" (5). Accordingly, those under 18 should be considered as "children" and marriages made before this age as "early marriages". According to the Turkish Civil Code, the age of marriage has been determined as 17 for men and women, and 16 by the judge's decision in extraordinary cases (6). When it is determined that girls under the age of fifteen are married, the person to whom they were married is tried and punished for the crime of "sexual abuse of the child", and the parents of these individuals consider as accomplices for this crime (7). In the Turkish legal system, men and women who are 17 years of age but not yet 18 years old can marry only with the permission of their parents. There is also a separate situation for people over the age of 16. From the letter of the law, it is understood that the age range that is 16 years old but not 17 years old is determined as the

"extraordinary marriage age". In a state of emergency or provided that there is a very important reason, a 16-year-old man and woman can marry with the permission of the judge (7). The existence of an extraordinary situation or a very important reason will be appreciated by the judge who made the decision on the permission to marry. According to the law, minors who have not yet reached the age of 15 cannot get married in any way. The law also prohibits those who do not have discrimination power from getting married.

The marriage of girls before completing their biopsychosocial development brings along many problems. Early marriage interrupts girls' childhood and it impedes fundamental rights such as freedom of expression, education, entertainment, play, and protection from sexual abuse (8, 9). These children are given responsibilities such as family, home, and childcare at an early age. In addition, they are separated from their peers and deprived of education. As a result, girls who were married at a young age feel excluded, isolated, and unhappy. All these lay the groundwork for serious mental health problems. Early marriages have been reported to cause more marital problems and divorces. Early marriage often means early pregnancy and motherhood. All pregnant adolescents are considered as a medically risky group which increases girls' risk of adverse health outcomes (10, 11).

There are many studies on this subject in the literature, and the interest in this field continues in our country as well with a few studies. In studies conducted in our country, there are determinations that this group is a disadvantaged group and is at risk in terms of psychopathology (12-17). In this paper with the largest sample in the country to support the existing data, we aimed to retrospectively examine the sociodemographic characteristics, psychiatric evaluations, and physical-abuse related factors of girls who married younger than 17 years and referred by the court to our outpatient clinic for criminal and forensic evaluation.

MATERIALS AND METHODS

A total of 115 adolescent girls aged over 15 years were included in the study. Sociodemographic information was obtained with the information forms prepared by the interviewer. Participants were also subjected to psychometric evaluation by psychologists and social review by social workers.

The study sample consisted of 115 cases under the age of 17 who were referred to Ağrı State Hospital Child and Adolescent psychiatry outpatient clinic for psychiatric assessment by the court for marriage permission between 2018-2020. Ethical approval was obtained from the Ataturk University Clinical Research Ethical Committee (B.30.2.ATA.0.01.00/227). In addition to the sociodemographic data of the cases, for the psychopathological screening of the cases, KSADS (The Kiddie Schedule for Affective Disorders and Schizophrenia) and clinical interviews based on DSM-5 were applied to all cases to prepare forensic reports. In order to exclude intellectual disability, the Porteus Maze test and Kent EGY intelligence test were applied to all cases (18, 19). The individuals who were determined with psychiatric disorders were started on treatment and were under follow-up, and some of them are still being followed.

The data were analyzed using the Statistical Program for Social Sciences-SPSS for Windows, 25.0). Descriptive statistics were given as mean, standard deviation, number, and percentage. Mann-Whitney U test was applied for continuous variables in the comparison between groups. The level of significance was accepted as $p < 0.05$ for all analyzes.

RESULTS

Table 1 shows the clinical and sociodemographic characteristics of the adolescents. Accordingly, the most common "Way of appearance of the marriage" is to make the marriage official (%69.5). 54.8% of these people were pregnant at the time of admission, 36.5% of them had experienced physical abuse at least once, and 71.3% of them did not have any psychiatric disorder.

Seventy-two point one (72.1%) of their mothers were illiterate, 65.3% of their fathers were primary school graduates, and only 2.7% of their spouses were university graduates. The age difference between them and their spouses was 7.96 ± 2.68 , and 25.2% of them were related to their spouses. (Table 2)

Table 3 shows the comparison of these people with the variables according to whether they have a psychiatric diagnosis or not. Accordingly, a significant relationship was found between the age difference between their spouses and the duration of the marriage. ($p < 0.05$). The spouses of the physically abused group were older, the age difference was larger, and this difference was found to be significant as well. ($p < 0.05$). (Table 4)

Characteristic	Value
Age (mean +sd), years	16.0±0.08
Marriage duration (mean+sd), months	6.82±6.27
The way of appearance of the marriage, (%)	
Applying to court to make the marriage official	80 (69.5)
Pregnancy follow-up	14 (12.2)
Reflection of spousal conflict on judicial units	6 (5.2)
Adolescents denunciate	4 (3.5)
After suicide attempt	4 (3.5)
Denunciate by one of the parents	4 (3.5)
Routine police check	3 (2.6)
Level of education (mean+sd), years	5.41±1.7
Pregnancy and birth history, (%)	
Pregnant	63 (54.8)
Gave birth	7 (6.1)
None	45 (39.1)
Sexual education given by parents %, yes	24 (20.9)
Housewife %, yes	115 (100.0)
Smoking %, yes	22 (17.6)
Alcohol use %, yes	7 (2.8)
Substance use %, yes	0 (0.0)
Chronic physical illness* %, yes	2 (1.7)
Exposure to physical abuse by spouse %, yes	42 (36.5)
Psychiatric Diagnosis	
Anxiety disorder	7 (6.08)
Depressive disorder	10 (8.69)
Post-Traumatic Stress Disorder	2 (1.73)
Adjustment disorder	14 (12.2)
None	82 (71.3)
*Epilepsy, Sd: standard deviation	

DISCUSSION

The present study was designed to determine the effect of sociodemographic characteristics, clinical diagnoses, and factors that may be related to these diagnoses and factors associated with physical abuse of 115 adolescent girls who were older than 16 and younger than 17 who were referred for forensic evaluation. The most obvious finding to emerge from the analysis is that gives us an idea about the sociodemographic data of these children and their families, such as their education level and household income level, and that the age difference is significant in both psychiatric diagnoses and physical abuse.

Table 2. Sociodemographic Characteristics of Parents and Spouses

Mother's Education (%)	
Illiterate	83 (72.1)
Primary Education	32 (27.9)
High School	0 (0.0)
University	0 (0.0)
Father's Education (%)	
Illiterate	37 (32.2)
Primary Education	75 (65.3)
High School	2 (1.7)
University	1 (0.8)
Total Household Income of Parents (%)	
Below poorment limit	81 (70.4)
Above poorment limit	34 (29.6)
Age (spouse) (mean +sd), years	23.9±2.5
Age difference with her spouse (mean +sd), years	7.96±2.68
Spouse Education (%)	
Illiterate	8 (6.9)
Primary Education	92 (80.0)
High School	12 (10.4)
University	3 (2.7)
Consanguineous marriage %, yes	29 (25.2)
Post-marital lifestyles (%)	
Nuclear family	44 (38.2)
Extended family	71 (61.8)
Residence (%)	
Rural	55 (47.8)
Urban	60 (52.2)

Table 3. Comparison of Variables According to Psychiatric Diagnosis

	psychiatric diagnosis (+) n=33	psychiatric diagnosis (-) n=82
Age (mean +sd), years	16.04±0.31	16.12±0.73
Age (spouse) (mean +sd), years	24.7±1.3	23.3±2.7
Age difference with her spouse (mean +sd), years*	8.56±2.34	5.19±2.51
Marriage duration (mean+sd), months*	8.02±4.59	6.12±4.09
Level of education (mean+sd), years	5.44±2.1	5.47±1.3

*p<0.05, Mann-Whitney U test was applied for continuous variables, Sd: standard deviation

Table 4. Comparison of Variables According to Exposure to Physical Abuse

	exposure to physical abuse (+) n=42 (36.5%)	exposure to physical abuse (-) n=73 (64.5%)
Age (mean +sd), years	16.02±0.04	16.0±0.12
Age (spouse) (mean +sd), years	27.9±2.3	23.1±1.7
Age difference with her spouse (mean +sd), years*	8.12±3.04	6.93±1.28
Marriage duration (mean+sd), months*	6.49±2.22	6.81±4.13
Level of education (mean+sd), years	5.39±3.2	5.41±1.5

*p<0.05, Mann-Whitney U test was applied for continuous variables, Sd: standard deviation

The literature indicates that sociodemographic factors stand out among the reasons why people get married at an early age (16, 20-22). Especially for girls, poverty, limited educational opportunities, households' livelihood problems, the perception that marriage will provide a kind of "protection" in terms of sexual relations and family honor, social norms, marriage life for girls who marry early, and the belief that it will be easier to adapt to the extended family facilitate early marriage (15, 23, 24). UNICEF states that poverty increases the risk of early marriage 2.5 times in its report on child marriages (1). In our study, it was determined that the incomes of the parents of these children were mostly below the poverty line and that the adolescents mostly had no education at all. Similarly, it was determined that the education level of the parents was low, especially most of the mothers had no education and were illiterate. Based on these data, it was thought that focusing on parents with low socioeconomic status, early identification of adolescents who did not continue their education and planning appropriate education for these cases would contribute to the prevention of early marriages while taking precautions regarding early marriages.

In papers on early marriage, it is seen that the average age difference varies between 4 and 9 years (15, 25). The fact that this rate was 8 years on average in our study is consistent with the literature. It has also been revealed that one out of every three to five marriages is consanguineous, and the rate of consanguineous marriage is 22.8% in the Northeastern Anatolia Region, which covers the province of Ağrı (26, 27). The fact that one out of every four

marriages was consanguineous in our study supports this data.

There are limited number of studies in terms of relationship between early marriages and psychiatric diagnosis in these population. Le Strat et al. (2011) stated that even when the sociodemographic characteristics and parity number of women who were married before the age of 18 were controlled, the rates of being diagnosed with psychiatric disorders and the health system applications in this field were still high (8). It has also been reported in various studies that there is an increased prevalence of psychiatric disorders in adolescents who married before the age of 18 in Turkey. These rates vary between 24.7% and 45.8% (12, 15, 16, 28). The fact that our study is the study with the largest sample size in country so far is a situation that might be taken into account when interpreting these data, as the reason for this difference may be the number of samples. These disorders were mostly noted as adjustment disorder and depressive disorder. Post-traumatic stress disorder was detected in only two cases. It is stated in formal reports that early marriage is traditionally supported in the society, and this type of marriage at a young age is usually realized by social agreement (29). For this reason, marriage at a young age may not be perceived as trauma by some cases. In these cases, rather than sexual abuse, depressive disorder and adjustment disorder are thought to be more developed due to reasons such as taking responsibilities such as family, home and child at an early age, separation from parents and peers, low social support, economic difficulties and conflicts with the mother-in-law, sister-in-law. Our results suggest that it would be controversial to focus only on sexual abuse in early marriages and that all psychosocial problems that are thought to affect mental health should be evaluated together. However, it was thought that these cases and their families were resistant to psychiatric assessment in order not to experience legal problems, and therefore the rate of mental disorders might be higher than that found. Our data support the view that early marriage brings with it an increased risk of mental disorders in children. In addition, even if the psychiatric disorder was not present in these children at the time of current application, this does not change the fact that early marriage poses a risk for the lives of the children in the future. It was thought that these children, who have not yet completed both their physical and mental development, should be monitored in terms of current risks. Likewise, the fact that there is a significant difference between the age difference and the increase in the marriage duration, which obtained from

the study, and the psychiatric diagnosis, appears as a data supporting this information.

Physical abuse is any intentional act causing injury or trauma to another person or animal by way of bodily contact. In most cases, children are the victims of physical abuse, but adults can also be victims, as in cases of domestic violence or workplace aggression. 36.5% of the cases stated that they were subjected to physical violence/abuse by the person they were married to. It is seen that the frequency of domestic violence in these cases is consistent to the data in the literature. There are studies in the literature reporting that girls who are married at a young age are more frequently subjected to physical violence by their spouses (30, 31). The prevalence of depressive symptoms was found to be higher in women who experienced domestic violence (32). Moreover, emotional problems, suicide attempts, alcohol and substance abuse, and aggressive behavior towards their children are also cooccurring conditions (33). There was also a significant difference between the age of the person to whom she was married and the age difference between them and physical abuse in the study. In societies where the patriarchal structure is dominant, the fact that families intervene more in the marriage decision and marry their daughters at an early age puts adolescents in a more disadvantageous position in their relations with their spouses and their spouses' families.

There was also a significant difference between the age of the person to whom she was married and the age difference between them and physical abuse in the study. In societies where the patriarchal structure is dominant, the fact that families intervene more in the marriage decision and marry their daughters at an early age puts adolescents in a more disadvantageous position in their relations with their spouses and their spouses' families (34, 35). Adolescents, who have a larger age gap with their spouses, are in a weaker position within the family and are exposed to more violence (35, 36).

The study was conducted with a retrospective chart review method, and it has limitations such as not being able to use the scale, not having a control group, and conducting the psychiatric assessment in the forensic process. Although there is no control group, as far as we know, the study has the largest sample in the country. We assume that it will contribute to the literature by providing data on psychiatric diagnosis and factors related to physical abuse with the current sample as well.

CONCLUSION

Early marriage is a serious social issue that needs to be evaluated in all its aspects. This problem has many psychological, sociological, economic, and legal dimensions. In the study, the socioeconomic and clinical characteristics of these adolescents and their parents were defined, and attention was drawn to the age difference between the spouses, which may be associated with physical abuse and psychiatric diagnosis. Although some of the cases we have been able to identify are only cases that apply to us for forensic assessment, there is a need to establish special networks that support the development of education, knowledge, and skills for these adolescents.

DECLARATIONS

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Conflicts of Interest/Competing Interests

No conflicting relationship exists for any author.

Ethics Approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. 26.03.2020/B.30.2.ATA.0.01.00/227.

Availability of Data and Material

Not applicable.

Authors' Contributions

MA: Designed the study, collected the data, performed the analysis. BT: Designed the study, collected the data, wrote the paper.

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Role of Soluble Fractalkine, GFAP and CD163 in Cognitive Functions After Open Heart Surgery in Diabetic and Non-diabetic Patients

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ABSTRACT

Purpose: In this study, the relationship between postoperative cognitive functions and serum fractalkine, Glial Fibrillar Acidic Protein (GFAP) and Cluster of differentiation 163 (CD163) levels in diabetic and non-diabetic patients after open heart surgery was evaluated.

Methods and Materials: This research was planned prospectively as observational clinical study. Cognitive functions, fractalkine, GFAP and CD163 levels were evaluated with preoperative day 1 and postoperative day 7 in 44 patients. Minimal test (MM) was used to evaluate cognitive functions.

Results: A positive correlation was found between preoperative CD163 concentrations and postoperative MM test scores in non-diabetic patients ($r=0.536$, $p=0.010$). There was also a positive correlation between postoperative CD163 concentrations and postoperative MM Test scores in non-diabetics ($r=0.461$, $p=0.031$). In diabetic patients, a positive correlation was found between preoperative and postoperative GFAP concentrations ($r=0.792$, $p<0.001$).

Conclusion: The underlying mechanisms of Postoperative cognitive dysfunction (POCD) are thought to be different in non-diabetic and diabetic patients. Evidence suggesting that preoperative serum CD163 levels may be a candidate for biomarkers directly related to postoperative cognitive performance in non-diabetic patients. In order to prevent POCD, which is associated with mortality, it is important to determine the predictors before surgery and to select the surgical method and anesthetics according to the risk assessment.

Keywords: cognitive functions, inflammation, CD163, fractalkine, GFAP, heart surgery

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Açık Kalp Cerrahisi Sonrası Diyabetik ve Diyabetik Olmayan Hastalarda Bilişsel İşlevlerde Fraktalkin, GFAP ve CD163'ün Rolü

ÖZET

Amaç: Bu çalışmada, diyabetik ve diyabetik olmayan hastalarda açık kalp cerrahisi sonrası postoperatif bilişsel fonksiyonlar ile serum fraktalkin, Glial Fibrillar Asidik Protein (GFAP) ve Cluster of Different 163 (CD163) düzeyleri arasındaki ilişki değerlendirildi.

Yöntem: Bu araştırma prospektif olarak gözlemsel klinik bir çalışma olarak planlandı. 44 hastada ameliyat öncesi 1. gün ve ameliyat sonrası 7. gün bilişsel işlevler, fraktalkin, GFAP ve CD163 düzeyleri değerlendirildi. Bilişsel işlevleri değerlendirmek için minimal test (MM) kullanıldı.

Bulgular: Diyabetik olmayan hastalarda preoperatif CD163 konsantrasyonları ile postoperatif MM testi skorları arasında pozitif korelasyon bulundu ($r=0.536$, $p=0.010$). Ayrıca diyabetik olmayanlarda postoperatif CD163 konsantrasyonları ile postoperatif MM Testi skorları arasında pozitif bir korelasyon vardı ($r=0.461$, $p=0.031$). Diyabetik hastalarda preoperatif ve postoperatif GFAP konsantrasyonları arasında pozitif bir korelasyon bulundu ($r=0.792$, $p<0,00$).

Sonuç: Postoperatif bilişsel işlev bozukluğunun (POCD) altında yatan mekanizmaların diyabetik olmayan ve diyabetik hastalarda farklı olduğu düşünülmektedir. Çalışmamız verileri, preoperatif serum CD163 seviyelerinin diyabetik olmayan hastalarda postoperatif bilişsel performansla doğrudan ilişkili biyobelirteçler için aday olabileceğini düşündürmektedir. Mortalite ile ilişkili olan POCD'yi önlemek için cerrahi öncesi öngörülerin belirlenmesi ve risk değerlendirmesine göre cerrahi yöntem ve anesteziğin seçilmesi önemlidir.

Anahtar Kelimeler: bilişsel işlevler, inflamasyon, CD163, fraktalkine, GFAP, kalp cerrahisi

Araştırma kayıtları: 20 Nisan 2021, no: 6759 (<https://www.researchregistry.com/browse-the-registry#home/registrationdetails/607ed790f296b7001ba00501/>)

Postoperative cognitive dysfunction (POCD), after anesthesia and surgery is a recognized clinical phenomenon (1). It was defined for the first time in 1955 under the name of “negative cerebral effects of anesthesia on old people” (2). Postoperative cognitive dysfunction is a clinical condition that lowers a person's quality of life by causing concentration, memory, language use disorders and learning disabilities (3,4). Early studies focused on POCD after cardiac surgery. Shaw et al. identified rates of POCD of 79% at 7 days after surgery, with 38% showing significant symptoms of neuropsychological impairment (5). In subsequent studies, it has been reported that POCD may occur after any type of cardiac and non-cardiac surgery (6). However, it is known that patients undergoing cardiac surgery have a higher risk of developing POCD compared to other operations (7,8). Postoperative cognitive dysfunction rates range from 27% to 66% after cardiac surgery (9,10) while highly variable rates were reported in which non-cardiac surgeries (6). It can lead to consequences such as loss of independence, quality of life, withdrawal from the community, and loss of work and social security (11). In addition, mortality rates were shown to increase in a 8.5-year follow-up study (12). In favor of the role of inflammatory response in POCD, preoperative administration of dexamethasone has been shown to reduce the inflammatory response and the risk of early POCD after cardiac surgery (13).

One of the major mechanisms responsible for the development of POCD is neuroinflammation and activation in astrocytes and microglia. It has been demonstrated by clinical and experimental studies in postoperative period (14,15). Inflammatory mediators in the central nervous system (CNS) can also affect memory and learning through direct or indirect mechanisms (16,17). In one study, inhibition of pro-inflammatory cytokine (IL-6) release in the brain has been reported to improve post-operative memory disorders (18).

Fractalkine or CX3CL1 is a chemokine molecule and is involved in both peripheral and central inflammatory processes (18). The synthesis site in the CNS is neurons and has receptors on microglia (CX3CR1). Soluble fractalkine released by neurons causes activation of microglial cells and leukocytes in the systemic circulation (19,20). Different results have been reported in the literature that fractalkine has both neuroprotective and neurotoxic effects (21). It has been suggested that in Alzheimer's Disease (AD), which is accompanied by cognitive and memory impairment, the level of fractalkine decreases and plays a role in neuroinflammatory processes in the disease (22,23).

Glial Fibrillar Acidic Protein (GFAP) is a marker showing astrocyte activation in neuroinflammatory events. GFAP serum levels are elevated in neuroinflammatory processes (24). In addition, a positive correlation has been reported between POCD and serum GFAP levels after non-cardiac surgery (25).

Cluster of differentiation 163 (CD163) is a marker expressed in microglia cells and showing activation. It is stated that CD163 plays a role in regulating the adaptive immune response and measuring in inflammation-related diseases in tissue or serum may be guiding in terms of the severity and prognosis of the disease (26).

Diabetes mellitus (DM) is a disease that can cause neuroinflammatory changes (27). Some patients have been shown to have impaired cognitive function, but their pathophysiology is not fully understood. Hyperglycemia, vascular disease, hypoglycemia and insulin resistance are thought to play a role in neuroinflammation (16). There are differences in neuroinflammatory mechanisms due to persistent hyperglycemia in diabetic patients. Persistent hyperglycemia-related polyol pathway, protein kinase C (PKC) pathway, mitogen-activated protein kinases (MAPK) pathway are activated and production of advanced glycation end products (AGEs) increase in DM. Thus, inflammatory mediators are released directly or indirectly (28). These mediators stimulate the generation of inflammatory mediators and activation of transcription factor NF- κ B which is a potent inducer of inflammatory processes (29). These AGEs act on various receptors present on microglia and macrophages stimulate production of cytokines and chemo attractant proteins (30). Inflammation also affects the structural features of neuron by the glycosylation of myelin protein. Thus, antigenicity varies and monocyte, macrophage and neutrophil infiltration occurs from the blood circulation and activate the glial cells of the nervous system (27,31).

In a meta-analysis comparing patients with diabetic and patients with non-diabetic, the risk of developing POCD was reported to be higher in diabetics (32). In experimental models, an increase in microglial activation and intercellular adhesion molecule-1 (ICAM-1) expression was detected in neuropathological analysis in the brain of diabetic animals (33).

The role of centrally soluble fractalkine, GFAP and CD163 and its relationship with cognitive dysfunction in neuroinflammatory changes after cardiac surgery have not

been previously investigated. In this study, the relationship between preoperative and postoperative fractalkine, GFAP and CD163 levels and cognitive functions was evaluated in diabetic and non-diabetic patients in order to detect the difference in inflammatory processes.

MATERIAL AND METHODS

Sample Selection

This research is a prospective and observational clinical study. It was performed Gazi University Faculty of Medicine Hospital, Department of Cardiovascular Surgery between the dates May 16, 2018 and January 21, 2019. Individuals who had undergone open heart surgery within the specified date range, who met the inclusion criteria and volunteered to participate in the study were included in the study. Power analysis was performed to calculate the minimum number of patients. There was no sample study in the literature investigating the relationship between cognition and neuroinflammatory markers in diabetic and non-diabetic patient groups who underwent open heart surgery. Therefore, other studies involving patient and control groups in which these markers were studied were used in power calculation. Using the mean \pm SD values of a study with Fractalkine, taking 80% power and ratio of sample size: 1 at 95% confidence interval (2-sided; patient group: 1.881 ± 1.372 , control group: 0.969 ± 655), the patient group for 22, the control group for 22, and the total group for 44 were calculated (34).

Using the mean \pm SD values of a study with CD163, taking 80% power and ratio of sample size: 1 at 95% confidence interval (2-sided; patient group: 85.7 ± 29.3 , control group: 57.8 ± 20.6), the patient group for 13, the control group for 13, and the total group for 26 were calculated (35). The study started on May 16, 2018 and the study was terminated when the number of patients in both groups reached 22 (January 21, 2019).

22 diabetic and 22 non-diabetic volunteers aged 40 years and older who underwent cardiopulmonary-bypass surgery (CPB) were included in the study. Coronary artery bypass graft (n:28), valve replacement (n:4), coronary artery bypass graft plus valve replacement (n:11) and intracardiac mass excision (n:1) were performed underwent CPB. Those with a known autoimmune disease, active infection, and neuropsychiatric disease were excluded from the study. In order to evaluate cognitive functions, preoperative day before and on postoperative 7th day, MM was performed. Serum fractalkine, GFAP and CD163 levels were measured simultaneously.

Biochemical Methods

Blood samples taken from patients were taken into standard yellow capped tubes, centrifuged at $+4^\circ\text{C}$ for 10 minutes at 4000 rpm and frozen at -80°C until working. Fractalkine, GFAP and CD16 ELISA kits were purchased from Cloud-Clone Corp USA. While preparing the reagents, 1 ml of standard dilution was added to the stock standard to dissolve. Serial dilutions were then made. The working protocol of the kits was performed as follows.

a. Prepared samples were pipetted into 7 standard and 1 blind 100 microliter plate wells. The plate was covered and incubated at 37°C for 1 hour.

b. After incubation, the wells were completely emptied. No washing was done at this stage.

c. Reagent A working solution, prepared 100 microliters, was pipetted into all wells. It was incubated for 1 hour at 37°C .

d. At this stage, all wells were washed 3 times with 350 microliter wash solution.

e. Reagent B working solution, prepared 100 microliters, was pipetted into all wells. It was incubated for 30 minutes at 37°C .

f. Step 4 was repeated. Washing was done 5 times.

g. 90 microliters of substrate solution was added to all wells. It was incubated at 37°C , hiding from light for 15 minutes.

h. 50 microliters of stop solution was added to all wells. It was gently mixed. It was taught in 450 nm ELISA reader. By drawing the standard curve graphs, the concentration of all samples was calculated.

Anesthesia Protocol

The anesthesia protocol of all patients included in the study was the same. Following standard monitoring of American Anesthesia Society (ASA), anesthesia was induced with 5-7 mg/kg thiopental-sodium, endotracheal intubation was performed after muscle relaxation with 0.6 mg/kg rocuronium. In the maintenance of anesthesia, sevoflurane was used at a concentration of 1 minimum alveolar concentration (about 2%) and remifentanil infusion at a dose of 0.05-0.2 mcg/kg/min. Skeletal muscle relaxation was maintained by using rocuronium as a 10 mg bolus every 45 minutes.

Cardiac Surgery Procedure

During cardiac surgery can be performed with on pump CPB. Perfusion is conventionally performed by the on-pump, non-pulsatile cardiopulmonary bypass technique. For cardiopulmonary bypass, the patients were anticoagulated with 300-400 U/kg of heparin to achieve an activated clotting time (ACT) greater than 400 seconds. CPB was initiated following cannulation of the aorta and the right atrium. A Stockert SIII non-pulsatile roller pump (Stockert Instrumente GmbH) and a membrane type oxygenator (Dideco Compact Flo Evo, Sorin Group, Mirandola, Italy) were used. The pump prime solution contained 1000-1500 mL of lactated Ringer's solution to maintain a hematocrit level of 26 ± 2 %. Pump flow was set at 2.2-2.4 L/m²/minute to maintain the mean non-pulsatile arterial pressure between 50-70 mmHg. The body temperatures of the patients were cooled down to 30°C. For myocardial protection, potassium blood cardioplegic solution was administered every 20 minutes and, additionally, cold (4°C) Isolyte S solution was applied topically to the surface of the heart at the same intervals. Cross-clamp time (minutes) and CPB time (minutes) were recorded.

Statistical Analysis

Research data was evaluated through SPSS 22.0 statistical software. Descriptive statistics are presented as mean (\pm) standard deviation, median (min; max). Parametric and non-parametric distribution properties of all data were examined with Shapiro-Wilks Tests and histogram distributions. Wilcoxon Test, Mann Whitney U Test and Spearman Correlation Test were used as appropriate statistical methods. Statistical significance was accepted as $p < 0.05$.

The Equator Network Guideline (the reporting of studies conducted using observational routinely collected health data statement) was followed in the preparation of this article and presentation of clinical data (36). In error, we did not prospectively register this trial, but we have registered it retrospectively at the Research Registry (<https://www.researchregistry.com/>), with registration date April 20, 2021 and registration number 6759.

RESULTS

Total of 44 patients who participated in the study, 29 (65.9%) were male and 15 (34.1%) were female, and the mean age was 62.8 ± 9.47 (min: 46, max: 84). The mean (\pm) standard deviation, median (min; max) values of the patients' pre-op and post-op CD163, fractalkine, GFAP levels and MM Test scores are shown in Table 1 according to their diabetic and non-diabetic status. In both two groups there was no significant difference when CD163, fractalkine, GFAP levels and MM Test score were compared pre-operatively and post-operatively.

There was no statistically significant difference between diabetic and non-diabetic patients in terms of preoperative CD163 ($p=0.734$), fractalkine ($p=0.338$), GFAP levels ($p=0.833$) and MM Test score ($p=0.572$). Also, there was no statistically significant difference between diabetic and nondiabetic patients in terms of postoperative CD163 ($p=0.236$), fractalkine ($p=0.542$), GFAP ($p=0.775$) levels and MM Test score ($p=0.447$).

Table 1: Preoperative and postoperative fractalkine, GFAP, CD163 levels and minimal test scores of the patients					
	Preoperative		Postoperative		p* value
	Mean \pm SD	Median (min-max)	Mean \pm SD	Median (min-max)	
Non-diabetic patients (n:22)					
CD163 (ng/ml)	16,62 \pm 6,97	16,82 (1,44-30,63)	17,87 \pm 7,15	17,41 (5,39-33,32)	0,485
Fractalkine (ng/ml)	0,21 \pm 0,22	0,16 (-0,005-1,08)	0,17 \pm 0,10	0,14 (0,04-0,49)	0,903
GFAP (ng/ml)	1,33 \pm 3,08	0,11 (0,03-11,85)	0,34 \pm 0,48	0,10 (0,03-1,95)	0,330
MM Test	20,59 \pm 5,12	20,50 (12-29)	20,27 \pm 6,11	19,50 (11-29)	0,314
Diabetic patients (n:22)					
CD163 (ng/ml)	17,44 \pm 5,66	16,93 (5,50-29,71)	20,04 \pm 5,48	18,91 (10,05-29,67)	0,158
Fraktalkine (ng/ml)	0,18 \pm 0,14	0,14 (0,05-0,73)	0,19 \pm 0,09	0,18 (0,08-0,38)	0,140
GFAP (ng/ml)	0,56 \pm 0,81	0,17 (0,02-3,48)	0,24 \pm 0,35	0,13 (0,04-1,73)	0,074
MM Test skoru	21,23 \pm 3,90	22 (14-28)	21,68 \pm 3,94	22,5 (15-30)	0,600
MM: Minimal Test; GFAP: Glial Fibrillar Acidic Protein; CD163: Cluster of differentiation 163; * Wilcoxon test was used.					

In our study, the correlations between preoperative and postoperative CD163, GFAP, Fractalkine levels and MM Test scores in both diabetic and non-diabetic patients were examined. There was a positive correlation between preoperative and postoperative CD163 concentrations in non-diabetic patients ($r = 0.426$, $p = 0.048$). Preoperative and postoperative fractalkine levels also showed a positive correlation in non-diabetics ($r = 0.436$, $p = 0.042$).

There was a positive correlation between preoperative and postoperative MM Test scores in non-diabetic ($r = 0.854$, $p = 0.000$) and diabetic patients ($r = 0.555$, $p = 0.007$).

A positive correlation was found between preoperative CD163 concentrations and postoperative MM test scores in non-diabetic patients ($r=0.536$, $p=0.010$) (Figure 1).

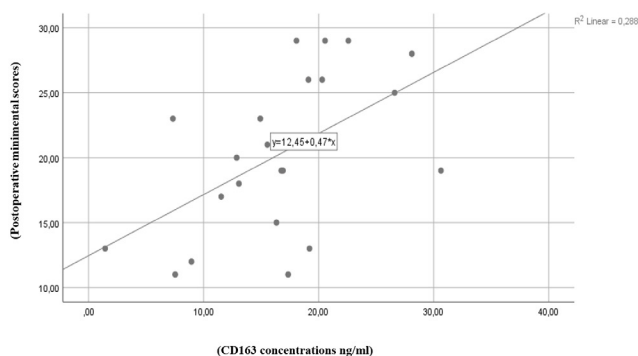


Figure 1: Correlation between preoperative CD163 concentrations and postoperative Minimal Test Scores in non-diabetic patients ($r = 0.536$, $p=0,010$)

There was also a positive correlation between postoperative CD163 concentrations and postoperative MM Test scores in non-diabetics ($r = 0.461$, $p = 0.031$) (Figure 2).

In diabetic patients, a positive correlation was found between preoperative and postoperative GFAP concentrations ($r = 0.792$, $p = 0.000$) (Figure 3). There was a positive correlation between preoperative CD163 concentrations and postoperative GFAP concentrations in diabetics ($r = 0.440$, $p = 0.040$).

A negative correlation was found between preoperative MM Test scores and postoperative fractalkine concentrations in diabetic patients ($r = -0.516$, $p = 0.014$) (Figure 4).

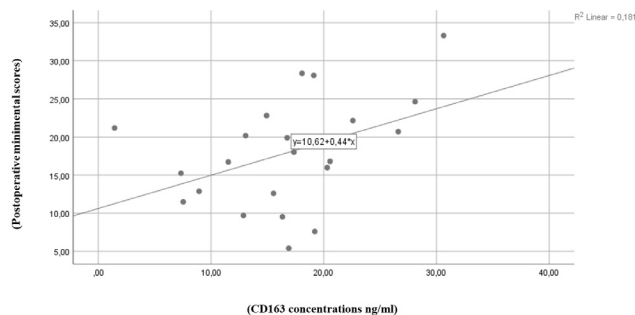


Figure 2: Correlation between postoperative CD163 concentrations and postoperative Minimal scores in non-diabetic patients ($r=0,461$, $p=0,031$)

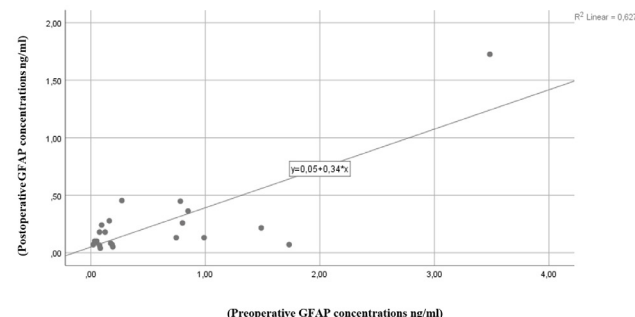


Figure 3: Correlation between preoperative and postoperative Glial Fibrillar Acidic Protein (GFAP) concentrations in diabetic patients ($r = 0.792$, $p = 0.000$)

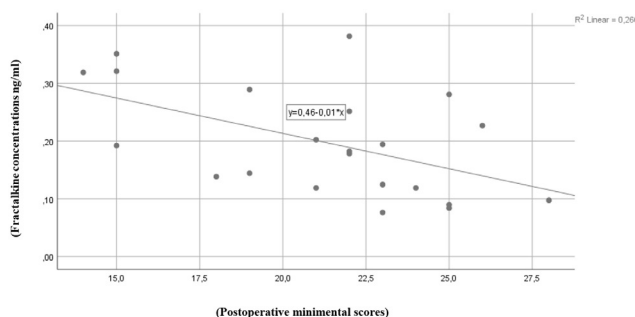


Figure 4: Correlation between preoperative fractalkine concentrations and postoperative Minimal test scores in diabetic patients ($r = -0.516$, $p = 0.014$)

Variables related to surgery and hospitalization in diabetic and non-diabetic patients were also compared. In the diabetic group, the mean clamp time was 85.95 ± 31.20 minutes, while the CPB time was 133.90 ± 36.69 minutes. The mean clamp time in the non-diabetic group was 100.22 ± 47.82 , while the CPB duration was 140.59 ± 51.23 minutes, and there was no significant difference between the two groups ($p = 0.445$, $p = 0.897$, respectively).

While the duration of hospitalization was 12.31 ± 4.34 days in the diabetics, it was 12.50 ± 5.71 days in the non-diabetics. The length of stay in the intensive care unit (ICU) was 2.72 ± 1.12 days in the diabetics, 2.90 ± 1.71 days in the non-diabetics, and there was no difference between the two groups in terms of duration of hospitalization and length of stay in the ICU ($p = 0.463$, $p = 0.855$, respectively).

When the patients were evaluated in terms of their comorbidities, it was found that all of them had hypertension. Chronic obstructive pulmonary disease was present in 22.7% (n: 5) of diabetic patients, 4.5% (n: 1) of non-diabetics and no statistically significant difference was found between them ($p = 0.07$).

DISCUSSION

In neuroinflammatory diseases, biomarkers are tried to be developed with blood samples (37,38). Although there are neuroinflammatory mechanisms that may be common with POCD especially in Alzheimer's disease, biomarker studies for POCD are very limited (39-41). CD163 has been suggested to be the specific biomarker of monocyte/macrophage cell populations with a strong anti-inflammatory effect (42,43). Expression of CD163 allows the differentiation of M2 subtype cells of mononuclear phagocytes, which cause the release of anti-inflammatory mediators (44). Although monocyte/macrophage has been shown as the source of serum CD163 levels in the literature, CD163 released from microglia in CNS may also contribute to this (27).

In our study, the positive correlation of CD163 levels with MM test scores in both preoperative and postoperative periods suggests that CD163 may be a biomarker reflecting cognitive functions in non-diabetic patients. This finding is consistent with the activation of the M2 subtype form mentioned above and the microglia and macrophages transformed in the anti-inflammatory process and the accompanying soluble CD163 release. In addition, the positive correlation of CD163 levels with MM Test scores suggests that the release of established microglia originated

CD163 in the CNS can also significantly contribute to the level of CD163 in serum. A study examining the relationship between serum CD163 level and POCD has not been found in the literature. Since the mortality rates are also high in patients with high POCD score, biomarkers that can be stabilized from serum are important in terms of predicting both cognitive impairment and mortality risk of patients. Predicting the development of POCD can lead to planning an intervention for it. For example, in a previous study, prophylactic dexamethasone use was reported to reduce the systematic inflammation response and the incidence of POCD in the postoperative period after cardiac surgery compared to the placebo group (13). It may be important to develop a biomarker for these interventions, especially for people who are thought to have risk factors.

In our study, while no correlation was found between pre-op CD163 and pre-op GFAP levels, a significant positive correlation was found between pre-op CD163 levels and post-op GFAP levels. Although CD163 is an anti-inflammatory molecule, GFAP is a molecule that reflects astrocyte activation and the inflammatory process (45,46). This result suggests that the risk of inducing neuroinflammatory processes in the post-op period is higher in patients with diabetic compared to non-diabetic patients. In the meta-analysis in which 2642 patients were evaluated, it was reported that in diabetics, POCD increased 1.26 times compared to non-diabetic patients (32). In our study, although inflammatory processes were thought to be induced in diabetics in the postoperative period, it was found that cognitive functions did not show a significant change compared to both the preoperative period and non-diabetic patients. This situation has been interpreted that other patient-related variables such as metabolic and genetic may be effective in POCD besides neuroinflammation. In addition, accompanying post-op GFAP increase with pre-op CD163 level in diabetic patients can be interpreted as an adaptive mechanism developed against the tendency of neuroinflammation already present in Type 2 DM patients.

Upregulated expression of CD163, a macrophage-specific protein, is one of the major changes in the macrophage switch to alternative activated phenotypes in inflammation. Accordingly, a high CD163 expression in macrophages is a characteristic of tissues responding to inflammation. The scavenging of the oxidative and proinflammatory hemoglobin, leading to stimulation of the heme-oxygenase-1 and production of anti-inflammatory heme metabolites indicates that CD163 thereby indirectly contributes to the anti-inflammatory response (47). Increased

production of AGEs act on various receptors present on microglia and macrophages stimulate production of cytokines and chemo attractant proteins as a result of persistent hyperglycemia (30). Therefore, continuous CD163 activation may lead to increased proinflammatory response in diabetics, and its indirect anti-inflammatory effect may be insufficient compared to non-diabetic patients.

Akerfelt et al. reported that there was a significant and permanent decrease in circulating fractalkine level after orthopedic and coroner bypass surgery (48). Xu et al. reported that fractalkine was involved in the inflammatory and remodeling process and it is negative correlated with myocardial salvage in myocardial infarction patient treated with primary percutaneous coronary intervention (49). Fractalkine level has been shown to decrease in AD, where cognitive impairment is at the forefront, and it has been suggested that this molecule plays a role in the neuroinflammatory processes responsible for the disease (23). Our study showed that serum fractalkine levels decreased in non-diabetic patients, although it was not statistically significant, but this correlation was not correlated with the MM test. On the other hand, statistically significant negative correlation with preoperative MM scores in diabetics suggests that fractalkine can be used as an important parameter in demonstrating a possible deterioration when POCD is evaluated by advanced neuropsychiatric tests.

In a review evaluating anesthetics and POCD, it is stated that a significant proportion of people related to risk factors develop POCD, but it is emphasized that the role of anesthetic selection in the development of cognitive disorder is small (50). Despite this, in our study, standard anesthesia procedure was applied to patients so that the drugs used in anesthesia are not a confounder, and thus, this difference between patients was tried to be eliminated.

There are no standard assessment criteria defined for POCD. The criteria routinely used are a percentage change from baseline in a defined number of neuropsychological tests (usually a decline >20% in two or more tests) (51). In previous studies, it was observed that different neuropsychiatric tests were applied to patients, and as a result, several tests were evaluated and changes in cognitive functions were reported (52,53).

In diabetic and non-diabetic patients, the clamping time, CPB duration, ICU stay and hospitalization times, which

can affect cognition and neuroinflammatory markers, do not differ between the two groups, so the groups can be considered homogenized in these respects and this is a strong aspect of this study. In addition, comorbidities are also homogeneous between groups. Conducting studies in which the number of samples is expanded is thought to be important in terms of showing whether this result will be repeated or not.

There are some limitations of our study. Firstly, only the MM test was used to evaluate cognitive functions, which may be the reason for preoperative and postoperative score similarity in the results. The use of the neuropsychiatric test battery, in which cognitive functions are evaluated in more detail, may be a reinforcement in future studies. Secondly, any test before surgery was not used to examine the presence of dementia. It was questioned whether there was a clinical diagnosis for dementia and whether there was a history of treatment, but a detailed neuropsychiatric evaluation could not be made. Finally, although a sample size with a statistically sufficient potency has been reached, a comparison between larger patient groups and groups divided according to comorbidities may be important in evaluating diabetes-specific responses.

CONCLUSION

The underlying mechanisms of POCD are thought to be different in non-diabetic and diabetic patients. Evidence suggesting that preoperative serum CD163 levels may be a candidate for biomarkers directly related to postoperative cognitive performance in non-diabetic patients.

Fractalkine can be used as an important parameter in demonstrating a possible deterioration when POCD is evaluated by advanced neuropsychiatric tests.

Cardiac surgery to be performed in patients with diabetic and non-diabetic should be performed differently, taking into account the factors affecting neuroinflammatory processes. It is thought that this study will make an important contribution to the literature as it is the first clinical study established with the hypothesis that the effect of neuroinflammation on POCD in diabetic patients may be different.

DECLARATIONS

Acknowledgement

None.

Disclosure of Interest

The authors declare that they have no competing interest.

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Ethics Committee Approval

Ethical approval was obtained from Ankara Numune Education and Research Hospital on April 25, 2018 (Decision number: 1961/2018). Due to the change of principal investigator change, second approval was required and obtained from Ankara City Hospital No.1 Clinical Research Ethics Committee with the decision taken on June 20, 2019 and numbered E1 / 005/2019.

Data-sharing Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions

Concept – A.Ozbay., S.B. D.E.; Design – A.O., A.Ozbay., S.I.O.; Supervision – O.G., S.B. D.E.; Resources – A.C.K, H.D.; Materials – A.Ozbay., A.O.; Data Collection and Processing – A.Ozbay., A.O.; Analysis and/or Interpretation – A.C.K, H.D., S.I.O. O.G.; Literature Review – A.C.K., S.B., A.Ozbay, D.E.; Writing – A. Ozbay.,S.B., A.C.K., ; Critical Review – O.G., S.I.O., D.E., S.B.

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Is it Really Necessary to Perform Colposcopy in Patients with Ascus and HR HPV Positivity?

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ABSTRACT

Introduction: Papanicolaou (Pap) smear is a very important screening method for detection of cervical cancer or cell changes that can lead to it. Atypical squamous cells of undetermined significance (ASCUS) is the most common abnormality seen among all cervical cytologies with the percentage of 4-5% . Human papillomavirus (HPV) infection is regarded as a major cause of cervical intraepithelial neoplasia (CIN) and cervical cancer. Colposcopy is recommended for all women with high-grade squamous intraepithelial lesion (HSIL) and atypical squamous cells-cannot exclude high-grade squamous intraepithelial lesion (ASC-H) for cervical cancer screening . It is also recommended for high-risk HPV (HR HPV) positive women with ASCUS. The aim of this study is to evaluate the importance of colposcopy in patients with ASCUS and HR HPV positivity.

Materials and Methods: We performed a retrospective study approved by the ethics committee of Acıbadem University. Women with diagnosis of ASCUS and HR HPV positivity who underwent colposcopic evaluation at 2 different gynecologic oncology clinics of our university from January 2011 to January 2019 were included in our study. The age range was from 21 to 48 and the mean age of patients' was 29. Subjects who were pregnant, hysterectomized or had previous cytological abnormalities were excluded.

Conclusion: In this study, we aimed to evaluate the significance of colposcopy in patients with ASCUS and high-risk HPV positivity, especially strains 16 and 18. As mentioned in some other studies, immediate colposcopy is an expensive screening procedure for further evaluation of ASCUS .

Keywords: Ascus, hpv, colposcopy

Yüksek riskli HPV pozitif ve ASCUS tanılı hastalarda kolposkopik inceleme ne kadar gerekli?

ÖZET

Pap smear rahim ağzı kanseri veya buna yol açabilecek hücre değişikliklerinin tespiti için çok önemli bir tarama yöntemidir. Önemi belirsiz atipik skuamöz hücreler (ASCUS), tüm servikal sitolojiler arasında %4-5 görülme sıklığı ile en sık görülen anormalliktir. İnsan papilloma virüsü (HPV) enfeksiyonu ,servikal intraepitelial neoplazi (CIN) ve rahim ağzı kanserinin başlıca nedeni olarak kabul edilir. Servikal kanser taramasında yüksek dereceli skuamöz intraepitelial lezyon (HSIL) gelen hastalara kolposkopi önerilir. Kolposkopi aynı zamanda yüksek riskli HPV pozitif ve ASCUS tanılı hastalara da önerilir. Bu çalışmanın amacı ASCUS ve yüksek riskli HPV pozitifliği olan hastalarda kolposkopinin önemini değerlendirmektir.

Anahtar Sözcükler: Ascus, hpv, kolposkopi

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Papanicolaou (Pap) smear is a very important screening method for detection of cervical cancer or cell changes that can lead to it. Atypical squamous cells of undetermined significance (ASCUS) is a commonly seen abnormality among all cervical cytologies with the percentage of 4-5% (1). Human papillomavirus (HPV) infection is accepted as a main reason of cervical intraepithelial neoplasia (CIN) and cervix cancer. According to the results of cervical cytology, treatment of most abnormalities is clearly defined by guidelines. However, there is still controversy about treatment of ASCUS and ideal clinical approach to these women is a topic of conflict (2). Repeating the cytological testing, performing colposcopy or determining the high risk types of HPV are all reasonable managements of women with ASCUS (3).

Human papillomaviruses are known to be responsible of various squamous tumors in the skin, and on gastrointestinal, respiratory and genitourinary tract. The HPV lesions seen in the uterine cervix are associated with concomitant CIN, cervical carcinoma in situ (CIS) and invasive cervical cancer. That causes HPV screening tests to be a part of evaluating patients with ASCUS (4). Specific HPV types in HPV screening tests may vary between laboratories. Although types 16 and 18 are accepted oncogenic and cause for 70% of cervical cancers worldwide, at least 12 more types are also known to be oncogenic (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68) (5).

Colposcopy is advised for all the women in who are diagnosed with high-grade squamous intraepithelial lesion (HSIL) and atypical squamous cells-cannot exclude high-grade squamous intraepithelial lesion (ASC-H) for cervical cancer screening (6). It is also recommended for high-risk HPV (HR HPV) positive women with ASCUS.

In our study we planned to investigate the importance of colposcopy in patients with ASCUS and HR HPV positivity.

MATERIALS AND METHODS

Study Population

We performed a retrospective study approved by the ethics committee of Acibadem University. Women with diagnosis of ASCUS and HR HPV positivity who underwent colposcopic evaluation at 2 different gynecologic oncology clinics of our university from January 2011 to January 2019 were included in our study. The age range was from 21 to 48 and the mean age of patients' was 29. Subjects who were pregnant, hysterectomized or had previous cytological abnormalities were excluded.

Cervical Cytology

The technology of Gamidor was used for the tests. Pap smear was planned by using liquid-based cervical cytology with thin layer cell preparation process. Bethesda classification system was used to analyze samples (7). The results were analyzed as normal, atypical squamous cells of undetermined significance (ASCUS), low-grade squamous intraepithelial lesion (LSIL), atypical squamous cells-cannot exclude high-grade squamous intraepithelial lesion (ASC-H) and high-grade squamous intraepithelial lesion (HSIL).

HR HPV DNA was determined by hybrid capture 2 (HC-2) assay. 14 types of HR HPV (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68) were detected by PCR (8). HPV DNA results were defined as positive with a high oncogenic risk HPV strain (16 or 18), positive with other HPV strains or negative.

Colposcopy

Patients with diagnosis of ASCUS and HR HPV positivity who consented to the procedure underwent colposcopic examination after applying 3% acetic acid solution and painting of the cervix with Lugol's solution. The results were grouped into 2 categories: normal colposcopic findings (original squamous epithelium, columnar epithelium and normal transformation zone) and pathological results (acetowhite epithelium, mosaic epithelium, leucoplasia and presence of atypical vessels). For examinations that suggested any cervical abnormality, biopsies were taken from the pathological finding zones, and if there was no visible lesion, from 4 quadrants.

Endocervical curettage was performed in all cases.

Statistical Methods

The data were inputed into a computerized database. The Statistical Package for the Social Sciences (IBM SPSS) software version 23.0 (SPSS, Armonk, NY, USA) was used for analyzing data. Pearson Chi-Square tests for contingency tables were used to assess the associations between categorical variables, and Cramér's V coefficient was used as a measure of association. All statistical tests were investigated significant at $p < 0.05$.

RESULTS

Among 115 patients evaluated for ASCUS smear result according to the Bethesda classification system, 28 (45.9%) had normal biopsy results, 21 (34.4%) were found to have CIN1, and 12 (19.7%) were found to have CIN2-3. The

distribution of histopathological diagnosis from biopsies of patients with ASCUS can be observed on Table 1.

Table 1. Biopsy results

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NORMAL	28	45.9	45.9	45.9 80.3
	CIN1	21	34.4	34.4	
	CIN2-3	12	19.7	19.7	
	Total	61	100.0	100.0	100.0

Colposcopic appearance after the acetic acid application can be observed on Table 2. Of the 61 patients, 19 (31.1%) had normal colposcopic findings, 28 (45.9) had acetowhite epithelium, and 14 (23.0) had mosaic epithelium.

The comparison between colposcopic appearance and biopsy results can be observed on Table 3.

Table 2. Colposcopic appearance after the acetic acid application

		Fre- quency	Percent	Valid Percent	Cumu- lative Percent
Valid	Normal Findings	19	31.1	31.1	31.1 52.5 98.4
	Mosaic Appearance	13	21.3	21.3	
	Acetowhite Appearance	28	45.9	45.9	
	Mosaic- Punctuation	1	1.6	1.6	
	Total	61	100.0	100.0	100.0

Among the patients with normal colposcopic findings, 17 (89.5%) had normal biopsy results, 2 (10.5%) were found to have CIN1, and none (0.0%) were found to have CIN2-3. Of the patients with acetowhite appearance, 11 (39.3%) had normal biopsy results, 15 (53.6%) were found to have CIN1, and 2 (7.1%) were found to have CIN2-3. Among the patients with mosaic appearance, none (0.0%) had normal biopsy results, 4 (28.6%) were found to have CIN1, and 10 (71.4%) were found to have CIN2-3.

The distribution of HPV results according to colposcopic appearance can be observed on Table 4.

Among the patients with with normal colposcopic findings, 4 (21.1%) were positive with a high oncogenic risk HPV strain (16 or 18), 5 (26.3%) were positive with other HPV strains, and 10 (52.6%) had negative HPV result. Of the patients with acetowhite appearance, 12 (42.9%) were positive with a high oncogenic risk HPV strain (16 or 18), 12 (42.9%) were positive with other HPV strains, and 4 (14.2%) had negative HPV result. Among the patients with mosaic appearance, 7 (50.0%) were positive with a high oncogenic risk HPV strain (16 or 18), 5 (35.7%) were positive with other HPV strains, and 2 (14.3%) had negative HPV result.

The comparison between HPV results and biopsy results can be observed on Table 5.

Table 3. Colposcopic appearance vs. Biopsy results

			Biopsy results			Total
			NORMAL	CIN1	CIN2-3	
Colposcopic appearance	Normal Findings	Count	17	2	0	19
		% within Colposcopy Findings with acetic acid	89.5%	10.5%	0.0%	100.0%
	Mosaic Appearance	Count	0	3	10	13
		% within Colposcopy Findings with acetic acid	0.0%	23.1%	76.9%	100.0%
	Acetowhite Appearance	Count	11	15	2	28
		% within Colposcopy Findings with acetic acid	39.3%	53.6%	7.1%	100.0%
	Mosaic- Punctuation	Count	0	1	0	1
		% within Colposcopy Findings with acetic acid	0.0%	100.0%	0.0%	100.0%
Total		Count	28	21	12	61
		% within Colposcopy Findings with acetic acid	45.9%	34.4%	19.7%	100.0%

			HPV results			Total
			Negative	16-18 +	Other +	
Colposcopic appearance	Normal Findings	Count	10	4	5	19
		% within Colposcopy Findings with acetic acid	52.6%	21.1%	26.3%	100.0%
	Mosaic Appearance	Count	2	6	5	13
		% within Colposcopy Findings with acetic acid	15.4%	46.2%	38.5%	100.0%
	Acetowhite Appearance	Count	4	12	12	28
		% within Colposcopy Findings with acetic acid	14.3%	42.9%	42.9%	100.0%
	Mosaic-Punctuation	Count	0	1	0	1
		% within Colposcopy Findings with acetic acid	0.0%	100.0%	0.0%	100.0%
Total		Count	16	23	22	61
		% within Colposcopy Findings with acetic acid	26.2%	37.7%	36.1%	100.0%

			Biopsy results			Total
			NORMAL	CIN1	CIN2-3	
HPV results	Negative	Count	7	8	1	16
		% within HPV results	43.8%	50.0%	6.3%	100.0%
	16-18 +	Count	9	13	1	21
		% within HPV results	39.1%	56.5%	4.3%	100.0%
	Other +	Count	9	10	3	22
		% within HPV results	40.9%	45.5%	13.6%	100.0%
Total		Count	25	31	5	61
		% within HPV results	41.0%	50.8%	8.2%	100.0%

Among the patients who were positive with a high oncogenic risk HPV strain (16 or 18), 9 (39.1%) had normal biopsy results, 13 (56.5%) were found to have CIN1, and 1 (4.3%) were found to have CIN2-3. Of the patients who were positive with other HPV strains, 9 (40.9%) had normal biopsy results, 10 (45.5%) were found to have CIN1, and 3 (13.6%) were found to have CIN2-3. Among the patients with negative HPV results, 7 (43.8%) had normal biopsy results, 8 (50.0%) were found to have CIN1, and 1 (6.3%) were found to have CIN2-3.

DISCUSSION

Cervix cancer is the fourth most commonly occurring cancer in women, and lack of effective global screening programs in developing countries prevent decline in the incidence and related mortality (9). Since cervix cancer has a long pre-invasive stage, detection of cervical intraepithelial neoplasia (CIN) that can progress to be an invasive lesion holds importance for earlier treatment (10).

Being the most common Pap smear result (1), ASCUS still is an incompletely defined entity and management of these patients remains controversial. Nearly 10% to 20% of patients with ASC-US prove to have a varying degree of cervical intraepithelial neoplasia (CIN), which are distinctive precursor lesions of cervical squamous cell carcinoma. As the result of ASCUS could have consequences of normal cervical mucosa to invasive cervical cancer, it is always confusing for clinicians. Deciding how to manage, how to treat the result of ASCUS is debated.

Repeating the Pap smear, performing a colposcopic examination or testing for HPV DNA positivity are all possible next steps. A study that compared management algorithms of women with ASCUS showed that repeating the cytologic testing combined with a HPV DNA test was 34% less costly than immediate colposcopy (11). However, patient follow-up still remains a problem in this management. Cytologic follow up is more acceptable than the other managements of diagnosis ASCUS. To repeat Pap smears

every six months for 2 years is recommended. As the high percentage of these will regress and will not require any treatment follow up seems to be the best option.

Moreover, this sensitive test combination has low-specificity, which makes it less useful against colposcopy in many settings (11).

In our study, we planned to investigate the significance of colposcopy in patients with ASCUS and high-risk HPV positivity, especially strains 16 and 18. As mentioned in some other studies, immediate colposcopy is an expensive screening procedure for further evaluation of ASCUS (12).

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Mid- and Long-Term Effect of Kinesio Taping on Temporomandibular Joint Dysfunction: A Randomised-Controlled Trial

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ABSTRACT

Purpose: This study aimed to determine the mid- and long-term effects of Kinesio-taping (KT) on individuals with temporomandibular joint disorders (TMD).

Methods: Thirty-three patients were randomly divided into two groups as group 1 was control, group 2 was KT group. KT treatment was applied in six sessions (one session/week) for 6 weeks. At the end of the 6th month, the visual analogue scale (VAS) values and range of motion of the jaw before and after the treatment were recorded.

Results: After the treatment in both groups, a statistically significant decrease in pain VAS values of the lateral pterygoid and masseter muscles was observed at the 6th month control ($p < 0.05$). In the intergroup evaluation, a statistically significant difference, in favour of the study group, was noted in all clinical parameters evaluated before treatment and at week 6 after treatment ($p < 0.05$). Compared with the control group, a statistically significant difference, in favour of the study group, in all clinical parameters evaluated except lateral pterygoids and protrusion VAS score was found at 6th months ($p < 0.05$).

Conclusions: The results of this study suggest that KT application could be a preferred treatment option in patients with TMD, pain and movement limitation. Further investigation is needed for widespread application.

Keywords: Athletic tape, pain, temporomandibular joint disorders

Temporomandibular Eklem Disfonksiyonu Üzerine Kinezyo Bantlamanın Orta ve Uzun Dönem Etkisi: Randomize Kontrollü Çalışma

Abstract

Amaç: Bu çalışma, kinezyo bantlamanın (KB) temporomandibular eklem bozukluğu (TEB) olan bireyler üzerindeki orta ve uzun dönem etkilerini belirlemeyi amaçladı.

Gereç ve Yöntem: Otuz üç hasta rastgele grup 1 kontrol, grup 2 KB grubu olmak üzere iki gruba ayrıldı. KB tedavisi 6 hafta boyunca altı seans (bir seans/hafta) uygulandı. 6. ayın sonunda, tedavi öncesi ve sonrası vizüel analog skala (VAS) değerleri ve çene hareket açıklığı kaydedildi.

Bulgular: Tedavi sonrası her iki grupta da 6. ay kontrolünde lateral pterygoid ve masseter kaslarının ağrı VAS değerlerinde istatistiksel olarak anlamlı azalma gözlemlendi ($p < 0.05$). Gruplar arası değerlendirilmede, tedaviden önce ve tedaviden sonra 6. haftada değerlendirilen tüm klinik parametrelerde çalışma grubu lehine istatistiksel olarak anlamlı bir fark kaydedildi ($p < 0.05$). Kontrol grubu ile karşılaştırıldığında, 6. ayda lateral pterigoidler ve protrüzyon VAS skoru dışında değerlendirilen tüm klinik parametrelerde çalışma grubu lehine istatistiksel olarak anlamlı fark bulundu ($p < 0.05$).

Sonuç: Bu çalışmanın sonuçları, TEB, ağrı ve hareket kısıtlılığı olan hastalarda KB uygulamasının tercih edilen bir tedavi seçeneği olabileceğini düşündürmektedir. Yaygın uygulama için daha fazla araştırmaya ihtiyaç vardır.

Anahtar Kelimeler: Atletik bantlama, ağrı, temporomandibular eklem rahatsızlıkları

Temporomandibular joint (TMJ) disorders (TMD) are a group of diseases that affect the supporting structures around the jaw as well as the joint (1). The main symptoms of TMD include clicking sound in the TMJ, pain and abnormal movements in the mandibula (2). The aetiology of TMD is considered multifactorial. Biomechanical, neuromuscular, biopsychosocial and neurobiological factors also affected the development of TMD (3). Studies have shown that TMD is more common in women aged 20–40 years (4,5).

The classification of TMD has caused confusion for years. Welden Bell published a classification that categorised TMD by region. This classification was slightly changed by the American Dental Association (6). Finally, the classification known as Research Diagnostic Criteria (RDC)/TMD, which includes psychological factors for the first time, was created by Samuel Dworkin and Linda LeResche. This classification has two axes. The first axis (clinical aspect of TMD) is composed of three groups: 1) muscle findings, 2) disc displacement and 3) arthralgia, arthritis and arthrosis. The second axis is related to the psychological state and pain of the patient (4). The aim of TMD treatment is to relieve pain and joint sounds and to ensure normal function (2). However, it has been argued whether surgical treatments should be performed if primarily preferred non-invasive conservative treatments were insufficient (6–8). Conservative TMD treatment includes splint applications to eliminate mechanical stress (6), physical therapy methods to alleviate skeletal and muscular pain (7), arthrocentesis and intra-articular injection methods to ensure the removal of pain mediators by washing the joint space (8).

Physical therapy methods are aimed to relieve musculoskeletal system pain, reduce inflammation and regulate oral motor functions. Many physical therapy methods are used in patients with TMD (9). Kinesio tape (KT), which has been used in TMD as a conservative treatment method, was applied as a physiotherapy treatment method in this study. KT is a latex-free, thin cotton tape. The use of KT, which was developed in Japan 25 years ago, has become widespread, especially in America, Europe and our country (10,11).

This study aimed to investigate the mid-and long-term effectiveness of KT application combined with conservative minimally invasive treatment methods in relieving pain

and other complaints in TMDs and to compare treatment outcomes. In this study, we hypothesised that KT application in addition to medical and exercises is effective in reducing pain and eliminating movement limitation in TMDs.

MATERIAL AND METHODS

Subjects and Study Design

Forty patients with TMD were evaluated for eligibility and randomisation, but seven did not meet the inclusion criteria and were excluded from the study. Participants were divided into two groups as Control and Kinesio taping (KT) groups by the block randomization method using a computer-assisted randomization program (<https://www.randomizer.org/>) by an independent researcher. Finally, 33 patients aged 18–65 years who presented to the Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, *** University, between September 2017 and August 2017 and were diagnosed with TMD clinically at the end of anamnesis and physical examination were included in this study. Patients were randomly included into the study group (n = 16) and control group (n = 17). In total, 33 patients with TMD, including 12 women and 4 men, with a mean age of 28.76 ± 0.98 years, were included in the study group, and 11 women and 6 men with a mean age of 25.87 ± 2.32 years were included in the control group.

The inclusion criteria were as follows: agreed to participate in the study by signing the consent form, aged 18–65 years with tooth grinding complaint, without systemic illness according to the research criteria of RDC/TMD, which include psychological factors (4).

The exclusion criteria were as follows: a disease that can cause facial pain such as sinusitis, migraine, tension headache and trigeminal neuralgia; TMJ secondary to inflammatory disease; TMJ subluxation and degenerative problem that restricts neck movements, and previous trauma to the joint area. It was determined not having a cystic lesion or a tumoral mass in the joint area.

The Control and KT groups both contained people with temporomandibular joint problems with a comparable age and sex distribution. The flow chart of the study is shown in Figure 1.

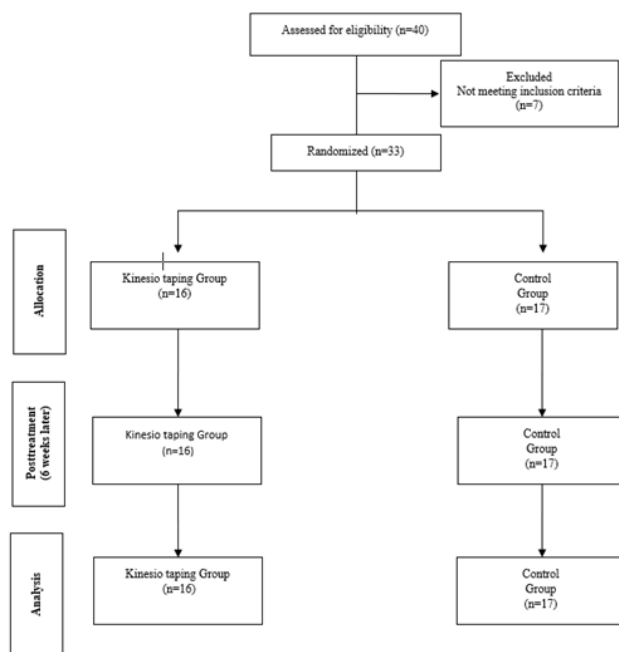


Figure 1. CONSORT flow diagram.

Approval (decision no. 2016/039) was obtained from *** University Faculty of Medicine Clinical Research Ethics Committee for this research, which was planned as a prospective controlled study. The study was carried out in accordance with the principles defined in the Declaration of Helsinki. The enrolled patients approved and signed the informed consent form that they accepted the treatment.

Measurements

Detailed anamnesis of the patients was taken, and physical examinations were performed before they were enrolled in the study. The intervention and evaluation of outcomes was performed by the same physician.

Evaluation parameters

Pain severity in the morning and during movement

Pain intensity in the masseter and lateral pterygoid muscles

The maximum mouth opening of the jaw and painless mouth opening

Amount of protrusion and lateral movements

Evaluations were performed by the same physician before treatment, 6 weeks after treatment and 6 months at the end of treatment.

The pain intensity at rest and during movement was measured with the visual analogue scale (VAS), with 0 indicating the absence of pain and 10 as the most severe pain. Patients marked their jaw pain at rest and during movement on the VAS scale. The pain in the masseter and lateral pterygoid muscles was also evaluated with VAS on palpation.

Maximum mouth opening, protrusion and lateral movements of the jaw were measured with an electronic calliper (Gfb 200-mm digital calliper). During measurements, patients were asked to sit in the axial plane parallel to the floor. The maximum mouth opening distance was measured as inter-incisal distance. No standard accepted values regarding mouth openings were established, so the lower and upper limits determined by Dworkin and LeResche were used in this study. For recording of measurements, the accepted upper limit was 53–58 mm, the normal opening limit was 40 mm, and the lower normal limit was 35 mm (12). Lateral movements were recorded as the distance after maximum movement of the mandible on the axial plane from the inter-incisal midline to both right and left directions, and the accepted lower limit was 8 mm (12). The normal limit of the protrusion motion was 10–15 mm, and the lower limit was 6 mm (12). Protrusion motion was measured through the deviation of the upper and lower jaws in the anteroposterior direction from the inter-incisal line.

Treatments

Nonsteroidal anti-inflammatory drugs, myorelaxants, nocturnal splint therapy and exercise therapy were applied to both groups for 6 weeks, while KT was further applied to the study group. Although there is no specific protocol in the treatment of TMD, analgesics, anti-inflammatory drugs, muscle relaxants, antidepressants are the main drugs used (13). In our study, appropriate doses of medical treatment were applied according to the symptoms of the patients. Also, KT was applied in a Y shape on the masseter muscle for 4 days for study group and repeated once a week. Treatment was continued for 6 weeks (14–16). (Figure 2)

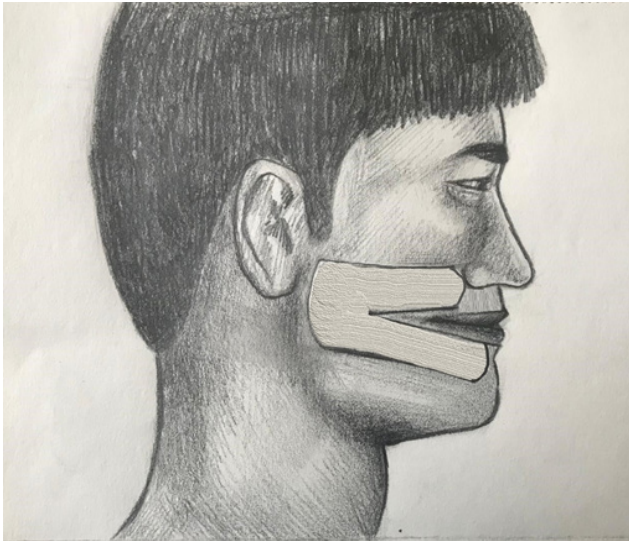


Figure 2. Kinesio taping application

In both groups, participants were instructed to perform home exercises during the follow-up period. Stretching exercises, with the help of the thumb and index finger, were prescribed to patients with limited mouth opening. Two sets of isotonic strengthening exercises and posture exercises, two times/day, for ten repetitions, were also prescribed (17). This programme was demonstrated to the patient several times by the same physician and performed repeatedly.

Statistical Analysis

SPSS Statistics Version 21.0 (IBM Corp., Armonk, NY) was used to evaluate data statistically. Wilcoxon-related two-sampling test and Friedman test were used in the within-group evaluation of the efficacy of the treatment (at the beginning of the treatment, 6 weeks after treatment and 6 months later) depending on time. Mann-Whitney U test was used in the intergroup evaluation of treatment efficacy depending on time. Chi-square test was used to compare categorised data. The statistical significance level was accepted as $p < 0.05$.

The sample size of the study was determined with G* Power (G* Power Ver. 3.0.10, Franz Faul, Universität Kiel, Germany). Pilot testing was performed on 6 volunteers (3 patients in the kinesio taping group, and 3 patients in the control group) to determine the number of participants required. Power analysis based on the results of the pilot study was completed to achieve a significant α level (0.05), power (0.90), and effect size (1.32). The results of the power analysis showed that the current study would require at least 14 participants in each group.

RESULTS

For this study, 40 patients with TMD were evaluated for eligibility, but seven were excluded according to the exclusion criteria. The remaining 33 patients were randomly divided into the control and study groups. Baseline demographic and clinical indices of the groups are presented in Table 1. Demographic data, protrusion, VAS for masseter muscle pain values, and VAS for pterygoid muscle pain values were similar in the control and study groups ($p > 0.05$). The lateral movements, painless mouth opening, maximum mouth opening, and VAS for functional pain values were significantly worse in the study group than in the control group ($p < 0.05$).

Table 1. Descriptive statistics

	Control (n:17)	Kinesio taping (n:16)	p
Age	28.76±0.98	25.87±2.32	p: 0.251 *
Gender (Male - Female)	5 m (%29.4) / 12 f (%70.6)	2 m (%12.5) / 14 f (%87.5)	p: 0.235 **
<i>n: number of participants, m: Male, f: Female, VAS: Vizuel analog scale. (* The mean age was evaluated with the Mann Whitney U test. ** Chi-square test was used to compare categorised data. Statistical significance level was accepted as $p < 0.05$.</i>			

Table 2 presents the results of comparing changes in clinical parameters within groups over time. While a statistically significant increase was observed in the level of pain, maximum mouth opening and left and right lateral movements (excluding protrusion in the 6th month) from the beginning to week 6 of treatment and from the beginning to month 6 of treatment in the study group, a statistically significant decrease was observed in pain VAS and morning pain VAS ($p < 0.05$). However, these results were not statistically significant ($p > 0.05$) in the control group. A statistically significant decrease was observed in the right and left masseter VAS and right and left lateral pterygoid VAS from the beginning to week 6 and from the beginning to month 6 after treatment in both the study and control groups ($p < 0.05$).

Table 3 compares the differences between the baseline and end-of-treatment values of clinical parameters in both groups. In the intergroup evaluation, a statistically significant difference, in favour of the study group, was found in the values of all clinical parameters before treatment and at week 6 after the treatment ($p < 0.05$). Moreover, In the intergroup evaluation, a statistically significant difference, in favour of the study group, was found in the values of all clinical parameters (excluding protrusion and lateral pterygoids in the 6th month) before treatment and at month 6 after the treatment ($p < 0.05$). Also, for the intergroup evaluation, no statistically significant difference, in favour of the study group, was noted on the right and left lateral pterygoid VAS and protrusion before treatment and at month 6 after treatment ($p > 0.05$).

Table 2. Comparison of changes in clinical parameters within groups over time					
		Control		Kinesio taping	
		Mean±Sd	Median (IQR 25 – 75)	Mean±Sd	Median (IQR 25 – 75)
Left lateral movement (mm)	Baseline	23.21±3.51	24.17(20.90 – 24.47)	18.78±2.63	18.05(17.02 – 21.01)
	6 th Week	22.82±1.78	22.67(21.48 – 24.11)	21.91±2.59	21.70(21.22 – 23.68)
	6 th Month	22.70±2.69	22.94(21.54 – 24.78)	20.78±2.67	18.99(20.94 – 22.67)
	p ₁	0.586		0.001	
	p ₂	0.836		0.012	
Right lateral movement (mm)	Baseline	22.47±3.55	21.82(21.22 – 24.57)	18.36±2.99	17.39(16.05 – 21.74)
	6 th Week	21.52±2.92	22.60(19.41 – 24.10)	21.48±1.95	22.18(19.65 – 22.91)
	6 th Month	21.93±3.03	22.09(20.15 – 23.24)	20.43±2.73	20.98(17.55 – 22.91)
	p ₁	0.246		0.000	
	p ₂	0.469		0.003	
Painless mouth opening (mm)	Baseline	34.46±5.52	36.58(31.63 – 37.93)	24.70±8.10	24.65(17.58 – 29.79)
	6 th Week	32.32±7.87	32.08(26.45 – 38.42)	31.89±7.50	31.32(26.37 – 38.09)
	6 th Month	30.65±7.24	32.90(26.41 – 37.27)	29.98±5.96	29.10(24.45 – 34.27)
	p ₁	0.523		0.001	
	p ₂	0.098		0.016	
Maximum mouth opening (mm)	Baseline	44.58±7.02	44.42(41.43 – 49.07)	31.97±8.99	34.69(24.67 – 38.83)
	6 th Week	43.22±6.44	42.04(38.04 – 48.68)	43.05±6.24	42.87(38.82 – 48.65)
	6 th Month	45.73±6.73	46.18(42.69 – 48.52)	41.74±8.73	40.06(34.18 – 50.24)
	p ₁	0.266		0.000	
	p ₂	0.717		0.006	
Protrusion	Baseline	3.80±1.84	3.36(2.08 – 5.61)	2.82±1.28	2.71(1.70 – 3.47)
	6 th Week	3.71±1.79	3.36(2.45 – 4.52)	4.10±1.52	4.34(2.68 – 5.38)
	6 th Month	3.93±1.90	3.76(2.19 – 5.02)	3.61±1.50	3.36(2.34 – 4.99)
	p ₁	0.687		0.004	
	p ₂	0.679		0.060	
VAS for Functional Pain (cm)	Baseline	5.52±2.21	5.00(4.00 – 7.00)	7.37±2.24	8.50(5.50 – 9.00)
	6 th Week	4.58±2.34	5.00(3.00 – 6.00)	1.75±2.11	0.00(1.00 – 3.00)
	6 th Month	4.64±2.34	4.00(3.00 – 6.5.)	2.00±1.70	1.50(0.25 – 4.00)
	p ₁	0.227		0.000	
	p ₂	0.227		0.003	
VAS for right masseter muscle pain (cm)	Baseline	2.29±0.58	2.00(2.00 – 3.00)	2.62±0.50	3.00(2.00 – 3.00)
	6 th Week	1.76±0.66	2.00(1.50 – 2.00)	0.37±0.61	0.00(0.00 – 1.00)
	6 th Month	1.62±0.61	2.00(1.00 – 2.00)	0.83±1.02	0.50(0.00 – 1.75)
	p ₁	0.030		0.000	
	p ₂	0.020		0.003	
VAS for left masseter muscle pain (cm)	Baseline	2.29±0.58	2.00(2.00 – 3.00)	2.62±0.61	3.00(2.00 – 3.00)
	6 th Week	1.76±0.66	2.00(1.50 – 2.00)	0.62±0.71	0.50(0.00 – 1.00)
	6 th Month	1.62±0.61	2.00(1.00 – 2.00)	1.25±1.05	1.00(0.25 – 2.00)
	p ₁	0.030		0.001	
	p ₂	0.020		0.005	
VAS for right lateral pterygoid muscle pain (cm)	Baseline	2.70±0.46	3(2 – 3)	2.87±0.34	3.00(3.00 – 3.00)
	6 th Week	1.58±0.79	1(1 – 2)	0.31±0.060	0.00(0.00 – 0.75)
	6 th Month	1.31±0.70	1(1 – 2)	1.25±1.05	1.00(0.25 – 2.00)
	p ₁	0.002		0.000	
	p ₂	0.001		0.006	
VAS for left lateral pterygoid muscle pain (cm)	Baseline	2.70±0.46	3(2 – 3)	2.87±0.34	3.00(3.00 – 3.00)
	6 th Week	1.58±0.79	1(1 – 2)	0.37±0.61	0.00(0.00 – 1.00)
	6 th Month	1.31±0.70	1(1 – 2)	1.00±1.04	1.00(0.00 – 2.00)
	p ₁	0.002		0.000	
	p ₂	0.001		0.003	

VAS: Visual analogue scale, p1 Value from baseline to 6th week, p2 Value from baseline to 6th month, IQR: Interquartile range

Table 3. Compares the differences between the baseline and end-of-treatment values of clinical parameters in both groups

		Control		Kinesio taping		p
		Mean±Sd	Median (IQR 25 – 75)	Mean±Sd	Median (IQR 25 – 75)	
Left lateral movement (mm)	Baseline-6 th Week	-0.38±3.15	0.09 (-2.62 – 1.41)	3.13±2.50	2.92 (1.19 – 4.47)	0.002
	Baseline-6 th Month	-0.26±2.67	-0.38 (-2.08 – 2.00)	2.81±2.84	3.09 (0.41 – 4.93)	0.012
Right lateral movement (mm)	Baseline-6 th Week	-0.94±2.66	-0.19 (-1.94 – 0.75)	3.11±1.89	3.36 (1.64 – 4.44)	0.000
	Baseline-6 th Month	-0.58±3.63	-0.87 (-1.79 – 1.29)	3.13±2.23	2.73 (1.37 – 5.15)	0.002
Painless mouth opening (mm)	Baseline-6 th Week	-2.13±9.37	-1.40 (-8.23 – 6.96)	7.18±5.69	5.94 (4.44 – 12.77)	0.006
	Baseline-6 th Month	-3.58±8.29	-3.35 (-8.46 – 0.56)	5.94±8.17	5.56 (0.01 – 10.44)	0.004
Maximum mouth opening (mm)	Baseline-6 th Week	-1.35±5.56	-0.85 (-2.96 – 0.86)	11.07±5.78	9.64 (6.28 – 13.24)	0.000
	Baseline-6 th Month	-14.23±10.18	-14.79 (-17.96 – -8.37)	-1.29±9.35	-0.63 (-7.98 – 3.54)	0.001
Protrusion	Baseline-6 th Week	-0.09±1.63	0.16 (-1.30 – 0.86)	1.27±1.43	1.44 (0.18 – 2.17)	0.028
	Baseline-6 th Month	0.26±1.34	0.01 (-0.22 – 0.70)	1.10±1.54	1.14 (-0.13 – 2.05)	0.114
VAS for Functional Pain (cm)	Baseline-6 th Week	-0.94±2.96	0.00 (-3.50 – 1.50)	-5.62±2.27	-5.00 (-7.75 – -3.25)	0.000
	Baseline-6 th Month	-0.88±3.15	-1.00 (-2.00 – 0.50)	-5.75±2.80	-5.50 (-8.75 – -4.00)	0.001
VAS for right masseter muscle pain (cm)	Baseline-6 th Week	-0.52±0.87	0.00 (-1.00 – 0.00)	-2.25±0.68	-2.00 (-3.00 – -2.00)	0.000
	Baseline-6 th Month	-0.62±0.88	-0.50 (-1.00 – 0.00)	-1.83±0.93	-2.00 (-2.75 – -1.00)	0.004
VAS for left masseter muscle pain (cm)	Baseline-6 th Week	-0.52±0.87	0.00 (-1.00 – 0.00)	-2.00±0.96	-2.00 (-3.00 – -2.00)	0.000
	Baseline-6 th Month	-0.62±0.88	-0.50 (-1.00 – 0.00)	-1.58±1.08	-1.50 (-2.75 – -1.00)	0.025
VAS for right lateral pterygoid muscle pain (cm)	Baseline-6 th Week	-1.11±0.85	-1.00 (-2.00 – 0.00)	-2.56±0.62	-3.00 (-3.00 – -2.00)	0.000
	Baseline-6 th Month	-1.37±0.80	-2.00 (-2.00 – -1.00)	-1.58±1.24	-2.00 (-2.75 – -1.00)	0.473
VAS for left lateral pterygoid muscle pain (cm)	Baseline-6 th Week	-1.11±0.85	-1.00 (-2.00 – 0.00)	-2.50±0.63	-3.00 (-3.00 – -2.00)	0.000
	Baseline-6 th Month	-1.37±0.80	-2.00 (-2.00 – -1.00)	-1.91±0.99	-2.00 (-3.00 – -1.00)	0.131

VAS: Visual analogue scale, IQR: Interquartile range

DISCUSSION

In this study, the hypothesis was that KT application in addition to medical and exercise is effective in reducing pain and eliminating movement limitations in TMDs. The results of the study confirmed this hypothesis: KT application in addition to medical treatment and exercise was more effective in reducing pain and increasing range of motion.

TMD is a common jaw problem accompanied with pain and loss of function. Physical therapy is important in these disorders given the accompanying pain and loss of function. Kraus et al. (18) investigated 511 patients with TMD and observed that 96% of these patients complained of jaw pain, of which 69% had neck pain and 74% had headache, so these patients also visited specialists other than dentists. Similar complaints were encountered in our patients. Physical therapy methods, as conservative treatment methods, were used in both groups. Exercise, which is one of the conservative treatment methods, is widely used in TMDs and has positive results.

One of the conservative treatment options used in TMDs is KT (19). KT is a simple, non-invasive treatment option. In some cases, KT application slows down the healing process of damaged tissue due to its compressive effect on the tissue and does not provide any support to deep tissues such as the fascia. In KT application, more successful outcomes can be obtained because KT has similar structural features and flexibility to the human skin without limiting joint movements (11).

Benlidayi et al. (19) investigated KT applications in 28 patients with TMD and divided them into study and control groups. Medical therapy, physical therapy exercises and KT to the masseter muscle were applied to the study group, while medical therapy and physical therapy exercises were applied to the control group. After 6 weeks of treatment, the maximum mouth opening, improvement in functional limitation and increase in right lateral movements were more significant in the study group (19). These results are consistent with our study, in which patients were followed for 6 months. In this study, while the decrease in temporal muscle pain was significant in the study group, no difference was found in the control group. While no difference was found between the groups in masseter muscle pain, a significant difference was found. This difference may be due to KT application for 6 weeks. Benlidayi et al. (19) applied KT three times in 6 weeks.

Scientific data on the mechanism of action and effectiveness of KT application are still insufficient. In a previous study, it is thought that by supporting the muscle tissues in the joint area, the muscle can be strengthened, joint stabilisation can be increased and joint movements are easier (20). An inhibition mechanism occurs since the decrease in pressure on structures such as muscles, ligaments, tendons and nerves reduces the stimulation of pain mediators; therefore, pain is reduced (21).

In 2014, Bae et al. (22) investigated 17 male and 25 female patients (aged 20–30 years) with myofascial pain and divided them randomly into two groups. They applied KT to the trigger points of the sternocleidomastoid muscle of patients in the study group, and they did not apply any treatment to the patients in the control group. Consequently, they observed a significant decrease in VAS pain values and pain threshold values caused by pressure in the study group compared with the control group, while a significant increase was found in TMJ movements. This study is valuable because it examined the effectiveness of KT alone. It concluded that KT can be a preferred physical therapy method in muscle-induced pain (22).

Ozturk et al. (23) conducted a placebo-controlled study on 37 patients with myofascial pain syndrome, and they concluded that KT application on the trapezius muscle reduced muscle tension and caused a decrease in VAS pain values. It is effective in reducing pain by removing the skin from deep tissues in the area where KT is applied and in providing the volumetric area required for blood and lymph flow (11). The neurophysiological effects caused by KT prevent pain transmission at the spinal level with the gate-control mechanism. In the gate-control theory put forward by Melzack and Wall in 1965, (24) nerve currents, such as during touch, which are not related to pain, compete with pain currents trying to reach the brain.

Wei-Ting et al. (25) suggested that KT application was a more effective treatment option when used in combination with other treatment methods for myofascial pain. These results are consistent with our study. As regards the side effects or contraindications of KT, skin reactions can be seen in the KT applied area, which may occur as an allergic reaction or local irritation. Allergic reaction often develops against the polyacrylate adhesive that provides the adhesive properties of the tape. More rarely, reactions may be due to the dye that gives the colour of the tape. In these situations, the tape should be removed. No such side effects were observed in our study (11). Considering the results of our questionnaire survey, joint disorders of the patients did not significantly affect their general quality of life.

CONCLUSION

In this study, KT has positive effects on pain in the early period, increasing the mouth opening. When combined with exercise therapy, KT application was found to increase maximum mouth opening, as it reduced pain, increased exercise tolerance and provided motivation. Given these effects, KT can be indicated to patients with TMD, pain and movement limitation.

This study had several limitations. The female patients were predominant in the study population, controlling the regular home exercises as recommended is difficult, and the pain scales based on subjective parameters may have affected the results of the study. The baseline measurements of the groups have differences especially in joint range of motions. This may have influenced the results of the study. In this study, the effect of KT on joint disorders was observed, but these data should be supported with placebo studies. The effectiveness of different application protocols in different indications in KT technique requires investigation.

DECLARATIONS

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Declaration of Interest

No potential conflict of interest was reported by the authors.

Data Availability Statement

Data will be made available on request.

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Evaluation of Information Attitudes and Behaviors of Yozgat Bozok University Employees towards Rational Drug Use

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ABSTRACT

Purpose: Universities are one of the main institutions which play important roles in the society. The aim of our study was to evaluate the knowledge, attitudes and behaviors of the employees of Yozgat Bozok University in terms of rational drug use.

Materials and Methods: Data was collected by the application of a questionnaire consisting of 4 sections and 41 questions in the electronic environment. All the data was evaluated using descriptive statistical methods. Mann-Whitney U and Kruskal Wallis tests were used to calculate differences between socio-demographic parameters like income, education, occupation, gender and age.

Results: The total number of the participants were 189 and %45 were men and %55 were women. Knowledge of rational drug use was found low in the men, in the primary and high school education groups and in the poor income group ($p<0.05$). Vitamins and analgesics were the main drug groups used without any advice of a physician.

Conclusion : Insufficient knowledge of the rational drug use is much more prominent in the low income group, in men and in low educated population but the role of internet is an additional important factor on the drug use which may become much more important in the future. In order to improve the rational drug use, the actions of the organizations and health institutions are expected to consider the role of socio-economic parameters and the internet.

Keywords: Rational drug use, survey, level of knowledge, drug safety.

Yozgat Bozok Üniversitesi Çalışanlarının Akılcı İlaç Kullanımına Yönelik Bilgi Tutum ve Davranışlarının Değerlendirilmesi

ÖZET

Amaç: Üniversiteler toplumda önemli rol oynayan kurumlardan biridir. Çalışmamızın amacı Yozgat Bozok Üniversitesi çalışanlarının bilgi, tutum ve davranışlarını Akılcı İlaç Kullanımı açısından değerlendirmektir.

Gereç ve Yöntem: Veriler elektronik ortamda 4 bölüm ve 41 sorudan oluşan anket uygulaması ile toplanmıştır. Tüm veriler tanımlayıcı istatistiksel yöntemler kullanılarak değerlendirildi. Gelir, eğitim, meslek, cinsiyet ve yaş gibi sosyo-demografik parametreler arasındaki farkları hesaplamak için Mann-Whitney U ve Kruskal Wallis testleri kullanıldı.

Bulgular: Toplam katılımcı sayısı 189 olup, %45'i erkek, %55'i kadındır. Akılcı ilaç kullanımı bilgisinin seviyesi, erkeklerde, ilköğretim ve lise mezunlarında ve düşük gelir sahip olanlarda yetersiz bulundu ($p<0.05$). Doktor tavsiyesi olmadan kullanılan başlıca ilaç gruplarının vitaminler ve analjezikler olduğu tespit edildi.

Sonuç: Akılcı ilaç kullanımına ilişkin bilginin yetersizliği, düşük gelirlilerde, erkeklerde ve eğitim seviyesi düşük olanlarda çok daha belirgin olmakla birlikte, ilaç kullanımında internetin rolü gelecekte çok daha önemli hale gelebilecek bir faktördür. Akılcı ilaç kullanımını geliştirmek için, kuruluşların ve sağlık kurumlarının yapacakları faaliyetlerinde sosyo-ekonomik parametreleri ve internetin rolünü dikkate alması yerinde bir davranış olacaktır.

Anahtar Kelimeler: Akılcı ilaç kullanımı, anket, bilgi düzeyi, ilaç güvenliği.

The primary aim of the health services is protection of society from diseases. Drugs are one of the important applications for prevention, diagnosis and treatment of diseases (1). Nairobi meeting of the World Health Organization (WHO) in 1985 is a cornerstone for the beginning of Rational Drug Use (RDU) studies. RDU was defined by WHO as “patients use drugs that are appropriate for their clinical needs, in appropriate doses, for a sufficient period of time, at the least cost to themselves and to society” (2–5).

Rational drug use has also an important role on the avoidance of preventable adverse drug reactions (6). Use of medicines without consulting a doctor but with the advice of neighbours, friends or relatives, compliance problems including application of incorrect dose and stopping the treatment early are the most common types of irrational drug use (7,8). Based on the WHO data, irrational use of all medicines are more than 50% resulting many problems including antibiotic resistance (9). Irrational drug use is one of the serious health problems in Turkey and “Rational Drug Use National Action Plan” was started by the Turkish Ministry of Health (10). Studies on RDU of antibiotics were reported for the West, East, North and South regions of Turkey (11) but to the best of our knowledge, there is no report on the RDU of Yozgat, except our first preliminary report (14). Yozgat is a central Anatolian province surrounded by the Kızılırmak (ancient name is Halys) river and 50 km away from Hattusa, the ancient capital of the Hittite civilization and it is located on the ancient migration path of Anatolia and Caucasian highlands (12). The aim of our study is to investigate the RDU of the staff of Yozgat Bozok University.

MATERIALS AND METHODS

Type of Research

This research is a descriptive study for the evaluation of the knowledge, attitudes and behaviors of the academic and administrative staff of Yozgat Bozok University about RDU. The study was approved by the Clinical Research Ethics Committee of Yozgat Bozok University (no: 2017-KAEK-189-2021.04.14_12).

Data Collection Tools

In order to evaluate the rational drug use, a questionnaire consisting of four sections and 41 questions was prepared electronically by the authors. Section I of the questionnaire consists of 13 questions and was prepared to determine the sociodemographic and personal background characteristics of the participants. Section II was prepared to

evaluate the level of knowledge of the participants about RDU with 16 questions. Section III was prepared to evaluate the attitudes and behaviors of the participants on the use of drugs in their suitable form, dose and duration against diseases, with 8 questions and Section IV was aimed to evaluate the rational drug use behavior with 5 questions. The scale was prepared according to a previous study used to evaluate the knowledge level of the participants (13). The questionnaire prepared in the electronic environment was sent to all staff of the university via e-mail and short messages in september-november 2021, ensuring their participation in the study.

The Universe of the Research

The questionnaire was sent to all the staff of the university thus sampling was not performed and the study was completed with 189 academic and administrative personnel who agreed to participate in the study.

Analysis of Data

Data analysis was done using IBM SPSS 23.0 package program. Demographic characteristics and attitudes of the participants were analysed using descriptive statistics (frequencies, ratios, mean, median, standard deviation and minimum-maximum). Kolmogorov-Smirnov test showed us that the data was not normally distributed. Kruskal Wallis and Mann Whitney U non parametric tests were used for comparison of differences of the parameters including income, education, occupation, gender and age. Significance level was accepted as $p < 0.05$ and denoted by an asterisk.

RESULTS

Gender

55% (n:104) of the participants in the study were male and 45% (85) were female.

Age

The age of participants was found as 36-45 years with 42.9% (n:81).

Educational Status

0.52% (n:4) of the participants were primary school, 4.2% (n:8) high school or equivalent, 29.1% (n:55) associate degree and undergraduate, 64% higher had bachelors and doctorate degrees. 62.2% of the participants (n:115) were academic staff and 37.8% (n:70) were administrative staff.

Income Level

The rate of those with an income level of 7501-10000 TL was 46% (n: 87) and the rate of those with 1-5 years of service was 28.6% (n: 54).

The values about the socio-demographic characteristics of the participants given above were given in Table 1.

Variables		(n)	(%)
Gender	Female	85	45
	Male	104	55
Age groups	25 and less	5	2,6
	26-35	68	36
	36-45	81	42,9
	46-55	25	13,2
	56 and above	9	4,8
	Education status	Primary education	4
High school and equivalent		8	4,2
Associate degree (2-year college)		15	7,9
Undergraduate (At least 4 years of college)		40	21,2
Postgraduate (Master's)		41	21,7
Staff status	Academical personnel	115	62,2
	Administrative Staff	70	37,8
Income rate	0 TL – 2500 TL	1	0,5
	2501 TL – 5000 TL	33	17,5
	5001 TL – 7500 TL	39	20,6
	7501 TL – 10000 TL	87	46
Term in Office	10001 TL and above	29	15,3
	1 year and less	10	5,3
	1-5 years	54	28,6
	6-10 years	53	28
	11-15 years	40	21,2
Presence of chronic disease	16 years and above	32	16,9
	No	154	81,5
Regularly drug use	Yes	35	18,5
	No	147	22,2
Regularly drug use	Yes	42	77,8
	No	42	77,8

RDU Scale

The mean±standard deviation of scores of the participants obtained from the scale was 29.7±2.5, the median was 30.0, and the extreme values varied between

20.0-32.0. The scores of the RDU scale were low in the following participants:

- the primary education and high school,
- those with an income level of 2501-5000 TL, and
- men (Table 2)

Table 2: Comparison of the median scores of the participants in the study according to their sociodemographic characteristics

Variables		Scale Score Median (minimum-maximum)	Test Value
Age groups	25 and less (n:5)	30 (28-30)	0,423
	26-35 (n:67)	30 (20-32)	
	36-45 (n:78)	30 (23-32)	
	46-55 (n:25)	30 (22-32)	
	56 and above (n:8)	30 (26-32)	
Gender	Male (n:98)	30 (20-32)	0,028*
	Female (n:85)	30 (20-32)	
Education status	Primary education (n:4)	27,75 (26-32)	0,018*
	High school and equivalent (n:8)	27,25 (22-32)	
	Associate degree (2-year college) (n:15)	31 (28-32)	
	Undergraduate (At least 4 years of college) (n:40)	30 (20-32)	
	Postgraduate (Master's) (n:41)	30 (20-32)	
Income rate	Postgraduate (PhD) (n:80)	30 (23-32)	0,046*
	2501 TL – 5000 TL (n:33)	29,5 (22-32)	
	5001 TL – 7500 TL (n:36)	30,5 (20-32)	
	7501 TL – 10000 TL (n:86)	30 (20-32)	
	10001 TL and above (n:28)	30 (26-32)	
Term in Office	1 years and less (n:10)	30 (27-32)	0,656
	1-5 years (n:54)	30 (24-32)	
	6-10 years (n:53)	30 (20-32)	
	11-15 years (n:40)	30,5 (20-32)	
	16 years and above (n:32)	30 (23-32)	
Presence of chronic disease	No (n:154)	30 (22-32)	0,528
	Yes (n:35)	30 (20-32)	
Regularly drug use	No (n:147)	30 (22-32)	0,486
	Yes (n:42)	42	

*p<0.05

Attitude for RDU

The majority (91.5%) (n:173) of the participants stated that they preferred to consult a physician about their disease and drugs. The rate of non-pharmaceutical product use such as herbal and natural products is 36.5% (n:69). Drug use without an advice of a physician is 57.7% (n: 109) and consequently harmed by drugs without the advice of a physician is 8.7% (n: 14). Most of the participants (94.1%) (n: 176) preferred to consult a physician in case of any adverse drug reaction and 3.8% (n: 7) preferred to find a solution on their own. In case of lack of a physician, 61.6% (n:104) of the participants preferred to get information about drugs from the pharmacist, while 23.7% (n:40) preferred to use the internet. The majority of the participants stated to use the drugs in proper dose (99.5%) (n: 187), duration 92% (n: 173) and storage conditions 98.9% (n: 186) (Table 3).

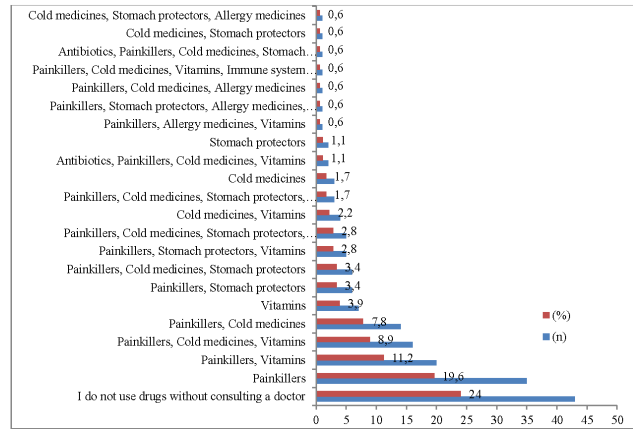


Figure 1: Which drug(s) the participants used without consulting a physician

Questions	(n)	(%)
Who do you contact first about your illness and medications? (n:189)	Physician	173, 91,5
	Pharmacist	3, 1,6
	Internet	8, 4,2
	Relatives (Spouses, relatives, friends, etc.)	3, 1,6
	To myself	1, 0,5
	I don't apply	1, 0,5
Do you use non-pharmaceutical products such as herbal and natural products? (n:189)	No	120, 63,5
	Yes	69, 36,5
Have you ever used medication without a doctor's advice at any point in your life? (n:189)	Yes	109, 57,7
	No	80, 42,3
Have you ever been harmed by the drugs you use without a doctor's advice? (n:161)	No	147, 91,3
	Yes	14, 8,7
Who do you contact when the drugs you use have side effects? (n:187)	I consult a doctor	176, 94,1
	I'm looking for a solution myself	7, 3,8
	I consult a pharmacist	4, 2,1
From whom do you get the information about the drugs used without a doctor's recommendation? (n:169)	Pharmacist	104, 61,6
	Internet	40, 23,7
	Pharmaceutical prospectus	8, 4,7
	Relatives (Spouses, relatives, friends, etc.)	7, 4,1
	Assistant health worker (Nurse, midwife, health officer, etc.)	6, 3,5
	I didn't take any medicine without the doctor's advice	4, 2,4
Do you use drugs as prescribed? (n:188)	Yes	187, 99,5
	No	1, 0,5
Do you pay attention to the proper storage of medicines? (n:188)	Yes	186, 98,9
	No	2, 1,1
Do you use the medicine for the period specified by the doctor? (n:188)	Yes	173, 92
	No	15, 8
Would you prefer the cheaper one among the drugs with the same effect? (n:186)	No	104, 55,9
	Yes	82, 44,1

DISCUSSION

The size of the world pharmaceutical industry was 1 trillion 300 billion dollars in 2019, it is expected to grow by 4.5% on average in the 2020-2023 period and exceed the level of 1.5 trillion dollars. The largest market in the world pharmaceutical industry is the United States of America (USA). While 65.2% of the new drugs produced in the 2013-2018 period were sold in the US market, 17.7% were sold in the European markets consisting of Germany, France, Italy, Spain and the United Kingdom. In Turkey, it is stated that the market size has reached the level of 29.5 billion TL as of September 2019 (14). In a report evaluating the pharmaceutical industry, when the number of units of box sold in Turkey is considered, it is reported that 1.7 billion boxes are sold and antibiotics are the most sold drug group on a box basis (14).

Irrational use of antibiotics with excessive antibiotic consumption is regional and also a worldwide health problem. A significant regional variation (east versus west Anatolia) for the antibiotic use for the was reported (11). Although Yozgat is located at the central Anatolia, very few (1.6%) of the participants in our study preferred to use antibiotics without consulting a physician (Figure 1). A possible explanation for this value may be the educational status of the participants which require further investigations.

Analgesic drug use without consulting a physician was found high in our study which was also reported in previous studies (15–18). It is known that non-steroidal anti-inflammatory drugs (NSAID) cause bone marrow depression and serious gastrointestinal side effects, especially cause antihypertensive drug interactions, and aspirin can cause Reye's syndrome in children. The irrational use of analgesics without the advice of a physician will augment the NSAID related adverse drug reactions.

High RDU levels are reported in women, in high education and high income groups (Table 2) which are also reported by previous studies (13,19). These results show that as the socio-cultural, educational and income levels increase, an improvement of the RDU behaviour is expected.

The rate of consulting a physician for diseases and drugs in our study is 91.5%. The value of our study is higher than the same parameters of a study performed in Firat University (69.2%) in 2016 and in Muğla University (58.9%) in 2005 (7,20). They represent west (Muğla) and east (Firat, Elazığ) and Yozgat is just in between these regions. All the three studies were conducted in the university

environments with similar population characteristics. A possible explanation of these different values may be related to time (2005, 2016 and 2021). The role of the time suggests the role of access to the information sources via internet and information technologies. One of the results of our study is a significant value of internet (23.7%) (Table 3) suggesting the growing role of internet on the RDU related information. It is possible to say that one of the striking outcomes of our study is the role and impact of internet on the RDU.

CONCLUSION

To our surprise, irrational antibiotic use was very low in our study. Yozgat is a central Anatolian province and different values of RDU were not related to the regional differences but income and educational factors were much more prominent. Gender specific difference on RDU with higher awareness of women is important and also the role of internet and information technologies were surprisingly playing important role on the RDU which may have much more impact in the future.

DECLARATIONS

Conflict of Interest and Financial Situation

Our work was not funded by an institution or organization. There is no conflict of interest among the authors in this study.

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Effects of Vitamin C Supplementation on the Metabolic Abnormalities Associated with Diabetes Mellitus

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ABSTRACT

It is known that exogenous antioxidant supplementation may be beneficial against micro and macrovascular complications of diabetes. This study aimed to investigate the effect of vitamin C supplementation on insulin secretion, hyperlipidemia, oxidative stress and paraoxonase-1 enzyme (PON1) activity which are impaired due to chronic hyperglycemia in diabetic rats. For this purpose, twenty-four Wistar albino rats were divided into 3 groups as group C, DC and DCC. The rats in DC and DCC groups were induced diabetes by single dose streptozotocin injection (45 mg/kg). C and DC groups fed with standard rat diet (vitamin C free), DCC group fed with experimental diet supplemented with vitamin C at a dose of 200 mg/kg. According to the findings, rats in group C consumed less feed and water compared to diabetic rats during 8-weeks experimental period ($p < 0.001$). In addition, total cholesterol and triglyceride levels of group C were lower than diabetic groups while PON1 activity and insulin values were higher ($p < 0.05$). On the other hand, there were no significant differences between DC and DCC groups in terms of insulin, triglyceride, HDL, LDL and total cholesterol levels but TAS and PON1 activity levels of group DCC were significantly higher than group DC ($p < 0.05$). As a conclusion, vitamin C supplementation may be helpful in increasing PON1 activity and antioxidant capacity in the presence of diabetes.

Keywords: Diabetes mellitus; oxidative stress; hyperlipidemia; paraoxonase 1; ascorbic acid

C Vitamini Desteğinin Diabetes Mellitus ile İlişkili Metabolik Anormallikler Üzerindeki Etkileri

ÖZET

Eksojen antioksidan takviyesinin, diyabetin mikro ve makrovasküler komplikasyonlarına karşı faydalı olabileceği bilinmektedir. Bu çalışmada C vitamini desteğinin, diyabetik ratlarda, kronik hiperglisemiye bağlı olarak bozulan insülin sekresyonu, hiperlipidemi, oksidatif stres ve paraoksonaz-1 enzim (PON1) aktivitesi üzerine etkilerinin araştırılması amaçlanmıştır. Bu amaçla, yirmi dört adet Wistar albino cinsi rat C, DC ve DCC grupları olarak 3 gruba ayrıldı. DC ve DCC grubundaki ratlarda, tek doz streptozotocin enjeksiyonu ile diyabet oluşturuldu (45 mg/kg). C ve DC grubundaki ratlar standart rat yemi (C vitamini içermeyen) ile beslenirken, DCC grubundaki ratlar 200 mg/kg dozunda C vitamini ile desteklenmiş deneysel yemle beslendi. Elde edilen bulgulara göre, C grubundaki ratların sekiz haftalık deney süresinin sonunda diyabetik ratlara göre daha az yem ve su tükettiği görüldü ($p < 0,001$). Bunun yanı sıra C grubundaki ratların toplam kolesterol ve trigliserid düzeylerinin diyabetik gruplara göre daha düşük, PON1 aktivite ve insülin değerlerinin ise daha yüksek olduğu saptandı ($p < 0,05$). Bir diğer yandan, DC ve DCC grupları arasında toplam kolesterol, trigliserid, HDL kolesterol, LDL kolesterol ve insülin düzeyleri açısından anlamlı farklılık gözlenmesi de, DCC grubunun TAS ve PON1 aktivite düzeylerinin DC grubuna göre anlamlı olarak daha yüksek olduğu belirlendi ($p < 0,05$). Sonuç olarak, diyabet varlığında, C vitamini takviyesi PON1 aktivite düzeyini ve antioksidan kapasiteyi artırmada etkili olabilir.

Anahtar Kelimeler: Diyabet; oksidatif stres; hiperlipidemi; paraoksonaz 1; askorbik asit

Diabetes Mellitus (DM) is a group of metabolic diseases that are characterized by hyperglycemia. The generation of reactive oxygen species (ROS) increases in DM due to chronic hyperglycemia and increased ROS levels have a crucial role in the pathogenesis of diabetes related complications. The ROS production can be controlled by nonenzymatic and enzymatic antioxidants in healthy people. However, endogenous antioxidants can not downregulate the production of ROS in diabetic people (1). Therefore, routine antioxidant support in diabetic people is a matter of debate. Antioxidant supplementation to diabetic people is more discussed in these days due to the COVID-19 pandemic process. High fasting blood glucose level (>7.00 mmol/L) is a strong and independent predictor of COVID-19-related poor outcomes (2) and 28-day mortality (3). On the other hand, it is currently being discussed that intravenous high-dose vitamin C supplementation may be beneficial in the early stages of COVID-19. Vitamin C supplementation may improve alveolar fluid clearance, regeneration of antioxidant molecules such as α -tocopherol, urea, glutathione and β -carotene and epithelial cell functions in diabetic patients (4), and may be beneficial in protecting against a variety of diseases including COVID-19.

Although the effects of vitamin C on regulating fasting glucose levels (4), decreasing HbA1c levels (5) and improving insulin sensitivity (6) has been reported, the results differ and the mechanism of action is not fully elucidated. But in the presence of DM, it is stated that ascorbic acid (reduced form of vitamin C) is required to optimize insulin secretion function of islet cells due to impaired insulin secretion and ascorbate cycle (7). It is also noted that vitamin C is an important antioxidant for the protection of pancreatic beta cells against glucose toxicity (8). In addition, Kaneto et al. (1999) determined that β cells of diabetic mice supplemented with antioxidants were larger than those whom were not and it was concluded that antioxidants such as vitamin C prevent apoptosis without affecting the proliferation of beta cells.

It is a well-known fact that the risk of coronary heart disease increases and the lipid profile deteriorates in DM. The protective roles of vitamin C against these problems noted in the literature (9). Additionally vitamin C deficiency can lead to the deterioration of the transport of long-chain fatty acids to the mitochondria and so increased triglyceride synthesis in diabetic patients (10). Considering evidences of lower vitamin C levels in diabetic people than in healthy people (11), and association between low vitamin C levels and increased risk of coronary heart disease (12),

meeting the daily requirement of vitamin C may be protective against these complications arising from DM. The aims of this study were to investigate the effects of vitamin C supplementation on lipid profile, insulin secretion, and oxidative stress in diabetic rats.

MATERIALS and METHODS

Animals and Experimental Induction of Diabetes

The study started after the ethical approval (Ankara University Animal Experiments Local Ethics Committee (Meeting No. 2017-3, Decision No. 2017-3-21). Three months old 24 male Wistar albino rats with an average body weight of 304.75 ± 9.35 g (obtained from the Ankara University Animal Research Laboratory, Ankara/Turkey) were used in the study. The rats were housed in the polycarbonate cages in a room with a 12 h day-night cycle, relative humidity at 21 °C and treated according to the "Guide for the Care and Use of Laboratory Animals". Rats were randomly divided into 3 groups (C, DC, DCC) as 8 rats in each group and then diabetes was induced in 2 groups (DC, DCC) by a single intraperitoneal injection of streptozotocin (Sigma-Aldrich, USA / 45 mg/kg in 0.5 mL of 0.01 M sodium citrate buffer, pH: 4.5). Rats with fasting blood glucose levels above 250 mg/dL at 7 days after streptozotocin injection were used as the diabetic animals (group DC and DCC). Then, during the 8 weeks experiment period, C and DC groups were fed with standard rat diet (vitamin C free), the DCC group was fed with experimental diet. Standard rat diet prepared according to National Research Council (NRC) standards. Vitamin C was added to standard rat diet with a dose of 200 mg/kg to prepare experimental diet.

Collection of Blood Samples and Serum Biochemical Assays

The rats were anaesthetized using Ketamine HCl (70 mg/kg) and Xylazine (10 mg/kg) and blood samples were collected via cardiac puncture after overnight fasting at the end of the experimental period. After the centrifugation of blood samples (3500 rpm for 10 min) serum was stored at -80 °C prior to analysis. The serum samples were analyzed for determination of triglyceride (TG), total cholesterol (TC), low density lipoprotein cholesterol (LDL-C), high density lipoprotein cholesterol (HDL-C), insulin, total oxidant status (TOS), total antioxidant status (TAS), paraoxonase 1 activity (PON1) by using a commercial kit.

Calculation of OSI

The OSI was defined as the ratio of the TOS level to TAS level. The mmol value of TAS level was converted to μ mol

value as in the TOS level and calculated according to the following formula.

$$OSI = \frac{TOS, \mu\text{mol H}_2\text{O}_2 \text{ Eq/L}}{TAS, \text{mmol Trolox Eq/L} \times 10}$$

Statistical Analysis

All data are expressed as mean ± SEM. The parameters were statistically analyzed by one way analysis of variance (ANOVA) with Tukey post hoc test. Statistical significance was considered at p<0.05.

RESULTS

Feed and Water Consumption, Body Weight

Induction of diabetes resulted in significant increases in the feed and water consumption (Table 1). Ultimate body weight of diabetic groups were also significantly lower than the control group (p<0.001). No significant difference was observed between diabetic groups in terms of ultimate body weight, average feed and water consumption (p>0.05).

Plasma Lipids

Our results show that total cholesterol and triglyceride levels of DC and DCC groups were higher than group C (total cholesterol: p<0.001, p=0.008 for DC and DCC groups, respectively; triglyceride: p<0.001 for both groups) but there was no significant difference between the groups in terms of HDL levels (p>0.05). In addition, the mean LDL-C level of the group DC was significantly higher than the group C (p=0.004), but no significant difference was found between the group DCC and the other groups (p>0.05) (Table 2).

Insulin, Paraoxonase1 Activity, Total Antioxidant Status (TAS), Total Oxidant Status (TOS) and Oxidative Stress Index (OSI)

The mean insulin, TAS, PON1 activity levels were significantly lower (p<0.001) and TOS, OSI values were significantly higher (p=0.002, p<0.001, respectively) in the group DC compared to the group C. No significant difference was found between the DCC and other groups in terms of TOS and OSI values, whereas the mean TAS and PON1 activity values of group DCC were significantly higher than the group DC (p=0.05, p=0.044, respectively). In addition, the mean insulin and PON1 activity levels of group DCC were significantly lower than the group C (p=0.001, p=0.043) (Table 3).

Table 1. Groups' live body weights at the beginning and end of the experiment, and their mean feed and water consumption during the study period (mean ± SEM, n=8).

	C	DC	DCC
AFI (g/day)	17.9±0.4	22.0±0.6 ^{a*}	22.0±0.6 ^{a*}
AWI (mL/day)	41.4±2.1	86±5.1 ^{a*}	84±5 ^{a*}
IBW (g)	299.7±3.3	303.5±2.7	310.6±3.2
UBW (g)	351.6±3.2	229.9±3.8 ^{a*}	232.6±3.6 ^{a*}

AFI; average food intake, AWI; average water intake, IBW; initial body weight, UBW; ultimate body weight. ^aSignificantly different from group C. ^{*}(p<0.001).

Table 2. Groups' mean TC, TG, HDL-C and LDL-C values (mg/dL) at the end of the experiment (mean ± SEM, n=8).

	C	DC	DCC
TC	78.9±4.2	122.5±7.3 ^{a*}	114.1±8.3 ^a
TG	78.4±5.4	198.4±13.1 ^{a*}	174.4±14.3 ^{a*}
HDL-C	33.2±2.9	24.9±2.1	29.5±3.1
LDL-C	37.7±3.2	56.4±4.0 ^a	50±3.6

^aSignificantly different from group C. ^a(p<0.05), ^{*}(p<0.001).

Table 3. Groups' mean insulin (pg/mL), TAS (mmol/L), TOS (μmol/L), PON1 activity (U/L) and OSI levels (AU) at the end of the experiment (mean ± SEM, n=8).

	C	DC	DCC
Insulin	198.2±5.4	137.6±5.9 ^{a*}	140.2±6.6 ^{a*}
TAS	1.66±0.09	1.07±0.07 ^{a*}	1.38±0.07 ^b
TOS	5.53±0.62	10.73±0.96 ^a	8.77±1
PON1	14.3±1.3	4.7±0.5 ^{a*}	9.5±1 ^{a,b}
OSI	0.33±0.03	1.07±0.17 ^{a*}	0.67±0.11

^aSignificantly different from group C. ^bSignificantly different from group DC. ^{a,b} (p<0.05), ^{*} (p<0.001).

DISCUSSION

Feed and Water Consumption, Weight Loss

Polyphagia and polydipsia are among the most important signs and symptoms of DM. In the presence of diabetes elevated rate of gluconeogenesis and lipolysis in order to meet the energy needed by cells causes weight loss. In addition, loss of energy due to glucose excretion in urine is the other cause of weight loss. The results show that vitamin C can not adequately protect the live weight of diabetic rats against proteolytic and lipolytic effects of DM. In various studies in the literature, weight loss was noted in STZ-induced diabetic rats (13,14) and the findings obtained in this study are consistent with the literature data.

Insulin and Lipid Profile

Increased serum total cholesterol, LDL cholesterol and triglyceride levels in diabetes are caused by changes in lipoprotein lipase and hepatic lipase activities due to insulin deficiency or insensitivity. Besides hypercholesterolemia and hypertriglyceridemia, other characteristics of diabetic dyslipidemia is decrease in HDL-C concentration. The findings of the changes in plasma total cholesterol, triglyceride and LDL cholesterol levels of the group DC are consistent with similar studies in the literature (15,16). Decreased lipoprotein lipase and hepatic triglyceride lipase activities resulting from decreased insulin level are thought to be responsible for this condition.

Findings about the effects of vitamin C on insulin secretion, insulin resistance and diabetic dyslipidemia are inconsistent. In a study conducted with 84 individuals with type 2 diabetes, it was reported that vitamin C intake (1000 mg) for 6 weeks significantly decreased FBG, triglyceride and LDL levels, while there was no statistically significant effect on total cholesterol, HDL and insulin levels (17). With the intake of 500 mg vitamin C for 3 months, HDL cholesterol levels significantly increased but no significant changes were observed in triglyceride, total cholesterol, LDL cholesterol and FBG values in type 2 diabetic individuals (18). In a similar study, supplementing type 2 diabetic individuals with the same dose of vitamin C for the same time period has no significant effect on the levels of FBG, HDL and triglycerides, while LDL cholesterol and total cholesterol levels significantly decreased (19). In another study it was reported that diabetic rats supplemented with vitamin C intragastrically (60 mg/kg) had higher HDL levels than diabetic rats without vitamin C supplementation and there was no significant difference in FBG, total cholesterol, triglyceride, VLDL and LDL levels between the groups (20). According to findings of this study, vitamin C supplementation at a dose of 200 mg/kg (rat bait) has no statistically effect on insulin, LDL cholesterol, total cholesterol and HDL cholesterol and these results are consistent with the results obtained by Uslu (2013). It is thought that contradictions between the findings in literature data are result from differences in methodology (application technique, duration, dose etc.) of studies.

Oxidative Stress

The production of reactive oxidant species (ROS), which causes oxidative damage due to long-term hyperglycemia in diabetes, increases and the oxidative balance deteriorates in favor of oxidants. Different methods have been used to evaluate oxidative stress and antioxidant capacity in diabetes. In various studies, malondialdehyde (MDA) levels

were observed as indicators of lipid peroxidation and it was noted that MDA levels increased in diabetic rats. On the other hand, antioxidant capacity was evaluated with superoxide dismutase (SOD), glutathione (GSH) and catalase (CAT) levels in the same studies and it was stated that these parameters decreased in diabetic rats (15,21). In the evaluation of oxidative stress and antioxidant status in recent years, TOS and TAS levels are measured instead of these parameters. In addition, the measurement of TAS level may give more valuable information than the individual measurement of aforementioned antioxidants. In the studies conducted in this context, it was observed that TOS levels increased and TAS levels decreased in the presence of diabetes, and the results obtained in this study were consistent (22).

In various studies it has been reported that vitamin C has potent effectiveness in increasing GSH and plasma antioxidant capacity and decreasing lipid peroxidation (23,24). Contrary to these results, it was concluded that vitamin C had no effect on TAS and TOS levels in diabetic rats (20). According to the results of similar studies effects of vitamin C on oxidative stress may vary depending on the differences of vitamin C administration (duration, dose, application way). As a result, according to the data in the literature and the results obtained from this study, it is possible to suggest that vitamin C may be protective against impaired oxidant-antioxidant balance in the presence of diabetes.

PON1 Activity

Paraoxonase 1 (PON1) is an antioxidantizing enzyme that protects HDL and LDL against oxidation with contributing to the hydrolysis of lipid peroxides into oxidized lipoproteins and PON1 activity levels may change depending on many environmental and genetic factors. The main factor is oxidative stress which downregulates serum PON1 expression due to the changes in the redox status. There are many studies about the association of PON1 enzyme activity with diabetes, and the majority of these studies have reported that PON1 enzyme activity is lower in diabetic subjects than in healthy subjects (25,26). Tartan et al. (2007) also reported that patients with a shorter duration of diabetes had higher PON1 activity than patients with a longer duration of diabetes (27). When the results were compared with similar studies in the literature, it was concluded that PON1 activity levels in normal rats were significantly higher than in diabetic rats and these results were consistent with the results obtained in the study.

Vitamin C has been found to be effective in increasing PON1 activity levels. Jarvik et al. (2002) reported that PON1 activity was increased by the administration of vitamin C in combination with vitamin E (28). In a study conducted by Ferretti et al. (2008), after supplementing with vitamin C (500 mg/3 times a week) to hemodialysis patients for 6 months, the mean value of PON1 activity was found significantly higher and lipid hydroperoxide level was significantly lower in the vitamin C supplemented group (29). According to the results obtained from the study, the increase in Paraoxonase enzyme activity was observed with vitamin C supplementation and the results were consistent with the literature.

CONCLUSION

Exogenous antioxidant support in diabetes has a crucial role in preventing the complications related to the disease. Vitamin C supplementation increased the antioxidant capacity in diabetic rats. In addition, PON1 activity which has antioxidant and antiatherogenic activity also increased with vitamin C supplementation. Meeting the daily requirement of vitamin C of diabetic individuals can be effective in improving the prognosis of the disease. Researches which aims to investigate hypoglycemic and hypolipidemic activity of vitamin C with different techniques and methodologies may be useful.

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Evaluation of the Nutrition and Health Status of Pregnancy According to the Severity of Emezis

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ABSTRACT

Objective: Gestational emesis affects the whole pregnancy process and the newborn baby after pregnancy, starting from the early stages of pregnancy. In this study, it was aimed to investigate the factors affecting gestational emesis.

Materials-Methods: This study evaluated the relationship between the severity of nausea-vomiting and nutrition and health status of 100 pregnant women aged 18-40 years who applied to the Nutrition-Diet and Gynecology Clinic in a private hospital.

Results: The mean age of the participants was 29.66±5.47. It was determined that the severity of vomiting increased as the number of pregnancies of the participants increased (p<0.05). It was determined that as the severity of vomiting increased, the energy intake averages of the pregnant women decreased significantly. Those with 'severe' emesis were found to be significantly lower than those with 'moderate' emesis, which derived most of their energy from carbohydrates and fats (p=0.002, p=0.02, respectively).

Conclusion: Many underlying factors affect the severity of vomiting in pregnant women. The increase in the severity of vomiting adversely affects the nutritional and health status of pregnant women. For this reason, the severity of nausea and vomiting should be taken into account in ensuring proper nutrition and improving health conditions in pregnant women.

Keywords: Pregnancy, hyperemesis gravidarum, nutritional status

Gebelerde Beslenme ve Sağlık Durumunun Emezis Şiddetine Göre Değerlendirilmesi

ÖZET

Amaç: Gestasyonel emezis, gebeliğin erken dönemlerinden başlayarak tüm gebelik sürecini ve gebelik sonrası yeni doğan bebeği etkiler. Bu çalışmada gestasyonel kusmayı etkileyen faktörlerin araştırılması amaçlandı.

Gereç-Yöntem: Bu çalışmada, özel bir hastanede Beslenme-Diyet ve Kadın Hastalıkları Kliniği'ne başvuran 18-40 yaş arası 100 gebenin bulantı-kusma şiddeti ile beslenme ve sağlık durumu arasındaki ilişki değerlendirildi.

Bulgular: Katılımcıların yaş ortalaması 29.66±5.47 idi. Katılımcıların gebelik sayısı arttıkça kusma şiddetinin arttığı belirlendi (p<0.05). Kusma şiddeti arttıkça gebelerin enerji alım ortalamalarının önemli ölçüde düştüğü belirlendi. 'Şiddetli' emezisi olanlar, enerjisinin çoğunu karbonhidrat ve yağlardan alan 'orta' emezisi olanlara göre anlamlı derecede daha düşük bulundu (sırasıyla p=0.002, p=0.02).

Sonuç: Gebe kadınlarda kusmanın şiddetini birçok altta yatan faktör etkiler. Kusmanın şiddetinin artması gebelerin beslenme ve sağlık durumlarını olumsuz etkiler. Bu nedenle gebelerde doğru beslenmenin sağlanması ve sağlık koşullarının iyileştirilmesinde bulantı ve kusmanın şiddeti dikkate alınmalıdır.

Anahtar Kelimeler: Gebelik, hiperemesis gravidarum, beslenme durumu

During pregnancy, biological, physiological, and spiritual changes are experienced. These changes are arranged to prepare pregnant women for motherhood and birth starting from the first weeks of pregnancy (1,2). In addition, gestational diabetes, hypertension, thyroid, cardiovascular diseases, lipid disorders, and emesis are pathological conditions during pregnancy. Therefore, effective treatment of all diseases during pregnancy is crucial for maternal and infant health (3).

Emesis is a vital complaint that affects the daily life of women during pregnancy and reduces their quality of life. In the early pregnancy period, 50-90% of pregnant women may face the problem of emesis (4).

Hyperemesis Gravidarum (HG) is a more severe form of nausea and vomiting during pregnancy. HG is a clinical picture that can progress with severe nausea, vomiting, dehydration, ketosis, electrolyte, acid-base imbalance, and sometimes hepatic and renal failure. Although the incidence of HG varies from society to society, it is generally accepted to be around 0.5-1% (5,6).

Suppose the symptoms are not controlled in hyperemesis pregnant women with significant weight loss, electrolyte, and metabolic disorders. In that case, fetal death may occur by causing low birth weight, growth retardation, risk of preterm birth, fetal anomalies, and even maternal malnutrition (7).

Emesis seen during pregnancy can lead to loss of workforce, the need for hospitalization, and high costs in the health economy by causing the quality of life impairment in women. For these reasons, it is essential to diagnose and treat emesis on time in pregnant women (6).

The research was planned and carried out as a descriptive study in order to evaluate the relationship between nutrition and health status of pregnant women according to the severity of emesis in volunteer pregnant women who applied to the Nutrition-Diet and Obstetrics Polyclinic in a private health institution.

MATERIALS AND METHODS

Participants Selection

This cross-sectional and descriptive study was carried out at Acıbadem Healthcare Group International Hospital, Nutrition-Diet and Gynecology Polyclinic in Istanbul between September 2013 and June 2014. A hundred (100) pregnant women between the ages of 18-40 and at 5-15

weeks of gestation and who agreed to participate in the study were included.

Data Collection

In order to determine the health status, nutritional habits, food consumption status, and severity of emesis of the pregnant individuals included in the study, a questionnaire was applied with the investigation method. In addition, questionnaires were conducted by face-to-face interview method. This applied questionnaire consists of the following sections developed by the researcher.

Participants' demographic data (age, gender), anthropometric measurements (height, weight), body mass index (BMI), education status, job, presence of health insurance, presence and frequency of gestational emesis, number of pregnancies, age at first pregnancy, frequency of feeding, the distribution of food consumed, information about pregnancy (pre-pregnancy weight, gestational week) and history of hospitalization due to emesis were questioned.

BMI was calculated based on height and pre-pregnancy weight. BMI: $\text{bodyweight} / (\text{height})^2$ was calculated with the formula. According to WHO criteria, individuals participating in the study, pre-pregnancy obesity are grouped according to body weight (8).

Pregnancy Unique Quantification of Emesis and Nausea Test (PUQE)

The PUQE test was used to determine the severity of gestational abortion (9). Pregnant women are questioned about the presence of nausea or stomach discomfort in the last 12 hours, whether the vomiting is observed, how many times they have vomited if there is vomiting and the presence of nausea or retching without vomiting. Scoring is done based on the answers to these questions. It was classified as 'mild emesis' in pregnant women with a score between 3-6, 'moderate emesis' with a score between 7-12, and 'severe emesis' in pregnant women with a score between 13-15. In the last part of the questionnaire, the pregnant women's abortion status and their views on this subject, their effects on their psychological status, and social life were questioned.

Evaluation of Food Consumption

The participants' one-day food consumption and food consumption frequency were questioned and evaluated with the "Re-call method". Energy and nutrients

evaluation was made in the Nutrition Information System (BEBIS) program (10). The intake of macronutrients such as energy, carbohydrates, protein, fat, and micronutrients such as vitamins and minerals related to the food consumption of the individuals were determined.

Ethics Committee Approval

The study was presented to Haliç University Clinical Research Ethics Committee and approved by the ethics committee (18/07/2017-32). Permission was obtained from the Chief Physician of Acıbadem University International Hospital. Written informed consent with the Declaration of Helsinki was obtained from study participants.

Statistical Analysis

In the analysis of the data, the mean and standard deviation, minimum and maximum values of the features; Frequency, and percentage values were used to define categorical variables. One Way ANOVA test statistic was used to compare the means of more than two independent groups. If a difference was detected with ANOVA, it was evaluated with Tukey statistics as a Post-Hoc test. Chi-square test statistics were used to evaluate the relationship between categorical variables. The statistical significance level of the data was taken as $p < 0.05$. In the evaluation of the data, www.e-picos.com New York software and MedCalc statistical package program were used.

RESULTS

The study was conducted on 100 pregnant participants between 18 and 40 between September 2017 and June 2018. It shows the distribution of the participants according to general characteristics (table 1).

The mean age of the pregnant women was 29.66 ± 5.47 (18-40) years. The mean height of the pregnant women was 163.63 ± 5.22 cm. The gestational week ranged from 5 to 15 weeks, and the mean gestational week was 9.86 ± 2.65 . Before pregnancy, the mean weight of the pregnant women was 61.38 ± 10.87 kg, and the current mean weight was 61.370 ± 10.69 kg. When the BMI distribution was examined, 12% of the pregnant women were underweight, 65% were standard, 17% were slightly overweight, and 6% were obese. Considering the educational status, half of the pregnant women (50%) were university graduates. When their employment status was evaluated, it was determined that 46% of the pregnant women were not

working, and 54% were working. When the distribution of pregnant women according to the severity of emesis was examined, it was found that 30% had mild, 37% had moderate, and 33% had severe emesis (table 1). There was a statistically significant difference between the severity of emesis according to the functional status of the pregnant women. The rate of severe emesis severity of unemployed, pregnant women (47.8%) was statistically significantly higher than that of employed pregnant women (20.4%) ($p = 0.001$). When the pre-pregnancy BMI values of the pregnant women were compared with the severity of emesis, there was no statistically significant relationship between the severity of emesis according to the BMI value ($p > 0.05$) (table 2).

	Min-Max	Mean \pm SD	
Age (year)	18-40	29,66 \pm 5,47	
Height (cm)	153-180	163,63 \pm 5,22	
Gestational week	5-15	9,86 \pm 2,65	
Bodyweight before pregnancy (kg)	45-104	61,38 \pm 10,87	
Bodyweight during pregnancy (kg)	46-102	61,370 \pm 10,69	
N=100	Features	n	%
BMI	Weak	12	12
	Normal	65	65
	Lightweight	17	17
	Obese	6	6
Educational status	Illiterate	1	1
	Primary school	15	15
	Middle School	9	9
	High school	25	25
	University	50	50
Working status	Housewife (Not Working)	46	46
	Working	54	54
Emesis status	Light	30	30
	Middle	37	37
	Heavy	33	33
First gestational age	18 years and under	5	5
	19-25 years	32	32
	26-30 years	36	36
	30 years and older	27	27
Number of Meals Consumed	2	6	6
	3	21	21
	4	25	25
	5	19	19
	6		

SD: standard deviation, BMI: body mass index, cm: centimeter, kg: kilogram

Table 2. Evaluation of the Severity of Emesis Scording to the Behavior and Lifestyle of Pregnant Women

N=100		Emesis						p-value
		Light		Medium		Heavy		
		n	%	n	%	n	%	
Working Status	Housewife (Not Working)	16	34,8	8	17,4	22	47,8	0,001
	Working	14	25,9	29	53,7	11	20,4	
BMI	Weak	7	58,3	1	8,3	4	33,3	0,149
	Normal	15	23,1	29	44,6	21	32,3	
	Lightweight	5	29,4	6	35,3	6	35,3	
	Obese	3	50	1	16,7	2	33,3	
How many pregnancies have you had?	1	12	26,1	24	52,2	10	21,7	0,011
	2	11	33,3	10	30,3	12	36,4	
	3	7	46,7	2	13,3	6	40	
	≥4	-	-	1	16,7	5	83,3	
Is your current pregnancy planned?	Yes	21	30,9	26	38,3	21	30,9	0,806
	No	9	28,1	11	34,4	12	37,5	
Meal skipping status	Yes	11	36,7	19	51,4	26	78,8	0,003
	No	19	63,3	18	48,6	7	21,2	
Did the emesis problem require you to be hospitalized?	Yes	1	9,1	2	18,2	8	72,7	0,012
	No	29	32,6	35	39,3	25	28,1	
Have you been referred to a dietitian because of emesis?	Yes	1	7,7	5	38,5	7	53,8	0,108
	No	29	33,3	32	36,8	26	29,9	

BMI: body mass index, Chi-Square test, p<0.05

When the severity of vomiting was compared with the number of pregnancies, there was a statistically significant relationship between the severity of vomiting and the number of pregnancies (p<0.05) (table 2). Therefore, it was determined that as the number of pregnancies increased, the severity of abortion also increased. However, there was no statistically significant relationship between the currently planned pregnancy status and the severity of emesis (p>0.05). While the incidence of 'severe' emesis was 83.3% in women with four or more pregnancies, moderate emesis was 52.2% in those with their first pregnancy (table 2).

When skipping meals of pregnant women were compared according to emesis severity, a statistically significant relationship was found between emesis severity and meal skipping (p<0.01). Furthermore, it was determined that the rate of skipping meals increased as the severity of emesis increased.

A statistically significant correlation was found between the severity of emesis of pregnant women according to hospitalization status due to emesis (p<0.05). The incidence of severe emesis in pregnant women hospitalized for emesis was significantly higher than those who were not hospitalized. There was no statistically significant relationship between the severity of vomiting and referral to a dietitian after vomiting (p>0.05) (table 2).

When the severity of emesis and the number of nutrients consumed by the pregnant women for a day were compared, there was a statistically significant relationship between the daily energy intake averages of the pregnant women according to the severity of emesis (p<0.05).

The mean daily energy intake of the cases with severe emesis severity was significantly lower than those with mild emesis severity. There was a statistically significant correlation between the daily protein averages of the pregnant women according to the severity of emesis. The mean daily protein intake of the cases with severe emesis

severity was significantly lower than those with mild emesis severity ($p<0.05$). There was a statistically significant relationship between pregnant women's mean daily fat intake according to the severity of emesis ($p<0.05$). The mean daily fat intake of the cases with moderate emesis severity was significantly higher than those with severe emesis severity ($p<0.05$). In addition, according to the severity of emesis, there was a statistically significant difference between the daily energy averages of the pregnant women ($p<0.01$).

The mean daily fat intake rate of cases with moderate emesis severity was significantly higher in pregnant women with severe emesis severity ($p<0.01$). According to the severity of emesis, there was a statistically significant relationship between the daily carbohydrate ratios of the pregnant women ($p<0.05$). The mean daily carbohydrate intake rate of the cases with moderate emesis severity was significantly higher than those with severe emesis severity ($p=0.02$) (table 3).

Table 3. Evaluation of Daily Consumed Food Items According to Emesis Severity				
	Emesis Severity			p-value
	Light	Medium	Heavy	
	Mean±SD	Mean±SD	Mean±SD	
Energy (kcal)	1240,3±186,59	1219,31±201,38	1105,29±269,24	0,036*
Protein (g)	62,14±12,45	64,8±16,22	55,24±14,93	0,027*
Protein (%)	20,57±4,58	21,57±4,11	20,34±3,71	0,424*
Fat (g)	42,87±14,4	45,23±12,33	35,84±12,67	0,012*
Oil (%)	30,2±6,86	32,84±6,33	27,5±5,76	0,003*
Carbs (g)	149,42±33,63	135,45±26,08	140,78±28,94	0,159*
Carbs (%)	49,3±7,71	46,35±7,42	51,09±6,34	0,024*
Water (g)	1075,17±275,05	1103,25±257,66	1012,64±300,08	0,393*
Phosphorus (mg)	1170,19±273,73	1191,05±308,73	1164,72±249,27	0,918*
Fiber (g)	20,78±4,91	21,21±5,28 (21,03)	18,95±5,22 (18,44)	0,205**
Polyunsaturated (g)	9,13±3,43 (8,53)	9,07±3,73	6,74±2,64	0,172*
Cholesterol (mg)	164,54±109,46 (114,6)	191,47±104,59 (224,8)	127,75±117,21 (78,9)	0,041**
Vit. A (µg)	1333,25±416,56	1494,97±533,98	1110±564,18	0,01*
Carotene (mg)	4,97±1,4	5,35±2,04	4,16±2,25	0,032*
Vit.E (mg)	11,04±3,46	11,16±3,4	8,85±3,11	0,008*
Vit. B1 (mg)	0,79±0,17	0,83±0,18	0,73±0,16	0,041*
Vit. B2 (mg)	1,4±0,34	1,41±0,4	1,39±0,32	0,959*
Vit. B6 (mg)	1,13±0,23	1,18±0,26	1,08±0,27	0,239*
Total folic acid (µg)	235,35±57,6	259,42±59,26	237,02±56,2	0,159*
Vit. C (mg)	116,87±46,2	129,7±53,31	107,82±43,27	0,170*
Sodium (mg)	2705,56±706,85	2516,96±636,66	2544,89±547,38	0,442*
Potassium (mg)	2255,62±472,44	2378,36±583,88	2153,56±527,32	0,221*
Calcium (mg)	851,16±242,6	852,01±292,85	911,97±204,35	0,539*
Magnesium (mg)	224,74±62,52	240,25±55,47	209,32±61,76	0,105*
Iron (mg)	9,0±1,9	9,21±1,9	7,87±2,11	0,014*
Zinc (mg)	9,3±2,35	9,02±2,19	8,13±2,02	0,092*
Lactose (g)	9,54±6,08 (8,5)	10,55±6,63 (10,43)	9,94±5,87 (8,19)	0,836**
Starch (g)	87,29±29,16	70,88±22,45	82,19±22,16	0,022*
Galactose (g)	2,25±0,95 (2,32)	1,96±1,09 (2,05)	2,41±1,21 (2,16)	0,379**
Vit. B12 (µg)	5,05±1,95	5,02±2,04	4,47±2,32	0,462*

SD: standard deviation, kcal: kilocalories, g: gram, mg: milligram, µg: microgram, Vit: vitamin, *Oneway ANOVA test, **Kruskal Wallis test, $p<0,05$.

There was a statistically significant relationship between the mean amount of vitamin A taken by the pregnant women according to the severity of emesis. The mean daily Vitamin A intake of pregnant women with moderate emesis severity was statistically significantly higher than those with severe emesis severity ($p < 0.01$). There was a statistically significant difference between the mean daily intake of Vitamin E according to the severity of emesis ($p < 0.01$). The mean daily Vitamin E intake of the pregnant women with mild emesis and the cases with moderate emesis severity was significantly higher than those with severe emesis severity. There was a statistically significant difference between the mean daily intake of Vitamin B1 according to the severity of emesis ($p < 0.05$). Daily Vitamin B1 means of pregnant women with moderate emesis severity was significantly higher than those with severe emesis severity ($p < 0.05$). According to the severity of emesis, there was a statistically significant relationship between the daily iron mineral averages of the pregnant women. The mean daily iron intake of cases with moderate emesis severity was significantly higher than those with severe emesis severity (table 3).

DISCUSSION

Nausea and vomiting, an essential determinant of pregnancy, turns into a significant health problem as its frequency and severity increase. Mild emesis complaints are present in 50-70% of pregnant women in the first months of pregnancy. It typically starts at 4 to 8 weeks of pregnancy and lasts until 14 to 16 weeks. Since the clinical picture usually occurs in the morning, it is also called 'morning sickness' (4).

BMI values of 65% of the pregnant women between the ages of 18 and 40 who participated in the study were between 18.5-25. Thus, most of the pregnant women participating in the study had normal BMI. Irge et al. similarly, it was found that 68.3% of the pregnant women had typical BMI values (11). Women who gain weight within the recommended limits during pregnancy have the healthiest pregnancy outcomes regarding maternal and fetal conditions (low birth weight, macrosomia, spontaneous preterm birth rates, cesarean delivery, maternal postpartum obesity) (12). In our study, the BMI value, an important parameter, and the severity of abortion were compared, and no statistically significant result was found ($p > 0.05$). However, Sucu et al. found that the mean weight and body mass index of patients with severe acupuncture severity were significantly lower than those with mild acupuncture severity (13).

Tas et al., in the study, were conducted to evaluate the nutritional status of pregnant women; it was determined that the majority of the participants (82.3%) were housewives (12). When we evaluated whether there is a relationship between the active status of pregnant women and the severity of emesis in our study, the severity of emesis in housewives was found to be statistically higher than that of working pregnant women ($p < 0.01$). This can be explained by the increase in occupations with working life and the inability of pregnant women to listen to themselves enough to experience severe nausea and vomiting. On the other hand, in Ozdil et al., no significant relationship was found between pregnant women with and without hyperemesis, employment status, education level, and income level (14).

In our study, the majority of pregnant women (68%) with a first gestational age of 19-30. It is known that the first gestational age is essential for a healthy pregnancy and healthy birth. Pregnancy at a very early age and in advanced ages may increase the risk of some abnormal conditions (9). Shallow et al. found in their study that the frequency of emesis was higher in early-age pregnancies (15).

It is known that unwanted pregnancies and having many pregnancies can have negative consequences on individuals (16). When the number of pregnancies and the severity of vomiting were compared, it was found that there was a statistically significant agreement between them. As the number of pregnancies increased, the severity of abortion also increased. In our study, no statistically significant difference was found between the currently planned pregnancy status and the severity of emesis. Moos MK reported that the pregnancies of cases with high severity of nausea were unplanned pregnancies at a high rate (17).

In our research, the number of meals consumed four or more constitute 73% of the study. Noğay et al. In the study conducted to evaluate pregnant women's nutritional status, a large part of the participants (55.7%) skipped lunch. Pregnant women stated that they got up late (45.5%) for skipping meals (18). Irge et al., in their study, it was determined that 81.2% of the women had nutritional problems during pregnancy, and 33.2% of the pregnant women did not eat regularly and skipped meals (11). In our study, when skipping meals of pregnant women were compared according to the severity of emesis, it was found to be statistically related ($p < 0.01$). It is seen that as the severity of emesis increases, skipping meals also increases. It was

determined that pregnant women with severe emesis skipped meals due to nausea.

In our study, those who were hospitalized due to emesis constitute 11% of the study. Ozdil et al. In his study, the mean duration of hospital stay of 41 pregnant out of 100 hospitalized for hyperemesis was determined as 5.2 ± 2.7 days, and the mean amount of weight loss was 4.5 ± 3 kg (14). Another study showed that the hospitalization of pregnant women with severe nausea or vomiting is critical in understanding their physical and psychological problems and increasing the quality of care (7).

In the study of Koren et al., 2.5% of the mild abortion group, 6% of the moderate group, and 33% of the severe group received indications for hospitalization, and the difference between the severe group and the other groups was found to be statistically significant (9). In our study, the severity of vomiting was statistically significantly higher in pregnant women hospitalized after vomiting than pregnant women treated as outpatients.

Pregnant women who were referred to a dietitian about emesis constitute 13% of the study. In our study, no statistically significant relationship was found between the severity of abortion and being referred to a dietitian. Işık et al. In his study, it was determined that pregnant women received information about the problems in pregnancy primarily from health personnel, dietitians, and unique books. In the same study, it was determined that the most common and most common disorders were emesis (91.4%) (3). In another study, half of the participants stated that they received information from health personnel about what to do in vomiting (2).

Swensen et al., in their study, the one-day energy intake of pregnant women was below the recommended (20). In Fejzo and Poursharif, similar to our study, the average energy intake of women diagnosed with HG was examined. In the study results, weight loss in HG was defined as $> 15.0\%$ of the pre-pregnancy weight, and it was stated that 26.1% of women experienced excessive weight loss due to insufficient energy intake (21). In our study, daily energy intake was well below the recommendations, especially in individuals with severe abortion severity.

In our study, daily protein ratios of pregnant women from energy were compared according to the severity of emesis, but no statistically significant difference was found. However, the daily protein intake of pregnant women

according to the severity of suckling showed a statistically significant difference. In our study, the amount of daily protein intake was found to be 55.24 ± 14.93 g in patients with severe emesis. A developing baby's body cells, changes in the mother's body, especially the placenta, need protein. In addition, the baby's growth in the mother's womb means an average of 950 g of protein accumulation. Therefore, pregnant women need an extra 20 grams of protein daily (22).

Our study determined that there was a significant difference between the severity of emesis and the rates of energy from daily fat and carbohydrates. It is recommended that 55-60% of daily energy comes from carbohydrates and 25-30% from fats during pregnancy (23). In our study, the daily energy intake of carbohydrates from patients with moderate emesis severity was significantly higher than those with severe emesis. Daily carbohydrate intake rates of pregnant women with severe emesis were found below the recommended value. When the fat intake rates of pregnant women were examined, it was seen that it was within the recommended limits for people with severe vomiting. However, the daily fat intake rates of patients with moderate emesis severity were significantly higher than those with severe emesis severity.

Our study observed that the only significant difference between the average daily mineral intake of pregnant women according to the severity of emesis was iron. The mean daily iron intake of the cases with moderate emesis severity was significantly higher than the cases with severe emesis severity. The daily recommended amount of iron was found below the recommendations for all emesis intensities. Studies have also shown that the use of iron preparations during pregnancy may trigger emesis. It has also been reported that iron use can be interrupted when emesis is severe (13).

CONCLUSION

Nausea and vomiting, an essential determinant of pregnancy, turns into a significant health problem as its frequency and severity increase. As the severity of nausea and vomiting increases, it is a condition that should be identified and treated immediately, as it can threaten the health status of pregnant women.

The most important result of our study is that the severity of emesis and nutritional status are seriously affected. Based on this result, it is necessary to detect emesis and monitor the nutritional status to maintain and terminate the pregnancy in a healthy way.

DECLARATIONS

Conflict of Interest

There is no conflict of interest in our work.

Ethical Approval

The study was presented to Haliç University Clinical Research Ethics Committee and approved by the ethics committee (18/07/2017-32).

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The Relationship between Motor Levels of Children with Cerebral Palsy and Their Eating and Drinking Skills and Energy Intakes

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ABSTRACT

Aim: Cerebral Palsy (CP) is defined as a musculoskeletal system disorder characterized by a non-progressive but the most important symptom of the disease is loss of motor function. In addition to difficulty in movement, as the severity increases, various problems are seen depending on where the brain damage occurred and the extent of the damage. Among these problems, nutritional problems have an important share. This study was conducted to evaluate the relationship of eating and drinking skills with the intake of energy and some nutrients according to gross motor skills of children with CP.

Study Design: The research was conducted on 74 volunteer children (52.7% male; 8.7±3.32 years) and their parents. For the evaluation of the nutritional status of the children, a 3-day food intake record and Eating and Drinking Ability Classification System (EDACS) was used.

Results: In all age groups, the daily energy, carbohydrate and fiber intake of children in the GMFCS IV-V group is less than those in the GMFCS I-II-III group. There was a statistically significant positive strong relationship between GMFCS and EDACS, however there was a low negative correlation between GMFCS and average daily carbohydrate intakes.

Conclusions: Results are supported by this study and EDACS can be an easy and practical method in classifying children's eating and drinking skills in order to create a common language in the literature.

Keywords: Nutrition, Cerebral Palsy, Children

Serebral Palsili Çocukların Motor Düzeyleri ile Yeme-İçme Becerileri ve Enerji Alımları Arasındaki İlişki

ÖZET

Amaç: Serebral Palsi (SP), ilerleyici olmayan motor fonksiyon kaybı ile karakterize kas-iskelet sistemi bozukluğu olarak tanımlanmaktadır. Hareket zorluğunun yanı sıra, beyin hasarının meydana geldiği bölge ve hasarın boyutuna bağlı olarak çeşitli problemler görülmektedir. Beslenme sorunları da bu problemler arasında yer almaktadır. Bu çalışma, SP'li çocukların kaba motor becerilerine göre yeme ve içme becerileri ile enerji ve bazı besin ögesi alım düzeyleri arasındaki ilişkiyi değerlendirmek amacıyla yapılmıştır.

Yöntem: Bu çalışma, gönüllü 74 çocuk (%52,7 erkek; 8,7±3,32 yıl) ve ebeveynleri üzerinde gerçekleştirilmiştir. Çocukların beslenme durumlarının değerlendirilmesi için 3 günlük besin tüketim kaydı ile Yeme ve İçme Becerisi Sınıflandırma Sistemi (EDACS) kullanılmıştır.

Bulgular: Tüm yaş gruplarında GMFCS IV-V grubundaki çocukların günlük enerji, karbonhidrat ve lif alımı GMFCS I-II-III grubundaki çocuklara göre daha azdır. GMFCS ve EDACS arasında istatistiksel olarak anlamlı, pozitif ve güçlü bir ilişki varken, GMFCS ve ortalama günlük karbonhidrat alım düzeyleri arasında düşük negatif korelasyon vardır.

Sonuç: Literatürde ortak bir dil oluşturmak için EDACS çocukların yeme içme becerilerinin sınıflandırılmasında kolay ve pratik bir yöntem olabilir ve sonuçlar bu çalışma ile desteklenmektedir.

Anahtar sözcükler: Beslenme, Serebral Palsi, Çocuk

Cerebral Palsy (CP) is defined as a musculoskeletal system disorder characterized by a non-progressive but permanent abnormal posture and movement disorder that occurs due to a brain defect in the developing fetal period or infant brain (1). In community-based studies, it is reported that global incidence rate of CP is 1.5-4 per 1000 live births (2-4). In Turkey, 4.4/1000 live births were reported in children of 2-16 years (5).

In recent years, individuals have been widely classified according to motor impairment, limb involvement, and the gross motor function classification system (GMFCS) (6,7). The GMFCS classifies children from level I to level V based on their age-specific gross motor activity. As the level increases, the child's care and dependence status increases (7).

Although the most important symptom of the disease is loss of motor function, its severity is also important. In addition to difficulty in movement, as the severity increases, various problems are seen depending on where the brain damage occurred and the extent of the damage (1,8). Among these problems, nutritional problems have an important share. Some behaviors such as gastroesophageal reflux (GER), constipation, refusal of food, and problems with swallowing cause nutritional difficulties (9). Energy and nutrient intake of children with nutritional problems/difficulties are also affected (10). As CP severity increases, the problems as well as the difficulty in feeding increase. For this reason, the eating and drinking skill classification system, which was developed by taking into account CP severity of the children, aims to classify, using meaningful distinctions, how individuals with CP practically eat and drink in life (11).

The number of studies evaluating the energy and nutrient intake of children with CP and associating them with gross motor activities is limited (9,10). This study was conducted to evaluate the relationship of eating and drinking skills with the intake of energy and some nutrients according to gross motor skills of children with CP.

METHODS

Study Design

This is a descriptive cross-sectional study. In the study, 'survey method' was used as the data collection tool, and data collection was carried out via face-to-face interviews. The patients who visited the Pediatrics Unit were interviewed twice during the research. During the first interview, the survey questionnaire was administered by the

researcher in the mothers of the children or in those who provided care in cases where the mother could not be reached. For the evaluation of the nutritional status of the children, a 3-day food intake record was used. Training on how to fill the 3-day food intake record was provided by the researcher to the caregivers and they were asked to fill it up before the next meeting. In addition, during the first interview, the Eating and Drinking Ability Classification System (EDACS) was filled via face-to-face interviews with the caregivers.

In the second meeting, the 3-day food intake record requested from the caregivers was examined. The caregivers were asked to complete the missing parts that were detected by the researcher.

The child's gross motor function status was evaluated using the GMFCS and grouped at five different levels. Then, the participants were pooled in two groups: GMFCS I-II-III as "good and moderate", and GMFCS IV-V as "severe" (7).

Participants

When the test power was 80% and 90% and at the 5% significance level, sample values were calculated as 52 and 68, respectively. Therefore, the study was carried out with 74 children (52.7% male/47.3% female) between the ages of 5 and 13 years, and who were diagnosed with CP and referred to the Pediatric Rehabilitation Unit of the Physiotherapy and Rehabilitation Department of the Faculty of Health Sciences, Gazi University.

Those who have been diagnosed with any other genetic and/or neurological disease other than CP, children and adolescents whose caregivers could not be reached, and those with a contracture to prevent height measurement were not included in the study. Children and adolescents 5-13 years with a diagnosis of CP were included in the study. Approval of the Ethics Commission of Gazi University was obtained (# 77082166-604.01.02). An Informed Voluntary Consent Form was read and signed by the parents of all children participating in the study.

Data Collection

The reported amount of food and/or drink consumed daily by the children was quantified. The amount of the nutrients included in the meals consumed by the children was calculated using the books titled: *Standard Meal Tariffs* (12) or *Samples from Turkish Cuisine* (13) Daily dietary energy and nutrients were analyzed using the

Nutrition Package Information Systems Program (BEBIS). The daily energy and nutrient status of the children calculated through the data obtained from the 3-day food intake record forms were compared with the Daily Reference Intakes (DRI) data based age and gender, and intake ratios were calculated (14).

Eating and Drinking Ability Classification System (EDACS)

The children's eating and drinking abilities were assessed using EDACS (11). The EDACS is a classification system used to determine the level of eating skills in children with CP and ranges from level I to level V.

Data Analysis

SPSS for Windows 22.0 statistical package program was used to evaluate the data (15). Whether the data were normally distributed according to the groups was examined via the Shapiro-Wilk test and appropriate graphical methods. The categorical data obtained are expressed in numbers and percentage (%) values. Average (X), standard deviation (SD), minimum and maximum values were used as descriptive statistics for numerical variables. In numerical variables, the Independent Samples T-Test was used to compare two normally distributed independent groups, and the Mann-Whitney U test was used to compare two independent groups in non-normally distributed variables. The Pearson Test was used to determine the correlation coefficients and statistical significance of numerical variables with normal distribution. The Spearman's Test was used for variables, of which at least one does not exhibit normal distribution, or for ordinal variables. In defining the correlation coefficient (r) value:0.05-0.30: low/insignificant correlation;0.30-0.40: low/moderate correlation,0.40-0.60: moderate correlation;0.60-0.70: good correlation;0.70-0.75 very good correlation;0.75-1.00: perfect correlation (16). In evaluating the significance levels (p values) of the data, $p < 0.05$ was considered as significant.

RESULTS

According to GMFCS, 69% of the children were in the GMFCS I-II-III group, while 31% were in the GMFCS IV-V group. Of the children, 66.7% of the GMFCS I-II-III group and 65.2% of the GMFCS IV-V group were in the 5-8 age group.

Table 1 shows the dependency of the children during eating according to the GMFCS. While 74.5% of the children at GMFCS I-II-III were independent while eating, 60.9% of the children at GMFCS IV-V were dependent during

eating. All of the children at GMFCS I-II-III and 60.9% of the children at GMFCS IV-V were in EDACS I-II-III.

The percentages of the energy and the macro and micronutrients consumed by the children and adolescents with the daily diet according to the gross motor function level and the recommended amounts according to the age groups are given in Table 2. The difference between the other parameters except carbohydrate (9-13 years; GMFCS I-II-III $183.2 \pm 89.27\%$ and GMFCS IV-V meet $116.9 \pm 46.75\%$) and sodium intake (9-13 years; GMFCS I-II-III $128.9 \pm 44.37\%$ and GMFCS IV-V meet $80.0 \pm 31.96\%$) according to GMFCS was not statistically significant for both age groups ($p > 0.05$) (Table 2).

Table 1: Addictive situations in eating of the children according to the Gross Motor Function Classification System (GMFCS)

	GMFCS I-II-III (n=51)		GMFCS IV-V (n=23)	
	n	%	n	%
Status of Dependence during Eating				
Independent	38	74.5	2	8.7
Slightly Dependent	6	11.8	3	13.0
Moderately Dependent	7	13.7	4	17.4
Dependent	-	-	14	60.9
EDACS				
I-II-III	51	100	14	60.9
IV-V	-	-	9	39.1
Age, mean (SD) range, year	8.8±3.33		8.5±3.34	
EDACS, Eating and Drinking Ability Classification System				

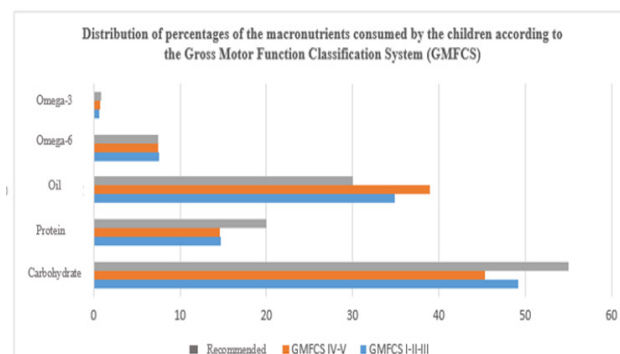


Figure 1: The macro nutrients and fatty acid distribution of the energy to be taken daily according to the DRI recommendations

Table 2: Children’s dietary intake of energy and macronutrient and the percentage of meeting the recommended amounts according to Gross Motor Function Classification System (GMFCS)

	Age: 5-8 years (n=49)				p	Age: 9-13 years (n=25)				p
	GMFCS I-II-III (n=34)		GMFCS IV-V (n=15)			GMFCS I-II-III (n=17)		GMFCS IV-V (n=8)		
	$\bar{X}\pm SD$	$\bar{X}\pm SD$ (%)*	$\bar{X}\pm SD$	$\bar{X}\pm SD$ (%)*		$\bar{X}\pm SD$	$\bar{X}\pm SD$ (%)*	$\bar{X}\pm SD$	$\bar{X}\pm SD$ (%)*	
Energy (kcal)	1294.2±279.17	76.3±16.81	1255.9±292.28	73.9±16.75	.712	1799.5±667.89	83.4±30.90	1315.3±421.61	59.5±18.06	.081
Energy (kcal/kg)	65.15±19.40	-	76.3±21.87	-	.140	51.4±12.15	-	59.2±15.57	-	.315
Protein (g/kg)	2.5±0.83	326.1±108.59	2.6±1.07	343.9±141.09	.099	1.8±0.71	234.6±93.69	2.3±0.76	306.3±99.43	.071
Carbohydrate (g/day)	154.8±40.82	119.0±31.40	146.2±63.28	112.4±48.67	.488	238.1±116.05	183.2±89.27	151.9±60.77	116.9±46.75	.036
Fiber (g)	15.9±6.04	63.7±24.15	11.8±6.53	47.1±26.13	.051	20.5±14.39	73.5±54.18	15.2±8.60	51.8±27.62	.351
Vitamin C (mg)	113.5±85.91	453.9±343.65	83.8±61.65	335.2±246.58	.515	97.6±81.84	216.8±181.86	82.8±69.40	183.9±154.23	.683
Vitamin B12 (mcg)	3.8±2.01	316.0±167.69	3.1±2.36	256.6±196.39	.273	3.6±2.59	201.5±143.74	4.5±3.35	252.2±185.92	.449
Thiamin (mg)	0.7±0.22	123.7±36.11	0.6±0.21	106.2±35.09	.103	0.9±0.48	96.7±52.86	0.7±0.23	79.9±31.03	.502
Riboflavin (mg)	1.1±0.39	184.4±66.18	1.1±0.41	175.8±67.64	.625	1.1±0.46	126.9±50.62	1.1±0.32	127.4±36.02	.727
Niacin (mg)	9.2±5.89	114.7±73.71	8.1±6.39	100.7±79.91	.250	11.7±6.96	97.1±57.99	9.5±6.26	79.1±52.16	.485
Calcium (mg)	586.0±278.68	58.6±27.87	589.3±279.62	58.9±27.96	.983	546.3±278.68	42.0±21.44	541.5±217.49	41.7±16.73	.727
Iron (mg)	8.1±2.88	81.4±28.89	6.7±2.38	67.0±23.80	.118	10.9±6.43	136.6±80.33	8.7±3.74	108.4±46.76	.294
Zinc (mg)	6.6±1.85	131.2±36.91	5.4±2.20	108.7±44.06	.068	9.0±3.91	112.7±48.90	6.8±2.93	85.3±36.62	.145
Sodium (g)	1.1±0.70	76.5±50.20	1.1±0.57	78.6±40.63	.712	1.8±0.62	128.9±44.37	1.1±0.45	80.0±31.96	.009
Potassium (g)	2.0±0.61	53.3±16.15	1.9±0.66	48.8±17.31	.398	2.0±1.01	44.9±22.53	1.9±0.70	42.6±15.65	.954

*Calculated based on Daily Reference Intakes (DRI); Mann Whitney U testi; p<0.05.

In Figure 1, the macro nutrients and fatty acid distribution of the energy to be taken daily according to the DRI recommendations are shown according to the groups of gross motor function levels. The difference between groups was not statistically significant (p>0.05).

Table 3 presents the relationship between children’s GMFCS levels and energy and some macro-micro nutrient intakes. There was a statistically very good correlation between GMFCS and EDACS (r = 0.736, p = 0,000). There was a negative low correlation between GMFCS levels and average daily carbohydrate (r = -0.326; p = 0.005), fiber (r = -0.348; p = 0.002), thiamine (r = -0.243; p = 0.037), iron (r = -0.241; p = 0.039 with GMFCS), zinc (r = -0.246; p = 0.034), and sodium (r = -0.264; p = 0.023) intake amounts.

Table 3: Relationship between children’s gross motor function levels (GMFCS) and Eating and Drinking Skill Classification System (EDACS), energy, and some nutrients intakes

	GMFCS	
	r ^y	p
EDACS	0.736	.000
Energy (kcal)	-0.207	.076
Energy (kcal/kg)	0.194	.098
Protein (g/kg)	0.171	.144
Carbohydrate (g/day)	-0.326	.005
Fiber (g)	-0.348	.002
Vitamin C (mg)	-0.108	.359
Vitamin B12 (mcg)	0.006	.962
Thiamin (mg)	-0.243	.037
Riboflavin (mg) ^y	-0.008	.948
Niacin (mg)	-0.123	.296
Calcium (mg) ^y	0.043	.719
Iron (mg)	-0.241	.039
Zinc (mg)	-0.247	.034
Sodium (mg)	-0.264	.023
Potassium (mg)	-0.076	.520

^ySpearman Correlation Analysis; ^yPearson Correlation Analysis;
*p<0.05 **p<0.001

DISCUSSION

In 74 children aged 5-13 years with a CP diagnosis, in order to determine nutritional status and eating-drinking skills based on GMFCS, general information, their food consumption records, eating and drinking skills, anthropometric measurements, and gross motor function levels were inquired and assessed. One of the important factors affecting the growth of children with CP is the nutritional status. Nutritional problems in children with CP make it difficult to provide care for these children and their struggles with the disease (17,18). By following closely the dietary habits of these children, the chance of early intervention can be obtained (19).

With the increase in motor impairment in children with CP, nutritional problems and dependence while eating increase (19). Dahlseng et al. (20) reported that 19.9% of the children were completely dependent while eating. They showed that children's dependence during eating and their status of joining family meals are affected by the gross motor function level. It is also observed in this study that children and adolescents with severe CP are more dependent during eating, they have a lower rate of joining family meals, and they start joining the family meal at a later age than those who are mildly/moderately involved ($p < 0.05$).

Gangil et al. (21) conducted a study in 100 children with CP aged 1-9 years old, and reported that all children had oral motor dysfunction, and especially children with spastic quadriplegia and hypotonic children had poorer feeding ability. In addition, these researchers found that 16% of the children participating in the study could not feed themselves, 19% had swallowing problems, and 20% could not control their saliva (21).

Many factors that are not found in healthy children can affect the energy needs of children with CP. The brain damage that exist in children with CP determines the motor type and disease severity of each child, and thus, determines their mobility level and muscle functions. Therefore, the resulting clinical picture can change their total energy expenditure and needs (22). Some studies argue that children with CP require less energy than healthy children (23,24) while some others argue that involuntary movements (such as, dyskinetic subtypes) require more energy (25,26). In this study, the 3-day food intake records of the children were evaluated, and the daily energy and nutrient consumption levels were examined without including vitamin and mineral supplements.

Lopes et al. (27) evaluated the energy intake and nutrient consumption of 90 children with chronic encephalopathy aged 2-13 years. When energy intakes were compared with the DRI, it was observed that the energy intakes of the children in the 2-3 years age group were parallel to the recommended levels, while children in the 4-6 age range who were hemiparetic and tetraparetic remained below the recommended levels. Boys and girls aged 9-13 years were also found to have energy intakes below the DRI. Sullivan et al. (28) reported that 71% of the tetraparetic children had low energy intake, which was regardless of gender. Thommessen et al. (29) found that children of 1-16 years of age with nutritional problems and disabilities had lower energy intakes than those with disabilities, but not suffering nutritional problems. It has been reported that energy intakes in children with CP is 71%-96% of the recommended values for healthy children in the same age group (23,28). In this study, based on the 3-day food intake records of the children, the daily energy intakes of children in the 5-8 age group at GMFCS I-II-III meets $76.3 \pm 16.81\%$ of the DRI, and in the 9-13 age group, it was observed that it meets $83.4 \pm 30.90\%$. It was found that the rates of daily energy intakes of the children and adolescents aged 5-8 years and 9-13 years at GMFCS IV-V in terms of meeting the DRI recommendations were $73.9 \pm 16.75\%$ and $59.5 \pm 18.06\%$, respectively (Table 2). Although there was a difference between the GMFCS groups, there was no significant relationship between GMFCS and energy intake levels (Table 3). This result contradicts studies supporting the decrease in energy intake as the severity of influence increases (22,30,31). This may be due to the fact that the present study did not include many severely affected children or adolescents, and children and adolescents fed enterally or parenterally were not included in the study.

Balancing macronutrients is as important as energy intake (32) Walker et al. (22) assessed the protein intake in 73 children with CP in an average age of 2.6 ± 0.8 years, and found that the daily protein intake per kilogram in children at GMFCS I-II-III was 3.1 ± 0.7 , and those at GMFCS IV-V was 2.7 ± 1.2 . The ratio of energy from fat was found to be $33.7 \pm 7.3\%$ in children at GMFCS I-II-III, and $34.5 \pm 7.1\%$ in children at GMFCS IV-V. In addition, the distribution of macronutrients in the diet, regardless of energy intake, was found balanced and similar in all children.

Kilpinen-Loisa et al. (31) evaluated the nutritional intake of 54 children with motor impairment (59% children with CP, median age 10.9 years) with the 3-day food intake record and found that 17% of total energy was from protein, 32% from fat, and 50% from carbohydrates. Sabuncular (33) found that 55% of energy was provided from carbohydrate, 12.8% from protein, and 32.1% from fat. Sangermano et al. (34) evaluated the daily energy intakes of 30 children with neurological problems in an age range of 2-15 years using the 3-day food intake record. It was found that there was an increase in fat and protein intakes (37% of total energy from fat, 17% from protein), and a decrease in carbohydrate intake (46% of total energy from carbohydrate).

The amount of protein intake per kilogram in children and adolescents at GMFCS I-II-III and GMFCS IV-V was well above the recommended percentage, and the rate of energy from fat was high (34.0-38.5%) and from carbohydrates (45.4-50.1%) was low in all age groups. The amount of fiber intake was well below the recommended level for all age groups and both genders (Table 2). Balancing macronutrients is as important as energy intake. In this context, it is seen that the study group displays an unbalanced diet modeling by taking high fat and low carbohydrates, which is in line with some studies (27,34). These may be the reasons for the unbalanced diet pattern revealed by the study: tendency of school-age children to consume fast food and similar foods during school time, fatty foods are more delicious, some children and adolescents' dependence on feeding.

It is stated that chewing and swallowing problems, inability to feed on their own, and long and stressful meal times may cause inadequate macro and micronutrients in children with CP (35). Micronutrients have important roles in many metabolic pathways and needed for metabolism to work in an order (36). Insufficiency of one or a few micronutrients can cause symptoms, and in children with neurological problems, such deficiencies can be difficult to be distinguished. Low energy intake can also result in inadequate micronutrient intake (37).

Grammatikopoulou et al. (38) found that children with CP had low intake of vitamin A, biotin, folate, vitamin K, and copper, and also observed that other micronutrients were in line with the recommended rates or above. Calis et al. (30) evaluated the 7-day food intake record of 176 children with CP, and the daily average calcium intake was found to meet 87% of the recommended values, 77% for vitamin A, 13% for vitamin B6, and 78% for folate. Kalra et

al. (39) evaluated 50 children with CP, and argued that there is a difference between GMFCS levels and nutrient intakes, and the amount of intake decreases as the severity of the involvement increases. However, when they compared the nutritional consumption of children with CP and healthy children, they found that children with CP had lower intake of copper, iron, and magnesium. The Oxford Nutrition Study II (28) reported that children with CP met 77% of calcium, 96% of phosphorus, and 89% of riboflavin compared to the DRI. Contrary to these studies, Baglam (40) found in 96 neurological children that the children's levels of vitamin A, vitamin E, vitamin B1, vitamin B2, niacin, vitamin B6, and vitamin B12 were well above the recommendations, and argued that this was due to the vitamin and mineral supplements used. Patrick and Gisel (37) argue that nutritional problems in children with neurological problems are due to inadequate energy intake rather than micronutrient deficiencies.

In this study, children and adolescents at GMFCS I-II-III and in age groups of 5-8 and 9-13 met $199.8 \pm 179.19\%$ and $112.7 \pm 73.26\%$ of the average daily vitamin A needs, respectively, and the difference between age groups was statistically significant ($p < 0.05$). Mildly involved children's rate of meeting calcium (42.0%-58.6%) and potassium (44.9%-54.2%) DRI were low in all groups ($p > 0.05$). When the micronutrient intake levels of the severely affected children were evaluated, the average daily calcium intake of children aged 5-8 years at GMFCS IV-V was 589.3 ± 279.62 mg, and the average daily calcium intake of children in the 9-13 age group was 541.5 ± 217.49 mg. The amount of magnesium intake decreased as the age increased ($p < 0.05$). However, there was no relationship between the severity of the involvement and the intake levels of micronutrients. While the results of this study contradict with some studies (30,39) in the literature, they also coincide with some other studies (37,40). The reason for this outcome may be that the percentage of children with less severe involvement in this study is low, and that the diet they consume is insufficient in volume but high quality.

Although a significant amount of time is allocated for feeding children with CP, it is observed that children and adolescents are malnourished especially in terms of energy, fiber, and calcium. Though there is no statistical difference between GMFCS levels and energy and nutrients, it is known that malnutrition is more evident in children with moderate and severe involvement (27,41). In addition, the reason for the lack of insufficiency in energy and macro and micronutrients in this study is that the rate of children

with chewing and swallowing problems was low in the study.

The EDACS was used to classify how children with CP eat and drink in daily life using meaningful distinctions. A very good correlation was found between GMFCS and EDACS ($r = 0.736$, $p = 0.000$). Sellers et al. (11) found that there was a good positive relationship between EDACS and GMFCS, and that there were more limitations in the eating and drinking skills of children and adolescents whose gross motor functions were more affected. The EDACS can be an easy and practical method to classify children's eating and drinking skills in order to create a common language in the literature.

CONCLUSIONS

The nutritional status of children with CP is of great importance to closely follow their growth and development. EDACS can be a good tool for evaluating nutritional habits, as it is a practical and easy tool besides food consumption records.

DECLARATIONS

Conflict of Interest

Authors declare that there is no conflict of interest.

Ethical Approval

The study procedures were approved by the Ethics Commission of GAZİ University (Date: 20.01.2016, Number:77082166-604.01.02-). Informed consent was obtained from all individual participants included in the study.

Human and Animal Rights Statement

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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Determination Of Non-pharmacological Methods Used by Midwifery Students in Premenstrual Syndrome

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ABSTRACT

Purpose: To determine the non-pharmacological methods used by midwifery students with premenstrual syndrome.

Methods: This descriptive study was conducted with 293 midwifery students online between February and May 2021 using the Premenstrual Syndrome Scale (PMSS) and Nonpharmacological Methods Questionnaire Form.

Results: The mean score of PMSS was 124.38 ± 39.1 and the 54.6% of the students experienced PMS of moderate severity. While the rate of applying only non-pharmacological methods for PMS was 27.3%, the rate of applying in addition to pharmacological methods was 37.5%. The most commonly used non-pharmacological methods were hot application, shower with hot water, and plenty of water consumption

Conclusion: Most of the midwifery students who participated in the study had moderate PMS. Students preferred non-pharmacological methods more in addition to pharmacological methods. It may be recommended to plan interventions to increase the level of knowledge and awareness of midwifery students about non-pharmacological methods that can be used for PMS.

Keywords: premenstrual syndrome; non-pharmacological method; midwifery; PMS

Ebelik Öğrencilerinin Premenstrüel Sendromda Kullandığı Non-farmakolojik Yöntemlerin Belirlenmesi

ÖZET

Amaç: Premenstrüel sendrom yaşayan ebelik öğrencilerinin kullandıkları nonfarmakolojik yöntemleri belirlemek.

Yöntem: Bu tanımlayıcı çalışma 293 ebelik öğrencisiyle Şubat-Mayıs 2021 arasında online olarak Premenstrüel Sendrom Ölçeği (PMSÖ) ve Nonfarmakolojik Yöntemlere İlişkin Anket Formu kullanılarak ile gerçekleştirildi.

Bulgular: PMSÖ puan ortalaması 124.38 ± 39.1 bulundu ve öğrencilerin %54,6'sının orta şiddette PMS yaşadığı belirlendi. PMS için sadece non-farmakolojik yöntemleri uygulama oranı %27,3 iken, farmakolojik yöntemlere ek uygulama oranı ise %37,5 idi. En sık kullanılan nonfarmakolojik yöntemlerin sıcak uygulama, sıcak su ile duş ve bol su tüketimi olduğu saptandı.

Sonuç: Çalışmaya katılan ebelik öğrencilerinin çoğunun orta düzeyde PMS yaşadığı ve çoğunun nonfarmakolojik yöntemleri farmakolojik yöntemlere ek olarak tercih ettiği belirlendi. Ebelik öğrencilerinin PMS için kullanılabilecek nonfarmakolojik yöntemleri yeterince uygulamadığı belirlendiği için bu konudaki bilgi ve farkındalık düzeylerini artıracak müdahalelerin planlanması önerilmektedir.

Anahtar Kelimeler: premenstrüel sendrom; non-farmakolojik yöntem; ebelik, öğrenci; PMS

Premenstrual syndrome (PMS) is a disorder that usually occurs in the second half of the menstrual cycle and is characterized by physical and behavioral symptoms that affect certain aspects of a woman's life. The difference between PMS and normal premenstrual symptoms experienced by many women is that it affects daily life (1,2). According to the American College of Obstetricians and Gynaecologists (ACOG), if a woman has at least one emotional and at least one physical symptom that affects her social, academic, or work life, PMS can be mentioned, but these symptoms appear about five days before menstruation and must be seen during at least three menstrual cycles. The distinctive emotional symptoms of PMS; anxiety, depression, irritability, confusion, tantrums, social isolation while physical symptoms; breast tenderness, headache, swelling in the extremities, and swelling in the abdomen (3,4). It is seen that the changes in estrogen and progesterone hormone levels are effective in the formation of these symptoms (5,6).

Approximately 80% of women are exposed to some changes that can be considered as PMS symptoms in the premenstrual period, and the majority of this group is people in the 15-25 age group (7,8). Some women experience PMS symptoms at a much more severe level, which can negatively affect work/school attendance, academic success, social life, and quality of life (8). According to Bilir, et al. (9), the rate of university students with PMS is 71.3% and the most common symptoms are abdominal bloating and irritability. It was also observed that 7.6% of these students used oral contraceptive drugs for treatment purposes (9). According to Işık, et al. (10), the most common PMS problems experienced by the students participating in the study were fatigue and outbursts of anger, while 33.2% of them had severe PMS, and 70.4% of these students used medication for their symptoms (10).

There is no specific treatment for this problem, which greatly affects the quality of life, but it is known that using natural products during this period alleviates the symptoms. Thus, non-pharmacological treatment types are recommended first for people with PMS symptoms (11,12). Nonpharmacological treatment methods; diet arrangements, regular exercise, psychotherapy, massage, yoga, relaxation exercises, hot application, breathing exercises, alcohol, caffeine, and nicotine restriction, regular sleep, edema, salt restriction in the diet to reduce breast pain and tenderness, herbal teas such as chamomile tea, lemon balm tea teas; aromatherapy (lavender, rose, geranium, oil) acupressure, acupuncture, vitamin B6, calcium and magnesium supplementation is a wide range

of applications (13-15). Recently, non-pharmacological applications are frequently preferred because they are accessible, easily applicable, and inexpensive (16). In the study of Tufan (17), the most frequently used non-pharmacological method for PMS by midwifery and nursing students was hot application, while the least used methods were aromatherapy, yoga, and meditation.

Although non-pharmacological methods that can be used for PMS are quite diverse (11), studies on non-pharmacological methods preferred by students in PMS are limited. Students should be informed and educated about various non-pharmacological methods that are accessible and easily applicable in PMS (17). This study was carried out to determine the non-pharmacological methods preferred by midwifery students who have PMS problems.

Research Questions

1. What is the incidence of PMS in midwifery students?
2. What are the non-pharmacological methods used by midwifery students with PMS?

Material and Methods

Type of the Study: This research was conducted in a cross-sectional descriptive type to determine the non-pharmacological methods used by midwifery students of a university who have PMS problems.

Place and Time: The study was carried out on the online platform between February and May 2021, as universities continue their education processes with distance education methods due to the pandemic.

Population and the Sample: The universe consisted of all midwifery students in the midwifery department of a university (n=326). All students between the ages of 18-40 who were midwifery students and met the criteria for voluntarily participating in the study were included in the sample (n=293). Participants who did not want to participate voluntarily in the study were excluded.

Data Collection Tools: Nonpharmacological Methods Questionnaire and Premenstrual Syndrome Scale used for collecting the data.

Nonpharmacological Methods Questionnaire: This form, which was prepared by the researchers using the literature (17-19), and consists of 33 questions

about sociodemographic characteristics and non-pharmacological methods applied in premenstrual syndrome.

Premenstrual Syndrome Scale (PMSS): The scale was developed by Gençdoğan (20) based on DSM-III and DSM-IV-R criteria to detect the presence of PMS (1=Never, 2=Very little, 3=Sometimes, 4=Often, 5=Continuously). It is a scale consisting of 44 questions. The total score obtained from the scale varies between 44-220 and 0-44 points are evaluated as no PMS, 45-103 points as mild PMS, 104-163 points as moderate PMS, 164-220 points as severe PMS (20).

Data Collection: The data were collected on the online platform due to distance education. With the approval of the department chair, the online survey links were delivered to all students by determining when on which day and at what time they would be shared. "Premenstrual Syndrome Scale (PMSS)" and "Nonpharmacological Methods Questionnaire" were used for data collection. It took approximately 20 minutes for the participants to answer the scales and questionnaires.

Statistical Analysis: A statistical package program was used for data analysis. The normal distribution of variables was analyzed according to the Kolmogorov Smirnov test, data were analyzed using descriptive statistical methods (number, percentage, mean and standard deviation) and independent t-test, Mann-Whitney U test, One Way ANOVA, and Spearman correlation tests.

Ethical Approval: The principles of the Declaration of Helsinki were complied with in the study and online consent form was obtained from the participants. The study was approved by Istinje University Ethical Committee of Human Research (Protocol Number: 2020/135).

Results

Table 1 shows the sociodemographic characteristics of the participants. The mean age of the students participating in the study was 21.11 ± 2.05 , the mean body mass index (BMI) was determined to be 21.75 ± 3.63 . It was determined that 96.6% of the participants were single and 79.9% had a nuclear family, 76.8% of them lived with their families during the education period, and 68.6% of them had income equal to their expenses.

When the ages of menarche were questioned, it was found that 74.4% of them had menarche between the ages of 9-13. It was observed that the menstrual cycle length

was between 21-35 days for 86.3% of the students and the mean menstrual cycle duration was between 3-10 days for 94.9% of them (Table 1).

In Table 2, the scores of the participants in PMSS and their PMS severity are given. The total mean score of the participants in PMSS was found to be 124.38 ± 39.19 points, and when the severity of PMS was analyzed, it was found that 54.6% (n=160) of the participants had moderately severe PMS (Table 2).

Table 3 shows the findings regarding the non-pharmacological methods used by the participants for PMS. 27.3% of the participants preferred non-pharmacological methods, and 37.5% preferred both pharmacological and non-pharmacological methods. It was determined that PMS complaints decreased in 96.2% of the participants who exercised regularly for PMS. While 55.3% of the participants did not do any application to reduce the breast pain seen in PMS, it was observed that the practitioners mostly used unsupported bras (25.3%). It was determined that 51.9% of the participants consumed herbal teas for PMS, and it was seen that the most preferred herbal tea was lemon balm tea (30.8%). It was observed that 33.4% of the participants preferred hot water bags to reduce back, head, and abdominal pain in PMS. When the participants' use of the acupuncture method for PMS was questioned, it was determined that there were no participants using acupuncture. It was determined that only 10.6% of the participants applied aromatherapy and the method of application was massaging the painful area with the oil used for aromatherapy (28.1%). When the changes in eating habits in the premenstrual period were examined, it was seen that 51.5% of the participants increased their tendency to foods such as chocolate and pastry.

It has been determined that non-pharmacological methods are mostly used to relieve pain (66.6%), and information about non-pharmacological methods that can be used in PMS is mostly obtained through lectures (28.3%) and internet/social media (22.9%) (Table 3).

In Table 1, PMSS scores were analyzed according to the characteristics of the participants. It was determined that there was a statistically significant difference between the PMSS scores of the participants according to their grade levels (F:2.882; p:0.036), and according to this difference, the PMSS scores of the fourth-grade students were lower than the other grades.

Table 1. Characteristics of the Participants and Comparison with PMSS Scores				
Features		Mean±S.D	Min-max	Test/p
Age		21.11±2.05	18-38	<i>rs: -.000 / p: 0.089</i>
Height		163.64±5.49	147-183	<i>rs: 0.071 / p: 0.226</i>
Weight		58.34±10.54	41-115	<i>rs: 0.081 / p: 0.166</i>
BMI		21.75±3.63	14.19-36.30	<i>rs: -0.053 / p: 0.371</i>
		n	%	
Grade	1	67	22.9	F: 2.882 / p: 0.036*
	2	88	30.0	
	3	82	28.0	
	4	56	19.1	
Income level	Less than expenses	34	11.6	<i>F: 1.046 / p: 0.352</i>
	Equal to expenses	201	68.6	
	More than expenses	58	19.8	
Social insurance	Yes	223	76.1	<i>t: 1.083 / p: 0.281</i>
	No	70	23.9	
Marital status	Single	283	96.6	<i>t: 1.140 / p: 0.255</i>
	Married	10	3.4	
Family type	Nuclear	234	79.9	<i>F: 1.565 / p: 0.211</i>
	Extended	39	13.3	
	Broken (divorced)	20	6.8	
Where do you stay during the training period?	With family	225	76.8	<i>F: 0.115 / p: 0.951</i>
	With relatives	14	4.8	
	Student home	19	6.5	
	At dormitory	35	11.9	
Weight range by BMI	Thin	50	17.1	<i>F: 0.688 / p: 0.601</i>
	Normal	193	66.1	
	Slightly obese	39	13.4	
	Moderately obese	9	3.1	
	Heavily obese	2	0.3	
Menarche age	<9	2	0.7	<i>t: -0.151 / p: 0.880</i>
	9-13	218	74.4	
	>13	73	24.9	
Frequency of menstrual period	<21 days	14	4.8	<i>F: 1.731 / p: 0.179</i>
	21-35 days	253	86.3	
	>35 days	26	8.9	
Length of menstrual period	<3 days	13	4.4	<i>t: 0.330 / p: 0.742</i>
	3-10 days	278	94.9	
	>10 days	2	0.7	
Are you sexually active?	Yes	17	5.8	<i>t: 0.197 / p: 0.846</i>
		276	94.2	

F: One Way ANOVA, t: independent t test

Features		Mean±S.D	min-max
PMSS Total Score (44-220)		124.38±39.19	44-219
		n	%
PMS Severity	No PMS	5	1.7
	Low PMS	79	27.0
	Moderate PMS	160	54.6
	Severe PMS	49	16.7

Questions		n	%	Test/p
Which one would you apply for PMS?	Pharmacological methods	47	16.0	<i>KW: 4.053</i> <i>p: 0.256</i>
	Non-pharmacological methods	80	27.3	
	Both	110	37.5	
	None	56	19.1	
Do you know about non-pharmacological methods?	Have no idea	36	12.3	<i>F: 1.571</i> <i>p: 0.196</i>
	Little	100	34.1	
	Moderately	134	45.7	
	Too much	23	7.8	
Do you exercise regularly for PMS?	Yes	53	17.7	<i>t: -0.126</i> <i>p: 0.900</i>
	No	240	82.3	
What methods do you use for breast pain during PMS?	Hot application	36	12.3	<i>F: 1.130</i> <i>p: 0.343</i>
	Unsupported bras	74	25.3	
	Massage	17	5.8	
	Applying cabbage to breasts	4**	1.4	
	Nothing	162	55.3	
Do you apply to herbal teas during the PMS period?	Yes	159	51.9	<i>t: -1.369</i> <i>p: 0.172</i>
	No	134	48.1	
If you are applying, which herbs and herbal teas do you consume the most? (n=159)	Mint tea	21	13.2	<i>F: 0.774</i> <i>p: 0.544</i>
	Lemon balm tea	49	30.8	
	Ginger tea	17	10.7	
	Camomile tea	26	16.4	
	Other	46	28.9	
What methods do you use for your back-head-abdominal pain?	Herbal oils	21	7.2	<i>F: 1.157</i> <i>p: 0.330</i>
	Hot water bag	98	33.4	
	Massage	49	16.7	
	Sash tying	19	6.5	
	Shower with hot water	66	22.5	
	None	40	13.7	
Do you use acupuncture for PMS?	No	239	100	**
Do you use aromatherapy for PMS?	Yes	32	10.6	<i>Z: -0.382</i> <i>p: 0.702</i>
	No	261	89.4	

If so, what is your aromatherapy method? (n=32)	Massage to the painful area	9	28.1	<i>F: 0.220</i> <i>p: 0.925</i>
	Dripping in bath water	5	15.6	
	Inhale the steam by dripping into the water	7	21.9	
	Applying essential oil to the wrists	7	21.9	
	Smelling	4	12.5	
What do you do to reduce swelling in your body?	Detox	41	14.0	<i>F: 0.492</i> <i>p: 0.688</i>
	Sport	27	9.2	
	Abundant water consumption	147	50.2	
	Nothing	78	26.6	
How does your eating habits change in PMS?	Increase in fruit and vegetable consumption	22	7.5	<i>KW: 6.846</i> <i>p: 0.232</i>
	Increase in tea, caffeine and carbonated beverage consumption	39	13.3	
	Increase in consumption of chocolate and pastries	151	51.5	
	Increase in nut consumption	30	10.9	
	Decreased appetite	32	10.9	
		19	6.5	
How do you manage mood swings in PMS?	Self-suggestion	50	17.1	<i>F: 1.136</i> <i>p: 0.340</i>
	Sharing with relatives	38	13.0	
	Divert attention	60	20.5	
	Avoiding environments that cause mood changes	85	29.0	
	Nothing	60	20.5	
What is your purpose of using non-pharmacological applications in the premenstrual period?	To reduce pain	195	66.6	<i>F: 0.896</i> <i>p: 0.444</i>
	To relieve	57	19.5	
	For being natural	41	13.9	
Where did you learn about non-pharmacological and pharmacological methods?	Internet/social media	67	22.9	<i>F: 1.210</i> <i>p: 0.307</i>
	Healthcare professionals	45	15.4	
	Friend-family	63	21.5	
	Curriculum	83	28.3	
	All	35	11.9	

*F: One Way ANOVA test; t: student t test; KW: Kruskal Wallis test; Z: Mann Whitney-U test; **: Not included to analysis*

It was determined that there was no significant relationship between the participants' age ($r_s: -.000$; $p: 0.089$), weight ($r_s: 0.081$ $p: 0.166$) and height ($r_s: 0.071$; $p: 0.226$) and PMSS scores. There was no significant difference between the PMSS scores according to the participants' income status, social security, marital status, family type, place of residence during the education period, age of first menstrual period, menstrual cycle length, and frequency, and being sexually active ($p > 0.05$).

In Table 3, the PMSS scores of the participants and the non-pharmacological methods they applied were compared. According to this; it was observed that there was no significant difference between the PMSS scores of the participants according to the non-pharmacological method they preferred for PMS, the purpose of using these methods, and the sources of information ($p > 0.05$).

Discussion

In this study, it was determined that the mean score of the participants in PMSS was 124.38 ± 39.19 points, and 54.6% of the participants had moderately severe PMS. In response to the research question, it was determined that 98.3% of midwifery students had PMS problems. In Çıtak's (21) study, the mean PMSS score was 116.96 ± 31.06 . In the study of Uçar (22), it was found that women with PMS got an average of 129.67 ± 19.17 points from PMSS. In Akmalı's (23) study, it was determined that women of reproductive age scored an average of 111.42 ± 35.88 on PMSS. The mean PMSS score in Erbil's study (24) was 120.82 ± 33 , and it was 122.05 ± 33.93 in Şener's (25) study. The PMSS score obtained in our study is similar to the study of Şener and Erbil.

It was determined that 74.4% of the participants had their first menarche between the ages of 9-13. According to Gökçe (26), the age of menarche in 87.6% of the participants is 10-15 years. In the study of Kısa, et al. (18), the mean age of menarche was found to be 13.21 years. This finding obtained in our study is similar to the literature. In our study, 86.3% of the students had menstrual cycle length between 21-35 days. In Şener's study (25), it was found that 57.9% of his students had a menstrual cycle between 28-31 days. In Vatanserver's study (12), 80% of the students stated that the cycle duration was between 22-34 days. A normal menstrual cycle period is 22-30 days (27). According to this result, the menstrual cycle length obtained in our study is similar to the literature.

It was found that 27.3% of the participants used non-pharmacological methods for PMS, while 37.5% used both pharmacological and non-pharmacological methods. In Tufan's study (17), 76.2% of the students stated that they primarily used non-pharmacological methods in the premenstrual period. In response to the research question, the most commonly used non-pharmacological methods were determined as herbal tea, plenty of water consumption, hot application, and hot water bag. In Tufan's study, hot application, sleeping/resting, and taking a shower are preferred the most (17). The data in our study are similar to the literature.

It was determined that 51.9% of the participants applied to herbal teas for PMS complaints, according to Dönmez and Gümüşsoy (28) 34.5% of the participants in the study applied to herbal teas. In our study, 50.2% of the participants consume water to reduce swelling in the body. According to Topatan and Kahraman (29), 34.2% of the

participants drank plenty of warm water and herbal tea. The data in this study are similar to the literature.

There were no participants using acupuncture in this study. Jang et al. (30) found that the application of acupuncture in the luteal or follicular phase reduced PMS symptoms by 50% or more. Armour et al. (31) mention in their review that acupuncture can reduce PMS symptoms. It is seen that our study is not similar to the literature. It is thought that this situation is due to the lack of knowledge of the participants about acupuncture and the cost of acupuncture application. The rate of participants using aromatherapy for PMS complaints was 10.6%. The rate of participants using aromatherapy in Tufan's (17) study was 3.1%. and Turan et al. (32) found that aromatherapy prevented pain in PMS. In the study of Uzunçakmak and Alkaya (33), lavender oil inhalation was found to be effective on PMS. In the study of Bolsoy (34), the most frequently used oils in aromatherapy are; evening primrose and lavender oil. Our study is similar to the literature.

It was found that 33.4% of the students preferred hot water bags to reduce back, head, and abdominal pain in PMS. In the study of Aşçı et al. (35), one of the three most commonly used methods in dysmenorrhea is applying heat to the abdomen. In the study of Tufan (17), the most frequently used non-pharmacological method in the premenstrual period is hot application (75.6%). In this direction, the rate of application of heat to the waist, head, and abdomen is similar to the literature.

It was determined that 17.7% of the participants exercised regularly. According to Çitil and Kaya (36), the rate of midwifery students who exercise regularly is 20.8%. It was determined that 40% of the participants in Yeşildere Sağlam's (37) study exercise. Our study was similar to study performed by Çitil and Kaya (36). When the nutritional habits of the students in the premenstrual period were examined, it was found that the consumption of chocolate and pastry foods increased by 51.5%. In the study of Selçuk et al. (38), the prevalence of PMS is high in those who consume fast food the most frequently. It was determined that the participants mostly (29.0%) preferred the option of "staying away from environments that would cause mood changes" in the management of mood changes in PMS. In the study of Özmermer (39), 40.9% of the participants stated that for mood management; and they applied massage, music, rest, and exercise.

Conclusion

More than half of the students had moderate PMS, 27.3% of the students preferred non-pharmacological methods for PMS complaints, and 37.5% preferred non-pharmacological methods in addition to pharmacological methods. The participants mostly used non-pharmacological methods to relieve pain. The non-pharmacological applications preferred by the participants for PMS complaints were herbal teas, aromatherapy, hot compresses, and massage. It has been found that the situation of doing regular exercise is very low, students' awareness of exercise should be increased. Consumption of chocolate and pastry increases in eating habits during the PMS period and it is thought that this affects PMS, therefore it is recommended to improve eating habits. It was observed that none of the students preferred acupuncture. In reducing PMS symptoms, students should be given more information about non-pharmacological methods and they should be enabled to use these methods effectively. There is a need for multidisciplinary and multidimensional studies on nonpharmacological methods in PMS.

Declarations

Funding

'Not applicable.'

Conflict of Interest

'Not applicable.'

Ethics Approval

The study was approved by Istinye University Ethical Committee of Human Research (Protocol Number: 2020/135).

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Availability of Data and Material (Data Transparency)

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Authors' Contributions

EB and RGK: Design, EB: Literature search, EB: Data collection and interpreting, EB and RGK: Statistical analysis and reporting EB, and RGK: Writing, EB and RGK: Critical reading.

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Determining Diabetes Risk and Health Literacy Levels in Individuals Aged 45 and Above: A Descriptive Correlational Study

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ABSTRACT

Purpose: The aim of this study is to determine actual and perceived diabetes risk in individuals aged ≥ 45 and their health literacy levels.

Methods and Materials: The study is of descriptive, correlational design and was conducted with 82 university staff members of ages ≥ 45 years. Along with Finnish Diabetes Risk Score (FINDRISC), was used to collect data of the question, "Please comment on your diabetes risk?" and the Health Literacy Scale for Turkey (HLST-32).

Results: About of twenty-six percent for the participants exhibited a high/very high actual diabetes mellitus risk. A positive and significant correlation was found between the participants' actual and perceived risk of diabetes mellitus ($r=0.771$, $p<0.001$). Seventy-two percent of the individuals displayed inadequate, problematic/limited levels of health literacy. There was no significant correlation between actual and perceived diabetes mellitus risk and health literacy scores.

Conclusion: Individuals are aware that they are at risk of developing diabetes mellitus. About three out of every four participants had a low health literacy level. The fact that a more educated group such as university personnel demonstrated low health literacy compared to the general public is an issue that must be addressed.

Keywords: Diabetes mellitus, actual risk, perceived risk, health literacy, university staff

45 Yaş ve Üzeri Bireylerin Diyabet Riski İle Sağlık Okuryazarlık Düzeylerinin Belirlenmesi: Tanımlayıcı, İlişki Arayıcı Bir Çalışma

ÖZET

Amaç: Bu çalışmada, riskli grupta yer alan ≥ 45 yaş bireylerin gerçek ve algıladıkları diyabetes mellitus riskleri ile sağlık okuryazarlık düzeylerinin belirlenmesi amaçlanmıştır.

Yöntem: Tanımlayıcı, ilişki arayıcı tipteki çalışmaya, ≥ 45 yaşında, üniversite personeli olan 82 kişi dahil edilmiştir. Veriler, Finlandiya Tip-2 Diyabet Risk Anketi (FINDRISK), "diyabet riskinizi yorumlayınız" şeklindeki soru ve Türkiye Sağlık Okuryazarlığı Ölçeği (TSOY-32) ile toplanmıştır.

Bulgular: Bireylerin yaklaşık %26'sının gerçek diyabetes mellitus riski yüksek-çok yüksek düzeydedir. Katılımcıların gerçek ve algıladıkları diyabetes mellitus riski arasında pozitif yönde anlamlı bir ilişki varlığı saptanmıştır ($r=0.771$, $p<0.001$). Bireylerin %72'sinin sağlık okuryazarlık düzeyi yetersiz, sorunlu-sınırlı düzeydedir. Sağlık okuryazarlık düzeyi puanının gerçek ve algılanan diyabetes mellitus riski ile anlamlı düzeyde ilişkisi bulunmamaktadır.

Sonuç: Bireyler diyabetes mellitus risklerinin farkındadır. Her dört katılımcıdan yaklaşık üçünün sağlık okuryazarlığı düşük düzeydedir. Genel topluma göre daha eğitilmiş bir grupta olan üniversite çalışanlarının sağlık okuryazarlıklarının düşük olması ele alınması gereken bir konudur.

Anahtar Kelimeler: Diyabetes mellitus, gerçek risk, algılanan risk, sağlık okuryazarlığı, üniversite personeli

The period between registering normal glucose metabolism and unmistakable diabetes mellitus (DM) is known as the “prediabetic period” and evolves into unmistakable Type 2 DM in 5%-10% of individuals (1,2). In 2020, one out of every three Americans is a prediabetic. More importantly, eight out of every ten adults are unaware that they are prediabetic (3). According to the data of the World Health Organization (WHO), 1.5 million people lost their lives to diabetes in 2019. Almost half of these deaths (48%) were individuals under the age of 70. WHO data reveals that the rate of premature mortality increased by 5% over the period 2000-2016. WHO stresses that a healthy diet, physical activity, the use of medications, and regular screening are important interventions in the prevention of diabetes onset (4). According to the 2019 data of the International Diabetes Federation (IDF), Turkey’s diabetes prevalence rate of 11.1% is the highest in the world (5). The “Turkish Diabetes Epidemiology Project (TURDEP-II-2010)” reports a frequency of 28.7% for prediabetes in Turkey (1). Compared with TURDEP-I, it can be seen that in the 12 years that have elapsed, Turkey prediabetes prevalence has soared by 106% (6).

It is reported that individuals with DM are not aware of their condition and do not know the risks of the illness (3). Health education can be provided to raise levels of awareness in this context (7). Screening should be carried out to determine levels of risk in this group such that individuals are checked for fasting blood glucose, administered an Oral Glucose Tolerance Test (OGTT) and measured for A1C (8). The Turkish Endocrinology and Metabolism Association (TEMA, 2020) (9) recommends the use of the FINDRISC (Finnish Diabetes Risk Calculator) in screening groups at risk of DM. The advice is to achieve the screening of groups at risk as a priority, taking initiatives to reduce these individuals’ level of risk in an effort to fully protect against the development of chronic forms of the disease (9).

The steady advances made in informatics technologies brings with it the ensuing modernization of health services and also the need to improve the health literacy (HL) of individuals seeking these services (10). In order to benefit from health services, individuals must be familiar with many digital applications that enable them to get a doctor’s appointment, schedule an examination, procure the prescribed medications, all of which fall into the realm of HL (11). HL will guide individuals in their decisions and behaviors regarding healthcare and community health, provide them with basic knowledge about health and healthcare services, help them access, understand and make

use of the information they need (12). HL serves to facilitate individual efforts to make decisions about their health in daily life, raise the quality of their lives, improve their health and prevent the onset of disease (12,13).

The “Health Literacy Levels in Turkey and Related Factors Survey (2019)” (13) conducted by the Ministry of Health, Health Improvement General Directorate (HIGD) has found that 7 out of every 10 individuals in Turkey have a low level of HL. It is seen in the literature that an adequate level of HL improves health-promoting behavior as well as health data (e.g., blood glucose levels), thus reducing the prevalence of chronic illness and the risk of developing disease (15,16).

HL is indirectly related to DM risk through the changes that are advised to pursue a healthy lifestyle. At the same time, a low level of HL points to negative health indicators (15). Inadequate HL prevents individuals from accessing accurate health information, leads them into neglecting to engage in risk control and causes their condition to worsen (17). ADA (2020) (8), classifies the 45-and-over age group as a risk group for DM. Determining the groups at risk and defining prevention strategies is an ongoing project in the fight against DM throughout the world. The aim of this study was to determine the actual and perceived DM risks of individuals of 45 and over, as well as their HL levels.

MATERIAL AND METHODS

Study Design

This is a descriptive, correlational study.

Sample

The population of the study comprised 240 individuals, ages 45 and over, who were staff personnel at a state university as of 2020. Sample size, as calculated in this known population, was found to be 147. The sample group was made up of individuals volunteering to participate in the study over the period July 2020-May 2021. Since the data collection phase of the study coincided with the COVID-19 pandemic, the targeted sample size could not be reached, and the research was carried out with 82 (55.7%) individuals.

Inclusion criteria for the study were: Being of age 45 and over and a part of the academic and administrative staff at the state university where the study was conducted, not being pregnant or having any malignant condition, not having a problem with hearing or sight, having at least

an elementary school education, being fluent in spoken Turkish, and consenting to participate in the study. The data of the study were collected from the participants by means of an electronic link to a questionnaire sent out through the state university's email network.

Data Collection

Descriptive Characteristics Data Collection Form

This is a form that queries the individual characteristics of the participants. Created by the authors, the form consists of questions about gender, type of personnel and smoking-drinking habits.

The FINDRISC Questionnaire

The Finnish Type-2 Diabetes Risk Score (FINDRISC) instrument was used to determine the participants' risk of developing DM. TEMA recommends the use of FINDRISC in DM screenings (6,9). FINDRISC was developed in 1987 by Lindström and Tuomilehto (18) for the purpose of determining people at risk for Type-2 DM. The validity of the measure was the subject of a cohort study in 1992 (18). The Turkish validity and reliability study for FINDRISC was produced by Etbaş Demirağ (19) in 2016.

FINDRISC consists of eight questions (age, body mass index-BMI, waist circumference, exercising, consumption of fruit and vegetables, hypertension, pre-pregnancy blood glucose level and family history of DM). Possible FINDRISC scores are "0-26" (18). Risk levels are classified as follows (Table 1)

Diabetes Risk Score		
Total Score	Risk Degree	10 Year Risk
<7	Low	%1(1/100)
7-11	Slight	%4(1/25)
12-14	Moderate	%16(1/6)
15-20	High	%33(1/3)
>20	Very High	%50(1/2)

Perceived Diabetes Risk

The perceived DM risk of the individuals was noted by means of the item, "Please comment on your DM risk." The participants were asked to define their perceived risk of DM by selecting a response from the choices of low, slight, moderate, high and very high risk.

The Health Literacy Scale for Turkey (HLST-32)

Developed by the European Health Literacy Survey Consortium, HLST-32 was designed to be used to assess HL in literate individuals of the ages of 15 and over (20). The Turkish adaptation of the scale was created by Okyay and Abacıgil (21) (2016). Cronbach's alpha internal consistency coefficient was found to be 0.92 (21). Cronbach's alpha for the overall scale in the study sample was 0.94.

Each item in the 32-item HLST-32 was rated on a 4-point scale of 1=Very easy, 2=Easy, 3=Difficult, 4=Very difficult. A response of "I don't know" is coded as 5. The responses were reversely scored in the calculation of the total score. For ease of calculation, the formula "Index=(arithmetic mean-1)x[50/3]" was used for standardization such that the total score would be in the range of 0-50. The scores for the level of HL are evaluated in four categories: 0-25: inadequate, >25-33: problematic-limited, >33-42: adequate, and >42-50: excellent (21).

Statistical Analysis

Data was analysed with the licensed SPSS (Statistical Package for the Social Sciences) 23.0 software. The distribution of FINDRISC and HL levels was assessed with frequency analysis. Skewness and kurtosis coefficients were evaluated to see whether the data displayed normal distribution; it was seen that the continuous data (HL scores) did display normal distribution. The correlations between variables was examined with Pearson's correlation analysis. A post hoc calculation of power was calculated in the G*Power program. The calculation of the power of the study was performed at a confidence level of 95% and a level of significance of 0.05. The power of the post hoc r test was found to be 86%. Since this value was 0.80 or over, this indicated that the power of the test was good and sensitivity was high (22).

RESULTS

An examination of the study participants' sociodemographic characteristics showed that their mean age was 51.34±4.49 and 75.6% were between the ages 45-54. Men comprised 79.3% of the participants and 59.7% of the group were working as administrative personnel (Table 2).

A review of the variable DM risk factors revealed that 25.7% of the participants were obese according to the BMI, the weight circumference of 36.6% was >88 cm, 19.7% were physically inactive, 30.4% smoked, 4.9% drank and 19.5% had hypertension (Table 2). A review of the invariable DM risk factors indicated that 41.4% of the participants had a history of DM/prediabetes in the family (Table 2).

Table 2: Demographic Characteristics of the Participants

Variables		Groups	(n=82)	%
Age	Mean±SD	45-54	62	75.6
		55-64	19	23.1
	51.34±4.49	>64	1	1.30
Gender		Male	65	79.3
		Female	17	20.7
Personal		Academic professionals	33	40.3
		Non-academic professionals	49	59.7
BMI		<25 kg/m ²	19	23.1
		25-30 kg/m ²	42	51.2
		>30 kg/m ²	21	25.7
Waist circumference		Less than 94 cm (male) or 80 cm (female)	21	25.6
		94-102 cm (male) or 80-88cm (female)	31	37.8
		More than 102 cm (male) or more than 88 cm (female)	30	36.6
HT		Yes	16	19.5
		No	66	80.5
Direct family history with DM, preDM		Yes	34	41.4
		No	48	58.6
Physical Activity		≥30 minutes everyday	46	56.0
		<30 minutes everyday	20	24.3
		Inactive	16	19.7
Cigarette smokers		Yes	25	30.4
		No	57	69.6
Alcohol consumption		Yes	4	4.90
		No	78	95.1

BMI: Body mass index; HT: Hypertension; DM: Diabetes mellitus; PreDM; Prediabetes

The actual and perceived DM risk and HL levels of the individuals in the study were reviewed. Accordingly, the FINDRISC questionnaire revealed a high risk of DM in 20.7% and a very high risk in 5.1% of the participants. The perceived DM risk was high in 15.9% and very high in 3.6%. In 72% of the individuals, it was seen that their HL were at the inadequate-problematic/limited level (Table 3).

Table 3: Actual-Perceived Diabetes Risks and Health Literacy Levels of the Participants

Variables		Classification	(n=82)	%
Actual DM Risk		Low	14	17.0
		Slight	32	39.0
		Moderate	15	18.2
		High	17	20.7
		Very High	4	5.10
Perceived DM Risk		Low	32	39.0
		Slight	21	25.6
		Moderate	13	15.9
		High	13	15.9
		Very High	3	3.60
Health Literacy Score	Mean±SD	Inadequate	18	22.0
		Problematic-limited	41	50.0
		Adequate	12	14.6
		Excellent	11	13.4
		31.39±9.19		

DM: Diabetes mellitus.

A positive and significant correlation was found between actual and perceived DM risk ($r:0.77, p<0.001$). There was no significant correlation between actual and perceived DM risk and HL scores (Table 4).

Table 4: Correlation for the Relationship between Health Literacy Levels and Actual Perceived Diabetes Risks of the Participants

Variables		Actual DM Risk	Perceived DM Risk	Health Literacy
Actual DM Risk	r	1	0.771*	0.105
	p		<.001	0.350
Perceived DM Risk	r		1	0.091
	p			0.417
Health Literacy Score	r			1
	p			

**r=0.60-0.79; DM: Diabetes mellitus*

DISCUSSION

When the factors affecting DM risk were examined, it was found that 51.2% of the participants were at risk of obesity, 25.7% were obese according to the BMI, the waist circumference of 74.4% placed them in the risk interval (>80 cm), 19.5% had hypertension, and 19.7% led inactive lives.

The authors of a cross-sectional study conducted in the US reported that 90% of their participants were extremely overweight or obese and 50.6% had hypertension, asserting that these factors could be associated with DM risk (23). In another study examining DM risk and impacting factors among Korean immigrants, it was shown that 21.3% of the individuals were slightly overweight while 55.3% were obese according to the BMI, and it was suggested that these factors could be associated with the DM risk (15). The review of the DM risk factors examined in this study produced lower rates than in similar studies with adults in the literature, but it was seen that obesity was the most significant risk factor.

Among the study participants, 25.8% were at a high-very high risk of DM; 19.6% perceived their DM risk to be high-very high. The additional correlation analysis performed revealed a positive and significant correlation between actual and perceived DM risk ($r:0.77$, $p<0.001$). It can therefore be said that the participants correctly assessed their DM risk. A study in China that looked into the actual and perceived DM risks of mothers, their were at low risk for DM (90%), and that the majority (88.7%) again perceived their DM risk to be low (24). In another study conducted in the US, one-third of individuals with high DM risk (about 40%) perceived themselves to be at “no risk” of DM and exhibited “false optimism” in this context (25). It should not be forgotten that perceiving one’s risk to be lower than it actually is (false optimism) may be the biggest barrier to reducing individual risks. In fact, individuals who are aware of their existing risks may make an effort to affect a change or adopt a lifestyle conducive to change, such as increasing their level of engaging in physical activity.

It was found in the study that a large majority of the participants (72%) were at an inadequate and problematic/limited HL level. These results are consistent with various other studies in the literature that state that approximately 65% of Turkey’s population are at a problematic or inadequate HL level (26). In another study in which the same measuring tool was utilized, it was reported that 70% of the study participants displayed inadequate, problematic/limited HL levels (27). In Brazil, researchers have reported that 56.5% of individuals aged ≥ 60 exhibit inadequate-problematic HL levels. The same research states that individuals with an adequate level of HL have better health outcomes (28). In a study conducted in Kuwait, it was found that 64% of individuals displayed inadequate, problematic/limited HL (29). In other studies conducted similarly, it is emphasized that 81.5%-90.8% of individuals

display inadequate, problematic/limited levels of HL (21,30).

In this study, no significant correlation was found between the level of HL and actual and perceived DM risk. The literature points to a directly proportional correlation between HL and DM. In a study carried out in Indonesia, revealed a significant correlation between the level of HL and DM risk (31). Another study reporting similar results showed that inadequate or low HL levels were associated with DM risk, and that individuals with high DM risk were more likely to display a low HL level. The most important reason for this, it is asserted, is the lack of sufficient knowledge about DM as part of HL and by the same token, the failure to make behavioral changes (32). The participants’ actual and perceived DM risks in this study, their awareness about this matter can to some extent be taken to mean that their HL concerning the risk of DM was at a good level.

CONCLUSION

It was seen in this study that there is a directly proportional and consistent relationship between actual and perceived DM risk and that there is no correlation between HL and actual and perceived DM risk. It can be said that the participants had a correct perception of their risk for DM and in this context, they were at an advantage in terms of making healthy changes in their behaviors. It was noted that in the study group, approximately 74.4% of the sample were at risk in terms of the DM risk factors of BMI and waist circumference. Instead of probing into general HL in this context, future studies should be devoted to measuring HL as it relates to the risk of DM.

Limitations

It is considered a limitation that health history of participants was taken into consideration according to participants’ own statements.

DECLARATIONS

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Disclosure of Interest

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Ethics Committee Approval

This study was approved by Ethics committee of Amasya University Clinical Research Ethics Committee (Approval No: E.12759 dated 29/06/2020). Online informed consent was obtained from the participants who agreed to take part in the study. This study was conducted following the guidelines for Good Clinical Practice of the World Medical Association (WMA), the Declaration of Helsinki.

Author Contributions

Concept – İ.T., S.G.; Design – İ.T., S.G.; Supervision – S.G.; Resources – İ.T., S.G.; Materials – İ.T., S.G.; Data Collection and Processing - İ.T., S.G.; Analysis and/or Interpretation – İ.T., S.G.; Literature Review – İ.T., S.G.; Writing – İ.T., S.G.; Critical Review - S.G.

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Experiences and Needs of Nurses Caring for COVID-19 Patients: A Phenomenological Study

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ABSTRACT

Purpose: This study was conducted by using the qualitative study method descriptive phenomenological approach in order to explore the experiences and needs of nurses working during the COVID-19 pandemic.

Methods and Materials: This study was conducted using a descriptive phenomenological approach. The Questionnaire Form and the Semi-Structured Interview Form were used for data collection.

Results: Themes and sub-themes as a result of interviews with nurses were the effects of the pandemic (psychological effects, working conditions, social effects), fear and worries (stress and uncertainty, infecting beloved ones and others), satisfaction (motivation of being a nurse, care for patients with COVID-19 and interaction with them, team harmony and positive energy), needs (need for auxiliary staff, need for additional nurses, need for psychological support), occupational health and safety (difficulties and pressures related to personal protective equipment, thermal comfort issues, nutritional problems, occupational accidents, relationship between COVID-19 and occupational disease).

Conclusion: Nurses who cared for patients diagnosed with COVID-19 in Turkey were negatively affected by the pandemic both psychologically and socially.

Keywords: COVID-19, nursing, needs

COVID-19 Hastalarına Bakım Veren Hemşirelerin Deneyimleri ve Gereksinimleri: Bir Fenomenolojik Araştırma

ÖZET

Amaç: Bu araştırma, COVID-19 pandemi sürecinde görev yapan hemşirelerin deneyimlerini ve gereksinimlerini belirlemek amacıyla nitel araştırma yöntemi olan tanımlayıcı fenomenolojik yaklaşım kullanılarak gerçekleştirilmiştir.

Yöntem: Bu çalışma, tanımlayıcı fenomenolojik bir yaklaşım kullanılarak yapılmıştır. Araştırmanın verileri Anket Formu ve Yarı Yapılandırılmış Görüşme Formu ile toplanmıştır.

Bulgular: Hemşireler ile yapılan görüşmeler sonucunda ortaya çıkan tema ve alt temalar; salgının etkileri (psikolojik etkiler, çalışma koşulları, sosyal etkiler), korku ve endişeler (stres ve belirsizlik, sevdiklerine ve başkalarına bulaştırma, mesleki doyum (hemşire olmanın motivasyonu, COVID-19'lu hastalara bakım ve etkileşim, takım uyumu ve pozitif enerji), gereksinimler (yardımcı personel ihtiyacı, hemşire ihtiyacı, psikolojik destek ihtiyacı), iş sağlığı ve güvenliği (kişisel koruyucu donanımlar (KKD) ilgili zorluklar ve baskılar, termal konfor sorunları, beslenme problemleri, iş kazaları, COVID-19 hastalığı meslek hastalığı arasındaki ilişki).

Sonuç: Türkiye'de COVID-19 tanısı alan hastalara bakım veren hemşireler pandemiden hem psikolojik hem de sosyal olarak olumsuz etkilenmiştir.

Anahtar kelimeler: COVID-19; hemşireler; ihtiyaçlar

Coronaviruses are a large family of viruses that can cause various diseases ranging from the common cold and influenza (flu) to more severe diseases including severe respiratory failure, Middle East Respiratory Syndrome and Severe Acute Respiratory Syndrome (1). Today, many subtypes of coronavirus have been reported to cause illnesses in humans. A novel type of coronavirus causing disease in humans was identified in December 2019, in Wuhan City, Hubei province of China and the disease was recognized as Coronavirus disease 2019 (COVID-19) (2). The World Health Organization declared COVID-19 as a “pandemic” when the new type of coronavirus was observed simultaneously in many continents (3).

The COVID-19 pandemic has significantly infected all segments of the populations worldwide. Nurses are one of the most affected groups by this pandemic. Nurses are the major group of healthcare professionals having close contact with the patient while providing care and while communicating with the patients and their relatives (4). Various situations such as intensive working hours, increased workload, inadequate equipments, risk of contamination and spreading of the virus, fear of death, unfair criticism by the society affected nurses adversely during the COVID-19 process. In addition, the lack of specific drugs against COVID-19, staying away from family and beloved ones, death news in the media and insufficient support intensified the effects of the course (5). It was noted in the literature that nurses suffered from psychosocial problems, stress and anxiety disorders, and sleep disorders in this period (6). Sun et al. (2020) conducted a study on the experiences of nurses providing care for COVID-19 patients, where they reported fear and anxiety initially, and different coping strategies to get by (7). Liu et al. (2020) reported that nurses experienced fatigue due to the increased workload, difficulties related with protective equipments, uncertainty and fear of being infected as well as infecting others during the COVID-19 process (8). Kaçkın et al. (2020) indicated that COVID-19 pandemic changed social and business lives of the nurses considerably, and had negative psychological impacts, thus raised the need for psycho-social support (5). Jia et al. (2020) reported that nurses faced ethical problems during the COVID-19 period, had inadequate psychosocial support, and experienced role ambiguities between nurses and physicians (9).

Nursing services can be planned and the strategies supporting the nurses can be developed by determining the needs and experiences of nurses during this COVID-19 pandemic. For this reason, our study aims to identify the

experiences and needs of the nurses providing medical care to COVID 19 patients in this process and to develop relevant solutions.

MATERIAL AND METHODS

Study Design and Setting

This study was conducted using a descriptive phenomenological approach, which is a qualitative research method, with a view to determine the experiences of nurses during the COVID-19 pandemic process. Descriptive phenomenology describes experiences in daily life. These experiences are related to hearing, seeing, feeling, believing, remembering, decision making and evaluating. Descriptive phenomenological research method is chosen when a researcher wants to understand and reveal an event or situation (10). This approach was preferred in the present study with a view to reveal the experiences and psychosocial problems of nurses providing care to COVID-19 patients in Turkey, as well as to understand their feelings, thoughts and perspectives. The present article was written in accordance with the consolidated criteria for reporting qualitative research (COREQ). This study was carried out between September 7 and September 13, 2020 in a state hospital in Turkey.

Participants

The sample of the study consisted of nurses providing care to patients diagnosed with COVID-19. The most important requirement of the phenomenological model in terms of the study groups is that the participants are selected among those having fully experienced the phenomenon in all aspects (11). For this reason, the nurses speaking and understanding Turkish and providing care to the patients diagnosed with COVID-19 were included in this study. Purposive sampling technique was used in this study. Repetition of the responses (reaching the data saturation point) was used to determine the sample size, and a total of 15 interviews were made (12).

Data Collection

The Questionnaire Form and the Semi-Structured Interview Form were used for data collection. The questionnaire form was created by the researchers based on the literature (5,13). This form consisted of 8 questions including the nurses' personal characteristics and business experience. This form includes questions; age, gender, marital status, presence of children, number of children, original department, educational level, working experience. In addition, a semi-structured interview form was also used, prepared by taking advantage of the literature (7,14,15), for determining the experiences of nurses caring for COVID-19 patients (Table 1).

Table 1. Guide for Preparing Interview Questions.

1. How did the pandemic period affect you? Positive: Negative:
2. Could you tell us about your thoughts about COVID-19 patients?
3. What are the issue/issues worrying you at most during the pandemic period? What are the issue/issues that you are worried most during the pandemic period? Can you explain?
4. How did the pandemic affect your social life? Can you explain?
5. How did the pandemic affect your family life? Can you explain?
6. Could you tell us about the care process of COVID-19 patients?
7. How would the quality of care given to COVID-19 patients be increased and be more effective?

The appropriate date and time was as specified for individual interviews with nurses participating in the study. Written consents were obtained from the volunteering nurses, and their permission for using a tape recorder during the interview. For data collection, semi-structured interview technique was used by the researchers interviewing with the nurses in a reserved room within the institution. Each interview took approximately 35-45 minutes, and performed by three researchers. Sufficient repetition of same or similar responses suggested the researchers to terminate the interviews. During the interviews, notes were taken by the researchers and a tape recorder was used.

Data Analysis

Descriptive statistics and thematic content analysis method (semi-structured interview data) were used in the analysis of the data. In content analysis, similar data are brought together within the framework of certain themes and concepts and compiled and interpreted in a way that the reader can understand (16). This research method involves the stages of code, category and theme construction. In the first stage of data analysis, the audio recordings obtained from the qualitative interviews were analyzed by the researchers immediately after the interviews, each interview was transcribed into a separate word file, and 35 pages of data set was obtained at the end. Each tape recording was carefully listened twice after being transcribed. The data were repeatedly read and evaluated by three researchers. The results obtained from study data were analyzed by three researchers at different times. Consensus was reached and the framework was constructed with five categories, considering the topics in the semi-structured interview questions and the literature data. Within this framework, the notes were reviewed several times and the similarities in the expressions were compared and conceptualized. So, the themes and sub-themes that will be placed under the categories were specified.

Data saturation point was tried to be observed in this way. While conducting the analysis, attention was paid to the sub-themes and themes to have a meaningful integrity within themselves and to form an holistic integrity with each other, reflecting the whole concept map. The transcripts were analyzed and evaluated and finally five themes and ten sub-themes were determined through the collaboration of researchers, along with discussions and the exchange of ideas.

Validity and Reliability of the Study

Creswell and Miller criteria were taken into consideration for validity and reliability in the study (17). For this reason, "credibility" was used in place of "internal validity" and "transferability" in place of "external validity". Credibility; This is because the research results are clear, consistent, and can be confirmed by other researchers. The results of the research are given with direct quotations from the nurses' statements. Attention has been paid to the fact that the quotations are relevant and explanatory with the specified themes and sub-themes. Transferability means that research results cannot be generalized, but can be adapted to such settings. The qualitative findings of the study were given in detail in such a way that they can be compared with the data of similar studies.

As for reliability in qualitative research, "consistency" is preferred instead of "internal reliability" while "confirmability" instead of "external reliability". Consistency is to accept the variability of cases and to reflect this variability in the study in a consistent manner (16,17). The researchers asked the questions with a similar approach to each and every participant nurse throughout the semi-structured interviews, and recorded. The qualitative data of the research were presented by using direct quotations. Confirmability is defined as the researcher continuously cross-checking the obtained results by means of the gathered data, and offering a logical explanation to the reader (16,17). The results obtained by the researchers were transferred to readers in a clear and understandable form to ensure confirmability in this study. The qualitative results of the research were compared with the data of similar studies, substantiated by the literature and explained in the discussion section.

Ethical Consideration

The ethics committee permission (Number: 78646441-050.01.04, Date:02/07/2020-E.6972) and institutional permission (Number:11720518-604.02,Date:25/08/2020) were obtained before collecting the data. Participation in the research was absolutely voluntary. The nurses were informed about the aim of the study, and a written statement of consent was obtained for their voluntary participation.

RESULTS

Characteristics of the Respondents

Mean age of the nurses participating in the study was 35.2 ± 6.5 years and total work time was 11.93 ± 7.03 years. It was determined that the majority of the nurses were women (86.7%), had undergraduate education (66.7%), were married (66.7%) and had children (66.7%). Also, 40.0% (n=6) of the nurses were on duty in internal medicine service while 20% (n=3) in the emergency room, and 26.7% (n=4) stated that they stayed away from home during the pandemic. Table 2 outlines the baseline characteristics of the participants.

Phenomenology

We explored the experience of nurses concerning COVID-19 patients during the outbreak using phenomenological methods. The data revealed five levels of themes (Table 3): "effects of the pandemic", "fears and worries", "professional satisfaction", "needs", and "occupational health and safety". The sub-themes that deepen these themes are explained below. Direct quotes were used to present participants' perceptions and views. In the texts cited directly from the nurses' statements, the names of the nurses were coded as Participant 1, Participant 2, and so forth, according to the interview order (Table 4).

Table 3. Summary of Themes and Subthemes.

Themes	Subthemes
Effects of the pandemic	- Psychological effects - Working conditions - Social effects
Fears and worries	- Stress and uncertainty - Infecting beloved ones and others
Professional satisfaction	- Motivation of being a nurse - Care for patients with covid-19 and interaction with them - Team harmony and positive energy
Needs	- Need for auxiliary staff - Need for additional nurses - Need for psychological support
Occupational health and safety	- Difficulties and pressures related to personal protective equipment - Thermal comfort issues - Nutritional problems - Occupational accidents - Relationship between covid-19 and occupational disease

Table 2. Demographics of Participating Nurses (n=15)

Participants	Age (Year)	Gender	Marital status	Presence of children	Number of children	Original department	Educational level	Working experience (Year)
Nurse 1	37	Female	Married	Yes	1	Emergency	High school graduate	10
Nurse 2	30	Female	Single	No	-	Emergency	Associate's degree	4
Nurse manager 3	42	Female	Single	No	-	Emergency	Bachelor's degree	15
Nurse 4	42	Female	Married	Yes	2	Internal medicine	High school graduate	19
Nurse 5	34	Female	Married	Yes	1	Internal medicine	Bachelor's degree	10
Nurse 6	34	Female	Married	Yes	3	Internal medicine	Bachelor's degree	10
Nurse 7	38	Female	Married	Yes	3	Internal medicine	Bachelor's degree	19
Nurse 8	30	Female	Married	Yes	1	Internal medicine	Bachelor's degree	7
Nurse 9	23	Female	Single	No	-	Internal medicine	Bachelor's degree	1
Nurse manager 10	45	Female	Married	Yes	2	Palliative	Bachelor's degree	25
Nurse manager 11	40	Female	Married	Yes	2	Palliative	Bachelor's degree	15
Nurse 12	40	Male	Single	No	-	Intensive care	Master's degree	20
Nurse 13	23	Female	Single	No	-	Intensive care	Associate's degree	1
Nurse 14	35	Female	Married	Yes	2	Surgical	Master's degree	11
Nurse 15	35	Male	Married	Yes	2	Intensive care	Master's degree	12

Table 4. Themes, Sub-Theme and Sample Quotations Identified in Interviews with Nurses.		
Theme	Sub-theme	Quotations
Effects of the pandemic	Psychological effects	<p>- I was the one who contacted the first positive patient in this hospital. Therapy process was uncertain in those days. Everyone was very unprepared. At first they quarantined me at home. I sent my children to my mother. We stayed together with my husband, but I stayed in a separate room. You'd become paranoid in such a situation. I was wiping and cleaning all over. I was feeling as if the virus was spreading from me (Participant 1).</p> <p>- People presume that we are COVID-19 patients just because we are nurses. We are inevitably psychologically affected (Participant 12).</p>
	Working conditions	<p>- We switched to flexible working hours. We work 24 hours a day. We collected a lot of overtime payments. We started working more than usual. I am in the mood that I will continue to another shift the next day. (Participant 1).</p> <p>- We started working for 24 hours. We care for COVID-19 patients as well as other critical patients. We have to don and doff PPE many times a day. We sweat a lot (Participant 2)</p> <p>- I was working in the operating room before. When I first came to this service, I was very afraid that I will take care of COVID positive patients. But there is nothing we can do, there are very few staff. That's why we have to do everything of the patients, daily care and giving treatments. I find myself drenched in sweat after I'm finished with treatments (Participant 13).</p>
	Social effects	<p>- We cannot go anywhere with the children that we used to go before the pandemic. We only go to open air places, to the countryside. Our neighborly relations are almost over. We do not have any contact with anyone (Participant 7).</p> <p>- My social life is affected considerably. I'm afraid of going out at all. I feel safer when I'm in the hospital. I see our COVID-19 patients outside, some of them already recovered or some should be still in quarantine at home, then I get extremely angry and feel concerned, considering that they can infect other people. Although I love traveling, I cannot (Participant 9).</p> <p>- I haven't been to any cafe or restaurant since pandemic started. I feel more concerned outside because I believe that we are more likely to get the disease from the outside, not from the hospital (Participant 5).</p>
Fear and Worries	Stress and uncertainty	<p>- Does this disease infect us? What would happen to us? How will be the whole process? We get very different reactions when we say outside that we are healthcare staff. They immediately put on their masks. They suppose that we spread the virus all over. The last patients admitted to our unit are very critical. When the patients are diagnosed with COVID-19, they start asking questions as to what will happen to them, in anxiety. The other Patients in the hospital have very negative approach to COVID positive patients. When we have our overalls, patients run away from us. (Participant 2).</p> <p>- Sometimes it feels like we run around in circles, we waste time. We fall into despair. We're struggling here. But everyone is very comfortable outside. Uncertainty is also very exhausting (Participant 4).</p> <p>- There is an uncertainty, when will it end and what will happen? We do not know what will be our end. We are right in the middle of this outbreak in person. That's why we're afraid (Participant 5).</p>
	Stress and uncertainty infecting beloved ones and others	<p>- I'm very worried about getting and transmitting COVID-19. I am doing my job. I may get the virus, but I have no right to infect my child and husband. I feel guilty about this (Participant 8).</p> <p>- I was never afraid of having COVID-19. But I was worried about infecting my friends. Beyond that, I wasn't concerned (Participant 9).</p> <p>- What I am mostly worried about is spreading the virus, infecting others (Participant 13).</p>
Professional Satisfaction	Motivation of being a nurse	<p>- They used to consider us as auxiliary health personnel. Now they consider us at a higher status. The COVID-19 pandemic changed the way people see the nurses. Even the way they talk to us changed. They realised that we are an important part of the health sector. They show more respect to us. They look into our eyes with hope (Participant 6).</p> <p>- Nursing is very valuable, I believe there is conscience in those who perform this profession. In other countries, many nurses left the profession. But in our country, nurses work very conscientiously and nobody quit their job (Participant 3).</p>
	Care for patients with Covid-19 and interaction with them	<p>- Some patients are brought to the hospital hurriedly when their test is detected positive. We try to meet their needs in the hospital. It's like a prison for the patients to be here. We are doing our best. We try to give some psychological support. Sometimes families refuse meeting with their patients, sometimes patients don't want to see their families. During this period, nurses and patients begin communicating more than ever. Patients' gratitude and appreciation motivate us, no matter how tired we are (Participant 3).</p> <p>- There are some patients coming from the peripheral villages. Sometimes they don't even have slippers. We meet all kinds of needs for them. Sometimes patients' relatives do not want to stay with them and run away. We work for these patients in close contact while everyone run away from them and we are happy about it. Patients also remark that they are very satisfied with us (Participant 13).</p>
	Team harmony and positive energy	<p>- I think the nurses are getting stronger. Health professionals increased in value in the eyes of the people. Self-confidence increased in nurses. We are more appreciated today. Nurses started reading much more research. Our qualifications increased, we improve, we learn up-to-date new information. Our cooperation increased as well, we care about each other more. Discrimination between doctors and nurses disappeared and this union developed much more today. It was a very positive result indeed. We see more value from the institution, this makes us feel very comfortable. We started acting in unity and integrity. We have a health minister who is concerned about our problems. I am very happy with the current situation. We did not have any big trouble, even our manager himself worked just as we did. (Participant 3).</p>

Needs	Need for auxiliary staff	<ul style="list-style-type: none"> - We take care of all the personal problems of the patients individually. We provide everything including water and food. We provide their communication with families and even external contacts. We try to reach their relatives whenever they need. While working at this pace, it becomes very difficult to keep up with other patients. It takes a lot of our time to put on and take off overalls (Participant 9). - There should also be a staff for daily care of the patients. Nursing care is different, but we need additional staff to meet self-care needs. For example, there are patients with no relatives or no companion. I think it is necessary to allocate separate staff for such patients. Because we are not working in ordinary times. A separate staff member is required for personal care of the patients. They constantly need this or that. We need to order these, and it takes time (Participant 5).
	Need for additional nurses	<ul style="list-style-type: none"> - Working hours should rather decrease. More nurses are needed. 24 hours long working is very heavy and exhausting (Participant 2). - We have shifts very often. We are very few nurses. The number of nurses should be increased. 24 hours working is very tiring. Night-time hospitalizations are common because test results are announced at night, (Participant 5).
	Need for psychological support	<ul style="list-style-type: none"> - We are worried about what would happen to us. The patients are affected very negatively when they see the patients who can't breathe and die on social media, television and internet. If we were not involved in this business, if we were an outside person, we would feel the same. Psychological support is a large part of the treatment. Nurses need psychological support as well. Married health personnel, particularly those with children are also affected in this period very negatively. They manage both hospital and the house. They support both the patients and their households. That's why we have experienced too much burnout (Participant 6).
Occupational Health and Safety	Difficulties and pressures related to personal protective equipment	<ul style="list-style-type: none"> - After removing the mask, problems such as sore throat and pharyngitis occur. Our breath come back somehow. The mask irritates my throat. (Participant 1). - We can't work comfortably. Goggles and face shields create a lot of difficulty for us. Clothes are very stifling, we sweat a lot. It is very troublesome to put on and remove those overalls, there is a risk to contaminate ourselves with the secretions smeared on us while taking them off. Its psychological aspect is even worse (Participant 5). - We feel tiredness and sleepiness because we wear masks the whole day. Recently, the number of patients with respiratory distress increased and patients became more critical. The risk of contact is higher. People are very unconscious, they don't believe and don't wear masks. In this period, nurses work with more devotion. Except for 2 departments in the hospital, everywhere is reserved for positive cases and all the patients are referred from the emergency room, which increases our workload (Participant 8).
	Thermal comfort issues	<ul style="list-style-type: none"> - When we wear our overalls, we almost get soaked completely. There is a hanger here and we dry the overalls on the hanger. When we come to the room, we catch colds, since all the windows are open (Participant 6). - Because I love working, the COVID-19 pandemic did not affect me adversely, except for wearing overalls, working in it, sweating and smelling sweat all day long (Participant 9).
	Nutritional problems	<ul style="list-style-type: none"> - The most important problem for us and for the patients is the meals. They are insufficient and tasteless and the dishes are not compatible with each other. There are complaints from both the patients and the employees. In addition, we suggest to give patients snacks such as fruit, yogurt, etc. I think the meals provided are not nutritionally adequate as well. Patients cannot afford buying everything from the canteen. Patients have trouble with canteen, because it is expensive and you can't find everything. A solution can be found in this respect, by the institution (Participant 9). - We are having trouble with meals. It is an outsourced catering service and we are not happy with that. They are not good in quality and quantity (Participant 12). - Snacks should be added by the institution and fruit should be given as snacks. Volunteer support lines need to be established. There might be volunteers ready to bring along some food for the patients (Participant 14)
	Occupational accidents	<ul style="list-style-type: none"> - Sometimes those masks and overalls make me nervous. Overalls make me sweat a lot, I can't breathe. Since the face shield becomes foggy, I have difficulty in seeing what I am doing while providing care for the patients. For this reason I'm afraid of making mistakes (Participant 2). - Overalls and face shield induce panic attack. The face shield becomes misted, so it is difficult to implement a vascular access (Participant 12).
	Relationship between Covid-19 and occupational disease	<ul style="list-style-type: none"> - My hand was pierced by a needle contaminated with a COVID positive patient. So I was very much concerned. I had a test. Now it is 7 days. It was recorded as a work accident. Even if there is no infection, there is a risk. In the classification of occupational diseases, there is a section called contagious occupational diseases. COVID-19 is not included in this section. I think COVID-19 should be considered as an occupational disease. This would increase our work standards (Participant 2).

Theme 1: Effects of the Pandemic

This study revealed that nurses providing care to COVID-19 patients were adversely affected, both psychologically and socially, in Turkey. The nurses reported that ever-changing working conditions and different routines during the pandemic were extremely difficult.

Theme 2: Fears and Worries

The nurses stated that their stress levels increased as the course of COVID-19 pandemic conditions prevailed and uncertainty increased. Most of them remarked that they were under psychological pressure, and suffered fear and anxiety. They felt depressed and anxious as they faced death and other painful scenes.

Theme 3: Professional Satisfaction

Despite tough conditions and various difficulties, most of the nurses reported that they were happy in coping with the disease. First of all, they indicated that they felt the patients' goodwill, respect, cooperation and gratitude. Secondly, the support given by the family and by the colleagues made them happy. On top of these, institutional support and motivation in the hospital made the nurses feel esteemed.

Theme 4: Needs

The nurses stated that they needed supplementary personnel and nurses and psychological support while providing care to COVID-19 patients.

Theme 5: Occupational Health and Safety

Using personal protective equipment (PPE) while working with COVID-19 patients has a protecting effect for the nurses and a limiting effect on infection. However, long time use of PPE caused skin problems, lack of thermal comfort and work accidents. Loss of excessive fluid out of the body due to sweating while in PPE and inadequate intake would cause serious health problems. The nurses also reported that PPE would cause work accidents while treating patients. They pointed out that the COVID-19 disease should be recognized as an occupational disease by the regulations. In addition, they reported that refectory meals were insufficient and with little nutritional value. They claimed that bad hospital meals made it even more difficult for the patients to eat, as they already had no appetite due to COVID-19.

DISCUSSION

In this study, experiences of the nurses providing medical care to COVID-19 patients were examined using phenomenological methods and the findings were summarized in 5 themes: effects of the pandemic, fears and worries, professional satisfaction, needs, occupational health and safety.

Within the framework of the first theme of this study, these nurses perceived the effects of the pandemic, not only psychologically and socially but also in terms of working conditions. It was observed in other parts of the world too, that nurses experience similar fear, anxiety, stress and psychological pressure during outbreaks (7,18). The results of this study are similar. This can be attributed to insufficient knowledge about the pandemic, inadequate preventive measures, and lack of satisfactory community support to nurses.

Fears and worries of nurses constitute the second theme of the study. It was shown that psychological support provided by professional organizations, family, and social environment can relieve their anxiety and stress (19,20). However, in this study, it was observed that nurses could not have adequate social support and they were in stress due to the risk of infecting their families. Uncertainties regarding the course of the disease also caused despair and stress. It was also shown in other studies that, nurses felt hopeless and stressful due to the very same factor (21,22). Due to its specific nature, nursing is a highly stressful profession. Nurses confront severe pain, grief, and death every day, as very few people do.

The third theme of the research is professional satisfaction. Nurses were satisfied with their jobs and remained motivated, despite the burden of a heavy workload and the risk of disease transmission. Nurses fighting against the COVID-19 pandemic were considered as heroes, which caused higher level of job satisfaction and less psychosocial problems (20). These findings are consistent with the results of our study. The initial fears and worries experienced by our nurses working with COVID-19 patients disappeared over time, and their close interactions with patients induced positive emotions in patients (7). This was considered to improve the recovery of patients. Because, positive interactions between nurses and patients was shown to be important in boosting patients' morale and improving patients' satisfaction with healthcare service, coping with disease, compliance with treatment and motivation for recovery (23).

The fourth theme of this study is the needs. Number of nurses in hospitals has been always short of the required number. However, reinforcing pandemic services with extra healthcare and auxiliary personnel is highly important in this pandemic process. Such assistance and support teams were established for nursing management worldwide (24). Again, working hour changes and frequent shifts increased their workload even more. Similar results were obtained also in other studies (25). Additional healthcare staff should be employed in order to reduce the pressure and workload on healthcare personnel and the needs should be provided as soon as possible and at the best conditions (21).

Psychological support is another issue that nurses need most and is disregarded. Regular psychological support must be offered to healthcare staff during the pandemic process (25). As the fight against pandemic continued, it was extremely important to improve and strengthen the mental state of healthcare workers in terms of protecting the health of the patients as well as the healthcare workers. Healthcare professionals could receive online psychological support in this period, if they needed (21). Other duty attempts were also suggested in order to protect the mental health of the nurses. It is even easier to get access to these services in case they are provided through channels such as tv or social media. It was determined that institutional support as well as family and social support helped nurses in reducing stress levels (19).

Occupational health and safety is the last theme of the study. Hospitals are very hazardous places to work (26). Almost all risk factors can be found in hospitals. Nurses were always face to face with these factors, also in pre-pandemic times, but now during the pandemic, they were directly threatened by them. Nurses constitute the largest group among healthcare professionals and they provide direct care to patients diagnosed with COVID-19 at a distance of less than 1 meter. For this reason, it is important for the nurses to know standard, droplet and contact isolation precautions and to use personal protective equipment (PPE) in order to protect themselves and other members of the healthcare team and to provide care safely (27).

Changes in PPE use in particular, and increased use of PPE caused stress and difficulties in care. Working with overalls and other protective equipment for a long time causes excessive sweating in the staff, leading to great discomfort and excessive fluid loss as well as skin reactions requiring medical treatment (28). In addition, prolonged and possibly inadequate use of PPE made them worried about its safety in terms of disease transmission risks (29). The nurses participated in the study had sufficient knowledge about the use of PPE and had updated trainings, reviewed new brochures, and followed the instructions regularly. Our data were in line with the data of the studies measuring the knowledge of nurses on PPE use (30,31). Increasing the number of employees and rest breaks, and eventually minimizing the duration of PPE use, will definitely reduce these problems (30). Although nurses suffered from PPE deficiency in the early stages of the pandemic, they stated that this problem was resolved in a very short time.

Regular donning and doffing PPE causes also physical fatigue and stress (32). However, proper use of PPE is obligatory even for routine procedures (33). It was also reported that skin problems occur due to wearing overalls and medical treatment is required (28). Wearing a full-body PPE also causes the staff not to meet their physical needs during this period. Nurses' complaints including fatigue, weakness, dizziness, etc., may be due to fluid-electrolyte imbalance as a result of excessive fluid loss and failure in its replacement. Inadequate or poor quality PPEs, and fluid loss were shown to cause dermatoses all over the body, particularly on the lips, nose, around the eyes and hands (34,35). It is recommended that, nurses should be provided appropriate and high quality PPEs, a healthy and balanced daily diet, sufficient amounts of fluid, and frequent breaks during shifts (33).

Occupational accident is another sub-theme of occupational health and safety. Nurses generally hold PPE responsible as the main reason for the work accidents they had. They stated that they experienced accidents especially because PPE was not convenient for working comfortably, face shield was preventing vision due to fogging up and equipment was even creating situations like panic attack. Needlestick injuries are recognized as the major occupational accident in the health sector. Likewise, injury by contaminated sharp material or contact with contaminated material also creates a significant occupational hazard for the staff (36). Increased use of PPE during the pandemic period resulted in high probability occupational accidents for nurses.

Legal recognition of COVID-19 as an occupational disease is another important theme concerning all healthcare professionals and mentioned by the nurses in this study. A guide was published for recognizing COVID-19 as an occupational disease, why and how this could be implemented. In this guide, very high-risk professions were determined and nurses were included in the high-risk group (37). Moreover, it was emphasized in the guide that COVID-19 should be an occupational disease and the healthcare staff who died because of that should be considered as occupational martyrs (38). In the diagnosis of occupational disease, it is important to diagnose the disease correctly and prove that the disease is caught at the workplace (39).

Impact of the Research

This study was produced a deep understanding regarding the experiences of the nurses providing care for COVID-19

patients. Besides, it was emphasized in this study, we found that positive emotions co-exist together with negative emotions during the pandemic, on the basis of professional satisfaction. It is also realized that burnout can occur due to the increased workload on nurses during the pandemic period and well-known difficulties of working with protective equipment. Therefore, significant interventions should be planned to reduce the risks of burnout and help nurses deal with their problems effectively. This study is considered to contribute to the psychological intervention plans, to be applied for the psychological effects of the COVID-19 pandemic.

Limitations

The present study also had certain limitations. First, because of the nature of epidemic prevention and control, we couldn't hold focus group discussions and collect data from multiple centers in order to avoid cross-infection. Secondly, this is a short-term study. We did not have the opportunity to follow the changes in the nurses' experiences longitudinally.

CONCLUSION

This study used a phenomenological approach, and provided a comprehensive and thorough understanding of the experiences of nurses providing care for COVID-19 patients in Turkey. It revealed that nurses were adversely affected by the pandemic both psychologically and socially. Although the nurses participated in this study were mostly supported by the society, occasionally they also encountered stigmatizing attitudes.

DECLARATIONS

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Author Contributions

Designed the study: EI, SCÖ, DY. Collected data: EI, SCÖ, DY. Analyzed data: EI, SCÖ, DY. Supervised the analysis: EI, SCÖ, DY. Contributed to interpretation of findings: EI, SCÖ, DY. Drafted the paper: EI, SCÖ. Critical review providing important intellectual content: EI, SCÖ. All authors have approved the final version of the paper.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Determining Clinical Comfort, Worry and Status of Liking Children among Pediatric Nursing Students: Case of Two Different Universities

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ABSTRACT

Purpose: The aim of this study is to determine clinical comfort, worry and status of liking children among pediatric nursing students studying in universities located in east and west of Turkey.

Methods: The data of this descriptive and correlational study were collected in nursing faculties located in east (A University) and west (B University) provinces between April-May 2020. The sample of the study consisted of 211 students who participated in the online survey voluntarily between the specified dates. The data of the study were collected using "Sociodemographic Characteristics Form", "Clinical Comfort and Worry Assessment Tool of Pediatric Nursing Students" and "Barnett Liking of Children Scale (BLCS)".

Results: In the study, the comfort subscale mean score was higher in the nursing students studying in the University B and the difference was found to be statistically significant ($p < 0.05$). Although BLCS mean score was higher in the nursing students studying in the University A, the result was not statistically significant ($p > 0.05$). It was determined that there was a statistically positive moderate significant correlation between levels of liking children and the comfort subscale and a statistically negative moderate significant correlation between levels of liking children and the worry subscale in nursing students studying in the Universities A and B.

Conclusions: It was found that the liking of children status of the students studying in the Universities A and B was high. Students' levels of stress, anxiety and liking children in the pediatric clinic rotation should be determined.

Keywords: Child, nursing, pediatric.

Pediatric Hemşireliği Öğrencilerinin Klinik Rahatlık, Endişe ve Çocuk Sevme Durumlarının Belirlenmesi: İki Farklı Üniversite Örneği

ÖZET

Amaç: Araştırma, Türkiye'de doğu ve batı ilindeki bir üniversitede öğrenim gören pediatri hemşireliği öğrencilerinin klinik rahatlık, endişe ve çocuk sevme durumlarının belirlenmesini amaçlamaktadır.

Metot: Tanımlayıcı ve ilişkili arayıcı tipte olan araştırma verileri, doğu (A üniversitesi) ve batı (B üniversitesi) ilinde bulunan bir hemşirelik fakültesinde Nisan-Mayıs 2020 tarihleri arasında toplandı. Araştırmanın örneklemini belirtilen tarihlerde gönüllü olarak online ankete katılan 211 öğrenci oluşturdu. Araştırmanın verileri "Sosyodemografik Özellikler Formu", "Pediatric Hemşireliği Öğrencileri Klinik Rahatlık ve Endişe Değerlendirme Aracı" ve "Barnett Çocuk Sevme Ölçeği (BÇSÖ)" ile toplandı.

Bulgular: Araştırmada rahatlık alt boyutu puan ortalaması B üniversitesinde eğitim gören hemşirelik öğrencilerinde daha yüksek olup aradaki fark istatistiksel olarak anlamlı bulundu ($p < 0.05$). BÇSÖ puan ortalaması A üniversitesinde eğitim gören hemşirelik öğrencilerinde daha yüksek olmasına karşın sonuç istatistiksel olarak anlamlı değildi ($p > 0.05$). A ve B üniversitesinde eğitim gören hemşirelik öğrencilerinin çocuk sevme düzeyi ile klinik rahatlık alt boyutu arasında istatistiksel pozitif yönlü, çocuk sevme düzeyi ile ve endişe alt boyutu arasında istatistiksel negatif yönlü, orta derecede anlamlı ilişki saptandı. ($p < 0.05$).

Sonuç: Araştırmada A ve B üniversitesindeki öğrencilerin çocuk sevme durumlarının yüksek olduğu bulundu. Pediatric hemşireliği dersi uygulama rotasyonunda öğrencilerin stres, kaygı ve çocukları sevme düzeyleri belirlenmelidir.

Anahtar Kelimeler: Çocuk, hemşirelik, pediatri.

Nursing education is an educational process in which clinical practice and theoretical knowledge are carried out together and complement each other. The main purpose of nursing education is to bring students basic knowledge, skills, behaviors, and attitudes in professionally cognitive, affective, and psychomotor dimensions. As in all education programs of all disciplines based on practice, theoretical knowledge and clinical experience is very important for nursing. In this education system, students reflect the theoretical knowledge they received throughout their education life as a skill in the clinical field, he/she also experience new knowledge, skills, and communication experiences (1,2). Since nursing students spend a significant part of their education period in the clinical environment, clinical competencies and professional identities of future nurses are shaped in this environment (3). Some difficulties that may occur in this learning environment cause students to experience stress and anxiety or on the contrary to experience a very comfortable and very relax clinical experience in clinical sense (4).

Clinical practice successes of students are affected as a result of their positive or negative experiences in their clinical practices and their personal characteristics. These clinical practice successes are affected by factors such as anxiety, stress, concern, motivation, and self-efficacy levels (5). When the literature is examined, it was determined that nursing students mostly experience anxiety and stress in the clinical practice of Pediatric Nursing course within the scope of their education and concern while providing care (6-11). The studies have revealed that these anxieties of students in the pediatric clinics are caused by thoughts such as touching to a newborn baby, low doses of medication of children, harming the child, failure to communicate with the child and caregiver and thus inability to provide effective and suitable care, and inability to provide adequate psychosocial support (6,10). Clinical practice of this course can cause additional difficulties and stresses for students due to the difficulties of working with more than one family member and following changes in developmental needs. Education about health problems of children and their management are important outcomes of clinical experience in pediatric nursing (12). Because of all these reasons, it is seen that clinical nursing practices and especially pediatric nursing experiences can be stressful for students.

It is important that members of profession dealing with children primarily have a high level of liking children (13). Pediatric nursing is one of the most important nursing

fields established on child love, communication, and empathy (14). Since students work with child patients in pediatric clinics, they may feel positive emotions such as hope, love, trust, and happiness on the one hand and they may also feel negative emotions such as anger, fear, stress, and despair on the other hand (8). While these positive emotions increase the motivation and learning ability of the students, the negative emotions experienced decrease their willingness to learn and care. Students' levels of liking children decrease these negative attitudes significantly (7).

Courses about child in the school and clinical practices made in pediatric clinics affect and change the nursing students' levels of liking children (15,16). It has been found in many studies in the literature that the care applied by nursing students and nurses working in pediatric health care is associated with their levels of liking children and the pediatric nurses and student nurses' levels of liking children are affected by many factors. Some of these factors are seen to be the variables such as age, gender, marital status, number of siblings, status of having children, family structure, democratic family attitude, caregiving status, status of playing with child, and desire to work in pediatric clinics. Another important factor is internships in pediatric clinics (7,15,17).

Stress and anxiety experienced by students practicing in pediatric clinic affect their clinical performances and pose a clear threat to their success in clinical rotation. High anxiety level causes clinical skills not to be reflected on the patient and impairs the quality of care (6). On the contrary, it is believed that a student with good clinical comfort will better reflect all skills such as clinical skill, motivating and cooperating with the family, communicating with the child so that the quality of care will be enhanced. The aim of this study is to determine clinical comfort, worry and status of liking children among pediatric nursing students studying in universities located in east and west of Turkey.

Research Questions

- What is the level of clinical comfort and worry among Pediatric Nursing students in A and B university?
- What is the level of liking children among Pediatric Nursing students in A and B university?
- Is there a relationship between the clinical comfort, worry and status of liking children among Pediatric Nursing students A and B university?

MATERIALS AND METHODS

Setting and Sample

The data of this descriptive and correlational study were collected in nursing faculties located in east (A University) and west (B University) provinces between April-May 2020. The population of the study was composed of a total of 400 third-year students (250 students in A University; 150 students in B University) taking pediatric nursing course in the faculties where the study was conducted. Simple random sampling method was used in the study. The sample of the study consisted of 211 students (111 students in A University; 100 students in B University) who participated in the online survey voluntarily between the specified dates. As a result of the prior power analysis performed by using the G.Power 3.1.9.2 program, when 210 students were included in the study, it was determined that its size effect was 0.5, power was 95% and α type error estimation was 0.05. By predicting that there would be losses, 215 students were included in the study and the study was completed with 211 students. This number pointed out that the sample size was adequate (18).

Measurement

The data of the study were collected using "Sociodemographic Characteristics Form", "Clinical Comfort and Worry Assessment Tool of Pediatric Nursing Students" and "Barnett Liking of Children Scale".

Sociodemographic Characteristics Form

The information form prepared by the researcher in line with the relevant literature (7,8,11,15) involves questions about the students' age, gender, high school they graduated from, the place they have mostly resided in, family type, number of siblings, parents' education level, parent's working status, income status, liking of pediatric clinics, and status of having anxiety and stress in pediatric clinics.

Clinical Comfort and Worry Assessment Tool of Pediatric Nursing Students

The measurement tool was developed by Al-Qaaydeh et al., in 2012 (6). It was adapted to Turkish by Arslan et al. in 2018 (4). It is composed of a total of 11 questions showing worry level (5 questions) and the comfort level (6 questions) during practice of the students in the pediatric clinic. It is a 4-Point Likert type scale including "I strongly agree", "I agree", "I disagree" and "I strongly disagree" options. The items 3 and 5 of the comfort subscale of the scale are reverse items. Instrument subscales are calculated by averaging individual items to determine an average comfort score and average worry score. Higher scores in the Comfort and Worry subscales indicate respectively

higher comfort and worry levels. The Cronbach's alpha reliability coefficient of the scale was found as .89 for worry subscale and .68 for comfort subscale (4). In this study, the Cronbach's alpha coefficient of the scale was found as .79 for worry subscale and .71 for comfort subscale.

Barnett Liking of Children Scale

It was developed by Barnett and Sinisi to measure people's attitude toward children (19). Turkish validity and reliability study of the scale was conducted by Duyan and Gelbal (20). The items in the scale prepared according to 7-point Likert system are scored as "1=I strongly disagree and 7=I strongly agree". Total score to be taken from the scale consisting of 14 items varies between 14-98 points. Higher total score indicates that the people love children more. The items 3, 6, 10, and 13 of the scale are reversely scored. 14-38 points taken from the scale are rated as low, 39-74 points are rated as moderate and 75-98 points are evaluated as high score of liking children. The Cronbach' Alpha reliability coefficient of the scale was found as .92 (20). In this study, the Cronbach's alpha coefficient of the scale was found as .94.

Data Collection

In order to collect the data, ethics committee approval and written permissions from the related institutions were obtained. The data collection tools were applied as volunteerism-based participation in an online survey between the days of data collection. The survey link was created via Google forms. The survey link created by the researcher was sent to the students electronically and the students were asked to fill out and share the survey link. It took approximately 10-15 minutes to complete it.

Data Analysis

The data were assessed in SPSS (Statistical Package For Social Sciences) 20.0 packaged software in the computer environment. Descriptive statistics and mean as well as Kurtosis and skewness coefficients for the determination of compliance of data to normal distribution were used to analyze the data. Independent samples t-test (in normal distributions) was used. Cronbach's alpha coefficient calculation and correlation analysis were carried out. Significance level was accepted as $p < 0.05$.

Ethical Considerations

Before starting the study, approval from Ethics Committee and then written permission from the related institutions were obtained. After the students included in the study were informed about the purpose and the application method of the study, their verbal and written consents were obtained. Ethical principles were provided in the study.

RESULTS

It was determined that 82% of the nursing students studying in University A were female, 83.8% were in the age range of 21-23 years, 71.2% graduated from Science/Anatolian High School, 51.4% were residing in city center, 82.9% had a nuclear family, 52.3% had 1-3 siblings, 81.1% had social security, 70.3% expressed their income status as "income is equal to expenses", 50.5% of their mothers were primary school graduates, 94.6% were unemployed, 48.7% of the fathers were primary school graduates and the professions of 29.7% were in civil servant/worker group, 81.1% liked the internship in pediatric clinics, 74.8% experienced anxiety and stress in these clinics, and 86.5% played games with children (Table 1).

It was also found that 80% of the nursing students studying in University B were female, 77% were in the age range of 21-23 years, 72% graduated from Science/Anatolian High School, 59% were residing in the city center, 82% had a nuclear family, 58% had 4 or more siblings, 87% had social security, 68% expressed their income level as "income is equal to expenses", 55% of mothers had primary school degree and 91% were unemployed, 47% of the fathers were secondary school graduates and 39% were in the self-employment group, 72% liked the internship in the pediatric clinics, 84% experienced anxiety and stress in the pediatric clinics, and 76% played games with children (Table 1).

Table 1. Distribution of Students According to Sociodemographic Characteristics (n=211)

Sociodemographic Characteristics		Total		A uni.		B uni.	
		n	%	n	%	n	%
Gender	Female	171	81	91	82	80	80
	Male	40	19	20	18	20	20
Age	18-20	29	13.7	16	14.4	13	13
	21-23	170	80.6	93	83.8	77	77
	24 and over	12	5.7	2	1.8	10	10
School graduation	General High School	38	18	15	13.5	23	23
	Science/Anatolian High School	151	71.6	79	71.2	72	72
	Vocational High School	11	5.2	9	8.1	2	2
	Private High School	11	5.2	8	7.2	3	3
Living place	City	116	55	57	51.4	59	59
	Country	57	27	34	30.6	23	23
	Village	38	18	20	18.0	18	18
Family type	Nuclear	174	82.5	92	82.9	82	82
	Extended	37	17.5	19	17.1	18	18
Number of siblings	0	7	3.3	1	0.9	6	6
	1-3	94	44.6	58	52.3	36	36
	4 and over	110	52.1	52	46.8	58	58
Social security status	Available	177	83.9	90	81.1	87	87
	No	34	16.1	21	18.9	13	13
Income level	Less than expenditure	47	22.3	22	19.8	25	25
	Equal income and expenditure	146	69.2	78	70.3	68	68
	More than expenditure	18	8.5	11	9.9	7	7
Mother's educational background	Illiterate	49	23.2	33	29.7	16	16
	Primary school	111	52.6	56	50.5	55	55
	Secondary school	51	24.2	22	19.8	29	29
Father's educational background	Illiterate	11	5.2	9	8.1	2	2
	Primary school	94	44.6	54	48.7	40	40
	Secondary school	76	36	29	26.1	47	47
	Faculty	30	14.2	19	17.1	11	11
Mother's employment status	Unemployed	196	92.9	105	94.6	91	91
	Employed	15	7.1	6	5.4	9	9
Father's occupation	Unemployed	29	13.7	21	19.0	8	8
	Civil servant/worker	63	29.9	33	29.7	30	30
	Self-employment	69	32.7	30	27.0	39	39
	Retired	50	23.7	27	24.3	23	23
Liking the internship in children's clinics	Yes	162	76.8	90	81.1	72	72
	No	49	23.2	21	18.9	28	28
Anxiety and stress in pediatric clinics	Yes	167	79.1	83	74.8	84	84
	No	44	20.9	28	25.2	16	16
Playing with the child	Yes	172	81.5	96	86.5	76	76
	No	39	18.5	15	13.5	24	24

In the study, the comfort subscale mean score was higher in the nursing students studying in the University B and the difference was found to be statistically significant ($p < 0.05$). Although BLCS mean score was higher in the nursing students studying in the University A, the result was not statistically significant ($p > 0.05$, Table 2).

Clinical Comfort and Worry Assessment Tool of Pediatric Nursing Students	A uni. Mean±SD	B uni. Mean±SD	t*	p**
Comfort	14.47±2.59	15.44±2.42	-2.773	0.006
Worry	11.77±2.59	11.40±2.95	0.982	0.327
Total	26.25±2.56	26.84±3.00	-1.535	0.126
Barnett Liking of Children Scale	80.13±15.00	77.54±17.50	1.150	0.252

*Independent samples t-test
** $p < 0.05$

It was determined that there was a statistically positive moderate significant correlation between levels of liking children and the comfort subscale and a statistically negative moderate significant correlation between levels of liking children and the worry subscale in nursing students studying in the Universities A and B ($p < 0.05$, Table 3).

A Uni.		Comfort	Worry
BLCS	r	0.521	-0.496
	p*	0.020	0.039
	n	111	111
B Uni.		Comfort	Worry
BLCS	r	0.423	-0.425
	p*	0.025	0.025
	n	100	100

* $p < 0.05$

DISCUSSION

Students taking the Pediatric Nursing course may experience stress and anxiety when they first encounter sick children in clinical rotations. The stress and anxiety experienced by the students during the rotation of pediatric clinic may prevent their learning and decrease their clinical performances. Therefore, it is very important to understand the main reasons of the anxiety and stresses of the students and manage them (11).

In the present study, it was found that the nursing students studying in the Universities A (74.8%) and B (84%) expressed that they experienced high levels of anxiety and stress in pediatric clinics. In the study conducted by Lassche et al., in 2013, it was found that nursing students experienced high anxiety and low comfort in internship in the pediatric clinic at the beginning of the semester (10). The similarity between our study and Lassche et al., is that nursing students stated that they experienced high levels of anxiety and stress during their pediatric clinic internship at the beginning of the semester. This may be caused by the factors like students' encounter sick children for the first time, their insufficient knowledge about how to practice on these young age group they meet for the first time, and their inability to communicate with the children or their family.

It was determined in the present study that the comfort levels of nursing students studying in the Universities A and B were high and their anxiety levels were low. The comfort level of the nursing students studying in the University B was higher than those in the University A. In the study conducted by Mutlu et al., in 2020 with the title of "Investigating the correlation of the clinical comfort and anxiety state with self-efficacy perception in students taking the Pediatric Nursing course", they found similar results (11). In the study conducted by Çunkuş et al., in 2021 with the title of "The relationship between worry and comfort levels and communication skills of nursing students during pediatric clinic applications: a descriptive study", they found similar results (21). This similarity may be related to the sample groups of our and other studies.

One of the main characteristics of nurses working in the pediatric field is that they like children (14). In the present study, it was found that the liking of children levels of the nursing students studying in the universities A and B were high. In the other studies conducted with nursing students, the liking of children status was also found to be high (7,8,16,22-24). The results of the present study are similar to the study results in literature. In addition, it is a pleasing result that nursing students have a high level of liking children. These students are believed to have less anxiety and stress in case of working in pediatric clinics in their future professional lives, to be able to gain the family's confidence by involving them into the care, to communicate with the child comfortably, to be able to provide care with therapeutic games and thus keep the quality of care at high level required.

It was determined that there was a statistically positive moderate significant correlation between the liking of children level of the nursing students studying in the Universities A and B and the comfort subscale and a statistically negative moderate significant correlation between their level of liking children and the worry subscale. It can be asserted that nursing students liking children are more comfortable and less anxious in the pediatric clinic. This result can be thought to be associated with the education the students received, positive experiences, the sensitivity to raise children in the society and good communication between the students and their parents.

LIMITATIONS

The limitation of this research is that it was conducted among nursing students in two universities where the researchers work. The results cannot be generalized to all undergraduate nursing students in Turkey.

CONCLUSION

In the present study, it was found that the liking of children status of the students studying in the Universities A and B was high. The comfort level of nursing students studying at University B was higher compared to those studying in University A. There was a statistically positive moderate significant correlation between levels of liking children and the comfort subscale and a statistically negative moderate significant correlation between levels of liking children and the worry subscale in nursing students studying in the Universities A and B.

IMPLICATIONS FOR PEDIATRIC NURSING

Members of the profession who take care of the child should have a high level of child love. Students' levels of stress, anxiety and liking children in the pediatric clinic rotation should be determined to improve the quality of care. The causes of students experiencing stress and anxiety should be found and solutions should be found. Simulation training is recommended prior to clinical practice. Future research should be done using this tools to evaluate pediatric nursing students at different universities.

DECLARATIONS

Ethical Approval

This study received 06/04/2020 dated and 2020-3/2 numbered approval was taken from Erzurum Atatürk University Faculty of Nursing Ethical Board.

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Authorship Statement

All listed authors meet the authorship criteria and that all authors are in the agreement with the content of the manuscript.

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COVID-19 Contagion and Death Anxiety of Nurses Working in Pandemic Clinics

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ABSTRACT

Purpose: Today the coronavirus disease (COVID-19) which has affected the whole world, has maximized the anxiety level of nurses working in the forefront by increasing their possibility of getting sick or dying and increasing the number of cases and deaths in the world and in Turkey. This study aimed to examine COVID-19 contagion and death anxiety in nurses working in pandemic clinics that are in the western region of Turkey.

Method: The descriptive cross-sectional study was conducted with 278 nurses between May 15, 2020, and June 15, 2020. The study collected the data using the Nurse's Information Form and the Thorson-Powell Death Anxiety Scale. The study used the Independent Samples t-test, ANOVA and the Tukey tests in the post-hoc test to determine the intergroup differences.

Results: The mean age of the nurses was 36.30±8.01 years and 80.6% of them were female, 70.2% had bachelor's degree, 69.2% were married. Of the nurses, 60.4% had changed their environment in the process, 75.5% needed psychological support and 53.3% experienced loss due to COVID-19. The mean score of Thorson-Powell Death Anxiety Scale was 51.17±8.18.

Conclusion: This study revealed that the nurses had a moderate death anxiety level. Factors such as fear of transmitting the disease to their family and losing them, long working hours, working in the intensive care unit and emergency service for a long time and the inability to receive psychological support had an effect on the death anxiety of the nurses.

Keywords: Death anxiety, nurse, COVID-19, pandemic

Pandemi Kliniklerinde Çalışan Hemşirelerin COVID-19 Bulaşma ve Ölüm Kaygısı

ÖZET

Giriş ve Amaç: Günümüzde tüm dünyayı etkisi altına alan koronavirus hastalığı (COVID-19) Türkiye'de ve dünyada vaka ve ölüm sayılarının artmasına, ön saflarda çalışan hemşirelerin de hasta olma veya ölmeye ihtimalini artırarak kaygı düzeylerinin en üst seviyede yaşamalarına neden olmuştur. Bu çalışma, Türkiye'nin batı bölgesinde pandemi kliniklerinde çalışan hemşirelerin Kovid-19 bulaşma ve ölüm kaygısının incelenmesi amacıyla yapıldı.

Yöntem ve Gereçler: Tanımlayıcı ve kesitsel tipteki araştırma 15 Mayıs-15 Haziran 2020 tarihleri arasında 278 hemşire ile yapıldı. Araştırmanın verileri "Hemşire Bilgi Formu", "Thorson-Powell Ölüm Kaygısı Ölçeği" (TPÖKÖ) kullanılarak toplandı. Verilerin değerlendirilmesinde Independent-Samples t-testi, varyans analizi testleri, gruplar arasındaki farklılıkların belirlenmesinde ise Post-Hoc testinde Tukey testleri uygulandı. Testlerde anlamlılık düzeyi p<0.05 olarak kabul edildi.

Bulgular: Hemşirelerin yaş ortalaması 36,30±8,01, %80,6'sı kadın, %70,2'si lisans mezunu, %69,2'si evlidir. Hemşirelerin %60,4'ünün bu süreçte yaşadıkları ortamı değiştirdikleri, %75,5'inin psikolojik yardım gereksinimlerinin olduğu, %53,3'ünün COVID 19 nedeniyle kayıp yaşadığı saptandı. Thorson-Powell Ölüm Kaygısı Ölçeği puan ortalaması 51,17±8,18 olarak bulunmuştur.

Sonuç: Bu çalışma hemşirelerin orta düzeyde ölüm kaygısı yaşadığını ortaya koymuştur. Hastalığı ailesine bulaştırma ve onları kaybetme korkusu, uzun çalışma saatleri, yoğun bakım ve acil serviste uzun süre çalışma ve psikolojik destek alamama gibi faktörlerin hemşirelerin ölüm kaygısını arttırdığı bulunmuştur.

Anahtar kelimeler: Ölüm kaygısı, hemşire, Kovid-19, pandemi

Every culture has different attitudes toward death. In addition, people's perception of death as a phenomenon and their anxiety regarding death are shaped by the general attitude of their culture (1,2). The perception of death is also formed as a result of individuals' personal experiences and develops depending on what they have seen concerning death, the age period they are in, and their religious and cultural values. Hence, everyone's perception of death is unique (3,4).

Nurses are among the healthcare professionals who encounter death most frequently (2,5). A person dying affects not only their family negatively, but also those nurses who have been maintaining the individual's care and treatment for a long period of time. This also causes nurses to experience mental issues (4,6). Kang et al. (2020) indicate that the negative feelings experienced by nurses who constantly work with hospice patients will eventually wear them out psychologically (7). Some studies have also stated that nurses caring for hospice patients think about the death of their relatives and their own death, and thus experience death anxiety (8–10).

The coronavirus disease (COVID-19) which has affected the whole world today is a serious infectious disease resulting in death for people of all ages and sexes (11–13). The World Health Organization (WHO) accepted that COVID-19, which spread across the world in a very short time, was an international health problem and declared it a pandemic on January 30, 2020 (14). The Occupational Safety and Health Administration (OSHA) identifies COVID-19 as a high-risk infectious disease because it spreads from person to person rapidly, and states that the highest at-risk group facing this infection is healthcare professionals (15). According to a report by the International Council of Nurses (ICN) dated 11 March 2021, more than 3000 nurses worldwide have died from the virus (16). Nurses are the healthcare professionals who work with patients the most frequently and for the longest periods of time. Nurses working in close contact with patients during the struggle with COVID-19 have provided nursing services in every unit and at every age group where the COVID-19 pandemic has been seen (17,18). Guan et al. (2020) stated that 3.5% of patients in China, and Lázaro-Pérez et al. stated that 10% of patients in Spain, were medical personnel (19,20). During the process nurses have maintained all necessary treatment and care of patients, especially in respiratory tract applications which require very close contact, such as intubation, aspiration, resuscitation and mouth care, despite having limited protective equipment (21,22). Nurses in Turkey have continued to

work not only in hospitals, but also in tasks such as case identification during the pandemic, infection control, following cases in home lockdown and contacts and society training (22). During the pandemic, most nurses have had to be separated from their family, children, parents and partners for months due to social isolation (22,23). In particular, the increase in the number of cases and deaths in Turkey and around the world increased the possibility that nurses would become sick and/or die and greatly increased their anxiety level. In addition, death anxiety in nurses brought significant consequences in terms of social life. The first of these consequences was that society excluded nurses, like most other healthcare professionals, because they were considered a group with a high risk of contamination. Another one is that nurses have faced problems such as long working hours, tiredness, burnout, depression and anxiety, as well as other personal, social and economic problems caused by the pandemic, and have required treatment for these (24).

In order for nurses to provide effective care and psychosocial support to hospice patients and their families, it is important that their levels of death anxiety be determined. This study aimed to examine COVID-19 contagion and death anxiety in nurses working in pandemic clinics that are in the western region of Turkey. The following research questions were proposed for this purpose:

- What is the death anxiety level of nurses during the COVID-19 pandemic?
- What are the factors affecting a death anxiety level of nurses?

METHODS

Sample

The study was a descriptive cross-sectional study. The universe of the study comprised 504 nurses working in two hospitals where COVID-19 cases were intense in the western region in Turkey between May 15, 2020, and June 15, 2020. Sampling was carried out using the power analysis method. The sample size was calculated at 5% margin of error and 95% confidence level (sample=266). The data forms were sent to the electronic mail addresses of all working nurses with permissions from relevant institutions. Of the nurses responding, 14 reported that they did not want to participate and 278 completed the forms and comprised the sample of the study.

Measurement Tools

The Nurse's Information Form: The information form includes questions regarding the socio-demographic and working conditions and their psychosocial state during the COVID-19 pandemic.

The Thorson-Powell Death Anxiety Scale (TPDAS):

The scale was developed by Thorson and Powell (1992) (25) and Turkish validity and reliability was conducted by Karaca and Yıldız (2001) (26). The 5-point Likert scale has scores from 0 to 4 ("strongly agree", "agree", "undecided", "disagree", "strongly disagree"). The lowest and highest possible scores obtainable from the scale are 0 and 100, respectively. When evaluating the scale, scores between 0-25 indicate a low death anxiety level, 26-50 indicate a mild death anxiety level, 51-75 indicate a moderate death anxiety level, and 76-100 indicate a high death anxiety level. The scale has four subscales (anxiety about losing physical and mental functions, anxiety about the next world, anxiety about decaying and spoiling, anxiety about experiencing pain and torment in the death process). An increase in the score for all these subscales is interpreted as an increase in death anxiety. The Cronbach's alpha value of the scale was 0.84 in the study by Thorson and Powell and 0.79 in the study by Karaca and Yıldız (25,26).

Statistical Analysis

The study evaluated the data using the SPSS 22.0 (IBM) package program. The study evaluated the descriptive data using number, percentage, mean and standard deviation. As a result of the Kolmogorov-Smirnov test the study found that the data was normally distributed. Therefore, in evaluating the data the study used the Independent Samples t-test, variance analysis and the Tukey tests in the post-hoc test to determine the intergroup differences. A significance level of $p < 0.05$ was accepted in the tests (27).

RESULTS

The mean age of the nurses was 36.30 ± 8.01 years, 80.6% of them were female, 70.2% had bachelor's degree. The other demographic characteristics of the nurses are demonstrated in Table 1.

Approximately 60.4% of the nurses had changed their environment during this process. Of the nurses, 75.5% needed psychological support during the pandemic, 28.1% had caught the COVID-19 infection, 72.7% had a family member who had caught COVID-19, and 53.3% had experienced a loss due to COVID-19. The COVID-19-related other information of the nurses are demonstrated in Table 2.

Table 1: Participants Demographic Characteristics (n=278)

	n	%
Age	36.03±8.01	
Gender		
Female	224	80.6
Male	54	19.4
Education		
Associate	39	14.0
Bachelors	196	70.5
Postgraduate	43	15.5
Marital status		
Married	194	69.8
Single	84	30.2
Having a child		
Yes	191	68.7
No	87	31.3
Years of service		
>5 years	51	18.3
6-10 years	76	27.3
<11 years	151	54.4
Working unit		
*COVID-19 clinics	177	63.7
Intensive care	68	24.5
Emergency	33	11.8
Working hours / Day		
8-16 hours	137	49.3
24 hours	141	50.7
Presence of chronic disease in the family		
Yes	249	89.6
No	29	10.4
*COVID-19: coronavirus disease 2019		

In the study the Cronbach's alpha coefficient of the TPDAS was 0.75. The mean total scale score was 51.17 ± 8.18 ; the anxiety about losing physical and mental functions subscale score was 14.91 ± 4.61 , the anxiety about the next world subscale score was 13.18 ± 3.20 , the anxiety about decaying and spoiling subscale score was 8.37 ± 2.67 , and the anxiety about having pain and torment in the death process subscale score was 13.69 ± 3.46 .

The comparison of demographic characteristics and COVID-19 related information of the nurses with TPDAS scores are demonstrated in Table 3.

Table 2. Data of Participants on the COVID Pandemic Process		
	n	%
Psychological support requirements		
Yes	210	75.5
No	68	24.5
Changing the environment during the pandemic process		
Yes (n=168)		
At your friend	12	4.3
In the town hall.	20	7.2
In the hospital guesthouse	33	11.9
In hotel	103	37.1
No	110	39.6
Contracting COVID-19		
No	200	75.9
Yes	78	28.1
COVID-19 positivity in family/relatives		
Yes	206	74.1
No	72	25.9
Death/loss due to COVID-19		
Yes	151	54.3
No	127	45.7
Effects of the pandemic process		
Fear of getting sick	89	30.8
I can't see their children	19	6.6
Stay away from family	50	17.3
Fear of contagion	103	35.6
People acting like they're contagious	28	9.7
Coping with loss *		
Cry	223	77.2
Praying	239	82.7
Sharing with those around you	208	72.0
Using medication	47	16.3
Natural acceptance	37	12.8
* More than one answer to this question has been accepted.		

DISCUSSION

Some studies have demonstrated that in a period of epidemics people have an increased sense of existential anxiety and think about their death more often (17,28). This study aimed to examine COVID-19 contagion and death anxiety in nurses working in pandemic clinics that are in the western region of Turkey. The fact that we conducted the study in pandemic hospitals in the western region of Turkey where cases spread rapidly, reveals the strengths

of the study, especially considering that the nurses who volunteered to participate did so despite the difficult working conditions in the first days of the pandemic.

The study evaluated death anxiety in nurses in the pandemic process using the TPDAS. The nurses had a moderate level of death anxiety (51.17 ± 8.18). The study conducted by Yiğit and Açıkgöz (2021) found that nurses had a high level of death anxiety. Kang et al. (2020) stressed that the psychosocial problems of healthcare professionals are greater than those of the general population and that these problems should not be ignored. Nurses' attitude toward death negatively affects their death anxiety and the quality of care they provide. According to Matsui et al. (2010) high death anxiety in nurses negatively affects their ability to offer quality care to patients and their attitude towards caregiving (29).

The ICN defines nurses as the largest occupational group that is at the forefront in dealing with epidemics. During this process nurses take on difficult tasks under extraordinary conditions to protect the life of patients and cure them (16). In our study, comparing the TPDAS and sub-dimension scores according to the gender of the nurses, the male nurses obtained higher scores in the anxiety about losing physical and mental functions sub-dimension scores, the anxiety about the next world sub-dimension scores and the anxiety about having pain and torment in the death process sub-dimension scores; however, the difference in scores was not statistically significant ($p > 0.05$). The study by Yiğit and Açıkgöz found a similar result (30). It can say that the result of the current study is associated with the fact that nurses working on the frontlines in the COVID-19 pandemic work under the same conditions without any discrimination by gender.

Our study found that the age of the nurses did not affect death anxiety. We can say that this result is associated with the rapid spread of the COVID-19 infection, its impact on people of all age groups and the despair felt by nurses in the face of the rapidly worsening condition of the patients they are caring for. The studies conducted by Galehdar et al. (24) and Peters et al. (31) on death anxiety found that younger nurses have a stronger death anxiety than nurses of a more advanced age and have greater difficulty coping with emotional issues.

Table 3. Comparison of Descriptive Characteristics of Nurses and Death Anxiety Scores

	n (%)	Fear of isolation and immobility	Fear of the finality of death	Fear of burial and decomposition	Fear of pain	Total score
Gender						
Female	224 (80.6)	14.86±4.37	13.16±3.15	8.38±2.61	13.62±3.32	50.04±8.58
Male	54 (19.4)	15.14±5.51	13.27±3.45	8.31±2.96	13.96±3.98	50.70±11.43
		t=-0.409 p=0.68	t=-2.311 p=0.81	t=0.181 p=0.85	t=-0.635 p=0.52	t=-0.473 p=0.63
Marital status						
Married	194 (69.8)	14.58±4.38	13.02±3.24	8.41±2.68	13.69±3.46	49.68±9.36
Single	84 (30.2)	15.67±5.03	13.55±3.10	8.27±2.67	13.79±3.45	51.30±8.71
		t=-1.819 p=0.07	t=-1.276 p=0.20	t=0.410 p=0.68	t=-0.327 p=0.74	t=-1.360 p=0.17
Education						
Associate	39 (14.0)	16.15±4.85	12.64±3.10	8.15±2.28	13.43±3.29	50.38±8.86
Bachelors	196 (70.5)	14.66±4.61	13.20±3.15	8.37±2.74	13.70±3.48	49.95±9.02
Postgraduate	43 (15.5)	14.95±4.29	13.60±3.50	8.55±2.74	13.86±3.58	50.97±10.30
		F=1.70 p=0.18	F=0.933 p=0.39	F=0.232 p=0.79	F=0.159 p=0.85	F=0.229 p=0.79
Years of service						
>5 years	51 (18.3)	14.80±4.24	13.35±3.08	8.19±2.72	13.43±3.36	49.78±8.23
6-10 years	76 (27.3)	15.52±4.72	12.92±2.92	8.27±2.68	13.75±3.70	50.47±8.91
<11 years	151 (54.4)	14.64±4.67	13.26±3.38	8.48±2.67	13.75±3.38	50.15±9.66
		F=0.933 p=0.39	F=0.373 p=0.68	F=0.788 p=0.68	F=0.179 p=0.86	F=0.868 p=0.91
Working unit						
COVID clinic	177 (63.7)	14.84±4.40	13.27±3.22	8.40±2.70	13.54±3.34	48.75±7.50
Intensive care	68 (24.5)	13.94±4.19	12.85±2.81	8.45±2.55	13.50±3.38	50.07±9.15
Emergency	33 (11.8)	17.30±5.73	13.18±3.20	8.06±2.80	14.87±4.03	56.63±11.61
		F=6.18 p=0.0002	F=0.506 p=0.60	F=0.265 p=0.76	F=2.21 p=0.11	F=3.222 p=0.04
Working hours/Day						
8-16 hours	137 (49.3)	15.89±4.68	13.38±3.51	8.40±2.72	14.05±3.70	48.65±8.35
24 hours	141 (50.7)	13.97±4.35	12.99±2.86	8.34±2.64	13.34±3.17	51.72±9.75
		t=3.540 p=0.000	t=1.025 p=0.30	t=0.168 p=0.86	t=1.701 p=0.09	t=2.821 p=0.005
Presence of chronic disease in the family						
Yes	249 (89.6)	14.57±4.33	13.06±3.04	8.26±2.55	13.49±3.31	49.35±8.44
No	29 (10.4)	17.89±5.78	14.48±4.16	9.34±3.45	15.44±4.17	57.17±12.12
		t=-3.762 p=0.000	t=-2.318 p=0.02	t=-2.075 p=0.03	t=-2.923 p=0.004	t=-4.482 p=0.000
Need for psychological support						
Yes	210 (75.5)	14.61±4.42	13.08±3.00	8.12±2.51	13.48±3.27	49.30±8.43
No	68 (24.5)	15.85±5.06	13.50±3.76	9.13±3.06	14.35±3.91	52.83
		t=1.702 p=0.19	t=6.029 p=0.01	t=5.812 p=0.01	t=2.169 p=0.01	t=7.765 p=0.006
Contracting COVID-19						
No	200 (75.9)	14.57±4.33	13.06±3.04	8.26±2.55	13.49±3.31	49.35±8.44
Yes	78 (28.1)	17.89±5.78	14.48±4.16	9.34±3.45	15.44±4.17	57.17±12.12
		t=7.75 p=0.006	t=5.96 p=0.01	t=8.80 p=0.003	t=4.64 p=0.03	t=7.33 p=0.000

COVID-19 positivity in family/relatives						
Yes	206 (74.1)	14.50±4.38	13.16±2.96	8.25±2.57	13.56±3.35	49.49±8.49
No	72 (25.9)	16.09±5.06	13.23±3.84	8.72±2.93	14.06±3.75	52.12±10.82
		t=-2.547 p=0.01	t=-0.151 p=0.88	t=-1.283 p=0.20	t=-1.069 p=0.28	t=-2.108 p=0.003
Death/loss due to COVID-19						
Yes	151	13.95±3.88	13.09±2.79	8.19±2.42	13.18±3.29	48.43±7.93
No	127	16.06±5.13	13.29±3.64	8.59±2.95	14.29±3.56	52.24±10.13
		t=-3.895 p=0.000	t=-0.497 p=0.62	t=-1.237 p=0.21	t=0.276 p=0.007	t=-3.518 p=0.001
t= Independent Samples t-test; F= Variance analysis (ANOVA); p<0.05						

In our study there was no significant difference between the nurses' marital status, state of having children and death anxiety. However, the study by Yiğit and Açıkgöz in Turkey found that nurses who were married and had children had a high anxiety level and that single nurses considered their own marital status to be an advantage (30). Nevertheless, the study conducted by Ariapooran et al. found that single nurses experienced a high level of psychosocial problems (18).

In the current study there was no significant difference between the nurses' years of employment in the profession, educational level and death anxiety. We can say that the reason why the study found no significant difference between the nurses' professional experience, educational level and death anxiety was associated with the fact that all the nurses participating had encountered with COVID-19 for the first time, had limited information about the disease and worked under the same conditions. Galehdar et al. stated that as the professional experience of nurses increases, their anxiety level also increases, and this is related to having increased responsibility in the workplace (24). The study by Yiğit and Açıkgöz stated that nurses' educational level did not affect death anxiety; however, working in shifts and for long hours leads to more anxiety over a period of years (30).

The study found that 75.5% of the nurses needed psychological support and the nurses needing psychological support had a high level of death anxiety. In previous epidemics, such as the Severe Acute Respiratory Syndrome (SARS) in 2003 (32), the new influenza A/H1N1 (swine flu) in 2009 (33) and the Middle East Respiratory Syndrome (MERS) in 2012 (MERS) (17), it was reported that nurses working in the frontlines experienced anxieties concerning the risk of getting infected, transmitting the disease to family members, and the limitations imposed on

their personal freedoms. The ICN reported that a significant proportion of healthcare professionals carrying out their duties in past epidemics had symptoms of sleeplessness, anxiety, depression and posttraumatic stress disorder, and that some of them still had these symptoms three years later (16). Galehdar et al. reported in their study that nurses experienced intense stress due to the severe workload caused by separation from family, sleeplessness and lack of staff in the pandemic, and they needed psychological support (24). Kang et al. reported that nurses living with their family had a great fear of death (7). The current study found that the nurses were not able to receive the psychological support which could have reduced their anxiety during this process, and their coping methods were crying (77.2%), praying (82.7%) and self-medication (16.3%). Matsui et al. reported in their study that religion is a strong mediating factor and that "most nurses accept death as a natural part of life and a door opening to the next world" (29).

In the current study the nurses working in the emergency service and COVID-19 intensive care unit had higher death anxiety scores than the nurses working in other units. We can say that this result is associated with the higher risk of infection for nurses working in intensive care units, their close contact during interventions, especially intubation, mouth care and feeding, and an increase in the number of critical patients and deaths in intensive care units. In addition, the fact that intensive care nurses work continuously for 24 hours a day, are separated from their families, and the risks posed to their own lives and the lives of their relatives increases death anxiety. This anxiety may reduce the physical and mental strength that is necessary in the efforts to prevent the disease from spreading and to heal those who have caught the disease. Moreover, when nurses feel responsible, unsuccessful and inadequate because of the death of a patient whom they have cared for,

this will increase their anxiety. In their study, Ariapooran et al. found that nurses working in the intensive care unit and emergency service had a high level of anxiety (18). The results of the current study are in agreement with the literature. In particular, the emergency services, where the first contact is naturally made with the patient in the COVID-19 pandemic, are the most dangerous environments for those providing healthcare services (11). According to the data concerning the COVID-19 pandemic in Italy, Whiteside et al. found that the infection rate in healthcare professionals working in emergency services was approximately 10% (34). In the current study, among the reasons why nurses working in the emergency service had a high level of anxiety about catching the disease and dying, were the high population of patients applying to the emergency service, the inadequacy of personal protective equipment, working for longer than 24 hours in total and a lack of staff.

The current study found that the nurses who had a chronic illness in their family and who had experienced a loss in their family due to COVID-19 had a high level of death anxiety, which was noteworthy. Separation from family due to the pandemic, inability to intervene in the health problems of relatives, and the high risk of death in people with a chronic illness increase death anxiety in nurses. In addition, the fact that there was insufficient information about the disease at the beginning of the pandemic, and that most of the people who died were of advanced age and had a chronic illness, increased the nurses' anxiety. The study conducted by Hu et al. in China found that nurses who had lost their loved ones had a high level of anxiety (10). Fernandez et al. stated in their study that nurses had a high level of anxiety about themselves and their families (23). The study by Yiğit and Açıkgöz found no correlation between the presence of a chronic illness in relatives or loss of relatives and death anxiety (30).

Study Limitations

The most important limitations to the study were that the data was collected via the internet. At the time the data were collected, the number of cases in Turkey was quite high. Nurses were working more than 24 hours. They had limited time to look at and reply to their emails. These caused the study to be completed with a limited number of data. In addition, the study was conducted with nurses working in western region of Turkey and the study did not include all nurses.

CONCLUSION

This study revealed that the nurses had a high fear of catching the COVID-19 and a moderate death anxiety level. Factors such as fear of transmitting the disease to their family and losing them, long working hours, working in the intensive care unit and emergency service for a long time and the inability to receive psychological support had an effect on the death anxiety of the nurses. The presence of a chronic illness in the family and the loss of relatives also increased death anxiety. Our primary goals should be to protect the physical and mental health of nurses who work in environments where there is a high risk of transmission of the virus, and to enable them to work efficiently. We also recommend that hospital administrations support healthcare professionals as this may minimize their anxiety about their own health, the health of their families and their daily lives, and increase their productivity at work.

Ethical Considerations

Ethical approval was obtained from the Scientific Research Ethics Committee of the relevant university (decision no. KAEK/2020-12). The study was conducted in accordance with the principles of the Helsinki Declaration. The nurses were informed about the study with the text at the beginning of the questionnaire and those who agreed to participate in the study filled in the questionnaire.

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The Emotional Labor and Caring Behaviors of Nursing Students

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ABSTRACT

Purpose: While providing care, which is the nature of nursing, nurses exhibit different emotional labor behaviors. This study was conducted to determine the emotional labor behaviors and caring behaviors of nursing students and the correlation between them.

Methods: This study was conducted with cross-sectional correlational research design on 228 students who were studying in nursing department and were providing care to patients in the clinic. The data were collected using the Student Information Form, Emotional Labor Behavior Scale for Nurses, and Caring Behaviors Inventory.

Results: The mean age of the students was 20.78±1.72. While their emotional labor score was 4.07±0.57, their caring behaviors score was 5.08±0.68. Emotional labor and caring behaviors subscale and total score of the students who were female, preferred nursing since it is a healthcare profession, and were satisfied with their department were higher than the other groups. Emotional labor score of the third-year students and caring behaviors subscale and total score of the first-year students were higher than the other groups. In the study, a positive correlation was determined between emotional labor and caring behaviors total scores.

Conclusion: It was shown that emotional labor and caring behaviors scores of the students were higher than the average and the gender, the class, the reason for preferring the department, and satisfaction with the department were important indicators for emotional labor in care.

Keywords: Caring behavior, emotional labor, nursing care, nursing education, nursing students

Hemşirelik Öğrencilerinin Duygusal Emek ve Bakım Davranışları

ÖZET

Amaç: Hemşireliğin doğası olan bakımı verirken hemşireler farklı duygusal emek davranışları sergilemektedir. Bu araştırma, hemşirelik öğrencilerinin duygusal emek ve bakım davranışlarını ve aralarındaki ilişkiyi belirlemek amacıyla yapılmıştır.

Yöntem: Araştırma, hemşirelik bölümünde okuyan, klinikte hasta bakımı vermiş 228 öğrenciyle kesitsel ve ilişki arayıcı araştırma deseninde gerçekleştirilmiştir. Veriler, öğrenci bilgi formu, Hemşirelerin Duygusal Emek Davranışı Ölçeği ve Bakım Davranışları Ölçeği kullanılarak toplanmıştır.

Bulgular: Öğrencilerin yaş ortalaması 20.78±1.72'dir. Çalışmaya katılan öğrencilerin duygusal emek davranışı puan ortalaması 4.07±0.57, bakım davranışları puan ortalaması 5.08±0.68'dir. Kız öğrencilerin, sağlık hizmeti veren meslek olduğu için hemşireliği seçenlerin ve bölümünden memnun olanların duygusal emek davranışı ve bakım davranışları alt boyut ve toplam puan ortalaması diğer gruplara göre daha yüksektir. Üçüncü sınıfların duygusal emek davranışı, birinci sınıfların ise bakım davranışları alt boyut ve toplam puan ortalaması diğer gruplara göre daha yüksektir. Çalışmada duygusal emek davranışları ve bakım davranışları toplam puan ortalamaları arasında pozitif yönlü bir ilişki saptanmıştır.

Sonuç: Öğrencilerin duygusal emek ve bakım davranışları puanlarının ortalamasının üzerinde olduğu, cinsiyet, öğrenim görülen sınıf, bölümünü tercih etme sebebi ve bölümünden memnun olmanın bakımda duygusal emeğin önemli bir belirleyicisi olduğunu göstermiştir.

Anahtar kelimeler: Bakım davranışı, duygusal emek, hemşirelik bakımı, hemşirelik eğitimi, hemşirelik öğrencileri

In recent years, emotional labor behaviors have become an important concept in units which are human-centered and are based on face-to-face relationship and interaction such as educational institutions and health sector since interest in emotions has rapidly increased (1,2). Emotional labor is an effort made by the nurses who constantly communicate with the sick/healthy individuals to express their autonomous, superficial or deep feelings during patient interviews, provide the care they want, and make the sick/healthy individuals feel safe and comfortable (3). Nurses, who have an important role in rapidly changing and developing healthcare services, should closely follow both innovations in medical technology and social changes in order to provide appropriate care based on the needs of the society (4). Emotional labor has an important place both for nurses to provide their care as they wish and for the patient/healthy individuals to feel safe and comfortable. However, emotional labor is not well known and supported and its importance is ignored in the clinics (4). Emotional labor has always existed, but only in the last decade, this concept has been explored by nurses (5). In a study conducted with nurses, it was determined that emotional labor affected both nurses and patients and also it could affect the quality of care provided. Emotional labor is an important issue for optimal professional development in terms of both professional satisfaction and proper functioning of healthcare services (5). It is required to examine this concept in nurses as well as students during nursing education (5-7). Clinical practice is an experience filled with emotions and emotional labor especially for students (7,8). Therefore, it is important to introduce the concept of emotional labor in universities, make student nurses aware of their emotions and determine this situation for students to properly display their emotional labor behaviors in the future (7). In a study conducted with third- and fourth- year nursing students, it was determined that clinical learning was full of emotions and students were engaged in managing emotions, which was perceived as emotional labor. Some studies have been conducted on the emotional labor of the third- and fourth-year students (7), but students start to work in the clinic and provide patient care in the first and second year of the nursing education. There is no study examining the emotional labor of 1st - and 2nd -year undergraduate students.

It is expected for nursing students to internalize the meaning of care, the philosophy of nursing care, the results of the nursing care on the patients and how they can enhance the quality of nursing care. Therefore, it is important to determine how nursing students perceive the nursing

care they provide. However, the number of studies on how care is perceived by nursing students is limited in the literature (9-11). Examining the correlation between emotional labor and care has a high priority for nursing (5). There are a limited number of studies in the literature describing the concept of emotional labor and examining the correlation between emotional labor and care (4-6,10). In the literature, studies have been found that examine nurses' emotional labor behavior (9), students' emotional labor (6,7,10), students' caring behaviors (11), and nurses' caring behaviors (12). However, there is no study explaining the emotional labor and caring behaviors of nursing students in all classes of undergraduate studies.

This study was conducted to determine the emotional labor behaviors and caring behaviors of nursing students and the correlation between them.

Within the framework of this general purpose, answers to the following questions were sought. Research Questions:

- How are the emotional labor behaviors of the students? Do some characteristics of the students affect their emotional labor behaviors?
- How are students' caring behaviors? Do some characteristics of the students affect their caring behaviors?
- Is there any correlation between the emotional labor and caring behaviors? Do emotional labor behaviors affect caring behaviors?

MATERIALS AND METHODS

Purpose and Type of the Study

This cross-sectional and correlational study was conducted to determine the emotional labor and care behaviors of nursing students and to determine the relationship between them.

Population & Sample

The population was composed of all students in the nursing faculty. In the study, it was aimed to reach the population without making sample selection. The population included 257 nursing students (85 male students, 172 female students) studying in the 2017-2018 Academic Year. The inclusion criteria of the study were determined as follows; being a nursing student, providing patient care at the hospital (students go to the hospital for practical training and provide patient care after the second half of the first year of nursing education) and agreeing to

participate in the study. The exclusion criteria of the study were determined as follows; not agreeing to participate in the study, not attending school regularly and filling out the data collection tools incompletely. The sample of the study was composed of a total of 228 students including 57 male students and 171 female students. 88.71% of the students in the population were reached. A total of 29 students (1 female and 28 male), were not included in the study.

Location and Time of the Study

The study was conducted with nursing students in the Faculty of Health Sciences of a university in Turkey in the 2017-2018 Academic year.

Data Collection Technique and Tools

The data were collected by the researchers via the survey under observation. Within the scope of the data collection process, the researchers distributed the forms to the students in the classrooms by asking them to fill out the forms. The students were informed that they would be not obliged to write their name-surname on the forms in order to avoid them being affected by answering the questions and to refrain from sharing their opinions. Student Information Form, Scale of Emotional Labor Behavior for Nurses (ELBSN), and Caring Behaviors Inventory (CBI-24) were used in the study.

Student Information Form

The form, prepared by the researcher upon the literature review consists of six questions about socio-demographic characteristics of the students (age, gender, graduation school, educational level, the reason of preferring the department, the level of satisfaction with the department) (6,7,9,12).

Emotional Labor Behavior Scale for Nurses (ELBSN)

ELBSN, which was developed by Değirmenci in 2016 (13), measures the opinions and attitudes of the nurses about emotional labor behavior. This 5-item Likert scale has three subscales (superficial behavior, in-depth behavior, and sincere behavior) and 24 items. The items are scored between 1 and 5 and there is no reverse scoring on the scale. High score signifies high level of emotional labor (13).

Subscales of the scale;

- Superficial Behavior Subscale, Cronbach's alpha coefficient=0.926.

- In-Depth Behavior Subscale, Cronbach's alpha coefficient=0.976.
- Sincere Behavior Subscale, Cronbach's alpha coefficient=0.913.

In the present study, the Cronbach's alpha coefficient of ELBSN was 0.939.

Caring Behaviors Inventory (CBI-24)

Caring Behaviors Inventory was developed by Wu, Larrabee, & Putman, in 2006 (14), and its Turkish validity and reliability study was conducted by Kursun and Kanan (15). It is a 6-item Likert type scale with 4 subscales and 24 items and the items are rated as 1=never, 2=almost never, 3=sometimes, 4=generally, 5=often, 6=always. The CBI-24 was developed for the purpose of the evaluation of nursing care quality by patients and nurses. In this study, CBI-24 was used for nursing students' self-evaluation of the nursing care they provided.

Subscales of the scale;

- Assurance Subscale, Cronbach's alpha coefficient=0.954.
- Knowledge-Skill Subscale, Cronbach's alpha coefficient=0.898.
- Respectfulness Subscale, Cronbach's alpha coefficient=0.945.
- Connectedness Subscale, Cronbach's alpha coefficient=0.939.

In the present study, the Cronbach's alpha coefficient of CBI-24 was found to be 0.954.

Ethical Considerations

The study was carried out in accordance with the Declaration of Helsinki. In order to conduct the study, the approval (date and number of approval: 2017/33) was obtained from the Erciyes University's Social and Humanities Ethics Committee and a written institutional permission was received from the center where the study was conducted (date and number of approval: 2017/15386878-044). The participants were informed about the purpose of the study and their written informed consents were received. The participation of the students was based on "voluntariness" and they were informed about the study.

Data Analysis

The data were assessed by using IBM SPSS Statistics 22.0 statistics package program (IBM Corp, Armonk, NY). Normal distribution of the data was evaluated by using the Shapiro Wilk normality test, Q-Q plot, and histogram graphics. According to the Shapiro Wilk test, non-parametric tests be applied for comparisons of non-normally distributed data. Descriptive statistical methods (quantity, percentage, mean, median, standard deviation) as well as Kruskal-Wallis and Mann-Whitney U tests were used to evaluate the data. Spearman's correlation analysis was used to determine the correlation between variables. Multiple Linear Regression model was performed. The value of $p < 0.05$ was considered as statistically significant.

RESULTS

Characteristics of the Sample

The population of the study consists of 257 students. The study was completed with 228 students, upon reaching 88.71% of the population. It would be correct to examine the findings based on this information. A total of 29 students, (one female and 28 male), were not included in the study. Nursing students, who did not want to participate in the study (17 male students, 1 female student), did not complete the data collection forms (8 male students), and did not attend the lessons during the data collection process, were not included in the study (3 students). It was determined that the mean age of 228 students was 20.78 ± 1.72 , 75% were female students, 28.5% were third-year students and 47.4% preferred the department to have a job, and 48.2% were partly satisfied with their department (Table I). Table I shows emotional labor behavior scale and caring behavior inventory scores of the nursing students.

Tables I. Descriptive Characteristics of Students and Total Scores of Scales and Subgroups						
Descriptive Characteristics	n	%	(X± SS)	Min-Max	Median (Q1-Q3)	95%CI
Age ($\bar{X} \pm SD$)	-	-	20.78±1.72	18-30	20.57 (19.51-21.73)	20.54-21.01
Gender						
Female	171	75	-	-	-	-
Male	57	25	-	-	-	-
Class						
1st class	58	25.4	-	-	-	-
2nd class	55	24.1	-	-	-	-
3rd class	65	28.5	-	-	-	-
4th class	50	21.9	-	-	-	-
Reason for department preference						
A good income	26	11.4	-	-	-	-
Having a job	108	47.4	-	-	-	-
Patient care	7	3.1	-	-	-	-
Love to help people	62	27.2	-	-	-	-
Providing health care	25	11.0	-	-	-	-
Satisfaction from department						
Not satisfied	20	8.8	-	-	-	-
Partially satisfied	110	48.2	-	-	-	-
Satisfied	98	43	-	-	-	-
Scale and subscales						
Superficial Behavior	-	-	4.03±0.59	1.5-5.0	4.00 (3.70-4.50)	3.95-4.10
In-depth Behaviour	-	-	4.07±0.64	1.3-6.8	4.07 (3.76-4.46)	3.98-4.15
Sincere Behavior	-	-	4.11±0.66	1.0-5.0	4.00 (3.80-4.60)	4.02-4.19
ELBS (Total)	-	-	4.07±0.57	1.3-5.3	4.08 (3.79-4.44)	3.99-4.14
Assurance	-	-	5.14±0.70	2.9-6.0	5.25 (4.75-5.25)	5.05-5.23
Knowledge-Skill	-	-	5.12±0.71	3.0-6.0	5.20 (4.65-5.80)	5.02-5.21
Respectfulness	-	-	5.10±0.69	3.2-6.0	5.16 (4.66-5.66)	5.00-5.18
Connectedness	-	-	4.87±0.77	2.8-6.0	5.00 (4.40-5.40)	4.76-4.96
CBI-24 (Total)	-	-	5.08±0.68	3.1-8.5	5.12 (4.70-5.58)	4.99-5.17

Scale of Emotional Labor Behavior for Nurses

Emotional labor scores of the nursing students, who were female, third-year students, preferred the department to have a healthcare profession and were partially satisfied with the department, were found to be higher than the scores of the other groups. In-depth behavior scores of the nursing students, who were female, first-year students, preferred the department since it is a profession providing patient care, and were satisfied with their department, were higher than the scores of the other groups. Sincere behavior scores of those who were first-year students, were satisfied with their department and preferred the department since they love to help people, were higher than the scores of the other groups. Superficial behavior scores of those who were females, first and third-year students, were partially satisfied with their department, and preferred the department since it is a healthcare profession, were higher the scores of than the other groups ($p > 0.05$, Table II).

Caring Behaviors Inventory

It was determined that those who were female, first-year students, were satisfied with their department and preferred the department because it is a healthcare profession, obtained higher scores from the overall caring behaviors inventory and all of the its subscales compared to the other groups.

Total score of caring behaviors inventory and scores of assurance and respectfulness subscales were higher in the first-year students compared to the other groups. Third-year students had higher scores from the knowledge-skill and connectness subscales of the caring behaviors inventory (Table III).

Tables II. Emotional Labor Behavior Scale and Comparison of Characteristics of Students								
Descriptive Characteristics	Superficial Behavior Median (Q1-Q3)	Test value p	In-depth Behaviour Median (Q1-Q3)	Test value p	Sincere Behavior Median (Q1-Q3)	Test value p	ELBS Median (Q1-Q3)	Test value p
Gender								
Female	4.16 (3.66-4.33)	Z=-0.064	4.07 (3.66-4.33)	Z=-1.002	4.00 (3.80-4.60)	Z=-1.382	4.08 (3.79-4.45)	Z=-0.775
Male	4.00(3.75-4.50)	p=0.949	4.00 (3.65-4.42)	p=0.316	4.00 (3.60-4.40)	p=0.167	4.04 (3.76-4.31)	p=0.438
Class								
1st class	4.16 (3.79-4.50)	$\chi^2=7.650$ p=0.054	4.23 (3.84-4.63)	$\chi^2=5.467$ p=0.141	4.20 (3.80-4.60)	$\chi^2=1.322$ p=0.724	4.25 (3.79-4.59)	$\chi^2=4.408$ p=0.221
2nd class	4.00 (3.66-4.33)		4.00 (3.61-4.38)		4.00 (3.60-4.40)		4.00 (3.70-4.29)	
3rd class	4.16 (3.83-4.50)		4.07 (3.76-4.42)		4.00 (4.00-4.60)		4.00 (3.83-4.47)	
4th class	3.91 (3.50-4.33)		4.00 (3.69-4.48)		4.00 (3.80-4.60)		4.08 (3.73-4.30)	
Reason for department preference								
A good income	3.91 (3.62-4.33)	$\chi^2=4.483$ p=0.345	4.03 (3.59-4.86)	$\chi^2=5.071$ p=0.280	4.00 (3.35-5.00)	$\chi^2=3.076$ p=0.545	4.02 (3.61-4.66)	$\chi^2=3.719$ p=0.445
Having a job	4.08 (3.83-4.45)		4.00 (3.69-4.38)		4.00 (3.80-4.40)		4.00 (3.79-4.37)	
Patient care	3.83 (3.66-4.50)		4.15 (4.00-4.61)		4.00 (3.60-4.40)		4.00 (3.91-4.58)	
Love to help people	4.08 (3.79-4.50)		4.11 (3.84-4.53)		4.20 (3.80-4.60)		4.14 (3.79-4.43)	
Providing health care	4.33 (3.91-4.58)		4.15 (3.92-4.61)		4.40 (3.80-4.90)		4.29 (3.93-5.4.50)	
Satisfaction from department								
Not satisfied	3.91 (3.54-4.45)	$\chi^2=0.840$ p=0.657	4.00 (3.50-4.44)	$\chi^2=2.138$ p=0.343	4.10 (3.65-4.55)	$\chi^2=0.557$ p=0.757	4.04 (3.52-4.50)	$\chi^2=1.322$ p=0.516
Partially satisfied	4.08 (3.83-4.33)		4.00 (3.69-4.38)		4.00 (3.80-4.40)		4.00 (3.79-4.41)	
Satisfied	4.00 (3.66-4.50)		4.15 (3.84-4.53)		4.20 (3.80-4.70)		4.16 (3.79-4.54)	
* $p < 0.05$ ** $p < 0.01$								

Knowledge-skill subscale scores, were higher in female students compared to male students ($p= 0.047$). Caring behaviors inventory total score ($p= 0.012$) and assurance subscale ($p= 0.005$) and knowledge-skill subscale scores ($p= 0.001$) were higher in first-year students than the other groups. Caring behaviors inventory total score ($p= 0.004$) and assurance subscale score ($p= 0.004$) were higher in those preferring the department since it is a healthcare profession when compared to the other groups.

Respectfulness subscale score were higher in those who preferred the department since it is a healthcare profession and they loved to help people, when compared to the other groups ($p= 0.025$).

Caring behaviors inventory total score ($p= 0.001$) and scores of assurance subscale ($p=0.000$), respectfulness subscale ($p= 0.005$) and connectness subscale ($p= 0.011$) were higher students who were satisfied with the department when compared to the other groups. Knowledge-skill subscale scores were higher in those who were not satisfied with the department than the other groups ($p= 0.009$, Table III).

Tables III. Caring Behaviors Inventory and Comparison of Characteristics of Students										
Descriptive Characteristics	Assurance Median (Q1-Q3)	Test value <i>p</i>	Knowledge-Skill Median (Q1-Q3)	Test value <i>p</i>	Respectfulness Median (Q1-Q3)	Test value <i>p</i>	Connectness Median (Q1-Q3)	Test value <i>p</i>	CBI-24 Median (Q1-Q3)	Test value <i>p</i>
Gender										
Female	5.25 (4.75-5.75)	Z=-0.977 p=0.329	5.20 (4.80-5.80)	Z=-1.989 p=0.047	5.16 (4.66-5.66)	Z=-1.500 p=0.134	5.00 (4.40-5.40)	Z=-0.606 P=0.544	5.16 (4.70-5.62)	Z=-1.348 p=0.178
Male	5.12 (4.75-5.62)		5.00 (4.60-5.40)		5.00 (4.50-5.50)		4.80 (4.20-5.40)		5.04 (4.58-5.14)	
Class										
1st class	5.50 (5.00-5.78)	$\chi^2=12.673$ p=0.005	5.40 (4.80-5.80)	$\chi^2=17.121$ p=0.001	5.33 (4.83-5.66)	$\chi^2=4.752$ p=0.191	5.00 (4.35-5.40)	$\chi^2=6.098$ p=0.107	5.27 (4.75-5.63)	$\chi^2=10.883$ p=0.012
2nd class	5.00 (4.37-5.50)		5.00 (4.40-5.20)		5.00 (4.50-5.66)		4.80 (4.20-5.00)		5.00 (4.50-5.25)	
3rd class	5.25 (5.00-5.75)		5.20 (5.00-6.00)		5.16 (4.66-5.75)		5.00 (4.60-5.70)		5.16 (4.87-5.75)	
4th class	5.25 (4.59-5.75)		5.20 (4.60-5.65)		5.16 (4.29-5.66)		5.00 (4.20-5.45)		5.25 (4.53-5.63)	
Reason for department preference										
A good income	5.06 (4.50-5.50)	$\chi^2=15.660$ p=0.004	5.20 (4.50-5.80)	$\chi^2=7.985$ p=0.092	5.00 (4.33-5.66)	$\chi^2=11.182$ p=0.025	4.80 (3.95-5.20)	$\chi^2=18.539$ p=0.001	5.06 (4.37-5.41)	$\chi^2=15.626$ p=0.004
Having a job	5.06 (4.50-5.62)		5.00 (4.60-5.60)		5.00 (4.50-5.66)		4.80 (4.20-5.40)		5.00 (4.58-5.47)	
Patient care	4.50 (4.12-5.75)		5.00 (4.40-5.40)		4.66 (4.00-5.16)		4.40 (3.80-5.00)		4.66 (4.08-5.45)	
Love to help people	5.37 (5.00-5.75)		5.40 (5.00-5.80)		5.33 (4.95-5.83)		5.20 (4.80-5.60)		5.29 (4.98-5.66)	
Providing health care	5.50 (5.25-6.00)		5.40 (5.00-6.00)		5.33 (4.91-6.00)		5.20 (4.60-5.80)		5.41 (5.08-5.79)	
Satisfaction from department										
Not satisfied	5.25 (4.15-5.84)	$\chi^2=15.646$ p=0.000	5.50 (4.10-6.00)	$\chi^2=9.498$ p=0.009	5.16 (4.25-5.75)	$\chi^2=10.525$ p=0.005	4.60 (4.05-5.40)	$\chi^2=8.993$ p=0.011	5.00 (4.16-5.65)	$\chi^2=14.981$ p=0.001
Partially satisfied	5.00 (4.50-5.50)		5.00 (4.60-5.60)		5.00 (4.62-5.66)		4.80 (4.20-5.20)		5.00 (4.54-5.41)	
Satisfied	5.50 (5.00-5.81)		5.40 (5.00-5.80)		5.33 (4.91-5.83)		5.00 (4.60-5.60)		5.29 (4.97-5.72)	
* $p < 0.05$ ** $p < 0.01$										

Results of the Correlations Between Scale of Emotional Labor Behavior for Nurses and Caring Behaviors Inventory

In Spearman's correlation analysis, a positive moderate significant correlation was determined between ELBSN and CBI-24 total scores ($r = 0.544$, $p < 0.001$, Table IV).

In the regression analysis, caring behavior was the dependent variable, the independent variables were gender, emotional labor and students' reasons for the department preferences.

Table V shows results of multiple linear regression analysis made to explain caring behavior. The results indicated that the established model was significant ($F: 11.994$; $p < 0.05$). The DW coefficient showing the correlation between the errors in the model is in the range $1.5 < DW < 2.5$, that is, there is no autocorrelation problem.

The coefficient estimated for gender was insignificant ($p > 0.05$). Providing healthcare services and helping people were significant in the department preference ($p < 0.05$). In addition, it was found that there was no correlation between independent variables ($VIF < 10$). In the model, gender and the reasons for department preference were used as dummies. When the scores obtained from the emotional labor behavior scale increased by 1 point, it was observed that the scores obtained from the patient care behavior increased by 0.508 points. In addition, it was determined that the individuals who preferred this department to help people had 3.208 points ($2.824 + 0.384$) higher from the patient care scale than those who preferred this department for the other reasons. R^2 , which is the power of independent variables to explain the dependent variable, was found to be 0.225.

Tables IV. Correlations Between Emotional Labor Behavior Scale and Caring Behaviors Inventory

	1	2	3	4	5	6	7	8	9
1. Assurance	-	0.691**	0.815**	0.795**	0.935**	0.465*	0.496**	0.416**	0.538**
2. Knowledge-Skill	-	-	0.670**	0.635**	0.806**	0.348**	0.455**	0.441**	0.479**
3. Respectfulness	-	-	-	0.824**	0.922**	0.427**	0.463**	0.393**	0.489**
4. Connectness	-	-	-	-	0.906**	0.377**	0.410**	0.363**	0.432**
5. CBI-24	-	-	-	-	-	0.458**	0.512**	0.446**	0.544**
6. Superficial Behavior	-	-	-	-	-	-	0.640**	0.618**	0.796**
7. In-depth Behaviour	-	-	-	-	-	-	-	0.643**	0.945**
8. Sincere Behavior	-	-	-	-	-	-	-	-	0.794**
9. ELBS (Total)	-	-	-	-	-	-	-	-	-

Table V. Multiple Linear Regression Model

	Beta	t	p	F	p	DW	Adj. R ²
Constant	2.824	8.838	0.000	11.994	0.000	1.897	0.225
Emotional Labor	0.508	7.171	0.000				
Gender = Male	-0.024	-0.255	0.799				
Reason for department preference = Having a Profession	0.117	0.879	0.380				
Reason for department preference = Patient Care	-0.159	-0.616	0.538				
Reason for department preference = Helping People	0.384	2.678	0.008				
Reason for department preference = Providing Health Services	0.390	2.274	0.024				

$p < 0.05$

DISCUSSION

Nursing is a profession that includes interactions and relationships with other people, so emotional labor is an undeniable reality during the care given (5). It is important to determine the emotional labor and caring behaviors of nurses and nursing students (4,5). In the literature, a study conducted with nurses reported that nurses' emotional labor scores were low (9). Emotional labor was high in a study conducted with student nurses (10), In another study conducted with nursing students, students' perception of care was high (11). In the study, which examined the perceptions of nursing students on emotional labor and caring behaviors, it was found that students' perceptions on emotional labor and caring behaviors were above average, some variables belonging to students affected caring behavior and emotional labor behaviors.

Emotional labor in nursing involves the normalization of emotions in the professional role and harmonization with the emotions of the patients (6,9). Although the emotional labor is not gender-specific, most of the studies have suggested that women make a great effort emotionally and apply more emotional labor (2,8). In a previous study, it was reported that the emotional labor behavior scores of female nursing students were significantly higher than the scores of males (10). The results of the study are similar to the literature and previous studies. The emotional labor behavior scores of female students were higher than the scores of male ones. Male students were also reluctant to participate in the study. It is thought to be a reason for male students not completing data or being unwilling to participate in the study; Especially in the developmental period, avoidance of talking about emotions, inability to normalize talking about emotions, and anxiety about encountering stigma when talking. The meta-cognitive belief in men and the understanding that "I should not show my feelings" in strong male-specific behavior may have also prevented students from participating in the study (16).

Similar to emotional labor, caring behavior inventory scores of the students were higher in female students. In their study, Gül and Arslan reported that there were significant differences between the genders in terms of caring behavior and female students' mean scores were higher (11). Contrary to the studies, another study reported that the scores obtained from the caring behavior inventory did not differ according to gender (12). This is thought to be associated with the fact that women are more sensitive to the problems of others and establish better relationships

with them and they are more willing in providing care to the patients compared to men. The reason for the different results between the studies is that the studies reporting differences in caring behaviors according to gender were conducted on students, and the study reporting no difference was conducted on nurses. It can be asserted that male nurses adopt caring behaviors more because of the process of internalizing care, accepting the profession and adaptation after starting the profession. It is important to prevent this in order to convey the philosophy of care in nursing undergraduate education by purifying it from a genderist approach (11).

Care is a fundamental nursing value and desirable feature in nursing students but decreases can be seen in caring behaviors of the students during the education period (17). Murphy et al., found in their study that caring behavior scores of the third-year students were lower than the scores of the first years (17). In a previous study, it was reported that students' perception of nursing caring behaviors increased during the nursing education process (18). In the present study, caring behaviors scores of the first and third-year students were higher. In another study; caring behavior scores ordering from high to low were obtained respectively, in third, first, second and lastly fourth classes (11). High caring behaviors of the first and third-year students in the present study were thought to be associated with the fact that desire of care giving depends on the care-related current information and the first-year students start to the profession and the care giving desire increasing with the self-confidence was provided by many theoretical and practical courses taken in the third-year students. Additionally, lack of chairside clinical practices in the fourth-year curriculum may have caused the decrease in caring behaviors.

The care is the central focus and essence of nursing (19). Nurses provide healthcare services by making an effort to relieve the distress of the patients they provide care (20,21). Caring behavior scores of the students, who preferred the nursing department since it is a profession providing healthcare service, were higher in the present study, which supports the literature.

Another measure of success in the nursing care is satisfaction. Individuals who are satisfied with their work make their workplace more pleasant. Besides, it provides greater job satisfaction and the satisfaction of the patients receiving care may also increase (22). Consistent with the literature, in the study, it was determined that the students

who were satisfied with the nursing department had higher caring behavior scores.

The clinical learning experience is full of emotions and the students use emotional labor in the management of emotions (6,8,23). Students can also gain emotional labor during their clinical training experiences by interacting with clinical nurses and teaching staff (23). It is generally accepted that the nurses should have emotional labor in order to provide good care (4,6). It is argued that the emotional commitment of the nurses to the patients goes beyond their personal feelings and contributes to the quality and perfections of nursing care (6). Living with emotions is necessary for the nurses to cope with the morally difficult clinical situations and enables them to have ethical and meaningful interactions with distressed people (24,25). In the study, a positive correlation was found between nursing students' caring behaviors and emotional labor behaviors. In addition, it was determined that when the emotional labor scores of the nursing students increased, the patient care behavior perception scores also increased. Understanding of emotional labor will help to create caregiving clinical learning environments for nursing students (23,26). Therefore, further studies on emotional labor are needed.

It is known that the teaching staff and qualified nurses play a major role in teaching emotional labor to the nursing students. In order to the students to learn how to behave and to be successful in managing the emotions when a patient loses his/her life in the clinic, emotional labor should be included in the curricula in the schools (4,6,27).

Limitations of the Study

As the study was conducted only with the nursing students of the Health Sciences Faculty of a university, the results were limited only with this faculty. They cannot be generalized for the nursing departments of all the faculties.

CONCLUSION

Consequently, it was determined that the emotional labor and caring behaviors of the nursing students were higher than the average and there was a significant correlation between the caring behaviors and emotional labor. Gender, the year, reason for preferring the department and the status of being satisfied with the department were determined to be effective on caring behaviors. In this respect, it is suggested to involve the subject of emotional labor in the curriculum, to continue clinical

practices of the students until graduation and to train and direct the nursing students about this subject by faculty members and qualified nurses before starting to work in the profession.

Implications for Practice

Determining the emotional labor and caring behaviors of nursing students before starting the profession is important in terms of foreseeing the deficiencies and misbehaviors of students in this field in the education process and finding solutions. Because emotional labor behavior, which is especially improperly developed and reflected in care, can cause both burnout of nurses and a decrease in patient satisfaction.

Implications for Research

There are a limited number of studies in the literature that determine the emotional labor and caring behaviors of nursing students. There is no study that evaluates both concepts together. This study is thought to contribute to the field in this sense. Demonstrating appropriate emotional labor behavior in care is important for both nurses and patients, and its positive contribution to the health care system.

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Conflict of Interest

None declared.

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An Analysis of Albumin Level and Vitamin D Deficiency in Patients Treated in Palliative Care Centers

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ABSTRACT

Objectives: The main objective of palliative care is to keep symptoms under control and to increase the quality of life. The present study aimed this study is to define the serum albumin and vitamin 25-hydroxy D (25 [OH] D) levels in patients who receive palliative care.

Material/Method: This study has been carried out in a descriptive-retrospective manner. Demographic data and laboratory results of 41 patients hospitalized in a State Hospital Palliative Care Center were analyzed.

Results: A ratio of 48.8% of the participants was female, 51.2% was male and the average age was 74.21 ± 2.21 (Min: 40-Max: 96). A rate of 22% of the patients suffered from cerebrovascular disease, 19.5% from alzheimer, 9.8% from heart failure, 7.3% from oral intake disorders. The serum albumin levels were found to be low in 80.5% of the patients, the serum calcium levels were normal in 70.7%. A lack of Vitamin D was found in 63.4% of the patients and 19.5% suffered from vitamin D deficiency, while the vitamin D level was found to be normal in only 17.1% of the patients. The average 25 (OH) D level of the patients was found to be 17.1 ± 15.54 ng / mL.

Conclusion: Patients who are followed up within the scope of palliative care are at risk of malnutrition, low serum albumin levels and vitamin D deficiency. Therefore the follow-up and treatment of patients is important in this respect.

Keywords: Albumin, Nutrition, Palliative care, Vitamin D

Palyatif Bakım Merkezinde Tedavi Gören Hastalarda Albümin Düzeyi ve D Vitamini Eksikliğinin İncelenmesi

ÖZET

Amaç: Palyatif bakımın temel amacı semptomların kontrol altına alınması ve yaşam kalitesinin yükseltilmesidir. Bu çalışma palyatif bakımdaki hastaların serum albümin ve 25-hidroksi D (25[OH]D) vitamini düzeyini belirlemek amacıyla tanımlayıcı olarak yapılmıştır.

Materyal/Yöntem: Bu araştırma tanımlayıcı-retrospektif olarak gerçekleştirilmiştir. Bir Devlet Hastanesi Palyatif Bakım Merkezinde yatan 41 hastanın demografik verileri ve laboratuvar sonuçları incelenmiştir.

Bulgular: Katılımcıların %48.8'i kadın, %51.2'si erkektir ve yaş ortalaması 74.21±2.21 (Min:40-Max:96)'dır. Hastaların %22'si serebrovasküler hastalık, %19.5'i Alzheimer, %9.8'i kalp yetmezliği, %7.3'ü oral alım bozukluğu tanısı ile takip edilmektedir. Hastaların %80.5'inde serum albümin düzeyi düşük, serum kalsiyum düzeyi %70.7'sinde normal düzeydedir. Hastaların %63.4'ünde vitamin D eksikliği ve %19.5'inde D vitamini yetersizliği tespit edilirken, sadece %17.1 hastada D vitamini seviyesi normal olarak bulunmuştur. Hastaların 25-hidroksi vitamin D seviye ortalamaları 17,1±15,54 ng/mL bulunmuştur.

Sonuç: Palyatif bakım hizmeti alan hastalar malnütrisyon, düşük serum albümin düzeyi ve D vitamini eksikliği açısından risk altında olup, hastaların bu açıdan takip edilerek tedavisinin sağlanması yaşam kalitesinin korunması için önem teşkil etmektedir.

Anahtar Kelimeler: Albümin, Beslenme, D Vitamini, Palyatif bakım,

According to the World Health Organization (WHO), palliative care is defined as the prevention and alleviation of the suffering of adult and pediatric patients (1). The main purpose of palliative care is to approach the symptoms, pain and stress caused by a serious illnesses in such a manner as to provide extra support to the patient along with enhancing the quality of life, dignity and comfort of the individual (2). There is an ongoing need for palliative care in case of chronic health problems that limit life in many parts of the world. According to estimates of the WHO 40 million people need palliative care each year (3).

Patients requiring palliative care generally experience malnutrition due to nutritional disorders (4). Vitamin deficiency due to nutritional disorders causes symptoms such as pain, weakness, fatigue and depression which reduce the quality of life in patients (2). Nutrition in elderly patients can be evaluated by anthropometric measurements, laboratory evaluations, clinical evaluation and assessment of the diet. It is known that low serum albumin levels in elderly individuals are associated with malnutrition and mortality (5).

Vitamin D is a prohormone that is vital for the calcium/phosphate balance, bone structure and physiological functioning. It is absorbed by the skin when exposed to ultraviolet B and obtained when consuming synthesized foods (6). Vitamin D deficiency is an important public health problem that is seen in approximately one out of 7 people worldwide (7,8). Vitamin D deficiency affects almost 50% of the global population and is recognized as a public health problem that affects not only the elderly but people in all life stages (8). A study conducted in the United Kingdom found that Asian 53.7% and black 34.9% participants had a higher proportion of vitamin D deficiency than white participants 12% (9).

Its clinical effects have been documented in many studies. VDD has been associated with cardiovascular diseases, increased risk of fractures, dyslipidemia, increased inflammation, glucose metabolism disorders, weight gain, infectious diseases, multiple sclerosis, mood disorders, cognitive dysfunction, impaired physical functions and mortality rates connected to all types of reasons (10).

Although palliative care differs from country to country worldwide, palliative care in our country has a short history. Palliative care services have been provided since the publication of the directive of the Ministry of Health of our

country in 2015 (11). Palliative care has been neglected in our country due to reasons such as the Turkish family structure, the culture, the absence of expertise in the field of palliative care and the lack of this subject in education. Although the number of palliative care centers has increased over time, their number is actually quite small (12). According to data over the year 2019, there are 365 palliative care centers in our country (11).

Since malnutrition is common in palliative patients and low vitamin D and albumin levels are an important benchmark in the occurrence of this condition, this study has been carried out to prevent malnutrition in palliative patients, to determine the level of vitamin D and albumin, to reveal the requirements and to determine the opinions and suggestions in order to shape the planned care and treatment in this regard.

MATERIALS AND METHODS

Design, Population and Sample

In this descriptive study, the clinical files of 41 patients between the ages of 18 and 45, treated in a Palliative Care Center in Turkey between the 01st of June and 31st of December were retrospectively drafted. The 41 patients who stayed in the palliative care center for two consecutive days were included in the study. The 4 patients who deceased the same day they were admitted, were not included. The demographic data (age, gender, social security) and blood (serum 25 (OH) D, calcium, albumin levels, hemoglobin, vitamin B12 and some laboratory findings) values of patients were retrospectively obtained from observation files. The serum 25 (OH) D, calcium, albumin levels and some laboratory findings of all patients who received a diagnosis for admission to the palliative care center were analyzed. In clinical practice the serum 25 (OH) D concentration is used for the evaluation of vitamin D levels. Vitamin D deficiency (VDD) is defined as a 25 (OH) D level below 20 ng/mL (50 nmol/L) and vitamin D insufficiency as a level between 21-29 ng/mL (525-725 nmol) (13). The frame of reference for albumin in this study is 3.5-5.2 gr/dL, for vitamin B12 it is 180-900 pg/mL, for calcium it is 8.4-10.6 mg/dL, for leukocytes it is (4-10) $10^3/uL$, for lymphocyte it is (0.8-4) $10^3/uL$, for hemoglobin it is (12-16) g/dL, for hematocrit it is (35-47) %, for CRP it is (0-5) mg/L.

Statistical Analysis

The SPSS 21 statistics program was used for the evaluation of the data and the numbers, percentages, mean, standard deviation and chi-square test have been used

in the analysis. A value of $p < 0.05$ was considered to be significant.

RESULTS

In this study, in which the records of 41 patients who received treatment at the Palliative Care Center in X city were examined, the average age of the patients was 74.21 ± 2.21 (Min:40-Max:96). A rate of 48.8% of the patients was male and 51.2% was female. Patients under the age of 65 years formed 29.3% of the group, whereas 70.7% was 65 years or older. The majority of the patients had social security (92.6%). The average hemoglobin level of the patients was 11.0 ± 2.0 g/dL. The hemoglobin levels were found to be below normal and insufficient in 73.2% of the admitted patients, as was the case for the hematocrit levels in 63.4% of the patients, the serum albumin levels in 80.5% of the patients and the serum calcium levels in 26.8% of the patients. The leukocyte levels in one third of the patients were found to be above normal and high, as was the case for the CRP levels of 95.1% of the patients, glucose levels of 48.8% of the patients and BUN levels of 56.1% of the patients (Table 1).

When the diagnoses of the patients are examined, cerebrovascular disease with 22%, Alzheimer's with 19.5%, malignant diseases with 19.5%, heart failure with 9.8% and oral intake disorders with 7.3% are the most common. A statistically significant difference was found between the sexes of the patients and their diagnosis ($p < 0.05$) (Table 2).

The mean 25-OH D level was found to be 15.4 ± 14.6 ng/ml in women and 18.2 ± 12.4 ng/ml in men. When the relationship between the sex of patients and their vitamin D and albumin levels were examined, no significant difference was found, although albumin and vitamin D levels in women were found to be lower than in men (Table 3).

It was observed that 26 of the patients (63.4%) were deficient in 25 (OH) vitamin D. The majority of patients (87.9%) had vitamin D levels < 30 ng/mL. Vitamin D deficiency is statistically more common in men than in women but no significant relationship was found between them. It was determined that there was no statistically significant difference between the ages, sexes and diagnoses of the patients in terms of vitamin D deficiency and insufficiency (Table 4).

Table 1. Some Socio-Demographic Specifications of Participants and Clinical Data (n=41)

	n	%	Mean ± SD
Age			
≤65	12	29,3	74.21±2.21
>65	29	70,7	
Sex			
Male	21	48,8	
Female	20	51,2	
Social security			
Yes	38	92,6	
No	3	7,4	
Vitamin D			
Deficient	26	63,4	17.18±15.54
Insufficient	8	19,5	
Normal	7	17,1	
CRP			
Normal	2	4,9	65,68±45.28
High	39	95,1	
Calcium			
Low	11	26,8	8.78±0.95
Normal	29	70,7	
High	1	2,4	
Hemoglobin			
Low	30	73,7	11.01±2.06
Normal	10	24,4	
High	1	2,4	
Hematocrit			
Low	26	63,4	34.12±6.16
Normal	14	34,1	
High	1	2,4	
Lymphocyte			
Low	9	22,0	1.40±0.65
Normal	32	78,0	
Leukocyte			
Low	2	4,9	8.69±3.32
Normal	26	63,4	
High	13	31,7	
Albumin			
Low	33	80,5	3.01±0.51
Normal	8	19,5	
Vitamin B12			
Low	10	24,4	516,24±72,53
Normal	24	58,5	
High	7	17,1	

Table 2. Comparison of the Reasons for Receiving Palliative Care on the Basis of the Sex of Patients

Patient diagnosis	Female		Male		Total		X ²	p
	n	%	n	%	n	%		
CVD	7	77.8	2	22.2	9	22.0	18,598	0,046
Alzheimer	1	12.5	7	87.5	8	19.5		
Malignant diseases	4	50.0	4	50.0	8	19.5		
Heart failure	4	100.0	0	0.0	4	19.5		
Oral intake disorders	1	33.3	2	66.7	3	7.3		
COPD	1	50.0	1	50.0	2	4,9		
Huntington disease	0	0.0	2	100.0	2	4,9		
Prostate hypertrophy	0	0.0	2	100.0	2	4.9		
Soft tissue disorders	1	100.0	0	0.0	1	2.4		
Pressure ulcer	0	0.0	1	100.0	1	2.4		
Acute kidney failure	1	100.0	0	0.0	1	2.4		
Total	20	51.2	21	48.8	41	100.0		

Table 3. Comparison of Albumin and Vitamin D Levels on the Basis of the Sex of Patients

	Sex						X ²	p
	Female		Male		Total			
	n	%	n	%	n	%		
Vitamin D								
Deficient (20ng/ml and below)	12	46,2	14	53.8	26	100.0	0,773	0,680
Insufficient (between 21-29ng/ml)	5	62,5	3	37.5	8	100.0		
Normal (30ng/ml and higher)	3	42,9	4	57.1	7	100.0		
Albumin								
Low levels (below 3.5gr/dL)	17	51.5	16	48.5	33	100.0	0,697	0,377
Normal levels (between 3.5gr-5.2gr/dL)	3	37.5	5	62.5	8	10.0		

Table 4. Comparison between Patients Who Suffer From Vitamin D Deficiency and Insufficiency

	Vitamin D <20 ng/mL		Vitamin D ≥20 ng/mL		X ²	p	Vitamin D <30 ng/mL		Vitamin D ≥30 ng/mL		X ²	p
	n	%	n	%			n	%	n	%		
n=41												
Percentage of patients	26	63,4	15	36,6			34	87,9	7	17,1		
Sex												
Female	12	60.0	8	40.0	0,196	0,453	17	85.0	3	15.0	0,119	0,529
Male	14	66.7	7	33.3			17	81.0	4	19.0		
Age												
Younger than 65	8	66.7	4	33.3	0,077	0,536	9	75.0	3	25.0	0,753	0,328
65 And older	18	62.1	11	37.9			25	86.2	4	13,80		
Diagnosis												
CVD	5	55,6	4	44,4	5,381	0,864	8	89,9	1	11,1	14,42	0,155
Alzheimer	5	62,5	3	37,5			8	100	0	0		
Cancer	6	75	2	25			7	87,5	1	12,5		
Heart failure	2	50	2	50			2	50	2	50		
Oral intake disorders	1	66,7	1	33,3								
COPD	1	50	1	50			1	50	1	50		
Huntington disease	2	100	0	0			2	100	0	0		
Prostate hypertrophy	1	50	1	50			1	50	1	50		
Soft tissue disorders	1	100	0	0.0			1	100	0	0		
Pressure ulcer	1	100	0	0.0			1	100	0	0		
Acute kidney failure	0	0.0	1	100			0	0	1	100		

DISCUSSION

With an aging population and an increasing number of individuals with chronic, life-threatening and incurable health problems, the need for palliative care continues to rise (3,14). When the literature is examined it is seen that malnutrition, malabsorption due to insufficient food intake or metabolic disorders are observed in patients receiving palliative care (15,16). Therefore, this study has been carried out to examine certain blood values associated with many diseases in patients receiving palliative care.

When the reasons for patients receiving palliative care were examined in this study, it was found that 22% suffered from cerebrovascular disease, 19.5% from Alzheimer's, 19.5% from malignant diseases, 9.8% from heart failure, 7.3% from oral intake disorders, 4.9% from chronic obstructive pulmonary disease, 4.9% from huntingon's disease, 4.9% from prostate hypertrophy, 2.4% from soft tissue disorders, 2.4% from pressure ulcers and 2.4% from acute renal failure. In a similar study conducted by Çınar et al., it was observed that the group of patients in a palliative care center that required the most care suffered from Alzheimer's (33.3%) and 16.7% from cerebrovascular diseases, which is similar to our study (17). In our study, approximately one-fifth of those who needed palliative care suffered from cancer. The WHO has stated that most adults in need of palliative care have chronic diseases such as cardiovascular diseases (38.5%), cancer (34%), chronic respiratory diseases (10.3%), AIDS (5.7%) and diabetes (4.6%) and that patients with many other conditions such as kidney failure, rheumatoid arthritis, chronic liver disease, congenital anomalies drug-resistant tuberculosis and neurological diseases such as multiple sclerosis, parkinson's disease, dementia may require palliative care (3). It was reported that approximately one-third of those in need of palliative care were cancer patients (1). This result shows that not only cancer patients but those suffering from other diseases may need palliative care as well.

Evaluation of the nutrition of patients receiving palliative care and support when necessary is one of the most important approaches of palliative treatment (16). Studies indicate that vitamin D supplementation in patients requiring palliative care, including cancer patients, shows significant improvements in pain and depression problems (18). In this study, 63.4% of the patients suffered from vitamin D deficiency and 19.5% suffered from vitamin D insufficiency, which amounts to a very high frequency of 82.9% of the patients being vitamin D deficient and insufficient. Vitamin D levels were found to be normal in only

17.1% of the patients. In the study of Dev et al. (19) on a group of cancer patients, the rate of vitamin D deficiency was found to be 47%. Lovell et al. (20) found that 88% of palliative care patients suffered from vitamin D deficiency, Vollbrach (15) found that 79.7% of palliative patients suffered from vitamin D deficiency and Yılmaz and Toprak (21) found that 70.3% of domiciliary care patients suffered from vitamin D deficiency. The findings in our study were similar to these studies.

Patients requiring palliative care are at greater risk for vitamin D deficiency/insufficiency as a result of less exposure to sunlight, lower oral intake and a decreased ability to absorb dietary vitamin D (19,22). In addition, studies mentioned in the literature have found a relationship between vitamin 25(OH)D and extremity functions, muscle strength and physical activity and it has been determined that vitamin D deficiency may increase the risk of falling in the elderly (10,13). In a cross-sectional study conducted on 30 palliative cancer patients in Spain, a statistically significant relationship was found between 25-OHD vitamin levels and the general quality of life (23). The conclusions drawn in the literature were found to be of importance for palliative patients in the geriatric age group in our study, as vitamin D deficiency is also a risk factor for osteoporosis, falls and fractures.

The palliative care process requires multidisciplinary approaches that aim to protect and increase the quality of life by focusing on the relief of symptoms experienced by patients and to increase the vital functions by considering the priorities of patients and their families. In addition to the treatments, palliative patients should benefit from nursing services in order to maintain a higher quality of life and enjoy an extended life span. In this regard, nurses should encourage palliative patients to engage in physical activity along with observing vitamin D supplementation.

Malnutrition due to protein energy deficiency is the most common nutritional disorder in the elderly (24). With age, the need for vitamins such as protein, calcium, vitamin D, B12 and folate increases and the need for calories decreases (25). One of the auxiliary biochemical markers in detecting malnutrition is albumin (5). Çevik et al. determined the malnutrition level of patients using the nutritional screening guidelines on the elderly and found that as malnutrition increased and deepened, serum albumin and total protein levels decreased. In addition, they reported that this decrease was not significant in the early stages of malnutrition (26). In their prospective cohort studies, Nuvenna et al. (27) drew attention to the higher effect of albumin on mortality than malnutrition.

In this study, the serum albumin level was found to be low in 80.5% of the palliative patients, with a mean of 3.01 ± 0.51 . In 2018, Dilekci et al. found low serum albumin levels in domiciliary care patients with an average of 3.66 ± 0.64 . (28). The findings in our study revealed that palliative patients in the geriatric age group had physical dependencies and nutritional deficiencies due to chronic problems and were therefore at risk of malnutrition.

Studies show that albumin levels are the most important indicator in determining the prognosis in elderly patients (29,30). Nurses who provide palliative care should monitor and support the nutrition of patients and the necessary observations will be important in preventing risks. Preservation of albumin levels in these patients will contribute significantly to facilitating the wound healing process, preventing infections and maintaining metabolic functions.

Limitations of the Study

This study has certain limitations. Patient registers of palliative centers of hospitals have been included in the study. The study data only include hospital registries of patients who participated in the study. Therefore the results of our study cannot be generalized to all patients in palliative centers. The absence of some data in the existing registries such as anthropometric measurements and daily nutritional content, as well as the fact that the study was conducted in only one city in Turkey may limit the generalizability of the findings. Therefore more research is needed to explore national trends.

CONCLUSION

The literature suggests that cognizance should be taken of vitamin D and albumin levels of patients treated in palliative care centers and that these levels should be supplemented. For this reason, it is important that nurses involved in palliative patient care identify the needs of patients, ensure that they receive qualified care, provide the necessary support in nutrition and physical activity, encourage the patient and play a team-based active role.

The results obtained within the scope of this study support the existing literature and contribute to new literature. Focusing on improving the quality of life, dignity and comfort of palliative patients, it is recommended to prevent malnutrition and support it in both curative and life-prolonging treatments. It is suggested that the nurse maintains a coordinating role at every stage of the disease trajectory and in all aspects of care.

DECLARATIONS

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None.

Conflicts of Interest

The authors declare that they have no competing financial interests or personal relationships that may affect the work reported in this article.

Ethical Considerations

The institutional permission for the study was given by the X State Hospital on 02.03.2020. Permission was granted by the Ethics Board of the XXX University for carrying out this study (number: 2020.02 , date: March 03, 2020).

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Health Problems and Physical Activity Levels of Individuals with Chronic Diseases During Covid-19 Lockdown

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ABSTRACT

Objective: This study aims to investigate through the Omaha System (OS) the health problems and physical activity (PA) levels of the individuals with chronic diseases during COVID-19 lockdown and related factors.

Method: A descriptive-correlational design was used in the study. The research sample consisted of 182 individuals who had chronic diseases and were in home isolation. Personal information form, "Omaha System Problem Classification Scheme (PCS)", and "International Physical Activity Questionnaire (IPAQ-Short Form)" were used to collect data.

Results: The rate of individuals having insufficient PA was 57.7%. The most common health problems in PCS were nutrition, oral health, sleep and rest pattern. A significant relationship was found between the PA level and time spent sitting, isolation period and environmental domain problems ($p<0.05$).

Conclusions: Individuals with chronic diseases were determined to have insufficient physical activity and nutrition, oral health, sleep problems during COVID-19 lockdown.

Keywords: Chronic disease, COVID-19, Physical activity, Social isolation

COVID-19 Sokağa Çıkma Kısıtlaması Sürecinde Kronik Hastalığı Olan Bireylerin Sağlık Sorunları ve Fiziksel Aktivite Düzeyleri

ÖZET

Amaç: Bu çalışma, COVID-19 karantinası sürecinde kronik hastalığı olan bireylerin sağlık sorunları ve fiziksel aktivite (FA) düzeylerini ve ilişkili faktörleri Omaha Sistemi (OS) aracılığıyla araştırmayı amaçlamaktadır.

Yöntem: Araştırmada tanımlayıcı-ilişkisel desen kullanılmıştır. Araştırma örneklemini, kronik hastalığı olan ve ev izolasyonunda olan 182 birey oluşturmuştur. Veri toplamak için kişisel bilgi formu, "Omaha Sistem Problem Sınıflandırma Şeması (PSL)" ve "Uluslararası Fiziksel Aktivite Anketi (IPAQ-Kısa Form)" kullanılmıştır.

Bulgular: FA düzeyi yetersiz olan bireylerin oranı %57.7 olup, PSL'de en sık görülen sağlık sorunları beslenme, ağız sağlığı, uyku ve dinlenme düzenidir. FA düzeyi ile oturma süresi, izolasyon süresi ve çevre sorunları arasında anlamlı bir ilişki bulunmuştur ($p<0.05$).

Sonuç: Kronik hastalığı olan bireylerin COVID-19 karantinası sürecinde yetersiz fiziksel aktivite ve beslenme, ağız sağlığı, uyku sorunları yaşadığı belirlendi.

Anahtar Kelimeler: COVID-19, Fiziksel aktivite, Kronik hastalık, Sosyal izolasyon

COVID-19 is an infectious disease progressing with severe acute respiratory syndrome caused by the virus named SARS-CoV-2 first detected in Wuhan, China, in December 2019 (1). Since the outbreak of COVID-19, authorities of most countries determined the most affected groups by covid19 and focused on this groups to maintain public health. Although having varied according to studies over time, since the initial outbreak of the pandemic, the groups at risk of severe illness due to COVID-19 are the elderly, those with chronic diseases, and healthcare workers (2).

Because of the COVID-19 pandemic, it is recommended around the world that people isolate themselves (3). Thereupon, on March 22, 2020, a curfew was declared by the government in Türkiye. The curfew required citizens to remain in their homes and only leave for urgent and basic needs, adhering to mask, distance and hygiene rules. This restriction was applied as strictly as possible to protect especially elderly individuals over 65 years of age and individuals with chronic diseases. Social support units were established within local governments to meet the basic needs of people living alone (4).

Individuals with chronic diseases are one of the groups most affected by the isolation, quarantine, and restrictions due to COVID-19 (2). During the pandemic period, the use of classification systems in evaluating the health status of individuals with chronic diseases and planning appropriate interventions is necessary to maintain the provision of services more effectively and with higher quality. The OS is the oldest and most common classification system used to identify the problems associated with health status, to plan appropriate interventions and to evaluate outcomes (5, 6). OS is known to be used effectively in many fields such as community health in the "first place, home care, mother-baby health, school health, family health, occupational health and acute care services" (7). Since the beginning of the COVID-19 pandemic, care plans have been created for COVID-19 by the developers and users of the system and integrated into the OS, contributing significantly to the recognition of the problems of society and taking appropriate initiatives during the pandemic period (8,9).

Studies report that, during the pandemic period, due to isolation and restrictions, there are disruptions in individuals' chronic disease management and decreases in their physical activity levels; furthermore, their health, cardiovascular health in the first place, is adversely affected

(10,11). World Health Organization (WHO) lists insufficient physical activity, which is responsible for 6% of deaths worldwide, as the fourth leading cause of death globally (12). Even short-term (1-4 weeks) inactivity has been associated with increased cardiovascular risk factors (13).

In order to protect the individuals from the negative effects of COVID-19, evaluating their current health status and taking initiatives for them to maintain a healthy lifestyle is an urgent need (14). The researchers encountered no studies investigating by means of OS the individuals with chronic health problems during the COVID-19 pandemic. In this context, this study was conducted to diagnose the health problems of individuals with chronic diseases during the COVID-19 restrictions, to determine through OS their physical activity levels and related factors.

The research questions are as follows: (a) What is the physical activity level of individuals with chronic diseases who are in home isolation during the COVID-19 pandemic? (b) What are their health problems according to the PCS? (c) Are there statistically significant relationships among health problems, socio-demographic factors, duration of isolation and physical activity levels?

MATERIALS AND METHODS

Research Design and Participants

Descriptive and correlational design was used. The research population consisted of individuals with chronic diseases and in home isolation, who were relatives of the students taking the public health nursing practice course at a foundation university in Istanbul, Türkiye, between May 1 and May 31, 2020 (n=220). The sample of the study consisted of 182 individuals who agreed to participate in the study voluntarily. The sample size was calculated using the full census sampling method (percentage of the population covered: 82%).

Data Collection Tools

Data collection tools consist of "Personal Information Form", "Omaha System Problem Classification Scheme (PCS)", and "International Physical Activity Questionnaire (IPAQ-Short Form)".

Personal Information Form: It consists of 7 questions regarding the participants' "age, sex, marital status, educational status, body mass index (BMI), chronic diseases and the number of days spent in home isolation".

Omaha System Problem Classification Scheme (PCS):

PCS, which is one of the three basic components of the Omaha System, is a list that diagnoses health problems with four problem domains, 42 problems and 335 signs/symptoms. Environmental domain problems included in the list are *“Income, Sanitation, Residence, Neighborhood/Workplace Safety; Psychosocial domain problems are Communication with community resources, Social contact, Role change, Interpersonal relationship, Spirituality, Grief, Mental health, Sexuality, Caretaking/Parenting, Neglect, Abuse, Growth and development; Physiological domain problems are Hearing, Vision, Speech and language, Oral health, Cognition, Pain, Consciousness, Skin, Neuro-musculo-skeletal Function, Respiration, Circulation, Digestion-hydration, Bowel function, Urinary function, Reproductive function, Pregnancy, Postpartum, Communicable/infectious condition and Health-related Behavior domain problems are Nutrition, Sleep and rest pattern, Physical activity, Personal care, Substance use, Family planning, Health care supervision, Medication regimen”* (15). The Turkish validity and reliability study of the scale was conducted in 2006. The median kappa values for the problems are 0.81 (16).

International Physical Activity Questionnaire (IPAQ-Short Form):

This questionnaire was developed in 1996 to be used in adults between the ages of 18-65, aiming to measure the level of physical activity, make international comparisons, and obtain surveillance. The validity-reliability study of the IPAQ in Türkiye was conducted by Saglam et al. (2010). The Kappa coefficient of the Turkish version of the scale is 0.69. The form consists of 7 questions to obtain information about the “time spent sitting, walking, and during moderate and vigorous physical activity”. The scale is scored by “multiplying the duration (minutes), frequency (days) and MET (Metabolic Equivalent of Task; walking=3.3 METs, moderate physical activity=4.0 METs, vigorous physical activity=8.0.METs) of the activities performed during the last week prior to its filling out. From this calculation, a physical activity score in the form of MET-minutes/week is obtained. The score obtained is evaluated in 3 categories as inactive, minimally active and active. Inactive is below 600 MET-min/week, minimally active between 600-3000 MET-min/week, active over 3000 MET-min/week” (17,18).

Data Collection

The data were collected by phone calls between May 1 and May 31, 2020, when a curfew was imposed on individuals over 65 years of age and with chronic diseases in Türkiye. Students trained to use Omaha System collected the data under the supervision of the first and 2nd authors.

Ethical Consideration

Before the research, approval was obtained from the Istanbul Medipol University Ethics Committee Presidency (Number:10840098-772.02-E.43574, date: 03.09.2021). Written informed consent was received from the individuals participating in the study.

Data Analysis

The data obtained in the research were analyzed in the computer environment using the software SPSS version 22.0 for Windows (IBM Corporation, Armonk, NY). Descriptive statistics were used for demographic data. The number of isolation days and time spent sitting were compared with physical activity levels using independent t-tests and with health problems using chi-square analysis. While determining physical activity levels, 600 METs were used as the cut-point. Accordingly, below 600 METs was categorized as inactivity, 600 METs and above as moderate-vigorous physical activity (MVPA). In BMI analysis, 25 kg/m² was used as the cut-point. Below 25 was categorized as underweight or normal, and 25 and above was categorized as overweight or obese. Spearman correlation analysis was used to determine the relationship between variables. The significance level was accepted to be $p < 0.05$.

RESULTS

This study was carried out with individuals having chronic diseases. Considering the distribution of the diseases, hypertension was the most common among all (47.3%, $n=86$), which was followed by diabetes mellitus (32.4%, $n=59$) and cardiovascular diseases (19.8%, $n=36$). Of the individuals participating in the study, 57.7% ($n=105$) had inactivity and 42.4% ($n=77$) had MVPA. Other sociodemographic characteristics of the individuals are given in Table 1.

Figure 1 shows the health problems of the individuals with chronic diseases and in home isolation during the COVID-19 pandemic, as diagnosed according to the PCS. Accordingly, most common problems are nutrition 82.4% ($n=150$), physical activity 76.9% ($n=140$), oral health 52.7% ($n=96$), sleep and rest pattern 52.7% ($n=96$), respectively. The most common problem diagnosed in the “environmental domain” is residence (32.4%, $n=59$); in the “psychosocial domain”, social contact (41.2%, $n=75$); in the “physiological domain”, oral health (52.7%, $n=96$); and in the “health-related behaviors domain”, nutrition (82.4%, $n=150$).

Table 1: Bivariate analysis of physical activity and demographic variables for Turkish adults (n=182)

Variables	N (%) / Mean ± SD	Inactive N (%) / Mean ± SD	Moderate to vigorous active N (%) / Mean ± SD	t (df)	χ ² (df)	p
Age, years	47.37 ± 11.04	48.12 ± 10.14	46.34 ± 12.16	1.035 (180)		0.279
BMI, kg/m²	28.15 ± 5.05				0.915 (1)	0.339
Underweight and normal	50 (27.5)	26 (24.8)	24 (31.2)			
Overweight and obese	132 (72.5)	79 (75.2)	53 (68.8)			
Gender					5.350 (1)	0.021*
Male	72 (39.6)	34 (32.4)	38 (49.4)			
Female	110 (60.4)	71 (67.6)	39 (50.6)			
Education					8.395 (2)	0.015*
Primary school	82 (45.1)	54 (51.4)	39 (37.1)			
High school	67 (36.8)	39 (37.1)	28 (36.4)			
University	33 (18.1)	12 (11.4)	21 (27.3)			
Marital Status					1.325 (1)	0.25
Married	151 (83)	90 (85.7)	61 (79.2)			
Single	31 (17.0)	15 (14.3)	16 (20.8)			
Type of Chronic Diseases						
Hypertension	86 (47.3)	48 (45.7)	38 (49.4)		0.236 (1)	0.627
Cardiovascular diseases	36 (19.8)	22 (21.0)	14 (18.2)		0.215 (1)	0.643
Diabetes Mellitus	59 (32.4)	35 (33.3)	24 (31.2)		0.095 (1)	0.758
Pulmonary diseases	28 (15.4)	13 (12.4)	15 (19.5)		1.720 (1)	0.19
Others	20 (10.9)	14 (13.3)	6 (7.8)		1.394 (1)	0.238
Isolation Period, day	46.93 ± 26.02	51.26 ± 23.644	41.04 ± 28.047	2,661 (180)		0.009*
Time Spent Sitting, hour	6.82 ± 3.25	7.35 (3.345)	6.09 (3.023)	2,651 (171.971)		0.009*

Abbreviation: BMI, body mass index.
*p < .05.

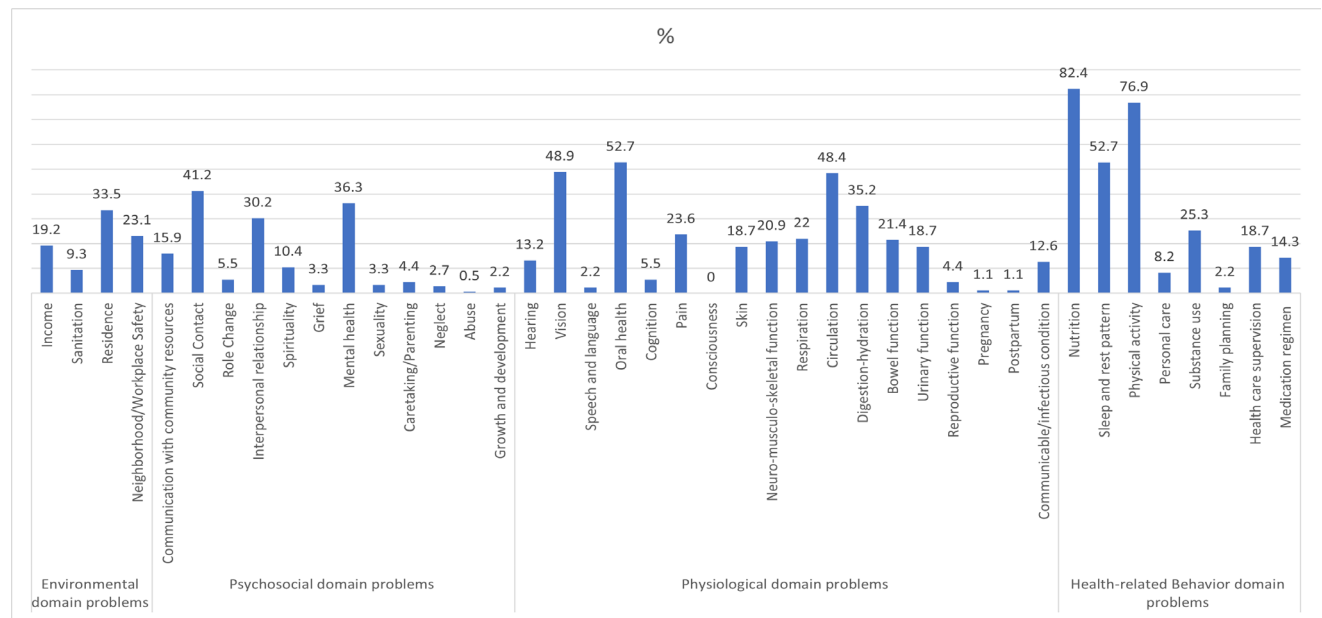


Figure 1. The Domains and Problems of Adults With Chronic Diseases (n=182)

When the physical activity levels of individuals were evaluated according to their sociodemographic characteristics, individuals with a higher number of isolation days were determined to have a higher inactivity rate than individuals with a lower number of isolation days ($p < 0.05$). Women, primary and high school graduates, and individuals with sanitation problems, neighborhood/workplace safety problems and skin problems were found to have a higher inactivity rate than others ($p < 0.05$).

The MVPA levels of males and university graduates were determined to be higher than those of other individuals in Table 2 ($p < 0.05$).

As a result of the spearman correlation analysis, weak negative correlations were found between IPAQ and the number of isolation days ($r = -.202$; $p < .01$), time spent sitting ($r = .192$; $p < .01$), Environmental domain problems in Table 3 ($r = .151$; $p < .05$).

Table 2: Bivariate analysis of physical activity and health problems for Turkish adults (n=182)

Variables	N (%) / Mean±SD	Inactive N (%) / Mean±SD	Moderate to vigorous active N (%) / Mean±SD	t (df)	χ^2 (df)	p
Income problem	35 (19.2)	22 (21)	13 (16.9)		0.474(1)	0.491
Sanitation problem	17 (9.3)	15 (14.3)	<5 (<5)		7.167(1)	0.007*
Residence problem	59 (32.4)	36 (34.3)	25 (29.9)		0.395(1)	0.530
Neighborhood/ workplace safety problem	42(23.1)	30(28.6)	12(15.6)		4.221(1)	0.040*
Communication with community resources problem	29(15.9)	13(12.4)	16(20.8)		2.339(1)	0.126
Social contact problem	75(41.2)	49(46.7)	26(33.8)		3.052(1)	0.081
Interpersonal relationship problem	55(30.2)	34(32.4)	21(27.3)		0.550(1)	0.458
Spirituality problem	19(10.4)	12(11.4)	7(9.1)		0.260(1)	0.610
Mental health problem	66 (36.3)	40 (38.1)	26 (33.8)		0.360(1)	0.548
Hearing Problem	24(13.2)	12(11.4)	12(15.6)		0.670(1)	0.413
Vision Problem	89(48.9)	56(53.3)	33(42.9)		1.951(1)	0.161
Oral health Problem	96(52.7)	55(52.4)	41(53.2)		0.013(1)	0.908
Pain problem	43 (23.6)	23 (21.9)	20(26)		0.408(1)	0.523
Skin problem	34(18.7)	25 (23.8)	9(11.7)		4.296(1)	0.038*
Neuro-musculo-skeletal function problem	38(20.9)	20(19)	18(23.4)		0.504(1)	0.478
Respiratory problem	40(22)	21(20)	19(24.7)		0.566(1)	0.452
Circulatory problem	88(48.4)	47(44.8)	41(53.2)		1.281(1)	0.258
Digestion-hydration problem	64(35.2)	38(36.2)	26(33.8)		0.115(1)	0.735
Bowel function problem	39(21.4)	26(24.8)	13(16.9)		1.638(1)	0.201
Urinary function problem	34(18.7)	19(18.1)	15(19.5)		0.056(1)	0.813
Communicable/ infectious condition problem	23 (12.6)	15 (14.3)	8 (10.4)		0.611(1)	0.434
Nutrition problem	150(82.4)	90(85.7)	60(77.9)		1.861(1)	0.172
Sleep and rest patterns problem	96(52.7)	58(55.2)	38(49.4)		0.618(1)	0.432
Physical activity problem	140 (76.9)	92(87.6)	48(62.3)		15.995(1)	<0.001*
Personal care problem	15(8.2)	6(5.7)	9(11.7)		2.096(1)	0.148
Substance use problem	46(25.3)	29(27.6)	17(22.1)		0.722(1)	0.395
Health care supervision problem	34(18.7)	17(16.2)	17(22.1)		1.014(1)	0.314
Medication regimen problem	26(14.3)	12(11.4)	14(18.2)		1.655(1)	0.198

Note: Problems present in ten or fewer participants were not listed: Role change, Grief, Sexuality, Caretaking/parenting, Neglect, Abuse, Growth and development, Speech and language, Cognition, Consciousness, Reproductive function, Pregnancy, Postpartum, Family planning.

* $p < .05$.

Table 3: Correlation Analysis of Variables (n=182)

	Mean	SD	1	2	3	4	5	6	7	8	9	10
1. IPAQ, MET	1287.01	2035.12	1	.022	-.023	-.102	-.202**	-.192**	-.151*	-.094	-.104	-.128
2. Chronic diseases	1.26	.55		1	.159*	.152*	.092	.057	.006	.116	.113	-.031
3. Age, year	47.37	11.04			1	.250**	.029	-.027	-.105	-.056	.161*	-.121
4. BMI, kg/m2	28.15	5.05				1	-.003	-.021	-.113	-.119	.116	.086
5. Isolation period, day	46.93	44253,00					1	.087	.103	.122	.026	-.010
6. Time spent sitting, hour	6.82	3.25						1	-.059	.018	-.087	.018
7. Environmental domain problems	0.85	1.09							1	.273***	.273***	.346***
8. Psychosocial domain problems	1.56	1.64								1	.321***	.242**
9. Physiological domain problems	3.51	2.50									1	.254**
10. Health-related behavior domain problems	2.81	1.26										1

Abbreviation: IPAQ, International Physical Activity Questionnaire. MET, Metabolic Equivalent of Task. BMI, body mass index.
* $p < .05$. ** $p < .01$. *** $p < .001$

DISCUSSION

During the pandemic period, chronic disease management of individuals has been disrupted and their physical activity levels have decreased due to isolation and restrictions, which has adversely affected their health, particularly their cardiovascular health (10,11). In order to protect and maintain public health, it is important to evaluate individuals with chronic diseases in a holistic way. In the present study, the health problems of individuals with chronic diseases during COVID-19 restrictions were diagnosed through OS, and their physical activity levels and related factors were determined. In the study, the most common chronic diseases in individuals were hypertension, diabetes mellitus and cardiovascular diseases, respectively, and 72.5% of individuals were overweight or obese. WHO reports that obesity and chronic diseases are important risk factors for COVID-19 more than 2.8 million people die each year due to overweight and obesity (3). Hospitalizations and the need for ventilation are reported to likely increase in individuals with chronic diseases such as obesity, hypertension and diabetes (19,20). In a meta-analysis aiming to investigate the connections between obesity and mortality in COVID-19, overweight/obese individuals were determined to be at risk of severe comorbidities, need for advanced respiratory support and high mortality (21).

Several studies have reported that COVID-19 restrictions increase health problems and physical inactivity (14, 22).

The physical activity level of more than half of the participants in this study was found as inactive (17). The time spent sitting by the participants in a day was found to be approximately 7 hours. In a cross-sectional study by Rahman, et al. (22) the prevalence of physical inactivity was found to be lower (37%), and high sedentary behavior (>8h/day) was reported to be 20.9%. In another cross-sectional study by Martinez, et al. (14) 79.4% of 1613 Brazilian adults stated that the pandemic negatively affected their level of physical activity and their frequency of performing physical activity decreased. Whereas, many guidelines recommend that adults and the elderly be active in their daily lives and do at least 150 minutes of moderate physical activity per week (23, 24). Nevertheless, in addition to the concerns of individuals with chronic diseases for getting infected, restrictions and measures have made the recommended physical activity levels rather difficult to reach.

In the study, according to the PCS, the two most common problems in individuals with chronic health issues were determined as nutrition and physical activity, respectively. Similar to the present study, previous studies have also reported that social restrictions due to COVID-19 negatively affect nutrition and physical activity behaviors (25). In a study utilizing the OS before the COVID-19 pandemic, unlike the present study, the most common problems in adults with insufficient physical activity levels were reported to be in the physiological field, which was followed by the environmental and psychosocial fields, respectively

(26). In the present study, problems in the “physiological domain” and “health-related behaviors” domain stand out as the priority problem areas.

In this study, physical inactivity levels of women were found to be lower than those of men. Women have various roles such as a mother, wife and working woman, making it difficult for them to perform regular physical activity (27). In the study of Rahman, et al.(22) the levels of physical inactivity and sedentary behavior of women are stated to be higher than those of men. Based on this information, it can be said that COVID-19 restrictions also affect women’s physical activity negatively.

In the present study, the physical activity level of the university graduates was determined to be higher than that of the groups with a lower education level. Rahman, et al.(22) stated that the low education level is one of the risk factors that increase physical inactivity. In a study that had a 10-year follow-up period and was conducted with Dutch adults, individuals with higher education levels were found to be more active than those with lower education levels (28). Piirtola et al. (29) found in their 35-year long-term study that education level has an independent role in developing long-term physical inactivity and that people with low education levels had a high level of physical inactivity. The study results suggest that special efforts are needed to promote physical activity among people with low education levels.

In the study, individuals with a higher number of isolation days or determined to have an “environmental domain” problem had lower IPAQ scores. In other words, their inactivity was determined to increase. “Environmental domain” problems are stated to be one of the important predictors of PA behavior (26). Unlike the present study, in a study conducted during COVID-19 lockdown, lower income, not being Caucasian, having high-risk medical conditions, higher BMI, negative experiences related to mental health, and symptoms related to increased physical health were all found to be significantly associated with low physical activity level (25). The associated variables are seen to vary according to the different models used in the studies.

CONCLUSIONS

This study shows that the most common health problems in individuals who have chronic diseases and are in home isolation are physical activity, nutrition, and sleep and rest pattern. More than half of the individuals participating in

the study are inactive, and there is a linear relationship between the number of isolation days and inactivity.

It is recommended that individuals be encouraged to perform regular physical activity during home isolation due to COVID-19 and home-based physical activity programs be planned. In preventing adverse health outcomes due to physical inactivity, health professionals and public health institutions can implement programs, develop guidelines and policies to increase physical activity. The OS can be used as part of the COVID-19 guideline to diagnose community health problems, set appropriate goals and conduct appropriate initiatives during the COVID-19 pandemic. Additional research is needed to determine the present group’s level of physical activity during the pandemic period and effective factors.

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Conflict of Interest

No conflict of interest was declared by the authors.

Author Contribution

Concept: SK, AD; Design: SK, AD; Literature Review: AD, SB; Data Collection and Processing: SK, AD; Analysis or Interpretation: SK; Writing: SK, AD, SB; Critical Review: SK,AD.

Data Availability

Available upon request.

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Underpricing Anomaly in Initial Public Offerings: An Application on Borsa İstanbul Health Sector

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ABSTRACT

The phenomenon of underpricing in initial public offerings has been one of the topics debated in the literature for a long time. Examining underpricing, which is an example of price anomalies, and analyzing its determinant factors are vitally important for the establishment of efficient capital markets. The aim of this study is to contribute to the existing literature on the underpricing anomaly observed in initial public offerings. For this purpose, the initial public offerings of companies in the health sub-sector whose stocks are traded in Borsa İstanbul for the period 2006 – 2021 are examined. The short-term price performance of the stocks included in the sample after the initial public offering is analyzed. The main problem for which the answer is sought in the study is whether an investor who buys stocks from the issuance in the initial public offering of the sample companies can get more returns than the market when they hold and sell these stocks for a short period of time.

The change in the initial returns of the initial public offerings of health companies, especially as a result of increasing health awareness after Covid-19, is also examined.

In the analysis, raw return (RR), abnormal return (AR), cumulative abnormal return (CAR) and compound abnormal returns (BHAR) are calculated during the 1, 3 and 7 days, which are considered as analysis period. If the AR, CAR and BHAR calculated in the analysis are greater than 0 and their values are statistically significant according to the t-test result, the existence of underpricing can be accepted.

According to the results of the analysis, an underpricing anomaly has not been found out in the initial public offerings of the health companies that formed the sample. Based on this finding, it can be expected that investors who bought a stock in an initial public offering would not have an abnormal return if they held it in portfolio basket for 1, 3, and 7 days of the analysis period. It can be recommended that investors not to choose health sector companies while investing in the public offering in terms of obtaining positive higher returns.

Keywords: Initial Public Offering, Underpricing Anomaly, Abnormal Return, Healthcare Institutions, t-test

İlk Halka Arzlarda Düşük Fiyatlama Anomalisi : Borsa İstanbul Sağlık Sektörü Üzerine Bir Uygulama

ÖZET

İlk halka arzlarda düşük fiyatlama olgusu uzun zamandır literatürde incelenen konuların başında gelmektedir. Bir fiyat anomali örneği olan düşük fiyatlamasının incelenmesi ve sebeplerinin analiz edilmesi etkin sermaye piyasalarının oluşturulması için hayati derecede önemlidir.

Bu çalışmanın amacı ilk halka arzlarda görülen düşük fiyatlama anomalisi ile ilgili mevcut literatüre katkı yapmaktır. Bu amaçla Borsa İstanbul'da hisse senetleri işlem gören sağlık alt sektöründeki firmaların 2006 – 2021 dönemi için ilk halka arzları incelenmiştir. Örnekleme dahil edilmiş halka arz olan hisse senetlerinin ilk halka arz sonrası kısa dönem fiyat performansı analiz edilmiştir. Çalışmada cevabı aranan temel sorunsal, sağlık sektöründe yer alan örneklem firmalarının ilk halka arzında ihraçtan hisse senedi satın alan bir yatırımcının bu hisse senetlerini kısa dönem boyunca elinde tuttuğu zaman piyasaya göre daha fazla getiri elde edemeyeceğidir.

Anahtar Kelimeler: İlk Halka Arz, Düşük Fiyatlama Anomalisi, Anormal Getiri, Sağlık Kuruluşları

Price stability of financial instruments plays a critical role in terms of sustainable returns for investors trading in capital markets. Price stability, on the other hand, is observed when there are no abnormal price movements in the market and when volatility is not excessive. In a market where price stability is ensured, no investor will be able to obtain an abnormal return. There are many theories in the literature regarding the price movements of financial instruments. The most well-known and still accepted in the current literature is the Efficient Market Hypothesis put forward by Fama in 1965. Fama (1965), in his study named random walk in the stock market, states that the current prices of stocks reflect all the historical information about that stock (7). The hypothesis assumes that investors successfully use past price information in current price formation (12). In such an efficient market, there is no problem of using asymmetric information between investors, as prices contain all kinds of information about the stock (5). As a result, no investor can make more profit than the others (2).

However, in real life, some anomalies can be seen in the price movements of financial instruments, especially stocks. In capital markets, it may be possible for some investors to earn more profit than others, in other words, to earn excessive profits. There are many macro and micro determinants of this situation. The existence of asymmetric information among investors is the foremost among these reasons.

These price anomalies emerged in the market can be observed in the short term after the public offering of newly publicly offered stocks as well as in the stocks that have already been offered to the public.

These price anomalies observed in the short and long term after the IPO are called short-term underpricing and long-term underperformance anomalies in the literature (11). One of the reasons for the underperformance in the long run is the window of opportunity, which causes many companies to attack the public offering, but leads to negative or low returns in the long run, due to the fact that investors are overly optimistic about the general economic conjuncture (11). In addition to the overly optimistic and pessimistic reaction of the investors, price anomalies can also be seen due to the existence of asymmetric information between investors. In summary, contrary to the assumptions of the efficient market hypothesis, many anomalies can be observed in real life.

In this study, the short-term underpricing anomaly, which is one of the most frequently mentioned anomalies in the literature, will be examined. For this purpose, initial public offerings of companies in the health sub-sector conducted during the 2006-2022 period will be examined, and the existence of underpricing anomaly in these public offerings will be investigated. As a result of the study, it will be determined whether an investor who buys stocks from the initial public offering of the sample companies and holds it for 1, 3 and 7 days, which is accepted in this study as short-term, can make excessive profits compared to the market average. In the study, the t test will be performed on SPSS 22 version.

In the second part of the study, the conceptual framework for price anomalies will be drawn. In the 3rd section, the findings of the studies conducted in the national and international literature will be examined and in the 4th section, the existence of short-term underpricing anomaly in the initial public offerings of the companies operating in the health sector will be analyzed. In the 5th chapter, which is the last part of the study, the interpretation of the results and findings will be carried out.

Theoretical Framework of Underpricing in Initial Public Offerings

While a firm determines the price it will sell to investors in the primary market in the initial public offering, it actually determines the value of the company, in other words, it evaluates the company and finds the potential public offering price by dividing the value it finds by the number of shares to be sold (6). Pricing in public offering is one of the most important issues in corporate finance, as it is the stage where the business model of the firm is evaluated and priced. Intermediary institutions that mediate the public offering of companies may underprice their stocks by showing the company at a lower value in order to ensure the success of the public offering and to sell all the stocks (2). Underpricing refers to the determination of stocks below their fair value. Underpricing is considered a price anomaly because it represents a price level beyond the fair value of the stock. While underpricing guarantees the successful marketing of all stocks in the initial public offering, it also represents decreased IPO proceed (money left on the table) for the firm (15).

The underpricing anomaly is one of the most emphasized issues in the financial literature. Rock (1986), Ibbotson (1975), Ibbotson and Jaffe (1975), Ljungqvist (2004), Ritter

(1984) and Ritter (1991) are the authors who made the most important contributions to the formation of the theoretical framework on this subject. However, the underpricing hypothesis has been applied by many academics all over the world in various country and sector categories.

Underpricing can be seen as a cost as it represents the loss of export revenue of the firm and the volume of underpricing increases over time. In the USA, loss of IPO proceed of firms due to underpricing is 3.3 Billion USD between 1980-1989, 30.8 Billion USD between 1990-1998, 66.79 Billion USD in 1999-2000 (only 2 years) and 130.22 Billion USD in the period 2001-2021 (19). As can be seen, the size of the underpricing seen in initial public offerings gradually increases over time.

There are hypotheses such as the Changing Risk Composition Hypothesis, the Realignment of Incentives Hypothesis, and the Issuer's Changing Objective Function Hypothesis (16) in order to explain this change in the underpricing seen in the initial public offerings over time. According to the changing risk composition hypothesis developed by Ritter in 1984, it is assumed that riskier initial public offerings will be more underpriced (17). The realignment of incentives and the changing issuer objective function hypotheses both assume changes over time in the willingness of issuers to accept underpricing. Both hypotheses assume that investment banks seek to benefit from the rent-seeking behavior that occurs when there is excessively underpricing.

There are many models developed in the literature on the determinants of underpricing. These models include asymmetric information, institutional reasons, control considerations, and behavioral approaches (13). The hypotheses developed under the asymmetric information model are the winner's curse hypothesis, principal-agent models and underpricing as a signal of firm quality models. In the model named winner's curse, which was developed by Rock in 1986, the oldest and most well-known of these methods, investors in an IPO are divided into investors who know whether the stocks are underpriced or not, and investors who are not aware of the price of the stocks (20). Investors who know that the stocks in an IPO are underpriced will show high demand for these stocks, but they will not prefer to buy these stocks when they are overpriced. However, investors who do not have adequate information about the fair value of the stocks may demand stocks from the public offering in both cases, and when the stocks are overvalued high in this way, they may purchase these stocks far above their fair value.

Principal-agent models try to explain the behavior of investment banks in the pricing process in the IPO. The role of investment banks in the public offering process, their functions in pricing and allocation, as well as the agency problems between them and the issuer are discussed. When an IPO is underpriced, a rent competition may occur between investors by using an investment bank, since this will mean a wealth transfer from the public offering company to the investors (13).

The Behavioral approach model, deals with the effect of investors' behavior on pricing in the public offering process. In this model, it is investigated how investors deviate from information-based market efficiency and show irrational behaviors and affect pricing in the public offering process (22). Behavioral effects of investors are especially seen in the public offering of companies that are relatively young and therefore do not have enough information about their sustainability. The model that will give the most optimal response to the expectations of the investors was first developed by Ljungqvist, Nanda, and Singh in 2004. In this model, in a situation where investors have optimistic expectations about the firm, it is assumed that the investors of the issuer firm will want to maximize its issuance income by holding as many stocks as possible under the downward sloping demand curve. When the issuer injects too many stocks into the market, this will lower the stock price. For this reason, the company will be able to keep the price high by keeping the stocks in this way. However, this is a strategy that can be applied for the short term, and the stock price will return to its fair value in the long run.

In the control considerations model, underpricing allows company managers to protect their private interests by acting strategically while making an IPO (4). For this reason, company managers avoid allocating large shares to investors in public offerings. In particular, it is accepted that an allocation to a larger number of investors will protect existing partners against the hostile takeover problem (8).

Literature Review

In this part of the study, studies performed on the underpricing anomaly in IPOs in the international literature will be examined. Underpricing anomaly literature have generally focused on the existence of underpricing, its size, change of its volume over time, and its macro and micro determinants. There are numerous studies carried out at different times on different countries' stock exchanges. Table 1 summarizes model developed to explain underpricing and its determinants as follows:

Table 1. Models in Existing Literature on IPO Underpricing	
MODELS	EXPLANATIONS
Asymmetric Information Models	
The Winner's Curse – Rock (1986)	He stated that asymmetric information among investors in initial public offerings will lead to underpricing or overvaluation.
Information Revelation Theories - Benveniste and Spindt (1989)	They found that the possible underpricing in the public offering encouraged investors to disclose information about their valuation about the company at the preliminary prospectus stage, and this information was used to determine the public offering price.
Principal-Agent Models - Michael Jensen and William Meckling (1976)	The model is based on the separation of objectives between the managers of the firm and the investment banks that mediate the public offering. While firm managers seek to maximize IPO revenue, investment banks may underprice stocks to ensure the success of the IPO.
Underpricing as a Signal of Firm Quality - Ibbotson (1975), Allen and Faulhaber (1989)	By underpricing the IPO price of high-quality firms, it makes it difficult for low-quality firms to imitate them. So they use the IPO price as a signal. In addition, with the statements made before the IPO, they inform the investments about the real quality of the company and thus eliminate the low quality companies.
Ownership and Control	
Underpricing as a Means to Retain Control - Brennan and Franks (1997)	He argues that company managers are planning to take control of the company management in the new capital distribution after the public offering by using underpricing and to prevent a possible hostile takeover attempt.
Underpricing as a Means to Reduce Agency Costs - Brennan and Franks (1997), Stoughton and Zechner (1998)	When the managers have a share in the company remarkably, they may not prefer high underpricing in IPO.
Behavioral Explanations	
Cascades - Welch (1992)	In initial public offerings made sequentially over time, investors participating in the IPO may set aside their own bids by focusing on previous investors' bids. Welch called this interaction among investors the informational cascade.
Investor Sentiment - Ljungqvist, Nanda, and Singh (2004)	They found that the overly optimistic or pessimistic expectation of investors about the future performance of a stock is very influential on the firm's pricing and share allocation transactions in the IPO.
Prospect Theory And Mental Accounting - Loughran and Ritter (2002)	It examines the effect of firm managers' behavior on underpricing in an initial public offering. They found that company managers were not upset by the loss of IPO revenue due to underpricing, on the contrary, they tried to compensate for this loss with new public offerings to be made in the future by taking advantage of the increasing prices of the stocks offered to the public over time.

Analysis of Underpricing on Istanbul Exchange Health Sector

Dataset and Sample Structure

In this part of the study, an analysis will be made regarding the existence of underpricing in initial public offerings. The analysis will be applied to healthcare institutions whose stocks are traded in Istanbul Exchange, which have made their first public offering in the period of 2006-2021. During the analysis period, the first public offering of a total of 9 health institutions took place. Sample companies and public offering information are shown in Table 2 as follows:

The data used in the analysis consists of the public offering prices of the sampled companies, the closing prices of the 1st, 3rd and 7th days after the public offering, and the closing values of the Borsa İstanbul 100 national index. Public offering prices were obtained from www.spk.gov.tr, stock and index closing information was obtained from www.investing.com.

Table 2: Sample Firms IPO Summary Information		
Equity Code	Offering Date	Offering Price - TRL
ANGEN	21/10/2021	22,5
EGEPO	25 - 26 August 2021	5
GENIL	30.07.2021	10,75
MEDTR	25.06.2021	28
MPARK	6.02.2018	19
RTALB	27.05.2014	13
TRILC	25-26 February 2021	10
LKMNH	26.01.2011	4,13
SELEC	19-21 April 2006	5,35
Source: www.spk.gov.tr		

Methodology

In the study, abnormal return is defined as the difference between the raw returns (RR) of stocks and the market return, in accordance with the international literature. While the raw return is taken into account as the daily return of the stocks of the sample companies, the market return is accepted as the daily return of the Istanbul Exchange 100 National Equity Index. The 1st, 3rd and 7th days after the public offering were taken into account as the analysis period. Cumulative and compound return calculations of the abnormal returns were also made. The expression used to calculate the abnormal return is shown in Equation 1 below (3):

$$AR_{it} = R_{it} - R_{mt} \quad (1)$$

The explanation of the notations in the equation is as follows:

AR_{it} : The abnormal return of stock i in period t,

R_{it} : The raw return of stock i in period t,

R_{mt} : The raw return of market i in period t,

In the study, the existence of underpricing will be determined according to whether the calculated abnormal return is greater than 0, in other words, whether it is positive or not. The hypotheses to be used in testing the existence of underpricing were created separately for AR, CAR and BHAR and are shown as follows:

$H_0: \overline{AR}_t \leq 0$ There is no underpricing

$H_a: \overline{AR}_t > 0$ There is underpricing

$H_0: \overline{CAR}_t \leq 0$ There is no underpricing

$H_a: \overline{CAR}_t > 0$ There is underpricing

$H_0: \overline{BHAR}_t \leq 0$ There is no underpricing

$H_a: \overline{BHAR}_t > 0$ There is underpricing

The t-test was performed using SPSS version 22 for the rejection or acceptance of the hypotheses.

Test Results – Findings

In the study, the short-term price performances of the stocks offered to the public were calculated separately for the first day, the first 3 days and the first 7 days. For this purpose, first of all, descriptive statistics related to the data sets discussed in the study were examined.

Table 3. Descriptive Statistics on First Day Performances

	Stock Price	BIST 100 Index Closing Value
Mean	11.09	1139.75
Standard Deviation	8.29	393.80
Kurtosis	-0.62	-1.18
Skewness	0.75	-0.73
Min	1.52	447.46
Max	28.00	1541.98

Source: Author's Own Calculations

Considering the first day performances of stocks and BIST 100 Index, it is seen that the average price of the stocks in question is 11.09, and the BIST 100 index is 1139.75. While the stock prices took the lowest value of 1.52 and the highest value of 28 for this period, the BIST 100 index varies between 447.46 and 1541.98. When the kurtosis coefficient is examined, it is seen that both variables have negative values, that is, they have a flatter structure than the normal distribution. The skewness coefficient is positive in stocks and negative in BIST 100 index. In other words, the distribution of stocks exhibits a left-skewed structure, while the BIST 100 index exhibits a right-skewed structure.

Table 4. Descriptive Statistics on First 3 Days Performances

	Stock Price	BIST 100 Index Closing Value
Mean	10.22	1144.22
Standard Deviation	7.92	394.19
Kurtosis	-0.70	-1.19
Skewness	0.72	-0.69
Min	1.32	437.52
Max	28.00	1549.15

Source: Author's Own Calculations

Looking at the performances of the stocks and BIST 100 Index in the first three days, it is seen that the average price of the stocks in question is 10.22, and the BIST 100 index is 1144.22. While the stock prices are at the lowest 1.32 and the highest 28 for this period, the BIST 100 index varies between 437.52 and 1549.15. When the kurtosis coefficient is examined, it is seen that both variables have negative values, that is, they have a flatter structure than the normal distribution. The skewness coefficient is positive in stocks and negative in BIST 100 index. In other words, the distribution of stocks exhibits a left-skewed structure, while the BIST 100 index exhibits a right-skewed structure.

	Stock Price	BIST 100 Index Closing Value
Mean	9.81	1149.74
Standard Deviation	7.52	393.75
Kurtosis	-0.82	-1.17
Skewness	0.64	-0.67
Min	1.29	437.52
Max	28.00	1564.94

Source: Author's Own Calculations

Looking at the first day performances of stocks and BIST 100 Index, it is seen that the average price of the stocks in question is 9.81, and the BIST 100 index is 1149.74. While the stock prices are at the lowest 1.29 and the highest 28 for this period, the BIST 100 index varies between 437.52 and 1564.94. When the kurtosis coefficient is examined, it is seen that both variables have negative values, that is, they have a flatter structure than the normal distribution. The skewness coefficient is positive in stocks and negative in BIST 100 index. In other words, the distribution of stocks exhibits a left-skewed structure, while the BIST 100 index exhibits a right-skewed structure.

The compatibility of \bar{R} , (\overline{AR}) , (\overline{CAR}) and (\overline{BHAR}) statistics calculated before the analysis with normal distribution in the first seven days was tested with Jarque-Bera tests.

Days	\bar{R}		\overline{AR}		\overline{CAR}		\overline{BHAR}	
	Test Statistics	p-Val	Test Statistics	p-Val	Test Statistics	p-Val	Test Statistics	p-Val
1	1.24	0.54	1.27	0.53				
2	0.57	0.75	0.68	0.71	1.06	0.59	0.39	0.82
3	0.94	0.63	0.71	0.70	0.92	0.63	2.44	0.30
4	7.04	0.03	9.57	0.01	0.88	0.64	14.74	0.00
5	0.45	0.80	0.53	0.77	0.94	0.62	15.27	0.00
6	1.08	0.58	1.29	0.52	0.99	0.61	15.50	0.00
7	0.65	0.72	0.66	0.72	0.97	0.62	15.55	0.00

Source: Author's Own Calculations

According to Jarque Bera tests stated in Table 6.

For the statistics of \bar{R} , (\overline{AR}) and (\overline{BHAR}) on Day 4, and for the statistics of (\overline{BHAR}) on Days 5, 6 and 7, at 95% confidence interval, the null hypothesis was rejected. Accordingly, it can be said that these series are not suitable for normal distribution. For the statistics other than these statistics, Wilcoxon Sequential Sign test, which is one of the non-parametric tests, was applied for not normal statistics, while the t-test was applied in the continuation of the analysis.

The price performance of the sample companies on the first day after the initial public offering is provided in Table 7 as follows:

Day	n	\bar{R}	t-ist.	(\overline{AR})	t-ist
1 st Day	9	-31.06	-0.73	-31.84	-0.76

Note: n; is the number of observations. The critical values for the t-test are -1.38, -1.83 and -2.82 for the 10%, 5% and 1% confidence level, respectively.

According to the results in Table 7, the first day raw returns of the stocks offered to the public are negative but statistically insignificant. The first day abnormal returns of stocks are negative and statistically insignificant. Considering the results, the H0 hypothesis cannot be rejected since the t-statistics values are not less than the critical value. In this case, by looking at the returns on the first day after the public offering, it can be stated that the underpricing phenomenon is not valid for the stocks offered to the public.

The price performance of the sample companies on the first 3 days after the initial public offering is provided in Table 8 as follows:

Table 8 First Three-Day Price Performances of Stocks

Day	n	\bar{R}	t-ist.	(\overline{AR})	t-ist.	(\overline{CAR})	t-ist.	(\overline{BHAR})	t-ist.
1	9	-31.06	-0.73	-31.84	-0.76	-31.84	-0.76	-31.84	-0.76
2	9	2.31	0.33	2.41	0.31	-29.43	-0.65	-1.31	0.00
3	9	2.19	0.35	1.98	0.33	-27.45	-0.58	-126.69	-0.05

Note: n; is the number of observations. The critical values for the t-test are -1.38, -1.83 and -2.82 for the 10%, 5% and 1% confidence level, respectively.

According to the findings in Table 8, the average raw returns of the stocks of the companies offered to the public in the first three-day period when they started to be traded in the stock market are positive except for the first day, but since the t-statistics values are not less than the critical value, it is statistically insignificant. The average abnormal returns, average cumulative abnormal returns and average compounded returns of stocks are similarly negative and t-statistics are not less than the critical value, so they are statistically insignificant.

According to the findings, all three null hypotheses cannot be rejected. In other words, by looking at the first three days' data, it can be accepted that the underpricing phenomenon is not valid for the stocks offered to the public.

The price performance of the sample companies on the first 7 days after the initial public offering is provided in Table 9 as follows:

Table 9 First Seven-Day Price Performances of Stocks

Day	n	\bar{R}	t-ist.	(\overline{AR})	t-ist.	(\overline{CAR})	t-ist.	(\overline{BHAR})	t-ist.
1	9	-31.06	-0.73	-31.84	-0.76	-31.84	-0.76	-31.84	-0.76
2	9	2.31	0.33	2.41	0.31	-29.43	-0.65	-1.31	0.00
3	9	2.19	0.35	1.98	0.33	-27.45	-0.58	-126.69	-0.05
4	9	0.48	0.12	-0.01	0.00	-27.45	-0.58	-8191.21	-0.41
5	9	-1.25	-0.22	-1.28	-0.22	-28.73	-0.64	-67844.81	-0.29
6	9	2.27	0.62	2.09	0.58	-26.64	-0.57	-787597.91	-0.32
7	9	2.20	0.48	1.96	0.42	-24.68	-0.51	-8935912.59	-0.32

Note: n; is the number of observations. The critical values for the t-test are -1.38, -1.83 and -2.82 for the 10%, 5% and 1% confidence level, respectively.

In the first seven-day period when the stocks of the companies offered to the public started to be traded in the stock market, except for the first and fifth days, the average raw returns are positive, but the t-statistics values are not less than the critical value, so it is statistically insignificant. On the first and fifth days, mean raw returns are negative but statistically insignificant.

Average abnormal returns of stocks in the first seven-day period, except for the first, fourth and fifth days, are positive but statistically insignificant. On the first, fourth and fifth days, average abnormal returns are negative but statistically insignificant.

Average cumulative abnormal returns are negative but statistically insignificant in the first seven-day period.

Average compound returns are also negative and statistically insignificant in the first seven days.

In this case, all three null hypotheses are not rejected. In other words, based on the findings for the first seven days, it can be accepted that the underpricing phenomenon is not valid for the stocks offered to the public.

Conclusion and Discussion

The price stability of financial instruments has vital importance for investors trading in capital markets to achieve sustainable returns in the medium and long term. Although there are many macro and micro factors that ensure price stability, the main ones are preventing the use of asymmetric information, possible manipulative behaviors of company managers and investment banks in the public offering process (i.e. agency problem), macroeconomic conjuncture, interaction between investors, and investors' abnormal overly optimistic and pessimistic expectations about future price movements, and so on.

The efficient market hypothesis comes first among the hypotheses that have been put forward in the finance literature about the functioning of the markets and the investment process and are still accepted today. According to this hypothesis, stock prices contain all current and future information about that stock, and therefore there is no asymmetric information between investors. Information is shared simultaneously and fairly among all investors in the market, so that unfair competition is not in question.

However, it is clear that stock markets do not work that way in real life. Due to the reasons explained above, some price anomalies can be seen in stock prices. These anomalies seen in the literature are defined as short-term underpricing anomalies and long-term underperformance anomalies.

The short-term underpricing anomaly assumes that the stocks to be offered to the public are valued at a lower price than their fair value, so that investors who will buy these shares from issuance will be able to make abnormal profits compared to the market in the short term.

In this study, the existence of underpricing was investigated in Istanbul Exchange health sector. For this purpose, the public offering information and the short-term price performance after the public offering of 9 companies that were first publicly offered in Istanbul Exchange in the period of 2006-2021 were examined and it was examined whether the investors could obtain a residual return above the market for the relevant period if they purchased these stocks from the issuance.

According to the results of the t-test performed on the SPPS program, the return of investors who buy the stock from the issuance and sell all these stocks after holding during the first day, the first three days and the first seven days is generally negative but statistically insignificant. In other words, it could not be statistically confirmed that the investors who bought the stocks of these 9 companies that made the initial public offering from the issuance, would be able to obtain higher returns than the market. Therefore, the null hypothesis could not be rejected and the underpricing anomaly for the analysis period and sample could not be confirmed in Istanbul Exchange.

These findings are consistent with our a priori expectations, but not with previous literature results. It was our a priori expectation that the public offerings made during the post-Covid period would not be underpriced or would be priced less, especially due to the increased health awareness after the Covid-19 global epidemic. As a matter of fact, we observed this situation in the public offerings made in 2019 and later. However, the results of the study are inconsistent with Ritter (1984), (1991), Ibbotson (1975), Allen and Faulhaber (1989), Welch (1992) and many of the recent studies. Many of these recent studies have confirmed the underpricing anomaly in initial public offerings.

Limitations of the Study and Further Suggestions

Although the analysis period is relatively wide in the study, it is not possible to generalize the results obtained due to the small number of companies in the sample. In addition, it is possible to obtain more comprehensive results with the analysis to be made on different sectors and country groups.

DISCLOSURES

Authorship

The authors of this study contributed equally to collecting data, reviewing the literature, interpreting statistics, drafting the article, and writing the final version.

Conflict of Interest

None

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Data Availability

Available upon request

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The Effect of Personal Face Mask Use on Hearing Sensitivity Awareness

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ABSTRACT

Background and Objectives: The speech information obtained from the acoustic cue alone is not sufficient. The visual component of speech is crucial for speech perception. This study aims to show that individual hearing sensitivity awareness has increased due to the blocking of visual components of speech as a result of the use of personal face masks with the Covid 19 pandemic.

Subjects and Methods: A scale was prepared with questions that measured individuals' ability to use auditory stimuli in various conditions before and after the pandemic. The scale prepared consists of two sections and a total of 15 items. The questions in the first section are about pre-pandemic hearing loss awareness, and the second section is about post-pandemic hearing loss awareness. The age average of 1046 people included in the study was 49.47 ± 11.06 .

Results: Those who do not feel the need to repeat what was spoken in face-to-face meetings before the pandemic need to repeat what was spoken significantly after the pandemic ($p < 0.001$). The findings show the increased need to repeat spoken words in individuals who wear face masks. Also, people have trouble recognizing speech in noisy environments is due to the absence of visual speech cues, compared to the absence of such trouble before the pandemic.

Conclusion: The use of personal face masks in the post-pandemic period has changed the awareness of individual hearing sensitivity due to the disappearance of the visual element of speech.

Keywords: Covid-19, Hearing Loss, Mask

Kişisel Yüz maskesi kullanımının İşitme Hassasiyetine Etkisi

ÖZET

Amaç: Konuşma algısı için, akustik ipuçlarından elde edilen konuşma bilgisi tek başına yeterli değildir. Konuşmanın görsel bileşenleri de konuşma algısı için çok önemlidir. Covid 19 pandemisi nedeni ile kişisel maske kullanımı zorunlu hale gelmiştir. Bu çalışma, kişisel yüz maskelerinin konuşmanın görsel bileşenlerinin engellenmesi nedeniyle bireysel işitme duyarlılığı farkındalığının arttığını göstermeyi amaçlamaktadır.

Gereç ve Yöntemler: Pandemi öncesi ve sonrasında bireylerin çeşitli durumlarda işitsel uyarıyı kullanma becerilerini ölçen sorulardan oluşan bir ölçek hazırlanmıştır. Hazırlanan ölçek iki bölüm ve toplam 15 maddeden oluşmaktadır. Birinci bölümdeki sorular pandemi öncesi işitme kaybı farkındalığı ile ilgili, ikinci bölümde ise pandemi sonrası işitme kaybı farkındalığı ile ilgili sorular yer almaktadır. Araştırmaya dahil edilen 1046 kişinin yaş ortalaması 49.47 ± 11.06 'dır.

Bulgular: Pandemi öncesinde yüz yüze yapılan görüşmelerde konuşulanları tekrar etme ihtiyacı hissetmeyenler, pandemi sonrasında önemli ölçüde konuşulanları tekrarlatma ihtiyacı duymaktadır ($p < 0,001$). Bulgularımız, maske takan kişiler konuştuğunda, dinleyicilerin kelimeleri tekrar etme ihtiyacının arttığını göstermektedir. Ayrıca, katılımcılar pandemi öncesinde gürültülü ortamlarda konuşmayı tanımda güçlük çekmezken, pandemi sonrasında problem yaşadıklarını bildirmişlerdir. Bu durum görsel konuşma ipuçlarının maske ile engelleniyor olmasından kaynaklanmaktadır.

Sonuç: Pandemi sonrası dönemde kişisel yüz maskelerinin kullanılması, konuşmanın görsel unsurunun ortadan kalkması nedeniyle bireysel işitme duyarlılığı farkındalığını değiştirmiştir.

Anahtar Kelimeler: Covid-19, İşitme Kaybı, Maske

Hearing loss is gradually progressed and is linked to aging, as in presbycusis, and therefore, not easily noticed. Since the information received from auditory stimuli decreases due to hearing loss, communication skills are maintained by other pragmatic properties of language and visual speech cues (i.e., lip reading) (1). Most individuals are not even aware of this process.

The Corona Virus Pandemic Infection 'COVID-19' was first reported in Wuhan, Chi-na, in December 2019. On March 11th, 2020, the World Health Organization (WHO) declared COVID-19 a pandemic (2). The COVID-19 pandemic has caused severe effects on public health on a global scale. In line with the recommendations of the World Health Organization, each country has introduced its own public health measures in order to bring the pandemic under control. The most contagion of COVID-19 is known to be respiratory transfer. Therefore, the most effective protection method is the use of personal face masks. As of April 3rd, 2020, restrictions imposed in Turkey also included a prohibition on going out without wearing a face mask (3).

It is known that hearing loss increases social isolation, and therefore those with hearing loss communicate less with other individuals. People with hearing loss are able to maintain communication with the support of speech cues such as visual cues and lip-reading (4,5). During the pandemic period, individuals with age-related hearing loss have become more socially isolated due to the quarantine restrictions and social distance precautions introduced after the outbreak. In addition, the use of personal face masks has also increased the communication problems of these individuals.

This study aims to suggest that as a result of personal face mask use, the visual component of the speech is inhibited, and since the speech information derived from acoustic cue on its own is not sufficient, the hearing sensitivity awareness of individuals has been on the increase since the COVID-19 pandemic period.

SUBJECTS AND METHODS

The study has been approved by Ethics Committee meeting no 2020/20 with the decision number 2020-20/10 on the date of September 17th, 2020.

In this study, a questionnaire was designed with a number of questions measuring individuals' ability to use auditory stimuli in various conditions before and after the pandemic. The questionnaire consisted of two sections and a total of 15 items. The questions in the first section are about pre-pandemic hearing loss awareness, and the second section is about post-pandemic hearing loss awareness.

The study sample group consisted of voluntary individuals between the ages of 40-99. The questionnaire was transmitted to individuals face-to-face and in question-and-answer form or by providing answers to the digital version of the questionnaire through the application of WhatsApp via Google Forms. In order to ensure the anonymity of the study, demographic information was not included; however, only age and gender were questioned for statistical analysis.

Statistical Method

The descriptive statistics of the data are given as frequency (percentage) for categorical data, while for the numeric variables, it has been given as average \pm standard deviation. The McNemar test was used to evaluate the difference between categorical dependent variables, and Pearson Chi-Square test was used to determine the difference between categorical independent variables. All statistical analyses were examined and reported at $\alpha=0.05$ significance level in IBM SPSS Statistics 22.0.

RESULTS

The age average of 1046 people included in the study was found to be 49.47 ± 11.06 . It was found that 624 (59.7%) people were female, and 422 (40.3%) people were male.

According to the Kuder Richardson-20 (KR-20) method used in the evaluation of Test Measurement Reliability, the reliability coefficient was found to be 0.86. According to this coefficient, the measurement tool is reliable.

The questions used in the measurement tool were given in Figure-1, and the statistical frequency distribution of all questions applied was given in Figure-2.

The results of the statistical evaluation of 4 dependent questions pre-pandemic and pandemic periods are presented below.

Answers to the questions regarding the need to turn on the TV volume or hearing phone and/or doorbell ringing (indoor questions) are similar in pre-pandemic and pandemic periods. ($p=1$)

If your answer "Yes" please ✓ box

Pre-Pandemic Period	Pandemic Period
<input type="checkbox"/> Did you think that you suffered from hearing loss?	<input type="checkbox"/> Do you have trouble understanding speech in noisy environments?
<input type="checkbox"/> Did you have difficulty understanding speech in noisy environments?	<input type="checkbox"/> Do you need to turn up the volume while watching TV?
<input type="checkbox"/> Did you need to turn up the volume while watching TV?	<input type="checkbox"/> Do you find it difficult to hear sounds such as the telephone or the doorbell?
<input type="checkbox"/> Did you have trouble hearing sounds such as the telephone or the doorbell?	<input type="checkbox"/> Having trouble finding the direction the sound is coming from?
<input type="checkbox"/> Did you have trouble finding the direction the sound?	<input type="checkbox"/> Do you feel the need to repeat the conversations when people wearing masks speak?
<input type="checkbox"/> Did you feel the need to repeat the conversations?	<input type="checkbox"/> Do you think the obligation to wear a mask makes it difficult for you to understand speech?
<input type="checkbox"/> Did you need repetition to face to face conversations?	<input type="checkbox"/> Do you have difficulty following conversations in mask-wearing environments?
	<input type="checkbox"/> How you notice any change in your hearing during the pandemic period?

Figure 1: Auditory Sensitivity Awareness Questionnaire Form

statistically significant when compared to individuals who thought to have a hearing problem in the pre-pandemic period ($p<0.001$).

While individuals who found it trouble to find the direction of sounds in the pre-pandemic period continued to have trouble in the pandemic period, 8,8% of individuals who didn't have trouble in the pre-pandemic period reported having trouble finding the sound directions in the pandemic period ($p<0.001$) (Table 1).

Correlations between the independent questions asked in pre-pandemic and pandemic periods were evaluated. It was concluded that individuals began to have difficulty in speech recognition in noisy environments with the introduction of a personal face mask even though they did not think that they had hearing loss after the pandemic ($p<0.001$) (Table 2).

The need for asking individuals wearing a face mask to repeat spoken words during the pandemic period was statistically significant in individuals who did not have trouble in identifying the direction of the sound pre-pandemic period compared to those with such trouble ($p<0.001$) (Table 3).

The percentage of individuals who thought that the requirement for wearing a face mask after the pandemic made it difficult to recognize speech was found to be significantly higher in individuals who did not have trouble in identifying the direction of sound pre-pandemic period as compared to those having trouble in identifying the direction of sound ($p<0.001$) (Table 4).

The need to repeat the conversations when people spoke with masks pandemic period was found significantly higher in individuals who didn't need to repeat the conversations in the pre-pandemic period than those who felt the need to repeat the conversations before the pandemic period. ($p<0.001$) (Table 5).

The percentage of individuals who thought that there were some changes in their hearing after the pandemic was significantly higher for individuals who did not feel the need for the repetition of spoken words during face-to-face conversations before the pandemic as compared to those who needed such repetition ($p<0.001$) (Table 6).

Distribution of Participants' Answers

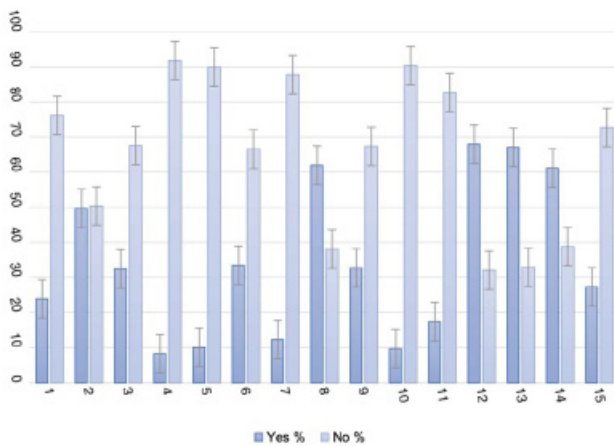


Figure-2: Distribution of Questions in the Measuring Instrument
* Data is described in frequency (percentages).

The number of individuals who did not assume to have a hearing loss problem in the pre-pandemic period and found it hard to speech discrimination in noisy environments (outdoor questions) in the pandemic period is

Table-1: Evaluation of Pre-Pandemic & Post-Pandemic Dependent Questions in the Questionnaire

Pre-Pandemic			Post-Pandemic		p-value
			Yes	No	
Difficulty understanding speech in noisy environments	Yes	n	467	46	p<0.001
		%	72.6%	11.7%	
	No	n	176	346	
		%	27.4%	88.3%	
The need to turn up the volume while watching TV	Yes	n	292	45	1
		%	86.40%	6.40%	
	No	n	46	655	
		%	13.60%	93.60%	
Trouble hearing sounds such as the telephone or the doorbell	Yes	n	72	11	0.009
		%	72%	1.20%	
	No	n	28	922	
		%	28%	98.80%	
Trouble finding the direction the sound	Yes	n	97	6	p<0.001
		%	54.20%	0.70%	
	No	n	82	848	
		%	45.80%	99.30%	

**p-value is the one found in McNemar's test.*

Table-2: Evaluation of the Correlation Between Perceived Hearing Loss Before the Pandemic and Experiencing Difficulty in Speech Recognition in Noisy Environments After the Pandemic

Pre-Pandemic			Do you have any difficulty in understanding conversations in noisy environments after the pandemic?		p-value
			Yes	No	
Do you think you have any hearing loss?	Yes	n	227	17	p<0.001
		%	35.7%	4.3%	
	No	n	409	377	
		%	64.3%	95.7%	

**p-values are those found in Pearson's chi-squared test*

Table-3: Evaluation of the Correlation Between Experiencing Difficulty in Identifying the Direction of Sound Before the Pandemic and the Need for the Repetition of Conversations by Individuals Wearing a Face Mask After the Pandemic

			Do you feel the need for the repetition of conversations by individuals wearing a face mask after the pandemic?		p-value
			Yes	No	
Did you have trouble finding the direction the sound?	Yes	n	90	13	p<0.001
		%	12.8%	3.9%	
	No	n	612	319	
		%	87.2%	96.1%	

**p-values are those found in Pearson's chi-squared test*

Table-4: Evaluation of the Correlation Between Experiencing Difficulty in Identifying the Direction of Sound Before the Pandemic and Experiencing Difficulty in Speech Recognition Due to the Requirement for Wearing a Face Mask After the Pandemic

			Do you think that the requirement for wearing a face mask after the pandemic has made it more difficult for you to understand conversations?		p-value
			Yes	No	
Did you have trouble finding the direction the sound?	Yes	n	83	19	p<0.001
		%	11.9%	5.6%	
	No	n	612	323	
		%	88.1%	94.4%	

*p-values are those found in Pearson's chi-squared test

Table-5: Evaluation of the Correlation Between the Need for the Repetition of Conversations Before the Pandemic and Experiencing Difficulty in Speech Recognition Due to the Requirement for Wearing a Face Mask After the Pandemic

			Do you feel the need for the repetition of conversations by individuals wearing a face mask after the pandemic?		p-value
			Yes	No	
Did you need repetition in face-to-face conversations before the pandemic?	Yes	n	300	44	p<0.001
		%	42.9%	13.3%	
	No	n	399	288	
		%	57.1%	86.7%	

*p-values are those found in Pearson's chi-squared test

Table-6: Evaluation of the Correlation Between the Need for the Repetition of Conversations During Face-to-Face Conversations Before the Pandemic and Perceived Change in Hearing After the Pandemic

			Have you noticed any change in your hearing during the pandemic?		p-value
			Yes	No	
Did you need repetition in face-to-face conversations before the pandemic?	Yes	n	58	70	p<0.001
		%	20.6%	9.3%	
	No	n	223	682	
		%	79.4%	90.7%	

*p-values are those found in Pearson's chi-squared test

DISCUSSION

Hearing losses are mainly characterized by gradual progression and are irreversible in many cases. However, as age-related changes are frequently observed, individuals often wait until older to undergo auditory assessments. In addition, visual speech cues have been removed due to the requirement for wearing a personal face mask after the outbreak of the COVID-19 pandemic.

The lack of visual speech cues is therefore considered the main reason for the change in the perceptions of individuals regarding their auditory sensitivity and an increase in their awareness of hearing loss. The objective of this study is to conduct a statistical evaluation of the change in such individual awareness.

The questionnaire was administered to individuals between the ages of 40 and 99 by taking into consideration the fact that hearing loss is associated with aging and inherently characterized by gradual progression. The reliability coefficient was calculated as 0.86 based on KR-20 analysis. This value is considered reliable for psychometric questionnaire studies. The survey included questions such as "Need to turn up the volume while watching TV and have difficulty hearing certain sounds such as phone ringing, doorbell," which were not related to wearing a face mask but related to in-door conditions. In addition, dependent questions for this pre-pandemic and pandemic period were evaluated as a preliminary assessment. As expected, no significant change was observed in the answers provided by participants to these questions. However, statistically significant changes were identified in the answers provided to the questions related to speech recognition in noisy environments (outdoor conditions) and the identification of the direction of the sound. Such changes are anticipated as a result of face mask use. The results obtained from dependent questions are in line with the expectation and demonstrate that participants' answers are consistent.

The link between suspected hearing loss in the pre-pandemic period and understanding speech in pandemic noise was investigated.

They reported that although the participants had no suspected hearing loss in the pre-pandemic period, their ability to distinguish in noisy environments was impaired during the pandemic period.

Participants who did not feel the need to repeat spoken words in face-to-face conversations before the pandemic reported that their need for repetition increased significantly after the pandemic (if the speaker was wearing a face mask), and they felt impaired speech. Auditory and visual speech signals are produced through the vocal apparatus of the speaker. Time-dependent variations in phonetic and kinematic patterns are strongly correlated. People use these visual and auditory correlations to decode the message more effectively during face-to-face conversations (6-10).

Speech perception has been researched through the use of various methods over the years. Speech perception is inherently a multimodal form of perception (9). Such type of perception is established by a combination of various visual, auditory, and sensory stimuli and cues. As in the

McGurk effect, acoustic information is not reliable on its own without the visual components of the speech (11). Visual speech may increase the comprehensibility of auditory speech, especially in cases where the speech contains complex messages. With the McGurk effect, auditory information is improved by tactile stimuli and the articulating face. Observable speech cues have an effect on the manner of hearing the speech (12).

The findings suggest that the increased need for the repetition of spoken words by individuals wearing a face mask and having trouble in speech recognition in noisy environments after the pandemic compared to the absence of such difficulty before the pandemic result from the lack of visual speech cues (13-17).

As mentioned in the results of the study by Jaekl et al., it is evident that dynamically-structured facial information increases the comprehensibility of speech in terms of audio-visual speech perception (18). Face mask use leads to the presentation of only the isolated acoustic content of the speech information. Individuals who did not have any difficulty in identifying the direction of sound before the pandemic reported that they felt an increased need for the repetition of spoken words by individuals wearing a face mask in addition to experiencing greater difficulty in speech recognition after the pandemic. This finding is an indication that such individuals were unable to adequately analyze isolated auditory information in environments where people have to wear a face mask. This may have resulted from two main reasons: (i) the absence of visual components in speech and (ii) decreased acoustic transmission (19). Presumably, such individuals were those who thought that their hearing abilities were quite normal before the pandemic. As demonstrated in this study, increased difficulty in speech recognition in noisy environments after the pandemic can be explained by the lack of visual speech cues resulting from the use of face masks by individuals in such environments. Similarly, individuals who did not have any difficulty identifying the direction of sound before the pandemic felt an increased need for the repetition of spoken words by people wearing a face mask after the pandemic indicates that such individuals had increased awareness of their hearing losses. The increased demand for hearing aids after the pandemic is another indication of this awareness (20).

CONCLUSION

According to the analysis conducted, it was concluded that the hearing-related problems of those who did not

have any hearing-related complaints in the pre-pandemic period have significantly increased after the pandemic with the constant use of personal face masks.

The questionnaire designed for this study is intended to contribute to the awareness of auditory sensitivity and allow for the regular recording of statistics.

DECLARATIONS

Conflict of Interest

The authors declare that they have no conflict of interest.

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