Karya Journal of Health Science

e-ISSN: 2717-9540

Volume/Cilt 5
No/Sayı 3

2024

Karya Journal of Health Science

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Indexes

Karya Journal of Health Science

Volume/Cilt 5, No/Sayı 3, Page/Sayfa 77-116

Contents/İçindekiler

Research Article/Araştırma Makalesi

Karya J Health Sci. 2024;5(3):77-81
RESEARCH ARTICLE/ARAŞTIRMA MAKALESİ doi: 10.52831/kjhs.1460099 e-ISSN:2717-9540

KARYA JOURNAL OF HEALTH SCIENCE

journal homepage: www.dergipark.org.tr/kjhs

ACUTE EFFECT OF ANKLE DYNAMIC TAPING AND KINESIO TAPING ON BALANCE AND LOWER EXTREMITY FUNCTIONAL PERFORMANCE IN HEALTHY INDIVIDUALS

SAĞLIKLI BİREYLERDE AYAK BİLEĞİNE UYGULANAN DİNAMİK BANT VE KİNEZYO BANDIN DENGE VE ALT EKSTREMİTE FONKSİYONEL PERFORMANSINA AKUT ETKİSİ

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ABSTRACT

Objective: The ankle-foot complex is integral to maintaining balance as it gathers proprioceptive data. Dynamic taping (DT) and Kinesio taping (KT) are special elastic therapeutic tape applied to the skin. This study aims to investigate the acute effect (2 hours) of DT and KT on dynamic balance and functional performance in healthy individuals.

Method: A total of 15 adults (7 males and 8 females) were included in the study. Participants underwent testing under three conditions (No taping, DT, and KT). Balance was assessed with Y Balance Test, while functional performance was evaluated with Single Hop Test, Triple Hop Test, Cross Over Hop Test, and 6 Meter Timed Hop Test.

Results: There was a significant difference in Y balance posteromedial test between three conditions ($p<0.05$). This difference was between no taping and KT. However, there were no significant differences in Single Hop, Cross Over Hop, 6-Meter Timed Hop, and Triple Hop tests among the three conditions ($p>0.05$).

Conclusion: The results of this study suggest that ankle KT enhances dynamic balance in healthy individuals.

Key Words: Ankle, Balance, Kinesio taping, Dynamic taping

ÖZ

Amaç: Ayak ve ayak bileği kompleksi, proprioseptif bilgileri toplayarak dengenin korunmasında önemli bir rol oynar. Dinamik bantlama (DT) ve Kinesio bantlama (KT), cilde uygulanan özel elastik terapatik bantlardır. Bu çalışmanın amacı sağlıklı bireylerde DT ve KT'nin dinamik denge ve fonksiyonel performans üzerindeki akut etkisini (2 saat) araştırmaktır.

Yöntem: Çalışmaya toplam 15 kişi (7 erkek ve 8 kadın) dahil edildi. Katılımcılar üç koşulda (bantlama yok, DT ve KT) değerlendirildi. Denge Y Denge Testi ile değerlendirilirken, fonksiyonel performans Tek Bacak Sıçrama Testi, Üçlü Sıçrama Testi, Çapraz Sıçrama Testi ve 6 Metre Zamanlı Sıçrama Testi ile değerlendirildi.

Bulgular: Üç koşul arasında Y denge posteromedial testinde anlamlı bir fark vardı ($p<0,05$). Bu fark bantlama yokken ve KT arasındaydı. Bununla birlikte Tek Bacak Sıçrama, Üçlü Sıçrama, Çapraz Sıçrama ve 6 Metre Zamanlı Sıçrama Testlerinde üç koşul arasında anlamlı bir fark yoktu ($p>0,05$).

Sonuç: Bu çalışmanın sonuçları, sağlıklı bireylerde ayak bileğine uygulanan KT'nin dinamik dengeyi arttırdığını öne sürmektedir.

Anahtar Kelimeler: Ayak bileği, Denge, Kinezyo bant, Dinamik bant

INTRODUCTION

Ankle sprains frequently occur during sports and physical activities. According to a systematic review and meta-analysis, the prevalence of ankle sprains is approximately 11.88% [1]. Failure to provide adequate treatment for acute ankle sprains or the lack of therapy can result in nearly 40% of patients experiencing Chronic Ankle Instability (CAI) [2]. CAI is a common type of musculoskeletal injury associated with significant socioeconomic burdens. Factors such as female gender, young age, and specific sports activities are often linked to ankle injuries, increasing the risk of sprains. A considerable portion of ankle sprains require medical intervention and can lead to chronic ankle instability. Treatment and prevention methods include ice, taping, immobilization, and functional therapy. Elastic tapes, commonly used among taping methods, are part of the treatment options [3]. Kinesio tape (KT) has emerged as an alternative to traditional sports tapes, standing out with its elastic structure. This tape can extend to 140% of its initial length and aims to strengthen weakened muscles, increase fluid, and blood circulation, reduce neurological pressure, and alleviate muscle tension [4]. The literature contains significant evidence supporting the beneficial impacts of applying KT on ankle instability. However, uncertainties still exist about its impact on postural sway and balance [5-7]. In a study conducted by Simon et al. (2014), significant changes in proprioception sense were observed immediately after KT application in the experimental group. Nevertheless, there was no notable variance observed in the assessment carried out 72 hours following the application [5]. In a study by Jackson et al. (2016), a significant difference in balance parameters was found in the evaluation conducted 48 hours after KT application. It was noted that improvements in balance continued even after the tape was removed at 72 hours [6]. In a study by de-la-Torre-Domingo et al. (2015), no significant differences in balance measurements were noted between KT application and no taping [7]. As can be seen, there are still uncertainties about the effects of KT application on postural sway and balance.

Article Info/Makale Bilgisi

Submitted/Yükleme tarihi: 03.28.2024, **Revision requested/Revizyon isteği:** 04.29.2024, **Last revision received/Son düzenleme tarihi:** 05.14.2024, **Accepted/Kabul:** 05.28.2024

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In recent years, dynamic taping (DT) has emerged as an innovative form of tape offering unique properties. DT is characterized by its elasticity and rebound capabilities, allowing it to stretch up to 200% and provide four-way flexibility. These features enable the tape to support resistance, deceleration, energy storage, and movement without impeding the range of motion during everyday activities or sports performance. Unlike traditional KT, DT is administered to the muscle while it's in a shortened position, imitating bone attachments and optimizing muscle length. Consequently, the tape absorbs energy during stretching and releases it during muscle contraction, facilitating power production by the muscle [8]. Despite growing interest, there remains limited data on the overall impact of DT, particularly on balance and functional performance, especially when applied to the ankle [9]. With this knowledge gap in mind, this study aims to assess the impacts of ankle DT and KT on balance and lower extremity functional performance among healthy individuals.

METHOD

Study Design and Participants

This randomized cross-over, double-blind study was conducted at the Physiotherapy and Rehabilitation Laboratory of Mugla Sitki Kocman University in March 2024. This study required a minimum of 12 participants after considering a power of 0.95, a level of 0.05 in repeated measures analysis of variance (ANOVA), and an effect size of 1.45 obtained in a preliminary study [9].

Inclusion Criteria: The inclusion criteria for participants were as follows:

- Age between 18 and 25 years.
- Enrolled as a university student actively involved in daily activities (individuals categorized as professional athletes or with a sedentary lifestyle were excluded).
- A score of 28 or higher on the Cumberland Ankle Instability Tool (This tool assesses self-reported ankle instability using 9 questions scored on a 30-point scale. Scores below 27 indicate functional ankle instability) [10].

Exculution Criteria: The exculution criteria for participants were as follows:

- History of ankle sprains, lower extremity fractures, and surgery.
- Presence of neurological or vestibular disorders.
- Allergy to taping.

Procedures

The participants were assessed under three conditions (no taping, taping with KT, and taping with DT) on their dominant ankles at 2-hour intervals, following a randomized order. Randomization was supervised by an assistant who was not involved in the intervention, evaluation or participant recruitment. Concealment of assignments was maintained using sealed opaque envelopes containing details of conditions: no taping, KT, or DT. Physical therapists, who were not part of the allocation or intervention process, evaluated participants in a randomized sequence every 2 hours while remaining blinded to previous records. Before formal testing, participants received instructions for each assessment, and the examiner demonstrated each testing procedure.

Taping applications and participant evaluations were carried out by different researchers and the researcher who made the evaluation was blinded to the taping application. Since the participants wore long socks, the evaluator was blinded to the taping application. The taping application lasted approximately 5 minutes. The assessment was performed 2 hours after the taping application. During these 2 hours, the participant was asked to walk, warm up and get used to the tape. At the end of the evaluation, the tapes were removed.

The KT technique (Kinesio USA, Albuquerque, New Mexico, USA) was utilized for the correction of lateral ankle sprain (Figure 1). Two strips of tape were applied: the first strip was used for functional correction, extending from insertion to origin with 50% tension to assist dorsiflexion and eversion. The second strip, applied at 75-100% tension, aimed to correct the anterior talofibular ligament, which is often damaged in lateral ankle sprains. This tape started under the heel and passed under the malleolus, then continued under the heel again and over the malleolus and the taping was complete. All taping procedures were performed by the same researcher [11].

Figure 1. Kinesio tape application

In the DT method, tailored strips of varying lengths were employed, considering the participants' anthropometric features (Figure 2). Participants began by assuming a starting position of plantar flexion and eversion. The DT strip was then affixed and secured at the head of the first metatarsal joint, extending downward to the top of the calcaneus at the rear. Following this, the DT strip was wrapped around the inner side of the heel and anchored from the lateral aspect of the foot. The anchoring point was positioned at one-third of the medial aspect of the tibia [12].

Figure 2. Dynamic tape application

Outcome Measures

Participant demographics were recorded, and leg dominance was established by instructing participants to kick a soccer ball. Both taping and evaluations were conducted on the dominant leg. Balance assessment was carried out with the Y Balance Test. Functional performance was assessed with the Single Hop Test, Triple Hop Test, Crossover Hop Test, and 6-Meter Timed Hop Test.

The Y Balance Test (YBT): YBT is a straightforward and dependable assessment tool utilized to gauge dynamic balance. Its purpose is to evaluate physical performance, demonstrate functional symmetry, and pinpoint athletes at a heightened risk of lower extremity injuries. During the YBT, participants stand on one foot while extending the other foot as far as possible in the anterior, posterolateral, and posteromedial directions simultaneously. This test assesses strength, stability, and balance across multiple planes. Each participant undergoes the test three times, and the average score is determined by dividing it by leg length and multiplying by 100 [13].

The scores for each reach direction were normalized based on the participant's leg length. Three consecutive trials were performed, and the average of these trials was calculated to ascertain the normalized mean reach distance. The composite score was derived using the following equation:

$$Composite score = \left[\frac{(AT+PM+PL)}{(Leglength \times 3)}\right] \times 100$$

AT: Anterior, PM: Posteromedial, PL: Posterolateral

The Single Hop Test (SHT): SHT is a commonly employed assessment tool among clinicians. Particularly prevalent in the functional return phase of rehabilitation protocols, its aim is to evaluate the functional stability of the knee. Participants are tasked with executing the longest possible jump on one leg along a straight line while maintaining balance and securely landing on the ground. The distance from the starting line to the point of landing completion is measured. Participants initiate the test by standing on the taped leg, aligning their toes at the starting line. They are then directed to leap forward as far as possible and land on the same leg, with the distance from the starting line to the landing point recorded. The test is repeated three times, and the average outcome is documented [14].

The Triple Hop Test (THT): THT requires participants to execute three consecutive jumps on one leg, striving for maximum distance while sustaining balance and securing their landing on the ground. The distance is measured from the starting line to the tip of the landing foot. Participants begin by standing on the taped leg with their toes aligned at the starting line. They are instructed to execute a maximum of three jumps. The researcher then measures the distance from the starting line to the point where the participant completes the third jump. The test is conducted three times, and the average outcome is documented [14].

Crossover Hop Test (CHT): In the CHT participants position themselves on the taped leg, aligning their toes with the starting line. If using their right leg for jumping, they stand on the right side of the 8-meter tape; if employing the left leg, they stand on the left side. Participants are then instructed to execute three maximum jumps in a crossover pattern with the taped leg, ensuring that each jump crosses the tape. The distance is measured from the starting line to the point where the participant completes the third jump, with the measured distance recorded at the point where the participant's heel contacts the ground. The test is performed three times, and the average outcome is documented [14].

6-Meter Timed Hop Test (6MTHT): The purpose of 6MTHT was for participants to execute swift jumps on one leg, covering 6 meters without losing balance and securely landing on the ground. Participants positioned themselves on the taped leg, aligning their toes with the starting line. Upon the researcher's cue of "1, 2, 3, start," the stopwatch began, and participants were instructed to traverse the 6-meter distance as rapidly as possible using the designated leg. The test duration was measured until the participant crossed the finish line. The test was repeated three times, and the average outcome was documented [14].

Ethical Approval

All participants gave informed consent after reading and signing an informed consent form. The study protocol was approved by the Health Sciences Ethics Committee of Mugla Sitki Kocman University (date: 18.03.2024, approval number: 49).

Statistical Analysis

All data were analyzed using the IBM SPSS version 20.0 for Windows (IBM Corp., Armonk, NY, USA). Histograms, probability plots and Shapiro-Wilk test were used to determine whether the variables were normally distributed. Descriptive statistics are presented as median and Interquartile Range (IQR). The Kruskal-Walli's test was used to compare balance and performance tests under the three conditions (no taping, DT and KT). The p value was set at $p<0.05$ for statistical significance.

RESULTS

The study included 15 participants that were 8 men and 7 women (mean±standard deviation of age: 21.47±1.84 years, height: 171.00±7.87 cm, body weight: 67.47±14.50 kg, and body mass index: 23.05±4.55 kg/m^2). Median and IQR scores for balance and functional performance in the three conditions are shown in Table 1.

Table 1. Comparison of the balance and functional performance scores among the three conditions (n=15)

Variables	Median (Interquartile range)			p value
	No taping	Dynamic taping	Kinesio taping	
Y balance anterior	117.0 (37.34)	123.33 (31.16)	123.33 (39.67)	0.901
Y balance posteromedial	111.0 (22.0)	120.83 (21.33)	124.0 (17.0)	**0.035** No taping-KT=0.034
Y balance posterolateral	117.67 (19.17)	129.0 (21.5)	126.50 (14.84)	0.085
Composite Score	126.68 (13.14)	137.16 (18.20)	138.25 (17.30)	0.073
Single Hop	89.75 (33.67)	96.91 (46.50)	91.62 (37.5)	0.904
Cross Over Hop	254.81 (110.67)	292.36 (130.34)	282.85 (123.16)	0.428
6 Meter Timed Hop	2.77 (0.93)	2.54 (0.80)	2.72 (0.75)	0.413
Triple Hop	321.83 (115.33)	346.48 (123.0)	343.27 (166.66)	0.682

KT: Kinesio taping; DT: Dynamic Taping; Kruskal-Walli's test was used for all p-values.

There was a significant difference in Y balance posteromedial test between taping conditions ($p<0.05$). This difference was between no taping and KT (Figure 3). However, there were no significant differences in Single Hop, Cross Over Hop, 6-Meter Timed Hop, and Triple Hop tests among the three conditions ($p>0.05$).

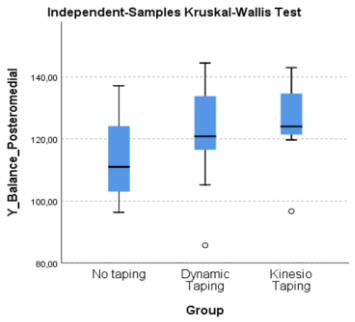

Figure 3. Box plot of Y Balance Posteromedial scores of the participants under the three conditions

DISCUSSION

The aim of this study was to investigate the acute effect of ankle DT and KT on balance and functional performance in healthy individuals. The results indicated that there was no difference in lower extremity functional performance among taping conditions, while there was a notable enhancement in dynamic balance in favoring of KT.

Previous studies have investigated the use of ankle KT and obtained significant evidence [6,15]. Jalaludin et al. (2022) conducted a systematic review that offers proof that KT application confers benefits in enhancing balance for both those with and without ankle instability [15]. Similarly, with this systematic review, the current study showed

that ankle KT enhances dynamic balance in healthy individuals. Additionally, the KT techniques implemented in this study aims to prevent ankle instability. One strip following the anatomy of the foot includes a correction for eversion and dorsiflexion to reduce lateral ankle sprain stress, while the other strip aims to support ankle stabilization. Therefore, this technique may be a prophylactic intervention approach for ankle sprains by improving dynamic balance in healthy individuals.

DT reduces the workload of muscle fibers when applied when muscle short position. The energy held by DT during movement contributes to muscle activation at the end of the movement, thereby enhancing muscle performance. The application techniques of DT differ from KT and are generally applied while the muscle is in a shortened position. There are also material differences between DT and KT. In addition, KT can stretch longitudinally up to 140% of its original length, while DT can stretch in multiple directions (both transversely and longitudinally) exceeding 200% [8]. Therefore, it is thought that the differences in material and application technique between DT and KT lead to different results on dynamic stability.

So far, there are four studies in the literature on DT applied on the foot and ankle [9,12,16,17]. Lim et al. (2021) compared the results of DT and KT applied to the ankle in 15 participants with CAI. Compared to the control group, an increase in reach distances in the AM, M and PM directions was observed with DT, while an increase in the M and PM directions was determined with KT. However, no significant difference was found between DT and KT in balance parameters in their study [9]. The study by Kodesh et al. (2021) compared the results of a total of 36 participants, 18 controls and 18 participants with CAI, after DT application to the gastrocnemius muscle [16]. The dynamic balance of the groups was evaluated 10 minutes and 24 hours after the application. It was found that DT applied to the gastrocnemius muscle improved balance control in both individuals with CAI and the control group. However, a greater increase in balance was observed in those with CAI. Doğan et al. (2021) conducted a study comparing the change in balance after ankle DT, KT and placebo tape in 24 professional football players without injury [17]. The results revealed that DT improved balance better in their study. Lim et al. (2020) showed that DT and KT application on the medial longitudinal arch were not superior to each other in improving dynamic balance in 22 asymptomatic flexible flat-footed individuals [12]. In the present study, although we used the same DT technique as Lim et al. (2021) [9], our balance results differed. However, while DT was applied to individuals with CAI in the Lim et al. study, it was applied to healthy individuals in the current study. We think that the effect of taping on balance may be different in healthy and CAI individuals. The fact that Kodesh et al. (2016) [16] found more improvement in balance with DT in individuals with CAI and Lim et al. (2020) [12] showed no improvement in balance with DT in asymptomatic individuals supports our interpretation.

Rigid taping can also be used on the ankle in addition to DT and KT; however, studies have shown that balance does not improve when using rigid bands [18]. The first effective strategy for maintaining balance is the ankle strategy. The ankle maintains balance with slow and rhythmic oscillations in the anteroposterior and mediolateral directions [19]. Therefore, rigid taping of the ankle may have a negative effect on the balance adjustment strategy. Therefore, it can be said that the rigid and strong material structure of DT provides better stabilization to the ankle than KT, which may have a negative effect on balance.

In the current study, neither DT nor KT showed a significant difference in lower extremity functional performance. Similarly, Doğan et al. (2021) conducted a study that observed no significant difference in functional performance between ankle DT and KT in healthy soccer players [17]. Wang et al. (2018) showed in their systematic review and meta-analysis that KT outperforms other taping techniques in enhancing ankle functional performance [3]. However, this systematic review did not include studies relevant to DT. Therefore, considering the significant differences in materials and application techniques between DT and KT, more research results on this area are needed in the future.

Limitations

There are several limitations to this study. Firstly, it only included a group of healthy individuals. Although the participants were physically active university students, it is unclear how the results would apply to athletes and the injured population. Secondly, future studies should evaluate the long-term effects of these tapes, as this research only examined their immediate effects. Thirdly, there are a variety of taping techniques available and as the effects on the ankle may vary depending on the taping technique used, future studies should compare different taping methods. Finally, more longitudinal studies are needed to assess the practical implications of the results of this study. Such studies could contribute to clinical practice.

CONCLUSION

In this study, the effect of ankle DT and KT on balance and functional performance in healthy individuals was compared and it was found that while there was no difference between the tapes in functional performance, KT improved balance. Therefore, ankle KT before exercise or sport in healthy individuals may improve balance and provide protection from ankle injuries. However, the primary function of DT during movement is a rebound effect that allows for mechanical, deceleration and load absorption. Therefore, DT may show more effective results during more dynamic tasks such as running, jumping or specific exercises. Future studies should take this factor into account in comparisons between the two tapes.

Ethical Approval: *2024/49 Health Sciences Ethics Committee of Muğla Sıtkı Koçman University*

Conflict of Interest: *The authors have no conflicts of interest to declare.*

Funding: *None.*

Acknowledgements: *None.*

Author Contribution: Concept: *MK,ACP;* ***Design:*** *MK,BB,KB;* ***Data collecting:*** *MK,ACP,SSM;* ***Statistical analysis:*** *MK,ACP,SSM;* ***Literature review:*** *MK,ACP,SSM;* ***Writing:*** *MK,ACP,SSM,BB,KB;* ***Critical review:*** *BB,KB.*

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Karya J Health Sci. 2024;5(3):82-87
RESEARCH ARTICLE/ARAŞTIRMA MAKALESİ doi: 10.52831/kjhs.1459231 e-ISSN:2717-9540

KARYA JOURNAL OF HEALTH SCIENCE

journal homepage: www.dergipark.org.tr/kjhs

COMPARISON OF FUNCTIONAL OUTCOMES AND KINESIOPHOBIA LEVELS AFTER ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION WITH HAMSTRING TENDON AUTOGRAFT VERSUS FRESH-FROZEN ALLOGRAFT: A CROSS-SECTIONAL STUDY

HAMSTRİNG TENDON OTOGREFTİ VEYA TAZE DONDURULMUŞ ALLOGREFT İLE ÖN ÇAPRAZ BAĞ REKONSTRÜKSİYONU YAPILAN BİREYLER İLE SAĞLIKLI BİREYLER ARASINDA FONKSİYONEL SONUÇLARIN VE KİNEZYOFOBİ DÜZEYLERİNİN KARŞILAŞTIRILMASI: KESİTSEL BİR ÇALIŞMA

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ABSTRACT

Objective: Determining the best graft in the selection of various graft types for anterior cruciate ligament reconstruction (ACLR) is still unclear. The study aimed to compare the functional outcomes and kinesiophobia among individuals who underwent ACLR with either hamstring tendon autograft or fresh-frozen allografts and healthy individuals.

Method: A total of 44 individuals undergoing ACLR and 30 healthy individuals were assessed. Individuals who underwent ACLR with hamstring tendon autograft (Group 1) or fresh-frozen allograft (Group 2) and a control group with similar activity levels (Group 3) were included in this study. The surgical groups were evaluated 12-48 months after surgery. Evaluations included detailed history, knee muscle strength, single-leg hop test, and kinesiophobia.

Results: There were 24 individuals (mean age 31.71±9.78 years) in Group 1, 20 individuals (mean age 32.35±5.58 years) in Group 2, and 30 healthy controls (mean age 33.77±7.09 years) in Group 3. There was no difference between the surgical groups in terms of single-leg hop test, kinesiophobia, and muscle strength ($p>0.05$). However, there were significant differences between the ACLR groups with the control group in terms of muscle strength of injured side ($p<0.002$), single-leg hop test ($p<0.029$), and kinesiophobia level ($p=0.005$).

Conclusion: This study showed that no graft type was superior to another in terms of functional outcomes and kinesiophobia after ACLR. In addition, the need for long-term rehabilitation of individuals with ACLR should be taken into consideration to reach their pre-operative functional level.

Key Words: Allografts, Autografts, Anterior Cruciate Ligament Reconstruction, Kinesiophobia, Functional Performance

ÖZ

Amaç: Ön çapraz bağ rekonstrüksiyonu (ÖÇBR) için çeşitli greft tiplerinin seçiminde en iyi greftin belirlenmesi hala belirsizdir. Bu çalışma, hamstring tendon otogrefti veya taze dondurulmuş allogreft ile ÖÇBR uygulanan bireyler ile sağlıklı bireyler arasındaki fonksiyonel sonuçları ve kinezyofobiyi karşılaştırmayı amaçladı.

Yöntem: ÖÇBR uygulanan toplam 44 kişi ve 30 sağlıklı birey değerlendirildi. Bu çalışmaya hamstring tendon otogrefti (Grup 1) veya taze dondurulmuş allogreft (Grup 2) ile ÖÇBR uygulanan bireyler ve benzer aktivite düzeyine sahip kontrol grubu (Grup 3) dahil edildi. Cerrahi gruplar ameliyattan 12-48 ay sonra değerlendirildi. Değerlendirmeler arasında ayrıntılı öykü, diz kas kuvveti, tek bacakta sıçrama testi ve kinezyofobi yer aldı.

Bulgular: Grup 1'de 24 kişi (ortalama yaş 31,71±9,78 yıl), Grup 2'de 20 kişi (ortalama yaş 32,35±5,58 yıl), Grup 3'te ise 30 sağlıklı kontrol (ortalama yaş 33,77±7,09 yıl) vardı. ÖÇBR grupları arasında kas kuvveti, tek bacak sıçrama testi ve kinezyofobi açısından anlamlı fark yoktu ($p>0,05$). Ancak ÖÇBR grupları ile kontrol grubu arasında ameliyatlı taraf kas kuvveti ($p<0,002$), tek bacak sıçrama testi ($p<0,029$) ve kinezyofobi düzeyi ($p=0,005$) açısından anlamlı farklılıklar vardı.

Sonuç: Bu çalışma, ÖÇBR sonrası fonksiyonel sonuçlar ve kinezyofobi açısından herhangi bir greft tipinin diğerine üstün olmadığını gösterdi. Ayrıca ÖÇBR'li bireylerin ameliyat öncesi fonksiyonel seviyeye ulaşabilmeleri için uzun süreli rehabilitasyon ihtiyaçları göz önünde bulundurulmalıdır.

Anahtar Kelimeler: Allogreftler, Otogreftler, Ön Çapraz Bağ Rekonstrüksiyonu, Kinezyofobi, Fonksiyonel Performans

Article Info/Makale Bilgisi

Submitted/Yükleme tarihi: 03.16.2024, **Revision requested/Revizyon isteği:** 05.07.2024, **Last revision received/Son düzenleme tarihi:** 07.17.2024, **Accepted/Kabul:** 08.29.2024
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INTRODUCTION

Anterior cruciate ligament (ACL) injuries are among the most common injuries in the world, and it was reported there are approximately 250,000 injuries in the United States each year [1]. The incidence rate of ACL injuries in females is higher than in males when exposed to the same sport. However, the annual number of ACL injury incidence is higher in males because men play higher-risk sports than females [2]. Anterior cruciate ligament reconstruction (ACLR) has recently been used as the standard treatment for ACL injury [3]. Different types of grafts are used in ACLR, such as autografts and allografts. The commonly used autografts are hamstring, quadriceps tendons, and bone-patellar tendon-bone (BPTB). Similarly, achilles, tibialis anterior and posterior muscles, hamstring and quadriceps tendons, and BPTB are the available allografts [4].

The hamstring tendon autograft has been significantly increased recently [5]. It has been reported to have lower donor site morbidity, anterior knee pain, and immune response, as well as greater satisfaction than other autografts such as BPTB and quadriceps tendon [6-9]. On the other hand, when allografts are used, they can provide shorter surgical time, without donor site morbidity, and a more controllable graft size. However, there are the disadvantages of allografts such as low regeneration capabilities and causing blood-borne diseases such as HIV, Hepatitis B, and C [10]. Although both types of grafts are frequently preferred due to their advantages, autografts using the hamstring tendon have a significant disadvantage. It is stated that since the individual's hamstring tendon is used in hamstring tendon autografts knee flexion strength (ranging from 10% to 20%) is reduced [11,12]. Contrary to previous studies, there are also studies indicating that hamstring tendon autografts and fresh-frozen allografts are similar in terms of knee laxity and subjective clinical results [3,5,9,12-17]. Additionally, higher incidence of graft laxity and weaker knee stability after ACLR have been reported in hamstring tendon autografts [18].

Single-leg hop performance and muscle strength offer important clues to return to functional performance before ACL injury [19]. However, studies comparing both graft types in terms of functional outcomes after ACLR are quite limited [9,12,16,17]. In these studies, functional performance was evaluated only with hop tests (single-leg hop and vertical hop), and the results were found to be similar. Therefore, there is a need for a multifaceted evaluation of functional performance. Knee strength, which is an important determinant of functional performance [20], has not been compared between the two graft types so far.

Approximately 50% of patients with ACLR fail to return to pre-injury activity levels despite improved performance on physical tests [21,22]. It is stated that psychological problems significantly affect the return to sports after injury, but despite this, there is still a need for high-quality observation and intervention studies [23]. Kinesiophobia (eg, fear of movement/reinjury) has been identified as one particularly important psychological factor in post-ACLR [24,25]. Although the kinesiophobia level generally decreases post-ACLR, people suffer from kinesiophobia for many years [25]. Kinesiophobia has been associated with worse physical performance, decreased activity levels, and increased risk of secondary injury after ACLR in individuals with an average activity level of 5.7±1.3 according to the Tegner activity scale [26]. On the other hand, as mentioned above, some disadvantages as well as advantages have been reported in individuals who underwent ACLR with different graft types. Based on this, comparing kinesiophobia in terms of different graft types will be a guide in choosing the appropriate graft type and rehabilitation. However, to date, no study has examined the changes in kinesiophobia levels in different graft types post-ACLR.

In this cross-sectional study, we used hamstring tendon autograft and fresh-frozen allografts for ACLR. The main aim of this study was to compare long-term results of functional outcomes and kinesiophobia in both graft types. The secondary aim was to compare both surgical groups with healthy controls (HC). Our hypothesis was that fresh-frozen allografts would have better functional results and kinesiophobia levels than hamstring tendon autografts. It was also expected that both groups would have worse functional results and kinesiophobia levels than healthy controls.

METHOD

Study Design

This study was a cross-sectional study of people undergoing anatomic single-bundle ACLR using either hamstring tendon autografts or fresh-frozen allografts. We conducted an assessor-blind study. During the assessments, the surgical group the patients were in was hidden, and the assessor evaluated all individuals in a random order without knowing the type of surgery. The information taken from the electronic medical records included their contact information, date of surgery, graft type used, and any associated injuries such as meniscal injuries and other knee injuries. Participants, who met the inclusion criteria, were invited to a university hospital. Assessments were made between December 2023 and January 2024 after ethics approval. After demographic information was collected pain during activity and rest, surgical satisfaction, functional outcomes (using single-leg hop test and knee muscle strength), and kinesiophobia were assessed for the participants who underwent ACLR. Additionally, knee strength, single-hop test, and kinesiophobia were assessed in HC.

Participant

Forty-four male individuals were included in the study, in which ACLR was performed by the same surgeon. The individuals were divided into two groups hamstring tendon autograft (Group 1, n=24) and fresh-frozen allografts (Group 2, n=20). Additionally, the HC group (Group 3, n=30) was included. The participants undergoing ACLR are shown in Figure 1.

Participants were recruited in Gaziantep through direct referral from primary care clinicians, social media and advertisements. Patients meeting the inclusion criteria were divided into 3 groups (n=20 Mat, n=20 Reformer Pilates, n=20 Hammock Yoga) using a closed envelope randomisation method. The same clinician repeated the baseline assessment and the final assessment after 8 sessions (4 weeks). Only pain severity (VAS) was assessed at baseline, and in the 1st, 2nd, 3rd, and 4th weeks (total of 5-time intervals). No one dropped out of any group while studying (Figure 1).

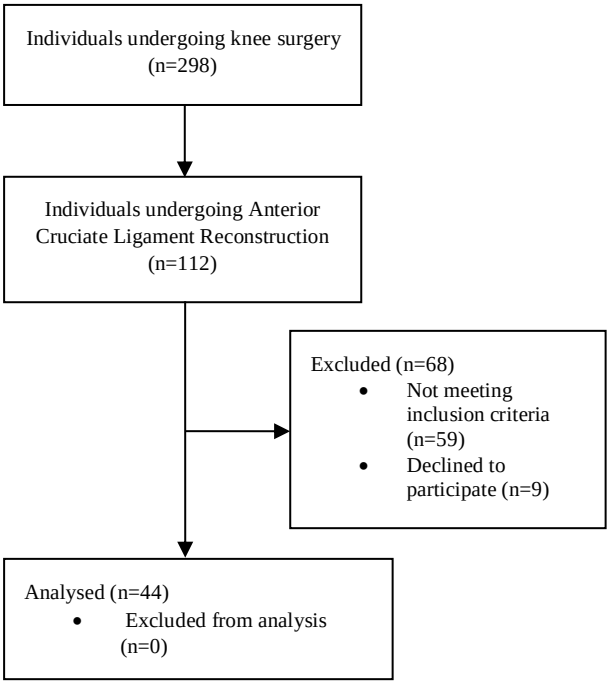

Figure 1. Flow chart of individuals undergoing ACLR

Inclusion Criteria: Inclusion criteria for the surgical groups (Group 1, Group 2) were as follows:

- Unilateral ACLR (Anterior Cruciate Ligament Reconstruction),
- Age between 18 and 65 years,
- Type of surgery involving hamstring tendon autografts or fresh-frozen allografts, with or without concomitant partial meniscectomy or meniscal repair,
- A postoperative period of 12 to 48 months.

Exclusion Criteria:

- Total meniscectomy or revision surgery,
- Multi-ligamentous knee injury or surgery,
- Chondral surgery,
- Combined ligament injury,
- Contralateral knee ligament injury.

Healthy volunteers whose age, gender, and activity levels were compatible with the surgical groups and who did not have any orthopedic surgery or knee injury that could affect the assessments were included in the study as a control group. Activity level was determined by the Tegner activity scale. The Tegner activity scale is a numerical scale with activity levels ranging from 0 (sick leave or disability pension due to knee problems) to 10 (competitive sports on a very high level) [27]. None of the participants were elite athletes.

Rehabilitation

The participants of the ACLR groups underwent a similar rehabilitation for about 3-5 days under the supervision of therapists and were discharged to receive a home exercise program. Partial weight-bearing with crutches was allowed for the first two weeks and knee flexion exceeding 90 was avoided. Then, an increasing amount of knee flexion was allowed. Plyometric exercises were allowed at the end of three months and contact sports were allowed at the end of 12 months [28].

Outcome Measures

Functional outcomes were assessed using the single-leg hop test and knee muscle strength. Kinesiophobia was assessed using The Tampa Scale for Kinesiophobia-17 (TSK-17).

Hop Distance: The Single-Leg Hop Test was used to assess the hop distance. The participants were tested starting with a single-leg stance. The upper limbs were positioned with the hands at the waist. They performed a single leg hop for maximal jump distance on the same leg. Horizontal hop distance was measured from the toe in the starting position to the heel edge at the landing [29]. The mean of three trials for each side was calculated for the data analysis after one trial jump.

Muscle Strength: Isometric knee muscle strength was measured using a Baseline® hand dynamometer (Fabrication Enterprises Inc., NY, USA). Participants were given to warm up with slow walking activities for 5 minutes before the testing. The dynamometer was positioned proximal to the lateral malleolus in the anterior or posterior aspect of the tibia to measure knee muscle strength. Then the strength was measured at 90° flexion position of the knee while the participants were sitting with their arms crossed over their thighs. Those were asked to give a maximal effort against the dynamometer and hold for five seconds after they conducted one practice trial. Meanwhile, the assessor remained stationary by applying counterforce with a hand dynamometer. In this way, the tests were repeated three times for each side, and the averages of the tests were used to measure the outcome [30].

Kinesiophobia: Kinesiophobia was evaluated using the TSK-17 scale. It contains 17 self-report items related to fear of movement, re-injury, and pain. The total score ranges 17-68. Higher scores indicate higher levels of kinesiophobia. In this study, Turkish versions of the TSK-17 were used [3].

Pain: The unidimensional Visual Analog Scale (VAS) was used to evaluate pain intensity during rest and activity and surgical satisfaction in people with ACLR. The scale ranges from “no pain" or "no surgical satisfaction” (score of 0) to “maximum pain” or "maximum surgical satisfaction" (score of 10). The score was determined by measuring the distance on the 10 cm line pointed by the individual [31].

Ethical Approval

This study was approved by the Ethics Committee of the University’s Institutional (approval number: 2023-12/57) and conducted by the Declaration of Helsinki. Additionally, written informed consent was obtained from all study participants and institutional permissions were obtained from the hospital where the assessments were performed.

Statistical Analysis

Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) version 23.0 (SPSS, Chicago, IL). The normality of data was assessed by the Shapiro–Wilk test. Results were reported as mean±SD for normally distributed scale variables, median (interquartile range [IQR]) for non-normally distributed scale variables, and frequency (%) for categorical variables. The Chi-square test was used to compare categorical variables between the groups. The analysis of variance (ANOVA, Tukey test) or Kruskal-Wallis test was used to analyze the differences between the three groups. Independent-samples t-test or Mann-Whitney U test was used to analyze the differences between the two groups. All the significance tests were conducted at the 5% level. Post hoc power analysis was performed using TSK-17 and injured knee extensor strength score of the surgical groups and the power was found to be 0.98 and 0.87, respectively.

Table 1: Demographics and characteristics of participants

	Group 1 (n=24) Mean±SD Median (IQR)	**Group 2 (n=20) Mean±SD Median (IQR)**	**Group 3 (n=30) Mean±SD Median (IQR)**	**p**
Age (years)	31.71±9.78	32.35±5.58	33.77±7.09	0.607
Height (cm)	177.25±6.31	175.70±7.47	176.83±6.91	0.748
Weight (kg)	86.79±13.96	86.6±14.43	81.75±10.40	0.268
BMI (kg/m2)	27.52±3.85	28.03±4.22	26.11±2.60	0.134
Tegner activity scale	4.96±1.57	5.75±1.77	5.86±1.43	0.093
Time since surgery (mo.)	27.08±11.79	33.3±12.21	-	0.094
Surgical satisfaction (10 cm)	6.78 (4.42-8.78)	8.39 (6.11-10.00)	-	0.208
Pain during activity (10 cm)	0.62 (0.00-2.65)	0.26 (0.00-3.85)	-	0.960
	Group 1 (n=24) n (%)	**Group 2 (n=20) n (%)**		**p**
Injured side Right	15 (62.50)	11 (55)	-	0.614
Injured side Left	9 (37.50)	9 (45)		
Only ACLR	14 (58.33)	11 (55)	-	
ACLR+Meniscus repair	9 (37.50)	7 (35)	-	0.747
ACLR+Partial meniscectomy	1 (4.16)	2 (10)	-	

**: p<0.05; BMI: Body mass index; ACLR: Anterior Cruciate Ligament Reconstruction; IQR: Interquartile range. The analysis of variance (ANOVA, Tukey test) test was used to analyze the differences between the three groups and the variables are presented as Mean ± Standard deviation (SD). The independent-samples t-test or the Mann-Whitney U test were used to analyze the differences between the two groups and the variables are presented as Mean ± Standard deviation (SD) or median (interquartile range [IQR]), respectively. The Chi-square test was used to compare categorical variables between the groups.*

RESULTS

A total of 44 ACLR (Group 1; 24, and Group 2; 20) and 30 HC participated in this study. There was no significant difference between the three groups in terms of demographic information and activity score (p>0.05). In addition, there was no significant difference between the ACLR groups in terms of time since surgery, surgical satisfaction, pain during activity, injured side, and additional intervention during surgery (p>0.05), (Table 1). Both surgical groups had no pain during rest.

The knee muscle strength of the injured side and single-leg hop test scores in both surgical groups were significantly lower than HC (p<0.05). Additionally, the TSK-17 scores of both surgical groups were significantly higher than HC (p<0.05). There was no difference between the three groups in terms of knee muscle strength on the non-injured side (p>0.05). There was no difference between both surgical groups in terms of knee muscle strength, single-leg hop test, and kinesiophobia level (p>0.05), (Table 2).

Table 2: Comparison of ACLR groups and healthy controls for outcome variables

		Group 1 (n=24) Mean±SD Median (IQR)	Group 2 (n=20) Mean±SD Median (IQR)	Group 3 (n=30) Mean±SD Median (IQR)	p	p		
						1 vs 2	1 vs 3	2 vs 3
Knee Flexor Strength (N)	Injured	13.99 (11.08-18.60)	12.83 (9.74-16.66)	18.83 (16.24-22.74) (right)	**0.000***	0.305	**0.001***	**0.000***
	Non-injured	16.83 (13.91-21.43)	15.49 (13.41-20.57)	18.16 (14.49-21.41) (left)	0.517	0.402	0.801	0.263
Knee Extensor Strength (N)	Injured	24.52±7.52	24.17±6.47	30.42±6.01 (right)	**0.001***	0.874	**0.002***	**0.001***
	Non-injured	27.60±7.37	26.93±6.02	28.41±6.61 (left)	0.740	0.745	0.671	0.424
Single-Leg Hop test (cm)	Injured	107.33 (88.83-116.12)	111.0 (99.58-131.74)	147.49 (134.91-160.32) (right)	**0.000***	0.253	**0.000***	**0.000***
	Non-injured	126.96±26.55	129.94±28.49	144.25±20.75 (left)	**0.029***	0.722	**0.010***	**0.045***
TSK-17		41.08±4.63	40.45±7.35	36.46±4.50	**0.005***	0.730	**0.001***	**0.039***

N: Newton; TSK-17: Tampa Scale for Kinesiophobia-17.

DISCUSSION

The choice of graft type for ACLR depends on the functional demands of the individual and the advantages and disadvantages associated with each surgical procedure. This study aimed to examine the long-term differences of the commonly preferred hamstring tendon autograft and fresh-frozen allografts in terms of single-leg hop performance, muscle strength, and kinesiophobia level. Our study demonstrated that muscle strength, single-leg hop performance, and kinesiophobia level were similar between both ACLR groups. However, they had significantly lower muscle strength on the injured side, single-leg hop test scores on both sides, and higher kinesiophobia levels than healthy controls.

Single-leg hop performance and muscle strength are key indicators for knee function after ACLR [19]. Therefore, the evaluation of single-leg hop performance and muscle strength offers important clues for the comparison of lower extremity function between different graft types after ACLR. In previous studies, the functional results of people who underwent ACLR using hamstring tendon autograft or fresh-frozen allograft were compared after 2-5.5 years of follow-up, and it was found that the single-leg hop test and vertical hop test results were similar [9,17]. Similarly, Harner et al. [16] compared people with autografts and fresh-frozen allografts at 3–5 years after surgery. They found no statistically significant difference between the groups in terms of single-leg hop and vertical hop performances. This study included people 1-4 years after hamstring tendon autograft or fresh-frozen allografts ACLR. Results showed once again that in parallel with the previous studies, both graft types have similar results in terms of single-leg hop performance. When the literature was examined in terms of knee muscle strength, studies comparing BPTB autograft and BPTB allograft (duration up to 3 years after surgery) reported similar knee muscle strength results [19,32,33]. Similarly, Jung et al. founded similar knee muscle strength results in their study comparing hamstring autograft with tibialis anterior allograft [34]. On the contrary, Landes et al. compared semitendinosus-gracilis autografts with tibialis anterior allografts at 2 years after ACL reconstruction and found that hamstring autograft had lower isometric knee flexor torque [35]. We could not find any study comparing the hamstring tendon autograft and fresh-frozen allograft techniques in terms of muscle strength. In the current study, although the graft types differed compared to those in the previous study [19,32-34], no difference was found between the two surgical groups in terms of both side flexor and extensor strength. The results of the study showed that the use of individuals' hamstring tendons in reconstructions using hamstring tendon autograft did not negatively affect functional performance and kinesiophobia levels as much as expected.

Kinesiophobia level is one of the variables associated with reaching the functional level and returning to sports before the injury [36]. In addition, kinesiophobia has important implications for the individual's perception of function in the long term after ACLR [26]. Although the importance of kinesiophobia post-ACLR has been shown in many studies [26,36], no studies are comparing different graft types in terms of kinesiophobia. Graft types have advantages and disadvantages in various aspects such as their structures and application methods [5,9,37]. For this reason, a comparison of autograft with allograft in terms of kinesiophobia may guide us to better understand the effects on the individual's fear of injury. In this study, kinesiophobia was assessed using the TSK-17. The results of our study showed that both graft types have similar effects in terms of kinesiophobia in the long term. Based on these results, we think that individuals underwent ACLR with hamstring tendon autograft or fresh-frozen allograft have similar kinesiophobia levels, so these two graft types will not make a significant difference in determining rehabilitation goals.

Another outcome of our study was the comparison of ACLR groups and HC. One study showed that individuals with ACLR exhibited lower jumping performance than matched healthy controls [38]. In a systematic review and meta-analysis compiling 21 studies, it was stated that knee muscle strength deficits in individuals with ACLR remained significantly low for many years (up to 4 years after ACLR) despite surgery and rehabilitation [39]. Another study stated that individuals who do not participate in sports regularly have higher kinesiophobia levels after ACLR than healthy controls [40]. In our study, consistent with the literature, both surgical groups had lower muscle strength and single-leg jumping performance and higher kinesiophobia levels compared to HC. This has shown that there is a need for rehabilitation in both surgical groups in the long term.

Limitations

This study had several limitations. Only male participants with ACLR were included in this study. Therefore, the results of the study cannot be generalized to the entire people with ACLR. Another limitation of the study was that the choice of the graft could not be controlled. The choice of the graft may have been decided by the participants themselves or the operating surgeon. Therefore, there may be bias in graft selection. Finally, the individuals included in the study received physiotherapy only in the first week, regardless of the graft type. However, afterward, individuals were followed by a home program. For this reason, it could not be followed exactly how often and how regularly individuals performed the exercises. This may have caused the difference between them and healthy individuals to increase.

CONCLUSION

Based on the results of this cross-sectional study, the use of hamstring tendon autograft and fresh-frozen allograft for ACLR with non-athlete males had similar functional outcomes and kinesiophobia levels. In addition, both graft types had lower functional outcomes and higher kinesiophobia than healthy controls. The results suggest that the requirement for rehabilitation of individuals persists in the long-term following both types of ACLR.

Ethical Approval: *2023-12/57 Non-Interventional Research Ethics Committee of Sivas Cumhuriyet University*

Conflict of Interest: *The authors have no conflicts of interest to declare.*

Funding: *None.*

Acknowledgements: *The authors are grateful to all participants in this study.*

Author Contribution: Concept: *SE,ZÖ;* ***Design:*** *SE,ZÖ;* ***Data collecting:*** *SE;* ***Statistical analysis:*** *SE,ZÖ;* ***Literature review:*** *SE,ZÖ;* ***Writing:*** *SE,ZÖ;* ***Critical review:*** *SE,ZÖ.*

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Karya J Health Sci. 2024;5(3):88-93
RESEARCH ARTICLE/ARAŞTIRMA MAKALESİ doi: 10.52831/kjhs.1469503 e-ISSN:2717-9540

KARYA JOURNAL OF HEALTH SCIENCE

journal homepage: www.dergipark.org.tr/kjhs

TURKISH VALIDITY AND RELIABILITY STUDY OF THE PATIENT PARTICIPATION SCALE

HASTANIN BAKIMINA KATILIM ÖLÇEĞİ'NİN TÜRKÇE GEÇERLİK VE GÜVENİRLİK ÇALIŞMASI

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ABSTRACT

Objective: The aim of this study is to establish the Turkish validity and reliability of the Patient Participation Scale.

Method: This methodological study was conducted with 214 patients receiving outpatient or inpatient treatment in Turkey. Personal Information Form and Patient Participation Scale were used to collect the research data. Language equivalence, content validity and construct validity were performed to determine the validity of this scale. Within the scope of reliability analysis, Cronbach's alpha value and split-half reliability analysis were used to assess consistency.

Results: The content validity index score of this scale was determined as 1.0. The Barlett Sphericity Tests value was (2260.928, p<0.00) and the Kaiser-Meyer-Olkin (KMO) value was 0.86 and the data set of the scale was found to be suitable for factor analysis. The Cronbach's Alpha coefficient of the scale was found to be 0.90. As a result of the analysis, the Guttman Equivalent Halves Coefficient was calculated as 0.91 and the Spearman-Brown Correlation Coefficient was calculated as 0.92 and it was concluded that the reliability of the scale was at an acceptable level.

Conclusion: The study was concluded that the Turkish form of the Patient Participation Scale is a valid and reliable measurement tool for evaluating the process of participation in the care process in patients receiving outpatient or inpatient treatment.

Key Words: Care, Patient, Validity, Reliability

ÖZ

Amaç: Bu çalışmanın amacı, Hastanın Bakımına Katılım Ölçeği'nin Türkçe geçerlilik ve güvenilirliğini tespit etmekti.

Yöntem: Bu metodolojik çalışma, Türkiye'de ayakta ve yatarak tedavi gören 214 hasta ile gerçekleştirildi. Araştırma verilerinin toplanmasında Kişisel Bilgi Formu ve Hastanın Bakımına Katılım Ölçeği kullanıldı. Bu ölçeğin geçerliğin belirlenmesi için dil eşdeğerliği, kapsam geçerliği ve yapı geçerliği yapıldı. Güvenilirlik analizi kapsamında, tutarlılığı değerlendirmek için Cronbach alfa değeri ve split-half güvenilirlik analizi kullanıldı.

Bulgular: Bu ölçeğin, kapsam geçerlik indeksi puanı 1,0 olarak belirlendi. Barlett Küresellik Testleri değeri ise (2260,928, p<0,00) ve Kaiser-Meyer-Olkin (KMO) değeri 0,86 olarak belirlenen ölçeğin veri setinin faktör analizine uygun olduğu bulundu. Ölçeğin Cronbach Alfa katsayısı 0,90 olarak bulundu. Analiz sonucunda, Guttman Eş Değer Yarılar Katsayısı 0,91 ve Spearman-Brown Korelasyon katsayısı 0,92 olarak hesaplanmış ve ölçeğin güvenirliğinin kabul edilebilir düzeyde olduğu sonucuna ulaşıldı.

Sonuç: Araştırmada, Hastanın Bakımına Katılım Ölçeği'nin Türkçe formunun ayakta veya yatarak tedavi gören hastalarda bakım sürecine katılım sürecini değerlendirmek için geçerli ve güvenilir bir ölçüm aracı olduğu sonucuna varıldı.

Anahtar Kelimeler: Bakım, Hasta, Geçerlik, Güvenirlik

INTRODUCTION

The World Health Organization emphasizes the importance of holistic and patient-centered care in all health problems [1]; similarly, the World Medical Association and the Council of Europe state that patients have the right to information and decision-making in all treatment processes [1,2]. Studies show that greater patient involvement in treatment decision-making is associated with higher patient satisfaction, better adherence and more favorable clinical outcomes [2,3]. Considering these positive effects, patients are presently promoted to rest during the care process and actively participate in the decision-making process, and the concept of 'patient participation behavior in care' is gaining importance in the literature. [4]. Participatory behavior in patient care means that a patient actively participates in all processes that may have an impact on their health and well-being [3,5,6]. In this context, it is accepted that the patient's care participation behavior has the potential to improve the quality of health services and may positively affect patient satisfaction [7].

The patients' care participation behavior includes various components such as sharing knowledge and experiences, performing self-management activities, mutual trust relationship with health professionals, and sharing power or control [6,8]. Sharing information and experiences involves the patient learning about their health condition and asking questions about the treatment process [8,9]. Studies show that as patients' knowledge and health literacy levels increase, their engagement in care increases [2,10]. Sharing power or control involves health professionals collaborating in decision-making about the patient's care and gaining the ability to manage the patient's care [9,11]. It is observed that as patients' levels

Article Info/Makale Bilgisi

Submitted/Yükleme tarihi: 04.16.2024, **Revision requested/Revizyon isteği:** 06.03.2024, **Last revision received/Son düzenleme tarihi:** 07.30.2024, **Accepted/Kabul:** 07.31.2024
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of knowledge and sense of control increase, they actively participate in care decisions [11]. The ability to perform self-management activities includes patient participation in physical and mental activities and encompasses patient safety practices today. The mutual relationship with health professionals, based on respect and trust, promotes patient participation, thereby improving patient safety and satisfaction [12,13]. Patients' involvement in health care is continuous during hospitalization and outpatient care. Patients interact with various health professionals while hospitalized and take an active role in managing their own recovery after discharge [6]. Patient engagement can increase health literacy, support treatment adherence, reduce medication errors, strengthen collaboration between health professionals and patients, and improve the quality and safety of patient-centered care. Therefore, assessing patients' engagement in care is essential [14,15]. Although there are scales that evaluate patients' emotional, behavioral and cognitive competencies or quality of care during their care [16,17], a comprehensive assessment tool is lacking. This study aims to examine the Turkish validity and reliability of the scale developed by Song and Kim (2023), which assesses patients' participation in care during both inpatient and outpatient treatment processes [6]. As a result of the study, a new assessment tool suitable for use in Turkish society will be presented, contributing to future scientific studies.

METHOD

Study Design

The research is a validity and reliability study designed using a methodological approach.

The research was conducted on online platforms between October 15, 2023, and January 15, 2024. An anonymous online survey was hosted on the Google Forms platform (Google LLC, Mountain View, California, USA) and shared to various groups via social media sources, including Facebook, WhatsApp, Instagram, and email.

Participant

The research population consisted of individuals with hospitalization and outpatient treatment experience in Turkey. A non-probability sampling method was used for the present study. One of the most basic and straightforward non-probability methods for recruiting online participants is known as 'river sampling,' which is also referred to as intercept sampling or real-time sampling. This technique involves directing potential participants to a survey via a link placed on a webpage, in an email, or in other locations where it is likely to attract the attention of individuals within the target audience [18]. For validity and reliability studies, it is recommended that the sufficient sample size for data analysis be between 5 to 40 times the number of items in the measurement tool [19,20]. In accordance with this information, the study originally planned to include 210 participants, intending to involve 10 participants per item for validity and reliability analysis of the scale. Ultimately, the research was conducted with 214 participants. When the inclusion criteria are examined, it is observed that the original study included all participants who had experience in inpatient or outpatient treatment [6]. Therefore, the inclusion criteria were to volunteer to participate in the study, to be over 18 years of age, and to have experience in inpatient or outpatient treatment.

Outcome Measures

Data were collected using the Participant Information Form and the Patient Participation Scale.

Participant Information Form: Researchers developed this form to evaluate the participants' age, gender, education level, marital status, employment status, income status, and presence of chronic disease.

Patient Participation Scale: The Patient Participation Scale was developed by Song and Kim in 2023 to measure patients' participation in healthcare. The original structure of the scale consists of 21 items and 4 sub-dimensions (Sharing knowledge and experience sub-dimension (1-8), Independent realization of self-management activities sub-dimension (9-15), Establishing a mutual trust relationship sub-dimension (16-19) and Participating in the decision-making process sub-dimension (20,21). The scale is a five-point Likert-type scale ranging from 1 (Strongly disagree) to 5 (Strongly agree). The lowest score is 21 and the highest score is 110. It is interpreted that as the scale score increases, the total Cronbach alpha value of the scale is 0.92 and the Cronbach alpha values of the sub-dimensions are calculated between 0.64-0.88 [6].

Validity and Reliability Stages of the Patient Participation Scale

Language Equivalence: Translation and back-translation technique was used to ensure language equivalence of the scale. The scale was translated from English to Turkish by two academic nurses who were fluent in English. Then, the translations were examined by the researchers, and a consensus was reached. The scale, which was translated into Turkish, was translated back into English by two academic nurses who were fluent in English. The literature emphasizes the importance of cultural adaptation and mastery of health literature in scale retranslations and therefore, it is important that retranslation is performed by people who have a good command of culture and literature [21]. Again, the translations were reviewed by the researchers, resulting in a consensus and confirming the equivalence of the scale.

Content Validity: The content validity of the scale was assessed using the Davis technique. According to the Davis technique, each item on the scale was evaluated by the experts as “(1) Not appropriate”, “(2) Seriously revised”, “(3) Slightly revised”, “(4) Appropriate”. After collecting opinions from all experts, the sum of the options “slightly revised” and “appropriate” was divided by the total number of experts and the content validity index (CVI) were calculated [22]. In order to evaluate the content validity of the scale, it was presented to the opinion of 5 faculty members who are experts in the field of nursing (2 mental health nursing specialists and 3 internal medicine nursing specialists). The literature suggests that a CVI score above 0.80 indicates adequate content validity [18].

Construct Validity: Kaiser-Mayer-Olkin (KMO) (>0.80) and Bartlett's sphericity test ($p<0.05$) were used to determine the suitability and adequacy of the data for factor analysis. First, confirmatory factor analysis (CFA) was used to evaluate the factor analysis of the scale. The fit adequacy of the CFA model was tested with the maximum likelihood method and χ^2/SD, RMSEA, SRMR, IFI, AGFI, CFI, and GFI indices [22,23]. Exploratory factor analysis (EFA) was used to determine the structure determined in the current sample. The Principal Axis extraction and varimax rotation techniques were utilized to determine the EFA factor analysis [22].

Reliability: Cronbach's alpha, split-half, and item analysis were employed to assess the reliability of the scale. A Cronbach's alpha coefficient of 0.70 or above was considered to indicate sufficient internal consistency of the scale. In the split-half method, the measurement tool's items were divided into two groups: odd-numbered and even-numbered items. The reliability levels of these groups were evaluated using the Spearman-Brown Correlation Coefficient and the Guttman Split Halves Correlation Coefficient, and reliability was considered sufficient if both coefficients were above 0.70. During item analysis, item-total correlation analysis was conducted to examine each item's relationship with the total score of the scale. It was deemed essential that each item's correlation value exceeded +0.25 and was positive [22].

Data Collection

Research data were collected online (Facebook, WhatsApp, Instagram, and email) using Google Forms. Participants who agreed to contribute to the study were sent a Google Forms link via WhatsApp and email. These participants shared the link via Facebook, WhatsApp, Instagram, and email, enabling more participants to become involved

in the study. In this way, volunteer participants clicked on the link and answered the research questions.

Ethical Approval

The author of the patient participation scale was contacted via e-mail, and necessary permissions were obtained for validity and reliability analysis. Conducting the research was approved by the Sakarya University of Applied Sciences Ethics Committee (date: 04.08.2023 and approval number: 34/7). Before starting the research, an informed consent form was presented to the participants, and their informed consent was obtained. Participants who ticked the check box answered the research questions.

Statistical Analysis

The SPSS 23.0 and AMOS 23.0 programs were used to analyze the data. Statistics such as percentage, mean, and standard deviation were used in the analysis of descriptive data. The scale's content validity was evaluated using the CVI and Davis techniques. Content validity of the scale was assessed using the CVI and Davis techniques. Construct validity was evaluated through CFA and EFA. Reliability analysis involved calculating Cronbach's alpha coefficient, employing the split-half method, and assessing item-total correlations to ensure validity and reliability of the scale.

RESULTS

The average age of the participants is 37.2±14.6 years. 76.2% are women, and 61.2% have a bachelor's degree. 53.3% are married, 63.1% are unemployed, 58.4% have income equal to expenses, and 54.7% have a chronic disease. Among participants with chronic diseases, the most common chronic diseases were heart failure (52.3%), Mediterranean fever (51.9%), hypertension (48.1%), COPD-asthma (46.7%), or diabetes (45.8%). Individuals with chronic diseases could have more than one disease. Participants who stated that they applied to a health board in the last 6 months constitute 70.6% of the sample, 71% who stated that the last department they applied to was a polyclinic, and more than half (62.1%) of those who stated that they had no inpatient experience (Table 1).

Validity

The translation-back-translation technique was used to ensure language equivalence of the scale. After the translation and back-translation technique, the researchers reached a consensus among themselves and the Turkish version of the scale took its final form. Then, the scale was presented to five experts to evaluate its content validity. Davis technique and CVI were used to evaluate the scale's content validity [18], and no items were removed from the scale at this stage. CVI value was found to be 1.00.

The construct validity of the scale was evaluated with EFA and CFA. KMO (0.86) test and Bartlett's sphericity test (2260.928, p<0.00) were used to evaluate the suitability of the data for factor analysis. If the KMO value is greater than 0.60 and the Bartlett test of sphericity is significant, the data are interpreted as suitable for factor analysis, and the sample size is sufficient. CFA was applied to the scale, whose original structure consisted of four factors, and its suitability in this study was tested. DFA was tested with χ^2/SD, RMSEA, SRMR, CFI, IFI, AGFI, and GFI fit index values [19,20]. As a result of the CFA analysis conducted with the sub-dimensions of the original scale, most of the fit index values of the original four-factor structure of the scale were found to be below acceptable limits (Table 2). When the covariance of the factors in the original scale was examined, it was found that there was no significant relationship between the fourth factor (F4) and the other factors (F1, F2, and F3). In addition, it was thought that the 10th item in the fourth factor could be removed because its sub-factor predictability was insignificant. Considering all these situations, removing items 9 and 10 from the fourth factor was decided.

Table 1. Descriptive characteristics of the participants (n = 214)

	Mean±SD
Age	37.2±14.6
Gender	**n (%)**
Woman	163 (76.2)
Man	51 (23.8)
Educational Status	
Primary school	26 (12.1)
Middle school	9 (4.2)
High school	32 (15.0)
Bachelor	131 (61.2)
Undergraduate (BSc) and over	16 (7.5)
Marital status	
Married	114 (53.3)
Single	100 (46.7)
Working Status	
Working	79 (36.9)
Not working	135 (63.1)
Income status	
Income is less than expenses	60 (28.0)
Income equals expenses	125 (58.4)
Income exceeds expenses	29 (13.6)
Presence of chronic disease	
Yes	97 (45.3)
No	117 (54.7)
Disease types of people with chronic diseases†	
Heart failure	112 (52.3)
Mediterranean Fever	111 (51.9)
Hypertension	103 (48.1)
COPD/Asthma	100 (46.7)
Diabetes	98 (45.8)
Last time to apply to a health institution	
last 6 months	151 (70.6)
6 months- 1 year	35 (16.4)
1-3 years	17 (7.9)
more than 3 years	11 (5.1)
Department last applied to in the hospital	
Emergency room	53 (24.8)
Outpatient Service	152 (71.0)
Inpatient Service	9 (4.2)
Inpatient experience time	
No	133 (62.1)
Daily	14 (6.5)
1 day	17 (7.9)
2-3 days	24 (11.2)
4-7 days	9 (4.2)
more than 7 days	17 (7.9)

SD: Standard deviation; †: More than one option is marked.

Table 2. Confirmatory factor analysis results of the scale (n = 214)

Index†	Good Fit	Acceptable Value	Analysis Result
$\chi 2$/sd	<2	<5	3.240
RMSEA	<0.05	<0.08	0.103 (0.09-0.11; p < 0.00)
SRMR	<0.05	<0.10	0.989
CFI	>0.95	0.90-0.95	0.824
IFI	>0.95	0.90-0.95	0.826
AGFI	>0.95	0.90-0.99	0.721
GFI	>0.95	0.85-0.95	0.786

†χ^2/sd: Chi-square (χ^2) value by the degree of freedom; RMSEA: Root Mean Square Error of Approximation; SRMR: Standardized-Root Mean Square Residual; CFI: Comparative Fit Index; IFI: Incremental Fit Index; AGFI: Adjustment Goodness of Fit Index; GFI: Goodness of fit Index.

EFA was applied to the scale to determine the factor structure suitable for our culture and language. Principal Axis was used as the extraction method when determining the factor structure. Varimax was used as the rotation technique. The EFA evaluation found that the factor loadings varied between 0.436 and 0.850, and three suitable factors with eigenvalues greater than 1 were revealed (Table 3). In this three-factor structure, which was different from the original scale, only two items (5th and 12th items) were changed, and the structure validity was tested by preserving the factor naming of the original scale. The three-factor structure explained 58.28% of the total variance. The literature

Table 3. Factor structure of the patient participation scale

	Sharing knowledge and experience	Performing self-management activities independently	Establishing a mutual trust relationship
S1	0.661		
S2	0.766		
S3	0.768		
S4	0.588		
S5		0.589	
S6	0.692		
S7	0.581		
S8	0.623		
S11		0.622	
S12	0.576		
S13		0.596	
S14		0.436	
S15		0.724	
S16		0.781	
S17		0.656	
S18			0.734
S19			0.813
S20			0.850
S21			0.811

states that it is acceptable for the explained variance to be between 0.40 and 0.60 [19,22]. In the new version of the scale, which consists of a total of 19 items, the sub-dimension "Sharing knowledge and experience" consists of 8 items (1-4, 6-8,12), and the sub-dimension "Performing self-management activities independently" consists of 7 items (5,11,13-17), it was determined that the "Establishing a relationship of mutual trust" sub-dimension consists of 4 items (18-21).

Reliability

Internal consistency analysis (Cronbach's alpha reliability coefficient), split halves and item analysis were used to evaluate the scale's reliability. The Cronbach's alpha reliability coefficient of the scale was found to be 0.90, the sub-dimension of sharing knowledge and experience was 0.86, the sub-dimension of performing self-management activities independently was 0.82, and the sub-dimension of establishing a mutual trust relationship was 0.87. These findings show that the scale's internal consistency is at a good level. This study also used the equivalent halves method to evaluate reliability. In the equivalent halves method, the measurement tool is divided into two equal halves, and the equivalence between the two halves is examined. As a result of this examination, the existence of a significant and high correlation between the measurement results of the quasi-scales reveals that the internal consistency reliability of the scale is high. In this study, the scale items were divided into two equal halves, odd and even, and the equivalence between the two halves of the scale was analyzed.

Table 4. Scale item means, standard deviations, item whole correlation coefficient, and Cronbach alpha reliability coefficient when item deleted (n = 214)

		Mean	SD	Item overall correlation coefficient	Cronbach alpha reliability coefficient when the item is deleted
1.	I tell the healthcare professionals about my current condition and symptoms in detail.	4.52	0.69	0.51	0.88
2.	I inform the healthcare professionals if new symptoms occur or existing symptoms change.	4.38	0.74	0.55	0.88
3.	I inform the healthcare professionals of specific information to refer to for my treatment.	4.56	0.58	0.57	0.88
4.	I tell the healthcare professionals how I am managing my disease.	4.35	0.71	0.61	0.88
5.	I check with the healthcare professionals whether the information and knowledge I have acquired (food, medications, and treatment methods, etc.) are correct.	4.24	0.76	0.62	0.88
6.	I ask the healthcare professionals any questions I may have about the disease or the treatment.	4.35	0.71	0.55	0.88
7.	I ask for further explanation if I do not understand the healthcare professional's explanation.	4.35	0.78	0.55	0.88
8.	I listen carefully to the healthcare professional's explanation.	4.63	0.49	0.54	0.88
11.	I consult with the healthcare professionals if I find a more suitable alternative during the treatment process.	4.36	0.65	0.46	0.88
12.	I check my vital signs (blood pressure, pulse rate, body temperature, and respiration rate) or test results and compare them with previous results.	4.65	0.52	0.54	0.88
13.	I observe whether new symptoms occur or existing symptoms change.	4.36	0.75	0.68	0.88
14.	I check if my treatment proceeds according to the guided schedule.	4.16	0.87	0.47	0.88
15.	I comply with the infection prevention activities, such as hand washing (hand hygiene).	4.03	0.99	0.60	0.88
16.	I comply with the fall prevention activities given by the hospital	4.21	0.70	0.53	0.88
17.	I monitor whether the healthcare professionals identifies the patient before performing examination, medication, or tests.	3.96	0.81	0.52	0.88
18.	I monitor whether the healthcare professionals washes their hands (hand hygiene) before performing any tests, medications, or treatments.	3.83	0.91	0.61	0.88
19.	I believe that my healthcare professional is well aware of my condition and treatment progress.	3.81	0.91	0.52	0.88
20.	I think the healthcare professionals respects me.	4.52	0.69	0.58	0.88
21.	I think the HCP listens to me.	4.38	0.74	0.54	0.88
F1		35.62	3.88		
F2		30.09	3.91		
F3		15.83	2.86		
Total		81.56	8.87		

SD: Standard deviation.

As a result, the Spearman-Brown Correlation Coefficient (0.92) and the Guttman Equivalent Halves Coefficient (0.91) were calculated. In order for the scale to be interpreted as reliable, the Spearman-Brown Correlation Coefficient must be >0.70, and the Guttman Equivalent Halves Correlation Coefficient must be >0.70Therefore, the reliability of this scale was found to be at an acceptable level. When the item-total correlation coefficients of the scale are examined, the item-total correlation coefficients are expected to be positive and greater than +0.25 [22]. When looking at this study, it was seen that all item correlation coefficients were between +0.46 and +0.68 (Table 4). Additionally, when the items of the scale were examined, it was found that there was no significant increase in the Cronbach Alpha reliability coefficient if the items were removed.

The mean score of the Patient Participation Scale was found to be 81.56±8.87 (Table 4). The average score obtained from the entire scale is above the average, which is interpreted as the participants' participation in their care being above average.

It was found that the situations in which patients had the highest involvement in their care were the following items, with an average score of 4.52±0.69: "Item 1. I explain my current situation and symptoms to healthcare professionals in detail." and “Item 20. I feel that the health professional respects me.” It was revealed that their participation in care was lowest in the following item, with an average score of 3.81±0.91: "Item 19. I believe that the health professional has enough information about my condition and treatment process." (Table 4).

DISCUSSION

This study, which was conducted to realize the Turkish adaptation of the Patient Participation Scale developed by Song and Kim (2023), showed that the scale is a valid and reliable instrument for the Turkish population. As a result of the findings, it was determined that the scale consisted of three sub-dimensions and 19 items. The scale can be used to determine the level of participation of the Turkish community in the care process.

For the Turkish language validity of the scale, the translation-back translation method was utilized. The literature emphasizes that language validity cannot only be achieved by direct translation from the original language, but also that the scale should be appropriate to the culture of the society in which it is adapted [23,24]. Therefore, it was crucial that the scale's translation was conducted by experts in the field who are familiar with the cultural context of the society [24]. In this study, four experts undertook the translation process, ensuring language validity [23]. Content validity was conducted using the Davis technique to determine whether the measurement tool accurately reflects the scope it is intended to measure [19,25]. In addition, the Critical Appraisal Index (CAI) for the scale was calculated. According to the Davis technique, the CVI should be above 0.80 [19]. In this study, the CVI value was found to be 1.00 and was found to be at the desired level. Thus, it is evident that the scale meets the criteria for content validity and effectively measures the intended constructs [23].

The homogeneity of the items in the measurement tool is assessed by construct validity analysis. Sufficient data must be available for construct validity analyses [25]. As a result of the analysis, the Kaiser-Meyer-Olkin (KMO) coefficient was 0.86 and the Bartlett's test chi-square value was 2260.928. According to literature, the KMO coefficient ranges from 0 to 1, with values closer to 1 indicating better suitability for factor analysis [26]. Classifications suggest KMO values as excellent (greater than 0.90), good (between 0.80-0.90), fair (between 0.70-0.80) and poor (between 0.50-0.70) [26,27]. In addition, Bartlett's test determines whether there is a relationship between the variables and a significant result indicates that the data matrix is appropriate [28]. The significant Bartlett's test in this study confirms that the data were compatible, the sample had a normal distribution, the sample size was sufficient for analysis, and the data were suitable for factor analysis. CFA is used to statistically test a predetermined structure [29]. However, in this study, the CFA fit indices did not meet acceptable thresholds. Therefore, EFA was applied to adapt the scale to Turkish culture and to determine the factor structures.

As a result of EFA, it was found that the scale had a three-factor structure and explained 58.28% of the total variance. While the scale lacks a validity and reliability study in a different language, the original study reported that the factor structure explained 61.9% of the total variance [6]. While more than 30% of the total variance explained is sufficient for single-factor scales, it is recommended that this value should be between 40-60% for multi-factor scales [22,30]. When the factor distributions in the scale were examined, it was determined that eight items explained the first factor, seven items explained the second factor and the remaining four items explained the third factor. This suggests that the scale is suitable for Turkish culture with its three-dimensional structure, and the variance analysis results are deemed acceptable. As a result of the reliability analysis of the study, the Cronbach's alpha reliability coefficient of the overall scale was 0.90. The sub-dimensions showed reliable internal consistency with coefficients of 0.86 for sharing knowledge and experience, 0.82 for performing self-management activities independently, and 0.87 for establishing a mutual trust relationship. Although there is no validity and reliability study of the scale in a different language, in the original study of the scale, Cronbach's alpha reliability coefficient was 0.88 for sharing knowledge and experience, 0.83 for performing self-management activities independently, 0.88 for establishing a relationship of mutual trust, and 0.92 for the total scale [6]. Studies emphasize that a Cronbach's alpha value of 0.70 and above indicates that the scale is reliable, while a value of 0.80 and above indicates a very high level of reliability [31,32]. In addition to Cronbach's alpha, item-total correlation is used to assess internal consistency. Although no universal standard range exists for this correlation, a positive value of at least 0.25 is generally considered acceptable [22,32]. Items with negative skewness or values below this threshold are typically removed from the scale [30]. In this study, item-total correlation values ranged from +0.46 to +0.68, all of which were positive.

Limitations

This study has two limitation. The study was conducted online. This may have limited access to patients without access to online platforms. Another limitation of the study is that the study was conducted using the non-Probability sampling method.

CONCLUSION

Following validity and reliability analyses, it was concluded that the Participation in Patient Care Scale is a valid and reliable measurement tool for patients receiving inpatient or outpatient treatment in the Turkish society. In the study, it was determined that the content validity, model fit and reliability of the scale were high. Moreover, the scale, comprising 19 items with a three-factor structure, was identified as suitable for measuring patient participation in care processes in Turkey in a multidimensional manner.

Ethical Approval: *2023-34/7 Sakarya University of Applied Sciences Ethics Committee*

Conflict of Interest: *The authors have no conflicts of interest to declare.*

Funding: *None.*

Acknowledgements: *The authors would like to thank all the patients’ voluntary participation. Without the patients’ voluntary participation, this study would not have been possible.*

Author Contribution: Concept: *AB,MSK,SÖ;* ***Design:*** *AB,MSK,SÖ;* ***Data collecting:*** *AB,MSK,SÖ;* ***Statistical analysis:*** *AB,MSK,SÖ;* ***Literature review:*** *AB,MSK,SÖ;* ***Writing:*** *AB,MSK,SÖ;* ***Critical review:*** *AB,MSK,SÖ.*

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Karya J Health Sci. 2024;5(3):94-99
RESEARCH ARTICLE/ARAŞTIRMA MAKALESİ doi: 10.52831/kjhs.1534151 e-ISSN:2717-9540

KARYA JOURNAL OF HEALTH SCIENCE

journal homepage: www.dergipark.org.tr/kjhs

TRANSLATION, CULTURAL ADAPTATION, RELIABILITY, AND VALIDITY OF THE TURKISH VERSION OF THE HEADACHE IMPACT QUESTIONNAIRE

BAŞ AĞRISI ETKİ ANKETİ'NİN TÜRKÇE VERSİYONUNUN ÇEVİRİSİ, KÜLTÜREL UYUMU, GÜVENİLİRLİĞİ VE GEÇERLİLİĞİ

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ABSTRACT

Objective: To prove the reliability and validity of the Turkish version of the Headache Impact Questionnaire (HImQ) for evaluating individuals with headaches.

Method: 102 individuals (31.12±12.39 years) with headaches participated in the study. Test-retest and internal consistency analyses were used to assess the reliability of the HImQ, and Exploratory (EFA) and Confirmatory Factor Analysis (CFA), and correlation analysis was used to determine its validity. For correlation analysis, the total scores of the HImQ, Headache Impact Test-6 (HIT-6), and Migraine Disability Assessment Scale (MIDAS) were calculated.

Results: The Turkish version of the HImQ demonstrated high reliability with an Intraclass Correlation Coefficient of 0.846 and a Cronbach's α of 0.769. Structural validity through EFA indicated a three-factor structure, supported by KMO (0.759) and Bartlett's sphericity test values (780.133; p<0.001). CFA confirmed this structure with good fit indices. Convergent validity was supported by good correlations between the HImQ and HIT-6 (r=0.429; p=0.000), and MIDAS (r=0.487; p=0.000). No floor or ceiling effects were detected.

Conclusion: This study established the Turkish HImQ as a reliable and valid measure for evaluating the impact of headaches on daily functioning. With strong internal consistency, test-retest reliability, and supported validity, the scale proved effective for clinical and research use in the Turkish-speaking people. It provides a solid framework for assessing headache-related disability in daily life.

Key Words: Headache, Migraine, Questionnaire, Psychometrics

ÖZ

Amaç: Baş ağrısı olan bireylerin değerlendirilmesinde Baş Ağrısı Etki Anketi'nin (BEA) Türkçe versiyonunun güvenilirliğini ve geçerliliğini kanıtlamaktı.

Yöntem: Çalışmaya baş ağrısı yaşayan 102 birey (31,12±12,39 yıl) katıldı. BEA'nın güvenilirliğini değerlendirmek için test-tekrar test ve iç tutarlılık analizleri, geçerliliğini belirlemek için ise Açımlayıcı Faktör Analizi (AFA), Doğrulayıcı Faktör Analizi (DFA) ve korelasyon analizi kullanıldı. Korelasyon analizinde, BEA, Baş Ağrısı Etki Testi-6 (BET-6) ve Migren Engellilik Değerlendirme Ölçeği (MEDÖ) toplam puanları hesaplandı.

Bulgular: BEA'nın Türkçe versiyonu, 0.846'lık bir iç tutarlılık katsayısı ve 0.769'luk bir Cronbach's α ile yüksek güvenilirlik gösterdi. AFA ile yapılan yapısal geçerlilik, Kaiser-Meyer-Olkin test (0.759) ve Bartlett'in sphericity testi değerleri (780,133; p<0,001) ile desteklenen üç faktörlü bir yapı ortaya koydu. DFA bu yapıyı iyi uyum indeksleri ile doğruladı. BEA ile BET-6 (r=0,429; p=0,000) ve MEDÖ (r=0,487; p=0,000) arasındaki iyi korelasyonlar, yakınsak geçerliliği destekledi. Taban ve tavan etkileri tespit edilmedi.

Sonuç: Bu çalışma, baş ağrılarının günlük işlevsellik üzerindeki etkisini değerlendirmek için güvenilir ve geçerli bir ölçüt olarak Türkçe BEA'yı ortaya koydu. Güçlü iç tutarlılık, test-tekrar test güvenilirliği ve desteklenen geçerlilikle, ölçek Türkçe konuşan bireylerde klinik ve araştırma kullanımı için etkili olduğunu kanıtladı. Günlük yaşamda baş ağrısıyla ilişkili engelliliği değerlendirmek için sağlam bir çerçeve sağlar.

Anahtar Kelimeler: Baş Ağrısı, Migren, Anket, Psikometri

INTRODUCTION

Headaches are probably the most common reason for referral to neurologists in the 21st century [1]. Headaches are classified as primary or secondary headaches. Primary headaches include migraine, tension-type, and trigeminal autonomic cephalgias that are not related to an underlying medical condition. Secondary headaches occur with association with a certain disorder known to cause headaches. Headaches associated with trauma or head and/or neck injury are examples [2]. Migraine and tension-type headaches are the most common primary headaches, while cervicogenic headache is the most common secondary headache [3,4].

Headache is one of the most common health problems associated with various medical costs, socioeconomic status, and reduced quality of life [5-7]. Headache disorders are among the main causes of disability worldwide; however, most individuals are unfortunately not professionally diagnosed. Instead, individuals turn to over-the-counter medication to self-manage symptoms [8]. Information about any headache attack is not sufficient to characterize the overall severity of the disease. Accordingly, the Headache Impact Questionnaire (HImQ) was developed to evaluate the headache experience over a period rather

Article Info/Makale Bilgisi

Submitted/Yükleme tarihi: 08.16.2024, **Revision requested/Revizyon isteği:** 10.27.2024, **Last revision received/Son düzenleme tarihi:** 11.02.2024, **Accepted/Kabul:** 11.04.2024

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than any headache. Because physicians and patients often cannot communicate effectively about headache severity, it was thought that a simple self-administered questionnaire measuring the impact of headaches could improve doctor-patient communication and facilitate treatment decisions. Such a questionnaire can also provide a screening tool to identify individuals in need of care and an outcome measure for clinical practice, clinical trials, and epidemiological studies. HImQ, which was developed to measure the impact and quality of life of individuals suffering from headaches, evaluates the frequency and duration of headaches, the degree of pain severity, daily living activities, disruptions in work or school life, the influence of leisure activities of the individual, and other symptoms that may occur [9].

Primary care providers will constantly encounter headache as a clinical problem. Appropriate treatment after early and accurate diagnosis will help reduce pain, suffering and economic burden. However, before all of this, it is important to evaluate the headache and its effects correctly and to deal with it from many perspectives. While there are established headache-specific measures, it was aimed to address unique aspects of headache assessment that the HImQ offers, which are particularly relevant for the Turkish population. The HImQ provides a comprehensive evaluation across multiple dimensions of headache impact, including frequency, duration, pain intensity, disruptions to daily living activities, and other symptoms related to headaches. Furthermore, the HImQ's development process, rooted in previous population-based headache studies, underscores its strength as a validated tool across diverse headache types and impacts, making it an ideal candidate for thorough psychometric analysis in a Turkish context. Therefore, the aim of this study was to adapt, and analyze the validity and reliability of the Turkish version of the self-administered HImQ, which was developed to evaluate the headache experience for a certain period rather than any headache.

METHOD

Study Design and Participants

This study was designed as a methodological research to evaluate the validity and reliability of the Turkish version of the HImQ.

The sample of the study consisted of at least 99 individuals over the age of 18 with headache complaints. Based on the original study of HImQ developed by Stewart et al. [9] the expected reliability level, minimal acceptable reliability level, α, and β was taken as $\rho1=0.85$, $\rho0=0.75$ [10], 0.05, and 0.20, respectively. The sample size was determined as 99.

The study sample comprised individuals aged 18 and older who had headache complaints and were residents of Tokat, Turkey. The participants of the study were Tokat Gaziosmanpaşa University students, employees and individuals residing in Tokat. Potential participants were approached and verbally invited to join the study, with detailed information provided about the research objectives and procedures. Those who expressed interest and gave their consent were subsequently enrolled in the study. The questionnaires were filled out face to face by individuals at Tokat Gaziosmanpaşa University Faculty of Health Sciences. Additionally, individuals who received any headache diagnosis from a neurologist at any point in their lives were recorded. However, having a specific headache diagnosis was not a prerequisite for participation; simply having a complaint of headache was sufficient for inclusion in the study.

Inclusion Criteria: Individuals meeting the following conditions were included in the study:

- Had a headache complaint for at least 3 months,
- Had a diagnosis of headache at any time in their life (a formal diagnosis was not required; having a complaint was sufficient),
- Could speak, read, and write in Turkish,
- Were over 18 years of age,
- Volunteered to participate in the study.

Exclusion Criteria: Individuals were excluded if they:

- Could not speak, read, or write in Turkish,
- Had any neurological, psychiatric, or cognitive impairments.

Translation

The steps for translation and cultural adaptation, based on the Beaton guidelines, were as follows [11]: 1) The original version of the HImQ was translated into Turkish separately by two native Turkish speakers (proficient in the English language); 2) Then the translations were combined by these two translators to form a single translation; 3) The final Turkish version of the HImQ was translated back into English by two translators who were unaware of the study; 4) Later, the translations were combined by these two translators to create a suitable and single translation; and 5) Back translation and cultural adaptation were conducted by an expert committee consisting of a physiotherapist, an English linguist, and two translators, and the final form of the scale was created.

Face validity simply refers to whether an instrument measures what it is intended to and whether it serves as a reasonable method for the intended purpose. Generally, testing on 15-30 individuals is sufficient. Face validity of the prefinal Turkish version of HImQ was tested on 30 individuals with headaches [12]. Since no negative or incomprehensible feedback was received from these individuals, the prefinal version was accepted as the final version. Seven days later, 70 subjects who were contacted again were included in the test-retest analysis. A sample size of 70 participants for the retest analysis is considered adequate and exceeds common standards for reliability testing. Specifically, reliability is typically rated positively when the Intraclass Correlation Coefficient (ICC) or weighted Kappa reaches a threshold of 0.70 or higher, with a minimum sample size of 50 patients being sufficient for robust statistical analysis [13]. Thus, having 70 individuals in the retest group not only meets but also enhances the reliability assessment's statistical power, providing confidence in the consistency of the results.

Outcome Measures

Sociodemographic Form: Sociodemographic information on individuals' age, weight, height, body mass index, complaint duration, gender, presence of migraine, smoking, and alcohol use were recorded.

The Headache Impact Questionnaire (HImQ): HImQ is a self-administered questionnaire designed to measure the frequency and duration of headaches, the degree of pain intensity, the disruptions in activities of daily living, work or school life, the impact of the individual's leisure activities, and other symptoms that may occur in individuals with headache complaints. The scale consists of 16 items. Early in the development of HImQ, the first draft questionnaire was created based on questions used in previous population-based migraine headache studies. When calculating the total score of the HImQ, not all items are included. The total score is calculated as follows:

item 4+[item 14*(item 1-item 13)]+[item 12*(item 1-item 11)]+[item 10*(item 1-item 9)].

The test-retest correlations of the items were found to be between 0.64-0.86. It has been reported that HImQ is at an acceptable level in terms of intended psychometric properties [9].

The Headache Impact Test-6 (HIT-6): HIT-6 evaluates conditions such as pain, psychological stress, and social and cognitive functions in individuals with headaches. It consists of 6 items and each question contains a 5-point Likert-type answer. The total score ranges from 36-78. An increased score indicates greater exposure to headaches [14]. Its Turkish validity and reliability were performed [15].

The Migraine Disability Assessment Scale (MIDAS): MIDAS is a 5-item scale developed in 1999 to measure the effect of headaches on the quality of life in patients diagnosed with migraine [16]. It has

widespread use. It was used in this study because it evaluated the quality of life. Turkish validity and reliability were established [17].

Ethical Approval

All participants were informed about the assessments before the study, volunteered for the study in compliance with the Helsinki Declaration, and signed the Informed Consent Form. The necessary permission and approval were obtained from the Tokat Gaziosmanpaşa University Ethics Committee of Clinical Investigations for the study (date: 25.08.2022, approval number: 2022/14) and the study was registered in ClinicalTrials.gov (NCT04765501).

Statistical Analysis

Statistical Package for Social Sciences (SPSS) version 22.0 software was used for statistical analyses. Analyses are expressed as mean±standard deviation and as a percentage.

Internal consistency and test-retest analyses were used to determine the reliability of the HImQ. Internal consistency analysis was calculated by Cronbach's α, and test-retest values were calculated by Intraclass Correlation Coefficient (ICC). A Cronbach α value of ≥0.70 was considered acceptable [13]. ICC values ≤0.5, 0.50-0.75, 0.75-0.90, and >0.90 represented weak, moderate, good, and excellent reliability, respectively [18]. To evaluate the agreement and systematic variation between test and retest scores, a t-test was conducted, and Bland-Altman plots with 95% agreement limits were used [12]. Reproducibility was assessed using the standard error of measurement (SEM) and minimal detectable change (MDC). The SEM and MDC were calculated using the following formulas [18]:

SEM95: SD/√(1-ICC); where SD is the standard deviation of participants and ICC is the reliability coefficient

MDC95: z*SEM*√2; where z=1.96 (based on 95% confidence) and SEM is the standard error of measurement

The structural validity of HImQ was evaluated with Exploratory Factor Analysis (EFA) and Confirmatory Factor Analysis (CFA). The following metrics were examined: Kaiser-Meyer-Olkin (KMO) test, Bartlett's test of sphericity (BTS), as well as the percentage of variance explained, eigenvalues, and factor loadings. A KMO value of 0.50 or higher is considered acceptable for assessing the adequacy of performing EFA on a variable set [19]. BTS values with a p-value below 0.05 suggest that the covariance matrix is appropriate for factor analysis [20]. An acceptable percentage of variance explained is 50% or greater [21]. Factors with eigenvalues greater than 1 were considered [19], and loadings above 0.40 were deemed significant and thus included in the analysis [12]. For CFA, the fit of each factor structure was assessed using several criteria: chi-square/degrees of freedom (CMIN/DF), Goodness of Fit Index (GFI), Root Mean Square Error of Approximation (RMSEA), and Standardized Root Mean Squared Residual (SRMR). Acceptable thresholds for these indices include a CMIN/DF less than 3, a GFI greater than 0.90, an RMSEA below 0.10, and an SRMR less than 0.10 [22]. Terwee et al. recommend a minimum sample size of 100 individuals for CFA [13]. The convergent validity of the questionnaire was calculated by correlating the total score of the HImQ with the total scores of the HIT-6, and MIDAS. Pearson's and Spearman's correlations were used for this analysis, and it was interpreted as excellent (r=0.81-1.00), very good (r=0.61-0.80), well (r=0.41-0.60), poor (r=0.21-0.40), and bad correlation (r=0-0.20) [23].

The percentage of the lowest (0 point) and highest (37810 points) questionnaire score was calculated to determine the floor and ceiling effect of the Turkish version of the HımQ [13].

All values were considered significant at $p<0.05$.

RESULTS

The initial test group consisted of 102 individuals with a mean age of 31.12±12.39 years (81 women and 21 men), while the retest group consisted of 70 individuals with a mean age of 32.73±12.87 years (52 women and 18 men). The duration of headache complaints for the initial group was 65.26±64.61 months, whereas for the retest group, it was 66.20±71.98 months. Additionally, in the first group, 47 individuals (46.1%) were diagnosed with migraine, compared to 27 individuals (38.6%) in the second group. Detailed information about the individuals is presented in Table 1.

Table 1. Characteristics of individuals

	Test group (n=102)	Retest group (n=70)
	Mean±SD	**Mean±SD**
Age (years)	31.12±12.39	32.73±12.87
Weight (kg)	68.18±14.60	70.93±14.53
Height (m)	1.67±0.08	1.68±0.09
BMI (kg/m^2)	24.46±4.76	25.13±5.08
Complaint duration	65.26±64.61	66.20±71.98
Pain intensity	68.86±18.16	68.30±19.44
HImQ	1554.67±1604.37	1267.57±1047.32
HDQ	44.01±14.31	42.06±13.43
HIT-6	61.92±6.43	61.07±6.75
MIDAS	36.90±33.82	38.49±34.62
	n (%)	**n (%)**
Gender		
Female	81 (79.4)	52 (74.3)
Male	21 (20.6)	18 (25.7)
Presence of migraine		
Yes	47 (46.1)	27 (38.6)
No	55 (53.9)	43 (61.4)
Smoking		
Yes	33 (32.4)	22 (31.4)
No	69 (67.6)	48 (68.6)
Alcohol use		
Yes	9 (8.8)	6 (8.6)
No	93 (91.2)	64 (91.4)

SD: Standard deviation; kg: Kilogram; m: Meter; BMI: Body mass index; kg/m^2: Kilogram/Meter^2; HımQ: Headache Impact Questionnaire; HIT-6: Headache Impact Test-6; MIDAS: Migraine Disability Assessment.

Table 2. Item properties for the HımQ (n=102)

Item	Mean	SD	Corrected item-total correlation	Cronbach's α if item deleted
1. HAFREQ	16.74	11.87	0.343	0.759
2. LASTHA	6.78	7.50	-0.136	0.781
3. DURATION	3.73	3.18	0.267	0.769
4. PAININT	6.92	1.78	0.616	0.767
5. PAINSEV%	62.94	19.58	0.537	0.739
6. LIEDOWN%	64.41	23.78	0.593	0.732
7. LIEDOWNF	11.43	11.35	0.404	0.756
8. MISWORK%	26.57	26.31	0.385	0.763
9. MISWORKF	2.29	2.95	0.380	0.767
10. WORKEFF%	45.00	27.85	0.427	0.760
11. MISCHOREF	8.19	10.09	0.289	0.763
12. CHOREFF%	54.71	21.70	0.698	0.719
13. MISNWORKF	7.57	7.90	0.416	0.759
14. NWORKEFF%	54.90	22.10	0.729	0.714
15. NAUSEA	1.22	0.95	0.404	0.770
16. SENSITIVITY	2.32	0.86	0.432	0.771

Cronbach's α: 0.917; Intraclass Correlation Coefficient (ICC): 0.846; Standard Error Measurement (SEM): 387.3824; Minimal Detectable Change (MDC): 1073.769; HAFREQ: Number of days with headache; LASTHA: The latest headache; DURATION: Headache duration; PAININT: Headache intensity; PAINSEV%: Percentage of severe headaches; LIEDOWN%: Percentage of rest in headache; LIEDOWNF: Number of rests more than 1 hour due to headache; MISWORK%: Missing work or school due to headaches; MISWORKF: Number of days missing work or school due to headaches; WORKEFF%: Percentage of decreased ability to work or school due to headache; MISCHOREF: Inability to do housework or chores due to headache; CHOREFF%: Percentage of not being able to do housework or chores; MISNWORKF: Number of days spent away from non-work activities due to headaches; NWORKEFF%: Percentage of not being able to do non-work activities; NAUSEA: Frequency of nausea; SENSITIVITY: Frequency of light or sound sensitivity.

For the Turkish version of the HImQ, the Intraclass Correlation Coefficient (ICC) was 0.846, and the Cronbach's α value was 0.769. The SEM and the MDC were found to be 387.38 and 1073.77, respectively. Table 2 shows the mean, standard deviation, corrected item-total correlation, and Cronbach's α if item deleted values for the questionnaire items. Additionally, Bland-Altman plots supported the reliability of the HImQ (Figure 1).

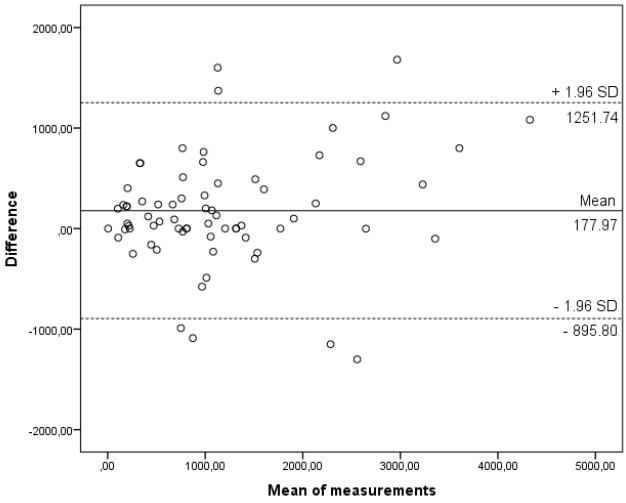

Figure 1. Bland–Altman's plots of the HImQ test–retest scores (n=70)

The structural validity assessed through EFA revealed a three-factor structure. The Kaiser-Meyer-Olkin (KMO) test value (0.759) and Bartlett's sphericity test value (780.133; p<0.001) supported the adequacy of the sample size for this analysis (Table 3 and Figure 2).

Table 3. Factor analysis results for the HımQ (n=102)

Items	Factor 1	Factor 2	Factor 3
3. DURATION	0.443		
4. PAININT	0.702		
5. PAINSEV%	0.680		
6. LIEDOWN%	0.671		
12. CHOREFF%	0.776		
14. NWORKEFF%	0.774		
15. NAUSEA	0.675		
16. SENSITIVITY	0.597		
1. HAFREQ		0.847	
2. LASTHA		-0.523	
7. LIEDOWNF		0.840	
11. MISCHOREF		0.854	
13. MISNWORKF		0.755	
8. MISWORK%			0.832
9. MISWORKF			0.811
10. WORKEFF%			0.767
Percent Variance (%)	24.457	45.704	58.994

Kaiser-Meyer-Olkin test: 0.759; Bartlett's test: 780.133 p<0.001; Minimum Discrepancy Function by Degrees of Freedom (CMIN/DF): 1.99; Root Mean Square Error of Approximation (RMSEA): 0.099; Standardized Root Mean Squared Residual (SRMR): 0.076; Goodness of Fit Index (GFI): 0.95; HAFREQ: Number of days with headache; LASTHA: The latest headache; DURATION: Headache duration; PAININT: Headache intensity; PAINSEV%: Percentage of severe headaches; LIEDOWN%: Percentage of rest in headache; LIEDOWNF: Number of rests more than 1 hour due to headache; MISWORK%: Missing work or school due to headaches; MISWORKF: Number of days missing work or school due to headaches; WORKEFF%: Percentage of decreased ability to work or school due to headache; MISCHOREF: Inability to do housework or chores due to headache; CHOREFF%: Percentage of not being able to do housework or chores; MISNWORKF: Number of days spent away from non-work activities due to headaches; NWORKEFF%: Percentage of not being able to do non-work activities; NAUSEA: Frequency of nausea; SENSITIVITY: Frequency of light or sound sensitivity.

However, if the items forming the factors are more similar, naming is preferred. In the original version, a four-factor structure emerged and no naming was done. Therefore, it could not be done in this study. The construct validity of this three-factor structure was confirmed through CFA (Figure 3). The CFA results showed a CMIN/DF value of 1.99, RMSEA value of 0.099, SRMR value of 0.076, and GFI value of 0.95. Convergent validity was examined by correlating the HImQ with the HIT-6, and MIDAS. This analysis also showed a good correlation between the HImQ with HIT-6 (r=0.429; p=0.000) and MIDAS (r=0.487; p=0.000).

No floor or ceiling effects were observed, with both percentages being 0% for each assessment.

DISCUSSION

The aim of this study was to investigate the validity and reliability of the Turkish version of the HImQ in individuals with headache complaints. The adaptation and statistical results show that the HImQ is an appropriate, valid, and reliable assessment tool for individuals with headache complaints in the Turkish population.

Clinical scales and patient-reported outcome measures (PROMs) for headache disorders include various instruments like the Headache Activities of Daily Living Index and the Headache Disability Questionnaire, many of which are specifically designed for migraine and have established validity and reliability [24]. While the HImQ was developed for migraine patients, its items also apply to individuals with headache complaints lacking a formal diagnosis. Therefore, it is essential to evaluate the validity and reliability of the Turkish version of the HImQ.

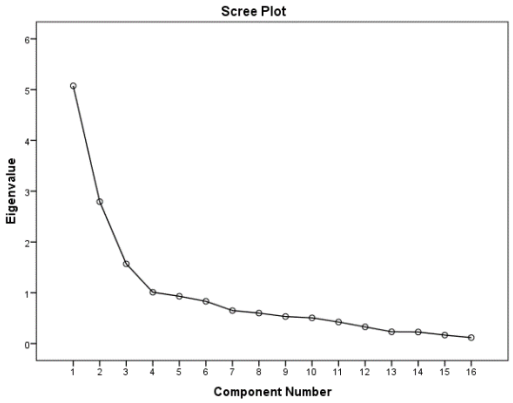

Figure 2. Scree plot of the HımQ (n= 102)

The internal consistency of the Turkish version of the HImQ was assessed using Cronbach's alpha coefficient, which was found to be 0.769. When compared with the original version of the HImQ [9], which had a Cronbach's alpha of 0.83, the Turkish version shows a similar, albeit slightly lower, internal consistency. This slight difference could be attributed to cultural and linguistic factors, which might influence how individuals interpret and respond to items on the scale. Nonetheless, the Cronbach's alpha value for the Turkish version still falls within the acceptable range, indicating comparable reliability to the original version.

Test-retest reliability was also evaluated in this study, which is a critical component for ensuring that the instrument produces stable and consistent results over time. According to the literature, there is no definitive time interval for test-retest analysis [25,26]. According to Marx et al., test-retest intervals of 2 days to 2 weeks are sufficient for evaluating the stability of responses over time [25]. In the original study by Stewart et al., the test-retest interval ranged from 33 to 55 days, and the reported Intraclass Correlation Coefficient (ICC) values were between 0.77 and 0.85 [9]. The current study employed a shorter, 2-week interval, aligning with commonly accepted practices in the literature for headache-related scales. The ICC value for the Turkish version was found to be 0.846, which is in line with the reliability of the original version. An ICC value above 0.75 generally indicates good reliability, further supporting the robustness of the Turkish version of the HImQ.

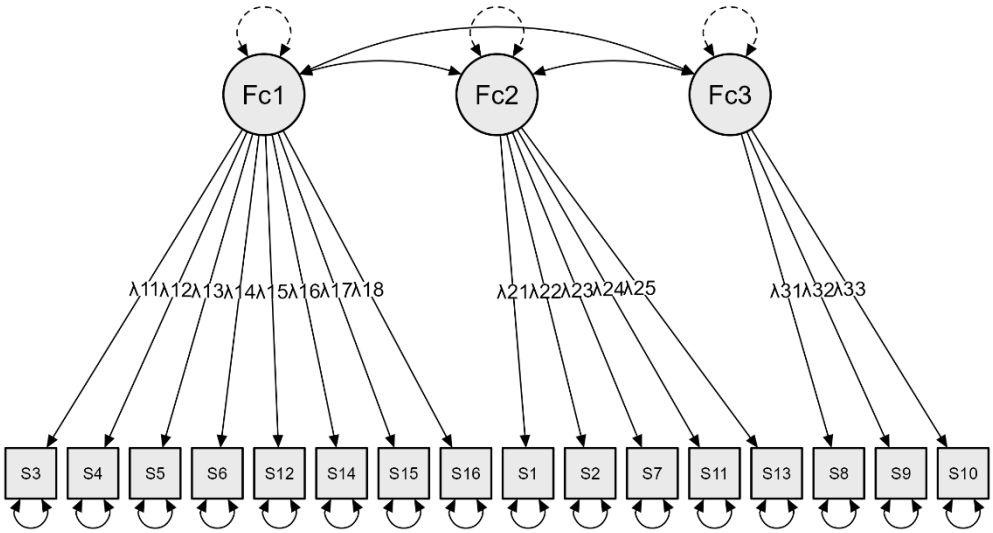

Figure 3. The CFA diagram shows the three-factor structure of the Turkish version of the HImQ (n=102)

In addition to internal consistency and test-retest reliability, this study also introduced measurements of the SEM and MDC, which were not reported in the original study [9]. The SEM and MDC provide insights into the measurement precision of the scale and the smallest change that can be detected beyond measurement error, respectively. The SEM value of 387.38 and MDC value of 1073.77 suggest that the Turkish version of the HImQ has reasonable sensitivity for detecting changes in headache impact over time. However, it is important to note that these values may vary depending on the population and the context in which the scale is used. Therefore, further studies across different populations and headache types are necessary to provide more generalized conclusions regarding these psychometric properties.

The KMO and Bartlett's test results indicated that the sample size was both appropriate and sufficient for factor analysis, with the KMO value being greater than the acceptable threshold of 0.50, and Bartlett's test of sphericity confirming that the data were suitable for factor analysis ($p<0.001$). Structural validity, which examines how well the scale measures the theoretical construct it is intended to assess, was evaluated through both EFA and CFA. The EFA revealed that the Turkish version of the HImQ demonstrated a three-factor structure, which is slightly different from the four-factor structure found in the original version of the Hımq [9]. This discrepancy could be attributed to cultural differences in how headache-related symptoms are perceived and reported by Turkish-speaking individuals compared to those in the original study population. Despite the difference in factor structure, the CFA provided further support for the validity of the Turkish version of the HImQ. The CFA results showed that the values for key fit indices-CMIN/DF, RMSEA, SRMR, and GFI-all fell within the acceptable range, indicating a good fit between the hypothesized model and the observed data. Specifically, a CMIN/DF value less than 3, an RMSEA value below 0.10, an SRMR value below 0.08, and a GFI greater than 0.90 are all considered indicative of a well-fitting model. These findings suggest that the three-factor structure of the Turkish version of the HImQ is statistically sound and appropriate for use in this population. This study represents the first instance where CFA was applied to the HImQ, as the original validation study did not conduct CFA to confirm the factor structure identified in EFA. The fact that the current study was able to validate the structural validity of the Turkish version through CFA adds to the robustness of the scale's psychometric properties.

In addition to structural validity, convergent validity-a subtype of construct validity-was also examined in this study. Convergent validity assesses whether two measures that theoretically should be related are indeed correlated in practice. In this case, the total scores of the Turkish HImQ were compared with scores from two well-established headache-related scales, the HIT-6 and the MIDAS. The statistically significant correlations observed between the HImQ and both the HIT-6 ($r=0.429$, $p=0.000$) and MIDAS ($r=0.487$, $p=0.000$) indicate that the HImQ is appropriately measuring headache-related disability and impact, similarly to these widely recognized instruments. This further supports the convergent validity of the Turkish version of the HImQ, indicating that it is a valid tool for assessing the broader impact of headaches on individuals' lives.

Overall, the results of this study indicate that the Turkish version of the HImQ is a reliable tool for assessing the impact of headaches in a Turkish-speaking population. However, further research is needed to explore its applicability across various subgroups, as well as its potential use in longitudinal studies where sensitivity to change over time is critical. The results of the EFA, CFA, and convergent validity analyses confirm that the Turkish version of the HImQ is a valid instrument for assessing headache-related impact in a Turkish-speaking population. The introduction of CFA in this study adds a layer of rigor to the validation process, and the strong correlations with other headache assessment tools highlight the scale's practical relevance in both clinical and research settings.

Limitations

One limitation of this study is that the Turkish version of the HImQ was evaluated solely within individuals with headache complaints, which may restrict its generalizability to other headache diagnoses or populations. Further research involving various headache types is needed to explore the scale's applicability across different headache disorders. Additionally, sensitivity and specificity analyses for different headache diagnoses were not conducted, which limits our understanding of the scale's diagnostic precision. Another limitation is the lack of longitudinal data to assess the HImQ's ability to detect changes over time. Future studies should address these aspects to provide a more comprehensive evaluation of the HImQ's utility and effectiveness.

CONCLUSION

This study confirms that the Turkish version of the HImQ is a valid and reliable tool for assessing the impact of headache complaints on daily functioning. The scale demonstrates strong internal consistency and test-retest reliability, with a well-supported factor structure and good convergent validity. The findings suggest that the HImQ can be effectively used to evaluate headache-related disability in the Turkish population, providing valuable insights for both clinical assessment and research. Overall, the Turkish HImQ offers a robust tool for understanding and addressing the daily impact of headaches in clinical settings.

Ethical Approval: *2022-14 Tokat Gaziosmanpaşa University Clinical Research Ethics Committee*

Conflict of Interest: *The author has no conflicts of interest to declare.*

Funding: *None.*

Acknowledgements: *The researcher would like to thank the individuals who participated in the study.*

Author Contribution: Concept: *HA;* ***Design:*** *HA;* ***Data collecting:*** *HA;* ***Statistical analysis:*** *HA;* ***Literature review:*** *HA;* ***Writing:*** *HA;* ***Critical review:*** *HA.*

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Karya J Health Sci. 2024;5(3):100-103
RESEARCH ARTICLE/ARAŞTIRMA MAKALESİ doi: 10.52831/kjhs.1536122 e-ISSN:2717-9540

KARYA JOURNAL OF HEALTH SCIENCE

journal homepage: www.dergipark.org.tr/kjhs

RELATIONSHIP BETWEEN FALLS AND FEAR OF FALLING AND SELF-REPORTED DUAL-TASK DIFFICULTIES, COGNITIVE AND PHYSICAL FUNCTIONS IN OLDER ADULTS

YAŞLI BİREYLERDE DÜŞME VE DÜŞME KORKUSU İLE ÖZ-BİLDİRİME DAYALI İKİLİ GÖREV ZORLUKLARI, BİLİŞSEL VE FİZİKSEL FONKSİYONLAR ARASINDAKİ İLİŞKİNİN İNCELENMESİ

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ABSTRACT

Objective: The relationship between falls and fear of falling and self-reported dual-task difficulties and cognitive and physical functions is yet to be determined. The aim of this study was to investigate the association between falls and fear of falling and self-reported cognitive and physical functions and dual-task difficulties in older adults.

Method: Fifty older adults were enrolled in this study (29 females/21 males, median age:69). The Falls Efficacy Scale-International (FES-I) was used to assess fear of falling, physical functioning subscale of the 36-item Short-Form Health Survey (PFS) was applied to assess perceived physical function, Cognitive Failure Questionnaire (CFQ) was used to assess perceived cognitive impairment, and Dual-task Questionnaire (DTQ) was administered to evaluate perceived dual-task difficulties. The presence of falls and the number of falls were also documented.

Results: A moderate correlation was found between the number of falls and FES-I, CFQ, and PFS (rho=-0.394 to 0.499, p<0.05). However, it was strongly correlated with DTQ (rho=0.553, p<0.05). FES-I was weakly correlated with DTQ (rho=0.287, p<0.05), moderately correlated with the number of falls (rho=0.412), and strongly correlated with PFS (rho=-0.732, p<0.05). There was no correlation between FES-I and CFQ (r=0.243, p<0.05). Regression analysis showed that PFS was the determinant of fear of falling, and the model explained the 51% variance of the FES-I.

Conclusion: Overall, the findings suggest that falls and fear of falling may be associated with self-reported physical, cognitive, and dual-task measures and these perceived abilities may be an important screening tool for better-identifying persons with fall risk and fear of falling.

Key Words: Older Adults, Falls, Balance

ÖZ

Amaç: Düşme ve düşme korkusu ile öz-bildirime dayalı ikili görev zorlukları, bilişsel ve fiziksel işlevler arasındaki ilişki henüz belirlenmemiştir. Bu çalışmanın amacı yaşlı bireylerde düşme ve düşme korkusu ile öz-bildirime dayalı bilişsel ve fiziksel fonksiyonlar ve ikili görev zorlukları arasındaki ilişkinin incelenmesiydi.

Yöntem: Elli yaşlı yetişkin bu çalışmaya dahil edildi (29 kadın/21 erkek, ortanca yaş: 69). Düşme korkusunu değerlendirmek için Uluslararası Düşme Etkinliği Ölçeği (DEÖ), algılanan fiziksel fonksiyonları değerlendirmek için 36 maddelik Kısa Form Sağlık Anketinin fiziksel işlevsellik alt ölçeği (FİAÖ), algılanan bilişsel durumu değerlendirmek için Bilişsel Durum Ölçeği (BDÖ) ve algılanan ikili görev zorluklarını ölçmek için İkili Görev Ölçeği (İGÖ) anketleri uygulandı. Ek olarak, düşme varlığı ve düşme sayısı rapor edildi.

Bulgular: Düşme sayısı ile DEÖ, BDÖ ve FİAÖ arasında orta düzeyde bir korelasyon bulundu (rho=-0,394-0,499, p<0,05). Ancak, İGÖ ile düşme sayısı arasında güçlü bir korelasyon vardı (rho=0,553, p<0,05). DEÖ, İGÖ ile zayıf korelasyon (rho=0,287, p<0,05), düşme sayısı ile orta düzeyde korelasyon (rho=0,412) ve FİAÖ ile güçlü düzeyde korelasyon (rho=-0,732, p<0,05) gösterdi. DEÖ ile BDÖ arasında anlamlı korelasyon bulunmadı (r=0,243, p<0,05). Regresyon analizi FİAÖ 'nin düşme korkusunun belirleyicisi olduğunu ve modelin DEÖ varyansını %51 oranında açıkladığını gösterdi.

Sonuç: Çalışmamız, düşme ve düşme korkusunun öz-bildirime dayalı fiziksel, bilişsel ve ikili görev ölçümleri ile ilişkili olabileceğini ve bu algılanan yeteneklerin düşme riski ve düşme korkusu olan kişileri daha iyi tanımlamak için önemli bir tarama aracı olabileceğini göstermektedir.

Anahtar Kelimeler: Yaşlı Yetişkinler, Düşme, Denge

INTRODUCTION

Falls are a major public health concern in older adults because of their high prevalence and the serious consequences, such as injury, reduced mobility, loss of independence, and increased mortality. In a recent meta-analysis, the global prevalence of falls in older adults of the world was found to be 26.5% [1]. As the world's population ages, this prevalence may increase, and therefore, understanding the factors that contribute to falls becomes increasingly important for developing effective prevention strategies [2]. Among these factors, fear of falling (FoF) has emerged as an important psychological concern, as it can independently contribute to increased fall risk and is associated with reduced physical and cognitive functioning. It is also a common problem in older adults, with a prevalence of 49.6% [3].

Article Info/Makale Bilgisi
Submitted/Yükleme tarihi: 08.20.2024, **Revision requested/Revizyon isteği:** 10.10.2024, **Last revision received/Son düzenleme tarihi:** 10.11.2024, **Accepted/Kabul:** 10.22.2024
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Many factors have been found to be associated with falls and FoF in older adults. Demographic factors such as higher age, lower education, and female sex have been linked to falls and FoF. Physical functions, including balance, coordination, gait speed, gait symmetry, gait adaptability, and muscle strength and power are also well-known risk factors in many populations [4-9]. Cognitive functions, mainly attention and executive functions, are crucial for navigating complex environments and managing the simultaneous tasks often required in daily life [10]. Recent research also supports the importance of dual-tasking abilities, which are used to manage cognitive and motor tasks simultaneously and to be a key indicator of fall risk [11]. Overall, these findings indicate the link between falls and FoF and physiological and demographic factors. However, self-reported measures have the potential to provide valuable insights into an individual's subjective experience of their health status, capturing aspects that may not be evident through objective assessments alone [12].

Current evidence reveals a lack of data examining the relationship between falls and FoF with self-reported dual-task difficulties, cognitive and physical functions. However, self-reported difficulties can provide early warning signs of functional decline and highlight areas where interventions can be targeted to reduce the risk of falls. Hence, this study aimed to investigate the complex relationships between falls, FoF and self-reported cognitive and physical functions in older adults. By examining these relationships, we aim to gain insight into the multifactorial nature of falls and the role of perceived symptoms in fall risk and provide insights into the development of comprehensive interventions that improve both cognitive and physical health, ultimately reducing falls and improving the quality of life of older people.

METHOD

Study Design and Participant

This cross-sectional study recruited 50 participants. Participants were selected using a convenience sampling method, including individuals who could be reached through personal networks of the research team. Inclusion criteria included age ≥65 years. Exclusion criteria included cognitive problems hindering understand questions, being ambulate in daily life, and any disorder might potentially affect gait and balance such as, neurological disorders (e.g., Parkinson's disease, stroke), musculoskeletal disorders (e.g., arthritis, osteoporosis), vestibular disorders (e.g., vestibular neuritis), peripheral neuropathy, or any sensory deficits.

The sample size calculation was decided based on the regression analysis. At least 10 participants were considered for each variable to be examined in the regression analysis [13]. Therefore, it was aimed to evaluate at least 40 participants for the four independent variables (FoF, self-reported physical functioning, self-reported cognitive deficits, and self-reported dual-task difficulties).

Outcome Measures

Fall History: Patients were asked about the number of falls in the past six months. Following the World Health Organization (WHO) definition, a fall was defined as "an event where the participant unintentionally came to rest on the ground or a lower level" [14]. If the answer was yes, the participant was asked how many times they had a fall.

Fear of Falling (FoF): FoF was assessed using the Turkish version of the Falls Efficacy Scale-International (FES-I). It contains 16 items, and higher scores indicate a greater FoF. The FES-I has good measurement properties (Cronbach's a of the Turkish FES-I was 0.94, intraclass correlation coefficient: 0.97 to 0.99) in older adults [15].

Self-Reported Dual-Task Difficulties: The Dual-task Questionnaire (DTQ) is a 10-item self-report measure of dual-task difficulties in daily life. Individuals rate the difficulty they experience in dual-task activities from 0 (never) to 4 (very often). Higher scores indicate greater dual-task difficulties. The Turkish version of DTQ is a valid and reliable measure in older adults [16].

Self-Reported Cognitive Functions: The Cognitive Failure Questionnaire (CFQ) is a self-report questionnaire designed to assess deficits in perception, memory and motor function [17]. It contains 25 items, with participants rating each item on a five-point scale from 'never' to 'always'. Higher scores reflect a greater tendency towards cognitive decline. The CFQ is a valid and reliable tool in the Turkish population [18].

Self-Reported Physical Functioning: The physical functioning subscale of the 36-Item Short-Form Health Survey (PFS) was used to assess self-reported physical deficits [19]. The PFS has been employed as a stand-alone instrument for the description of activity limitations in various groups, including older adults and people with neurological conditions, and it has strong measurement properties. It encompasses ten items, and items are rated according to perceived limitations on the activities (1: yes, limited a lot; 2: yes, limited a little; or 3: no, not limited at all). Higher scores show better physical functioning.

Ethical Approval

The Social Research Ethics Board of Izmir Katip Celebi University (date: 20.03.2024, approval number: 2024/04-06). All participants provided written informed consent before inclusion in this study.

Statistical Analysis

IBM SPSS Statistics for Windows was used (Version 25.0. Armonk, NY: IBM Corp.) to analyze data. Evaluation of the histogram and plots was performed to determine the distribution of the data. Descriptive statistics were reported as mean and standard deviation (SD) for normally distributed data and median and interquartile ranges (IQR) for non-normal distributed data. Spearman's rank correlation was used for non-normally distributed variables and Pearson's correlation for normally distributed variables was performed to determine the association between falls, FoF, CFQ, PFS, and DTQ. Correlation coefficients between 0.1 and 0.29 were interpreted to be small, 0.3 to 0.49 to be moderate, and 0.5 to 1.0 to be strong [20]. Hierarchical binary regression models were conducted to explain the relationship between FoF and other self-reported measures. Logistic regression analysis was conducted to analyze relationship between being fallers and self-reported measures. The odds ratios (ORs) with 95% confidence intervals (95% CIs) were calculated using logistic regression for fall risk.

RESULTS

Table 1 summarizes the baseline demographics and descriptives of outcome measures of participants. The median age was 69, with a range from 65 to 85. Fifty-eight percent of the participants were female.

Table 1. Descriptive measures of the participants

	Mean±SD or Median (IQR)	Range (Min-max)
Age	69 (66.5-74.5)	65-85
Sex: Female/Male, n (%)	29 (58%)/21 (42%)	-
Falls: Faller/Non-faller, n (%)	27 (54%)/ 23 (46%)	-
Number of falls	1 (0-1)	0-4
FES-I	29.3±7.83	16-49
PFS	60 (41.3-83.8)	25-95
CFQ	29.7±12.3	2-57
DTQ	10 (6-14)	1-26

IQR: Interquartile ranges; SD: Standard deviation; FES-I: Falls Efficacy Scale-International; PFS: Physical Functioning Subscale of the 36-Item Short-Form Health Survey; CFQ: Cognitive failure Questionnaire; DTQ: Dual-task Questionnaire.

Correlation coefficients among outcome measures are presented in Table 2. Moderate correlations were found between a number of falls and FES-I, CFQ, and PFS (rho=-0.394 to 0.499). However, it was strongly correlated with DTQ (rho=0.553). FES-I was weakly correlated with DTQ (rho=0.287), moderately correlated with a number of falls (rho=0.412), and strongly correlated with PFS (rho=-0.732). There was no correlation between FES-I and CFQ (r=0.243).

Table 2. Correlation coefficients between outcome measures

		FES-I	Number of falls	PFS	CFQ
Number of falls	Correlation coefficient	0.412	-	-	-
	p value	0.003	-	-	-
PFS	Correlation coefficient	-0.732	-0.394	-	-
	p value	< .001	0.005	-	-
CFQ	Correlation coefficient	0.243	0.499	-0.303	-
	p value	0.089	< .001	0.032	-
DTQ	Correlation coefficient	0.287	0.553	-0.395	0.787
	p value	0.043	< .001	0.005	< .001

FES-I: Falls Efficacy Scale-International; PFS: Physical Functioning Subscale of the 36-Item Short-Form Health Survey; CFQ: Cognitive failure Questionnaire; DTQ: Dual-task Questionnaire.

Table 3 presents a logistic regression model for assessing the impact of FES-I, PFS, CFQ, and DTQ on the presence of a history of falls. None of the variables was a significant predictor of falls. Nagelkerke R^2 was 0.174

Table 4 presents the multiple linear regression models to show the impact of self-reported outcome measures (i.e., PFS, CFQ, and DTQ) on FoF. PFS was the only significant variable explaining FES-I, and the model explained the 51% variance of the FES-I.

DISCUSSION

The aim of this study was to investigate whether falls and FoF were related to self-reported cognitive and physical functions and dual-task difficulties in older adults. Findings from the present study showed that falls are linked to self-reported physical and cognitive functions, but particularly perceived dual-task difficulties. FoF was related to self-reported physical functions and dual-tasking, and physical functioning was the significant predictor of FoF in community-dwelling older adults.

Lusardi et al. suggest that there is no single measure to predict falls in older adults, given the multifactorial nature of the falls [21]. They recommend the use of the combination of self-report tools and performance-based measures to better identify persons under risk. However, there is lack of evidence on the relationship between self-reported functioning and falls. We found a moderate correlation between a number of falls and FES-I, CFQ, and PFS. Recently, a longitudinal study supported our finding by showing that a decreased self-reported lower extremity function is associated with a risk of incident falls within a year [22]. It is not surprising that falls are associated with physical functioning, as they mostly occur while walking and during transfer [21].

Table 3. Logistic regression analysis

						95% Confidence Interval	
Predictor	**Estimate**	**SE**	**Z**	**p**	**Odds ratio**	**Lower**	**Upper**
PFS	0.0184	0.0213	0.861	0.389	1.019	0.98	1.06
CFQ	-0.0359	0.0433	-0.829	0.407	0.965	0.89	1.05
FES-I	-0.0171	0.0586	-0.292	0.770	0.983	0.88	1.10
DTQ	-0.0147	0.0918	-0.161	0.872	0.985	0.82	1.18

Nagelkerke R^2: 0.174

FES-I: Falls Efficacy Scale-International; PFS: Physical Functioning Subscale of the 36-Item Short-Form Health Survey; CFQ: Cognitive failure Questionnaire; DTQ: Dual-task Questionnaire.

Table 4. Multivariate regression analysis for FES-I

			95% Confidence Interval			
Predictor	**Estimate**	**SE**	**Lower**	**Upper**	**t**	**p**
PFS	-0.2604	0.0387	-0.33	-0.18	-6.724	< .001
CFQ	0.0378	0.1034	-0.17	0.25	0.366	0.716
DTQ	-0.0654	0.2225	-0.51	0.38	-0.294	0.770

R^2 0.538, Adjusted R^2 0.507

FES-I: Falls Efficacy Scale-International; PFS: Physical Functioning Subscale of the 36-Item Short-Form Health Survey; CFQ: Cognitive failure Questionnaire; DTQ: Dual-task Questionnaire.

The role of cognitive functions on motor activity is assessed by dual-task performance assessments. Currently, there is substantial data on performance-based dual-task walking or balance in older adults, showing a significant association between falls and dual-task performance. Additionally, several studies showed that perceived dual-task difficulties are related to FoF and falls [23]. In line with these findings, there was a strong correlation between the number of falls and self-reported dual-task difficulties in our study, and the magnitude of the correlation was higher than self-reported physical functioning and cognitive deficits. These findings may be attributed to the fact that dual-task activities better represent daily-life activities and have a more complex structure than single motor and cognitive tasks. However, in the logistic regression analysis, it was not the predictor of the presence of falls. Overall, although self-reported dual-task difficulty is not a predictor, it is a variable that shows a high correlation with the number of falls. It should be investigated in a larger sample to determine whether it could be a possible screening tool for determining those with fall risk.

The highest correlation was found between FoF assessed by FES-I and self-reported physical functioning. There was a weak correlation with the perceived dual-task difficulties and no significant correlation with

self-reported cognitive failures. This may be related to the fact that FES-I includes items that mainly focus on motor activities. Consequently, a decline in perceived physical functioning may lead to FoF regardless of perceived cognitive functions.

Limitations

The present study has several limitations. Firstly, we collected fall history data retrospectively. Thus, memory problems might affect the reliability of the data. Additionally, a small sample size may lead to nonsignificant results for the regression analysis. Another consideration is that we did not administer the performance-based assessments for walking and cognitive functions. Future research could examine the predictive ability of the self-reported and performance-based measures together. Additionally, further efforts in conducting a longitudinal study design are required to verify the role of self-reported measures for predicting falls and FoF.

CONCLUSION

This study has revealed a significant association between falls and FoF with self-reported cognitive and physical functioning, as well as dual-task difficulties in community-dwelling older adults. Notably, self-reported dual-task difficulties have shown the strongest correlation with falls, indicating the potential to serve as a screening tool for falls. Furthermore, self-reported physical functioning emerged as the determinant of FoF. These findings underscore the promising potential of self-reported outcomes in predicting falls and FoF in older adults, offering hope for the future of geriatric care.

Ethical Approval: *2024/04-06 Social Research Ethics Board of Izmir Katip Celebi University*

Conflict of Interest: *The authors have no conflicts of interest to declare.*

Funding: *None.*

Acknowledgements: *None.*

Author Contribution: Concept: *ZA,MKA;* ***Design:*** *ZA,MKA;* ***Data collecting:*** *ZA,MKA;* ***Statistical analysis:*** *ZA;;* ***Literature review:*** *ZA;* ***Writing:*** *ZA;* ***Critical review:*** *ZA,MK.*

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Karya J Health Sci. 2024;5(3):104-111
RESEARCH ARTICLE/ARAŞTIRMA MAKALESİ doi: 10.52831/kjhs.1538120 e-ISSN:2717-9540

KARYA JOURNAL OF HEALTH SCIENCE

journal homepage: www.dergipark.org.tr/kjhs

EFFECT OF TRAINING AND REMINDER SHORT MESSAGES ON THE FATIGUE LEVEL OF INDIVIDUALS WITH COPD: A RANDOMIZED CONTROLLED STUDY

KOAH'LI BİREYLERE VERİLEN EĞİTİMİN VE HATIRLATICI KISA MESAJLARIN YORGUNLUK DÜZEYİNE ETKİSİ: RANDOMİZE KONTROLLÜ ÇALIŞMA

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ABSTRACT

Objective: The study aimed to determine the effect of education and reminder short messages on fatigue levels in individuals with Chronic Obstructive Pulmonary Disease (COPD).

Method: Randomized controlled experimental study (ClinicalTrials.gov: NCT06286072). The study was conducted with 105 patients hospitalized with the diagnosis of COPD between December 15, 2023, and May 15, 2024. The patients were randomized into three groups, 35 in each group. The first group was assigned as the education+message group, the second group as the education group, and the third group as the control group (routine treatment and care). The education content consisted of COPD and fatigue management. The education was completed in three days. Messages included reminders of the education content and motivational sentences. Questionnaires were applied to all patients at baseline and the end of 8 weeks to determine their personal information, degree of dyspnea, general COPD status, and fatigue level.

Results: In intragroup comparisons, dyspnea and fatigue levels decreased significantly and the general COPD status improved in the education+message group ($p<0.001$). In the education group, dyspnea severity decreased ($p=0.014$) and the general COPD status improved ($p=0.013$). There was no significant difference in the control group. There were significant differences ($p<0.05$) in intergroup comparisons and the strongest effect was in the education +message, education, and control groups ($d_1>d_2>d_3$).

Conclusion: Education and 8-week short message intervention in patients with COPD effectively reduced dyspnea severity and fatigue and improved the general COPD status. Education alone was not successful in alleviating fatigue in the long term. Therefore, post-discharge patient follow-up should be taken into consideration.

Key Words: Fatigue, COPD, Education, Short Message Service

ÖZ

Amaç: Çalışma, Kronik Obstrüktif Akciğer Hastalığı (KOAH) olan bireylere verilen eğitimin ve hatırlatıcı kısa mesajların yorgunluk düzeyine etkisini belirlemek amacıyla yürütüldü.

Yöntem: Randomize kontrollü deneysel çalışma (ClinicalTrials.gov: NCT06286072). Çalışma, 15 Aralık 2023-15 Mayıs 2024 tarihleri arasında KOAH tanısı nedeniyle hastanede yatan 105 hasta ile yürütüldü. Hastalar her grupta 35 olmak üzere üç grupta randomize edildi. İlk grup eğitim+mesaj, ikinci grup eğitim, üçüncü grup ise kontrol (rutin tedavi ve bakım) olarak atandı. Eğitim içeriğini; KOAH ve yorgunluk yönetimi oluşturdu. Eğitimler üç günde tamamlandı. Mesajlar, eğitim içeriğini hatırlatıcı ve motive edici cümlelerden oluşturuldu. Tüm hastalara başlangıçta ve 8 hafta sonunda kişisel bilgilerini, dispne derecesini, KOAH genel durumunu ve yorgunluk seviyesini belirleyen anketler uygulandı.

Bulgular: Grup içi karşılaştırmalarda eğitim+mesaj grubunda dispne ve yorgunluk düzeyi anlamlı olarak azaldı, KOAH genel durumu iyileşti ($p<0.001$). Eğitim grubunda dispne şiddeti azaldı ($p=0.014$) ve KOAH genel durumu iyileşti ($p=0.013$). Kontrol grubunda anlamlı fark oluşmadı. Gruplar arası karşılaştırmalarda anlamlı fark elde edildi ($p<0.05$), en güçlü etki eğitim+mesaj, eğitim ve kontrol grubunda oldu ($d_1>d_2>d_3$).

Sonuç: KOAH'lı hastalara verilen eğitim ve 8 haftalık kısa mesaj uygulaması dispne şiddetinin ve yorgunluğun azaltılmasında, KOAH'ta genel durumunun iyileşmesinde etkilidir. Tek başına eğitim, uzun vadede yorgunluğu hafifletmede başarılı olmamıştır. Bu nedenle taburculuk sonrası hasta takipleri önemsenmelidir.

Anahtar Kelimeler: Yorgunluk, KOAH, Eğitim, Kısa Mesaj Servisi

Article Info/Makale Bilgisi

Submitted/Yükleme tarihi: 08.24.2024, **Revision requested/Revizyon isteği:** 10.11.2024, **Last revision received/Son düzenleme tarihi:** 10.11.2024, **Accepted/Kabul:** 10.14.2024
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INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is an important chronic disease characterized by damage in the respiratory tract. Increased mucus secretion in the airways, its thickening, and inflammatory processes lead to airway obstruction. The symptoms resulting from this pathogenesis cause significant problems in the patient's ability to perform daily activities. Various symptoms, including dyspnea in particular, cough, sputum, wheezing, and fatigue, occur [1]. The most important problem that physio pathological processes in the patient will cause is inadequate oxygenation. Fatigue is the leading problem caused by impaired tissue oxygenation [2].

Fatigue indicates tissue hypoxia and is a subjective finding that affects the patient's activities of daily living and reduces the quality of life. It causes the patient to feel exhausted, weak, and sluggish [3]. All these may lead the individual to postpone, not perform, or reduce the activities that he/she can or should perform. These effects may cause difficulties in treatment compliance [4,5] and even COPD exacerbations [4,6]. Fatigue can have not only physiological effects, but also psycho-social effects such as lack of motivation, distraction, and disruption of individual and family processes [7]. Nursing practices are of great importance in the elimination of fatigue, which can cause quite extensive consequences in the patient's life. Therefore, nursing care should include useful practices to improve patients' ability to cope with fatigue and alleviate fatigue.

In most of the non-pharmacological studies on the management of fatigue in patients, energy control, activity planning, acupuncture, acupressure, and massage have been highlighted. In the literature, it has been observed that patients with COPD experience intense fatigue and that the severity of fatigue decreases with the interventions made [8-11]. In the light of all these interventions, nursing care should include education on the causes of fatigue and what the patient can do to reduce fatigue. The aim should be to ensure that effective nursing interventions are practical and provide positive outcomes in a short time. In this context, it was thought that it would be useful to repeat the education provided routinely to each patient at certain intervals with motivating and reminding content [5].

It has been reported that education should be repeated at certain intervals to ensure and increase motivation [5,12]. Additionally, it was thought that reminding the patient of what he/she can do, and his/her power and importance would be beneficial. The workload of the nurse should not be increased while reaching out to the patient practically, especially by using today's communication networks [13]. Although it is impossible for nurses to repeat the education face-to-face at certain intervals for each patient, online interviews, phone calls, e-mail, or short message services can provide positive outcomes in reminding the focus points of the education. A study showed that not only disease, medication control, or nursing care, but also appointment reminders of patients significantly contribute to health costs [14]. In some studies, conducted with patients other than COPD patients, mobile phone calls, online tracking systems, and reminder short messages have been reported to be effective in nursing care [15-18]. Therefore, it is necessary to extend such practical and useful applications to all patient groups under current conditions.

In the literature, it has been reported that the use of short messaging in the management of chronic diseases, including COPD, has yielded effective results [5,19,20]. In the study of Ojeda (2018), it was found that 47.1% of COPD patients preferred short message service the most among communication technologies [21]. Short message service has been shown to provide asthma control [22], and to be effective in active monitoring and early detection of exacerbations in patients with COPD [23]. It has also been reported that patients define telehealth applications as the best service and are eager to use them [24].

Nurse-led education contributes positively to patient outcomes. In 2023, Qomi et al. applied nurse-led fatigue management for Multiple Sclerosis patients and achieved effective results [25]. In this context, it is thought that nurse-led education is needed to reduce fatigue and dyspnea which are also important symptoms of COPD patients, and to improve the general COPD status. In particular, it is predicted that supporting the education content with motivating and reminding short messages will be beneficial and will shed light on future studies to be carried out with remote communication content.

The study primarily aimed to determine the effect of education and reminder short messages on the fatigue level of individuals with COPD. The secondary aim of the study was to reveal the effect of the interventions on dyspnea severity and general COPD status.

METHOD

Study Design and Hypotheses

The study has a randomized controlled experimental design, which is one of the quantitative research methods.

Hypotheses of the study:

$H_{0\text{-}1}$: The level of fatigue does not decrease in patients who receive COPD education and reminder short messages.

$H_{1\text{-}1}$: The level of fatigue decreases in patients who receive COPD education and reminder short messages.

$H_{0\text{-}2}$: The level of fatigue does not decrease in patients who receive COPD education.

$H_{1\text{-}2}$: The level of fatigue decreases in patients who receive COPD education.

Participants

The study was carried out with patients diagnosed with COPD in the pulmonology clinic of a Training and Research Hospital. The patients were divided into three groups by randomization. The number of patients in each group was determined using G. Power Version 3.1.9.2 (Franz Faul, Universitat Kiel, Germany). Accordingly, based on the sample group of a similar study [5], it was decided to include 34 patients in each group of the study with type 1 error=0.5, a confidence of 95% (1-α), a test power of 95% (1-β), an effect size of d=0.59 in the one tailed analysis performed with the Wilcoxon signed-rank test (matched pairs). The Consolidated Standards of Reporting Trials (CONSORT) were adhered to throughout the study (Figure 1). Considering possible data loss, a total of 183 patients were included in the study. Thirty-five patients were excluded due to reasons such as declining to participate (n=22), having no mobile phone (n=9), and not meeting inclusion criteria (n=4). A total of 148 patients were randomly assigned to 3 groups. The study was completed with a total of 105 patients, 35 in each group, due to data loss during the study and follow-up phases.

Inclusion Criteria:

•Having been diagnosed with COPD for at least one year

•Being planned to be hospitalized for at least three days

•Having a mobile phone and being able to read the messages.

Exclusion Criteria:

•Having conditions other than COPD such as chronic fatigue syndrome or advanced heart failure which may cause excessive fatigue

•Inability to read messages from a mobile phone or being illiterate,

•Not agreeing to participate in the study.

Randomization

The primary aim of sample selection was to avoid bias and interaction between patients. Therefore, a number was assigned to each patient and these numbers were randomized in www.random.org in computerised simple randomisation. The patients were assigned three

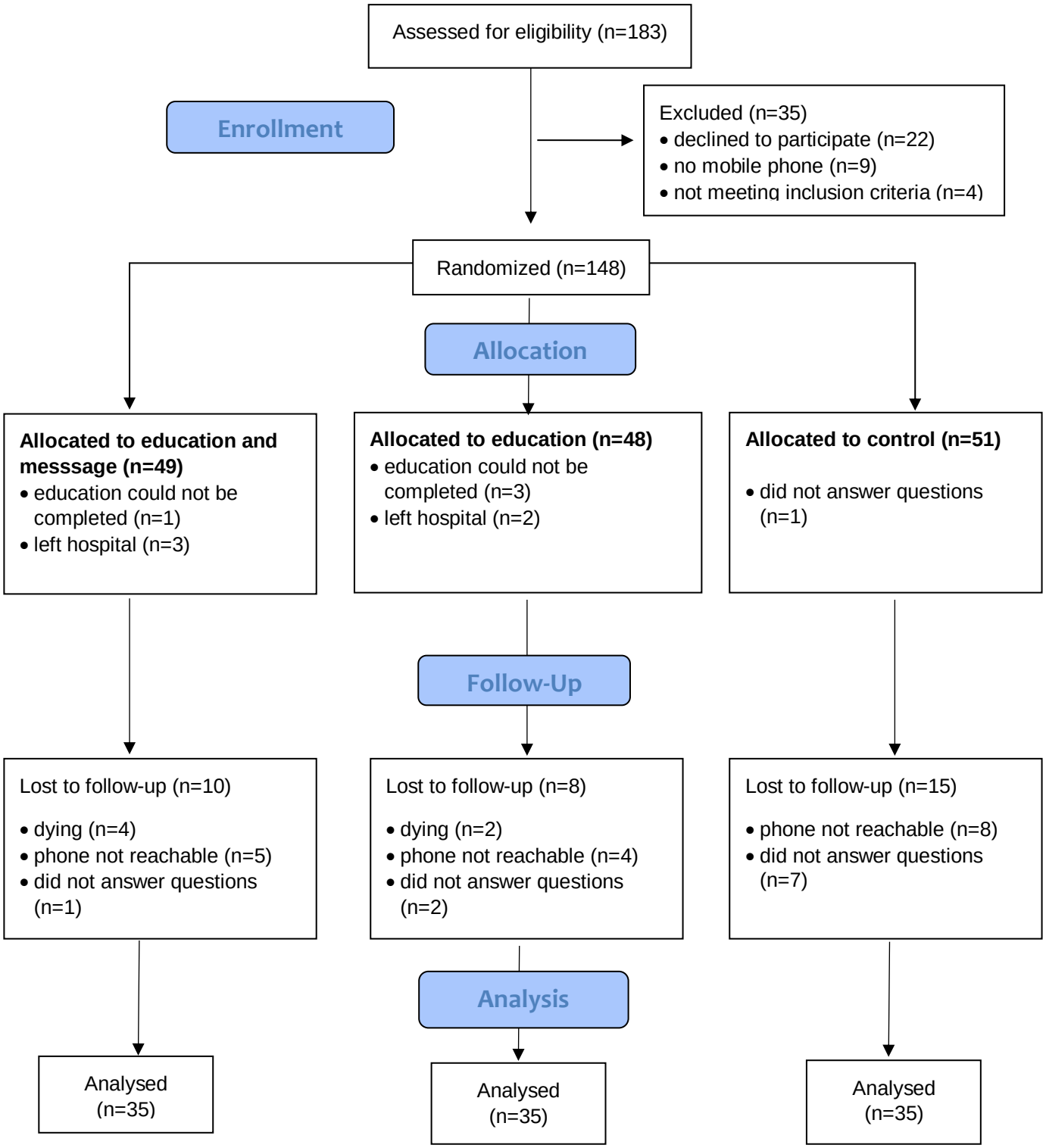

Figure 1. CONSORT Flow Diagram

groups. The first group was determined as education+message, the second group as education, and the third group as the control group which received routine treatment and care.

Outcome Measures

The data were collected using a personal information form, the Modified Medical Research Council (mMRC) dyspnea scale, the COPD assessment test (CAT), and the COPD-asthma fatigue scale (CAFS).

Personal Information Form: This form was prepared by the researcher in line with the literature [5,8-11] and includes questions regarding age, sex, educational status, duration of COPD diagnosis, and length of hospitalization.

Modified Medical Research Council Dyspnea Scale: The scale was developed by the British Medical Research Council and provides information about the degree of dyspnea during activity. The score ranges between 0-4; a score of 0 indicates the best condition (no dyspnea) while 4 indicates the worst condition (very severe dyspnea). A high score indicates an increased dyspnea severity [26]. The Cronbach alpha coefficient was not calculated because it is a unidimensional scale.

COPD Assessment Test: The Turkish validity and reliability of the scale were established by Yorgancıoğlu et al. (2012) and the scale aims to measure the general health status of individuals with COPD [27]. It consists of 8 questions and is a 5-point Likert-type scale. The score obtainable from the scale varies between 0-40 and a higher score indicates a worsening of the general COPD status. In our study, the Cronbach alpha coefficient for the pre-test was 0.95.

COPD and Asthma Fatigue Scale: The Turkish validity and reliability of the scale were established by Arslan & Öztunç (2013) and the scale aims to measure the fatigue level of patients with COPD [28]. It consists of 12 questions and is a 5-point Likert-type scale. The first 10 questions are scored in increasing order and the last two questions are scored in decreasing order. The resulting total score constitutes the raw score. The total score of the scale is calculated using the formula (total raw score-12/48) x 100 and varies between 12-100. A higher score indicates a higher fatigue level. In our study, the Cronbach alpha coefficient for the pre-test was 0.96.

Data Collection

The study was carried out between December 15, 2023, and May 15, 2024, after taking necessary permissions. The patients included in the study were interviewed in the patient room. First, the purpose of the study and how the patients would be followed up were explained. For the patients who would receive education, it was explained that the education would be given three days in a row, and preliminary information was given about the education planning according to the days. For the patients who would receive short messages, their ability to use their mobile phones and whether they could read the messages were evaluated. The baseline forms were filled out and recorded for the patients who met all the criteria and volunteered.

Interventions for Patient Groups

Education+message group: First, the patients were introduced, and routine treatment and care and the planned education process were explained. Phone numbers of the patients were recorded, and they were informed that they would be texted later. It was stated that they did not need to return the messages. Questionnaire forms were administered before the education sessions. The education was conducted face-to-face in the patient room. Education sessions were completed in 30 minutes on the first two days and 60 minutes on the third day. On the first day, the education content consisted of the definition of COPD, symptoms, correct use of drugs, recognition of conditions in which symptoms worsen and measures to be taken. On the second day, the physiology of fatigue, the factors causing fatigue, and the relationship between COPD and fatigue were explained. On the third day, breathing exercises and strategies for coping with fatigue were explained. These strategies were determined as appropriate time planning by knowing the tiring actions during the day, getting help for actions that they cannot do, avoiding inappropriate movements, avoiding allergens and bad air, eating a balanced and energizing diet, energy refreshment, relaxation recommendations, pre-activity rest periods, pre-activity inhaler use, positive perspective on life, improving quality of life, and accepting what they cannot do [1,5,7,8,12,17,20,25,29,30]. Following the discharge of the patients, motivational and reminder short messages were sent twice a week for 8 weeks in line with the content of the education. The table including the short messages was presented in the supplementary file. After 8 weeks, the questionnaire form was administered again.

Education group: Patients in this group were introduced in the first interview and questionnaire forms were administered. In addition to routine treatment and care, the planned education process was explained. This patient group received the same education as mentioned above for three days under the same schedule. No short messages were sent to the patients in this group. The questionnaire forms were repeated 8 weeks after discharge.

Routine treatment and care (Control) group: Patients in this group did not receive any planned education other than the routine treatment and care provided during hospitalization. In addition, no text messages were sent. Questionnaire forms were administered on the day they were included in the study and 8 weeks after discharge. After the study was completed, the education given to other patients was given in the same way on a suitable day determined by the patients to prevent bias.

Ethical Approval

Permissions were received from the Kırşehir Ahi Evran University Ethics Committee (date: 10/19/2023, approval number: 2023/09/05) and the Kırşehir Training and Research Hospital (date: 12/06/2023, approval number: E-42884709-020-231013765) prior to the start of the study. Ethical principles and the Declaration of Helsinki were followed throughout all stages of the study. Patients were included in the study voluntarily and an informed consent form was taken from them after explaining the purpose and content of the study. This study was registered at ClinicalTrials.gov (Registration Number:NCT06286072).

Statistical Analysis

The data were analyzed in SPSS V25 (IBM Corp., Armonk, New York, USA). The normality of the data was tested with the Shapiro-Wilk test. Descriptive statistics were presented as number (n), percentage (%), and mean ± standard deviation. In intergroup comparisons, Pearson Chi-Square (χ^2) was used for categorical data and ANOVA analysis was used for continuous data. Scale correlations were presented with Spearman's rho coefficient. The Wilcoxon test was used for intragroup comparisons and the Kruskal Wallis H Test for intergroup comparisons. Multiple comparisons were performed with Dunn's test. Analysis findings were presented as median (min-max). The level of significance was taken as $p<0.05$.

RESULTS

The demographic characteristics of the patients in the study were compared. There was no statistically significant difference between the groups, and they were similar to each other ($p>0.05$). The mean age of the patients was 57.29±17.32 years and 50.5% of them were male. The mean duration of COPD diagnosis was 9.876±9.163 years. The mean length of total hospitalization in the last year was 22.05±38.30 days (Table 1).

The mean total scale scores of the patients decreased from 1.66±0.9 at the first follow-up to 1.33±1.0 at the last follow-up for mMRC, from 18.14±10.15 to 13.52±9.9 for CAT and from 48.13±23.63 to 37.91±24.81 for CAFS. The decrease in the total scale scores indicated that the severity of dyspnea was alleviated, that the general COPD status improved, and that fatigue decreased. In addition, the relationship between the scales was examined and all of them were found to be significantly correlated ($p<0.001$) (Table 2).

Table 3 shows the intragroup pre-test and post-test comparisons and inter-group comparisons. Accordingly, there was a significant difference between the pre-test and post-test mean total mMRC scores of the patients in the education+message group (Z: -4.817; $p<0.001$) and in the education group (Z: -2.449; $p=0.014$). There was no significant effect in the control group ($p>0.05$). When the dyspnea severity of the groups was analyzed, it was seen that the post-test means had a significant difference (KW=41.308; $p<0.001$). According to the effect sizes, the effect size was highest in the education+message group and lowest in the control group ($d_1>d_2>d_3$).

Table 1. Demographic and clinical characteristics of the sample (*N* = 105).

Variables	Education+Message (n=35) n(%)	Education (n=35) n(%)	Control (n=35) n(%)	Total (N=105)	Test	*p*
Age (Mean±SD)	59.828±13.445	57.714±19.495	54.342±18.469	57.295±17.321	0.891**	0.413
Gender						
Female	19 (54.3)	17 (48.6)	16 (45.7)	52 (49.5)	0.533*	0.766
Male	16 (45.7)	18 (51.4)	19 (54.3)	53 (50.5)		
Education level						
Elementary school	13 (37.2)	11 (31.4)	12 (34.3)	36 (34.2)		
Middle School	7 (20)	8 (22.9)	11 (31.4)	26 (24.8)	2.438*	0.875
High school	9 (25.7)	10 (28.6)	9 (25.7)	28 (26.7)		
Bachelor	6 (17.1)	6 (17.1)	3 (8.6)	15 (14.3)		
Marital status						
Married	30 (85.7)	27 (77.1)	29 (82.9)	86 (81.9)	0.9*	0.638
Single	5 (14.3)	8 (22.9)	6 (17.1)	19 (18.1)		
Profession						
Housewife	8 (22.9)	7 (20)	9 (25.7)	24 (22.9)		
Worker	2 (5.7)	4 (11.5)	10 (28.6)	16 (15.2)		
Officer	8 (22.9)	9 (25.7)	7 (20)	24 (22.9)	11.045*	0.199
Retried	12 (34.2)	9 (25.7)	4 (11.4)	25 (23.8)		
Self-employment	5 (14.3)	6 (17.1)	5 (14.3)	16 (15.2)		
Time of diagnosis	9.571±7.978	11.857±10.784	8.2±8.358	9.876±9.163	1.435**	0.243
Number of Hospitalisation days in the last year due to COPD	28.714±54.192	26.114±31.284	11.342±19.787	22.057±38.303	2.140**	0.123
Regular use medicaitons						
Yes	30 (85.7)	27 (77.1)	26 (74.3)	83 (79)	1.495*	0.474
No	5 (14.3)	8 (22.9)	9 (25.7)	22 (21)		

**: Pearson Chi-Square; **: ANOVA; COPD: Chronic obstructive pulmonary disease.*

Table 2. Cronbach's alpha coefficients and correlation values of the scales, descriptive findings of the patients

SCALES	Time	Cronbach's alpha	Mean±SD	M (Min-Mak)	CAT	CAFS	MMRC
1. mMRC	**Pre**	-	1.666 ± 0.905	1 (0-4)	r=0.570		
	Post	-	1.333 ± 1.006	1 (0-5)	**p<0.001**		
2. CAT	**Pre**	0.954	18.142 ± 10.155	16 (4-40)		r=0.806	
	Post	0.960	13.523 ± 9.949	10 (0-39)		**p<0.001**	
3. CAFS	**Pre**	0.960	48.134 ± 23.633	43.75 (8.33-37.92)			r=0.624
	Post	0.899	37.916 ± 24.811	29.166 (4.17-100)			**p<0.001**

mMRC: Modified Medical Research Council; r: Spearman's rho; CAT: COPD assessment test; CAFS: COPD-asthma fatigue scale;.

There was a significant difference between the pre-test and post-test total CAT scores of the education+message group (Z= -5.17; p<0.001) and the education group (Z= -2.496; p=0.013). There was no significant effect in the control group (p>0.05). When the general COPD status of the groups was analyzed, it was observed that the post-test means showed a significant difference (KW=69.866; p<0.001). The effect size was highest in the education+message group and lowest in the control group ($d_1>d_2>d_3$).

When the fatigue level in the study was evaluated with CAFS, the pre-test and post-test results showed a significant difference in the inter-group comparisons of the education+message group (Z= -5.164; p<0.001).

Table 3. Comparison of mMRC, CAT, and CAFS results of the groups

	Groups	Pre Total		Post Total		Test	Cohen's Z test	Ranking
		(M±SD)	M(Min-Mak)	(M±SD)	M(Min-Mak)			
MMRC	Education+Message [a]	2.085 ± 0.742	2 (1 - 3)	1.228 ± 0.910	1 (0 - 3)	KW= 41.308 **p<0.001**	d_1: 2.79	$d_1>d_2>d_3$
		Z= -4.817 **p<0.001**						
	Education [a]	1.457 ± 0.885	1 (0 - 4)	1.285 ± 0.925	1 (0 - 3)		d_2: 0.90	
		Z= -2.449 **p=0.014**						
	Control [b]	1.457 ± 0.950	1 (0 - 4)	1.457 ± 1.093	1 (0 - 5)		d_3: 0.128	
		Z= -0.378 p=0.705						
CAT	Education+Message [a]	23.057 ± 8.390	23 (11 - 40)	10.885 ± 8.767	10 (0 - 31)	KW= 69.866 **p<0.001**	d_1: 3.59	$d_1>d_2>d_3$
		Z= -5.17 **p<0.001**						
	Education [a]	18.028 ± 10.376	16 (5 - 39)	16.428 ± 11.520	14 (0 - 39)		d_2: 0.928	
		Z= -2.496 **p=0.013**						
	Control [b]	13.342 ± 9.424	9 (4 - 39)	13.257 ± 8.792	10 (4 - 38)		d_3: 0.164	
		Z=-0.483 p=0.629						
CAFS	Education+Message [a]	58.511 ± 18.164	54.2 (33.3 - 97.9)	27.678 ± 19.677	25 (4.2 - 93.8)	KW= 65.821 **p<0.001**	d_1: 3.578	$d_1>d_2>d_3$
		Z= -5.164 **p<0.001**						
	Education [a]	47.202 ± 25.040	43.8 (10.4 - 97.9)	46.726 ± 28.170	39.6 (8.3 - 100)		d_2: 0.456	
		Z= -1.316 p=0.188						
	Control [b]	38.690 ± 23.408	33.3 (8.3 - 95.8)	39.345 ± 22.635	31.3 (10.4 - 95.8)		d_3: 0.016	
		Z= -0.047 p=0.963						

mMRC: Modified Medical Research Council; r: Spearman's rho; CAT: COPD assessment test; CAFS: COPD-asthma fatigue scale;. Z: Wilcoxon Test; KW: Kruskal Wallis H Tests; a-b: There is no difference between groups with the same letter.

There was no significant effect in the education and control groups ($p>0.05$). When the fatigue levels of the groups were analyzed, it was observed that the post-test means showed a significant difference (KW= 65.821; $p<0.001$). The effect size was found to be the highest in the education+message group ($d_1>d_2>d_3$). In line with this result, hypothesis H1-2 was accepted.

DISCUSSION

In the study which was conducted to determine the effect of education and reminder short messages on fatigue levels of patients with chronic obstructive pulmonary disease, it was determined that most of the patients were male and in the middle age group. Diseases occur at earlier ages due to climatic and global changes in the world in recent decades [31]. According to reports published, factors such as the increase in air pollution, the diverse use of tobacco products such as electronic cigarettes and hookahs due to the use of tobacco products at younger ages, exposure to chemical gases accelerate the destruction of the airways [1]. Therefore, chronic diseases such as COPD occur more frequently. The equalization in the sex distribution of COPD, which had been seen mostly in men in previous years, is remarkable. Women's exposure to harmful particles, significantly increased rates of smoking, and differences in lung volumes are risk factors for COPD [32]. These global changes were similarly observed in our study sample.

Modified Medical Research Council dyspnea scale, which is one of the most frequently used scales in COPD, was used to determine dyspnea severity and CAT was used to assess general condition. In our study, the reliability coefficients of the scales were within the appropriate limits [33]. On the dyspnea scale, according to the GOLD guideline, 0-1 is interpreted as mild dyspnea, while higher values can be interpreted as moderate-severe. The dyspnea levels of our patients at the first measurement were moderate-severe. The total CAT score, which is used to determine the severity of COPD disease, indicates low severity between 0-10, moderate severity between 11-20, high severity between 21-30, and very high severity between 31-40 [1]. Accordingly, the COPD disease severity of our patients in the study was moderate. These results were attributed to the fact that our sample group was not elderly and that the mean duration of diagnosis was 9.87 years. In the literature, it has been found that in COPD, advanced age and longer duration of the disease are associated with an increase in dyspnea severity and worsening of the general disease status [34]. These results are expected due to the nature of chronic diseases. Because chronic diseases affecting systems lead to disruption of the functioning of other systems over time and diseases bring along additional diseases. This situation becomes more serious with chronic illness in the respiratory system, which is a vital system. Inadequate oxygenation and problems in gas exchange can lead to damage and dysfunction of many tissues and organs. Therefore, diseases of the respiratory system bring many symptoms and serious problems along [1]. Among all these, fatigue is an important problem that negatively affects the care and work of the individual.

Fatigue is very common in COPD patients [8-11,35]. The main reason for this is insufficient tissue oxygenation. In addition, other diseases and the inability of the individual to maintain appropriate treatment also trigger fatigue. Actually, fatigue and care are in a cyclical relationship. As the fatigue level of the individual increases, he/she cannot accomplish the disease care he/she needs to do and does not have enough energy. The disruption in care leads to the occurrence of systemic pathologies in the later stages of the disease and ultimately to higher fatigue levels. This vicious cycle leads to problems that the

patient cannot overcome. Therefore, in COPD nursing care, it is extremely important to address and monitor fatigue in-depth and develop coping strategies [2]. Various approaches are available to relieve or alleviate fatigue. Very positive results have been reported in studies on this subject. In their study, Polat & Ergüney (2017) showed that the level of dyspnea and fatigue decreased in patients with COPD thanks to reflexology [10]. In their systematic review and meta-analysis, Paixão et al. (2024) reported that fatigue was reduced by physical activity interventions used in many studies [9].

One of the striking findings of our study was that the mean CAFS scores showed a significant difference in the education+message group, but not in the education and control groups. This result showed that education alone does not provide sufficient effect. It is understood that reminders and motivation are necessary in certain periods in strategies to cope with fatigue. This result was also supported by the effect size in intergroup comparisons ($d_1>d_2>d_3$). It is thought that the result obtained is associated with the physiology of fatigue. Fatigue causes the patient to feel mentally inadequate as well as negatively affects their daily work. In many studies, it has been shown that fatigue is associated with depression and anxiety [7,36,37]. This may lead to a loss of motivation in patients. For this reason, the results of our study suggest that it would be beneficial to remind the education content and support the patient at certain intervals in coping with fatigue. Akrom & Nurwijayanti (2015) showed that reminding and motivational short messages were effective in strengthening patient compliance in patients with COPD, supporting our study findings [5].

There is an important association between fatigue and symptoms in COPD. In their study, Goertz et al. (2019) showed that dyspnea was the best predictor in a multiple regression model on fatigue [4]. This is associated with muscle fatigue and weakness caused by dyspnea in the patient [38]. Strategies to cope with fatigue are expected to have a positive effect not only on fatigue but also on other important problems of COPD. In studies, this has been demonstrated in the relationship between fatigue and the general COPD status [3,4,8,11,34]. Likewise, in the study of Stridsman et al. (2018), it was reported that the CAT scale, which is used to evaluate the general COPD status, was also associated with fatigue [39]. In line with the results obtained from these studies, it can be suggested that being able to cope with fatigue will also contribute positively to the patient's general COPD status. According to the effect size of the comparisons between the groups in our study, strengthening the education with the right strategies led to a superiority of the groups over each other ($d_1>d_2>d_3$). Therefore, it can be suggested that correct nursing interventions are extremely valuable in achieving the maximum treatment effect. The result of this study design revealed that the follow-up of patients in certain periods is also very important. In the literature, studies involving patient follow-up have contributed positively in many ways [9-11,17,19,22]. These results show that our findings are supported by the literature.

Limitations

There are some limitations in the study. Firstly, the study results only reflect the findings of the group in which it was conducted and cannot be generalized to all patients. Due to the study design, it took time to reach a sufficient sample. In addition, patients who did not use phones could not be included in the sample. Some of those who used phones could not be reached during the follow-up period.

CONCLUSION

According to our study results, dyspnea, general COPD status and fatigue were moderate in patients with COPD. With the education given to the patients, improvements were achieved in these findings. However, the strongest effect was observed in the education+message group. This result showed the importance of follow-up in patient education. It can be suggested that it would be beneficial to integrate supportive non-pharmacologic methods in addition to pharmacologic treatments into nursing care.

New studies are needed due to the lack of sufficient studies on the subject. Basic issues such as the causes of fatigue in COPD patients, minimizing-increasing factors, actions to be taken to prevent disruption of care, and organization of daily work should be included in patient education. All education sessions should be repeated and reminded after discharge with the physical or technological means available. Accessible and uncomplicated practical approaches, especially for patients, and sustainable practices for nurses are the first choice. This way, patient outcomes can be maximally improved even in units where there is an insufficient number of nurses or excessive patient care. After reaching a sufficient level of evidence, necessary guidance to patients can be planned with smart tracking systems. It is evident that it will be extremely useful to process patient data in accordance with systems such as decision support systems during patient hospitalization and provide artificial intelligence-supported messages, calls, or online calls after the patient's discharge and in the follow-up of patients at certain intervals with nursing management. These issues will be discussed in the nursing of the future. For this reason, it is thought that the results and observations obtained in the study conducted with the classical method will provide resources for future studies involving patient follow-up systems.

Ethical Approval: *2023/09/05 Kırşehir Ahi Evran University Ethics Committee*

Conflict of Interest: *The author has no conflicts of interest to declare.*

Funding: *None.*

Acknowledgements: *The researchers would like to thank the individuals who participated in the study.*

Author Contribution: Concept: *YC;* ***Design:*** *YC;* ***Data collecting:*** *YC;* ***Statistical analysis:*** *YC;* ***Literature review:*** *YC;* ***Writing:*** *YC;* ***Critical review:*** *YC.*

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Karya J Health Sci. 2024;5(3):112-116
RESEARCH ARTICLE/ARAŞTIRMA MAKALESİ doi: 10.52831/kjhs.1574300 e-ISSN:2717-9540

KARYA JOURNAL OF HEALTH SCIENCE

journal homepage: www.dergipark.org.tr/kjhs

EVALUATION OF THE EFFECTS OF ER-YAG LASER WITH A DIGITAL SCANNING TIP ON DEBONDING OF CERAMIC BRACKETS VS. THE CONVENTIONAL METHOD

ER-YAG LAZERİN DİJİTAL TARAMA UCU İLE SERAMİK BRAKETLERİN DEBONDİNGİ ÜZERİNE ETKİSİ VE KONVANSİYONEL DEBONDİNG METOT İLE KARŞILAŞTIRILMASI

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ABSTRACT

Objective: The aim of this study was to evaluate the effect of the Erbium-doped Yttrium Aluminum Garnet (Er-YAG) laser with a digital and homogeneous scanning (X-Runner) tip on the debonding process of ceramic brackets, comparing with conventional methods.

Method: 80 extracted teeth were divided equally into four groups regarding the bracket material and the debonding procedure: Polycrystalline+ Laser (PL), Monocrystalline+ Laser (ML), Polycrystalline+ Conventional (PC) and Monocrystalline+ Conventional (MC). Enamel cracks were examined both before and after debonding and the remaining adhesive on the enamel surface was evaluated by using the adhesive reminant index (ARI) with the aid of a stereomicroscope. Additionally, the effect of the Er-YAG laser on pulpal temperature rise and the extent of penetration of Er-YAG laser beams into the adhesive were measured. The nonparametric Kruskal-Wallis statistical test was employed to evaluate remaining adhesive on the tooth surface and enamel cracks, while the Mann-Whitney statistical test was utilized to assess temperature rise.

Results: No significant differences in enamel cracks or fractures were observed between the experimental groups concerning both bracket material and debonding procedure ($p>0.05$). Significant differences were found in ARI scores and pulpal temperature changes between the ML and PL groups. ($p<0.05$) Additionally, SEM images revealed that the Er: YAG laser beam did not significantly penetrate the adhesive and had no impact on the enamel surface.

Conclusion: The Er:YAG laser, especially when used with the X-Runner head, provides precise control and minimal thermal impact, ensuring no damage to the enamel or pulp. Therefore, it can be safely utilized for the removal of ceramic brackets in clinical settings.

Key Words: Debonding, Er:YAG Laser, Monocrystalline, Polycrystalline

ÖZ

Amaç: Bu çalışmanın amacı, Erbiyum doped Yttrium Alüminyum Garnet (Er-YAG) lazerin, dijital ve homojen tarama (X-Runner) başlığı kullanılarak, seramik braketlerin debonding işlemi üzerindeki etkisini geleneksel yöntemlerle karşılaştırarak değerlendirmekti.

Yöntem: Seksen adet çekilmiş diş, kullanılan braket ve debonding prosedürü açısından dört gruba ayrıldı: Polikristalin+ Lazer (PL), Monokristalin+ Lazer (ML), Polikristalin+ Konvansiyonel (PC) ve Monokristalin+ Konvansiyonel (MC). Mine çatlakları hem debonding öncesinde hem de sonrasında incelendi ve mine yüzeyinde kalan yapıştırıcı stereomikroskop yardımıyla artık adesiv indeksi (ARI) kullanılarak değerlendirildi. Ayrıca, Er-YAG lazerin pulpal sıcaklık artışı üzerindeki etkisi ve Er-YAG lazer ışınlarının adeziv içine nüfuz etme derecesi ölçüldü. Diş yüzeyinde kalan yapıştırıcıyı ve mine çatlaklarını değerlendirmek için parametrik olmayan Kruskal-Wallis istatistiksel testi kullanılırken, sıcaklık artışını değerlendirmek için Mann-Whitney istatistiksel testi kullanıldı.

Bulgular: Deney ve kontrol grupları arasında braket materyali ve debonding prosedürü açısından mine çatlakları veya kırıkları açısından önemli bir fark gözlenmedi ($p>0,05$). ML ve PL grupları arasında ARI skorları ve pulpal sıcaklık değişimlerinde önemli farklar bulundu. ($p<0,05$). Ek olarak, SEM görüntüleri Er: YAG lazer ışınının yapıştırıcıya önemli ölçüde nüfuz etmediğini ve mine yüzeyinde hiçbir etkisi olmadığını ortaya koydu.

Sonuç: Er:YAG lazer, özellikle X-Runner başlığıyla kullanıldığında, hassas kontrol ve minimum termal etki sağlayarak mine veya pulpaya zarar vermemektedir. Bu nedenle, klinik ortamlarda seramik braketlerin çıkarılması için güvenle kullanılabilir.

Anahtar Kelimeler: Debonding, Er: YAG Lazer, Monokristalin, Polikristalin

Article Info/Makale Bilgisi

Submitted/Yükleme tarihi: 10.26.2024, **Revision requested/Revizyon isteği:** 11.16.2024, **Last revision received/Son düzenleme tarihi:** 11.18.2024, **Accepted/Kabul:** 11.19.2024
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INTRODUCTION

Orthodontic brackets come in three main types: plastic, ceramic, and metal. Metal brackets are commonly used, but there's growing demand for more aesthetically pleasing options. Initially, plastic brackets were used for their appearance but faced issues such as slot deformations, wing fractures, and discoloration [1]. Ceramic brackets, introduced in the 1980s, addressed many of these issues with improved resistance to deformation and discoloration. However, ceramic brackets can still cause problems like bracket fractures, increased friction, wear on teeth, and enamel fractures during removal [2,3].

Various debonding techniques have been developed to address these challenges, including conventional, ultrasonic, electrothermal, and laser methods [4]. Conventional debonding can lead to enamel damage, bracket fractures, and discomfort [5]. Laser systems stand out due to their ability to shorten the debonding time, reduce the required force, and thus enhance patient comfort [6,7]. To avoid potential unwanted side effects, the type of laser device, laser radiation technique, parameters used, as well as the type and technical specifications of the brackets, should be carefully assessed prior to the debonding procedure [8]. To date, Nd:YAG, CO2, and Er:YAG lasers, has been explored to reduce these issues. Among these, Er:YAG lasers produce less heat, which may minimize potential damage [9-11]. This study introduces the use of the X-Runner (LightWalker, Fotona, Slovenia) homogenous scanning system in combination with the Er:YAG laser for debonding, to the best of our knowledge, the first use of this digital scanning device in such procedures. The X-Runner head offers advanced capabilities, including digital control over the shape and size of the treatment area, as well as the ability to adjust the number of scans and the interval between them [12,13].

The purpose of this study is to evaluate the effectiveness of Er:YAG laser with a digital and homogeneous scanning (X-Runner) tip in the debonding process of ceramic brackets (both polycrystalline and monocrystalline) by evaluating enamel cracks, the residual adhesive remaining on the enamel surface, the effect of laser on intrapulpal heat and the extent to which the laser penetrates into the adhesive.

METHOD

Study Sample

Statistical power analysis was performed at α=0.05, 80% power, to determine the sample size, and as in similar studies, it was determined that at least 20 teeth were needed in each group [14]. For this experimental study, eighty extracted human mandibular incisors which were free of cracks, visible damage or fillings were collected in 4 months at the department of Oral and Maxillofacial Surgery at Bezmialem University. The roots were separated from the crowns 2 mm from the cementoenamel junction using an aerator to measure temperature changes. A hole was drilled in the lingual surface of the crowns for the thermocouple's J-type cable (Fig 1). Tooth enamel surfaces were examined under 60X magnification for cracks and breaks before and after the procedure using a scoring method by Kitahara et al. (Fig 2) [15].

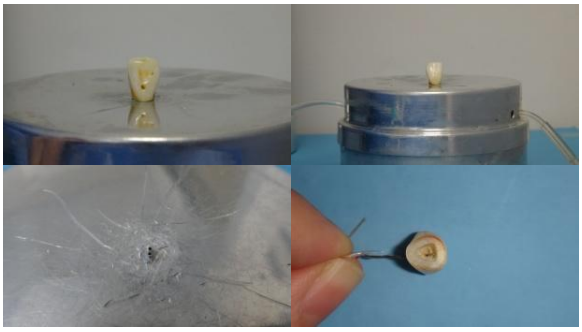

Figure 1. Placement of a Thermocouple on the Sample and Its Connection to the Fixture

Figure 2. Stereomicroscopic Images of Enamel Surfaces with and without Visible Cracks

Two types of brackets were used: polycrystalline brackets (Fascination ice, Dentaurum, Germany) with chemical retention and monocrystalline brackets (Inspire Ice, Ormco, USA) with mechanical retention. Teeth were polished, washed, dried, and etched with 37% orthophosphoric acid before applying Transbond XT primer and adhesive.

The samples were divided into four groups according to the bracket material and the debonding procedure: Polycrystalline+ Laser (PL), Monocrystalline+ Laser (ML), Polycrystalline+ Conventional (PC) and Monocrystalline+ Conventional (MC). Brackets were bonded to the crowns and light-cured. Afterwards, samples underwent thermal cycling (5,000 cycles between 5°C and 55°C with 30-second immersion and 15-second transition times).

Outcome Measures

A stereomicroscope (SMZ 1000, Nikon, Japan) was used to assess adhesive residues. The samples were examined at 1X (10 times) magnification and the ARI scoring was used to evaluate the adhesive residues remaining on the teeth (Table 1) [16]. Enamel surfaces were evaluated before and after adhesive removal, with further analysis using scanning electron microscopy (SEM) to assess laser penetration and proximity to enamel.

Table 1. Adhesive Remnant Index (ARI) Scoring

Definition	Score
No adhesive remains on the tooth surface	**0**
Less than 50% of the adhesive remains on the tooth surface	**1**
More than 50% of the adhesive remains on the tooth surface	**2**
All adhesive remains on the tooth surface	**3**

Data Collection

For debonding, polycrystalline brackets were removed using Weingart pliers by holding the mesial and distal wings of the bracket and rotating them from right to left; while monocrystalline brackets were removed using manufacturer-specific disposable plastic pliers. The pliers were positioned on the bracket wings in an occlusal and gingival orientation, and debonding was carried out with a single, straight motion from gingival to occlusal.

Er: YAG laser debonding was performed with the following parameters: 2970 nm wavelength, 1 W power, 600 mJ pulse energy, 2 Hz pulse frequency, non-contact mode, Medium Short Pulse (MSP) mode, without water, and 90% air. Using the digitally controlled X-Runner head, the scan shape was adjusted to be rectangular and slightly larger than the bracket base area (4mmx4mm). Each sample was scanned horizontally and homogeonously three times in succession, with no time intervals between scans. Out of 40 samples scanned, 32 were successfully debonded in three scans, and 6 were debonded in two scans. For 2 samples, 2 additional scans were performed to ensure complete debonding. Thermal changes occurring during Er: YAG laser application were measured using a setup that included a 0.36-mm-diameter J-type thermocouple (Omega Engineering, Stamford, Conn) and a data receiver with four sensors at the other end of the cable (Emko, EPLC9600-PID QUADRO).

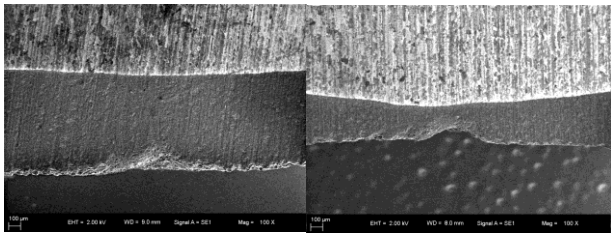

Figure 3. Cross-Sectional Images After Debonding of Monocrystalline Brackets (A), Pollycristalline Brackets (B)

Ethical Approval

All participants agreed to take part in the study and signed written informed consent. The study received ethical approval from Bezmialem Vakıf University Faculty of Dentistry Clinical Research Ethics Committee (date: 03.06.2015, approval number: 11/9).

Statistical Analysis

The statistical analysis was performed using the SPSS (SPSS/PC Version 16.0; SPSS Inc., Chicago, IL, USA) Significance level was set as $p<0.05$. Arithmetic mean (Mean) ± standard deviation (SD) and median values were used to define quantitative data. The Mann-Whitney test was used for the temperature increase evaluation. Kruskall-Wallis analysis, a nonparametic test, was used to evaluate whether there was a statistical difference between the groups in the enamel surface examination and ARI scoring evaluation.

RESULTS

The enamel surface evaluation findings before bonding and after debonding are shown in Table 2. No statistically significant difference was found between conventional- Er-YAG laser debonding groups before and after debonding in terms of enamel cracks and breaks ($p>0.05$). Similarly, when monocrystalline and polycrystalline brackets were evaluated in terms of enamel cracks, there was no statistically significant difference ($p>0.05$).

Table 2. Enamel surface evaluation findings before bonding and after debonding

Groups	N	Mean				Median		Min		Max		Std. Dev	
		T1	*P* value	T2	*P* value	T1	T2	T1	T2	T1	T2	T1	T2
ML	20	1,00		1,05		0,562	0,510	1,00	1,00	0	0	3	3
PL	20	0,80	0,647	0,90	0,707	0,523	0,447	1,00	1,00	0	0	2	2
MC	20	0,85		0,90		0,671	0,641	1,00	1,00	0	0	3	3
PC	20	0,90		0,90		0,447	0,447	1,00	1,00	0	0	2	2

ML: Monocrystalline Laser; PL: Polycrystalline Laser; MC: Monocrystalline Conventional; PC: Polycrystalline Conventiona;, Std. Dev: Standard deviation.

Table 3 shows the evaluation of residue adhesives remaining on the enamel surface using two different removal techniques. When ARI scores were evaluated in terms of both debonding procedure and bracket types, the difference between the groups was found to be statistically significant ($p<0.05$). Within the laser debonding groups (PL- ML), a significant difference in ARI scores was observed ($p<0.05$), with ML groups showing higher scores than PL. Comparing polycrystalline brackets, those debonded conventionally (PC) had higher ARI scores than those debonded with lasers (PL).

Table 3. ARI Score findings after debonding

Groups	N	Mean	Std. Dev	Median	Min	Max	*P* value
ML[a]	20	2,85	0,366	3,00	2	3	
PL[a]	20	2,45	0,510	2,00	2	3	
MC	20	2,85	0,489	3,00	1	3	0,044
PC	20	2,85	0,366	3,00	2	3	

ML: Monocrystalline Laser; PL: Polycrystalline Laser; MC: Monocrystalline Conventional; PC: Polycrystalline Conventional; Std. Dev: Standard deviation. The superscripts indicate a statistically significant difference between the groups.

Monocrystalline samples showed temperature changes between 2.6°C and 5.8°C, with an average increase of 3.71°C ± 1.15°C. Polycrystalline samples had changes ranging from 0.1°C to 5°C, with an average increase of 2.03°C ± 1.64°C. The monocrystalline group (ML) had significantly higher temperature increases compared to the polycrystalline group (PL) ($p<0.05$).

In the debonding process with Er:YAG laser X-Runner tip, SEM analysis was performed at 100 X magnification to see how much the laser penetrated into the adhesive resin. SEM images revealed that the Er: YAG laser penetrated 168 µm into a 670 µm adhesive layer for monocrystalline brackets and 126 µm into a 370 µm adhesive layer for polycrystalline brackets (Fig 3).

DISCUSSION

The findings of the present study revealed that, while the Er YAG laser does not cause a temperature increase that will damage the tooth, when the ARI values are examined, the effect of the laser using the X runner digital tip did not reach the enamel that remained in the adhesive. In laser debonding, no enamel cracks occurred and it was concluded that it can be used safely.

In recent years, alternative debonding procedures have been investigated to prevent microcracks in enamel and bracket damage during traditional debonding of ceramic brackets with pliers. Several studies have demonstrated that laser debonding of ceramic brackets is feasible and protects the enamel by leaving the adhesive on the bracket surface [17-19]. This suggests that laser debonding could be an effective method for removing ceramic brackets while preserving the enamel.

To date, CO2, Nd: YAG and Er: YAG lasers have been investigated for their ability to thermally soften adhesive resin during debonding. In this study, we selected the Er: YAG laser for its lower ceramic absorption and reduced thermal effects compared to other lasers [20,21]. Additionally, we explored the Er: YAG laser's X-Runner head, a previously unstudied feature. The X-Runner head, while similar to traditional non-contact Er: YAG handpieces, demonstrates superior control by allowing precise adjustments of parameters such as energy, frequency, mode, and air/water ratios through its digital display. It also allows for customization of the shape (circular, rectangular, or hexagonal) and size (width and height for rectangles, and diameter for circles and hexagons), as well as adjustment of the

number of scans and waiting time between them, ensuring uniform application [12,22].

In this study, no enamel fractures or cracks were observed in either monocrystalline or polycrystalline brackets during debonding with the Er: YAG laser or conventional methods, indicating the safety of both techniques for ceramic bracket removal. This finding aligns with the literature, which notes that enamel cracks can occur regardless of the debonding method used [23-25]. It also suggests that adhering to the manufacturer's guidelines can help prevent bracket fractures during conventional debonding.

Studies have indicated that the duration and energy of laser application can have iatrogenic effects on pulpal damage [26-28]. Research on lasers has found that a temperature increases of up to 5.5°C is considered safe, as 85% of the teeth used in these studies remained vital, while a temperature rise of 1.8°C was associated with no pulpal damage [28]. In the current study, the average increase in pulpal temperature during debonding was 3.71°C ± 1.15°C. The maximum temperature rise observed was 5.8°C, with most samples recording temperatures below 5.5°C. These results indicate that the Er: YAG laser with the X-Runner tip does not adversely affect pulpal temperature. Another finding of our study is that polycrystalline brackets are more effective than monocrystalline brackets in minimizing increases in pulp temperature.

In this study, ARI did not show any statistically significant difference between the Er: YAG laser and the conventional method. This finding aligns with the results reported by Dostalova et al. [29] and Sedky et al. [30] and Sarı et al. [31]. However, some studies have reported contrary findings [4,32]. These discrepancies may be attributed to variations in laser parameters and types utilized across different research studies. In the current study, the lowest ARI score (2) was found in the polycrystalline (PL) group. Alakus-Sabuncuoglu et al. [33] and Tozlu et al. [34] studied the effects of debonding ceramic brackets with Er:YAG laser by evaluating the residual adhesive index after the debonding procedure. The authors concluded that the use of Er:YAG laser for debonding polycrystalline ceramic brackets was associated with increased residual adhesive index scores, which is in contrast to our findings. Our findings suggest that mechanically bonded monocrystalline brackets may be more effective than chemically bonded polycrystalline brackets during the laser debonding process. However, these results are in consistent with other findings in the literatüre [12,35].

SEM analysis showed that, as supported by the literature, Er: YAG laser beams did not reach the enamel surface and remained confined to the bonding resin during the debonding process for both polycrystalline and monocrystalline brackets, confirming the procedure's safety [26,35,36].

Limitations

This study has some limitations that need to be addressed. We conducted our study on incisors. The number of laser scans or the method of laser application may vary in premolars or molars. Pulpal temperature can also be evaluated in these teeth. However, premolars and molars may differ in terms of enamel crack formation after bracket removal. Therefore, further studies are needed to address these limitations.

CONCLUSION

This study demonstrates that both Er: YAG laser and conventional methods are safe for debonding ceramic brackets, as no enamel fractures or cracks were observed. The Er: YAG laser effectively minimizes increases in pulpal temperature, with results suggesting a temperature rise well within safe limits. Furthermore, the advanced features of the X-Runner enhance its significance by providing superior precision and efficiency, making the Er: YAG laser with the X-Runner head a highly effective and reliable alternative for ceramic bracket removal.

Ethical Approval: *2015-11/9 Bezmialem Vakıf University Faculty of Dentistry Clinical Research Ethics Committee*

Conflict of Interest: *The authors have no conflicts of interest to declare.*

Funding: *None.*

Acknowledgements: *Authors would like to thank Dr. Tuğba Haliloğlu Özkan for her support on this article.*

Author Contribution: Concept: *AÜ,DD,ME;* ***Design:*** *AÜ,DD;* ***Data collecting:*** *ME,DD,Zİ;* ***Statistical analysis:*** *DD;* ***Literature review:*** *Zİ,ME,AÜ;* ***Writing:*** *DD;* ***Critical review:*** *Zİ,AÜ,ME.*

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