

ISSN: 1309-470X e-ISSN: 1309-5994

# SAĞLIK BİLİMLERİ DERGİSİ



Volume:16, Issue:2, April 2025



# SAĞLIK BİLİMLERİ DERGİSİ

ISSN: 1309-470X e-ISSN: 1309-5994

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Hakemli Süreli Yayın (Dergi, yılda 4 sayı olarak Ocak, Nisan, Temmuz, Ekim aylarında yayımlanır)

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## HEALTH SCIENCES JOURNAL

ISSN: 1309-470X e-ISSN: 1309-5994

## **JOURNAL TYPE**

Refereed Periodicals (The journal is published four times a year in January, April, July and October)

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Acıbadem University Health Sciences Journal İndexed in ULAKBİM TR Dizin, EBSCO, Google Scholar, Crossref, ROAD Directory of Open Access Scholarly Resources, Turkish Medline, Academi index ve İndex of Academic Journals and Türkiye Atıf Dizini.

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# **Evaluation of Blood Gas Instruments** with 6 Sigma Methodology

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Received: 24.11.2024 Accepted: 05.12.2024

#### ABSTRACT

**Purpose:** 6 sigma is one of the most effective quality tools for demonstrating laboratory analytical performance. 6 sigma tells us what level we are at and what rules to follow in case of poor performance. Blood gas analysis plays an important role in the assessment of critical illness, determining the aetiology and severity of disease. In our study, we aimed to evaluate the test performance of blood gas instruments in our hospital with 6 sigma methodology.

**Methods:** The study included pH, p0<sub>2</sub>, pCO<sub>2</sub>, glucose, lactate, ionised Ca, Na, K and Cl parameters analysed on Siemens RAPIDpoint 500e blood gas instruments in the emergency laboratory. In the sigma metric calculation TEa (total permissible error) rates, the values determined by RiliBAK (German Guidelines for Quality) were used. The causes of errors of poorly performing tests were evaluated with the quality goal index (QGI).

**Results:** At the results,  $PCO_2$  (Level 2) in Instrument I, Lactate (Level 1-2) in Instrument II and  $pCO_2$  (Level 1-2) in Instrument III are the tests with sigma values below 4. When we look at the low performance problems, precision in Instrument I  $pCO_2$  (Level 2), accuracy in Instrument II lactate (Level 1-2) and accuracy in Instrument III  $pCO_2$  (Level 1-2) were detected.

**Conclusion:** This study has allowed us to monitor laboratory blood gas testing performance very closely. With the 6 sigma methodology we have captured underperforming tests and investigated the reasons behind them

Keywords: Quality goal index, 6 Sigma, Total allowable error, Westgard rule, Bias

#### ÖZET

**Amaç:** 6 sigma, laboratuvar analitik performansını göstermek için en etkili kalite araçlarından biridir. 6 sigma bize hangi seviyede olduğumuzu ve kötü performans durumunda hangi kuralları izlememiz gerektiğini söyler. Kan gazı analizi, kritik hastalıkların değerlendirilmesinde, hastalığın etiyolojisinin ve ciddiyetinin belirlenmesinde önemli bir rol oynar. Çalışmamızda, hastanemizdeki kan gazı cihazlarının test performansını 6 sigma metodolojisi ile değerlendirmeyi amaçladık.

**Yöntem:** Çalışmaya acil laboratuvarında Siemens RAPIDpoint 500e kan gazı cihazlarında analiz edilen pH, pO<sub>2</sub>, pCO<sub>2</sub>, glukoz, laktat, iyonize Ca, Na, K ve CI parametreleri dahil edildi. Sigma metrik hesaplamasında TEa (toplam izin verilebilir hata) oranlarında RiliBAK (Alman Kalite Rehberi) tarafından belirlenen değerler kullanılmıştır. Kötü performans gösteren testlerin hata nedenleri kalite hedef indeksi (QGI) ile değerlendirildi.

**Bulgular:** Sonuçlara bakıldığında Cihaz I'de PCO<sub>2</sub> (Seviye 2), Cihaz II'de Laktat (Seviye 1-2) ve Cihaz III'de pCO<sub>2</sub> (Seviye 1-2) sigma değerleri 4'ün altında olan testlerdir. Düşük performans sorunlarına baktığımızda ise Alet I pCO<sub>2</sub>'de hassasiyet (Seviye 2), Alet II laktatta doğruluk (Seviye 1-2) ve Alet III pCO<sub>2</sub>'de doğruluk (Seviye 1-2) tespit edilmiştir.

**Sonuç:** Bu çalışma, laboratuvar kan gazı test performansını çok yakından izlememizi sağladı. 6 sigma metodolojisi ile düşük performans gösteren testleri yakaladık ve bunların arkasındaki nedenleri araştırdık.

Anahtar Kelimeler: Kalite hedef indeksi, 6 Sigma, İzin verilen toplam hata, Westgard kuralı, Yanlılık

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aboratory specialists are required to monitor point of care (POCT) devices that perform medical measurements at the patient's bedside, in addition to their own medical devices, in terms of quality requirements. The most important of these is blood gas devices.Blood gas analysis has an important role in the evaluation of critical illnesses and in determining the etiology and severity of diseases. It is widely used to assess the patient's metabolic status, causes of impaired gas exchange, oxygenation and all metabolic functions.In addition to the importance of arterial blood gas in making a diagnosis, especially in emergency situations, blood gas evaluation is extremely important in monitoring the effectiveness of invasive and noninvasive mechanical ventilation applied in patients with respiratory failure, monitoring long-term oxygen therapy users, and evaluating early targeted treatment in patients with sepsis and septic shock (1-3).

Apart from the oxygenation-ventilation (pO<sub>2</sub>, SaO2, pH, pCO<sub>2</sub> and HCO3) parameters examined in the blood gas, tests (Glucose, Lactate, iCa, Na, K, Cl,...etc.) are nowadays being added in such a way that they almost look like biochemistry analysers and blood counting devices (4-6). These parameters can be analysed in a very small blood sample and in a very short period of time, saving the clinician a great deal of time and enabling early diagnosis and treatment.Nowadays, due to the high number of patients admitted to the emergency department, clinicians use blood gas test requests until the routine laboratory tests of the patients are concluded, making the operation of the emergency department faster. In this case, laboratory specialists should follow the device follow-up and responsibility even more seriously considering the increasing blood gas test requests.

Each laboratory maintain its own quality monitoring and performancemonitoring at the most basic level with internal quality control and external quality control programmes. In addition to these, measurement uncertainty, precision, bias and total analytical error measurements are other quality indicators of analytical performance (7). It is not possible to capture and demonstrate laboratory errors only with internal quality control (IQC) and eksternal quality assessment programs (EQAS). This leads us to the 6 Sigma methodology, which is one of the different quality strategies.6 Sigma is a data-driven quality management system for identifying and reducing errors and variations in clinical laboratory processes. 6 Sigma is the ultimate measure of all processes that can fit within 6 Standard Deviations (SD) ( $\pm$ 3SD) on either side of the mean (8,9). It is a uniform way of defining quality in terms of defects per million opportunities.6 Sigma performances represent 3.4 defects per million operations. It shows how close the 6 Sigma value is to the world standard quality value or deviates from perfection (10).

A high sigma level means that analytical errors are low and test results are acceptable, whereas a low sigma level is considered an error and reduces the reliability of the process. When the sigma value is low, the quality target index (QGI) should be calculated to determine the underlying causes and test-specific performance deficiencies (11).

In our study, we aimed to evaluate the test performance of blood gas devices in our hospital with 6 sigma methodology.

## **Materials and Methods**

The study included three Siemens RAPIDpoint 500e gas analysers in Ümraniye Training and Research Hospital's emergency laboratory. The pH, pO<sub>2</sub>, pCO<sub>2</sub>, glucose, lactate, ionised Ca, Na, K and Cl parameters in blood gases were used.

From the IQC data, %CV values for each level were calculated according to the formula below.

 $CV\% = SD/mean \times 100$ 

External control membership of the instruments belong to the Qualicont programme. Bias data were taken from one month external quality control report. Bias data were calculated according to the formula below.

Bias %= (mean of laboratories using the same instrument and method) - (laboratory result)/ mean of laboratories using the same instrument and method x 100

Total allowable error percentages (TEa%) are taken from the RILIBAK 2014 guidelines (12).

The sigma metric values for each parameters were calculated according to the following formula and are shown graphically in Figure 1 in the appendix (11).



Sigma $\Sigma(\sigma) = (TEa \% - Bias\%) / CV\%$ 

Defects defined in Sigma metrics are measured in percentage defects or defects per million (DPM: defects per million). 1 Sigma represents 690,000 defects/million reports. 2 Sigma represents 308,000 defects/million reports. 3 Sigma represents 66,800 defects/million reports. 4 Sigma represents 6,210 defects/million reports. 5 Sigma represents 230 defects/million reports. 6 Sigma represents 3.4 defects/million reports. Therefore, any process greater than 6 Sigma indicates a very low variability and error rate. Depending on the sigma obtained, the process is divided into the following categories (8-10).

- >6: World class performance
- 5-6 : Excellent
- 4-5 : Good
- 3-4 : Acceptable
- 2-3 : Poor
- <2 : Unacceptable

For analytes with sigma metric values of 4 and below, the QGI (quality goal index) value was calculated according to the formula below. QGI is calculated to identify the reasons for analytes deviating from accuracy and precision. QGI<0.8 indicates deviation from accuracy, QGI =0.8-1.2 indicates deviation from accuracy and deviation from precision, QGI>1.2 indicates deviation from accuracy (10).

 $QGI = Bias / (1.5 \times CV)$ 

## Results

The 1-month internal quality control two-level CVs of 3 different blood gas instruments in our emergency laboratory, bias values obtained from the external quality control report and 6 Sigma metric values calculated for each control level are given in Table 1(A-B) below. TEa percentages obtained from the RILIBAK 2014 guideline are also shown in the Table 1A.

Table 1A: Internal quality control CVs from 3 different blood gas devices and RILIBAK 2014 guideline TEa percentages.										
•	1	Instrument I			Instrument II			Instrument III		
Α	Level 1 CV	Level 2 CV	% bias	Level 1 CV	Level 2 CV	% bias	Level 1 CV	Level 2 CV	% bias	TEA %
рН	0,10	0,09	0,171	0,07	0,10	0,144	0,08	0,09	0,367	0,8
pO2	1,72	1,75	3,225	1,74	1,97	3,16	2,12	2,18	0,322	12
pCO2	2,51	2,72	1,364	2,29	2,13	0,455	2,25	2,47	10,908	12
Glucose	0,82	0,70	1,882	0,72	0,73	4,441	0,91	0,64	2,861	15
Lactate	3,25	3,45	2,793	3,20	3,15	8,382	3,20	3,12	2,058	18
iCa	1,10	1,48	2,173	1,13	0,94	6,521	1,05	0,71	2,173	15
Na	0,52	0,67	1,528	0,76	0,64	0,063	0,59	0,64	1,591	5
к	0,34	0,35	1,432	0,37	0,33	0,158	0,55	0,70	1,433	8
CI	0,38	0,61	1,638	0,38	0,80	1,638	0,39	0,49	0,82	8

Table 1B: 6 Sigma metric calculations and performance results									
6	Instru	ment l	Instrument II		Instrun	nent III			
В	Level 1 CV	Level 2 CV	Level 1 CV	Level 2 CV	Level 1 CV	level 2 CV			
рН	6,51	6,87	10,08	6,79	5,45	4,70			
pO2	5,10	5,01	5,08	4,49	5,51	5,36		6 Sigma Metric	
pCO2	4,24	3,91	5,04	5,42	0,49	0,44		values	
Glucose	15,96	18,65	14,58	14,53	13,36	18,83		>6	
Lactate	4,68	4,41	3,01	3,05	4,98	5,11		5 - 6	
iCa	11,67	8,66	7,48	9,05	12,20	18,08		4 - 5	
Na	6,65	5,15	6,50	7,76	5,78	5,33		3 - 4	
к	19,28	18,62	21,25	23,89	11,86	9,34		2-3	
сі	16,83	10,49	16,83	7,98	18,55	14,68		<2	

When we look at the 6 Sigma metric values of the parameters from the Instrument I blood gas anaylser in our emergency laboratory, the parameters that resulted as >6 are pH (Level 1-2), Glucose (Level 1-2), iCa (Level 1-2), Na (Level 1-2), K (Level 1-2) and Cl (Level 1-2), respectively. Parameters with a 6 Sigma metric value between 5-6 are pO<sub>2</sub> (Level 1-2) and Na (Level2), respectively. Parameters with a 6 Sigma metric value between 4-5 are pCO<sub>2</sub> (Level 1) and Lactate (Level 1-2), respectively. Parameters with a 6 Sigma metric value between 3-4 are pCO<sub>2</sub> (Level 2). There are no parameters with a 6 Sigma metric value of 2-3 and <2. (Table 1.B).

When we look at the 6 Sigma metric values of the parameters from the instrument II blood gas analyser, the parameters that resulted as >6 were pH (Level 1-2), Glucose (Level 1-2), iCa (Level 1-2), Na (Level 1-2), K (Level 1-2) and Cl (Level 1-2), respectively.Parameters with a 6 Sigma metric value between 5-6 are pO<sub>2</sub> (Level 1) and pCO<sub>2</sub> (Level 1-2), respectively. Parameters with a 6 Sigma metric value between 4-5 are pO<sub>2</sub> (Level 2). Parameters with a 6 Sigma metric value between 3-4 are Lactate

(Level 1-2). There are no parameters with a 6 Sigma metric value of 2-3 and <2 (Table 1.B).

When we look at the 6 Sigma metric values of the parameters from the instrument III blood gas analyser, the parameters that resulted as >6 were Glucose (Level 1-2), iCa (Level 1-2), K (Level 1-2) and Cl (Level 1-2), respectively. Parameters with 6 Sigma metric values between 5-6 are pH (Level 1), pO<sub>2</sub> (Level 1-2), Lactate (Level 2) and Na (Level 1-2). Parameters with 6 Sigma metric values between 4-5 are pH (Level 2) and Lactate (Level 1). There are no parameters with a 6 Sigma metric value of 3-4 and 2-3. Parameters with a 6 Sigma metric value <2 are pCO<sub>2</sub> (Level 1-2) (Table 1.B).

The 6 Sigma Method decision graphs of the parameters whose metric values were calculated are shown in Figure 2 (A-B-C-D-E-F) below. In Instrument I, 94% of the tests resulted in sigma metric values above 4. In Intrument II, 88.8% of the tests resulted in sigma metric values above 4 and in Intrument III, 88.8% of the tests resulted in sigma metric values above 4 (Table 3).



Figure 2. 6 Sigma Method Decision Graph.

A: Instrument I Level 1 Sigma calculations, B: Instrument I Level 2 Sigma calculations, C: Instrument II Level 1 Sigma calculations, D Instrument II Level 2 Sigma calculations, E: Instrument III Level 1 Sigma calculations, F: Instrument III Level 2 Sigma calculations

Table 2: QGI values for analytes with Sigma metric values of 4 and below for all 3 instruments and reasons for poor performance and recommended Westgard rules.													
Sigma Value				Value					Q	GI			
Test		I		1	I			I	1	I	ш		
	L1	L2	L1	L2	L1	L2	L1	L2	L1	L2	L1	L2	
pCO2		3,91			0,49	0,44		0,33			3,23	2,95	
Lactate			3,01	3,05					1,75	1,77			
		a	n		n			n	n				

Recommended Westgard Rules
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		poor performance result				
Test	I	Ш	Ш			
pCO2	Level 2 precision		Level 1 ve 2 accuracy			
Lactate		Level 1 ve 2 accuracy				

<b>Table 3 :</b> Blood gas instruments performance chart, Number of defects (%)								
	none	precision	accuracy	both				
Instrument I	17 (94.4%)	1 (5.5%)	0	0				
Instrument II	16 (88.8%)	0	2 (11.1%)	0				
Instrument III	16 (88.8%)	0	2 (11.1%)	0				

For tests with sigma metric values below 4, QGI values were calculated and the reason for the poor performance was shown.  $PCO_2$  (Level 2) in Instrument I, Lactate (Level 1-2) in Instrument II and  $pCO_2$  (Level 1-2) in Instrument III are the ones with sigma values below 4. Instrument I  $pCO_2$  (Level 2) deviates from precision, Device II lactate (Level 1-2) deviates from accuracy and Device III  $pCO_2$  (Level 1-2) deviates from accuracy (Table 2).

However, the recommended Westgard Sigma rules are also specified (Table 2).

## Discussion

Sigma metrics is an improvement method that focuses on reducing variability in laboratory results. Unlike the traditional total quality management model, the six sigma model advocates five steps. These five steps are define, measure, analyze, improve and control (DMAIC: define, measure, analyze, improve and control). 6 Sigma is an excellent tool for estimating and comparing measurement and instrument quality and is a pointer for tests that require minimum quality control rules to monitor the performance of the method. Based on the sigma values obtained, quality control can be adapted as follows (9,13,14):

**1.**> $6\sigma$  (Excellent performance): IQC (internal quality control) can be run once a day and one level (alternating levels) and is followed by the 13.5s rule.

**2.** 4σ-6σ (fit for purpose): IQC can be run once a day and two levels at a time. The single IQC rule is followed.

**3.**  $3\sigma$ - $4\sigma$  (Poor performers): IQC can be run twice a day and two levels at a time and is followed using multiple rules.

**4.**<3σ (Problematic): IQC must be run three times a day with three levels. The test can be run repeatedly and should use the maximum IQC rule.

As this classification suggests, analytes with >6 sigma require very few quality control rules to monitor method performance. If the sigma is <3 or shows a wide variation between the two levels, it is imperative to closely monitor and even modify the method using multiple quality control rules (15).

In our Emergency Laboratory, the levels of pCO2 (Level 2) in Instrument I, Lactate (Level 1-2) in Instrument II and pCO<sub>2</sub> (Level 1-2) in Instrument III, which resulted in a sigma value <4 in blood gases, have started to be monitored more closely and have been put under monitoring. For the test where we scored low sigma value in Instrument III pCO<sub>2</sub> (Level 1-2), corrective preventive action was initiated to investigate the factor affecting the test performance and to find the root cause. calibration frequencies were increased to reduce bias or in-service training of employees was renewed to reduce CV. For instrument-related errors, issues such as review of temperature, humidity and optical parts, proper preparation of kit/control material, kit expiry date monitoring were taken into consideration. The number of daily control runs was ensured to be more in line with quality control procedures.

In diseases requiring intensive care, intensive monitoring such as arterial blood gas is needed to detect acute and life-threatening changes in condition, to initiate treatment interventions and to evaluate the response to treatment. In daily practice, blood gas measurement is widely used to assess the patient's metabolic status, causes of impaired gas exchange, severity, oxygenation and all metabolic functions. Blood gas analysis provides direct measurement of pH, partial pressure of oxygen  $(pO_2)$  and partial pressure of carbon dioxide  $(pCO_2)$  in arterial blood. In addition to these; other calculated parameters such as total hemoglobin concentration, oxyhemoglobin, carboxyhemoglobin and methemoglobin saturation, anion gap, base deficiency, base excess and bicarbonate can be used clinically (4,5,6).

Blood gas instruments are bedside testing instruments that require close laboratory attention. They are urgent laboratory equipment that usually require urgent results and whose results are of high importance for the patient and help the clinician to initiate preliminary diagnosis and treatment until the patient's routine tests are completed. Laboratory specialists need to personally monitor both the preanalytical and analytical phases. The responsibility for the performance and efficiency of the instruments also rests with the laboratory specialist.

In the literature, 6 sigma metric studies have been carried out mainly in biochemistry tests. V.Thomas et al and JS Koshy et al studies can be shown (10,15). Y.Ustundag et al. also performed sigma metric calculations in electrolyte tests which are common in blood gas and biochemistry instruments. They found the scores of Na and K tests in the blood gas instrument between 5-6 and the score of Cl test between 4-5. Y.Ustundag et all use the target values from the SEKK (EQA programme of the Czech Republic) guidelines, whose TEa % used in the sigma score is wider than that of RILIBAK (16). In our study, we used the RILIBAK guideline which contains a narrower target value. In our study, we calculated K and Cl test scores above 6 in all 3 instruments. Na test scores were level 1 in device I and both level scores were above 6 in instrument II. Instrument I Level 2 and instrument III scored between 5-6 at both levels. Xia Y. et al. also calculated scores from some parameters (pH, PO2 and PCO2) in blood gas in their study. pH test scored between 5-6, pCO2 between 3-4 and PO2 below 2 (17). In our study, we scored below 2 in PCO2 test only in instrument III like Xia Y. et al. In other instruments, it was generally scored between 5-6.

There is no blood gas 6 sigma scoring study in which the number of tests is more comprehensive and the emergency laboratory is examined in more than one device as in our study.

The limitation of this study is that the sigma metric calculation of the instruments within a period of 1 month. The reason for this is that the internal control samples of the instruments are selected in periods when there are few lot changes and the external quality control results are selected in periods when there are no deviations or warnings. In future studies, laboratories are recommended to perform new calculations by increasing the study period.

## Conclusion

Blood gas instruments are easier to use and give faster results than other laboratory devices. The laboratory specialist's approach to these devices should not be like the devices used in other laboratories. When we look at the tests that we stay within the limits of internal quality control and external quality control, which we normally think everything is going well, with 6 Sigma Methodology, we see our device performance more clearly. With 6 Sigma, we have been able to further improve test performance by implementing corrective and preventive actions such as changes in quality control rules, maintenance or changes in the technical equipment of the device, and control of preanalytical factors. This study has allowed us to monitor laboratory blood gas testing performance very closely.

## **Declarations**

## Funding

This study had no external funding.

## **Conflicts Of Interest**

The authors declare that they have no conflicts of interest.

## **Ethics Approval**

This study was approved by the Ethical Committee for Istanbul Health Sciences University Umraniye Training and Research Hospital, with the assigned decision no: 363 and date: 17.10.2024.

## Availability Of Data And Material

Data are available from medical records.

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Temel Onkoloji / Basic Oncology

# Effects of White and Black Garlic Extracts an Multiple Cancer Cells and Fibroblast Cells After Irradiation

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### ABSTRACT

**Purpose:** Garlic, is one of the oldest cultivated plants in the Liliaceae family. It has been used as a medicine for thousands of years. White and black garlic contain a variety of beneficial minerals, vitamins and many other substances used for human health. It is also used to treat a wide range of diseases including blood pressure and cholesterol, cancer, antiinflammatory, antioxidant, wound healing, asthma, arthritis, chronic fever, tuberculosis, rhinitis, malaria, severe skin diseases, digestive disorders, diabetes, kidney stones, anemia, jaundice and epilepsy. The aim was to investigate the effects of garlic extract on irradiated colon cancer, neuroblastoma cancer cells and fibroblasts.

**Methods:** In the study, colon, brain cancer, and fibroblast cells were replicated in a culture environment and treated for 24 hours with white garlic and fermented black garlic extracts. Cell viability was determined using the 3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide (MTT) test. All results were statistically analyzed with GraphPad Prism (Version 8.0.3).

**Results:** According to the results, the determined doses of garlics were treated with 24-hour garlic doses, after which the cells were first given 2 Gray radiation doses for combined radiation therapy. The MTT test determined cell vitality and evaluated the results through statistical analysis.

**Conclusion:** According to our study, we have concluded that white garlic has a protective effect on radiation damage, while black garlic increases cancer cell death.

Keywords: white and black garlic extract, cancer cells and fibroblast cells, irradiation

#### ÖZET

**Amaç:** Sarımsak, Liliaceae ailesindeki en eski yetiştirilen bitkilerden biridir ve binlerce yıldır tıbbi amaçlarla kullanılmaktadır. Beyaz ve siyah sarımsak, insan sağlığı için faydalı olan birçok mineral, vitamin ve diğer bileşenleri içermektedir. Kan basıncı ve kolesterol, kanser, anti-enflamatuvar, antioksidan, yara iyileşmesi, astım, artrit, kronik ateş, tüberküloz, rinit, sıtma, ciddi cilt hastalıkları, sindirim sistemi bozuklukları, diyabet, böbrek taşı, anemi, sarılık ve epilepsi gibi birçok hastalığın tedavisinde kullanılmaktadır. Bu çalışmanın amacı, sarımsak ekstraktlarının ışınlanmış kolon kanseri, nöroblastoma kanser hücreleri ve fibroblastlar üzerindeki etkilerini araştırmaktır.

**Yöntemler:** Çalışmada, kolon, beyin kanseri ve fibroblast hücreleri kültür ortamında çoğaltılmış ve beyaz sarımsak ile fermente siyah sarımsak ekstraktlarıyla 24 saat boyunca muamele edilmiştir. Hücre canlılığı, 3-(4,5-dimetiltiazol-2-il)-2,5-difeniltetrazolyum bromid (MTT) testi kullanılarak belirlenmiştir. Tüm sonuçlar GraphPad Prism (Sürüm 8.0.3) ile istatistiksel olarak analiz edilmiştir.

**Bulgular:** Sonuçlara göre, belirlenen sarımsak dozlarıyla 24 saatlik bir muamele sonrası hücrelere 2 Gray radyasyon dozu uygulanmıştır. Kombine radyoterapi uygulaması sonrası MTT testi ile hücre canlılığı ölçülmüş ve sonuçlar istatistiksel olarak değerlendirilmiştir.

**Sonuç:** Çalışmamıza göre, beyaz sarımsağın radyasyon hasarına karşı koruyucu bir etkisi olduğu, siyah sarımsağın ise kanser hücrelerinin ölümünü artırdığı sonucuna varılmıştır.

Anahtar Kelimeler: beyaz ve siyah sarımsak ekstraktı, kanser hücreleri ve fibroblast hücreleri, ışınlama

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Received: 19.12.2024 Accepted: 31.01.2025

he vegetable plant garlic is a member of the Alliaceae family. Garlic is a common spice with numerous health benefits primarily due to its various bioactive compounds such as organic sulfides, flavanoids and polysaccharides (1-4). Because of its many health-promoting qualities, garlic has been utilized in traditional medicine throughout history and across the globe (3, 5, 6). Garlic is a perennial plant that grows in both warm and temperate climatic zones (7, 8). It is one of the most commonly used herbal treatments. When you look at cancer and its side effects, vitamin C and potassium appear to be at the forefront. There are some herbal products and plants that contain the most of these substances and are used as alternatives to cancer treatment. Among them are propolis, garlic, curcumin, and rosehip (9). Scientific studies have identified a variety of health benefits, such as immunomodulatory, liver-protective, kidney-protective, anti-allergic, antioxidant, and anti-cancer properties (10-15). Numerous studies conducted in the last few decades have uncovered its amazing biological properties, which include anti-bacterial, anti-inflammatory, anti-cancer, antioxidant, immunity-boosting, anti-diabetic, and antiobesity qualities (3). Research on black garlic, a derivative of garlic that has more flavonoids and stronger antioxidant qualities than fresh garlic, has been increasing (3).

Cancer ranks as one of the foremost causes of mortality worldwide. For many cancer forms, cancer therapy remains a problem despite scientific advancements. Patients who get chemotherapy frequently have unpleasant side effects that lower their quality of life. It frequently has an impact on the decline in health as well. Scientists have been studying the role of flavonoids, primarily antioxidants, found in plants in order to find innovative and efficient ways to promote anticancer therapy, particularly with regard to minimizing side effects. To discover novel compounds with anti-cancer qualities and therapeutic potential, extensive research is being done. The development of cancer can be influenced by both internal and external factors. A significant contributor to cancer is the impact of free radicals, including reactive oxygen species produced within the human body (8, 15). Chronic inflammation can lead to increased proliferation, and oxidative stress is frequently linked to neighboring cell alterations that foster the growth of cancer. Owing to this connection, black garlic's anti-inflammatory and antioxidant qualities also function as indirect anti-cancer defenses (8). While numerous epidemiological studies provide promising evidence regarding the role of garlic in the etiology of gastric cancer, the pharmacological mechanism by which garlic may inhibit gastric cancer is not yet clear. In our study, extracts prepared from geographically indicated Taşköprü garlic and fermented black garlic added to cancer cells medium cultured in vitro and the effects of radiation examined at the cellular level.

## **Material and Methods**

### Cell Culture

The ATCC CRL-2266 human neuroblastoma cell line and the HT29 human colon cancer cell line from Thermo Fisher Scientific were the cancer cell lines while the healthy cell line used in this investigation was the ATCC CRL-1459 fibroblast cell line. CRL-2266 and HT29 were selected as standard models for neuroblastoma and colon cancer, respectively, while CRL-1459 represented healthy cells to assess selective toxicity. These well-characterized cell lines ensure reliable and reproducible results, enabling a comprehensive evaluation of treatment effects on both cancerous and healthy cells. The cells came from a global cell bank that is widely utilized. The cells were cultured in RPMI 1640 medium enriched with 10% serum. The conditions of the cells' living environment are replicated in this culture media. Trypan blue staining was used to evaluate cell viability under a microscope. Conditions for conducting experiments were such that cell viability was greater than 95%.

### Preparation of Garlic Extracts

Commercially purchased Taşköprü garlic and black garlic were extracted by dissolving them in water or oil. The Lowry method was used for protein quantification in the extractions. Protein quantification was performed for standardization purposes, as each measurement group was expected to contain the same amount of protein content Measurements were taken according to the protocol of a commercial kit for protein quantification; samples containing 5, 10, 20, 30, 40, and 50 micrograms of protein were prepared. A review of the literature was carried out to establish the appropriate dosages of Taşköprü garlic and black garlic for use in the experiments (16, 17). To assess cytotoxicity in MTT cell viability experiments, both types of garlic were applied to cell lines at doses of 1 mg, 2.5 mg, 5 mg, and 7.5 mg for a duration of 24 hours. Based on the experimental results, a dose of 5 mg of garlic was decided upon for use.

### Treatment of Cells with Radiation

The cells were cultured in a medium to achieve >95% viability and a density of  $1 \times 10^6$  cells/ml. Initially, cell viability was assessed using the MTT method to determine the dose-dependent effect. Briefly,  $2 \times 10^4$  cells were seeded into each well of a 96-well plate, and cell viability was evaluated 24 hours after treatment with 1 mg, 2.5 mg, 5 mg, and 7.5 mg doses of black and white garlic extracts using the IC50 assay. Following the IC50 experiments, the effective dose was determined to be 5 mg.

To evaluate the effects of garlics and/or 2 Gy radiation, HT29, SH-SY5Y and CCD-18Co cells were treated with 5 mg of both black and white garlic extracts, followed by irradiation (Elekta Synergy, Swedish) with a 2 Gy dose of radiation 24 hours later. The 2 Gy radiation dose is the dose that triggers apoptosis in tumor cells (18, 19). The cell cycle returns to normal 24 hours after 2 Gy irradiation. Our examination was conducted 24 hours post-irradiation to investigate normal cell damage. Cell viability was assessed using the MTT assay 24 hours after irradiation. The results were presented as the mean  $\pm$  SEM of four independent experiments.

#### Determination of Cell Viability

Cell proliferation was determined using the MTT method. The method is based on the reduction of the yellow tetrazolium salt to form purple formazan crystals by metabolically active cells. Living cells contain oxidoreductase enzymes that reduce MTT to formazan, which is insoluble in aqueous solutions. Formazan crystals were dissolved in a solubilization solution, and

the absorbance of the resulting colored solution was measured at 540 nm using a spectrophotometer.

### Statistical Analysis

In this study, the statistical analysis of the data was performed using the GraphPad (GraphPad Software, 8.0 Version, Boston, USA) statistical analysis tool. Two-way ANOVA (analysis of variance) is an analytical technique that allows the simultaneous evaluation of two or more factors that have an effect on the dependent variable. This analysis was applied to assess the statistical significance between experiment groups by evaluating the interaction between factors. To perform group comparisons, a nonparametric test was conducted, followed by a Two-way ANOVA test and Post Hoc Tukey's multiple comparison analysis.

## Results

## IC50 dose determination experiments of white and black garlic on neuroblastoma, colorectal cancer and fibroblast cells

Initially, to determine the dose-dependent effect, cell proliferation was determined 24 hours later in cells treated with extracts at doses of 1 mg, 2.5 mg, 5 mg, and 7.5 mg using the MTT assay. Cell proliferation assay results are shown in Fig1. and Fig2.

According to the experimental results, the 5 mg dose was determined to have the best effect, and a 5 mg dose was used for both black and white garlic in all experiments (Fig1 and Fig2).



**Figure 1:** The IC50 values of white garlic in inhibiting the proliferation of SH-SY5Y, HT29, and CCD-18Co cells were determined. Results are presented as the mean ± SEM of four independent experiments (White garlic concentrations: 1 mg, 2.5 mg, 5 mg, and 7.5 mg; Black garlic concentrations: 1 mg, 2.5 mg, 5 mg, and 7.5 mg)



**Figure 2:** The IC50 values of black garlic in inhibiting the proliferation of SH-SY5Y, HT29, and CCD-18Co cells were determined. Results are presented as the mean±SEM of four independent experiments (White garlic concentrations: 1 mg, 2.5 mg, 5 mg, and 7.5 mg; Black garlic concentrations: 1 mg, 2.5 mg, 5 mg, and 7.5 mg).



**Figure 3:** Determination of the cell proliferation data in SH-SY5Y, CDD-18Co, and HT29 cells. The MTT assay is used to determine the IC50 dose of white and black garlic. Cells were incubated with 1 mg, 2.5 mg, 5 mg, and 7.5 mg of white and black garlic for 24 hours (Abbreviations: **G:** white garlic; **BG:** Black garlic).

The effects of white and black garlic on cell proliferation in each cell line are shown comparatively according to increasing doses (Fig3).

In all cell lines, the most effective dose of white garlic was observed to be 5 mg (p<0.05). Similarly, although not statistically significant, the 5 mg dose of black garlic generally showed an inhibitory effect in CCD-18Co, HT29, and SH-SY5Y cells (p<0.05) (Fig 3). Based on these results, a 5 mg dose was used in combination treatments with radiation in all cell lines.

# The protective effect of white garlic (GE) on neuroblastoma, intestinal cancer, and fibroblast cells

The cells treated with 5 mg of white garlic extract for 24 hours. They were then irradiated with a 2 Gy dose of radiation, while no radiation was applied to the 1st and 2nd group cells. The effect of garlic was determined based on the results obtained from the MTT assay 24 hours later. White garlic caused a decrease in the proliferation of the HT29 cell line both alone and in combination with radiation (p<0.05). Similarly, white garlic significantly

inhibited proliferation in SH-SY5Y neuroblastoma cells (p<0.05). In healthy fibroblast cell lines used as a control, a 2 Gy radiation dose also significantly reduced viable cells (p<0,001) (Fig4). Overall, when cells were treated with white garlic in combination with radiation, an effect on cell proliferation was observed.







**Figure 4:** The effect of radiation in combination with white garlic on SH-SY5Y, CDD-18Co, and HT29 cells. The MTT assay demonstrates the combined effect of white garlic with radiation. Cells were incubated with 5 mg of white garlic for 24 hours followed by incubation with a 2 Gray radiation dose for an additional 24 hours (Abbreviations: GE, white garlic extract; IR, ionizing radiation)







**Figure 5:** The effect of irradiation in combination with black garlic on SH-SY5Y, CDD-18Co, and HT29 cells. The MTT assay demonstrates the combined effect of black garlic with irradiation. Cells were incubated with 5 mg of white garlic for 24 hours followed by incubation with a 2 Gray irradiation dose for an additional 24 hours (Abbreviations: BGE, black garlic extract; IR, ionizing radiation).

# The combined inhibitory effect of radiation and black garlic extract (BGE) on cancer cell death

Black garlic was found to exhibit inhibitory effects across all cell lines (p>0.05). However, when black garlic was combined with a 2 Gy radiation dose, it was observed to reduce cell survival more significantly in all groups. This combination effect was more pronounced in HT29 cells, while it was less noticeable in brain cells (p<0.05).

## Discussion

In this study, we aimed to compare the effects of white and black garlic on irradiated cancer and normal cells. Our findings suggest that white garlic offers protective effects, while black garlic seems to exacerbate damage. A study conducted on MCF-7 and MDA-MB-361 cell lines demonstrated that mature black garlic extract suppressed the proliferation, migration, invasion, and metastasis of ER+ breast cancer cells (20). It was also proposed that black garlic suppresses the production of anti-apoptotic proteins MCL-1 and BCL-2, inducing apoptosis in ER+ breast cancer cells. The increase in reactive oxygen species (ROS) in cancer cells leads to the activation of JNK, which in turn reduces MCL-1 expression (20).

In our study, black garlic alone demonstrated the most significant dose-dependent reduction in cell viability in SH-SY5Y cell lines, indicating its inhibitory effect on cancer cell proliferation. Park et al. (21) reported that hexane extract from mature black garlic induces apoptosis in human leukemia cells (U937) through both intrinsic and extrinsic caspase-dependent apoptotic pathways. The application of aged black garlic extract (ABGE) also shows promising therapeutic potential in colon cancer treatment. A study by Dong et al. found that ABGE inhibited proliferation and triggered apoptosis in HT29 colon cancer cells (22). In our study, the combined effect of 5 mg black garlic and/or radiation had the most significant impact on HT29 colorectal cancer cell lines. This anticancer effect may be linked to the regulation of the PI3K/Akt signaling pathway, which involves an increase in PTEN expression and a decrease in Akt and p-Akt levels (22). Another study examined the effect of matured black garlic extract on colon cancer models induced by 1,2-dimethylhydrazine (DMH) in mice and found that it inhibited cell proliferation by reducing cyclin B1 and cdk1 expression, which was associated with the suppression of NF-KB activity (23). In our study, 5 mg white garlic also exhibited inhibitory effects on HT29 and SH-SY5Y cell lines.

Another bioactive compound found in black garlic, S-Allyl-Mercapto-Cysteine (SAMC), has shown health-promoting properties. Studies by Zhang et al. (24) have demonstrated that SAMC induces apoptosis in the SW620 human colon cancer cell line via the JNK and p38 pathways, activating Bax and p53. Black garlic extract (BGE) has also been suggested to sensitize Lewis lung cancer cells to ionizing radiation, potentially through alterations in the cell cycle and modulation of Bax and BcL-2 expressions (20). Choromanska et al. assessed the toxic effects of diallyl disulfide (DADS) and garlic oil on glioma cells. Their findings revealed that DADS did not induce cytotoxicity in SW1783 and SW1088 glioma cell lines (25). Aged black garlic has been reported to protect against damage caused by ionizing radiation or toxic substances (26). A study by Kim et al. showed that black garlic extract did not exhibit cytotoxic effects when applied to RAW264.7 and RBL-2H3 cells (11).

In our study, both 5 mg of white and black garlic reduced cell viability in cancer cell lines. When a 2 Gy radiation dose was added, there was a significant decrease in cell viability. However, when 2 Gy radiation was applied alone in all cell lines, a greater reduction in cell viability was observed. Comparing all results, white garlic showed the greatest effect, while black garlic also exhibited a protective role. These findings suggest that garlic plays an important role in cancer treatment, especially when combined with radiation, and warrant further investigation.

## Conclusion

In this study, black garlic exhibited inhibitory effects across all cell lines, and when combined with a 2 Gy radiation dose, it reduced cell survival in all groups. However, the effect was less pronounced in brain cells. These findings suggest that while black garlic combined with radiation contributes to increased damage in cancer cells, its impact varies depending on the cell type. As a result of these results highlight the potential therapeutic value of white garlic and suggest that further studies are needed to better understand the mechanisms involved and the possible clinical applications of black garlic in combination with radiation therapy.

## Declarations

### Funding

The authors declare they have no financial interests.

#### Conflicts of Interest

No potential conflict of interest relevant to this article was reported.

#### **Ethics** Approva

No ethical approval is required.

### Data Availability Statement

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

### **Author Contributions**

Zehra Kanlı: Methodology, Performed the experiments, Analyzed the results, prepared figures, and conducted the Project. Hülya Cabadak, İlknur Alsan Çetin, Zehra Kanlı, Banu Aydın: Interpretation of data for the study. Banu Aydın; Supervision, Project administration, Methodology, Designed experiments, funding acquisition, conducted the project, all authors approved the final manuscript.

#### Acknowledgments

We thank İlknur Öztürk for her assistance in providing us with Taşköprü garlic.

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Temel Onkoloji / Basic Oncology

# Evaluation of SIRT1-Regulating miRNAs in Breast Cancer: miR-9, miR-34a, and miR-132 Expression Analysis

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## ABSTRACT

**Purpose:** Breast cancer is one of the most common malignancy for women and one of the most common causes of cancer related deaths for women. Genetic factors and family history play major roles in its etiology. For a possible genetic treatment genetic pathway should be illuminated.

Materials and Methods: The miRNeasy Mini Kit was used to isolate total RNA from tissues and normal breast tissues in patients with breast cancer who underwent mastectomy for treatment. Expression levels of miRNAs were measured and normalized with U6 gene.

**Results:** After measurement of expression levels, normalizing with U6 gene and statistical analysis, we found that there was no statistically significant difference between breast cancer tissues and normal breast tissues.

**Conclusion:** Limited number of studies reported that the levels of all three micro RNAs were found to be lower in breast cancer tissues than in normal breast tissue. In this study, no statistically significant difference was found between normal breast tissue and breast cancer tissues in terms of levels of these micro RNAs for all three micro RNAs.

Since there is conflicting and incomplete information about the SIRT1 enzyme in the literature, it is not unexpected that the results of our study are incompatible with the literature. Further studies are needed to clearly elucidate the mechanisms of SIRT1 and its regulating micro-RNAs.

In the studies to be done, the determination of the microRNA levels simultaneously with SIRT1's own expression levels can be enlightening on this issue.

Keywords: Breast Neoplasms, Sirtuin 1, MicroRNAs, MicroRNA-9, MicroRNA-34a, MicroRNA-132

#### ÖZET

**Amaç:** Meme kanseri kadınlarda en sık görülen malignitelerden biridir ve kadınlarda kansere bağlı ölümlerin en sık nedenlerinden biridir. Etiyolojisinde genetik faktörler ve aile öyküsü önemli rol oynamaktadır. Olası bir genetik tedavi için genetik yolun aydınlatılması gerekmektedir.

Gereç ve Yöntem: MiRNeasy Mini Kit, mastektomi yapılan meme kanseri tanılı hastaların kanserli dokularından ve normal meme dokularından total RNA'nın izole edilmesi için kullanıldı. MiRNA'ların ekspresyon seviyeleri ölçüldü ve UG geni ile normalize edildi.

Bulgular: Ekspresyon düzeylerinin ölçümü, U6 geni ile normalizasyon ve istatistiksel analiz sonrasında meme kanseri dokuları ile normal meme dokuları arasında istatistiksel olarak anlamlı bir fark olmadığı tespit edildi.

Tartışma: Sınırlı sayıda çalışma, her üç miRNA'nın da meme kanseri dokularında normal meme dokusuna göre daha düşük düzeyde bulunduğunu bildirmiştir. Bu çalışmada normal meme dokusu ile meme kanseri dokuları arasında her üç mikro RNA için de bu mikro RNA'ların düzeyleri açısından istatistiksel olarak anlamlı bir fark bulunamadı.

Literatürde SIRT1 enzimi ile ilgili çelişkili ve eksik bilgilerin olması nedeni ile çalışmamızın sonuçlarının literatürle uyumsuz olması beklenmedik değildir. SIRT1'in mekanizmalarını ve düzenleyici micro RNA'larını net bir şekilde aydınlatmak için daha ileri çalışmalara ihtiyaç vardır.

Yapılacak çalışmalarda SIRT1'in kendi ekspresyon seviyeleri ile eş zamanlı olarak microRNA seviyelerinin belirlenmesi bu konuda aydınlatıcı olabilir.

Anahtar Kelimeler: Meme Neoplazmları, Sirtuin 1, MicroRNA, MicroRNA-9, MicroRNA-34a, MicroRNA-132

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Received: 27.09.2024 Accepted: 28.01.2025 B reast cancer is one of the most common malignancy for women and one of the most common causes of cancer related deaths for women. Every year more than 1 million new cases are diagnosed with breast cancer in the world, and the second most common cause of cancer-related deaths in women is breast cancer (1).

Although there are new treatment approaches, it is still an important health problem because of its increasing incidence. Breast cancer is a multifactorial disease that many factors are playing roles in its etiology. Genetic factors and family history play major roles in its etiology. For a possible genetic treatment genetic pathway should be illuminated.

One of the worthwhile processes in the treatment of breast cancer is to reveal the effects of SIRT1, a member of the class III HDAC (histone deacetylase family), and the effects of miRNAs (micro-RNAs) involved in the regulation of this enzyme.

miRNAs are approximately 23 nt RNAs that do not code, and they show their effects by suppressing the translation or rendering target mRNAs unstable. miRNAs play an active role in many important processes such as proliferation, differentiation, apoptosis.

SIRT1 is known to play a key role in many physiological processes such as genome stability, metabolism, cell survival, and neurogenesis.

Deacetylase function of SIRT1 is thought to be associated with prolongation of survival in mammals. Because of this property, this protein is thought to act as a tumor promoter in the development of many cancers.

SIRT1 has been shown to be significantly higher in human prostate cancer (2), acute myeloid leukemia (3) and primary colon cancer (4). It is claimed that SIRT1 is high in such cancer tissues and it is the tumor promoter (5). In another study, SIRT1 has been shown to be found in lower rates in some cancer tissues such as glioblastoma, gallbladder cancer, prostate cancer and ovarian cancer compared to normal tissues (6). Again in this study, in the analysis of 44 breast cancer cases lower SIRT1 expression was found in cancerous tissues compared to normal tissues (6).

A comparison study of tumor and normal tissues of breast cancer patients between 2007 and 2008, has shown that there was a strong correlation between SIRT1 and Ki67 (Antigen Kiel 67), and at the inhibition of SIRT1 by sirtinol, there was a dramatic decline at the levels of life extruder bcl-2 (B-cell lymphoma 2) proteins in cancer tissue. These results make us to think that inhibition of SIRT1 can be used as a strategy in the chemotherapy of breast cancer. The results of RT-PCR (reverse transcription polymerase chain reaction) indicate that SIRT1 miRNA levels were found to be higher in tumor tissues than normal tissues. (92.59%, n=27) (7).

Many studies have investigated the relationship of various micro RNAs with SIRT1. So far, more than sixteen micro-RNAs have been thought to be associated with breast cancer, and studies have been conducted to support this. These miRNAs are miRNA-449a, miRNA-449, miRNA-22, miRNA-200a, miRNA-34a, miRNA-143/145, miRNA-217, miRNA-195, miRNA-199a, miRNA-132, miRNA-181c miRNA-9, miRNA-93, miRNA-181a/b, miRNA-204, miRNA-199b, miRNA-15a, miRNA-100 (8).

There were very few studies on the levels of miRNA-9, miRNA-34a and miRNA132 in breast cancer tissues, that's why we decided to investigate a possible relation between SIRT1 (Silent mating-type information regulation 2 homologue 1) and this miRNAs.

The aim of this study was to investigate the levels of SIRT1-related miRNAs in cancer tissues and normal breast tissues in patients with breast cancer who underwent mastectomy for treatment.

## **Material and Methods**

The miRNeasy Mini Kit (Qiagen GmbH, Hilden, Germany) was used to isolate total RNA (containing miRNA) from fresh tissue. Then, the cDNA (Complementary DNA) synthesis from miRNA was performed using the Qiagen miScript Reverse Transcription (RT) Kit II (Hilden, Germany).

The amounts of cDNA were adjusted to 50 ng /  $\mu$ l and made ready for use for qRT-PCR. cDNAs were stored at -80 ° C to extend the lifetime of them. The reaction components for qRT-PCR were then prepared using the Qiagen miScript SYBR Green PCR kit. The reaction components were prepared on ice and dispensed with

cDNAs into appropriate tubes and loaded onto the qRT-PCR Rotor-Gene Q (Qiagen) instrument and the reaction was carried out.

## Results

A total of 66 patients who underwent surgery for breast cancer in Gaziantep University Şahinbey Training and Research Hospital between 2012-2016 were included in the study. (Table 1 and Table 2) During the operation, samples from cancer tissues and normal breast tissues of these patients were taken and stored in nitrogen tanks and recorded. A total of 132 tissue samples were used in the study. Statistical analyses were performed using SPSS for Windows 26.0.

Table 1. Statistical information about patients							
	Female	Male					
Gender	66	-					
	Female	Male	All patients				
Average age	50.8	-	50.8				
	Invasive ductal carcinoma	Invasive lobular carcinoma	Other				
Histopathological diagnosis	56(84.8%)	7(10.6%)	3(4.5%)				
	Estrogen (+)	Progesterone (+)	c-erb b2 (+)				
Receptor	50 (75.7%)	49 (74.2%)	24 (36.3%)				
	Stage-1	Stage-2	Stage-3				
Disease stage	5 (7.5%)	31 (46.9)	30 (45.4)				

	Table 2. Pat	tients List (ER: estrogen receptor, PR: proges	terone receptor,	N: Negativ	e, P: Positive)	
	Age	Histopathological Diagnosis	Stage	ER	PR	C-ERB-B2
Patient-1	63	Metaplastic carcinoma	3	Ν	N	Ν
Patient-2	57	Invasive ductal carcinoma	1	Р	N	Ν
Patient-3	36	Invasive ductal carcinoma	2A	Р	N	N
Patient-4	44	Invasive ductal carcinoma	2A	Р	N	N
Patient-5	44	Invasive ductal carcinoma	2A	Р	N	N
Patient-6	44	Invasive ductal carcinoma	2A	Р	N	N
Patient-7	48	Invasive ductal carcinoma	2	Ν	Р	N
Patient-8	50	Invasive ductal carcinoma	2B	Р	Р	N
Patient-9	62	Invasive ductal carcinoma	2	Р	Р	N
Patient-10	57	Invasive ductal carcinoma	2A	Р	Р	N
Patient-11	62	Invasive ductal carcinoma	2	Р	Р	N
Patient-12	62	Invasive ductal carcinoma	2	Р	Р	N
Patient-13	55	Invasive ductal carcinoma	3A	Р	Р	N
Patient-14	66	Invasive ductal carcinoma	2B	P	Р	N
Patient-15	35	Invasive ductal carcinoma	2B	P	Р	N
Patient-16	47	Invasive ductal carcinoma	2	P	Р	N
Patient-17	59	Invasive ductal carcinoma	1	Р	Р	N
Patient-18	44	Invasive ductal carcinoma	2	P	Р	<u>N</u>
Patient-19	42	Invasive ductal carcinoma	3A	<u>Р</u>	Р	N
Patient-20	42	Invasive ductal carcinoma	3A	P	Р	N
Patient-21	65	Invasive ductal carcinoma	2B	P	Р	<u>N</u>
Patient-22	59	Invasive ductal carcinoma	3	P	Р	N
Patient-23	49	Invasive ductal carcinoma	2B	P	Р	<u>N</u>
Patient-24	57	Invasive ductal carcinoma	3	P	Р	<u>N</u>
Patient-25	42	Invasive ductal carcinoma	2	P	P	N
Patient-26	44	Invasive ductal carcinoma	3B	Р	Р	N
Patient-27	44	Invasive ductal carcinoma	3B	P	Р	N
Patient-28	44	Invasive ductal carcinoma	3B	Р	Р	N
Patient-29	44	Invasive ductal carcinoma	2	P	Р	<u>N</u>
Patient-30	44	Invasive ductal carcinoma	2	P	Р	N
Patient-31	38	Invasive ductal carcinoma	3	P	Р	N
Patient-32	42	Invasive ductal carcinoma	3	P	Р	<u>N</u>
Patient-33	42	Mixed (IDC + ILC)	2	P	Р	N
Patient-34	69	Invasive lobular carcinoma	2	P	P P	N
Patient-35	70	Invasive lobular carcinoma	2B	P	P P	<u>N</u>
Patient-36	67	Invasive lobular carcinoma	3	<u>Р</u> Р	P P	N N
Patient-37	56 56	Invasive lobular carcinoma	4 4	<u>Р</u>	P P	N
Patient-38 Patient-39	42	Invasive lobular carcinoma Invasive lobular carcinoma	3	<u>Р</u>	P P	N
Patient-40	61	Mixed (IDC + ILC)	3	 P	P P	N
Patient-40	78	Invasive ductal carcinoma	1	P	P P	N
Patient-42	44	Invasive ductal carcinoma	3C	 N	N I	P
Patient-43	44	Invasive ductal carcinoma	3C	N	N I	P
Patient-44	38	Invasive ductal carcinoma	3B	N	N	P
Patient-45	48	Invasive ductal carcinoma	3	N		P
Patient-46	49	Invasive ductal carcinoma	3B	N	N I	P
Patient-47	48	Invasive ductal carcinoma	3	N	N N	P
Patient-48	51	Invasive ductal carcinoma	2A	N	N I	Р
Patient-49	48	Invasive ductal carcinoma	3	N	N	P
Patient-50	47	Invasive ductal carcinoma	2A	P	N	P
Patient-51	35	Invasive ductal carcinoma	3	P	N	P
Patient-52	52	Invasive ductal carcinoma	4	Ν	Р	Р
Patient-53	45	Invasive ductal carcinoma	2	N	P	P
Patient-54	45	Invasive ductal carcinoma	2	Ν	Р	Р
Patient-55	60	Invasive ductal carcinoma	3	Ν	Р	Р
Patient-56	60	Invasive ductal carcinoma	3	Ν	Р	Р
Patient-57	84	Invasive ductal carcinoma	3	Ν	Р	Р
Patient-58	45	Invasive ductal carcinoma	2	Р	P	P
Patient-59	44	Invasive ductal carcinoma	2B	Р	Р	Р
Patient-60	57	Invasive ductal carcinoma	3A	P	P	P
Patient-61	52	Invasive ductal carcinoma	1	P	P	Р
Patient-62	52	Invasive ductal carcinoma	1	P	P	P
Patient-63	62	Invasive ductal carcinoma	2	P	P	P
				-		
	34	Invasive ductal carcinoma	26	Р	Р	Р
Patient-64 Patient-65	34 34	Invasive ductal carcinoma Invasive ductal carcinoma	2b 2b	<u>Р</u> Р	P P	<u>Р</u> Р

## Findings for miRNA-132

For miRNA-132, level analysis was performed in 132 tissue samples from 66 patients. In 33 of 66 patients, miRNA-132 levels in tumor tissue decreased compared to normal tissue, remained unchanged in 11 patients and increased in 22 patients. The detected levels were normalized by proportioning to U6 (housekeeping gene). In normal and tumor tissue groups, miRNA-132 expression levels were compared with U6 expression level by 2- $\Delta$ Ct method and the fold change value was obtained for these genes. After normalization for both groups, the data were analyzed by Student's T Test. In the analysis, no statistically significant difference was found between breast cancer tissues and normal breast tissues in terms of miRNA-132 levels in 66 patients with breast cancer. (P=0.42) (Table 3 and Fig. 1)

Table 3. Comparison of miRNA-132 levels (normalized) in tumor   and normal tissues.						
T-TEST RESULTS OF NORMALIZED miRNA-132 LEVELS						
Normal Tissue Tumor Tiss						
Average	0.498871773	0.568772895				
Variance	2.310752339	6.014650874				
Observation	66	66				
Projected Average Difference	0					
Df	109					
t Stat	-0.196812861					
P(T<=t) one-tailed	0.422170247					



### Findings for miRNA-34A

For miRNA-34a, level analysis was performed on 132 tissue samples from 66 patients. In 20 of these 66 patients, miRNA-34a levels in tumor tissue decreased compared to normal tissue, remained unchanged in 16 patients and increased in 30 patients. The determined levels were normalized by proportioning to U6 level. In normal and tumor tissue groups, miRNA-34a expression levels were compared with U6 expression level by 2- $\Delta$ Ct method and a fold change value was obtained for these genes. After normalization for both groups, the data were analyzed by Student's T Test. In the analysis, no statistically significant difference was found between breast cancer tissues and normal breast tissues in terms of miRNA-34a levels in 66 patients with breast cancer. (P=0.39) (Table 4 and Fig. 2)

Table 4. Comparison of miRNA-34a levels (normalized) in tumor   and normal tissues.						
T-TEST RESULTS OF NORMALIZED miRNA-34a LEVELS						
Normal Tissue Tumor Tissue						
Average	1.564416519	1.35568886				
Variance	16.26777161	28.13214371				
Observation	66	66				
Projected Average Difference	0					
Df	121					
t Stat	0.254484243					
P(T<=t) one-tailed	0.399776731					



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### Findings for miRNA-9

Level analysis was performed in 94 tissue samples taken from 47 patients for miRNA-9. (19 patients could not be analyzed for technical reasons) In 24 of 47 patients, miRNA-9 levels in tumor tissue decreased compared to normal tissue, remained unchanged in 4 patients and increased in 19 patients. The determined levels were normalized by proportioning to U6 level. By using the 2-ΔCt method, miRNA-9 expression levels in normal and tumor tissue groups were compared with U6 expression level and the relative coefficient value was obtained for these genes. After normalization for both groups, the data were analyzed by Student's T Test. In the analysis, 47 patients with breast cancer had no statistically significant difference between breast cancer tissues and normal breast tissues in terms of miRNA-9 levels. (P=0.17) (Table 5 and Fig. 3)

Table 5. Comparison of miRNA-9 levels (normalized) in tumor   and normal tissues.						
T-TEST RESULTS OF NORMALIZED miRNA-9 LEVELS						
Normal Tissue Tumor Tissue						
Average	0.150194972	0.036329229				
Variance	0.668264404	0.007031406				
Observation	47	47				
Projected Average Difference	0					
Df	47					
t Stat	0.949937406					
P(T<=t) one-tailed	0.173501725					



## Discussion

Nowadays, it is thought that genetic studies may lead a new way in the treatment of breast cancer which especially in female patients is a very important health problem and still causing serious mortality. One of the enzymes frequently investigated for this purpose is SIRT1, one of the members of the family of sutures. Relationships between increased or decreased levels of SIRT1 in tissue and many types of cancer have been established and a limited number of therapeutic interventions have been tried. Studies to ensure regulation of SIRT1 have shown that more than 16 miRNAs are involved in SIRT1 regulation so far. These miRNAs were; miRNA-449a, miRNA-449, miRNA-22, miRNA-200a, miRNA-34a, miRNA-143/145, miRNA-217, miRNA-195, miRNA-199a, miRNA-132, miRNA-181c, miRNA -9, miRNA-93, miRNA-181a / b, miRNA-204, miRNA-199b, miRNA-15a, miRNA-100. Of these, miRNA-34a was the most studied (8). (Figure 4)



Figure 4: SIRT1 regulation with miRNAs. It is shown that miRNAs regulate SIRT1 expression and functions directly and via HuR. miRNA-22, miRNA-34, miRNA-143/145, miRNA-195, miRNA-199a and miRNA-217 are found in vascular tissue and control SIRT1 protein. There are more than 16 miRNAs which regulate SIRT1 <sup>(12)</sup>.

**ABBREVIATIONS:** 

APC:	Adenomatous polyposis coli
BRCA-1:	Breast cancer gene 1
cDNA:	Complementary DNA
ER:	Estrogen receptor
HDAC:	Histone deacetylase family
IDC:	Invasive ductal carcinoma
ILC:	Invasive lobular carcinoma
miRNA:	Micro RNA
PR:	Progesterone receptor
RNA:	Ribonucleic Acid
RT-PCR:	Reverse transcription polymerase chain reaction
SIRT1:	Silent mating-type information regulation 2 homologue 1
qRT-PCR:	Quantitative real time reverse transcriptase
Ki-67:	Antigen Kiel 67

Although there are many studies on micro RNAs involved in the regulation of SIRT1 in the literature, the diversity of micro RNAs and their presence in many different tissues and their important roles in these tissues prevented them from focusing on a specific area. Therefore, there were very few studies on the levels of miRNA-9, miRNA-34a and miRNA132 micro-RNAs analyzed in breast cancer tissues in this study.

In a study conducted in 2008, it was shown that inhibition of SIRT1 with a specific inhibitor leads to hyperceretylation of p53 and increased p53-related transcription (10). Firestein et al. showed that the overexpression of SIRT1 in APC + (Adenomatous polyposis coli) rats resulted in a decrease but not an increase in colon cancer formation (11).

Wang et al showed lower levels of SIRT1 of BRCA-1-related breast cancer (Breast cancer gene 1) compared to BRCA-1 unrelated breast cancers in their analysis (12). They further stated that BRCA1 binds to the SIRT1 promoter and regulates it positively at both protein and mRNA levels and that BRCA1 defect may cause cancer transformation in BRCA1 mutant cells with decreasing SIRT1 levels.

In this study, three microRNAs thought to be associated with SIRT1 were studied: miRNA-132, miRNA-34a and miRNA-9. miRNA-34a, one of the miRNAs whose breast cancer relationship was questioned, has been shown to play a role in liver fat metabolism, b-cell exocytosis and cell apoptosis. miRNA-132 is involved in the production of stress-induced chemokine while miRNA-9 has been shown to play a role in insulin secretion (13).

miRNA34a has been shown to be low levels in cancer tissue of many organs (14).In another study, it was shown that the expression of this micro RNA in endothelial cells increased considerably and decreased its level by targeting SIRT (15). Decreased levels of this miRNA have also been shown in an analysis of prostate cancer tissues (16). In a study conducted in patients with hepatocellular cancer, miRNA-34a was shown to be inhibited by FXR receptors (Farnesoid X receptor) and as a result positive regulation of SIRT1 could be achieved. Only one study showed that miRNA-34a was found to be lower than normal in breast cancer tissues and it was suggested that correcting this may increase the response to radiotherapy in breast cancer (17). Although miRNA-9 is detected at low levels in many cancer tissues, it is not yet possible to classify it as a tumor suppressor or a carcinogenic miRNA. It was found to be increased in brain tumors (18) but low in breast cancer with metastasis, hepatocellular cancer, gastric carcinoma, ovarian cancer and malignant melanoma (19). On the other hand, epigenetic inactivation of miRNA has also been found in breast cancer, colorectal cancer and renal cell carcinoma (20). In a specific study on the relationship between miRNA-9 and breast cancer, lower miRNA-9 levels were also found in tumor tissues compared to normal tissues (21).

Increased levels of miRNA-132 have been shown in pancreatic cancer. In breast cancer investigations, this micro-RNA was found to be low in in-situ breast cancer tissues and was interpreted as behaving as a tumor suppressor (22). Similarly, in another study, miRNA-132 level was found to be decreased in breast cancer tissues (23).

## Conclusion

Limited number of studies reported that the levels of all three micro RNAs were found to be lower in breast cancer tissues than in normal breast tissue. In this study, no statistically significant difference was found between normal breast tissue and breast cancer tissues in terms of levels of these micro RNAs for all three micro RNAs.

Since there is conflicting and incomplete information about the SIRT1 enzyme in the literature, it is not unexpected that the results of our study are incompatible with the literature. Further studies are needed to clearly elucidate the mechanisms of SIRT1 and its regulating micro-RNAs.

In the studies to be done, the determination of the microRNA levels simultaneously with SIRT1's own expression levels can be enlightening on this issue. The fact that these micro RNAs are at normal levels despite the low levels of SIRT1, or that the levels of these micro RNAs remain normal despite the high levels of SIRT1 may provide more illuminating data for the relationship between SIRT1 and these micro RNAs.

## Declarations

Funding

Not applicable

## Conflicts of interest/Competing interests

All authors declare that they have no conflicts of interest.

## Ethics approval

Ethics committee approval was received for this study from the ethics committee of Gaziantep University (18.05.2015/157). Informed consent for the use of their data/samples was obtained from all participants.

## Availability of data and material

All of the data is available if necessary.

### Authors' contributions

M. Elçi, A. Aytekin, N. Aksoy, G. Maralcan

## **Acknowledgements**

This study is Muhsin Elçi's thesis and is stored with 435714 number in Higher Education Council archive.

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Public Health / Halk Sağlığı

# **Debriefing in Healthcare Simulation: A Bibliometric Analysis**

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Received: 14.09.2024 Accepted: 29.11.2024

#### ABSTRACT

**Purpose:** Debriefing facilitates the expression of actions and the rationale behind them, helps the students to correct their mistakes, and improves their knowledge and skills. This study aimed to provide a bibliometric analysis of the publications on debriefing and simulation that were indexed in the Scopus database.

**Methods:** The bibliometric analysis method was used to analyze relevant Scopus-indexed documents. The publications analyzed in the study were retrieved from the Scopus database using the keywords "debriefing" and "simulation". Bibliometric analysis was used to classify the articles according to country, journals, keywords, and other parameters.

**Results:** The search produced a total of 326 publications. The articles were mostly published in nursing journals. Thematic analysis of the keywords revealed six themes and 33 keywords. Nine of the ten most cited publications provided information about debriefing session standards.

**Conclusion:** The publications with the keywords debriefing and simulation appeared in 2004, and the annual increase in these publications indexed in the Scopus database indicated an increase in productivity. The publications mostly appeared in journals of nursing. The keywords used followed the publications' aim and content, mostly related to debriefing and nursing students. The most cited publications provided guiding information for conducting the process of debriefing.

Keywords: Bibliometric analysis; Debriefing; Healthcare; Simulation.

### ÖZET

**Amaç:** Çözümleme oturumu, eylemlerin ve ardındaki mantığının ifade edilmesini kolaylaştırırken öğrencilerin hatalarını düzeltmelerine, bilgi ve becerilerini geliştirmelerine yardımcı olur. Bu çalışma, Scopus veri tabanında indekslenen "çözümleme oturumu" ve "simülasyon" konusundaki yayınların bibliyometrik analiz yöntemi ile incelenmesini amaçlamıştır.

Yöntem: Scopus indeksli yayınların analizinde bibliyometrik analiz yöntemi kullanılmıştır. Çalışmada analiz edilen yayınlar, Scopus veri tabanından "debriefing" ve "simulation" anahtar kelimeleri kullanılarak elde edilmiştir. Makaleler; ülke, dergi, anahtar kelime ve diğer parametrelere göre bibliyometrik analiz yöntemi ile sınıflandırılmıştır.

**Bulgular:** Taramada toplam 326 yayın bulunmuştur. Makaleler çoğunlukla hemşirelik dergilerinde yayınlanmıştır. Anahtar kelimelerin tematik analizi, altı tema ve 33 anahtar kelime ortaya çıkarmıştır. En çok alıntı yapılan on yayından dokuzu çözümleme oturumu standartları hakkında bilgi sağlamaktadır.

**Sonuç:** Scopus veri tabanında indekslenen, "debrifing" ve "simulation" anahtar kelimelerini içeren yayınlar 2004 yılında ortaya çıktı ve yayınlardaki yıllık artış bu konudaki üretkenliğin arttığına işaret etmektedir. Yayınlar, çoğunlukla hemşirelik dergilerinde yer almıştır. Kullanılan anahtar kelimeler, yayınların amacına ve içeriğine uygundu, çoğunlukla çözümleme oturumu ve hemşirelik öğrencileriyle ilgiliydi. En çok alıntı yapılan yayınların ise, çözümleme oturumu sürecini yürütmek için yol gösterici bilgiler sağladığı sonucuna varılmaktadır.

Anahtar Sözcükler: Bibliyometrik analiz, Çözümleme oturumu, Sağlık bakımı, Simülasyon.

Copyright © 2025 the Author(s). Published by Acibadem University. This is an open access article licensed under a Creative Commons Attribution-NonCommercial-NoDerivatives (CC BY-NC-ND 4.0) International License, which is downloadable, re-usable and distributable in any medium or format in unadapted form and for noncommercial purposes only where credit is given to the creator and publishing journal is cited properly. The work cannot be used commercially without permission from the journal. S imulation has been an essential auxiliary method in clinical practices in the education of various health professions since the 1950s. It has recently become a permanent method in contemporary health education and training (1). Studies on the effectiveness of simulation-based education in healthcare have found that this method improves the level of knowledge, clinical judgment, skill performance, and self-reflection in a controlled and safe environment (1,2).

The simulation is composed of three basic stages. The first stage, the prebriefing, is the orientation session implemented to increase student satisfaction and the effectiveness of the simulation method. This stage is followed by the simulation experience, during which the students observe a developing case or implement their skills. Finally, the debriefing stage includes an analytical discussion on students' performances in the scenario (1). This last stage is considered the most important element of a successful simulation experience since it provides room for facilitated reflection, group discussion, and guides to improve performance (1,3). Standards Committee of the "International Nursing Association for Clinical Simulation and Learning (INACSL)" states that a planned debriefing session is a must in all simulationbased education activities (4).

Existing studies on the effectiveness of debriefing sessions in the education of health professionals reported the positive effects of debriefing on the improvement of technical and nontechnical skills, including the evaluation of vital signs, cardiopulmonary resuscitation, task management, teamwork, and these studies are increasing (5). Considering the increase in the number of simulation studies in healthcare services, it may be difficult for the simulation trainers to get a general view of the methods and techniques used in the debriefing process (6). This difficulty shows the importance of and the need for bibliometric methods that analyze the direction of developments in a scientific field, demonstrate the dynamics and structure of the field, and reveal the most important studies using various filters (7).

Bibliometric analysis, an effective method of processing big data, is widely used to qualitatively evaluate developments in a specific scientific discipline and the academic impact of these developments. Bibliometric analysis is a field that evaluates a set of publications using quantitative methods (8). Bibliometric analysis also provides additional statistics on data such as author, organization, keywords, etc., and allows the provided indicators to be visualized in a network. It also integrates information to develop research areas on a specific topic or the entire field (9).

Studies that use bibliometric analysis in healthcare mostly deal with various issues, including sufficiency, technological advancements, journal analysis, and clinical simulation (10,11). However, no studies have been found specifically on debriefing in healthcare simulations analyzed with bibliometrics globally. Due to this reason, this study provides a bibliometric analysis of the publications on debriefing and simulation indexed in the Scopus database.

### **Research Questions**

The study's purpose is to procure a bibliometric analysis of the publications on debriefing and simulation indexed in the Scopus database. The annual number of publications, journals that published these publications, keywords of the publications, country of publication, and the most cited ten publications were analyzed using bibliometric and thematic analysis.

The content of the publications was visualized using bibliometric mapping. The research questions included the following:

- What was the annual count of publications?
- In which journals were the articles published?
- What were the most frequently used keywords and the keywords that were used together?
- In which countries were the articles published?
- What were the most cited publications and their characteristics?

## **Materials and Methods**

## Type of the Research

Based on bibliometric literature analysis, this study had a descriptive design.

## Sample of the Research

The publications on debriefing and simulation, indexed in the Scopus Database, were used for the research sampling.

## Eligibility criteria

Publications that met the following criteria were included in the study:

- Original scientific articles or reviews
- Published in English.
- Used at least one of the simulation methods, including standardized patient, high-, medium- and low-fidelity simulation, and virtual reality methods.
- Conducted with the participation of health professionals and health sciences students, including medicine, dentistry, and nursing.

The following publications were excluded from the analysis:

- Conducted on participants other than health professionals or the students of health sciences.
- Publications other than scientific articles and reviews, including conference papers, book chapters, and editorial materials.
- Publications on the fields of navigation and security, which were based on mathematical modeling or calculative simulations.

### Search for Eligible Studies

The resource of literature was Scopus-indexed because Scopus claims "it indexes the largest selection of

peer-reviewed literature simulations in the healthcare field" (https://www.elsevier.com/en-au/products/scopus). We first retrieved the publications indexed in the Scopus database as of March 24<sup>th</sup>, 2022. Bibliometric and thematic analyses were conducted for the retrieved articles using the VOSviewer Software Version 1.6.5 (12). The date range was not selected to include all articles published until this study was conducted. The search was performed with "debriefing" and "simulation" keywords combined with the Boolean operator. The search was limited to "article" or "review" publication types in English with no year limit. The authors chose the Nursing (#2901), Medicine (#2701), Health Professions (#3601), and Dentistry (#3501) Scopus subject areas in order not to include publications on the fields of mathematical modeling or calculative simulations (https://service.elsevier.com/app/answers/ detail/a id/15181/supporthub/scopus/).

This search strategy identified 326 articles. Two publications that did not meet the inclusion criteria were counted out. The study was finalized with 324 articles published between 2004 and 2022, and each publication's bibliometric details were exported from the Scopus database in the "scopus.csv" format. Figure 1. illustrates the PRISMA flowchart of the analyzed publications. References to these publications were not analyzed.



The articles obtained at the end of the search were screened as a citation overview in the Scopus database. Since the screened articles were published between 2004 and 2022, the time interval was selected as 2004-2022 and excluded the self-citations of all authors. The data of the obtained articles were sorted on descending citation count. The ten most cited articles are tabulated according to the data provided by the Scopus database.

### Evaluation of the Data

The VOSviewer Software Version 1.6.5 (12) was used for bibliometric and thematic analysis. The SPSS Statistics Version 22.0 (IBM Corp., Armonk, NY, USA) was used for statistical analysis of the descriptive quantitative variables. Descriptive data were presented in numbers. The most cited ten publications were compiled with journal metrics extracted from the Scopus database. The presentation of the study results was made according to Preliminary guidelines for reporting bibliometric reviews of the biomedical literature (BIBLIO) (13).

### Ethical Aspect of the Research

The institutional review board approval or informed consent was not required.

## Results

We searched for the publications, which included the keywords "debriefing" and "simulation" and were indexed by the Scopus bibliographical database until March 24<sup>th</sup>. 2022. The annual number of publications, the journals in which the articles were published, keywords of the publications, country of publication, and the most cited ten publications were analyzed. We found 324 articles published between 2004 and 2022, which included the keywords "debriefing" and "simulation" and were conducted with the participation of health professionals or health science students. Analysis of the annual number of publications revealed a gradual increase until 2022. As Figure 2. illustrates, the number of publications in 2017 (n=41) first decreased in 2018 (n=25) and then increased in 2019 (n=30), 2020 (n=48), and 2021 (n=48). As of March 24<sup>th</sup>, five articles were published in 2022.






Figure 3. illustrates the articles that were published in which journals. The journals were "Clinical Simulation in Nursing" (n=75), "Simulation in Healthcare" (n=36), "Nurse Education Today" (n=18), "Nurse Education Perspectives" (n=16), "BMJ Simulation & Technology Enhanced Nursing" (n=12), "Nurse Education in Practice" (n=10), "Seminars in Perinatology" (n=8), "Nurse Educator" (n=7), "Journal of Surgical Education" (5), and "Nursing & Health Sciences" (n=3) respectively.

Figure 4. illustrates the clusters of 33 keywords that appeared at least six times in the 324 publications analyzed. In this analysis, to obtain the keywords with the highest incidence/frequency and relevance among the keywords, those with at least six or more frequencies were included. These keywords were classified into six groups using the VOSviewer software. The most frequently used ten keywords were "nursing education", "education", "feedback", "reflection", "patient simulation", "patient safety", "high-fidelity simulation", "nursing students", "facilitation" and "learning" respectively between 2013 and 2022 years.

Table 1. presents the thematic analysis of the keywords and the themes and items revealed by the VOSviewer software. For each cluster, the most cited keywords by the authors were used to label the themes. The themes followed the aims and the content of the publications analyzed.

Data retrieved from the Scopus database were also used to determine the most productive countries. The analysis revealed that 324 publications were published in 50 different countries. Figure 5. illustrated the most productive 25 countries. The countries with more than ten publications were the United States (n=183), Canada (n=57), Australia (n=22), United Kingdom (n=18), South Korea (n=18), France (n=11) and Norway (n=10), respectively.



Table 1. Thematic analysis of keywords				
Themes	Representative keywords			
Debriefing (red)*	Communication, crisis resource management, debriefing, faculty development, feedback, interprofessional education, psychological safety, simulation-based education, training			
Simulation (green)*	Deliberate practice, medical education, neonatal resuscitation, patient safety, quality improvement, resuscitation, simulation			
Nursing education (dark blue)*	Assessment, learning nursing education, patient simulation, reflection, self-debriefing, virtual simulation			
High-fidelity simulation (yellow)*	Clinical judgement, experimental learning, high-fidelity simulation, knowledge, nursing students, video- assisted debriefing			
Facilitation (purple)*	Facilitation, prebriefing			
Education (light blue)*	Education, nursing			
*The colors refer to the theme and ke	ywords are the colors VOSviewer Software uses to visualize the clusters.			

	Table 2. The ten most cited publications							
Rank	Author and Year	Journal	Scopus Citation	Title	Description			
1	INACSL Standards Committee (2016)	Clinical Simulation in Nursing	314	INACSL Standards of Best Practice: Simulation <sup>SM</sup> Simulation Design	Defines simulation design standards for effective simulation-based experience.			
2	Rudolph J.W., Raemer D.B., Simon R. (2014).	Simulation in Healthcare	297	Establishing a Safe Container for Learning in Simulation: The Role of the Presimulation Briefing	Defines the role of the Presimulation briefing.			
3	Eppich W., Cheng A. (2015)	Simulation in Healthcare	288	Promoting Excellence and Reflective Learning in Simulation (PEARLS) Development and Rationale for a Blended Approach to Health Care Simulation Debriefing	Describes the PEARLS model, a new framework for debriefing in healthcare.			
4	Dreifuerst K.T. (2009)	Nursing Education Perspectives	262	The essentials of Debriefing in simulation learning: A concept analysis	Analyzes the concept of debriefing and defines its basic components.			
5	Levet-Jones T. Lapkin S. (2014)	Nurse Education Today	201	A systematic review of the effectiveness of simulation debriefing in health professional education	Identifies, evaluates and synthesizes the best available evidence for the effectiveness of debriefing in simulation-based learning for healthcare professionals.			
6	Sawyer T., Eppich W., Brett-Fleegler M., Grant V., Cheng A. (2016)	Simulation in Healthcare	196	More Than One Way to Debrief: A Critical Review of Healthcare Simulation Debriefing Methods	Examines the timing, facilitation, speech structures, and process elements used in debriefing for healthcare simulation.			
7	Raemer D., Anderson M., Cheng A., Fanning R. (2011)	Simulation in Healthcare	167	Research regarding debriefing as part of the learning process	Reviews the current research on debriefing in simulation-based education and identifies future opportunities.			
8	Brett-Fleegler M., Rudaoph J., Eppich W., Monuteaux M., Fleefler E., Cheng A., Simon R. (2012)	Simulation in Healthcare	148	Debriefing assessment for simulation in healthcare: Development and psychometric properties	Develops and evaluates the validity and reliability of an assessment tool, namely, Debriefing Assessment for Simulation in Healthcare (DASH).			
9	Shinnick M.A., WOO M., Horwich T.B., Steadman R. (2011)	Clinical Simulation in Nursing	138	Debriefing: The Most Important Component in Simulation?	Conducts a quasi-experimental study on undergraduate nursing students to determine where more knowledge gains occur in a simulation experience.			
10	Neil M.A., Wotton K. (2011)	Clinical Simulation in Nursing	135	High-Fidelity Simulation Debriefing in Nursing Education: A Literature Review	Analyzes the literature on the use of debriefing in nursing education and makes recommendations for further studies.			

Table 2. presents the ten most cited publications retrieved from the Scopus database. The article entitled "INACSL Standards of Best Practice: Simulation<sup>SM</sup> Simulation Design" (2016) was the most cited publication (14). Only one of the ten most cited articles was a semi-experimental study to evaluate the effectiveness of debriefing in nursing students. The remaining nine articles dealt with the important points to be considered while conducting the debriefing session.

# Discussion

The study aimed to identify the features of the publications on debriefing and simulation in healthcare research. These publications indexed in the Scopus database were published from 2004 to 2022. Although the number of articles generally increased over time, the number of articles published in 2017 was more than those published in 2018. It is seen that similar results were obtained in the studies carried out (15,16). It is thought that this difference may be related to the publication of the article "INACSL Standards of Best Practice: Simulation<sup>™</sup> Simulation Design" in 2016, which is the primary resource used by the studies on simulation (14). INACSL provides best practices for simulation activities and advances simulation science as a teaching methodology, thereby promoting the use of simulation globally (15). The journal "Clinical Simulation in Nursing", which published this article, was also the journal in which most debriefing and simulation publications were published. The common point between the journals that published most articles on these subjects was their primary focus on simulation and education. Besides, although all studies on healthcare were included in the analysis, most journals on simulation and debriefing were related to the nursing field.

Keywords are condensed representations of the content of academic articles. Statistical analysis of the keywords may reveal the topics and the developmental dynamics in a scientific discipline. They supply information on how the scholars conceptualize their works and are crucial to monitoring scientific development (17). The main themes created from the co-occurrence of VOSviewer keywords characterize the literature's knowledge structure regarding debriefing and simulation. For this reason, it can be said that the four largest clusters represent the entire area. Within the context of our methodology, these keywords represented the publications on simulation and debriefing indexed in the Scopus database. Besides, most keywords were related to nursing education and debriefing, and most publications were published in journals on nursing. These results supported each other.

The most frequently used keywords were "nursing education", "education", "feedback", "reflection", "patient simulation", "patient safety", "high-fidelity simulation", "nursing students", "facilitation" and "learning" in the 324 articles that were analyzed. In the ten year bibliometric analysis of the journal "Clinical Simulation in Nursing", debriefing was one of the most frequently encountered keywords (18). It is stated that debriefing includes three strategies or techniques, namely "feedback", "debriefing", and/or "guided reflection" (4). In this study, we included studies using the keywords debriefing and simulation. Therefore, we encountered more keywords related to debriefing. Nevertheless, the keywords obtained were found to be compatible with simulation studies carried out in nursing education. Thematic analysis of keywords confirms our thoughts. Based on this, it can be seen that the keywords obtained are related to nursing education, debriefing, and simulation.

The publications included in the bibliometric analysis were produced in 50 different countries. Most publications were produced in the USA, followed by Canada and Australia, and these findings were parallel to other studies on the bibliometric analysis of a different database (8,16). The predominant position of the USA in simulation studies may be related to the high costs of simulation-based education, which seems easier to access in the USA (19). Since the developed countries have the infrastructure necessary for simulation-based education; it is logical to expect a higher number of publications on simulation in these countries. Simulation-based education is more financed in developed countries due to its costs, which has led to more studies being conducted. As seen in Figure 3., journals such as "Clinical Simulation in Nursing," "Nurse Education Today," and "Simulation in Healthcare" were the major journals publishing articles and editorials on the application of simulation research. It would be logical to conclude that these journals are more likely to be potential journals that will publish important developments in this field, and therefore more publications on the subject will be made in the USA, Canada, and Australia countries (15).

The analysis of the ten most-cited publications revealed that these articles were published between 2009 and 2016. The most cited article was "INACSL Standards of Best Practice: Simulation<sup>SM</sup> Simulation Design" on the standards for simulation design constituted by the INACSL Standards

Committee (14). The remaining most cited articles defined the standards for debriefing and evaluated the debriefing methods and the effectiveness of debriefing in healthcare simulations (20–28). Contrary to the general expectation of the relationship between the time of publication and citation rate, the most cited article was published relatively recently, in 2016, but received high citations in a relatively short time. Another study on the 100 most cited articles in healthcare simulation also found that the recently published articles had high citation rates (29). Only one of the ten most cited articles was a semi-experimental study that analyzed where the knowledge was acquired in the simulation experience. Dissemination of important research findings starts with publishing these findings in peer-reviewed journals but continues with the citation of the original article by following studies. The citation rate of a publication is considered an indicator of the importance of the publication (30). In our case, most publications could be used as guidelines to conduct the debriefing process. These studies are beneficial to direct implementation, facilitate decision-making, and advance the research. Due to this, the increasing visibility of these studies is not surprising as it indicates the field's maturation (29). High citation rates of the publications that provide guiding information on the debriefing process standards also indicate that more studies on debriefing are needed.

Health professionals, managers, and educators need to identify the most cited articles, the journals publishing these articles, the country of publication, and the most frequently used keywords. Identifying these issues may help further studies on professional practices, academic fields, or healthcare education to use up-to-date and high-quality information (8).

#### Limitations

Compared to other databases, the Scopus database included more journals on the subject of simulation. Nevertheless, the analysis of the publications indexed in a single database constituted a limitation of this study. The second limitation of this study was that only the publications on healthcare professionals were analyzed.

# Conclusion

As seen from published studies, interest in simulation as an education and training method in healthcare has been increasing in recent years. Simulation-based education offers many benefits, including providing a safe and controlled environment for students to practice their skills, as well as allowing for the inclusion of a wide variety of patient scenarios and contexts. Therefore, the use of simulation in healthcare education is becoming a necessity rather than an exception. However, the fact that the majority of publications are in developed countries reveals the need for financial support in developing countries. The resulting keywords show that the use of simulation is higher in nursing education than in other health-related departments. Additionally, the emergence of different keywords related to debriefing suggests that researchers are aware that it is an important part of simulation-based education. The literature on simulationbased education is expanding day by day. As more studies are conducted, additional analyses are recommended to better understand the relationship between research components.

## Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-forprofit sectors.

## **Conflict of Interest**

No conflict of interest has been declared by the authors.

## Ethical Approval

Not applicable as this study used already published data.

## Availability of Data and Material

#### Available.

## Authors' Contributions

All authors have made substantial contributions to this article being submitted for publication. All authors critically reviewed the manuscript and approved the final form.

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Public Health / Halk Sağlığı

# The Role of Diet and Exercise in Fighting Obesity

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#### ABSTRACT

**Purpose:** This study aimed to evaluate the effectiveness of the diet and exercise program for overweight and obese women.

Material and Method: A questionnaire was applied to the participants, and anthropometric measurements were made. Then, they were given a diet list and an aerobic exercise program for eight weeks. After eight weeks, the questionnaire and anthropometric measurements were repeated. In the study, the cases were divided into groups. The 1st group consisted of diet, the 2nd group with exercise, the 3rd group with diet and exercise, and the control group with no diet and no exercise.

**Results:** 32.6% of women were overweight, and 67.4% were obese. Group 1 was 29.2%, group 2 was 13.5%, and group 3 was 38.2%. The control group was 19.1%. A statistical decrease was observed in the participants' BMI, waist circumference, and hip circumference parameters between the groups (p<0.05). Weight and BMI differences in group 3 were significantly higher than weight and BMI differences in groups 1 and 2(p<0.001).

**Conclusion:** Diet and exercise influenced weight control by lowering anthropometric measures. In the fight against obesity, the combination of diet and exercise proved to be more effective than the separate implementation of these measures.

Keywords: Body weights and measures, diet therapy, exercise therapy, preventive health

#### ÖZET

Amaç: Fazla kilolu ve obez kadınlara verilen diyet ve egzersiz programının etkinliğinin değerlendirilmesi amaçlanmıştır.

**Materyal ve Metot:** Katılımcılara anket uygulanmış ve antropometrik ölçümleri yapılmıştır. Ardından 8 hafta boyunca uygulayacakları bir diyet listesi ve bir aerobik egzersiz programıyla eğitim verilmiştir. 8 hafta sonra anket ve antropometrik ölçümler tekrarlanmıştır. Çalışmada vakalar gruplara ayrıldı. 1. grup diyet yapan, 2. grup egzersiz yapan, 3. grup diyet ve egzersiz yapan ve kontrol grubu ise diyet ve egzersiz yapmayanlardan oluştu.

**Bulgular:** Kadınların %32,6'sı fazla kilolu, %67,4'ü obez idi. Katılımcıların %29,2'si grup 1, %13,5'i grup 2, %38,2'si grup 3'teydi. Kontrol grubu %19,1 idi. Katılımcıların VKİ, bel çevresi ve kalça çevresi parametrelerinde gruplar arasında istatistiksel bir azalma görülmüştür (p<0,05). Grup 3'teki ağırlık ve VKİ farkları, grup 1 ve 2'deki ağırlık ve VKİ farklarından anlamlı olarak yüksek çıkmıştır (p<0,001).

**Sonuç:** Diyet ve egzersiz antropometrik ölçüm değerlerinde düşüş sağlayarak, kilo kontrolüne etki etmiştir. Obezite mücadelesinde diyet ve egzersizin birlikte yapılması ayrı ayrı yapılmalarından daha etkili bulunmuştur.

Anahtar Kelimeler: Antropometrik ölçüm, diet, egzersiz, koruyucu sağlık

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Received: 19.02.2024 Accepted: 26.09.2024 besity is a significant public health problem in many countries worldwide, characterized by excessive increases in body fat (1). The fact that high-fat – high-energy foods become more accessible and cheaper, the decrease in physical activity, and the time spent with technological equipment reach severe levels lead to the prevalence of obesity (2).

The World Health Organization (WHO) uses Body Mass Index (BMI) to determine obesity generally. BMI is calculated by dividing weight in kilograms and length in square meters. BMI values are classified as < 18.50 low weight, 18.50-24.99 normal, 25-29.99 overweight, and  $\geq$  30.00 obese (3).

According to the World Obesity Atlas 2023 report, 14% of men and 18% of women are in the obese group in the population over the age of 20 worldwide (4). According to the WHO European Region Obesity Report 2022, 59% of adults (63% men, 54% women) in the European Region are overweight or obese. In the same report, Türkiye has the highest obesity prevalence in the WHO European Region. It has been reported that 66.8% of the adult population in Türkiye is overweight (64.0% male, 69.3% female), and 32.1% is obese (24.4% male, 39.2% female) (5).

The following methods are used in treating obesity: Diet-nutrition therapy, exercise and physical activity, behavioral therapies, pharmacological applications, and surgical applications. Among these methods, it is possible to control obesity when caloric intake is restricted and physical activity is increased (6).

Diet and exercise are the most critical factors influencing weight control and loss. Diet programs and exercise applications are used together or alone for weight loss. However, combined dietary energy restriction and exercise are more effective than diet and exercise programs in increasing cardiovascular conditioning, muscle strength, and fat mass loss (7, 8). In a study conducted with overweight/obese adults aged 55-75 years in Spain, it was stated that an energy-restricted diet and physical activitypromoted lifestyle change were effective in reducing adiposity (9). Kaikkonen et al. (10) also reported that an intensified diet program alone and in combination with exercise resulted in clinically significant weight loss and long-term weight maintenance. This study was designed to determine whether women who exercise and receive nutritional support to combat obesity comply with diet and exercise practices and to reveal the program's effect on anthropometric values.

# **Material and Methods**

**Ethical Approval:** The Noninvasive Clinical Research Ethics Committee of the Dicle University School of Medicine (Date:25/01/2018, decision no:29) approved the conduct of the study. Permission was obtained from Diyarbakır Gazi Yaşargil Training and Research Hospital Chief Physician to conduct the study. All participants were informed about the study and signed a written informed consent form stating they agreed to participate.

**Design of the Study:** The research design is a nonrandomized controlled trial with an 8-week follow-up. The study population consisted of women with BMI ≥25 who came to the Polyclinic of Nutrition and Dietetics of Health Sciences University Diyarbakır Gazi Yaşargil Training and Research Hospital. The study was conducted with 89 volunteer women who enrolled in the outpatient clinic between February, March, and April 2019 in 3 months. No sampling method was used. The criteria for inclusion and exclusion in the study were as follows.

Inclusion criteria: Volunteers who want to participate must be women between the ages of 15-65, have a BMI  $\ge 25$ , have a psychosocial fitness status, and not have any chronic disease (hypertension, COPD, etc.) that may prevent them from implementing the prescribed diet and exercise program.

Exclusion Criteria: Women who cannot participate voluntarily, women who are pregnant, and people who do not meet the specified age range and BMI value.

**Diet Training:** The dieticians gave a diet list suitable for the individual's total energy expenditure calories using the Harris-Benedict formula. This calorie level is the coefficient of the individual's basal metabolic rate (ideal weight + (own weight - ideal weight) x 25%) of the individual's physical activity level (very light:1.3, light:1.5, medium:1.6, heavy:1.9, very heavy: calculated by multiplying by 2.2) (11). After finding the total energy of the weight loss diet, the energy coverage percentages of macronutrients are planned to be 55-60% carbohydrates, 15-20% protein, and 25-30% fat (12). Meal times of individuals are planned as three main meals and 2-3 snacks to suit their lifestyles. In the first interview, individuals were given training on the portion amount of foods, food groups, and changes. During the program, the energy and macronutrient ratios of the diets of the individuals were not changed, but the change tables were explained to the individuals and how their diets would be enriched.

**Exercise Training:** Training was via a physiotherapistdesigned aerobic exercise program (fast walking or light jogging) that a person could perform alone for 45 minutes three days per week (warm-up; 10 minutes, aerobic exercise; 30 minutes, cool-down; 5 minutes). During the warm-up and cool-down periods, stretching and breathing exercises were performed to stretch all body parts and protect against possible injuries. As an aerobic exercise, a personalized fast-paced walking or light-paced jogging program was given at 50-60% of the target heart rate (13).

Participants were asked to use these programs for eight weeks. After eight weeks, the women were called back to the dietary polyclinic and asked if they were adhering to the diet and exercise program. At the beginning of the study, participants were not divided into groups and all participants were given a diet and exercise program. Those who implemented the given program and those who did not implement it constituted the groups within the scope of the study. At the end of the study, the cases were divided into groups. The 1st group consisted of diet, the 2nd group with exercise, the 3rd group with diet and exercise, and the control group with no diet and no exercise.

## Data Collection Instruments of Study and Application:

Participants were presented with a questionnaire consisting of 2 parts based on the relevant literature, and anthropometric measurements were performed before and after the program.

In the first part of the questionnaire, participants were asked 34 questions before the program regarding sociodemographic information, weight gain, dietary habits, and physical activity status. The second part was conducted at the end of the program. The participants were asked whether the program was implemented, and a form questioning the reasons was directed to those who did not. Anthropometric measurements consisted of height, weight, waist, and hip circumferences measured with a non-stretchable tape and scale routinely used by dietitians before and after the program.

#### Anthropometric measurements:

**Measurement of Body Length:** It was measured with heels together, back, shoulders, and head in an upright position.

**Measurement of Waist Circumference:** A measured tape was placed at the level of the umbilicus.

**Measurement of the Hip Circumference:** The tape measure was placed through the widest part of the hip.

**Body Mass Index:** It was calculated from the measurement values using the formula body weight (kg) / [height (m)]<sup>2</sup>. BMI values are < 18.50 underweight, 18.50-24.99 normal, 25-29.99 overweight, and  $\geq$ 30.00 obese.

**Waist/Hip Ratio (WHR)** is calculated using the waist circumference/hip circumference formula (14).

**Statistical Analysis:** Statistical analysis of the data was performed using the SPSS 21.0 package program. Data are reported with mean, standard deviation, and percentages. The Chi-Square test was used as a significant test to compare the data, and the t-test was used to compare the measured values. The significance of the difference between the pre-and post-measurements of each group was determined using the Wilcoxon signed-rank test, the Kruskal-Wallis analysis of variance for group comparisons, and the post hoc Games-Howell test to determine from which group the difference originated. All statistical tests are based on p < 0.05 for significance.

# Results

It was found that 32.6% of participants were overweight, and 67.4% were obese. It was observed that obese people are more common in the age group of 36 years and older, in married people, in people with low educational level, in homemakers with the same weight for more than ten years, and in people who were obese in childhood (p<0.05) (Table 1).

		Overweight (n=29) n (%*)	Obese (n=60) n (%*)	р	
	15-25 age	6 (31.6)	13 (68.4)		
Age	26-35 age	15 (40.5)	22 (59.5)	0.032	
	36 age and above	8 (24.2)	25 (75.8)		
	Single	8 (38.1)	13 (61.9)	0.014	
Martial status	Married	21 (30.9)	47 (69.1)	0.014	
	Illiterate	2 (20.0)	8 (80.0)		
Education	Primary school**	9 (25.0)	27 (75.0)	0.022	
	High school and above	18 (41.9)	25 (58.1)		
	Housewife	22 (31.9)	47 (68.1)		
Labor status	Student/non-employee	3 (33.3)	6 (66.7)	0.040	
	Working	4 (36.4)	7 (63.6)		
	1-4 years	19 (48.7)	20 (51.3)		
low many years have you had this weight?	5-9 years	8 (44.4)	10 (55.6)	0.001	
	10 years and above	2 (6.3)	30 (93.8)		
Were you obese in your	Yes	4 (12.9)	27 (87.1)	0.000	
childhood?	No	25 (43.1)	33 (56.9)	0.004	
lava veri averi a con a con a di seco	Yes	14 (28.6)	35 (71.4)	0.071	
Have you ever been on a diet?	No	15 (37.5)	25 (62.5)	0.371	

48.3% of participants had a normal appetite, 57.3% ate snacks, 66.3% skipped meals, the daily activity rate of

51.7% was considered normal, and 84.3% did not exercise regularly (Table 2).

Table 2. Nutritional Habits and Physical Activity Status of Participants					
		n (%)			
	Stomachless	5 (5.6)			
Appetite	Normal	43 (48.3)			
	Very appetite	41 (46.1)			
Consume snacks	Yes	51 (57.3)			
Consume snacks	No	38 (42.7)			
Meal skipping status	Yes	59 (66.3)			
meal skipping status	No	30 (33.7)			
	Slow	26 (29.2)			
Physical activity status	Normal	46 (51.7)			
	Very quick and intense	17 (19.1)			
	Yes	14 (15.7)			
To exercise regularly	No	75 (84.3)			
n: number of participants; %: percent					

29.2% of participants did diet only (group 1), 13.5% did exercise only (group 2), 38.2% did both diet and exercise (group 3), and 19.1% did neither (control group) (Figure 1).

It was found that diet (group 1) statistically affected the participants' weight, BMI, waist circumference, and hip circumference using the groups' first and last anthropometric measurements (p<0.001). The exercise (group 2) was effective on BMI, waist circumference, and hip circumference (p<0.05). The combination of diet and exercise (group 3) also significantly decreased the parameters of weight, BMI, waist circumference, and hip circumference (p<0.001). In the control group, there was no difference in the parameters of weight, BMI, waist circumference, hip circumference, and WHR (p>0.05) (Table 3).



		Group 1	Group 2	Group 3	Control
	FM	88.03±14.81	85.40±16.66	88.68±16.04	81.80±10.36
Wainht	LM	83.49±14.93	82.86±16.12	81.99±13.80	82.51±10.62
Weight	Test value	Z=-4.459	Z=-1.961	t=9.588	Z=-1.609
	р	0.001	0.050	0.001	0.108
	FM	35.12±5.54	32.95±5.87	35.41±7.06	32.55±4.62
вмі	LM	33.31±5.63	31.96±5.65	32.75±6.19	32.82±4.62
DIVII	Test value	Z=-4.458	Z=-2.040	t=9.340	Z=-1.569
	р	0.001	0.041	0.001	0.117
	FM	102.61±11.44	97.16±8.16	100.67±11.31	102.35±11.40
aist circumference	LM	99.13±11.48	94.08±8.40	96.94±10.48	102.47±11.26
	Test value	Z=-4.414	Z=-2.825	t=6.058	Z=-0.583
	р	0.001	0.005	0.001	0.560
	FM	121.84±12.63	120.08±11.56	122.05±12.14	114.70±6.61
Hip circumference	LM	117.80±11.01	115.00±11.70	117.02±11.69	114.76±6.60
hip circumierence	Test value	Z=-4.389	Z=-3.076	t=8.351	Z=-0.447
	р	0.001	0.002	0.001	0.655
	FM	0.84±0.06	0.81±0.06	0.82±0.05	0.89±0.06
WHR	LM	0.84±0.05	0.82±0.05	0.82±0.05	0.89±0.06
WIIK	Test value	Z=-1.359	Z=-0.314	t=-0.832	Z=-0.764
	р	0.174	0.754	0.411	0.445

The differences between the two measurement averages resulted in a statistically significant decrease in the parameters of weight, BMI, waist circumference, and hip circumference in the study groups (p<0.001). When differentiating between all groups, the anthropometric measurements decrease was significantly higher in the group 1, group 2, and group 3 than in the control group. The average weight difference ( $6.68 \pm 4.06$ ) and average BMI difference ( $2.65 \pm 1.65$ ) of the group 3 were significantly higher than both the average weight difference of the group 2 ( $0.98 \pm 1.34$ ) and the average weight difference ( $4.53 \pm 1.81$ ) and average BMI difference ( $1.81 \pm 0.70$ ) of the group 1 (Table 4).

<b>Table 4.</b> Comparison of anthropometric variation between groups between two measurements.									
	Group 1	Group 2	Group 3	Control	р				
Weight	4.53±1.81	2.54±3.64	6.68±4.06	0.71±1.57	0.001				
вмі	1.81±0.70	0.98±1.34	2.65±1.65	0.27±0.62	0.001				
Waist circumference	3.48±3.41	3.08±2.64	3.73±3.59	0.11±1.21	0.001				
Hip circumference	4.03±5.98	5.08±5.31	5.02±3.51	0.05±0.89	0.001				
WHR	0.00±0.04	0.00±0.04	0.00±0.02	0.00±0.00	0.516				
z: Mann Whitney U Test; t: t test; p<0.05									

# Discussion

Studies suggest that among Turkish women, low physical activity, the high number of births, long breastfeeding periods and short intervals between births, concomitant diabetes and diseases such as HT, psychological problems, low income, and low education level have a significant impact on obesity (15). It has been reported that the incidence of obesity increases after the age of 30 years and is highest in the age group of 40 to 44 years (16). Tzotzas et al. (17) reported that married, divorced, and widowed individuals were more likely to be overweight and obese than single individuals. Studies conducted in our country and worldwide found an inverse relationship between educational level and BMI (18, 19). Our study found that obese women were more often in the age group of 36 years and older, married, with a low education level, and homemakers. Psychological depression caused

by low socioeconomic conditions, limited range of motion at home, and weight that cannot be lost with ageing can be counted as the most crucial obesity risk factors. Questioning the exercise history of women, identifying the points they have difficulty maintaining the program, and the father's support to women in domestic responsibilities may increase individual exercise and diet compliance.

It was found that 66.3% of the participants skipped meals, 51.7% had normal daily activities, and 84.3% had not exercised regularly before. Meal skipping has been reported to be common in obese individuals (20). A review examining the long-term effects of physical activity found a negative association between physical activity and weight gain and obesity (21). Irregular feeding intervals and an inactive lifestyle can trigger further weight gain.

Our study found that diet statistically affects participants' weight, BMI, waist circumference, and hip circumference, according to the groups' first and last anthropometric measurements. Reducing caloric intake is one of the most essential steps in treatment (22). Significant weight loss was observed with low-carbohydrate or low-fat diets (23). A meta-analysis showed that low-carbohydrate diets effectively lost weight and improved HDL and TG lipid profiles (24). In particular, avoiding high-calorie food such as fast food, chips, etc., restricting access to unhealthy foods, maintaining a daily carbohydrate-fat-protein intake balance, and controlling excessive eating can prevent weight gain.

In our study, exercise was shown to affect BMI, waist circumference, and hip circumference only in the exercise-only group. Shaw et al. (25) emphasized that exercise is effective in weight loss in obese people and improves cardiovascular risk factors, even when weight loss is impossible. There are few studies on the effectiveness of exercise in obesity. Studies have shown that aerobic exercise decreases adipose tissue and that the combination of aerobic and resistance exercise is more effective in increasing regional and whole-body lean mass. It reduces total body weight and visceral fat mass slightly and prevents a decrease in lean mass (26, 27). Kaikkonen et al. (10) stated that adding exercise right at the beginning of the weight loss period reduced waist circumference. Indeed, there are health benefits, such as improved cardiovascular risk factors and reduced adiposity, after exercise training, with or without weight loss.

The combination of diet and exercise also significantly reduced weight, BMI, waist circumference, and hip circumference parameters. It is also known from some studies in the literature that exercise with energy restriction protects lean tissue and prevents the resting metabolic rate from decreasing (28). In studies using energy restriction and/or additional exercise to treat obesity, body weight, fat percentage, and abdominal fat loss were effectively observed. Studies in the literature also support these findings (9, 29). Calorie restriction and exercise training cause a decrease in body weight by providing a negative energy balance in which energy expenditure exceeds calorie intake.

# **Limitation of Study**

The fact that only overweight and obese women were included in the study resulted in the absence of male gender data and the inability to conduct possible gender analyses. Failure to distribute groups using appropriate randomization methods when designing the study and determining the group according to the program applied by the participant caused the group numbers to be not distributed homogeneously.

# Conclusion

In conclusion, it was observed that women do not have regular eating habits and are physically inactive. It has been noted that there is not enough sensitivity to follow a diet and exercise regularly. Diet and exercise have an impact on weight control by lowering anthropometric measurements. In controlling obesity, the combination of diet and exercise proved to be more effective than doing them separately. To prevent excessive weight gain, it would be beneficial to provide more comprehensive training on topics that increase women's awareness of diet and exercise. As for the sustainability of diet and exercise programs, people can be supported psychologically and socially. The study's limitations are that it only works with the female gender, and it does not give an idea about the effect of the given program on men or the comparison of the two genders. In the literature, many studies separately reveal the effect of diet or exercise on weight loss in the fight against obesity. This study shows that a combination of exercise and diet is having a significant impact even in as little as eight weeks. In addition, the fact that the study was conducted not only with obese but also with overweight individuals reveals the importance of prevention programs in terms of public health.

# **Declarations**

### Funding

This research did not receive financial support from any institution or project.

### **Conflict of Interest**

The authors declared no potential conflicts of interest related to the research, authorship, or publication of this article.

#### **Ethics** Approval

The Noninvasive Clinical Research Ethics Committee of the Dicle University School of Medicine (Date:25/01/2018, decision no:29) approved the conduct of the study. Permission was obtained from Diyarbakır Gazi Yaşargil Traning and Research Hospital Chief Physician to conduct the study.

#### Availability of data and material

All data and material are available on request from the authors.

## Authors' Contributions

Concept – MA, EDD; Supervision – MA, HK, NY; Materials – MA, HK, NY; Data Collection and/or Processing – HK, NY; Analysis and/or Interpretation – MA, HK, EDD; Writing – MA, EDD.

## Other information

This study was presented at the 7th National Physiotherapy and Rehabilitation Congress, April 18-20, Ankara, Türkiye.

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**Emergency Medicine / Acil Tip** 

# Transfer of Knowledge and Skills to Clinical Practice: Design and Initial Implementation of a Transition Program

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#### ABSTRACT

**Background:** This study aimed to describe the rationale and process of development, implementation and evaluation of a compulsory pass-or-fail transition program designed to facilitate the start-up of preclinical students (third year) to fourth year hospital based clerkships.

**Methods:** Using Kern's 6-step curriculum development model, we developed an innovative curriculum for 4th year medical students designed to ease the transition to clinical clerkship.

**Results:** The TCC (Transition to Clinical Clerkship) program is composed of hospital orientation and observation of roles and responsibilities of healthcare professionals in the hospital, routine investigation skills, procedural skills, rational prescribing, diagnostic reasoning, introduction to basic imaging. Educational strategies: building on preclinical knowledge and skills based clinical simulation and shadowing of nurses and physicians in the hospital environment were used. The TCC program had its first run in the clinical simulation center and the teaching hospitals during the whole month of September 2020 with 84 students and 90 multidisciplinary faculty participating. Evaluation and feedback from students and faculty were positive for all learning outcomes.

**Conclusion:** This paper describes the development and integration of a new transition program from preclinical teaching to clinical clerkship. Although, implemented during the pandemic period, the program ran smoothly and received positive feedback from students, faculty and coordinators.

Keywords: Clinical competence, professional competence, curriculum, medical education, clinical clerkship

#### ÖZET

**Giriş:** Klinik Stajlara Geçiş Programı (The Transition to Clinical Clerkship-TCC) üçüncü sınıf tıp fakültesi öğrencilerinin klinik stajların başladığı dördüncü sınıfa geçişlerini kolaylaştırmak için tasarlanmış zorunlu bir geçiş programıdır. Bu araştırmada TCC'nın geliştirilme, uygulama ve değerlendirme süreçlerini açıklamak amaçlandı.

Yöntem: Kern'in 6 adımlı müfredat geliştirme modeli kullanılarak, klinik staj dönemine geçişi kolaylaştırmak amacıyla 4. sınıf tıp öğrencileri için yeni bir program oluşturuldu ve uygulandı.

**Bulgular:** Klinik Stajlara Geçiş Programı (TCC), hastane oryantasyonu ve sağlık profesyonellerinin rol ve sorumluluklarının gözlemlenmesi, rutin araştırma becerileri, girişimsel beceriler, akılcı ilaç kullanımı, klinik akıl yürütme, temel görüntüleme yöntemlerinin tanıtımını içermektedir. Eğitim yöntemi olarak; simülasyona dayalı eğitim, çevrim içi eğitim, ve klinik ortamda gözlem kullanıldı. Dört haftalık TCC programı ilk olarak Eylül 2020'de 84 öğrenci ve 90 öğretim üyesinin katılımıyla uygulandı. Tüm öğrenim çıktıları öğrencilerden olumlu değerlendirildi.

**Sonuç:** Bu yazı, klinik öncesi dönemden klinik staja geçiş için yeni bir programın geliştirilmesini ve entegrasyonunu ve uygulamasını tarif etmektedir. İlk uygulama pandemi döneminde denk gelmesine rağmen, program sorunsuz bir şekilde işledi ve öğrencilerden, öğretim üyelerinden ve koordinatörlerden olumlu geri bildirim alındı.

Anahtar Kelimeler: klinik yeterlilik, profesyonel yeterlilik, müfredat, tıp eğitimi, klinik staj

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Received: 11.03.2024 Accepted: 29.01.2025

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edical students' transition to clinical clerkship has been shown to be challenging [1,2,3]. Several studies have documented the high levels of stress and anxiety among medical students at this point of transition [2,3]. Since the beginning of the millennium medical curricula have been enriched by such transition programs to overcome this challenge [4,5].

A similar development was observed at Acıbadem University which is a private institution of higher education with an emphasis on health sciences founded in 2007.

A compulsory program entitled TCC (The Transition to Clinical Clerkship) program was developed to facilitate the transition of third year medical students to the clinical clerkships in the fourth year.

The program development started in 2017 and the first implementation of the clinical transition course coincided with the second peak of the Covid-19 pandemic.

The pandemic unexpectedly led to significant changes in medical education worldwide and there is ample literature about hardships encountered during implementation of curricula to curfew circumstances [6,7].

The aim of this paper is to describe the structured process of developing an innovative clinical transition program entitled "Transition to Clinical Clerkship" (TCC) using blended teaching in different learning environments, and its implementation.

# **Material and Methods**

This paper is describing the design process of a projectbased transition program by Kern's Program Development Model. Ethical approval was obtained from the local ethical committee of Acıbadem Mehmet Ali Aydınlar University (ATADEK decision number:2021-09/12 dated 26.05.2021) and all methods were performed in accordance with the Declaration of Helsinki. Verbal consent was obtained from participants. The Kern model is composed of the following six steps [8];

# 1. Problem identification and general needs assessment:

Medical students' transition to clinical clerkship has been shown to be challenging. Clerkships are the first immersive opportunity where medical students start transferring their classroom learning to the real world and students need to affectively adjust to the new learning environment [1,2,3]. This transition requires students to undergo different learning experiences where they face considerable ambiguity and uncertainty. During this time students observe the practices, values, and norms of medical professionals in action. In addition, they are expected to participate in low-risk tasks, taking initiative, engaging in discussion about patient care and being a member of a team consisting of other health professionals. The transition from acquiring theoretical knowledge and conceptual understanding as a preclinical student to using and expanding this knowledge and understanding as a novice practitioner in the clinical environment is a familiar challenge in medical education.

Several studies have documented the high levels of stress and anxiety among medical students at this point of transition. Since the beginning of the millennium medical curricula have been enriched by such transition programs to overcome this challenge [4,5].

# 2. Targeted needs assessment:

There is an institutional program evaluation process which periodically uses standardized evaluation surveys for students and educators, focus groups, structured written reports of the medical education student committee, as well as, academic performance scores.

Iterating results from the institutional program evaluation report revealed a need to improve translation of preclinical students' knowledge and clinical skills performance acquired during the first three years of undergraduate medical education.

Responding to the need described above, the curricular development committee decided to adopt a new approach to improve the transition of clinical skills apprehended in the preclinical phase by developing a new course.

A specific committee for TCC curriculum development was assigned from members of the Medical Education and Curriculum Committee which is a standing committee of the medical school, as well as, academic clinicians. This TCC Curriculum development committee had the task to choose topics and formulate related aims and learning outcomes which were used to compose the program. The committee structured the program reviewing the curricular content of the preclinical period, using the targeted needs assessment steps of Kern's approach described below.

Review of expected clinical skills competency levels of students as defined by preclinical learning outcomes revealed the following topics: routine investigation (general physical examination including vital signs and auscultation findings and history taking), procedural skills (iv., sc., im. injection and catheterization, decontamination, disinfection, handwashing, sterile gloves, handling sterile and contaminated equipment), first aid and basic life support, ECG, as well as, motivational interviewing skills.

Learner expectations and perceptions gathered during standard program evaluation identified the following needs: recall of preclinical knowledge and iteration of skills training sessions and more time dedicated to simulated skills training, clustering clinical and procedural skills training as a block in the curriculum just prior to the clinical clerkship transition in year four, improving contextual learning e.g. in the real life clinical setting with professional role models.

The same method applied to clinical educators highlighted the discordance between clinical skills learned in the preclinical phase and their expected clinical skills level of students for the clerkship.

The course outline developed by TCC Curriculum Development Committee was shared with the education and curricular development committee and the Dean's Office for feedback and final approval. For implementation, a TCC Content Development Task Force was formed where all trainers of the course met at several workshops to finalize the outline and educational materials for each part of the course addressing specific learning outcomes.

# 3. Goals and Objectives:

The TCC curriculum development committee started convening one and a half years before the planned implementation date of the course. Except for reviewing institutional program evaluation results, a comprehensive literature review on interventions facilitating the transition of core concepts of the preclinical medical curriculum to the clinical clerkship period was undertaken. In the light of the results the committee concluded with formulating the aims and learning outcomes for the TCC program. The TCC curriculum development Committee provided the education and curricular committee with the TCC curriculum blueprint. This document outlined specific, achievable, and measureable aims, learning outcomes and assessment – evaluation plan of the TCC program.

# TCC Learning Outcomes:

# *i.* Preparation to clinical skills, participating authentic tasks/ activities

- a. Prioritize and perform history taking and general physical examination
  - Prepare him/herself, the patient and environment for physical examination
  - History taking with the checklist
  - Physical examination with the check list and simulated patient
  - Perform vital signs
- b. Perform basic procedural skills
  - IV, IM, SC injection
  - Inserting nasogastric tube and urinary catheterization
  - Auscultation exercise with task trainer
  - Airway management
  - ECG, monitorization

*ii.* Discuss common medical problems and practice clinical reasoning using core concepts of anatomy, pathophysiology and biochemistry

- Constructing different diagnosis (from symptoms to diagnosis)
- Perform clinical reasoning (preparation to clinical reasoning, facilitating analytic thinking)
- *iii. Define rational prescribing principles*

*iv. Introduction to routines, rules, norms and culture in the healthcare environment* 

a. Be familiar to the relationships in the workplace

b. Understand roles and expectations of the students in clerkship

• Tips and survival skills for clerkships, advice from prior students o Orientation to outpatient, inpatient service in real environment (how to work rounds, how the team works)

- Proper communication skills with patients, relatives, other health professionals
- c. Be familiar with hospital environment
  - Time management and priority
  - Self-care precautions (where and how to advice and seek for support)
  - Give medical orders (diet, consultations)
  - Electronic medical records
  - Health center rules, patient privacy
- d. Experience the confrontation to the other health care professionals in the hospital

v. Introduction to basic imaging methods

# 4. Educational Strategies:

For the different topic areas (history taking and physical examination, critical thinking, rational prescribing, proceduralskills, hospital orientation and inter-professional shadowing, introduction to basic imaging techniques) of this student-centered transition program, active learning

methodologies after standardizing of teaching materials were implemented. This program is unique in its timing within the medical curriculum (threshold course between year 3 and year 4), being a comprehensive teachinglearning block of four weeks and in the way that it is featuring clinical clerkship teachers for skills trainings and inter-professional and multidisciplinary teaching in various learning environments (simulated environment, hospital environment and during the pandemic on-line sessions). The theoretical sessions were planned to be held with team-based-learning (TBL), history taking and physical examination modules were planned to be held with simulated patients (SPs), procedural skills trainings were planned to be implemented via task trainers and manikin based simulators, critical thinking sessions were planned to be organized with virtual patients and casebased discussion sessions in the clinical simulation center. Observing role models in their professional environment was planned to be used for shadowing.

The TCC curriculum and all logistic information about the course was provided to all participants; students, educators, program coordinators, administrative and technical staff in advance (Table 1).

Table 1: Blueprint of Educational Strategy						
Learning Outcomes	Educational Methods	Learning Environment	Assessment			
Preparation to clinical skills, participating authentic tasks/ activities	Task trainers, manikin based simulators	Live-Simulation Center	Observation of performance based on skills checklists			
Discuss common medical problems (symptom based) Practice clinical reasoning with case based discussions recalling preclinical knowledge	Virtual patient	Live-Simulation Center	Active participation to case based discussions			
Define rational prescribing principles with case based discussions recalling preclinical knowledge	Team-based-learning (TBL)	Switched to on-line	Active participation to the workshop and submission of case based worksheets to the learning management system			
Introduction to routines, rules, norms and culture in the healthcare environment	Multidisciplinary Shadowing of Healthcare Professionals	Live -Teaching Hospitals	Active participation and full performance on student professional attitude evaluation checklist			
Introduction to routines, rules, norms and culture in the healthcare environment	Hospital orientation	Switched to on-line (virtual tour)	Active participation			
Introduction to basic imaging methods	Flipped-classroom	Switched to on-line	Active participation			

Table 2: General characteristics of participants				
Participants	Affiliation			
Students (n=84)	ACU SoM, 4th year students			
Faculty (n=90 )				
Anaestesiology (n=1)	ACU CASE			
Family Medicine (n=2)	ACU SoM			
Internal Medicine (n=27)	Teaching Hospitals			
Medical Education (n=1)	ACU SoM			
Nursing (n=33)	ACU CASE, Teaching Hospitals			
Pediatrics (n=21)	Teaching Hospitals			
Radiology (n= 5)	Teaching Hospitals			
Technical Staff (n=3)	ACU CASE			
Administrative/Secretarial Staff (n=9)	ACU CASE, Teaching Hospitals			
Coordinators (n=2)	Vice Medical Director, Vice Director of CASE			
Curriculum development committee (n= 13)				
Dean of ACU SoM	ACU SoM, Teaching Hospitals			
Vice Dean of ACU SoM in Charge of Medical Education	ACU SoM			
Chair and Faculty of the Department of Medical Education (n=2)	ACU SoM			
CMPS (Clinical Medicine Professional Skills ) program coordinator	ACU SoM			
Chair of the Department of Internal Medical Sciences and Co-coordinator	ACU SoM, Teaching Hospitals			
TCC Coordinators, (n=2)	ACU SoM			
Student Representatives from the Student Committee for Medical Education	tACU SoM			
Content Development Group (n=10 )				
Chair of the Assessment and Evaluation Standing Committee	ACU SoM			
CMPS (Clinical Medicine Professional Skills ) program coordinator	ACU SoM			
Chair of the Department of Internal Medical Sciences	ACU SoM, Teaching Hospitals			
Chair of the Department of Pediatrics	ACU SoM, Teaching Hospitals			
TCC Coordinators (n=2)	ACU SoM			
Physician at Internal Medicine in Acıbadem Healthcare Group	Teaching Hospitals			
Nursing (n=2)	ACU Nursing Faculty of Health Sciences			
ACU SoM: Acibadem University School of Medicine				

#### 5. Implementation:

After having been approved by the educational curriculum committee and the faculty board the program was implemented for the first time during the midst of the pandemic, in September 2020 in a block of four weeks and accommodated a variety of participants (Table 2).

#### Logistics:

TCC coordinators and members of the development task force were responsible for preparing educational materials, assessment protocols in accordance with the learning outcomes and coordinating the flow of the course. They were also involved in the implementation and on-site teaching.

A total of 84 students were divided into four main groups which were subdivided into three working groups of six to eight students, each. The orientation module hosted by the hospital administrators was switched to on-line mode. The students rotated between hospital, university campus, on-line teaching activities and selfdirected learning according to the TCC time table. The hospital shadowing activities were carried out by two different clinical specialties namely, pediatrics and internal medicine, and by nurses. The shadowing sessions were organized one-to-one (one student shadowing one instructor). Simulation sessions were organized by rotating groups (6-8 students, each) between different stations with one instructor per station. For on-line sessions, instructors met the students in four main groups. The time slots allocated for self-study had the secondary benefit to allow for make-up sessions for students who could not participate in their group activities according to time table. This was particularly important because the strategy of this course was to achieve mastery level for the learning outcomes. The assessment protocol required full participation and scoring was based on "all-or-nothing" observed performance.

#### **Encountered Difficulties:**

Due to the pandemic, some components temporarily had to be renounced at like a part of the hospital shadowing time, simulated patient encounters for routine investigation skills (history taking and physical examination skills) and student peer-teaching for procedural skills.

Another difficulty was the hardship of standardization of teaching materials and methods and problems in recruiting faculty for supervision of hospital shadowing due to concerns of crowded clinical setting and increased teaching workload. One other obstacle was the problematic time management for clinical faculty because of the distance between the teaching hospitals and campus for facilitating hands on skills training.

To overcome these problems, the course coordinators created time tables for students, as well as, for faculty and technical staff, which were endorsed by all participants.

Originally, simulated patients and student peer teaching were planned as a work force for history taking, physical examination and procedural skills. This could not be realized due to the pandemic. Instead, clinical faculty and student pairs successfully took over these tasks in simulation-based education.

### 6. Evaluation and Feedback:

For assessing student performance, a blueprint was designed (see attachment 1) with a pass or fail criterion expecting full performance and attendance.

For program evaluation purposes the course coordinators created feedback forms for students and educators as well as coordinators based on the modified Kirkpatrick evaluation form.

For course evaluation, feedback was gathered from students via a modified Kirkpatrick evaluation form. The Modified Kirkpatrick Feedback Form is used to assess the effectiveness of training or educational programs. It builds on the Kirkpatrick Model, with the following four levels of evaluation: reaction, learning, behavior, results. The form was applied separately for each module, covering questions on educator performance and an overall evaluation scored over a scale from 0-10. Feedback was collected from 79 out of a total of 84 participating students. It was noted that students scored on-line modules lower than those delivered via face-to-face practice (Table 3).

Table 3: Evaluation of Course Modules by Students							
Course Modules	Learning Environment	Educator Performance Score ("Please score the teaching performance of the educator(s).")	Overall Evaluation Score ("What is the likelihood of you recommending this course to a classmate?")				
Rational Prescribing	On-line-LMS	7,41	6,71				
Pediatric History Taking and Physical Examination	Live-Simulation Center	8,84	8,64				
Adult History Taking and Physical Examination	Live-Simulation Center	8,26	8,33				
Injection and Catheterization	Live-Simulation Center	8,78	8,69				
Auscultation, Monitorization and Airway Management	Live-Simulation Center	8,71	8,88				
Clinical Reasoning	Live-Simulation Center	7,96	7,67				
Basic Imaging Methods	On-line-LMS	6,68	5,71				
LMS: learning management sy	LMS: learning management system						

Open-ended feedback revealed points for improvement like; allowing more time and live clinical environment for the basic imaging technique section and a more structured and concise nurse shadowing schedule (due to unclear importance and context of the related learning outcome). For the rational prescribing module, it was recommended to change the time management in favor of cased-based discussions.

# Discussion

Despite efforts of enabling early patient contact and experience in real-life clinical settings, medical students are experiencing difficulties when passing from the preclinical to the clinical phase. It is known that transferring acquired knowledge and skills to a new unfamiliar setting can cause stress and anxiety in medical students, which can adversely affect learning and academic performance [9,10].

The program described in this paper emerged from a need for better integration and transfer of clinical skills from the preclinical to the clinical clerkship period. The six step Kern approach was used to design this transition program [8]. Initiating the program design with a needs assessment ensured that learning outcomes were relevant in meeting the so far insufficiently met the target of competency transfer to the clinical clerkship period (Table 1). Working with a structured program facilitated implementation in the way that infrastructural needs like workforce, technical facilities and learning environments could be foreseen and planned in advance (Table 2). The structure ensured that assessment methodologies were matching learning outcomes and learning environment [11, 12].

Student feedback results demonstrated the importance of the learning environment (on line or face-to-face) for achieving learning outcomes. In the academic year of 2020-2021, due to the pandemic, some modules originally designed to be delivered face-to-face had to be organized on-line which was the case for the rational prescribing and introduction to basic imaging methods parts of the course. Although, on-line education facilitated time management for clinical faculty and the institutional online learning management system was used effectively, students scored the two on-line modules lower as compared to face-to-face ones which is in accordance with the literature. [13,14].

# Conclusion

The purpose of this paper was to describe the structured approach to design and implement a new transition program to be integrated into the curriculum. Following all steps of Kern approach ensured that this program responded to a need in the curriculum to ease the transfer of preclinical knowledge and skills to the clerkship period. The final step of this program design model is evaluation; in the case of this transition program, student feedback could discriminate unexpected changes in teaching strategies (switching two of the modules from face-toface to on-line) with lower scores. In conclusion, when designing an educational program, it is important to choose a structured approach using a program design model and to follow all steps completely.

# **Declarations**

#### **Acknowledgements**

NA

#### **Declaration of Interest Statement**

The authors declare that they have no conflicting interests.

## Author Contributions Statement

D.K., P.T., D.D.: conception and design, acquisition and interpretation of data, drafting and revising the manuscript critically for important intellectual content

N.B.: contribution to design, revising the manuscript critically for important intellectual content

#### Data Availability Statement

The data that support the findings of this study are openly available in [Acibadem University] at https://openaccess.acibadem.edu.tr/items/fc00c 165b692-4563-8001-31fcd19e47da

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Emergency Medicine / Acil Tıp

# Assessment of Awareness and Knowledge Levels of Individuals Over the Age of 18 Regarding Automated External Defibrillator

Ebru Çelebi<sup>1</sup>, Ganime Esra Soysal<sup>1</sup>

#### ABSTRACT

**Purpose:** This study aimed to assess the levels of awareness and knowledge pertaining to automated external defibrillator (AED) devices among individuals aged 18 and older.

**Methods:** The population of this descriptive study consisted of all individuals over the age of 18 and the sample consisted of literate individuals who volunteered to participate in the study and had internet access. The sample size was determined as 185 people with G\*Power 3.1 programme. 217 people participated in the study. Data were collected between November and December 2021 using the 'Data Collection Form' and 'Information Form about OED'. These forms were sent to individuals via a link created on surveey.com. Written permission was obtained from the Human Research Ethics Committee of a university (Protocol No: 2021/426).

**Results:** The mean age of the study participants was 31.92±10.9 years. Of the participants, 65.9% (n:143) were employed in fields unrelated to healthcare, and 10.6% (n:23) held first-aid certifications. Findings revealed that 47.0% (n:102) of the participants had prior knowledge of AEDs, while 57.6% (n:125) were unaware of AED locations. A total of 53.0% (n:115) were uncertain about who could operate an AED, 84.3% (n:183) lacked knowledge about AED operation, and 79.7% (n:173) expressed a desire for AED device and usage training. Importantly, participants with first-aid training exhibited higher levels of AED-related knowledge.

**Conclusion:** Despite the relatively low baseline knowledge and awareness of AEDs among participants, there is a clear willingness to receive education on this life-saving device.

Keywords: Automated external defibrillator, emergency, cardiac arrest

#### ÖZET

Amaç: Bu çalışmada 18 yaş üstü bireylerin OED cihazına ilişkin farkındalık ve bilgi düzeylerinin incelenmesi amaçlanmıştır.

Yöntem: Tanımlayıcı türde olan bu çalışmanın evrenini 18 yaş üstü olan tüm bireyler, örneklemini ise okuryazar, çalışmaya katılmaya gönüllü ve internet erişimi olan kişiler oluşturdu. G\*Power 3.1 programı ile örneklem büyüklüğü 185 kişi olarak belirlendi. Çalışmaya 217 kişi katıldı. Veriler Kasım-Aralık 2021 tarihleri arasında, 'Veri Toplama Formu' ve 'OED Hakkında Bilgi Formu' kullanılarak toplandı. Bu formlar surveey.com üzerinden oluşturulan bir link ile bireylere gönderildi. Araştırmanın yapılabilmesi için bir üniversitenin İnsan Araştırmaları Etik Kurulu'ndan (Protokol No:2021/426) yazılı izin alındı.

**Bulgular:** Çalışmaya katılanların yaş ortalamalarının 31.92±10.9 olduğu, %65.9 (n:143)'sinin sağlık dışında başka bir alanda çalıştığı, %10.6 (n:23)'sının ilk yardım sertifikası aldığı görüldü. Katılımcıların %47.0 (n:102)'si OED ifadesini daha önce duyduğunu, %57.6 (n:125)'sı OED'nin nerelerde bulunabileceğini bilmediğini, %53.0 (n:115)'ü OED'yi kimlerin kullanabileceğini bilmediğini, %64.3 (n:183)'ü OED'nin nasıl kullanılacağını bilmediğini ve % 79.7 (n:173)'si ise OED cihazı ve kullanımı hakkında eğitim almak istediğini belirtti. İlk yardım ile ilgili eğitim alanların OED ile ilgili bilgi düzeylerinin, almayanlara oranla daha yüksek olduğu saptandı.

Sonuç: Çalışmaya katılanların OED ile ilgili bilgi ve farkındalıklarının düşük olmasına karşın eğitim almaya istekli oldukları görüldü.

Anahtar Kelimeler: Otomatik eksternal defibrilatör, acil, kardiyak arrest

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**Received:** 26.01.2024 **Accepted:** 15.03.2024

"This study was presented as a poster presentation at the "4th INTERNATIONAL 12th NATIONAL TURKISH SURGERY AND OPERATING ROOM NURSING CONGRESS" held in Antalya on 13-16 January 2022."

n contemporary times, the occurrences of disasters, earthquakes, and similar events necessitate the formulation of emergency plans and the cultivation of awareness (1). One of the most prevalent and critical situations requiring immediate intervention in such emergencies is cardiac arrest. The utilization of an automatic external defibrillator in first aid procedures is of paramount importance in order to enhance survival rates in cases of cardiac arrest. An automated external defibrillator (AED) is a compact, lightweight, and portable medical device designed for the purpose of saving lives in the event of sudden cardiac arrest. It operates by delivering an electric shock to an individual's heart in order to restore its normal rhythm as swiftly as possible. Sudden cardiac arrest is a critical medical emergency where the heart's electrical activity becomes irregular, potentially leading to a life-threatening condition. AEDs are equipped with user-friendly features and clear instructions that enable both trained and untrained individuals to administer the necessary electric shock to the affected person's chest (2-4). AEDs are commonly found in public places, workplaces, and healthcare facilities, providing a crucial means of intervention during a cardiac crisis. Early defibrillation plays a critical role in treating certain arrhythmias, highlighting the significance of raising awareness about Automated External Defibrillators (AEDs). Many countries have incorporated AED usage into pre-hospital procedures and Basic Life Support (BLS) guidelines, making AEDs readily available in public places such as airports, train stations, shopping malls, sports facilities, and large buildings to enhance the response to sudden cardiac emergencies (5,6). The timely and accurate application of Basic Life Support (BLS) is paramount for increasing survival rates, especially in the critical first 4 minutes after cardiac arrest. If this window extends beyond 8 minutes, it can result in irreversible damage to the individual's brain functions. The American Heart Association's (AHA) 2020 Cardiopulmonary Resuscitation (CPR) guidelines emphasize the importance of implementing the 'Life-Saving Chain' for effective CPR, consisting of five vital components: immediate recognition of cardiac arrest and activation of the emergency response system, early CPR, rapid defibrillation, effective advanced life support, and integrated post-cardiac arrest care. These CPR steps, encompassing the first three links in the chain, can also be administered by trained laypersons. It is crucial that these steps are carried out in a sequential and prompt manner to achieve successful BLS (7,8).

In cases of cardiac arrest occurring outside the hospital environment, it is disheartening to note that the survival rate of patients remains below 10%, despite ongoing efforts to advance resuscitative techniques within healthcare facilities (9). A study conducted by Berdowski et al. revealed that ventricular fibrillation (VF) was the initial rhythm in 27% of all out-of-hospital cardiac arrest cases, with an average survival rate of 7% among adults (10). In out-of-hospital cardiac arrest situations, it is crucial to maintain high-quality CPR until the arrival of the emergency medical team. Notably, in densely populated areas, the application of Automated External Defibrillators (AEDs) nearly doubles the survival rate in these cases. Encouragingly, individuals with access to AEDs should prioritize early defibrillation, as this combined with early CPR significantly enhances the likelihood of a positive outcome (11-13). AEDs can be operated not only by individuals with medical training but also by those with certified first aid training. In numerous countries, the inclusion of CPR and AED training has been made compulsory as part of general training at various levels (13).

While there are a limited number of studies assessing the public's awareness and knowledge of CPR, several studies have focused on the AED device and its usage. This study aims to evaluate the awareness and knowledge levels of individuals aged 18 and above regarding the AED device.

# **Materials and Methods**

This descriptive and cross-sectional study was conducted during the period of November to December 2021.

#### Universe and Sample:

The study encompassed individuals aged 18 and above as its target population. A non-probabilistic sampling method, specifically an easy sampling approach, was employed for sample selection. The sample size of 217 people was determined using the G\*Power 3.1 program, considering an effect size of 0.25 based on prior research findings. The study included individuals who were over 18, literate, willing to participate, and possessed internet access. This study included individuals residing in several provinces, such as Ankara, Adana, Aksaray, Balıkesir, Bartın, Batman, Bolu, Bursa, Canakkale, Corum, Diyarbakır, Düzce, Eskişehir, Gaziantep, Giresun, Isparta, Istanbul, Izmir, Kahramanmaraş, Karabük, Kastamonu, Kayseri, Kocaeli, Konya, Manisa, Mardin, Ordu, Sakarya, Samsun, Sanlıurfa, Sırnak, Tekirdag, Tokat, Trabzon, and Zonguldak In Turkey.

### Data Collection Tools:

Data were collected using a two-part data collection form developed by the researchers after reviewing relevant literature. The first part of the form gathered information about participants' sociodemographic characteristics and their first aid background, including whether they had received first aid training or worked in the healthcare sector. The second part of the form included 23 questions designed to assess participants' knowledge about Automated External Defibrillators (AEDs). Participants were required to respond to these questions by selecting "True," "False," or "I Don't Know." The data collection form was administered to participants through a link created on the "www.surveey.com" platform, with each participant spending approximately 15-20 minutes to complete it.

## Data Analysis:

The collected data were analyzed using computer software, with statistical measures such as numbers, percentages, means, and chi-square analyses employed. Skewness and kurtosis values were used to assess the normality of the data distribution, where values typically fall within the range of -2 to +2 for normally distributed data (14). Significance testing was conducted, with a p-value less than 0.05 indicating a significant difference between groups, while a p-value greater than 0.05 indicated no significant difference.

## Ethical Considerations:

For the execution of this study, a work permit was obtained from the Human Research Ethics Committee under protocol number 2021/426. Before commencing the study, all participants were provided with information regarding the study's purpose and the confidentiality of their data, assuring them that the data would only be used for scientific purposes. Participants were also asked for their consent to participate. Those who voluntarily agreed to participate were included in the study.

## Results

The study revealed that the mean age of the participants was  $31.92\pm10.9$  years, with 71.9% (n:156) of them being female. Additionally, 48.8% (n:106) were university graduates, 30.5% (n:65) were married, 26.3% (n:57) had children, and 70.5% (n:153) resided in urban centers.

Among the participants, 65.9% (n:143) were employed in fields unrelated to healthcare, and 10.6% (n:23) possessed a first aid certificate (Table 1).

Table 1. Defining features				
Definin	ng Features			
31,92±	10.9(18-65)	Mean±sd(min-max)		
Age		31,92±10.9(18-65)		
		(n)	(%)	
Gende	r			
Female		156	71.9	
Male		61	28.1	
Marita	l status			
Married	ł	65	30.0	
Single		152	70.0	
Educat	ion			
Primary	/-secondary school	9	4.2	
High so	hool	79	36.4	
License		706	48.8	
Graduate		23	10.6	
Status	of having children			
Yes		57	26.3	
No		160	73.7	
Living	place		-	
Provinc	e	153	70.5	
Town		50	23.0	
Village		14	6.5	
Status	of being a health worker	•		
	-Nurse	38	17.5	
	-Nursing Students	19	8.8	
Yes	-Other health workers (paramedic, anestesia	17	7.8	
les	technician, midwife, etc.)			
	Total	74	34.1	
No		143	65.9	
Status	of receiving first aid training	•		
Yes		151	69.6	
No		66	30.4	
Status	of receiving first aid certificat	e		
Yes		23	10.6	
No		194	89.4	

As detailed in Table 2, 47.0% (n:102) of the participants reported prior awareness of AED, with a notably higher awareness rate among women (36.9%; n:80) than men (10.1; n:22) (Chi-square:4,076;  $p \le 0.05$ ). Among those who were aware of AED, 41% (n:50) mentioned having encountered the term during first aid courses at university, 27% (n:33) had heard of it through their involvement in healthcare, and 19.7% (n:24) had acquired this knowledge via the internet or television. Others cited occupational health and safety training at work or having family members in healthcare as sources of their awareness about AED.

Table 2. Information status for the AED							
	Y	es	No				
Questions	(n)	(%)	(n)	(%)			
Have you heard the phrase "Automatic External Defibrillator (AED)"?	102	47.0	115	53.0			
Do you know where the AED is/can be found?	92	42.4	125	57.6			
Do you know who can use AED?	102	47.0	115	53.0			
Do you know how to use AED?	34	15.7	183	84.3			
Do you know what sudden cardiac arrest means?	174	80.2	43	19.8			
Have you ever encountered an individual who developed sudden cardiac arrest?	48	22.1	169	77.9			
Do you know that rapid use of AED can improve survival?	115	53.0	102	47.0			
Do you know that AED gives an audible alert?	71	32.7	146	67.3			
Would you like to receive training about the AED device and its use?	173	79.7	44	20.3			

In this study, 57.6% (n:125) of the participants were uncertain about the locations of AED devices, 53.0% (n:115) were unsure about who could operate AEDs, 84.3% (n:183) were unfamiliar with how to use AEDs, 80.2% (n:174) understood the meaning of sudden cardiac arrest, 22.1% (n:48) didn't know anyone who had experienced sudden cardiac arrest, 47.0% were unaware of the potential survival benefits of rapid AED usage, and 79.7% (n:173) expressed their interest in receiving training on AED devices and their use.

Among individuals with first aid training, 58.6% (n:85) correctly identified that AEDs are used to restore a stopped heart, while 4.1% (n:6) believed it to be a device supporting breathing, and 29.0% (n:42) thought it could only be operated by healthcare professionals (Table 3). Furthermore, 20.7% (n:30) of those with first aid training claimed they knew how to use AED devices. The overall AED utilization rate among all participants was 14.3% (n:30). Notably, 80% (n:168) of the participants could recognize signs of cardiac arrest, with significantly higher rates in areas where training was provided ( $p \le 0.05$ ). Surprisingly, 79.5% (n:167) of the participants expressed their desire to receive AED training despite having undergone first aid training.

Table 3. Information status for AED use							
Statements for the use of AED		True		False		l do not know	
		(%)	(n)	(%)	(n)	(%)	
AED is used to apply electric shock to the patient as soon as possible during sudden cardiac arrest.	138	63.6	4	1.8	75	34.6	
AEDs are lightweight and portable devices.	101	46.5	22	10.1	94	43.3	
AED gives the user an audible alert.	116	53.5	0	0.0	101	46.5	
AED is used only by medical personnel.	63	29.0	64	29.5	90	41.5	
AED analyzes the heart rhythm.	88	40.6	22	10.1	107	49.3	
AED is contained in a protective box in crowded environments (such as airports, airplanes, and shopping malls).	97	44.7	7	3.2	113	52.1	
Anyone who has received AED-certified first aid training can use it.	84	38.7	22	10.1	111	51.2	
A universal sign is used to indicate the presence of AED in the environment.	84	38.7	5	2.3	128	59.0	
AED is used only for adult persons.	18	8.3	82	37.8	117	53.9	
During AED use, the user does not need to know the current rhythm.	28	12.9	69	31.8	120	55.3	
When using AED, the device's directions must be applied with caution.	138	63.6	4	1.8	75	34.6	
Standard AED is available to anyone over the age of 8.	49	22.6	19	8.8	149	68.7	

		Those who receive first aid training (n: 151)			Those who have not received first aid training (n:69)		
		n	%	n	%		
Gender	- <u>-</u>	L					
Female		111	51.2	45	20.7	<i>p</i> :0.26	
Male		40	18.4	21	9.7		
Age	1	00	10.6	21	142		
18-24		88	40.6	31	14.3		
25-29		18	8.3	6	2.8	<i>p</i> :0.12	
30 and up		45	20.7	29	13.4		
Marital status	- <u>-</u>	42	10.4	22	10.0		
Married Single		42 109	19.4	23 43	10.6	<i>p</i> :0.18	
Education	1	1 109	50.2	43	19.8		
Primary-secondary school	1	5	22.3	4	4.1		
High school		49	22.3	30	13.8		
icense	-	79	36.4	27	13.8	<i>p</i> : 0.10	
Graduate		18	8.3	5	2.3		
Place to live		1 10	0.5	J	2.5		
Province	1	108	49.8	45	20.7		
Town		32	14.7	18	8.3	p: 0.51	
/illage		11	5.1	3	1.4	p. 0.51	
vinaye	Yes	87	40.1	15	6.9	<i>p:</i> 0.0001*	
Have you heard the AED phrase before?	No	64	29.5	51	23.5		
	Yes	76	35.0	16	7.4	<i>p:</i> 0.0001*	
Do you know where the AED is/can be found?	No	75	33.0 34.6	50	23.0		
	Yes	86	39.6	18	8.3		
Do you know who can use AED?	No	65	30.0	48	22.1	<i>p</i> : 0.0001	
	Yes	31	14.3	3	1.4		
Do you know how to use the AED?	No	120	55.3	63	29.0	<i>p:</i> 0.001*	
				41			
Do you know what sudden cardiac arrest means?	Yes	133	61.3		18.9	p: 0.0001*	
	No	18	8.3	25	11.5		
Have you ever encountered an individual who developed sudden cardiac	Yes	43	19.8	5	2.3	<i>p</i> : 0.0001*	
arrest?	No	108	49.8	61	28.1		
Do you know that rapid use of AED can improve survival?	Yes	96	44.2	19	8.8	<i>p:</i> 0.0001*	
· · · · · · · · · · · · · · · · · · ·	No	55	25.3	47	21.7	F	
Do you know that AED gives an audible alert?	Yes	62	28.6	9	4.1	p: 0.0001 <sup>+</sup>	
,	No	89	41.0	57	26.3	F	
Marilal variables to associate testinicate allocate the AFD devices and the set of	Yes	121	55.8	52	24.0	r 0.47	
Nould you like to receive training about the AED device and its use?					6.5	p: 0.47	

It was observed that 69.6% (n:151) of the participants had received first aid training. When comparing study participants based on their first aid training status in terms of gender, age, marital status, education level, and place of residence, no significant differences were identified ( $p \ge 0.05$ ). Additionally, those who had received

first aid training displayed higher levels of knowledge about AED compared to those who had not. Regardless of their awareness, both those with and without first aid training expressed a willingness to undergo AED device and usage training (Table 4).

# Discussion

In cases of out-of-hospital cardiac arrest, the survival rate experiences a significant boost when early defibrillation is combined with prompt cardiopulmonary resuscitation (CPR) efforts(10–12). Therefore, it is imperative to encourage the use of Automated External Defibrillators (AEDs), especially in densely populated areas, as they offer the potential for early defibrillation by trained first aid providers.

While there is limited research focusing on public awareness and knowledge of Basic Life Support (BLS) in our country, there is a scarcity of studies examining AED awareness and usage. A study assessing the readiness of healthcare professionals to administer BLS revealed that nurses often possess inadequate knowledge and may lack up-to-date information on the topic (15). Similarly, Aygin et al. (2018) noted that nurses' knowledge levels about providing BLS were at a moderate level, suggesting the need for regular updates (16). A study involving college students, despite half of them having received CPR education, indicated insufficient knowledge about the subject (17). Çelikli et al. reported that emergency medical technicians, paramedics, nurses, and other healthcare personnel exhibited low levels of knowledge regarding BLS application, with few participants identifying AED as part of CPR practices (18). Consequently, these studies collectively underscore the notion that individuals receiving CPR training, even within the healthcare sector, may have inadequate knowledge levels in this domain. In this study, it was observed that approximately 69.6% of participants had received first aid training. However, it is worth noting that while a considerable number had undergone first aid training, many were not certified in first aid, and these individuals generally lacked the know-how to operate AEDs. A closer examination of their knowledge regarding AED usage revealed a clear insufficiency in this regard.

Notably, a study conducted in sports facilities in Italy highlighted that a significant portion of participants believed that only those with substantial training should operate AEDs, even though they themselves lacked training in this area. Furthermore, this study revealed that participants generally possessed inadequate knowledge and skills related to the use, operation, and maintenance of AEDs (19). Similarly, research conducted in Australian sports facilities found that a significant number of participants, including healthcare workers, had witnessed sudden cardiac arrests but had not received prior AED training(20). Another study in South Korea reported that although KPR training was regularly provided to various first responders, including ambulance drivers, bus drivers, police officers, flight and train attendants, sports instructors, and tour guides, the use of AEDs did not conform to the guidelines established by the European Research Council (ERC) and the American Heart Association (AHA) (21). This discrepancy may be attributed to a lack of training from certified institutions. It is important to emphasize that AEDs can be operated not only by individuals with medical backgrounds but also by those with certified first aid training, as CPR and AED training have been mandatory components of general education at different levels in many countries (13). After the first aid trainings given in our country, people are subjected to the practical and written exams. The practical implementation of exams and trainings in this way increases their effectiveness. Trainings should be renewed at fixed intervals.

In a study on CPR conducted in our country, more than half of the participants reported never having heard of AED, and the majority were unaware of the locations of AED devices (22). Similarly, an overseas study found that over half of the participants had no knowledge of AED and lacked adequate understanding of AED usage (23). Consistent with these findings, our study indicated that while approximately half of the participants had heard of AED before, a substantial percentage remained unfamiliar with the correct operation of AEDs. Additionally, individuals who had previously completed first aid courses at university exhibited a higher awareness of AED. This discrepancy may be attributed to the educational background, with approximately half of the participants in our study having obtained a bachelor's degree. Interestingly, our research found that those who had undergone first aid training demonstrated better knowledge of AED compared to those who had not received such training. Furthermore, over half of the participants recognized the potential survival benefits associated with rapid AED use. Studies have demonstrated the greater effectiveness of early defibrillation compared to early CPR (11,12), as AED application significantly enhances survival rates, particularly in out-of-hospital cardiac arrest situations (10). Given the urgency of cardiac arrest and the importance of timely intervention, it is crucial to direct individuals towards certified first aid training.

Furthermore, our study showed a strong willingness among participants to receive education on AED devices

and their usage. Additionally, both those who had received first aid training and those who had not expressed a high interest in obtaining AED training. This suggests that individuals who attended first aid training or courses prior to changes in first aid regulations may not have received comprehensive instruction, but an awareness has been raised regarding AED usage. The revised first aid regulations now require compulsory AED training at certificate-issuing first aid centers.

Consequently, it can be inferred that individuals who have not undergone first aid training but are willing to receive AED training are open to personal development and are cognizant of the importance of saving lives. It is expected that technological advancements and the emphasis on first aid, AED devices, and related topics through the internet, media, and social media have contributed to raising public awareness.

## Study Limitations:

This study was limited by the accessibility to participants with internet access and higher educational levels. Furthermore, given the diverse provinces in our country, the fact that participants were selected from only 35 provinces represents another limitation of this research.

# Conclusion

Early defibrillation, along with prompt recognition of sudden cardiac arrest and the activation of emergency medical teams, is critical for improving survival rates. However, it is essential to have widespread AED deployment and ensure public awareness regarding the location, use, and purpose of AED devices. Although the awareness and knowledge levels of the participants in this study about AED were found to be low, their willingness to receive education was apparent. Given the potential impact of early defibrillation on survival rates, it is recommended to enhance AED training and utilization, incorporating it into curricula at all educational levels and conducting comparative studies with larger sample groups in this domain.

## Acknowledgments

This study did not receive financial support.

## Conflict of interest

The authors declare that they have no conflict of interest.

### Data availability

Data sharing not applicable to this article as no datasets were generated or analyzed during the current study.

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# Investigation of Corneal Changes in Contact Lens Users

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#### ABSTRACT

Purpose: Analysed the effects of contact lens use on the structural characteristics of the cornea.

Methods: Corneal changes analized by OCT, topography and specular microscope. Schirmer test was performed.

**Results:** Epithelial thickness, posterior K2, the number of endothelial cells and their density were found to be different in lens users and control group. When subgrouped according to duration of lens, endothelial cell numbers were statistically different between subgroups.

**Conclusion:** Silicon hydrogel lenses have hypoxic effects on the corneal structure. Recently refractive surgery has become popular. Most patients who want to undergo refractive surgery have used contact lenses in the past. That's why it's important to know the effect of contact lenses on the corneal structure.

Keywords: Anterior segment OCT, Contact Lens, Sirius topography, Specular microscopy

#### ÖZET

Amaç: Kontakt lens kullanımının, korneanın yapısal özellikleri üzerindeki etkilerini, değerlendirmek.

Metodlar: Kornea değişiklikleri; OCT(Optik Koherens Tomografi) kornea topografisi ve speküler mikroskopi kullanılarak analiz edildi. Schirmer testi yapıldı.

**Bulgular:** Gruplar arasında; posterior K2, epitel kalınlığı, endotel hücre sayısı ve endotel hücre yoğunluğu farklı bulundu. Kontakt lens kullanıcıları lens kullanım sürelerine göre gruplandırıldığı zaman endotel hücre sayıları farklılık gösterdi.

**Tartışma:** Silikon hidrojel lenslerin kornea yapısına hipoksik etkileri vardır. Son zamanlarda refraktif cerrahi oldukça populer hale gelmiştir. Refraktif cerrahi olmak isteyen hastaların bir çoğu geçmişinde kontakt lens kullanmıştır. Bu nedenle kontakt lenslerin korneaya olan etkilerini bilmek önemlidir.

Anahtar Kelimeler: Ön segment OKT, Kontakt Lens, Sirius topografisi, speküler mikroskopi

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Received: 25.12.2023 Accepted: 16.12.2024 ornea has an important role in the formation of visual function. Stroma, which creates about 90% of the cornea, is the main component that determines the mechanical and refractive characteristics of the cornea(1).The maintenance of hydration in the stroma is largely dependent on endothelial activity. The endothelium sustains the osmotic gradient required for this function through Na-K ATPases and carbonic anhydrase enzymes. The number (500 cells/mm<sup>2</sup>) and morphology of the endothelial cells are critical for the transparency of the cornea. The increase in the cell size (polymegathism) and the differences in cellular shape (pleomorphism) also affect the endothelial function(2).

Contact lenses leads to hypoxi for cornea and adversely affects oxygen-dependent metabolic activity(1). Hypoxia converts the corneal metabolism, which is normally aerobic, to anaerobic glycolysis, resulting in the backlog of lactic acid in the stroma. Lactic acid affects endothelial morphology and function by creating edema and stromal acidosis. Long-term persistent stromal edema causes changes in keratocyte morphology and function(3,4).

Contact lenses have been used to correct refractive errors since the early 19<sup>th</sup> century. Gas-permeable hard contact lenses and soft hydrogel lenses were introduced in the 1970s, and starting from 1998, high-permeability silicon hydrogel lenses have been widely used(5,6).

PMMA is the first material to be used for contact lens production. It is durable, transparent and highly wettable; however, due to its relatively high hypoxic activity, it is not preferred for lens manufacturing nowadays. The most commonly used rigid, gas permeable lenses are silicone acrylates, because of their high oxygen permeability due to silicone and optical transparency provided by PMMA(7,8).

Soft contact lenses are made of hydrogels and silicone hydrogels. Hydrogel lenses have water-retaining ability. This ability enables improvement in oxygen permeability, elasticity, light refractive strength and tensile strength(9,10). Silicone hydrogel lenses are produced by combining the water retention property of the hydrogel with the oxygen permeability of the silicone. Lotrafilcon A and Balafilcon A are the first silicone hydrogel lenses(11).

Hypoxic effects such as thinning in the corneal epithelium, limbal hyperemia and vascularization, microcyst formation, stromal thinning, and alteration of endothelial morphology that are observed after the use of hydrogel contact lenses were not observed in patients who use of silicone hydrogel lenses(12,13).

Modulus is a parameter which shows the deformation resistance of the contact lens and its mechanical properties. High modulus silicone hydrogel lenses are more rigid and resistant to deformation. High modulus lenses do not fully fit on the surface of the cornea and conjunctiva, which causes them to form a variable aqueous phase profile, particularly pronounced in the midperifera, and reflect the valve pressure more. As a result of contact between the protective mucin layer and lens epithelium, they may cause damage to the epithelium(14).

# **Material and Methods**

95 patients with refractive error, who have been using contact lenses for at least 3 months and a minimum of 8 hours a day were analyzed (Group 1). Patients who has any ocular surface diseases, corneal ectasia diseases, degenerative myopia, a cylindrical refraction defect of more than -2 degrees, and ocular trauma or surgery were not included. 95 patients were divided to groups according to duration of lens use. Patients who used lenses for 18 months or less were called Group 3, who used lenses for 19 months or more called Group 4. The patients had removed their lenses 8-12 hours before the examination. Measurements were performed in the morning to prevent diurnal effect. Control group consisting of 95 subjects who applied to our clinic and did not have any pathology in ophthalmologic examination (Group 2).

Stromal and epithelial thickness was measured with Heidelberg Spectralis Optical Coherence Tomography anterior segment module (AS – OCT (Heidelberg Engineering, Germany). Thickness were measured by using the central cornea typical vertex reflex by the same trained personnel.

Central corneal thickness(CCT), posterior K1 and K2 were obtained with the Sirius<sup>®</sup> topography(Costruzione Strumenti Ophthalmici, Florence, Italy). Endothelial values were obtained using a Nidek Cem 530 specular microscope. Schirmer test was performed without using topical anesthesia and the eye was closed for 5 minutes after placement of a tape at the junction of the lateral and middle one third of the conjunctival sac. Five minutes later, the amount of wetting in the strip was recorded in millimeters.

### Statistical Analysis

SPSS for Windows 21.0 was used for analysis. Mean, standard deviation, frequency and percentage values were used to evaluate the study data. The Kolmogorov-Smirnov test was used to determine whether the quantitative data met the normal distribution parameters. In the comparison of the two groups, t-test was used to compare the normally distributed variables and Mann-Whitney U test was used for the non-normally distributed variables. In comparison of more than two groups, Kruskal-Wallis test was used for variables with normal distribution and ANOVA with non-normal distribution. Chi-square test was used to compare categorical data. P <0.05 was considered statistically significant.

## Results

21 were male and 74 were female in group 1. 23 were male and 72 were female in group 2. The mean age of 22.8 in group 1, and 23.8 in group 2. Terms of gender distribution and mean age were similar in groups. The mean CCT was 538.02  $\mu$ m, 5.72 D for posterior K1, and 6.32 D posterior K2 in group 1. In group 2, mean values were 535.09  $\mu$ m for CCT, 5.76 D for posterior K1, and 6.13 D for posterior K2(**Table** 1). Posterior K2 was statistically significant (p<0.05).

Table 1: The comparison of topographic values of Groups 1 and 2							
	Group	Number	Mean	Std. Dev.	T-test value	P value	
сст	1	190	538.02	35.69	0.92	0.35	
	2	190	535.09	33.86			
	1	190	5.72	0.32	1.1.4	0.35	
postk1	2 190 5.76	5.76	0.23	-1.14	0.25		
	1	190	6.32	0.52		0.00	
postk2	2	190	6.13	0.25	4.50		
CCT: central corneal thickness, postk: posterior keratometry, std:standard							

Table 2: The comparison of schirmer, anterior segment OCT, specular values between groups								
	Group	Number	Mean	Std. Dev.	t-test value	p value		
Schirmer	1	190	22.73	8.29	0.33	0.73		
Schimer	2	190	22.42	9.31	0.55			
Characterist	1	190	446.69	36.29	0.54	0.53		
Stromal t	2	190	459.66	35.68	0.54			
	1	190	27.76	5.93	-2.88	0.00		
Epithelial thickness	2	190	29.73	7.22	-2.00			
	1	190	68.44	4.89	0.53	0.59		
Hex. cell	2	190	68.72	5.43	-0.53			
	1	190	2772.40	247.69	2.39	0.01		
Endothel den	2	190	2709.80	261.16	2.39			
Endothelial cell number	1	190	214.13	48.22	6 70	0.00		
	2	190	180.77	47.43	6.79	0.00		
stromal t: stromal thickness, Hex: hexagonal, Endothel den: endothelial cell density								

Epithelial thickness was 27.7  $\mu$ m in group 1 and 29.7  $\mu$ m in the group 2, and the difference was statistically significant. Endothelial density was 2772 in group 1 and 2709 in group 2, and there was a significant difference. Endothelial counts of the two groups, which were 214.1

in group 1 and 180.7 in group 2, were also statistically significantly different. On the other hand, the hexagonal cell count, stromal thickness and schirmer test results were similar between groups. (**Table 2**).

Patients wearing contact lens were further divided into 2 subgroups according to the duration of lens use. Group 3 consisted of 50.5% of the cases (48 cases), while Group 4 was 49.5% (47 cases). The mean age of Group 3 was 21.52  $\pm$  3.31 years, and of these patients 18.75% were men and 81.25% were women. Similarly, the mean age of group 4 was 24.19  $\pm$  4.99 years and of these 25.53% were men and 74.47% were women. Gender ratios were similar between the groups.

posterior K1, 6.37 D for posterior K2, 27.64  $\mu$ m for epithelial thickness, 456.90  $\mu$ m for stromal thickness, 68.79 for hexagonal cell ratio, 2784.7 for endothelial cell density, and 214.13 for endothelial number. In Group 4, 21.65 for schirmer, 542.89  $\mu$ m for CCT, 5.68 D for posterior K1, 6.26 D for posterior K2, 27.88  $\mu$ m for epithelial thickness, 466.48  $\mu$ m for stromal thickness, 68.08 for hexagonal cell ratio, 2759.8 for endothelial cell density, and endothelial number was 188.99. Between Groups 3 and 4, there was only a difference between the endothelial cell numbers (**Table 3**).

In Group 3; 23.78 for schirmer, 534 µm for CCT, 5.77 D for

Table 3: The comparison of topographical, specular and OCT values between Groups 3 ve 4								
	Duration of contact lens wear	Number	Mean	SD	t test value	P value		
Schirmer	0-18 months	96	23.78	8.54	1 77	0.07		
	>19 months	94	21.65	7.93	1.77			
((7	0-18 months	96	534.00	38.96	-1.72	0.08		
сст	>19 months	94	542.89	31.60	-1.72			
postk1	0-18 months	96	5.77	0.37	1.89	0.06		
postki	>19 months	94	5.68	0.26	1.09			
postk2	0-18 months	96	6.37	0.65	1.43	0.15		
postk2	>19 months	94	6.26	0.33	1.45			
	0-18 months	96	456.90	40.21	-1.82	0.07		
Stromal t.	>19 months	94	466.48	31.38	-1.82			
	0-18 months	96	27.64	5.82	0.26	0.78		
Epithel d.	>19 months	94	27.88	6.08	-0.26			
	0-18 months	96	68.79	4.77	0.00	0.22		
Hex. Cell	>19 months	94	68.08	5.00	0.99	0.32		
Endothelial cell density	0-18 months	96	2784.7	251.89	0.00	0.49		
	>19 months	94	2759.8	244.03	0.69			
Endothelial cell number	0-18 months	96	214.13	48.22				
	>19 months	94	188.99	44.74	5.26	0.00		
postk: posterior keratometry, stromal t:stromal thickness, Hex: hexagonal, Endothel d.:endothelial density								

## Discussion

The objectives of the development of this technology has been to provide the best visual acuity, to ensure that the lens conforms to the architecture of the cornea and not to limit the metabolic activity within the cornea. Contact lenses create a hypoxic environment and adversely affect corneal metabolism. Hypoxic effects have been minimized by the development of silicon hydrogel lenses. However, these lenses may adversely affect the corneal architecture as a result of mechanical and inflammatory effects due to their high stiffness modulus parameters(15,16).

Studies have also shown that the use of contact lenses is more common among women as we found(16,17). Women may prefer to wear contact lenses more due to aesthetic reasons, and they may have higher dexterity than men which is required for contact lens use.

Corneal refractive change has also been reported after use of soft lenses, and this change has been attributed to corneal edema(18–20). Silicon hydrogel lenses have high stiffness modulus and low water content, causing indentation effects on the conjunctiva and cornea, leading to central corneal flattening and epithelial lesions. The epithelial indentation effect was seen as post-lens debris, mucin balls or lipid plugs after removing the lens(21).

Topographic data showed there was no difference in posterior K1 and CCT between groups, whereas posterior K2 was significantly higher in group 1 compared to the control group. In group 3 and 4, we found that central corneal thickness, posterior K1 and posterior K2 were not different between the subgroups.

In a study, the patients were followed for 12 months during lens use and for 3 months after stopping lens wearing, and shown that the maximum flattening of the anterior curvature was observed at the 3<sup>rd</sup> month of contact lens wear, and the anterior curvature values increased again in the next 9 months. Observed that these values returned back to the initial values 3 months after stopping contact lens wear and a maximum thinning of the central corneal thickness at 12 months of lens wear(22). Other studies showed that hard gas permeable lenses and soft contact lenses (hydrogel and silicone hydrogel) affect corneal structure by causing flattening or steepness in the cornea, regular or irregular astigmatism, and loss of radial symmetry(19,21,23,24).The effect of soft contact lenses on the anterior curvature refraction ability may be due to the rearrangement of the corneal tissue caused by the mechanical interaction between the silicon hydrogel lens and the corneal surface, rather than the hypoxia. The compression effect of the contact lens on the cornea, the higher reflection of the valve pressures compared to the hydrogel lenses, and damage to the epithelium structure may result in changes in the anterior curvature(22,23).On the other hand, the effect on the posterior curvature may be hypoxic rather than mechanical. Nevertheless, further studies are needed to understand the effect of contact lenses on the posterior curvature.

Tyagi showed that silicone hydrogel lenses generally result in flattening of the anterior curvature and steepening of the posterior curvature(13). In this study, the topographic values were obtained 10 minutes after removing the lens which had been in use for 8 hours. In our study, there was a period of 8-12 hours without lens. This period was chosen to evaluate the cornea independently from the mechanical effects. These studies suggest that the topographic findings that are measured before keratorefractive surgery in patients wearing contact lenses may be misleading, especially in the early period. While CCT and stromal thickness did not differ significantly between the group 1 and 2, epithelial thickness was measured to be significantly lower in group 1. We did not observe a significant difference in epithelial thickness between the subgroups. Thus, the results of our study show that epithelial thickness decreases with the use of contact lenses; however, this was not exacarbated after 18 months of use.

There are studies suggesting that the soft contact lenses effect cct. This effect is usually in the acute phase. The fact that it is not seen at later stages suggests that the cornea may undergo an adaptation process(22,25).

Nourouzi et al.(22), showed that the mean cct measured by pachymetry was 550 when the lens was first removed, and that 74% of the patients had corneal stabilization within the first week and 26% in the second week after stopping lens use. Mean cct 15 days after stopping contact lens use were measured to be as 521.

Yildiz et al. (17) found the CCT measured through anterior segment was higher in lens users than in healthy subjects. It was observed that epithelial thickness measured by anterior segment OCT was lower in contact lens users. When lens wearers were further subgrouped as wearing less than 1 year or more than 1 year, there was no difference in terms of epithelial thickness between these groups, while the cct in the group wearing contact lenses for less than a year was found to be closer to the control group compared to patients wearing for more than 1 year(17). Lack of observation of the early effects of contact lenses in the later periods suggests that the cornea may adapt to the contact lenses with various mechanisms.

With a different approach, here, we evaluated the stromal thickness and epithelial thickness separately with the help of Heidelberg Spectralis OCT anterior segment module. Although we did not observe a difference in stromal thickness and cct by topography measurements, we found that the epithelial thickness decreased in group 1. Decreased epithelial thickness further suggest the formation of stromal edema. Although reduction in epithelial thickness is associated with stiffness modulus, stromal edema may be a response to epithelial damage or may be related to oxygen permeability of the lens.

Contact lenses may cause dry eye symptoms as a result of the lacrimal gland suppression due to the increase in evaporation and tear osmolarity by dividing the tear film layer into two and decrease the corneal sensitivity(22). It has been shown that half of the contact lens users stop using contact lenses due to dry eye symptoms(25).

Schirmer test results were not found to be significantly different between the groups. In the literature, studies investigating the presence of dry eye in patients wearing contact lenses generally found tear breakage time and the results of symptom analyzing questionnaires to be significantly different from the healthy controls, but no significant results were found with the schirmer test(23).

Plemorphism and polymegathism are biological indicators of endothelial function. Studies on conventional hydrogel lenses have shown that endothelial function is impaired due to hypoxia(24).

In our specular results, we did not find any difference in the percentage of hexagonal cells in contact lens users compared to the control group, but we found the endothelial cell number and density to be higher than the controls. When we subgrouped found that the percentage of hexagonal cells and endothelial cell density were not different, while the number of endothelial cells was lower in patients who have used contact lenses for more than 18 months. The mean age of the contact lens using patients was lower than the control group, although the difference was not statistically significant. This may have caused the endothelial cell number and density to be high in patients wearing contact lenses. The lower endothelial cell number in contact lens users over 18 months may also be explained by the age difference, or it may be due to hypoxic effects of the contact lenses since although the oxygen permeability of silicone hydrogel lenses is high, hypoxic effects may still be observed in the long term.In another study examining soft contact lenses in relation to the duration of use, it was observed that cell density andnumber of hexagonal cells decreased statistically significantly over 5 years of use(13).

In the study conducted by Kettesy et al.(26), silicone hydrogel lens (lotrafilcon b) was applied to patients who have been using hydrogel contact lenses for 5-6 years or participants who had never used any lens before, and the patients were followed at 2 weeks, 1 month, 3 months, 6 months and after that, every 6 months for 3 years and their specular values were compared. They found significant decrease in endothelial cell count in hydrogel lens users during the follow-up visits. In silicon hydrogel lens wearers, they observed an increase in cell density for up to 2 years after a decrease in the first month and then a decrease again in the third year. This study suggests that lotrafilcon B provides adequate oxygenation to the cornea after 3 years of use. An increase in percentage of hexagonal cells was observed in lotrafilcon B users after the first month(26).

The limitations of this study were that groups were not homogeneous and the lens usage duration was short (maximum 4 years). Further studies using homogenous groups in which the lenses are classified according to Dk/t and stiffness modulus would be important. Recently, due to expanded use of soft contact lenses and increased demand for keratorefractive surgery, it would be useful to know the effects of these lenses on the cornea in order to prevent complications regarding keratorefractive surgery.

# **Declarations**

## Funding

This study had received no financial support.

## Conflicts of Interest/Competing Interests

The authors declared no potential conflicts of interest concerning the research, authorship, and publication of this article.
#### **Ethics** Approval

The study was approved by the Adıyaman University Medical Faculty Local Ethics Committee (2017/2-12).

#### Availability of Data and Material

We can provide all the original data.

#### Authors' Contributions

MB: Study design, data collection, literature search, writing of the manuscript; AS: Study design, literature search, writing of the manuscript

#### Acknowledgment

#### Non Applicable.

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Internal Diseases / İç Hastalıkları

# Evaluation of Factors Affecting Survival and Chemotherapy Regimens in Patients with Gastric Cancer

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# ABSTRACT

**Methods:** This retrospective cohort study analyzed patients diagnosed with gastric cancer at our institution between 2009 to 2013. We examined demographic characteristics of the patients, the presence of Helicobacter pylori (HP), and survival outcomes, including disease-free survival and overall survival, according to different treatment protocols.

**Results:** The study included 122 patients (37 female and 85 male) with a mean age of 58.6  $\pm$  10.3 years. Among them, 41% received 5-fluouracil, leukoverine chemotherapy (MAYO regimen), 26.2% received docetaxel, cisplatin and fluorouracil combination (DCF regimen), 10.7% received epirubicin, cisplatin and fluorouracil (ECF regimen), and 6.6% received cisplatin-xeloda regimen. The average disease-free survival was 14.7  $\pm$  11.1 months, and the average overall survival time was 16.5  $\pm$  11.4 months. The MAYO regimen group showed significantly longer disease-free survival and overall survival compared to the other chemotherapy combination groups (p <0.001). In multivariate analysis, metastasis and TNM stage were identified as independent negative prognostic factors for both disease-free survival and overall survival.

**Conclusion:** Our study demonstrated that disease-free and overall survival rates are markedly low in patients with advanced gastric tumors and those with metastases at diagnosis, underscoring the limited efficacy of chemoterapy in these cases. However, the MAYO regimen was associated with better survival outcomes compared to other treatment protocols.

Keywords: Chemotherapy, Gastric cancer, Survival

#### ÖZET

**Amaç:** Çalışmamızın amacı mide kanserinin prognozunu etkileyen faktörleri incelemek ve farklı kemoterapi rejimlerinin hastalıksız sağkalım ve genel sağkalım üzerine etkisini değerlendirmektir.

Yöntem: Bu kohort çalışmada, 2009-2013 yılları arasında kurumumuzda mide kanseri tanısı alan hastalar retrospektif olarak incelendi. Hastaların demografik özellikleri, Helicobacter pylori (HP) varlığı ve hastaların tedavi protokollerine göre hastalıksız ve genel sağkalımları incelendi.

**Bulgular:** Ortalama yaşı 58,6  $\pm$  10,3 yıl olan 33 kadın ve 85 erkek çalışmaya dahil edildi. Hastaların %41'i 5-fluourasil, lökoverin kemoterapisi (MAYO rejimi), %26,2'si dosetaksel, sisplatin ve fluorourasil kombinasyonu (DCF rejimi), %10,7'si Epirubisin, sisplatin ve Fluorourasil (ECF rejimi) ve %6,6'sı Sisplatin-Xeloda rejimi aldı. Ortalama hastalıksız sağkalım süresi 14,7  $\pm$  11,1 ay, genel sağkalım süresi ise 16,5  $\pm$  11,4 aydı. MAYO rejimi grubunda hastalıksız sağkalım ve genel sağkalım kombinasyon kemoterapisi gruplarına kıyasla daha uzundu (p <0,001). Çok değişkenli analizde, metastaz ve TNM evresi hastalıksız ve genel sağkalım için bağımsız negatif prognostik faktörlerdi.

**Sonuç:** Çalışmamız ilerlemiş tümörlerde ve tanı anında metastazı olan hastalarda hastalıksız ve genel sağkalım oranlarının oldukça düşük olduğunu göstermiş ve özellikle bu grup hastalarda kemoterapi protokollerinin sınırlı etkisini ortaya koymuştur. Bununla birlikte, MAYO rejimi diğer tedavi protokollerine göre daha üstündü.

Anahtar Kelimeler: Kemoterapi, Mide kanseri, Sağkalım

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Received: 9.08.2024 Accepted: 27.12.2024

astric cancer is one of the most common cancers worldwide and the second most common cause of cancer-related deaths (1). In addition to environmental, genetic and familial factors, Helicobacter pylori (HP) infection plays a significant role in the development of gastric cancer. The incidence of gastric cancer is associated with socioeconomic status, with higher rates observed in developing countries (2,3). HP infection has been linked to condition such as gastritis, peptic ulcer disease and gastric malignancies. It has been a central focus of many clinical and microbiological studies, especially in recent years. The location of gastric cancer within the stomach can vary depending on etiological factors. For instance, HP infection and dietary factors are more closely associated with distal gastric cancer, whereas gastroesophageal reflux disease (GERD) and obesity are more strongly linked to the development of proximal and gastroesophageal cancers (4).

Surgery can be curative in early-stage gastric cancer, while adjuvant chemotherapy (CT) and radiotherapy (RT) have been shown to improve survival outcomes. However, survival rates decline significantly in advanced stages of the disease. Currently, postoperative chemotherapy is the standard of care for patients with early-stage gastric cancer. 5-fluorouracil and leucovorin chemotherapy (MAYO regimen) is the most commonly used CT protocol. For metastatic gastric cancer, the most effective results have been achieved using combinations of platinium and fluorouracil- based therapies. The combination of epirubicin, cisplatin and fluorouracil (ECF) is one of the standard chemotherapy combinations for metastatic gastric cancer (5-6).

One of the most favorable survival outcomes in treating metastatic gastric cancer has been achieved with the combination of docetaxel, cisplatin and fluorouracil (DCF) (7). In Asia, where gastric cancer has the highest prevalence, the cisplatin and Xeloda (capecitabine) regimen is a standard treatment protocols for patients with metastatic and unresectable gastric cancer.

Our study aimed to investigate the demographic characteristics of 122 gastric cancer patients treated in the Oncology Department of Istanbul Training and Research Hospital, assess their association with HP infection, and evaluate the impact of various treatment options on disease-free and overall survival.

# **Material And Method**

Our study retrospectively analyzed 122 patients diagnosed with gastric cancer who were followed in the medical oncology and radiation oncology departments between 2009 and 2013. At the time of analysis, the median followup period was 16 months.

We analyzed the patients' demographic characteristics and disease-related parameters, including sex, age, histological grade, stage, tumor location, chemotherapy regimen, chemotherapy response, and presence of Helicobacter pylori (HP) infection. Tumor localization and prognosis were also evaluated. Patients with metastatic disease at the time of diagnosis were compared with those who initially had no metastases but later developed metastases, in term of survival. Additionally, diseasefree survival and overall survival were compared based on factors such as stage at diagnosis, HP status (HP +/-), histological subtype and CT regimen in metastatic patients. Patients with insufficient data or no follow-up were excluded from the study. Overall survival was defined as the time from the start of treatment to death, while disease-free survival was defined as the time from the end of treatment to disease progression. Patients were staged according to the WHO 2000 classification. Chemotherapy protocols were used according to the NCCN guideline for gastric cancer, version 2.2013.

## Statistical Analyses

Mean, standard deviation, ratio and frequency values were used in the descriptive statistics of the data. Kaplan Meier (Log-rank / Mental Cox) and Cox-Regression analyzes were used for survival analysis. SPSS (IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp.) program was used in the analyzes. A p value of less than 0.005 was considered significant.

# **Results**

Of the 122 patients, 30.3% were female, 69.7% were male, with a mean age of 58.6  $\pm$  10.3 years. Overall survival ranged from 1 to 96 months, with a mean of 16.5  $\pm$  11.1 months. The most common tumor location was the antrum, present in 61.5% of cases (n=75). At diagnosis, the 57.4% of patients (n=70) had stage IV disease, and adenocarcinoma was the most prevalent histological type, accounting for 75.4% of cases (n=92). HP test results were available for 46 patients (37.7%), of whom 24 (52.1%) tested positive.

Demonstern		
Parameter	n	%
Age	58.64	10.3
Gender		
Female	37	30.3
Male	85	69.7
Localization of Tumor		
Antrum	75	61.5
Fundus	6	4.9
Cardia	19	15.6
Corpus	13	10.7
Other	9	7.4
Histopathological Subtype		
Adeno carcinoma	92	75.4
Undifferentiated carcinoma	1	0.8
Malignant epithelial carcinoma	1	0.8
Neuroendocrine carcinoma	2	1.6
Signet-ring cell carcinoma	24	19.7
Stage		
1	18	14.8
11	8	6.6
III	26	21.3
IV	70	57.4
Helicobacter Pylori +	24	19.7
Chemotherapy protocol	107	87.7
Cisplatin-Xeloda	8	6.6
DCF*	32	26.2
ECF <sup>†</sup>	13	10.7
MAYO <sup>#</sup>	50	41
Other	4	3.3
Number of Chemotherapy, mean (min-max)	4 (1-6)	1.5
Radiotherapy	90	73.8
Chemotherapy+ Radiotherapy	76	62.3
Surgery	117	95.9
Metastasis	53	43.4
Number of patients with progression	36	29.5
Time Without Progression (month)	14.7	11.1
Second Chemotherapy	19	15.6
Last Status		
Alive	68	55.7
Deceased	54	44.3
Survival Time (month)	16.5	11.4
DCF: Docetaxel, Capecitabine, 5-Flourourasil; ECF: Epirubicin, Cisplatin and Fluorouracil; MAYO: 5-Flourourasil+ leukoverine		

Following diagnosis, 95.9% of patients underwent surgery (n=117), 87.7% received chemotherapy (n=107), 73.8% received RT (n=90), and 62.3% received CRT (n= 76). Metastases were present in 43.4% of patients (n=53) at the time of diagnosis.

The chemotherapy regimens used included the MAYO protocol in 41% of patients (n=50), the DCF protocol in 26.2% (n= 32), the ECF protocol in 10.7% (n=13), the cisplatin-Xeloda protocol in 6.6% (n=8), and other protocols (cisplatin-etoposide, DC) in 3.3% (n=4).

The mean duration of chemotherapy was  $4.76 \pm 1.49$  months. The mean disease-free survival during followup was  $14.7 \pm 11.1$  months. Disease progression was observed in 36 patients (29.5%). A second chemotherapy regimen was administered to 19 (15.6%) of these patients. The median survival was  $16.5 \pm 11.4$  months (Table 1).

There was no significant difference between the HP (+) and HP (-) groups in terms of predicted disease-free (p=0,025) time and predicted survival (p=0.505).

In our study, when the survival rates of patients receiving chemotherapy were examined according to stage, the predicted progression-free period in the stage IV group [18.08 months (14.00-22.16)] was significantly (p < 0.001) shorter than that in the stage I group [29.40 months (23.41-35.59)], stage II [33.70 months (25.58-41.81)], and stage III [36.71 months (31.73-41.69)] (Table 2)

	Table 2	<b>2.</b> Surviva	al Accordi	ing to Sta	ige					
				%95 Cor Inte	nfidence rval					
		n	Predict	Min Max		p				
Progression-free time (month)										
	I	18	61.46	51.94	70.98					
Stago	11	8	33.70	25.58	41.81	< 0.001				
Stage	=	26	35.61	30.42	40.81	< 0.001				
	IV	70	18.08	14.00	22.16					
Survival time (	month	)								
	Ι	18	48.70	29.89	67.51					
Stage	=	8	30.10	20.33	39.88	< 0.001				
Stage	Ш	26	33.12	27.51	38.74	< 0.001				
	IV	70	16.68	13.35	20.01					

Predicted progression-free time (p<0.001) and predicted survival (p=0.002) were significantly longer in the MAYO group than in the Cisplatin-Xeloda and DCF group. However, there was no significant difference between the groups receiving cisplatin-Xeloda, DCF and ECF (p=0.036) (Table 3).

Table 3	. Survival A	ccord	ing to Ch	emothe	rapy Typ	e				
				% Confi Inte						
		n	Predict	Min	Max	p				
Progression-free time (month)										
	Cisplatin- Xeloda	8	10.52	6.66	14.38					
Type of	DCF	32	18.76	12.56	24.95	< 0.001				
Chemotherapy	ECF	13	25.38	16.98	33.78					
	Мауо	48	31.09	27.51	34.67					
Survival time (I	nonth)									
	Cisplatin- Xeloda	8	16.49	11.04	21.95					
Type of	DCF	32	17.93	12.59	23.27	0.002				
Chemotherapy	ECF	13	25.34	17.58	33.11	0.002				
	Мауо	48	31.77	27.65	35.88					

In univariate analysis for overall survival stage (p < 0.001), KT type (p=0.001), metastasis (p < 0.001) and presence of progression (p=0.002) were found to be factors affecting survival. On multivariate analysis, metastasis (p=0.006) and stage (p=0.031) were found to be independent factors (Table 4).

Table 4. Univaria	Table 4. Univariate and multivariate analysis of factors affecting   overall survival time											
	U	nivariate M	odel	Mu	Iltivariate N	lodel						
	OR	%95CI	р	OR	%95Cl	р						
Metastasis	4.84	2.66-8.79	<0.001	2.77	1.35-5.69	0.006						
Grade (I/ II/ III/ IV)	2.84	1.56-3.51	<0.001	1.63	1.05-2.55	0.003						
Histopathological Subtype	0.92	0.45-1.89	0.83									
Chemotherapy	0.57	0.27-1.21	0.141									
Chemotherapy Type	0.61	0.46-0.81	0.001									
H. Pylori	0.70	0.25-1.98	0.508									
Progression	2.37	1.39-4.05	0.002									

In univariate analysis for disease-free survival stage (p <0.001), KT type (p <0.001), metastasis (p <0.001) and HP pylori presence (p=0.043) were found to be factors affecting survival. After multivariate analysis, metastasis (p=0.037) and stage (p=0.039) were found to be independent factors (Table 5).

Table 5. Univari	Table 5. Univariate and multivariate analysis of factors affecting   progression-free time											
	l	Univariate Mo	odel	Mu	Iltivariate N	lodel						
	OR	%95Cl	p	OR	%95Cl	p						
Metastasis	4.97	2.45-10.07	<0.001	2.47	1.06-5.77	0.003						
Stage	2.63	1.56-4.42	<0.001	1.80	1.03-3.14	0.003						
Histopathological Subtype	0.69	0.27-1.78	0.438									
Operation	0.35	0.13-0.96	0.042									
Chemotherapy	3.88	0.53-23.38	0.181									
Chemotherapy Type	1.51	0.37-0.71	<0.001									
H. Pylori	0.20	0.04-0.95	0.043									

# Discussion

Gastric cancer, one of the leading causes of cancerrelated mortality worldwide, presents a set of challenges in diagnosis and treatment. It is 2-4 times more common in men than in women. Its incidence increases between the ages of 60 and 80. Several studies have established between HP infection and conditions such as gastritis, peptic ulcer and gastric cancer. Gastric cancer is typically diagnosed at an advanced stage (Stage III-IV) (2-4).

In our study, we present epidemiological and clinicopathological characteristics, survival times and progression-free survival times of patients with gastric cancer. The demographic data of our cohort align with previous studies, showing that gastric cancer is more common in men than in women, with the mean age of diagnosis between 55 and 60 years. The majority of tumors were located in the antrum, and 75% of cases were adenocarcinomas. It is also observed that most patients are diagnosed at an advanced stage.

The mean age of diagnosis of gastric cancer is typically reported as 56 years (8), with its incidence rising between the ages of 60 and 80. It is rarely observed before the age of 30 (9). In our study, the average age of patients was  $58.64 \pm 10.32$  years.

One study found that 36% of gastric cancers were located in the antrum, 36% in the corpus, 20% in the cardia and 8% diffusely (10). In our study, 61.5% of cases were located in the antrum, 15.6% in the cardia, 4.9% in the fundus and 7.4% in other locations (e.g, pylorus, diffuse), which is similar to previously reported results.

The relationship between HP and conditions such as gastritis, peptic ulcers and gastric cancer has been explored in numerous studies. Although different studies using varying methods have yielded mixed results, the most optimistic estimates suggest that HP infection accounts for approximately one-third of gastric cancers (11). Recently, a decline in the incidence of gastric cancer in the antrum and corpus has coincided with a reduction in the prevalence of HP infection (12,13).

In our study, HP results were available for 46 patients (37.7%), with 24 of these patients (52.17%) testing positive for HP. The results are positive in more than half of the patients whose results we can reach, which is higher than the general literature data. This result confirms the information that HP is more common in developing countries with inadequate socioeconomic conditions, such as our country (14).

We found no significant difference in overall (p=0.505) or disease-free survival time (p=0.025) between the HP (+) and (-) groups. This lack of difference may be attributed to the limited number of patients with available HP results and the advanced stage of disease in the majority of patients.

Surgical resection remains the primary curative treatment for gastric cancer (15). After curative surgery, the 5-year survival rate for tumors confined to the gastric mucosa ranges from 85-90%, while for T4 and lymph node positivity, the local and regional failure rate is 50-60% and the 5-year survival rate is 15-20% (16).

While radical surgery alone is preferred for earlystage disease, the addition of radiotherapy and/or chemotherapy is considered essential for improving local regional control and survival in patients with locally advanced disease (17,18).

The optimal combination and sequence of chemotherapy in the treatment algorithm for gastric cancer is currently under extensive investigation. The MAYO regimen has shown promising results in terms of progression-free and overall survival compared to other chemotherapy regimens, particularly in early-stage patients (19). However, the optimal treatment strategy remains a subject of ongoing research, with a focus on tailoring therapies based on individual patient characteristics and tumor biology (19, 20). Currently, perioperative chemotherapy, particularly for T3/T4a has gained prominence, particularly for T3/T4a tumors and/or those with regional lymph node involvement, is becoming more widely used. Furthermore, neoadjuvant chemotherapy has been associated with higher rates of pathological complete response (21).

In our study, the predicted progression-free survival for patients receiving the MAYO regimen [31.09 (27.51-34.67)] was significantly longer compared to those receiving the Cisplatin-Xeloda regimen [10.52 (6.66-14.38)] and the DCF regimen [18.76 (12.56) -24.95)] (p< 0.001). No significant difference in progression-free survival was observed between the Cisplatin-Xeloda, DCF, and ECF groups (p= 0.036) (Table 3).

Similarly, the predicted overall survival in the MAYO regimen [31.09 (27.51-34.67)] group was significantly longer compared to those receiving Cisplatin-Xeloda [10.52 (6.66-14.38)] and DCF [18.76 (12.56-24.95)] regimens (p<0.001). No significant difference in overall survival was observed between the Cisplatin-Xeloda, DCF, and ECF groups (p=0.038) (Table 3).

The observed longer progression-free survival and overall survival in the MAYO regimen group compared to the combination chemotherapy groups can be attributed to the fact that the MAYO regimen was primarily administered to patients with early- stage disease, while combination chemotherapy regimens were less effective due to severe side effects and patient intolerance.

A review on the effectiveness of chemotherapy versus supportive care, found that chemotherapy improved survival outcomes compared to supportive care alone. Consequently, systemic chemotherapy remains the mainstay of treatment for advanced gastric cancer. However, uncertainty persists regarding the optimal regimen. (22).

In the univariate analysis of factors affecting overall survival; stage and metastasis (p<0.001), chemotherapy type (p=0.001) and progression (p=0.002) were identified as significant factors. Multivariate analysis showed that stage and metastasis were independently of survival (p=0.031, p<0.006, respectively) (Table 4).

In the univariate model, it was observed that metastasis, stage and chemotherapy type (p<0.001) and H.P (p=0.043) affected the patient's progression-free time. In multivariate analysis, metastasis and stage were found to be effective in predicting disease-free survival (p=0.003) (Table 5).

In conclusion, there are numerous treatment options available for gastric cancer. Surgical resection should be considered for appropriate patients, followed by chemotherapy and/or radiotherapy. In cases where surgery is not feasible, one of the available chemotherapy regimens should be used in combination with radiotherapy.

# **Declarations:**

This study is derived from the author's thesis study conducted in 2013.

#### Funding:

The authors declare that the study received no funding.

#### Conflict of interest:

The authors declare no competing interests.

#### **Ethics Approval:**

This study was approved by the Istanbul Education and Research Hospital Ethical Committee. (Date 24.05.2013 and number: 258)

#### Availability of Data and Material:

Available.

#### Authors' Contributions:

All authors have made substantial contributions to this article being submitted for publications. All authors critically reviewed the manuscript and approved the final form.

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Psychiatry / Psikiyatri

# The Relationship Between Adult Attachment Styles and Social Anxiety Disorder: The Role of Parental Bonding in Outpatient Adults

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#### ABSTRACT

**Purpose:** This study aimed to explore the connection between attachment styles and social anxiety disorder (SAD) in patients receiving psychiatric outpatient treatment.

**Methods:** The research included 85 participants, comprising 45 individuals diagnosed with SAD and 40 healthy controls. The participants completed assessments on social anxiety, parental bonding, and attachment styles.

**Results:** Participants with SAD showed significantly lower maternal care scores  $(16.31 \pm 2.30)$  compared to the healthy control group  $(28.77 \pm 6.77, p < .001)$  and notably lower paternal care scores  $(16.84 \pm 3.14 \text{ vs}. 25.28 \pm 9.28, p < .001)$ . They also exhibited higher avoidant  $(25.88 \pm 7.39 \text{ vs}. 22.47 \pm 6.23, p = .034)$  and anxious attachment scores  $(23.65 \pm 7.66 \text{ vs}. 16.80 \pm 6.98, p < .001)$ . The Liebowitz Social Phobia Scale scores were positively correlated with avoidant (r = .433, p < .001) and anxious attachment (r = .458, p < .001), while negatively correlated with maternal (r = .566, p<.001) and paternal care (r=-.384,p<.001).

**Conclusion:** The study demonstrates that insecure attachment styles and inadequate parental care are closely linked to elevated levels of social anxiety. These results underscore the need for considering attachment-based interventions when treating social anxiety disorder.

Keywords: Social anxiety disorder, attachment styles, parental bonding, childhood, adult

#### ÖZET

**Amaç:** Bu çalışma, bir psikiyatri kliniğinde ayaktan tedavi gören hastalarda bağlanma stilleri ile sosyal anksiyete bozukluğu (SAB) arasındaki ilişkiyi araştırmayı amaçladı.

Yöntem: Çalışmaya 45-i SAB tanısı almış ve 40-ı sağlıklı kontrol grubu olmak üzere toplam 85 katılımcı dahil edilmiştir. Katılımcılar, sosyal anksiyete, ebeveyn bağlanması ve bağlanma stillerine yönelik değerlendirmeleri tamamladılar.

**Bulgular:** SAB tanılı katılımcılar, sağlıklı kontrol grubuna kıyasla anlamlı olarak daha düşük anne ilgisi (16,31  $\pm$  2,30) ve baba ilgisi (16,84  $\pm$  3,14) puanları bildirmiştir (p < 0,001). Ayrıca, kaçınmacı (25,88  $\pm$  7,39 vs. 22,47  $\pm$  6,23, p = 0,034) ve kaygılı bağlanma (23,65  $\pm$  7,66 vs. 16,80  $\pm$  6,98, p < 0,001) puanları anlamlı olarak daha yüksek bulunmuştur. Liebowitz Sosyal Fobi Belirti Ölçeği puanları, kaçınmacı bağlanma (r = 0,433, p < 0,001) ve kaygılı bağlanma (r = 0,458, p < 0,001) ile pozitif yönde korelasyon gösterirken, anne ilgisi (r = -0,566, p < 0,001) ve baba ilgisi (r = -0,384, p < 0,001) ile negatif yönde korelasyon göstermiştir.

**Sonuç:** Bu çalışma, güvensiz bağlanma stilleri ve yetersiz ebeveyn ilgisinin daha yüksek seviyelerde sosyal anksiyete ile yakından ilişkili olduğunu göstermektedir. Bulgularımız, sosyal anksiyete bozukluğunun tedavisinde bağlanma temelli müdahalelerin dikkate alınmasının önemini vurgulamaktadır.

Anahtar Kelimeler: Sosyal anksiyete bozukluğu, bağlanma stilleri, ebeveyn bağlanması, çocukluk, erişkin.

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Received: 11.08.2024 Accepted: 19.10.2024

ocial anxiety disorder (SAD), often referred to as social phobia, is a prevalent anxiety disorder, particularly among children and adolescents (1). It is marked by an enduring fear of social situations where individuals may encounter strangers, be judged, or have to perform, leading to excessive anxiety, avoidance behaviors, and a significant decline in functioning. The disorder typically emerges during adolescence when individuals become increasingly sensitive to social approval and acceptance. Although the onset generally occurs between ages 13 and 24, it is common for individuals to delay seeking treatment for 15-20 years, often believing their symptoms are personality traits rather than a treatable condition (1). Studies on social phobia prevalence have reported varying rates, with research conducted at various universities in Turkey indicating prevalence rates between 9% and 22% (1). The importance of social phobia has risen in recent years due to its chronic nature, its high comorbidity rate, and its substantial economic burden (1).

Attachment theory suggests that the need for a caregiver during infancy extends beyond nourishment to include the comfort derived from the caregiver's presence. John Bowlby developed this theory, proposing that "attachment behaviors" in infants, such as crying or distress when separated from the caregiver, are alleviated by the caregiver's return. These behaviors are viewed as an evolutionary mechanism that reinforces survival and a sense of security (2). The type of attachment formed is shaped by the relationship between the child and the caregiver, influencing the individual's expectations and behaviors in relationships throughout adulthood (3). Securely attached children tend to view themselves as valuable and worthy of love, whereas those with insecure attachments may become more anxious, withdrawn, or overly focused on independence (4).

The family plays a crucial role in providing the care and affection necessary for a child's well-being. Parental attitudes in child-rearing significantly influence the child's personality development and ability to adapt to society. Some studies suggest that interactions within the family during childhood can contribute to the development of social phobia (5). Overly protective or neglectful parenting practices have been shown to increase the risk of social phobia in children (6,7). Consequently, negative attachment experiences during childhood may predispose individuals to social anxiety disorders later in life (8,9). While it is well-established that attachment experiences significantly impact interpersonal relationships throughout an individual's life, their etiological role in developing social phobia is not yet fully understood (10). The number of studies in this area is limited. Previous research indicates that insecure attachment may be a risk factor for developing anxiety disorders and could play a role in the etiology of social phobia (11). Specifically, individuals with anxious/preoccupied attachment styles may experience greater stress in social situations, potentially increasing their risk of developing social phobia due to a fear of rejection (11). Recent studies have further clarified this relationship, demonstrating that insecure attachment, including both anxious and avoidant styles, is significantly associated with higher levels of social anxiety. For instance, Nielsen et al. found that individuals with high levels of attachment anxiety were more likely to exhibit elevated social anxiety symptoms (12). Similarly, Read et al. reported that both attachment anxiety and avoidance are directly linked to social anxiety, reinforcing the role of insecure attachment as a key risk factor (11). Furthermore, a recent study by Fattouh et al. involving Lebanese adolescents confirmed that dysfunctional attachment types, such as avoidant and anxiety-related attachments, lead to maladaptive interpersonal relationships and negative selfperceptions, which are directly associated with elevated social anxiety symptoms (13). These findings highlight the importance of considering attachment characteristics when understanding the etiology and persistence of social anxiety.

Our study aims to explore the connection between attachment styles and the severity of social phobia in patients receiving outpatient psychiatric care. By focusing on the potential role of attachment-based interventions in the treatment of social phobia, this research seeks to contribute significantly to the existing literature in this field.

# **Material and Method**

#### Procedure

This study included patients diagnosed with SAD according to the diagnostic criteria outlined in the Fifth Edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) (14). These patients were selected from those who sought treatment at a psychiatric clinic. Diagnoses were confirmed by a specialist psychiatrist following a comprehensive psychiatric evaluation and review of the patient's medical history. The inclusion criteria for participation in the study were as follows: 1) individuals aged between 18 and 45, 2) a diagnosis of

SAD as per DSM-5 criteria without any other psychiatric or neurological disorders, and 3) literacy. The control group consisted of healthy volunteers matched to the patient group based on age and gender, ensuring that these variables did not influence the study's outcomes. These volunteers were screened to confirm the absence of any psychiatric or neurological disorders, and they did not exhibit any symptoms of social anxiety. Individuals with a history of substance abuse, severe physical illnesses, or any other mental health issues were excluded from both the patient and control groups. Both the patients diagnosed with SAD and the healthy control group were thoroughly informed about the study's purpose and methodology, both verbally and in writing. Those who consented to participate completed the assessments, which included the Sociodemographic and Clinical Data Form, the Liebowitz Social Phobia Scale (LSAS), the Parental Bonding Instrument (PBI), and the Adult Attachment Scale (AAS). During this process, participants received comprehensive guidance on the completion of each assessment scale to ensure consistency and minimize response bias. The scales were administered in a controlled environment to maintain standardization, with trained research assistants available to address any queries or uncertainties. Participants were also explicitly informed about the importance of providing accurate and truthful responses and were reassured that all data collected would remain strictly confidential to foster an environment of trust and encourage candid reporting.

Approval for this research was granted by the Hamidiye Scientific Research Ethics Committee at the University of Health Sciences on May 13, 2023, with decision number 27740.

## Data Collection Tools

## Liebowitz Social Anxiety Scale

The LSAS, initially developed by Liebowitz in 1987 (15), was later adapted into Turkish by Soykan, Özgüven, and Gençöz in 2003 (16). This scale assesses the levels of anxiety and avoidance that individuals experience in social interactions and performance situations. The LSAS consists of 24 items, rated on a 4-point Likert scale, with each item evaluated separately under the categories of anxiety and avoidance.

## Adult Attachment Scale

The AAS comprises two parts. The first part, developed by Hazan and Shaver in 1987, categorizes individuals into three groups—secure, avoidant, and anxious/ ambivalent attachment styles—based on their childhood relationships with their parents (17). The second part of the scale, designed by Mikulincer et al. in 1990, assesses individuals' attachment patterns and consists of 15 items rated on a 7-point Likert scale (18). The Turkish adaptation of the second part of the scale was conducted by Sabuncuoğlu and Berkem in 2006 (19). Due to the low reliability (Cronbach's Alpha of. 42) found in the secure attachment subscale, Kesebir et al. (2012) revised the scale by removing unclear items and expanding it to 18 items (20). The revised scale demonstrated improved reliability, with Cronbach's Alpha values of .72 for secure attachment, .82 for avoidant attachment, and .85 for anxious/ambivalent attachment (20).

## Parental Bonding Instrument

The PBI, based on Bowlby's attachment theory, retrospectively assesses an individual's relationship patterns with their parents (21). The scale focuses on the social bond between the child and the primary caregiver, featuring two subdimensions: care and control/ overprotection. The Turkish adaptation of the PBI was carried out by Kapçı and Küçüker in 2006 (22). The scale asks individuals to evaluate their parents' behaviors during the first 16 years of life using a 4-point Likert scale. High scores in the care dimension indicate that the parents were warm and accepting, while low scores suggest cold and rejecting behaviors. In the control/overprotection dimension, high scores reflect overly controlling behavior. The reliability analysis of the PBI vielded Cronbach's Alpha coefficients of .87 for the mother form and .89 for the father form. Test-retest reliability coefficients were also calculated, with scores of .90 for the mother form and .89 for the father form across the entire scale (22). The PBI is considered a reliable tool for evaluating children's relationships with their parents, making it a valuable resource for research and clinical practice (22).

## **Statistical Analysis**

Data were analyzed using SPSS software (version 24.0) on a Mac OS system. We summarized the data through descriptive statistics such as means, percentages, standard deviations, and frequencies. The normality of numerical data was evaluated with the Kolmogorov-Smirnov test. To compare groups, we employed the Chisquare test for categorical data and the Student's t-test for continuous data. Relationships among parametric variables were examined using Pearson's correlation coefficient. A p-value of less than 0.05 was considered to indicate statistical significance.

## Results

The study included 85 participants: 45 with SAD and 40 healthy controls (HC). The mean $\pm$ SD age was 24.33  $\pm$  6.25 years in the SAD group and  $26.25 \pm 5.63$  years in the HC group, with no significant age difference between the groups (p = .143). The gender distribution was also similar, with 51.1% of the Social Phobia group and 51.5% of the HC group being male (p = .898). Significant differences were observed in education and employment status. The SAD group had significantly fewer years of education  $(13.86 \pm 3.09)$  compared to the HC group  $(15.55 \pm 3.08; p$ = .015). Additionally, a significantly higher proportion of participants in the SAD group were unemployed or had irregular employment (71.1%) compared to the HC group (37.5%; p = .002). Other characteristics such as marital status, smoking habits, history of alcohol or substance use, family migration, loss of a parent/caregiver during early childhood, family history of psychiatric disorders, history of suicide attempts, and history of psychiatric disorders during childhood and adolescence did not show statistically significant differences between the groups (Table 1).

Table 2 reveals significant differences in parental bonding and attachment styles between the SAD and HC groups. Participants with SAD reported significantly lower maternal care scores (16.31  $\pm$  2.30) compared to the HC group  $(28.77 \pm 6.77; p < .001; Cohen's d = 2.53)$ , indicating a very large effect size. In terms of maternal overprotection, the SAD group reported significantly lower scores (18.35  $\pm$  4.18) compared to the HC group (24.82  $\pm$  6.58; p < .001; Cohen's d = 1.18), also reflecting a large effect. Similarly, paternal care scores were significantly lower in the SAD group (16.84  $\pm$  3.14) compared to the HC group (25.28  $\pm$ 9.28; p < .001; Cohen's d = 1.18), suggesting a large effect size. Paternal overprotection scores were significantly lower in the SAD group (21.35  $\pm$  4.69) compared to the HC group  $(27.54 \pm 5.94; p < .001; Cohen's d = 1.16)$ , again showing a large effect size.

Table 1: Basic characteris	stics of Participants			
	Total Sam	ple (n=85)		
	Social Phobia (N:45)	Healthy Control (N:40)		
	Mean±SD / n (%)	Mean±SD / n (%)	р	
Age	24.33±6.25	26.25±5.63	.143	S
Sex (male)	23 (51.1)	21 (51.5)	.898	X²
Education (years)	13.86±3.09	15.55±3.08	.015	s
Employment (no/irregular)	32 (71.1)	15 (37.5)	.002	X²
Marital Status (married)	5 (11.1)	6 (15.0)	.594	X²
Smokers (yes)	16 (36.4)	8 (20.0)	.097	χ²
History of Alcohol/ Substance Use ( yes)	8 (17.8)	11 (27.5)	.283	χ²
History of Family Migration ( yes)	4 (8.9)	6 (15.0)	.383	χ²
Loss of a Parent/Caregiver During Early Childhood (yes)	3 (6,7)	0 (0.0)	.244	F
Family History of Psychiatric Disorders (yes)	14 (33.3)	8 (20.0)	.173	χ²
History of Suicide Attempts (yes)	4 (9.3)	0 (0.0)	.117	F
History of Psychiatric Disorders During Child and Adolescent (yes)	6 (14.0)	1 (2.5)	.111	X²
<sup>s</sup> Student's t-test/ x <sup>2</sup> Chi-squared test/ <sup>F</sup> Fisher Exact Test/ p<0.05 statistically sign	nificant			

	Total San	nple (n=85)		
	Social Phobia (N:45)	Healthy Control (N:40)		
	Mean±SD	Mean±SD	p	Cohen's d
Parental Bonding Instrument (mother form)				
Care	16.31±2.30	28.77±6.77	<.001	2.53
Overprotection	18.35±4.18	24.82±6.58	<.001	1.18
Parental Bonding Instrument (father form)				
Care	16.84±3.14	25.28±9.28	<.001	1.18
Overprotection	21.35±4.69	27.54±5.94	<.001	1.16
Adult Attachment Scale				
Secure	21.84±8.08	24.37±6.26	.131	.35
Avoidant	25.88±7.39	22.47±6.23	.034	.50
Anxious	23.65±7.66	16.80±.698	<.001	.93
Liebowitz Social Anxiety Scale	119.56±25.66	75.60±13.51	<.001	2.13

In terms of adult attachment styles, no significant difference was found in secure attachment between the two groups (p = .131; Cohen's d = 0.35), indicating a small effect size. However, the SAD group scored significantly higher on the avoidant attachment scale (25.88  $\pm$  7.39) compared to the HC group (22.47  $\pm$  6.23; p = .034; Cohen's d = 0.50), suggesting a medium effect size. The SAD group also scored significantly higher on the anxious attachment scale (23.65  $\pm$  7.66) compared to the HC group (16.80  $\pm$  6.98; p < .001; Cohen's d = 0.93), reflecting a large effect size. Additionally, the Liebowitz Social Anxiety Scale (LSAS) scores were significantly higher in the SAD group (119.56  $\pm$  25.66) compared to the HC group (75.60  $\pm$  13.51; p < .001; Cohen's d = 2.13), indicating a very large effect size.

The correlation analysis (Table 3) revealed significant associations between LSAS scores and both parental

bonding and adult attachment styles. LSAS scores were inversely correlated with maternal care (r = -.566, p < .001) and paternal care (r = -.384, p < .001), indicating that lower perceived parental care is linked to higher social anxiety. Similarly, negative correlations were found with maternal overprotection (r = -.449, p < .001) and paternal overprotection (r = -.399, p < .001), suggesting that reduced parental overprotection is associated with increased social anxiety. For adult attachment styles, LSAS scores were positively correlated with avoidant (r = .433, p < .001) and anxious attachment (r = .458, p < .001), while a negative correlation was found with secure attachment (r = -.294, p = .009), indicating that insecure attachment styles are linked to higher social anxiety, whereas secure attachment is associated with lower social anxiety.

Tablo 3: Correlation analysis of clinical variables										
Correlations										
			Parental Bondi	ار بار ۵	Attachmont	Scolo				
	Mother for	m	Father form			Adult Attachment Sc		cale		
		Care	Overprotection	Care	Overprotection	Avoidant	Anxious	Secure		
	Pearson Correlation	-,566**	-,449**	-,384**	-,399**	,433**	,458**	-,294**		
Liebowitz Social Anxiety Scale	Sig. (2-tailed)	0,000	0,000	0,000	0,000	0,000	0,000	0,009		
	N	79	79	79	79	77	77	79		
**. Correlation is significant at the	0.01 level (2-tailed	).								

# Discussion

This study sought to explore the relationship between attachment styles and SAD among patients. The findings highlight significant differences in parental bonding and adult attachment styles between individuals with social phobia and healthy controls, suggesting how these factors might influence the development and severity of social anxiety.

One key finding of our study was that individuals with social phobia perceived their parents, especially their mothers, as providing significantly lower levels of care. This suggests that these individuals experienced their parents as cold, rejecting, and neglectful, which may contribute to the development of social anxiety. Research has consistently shown that maternal care plays a particularly crucial role in the emotional regulation and social development of children. Inadequate maternal responsiveness is often linked to increased vulnerability to anxiety disorders (23). Since mothers are typically the primary attachment figures, their responsiveness and warmth are essential for fostering secure attachment, which can serve as a protective factor against social anxiety (6,7). This aligns with earlier research by McLeod et al. (24), which demonstrated that inadequate parental care is linked to higher levels of anxiety and depressive symptoms in offspring. Similarly, Lieb et al. (25) found that children who perceive their parents as uncaring are more likely to develop anxiety disorders, including social phobia. These consistent findings highlight the importance of early caregiving experiences, particularly maternal care, in shaping an individual's emotional and social development

Contrary to the common belief that overprotective parenting exacerbates anxiety, our study found that patients with social phobia reported lower levels of perceived parental overprotection compared to the control group. This finding is intriguing, as overprotectiveness is generally believed to contribute to anxiety by restricting a child's autonomy and fostering a fear of the outside world. Typically, excessive parental control is associated with higher levels of anxiety in children, as shown in studies like those by Parker et al. (26). However, in our sample, it appears that lower levels of perceived parental control were actually linked to higher social anxiety. Similar findings have been reported by Fattouh et al. who found that dysfunctional attachment strategies during formative years are associated with heightened anxiety symptoms and maladaptive interpersonal relationships (13). This suggests that these individuals might have felt a lack of guidance and support in navigating social challenges, which could lead to greater insecurity in social situations. This paradoxical effect implies that while some degree of parental control may provide necessary structure and security, too little control may leave individuals feeling unsupported and vulnerable to anxiety, as suggested by Bögels and Brechman-Toussaint (7).

Regarding adult attachment styles, our results showed that individuals with social phobia were more likely to exhibit avoidant or anxious/ambivalent attachment styles. This supports the idea that these specific insecure attachment patterns, characterized by either a fear of rejection (as seen in anxious attachment) or emotional distancing (as seen in avoidant attachment), may be associated with higher levels of social anxiety. Previous studies, such as those by Warren et al. (27), have similarly shown that anxious attachment is particularly linked to heightened sensitivity to social threats, which can exacerbate social anxiety. The positive correlation between avoidant attachment and social anxiety in our study also aligns with the work of Mikulincer and Shaver (4), who argued that avoidant individuals may experience underlying social fears despite outwardly minimizing the importance

of social interactions. Similarly, Read et al. demonstrated that avoidant and anxious attachment styles are strongly associated with social anxiety, reinforcing the idea that different insecure attachment styles may contribute to social anxiety through distinct but overlapping pathways (11). The anxious attachment heightens sensitivity to rejection, making individuals more prone to perceive social threats. In contrast, avoidant attachment reflects an underlying fear of social engagement despite an outward indifference to social interactions.

Secure attachment was found to have a significant negative correlation with the severity of social anxiety symptoms, indicating its protective role in mitigating anxiety. This finding aligns with Muris et al. (9), who emphasized the emotional resilience fostered by secure attachment against anxiety disorders. Secure attachment provides individuals with a stable base, reducing sensitivity to social threats and enhancing coping mechanisms during stress (28). The ability to rely on a caregiver during early development fosters a sense of safety and stability, which mitigates anxiety in challenging situations (2). Parental behaviors that promote security, such as warmth, responsiveness, and consistency, have been shown to build resilience against social anxiety (12). Our findings demonstrate consistently lower social anxiety symptoms among individuals with secure attachment, reinforcing its protective role. This supports attachment theory, which posits that secure attachment equips individuals with the psychological resources necessary for effectively managing stress and anxiety (2). Therefore, enhancing secure attachment through interventions could be beneficial in reducing social anxiety severity (11,28).

Additionally, we found that lower levels of perceived parental care were associated with more severe social anxiety symptoms, reinforcing the idea that inadequate early caregiving experiences can contribute to the intensity of social anxiety in later life. This aligns with the attachment theory proposed by Bowlby (8), who emphasized the long-term impact of early attachment experiences on emotional development. Interestingly, our findings also revealed a negative correlation between overprotectiveness and the severity of social anxiety symptoms, which is contrary to typical expectations. This suggests that, while excessive control might generally be seen as detrimental, in our sample, a lack of perceived control may have left individuals feeling unsupported and vulnerable, thereby increasing their social anxiety. This phenomenon has been discussed in studies like those by Rapee (29), where the absence of a perceived protective parental role was linked to greater emotional difficulties in children.

The findings of this study also highlight the need for considering attachment-based approaches in clinical settings for treating social anxiety. Attachment-Based Family Therapy and Emotion-Focused Therapy have shown promise in enhancing secure attachment, which can mitigate the risk of social anxiety by reducing the vulnerability to perceived social threats. Additionally, enhancing caregiving practices, such as promoting warmth, responsiveness, and consistency, is crucial in reducing the risk of insecure attachment, which is often a precursor to social anxiety symptoms (30). Our study's focus on parental bonding emphasizes its influence on social anxiety levels throughout different stages of life, which provides a developmental perspective that is crucial for understanding and effectively treating social anxiety. Integrating these insights into therapeutic practices may enhance current treatment models by addressing both the symptoms and the underlying vulnerabilities associated with attachment insecurities (2,4).

Several limitations to this study should be noted. First, the relatively small sample size may limit the generalizability of the findings to the broader population. The findings should be interpreted cautiously, as larger studies are needed to confirm these results. Second, the crosssectional design of this study prevents us from drawing any conclusions about the causality between attachment styles and social anxiety disorder. Future longitudinal research is needed to establish temporal relationships and causation. Third, using retrospective self-reports in the Parental Bonding Instrument may lead to recall bias, which could affect the accuracy of the data regarding childhood attachment experiences. Participants' memories of their early caregiving environments may be influenced by their current emotional state, potentially skewing the results. Additionally, the SAD and control groups were not fully matched in terms of educational attainment, with the SAD group showing a lower average education level. This difference could have influenced the outcomes, as educational level may affect coping strategies and the overall vulnerability to anxiety. Despite this limitation, the age and gender matching between groups helped minimize confounding factors related to developmental differences, allowing for a focused analysis of attachment styles and parental bonding.

# Conclusion

This study highlights the significant relationship between early attachment experiences and social anxiety disorder. Our findings suggest that both insufficient parental care, particularly inadequate maternal care, and insecure attachment styles are crucial factors in the etiology and severity of social phobia. These results emphasize the importance of considering attachment-based approaches in the assessment and treatment of social anxiety. Future research should further explore these dynamics, particularly through longitudinal studies to clarify the causal relationships between early attachment experiences and the later development of social anxiety symptoms.

# **Declarations**

#### Funding

The authors declared that this study received no financial support.

#### Conflicts of Interest/Competing Interests

The authors have no conflicts of interest to declare.

#### **Ethics** Approval

Approval for this research was granted by the Hamidiye Scientific Research Ethics Committee at the University of Health Sciences on May 13, 2023, with decision number 27740.

#### Availability of Data and Material

Data supporting the findings of this study are available from the corresponding author upon request.

#### Authors' Contributions

Conceived and designed the analysis: H.G.; K.Ç.; İ.Y.K; E.S.; H.B.; R.K.; U.T.

Collected the data: H.G.; K.Ç.; İ.Y.K

Contributed data or analysis tools: H.G.; K.Ç.; İ.Y.K; E.S.; H.B.; R.K.; U.T.

Performed the analysis: H.G.; E.S.; H.B.; R.K.; U.T.

### Wrote the paper: H.G.; K.Ç.; İ.Y.K; E.S.; H.B.; R.K.; U.T.

Other contribution: H.G.; H.B.; R.K.; U.T.

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Physical Medicine and Rehabilitation / Fiziksel Tip ve Rehabilitasyon

# The Level of Depressive Symptoms and Related Factors in Patients with Chronic Low Back and Neck Pain

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Received: 17.03.2024 Accepted: 31.08.2024

#### ABSTRACT

**Objective:**The number of patients with back and neck pain, which we frequently encounter in neurosurgery practice, is too high to be underestimated, especially in today's conditions. Unfortunately, it is known that it causes serious labour force and economic losses as well as negatively affecting the social lives of individuals. The etiology of low back and neck pain is multifactorial and it is usual to encounter with depressive mood.

**Material and Methods:** The study included 76 patients presenting with low back and neck pain and 48 healthy individuals who had not undergone spinal surgery in the control group. Beck Depression Scale (BDS) was used to question the sociodemographic characteristics of the patients and whether they had a history of previous spinal surgery. The data analysed in SPSS 22 software.

**Results:** In our study, BDI scores were found to be higher in the control group in those who regularly used analgesics for pain (p<0.05). In the patient group, BDI scores were higher in smokers, those who reported irregular diet and those who had previously received psychological support (p<0.05). In addition, patients who lived in the city centre, had irregular diet and smoked had higher BDI scores compared to the control group.

**Conclusion:** Chronic low back and neck pain affects the functional status of individuals and may cause psychological problems such as depression. Low back and neck pain are diseases characterised by multifactorial interactions. Patients may be recommended to undergo physical and psychological examinations and psychological counselling.

Keywords: Chronic low back, chronic neck pain, beck depression scale.

### ÖZET

Giriş: Beyin cerrahi pratiğinde sıklıkla karşılaştığımız bel ve boyun ağrılı hastaların sayısı özellikle günümüz koşullarında küçümsenmeyecek kadar fazladır. Bireylerin sosyal hayatlarının olumsuz etkilemesinin yanında ciddi iş gücü kaybı ile ekonomik kayıplara neden olduğu maalesef bilinmektedir. Bel ve boyun ağrıların etyolojisi multifaktöriyeldir ve depresif duyqu durum ile karşımıza çıkması olağandır.

Gereç ve Yöntem: Çalışmaya bel-boyun ağrısı şikayeti ile başvuran 76 hasta ve kontrol grubu olan daha önce spinal cerrahi geçirmemiş 48 sağlıklı birey dahil edilmiştir. Beck depresyon ölçeği (BDÖ) ile kişilerin sosyodemografik özellikleri, geçirilmiş herhangi bir cerrahi-spinal cerrahi öyküsü olup olmadığı da sorgulanmıştır. Çalışma verileir SPSS 22 programı kullanılarak analiz edilmiştir.

**Bulgular:** Çalışmamızda, BDÖ puanları kontrol grubunda; ağrısı için düzenli analjezik kullananlarda yüksek bulunmuştur (p<0,05). BDÖ puanları hasta grubundaki sigara kullanan, düzensiz beslendiğini ifade eden ve daha önce psikolojik destek alanlarda yüksekti(p<0,05). Ayrıca il merkezinde yaşayan, düzensiz beslenen, sigara kullanan hastaların kontrol grubuna göre BDÖ puanları yüksekti.

**Sonuç:** Kronikleşen bel ve boyun ağrıları bireylerin fonksiyonel durumlarını etkilerken depresyon gibi psikolojik sorunlar da doğurabilmektedir. Bel ve boyun ağrıları, multifaktöriyel etkileşimlerle karakterize hastalıklardır. Hastaların fiziksel ve ruhsal muayeneleri ile psikolojik danışmanlık almaları önerilebilir.

Anahtar Kelimeler: Kronik bel ağrısı, kronik boyun ağrısı, beck depresyon ölçeği.

Copyright © 2025 the Author(s). Published by Acibadem University. This is an open access article licensed under a Creative Commons Attribution-NonCommercial-NoDerivatives (CC BY-NC-ND 4.0) International License, which is downloadable, re-usable and distributable in any medium or format in unadapted form and for noncommercial purposes only where credit is given to the creator and publishing journal is cited properly. The work cannot be used commercially without permission from the journal. he majority of patients evaluated in the neurosurgery clinic are patients with complaints of low back and neck pain. Neck pain is the most common problem after back pain. The causes of back and neck pain are, as expected, multifactorial. Sociodemographic characteristics of individuals also affect back and neck pain, which may include their profession, income, educational status and working life.

While 70-80% of people experience low back pain throughout their lives, the incidence within a year varies between 11-12% (1,2). Pain becomes chronic if it lasts longer than 12 weeks. Various studies have shown that low back pain becomes chronic at a rate of 20% and neck pain becomes chronic at a rate of 40% (3-6).

These symptoms, such as waist and neck pain, affect the musculoskeletal system and can become chronic; It is known that in addition to negatively affecting people's social lives, it significantly reduces their functional-physical capacities and causes serious workforce loss and economic difficulties. It is known that in these patients, whom we frequently encounter in neurosurgery outpatient clinics, low back pain regresses within a month with conservative methods, and that it still persists after a year in 37-54% of the patients (7). The rate of patients receiving surgical treatment was found to be only 2% (8). The most common known cause of low back pain is lumbar disc herniation, followed by lumbar spinal stenosis, which is one of the degenerative spine diseases, spondylolisthesis, infections and malignancies. Epidemiological studies show that the prevalence of neck pain is close to that of low back pain. Although the incidence of neck pain varies throughout life, the incidence of neck pain also increases with advancing age (9).

Sampath et al. in their study on patients with cervical radiculopathy and neck pain, they compared surgical and conservative treatment methods and found that both treatment methods reduced pain, but surgical treatment was more effective than conservative methods (10).

Waist and neck pain is a crisis situation that can develop not only due to medical or organic reasons, but also due to physiological, social, economic and psychological reasons. Patients think that when they suffer from this pain, they will not be able to work and therefore will experience financial difficulties. On the other hand, they also feel physically weak and struggle with pain. Therefore, they may face thoughts such as turning into an addicted individual and helplessness, which may cause them to feel anxiety, a decrease in their interest and desire for the life they have in their daily lives, and a depressive state such as discontent, sadness, grief, unhappiness and hopelessness. It has been reported that feelings of anxiety and depression are more common, especially in people with physical diseases (11).

It is also known that back and neck pain increases with depression. Studies have shown that 75-80% of depression patients have clinical symptoms such as headache, waist and neck pain (12,13).

In our study, 76 patients who applied to the neurosurgery outpatient clinic due to back and neck pain between July and September 2023 and 48 healthy individuals as a control group were taken into consideration and compared by questioning the Beck depression scale (BDI), sociodemographic characteristics and any surgery or spine surgery history.

# **Material and Method**

Our research was conducted by the Kayseri City Hospital Neurosurgery Clinic between July and September 2023, with patients presenting to the outpatient clinic with chronic low back pain, chronic neck pain, or both. The people included in the study were informed about the study, their written consent was obtained, and the study was conducted in accordance with the principles of the Declaration of Helsinki. For the study, permission numbered 04.01.2023, 76397871 was obtained from our hospital and ethics committee approval dated 23/10/2023 and 2023/009-00 numbered was obtained from Nuh Naci Yazgan University, Ethics Committee.

# Study Design

The sample of the study was obtained as 120 people, including 75 patients and 45 control groups, using literature information and Number Cruncher Statistical System (NCSS) 2007 & Power Analysis and Sample Size (PASS) 2008 Statistical Software (Utah, USA). A total of 76 patients aged 18-75 with chronic low back and neck pain, regardless of gender, were included in the study. The control group consisted of 48 healthy individuals who had not previously undergone spine surgery. The patients and the control group were given a questionnaire that questions; sociodemographic data such as age, gender, place of residence, education and economic status, and consists of a total of 22 questions, 4 of which are open-ended, focusing on behavior regarding smoking and alcohol use, exercise, and nutrition, and includes a 21-question **Beck Depression Scale (BDS)** collected. The face-to-face interview method was conducted by a single researcher. The patient and control groups included in the study; Height (cm), Body Weight (kg), BMI (Body Mass Index) were calculated on a weight and height meter with 0.01 kg precision, barefoot and wearing sports clothes.

#### Inclusion and exclusion criteria

Patients with complaints of low back or neck pain that persisted for more than three months were included in the study. Patients with pain due to cancer, infection and trauma were excluded from the study. People under the age of 18 and over the age of 75 were not included in the research. The control group included healthy individuals over the age of 18 who had no back or neck pain for the last three months, no history of spinal surgery, and no acute disease. The control group was made up of healthcare workers and their families.

#### Beck depression scale form

Beck Depression Scale (BDS), which consists of 21 questions and is used safely in our country, includes 4 options each and scores between 0 and 3 (not at all, 0; mild, 1; moderate, 2; severe, 3). It is a scale about how the individual feels in the last week, including the same day, in terms of generalized anxiety symptoms such as feeling of distress, and its Turkish validity and reliability were determined by Hisli (1989), and the Cronbach's alpha coefficient of the scale was found to be 0.80 (14,15).

### History of spinal surgery and any previous surgery

The results of patients who underwent single or 2-level microdiscectomy, posterior stabilization and arthrodesis surgery up to 2 to 6 segments, narrow spinal canal surgery without single-distance arthrodesis, and patients who did not undergo spinal surgery were evaluated. Minimally invasive procedures (kyphoplasty, vertebroplasty, endoscopic discectomy) were not included in the study. All other previous surgical procedures are also marked as surgical history.

#### Statistical Analyses

The data collected for the study were recorded using the SPSS 22 program and analyzed in the same program. Frequency, percentage, mean value, standard deviation, highest and lowest (min-max) values and median were used for descriptive statistics. For statistical analysis of categorical data, Pearson Chi-square test and Fisher's Exact Test were applied for values below five. Shapiro Wilk test was used to check the suitability of the data for normal distribution. Since the data did not comply with normal distribution, Mann Whitney U test and Kruskall Wallis test were applied. Pearson Correlation coefficient was used to show the relationship between variables. Statistically significant difference was accepted as p<0.05.

# **Results**

Of the 124 people included in this study, 82 (66.1%) were women and the average age was 40.10±12.62 (min-max: 18-72) years. Of these 124 people, 76 (61.3%) are patients and 48 (38.7%) are controls. In the data obtained from the patients, the average age was determined as 43.80±14.1 years, and in the control group it was 34.52±6.8 years. It was observed that the number of women in the patient group was significantly higher among those aged 40 and over, those with secondary school education or lower, those who described their economic situation as poor, those who do not have any job and mostly live in the city center (p<0.05). While the average BDS score of the patients was 13.23±7.94, it was 11.29±10.26 in the control group. There was no significant difference in terms of scale scores in the patient and control groups (p = 0.057), but the BDS scores of the patients were higher than the control group. Sociodemographic data and BDS scores of the patient and control groups are given in **Table 1**. There was no significant relationship between BDS scores and sociodemographic variables in the patient and control groups, but BDS scores were lower in those with high education levels, those who defined their economic status as good, and men in the control group, and were higher in the unemployed group in the control group (p>0.05). However, BDI scores were found to be higher in the patient group living in the city center (*Table 1*).

	Table 1. Sociodemographic	finding	s and BE	OS score	s of the <sub>l</sub>	patient and co	ontrol gro	oups		
		Dation		Contra			BDS s	scores		P***
Variables		Patien	t group	Contro	l group	Patie	nt	Contr	ol	
		n	%	n	%	Average./sd	Median	Average./sd	Median	
	Female	56	73.7	26	54.2	13.3±8.5	12.0	12.7±11.4	11.4	0.413
Gender	Male	20	26.3	22	45.8	13.0±6.2	12.5	9.5±8.5	8.5	0.073
	р		0.0	25*		0.855*	***	0.263*	<del>***</del>	
	Under 40 age	40	52.6	34	70.8	12.8±7.5	13.0	10.4±7.1	9.5	0.176
Age	40 years and above	36	47.4	14	29.2	13.7±8.4	12.0	13.3±15.5	9.0	0.226
	р		<0.0	001*		0.778*	***	0.964*	<del>***</del>	
	Middle school and below	43	56.6	0	0.0	14.2±8.3	14.0	-	-	-
Education	High school	18	23.7	9	18.8	14.0±8.0	12.0	15.2±16.9	9.0	0.438
Level	University	15	19.7	39	81.3	9.5±5.4	11.0	10.3±8.1	9.0	0.938
	р	<0.001*			0.106*	***	0.587*	***		
	Good	9	11.8	20	41.7	9.5±4.0	9.0	8.4±5.8	8.0	0.508
Economical status	Moderate	54	71.1	22	45.8	13.7±7.2	13.0	12.8±12.7	10.0	0.174
Economical status	Worse	13	17.1	6	12.5	13.5±11.8	11.0	17.3±8.1	17.0	0.235
	р		0,0	01*		0.212***		0.063****		
	Nuclear family	71	93.4	44	91.7	13.2±8.1	12.0	11.4±10.4	9.0	0.083
Family type	Extended family	5	6.6	4	8.3	12.6±3.6	14.0	10.5±8.6	10.5	0.624
	р		0.73	34**		0.900***		0.926 <sup>*</sup>	***	
	Working	25	32.9	44	91.7	12.7±6.1	13.0	10.7±9.9	9.0	0.088
Working status	Not workig	51	67.1	4	8.3	13.4±8.7	12.0	17.3±13.6	19.5	0.581
	р		<0.0	001*		0.951*	***	0.247*	***	
	City Center	62	81.6	27	56.3	12.4±6.6	12.0	8.9±7.3	8.0	0.017
Longest lived place	Town	6	7.9	17	35.4	21.5±16.0	13.5	15.5±13.7	12.0	0.420
Longest lived place	Village	8	10.5	4	8.3	12.8±6.5	13.0	10.0±5.1	10.0	0.495
	р		0.0	01*		0.513*	***	0.154***		
All participants		76	100	48	100	13.2±7.9	12.0	11.2±10.2	9.0	<u>0.057</u>
%Column Percentage *pears	son chi square ** fisher's exact te	est *** Mo	ann Whit	ney U Tes	t, ****Krı	ıskall Wallis Tes	t. BDS: Be	ck depression s	cale.	

	Table 2. Some life beha	iviors an	d BDS so	ores in t	the patie	ent and contro	ol groups			
		Dation		Contro	l group		BDS s	cores		
Variables		Patien	Patient group		rgroup	Patie	nt	Contr	ol	p**
			%	n	%	Average./sd	Median	Average/sd	Median	
	Positive	24	31.6	18	37.5	15.8±8.8	17.0	9.3±6.4	10.5	0.018
Smoking	Negative	52	68.4	30	62.5	12.0±7.2	12.0	12.4±11.9	9.0	0.440
	р		0.4	97*		0.048	**	0.701	**	
	Positive	6	7.9	10	20.8	11.8±7.6	11.5	9.1±5.7	8.0	0.550
Alcohol users	Negative	70	92.1	38	79.2	13.3±8.0	12.5	11.8±11.1	9.5	0.132
	р	0.036*			0.637**		0.567	**		
	Yes	25	32.9	11	22.9	12.2±7.9	11.0	8.5±6.7	9.0	0.216
Regular exercise	No	51	67.1	37	77.1	13.7±7.9	13.0	12.1±11.0	9.0	0.120
	р		0.2	33*		0.352**		0.476**		
	Regular	59	77.6	27	56.3	11.9±6.3	12.0	9.7±7.4	8.0	0.092
Nutrition status	Irregular	17	22.4	21	43.8	17.8±10.9	15.0	13.3±12.9	11.0	0.060
	р		0.0	12*		0.023	**	0.298	**	
	18.5-24.9	28	36.8	22	45.8	11.9±9.6	10.0	9.5±7.7	8.5	0.469
DMI Creation	25.0-29.9	21	27.6	15	31.3	13.3±7.1	12.0	11.6±13.8	9.0	<u>0.074</u>
BMI Group	≥30	27	35.5	11	22.9	14.6±6.6	14.0	14.1±9.1	14.0	0.859
	р	1	0.3	25*	0	0.158 <sup>*</sup>	<del>***</del>	0.298***		
%Column Percentage *pears	, son chi square ** Mann Whitney	, U Test, *	**Kruska	Wallis Te	est <b>BDS:</b> E	Beck depression	n scale.	°		0

т	able 3. Disease and medicat	tion hist	ory and	BDI scor	es in the	patient and	control gi	roups		
		Dation		Contro	l group		BDS s	scores		
Vari	Variables		Patient group		rgroup	Patie	nt	Conti	ol	p***
		n	%	n	%	Average/sd	Median	Average/sd	Median	
	positive	32	42.1	7	14.6	14.2±8.5	13.0	13.5±7.4	12.0	0.956
At least one chronic disease	negative	44	57.9	41	85.4	12.6±7.5	11.5	10.9±10.7	9.0	0.131
uisease	р		0.0	01*		0.396*	<del>***</del>	0.249	***	
	Yes	6	7.9	5	10.4	12.0±3.4	12.0	10.4±9.3	9.0	0.715
Presence of chronic disease in the family	No	70	92.1	43	89.6	13.3±8.2	12.0	11.4±10.5	9.0	0.071
disease in the failing	р	0.748**			0.809***		0.852***			
	positive	29	38.2	6	12.5	14.4±8.8	13.0	12.3±7.2	12.0	0.598
Using medication regularly	negative	47	61.8	42	87.5	12.4±7.3	12.0	11.1±10.6	9.0	0.168
regularly	р	0.002*			0.330*** 0463***			***		
	positive	63	82.9	16	33.3	13.0±8.1	12.0	13.8±6.9	13.0	0.517
Using analgesics regularly	negative	13	17.1	32	66.7	13.9±6.8	12.0	10.0±11.4	7.5	0.041
regularly	р		<0.0	001*		0.530*	<del>***</del>	0.016	***	
	positive	23	30.3	9	18.8	13.6±7.9	13.0	14.8±9.0	14.0	0.721
Other surgical history	negative	53	69.7	39	81.3	13.0±8.0	12.0	10.5±10.4	9.0	0.030
	p 0.154*			0.713*	<del>***</del>	0.106*	<del>***</del>			
	Yes	19	25.0	8	16.7	17.6±10.1	18.0	12.6±7.0	12.0	0.221
Previous psychological treatment	No	57	75.0	40	83.3	11.8±6.5	12.0	11.0±10.8	9.0	0.140
treatment	р		0.2	73*		0.011	***	0.305*	<del>***</del>	
*Pearson Chi Square, ** fishe	r's exact test *** Mann Whitney	U Test, <b>B</b>	DS: Beck	depressio	on scale.					

There was no difference in smoking status between the patient and control groups, but the frequency of alcohol use was higher in the control group and the patient group stated that their nutritional status was more regular. Although there was no statistically significant difference between the groups, the prevalence of obesity was higher in the patient group. In the patient group, BDS scores were higher in those who smoked and reported irregular nutrition. BDS scores of smoking patients were higher than the smoking control group. Additionally, patients who described their nutritional status as irregular had higher BDS scores. Although there was no statistically significant difference, BDS scores were lower in healthy individuals who exercised regularly and ate regularly (p>0.05). A positive correlation was found between BMI and BDS scores of all participants (p = 0.041, p.cor. floor: 0.184). Details are given in **table 2**.

The presence of at least one chronic disease, regular medication use, and regular analgesic use history were significantly higher in the patient group (p<0.05). While BDS scores were high in the patient group who previously received psychological help, BDS scores were high in those who used regular analgesics in the control group (p<0.05). BDS scores of the control group, which did not use analgesics regularly and had not undergone surgery before, were significantly lower than the patient group. It is given in detail in **Table 3**.

# Discussion

It is known that as back and neck pain becomes chronic, the functional-physical capacities of individuals decrease significantly, serious workforce losses occur, which leads to economic difficulties and negatively affects their social lives. Yilmaz et al. in their study showed that chronic low back pain affects people psychologically and is an important problem that requires help (12). In a study conducted by Takahashi et al., it was found that patients with low back pain were more depressed (16). In another study conducted on Hungarian workers, it was found that low back pain was also associated with depression (17).

According to our study results, BDS total score was higher in the patient group compared to the control group. In addition, the high BDS total score in the control group using regular analgesics for pain control suggests that pain may have increased the frequency of depressive symptoms.

Yazıcı et al. stated that depression was higher in patients with chronic back and neck pain and those with low education levels. Although there was no statistically significant difference in our study, BDS scores were lower in the patient and control groups in those with higher education levels and those who described their economic status as good (13). Educational status may be related to pain management, methods of coping with stress, and therefore the development of depressive symptoms. A good economic situation may have increased the social well-being of both the patients and the control group and contributed to the decrease in depressive scores. In the control group, it was observed that the highest BDS scores were obtained in those who described their economic situation as poor and were not working. In our study, BDS scores were found to be higher in the patient group living in the city center. It was thought that patients would be more affected by the problems of big cities such as transportation, infrastructure and crowded living.

In a systematic review study evaluating chronic low back pain risk factors, depression was also included among the chronic low back pain risk factors. Additionally, smoking and obesity have been shown to be other risk factors (18). In our study, BDS scores were higher in the patient group who smoked and reported irregular nutrition. Healthy individuals who ate and exercised regularly had low BDS scores, and there was a positive correlation between BMI and BDS scores. It is conceivable that healthy lifestyle behaviors reduce chronic pain and therefore reduce depressive symptoms. Regular exercise and nutrition behaviors are indirect indicators that individuals are self-confident and make time for themselves. It comes to mind that depression and psychosocial problems are less common in individuals with high self-care and awareness. In our study, regular analgesic use was found to be high in the patient and control groups. Analgesics taken for pain control may be aimed at relieving chronic pain or eliminating the fear of pain. The relationship between chronic pain and depression is known and this relationship is bidirectional. In fact, a study conducted in Japan showed that individuals with depression felt more severe pain (19). In our study, BDS scores were low in the control group who did not use analgesics or had a history of surgery. In other words, depressive symptoms are less common in individuals who do not have pain, have no analgesic history, and have not had a serious health problem before.

# Conclusion

Chronic waist and neck pain is a disease characterized by bio-psychosocial multifactorial interactions. Due to its multidimensional nature, the evaluation and management of chronic low back and neck pain requires a multidisciplinary approach other than approaches focused on organic pathology. In addition to a detailed questioning and physical examination, the cause of the pain should be determined by using laboratory tests and imaging methods. Social, emotional, cognitive, environmental and behavioral factors should be revealed. For the correct approach and treatment to people, patients must be diagnosed by questioning every aspect of their lives, including not only their physical condition but also their emotional state. Thus, it is possible to complete the treatment successfully. Psychological counseling can also be offered to patients who need it. Collaborating with psychological science can make significant contributions to ensuring the well-being of patients.

# **Declarations**

# Ethical Consent

The study was approved by the local ethics committee of Nuh Naci Yazgan University with the ethics committee permission dated 23/10/2023 and 2023/009-00 numbered, and consent was obtained from all participants in accordance with the Declaration of Helsinki before entering the survey. Also permission of study approval was approved by the local ethics committee of Kayseri City Hospital with the ethics committee approval dated 04.01.2023 and numbered 76397871.

## Conflict of Interest

The authors have no conflict of interest regarding this study.

## **Financial Disclosure**

No financial support has been received for this study.

## Author Contributions

Detailing the work; project preparation, data collection and writing scientific papers, Op.Dr. YG has contributions. Op.Dr. ŞG contributed to the collection of data and writing and proof reading the scientific paper in the project. Dr.BO contributed to the collection of data, statistical analyses and proof reading.

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Rehabilitation / Rehabilitasyon

# Comparison of COVID-19 Fear and COVID-19-Related Behaviors of Intern Physiotherapy Students With and Without COVID-19

Raziye Erkan<sup>1</sup>, Emine Aslan Telci<sup>2</sup>, Sebahat Yaprak Çetin<sup>3</sup>

#### ABSTRACT

**Purpose:** This study aims to compare the coronavirus fear status, physical activity levels, coronavirus behaviors, and mental states of physiotherapy and rehabilitation intern students according to whether they have had COVID-19 or not and to determine the factors associated with coronavirus fear in students who have and have not had coronavirus.

**Methods:** The study included 103 students, with an average age of 22.95  $\pm$  1.93 years for those who had contracted COVID-19 and 22.57  $\pm$  1.4 years for those who had not. The evaluation utilized the COVID-19 Fear Scale, the Hospital Anxiety and Depression Scale, and the Physical Activity Questionnaire. Additionally, individuals' COVID-19 protective behaviors were assessed.

**Results:** When comparing the groups on COVID-19 fear levels, anxiety, depression, physical activity parameters, and COVID-19 protection behaviors, no significant differences were found between them. The fear scale and body mass index showed a moderately positive association in all participants without COVID-19; however, there was a weak positive relationship with gender, a weak positive relationship with HAD anxiety, and a negative relationship with vigorous activity in the COVID-19 group. (p<0.05).

**Conclusion:** The presence or absence of COVID-19 did not impact COVID-19 fear levels, mental health status, physical activity levels, or protective behaviors. The study concluded that a higher BMI, intense physical activity, elevated anxiety levels, and being female were associated with increased COVID-19 fear.

Keywords: COVID-19, fear, health behavior, physiotherapy, students

#### ÖZET

**Amaç:** Çalışmanın amacı, hastane ortamında staj yapan COVID-19 hastalığını geçiren ve geçirmeyen, fizyoterapi ve rehabilitasyon son sınıf öğrencilerinin COVID-19 korku durumlarını, fiziksel aktivite düzeylerini, COVID-19 davranışlarını ve ruhsal durumlarının COVID geçirip geçirmeme durumuna göre karşılaştırılması ve COVID-19 geçiren ve geçirmeyen öğrencilerin COVID-19 korkusu ile ilişkili faktörleri belirlenmesidir.

**Yöntem:** Çalışmaya yaş ortalaması 22,95 ± 1,93 yıl olan COVID-19 geçiren, yaş ortalaması 22,57 ± 1,4 yıl olan COVID-19 geçirmemiş toplam 103 öğrenci dahil edilmiştir. Değerlendirmede COVID-19 Korkusu Ölçeği, Hastane Anksiyete ve Depresyon Ölçeği ve Fiziksel Aktivite anketi kullanılmıştır. Ayrıca bireylerin COVID-19 korunma davranışları sorgulanmıştır.

**Bulgular:** Gruplar COVID-19 korku düzeyi, anksiyete, depresyon ve fiziksel aktivite parametreleri ve COVID-19 korunma davranışları açısından karşılaştırıldığında gruplar arasında fark olmadığı belirlenmiştir (p<0.05). COVID-19 geçirmeyen katılımcılarda korku ölçeği ile VKİ arasında orta düzeyde; cinsiyet ve HAD anksiyete ile zayıf düzeyde pozitif bir ilişki bulunmuştur. COVID-19 geçiren grupta ise şiddetli fiziksel aktivite ile negatif bir ilişki tespit edilmiştir(p<0.05).

**Sonuç:** Çalışmanın sonuçlarına göre, klinik stajlarını sürdüren son sınıf fizyoterapi öğrencilerinin COVID-19 geçirip geçirmemelerinin, COVID-19 korku düzeyleri, ruhsal durumları, fiziksel aktivite seviyeleri ve koronavirüsle ilgili davranışları üzerinde etkisinin olmadığı belirlenmiştir. Yüksek VKİ, şiddetli fiziksel aktivite ve yüksek anksiyete düzeyinin yanı sıra kadın cinsiyetinin de COVID-19 korkusunu artırdığı sonucuna ulaşılmıştır.

Anahtar Kelimeler: COVID-19, korku, sağlık davranışı, fizyoterapi, öğrenciler.

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Received: 11.05.2024 Accepted: 24.01.2025 he World Health Organization (WHO) declared the COVID-19 outbreak, which originated in Wuhan, China, in late 2019, a global pandemic. COVID-19 has significantly negatively impacted health, economy, society, and individuals (1). Treatment options include infection control, vaccination, and pharmacological interventions (2). However, preventing the spread of the virus remains the most effective approach, with measures like regular hand washing, respiratory hygiene, and avoiding crowded places helping to reduce transmission risks. In our country, 14 rules were implemented to control the spread of the pandemic (3).

Maintaining physical activity and boosting the immune system is also vital for protection (4). Psychological effects, such as anxiety and depression caused by the pandemic, should also be addressed (5). The COVID-19 pandemic is leading to widespread concern, fear, and anxiety among the general population, and uncertainty is a crucial factor in the emergence of mental health issues (6). This process triggers fear for oneself and loved ones and increases feelings of anxiety and immobility towards the unknown (7).

Healthcare workers are a very high-risk group for COVID-19 infection (8). Pandemic conditions cause psychological effects such as stress, fear, anxiety, and depression in healthcare workers (9). This is especially valid for students enrolled in programs connected to health. Students may be exposed to COVID-19 as a result of their practice in a hospital setting, which might result in unfavorable feelings, including stress and anxiety (10). Since health science students will be future health professionals, their attitudes and behaviors toward COVID-19 are increasingly important. Although there are studies on nursing, midwifery, and medical students, no study has been found on physiotherapy students.

The COVID-19 pandemic has been associated with an increased prevalence of depression and anxiety in the general population, with a particularly high incidence observed among healthcare workers. Physical activity levels have been identified as a potential factor influencing health outcomes, particularly concerning pandemic-related restrictions and social isolation. Therefore, it is important to examine physiotherapy students' depression, anxiety, and physical activity levels, with a specific focus on COVID-19 situations. This information may allow us to understand how students respond to the pandemic and develop strategies for similar conditions.

This study examined physiotherapy students' experiences during the COVID-19 pandemic and its effects. The study's primary aim was to compare the fear status, physical activity levels, behaviors, and mood of intern physiotherapy and rehabilitation students who had or had not had COVID-19 during their hospital internship. As a secondary aim, it sought to identify factors associated with the fear of COVID-19 among both groups of students. This research was expected to significantly contribute to the field by providing a new perspective on the challenges faced by health sciences students and enabling a more thorough understanding of their encounters amidst the COVID-19 pandemic, focusing specifically on physiotherapy students.

# 2. Material and Method

**2.1. Design:** This descriptive research was carried out in 2021 at the Pamukkale University (PAU) Physical Therapy and Rehabilitation Department, involving 4th-year students in internship programs at PAU Hospitals.

2.2. Participants: The study employed a previously prepared form comprising sociodemographic data and guestionnaires administered through face-to-face interviews. The study enrolled intern physiotherapy and rehabilitation students who volunteered and completed their internships at Pamukkale University Hospitals. All students were duly briefed on the study's objectives and provided consent by signing an informed consent document. In total, 136 internship students were invited to participate in the study; 19 declined. Fourteen students who had received the COVID-19 vaccination and had incompletely completed the questionnaires were excluded. The remaining 103 students (70 female and 33 male) were categorized into two groups based on their responses to the question "Have you had COVID-19?". The study was conducted on two groups of students: those who had had COVID-19 (n=19; 13 females, six males) and those who had not had COVID-19 (n=84; 57 females, 27 males).

## 2.3. Data Collection Tools

2.3.1 Sociodemographic Form: The information on the participants' age, gender, and body mass index (kg/m<sup>2</sup>) was recorded on a previously prepared form.

2.3.2. The Fear of COVID-19 Scale, adapted into Turkish by Satici et al., was assessed to measure fear of the virus. Its reliability was established with a Cronbach's alpha coefficient of  $\alpha$ = .82. This 7-item questionnaire employs a 5-point Likert scale (1: strongly disagree; 5: strongly agree). Higher total scores on the questionnaire signify elevated levels of fear (11).

2.3.3. Assessment of COVID-19 behaviors: Based on current recommendations from "the Centers for Disease Control and Prevention (CDC)", eight behaviors were selected to mitigate susceptibility to and spread of COVID-19: "Avoiding crowded areas, Washing hands with soap and water for at least 20 seconds, Using hand sanitizer, Staying home if feeling sick, Cleaning frequently touched surfaces, Covering coughs and sneezes with a handkerchief or elbow, Limiting close contact, Wearing a face mask."

Participants were asked to rate the likelihood of engaging in these actions over the current week, using a scale ranging from 1 = "very unlikely" to 5 = "very likely." (12).

2.3.4. Assessment of mental status: Participants' mental status was evaluated using the Hospital Anxiety and Depression Scale (HAD-S). The Turkish validity and reliability of the questionnaire were established by Aydemir et al. in 1997. This questionnaire comprises 14 questions, divided into two subscales assessing depression (7) and anxiety (7). Responses to the questionnaire range from "not at all" (0 points) to "severely" (3 points). The cut-off points for the Turkish version of the HAD scale were determined to be 10 for the anxiety subscale (HAD-A) and 7 for the depression subscale (HAD-D) (13).

2.3.5. Determination of physical activity level: Physical Activity Questionnaire was used to determine the level of physical activity. The Turkish validity and reliability of the questionnaire were established by Sağlam et al. The questionnaire evaluates physical activities, such as the time spent walking and moderate and vigorous activities in the last 7 days [14]. A "MET-minutes/week" score is calculated by multiplying the duration in minutes, frequency in days, and MET values. To estimate energy expended during physical activities, the weekly minutes of each activity are multiplied by the MET values assigned in the International Physical Activity Questionnaire. This calculation provides energy expenditures for all participants' vigorous, moderate, walking, sitting, and

total physical activities, measured in MET minutes per week (15).

**2.4.** Statistical Analysis: Data were analyzed using SPSS 22.0 software. The demographic characteristics of the participants were analyzed using percentage distributions, means, and standard deviations. Data normality was assessed using the Shapiro-Wilk test. The data showed a normal distribution, while the data did not. Based on this, parametric tests (independent samples t-test) were used for normally distributed data, and non-parametric tests (Mann-Whitney U test) were used for non-normally distributed of p<0.05 was used. Correlation analyses were performed using Pearson correlation analysis for non-normally distributed data.

## 2.5. Ethical Considerations

In this study, we affirm that we have adhered to all regulations outlined in the "Directive on Scientific Research and Publication Ethics of Higher Education Institutions." We confirm that none of the activities prohibited under this directive's section "Actions Contrary to Scientific Research and Publication Ethics" have been conducted. The Pamukkale University Non-Interventional Clinical Research Ethics Committee granted approval for this study under decision number E-60116787-020-39771 on March 30, 2021. The principles of the Declaration of Helsinki conducted this study.

# 3. Results

The two groups had no significant differences regarding age, height, weight, BMI, and gender distribution (p=0.65–0.96, Table 1). Similarly, no differences were observed between the groups in terms of COVID-19 fear level, anxiety, depression, and physical activity parameters (p>0.05, Table 2). When comparing the groups based on anxiety and depression cutoff scores, no significant difference was found in terms of anxiety (p>0.05). However, an important difference was observed in depression scores, with those who had experienced COVID-19 showing higher levels of depression (p<0.05, Table 3). Finally, no significant difference was detected when the groups were compared regarding COVID-19-related behaviors (p>0.05, Table 2).

Table 1. Co	mparison of demographic da	ata of the groups				
Sociodemographic Characteristics	Sociodemographic Characteristics With COVID-19(n=19) Without COVI Mean±SD Mean					
Age (years)	22.95 ± 1.93	22.57 ± 1.4	0.655			
Height (cm)	168.89± 7.51	169.31 ± 9,64	0.919			
Body weight (kg)	63.42± 11.81	65.08 ± 13,47	0.73			
BMI (kg/m ) <sup>2</sup>	22.08 ± 2.78	22.54 ± 3,18	0.711			
Gender	n (%)	n (%)	p2			
Woman	13 (%68.42)	57 (%67.86)				
Male	6 (%31.58)	27 (%32.14)	0.962			
1: Mann Whitney U test, 2: chi-square test, test, BMI: boo	ly mass index					

	With COVID-19(n=19) Mean±SD	Without COVID-19 (n=84) Mean±SD	p(z/t)
COVID-19 fear scale	$14.89 \pm 5.6$	15.7 ± 6.2	0.603 (t=-0.521)
HAD anxiety	6.63 ± 3.24	8.37 ± 4.4	0.099 (z=-1.651)
HAD depression	5.89 ± 3.0	7.24 ± 3.9	0.106 (t=-1.662)
Walking (min/hf)	1406.89± 990.7	1610.17 ± 1065.63	0.417 (z=-0.812)
Moderate activity (min/hf)	444.21±651.41	419.76 ± 877.97	0.562 (z=-0.58)
Severe activity (min/hf)	875.79±1349.8	1354.29 ± 4391.48	0.407 (z=-0.83)
COVID-19 behaviors			
1. Avoiding crowded areas	3.37 ± 1.21	3.75 ± 1.27	0.18 (z=-1.339)
2. Washing your hands	$4.84 \pm 0.55$	$4.86\pm0.44$	0.909(z=0.115)
3. Using hand sanitizer	$4.89 \pm 0.32$	4.68 ± 0.7	0.246 (z=-1.16)
4. Staying at home if ill	3.74 ± 1.52	3.75 ± 1.52	0.891(z=0.137)
5. Cleaning surfaces	$4.32 \pm 0.82$	4.21 ± 0.98	0.83(z=-0.205)
6. Covering coughs and sneezes	$4.89 \pm 0.32$	$4.65 \pm 0.86$	0.29(z=-1.052)
7. Limiting close contact	3.95 ± 1.08	4.02 ± 1.14	0.673(z=-0.422)
8. Wearing a face mask	$5.00 \pm 0.00$	4.96 ± 0.19	0.405(z=0.832)

Table 3. Mental status of students with and without COVID-19					
HAD	With COVID n(%)	Without COVID n(%)	All participants n(%)	р	
Anxiety score > 10	2 (%10.5)	27 (%32.1)	29(%28.2)	0.050	
Anxiety score< 10	17(%89.5)	57(%67.9)	74(%71.8)	0.058	
Depression score > 7	5 (%26.3)	43(%51.2)	48(%46.6)	0.045	
Depression score<7	14 (%73.7)	41(%48.8)	55(%53.4)		
HAD: Hospital anxiety depression scale, p< 0.05					

Table 4: BMI, mental status, gender and physical activity, COVID-19 Behaviors with COVID Fear Scale Relationship Table						
	With COVID-19 (n=19)		Without COVID-19 (n=84)		All participants (n=103)	
	r	р	r	р	r	р
Body mass index	-0.336	0.160	-0.323**	0.003	-0.304**	0.002
HAD anxiety	0.201	0.408	0.234*	0.032	0.250*	0.011
HAD depression	-0.020	0.934	0.053	0.634	0.035	0.728
Walking (min/hf)	-0.022	0.930	0.053	0.629	0.043	0.667
Moderate activity (dk/hf)	-0.032	0.034	0.042	0.704	0.037	0.714
Severe activity (dk/hf)	-0.489*	0.897	-0.013	0.909	-0.098	0.326
Total Physical activity (MET-dk/hf)	-0.308	0.130	0.001	0.990	-0.035	0.723
Gender					-0.242*	0.014
Avoiding crowded areas	0.253	0.296	0.051	0.647	0.082	0.411
Washing your hands	-0.268	0.267	-0.066	0.553	-0.107	0.280
Using hand sanitizer	-0.252	0.298	-0.065	0.556	-0.097	0.328
Staying at home if ill	-0.173	0.480	0.163	0.138	0.098	0.323
Cleaning surfaces	0.176	0.471	0.236*	0.030	0.218*	0.027
Covering coughs and sneezes	-0.252	0.298	0.203	0.063	0.131	0.187
Wearing a face mask	-0.252	0.298	0.204	0.062	0.182	0.062
Limiting close contact	-0.106	0.666	0.099	0.370	0.065	0.517
<i>p</i> < 0.05 statistically significant difference * we	eak relationship, *	** moderate relat	ionship			

The relationship between COVID-19 fear level, BMI, mental status, physical activity parameters, and fear levels was compared in all participants who had COVID-19 and those who did not have COVID-19. There was a moderate (p= 0.003), weak (p= 0.014), and weak positive correlation with gender (p= 0.014) and HAD anxiety (p= 0.011) between the fear scale and BMI in non-Covid and all participants. The COVID group had a negative correlation with vigorous activity, while no significant difference was found between the other parameters (p= 0.16-0.99, Table 4). When COVID-19 behaviors and fear levels of both groups and all participants were compared, no significant difference was found between the two groups (p= 0.18-0.66, Table 4).

# 4. Discussion

In this study, we aimed to explore the impact of COVID-19 on physiotherapy students' fear levels, mental health, physical activity, and protective behaviors during their hospital internships. The key findings of this study were that the presence or absence of COVID-19 did not significantly affect the students' levels of COVID-19 fear, anxiety, depression, or physical activity. Additionally, no notable differences were observed in COVID-19 protective behaviors between students who had contracted the virus and those who had not. However, we found that higher BMI, intense physical activity, higher anxiety levels, and being female were associated with increased fear of COVID-19. These results provide important insights into how physiotherapy students, as future healthcare professionals, experienced the pandemic and the factors influencing their responses to the ongoing health crisis.

Previous research has identified healthcare workers and health science students as high-risk groups significantly impacted by the psychological toll of the COVID-19 pandemic (8,9,10,16). As future healthcare professionals, these individuals face unique challenges and stressors during such crises. Intern physiotherapy students have actively integrated their theoretical knowledge with practical experiences throughout the pandemic. This study aimed to evaluate the levels of fear, mental wellbeing, physical activity, and behaviors associated with the COVID-19 pandemic among intern physiotherapy students, a group significantly impacted by the global health crisis. By comparing those who had contracted COVID-19 with those who had not, the study aimed to identify factors contributing to the fear of COVID-19 among this population.

This current study is the first to examine the relationship between trainee physiotherapists' coronavirus behaviors, physical activity, and mental health and their fear of COVID-19. Studies have been conducted on people in different occupational groups. Isikli et al. (17) found no difference between the COVID-19 fear levels of nurses with and without COVID-19 diagnosis and that the COVID-19 fears of the nurses participating in the study were below average. In a different study conducted on healthcare workers, it was again reported that healthcare workers mostly had a low fear of COVID-19. It was reported that laboratory technicians had the highest mean fear scores, followed by X-ray technicians, nurses, and physicians, respectively (18). Labraque et al. (19) suggested that COVID-19 fears of nurses working on the front lines increased during the pandemic. Individuals may adapt to the negative emotional state they initially experienced over time. In the recent study, no significant difference was found between the COVID-19 fear levels of the groups who had and did not have COVID-19. It is thought that the lack of a significant difference between the fear levels of students who have and have not had COVID-19 may be related to the pandemic that has been ongoing since December 2019 and that physiotherapy interns work in relatively less risky environments.

Anxiety is characterized as a reaction to remote, uncertain, and undefined threats. While no studies in the literature directly compare infected and uninfected groups, research among healthcare workers has consistently documented elevated levels of anxiety and depression (8, 20). In a study conducted among healthcare workers during COVID-19, half of the respondents defined at least mild depression (21). A study of health students reported that participants described themselves as being at the center of the risk of infection during the pandemic and that this situation led to an increase in depression (22). The study observed no disparity in anxiety levels between the groups; however, there was a notable advantage among those who had contracted COVID-19. It's possible that uninfected students felt more anxious than other students because they hadn't caught the disease and were still uncertain. The ongoing pandemic may have heightened students' stress and anxiety levels, potentially increasing their vulnerability to developing depression.

Studies have shown that the physical activity levels of university students decreased even more during the pandemic (23, 24). The recent comparison of COVID-19 exposure in terms of physical activity parameters found no statistically significant difference between the groups. It was observed that COVID-19 did not affect the level of physical activity. This situation may be related to the fact that both groups were active in the hospital last week. It may also be related to the fact that the physiotherapy students know the importance of maintaining or increasing physical activity during the COVID-19 pandemic.

Although there are no studies in the literature regarding infection status, it was reported that health science students practiced personal protective measures (25). Similarly, in a study of dental students, students were found to practice preventive behaviors (26). A recent study compared COVID-19 prevention behaviors and COVID-19 status and found no difference between the groups. According to the study's results, having COVID-19 is not effective in implementing pandemic preparedness measures.

Fear is characterized as a distressing emotional state that arises from perceiving stimuli as threatening. Exceptional circumstances like disease outbreaks and epidemics can provoke fear in numerous individuals (27). According to the literature findings, individuals tend to adopt preventive behaviors more readily when perceiving the threat as severe. Regarding COVID-19, it has been proposed that the perceived threat is a motivating factor for embracing behaviors that help prevent the spread of the virus (28). Recently, no relationship was found between COVID-19 behaviors and fear levels of COVID-19 and non-COVID-19 in all participants. This result can be interpreted as the fact that the students were from the health sciences and did not see COVID-19 as a threat because they worked in the hospital during the pandemic.

Studies have shown that a high BMI is a risk factor for COVID-19(29). In the current study, a relationship was found between BMI and fear levels in all participants who did not have COVID-19 and in all participants. Therefore, it can be concluded that the higher the BMI of the participants, the more anxious they were about COVID-19. Physical activity is also considered a risk factor (30). When examining the relationship between physical activity, which is also considered a risk factor, and fear of COVID-19, it was found that there was a relationship between the level of vigorous activity and fear of COVID-19 in participants who had COVID-19. In addition, being female was associated with fear of COVID-19 in our study. Shehada et al. (18) also found that women in their study had a higher fear of COVID-19 than men. The study found an association between anxiety and fear levels in both non-COVID-19 and all participants. This finding suggests that fear of contracting COVID-19 can lead to anxiety.

According to the study's results, the status of physiotherapy students attending clinical placements, whether they had COVID-19 or not, did not affect their mental state, level of physical activity, and coronavirus-related behavior. However, it was found that not having COVID-19, high BMI, intense physical activity, high anxiety levels, and female gender increased fear of COVID-19.

The results obtained can guide planning aimed at understanding the attitudes and behaviors of healthcare students in risky situations and supporting them in coping with similar situations. Limitations include the small number of students who contracted COVID-19 and the single-center nature of the study. Future research can ensure the generalisability of these findings by including larger groups of participants and students from different healthcare fields undergoing placements.

# Declarations

## Funding

This study had no external funding

## **Conflicts of Interest**

No conflict of interest was declared by the authors.

## **Ethics Committee Approval**

In this study, we hereby undertake that all the rules required to be followed within the scope of the "Directive on Scientific Research and Publication Ethics of Higher Education Institutions" have been complied with and that none of the actions specified under the heading "Actions Contrary to Scientific Research and Publication Ethics" of the said directive have been carried out. Approval was obtained from the Pamukkale University Non-Interventional Clinical Research Ethics Committee with the decision numbered E-60116787-020-39771 on 30.03.2021. This study was conducted in accordance with the principles of the Declaration of Helsinki.

## Availability of Data and Material

The materials used in this study are also available from the corresponding author upon reasonable request. Due to privacy and ethical restrictions, some data may not be publicly shared but are available from the authors under conditions that ensure participant confidentiality. For further information, please contact.

### Author Contributions

Conceptualization; Design: [RE, EAS]; Writing: [RE, SYÇ]; Investigation/Data collection: [EAS, SYÇ]

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Rehabilitation / Rehabilitasyon

# **Comparison of Dyspnea, Quality** of Life and Fatigue Levels in Heart **Failure Patients with and without Pacemakers - A Preliminary Study**

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questionnaire, respectively.

dyspnea and the level of fatigue (p < 0.05).

ABSTRACT

ÖZET

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relationship between dyspnea, quality of life and fatigue levels in heart failure patients, as well.

with the level of fatigue in heart failure patients, it was not correlated with the guality of life.

Keywords: Heart Failure, Artificial Pacemaker, Outcome Assessment, Dyspnea, Quality of Life, Fatique

Background/Purpose: The main purpose of this study was to compare dyspnea, quality of life, and fatique levels in

heart failure patients with and without pacemaker. In addition, the aim of our study was to examine whether there was a

Methods: A total of 20 patients with heart failure, 10 with and 10 without pacemaker, who were diagnosed with heart

failure by a cardiologist at the Corum-Hitit University Erol Olcok Training and Research Hospital, Cardiac Rehabilitation

Unit were included in our study. Dyspnea, guality of life, and fatigue levels were measured with "Modified Medical

Research Council Dyspnea Scale (MmRC)", "Minnesota Heart Failure Life Scale (MHF)" and "Fatigue Severity Scale (FSS)"

Results: A total of 20 heart failure patients, 10 with pacemakers with a mean age of 61.90±8.49 years and 10 without

pacemakers with a mean age of 59.30±10.68 years, were included in our study. There was no significant difference in terms of dyspnea, quality of life and fatigue levels in heart failure patients with and without pacemaker (p>0.05). In 20

heart failure patients, it was observed that there was a moderate correlation in the same direction between the level of

**Conclusion:** According to the results of our study, it was found that using a pacemaker in heart failure patients had no effect on dyspnea, guality of life and fatigue levels. In addition, it was found that while the level of dyspnea was associated

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Received: 05.02.2024 Accepted: 07.10.2024

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Amaç: Bu çalışmanın temel amacı kalp pili olan ve olmayan kalp yetmezliği hastalarında dispne, yaşam kalitesi ve yorgunluk düzeylerini karşılaştırmaktı. Ek olarak, çalışmamızın bir diğer amacı, kalp yetmezliği hastalarında dispne, yaşam kalitesi ve yorgunluk düzeyleri arasında da bir ilişki olup olmadığını incelemekti. Yöntemler: Çalışmamıza Çorum-Hitit Üniversitesi Erol Olçok Eğitim ve Araştırma Hastanesi Kardiyak Rehabilitasyon

Ünitesi'nde kardiyolog tarafından kalp yetmezliği tanısı konulan 10'u kalp pili olan ve 10'u kalp pili olmayan toplam 20 kalp yetersizliği hastası dahil edildi. Dispne, yaşam kalitesi ve yorgunluk düzeyleri sırasıyla "Modified Medical Research Council Dyspnea Scale (MmRC)", Minnesota Heart Failure Life Scale (MHF)", and "Fatigue Severity Scale (FSS)" anketleri ile ölçüldü.

Bulgular: Çalışmamıza yaş ortalaması 61,90±8,49 yıl olan kalp piline sahip 10, yaş ortalaması 59,30±10,68 yıl olan kalp piline sahip olmayan toplam 20 kalp yetersizliği hasta dahil edildi. Kalp pili olan ve olmayan kalp yetersizliği hastalarında dispne, yaşam kalitesi ve yorgunluk düzeyleri açısından anlamlı farklılık saptanmadı (p>0,05). 20 kalp yetersizliği hastasında dispne ile yorgunluk düzeyi arasında aynı yönde orta düzeyde bir korelasyon olduğu görüldü (p<0,05).

Sonuçlar: Çalışmamızın sonuçlarına göre kalp yetmezliği hastalarında kalp pili kullanımının dispne, yaşam kalitesi ve yorgunluk düzeylerine etkisinin olmadığı belirlendi. Ayrıca, kalp yetersizliği hastalarında dispne düzeyinin yorgunluk düzeyiyle ilişkili olduğu ancak yaşam kalitesiyle ilişkili olmadığı belirlendi.

Anahtar Kelimeler: Kalp Yetmezliği, Yapay Kalp Pili, Çıktıların Analizi, Dispne, Yaşam Kalitesi, Yorgunluk

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eart failure is a condition in which the heart does not work properly. This can be caused by a problem with the heart's structure or the way it functions. This can lead to a shortage of oxygen in the body (1). It is thought that heart failure, which affects approximately 1 to 2 percent of the adult population in developed countries, may affect more people in the coming years due to the aging of the population (2). It is estimated that the prevalence of heart failure will increase by 46 percent by 2030 (3). Heart failure affects about 2% of the Australian population as the prevalence, and about 30,000 new people are diagnosed with it each year (1).

In addition to the significant economic cost of heart failure disease on the health system, heart failure patients are also significantly affected by the disease (1). In this patient group, problems such as depression, anxiety, cognitive impairment, increased shortness of breath with exertion, decreased independence in activities of daily living, and sleep problems were found to be common (1, 2). These symptoms are also accompanied by stress, including the use of multiple medications, fluid management, and multiple medical appointments (1).

The main problems seen in clinically stable patients with heart failure are decreased exercise tolerance and worsened quality of life (3). Exercise intolerance, defined as the inability to perform physical activities with prominent dyspnea and/or fatigue symptoms, is the main feature of heart failure and is associated with low quality of life (4).

Pacemakers are medical devices used for treating cardiac arrhythmias by implanting for the body internally (5). Cardiac implantable electronic devices, including implantable cardioverter permanent pacemakers, defibrillators (ICDs) and cardiac resynchronisation therapy (CRT), which play an important role in the treatment of cardiac arrhythmias, are increasingly used by cardiologists (6). Pacemakers enable heart failure patients to achieve a consistent quality of life compared to their healthy peers and in most cases reduce mortality (7). Patients undergoing pacemaker treatment may experience changes in different aspects of their lives in terms of physical, social, emotional and psychological factors. (8). Therefore, it is extremely important to examine these parameters in patients with a diagnosis of heart failure and especially those receiving pacemaker therapy. On the

other hand, although there are a limited number of studies examining the quality of life after pacemaker treatment in patients with heart failure (8), it is thought that there is a need for studies examining parameters such as dyspnea and fatigue in patients with heart failure with pacemakers and examining the factors affecting these parameters.

Although the comparison of various symptom and patientfocused outcomes such as health-related guality of life in patients with heart failure and healthy individuals in the literature has been the subject of some studies (5, 9, 10), the number of studies comparing heart failure patients with and without a pacemaker is limited. While it was found that exercise intolerance accompanied by dyspnea and fatigue, which is the main problem of patients with heart failure, is associated with poor function and reduced quality of life (4), whether there is a difference between these parameters according to the use of a pacemaker has not been examined. In addition, similar cardiac rehabilitation programs can often be applied in clinics for patients with and without a pacemaker. The difference in dyspnea, quality of life and fatigue parameters between patients with and without a pacemaker may create significant differences in the content of cardiac rehabilitation programs for both groups of patients.

In the light of this information, the main purpose of our study is to compare the levels of dyspnea, quality of life and fatigue in heart failure patients with and without a pacemaker. In addition, in this study, we examined whether there is a relationship between dyspnea, quality of life and fatigue levels in patients with heart failure.

# 2. Material and Methods:

## 2.1. Ethics:

Ethics committee approval of the study was obtained by Hitit University Faculty of Medicine Clinical Research Ethics Committee on 11.03.2020 with Decision Number 188. All subjects were informed about the study prior to their participation and written informed consent was obtained from each subject. In addition, institutional permission was obtained from the hospital to conduct the study.

## 2.2. Participants:

A total of 20 patients with cardiac failure, 10 with and 10 without a pacemaker, who were diagnosed with heart failure by a cardiologist in Çorum-Hitit University Erol Olçok Training and Research Hospital, Cardiac Rehabilitation Unit were included in our study. Patients with Class I, II and III according to New York Health Association (NYHA) classification were participated in the present study. All patients included in the study were clinically stable patients with good cognitive function with a score of 24 or higher on the Mini Mental State Scale.

The patients with the following conditions were excluded from the study: patients with diastolic heart failure or had moderate and severe lung diseases (COPD, etc.), patients with Class IV according to NYHA classification, geriatrics with a score of 23 or less on the Mini Mental State Scale, patients who did not understand the assessment test protocol or did not wish to participate in the study.

# 2.3. Study Procedures

Sociodemographic data included age, weight, height, gender, and educational level. Heart Failure risk factors data included medical history, obesity, alcohol consumption, smoking, comorbidities, ejection fraction. The following parameters were assessed as outcome measurements: Medical Research Council Dyspnea Scale for dyspnea, Minnesota Heart Failure Life Questionnaire for quality of life, Fatigue Severity Scale for fatigue. In addition, Mini-Mental State Examination (MMSE) was used to assess for any cognitive mental status in patients (11). All patients were classified by New York Heart Association (NYHA) functional classification (12). All measurements for outcome parameters were performed by the same researcher.

## **Outcome Measures**:

## Dyspnea:

Dyspnea was measured using Medical Research Council Dyspnea Scale (MmRC). The MmRC dyspnea scale is based on various physical activities that cause shortness of breath. It is a 0-4 point scale in which one of the 5 statements that best describes the dyspnea levels of the patients is selected. Higher score in MmRC represents the more severe perceived levels of dyspnea. While "0 points" is defined as no dyspnea, "4 points" is defined as very severe dyspnea during basic activities of daily life (13).

## Quality of Life:

The disease-specific health-related quality of life was evaluated using The Minnesota Living with Heart Failure Questionnaire (MLHFQ). The MLHFQ scale represents a self-administered, 21-item, 6-point Likert scored, patientbased and disease-specific questionnaire for patients with heart failure.

According to this scale, total score could range from 0 to 105 points, with lower scores for total score, physical and emotional domains present better health-related quality of life. (14).

## Fatigue:

Fatigue level was determined by using Fatigue Severity Scale (FSS). This scale can be given as one of the best example of the unidimensional scales in the field. The scale, which was introduced in 1989 by Krupp, is a nineitem self-administered questionnaire that asks the patients to rate each statement according to their level of agreement. (15). Each item can range between 0 (strongly disagree) and 7 (strongly agree).

## 2.4. Statistical Analyses:

All statistical analyses were performed using IBM SPSS version 11.5 software (IBM Corporation, USA), with a p value of <0.05 considered statistically significant. All numerical data were expressed as mean  $\pm$  standard deviation. Data were summarized using tables, frequency, percentage, mean, standard deviation, maximum and minimum value.

Shapiro-Wilk Test were used to analyze the normality. Non-parametric tests were used in the study because of sample numbers and abnormal distribution. In order to examine associations between quantitative variables including dyspnea, quality of life, and fatigue, Spearmen's correlation coefficient (r), non-parametric test, was used. There were five different subgroups to examine the strength of relationship between variables according to Guilford's criteria (14). They were very high (r: 0.81–1.00), high (r: 0.61–0.80), moderate (r: 0.41–0.60), low (r: 0.21–0.40), and very low (r: 0.00–0.20).

In addition, Mann-Whitney U test was used to compare the study variables in both two different groups (patients with and without a pacemaker).

# 3. Results:

# 3.1. Descriptive Statistics:

This controlled clinical trial enrolled 20 patients of both genders aged between 39 and 73 years in Çorum-Hitit University Erol Olçok Training and Research Hospital, Cardiac Rehabilitation Unit. Although 23 patients were screened, a total of 20 patients diagnosed with heart failure participated in the study due to the inclusion criteria. The patients were almost male (n=19; 95.0%). 10 out of 20 patients had a pacemaker. Of the patients with pacemakers, 8 were implantable cardioverter defibrillators (ICD), while 2 were patients with cardiac resynchronization therapy (CRT). The flow chart of the study protocol and exclusion diagram for the participants are presented at Figure 1.



Table 1. Demographic characteristics of both groups				
Group I (With Pacemaker) Mean±SD	Group II (Without Pacemaker) Mean±SD	p-value		
61.90±8.49	59.30±10.68	0.554		
167.90±4.90	167.50±5.33	0.863		
83.59±12.98	80.33±11.42	0.559		
29.73±4.73	28.70±4.02	0.609		
0 / 10	1 / 9	-		
	Group I (With Pacemaker) Mean±SD 61.90±8.49 167.90±4.90 83.59±12.98 29.73±4.73	Group I (With Pacemaker) Mean±SD Group II (Without Pacemaker) Mean±SD   61.90±8.49 59.30±10.68   167.90±4.90 167.50±5.33   83.59±12.98 80.33±11.42   29.73±4.73 28.70±4.02		

SD: Standard Deviation, BMI: Body Mass Index, F: Female, M: Male

Table 2. Clinical characteristics and comorbidities of patients in both groups				
		Group I (With Pacemaker) Mean±SD	Group II (Without Pacemaker) Mean±SD	
Education Level	Primary School	4	7	
	High School	5	2	
	University	1	1	
Creation	Yes	2	1	
Smoking	No	8	9	
Alcohol	Yes	3	2	
	No	7	8	
Psychological Issue	Yes	6	7	
	No	4	3	
Mini Mental	-	27.00±1.56	27.40±1.95	
Pacemaker Type	ICD (n - %)	8 (80%)	_	
	CRT (n - %)	2 (20%)		
Ejection Fraction (LVEF %)	-	31.00±8.09	36.00±3.16	
	Class 2	6 (60%)	9 (90%)	
NYHA	Class 3	4 (40%)	1 (10%)	
SD: Standard Deviation, NYHA: New	v York Health Association			

Demographic and clinical characteristics are shown in Table 1 and Table 2, respectively. The mean age of the patients with and without pacemaker was  $61.90\pm8.49$ ,  $59.30\pm10.68$ , respectively. The mean of Ejection

fraction of patients with and without pacemaker was  $31.00\pm8.09$  and  $36.00\pm3.16$ , respectively. While 6 of the patients with pacemaker were Class 2 according to the NYHA, 9 of the patients without pacemaker were Class 2.
# 3.2. Examining the Relationship Between Clinical Evaluation *Parameters:*

Table 3 presents values of dyspnea, quality of life and fatigue for all patients with heart failure. There was statistically correlation between dyspnea and fatigue (r=0.479, p=0.033) in all patients participated in the study.

No significant correlation was found between dyspnea and quality of life (r=0.422, p=0.064) in all patients participated in the study. In addition, it was found that fatigue was not correlated to quality of life (r=0.262, p=0.265) for 20 patients with heart failure in the study, as well (Table 3).

3.3. Examining the Difference of Clinical Evaluation Parameters Between Patients with and without Pacemaker:

There was no significant difference in terms of dyspnea, quality of life and fatigue levels in heart failure patients with and without pacemaker (p>0.05) (Table 4).

		Quality of Life (Minnesota)	Fatigue (FSS)
Dyspnea (MmRC)	r	0.422	0.479
	р	0.064	0.033*
	n	20	20
	r	0.262	
Fatigue (FSS)	р	0.265	-
	n	20	

\*p<0.05

Table 4. The differences between both groups in terms of dyspnea, quality of life and fatigue									
	Group I (With Pacemaker) Mean±SD	Group II (Without Pacemaker) Mean±SD	Z	p-value					
Dyspnea (MmRC)	1.60±1.17	1.80±1.39	-0.312	0.755					
Quality of Life (Minnesota)	38.10±21.99	39.90±18.26	-0.303	0.762					
Fatigue (FSS)	3.34±1.49	3.78±1.11	-0.871	0.384					
Abbreviations: <u>MmRC</u> : Mea	lical Research Council Dyspnea	Scale; <u>FSS</u> : Fatigue Severity Scal	e;						

Minnesota: The Minnesota Living with Heart Failure Questionnaire

\*Mann Whitney U Test

\*p<0.05

# 4. Discussion:

Dyspnea, quality of life, fatigue are among the most common clinical findings in patients with heart failure. However, there are a limited number of studies investigating the relationship between these parameters. No study has been encountered in the literature, which examines patient-specific parameters and compares the differences according to the use of pacemakers in patients with a diagnosis of heart failure. To our knowledge, this is the first study to compare key clinical findings such as dyspnea, quality of life, and fatigue in patients with heart failure with and without a pacemaker. In addition to this purpose, we also investigated whether the level of dyspnea is associated with quality of life and fatigue levels in patients with heart failure.

There is an increase in chronic diseases with the aging population and the change in lifestyle in the world. Among these chronic diseases, cardiovascular diseases play a serious role (16). Nowadays, life expectancy can be prolonged by preventing deaths due to myocardial infarction, cardiovascular disease, heart valve diseases, hypertension and diabetes with advanced and modern treatment methods. However, with the aging of populations, there is a significant increase in the rate of heart failure. Nearly half of heart failure patients consist of individuals over the age of sixty (17). A total of 20 patients with a mean age of 60.60±9.48 years participated in our study. Of the patients, 19 (95%) were male and 1 (5%) was female. Lam et al. (2018) and Sciomer et al. (2020) examined in terms of gender, it was found that preserved ejection fraction as a type of heart failure was more common in female patients, and heart failure type with low ejection fraction was more common in male patients (18, 19). Consistent with the literature, the rate of female patients with heart failure was also less in our study, and the gender distribution of heart failure patients with low ejection fraction included in our study was predominantly male.

In our study, there were 15 people (75%) who were class II and 5 people (25%) who were class III according to the New York Heart Association classification (NYHA), and the mean EF of these 20 patients was 33.50±6.50%. It is stated that two parameters frequently used in patients with heart failure according to the criteria for inclusion in clinical trials in the literature are NYHA classification and left ventricular ejection fraction (20). NYHA Class II and III heart failure patients were included in our study, which is

similar to the literature. In addition, when the samples of the studies were examined, it was seen that the number of Class I heart failure patients included in the study and the number of studies that included Class I patients were relatively low (21-23). This showed us that the clinical incidence of Class I patients is low due to the absence/less complaints of fatigue and dyspnea during daily activities compared to other groups. The clinical incidence of Class I heart failure patients is therefore low, as failure patients generally seek treatment as a result of shortness of breath and fatigue during exertion.

One of the main findings of our study is that the level of dyspnea is associated with fatigue in patients with heart failure. Fatigue is one of the main symptoms of heart failure (23). In a study, 59% of patients with heart failure reported moderate to severe fatigue (24). One of the main clinical features of heart failure is limited exercise tolerance. Patients with heart failure often experience dyspnea and fatigue at relatively low workloads and reduced physical work capacity (25). Like dyspnea, fatigue reduces daily performance and quality of life by limiting self-care in heart failure patients (26). Ramasamy et al. showed that there is a positive and moderate relationship between dyspnea and fatigue levels in heart failure patients (27). In the literature, no other study examining the relationship between the level of dyspnea and fatigue in heart failure patients has been encountered. Parallel to the results of our study, there are studies conducted in other disease groups showing that dyspnea and fatigue levels affect each other. One of these, in the study of Tütün-Yümin et al. in coronary artery patients, it was found that dyspnea and fatigue levels were correlated with each other (28). In the light of this information, the positive and moderate relationship between dyspnea and fatigue levels in patients with heart failure in our study is an expected result and is consistent with limited studies in the literature.

In patients with systolic heart failure, the ejection fraction of the heart is reduced. The main problems seen in clinically stable patients with heart failure are decreased exercise tolerance and worsened quality of life (3). Depending on the decrease in exercise tolerance, the effects of physical inactivity and sedentary life may be observed. In addition, inspiratory muscle strength and endurance are decreased in heart failure patients, and as this weakness increases, patients also experience dyspnea. As respiratory muscle weakness progresses, this symptom begins to be seen even at rest in daily life (29). In a study conducted with heart failure patients, the incidence of severe dyspnea was reported as 69% (24). Dyspnea is a distinctive symptom of chronic heart failure and significantly impairs functional capacity and guality of life, regardless of the severity of the disease (30). As far as we know, there is no study in the literature examining the relationship between quality of life and dyspnea in patients with heart failure, whereas a study by Borges et al found a negative correlation between guality of life and functional classification in patients with pacemaker (7). On the other hand, in our study, no correlation was found between dyspnea level and guality of life in patients with heart failure. We consider this finding as an unexpected result compared to the literature. We attribute this to the less number of patients included in our study as the main reason for this findings. Because the correlation value between dyspnea level and guality of life is 0.064 and is very close to the level of significance.

Another important finding of our study is that the use of a pacemaker in patients with heart failure did not statistically affect the level of dyspnea, guality of life and fatigue levels. We attribute the fact that dyspnea, quality of life and fatigue parameters do not differ in heart failure patients with and without pacemakers, due to the functional classification of heart failure, the small number of samples and the variability of the duration of using pacemakers. Because, it has been revealed that functional classification in addition to age affects the level of quality of life and that functional classification scales are one of the important assessment tools in patients with pacemaker (7). In a study by Barros et al. examining the quality of life of patients after pacemaker implantation, it was shown that men had a better guality of life than women. In the same study, it was emphasized that age, gender, and duration of pacemaker implantation affect guality of life (8). In our study, patients with and without a pacemaker showed a similar distribution in terms of age and gender. However, in terms of functional classification, 40% of patients with pacemakers were in Class 3, while only 10% of patients without a pacemaker were in Class 3.

In our study, although there was no statistically significant difference between patients with and without a pacemaker in terms of basic clinical findings, it was observed that patients with pacemakers had relatively kinesiophobia and were more cautious while performing certain movements in terms of clinical observation. For this reason, it was thought that partial attention should be paid in determining the rehabilitation program in heart failure patients with pacemakers compared to those without pacemakers.

#### 4.1. Limitations:

Our study has several limitations. The main limitation of our study is the small sample size. The main reason for this is that the case inclusion process of our study coincided with the peak period of the pandemic and the highest risk of transmission. Another important limitation is that the sample is not a homogeneous group in terms of time and type of pacemaker implantation, gender, and distribution of functional classification.

The strengths of our study are that, as far as we know, it is the first study to compare the basic clinical findings of individuals with and without a pacemaker in heart failure patients, and that it sets an example for future studies. It is also important that patients with heart failure have an equal distribution in terms of age, gender and BMI in both groups. In addition, we used disease-specific questionnaires, such as the Minnesota Living with Heart Failure Questionnaire, whenever possible, to monitor patients' clinical conditions such as dyspnea, fatigue, and quality of life.

# 5. Conclusion:

According to the results of our study, it was found that using a pacemaker in heart failure patients had no effect on dyspnea, quality of life and fatigue levels. In addition, it was found that the level of dyspnea in heart failure patients was associated with the level of fatigue, but not with the level of quality of life.

# **Declarations:**

#### Sources of Support

The authors received no institutional and financial support for the research and/or authorship of this article.

#### **Conflict of Interest**

Authors declare that there is no conflict of interest.

#### Author Contributions

All authors have read and approved the paper, they have met the criteria for authorship.

#### Acknowledgement

All authors thank all the patients who participated in the study. This study was presented as an oral presentation in "8<sup>th</sup> National Physiotherapy and Rehabilitation Congress" in 2021. In addition, this study is a preliminary research of a PhD Thesis conducted in Bahçeşehir University.

#### Ethics approval

All the procedures performed in the studies involving human participants were in accordance with the ethical standards of the Clinical Research Ethics Committee of the Faculty of Medicine, Hitit University. All subjects were informed about the study prior to their participation and written informed consent was obtained from each subject.

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Geriatrics and Gerontology/ Geriatri ve Gerontoloji

# Examining The Attitudes Towards the Elderly of Home Care And Patient Transport Service Personnel Within A Local Government

Tuğba Arslan<sup>1</sup>, Fatma Özalp<sup>2</sup>

#### ABSTRACT

**Purpose:** Older people have the right to be cared for in society with respect and dignity. Positive/negative attitudes towards the elderly may affect the quality of care and service. In this study, it was aimed to determine the attitudes of the personnel in charge of home care services and patient transportation services towards the elderly, which are increasing in Turkey today.

**Methods:** The descriptive cross-sectional study included 66 personnel (health and support staff). Participants were administered a data collection tool consisting of a general information form and the KOGAN Attitudes Towards the Elderly Scale.

**Results:** The participants had been working in this position for  $30.53\pm13.94$  months, 45.5% of them were female, 77.2% of them had at least a high school diploma, and the average number of elderly they communicated with in a day was  $9.61\pm4.77$ . It was found that the total score of the KOGAN elderly attitude scale of the patient transportation service personnel was significantly higher than the home care services group (p<0.05). It was determined that educational and occupational status, age, working time, the number of elderly people with whom they had contact in their private and professional lives did not affect their attitudes towards the elderly (p>0.05).

**Conclusion:** The attitudes of home care and patient transport personnel towards the elderly were at a moderate level. This attitude may be related the elderly group served are long-term care patients and bedridden, regardless of personnel characteristics.

Keywords: home care services, patient transfer services, age attitude, ageism

#### ÖZET

Amaç: Yaşlılar toplum içerisinde saygın ve insan onuruna yakışır bir şekilde bakılma hakkına sahiptir. Yaşlıya yönelik olumlu/olumsuz tutum bakım ve hizmet kalitesini etkileyebilir. Çalışmada, Türkiye'de günümüzde giderek artan evde bakım hizmetleri ve hasta nakil hizmetlerinde görevli personelin yaşlılara yönelik tutumunun belirlenmesi amaçlanmıştır.

Yöntem: Tanımlayıcı kesitsel tipteki araştırmaya 66 personel (sağlık ve destek personeli) dahil edilmiştir. Katılımcılara genel bilgi formu ve KOGAN Yaşlılara Yönelik Tutum Ölçeği'nden oluşan veri toplama aracı uygulanmıştır.

**Bulgular:** Katılımcıların 30,53±13,94 aylık süredir bu görevde çalıştığı, %45,5'inin kadın, %77,2'sinin en az lise mezunu olduğu ve iş hayatında bir günde iletişim halinde olduğu yaşlı sayısı ortalamasının 9,61±4,77 olduğu görülmüştür. Hasta nakil hizmeti personelinin KOGAN yaşlı tutum ölçeği toplam puanının evde bakım hizmetleri grubuna göre anlamlı olarak daha yüksek olduğu bulunmuştur (p<0,05). Eğitim ve meslek durumu, yaş, çalışma süresi, özel hayatında ve iş hayatında ilişki kurduğu yaşlı sayısının yaşlılara yönelik tutumlarını etkilemediği belirlenmiştir (p>0,05).

**Sonuç:** Evde bakım ve hasta nakil personelinin yaşlılara yönelik tutumlarının orta düzeydeydi. Bu tutumun personel özelliklerinden bağımsız olarak hizmet verilen yaşlı grubunun uzun dönem bakım hastası ve yatağa bağımlı olması ile ilişkili olabilir.

Anahtar Kelimeler: evde bakım hizmetleri, hasta nakil hizmetleri, yaşlı tutum, yaş ayrımcılığı

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Received: 15.10.2024 Accepted: 08.01.2025

he global population of individuals aged 65 and above is growing at a faster rate than previously observed (1). In Turkey, the population aged 65 and above increased by 22.6%, reaching a total of 8,451,669 individuals (2). Advanced age is a process that is frequently accompanied by an increase in the incidence of chronic diseases, as well as musculoskeletal and neuromuscular system decline and disability loss (3). The most prevalent issue that arises during this phase is the necessity for the elderly to receive healthcare and care. The elderly may require a multifaceted and comprehensive support and care system. These needs are frequently met by the families and close social networks of the elderly. Nevertheless, long-term and regular assistance can be furnished by health and social service organisations. Hospital care, institutional care and home care are planned in accordance with the needs of the elderly (4). The elderly are entitled to reside and receive care in a manner that is respectable and dignified within society. Attitudes towards the elderly that are either positive or negative may affect the quality of care and service.

The term "home care service" is used to describe the provision of medical and social care for individuals in their own homes. In Turkey, the term "home care" is defined in the "Regulation on the Provision of Home Care Services" of the Ministry of Health, dated 10 March 2005 and numbered 25751. This document outlines the regulations pertaining to the provision of home care services in the country. The provision of health and care services, in addition to follow-up services, to patients in their own homes, in conjunction with their families, in accordance with the recommendations of physicians, by the healthcare team, with the objective of meeting their medical needs, including rehabilitation, physiotherapy and psychological treatment (5). In light of cost analyses and the preferences of those requiring care, the home care model has been identified as a viable option. The literature indicates that home care offers a range of benefits for patients, families and society. These include improvements in quality of life, functional independence, personalised planning, a reduction in the need for hospital or institutional care, continuity of care and a reduction in the risk of infection (6). Home care is comprised of two sub-units: healthcare and supportive care. It is provided by a team of health professionals and auxiliary personnel (7). The care of the elderly is frequently regarded as a 'Cinderella' service, with a lack of perceived attractiveness as a career option in healthcare. However, as the global population continues to age, the importance of this group's care is set to increase (8). In the context of patient transport services, individuals who are bedridden, sick, disabled or elderly are provided

with hospital-to-home, home-to-hospital and home-to-home transport services.

The home care team typically operates in close proximity to the older individual and their family, providing personal care and practical and emotional support. The provision of home care services represents a relatively novel field of practice. This introduces novel risks and the issue of supervision. It is imperative that home care services are provided with a comprehensive training programme and robust control mechanisms. Consequently, they are challenging organisations to manage. In light of the aforementioned difficulties pertaining to the care of the elderly and the provision of home care, it is plausible to hypothesise that the attitudes of the staff may potentially lead to instances of neglect and abuse of the elderly. In light of the potential for positive change in the attitudes of the elderly through educational initiatives, it is crucial to ascertain their attitudes in advance (10).

A substantial body of literature exists examining the attitudes of health professionals towards the elderly (11). A variety of professional groups have been the subject of analysis, including nurses, dentists (12), physiotherapists, dietitians, neurologists (13), physicians (14), psychologists, primary health care providers (15) and students engaged in studies within health-related departments or other academic disciplines (16). The attitudes of doctors and nurses have been widely reported; however, the data of other healthcare professionals have been reported in a limited number of studies, despite the necessity for such information (11). Only one study has analysed home care workers, and this study only included home support personnel (17).

The objective of this research is to examine the attitudes of personnel employed in home care and patient transport services towards older individuals within a local administrative context.

# **Materials and Methods**

#### **Research design**

The research is of the descriptive, cross-sectional variety. In 2022, the study was conducted on employees of home care and patient transport services within the Muğla Metropolitan Municipality, specifically those working for the Health and Social Services Department and the Health Services Branch Directorate. The attitudes of the participants towards the elderly were subjected to analysis and subsequent reporting.

#### **Participants**

The population under investigation is constituted by the employees of home care and patient transport services operated by a local administration (N=78). In order to calculate the sample size for the study, single group proportional data was used. In accordance with the 22% positive elderly attitude rate reported in the aforementioned study, the requisite sample size was calculated to be 60 individuals (18). The data collection process was based on the principle of voluntary participation, in accordance with ethical standards. All individuals who volunteered to participate in the study were included in the sample (n=66).

#### **Data Collecting Tools**

A form was employed to elicit the general information of the participants, including their age, gender, educational status, occupation, the unit in which they work, the duration of their employment in the relevant unit, the number of elderly individuals with whom they interact during their professional activities, and the number of individuals with whom they interact in their private lives. In order to ascertain the attitudes of the participants towards the elderly, the Turkish version of the Kogan Attitude Towards the Elderly Scale was employed. The scale is a six-point Likert-type scale comprising social content devoid of medical terminology (19). The Turkish validity and reliability study of the scale was conducted by more than one researcher and it was determined that it could be used to evaluate attitudes towards the elderly (20-22). In this study, the culturally adapted version of the scale was employed. The total score that can be obtained from the scale ranges from 26 to 156 points. A higher score indicates a more positive attitude, while a lower score indicates a more negative attitude (21).

#### **Statistical analyses**

The IBM SPSS 21.00 software was employed for the purpose of data analysis. Categorical variables were presented as numbers and percentages, while numerical variables were expressed as means and standard deviations. The suitability of the data set for normal distribution was determined by means of a Shapiro-Wilk test. As the data set did not fit the normal distribution, the Mann-Whitney U and Kruskal-Wallis tests were employed as nonparametric tests. Additionally, a Spearman correlation test was conducted to ascertain the relationship between the duration of education, age, working time, the number of elderly individuals encountered in private and business life, and the attitude towards the elderly. The significance level was set at 0.05.

## **Results**

The personnel included in the study exhibited a range of ages between 28 and 46. The number of elderly individuals with whom the respondents had private interactions ranged from zero to five, while the number of elderly individuals with whom they had business interactions ranged from one to twenty. The minimum period of employment in the relevant unit was established to be six months, with the maximum period being 86 months. The participants exhibited a range of educational backgrounds, from primary school to doctoral qualifications. A total of 11 distinct occupational profiles were identified. The personnel included four health officers, 21 nurses, four paramedics, two elderly care technicians, four emergency medical technicians, one physician, one dietician, one psychologist, 16 drivers, six clerical staff, and six general care staff. The demographic information of the participants is presented in Table 1 for the reader's convenience.

Table 1: General information of the participants						
		⊼±SD				
Age (year)	32.47±7.73					
Number of older people in cont life	act with in private	2.59±1.16				
Number of older people he/she a day in business life	9.61±4.77					
Working period (month)	30.53±13.94					
	n (%)					
Gender	Male	36 (%54.5)				
Gender	Female	30 (%45.5)				
	Primary education	15 (%22.7)				
Education	High School	29 (%43.9)				
Education	Licence	18 (%27.2)				
	Postgraduate	4 (%0.6)				
Denertment	Home Care	45 (%68.2)				
Department	Patient Transport	21 (%31.8)				
O an unational arrays	Healthcare staff	38 (%57.6)				
Occupational group	Support staff	28 (%42.4)				

Table 2: Participants' attitudes towards older people										
		KOGAN positive score		KOGAN negative score		KOGAN total score				
		Pearson r	р	Pearson r	р	Pearson r	р			
Age		-0.02	0.86 <sup>1</sup>	-0.19	0.14 <sup>1</sup>	-0.09	0.49 <sup>1</sup>			
Number of older peop private life	ble in contact with in	-0.03	0.83 <sup>1</sup>	0.19	0.39 <sup>1</sup>	0.01	0.91 <sup>1</sup>			
Number of older peop with in a day in busine	ole he/she is in contact ess life	-0.07	0.56 <sup>1</sup>	-0.09	0.45 <sup>1</sup>	-0.01	0.91 <sup>1</sup>			
Working period (month)		-0.02	0.89 <sup>1</sup>	-0.16	0.21 <sup>1</sup>	-0.13	0.31 <sup>1</sup>			
		x±SS	р	- x±SS	р	⊼±SS	р			
	Female	54.37±6.68	0.02 <sup>2</sup>	46.40±9.98	0.16	103.03±18.74	0.74 <sup>2</sup>			
Gender	Male	50.33±8.50		49.94±7.82		100.28±13.18	0.74-			
	Primary education	51.20±9.61		45.33±10.04		101.07±21.60	- 0.49 <sup>3</sup>			
Education	High School	51.72±8.45	0.90 <sup>3</sup>	50.24±8.73	0.22 <sup>3</sup>	101.97±15.23				
Education	Licence	52.72±5.89	0.90*	47.28±7.96	0.22	100.00±12.01				
	Postgraduate	56.50±5.97		50.50±10.47		107.00±15.77				
Demonstration	Home Care	51.09±8.42	0.18 <sup>2</sup>	46.64±9.73	0.05 <sup>2</sup>	99.24±17.31	0.022			
Department	Patient Transport	54.48±6.34	0.18-	51.95±5.74	0.05-	106.43±11.07	0.02 <sup>2</sup>			
Occupational group	Healthcare staff	53.84±4.84	0.152	50.21±7.33	0.132	104.05±10.18	0.052			
Occupational group	Support staff	49.89±10.49	0.15 <sup>2</sup>	45.79±10.42	0.13 <sup>2</sup>	98.11±21.07	0.05 <sup>2</sup>			

The Kogan positive attitude scores, which reflect the attitudes of the participants towards older people, were found to be 52.17  $\pm$  7.93. The Kogan negative attitude scores were  $48.33 \pm 8.97$ , while the Kogan total scores were 101.53 ± 15.88. The analysis of the general information of the participants revealed that age, the number of older individuals with whom they interact, and the duration of their employment in the relevant unit were not correlated with the scores on the Attitudes towards the Elderly Scale. Furthermore, the participants were classified according to gender, educational background, occupational group, and work unit, and the scores on the elderly attitude scale were evaluated. The statistical calculation revealed that the participants' KOGAN positive scores were significantly higher for women than for men. A significant difference was observed in the total scores of the participants' attitude scale towards the elderly between the patient transport group and the home care group (Table 2, p <0.05). Furthermore, the frequencies of the scores obtained for each question were analysed. In question 25 of the Kogan attitudes towards the elderly scale, which pertains to the assertion that "older people want more love than other people," 40% of the home care staff received one point, while 34.2% received two points. Similarly, 41.2% of the participants obtained a score of one point, while 29.4% obtained a score of two points in the same question.

# Discussion

This study, which investigated the attitudes of home care and patient transport workers towards older people within a local authority, analysed data from 66 participants aged 20-45. It was found that the participants, who were from different educational and professional backgrounds but who had come together for the same purpose, had contact with an average of 10 older people per day. This is considerably higher than the number of older people they come into contact with in their private lives. The participants' attitudes towards older people were found to be at a medium level. It was found that education, occupational status, age, working hours, the number of elderly people they had contact with in their private and professional life did not influence their attitude towards the older people. However, it was found that women had better attitudes towards older people than men, and patient transport workers had better attitudes towards older people than home care workers.

The participants' attitudes towards the elderly were found to be at a moderate level (KOGAN total  $101.53\pm15.88$ ). The fact that the attitudes towards the elderly in our study were at a moderate level was thought to be related to the continuity of the service with the fact that the elderly group

served were long-term care patients and bed dependent, regardless of the socio-demographic characteristics of the staff. There are many studies in the literature that examine the attitudes of health professionals towards older people. Different professional groups such as nurses, dentists, neurologists have been studied. In the studies examining the attitudes of health professionals towards older people, negative attitudes towards older people were reported in one study and mostly positive attitudes in another (13,15,24,25,26,28). In addition, home care workers were reported to have generally positive attitudes towards caring for dying people living at home (18). These results, which differ from our findings, may be due to the fact that a different multidisciplinary team was analysed in this study. In addition, most of the reported studies included a sample of women. In this study, the number of men and women was similar.

It was found that the age of the participants, the number of older people they had a relationship with in their private and professional lives, and the length of time they had been employed were not related to their attitudes towards older people. In fact, the study was designed with the expectation that these data might influence attitudes, but it was felt that the effect could not be sufficiently determined because it was carried out on a small sample. Studies have shown that attitudes towards older people change with age (13,14,17). History of living with older adult relatives (13) and weekly social contact with healthy older people (14) are associated with attitudes towards older people. However, length of experience in the workplace may or may not influence attitudes towards older people (15,17,25). The reason why the results of studies conducted in different countries do not show similar results for a subjective data such as attitudes may be explained by different cultural codes. In the home care study, the sample had been working for an average of 16 years (17). Given that the average experience of home care in this study was 30 months, it is not surprising that no positive effect of this short experience was found. In the study by Craftman et al. the participants were aged between 18 and 69 years (17). The age of the home care workers included in this study ranged from 28 to 46 years.

This study found that the attitudes of participants grouped according to their educational and professional status towards older people were similar. One study reported that nurses, occupational therapists and personal counsellors had more positive attitudes than home care workers (27). Similar to this study, it was reported that education did not influence attitudes towards older people (14,25). In a study examining students from different faculties, it was found that attitudes towards older people varied according to the faculty (28). This study included a sample with different levels of education and different professions, but gathered for the same purpose. This may be the reason for the different findings in the few studies in the literature.

Women were found to have better attitudes towards older people than men in this study. Several studies support this finding (14,29). The only study that looked at home care workers found that gender did not affect attitudes towards older people. However, there were only four male and 118 female participants in this study. In this study, the number of male and female participants was approximately equal (17).

In this study, it was found that patient transport workers had better attitudes towards older people than home care workers. Both groups included both health and nonhealth professionals. We believe that this finding is related to the fact that patient transport staff spend less time with the elderly and do not provide direct care. Indeed, in one study, frequent interaction with older patients was also associated with negative general attitudes towards older people (30). Home care workers reported generally positive attitudes towards caring for dying people living at home (17). The results of this first study to analyse patient transport and home care staff together are important.

The study is subject to several limitations. The study was conducted with a small number of participants working in a single centre. Consequently, the findings are not generalisable, and sub-analyses could not be conducted according to occupational groups. Although a reliable and valid scale was used as a data collection method, there is a possibility that participants may have concealed their negative attitudes and may not have answered the questions in a manner that reflected their own thoughts.

The findings of this study indicate that the attitudes of home care and patient transport unit employees, whose role in the provision of health care services is becoming increasingly prominent, towards the elderly are moderately positive. It is crucial to enhance the attitudes of this cohort, which interacts with an average of ten older individuals per day, towards the elderly and to mitigate ageism. Furthermore, it was established that employment in a home care unit and male gender were identified as factors that negatively influenced attitudes towards the elderly. It is evident that the findings of this research should be supported by a more comprehensive range of examples. Subsequently, the impact of elderly health training for staff on attitudes towards the ageing population and the influence of these attitudes on the quality of care should be investigated.

# Declarations

#### Fundings

There is no financial support or donation received for the research.

#### **Conflict of Interest**

The authors have no conflict of interest regarding this study.

#### **Ethics** Approval

Prior to undertaking the research, approval was sought and obtained from the Ethics Committee of Çankırı Karatekin University at a meeting held on 31 May 2021 and numbered 20. This approval was granted on the basis of the Committee's assessment of the ethical suitability of the research. Furthermore, permission was sought and obtained from Muğla Metropolitan Municipality, Department of Health and Social Services, where the research was conducted, on 22 November 2021. All participants were required to sign a voluntary informed consent form prior to their involvement in the research. The research was conducted in accordance with the principles set forth in the Declaration of Helsinki.

#### Availability of data and material

The data and material are available upon request.

#### Authors' contributions

TA and FÖ created the study idea. TA organized the study method, created evaluation forms, analyzed the data, and brought it to literature. FÖ, reached the individuals who participated, collected the data, entered into system, and brought it to literature. Both authors have read and approved the final version of the manuscript.

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Nursing / Hemşirelik

# Reasons for COVID-19 vaccine rejection: A qualitative study

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#### ABSTRACT

**Purpose:** The aim of this study was to investigate the reasons for refusal of those who refused to be vaccinated with any of the vaccines developed against COVID-19 (Coronavirus Disease) and to offer solutions.

**Methods:** In this descriptive and cross-sectional qualitative study, a semi-structured interview method was used as the data collection tool. Also, thematic analysis was chosen as the analysis method. The population of the study consisted of people who had not been vaccinated against COVID-19. The purposive sampling method was used as the sampling method. Informed consent was obtained from the participants.

**Results:** As a result of the study, six main themes and sub-themes related to the reasons for these refusals against vaccination were reached. These themes are Individual Effects of COVID- 19, Information, Confusion about Vaccination, Personal Fears of Vaccination, Belief in the Protectiveness and Reliability of the COVID-19 Vaccine, Pressure on Vaccination and Mask Use, and Preference for Vaccination Alternatives.

**Conclusion:** During pandemics, distrust and uncertainty are often among the reasons why people do not get vaccinated. Accordingly, it is necessary to carry out health services for vaccination and increasing social immunity more transparently, to ensure that the society has access to sufficient information about the vaccine, and to determine and implement appropriate policies to eliminate mistrust about the vaccine and the pandemic period.

Keywords: Vaccine refusal, COVID-19, pandemic, thematic analysis.

#### ÖZET

**Amaç:** Bu çalışmanın amacı, daha önce aşılanmamış ve çeşitli nedenlerle COVİD-19 hastalığına karşı geliştirilen aşılardan herhangi birini olmayan kişilerin görüşleri alınarak, aşı reddinin nedenlerini araştırmak ve çözüm önerileri sunmaktır.

Yöntem: Tanımlayıcı ve kesitsel olarak yapılan bu nitel çalışmada veri toplama aracı olarak yarı yapılandırılmış görüşme yöntemi; analiz yöntemi olarak tematik analiz kullanılmıştır. Araştırmanın evrenini COVİD-19 aşısı olmamış kişiler oluşturmuştur. Örnekleme yöntemi olarak amaçlı örnekleme yöntemi kullanılmıştır. Katılımcılardan bilgilendirilmiş onamları alınmıştır.

**Bulgular:** Çalışma sonucunda aşı reddinin nedenlerine ilişkin altı ana tema ve alt temaya ulaşıldı. Bu temalar COVID-19'un Bireysel Etkileri, Bilgi, Aşılama Hakkındaki Karışıklık, Aşılama Hakkındaki Kişisel Korkular, COVID-19 Aşısının Koruyuculuğuna ve Güvenilirliğine İnanç, Aşılama ve Maske Kullanımına Yönelik Baskı ve Aşı Alternatiflerine Yönelik Tercihtir.

**Sonuç:** Pandemi dönemlerinde insanların aşı yaptırmamasının nedenleri arasında güvensizlik ve belirsizlik sıklıkla yer alır. Buna göre aşılama ve toplumsal bağışıklığın artırılmasına yönelik sağlık hizmetlerinin daha şeffaf bir şekilde yürütülmesi, toplumun aşı hakkında yeterli bilgiye erişiminin sağlanması, aşıya ve pandemi dönemine yönelik güvensizliği ortadan kaldıracak uygun politikaların belirlenmesi ve uygulanması gerekmektedir.

Anahtar Kelimeler: Aşı reddi, COVİD-19, pandemi, tematik analiz.

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Received: 05.08.2024 Accepted: 03.12.2024 n 2019, the coronavirus outbreak in Wuhan, China, started to threaten the whole world globally (1). "Coronavirus disease is an infectious disease caused by the SARS-CoV-2 (Severe Acute Respiratory Syndrome-Coronavirus 2) virus"(2). As of March 2020, the COVID-19 (Coronavirus Disease) pandemic has turned into a process that urgently needs to be responded to for public health and has started to be closely monitored by the Ministry of Health (3).

Although non-pharmaceutical interventions such as wearing face masks, using hand sanitizers and observing social distancing rules are recommended in our country and other countries to protect against coronavirus disease, vaccination is considered to be the most reliable and effective method for a non-temporary solution (4). Vaccines play a role in creating an effective defense response to microorganisms that enter the body without causing disease (5). The number of people vaccinated with COVID-19 vaccines is almost one billion people in low-income countries and seventy percent of the population in high- income countries as of May 22, 2022 (2).

The Strategic Advisory Group on Immunization (SAGE), established in 1999 by the Director-General of the World Health Organization (WHO), expressed concern that the way forward to address vaccine hesitancy was not evident in 2012 due to declining vaccination rates worldwide, and established the Vaccine Hesitancy Working Group to assess and address the global challenge of vaccine hesitancy, which poses a significant threat to the integrity and acceptance of vaccines and immunization programs worldwide (6).

Despite scientific sources supporting that vaccines are safe and beneficial; vaccine rejection is still quite high (7). Antivaccine views are put forward by citing the side effects of vaccine (8). Vaccine hesitancy is a rapidly growing global threat that poses the risk of losing the gains achieved so far in the fight against vaccine-preventable diseases (9). As with all other vaccines, resistance has developed for various reasons to vaccines developed against COVID-19, which has a very huge area of effect in all countries.

This study aims to investigate the reasons for refusal of those who refused to be vaccinated with any of the vaccines developed against COVID-19 (Coronavirus Disease) and to offer solutions. In this way, evidence will be provided for policy implementations to prevent vaccine refusal. Training prepared for the community can be planned and tailored to the needs of individuals so that the process of reaching a solution can be completed quickly.

# **Material and Method**

In this descriptive and cross-sectional qualitative study, the semi-structured interview method was used as a data collection tool and thematic analysis was chosen as the analysis method. The ethical permission for the research was obtained The Health Sciences Ethics Committee of Ankara Yıldırım Beyazıt University approved the study on April 07, 2022, with the decision number 06 and research code 2022-764. The population of the study consists of people who have not been vaccinated against COVID-19. The purposive sampling method was used as the sample selection method. While selecting participants who have not been vaccinated against COVID-19 for this study, some criteria were taken into consideration such as, ease of access to participants, residence in the same city and the presence of common acquaintances. Interviews continued until data saturation was achieved and the interviews were completed with 12 people. First of all, the interviewees were selected from those who declared that they were not vaccinated against COVID-19. The interviewees were informed about the subject, and their consent was obtained. Before starting the interview, a voice recorder was used to ensure that what was said was included in the research in a complete form. The interview participants were identified by giving a pseudonym with their age and gender. Questions were asked under two headings: demographic questions and general questions about COVID-19. The audio recordings were converted into text format and the answers to the questions about demographic characteristics were analyzed using SPSS (IBM SPSS Statistics 22.0 (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY, IBM Corp.) and the characteristics such as median age, education level, occupational education level, etc. were grouped and tabulated as n-%. While analyzing this study, firstly the participants' voice recordings were transcribed verbatim in order to get to recognize the data. Giorgi's four-stage methodology, as cited by Dincer (2019), was used in the following methodology (10). The limitations of the study are that the participants did not have any previously produced COVID-19 vaccine. Demographic characteristics such as age, gender, and occupation were not differentiated when selecting the participants.

## Results

Among the participants, 58.33% (n=7) were female and 41.67% (n=5) were male with a median age of 29 years  $(min:25 - max:53; mean age = 32 \pm 9.63)$ . Among the participants, four were nurses (33.33%), two were teachers (16.67%), one was computer programmer (16.67%), and one was military personnel who had a bachelor's degree (66.67%; n=8). In addition, 41.67% (n=5) of the participants were single and 58.33% (n=7) were married 83.33% (n=10) of the participants did not have a chronic disease, and when asked whether they had been vaccinated before, 75% (n=9) of the participants stated that they had received childhood vaccinations, 8.33% (n=1) had received both childhood vaccinations and the 3-mixed vaccine when traveling abroad, 8.33% (n=1) had received childhood vaccinations and rabies vaccine in addition, and 8.33% (n=1) had received Tetanus vaccine because it was mandatory at work. It was observed that 66.67% (n=8) of the participants had no children, 8.33% (n=1) had one child and 25% (n=3) had two children (Table 1).

	Table 1 Demographic questions		
		n	%
Ago	25-35 years old	10	83,33
Age	36-55 years old	2	16.67
Gender	Female	7	58,33
Gender	Male	5	41,67
	Primary School Graduate	2	16,67
Education	High School Graduate	1	8,33
Status	Higher School Graduate	1	8,33
Statas	University Graduate	8	66,67
	Nurse	4	33,33
	Teacher	2	16,67
	Military Personnel	1	8,33
	Computer Programmer	1	8,33
	Retired	1	8,33
Profession	Tradesmen	1	8,33
	Housewife	1	8,33
	Sales Consultant	1	8,33
Marital Status	Single	5	41,67
Marital Status	Married	7	58,33
Whether there	No	10	83,33
is a Chronic Disease	Yes	2	16,67
	Childhood vaccinations	9	75,00
Previous Vacci-	Childhood vaccinations and the 3-valent mixed vaccine	1	8,33
nation Status	Childhood vaccinations and rabies	1	8,33
	Tetanus	1	8,33
	Chidless	8	66,67
Number of	1 Child	1	8,33
Children	2 Children	3	25,00

In order to protect the identities and private information of the participants, they were given a pseudonym using their participant number, gender and age (Table 2).

Table 2:	Table 2: Pseudonyms are given to participants according to age and gender						
No	Age	Gender	Person Nickname				
1	25	Male	E1, 25				
2	26	Female	K2, 26				
3	26	Female	K3, 26				
4	28	Male	E4, 28				
5	28	Female	K5, 28				
6	28	Female	K6, 28				
7	30	Female	K7, 30				
8	33	Male	E8, 33				
9	30	Female	K9, 30				
10	35	Male	E10, 35				
11	52	Female	K11, 52				
12	53	Male	E12, 53				

As a result of thematic analysis, the qualitative data were analyzed: Six main themes and their sub-themes are as follows:

A. COVID-19 individual effects

- Economic
- Loneliness
- Fear
- A negative process.

Some of the participants mentioned that COVID-19 caused the deterioration of economic conditions in countries. Also, they stated that some people lead an isolated life because they are afraid of contamination during the disease process, which leads to isolation. Moreover, they emphasized that they felt fear during the disease process due to uncertainty and information pollution about the disease. Participants who were psychologically and socially affected stated that this traumatizing effect negatively affected their opinions on the COVID-19 vaccine.

- B. Information confusion about vaccination
  - Lack of information about vaccination
  - Information pollution from social media, the internet, and the social environment.

Some of the participants said that they did not get vaccinated because they found the explanations of health services insufficient. The negative experiences of people who were vaccinated on social media, the internet and in their social circles influenced the opinions of the participants and affected them negatively about getting vaccinated.

C. Personal fears about being vaccinated.

• Observing negative experiences about risks and side effects.

As cause of infertility

As cause of heart attacks

- Fear of future unknown consequences of vaccination
- Disbelief in the disease, thinking it can be an artificial virus.
- Lack of trust

Participants stated that they did not want to be vaccinated against COVID-19 because the effect of the vaccine was not yet clear, and they did not know what the consequences would be for 5-10 years. Two participants indicated that they did not get vaccinated because they already had diseases and thought that it would be worse if they were vaccinated, while some of the participants remarked that they did not get vaccinated because they were told that there were side effects such as heart attack and infertility.

D. Belief in the protection and safety of the COVID-19 effects

• Short production time compared to other vaccines

• Deaths and illnesses despite vaccination

• Perceived low severity of illness.

Participants expressed their uncertainty about the COVID-19 vaccines administered in our country (Sinovac-BioNTech) because they are produced in a shorter time compared to all the vaccines they know. They stated that the fact that there were people who had a very bad disease and died despite being vaccinated pushed them to be immunized by being sick without vaccination.

E. Pressure to use vaccines and masks.

•Pressure from family, friends, and workplace

•Making vaccination mandatory for entry to shopping malls and public areas

In their answers to the questions, some of the participants stated that they did not take special precautions for COVID-19 and used masks because it was mandatory, on the other hand all other participants stated that they were attentive to isolation, hand hygiene, constantly used masks, carried hand sanitizer, kept their distance from people, did not visit and did not go to crowded places.

F. Preference for the use of vaccine alternatives

Participants preferred to use vaccine alternatives such as masks, distance, hygiene, and natural protection methods instead of vaccination. They stated that by doing so, they would protect themselves from the unknown side effects of the vaccine and protect themselves in a healthier process.

All main themes are directly related to each other and consist of main themes and sub-themes related to the themes and their relationship with each other (Figure 1). The demographic characteristics of the participants and the answers they gave when asked about the reasons for vaccine refusal are given below in Table 3 with the help of Leqizing-Mapping.



	Table 3 Demographic characteristics of participants and reasons for vaccine refusal									
Nickname	Gender	Age	Profession	Attitude towards vaccine	Being sick with COVID-19	COVID-19's Negative Impact of Consequences	Affected by information confusion about vaccination	Negative concerns about vaccine intake	Pressure to Vaccinate and Use Masks	Preference for Use of Vaccine Alternatives
E1, 25	Male	25	Tradesmen	0	0	$\checkmark$		$\checkmark$	$\checkmark$	$\checkmark$
K2, 26	Female	26	Teacher	0	٠	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
K3, 26	Female	26	Nurse	0	٠	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	
E4, 28	Male	28	İntensive care nurse	0	٠	$\checkmark$	$\checkmark$	$\checkmark$	√	√
K5, 28	Female	28	Nurse	0	٠		$\checkmark$	$\checkmark$	$\checkmark$	√
K6, 28	Female	28	Nurse	0	٠	$\checkmark$	$\checkmark$	$\checkmark$		
K7, 30	Female	30	Teacher	0	٠			$\checkmark$		
E8, 33	Male	33	Military personal	0	٠	$\checkmark$		$\checkmark$		√
K9, 30	Female	30	Sales Consultant	0	0	$\checkmark$		$\checkmark$		1
E10, 35	Male	35	Computer programmer	0		$\checkmark$		$\checkmark$		
K11, 52	Female	52	Housewife	0	0		$\checkmark$	$\checkmark$		
E12, 53	Female	53	Retired	0	0	$\checkmark$	$\checkmark$	$\checkmark$		

# Discussion

When the literature is examined, except for COVID-19 pandemic, reasons for rejection of vaccination are frequently encountered. Due to the deaths and other problems caused by COVID-19 disease, all countries have sought a solution. As in the pandemics that have occurred from the past to the present, vaccine development studies have started as soon as possible because the way to get rid of COVID-19 disease is vaccination. The vaccines developed were rejected by many people because they were developed in shorter periods of time rather than in sufficient time like the previous ones, and the lack of satisfactory information on how effective they are or what their side effects are, and this situation has emerged as an obstacle to social immunization (11).

Wu et al. investigated the symptoms of post-traumatic anxiety, stress and depression during the pandemic period and reported that the fear of being sick with the fear of uncertainty, desperation, despair and unhappiness felt like the same epidemic (12). In our study, the participants stated that they were very helpless and hopeless because they were afraid of the current and future consequences of the pandemic period. Due to this negative situation, participants developed resistance to vaccination.

In a study conducted in Mexico, Jones et al. found that individuals' risk perception and that their fear levels in the face of uncertainty have greatly increased, and their quality of life has decreased due to the frequent coverage of the COVID-19 outbreak in the news media (13). Similarly, in our study, participants who expressed their isolation due to the devastating effects of the epidemic expressed their concerns about how they return to normal life. This process negatively affected their quality of life due to the quite long duration of the pandemic period and their hesitation about the vaccine.

In the qualitative study conducted by Çapanoğlu with health care workers and families who refused vaccination, health care workers reported that they refused to be vaccinated because they thought that external powers wanted to harm our nation and country through vaccines, that vaccines have harmful side effects and that side effects are kept as a secret to pave the way for pharmaceutical companies to make profit, and that people in eastern provinces refused to be vaccinated because they believed it will result in infertility and low birth rates. Therefore, they refute to be vaccinated (14). In the results of our study, which is very similar to Çapanoğlu>s qualitative study, participants expressed similar reasons such as infertility, causing heart attack, getting affected negatively in the future, and the idea that the disease could be artificially produced is among the main reasons for not being vaccinated.

In the study conducted by Çıtak and Aksoy on vaccine refusal, when the reasons for vaccine refusal were examined, most people think that the vaccination includes most harmful chemical substance, the fear that vaccine producers may have malicious intentions, and the idea that natural immunization or preference for natural methods may be more effective in protecting against diseases (15). As in our study, participants tend to refuse vaccines in cases where they did not have trust. In cases of lack of trust in health services, people preferred to protect themselves with natural immunization without vaccination.

# Conclusion

To prevent contact-related contamination during the COVID-19 pandemic, optional psychological support should be provided at the point of returning to normal life for the society, which has become lonely due to social isolation, working life coming to a standstill and curfews imposed.

Online training should be organized to overcome the lack of information about vaccines used in our country, and it should be taken into consideration that everyone's educational needs can be different. Training should be easily accessible through official channels when they need them.

Since it is unpredictable how many years it would take humanity to achieve social immunity through natural means and the extent of the social damage it could cause, appropriate information should be provided to those who prefer natural means, emphasizing the importance of vaccination.

Scientific studies should be conducted on methods to increase social acceptance of vaccines to reduce vaccine refusal in the community and solutions should be proposed based on these studies. The use of mass media and social media in informing and raising awareness of the public about the results of scientific studies on vaccination and its effects will enable rapid progress in the fight against vaccine refusal. Healthcare personnel who carry out vaccination practices have great responsibilities in studies on vaccine refusal. Healthcare personnel should approach people who have concerns and doubts about vaccines and their beliefs in a respectful manner.

# **Declarations**

#### Acknowledgement:

This article is derived from A. Kahya's master thesis with the same title.

#### Funding

The authors declared that this study has received no financial *support*. Conflicts of interest/Competing interests

The authors have no conflicts of interest to declare.

#### Ethics approval

The Health Sciences Ethics Committee of Ankara Yıldırım Beyazıt University approved the study on April 07, 2022, with the decision number 06 and research code 2022-764.

#### Availability of Data and Material

Available.

#### Authors' contributions

Concept – A.G.K., M.D.;Design – A.G.K., M.D. Supervision – M.D.; Funding – A.G.K.; Materials – A.G.K., M.D.; Data Collection and/or Processing – A.G.K.; Analysis and/or Interpretation – A.G.K., M.D.; Literature Review – A.G.K., M.D.; Writer – A.G.K., M.D.; Critical Reviews – A.G.K., M.D.

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Nursing / Hemşirelik

# Nursing Students' Attitudes Toward Pain Assessment: A Critical Component in Pain Management- A Descriptive and Cross-Sectional Study

İpek Köse Tosunöz<sup>1</sup>, Sevgi Deniz Doğan<sup>2</sup>

#### ABSTRACT

Purpose: This study aimed to examine nursing students' attitudes toward pain assessment.

**Methods:** This descriptive cross-sectional study sample consisted of 184 nursing students (2nd, 3rd, and 4th grade) studying at a state university. Data were collected online between July and September 2023 using the "Participant Information Form" and "Nursing Students' Attitudes Scale Toward Pain Assessment" (NSASPA). Data was analyzed using the independent samples t-test, ANOVA, Pearson correlation, and linear regression analysis.

**Results:** Of the students, 71.7% were females, and 88% believed in the effectiveness of nurses in pain management. The mean score of the students' perceived pain assessment success in their clinical practice was  $6.86 \pm 1.71$  (min-max:1-10; on a scale from 0 to 10). The mean total score of NSASPA was  $63.65 \pm 7.23$ . The mean total score of the students who believed in the effectiveness of nurses in pain management and used pain assessment tools was statistically significantly higher (p<0.05). The students' attitudes toward pain assessment had a statistically significant effect on their perceived success in pain assessment, explaining 13.7% of the variance. The statement most frequently agreed with by students was "I would like to receive more pain assessment training."

**Conclusions:** Nursing students' attitudes toward pain assessment were positive. Students who believed in nurses' effectiveness in pain management and used pain assessment tools had more positive attitudes toward pain assessment. Students' positive attitudes toward pain assessment positively predicted their perceived success in pain assessment. Students most frequently agreed that they wanted more training in pain assessment.

Keywords: Attitude, nursing, students, pain, pain assessment.

#### ÖZET

**Amaç:** Bu çalışmanın amacı, hemşirelik öğrencilerinin ağrı değerlendirmesine yönelik tutumlarını belirlemektir. **Yöntemler:** Tanımlayıcı ve kesitsel tipteki çalışmanın evrenini bir devlet üniversitesinde öğrenim gören 184 hemşirelik öğrencisi (2., 3. ve 4. sınıf) oluşturmuştur. Veriler, Temmuz-Eylül 2023 tarihleri arasında "Katılımcı Bilgi Formu" ve "Hemşirelik Öğrencilerinin Ağrı Değerlendirmesine Yönelik Tutum Ölçeği (HÖADTÖ)" kullanılarak çevrimiçi olarak toplanmıştır. Veriler, bağımsız grup t-testi, ANOVA, Pearson korelasyon analizi ve doğrusal regresyon analizi kullanılarak analiz edilmiştir.

**Bulgular:** Öğrencilerin %71.7'si kadın olup %88'i hemşirelerin ağrı yönetiminde etkili olduğuna inanmaktaydı. Öğrencilerin klinik uygulamalarında ağrı değerlendirmesine yönelik algıladıkları başarı puan ortalamalarının 6.86±1.71 (min-maks: 1-10; 0 ile 10 arasında bir ölçekte) olduğu belirlenmiştir. Öğrencilerin HÖADTÖ toplam puan ortalaması 63.65±7.23'tür. Hemşirelerin ağrı yönetimindeki etkinliğine inanan ve ağrı değerlendirme araçlarını kullanan öğrencilerin ölçek toplam puan ortalamaları istatistiksel olarak anlamlı düzeyde daha yüksekti (p<0.05). Öğrencilerin ağrı değerlendirmesine yönelik tutumları, ağrı değerlendirmesindeki algılanan başarıları üzerinde istatistiksel olarak anlamlı bir etkiye sahipti ve değişimin %13.7'sini açıklamaktadır. Öğrencilerin en sık katıldığı ölçek ifadesi "Daha fazla ağrı değerlendirmesi eğitimi almak istiyorum (%74.5)" idi.

**Sonuçlar:** Hemş<sup>i</sup>relik öğrencilerinin ağrı değerlendirmesine yönelik tutumları olumluydu. Hemşirelerin ağrı yönetimindeki etkinliğine inanan ve ağrı değerlendirme araçlarını kullanan öğrenciler, ağrı değerlendirmesine yönelik daha olumlu tutuma sahipti. Öğrencilerin ağrı değerlendirmesine yönelik olumlu tutumları, ağrı değerlendirmesindeki algılanan başarılarını anlamlı düzeyde tahmin etti. Öğrencilerin çoğunluğu ağrı değerlendirmesi konusunda daha fazla eğitim istedikleri konusunda hemfikirdi.

Anahtar Kelimeler: Tutum, hemşirelik, öğrenciler, ağrı, ağrı değerlendirmesi.

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Received: 27.11.2024 Accepted: 25.02.2025 ain is a personal experience that is difficult to understand and describe (1). Pain is "an unpleasant sensory and emotional experience associated with or resembling actual or potential tissue damage" (2). Despite advances in healthcare, pain continues to be a major health problem. It is estimated that 30-70% of hospitalized patients experience pain. High pain prevalence is associated with increased mortality and morbidity, decreased quality of life, and increased healthcare costs (3). Uncontrolled and unrelieved pain may cause various physiological and psychological disorders in individuals. Therefore, pain should be prevented and controlled (4).

Effective pain management is a mandatory part of nursing care and is considered one of the most basic patient rights (4, 5). The first step in effective pain management is a valid and reliable pain assessment. It is emphasized that pain should be considered as the fifth vital sign, monitored, and assessed regularly (4). Individuals' intention to perform a behavior is determined by their attitudes toward the behavior, their subjective norms, and their perception of behavioral control. Therefore, it is accepted that our attitudes determine our behavior (6). Nurses' pain assessment depends on their attitudes toward pain and pain assessment (1,4,7). Nurses' negative attitudes toward pain and pain are a significant barrier to effective pain management (8).

Pain is one of the most frequently identified nursing diagnoses by nursing students (9). Nursing students are expected to play an active role in pain control. Therefore, nursing students' attitudes toward pain assessment, which may affect pain assessment, are of critical importance (4). Nursing students who have negative attitudes toward pain management and cannot evaluate pain accurately may not be able to contribute to pain management adequately (10). Assessment and management of pain are fundamental in nursing care, and nurses need to be equipped with adequate knowledge and positive attitudes toward pain assessment and management (11, 12). Nursing education should provide students with the knowledge and awareness to assess pain accurately when working as professional nurses (4). Pain management is included in the nursing curriculum as part of some courses or elective courses. However, studies have shown that nursing curricula lack the educational content to enable students to effectively manage their patients' pain (13). Students can be trained as nurses who can perform effective and accurate pain assessment not only by evaluating the knowledge provided through

education but also by evaluating their attitudes toward pain assessment in their clinical practice and developing positive attitudes (14). Nurse educators are responsible for ensuring that students are well-prepared for pain management. Nurse educators should assess students' knowledge and attitudes toward pain and create strategies to improve their readiness for pain management (15). It has been reported that although nursing students receive adequate pain assessment education and knowledge, they have difficulty in pain assessment because of their negative attitudes about pain and pain assessment (14). Nursing students' knowledge of pain management has not improved over the past 20 years despite curriculum renewal (16). In the literature, studies have mostly focused on nursing students' attitudes toward pain and pain management. Few studies have examined pain assessment. Effective pain assessment forms the basis of effective pain management, and studies on this subject, play a critical role in improving the guality of patient care. Therefore, more research is needed on this subject to increase the knowledge and skills of nursing students regarding pain assessment. This study was conducted to investigate nursing students' attitudes toward pain assessment.

# **Material and Method**

# Study Design and Setting

A descriptive cross-sectional study was conducted at the nursing department of a state university in the south of Turkey between July and September 2023.

# Sampling and Recruitment

The study population consisted of 2nd, 3rd, and 4th-grade undergraduate nursing students who continued their education in the 2022-2023 academic year (N=406). The distribution of the population by grade level is as follows: 2nd grade: 136 students, 3rd grade: 129 students, and 4th grade: 141 students. All students who met the inclusion criteria were included in the study. The inclusion criteria were as follows: having access to electronic and internet devices, having experience in providing patient care, and volunteering to participate in the study. The students included in the study all possessed experience in patient care. First-year students were not included in the sample because they could not participate in clinical practice due to two major earthquake disasters that affected 11 provinces of Turkey. According to the sample size calculated using the Raosoft sample-size calculator, with a 90% confidence level and a 5% margin of error, a minimum response rate of 163 would be required. The study was completed with 184 nursing students. The post hoc power analysis, conducted using the G-Power 3.1.9.7 software to compare mean scores between groups using and not using pain assessment tools via the Independent t-tests, yielded a power of 99% (effect size d= 1.61,  $\alpha$  = 0.05). This analysis indicates that the sample size represented the population well (17, 18).

#### Instruments

Data were collected with the "Participant Information Form" and "Nursing Students' Attitudes Scale toward Pain Assessment (NSASPA)".

Participant Information Form, created using the literature (4, 10), consists of six questions in which the sociodemographic characteristics of the students and some characteristics related to pain assessment are questioned. The questions were based on the student's gender, study year, perceived success in pain assessment, taking an elective course on pain management, using pain assessment tools, and belief in the effectiveness of nurses in pain assessment. To evaluate students' perceived success in pain assessment in their clinical practice, students were asked to mark on a scale from 0 to 10, with 0 indicating the lowest and 10 indicating the highest success.

Nursing Students' Attitudes Scale Toward Pain Assessment (NSASPA) was developed by Bulut et al. (4). It consists of 15 items and is a 5-point Likert type. Students indicate their level of agreement with the items as "strongly disagree (1)", "disagree (2)", "undecided (3)", "agree (4)" and "strongly agree (5)". The scale consists of two subscales: "significance" and "interest". The "Significance" subscale consisted of 12 reverse-scored negative items on the significance of pain assessment. The "Interest" subscale consisted of three positive items. The total score ranged between 15 and 75. Higher scores indicated more positive attitudes toward pain assessment. Cronbach's Alpha value of the scale was 0.93 for the total scale, 0.95 for the "Significance" subscale, and 0.70 for the "Interest" subscale. In this study, Cronbach's alpha value was 0.80 for the total scale, 0.80 for the "Significance" subscale, and 0.82 for the "Interest" subscale.

#### Data Collection

The study was designed as a self-administered online survey. The data were collected between July and September 2023. After approval of the study, the online survey link was sent to all students via WhatsApp through the class representatives of each class. The participating students completed the survey via Google Forms. Before accessing the survey, participants were presented with an informed consent at the beginning of the online data collection form. Participants were required to indicate their consent by affirmatively responding "Yes" to the question "Would you like to participate in this study?" after reviewing the informed consent information.

#### Data Analysis

Data were analyzed using IBM SPSS Statistics version 22.0. There was no missing data. The conformity of the data to normal distribution was evaluated with kurtosis and skewness values. Since the skewness and kurtosis values in the total scale and its sub-dimensions were within  $\pm 2$ . it was assumed that the data were normally distributed (19). Therefore, parametric tests were used. While the "Independent Samples t-test" was used to compare the means of two independent groups, the One-way analysis of variance (ANOVA) was used to compare the mean scores of three or more independent groups. Pearson correlation coefficient analysis was used to determine the correlation between students' attitudes toward pain assessment and their perceived success in assessing their patients' pain in clinical practice. The prediction of perceived success in pain assessment by levels of students' attitudes toward pain assessment was evaluated with simple linear regression analyses.

#### Validity and Reliability

The scale that was validated for the Turkish population and showed good validity and reliability was used in the study. Measurements with a reliability coefficient of 0.70 and above are considered reliable (20). In this study, Cronbach's alpha coefficient value of the total scale was 0.80.

# **Ethical Considerations**

The study was conducted in conformity with the Helsinki Declaration principles. The ethics committee approval (Isparta University of Applied Sciences Scientific Research and Publication Ethics Committee, Date: 14.06.2023, Number of meetings:155, Decision no: 16, Page: 17/16) and institutional permission were obtained before starting the study. Permission to use the scale was received from the author via e-mail. All students were informed about the purpose of the study, the right to withdraw, and the confidentiality of their personal information with the online voluntary participation form. The students could see the study questions after reading the voluntary participation form and responding "Yes" to the "Would you like to participate in the study?". Students were also informed that whether they participated in the study would not affect their course evaluations. All data were collected anonymously.

# Results

The study sample consisted of 184 nursing students. Of the participating students, 40.8% were 3rd-grade students and 71.7% were female. Most students (72.3%) took an elective course on pain management, 87% used pain assessment tools when evaluating their patients' pain in clinical settings, and 88% believed in the effectiveness of nurses in pain management (Table 1).

The score distributions for the students' perceived pain assessment success are given in Figure 1. On a scale of 0 (lowest) to 10 (highest) points, the mean score of the students' perceived pain assessment success in their clinical practice was  $6.86 \pm 1.71$  (min-max:1-10).

Characteristics	n	%	X	S.D.	Test* and <i>p</i>		
Study year							
Second year	49	26.6	62.91	8.25			
Third year	75	40.8	63.74	7.01	F= 0.397 p= 0.673		
Fourth-year	60	32.6	64.15	6.67			
Gender							
Female	132	71.7	64.26	6.56	t=1.625		
Male	52	28.3	62.11	8.60	<i>p</i> = 0.108		
Taking an elective course on pain management							
Yes	133	72.3	64.15	6.96	t=1.519		
No	51	27.7	62.35	7.84	<i>p</i> = 0.130		
Using pain assessment to	ols						
Yes	160	87.0	65.00	5.96	t=5.622		
No	24	13.0	54.70	8.66	<i>p</i> = 0.00		
Belief in the effectivenes	s of nurses	in pai	n mana	gemer	nt		
Yes	162	88.0	64.70	6.25	t=5.809		
No	22	12.0	55.90	9.22	<i>p</i> =0.000		



Students' total mean scores of NSASPA were  $63.65 \pm 7.23$ . The mean score of the "significance" subscales was  $52.40 \pm 5.98$  and  $11.25 \pm 2.85$  for the "Interest" subscales (Table 2).

A statistically significant difference was observed between NSASPA mean scores and belief in the effectiveness of nurses in pain management and using pain assessment tools (p < 0.05). Accordingly, students who believed in the effectiveness of nurses in pain management and those who used pain assessment tools showed higher attitudes toward pain assessment (p < 0.05).

There was a statistically significant positive correlation between NSASPA total and its Significance sub-scale mean scores and success in pain assessment in clinical practice (r=0.370; r=0.391, p<0.001; respectively). The correlation between the perceived success in pain assessment and Interest sub-scale mean scores was not statistically significant (r=0.119, p>0.05) (Not shown in a table).

The linear regression model results were significant, F(1,182) = 28,853, p < 0.001,  $R^2 = 0.137$ , indicating that approximately 13.7% of the variance in perceived success in pain assessment is explainable by students' attitudes toward pain assessment. Students' attitudes toward pain assessment significantly predicted perceived success in pain assessment, B = 0.087, t = 5.372, p < 0.001. This indicates that on average, a one-unit increase in NSASPA will increase the value of perceived success in pain assessment by 0.087 units (Table 3).

Table 2: Distribution of NSASPA mean scores (n=184)									
NSASPA	Number of items	Possible range	Observed range	$ar{X} \pm SD$	<b>Cronbach</b> α				
Significance	12	12-60	31-60	52.40 ± 5.98	0.80				
Interest	3	3-15	3-15	11.25 ± 2.85	0.82				
Total	15	15-75	42-75	63.65 ± 7.23	0.80				
$ar{X}$ : Mean, SD: Standard de	eviation; NSASPA: Nursing	Students' Attitudes Scale 1	Foward Pain Assessment		•				

Table :	Table 3: The effect of students' attitudes toward pain assessment on perceived success in pain assessment (n=184)								
Variable	В	SE	β	t	р	95.00% Cl [Lower, Upper]			
Constant	1.299	1.043	-	1.246	0.214	[-0.758, 3.357]			
NSASPA	0.087	0.016	0.370	5.372	0.000	[0.055, 0.120]			
		2							

Note. Results: F(1,182) = 28,853, p < 0.001, R=0.370, R<sup>2</sup> = 0.137

Unstandardized Regression Equation: Perceived success in pain assessment= 1.299+0.087\*NSASPA

The distribution of students' responses to NSASPA statements is given in Table 4. The "Strongly agree" and "Agree" responses given by the students in the scale expressions were combined as "Agree". Likewise, the numbers of students who answered "Disagree" and "Strongly disagree" responses were also combined as "Disagree". The three statements that students agreed with most frequently were "I would like to receive more

pain assessment training." (74.5%), "I am aware of my own culture and family values regarding pain assessment" (66.8%), and "I volunteer to conduct pain assessment." (61.4%). The statement they were most often undecided about (30.4%) was "I enjoy conducting pain assessment" and the statement they most frequently disagreed with (96.2%) was "I think that pain assessment is unnecessary" (Table 4).

Table 4: Distribution of responses to NSASPA expressions (n=184)									
	Agree	Undecided	Disagree						
NSASPA scale expressions		n(%)							
1. I think that pain assessment is unnecessary.	1 (0.5)	6 (3.3)	177 (96.2)						
2. I do not like performing pain assessment.	18 (9.8)	24 (13.0)	142 (77.2)						
3. I would remove pain training from the undergraduate curriculum if I could.	11 (6.0)	12 (6.5)	161 (87.5)						
4. I do not think that pain assessment reflects the actual pain experienced by the patient.	11 (6.0)	14 (7.6)	159 (86.4)						
5. I do not think that pain assessment is necessary.	8 (4.3)	4 (2.2)	172 (93.5)						
6. I conduct a pain assessment because I have to.	7 (3.8)	15 (8.2)	162 (88.0)						
7. I think that it is a waste of time to conduct a pain assessment.	4 (2.2)	5 (2.7)	175 (95.1)						
8. I get bored when conducting a pain assessment.	11 (6.0)	22 (12.0)	151 (82.1)						
9. I have a hard time concentrating when conducting a pain assessment.	2 (1.1)	16 (8.7)	166 (90.2)						
10. I do not believe that pain assessment is effective.	5 (2.7)	7 (3.8)	172 (93.5)						
11. I am hesitant to perform a pain assessment.	12 (6.5)	23 (12.5)	149 (81.0)						
12. I am aware of my own culture and family values regarding pain assessment.	123(66.9)	26 (14.1)	35 (19.0)						
13. I would like to receive more pain assessment training.	137 (74.5)	28 (15.2)	19 (10.3)						
14. I volunteer to conduct pain assessment.	113 (61.4)	49 (26.6)	22 (12.0)						
15. I enjoy conducting pain assessment.	97 (52.8)	56 (30.4)	31 (16.8)						

# Discussion

Nurses' attitudes toward pain and its assessment are crucial factors in pain management. Studies have mostly focused on attitudes toward pain and its management (21). This study, however, focused on pain assessment, which is a part of pain management using a different scale specifically developed for nursing students. This study provides important insights into nursing students' attitudes toward pain assessment.

In this study, students' total mean scores of NSASPA were  $63.59 \pm 7.25$ . Considering the lowest (15) and highest (75) scores that can be obtained from the scale, it can be said that the scale mean scores of the students are above the scale average. The findings showed that nursing students have positive attitudes toward pain assessment. Contrary to our study findings, two different systematic reviews reported that nursing students' positive attitudes toward pain were not at the desired level (16, 22). A systematic review, which included six studies with 1454 participants, emphasizes that nursing students' knowledge and attitudes toward pain management have not improved over the past 20 years (16). Another systematic review indicated that nursing students have limited knowledge

and often hold negative attitudes toward pain (23). Hançer and Yılmaz (24) found that nursing students did not have a positive attitude toward pain management. Reyala (25) also determined that nursing students had negative attitudes toward pain assessment and management. Hroch et al. (10) found that nursing students did not have positive attitudes about pain assessment and management. The difference between our study and the literature may be related to cultural differences.

In the current study, students who believed in the effectiveness of nurses in pain management had more positive attitudes toward pain assessment. This finding shows that when students believe nurses are effective in pain management, they exhibit more positive attitudes toward pain assessment. The literature shows that nursing students' positive perceptions of the nursing profession have a significant effect on their professional performance (26, 27). These findings suggest that as nursing students' belief in the profession's competence increases, they take their professional responsibilities more seriously and give more importance to pain assessment. It is thought that trainings that especially emphasize the role of nurses in pain management can positively affect students' attitudes toward pain assessment.

In this study, the majority of nursing students were using pain assessment tools. In Reyala's (25) study, the rate of student nurses using pain assessment tools was lower than in our study. Furthermore, we determined that nursing students who used pain assessment tools exhibited more positive attitudes toward pain assessment, this result is consistent with the study of Reyala's (25) and Al-Khawaldeh (13) who found a significant statistical difference in the level of nursing students' knowledge and attitude score about the frequency of using pain assessment tools. Alsagri (28) reported that students who used pain scales more frequently had significantly higher knowledge and attitude scores toward pain management. Similarly, Santos et al. (29) reported that nursing students using pain assessment tools had a higher level of knowledge about pain assessment. These findings suggest that students with a more favorable attitude toward pain assessment may be more inclined to use assessment tools.

In the current study, we found that students' positive attitudes toward pain assessment positively predicted their perceived success in pain assessment. Supporting our study, Al-Sayagh et al. (11) stated that nurses who have inadequate knowledge and negative attitudes toward pain management are inadequate in pain assessment. These findings emphasize the importance of enhancing nursing students' positive attitudes toward pain assessment. Students' positive attitudes toward pain assessment contributed to them feeling more competent in pain assessment. This shows the importance of positive attitudes in increasing student motivation and self-efficacy. Developing positive attitudes toward pain assessment will enable students to perform their professional skills more effectively and confidently.

Participating students most frequently agreed that they wanted more pain assessment education. Students' desire for more training in pain assessment should raise questions about the adequacy of current educational programs in this regard. In the systematic review conducted by Cousins et al. (16) to explore whether nursing students' level of pain knowledge and attitudes toward pain management has improved over the past 20 years, it was concluded that nursing education does not include sufficient focus on pain identification and management and that over the past 20 years, nursing students' knowledge of pain management has not improved despite curriculum renewal. Providing more comprehensive and effective training on this subject by nursing educators will contribute to meeting these demands of students. The other most common situation that students agreed on was

being aware of their culture and family values regarding pain assessment. Students' awareness of their culture and values regarding pain assessment can be considered an indicator of their awareness that these values can play a role in pain assessment and management processes. This allows students to be aware of personal biases during pain assessment, to manage them consciously in patient care, and to make more objective and professional assessments. These will contribute to effective pain management by providing an effective assessment. In the literature, the importance of meeting the care needs of patients in line with their cultural values and providing holistic care is emphasized (30). In this context, this finding can also be considered as a desired finding that reflects the cultural sensitivity of students in pain assessment, and their efforts to understand the cultural needs of patients and provide holistic care. In this study, the statement they most frequently disagreed with was "I think that pain assessment is unnecessary". This finding was desired and can be considered a positive finding in terms of pain assessment. In addition, this finding may be a positive sign about the professional development of students during the educational process. The students' low agreement with this statement shows their awareness of the necessity and importance of pain assessment as nurse candidates. In a study that supports our study finding, most nurses reported that pain assessment is a top priority for patients with pain (1). However, considering the importance of pain assessment in pain control, the presence of students who disagree with this statement, albeit at a low rate, should not be ignored. These students may have a different attitude due to their experiences or beliefs regarding pain assessment. Identifying and eliminating the underlying reasons for these thoughts of students who do not find pain assessment necessary will contribute to training nurses who are competent in pain management.

#### Limitations and strengths

Since pain is a multidimensional factor, the study's crosssectional design can be considered a limitation. Also, the study results were limited to nursing students registered in only one state university. The fact that a valid and reliable scale developed specifically for nursing students was used in this study can be considered a strength of the study. Another strength of the study is the large effect size, indicating a substantial difference between the groups.

# Conclusion

The majority of students believed in the effectiveness of nurses in pain management. Nursing students' attitudes toward pain assessment were positive. Nursing students who believed in the effectiveness of nurses in pain management and used pain assessment tools had more positive attitudes toward pain assessment. Students' positive attitudes toward pain assessment positively predicted their perceived success in pain assessment. Students most frequently agreed that they wanted more training in pain assessment.

It is recommended that pain assessment be included more in the nursing curriculum, that nursing educators provide more comprehensive and effective training on this subject, and that the effectiveness of the students should be emphasized in training. Nursing educators should make plans to increase the success and positive experiences of students in pain assessment. Students should be informed about pain assessment scales used in pain management and encouraged to use them in clinical practice. To obtain more detailed information on the subject, studies with different study designs and larger samples can be conducted.

# **Declarations**

#### Funding

There is no funding.

## Conflict of interest

The author declared that there is no conflict of interest.

#### Ethics approval

This study was approved by the Isparta University of Applied Sciences Scientific Research and Publication Ethics Committee (Date: 14.06.2023, Number of meetings:155, Decision no: 16, Page: 17/16).

#### Availability of data

The data and material are available upon request.

#### **Author Contributions**

Conceptualization: İKT, SDD; Methodology: İKT, SDD; Formal analysis and investigation: İKT, SDD; Writing original draft preparation: İKT, SDD; Writing - review and editing: İKT, SDD; Supervision: İKT, SDD

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Primary Health Care / Birincil Sağlık Bakımı

# Investigation of The Relationship Between Primary Headache Severity and Daily Food Preferences in Young Adults not yet Diagnosed with Migraine

Duygu Vardağlı<sup>1</sup>, Özlem Ortakçı<sup>2</sup>

#### ABSTRACT

**Purpose:** Migraine is a complex neurological disease. The aim of our study is to provide sustainable food-mediated benefit in migraine prophylaxis to people with severe symptoms who have not yet been diagnosed with migraine.

**Methods:** The study included 197 people between the ages of 18-45 who had not yet been diagnosed with migraine had strong symptoms, had no metabolic disease, psychiatric disease or disability. In the first stage of the study the internationally used "Headache Disability Index" scale was applied to the participants. After 4 weeks of consuming the recommended reference foods, the Headache Disability Index test was repeated and the score difference was accepted as data. Evaluation of the data SPSS 26 statistical program was used and p < 0.05 was considered significant.

**Results:** The inclusion of beef liver as a reference food in the diet resulted in a significant improvement in the Headache Disability Index F19 (p<0.003) recommendation, and the inclusion of broccoli provided statistically significant improvements in the E9 (p<0.039) and F13 (p<0.025) recommendations.

**Conclusion:** In people with severe migraine symptoms; Providing only the daily recommended amounts of vitamins A, B12, K1 and C to their diet through broccoli and beef liver foods; It provided improvement in emotional and functional disabilities.

Keywords: Migraine, Beef liver, Broccoli, Headache Disability Index, Sustainable health

#### ÖZET

Amaç: Migren kompleks nörolojik bir hastalıktır. Çalışmamızın amacı henüz migren tanısı almamış kuvvetli semptomları olan kişilere, migren proflaksisinde besin aracılı sürdürülebilir fayda sağlamaktır.

**Yöntemler:** Çalışmaya henüz migren tanısı almayan kuvvetli semptomları olan, herhangibir metabolik psikiyatrik hastalığı ve engeli bulunmayan 18-45 yaş arası 197 kişi dahil edildi. Araştırmanın ilk aşamasında katılımcılara uluslararsı alanda kullanılan "Headache Disability Index" ölçeği uygulandı. Önerilen referan besinler 4 hafta tüketildikten sonra "Headache Disability Index" ölçeği uygulandı. Önerilen referan besinler 4 hafta tüketildikten sonra "Headache Disability Index" ölçeği aktarılanarak, oluşan skor farkı veri olarak kabul edildi. Verilerin değerlendirilmesinde SPSS 26 istatistik programı kullanıldı ve p<0.05 anlamlı kabul edildi.

**Bulgular:** Diyete referans besin olarak karaciğerin dahil edilmesi Headache Disability Index F19 (p<0,003) önermesinde anlamlı iyileşme, brokolinin dahil edilmesi ise E9 (p<0,039) F13 (p<0,025) önermelerinde istatistiksel olarak anlamlı iyileştirmeler sağlamıştır.

**Sonuç:** Kuvvetli migren semptomları taşıyan kişilerde; brokoli ve karaciğer besinleri aracılığı ile, diyetlerine sadece günlük önerilen miktarlarda A, B12, K1 ve C vitaminlerinin sağlaması; emosyonel ve fonksiyonel engeliliklerde iyileşme sağlamıştır.

Anahtar Kelimeler: Migren, Karaciğer, Brokoli, Baş ağrısı engellilik indeksi, Sürüdürülebilir sağlık

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Received: 19.05.2024 Accepted: 30.10.2024 igraine is a recurrent neurological disease that causes deterioration in the person's quality of life with its symptoms. It mostly affects patients during their most productive years. It is known as the second leading cause of disability in the world (1).

Migraine affects 12-17% of the population annually, and its lifetime incidence is 43% in women and 18% in men (2,3).

According to the latest updated data, while the prevalence of migraine in the general population was 2.89% in 2008, it has been stated that this value increased to 14% in 2022, and the pathophysiology of migraine has not been fully elucidated yet (4).

Findings detected during migraine attacks can be listed as cerebral vasoconstriction, increased glutamate levels, magnesium deficiencies, monoaminergic pathway dysfunctions, mitochondrial damage, calcitonin generelated peptide retention, and neuroinflamation. Numerous studies support the role of neuroinflamation in the initiation and progression of migraine through different pathways (5).

Diagnostic criteria for migraine in the International Headache Classification (beta version; ICHD-3beta) published in 2013; recurrent headache characterized by a history of at least five years, headache attacks lasting 4-72 hours, and these two main symptoms; pain is defined as being accompanied by at least two of the following: predominance of pain on a certain side of the head, persistent throbbing, causing avoidance or abandonment of routine activities, and finally nausea/vomiting and/or hypersensitivity to light/sound (6).

Studies on ICHD-4 are ongoing and the aim is to work on revisions and collect data for approximately another 5 years (7).

The International Headache Society has been making revisions to the classification of headache disorders since 1988. The last evaluations were made for migraine classification and diagnostic criteria in 2004, and symptoms lasting at least 3 months and lasting 15 days were defined as chronic migraine, while migraine that did not meet these criteria was classified as episodic migraine. However, it is claimed that this classification is insufficient to understand the migraine burden and the patient's treatment needs (8). Despite its prevalence and impact, 50% of migraine patients are not yet diagnosed as having migraine by a clinician, and only 26% of those diagnosed receive minimal care. It is possible to say that there are still insufficient diagnostic and treatment practices to reach these rates. (9,10).

Current pharmacological and neuromodulation treatments for migraine prevention show low acceptability due to their limited effectiveness and adverse effects. Therefore, it is very important to identify the determinants of migraine headache and develop effective management strategies based on its pathophysiology (11,12).

Among non-pharmacological preventive treatments of migraine, nutritional interventions have been studied to offer innovative treatment strategies for primary headaches to avoid adverse effects and drug interactions (13,14).

There is a strong need to create practical approaches and reduce the burden of this disease with migraine preventive treatments.

The reasons that trigger attacks in migraine patients may not be specific to migraine, and may not be experienced by every migraine patient for example, many factors such as women's menstrual period, stress, differences in sleeping and eating patterns, loud noise, strong odors and bright light can trigger an attack. Approximately one quarter of the patients; it has been stated that many packaged products containing monosodium glutamate, meats and delicatessen products containing nitrites, drinks and cheeses containing tyramine, shelled cookies and chocolate containing phenylethylamine trigger migraine attacks citrus fruits, pickles and vinegar are among the possible causes. These foods do not need to be approved by all patients, and removing these products from the diet does not mean that there will be no migraine attacks (15).

While dehydration and starvation make migraines worse, it is recommended that daily caffeine consumption should not exceed 200 mg and aspartame content should be avoided (16).

Various studies have attempted to demonstrate the effectiveness of some alternative treatments. These include magnesium (400-600 mg/day) and riboflavin (400 mg/day). These are the ones that have just been discovered (17).

Prevention of nutrition-mediated migraine attacks; It is very important as it is a sustainable process in which the patient personally accompanies both the individual identification of root causes and prophylaxis/treatment/ patient follow-up.

For this reason, a study was conducted with volunteers between the ages of 18 and 45 who had strong symptoms that had not yet been diagnosed with migraine. For this; two different foods of animal and plant origin, which provide macro and micro nutrients in appropriate compositions, were determined as references. The change they make with the reference foods recommended in their diets at four-week intervals; it was investigated whether there were differences in the duration and severity of pain and in the emotional and functional areas where they experienced limitations due to pain, taking into account the Headache Disability Index scores and its components.

# **Material and Methods**

The study included 197 people between the ages of 18-45 who had not yet been diagnosed with migraine, had strong symptoms, had no metabolic disease psychiatric disease or disability. Participants who did not meet these criteria were not included in the study.

The research is a prospective descriptive-comparative study and the data of the participants were collected in digital environment between June 2021 –July 2021. To increase the possibility of accurate and reliable data collection; the minimum sample size was determined with the G\*Power (v3.1.9.7) program. In the power analysis,  $\alpha = 0.05$ , effect size = 0.2 and 95% power were selected and a total of 197 participants was calculated.

A voluntary "Informed Consent" form was obtained from all participants in the study. The study was approved by the İstanbul Esenyurt Ethics Committee numbered E-12483425-199-263 dated 12.01.2021

In the first stage of the study. the internationally used "Headache Disability Index" scale was applied to the participants. Four-week usage frequency changes in reference foods were recorded and then Headache Disability Index" scale was applied again. Score differences between test and retest were accepted as data.

Headache Disability Index (HDI) is a scale developed by Dr Jacobson GP, Ramadan NM and colleagues that tries

to detect the impact of headache on daily life. The test begins by asking participants to rate the severity of their headache (mild, moderate and severe), frequency (1 per month, more than 1 per month but <4, and more than 1 per week). Subsequently, 25 propositions inspired by case stories are presented. Propositions are scored as 4 points when the participant approves the proposition (Yes), 2 points when he/she partially approves it (Sometimes), and 0 points when he/she rejects it. When the test is repeated, a difference of 29 points or more suggests that the factors causing this change have a therapeutic effect (18).

SPSS 26 program was used for statistical analysis of the data in the study. One-way ANOVA test was used for multiple group comparisons. Bonferroni tests were performed for the correlation of significant groups and p <0.05 was considered statistically significant.

# Results

It was recorded how often the participants consumed broccoli and beef liver, which were chosen as reference foods, and then their Headache Disability Index scores were measured. Information about foods was given and diet follow-ups were made.

During this period; while 47.7% of the participants have never consumed broccoli, 53.5% consume it every 2-3 days; while 67.1% had never consumed beef liver, 56.8% started to consume it every other day. At the end of four weeks, a new Headache Disability Index score was created for them.

It was determined that our participants increased the frequency of use of the products at different levels, and the Headache Disability Index test-retest score difference was  $\geq$ 29 in 46.1%, and the score difference was <29 in 53.9%. The effect of different frequency of food consumption on each proposition in the index was investigated in participants with a score difference of  $\geq$ 29. According to the validity of the Headache Disability Index, it can be suggested that the change is therapeutically effective only when the test-retest score difference is  $\geq$ 29 (Table 1).

Although the specified reference foods and their consumption frequencies showed a percentage improvement on headache frequency and severity (Headache frequency 78.6% more than one per week-46.8% 1 per month; headache severity 72.1% severe-46.8% moderate), it did not create a statistically significant difference (Table 2).

Table 1.	Statistical significance and p values of referans foods in each index items on test to retest when Headache Dis	ability score	<u>e ≥29 point</u>
	Headache Disability Index Items	Broccoli	Beef liver
F1	Because of my headaches I feel handicapped.	0.358	0.880
F2	Because of my headaches I feel restricted in performing my routine daily activities.	0.998	0.527
E3	No one understands the effect my headaches have on my life	0.608	0.163
F4	I restrict my recreational activities (e.g., sports, hobbies) because of my headaches.	0.273	0.793
E5	My headaches make me angry	0.894	0.692
E6	Sometimes I feel that I am going to lose control because of my headaches.	0.806	0.116
F7	Because of my headaches I am less likely to socialize	0.732	0.886
E8	My spouse (significant other), or family and friends have no idea what I am going through because of my headaches.	0.574	0.244
E9	My headaches are so bad that I feel that I am going to go insane	0.039	0.283
E10	My outlook on the world is affected by my headaches.	0.980	0.134
E11	I am afraid to go outside when I feel that a headache is starting	0.823	0.742
E12	I feel desperate because of my headaches.	0.445	0.234
F13	I am concerned that I am paying penalties at work or at home because of my headaches.	0.025	0.729
E14	My headaches place stress on my relationships with family or friends.	0.727	0.783
F15	I avoid being around people when I have a headache.	0.698	0.909
F16	I believe my headaches are making it difficult for me to achieve my goals in life.	0.175	0.580
F17	I am unable to think clearly because of my headaches.	0.069	0.571
F18	l get tense (e.g., muscle tension) because of my headaches.	0.628	0.654
F19	l do not enjoy social gatherings because of my headaches.	0.738	0.003
E20	I feel irritable because of my headaches.	0.498	0.729
F21	I avoid traveling because of my headaches.	0.267	0.668
E22	My headaches make me feel confused	0.697	0.735
E23	My headaches make me feel frustrated.	0.907	0.350
F24	I find it difficult to read because of my headaches.	0.653	0.213
F25	I find it difficult to focus my attention away from my headaches and on other things	0.059	0.860

Table 2. Headache frequency and severity p values according to use in referans foods when Headache Disability score ≥29 point

Headache characteristics	Referans foods	
	Broccoli	Beefliver
Headache frequency	0.077	0.070
Headache severity	0.533	0.787

# Discussion

The macro and micro nutrients and amounts that healthy adults should consume daily for sustainable health are shared by the Food and Drug Administration. Accordingly, reference foods were selected by scanning the national food composition database. These foods; care was taken to ensure that it was from plant and animal sources produced/grown in our country and that it could provide half or one portion of any of the macro/micro nutrients needed daily in nutrition. Vitamin A, which is recommended to be taken 900 micrograms daily, was presented to the participants with beef liver, one of the reference foods. The fact that beef liver, which contains a minimum of 1691 micrograms of Vitamin A in every 100 grams, was consumed by the participants every other day, met this need containing Vitamin B12, which is well above the daily requirement, and providing 50% of the daily selenium requirement and 42% of the B6 requirement on its own, makes beef liver distinctive from other vitamin A sources.

Considering that migraine is a state of sterile inflammation, it comes to mind that vitamin A plays a role in both immunomodulation and T cell regulation. It is known to reduce the production of pro-inflammatory IL-6 and IFN-8 from T cells and increase the number of anti-inflammatory mediators such as IL-4. The decrease in serum Retinol binding protein amounts in migraine patients compared to control groups is one of the important findings that the amount of vitamin A in circulation decreases in migraine patients (19).

It is known that B12 reduces NO-mediated vasodilation by reducing the amounts of acetylcholine in the vascular area in the nervous system. Biochemically, its use in migraine prophylaxis comes to mind due to its scavenger effect on NO. In a study in which hydroxycobalamin was administered nasally to migraine patients, a decrease in the frequency of migraine attacks was detected in 10 out of every 19 patients. In children diagnosed with tensiontype headache, whose etiology is similar to migraine etiology, vitamin B12 levels are deficient to certain degrees (moderately deficient <200 pg/mL; severely deficient <160 pg/mL), and symptoms decrease in the follow-up after B12 serum levels are increased with replacement has been reported.

It can be thought that taking vitamins A and B12, which are the reference nutrients we recommend, which support antioxidant and anti-inflammatory capacity in the liver, together and in sufficient amounts, has an effect by improving the item "I do not enjoy social gatherings because of my headaches" (F19) in the Headache Disability Index.

Broccoli is another reference food, with 100 grams (half a portion) of it covering the entire vitamin C deficiency, which is recommended to be taken as 90 milligrams per day. It is very important that it contains vitamin K1 (104.3 micrograms-minimum), which meets almost the entire daily need (120 micrograms), and that vitamins C and K1 are presented together and in sufficient quantities. 90% of dietary vitamin K consists of the K1 form (20). There are study results showing that anti-inflammatory activity is achieved by taking daily recommended amounts of vitamin K1 from green leafy vegetables, even in different populations/ethnic groups (21). Studies have suggested that this anti-inflammatory effect develops by inhibiting I-kappaB kinase phosphorylation in tissues, preventing the nuclear translocation of NFkB and blocking gene expression. Suppression of the synthesis of the pleiotropic cytokine IL6, which is responsible for the production of other inflammatory factors, and the decrease in its circulating amounts strengthen this hypothesis. It has been stated that serum d-dimer and fibrinogen levels remain at normal levels in the  $\leq$ 65 age range when KI is used in daily recommended doses (22).

What is noteworthy here is that vitamin K did not exert its anti-inflammatory effect as a cofactor of the carboxylation reaction; a different biochemical pathway of vitamin K is mentioned.

In migraine, where increased oxidative stress and neurogenic inflammation in the brain tissue are thought to be possible pathophysiology, increased oxygen and nitrogen free radicals in the circulation and cerebrospinal fluid and decreased antioxidant capacity are the outcomes of many studies. However, in clinical studies, only pine bark extract has been used to support Vitamin C content by creating pharmaceutical preparations, and no nutritional content has been presented (23).

In our research, broccoli was recommended as a suitable composition that supports antioxidant and antiinflammatory capacity with the combination of vitamins C and K1. Broccoli causes improvement in the parameters "My headaches are so bad that I feel that I am going to go insane" (E9), and "I am concerned that I am paying penalties at work or at home because of my headaches" (F13) in migraine attacks. It can be suggested that.

Another study shared the incidence and prevalence of migraine in the world between 1990 and 2019 with color codes. According to the color code in Turkey; migraine incidence rate decreased from 1431.61 to <1503.832; the prevalence rate increased from 18813.44 to <20400.82 (24).

Looking at China, which produces and consumes the most broccoli; it is remarkable data for our study that migraine incidence (1291.2) and prevalence (17203.82) rates are much lower. The good news is that in 2024, broccoli will be harvested in Bafra, a district of Samsun province, with a harvest of over 12 tons. Increasing the applicability of the Mediterranean diet, which UNESCO declared as a world heritage, in Turkey and, more importantly, benefiting its own geography and the people living in this geography by consuming the products it grows, will be valuable steps for both sustainable agriculture and sustainable health (25,26). The biochemical pathway we encounter in both recommended reference foods is related to the antiinflammatory and antioxidant content and the reduction of NO synthesis and its effects. NO changes the molecular structure of serotonin and the changed serotonin is not recognized by its own receptors; It shows us that the serotonin sources to be included in the process will be ineffective unless significant control is achieved in NO levels (27-30).

Moreover, this effect was achieved with minimum concentrations of A, B12, C, K1, which are involved in metabolism, despite individual bioavailability differences.

# Conclusion

In our study, attention was paid to recommend reference foods among the products that can be accessed by the participants and then by the whole society and included in their daily diets. We believe that the foods and amounts that can be included in the diet are an important step for sustainable health. Another issue we paid attention to in the design of our study was; what will be recommended is that migraine prophylaxis can be achieved by regulating the daily use of nutrients, primarily macro and micro nutrients. For this reason, patients who have not yet been diagnosed with migraine, who are in the earlier stages of the disease, and who have the highest incidence were preferred. For this reason, those who have not yet been diagnosed with migraine, those in the earlier stages of the disease, and those at the ages with the highest incidence were preferred.

Another important point we want to emphasize in our study is; the point is that in therapeutic processes, it is not the specific macro/micro nutrients but the matches of these molecules needed in the biochemical pathways that are meaningful.

When the biochemical characters of the molecules are evaluated; it is noteworthy that vitamins A and K1 are lipid soluble, while vitamins C and B12 are water soluble. While these pairings require pharmaceutically advanced techniques, the food itself contains the appropriate composition to modulate these conditions.

We hope that with further research, we will encounter such molecular matches and examples of natural compositions found in plant and animal sources that support antioxidant and anti-inflammatory processes. It should not be forgotten that from time to time, foods not only satisfy our pleasure and desires with their taste, smell, texture and visuals, but also serve as a medicine with their content.

# **Declarations**

#### Funding

Not applicable

#### Conflicts of interest/ Competing interests

The authors declare no competing interests related to the subject matter or materials discussed in this article.

#### Ethics approval

A voluntary "Informed Consent" form was obtained from all participants in the study. The study was approved by the İstanbul Esenyurt University Ethics Committee numbered E-12483425-199-263 dated 12.01.2021.

#### Availability of data and material

Data can be shared if requested.

#### Authors' contributions

Conceived and designed the experiments: DV; performed the experiments: DV, ÖO; analyzed the data: DV; contributed reagents/ materials/ analysis tools: DV, ÖO; wrote the manuscript: DV, OÖ; final edit of paper: DV.

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Health Services and Systems / Sağlık Hizmetleri ve Sistemleri

# A New Communication Model Between Clients/Patients and Dietitians: Telenutrition, Evaluation of the Perspectives of Clients/Patients and Dietitians

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#### ABSTRACT

**Purpose:** The aim of this cross-sectional study was to determine the status, advantages, and disadvantages of telenutrition from the perspectives of clients/patients and dietitians.

**Methods:** A total of 100 clients/patients and 100 dietitians were assigned to this cross-sectional study. To assess the status as well as the advantages and disadvantages of telenutrition, a set of inquiries, based on the literature review, were posed to both clients/patients and dietitians.

**Results:** Both dietitians (%92) and clients/patients (%61) were found to use telenutrition mainly for weight loss diets. It was found that clients/patients who had time constraints due to their busy lifestyle (63%) and whose dietitian was in another city (36%) preferred telenutrition more frequently. Clients/patients (51%) were more concerned than dietitians (32%) that anthropometric measurements were not taken by the expert (p<0.05). 44% of clients/ patients stated that they frequently change their appointments due to the time-flexible system.

**Conclusion:** Telenutrition has become a necessity today due to the time constraints that many people complain about due to their busy lifestyles, difficulties in traveling to and from hospital/clinic, especially in the elderly age group, pandemics, or natural disasters. In this direction, the steps to be taken to improve telenutrition will increase the quality of telemedicine services. When making relevant improvements, the opinions of the clients/patients group receiving this service and the dietitians providing this service should be consulted and the participation of clients/patients in the formation of health policies should be supported.

Keywords: Client, Dietitian, Patient, Telehealth, Telenutrition

#### ÖZET

Amaç: Bu kesitsel çalışmanın amacı, danışan/hastaların ve diyetisyenlerin bakış açıları doğrultusunda telenütrisyon hizmetinin mevcut durumunu, avantaj ve dezavantajlarını belirlemektir.

Yöntem: Bu kesitsel çalışmaya toplam 100 danışan/hasta ve 100 diyetisyen dahil edilmiştir. Telenütrisyon hizmetinin mevcut durumunu, avantaj ve dezavantajlarını değerlendirmek için danışan/hastalara ve diyetisyenlere literatür taramasına dayanan bir dizi soru yöneltilmiştir.

**Bulgular:** Hem diyetisyenlerin (%92) hem de danışan/hastaların (%61) telenütrisyonu daha çok ağırlık kaybı diyetleri için kullandığı tespit edilmiştir. Yoğun yaşam tarzları nedeniyle zamanı kısıtlı olan (%63) ve diyetisyeni başka bir şehirde olan (%36) danışan/hastaların telenütrisyonu daha sık tercih ettiği saptanmıştır. Antropometrik ölçümlerinin uzman tarafından alınmamasından danışan/hastalar (%51), diyetisyenlere (%32) kıyasla daha fazla endişe duymaktadır (p<0.05). Danışan/hastaların %44'ü esnek zaman sistemi nedeniyle randevularını sık sık değiştirdiklerini belirtmiştir.

**Sonuç:** Telenütrisyon; birçok insanın yoğun yaşam tarzı nedeniyle şikayetçi olduğu zaman kısıtlılığı, özellikle yaşlı yaş grubunda hastaneye/kliniğe gidiş gelişte yaşanılan zorluklar, salgın hastalıklar ve/veya doğal afetler nedeniyle günümüzde bir gereklilik haline gelmiştir. Bu doğrultuda telenütrisyonun iyileştirilmesi için atılacak adımlar telesağlık hizmetlerinin de kalitesini artıracaktır. İlgili iyileştirmeler yapılırken bu hizmeti alan danışan/hasta grubunun ve veren diyetisyenlerin görüşlerine başvurulmalı, sağlık politikalarının oluşturulmasında danışan/hastaların katılımı desteklenmelidir.

Anahtar Kelimeler: Danışan, Diyetisyen, Hasta, Telesağlık, Telenütrisyon

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Received: 16.11.2024 Accepted: 18.01.2025
oday, 67.1% of the 8.12 billion population uses telecommunication services (1). It is known that 5.34 billion of these service users actively use mobile phones, 5.03 billion use the internet, and 4.70 billion use social media (1). Compared to the previous year, mobile phone usage increased by 1.8%, internet usage by 3.7%, and social media usage by 5.1% (1). When evaluated on a regular basis, it is noticeable that these rates are constantly increasing. Developing technology and communication tools facilitate information sharing in many fields today (2). This technology is also frequently used to bring healthcare professionals and patients together (2). In 2020, the social isolation caused by the Coronavirus disease-19 (COVID-19) pandemic and the difficulties in accessing health services caused applications such as telehealth, telemedicine, and telenutrition to come to the fore and related applications have started to come to the fore in many fields (2,3).

Telehealth is the sharing of health data, care information, and education among healthcare personnel and patients, students, and/or other healthcare personnel via telecommunications using telephone, computer, interactive television, or a combination of these means (4). Telenutrition is defined as the interactive use of electronic information and telecommunication technologies by a specialized dietitian to deliver nutritional care to clients/patients in a remote location (5). In this process, with telecommunication applications determined by the dietitian, all steps of medical nutrition therapy, such as taking anamnesis of the clients/patients, evaluation of anthropometric, laboratory, and physical findings, determination of nutritional behaviors with food consumption records and frequency, planning, and follow-up of medical nutrition therapy, can be managed (6). Thus, even if the patient and dietitian cannot come together in a physical environment, they can meet online and carry out treatment processes (6).

As in every process, telenutrition has some disadvantages (limited ability to use online platforms, lack of face-toface communication, etc.) and advantages (time-place flexibility, no travel costs to reach the hospital or clinic, etc.) (7). In addition, as it is a process that is just beginning to mature, there are points that need to be explored and clarified. In this direction, one of the steps to be taken to improve telenutrition is to consult the opinions of people who receive and use this service, list advantages, and disadvantages, and exchange ideas on how measures can be taken for disadvantages. In the literature review, it was observed that studies on telenutrition were mostly conducted on patients with inflammatory bowel syndrome (5, 8, 9) and studies were conducted to determine the rate of telenutrition during the pandemic period (7, 10). The motivational force in the planning of the study was the unavailability of a study that evaluates tele-nutrition practices in line with the communication model, interprets them from the perspective of the dietitian and the client/patient, and includes plans for the future in the literature review.

The aim of the study is to determine the current status of telenutrition, which is a newly maturing concept, in terms of clients/patients and dietitians, to identify its advantages and disadvantages, and to make predictions about what can be done in the future to improve telenutrition in order to improve communication in health services.

## **Material and Methods**

**Study design:** This cross-sectional study's sample size was calculated using G\*Power version 3.1.9.2 (11). The chisquare test was used to compare the perspectives of both clients/patients and dietitians regarding telenutrition. The sample size was determined based on hypothesized values of  $\alpha$ =0.05 and  $\beta$ =0.95, considering a medium effect size. The sample size, which was calculated as 191 in total, was revised to 200 considering the possibility of faulty questionnaires, and it was aimed to reach an equal number of participants: 100 dietitians and 100 clients/ patients. Data was collected in September 2023 on 100 dietitians providing telenutrition and 100 clients/patients receiving telenutrition via an online questionnaire (Google Forms). The dietitians providing telenutrition services for at least one year and clients/patients receiving telenutrition services for at least one year were included in the study.

**Data collection tools:** According to the literature review (5, 7-10, 12), 28 questions including open-ended questions and multi-optional questions about the advantages and disadvantages of telenutrition were prepared. This questionnaire form was designed to determine the current views of both dietitians and clients/patients, and all questions were asked of both dietitians and clients/ patients. The data were collected in September 2023 using an online questionnaire via Google Forms. Dietitians in Turkiye and clients/patients receiving telenutrition services were contacted for data collection through the Turkish Dietetic Association.

**Statistical analysis:** The data were analyzed using the IBM SPSS Statistics 22.0 statistical package program (Statistical Package for the Social Sciences, SPSS Inc., Chicago, USA). The normality of the data was assessed using the Shapiro-Wilk normality test. The data were expressed as number (n), percentage (%), mean ( $\bar{x}$ ), and standard error (±SE). The variables of two independent parametric groups were compared by t-test. Chi-square analysis was used to compare categorical variables. Values were considered significant at p<0.05 at a 95% confidence interval (13).

Finally, The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement guidelines were used to report this study in detail (14).

## **Results**

This study was conducted with 100 dietitians and 100 clients/patients who voluntarily agreed to participate

in the study. 86.0% (n=86) of the dietitians were female and 14.0% (n=14) were male; 79.0% (n=79) of the clients/ patients were female and 21.0% (n=21) were male. The mean age of the dietitians was  $28.35\pm6.56$  years and that of the clients/patients was  $32.26\pm6.70$  years. 25.0% (n=25) of the dietitians were married and 75.0% (n=75) were single; 71.0% (n=71) of the clients/patients were married and 29.0% (n=29) were single.

**Graphic 1** presents reasons why dietitians and clients/ patients prefer telenutrition. Either dietitians or clients/ patients were found to use telenutrition mostly in weight loss diets. Furthermore, it is observed that dietitians mostly use telenutrition for the follow-up of metabolic diseases, while clients/patients prefer telenutrition for the monitoring of nutrition habits. It was found that 20% of dietitians and 8% of clients/patients used telenutrition for other reasons.







The preferred social networks for telenutrition by dietitians and clients/patients are shown in **Graphic 2.** The first social media platform preferred by both dietitians (97.0%) and patients (95.0%) is WhatsApp. This is followed by Instagram with 47.0% for dietitians and 29.0% for clients/ patients. Telephone calls came in third, with dietitians (30.0%) and clients/patients (12.0%) sharing the same opinion.

When dietitians and clients/patients were asked how many minutes or hours a consultation period should be on average within the scope of telenutrition service, dietitians answered 35.00±10.00 minutes, and clients/ patients answered 40.00±5.00 minutes. No significant

difference was found between the opinions (p>0.05, \*independent two-sample t-test).

**Graphic 3** shows that, reasons for preferring telenutrition from the perspective of the dietitians and the clients/ patients. According to dietitians, clients/patients who cannot find time to come to the hospital/clinic due to busy daily routine prefer telenutrition more (67.0%). From the perspective of clients and patients, the preference for telenutrition is primarily due to their dietitians being in a different city (63.0%). The first two reasons are common to both perspectives: busy daily routines and the geographical separation of clients/patients and dietitians.

Table 1. Dietitians' and clients/patients' responses to the survey questions								
	Diet	itian	Clients/					
Questions	Yes	No	Yes	No	p*			
	n	n	n	n				
The fact that we are mutually accessible at any time increases the success of telenutrition.	80	20	86	14	0.331			
It is a positive opportunity for both sides to see the environment where the client/patient eats, the refrigerator, etc. by the dietitian.	59	41	69	31	0.141			
Not waiting in too long queues at the hospital/clinic for the interviews makes it possible to keep appointments more faithfully.	67	33	73	27	0.355			
One of the motivating aspects of telenutrition is that it doesn't involve traveling to the hospital/ clinic, searching for a parking space, or travel costs.	87	13	94	6	0.091			
One of the important advantages of telenutrition is that mutual communication can continue even in situations such as epidemics and earthquakes.	83	17	91	9	0.093			
Failure to have anthropometric measurements taken by an expert affects the reliability of the results.	32	68	51	49	0.006			
I think the process will be more successful when we meet face to face (client/patient-dietitian).	56	44	59	41	0.668			
The presence of distractions in the interview environment during the interview (noise at home, etc.) reduces the quality of the interviews.	26	74	25	75	0.871			
Not being able to get an opinion from other health personnel (physician, physiotherapist, psychologist, etc.) about the medical nutrition process causes the telenutrition service to be incomplete.	31	69	33	67	0.762			
The technological/technical problems I experience with the telenutrition platform I use cause breaks in appointments and interviews.	13	87	16	84	0.547			
Since I don't have sufficient knowledge and experience in social networks, I sometimes question the quality of the telenutrition service.	4	96	19	81	<0.001			
Since it is a time-flexible system, there are frequent appointment changes.	17	83	44	56	<0.001			
I have knowledge about the social insurance processes (repayment, etc.) of the telenutrition system.	40	60	53	47	0.065			
I know the legal aspects of the telenutrition system (personal data protection law, taxation).	67	33	64	36	0.655			
The ethical limits of telenutrition are clearly defined by law.	34	66	53	47	0.007			
Although I like to provide/receive services in the hospital/clinic environment, the current conditions lead me to telenutrition.	58	42	66	34	0.244			
* A Chi-square test was administered. Since the number of participants was 100 for both dieticians and clients/patients, n and % are equal.								

## Discussion

This study was conducted to learn the perceptions of dietitians who actively provided tele-nutrition and clients/patients who received tele-nutrition during the study period, to determine the current situation and to comment on what can be done in the future to develop tele-nutrition to improve communication in health services. In terms of the age range and gender of the participants in the study, it was observed that telefeeding was more preferred by younger people and women. The study conducted by Pierce and Stevermer (15) found that women, people aged 45-65 years and people over 65 years preferred telemedicine services during the pandemic. Since Turkey is an economically developing country and middle-aged and older people are culturally distant from technology, we may have obtained a different result from Pierce and Stevermer (15). According to 2022 data from the Turkish Statistical Institute (16), it is observed that the age group of 65-74 has the lowest rate of internet usage at 36.6%. This rate is 64.2% in the 55-64 age group and 83.6% in the 45-54 age group. The main benefits of telenutrition are that clients/ patients do not have to travel for consultations, struggle with parking, or endure waiting rooms. This allows them to access services from the comfort of their own homes, which is particularly important for elderly patients (12). The older age group may find it difficult to get to the hospital/clinic due to various comorbidities and may be confined to bed. Therefore, tele-nutrition in this age group should be promoted and at least basic information should be made available on social networks often used by governments or hospital administrations. In this way, it can be ensured that elderly customers/patients will receive a more appropriate service in the context of home health care.

When analyzing the data on telenutrition, it is clear that weight loss diets are at the top of the list for both dietitians and clients/patients. With the global obesity epidemic, dietitians in many countries are primarily focused on developing weight-loss diets and monitoring dietary habits (17). In this study, telenutrition was most commonly used for weight loss diet. So, this was an expected finding. The second area where dietitians frequently provide telenutrition is the follow-up of metabolic diseases. Congenital metabolic diseases (etc. phenylketonuria, glycogen storage disease)) are common in Turkey due to frequent consanguineous marriages (18). Lifelong medical nutrition therapy should be strictly maintained in metabolic diseases (19). In this population with rare diseases, many comorbidities, especially mental problems, are encountered if medical nutrition therapy is not adhered to (19).

In addition, since the number of dietitians working on congenital metabolic disease is limited, it may be difficult for patients who are not in the center to access a dietitian (19). Proper utilization of telenutrition will have positive results, especially for this patient group. Recent studies conducted with patients with phenylketonuria during the pandemic have found that the management of the disease (such as decreasing the frequency of drain diets and keeping phenylalanine values within the target range) is easier with the use of telenutrition (20, 21). Maintaining communication even in situations such as pandemics and natural disasters where the stress level increases significantly is another important step in ensuring the metabolic stabilization of patients. It is predicted that the widespread use of telenutrition in the follow-up of metabolic diseases will have positive results for patients.

When the reasons for preferring telenutrition were evaluated, it was found that clients/patients who could not find time to go to the hospital/clinic due to their busy daily routine and individuals whose dietitian was in a different city preferred telenutrition more frequently. Indeed, these processes constitute the most prominent positive aspects of telehealth services (22). Nowadays, many people's daily routines and work lives are very busy, causing them to live with time limitations and neglect themselves and their health. The fact that the dietitian from whom the person wants to receive medical nutrition therapy is in a different city also brings time and cost problems. Telenutrition is very useful in this respect. Thanks to telenutrition, even people living in different countries can communicate easily. In today's world where time limitations and economic problems are increasing day by day, it is predicted that promoting telenutrition will have beneficial results in this sense.

When analyzing the responses of the dietitians and the clients/patients to the survey questions, it was found that the opinions of both sides were similar on many questions (p>0.05, there was no difference between the groups, Table 1). In terms of anthropometric measurements, clients/patients were more worried than dietitians about not being measured by the expert. This situation was confirmed by the answers of the clients/patients to the open-ended question "What are your suggestions to improve telenutrition" as "I am not sure when I take my

measurements myself, I want to meet face to face on my measurement days, etc.". Anthropometric measurements are parameters that are one of the important indicators of the medical nutrition therapy process and should be taken in detail by experts in accordance with the technique (23). In order to eliminate this disadvantage, detailed education can be given to the clients/patients, the education given can be recorded and the clients/ patients can watch this education later, the dietitian can watch the clients/patients via video conferencing while the clients/patients are measuring, or face-to-face meetings can be held on measurement days. Augmented virtual reality applications can be developed for this process, and anthropometric measurements can be taken by performing three-dimensional environmental measurements of the individual in front of the screen with the help of artificial intelligence.

Approximately 20.0% of the clients/patients reported that they sometimes questioned the quality of the telenutrition service they received because they did not have sufficient knowledge and experience in social networks. Their ability to use social media may limit care for some clients/patients, or not all clients/patients may have access to the technology required for telenutrition (12). In this direction, it may be recommended that dietitians should determine whether the candidate who wants to receive this service is the right person before starting to provide telenutrition service and, if necessary, get support from an informatics expert for their clients/ patients. In addition, applications with simple interfaces can be developed and offered to the clients/patients. The use of these applications by other health professionals (doctors, physiotherapists, psychologists, etc.) will also increase the quality of the service provided.

44% of clients/ patients stated that they frequently change their appointments due to the time-flexible system. Continuity of treatment and regular followup of treatment in health services is a very important factor in achieving the targeted success. This situation is frequently emphasized in many studies in the literature (24-26). Medical nutrition therapy is a process that requires discipline. Clients/patients should be warned about regular follow-up appointments. It is thought that this situation will be prevented by setting rules for appointment follow-up (deterrent rules such as not being able to benefit from telenutrition for a while in case of frequent appointment changes). Social insurance processes, legal aspects, and ethical limits are other issues that need to be clarified regarding telenutrition. Implementations such as placing the telenutrition service, whose usage rate is increasing day by day, into the reimbursement process, evaluating it within home care services for the elderly age group, and monitoring the scope and invoice codes for telenutrition visits can be realized. The evaluations to be made within the framework of regulations and legislation will help these processes to proceed faster. On 10 February 2022, "Regulation on the Delivery of Remote Health Services" was published (27). It is projected that having a subheading for telenutrition in the relevant regulation is one of the most important steps to be taken toward clarifying the official dimensions of telenutrition.

In future studies to be carried out in this field, participants can be classified according to the regions they live in (rural, urban) the regional utilization rate of telenutrition, and the aspects of telenutrition that need to be developed according to the regions can be determined. In this study, the fact that no comparison was made according to regions constitutes the limitation of the study.

## Conclusion

Telenutrition has become a necessity today because of the time constraints experienced by many people because of their busy daily routine, the difficulties experienced in hospital/clinic arrival and hospital/clinic, especially in the elderly age group, pandemics, and natural disasters. In this direction, the steps to be taken to improve telenutrition (ensuring access to technology for all populations, increasing the knowledge and skill level of people for the use of social networks, determining the official processes of telenutrition, etc.) will increase the quality of telehealth services, communication in health care and improve public health.

## **Acknowledgments**

We would like to thank all clients/patients and dietitians who participated in our study.

## **Declarations**

## Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-forprofit sectors.

### Conflict of interest

The authors declare that they have no conflict of interest.

#### Ethics approval

This study was conducted according to the guidelines laid down in the Declaration of Helsinki. Approval from the Cappadocia University Scientific Research and Publication Ethics Committee (28.08.2023/23.14)) was obtained for the study.

#### Availability of data and material

The data sets are available in the Mendeley Data Repository.

#### Authors' contributions

Conceptualization: HKB, NÖ; Methodology: HKB, NÖ; Formal analysis and investigation: HKB, NÖ; Writing original draft preparation: HKB; Writing - review and editing: HKB, NÖ; Supervision: NÖ.

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Health Policy / Sağlık Politikası

# Analysis of Differences in Health Service Use by Socio-Economic Development Level in Turkey

## Nazan Kartal<sup>1</sup>

ABSTRACT

**Purpose:** In this research, comparisons were made with the socioeconomic development levels of the provinces in Turkey using some variables related to the use of health services.

**Methods:** SEGE-2017 index was used for the socio-economic development level, and the number of applications to physicians per person, the total number of applications to health institutions, the bed occupancy rate and the total number of surgeries were used for the health services utilization. Within the scope of the research, the provinces were ranked as low, medium and high according to the SEGE index and estimations were made according to the health services utilization.

**Results:** It was observed that the created model was 75.3% successful with logistic regression. According to the research results, it can be said that the socioeconomic development levels of the provinces are also reflected in the health services utilization. However, it is seen that the model fails to estimate the health services utilization in some provinces.

**Conclusion:** As a result, it is thought that the use of services can be facilitated if the difficulties in accessing health services are eliminated. It can be said that the factors affecting the use of health services and the planning of health services in these provinces should be reviewed.

Keywords: Health, Health Services Utilization, Socio-Economic Development, Turkey.

#### ÖZET

Amaç: Bu çalışmada sağlık hizmet kullanımına ilişkin bazı değişkenler kullanılarak Türkiye'deki illerin sosyo-ekonomik gelişme düzeyleri ile karşılaştırmalar yapılmıştır.

**Yöntem:** Sosyo-ekonomik gelişmişlik düzeyi için SEGE-2017 indeksi, sağlık hizmet kullanımını için de kişi başı hekime başvuru sayısı, sağlık kurumuna toplam başvuru sayısı, yatak doluluk oranı ve toplam ameliyat sayısı değişkenleri kullanılmıştır. Araştırma kapsamında, iller SEGE indeksine göre düşük, orta ve yüksek düzey olarak sıralanmış ve sağlık hizmet kullanımına göre tahminleme yapılmıştır.

**Bulgular:** Lojistik regresyon yöntemiyle oluşturulan modelin %75,3 oranında başarılı olduğu görülmüştür. Araştırma sonuçlarına göre, illerin sosyoekonomik gelişmişlik düzeylerinin sağlık hizmet kullanımına da yansıdığı söylenebilir. Ancak bazı illerde modelin sağlık hizmet kullanımını tahmin etmede başarısız olduğu görülmektedir.

**Sonuç:** Sonuç olarak, sağlık hizmetlerine erişimin önündeki zorlulukların ortadan kalkması durumunda hizmet kullanımında kolaylık sağlanabileceği düşünülmektedir. Bu illerde sağlık hizmet kullanımına etki eden faktörlerin ve sağlık hizmeti planlamasının gözden geçirilmesi gerektiği söylenebilir.

Anahtar Kelimeler: Sağlık, Sağlık Hizmet Kullanımı, Sosyo-Ekonomik Gelişmişlik, Türkiye

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Received: 30.12.2024 Accepted: 27.01.2025 hile economic indicators such as gross domestic product and employment levels were previously considered the most important indicators of development, this understanding has evolved over time. The view that factors related to social development should also be taken into account has gained widespread acceptance. A number of studies have been conducted which compare countries, provinces and regions with a view to determining the level of socioeconomic development. In these studies, which seek to identify and compare development differences and similarities, a ranking is typically produced using an index based on a range of indicators (1).

One such study is the Socio-Economic Development Ranking Studies (SEGE), which provides comparative analyses that objectively measure the socio-economic development levels of Level-2 regions, provinces and districts in Turkey. The objective of this study is to inform the development of various policies and strategies. The current SEGE study at the provincial level is SEGE-2017 (2). The SEGE-2017 index was constructed through the application of principal component analysis to a data set comprising 52 variables organised under eight headings: namely, demography, employment, education, health, competitive innovative capacity, finance, accessibility and quality of life (3). The results of the analysis led to the creation of the socio-economic development index scores and ranks for the provinces and regions, as well as the division of the provinces into six groups according to development levels and the Level-2 regions into four groups according to development levels (2).

An understanding of the factors that affect the utilisation of health services, particularly those resulting from unequal access, can assist policy makers in the planning of more effective policies and the reduction of undesirable conditions (4). In examining equity in access to health services in relation to need, it is first necessary to define the term 'need'. The term 'need' can be conceptualised in various ways. It can be defined as the initial health status, the capacity to benefit from care, the amount of care a person needs to achieve health equity, or the care required to achieve the highest possible health improvement (5). Nevertheless, in practice, need is frequently gauged in terms of health status (6,7).

The number of applications to health institutions, the number of applications to physicians per person, the procedures requested in examinations (MR imaging, CT imaging, ultrasound, doppler ultrasound, echo, mammography, etc.), the number of follow-ups (pregnancy, infant, child, puerperal), the number of surgeries performed, vaccination, births in health institutions, antenatal care coverage, etc. are indicators of health service use (8). As outlined by the OECD (9), indicators pertaining to the utilisation of health services encompass screening, diagnosis, prevention, vaccination activities, the average length of stay, transplants, acute care, dialysis, inpatient care, bed utilisation and discharge rates.

A review of the literature reveals a multitude of studies utilising diverse health indicators at the provincial level in Turkey. A selection of these studies is included in this section. Nevertheless, the number of studies that examine the relationship between the utilisation of health services at the provincial level and the level of development is relatively limited. It is anticipated that the present study will contribute to the existing literature by elucidating the discrepancies in the utilisation of healthcare services according to the level of socioeconomic development.

In their study, Kuvvetli and Dolu (1) corroborated the hypothesis that the level of socio-economic development in Turkey exhibited a decline from the cities in the west to those in the east. Furthermore, they substantiated the assertion that disparities in regional development were attributable to the index they devised through principal component analysis. In light of these findings, it was concluded that while major urban centres such as Istanbul, Ankara and Izmir exhibited the highest levels of general socio-economic development, the Ağrı, Şırnak and Hakkari provinces demonstrated the lowest.

In their 2023 study, Işıkçelik and Günaltay (10) employed the multidimensional scaling method using 2021 data pertaining to various health indicators. Their findings indicated that Istanbul was situated in a distinct position, while the provinces of Tunceli and Bayburt exhibited the most negative values.

Dörtkol (11) posited that the provinces with the highest scores as a result of the combined health index, developed on various health determinants such as education, income, employment, demography, air quality, physical environment, housing-infrastructure, health infrastructure and health workforce, along with various health outcomes, were Bolu, Karabük, Ankara, Trabzon and Istanbul, respectively. Conversely, the provinces with the lowest scores were Hakkari, Şanlıurfa, Muş, Ağrı and Şırnak. In a study published in 2022, Erkiliç (12) compared the infrastructure and human resource indicators of public health services by region using the CRITIC and TOPSIS methods. The study concluded that there is a need for greater investment in public health services, particularly in terms of infrastructure and human resources, with a focus on low-performing regions. This investment should aim to eliminate regional disparities in infrastructure and human resource status and allocation, as well as to improve infrastructure and human resource indicators.

The study conducted by Eren and Ömürbek (13), which classified Turkish provinces according to their health indicators using the MULTIMOORA method, revealed that regional disparities in development also resulted in significant variations in health outcomes.

In a study conducted by Gençoğlu (14), the development levels of provinces in terms of health indicators were examined using cluster analysis with data from 2015. The study revealed a positive correlation between the social and economic development levels of the provinces and the quality of health services.

In their 2013 study, Çelik (15) classified the provinces according to their health indicators in 2010, with the aim of examining the development and differences in health across the regions. The results of the cluster analysis indicated that the provinces could be grouped into ten distinct clusters. The analysis revealed that Hakkari, Şırnak, Şanlıurfa, Van, Kilis, Muş and Ağrı exhibited the most unfavourable health outcomes. The research findings revealed that provinces with similar characteristics, such as underdevelopment and small size, were grouped together in the same clusters.

# Methods

Despite the abundance of research employing provincebased health indicators, as previously noted, no study has examined socio-economic development levels exclusively through the lens of health service utilization variables. Consequently, this study is poised to make a significant contribution to the existing literature by underscoring this crucial relationship.

The study covered 81 provinces in Turkey. The study used the latest SEGE-2017 index data published at the provincial level to measure the level of socio-economic development (3). To measure the use of health services,

the number of physician applications per person, the number of surgeries, the bed occupancy rate and the total number of applications to health facilities were used. These variables related to the use of health services were taken from the data of the Health Statistics Yearbook 2019 (16). Although more recent data are available, the reason for preferring the 2019 data is that it was considered more accurate to choose a more recent date, as the SEGE index data belong to 2017. All statistical analyses were carried out using SPSS 26 (Statistical Package for the Social Sciences). Logistic regression analysis was used to analyse the data. Prior to the implementation of logistic regression analysis, province groups were categorized into six classes based on the SEGE-2017 index. These groups were then reduced to three classes and subsequently ranked as low, medium, or high. Provinces were also grouped according to health service use variables, with the classification system including categories of low, medium, and high. Consequently, the categorization of provinces in terms of health service utilization and socio-economic development levels was compared.

# **Findings**

Looking at Table 1 and examining the model fit information (LR  $\chi^2$  =76.232; sd.=8; p=.000) and the Pearson ( $\chi^2$  =161.464; sd.=152; p=.281) and deviation ( $\chi^2$  =91.497; sd.=152; p=1.000) values, it can be seen that the established model is statistically significant and shows a good fit to the real data. It is also noted that the pseudo R2-squared values are high.

Table 1: Model Fitting Results								
Model Fitting Information								
	-2 Log Likelihood	Chi-Square	df	Sig.				
Intercept Only	167,729							
Final	91,497	76,232	8	0,000				
Goodness-of-Fit								
	Chi-Square	df	Sig.					
Pearson	161,646	152	0,281					
Deviance	91,497	152	1,000					
	Pseudo R-Squ	Jare						
Cox and Snell	0,610							
Nagelkerke	0,698							
McFadden	0,454							

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In logistic regression analysis, the significance of the coefficients of the independent variables is tested using the likelihood ratio test. Looking at the information in Table 2, we can see that the effect of the number of physician applications per person is statistically significant at the 0.05 level, while the effects of variables such as the number of surgeries, the total number of the applications to health facilites and the bed occupancy rate are not significant.

Table 3 shows the results of the multinomial logistic regression analysis. Taking the reference category as high level, it was found that only the variable number of physician applications per person was statistically significant for assignment to low level. It was found that there was no statistically significant variable for assignment to the medium level.

Table 2: Likelihood Ratio Tests								
Likelihood Ratio Tes	sts							
	-2 Log Likelihood of Reduced Model Chi-Square df							
Intercept	115,463	23,966	2	0,000				
Physician applications per person	142,211	50,713	2	0,000				
Total surgeries	92,057	0,559	2	0,756				
Bed occupancy rate	96,677	5,179	2	0,075				
Applications to health facilities	91,932	0,435	2	0,805				

	Table 3: Multinominal Logistic Regression Test Results									
		В	Std. Error	Wald	df	Sig.	Exp(B)			
Low	Intercept	26,165	7,423	12,425	1	0,000				
	Physician applications per person	-3,657	0,937	15,222	1	0,000	0,026			
	Total surgeries	0,000	0,000	0,462	1	0,497	1,000			
	Bed occupancy rate	0,125	0,085	2,148	1	0,143	1,133			
	Applications to health facilities	0,000	0,000	0,311	1	0,577	1,000			
Medium	Intercept	7,554	4,271	3,128	1	0,077				
	Physician applications per person	-0,427	0,414	1,066	1	0,302	0,652			
	Total surgeries	0,000	0,000	0,149	1	0,699	1,000			
	Bed occupancy rate	-0,023	0,049	0,218	1	0,640	0,978			
	Applications to health facilities	0,000	0,000	0,014	1	0,906	1,000			
(Referance c	ategory: High level)						•			

The estimation results of the logistic regression model are shown in Table 4. 9 out of 20 cities in the high category were correctly predicted and 45% successful classification was achieved for this level. All 11 cities in the high category that were incorrectly classified were classified in the medium category. 35 out of 41 cities in the medium category were correctly classified and 85.4% classification success was achieved. 5 of the cities misclassified at this level were classified as high level and 1 as low level. 17 out of 20 cities in the low level category were correctly classified and 85% classification success was achieved. All 3 cities misclassified as low level were classified as medium level. The overall classification success of the analysis was calculated as 75.3%.

Table 4: Classification Results of Logistic Regression Analysis							
	Low	Medium	High	Percent Correct			
Low	17	3	0	85,0%			
Medium	1	35	5	85,4%			
High	0	11	9	45,0%			
Overall Percentage	22,2%	60,5%	17,3%	75,3%			

Table 5: Estimation of SEGE Level of Provinces According to the Model										
Provinces	SEGE Level	Health Utliziation Level		Provinces	SEGE Level	Health Utliziation Level		Provinces	SEGE Level	Health Utliziation Level
Adıyaman	2	3		Burdur	2	2		Sinop	2	3
Ağrı	1	1		Çankırı	1	1		Sivas	1	1
Ardahan	2	2		Çorum	1	1		Tokat	2	2
Batman	1	1		Düzce	2	3		Trabzon	2	2
Bayburt	2	2		Edirne	3	3		Tunceli	3	2
Bingöl	3	3		Elazığ	2	3		Uşak	2	2
Bitlis	3	3		Erzincan	3	3		Zonguldak	2	2
Diyarbakır	2	2		Erzurum	3	3		Ankara	2	2
Gümüşhane	3	3		Gaizantep	1	1		Antalya	1	1
Hakkari	2	2		Giresun	2	2		Aydın	2	2
lğdır	3	2		Hatay	3	2		Bilecik	1	1
Kars	1	1		Kahramanmaraş	3	2		Bolu	1	2
Kilis	1	1		Karabük	2	1		Bursa	2	2
Mardin	3	2		Karaman	3	3		Çanakkale	2	2
Muş	2	2		Kastamonu	3	3		Denizli	1	1
Siirt	3	3		Kırıkkale	2	2		Eskişehir	2	2
Şanlıurfa	3	2		Kırşehir	2	2		lsparta	2	2
Şırnak	2	2		Kütahya	2	2		İstanbul	1	1
Van	2	2		Malatya	2	2		İzmir	1	1
Yozgat	3	2		Manisa	1	1		Kayseri	2	2
Adana	1	1		Mersin	3	2		Kırklareli	1	2
Afyon	2	2		Nevşehir	1	1		Kocaeli	1	1
Aksaray	2	2		Niğde	2	2		Konya	3	2
Amasya	2	2		Ordu	2	2		Muğla	2	2
Artvin	2	2		Osmaniye	2	2		Sakarya	1	2
Balıkesir	3	2		Rize	2	2		Tekirdağ	2	2
Bartın	2	3		Samsun	3	2		Yalova	2	2

In order to examine the results in more detail, the estimated level of each city was determined according to the logistic regression analysis and the results are compared in Table 5. In the table, the levels are coded as 1: low level, 2: medium level and 3: high level.

## Discussion

In this study, comparisons were made with the socioeconomic development levels of the provinces in Turkey using some variables related to the use of health services. In this context, the provinces were classified as low, medium and high according to the SEGE index and estimates were made according to the use of health services. It was found that the model created was 75.3% successful. According to the research results, it can be said that the level of socio-economic development of the provinces is also reflected in the use of health services. However, it was observed that the model failed to estimate the use of health services in some provinces. It was observed that there were some provinces with high SEGE levels but low use of health services (Iğdır, Mardin, Urfa, Yozgat, Balıkesir, Hatay, Maraş, Karabük, Mersin, Samsun, Tunceli and Konya). In the provinces with low SEGE levels and high service utilisation (Adıyaman, Bartın, Düzce, Elazığ, Sinop), this situation can be explained by the application of public service obligations and sufficient investment in health. It is believed that if the difficulties in accessing health services are eliminated, the ease of use of services can be achieved. It can be said that the factors affecting the use of health services and the planning of health services in these provinces should be reviewed.

Gözlü and Tatlıdil (17) examined the access to health services of provinces using principal component analysis with different variables, including the use of health services. According to the results, Istanbul, Gaziantep and Kocaeli are the provinces with the highest access to services, while Bayburt, Ardahan and Tunceli are the provinces with the lowest access to services. When the data from the study were compared with the SEGE-2011 index, it was found that some eastern and southeastern Anatolian provinces such as Şanlıurfa, Batman, Mardin, Diyarbakır, Şırnak, Ağrı, Adıyaman, Van, Siirt and Muş have higher access to health services but are lower in the SEGE ranking.

Doğan (18) conducted a cluster analysis on the total amount of investment in the health sector under the Investment Incentive System, which is a continuous variable for the period 2001-2018, the number of hospitals, the number of beds per capita, the number of general practitioners and specialists per capita, the number of medical applications per capita, the level of drug use (DID) per capita, the population and the mortality rate, and the level of socio-economic development of the provinces (SEGE 2017), which is a categorical variable for the 81 provinces in Turkey. As a result of the research, 77 provinces were divided into 4 clusters. It was found that the fourth cluster consisted of the provinces with the lowest level of socio-economic development and the smallest population. It was found that the number of hospitals, the amount of investment under the Investment Incentive System, the number of beds per capita, the number of general practitioners and specialists per capita, the amount of daily medicine consumption, the number of medical consultations per capita and the mortality rate were the lowest in these provinces.

Keleş (19) examined the provinces in Turkey by ranking them according to health indicators, including health service utilisation indicators, using various multicriteria decision methods and found that provinces with small populations ranked lowest in terms of health performance. Köse (20) used cluster analysis to classify 12 statistical regions according to 2019 health service demand, production and capacity data. They found that the clustering of regions was influenced by the parameters of geographical proximity and population density, as well as the level of socioeconomic development. Kar and Özer (21) compared health care infrastructure, service use and health outcomes across statistical regions in Turkey. They found that Western Anatolia was the region with the highest use of health services, while Central-Eastern Anatolia was the lowest.

In 2005, maternal mortality rates were high in developing countries, in contrast to developed countries. Studies suggest that a significant proportion of maternal deaths could be prevented by providing access to essential maternal health services (22-24). It can be said that people living in poor and rural areas and small towns use health services at lower levels than other segments of society due to difficulties in accessing health services in terms of quantity and quality. This leads to differences in healthcare needs between different segments of society (25). Therefore, the removal of physical and financial barriers to accessing healthcare services is likely to have an impact on the use of healthcare services.

## Conclusion

It is suggested that future studies could benefit from different health and population indicators and different decision making techniques that vary according to the regional level. Furthermore, data from disparate years can be employed to ascertain whether the status of the provinces has undergone a transformation with respect to socio-economic development. Moreover, it should not be assumed that countries' health systems are independent of socio-economic development. A significant part of the sustainable development goals are directly and indirectly related to health. It is therefore evident that further studies are required which emphasise the relationship between development and health in developing countries such as Turkey. Also, when examining health indicators according to socioeconomic development status between provinces and regions, it is imperative to consider inequalities in health service utilization and to remove obstacles to health service utilization.

## **Declarations**

#### **Ethics Approval**

In this study since secondary data were used, there is no need for ethics committee approval.

#### **Conflicts of Interest**

No conflicts of interest to declare.

#### Availability of Data and Material

Yes.

### Funding

This study received no specific grant from any funding agency, commercial entity, or not-for-profit organization.

#### **Acknowledgments**

No to report.

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Health Care Administration / Sağlık Hizmetleri Yönetimi

# A Systematic Review on the Results of the Coordinator Approach in Transcatheter Aortic Valve Implantation

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#### ABSTRACT

**Purpose:** Communication and coordination between the patient, family, and heart team members remain a managerial challenge, although the heart team approach considers the Transcatheter Aortic Valve Implantation (TAVI) management multidimensional. The managerial difficulties of the TAVI have been overcome by a coordinator, usually a nurse, who is called the TAVI coordinator. This systematic review aims to holistically reveal the results of the coordination approach in TAVI management.

**Methods:** With the search designed based on study purpose in databases, 445 studies were identified [Science Direct (n=259), Scopus (n=62), Google Scholar (n=43), Medline+TR Index (n=13), PubMed (n=12), Web of Science (n=10), Emerald (n=4), Citations (n=42)]. Twenty-eight (28) studies were synthesized after systematic screening based on study criteria. The systematic review process used a systematic search and review typology. The research process was implemented based on the "PRISMA" checklist.

**Results:** Results indicated that TAVI or valve structural heart coordination accelerates the pathway, increases patient satisfaction, optimizes resource use, and reduces costs, helping to prevent medical error.

**Conclusion:** This study reveals the positive results of the coordination approach on the team, patient and hospital. It can bring the approach to the agenda of clinic and hospital managers as a managerial tool.

Keywords: Transcatheter aortic valve replacement, Hospital administration, Patient care team

#### ÖZET

Amaç: Kalp takımı yaklaşımı Transkateter Aort Kapak İmplantasyonu (TAVI) yönetimini çok boyutlu olarak ele alsa da hasta, aile ve kalp takımı üyeleri arasındaki iletişim ve koordinasyon, yönetimsel bir zorluk olmaya devam etmektedir. TAVI'nin yönetimsel zorlukları, TAVI koordinatörü olarak adlandırılan, genellikle hemşire olan bir koordinatör tarafından aşılmaktadır. Bu sistematik derleme, TAVI yönetiminde koordinasyon yaklaşımının sonuçlarını bütünsel olarak ortaya koymayı amaçlamaktadır.

**Yöntem:** Veri tabanlarında [Science Direct (n=259), Scopus (n=62), Google Scholar (n=43), Medline+TR Dizin (n=13), PubMed (n=12), Web of Science (n=10), Emerald (n=4), Citations (n=42)] çalışma amacına uygun olarak tasarlanan tarama sonucunda 445 çalışma belirlenmiştir. Çalışma kriterlerine dayalı sistematik taramanın ardından yirmi sekiz (28) çalışma sentezlenmiştir. Sistematik inceleme sürecinde sistematik bir arama ve inceleme tipolojisi kullanılmıştır. Araştırma süreci "PRISMA" kontrol listesi esas alınarak uygulanmıştır.

**Bulgular:** Sonuçlar, TAVI, kapak veya yapısal kalp koordinasyonunun hasta süreçlerini hızlandırdığını, hasta memnuniyetini artırdığını, kaynak kullanımını optimize ettiğini, maliyetleri düşürdüğünü ve tıbbi hataların önlenmesine yardımcı olduğunu göstermektedir.

**Sonuç:** Bu çalışma, koordinasyon yaklaşımının kalp takımı, hasta ve hastane üzerindeki olumlu sonuçlarını ortaya koymaktadır. Bu çalışma koordinasyon yaklaşımını bir yönetim aracı olarak klinik ve hastane yöneticilerinin gündemine getirebilir.

Anahtar Kelimeler: Transkateter aort kapak değişimi, Hastane yönetimi, Hasta bakım ekibi

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Received: 10.02.2024 Accepted: 13.01.2025 he access and scope of health services have been increasing with the development of technology. One of these areas is aortic stenosis (AS) treatment, which has a very high prevalence in the elderly population and is fatal. The surgical approach in treating AS was dominant in the past, but now, this treatment can be performed invasively with recent technologies. Transcatheter Aortic Valve Implantation (TAVI) is an invasive treatment method used successfully in treating AS.

TAVI is an invasive treatment process that requires a multidisciplinary team and many logistic factors (1, 2). In addition, considering that AS patients who undergo TAVI intervention are mostly over the age of 65–85 and have accompanying geriatric diseases, the fragility levels of these patients are also high. These issues make TAVI management more complex.

The TAVI in treating AS has been increasing over time, and the population age for which TAVI has been applied is gradually decreasing. The management processes of this treatment also evolved with the development of TAVI. A multidisciplinary heart team management was introduced to conduct the complex structure of the TAVI effectively and safely. The heart team includes a cardiologist, cardiovascular surgeon, radiologist, anesthesiologist, anesthesia technician, nurse, radiology technician, and clinical support staff. Depending on the patient's comorbidities, additional specialties might be included in the heart team. Although the heart team approach considers the TAVI management process multidimensional, communication and coordination between the patient, family, and heart team members remain a managerial challenge. The managerial difficulties of the TAVI have been overcome by a coordinator, usually a nurse, who is called the TAVI coordinator. However, the name of the TAVI coordinator varies in the literature (TAVI, TAVR, Valve, or Structural Heart Coordinator), whose primary duties and responsibilities are quite similar (3, 4). The primary purpose of the TAVI coordinator is to ensure effective coordination of the multi-stage TAVI treatment process, which requires a multidisciplinary team, from patient selection, logistics, human resources to communication during, pre, post-procedure and followup treatments, without deficiencies and interruptions (5). The TAVI has been managed to be safer, more effective, and more efficient with the TAVI coordination approach in many countries in Europe (6-10) and the United States of America (USA) (4, 5, 11-13). There are systematic review studies on the TAVI process and its medical outcomes. However, there is no systematic review study regarding the coordinator approach in TAVI process management in the literature. This systematic review aims to holistically reveal the results of the coordination approach in TAVI management. In this context, the following research questions were posed:

- 1. What is the distribution of studies on TAVI coordination by years and countries?
- 2. What are the methodological approaches used in the studies conducted on TAVI coordination?
- 3. What are the literature findings regarding the health outcomes of the TAVI coordination approach?
- 4. What are the literature findings concerning the managerial result of the TAVI coordination approach?

## 2. Material Method

*Research Method:* This study used a systematic review methodology to examine studies on the coordinator approach in managing TAVI. The systematic review process used a systematic search and review typology. The research process was implemented based on the "PRISMA" checklist developed by Page and McKenzie (14).

Search Strategy: In order to find studies suitable for the research purposes, all types of studies were obtained with the search criterion of ["Transcatheter Aortic Valve Implantation" or "Transcatheter Aortic Valve Replacement" or "TAVI" or "TAVR" or "VALVE" or "STRUCTURAL HEART" and "COORDINATOR" in "all field"]. The database search was conducted between December 1-15, 2023.

Inclusion and Exclusion Criteria: Criteria for inclusion in the study were as follows: the studies were determined to be conducted in the field of health services, to present findings, results, ideas, or comments regarding the coordination management approach in structural heart diseases, especially TAVI, and to be written in English. Exclusion criteria were as follows: studies were out of healthcare and unrelated to the research topic, unable to access the full text, and not presenting findings, results, ideas, or comments regarding the management process of structural heart diseases and TAVI in healthcare.

Including Studies: In databases search, 445 studies were identified [Science Direct (n=259), Scopus (n=62), Google Scholar (n=43), Medline+TR Index (n=13), PubMed (n=12), Web of Science (n=10), Emerald (n=4), Citations (n=42)].

The databases were selected based on their relevance and scope in medical and healthcare research. ScienceDirect, Scopus, PubMed, and Web of Science were chosen for their coverage of peer reviewed. Google Scholar was included to ensure a broader search scope. Medline+TR Index was selected to incorporate relevant Turkish medical studies, while Emerald focused on health management and policyrelated research. Citation tracking was used to identify additional relevant studies. The systematic screening process for the studies identified through the research strategy is illustrated in Figure 1. In the duplicate analysis, 39 studies identified by the EndNote software (n = 30)and the researchers (n = 9) were excluded. The remaining 406 studies were evaluated in terms of study name and abstract, and 332 studies unrelated to the study purpose were excluded. The remaining 74 studies were included in the full-text guality assessment. A total of 53 studies were excluded, the full text of which could not be accessed (n = 5), and studies unrelated to the study purpose (n = 48). During the full-text quality control process of the studies, citation scanning was performed, and five studies were included in the remaining 23 studies in the scope of the research. After the systematic search, 28 studies were synthesized.

*Synthesis and Presentation of the Findings:* A narrative and tabular approach was used to synthesize and present the findings of previous studies.

*Limitation of Study:* The study findings are limited to the English language publications found in the databases as a result of the search. Moreover, since the randomized controlled study on the research topic was limited, the findings of all study types were evaluated.



## 3. Results

The studies (n=28) of the TAVI coordinator approach within this research purpose were published between 2011 and 2023. 2019 (n=6) and 2022 (n=6) were the years in which the most frequent studies on TAVI coordinators were published. No studies regarding TAVI coordinators were published in 2015 and 2017. The key characteristics of the included studies are summarized in Table 1. Considering the country distribution of the studies on TAVI coordinators, all were published in countries with developed health systems. The USA (57.14%, n=16) and Canada (17.86%, n=5) were the countries with the most frequent studies on TAVI coordinators. Regarding

methodology, 42.84% (n=12) of the studies were based on literature and interpretation. Only 7.14% (n=2) of the studies within the scope of the research were interventioncontrol studies. Furthermore, 10.7% of the studies were TAVI pathway designs with the TAVI coordinator approach. The remaining studies were descriptive, qualitative, report, core curriculum, and retrospective archive screening. The 28 studies included in this review varied in sample size, selection criteria, and homogeneity. Sample sizes ranged from small qualitative cohorts to large prospective studies. While some studies included homogenous groups, such as TAVI patients, others examined broader populations with structural heart diseases (Table 2).

Table 1. Characteristics of Studies								
Characteristics n %								
	USA	16	57,14					
	Canada	5	17,86					
<b>C</b>	Germany	2	7,14					
Country	Australia	2	7,14					
	Holland	2	7,14					
	France	1	3,57					
	Book Section	4	14,29					
	Review	3	10,71					
	Idea, statement, editorial	6	21,43					
	Prospective Case Follow-up	3	10,71					
	Prospective Program Development	3	10,71					
Study Types &	Intervention-Control Study	2	7,14					
Research Methodology	Descriptive	2	7,14					
	Panel	1	3,57					
	Qualitative	1	3,57					
	Report	1	3,57					
	Core Curriculum	1	3,57					
	Retrospective Archive Screening	1	3,57					
	Total	28	100					

The research results regarding the coordination approach in TAVI can be evaluated under two headings: patient outcomes and administrative outcomes. The TAVI coordinator approach does not have a negative impact on patient outcomes and is qualified as safe (7, 15). No other studies regarding direct patient outcomes have been found in the literature. When the managerial results are examined, publications show that the approach increases communication between all stakeholders in the TAVI process (7, 16), reduces long waiting times (9, 17), and helps efficient resource use (18, 19). The TAVI coordinator approach was also mentioned to have the potential to prevent medical errors (20). Summary findings for the studies included in the research are elaborated in Table 2.

	Table 2. Summary Findings of Studies									
No	Study	Aim	Place	Method	Sample	Conclusion				
1	(Batchelor et al., 2023, pp. 3-10)	To evaluate the development of a multidisciplinary cardiovascular team and the challenges	USA	Expert Panel	-	The coordinator is an important component of the multidisci- plinary heart team. The lack of a heart team approach in centers with low patient volume has been revealed as a limitation (13).				
2	(Adhami et al., 2023, p. 464)	To evaluate patients' experiences and perspectives on early recovery during transcatheter inter- vention processes	TAVI Clinic, Brit- ish Columbia, Canada	A Prospective Qualitative Study	12 patients	The necessity of a valve coordinator nurse in transcatheter inter- vention processes has been demonstrated. As the primary point of contact for open communication, the valve coordinator nurse is important during the long waiting periods of TAVI patients (16).				
3	(Lauck & Smith, 2022, p. 70)					Patients benefit from the coordination management practice applied in the management of structural heart diseases, and it is effective (12).				
4	(Clarke, 2022, p. 90)	To provide a guide for cardiovascular nurses and allied health	USA	Book (24)	-	The coordinator plays a pivotal role in the management of the diagnostic and follow-up processes of structural heart diseases and can contribute to the prevention of medical errors (20).				
5	(Frantzen et al., 2022, p. 127)	professionals in heart valve diseases.	05/	DOOK (24)		Because TAVI patients also have geriatric problems, coordinator practice is essential in TAVI process management (25).				
6	(Speight, 2022, p. 169)					The challenging but most important duties of TAVI coordinators are leading the TAVI team and ensuring effective communication (28).				
7	(Bohmann et al., 2022, pp.13-15)	To investigate the impact of the TAVI Coordinator Program	3 TAVI Centers GERMANY	A Prospective In- tervention-Con- trol Study	(81 intervention, 84 control TAVI patients)	TAVI coordinator programs can improve the TAVI process, in- cluding pre-and post-TAVI care and patient satisfaction, without compromising safety (7).				
8	(Lauck et al., 2022, p. 221)	To present best practice examples in TAVI programs.	Vancouver, Brit- ish Columbia, Canada	Statement	-	The TAVI coordinator practice is an example of an effective best method. TAVI coordination is an important administrative ele- ment for effective communication during the treatment process. Nurses play an important role in shortening discharge times (11).				
9	(Bennetts et al., 2021, pp. 1813- 1814)	To set minimum standards for TAVI center accreditation in Australia	AUSTRALIA	Statement	-	In centers that perform 30 TAVIs annually, the TAVI coordinator is included in the accreditation criteria as the main member of the heart team (6).				
10	(Lortz et al., 2021, p. 324)	To evaluate the effect of the TAVI coordina- tor system on hospi- tal stay times in TAVI interventions.	West German Heart Center, Germany	Interven- tion-Control Study	409 TAVI pa- tients (2014- 2017)	TAVI coordinator practice can shorten hospital stays (9).				
11	(Perpetua & Russo, 2021, p. 605)	To reveal the expe- riences gained from transcatheter struc- tural heart disease processes	USA	Editorial	-	Triage by coordinators is important in the process of structural heart disease and resource use (18).				
12	(Elizabeth M. Perpetua et al., 2021, p. 173)	To make recommen- dations to optimize the care process in the structural heart program	USA	Review	-	There is a coordinator nurse role in recommendations for the coordination of the structural heart disease process (30).				
13	(De Ronde-Till- mans et al., 2020, p. 40)	Establish and eval- uate the Rotterdam TAVI care and treat- ment program.	HOLLAND	Program Desing	Single-center program design	The TAVI coordinator is one of the important elements of the project and coordinates the entire TAVI process (pre-, operation and post) (8).				
14	(Lauck et al., 2020, p. 538)	Making recommen- dations for the TAVI program during COVID-19	CANADA	Statement	-	The COVID-19 period proved the necessity of a nurse-led coordi- nation system in TAVI management (26).				
15	(Van Wiechen et al., 2020, p. 286)	Recommending a lean TAVI manage- ment process at all stages, from patient selection to post-pro- cedure	HOLLAND	Statement	-	The coordinator plays a vital role in the lean TAVI management and early discharge of patients (10).				
16	(Straiton et al., 2020, p. S409)	Examining the role of the coordinator in structural heart dis- ease management	AUSTRALIA	Descriptive Study	18 public hos- pitals	A structural heart coordinator existed in 10 of 18 public hospitals. They were mostly responsible for coordinating many structural heart diseases such as TAVI, MitraClip, and LAA (29).				
17	(Lauck S. et al., 2019, p. S204)	Demonstrating the effectiveness and reliability of nurse-led 3M TAVR manage- ment	Vancouver, CANADA	Prospective Case Follow-up	411 patients	The nurse-coordinated 3M (Multidisciplinary, Multimodal, Mini- malist) TAVR program is a safe and effective strategy to facilitate discharge after the procedure (15).				

	Table 2. Summary Findings of Studies									
No	Study	Aim	Place	Method	Sample	Conclusion				
18	(Johnson, 2019, pp. 18-19).	Revealing the devel- opment process of the structural cardiac coordinator system	USA	Statement	-	TAVI coordination has evolved from the valve implantation pro- cess to the coordination of all structural heart diseases. In particu- lar, in centers with high patient volumes, the coordination system is an important managerial tool (4).				
19	(Neuburger et al., 2019, p. 1737)	To present operation- al and institutional recommendations and requirements for the TAVI manage- ment process.	USA	Review	-	During the TAVI management process, a full-time TAVI coordinator should be assigned to the multidisciplinary heart team (23).				
20	(Perpetua et al., 2021, pp. 173- 175).	To reveal the role of the coordinator in the structural heart diseases multidisci- plinary heart team	USA	Descriptive Study	219 Structural heart coordi- nators	By profession, the TAVI coordinator is a member of the multidisci- plinary heart team. In this study, the characteristics and duties of the coordinator were revealed (22).				
21	(Tchetche et al., 2019, pp. 30-31)	To enhance the effectiveness of the TAVI management process, recommen- dations for improve- ment	FRANCE	Review	-	Using the coordination system in the TAVI management process can reduce costs and save time for physicians. The TAVI prepara- tion process managed by the coordinator can make it easier for the heart team to select appropriate patients (21).				
22	(Wood et al., 2019, p.467)	To evaluate the effec- tiveness and safety of next-day discharge using the Vancouver 3M TAVI management process.	CANADA, AMER- ICA	Prospective Case Follow-up	6 centers, 1400 patients	When medium- and high-volume centers use the Vancouver 3M TAVI management process (with a TAVI coordinator), their patients can be discharged safely the next day with effective results (19)				
23	(Almanfi, 2018, pp. 197-198)	To lay out the es- sential elements for starting a structural heart program	Indiana, USA	Report	-	The heart coordinator is one of the most important elements of the structural heart program. In addition to controlling all pre- and post-procedure processes, it plays a crucial role in effective communication with the patient and his family. In hospitals with high TAVI volumes, data recording and follow-up should be pro- vided to other personnel, and the heart coordinator should focus only on patient follow-up and care processes (27).				
24	(Lauck et al., 2016, p. 320).	To present the devel- opment, implemen- tation, and evaluation of a standardized clinical process to en- sure safe and prompt discharge from TAVI interventions.	Vancouver, CANADA	Prospective Case Follow-up	397 TAVI pa- tients (May 2012-September 2014)	The Vancouver TAVI program, with a TAVI coordinator on the heart team, can shorten hospital stays (17).				
25	(Hawkey et al., 2014, pp.859- 860)	To summarize best practice recommen- dations from centers with extensive ex- perience in program development.	USA	Core Curriculum	-	TAVI has caused a significant paradigm shift in structural heart disease process management. The success of TAVI process man- agement is based on effective coordination and communication (3).				
26	(Lauck et al., 2013, pp. 35-36)	Establish effective care processes to support transcatheter aortic valve replace- ment programs.	USA	Program Desing	-	The TAVI coordinator is a vital component in the TAVI manage- ment process, ensuring coordination among healthcare profes- sionals, the family, and the patient. Education of the patient and family is also the responsibility of the TAVI coordinator. It should be implemented under the guidance of the coordinator, from patient selection to triage and geriatric follow-up (5).				
27	(Bakaeen et al., 2012, p. 664).	Establish the TAVI program in the US Military Health System.	USA	Project	16 Veterans' In- tegrated Service Networks	The TAVI coordinator system was included in the TAVI program established in the US Military Health System (2).				
28	(Bavaria et al., 2011, p. 2073)	To examine manage- ment strategies in the referral process of TAVI patients in a hospital	Heart Center, USA	Retrospective Archival Re- search	681 TAVI patients 2007– 2010	The necessity of a cardiac team in the decision and follow-up pro- cesses of patients with TAVI has been demonstrated (Bavaria et al., 2011, p. 2075). The processes in a new existing clinic are followed by the TAVI coordinator nurse (1).				

## 4. Discussions

The TAVI application was initially managed only with the heart team concept. However, coordination among the heart team members, patients, and families emerges as a managerial challenge. Therefore, one of the essential components of the heart team is the coordinator. In this context, Bavaria and Szeto (1) have emphasized the necessity of the heart team in the management of the TAVI process. They started the TAVI coordinator practice in one unit where the study was conducted. Due to the increasing number of TAVI cases, TAVI programs with TAVI coordinators have been implemented in US military hospitals (2) and other hospitals (5, 8). It can be stated that with the increase in the number of TAVIs, the TAVI coordinator system also become widespread.

Evaluated studies mainly indicated that the TAVI coordinator should manage the TAVI pathway (8, 10, 11, 13, 16, 21-25). In fact, in Australia, the TAVI coordinator approach is considered one of the requirements of the accreditation process (6). Luck et al. (26) stated in their study that the COVID-19 process, in which healthcare systems were challenged, once again demonstrated the necessity of the TAVI coordinator approach.

Luck et al. (5) highlighted that the TAVI coordinator was a crucial component in terms of communication between health professionals, families, and patients. The study also revealed that the TAVI coordinator should be responsible for educating patients and their families. Another study finding is that the TAVI coordinator should manage the entire TAVI pathway, from patient triage to follow-up examinations. Similarly, Hawkey et al. (3) also touched upon the importance of the TAVI coordinator in their study, emphasizing that the most significant elements in the TAVI process were communication and coordination. Almanfi (27) also revealed similar findings in his report and even stated that TAVI data management should be given to other personnel so that the TAVI coordinator can focus only on the patient process.

In the Vancouver cohort study in 2016, 397 patients with TAVI were followed under the management of the TAVI coordinator, and this management approach was stated to shorten patient hospital stays (17). Similar results were obtained in the Vancouver study in 2019 (15). In addition, another Vancouver study published jointly by the USA and Canada revealed that patients could be safely discharged the next day in cases performed under the TAVI coordinator (19). Another Vancouver study in 2022 supports the findings (11). In their study, Van Wiechen et al. (10) mentioned that the coordinator influenced the early discharge process of TAVI patients. In their intervention and control study, Lortz et al. (9) demonstrated that the TAVI coordinator approach could shorten patient hospitalization duration, supporting the findings of the Vancouver studies. Similarly, Adhami et al. (16) stated that the TAVI coordination approach and the heart team were critical components in preventing long patient waiting times.

The TAVI coordinator approach was recommended in high-volume units (4, 13, 19). Bennetts et al. (6) expressed this situation more clearly and remarked that centers that perform more than 30 TAVI cases annually should switch to a TAVI coordinator program.

In addition, studies have indicated that the TAVI coordinator is an important factor in communication between health professionals, the patient, and the family (3, 11, 16, 27, 28).

Clarke (20) proposed that the coordinator in TAVI process management could contribute to the prevention of medical errors. Supporting this idea, in the interventioncontrol study, the TAVI coordinator program improved the pathway and did not negatively affect patient safety (7). Likewise, in the Vancouver study, the nurse-coordinated TAVI program was a safe and effective strategy (15, 19).

Studies have revealed the positive results of the TAVI coordination system on resource use. Perpetua and Russo (18) stated that patient triage performed by coordinators could positively affect resource utilization. Additionally, Tchetche et al. (21) indicated that TAVI programs managed by coordinators could reduce costs and save physicians more time.

In the intervention-control study, the TAVI coordinator system increased patient satisfaction (7). Similarly, another study reported that patients benefited from the TAVI coordinator management approach (12).

The TAVI coordinator approach evolved in many procedures in the cath lab over time. Left Atrial Appendage Closure (LAA), Mitra Clip, etc., cases requiring similar managerial requirements of TAVI and a multidisciplinary approach were managed with the same approach (4, 29). Therefore, the concept of TAVI coordinator is also called Valve or Structural Heart Coordinator.

# **5.** Conclusions

The preliminary study presents systematically and holistically the literature findings of the coordination approach in TAVI management. Evaluating the studies on TAVI coordinators, this management approach is necessary in the catheter laboratory. Results indicated that TAVI or valve structural heart coordination accelerates the pathway, increases patient satisfaction, optimizes resource use, and reduces costs. This study reveals the positive results of the coordination approach on the team, patient, and hospital. The findings bring the approach to the agenda of clinic and hospital managers as a managerial tool. Even though there are promising results in the literature on the TAVI coordination management approach, further studies are needed, considering that a significant part of the studies are literature reviews and descriptive studies.

Although the literature demonstrates promising results regarding TAVI coordination management, significant gaps remain. Future research should prioritize:

- Conducting large-scale, multicenter randomized controlled trials to evaluate the direct effects of TAVI coordination on clinical outcomes, patient satisfaction, and cost-efficiency.
- Comparing TAVI coordination practices across different healthcare systems to identify best practices.
- Investigating the sustainability of outcomes, such as patient quality of life and readmission rates, in hospitals with established TAVI coordination systems.
- Assessing the impact of standardized training programs for TAVI coordinators on patient and systemlevel outcomes.

By focusing on these areas, researchers can better understand the coordination approach in TAVI management.

# 6. Declarations

## Funding

No institution or fund supported this study.

## Conflict of interest

No conflict between the authors.

## Availability of Data and Material

This study's scanned and synthesized publications are available upon request.

## Authors' Contributions

Desing: UU, Collected Data: UU, YA, Analysis Data: UU, YA, Wrote Paper: UU, YA, Supervision: YA.

## Ethics Committee Permission

Since the study was conducted based on the literature databases, ethics committee permission was not required. This study was conducted within the principles of the Declaration of Helsinki.

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