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ORIGINAL ARTICLE

Validity and reliability of the full cup test in patients with chronic low back pain

Dolu bardak testinin kronik bel ağrılı hastalarda geçerlilik ve güvenilirlik çalışması

Hatice AĞIR,[1] Müyesser ARAS,[2] Esra Dilek KESKİN,[1] Hafsa Feyza ÖZER,[1] Gülten KARACA,[1] Ufuk ERGÜN,[3] Serap YÖRÜBULUT[4]

Summary

Objectives: This study aims to determine the validity and reliability of the full cup test (FCT), evaluating the pain severity in patients with chronic low back pain.

Methods: A total of 100 patients (70 women and 30 men) aged over 18 years with mechanical low back pain were enrolled in the study. Demographic and clinical characteristics were recorded. Pain severity was evaluated using the visual analog scale (VAS) and FCT, the functional state was assessed by the Oswestry Disability Index (ODI), and the quality of life was assessed using the Nottingham Health Profile (NHP). FCT was performed on the 1st day by two independent observers (G1 and G2) and 3 days after the first application, patients were readministered the FCT by G1.

Results: The mean age of participants was 56.04±12.33 years and mean body mass index was 27.7±4.3 kg/m^2. The reliability of the FCT and intraclass correlation coefficient (ICC) was found to be 0.989 for intrarater compliance, ICC was found to be 0.984 for inter-rater compliance, and Cronbach's alpha reliability coefficient was α=0.994. External construct validity of the scale was confirmed with expected correlations with all subgroups of NHP except for social isolation, VAS and ODI (p<0.01).

Conclusion: This study concludes that the FCT provides a reliable and valid instrument for measuring pain severity and loss of the function in patients with chronic mechanical back pain. We consider that FCT is a simple and easy test in patients with low education and advanced age.

Keywords: Full cup test; low back pain; reliability; validity.

Özet

Amaç: Bu çalışmanın amacı, kronik mekanik bel ağrısı olan hastalarda ağrı düzeylerinin Dolu Bardak Testi ile değerlendirilerek geçerlilik ve güvenilirlik çalışmasını yapmaktır.

Gereç ve Yöntem: Çalışmaya kronik bel ağrısı olan 18 yaşın üstündeki 100 hasta (70'i kadın, 30'u erkek) dahil edildi. Hastaların demografik bilgileri ile demografik ve klinik verileri kaydedildi. Hastaların ağrı durumu Görsel Analog Skalası ve Dolu Bardak Testi; fonksiyonel durumu Oswestry Özürlülük İndeksi; yaşam kalitesi ise Nottingham Sağlık Profili ile değerlendirildi. Hastalara ilk gün birbirinden bağımsız iki gözlemci (G1 ve G2) tarafından Dolu Bardak Testi uygulandı. Ayrıca hastalar aynı gün G1 tarafından Görsel Analog Skalası, Oswestry Özürlülük İndeksi ve Nottingham Sağlık Profili ile değerlendirildi. İlk uygulamadan üç gün sonra hastalara, G1 tarafından Dolu Bardak Testi tekrar uygulandı.

Bulgular: Hastaların yaş ortalaması 56,04±12,33 yıl, beden kitle indeksi ortalamaları 27,7±4,3 kg/m^2 idi. Dolu Bardak Testinin güvenilirlik analiz değerlendirmesinde gözlemci içi uyumu gösteren ICC değeri 0,989, gözlemciler arası uyumu gösteren ICC değeri 0,984 ve Cronbach's alfa güvenilirlik katsayısı ise α=0,994 olarak bulundu. Ölçek geçerliliği test edildiğinde Dolu Bardak Testinin Görsel Analog Skalası, Oswestry Özürlülük İndeksi ve Nottingham Sağlık Profilinin sosyal izolasyon hariç tüm alt grupları ile arasında istatistiksel olarak anlamlı ilişki tespit edildi (p<0,01).

Sonuç: Dolu Bardak Testinin kronik mekanik bel ağrısı olan hastalarda ağrıyı ve fonksiyon kaybını değerlendirmek için kullanılabilecek geçerli ve güvenilir bir ölçüm aracı olduğu görüldü. Düşük eğitim seviyeli ve ileri yaş hastalarda Dolu Bardak Testinin basit ve kolay bir test olduğunu düşünmekteyiz.

Anahtar sözcükler: Bel ağrısı; dolu bardak testi; geçerlilik; güvenilirlik.

[1]Department of Physical Medicine and Rehabilitation, Kırıkkale University Faculty of Medicine, Kırıkkale, Türkiye
[2]Department of Physical Medicine and Rehabilitation, Yıldırım Beyazıt University Faculty of Medicine, Ankara, Türkiye
[3]Department of Neurology, Kırıkkale University Faculty of Medicine, Kırıkkale,Türkiye
[4]Department of Statistics, Science and Literature, Kırıkkale University Faculty of Science and Literature, Kırıkkale, Türkiye

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Correspondence: Dr. Hatice Ağır. Kırıkkale Üniversitesi Tıp Fakültesi, Fiziksel Tıp ve Rehabilitasyon Anabilim Dalı, Kırıkkale, Türkiye.
Phone: +90 - 554 - 115 25 90 **e-mail:** haticeagir10@hotmail.com

Introduction

Pain is a substantial health problem affecting individual's quality of life which is commonly encountered both in neurology and physical medicine clinics. International Association for the Study of Pain describes the pain as "an unpleasant sensory and emotional experience which accompanies or identifies a present or probable tissue damage".[1] It is of great importance to use a common language for the assessment of pain to choose the proper medications and to evaluate their efficiency. Therefore, the first and most important step of pain management is assessment of its severity.[2] At present, there are several scales evaluating pain among which the most reliable indicator is patients' own statement. However, it should be kept in mind that there may be some patients having difficulty in describing their pain.[3] Along with the subjective nature of pain, age, cognitive status, educational level, previous pain experiences, and distinct cultural properties of societies cause variations in individuals' expression of pain, leading to misevaluation of pain and under- or overtreatment.[4]

Low back pain is a significant cause of morbidity in society and experienced by 80–85% of people at least once in their lives.[5] Since low back pain is encountered frequently in the society potentially leading to functional impairments when gets chronic and affects the quality of life in a negative way, the importance of specific methods to assess pain has increased. As well as objective methods, patient-reported outcome measures are employed in assessment and management of low back pain.[6]

In daily practice, visual analog scale (VAS), numeric rating scale (NRS), verbal rating scale (VRS), and McGill pain questionnaire are used for the determination of pain severity.[7]

It is not easy to assess pain severity by means of numeric scales in patients with low educational level. There are few studies on pain assessment of lowly educated patients[8] and a simple pain scale that is easy to understand and apply without any words or numbers is needed for these patients.

The "full cup test" (FCT) which is an instrument for determination of pain severity was developed by Ergün et al.[9] It is a simple and easy tool that may be preferred, especially in low educated patients. The FCT was evaluated in different patient groups and was proven to be valid and reliable with significant correlations to other pain indices.[10–13]

We determined to assess the validity and reliability of FCT in patients with chronic low back pain in the present study.

Material and Methods

This study included a total of 100 patients over 18 years presenting with chronic low back pain (>12 weeks) to Kirikkale University Faculty of Medicine Outpatient Clinic of Physical Medicine and Rehabilitation. Demographic data including age, gender, education, occupation, and body mass index (BMI) were recorded. A detailed examination of the musculoskeletal and neurologic systems was performed. The ethics committee approval dated December 27, 2018, and numbered 20/07 was obtained from Kirikkale University Ethics Board.

Exclusion criteria were having cognitive impairment to hamper understanding and filling the surveys, not willing to participate in the study, aphasia, pain due to inflammatory, infectious, and tumoral diseases or fractures, and referred pain from the internal organs.

Level of the pain was evaluated using the VAS and FCT; functional state was assessed using the Oswestry Disability Index (ODI), and the quality of life was determined by the Nottingham Health Profile (NHP).

Assessment methods

Pain scales

FCT

An empty cup was shown to patients and they were questioned "if your pain is the most severe when the cup is full or it was the final straw, where is your pain in this cup?" They were asked to draw a line with their fingers on the cup to indicate the intensity of their pain (Fig. 1). FCT score was calculated following the formula "length of the line (cm)/height of the cup (cm)×100."[9]

VAS

VAS is a patient reported numeric scale. It is an equally divided line from 0 to 10 cm. Zero corresponds to "no pain," and 10 to "the worst pain all my life." The patients were asked to mark the level of their low

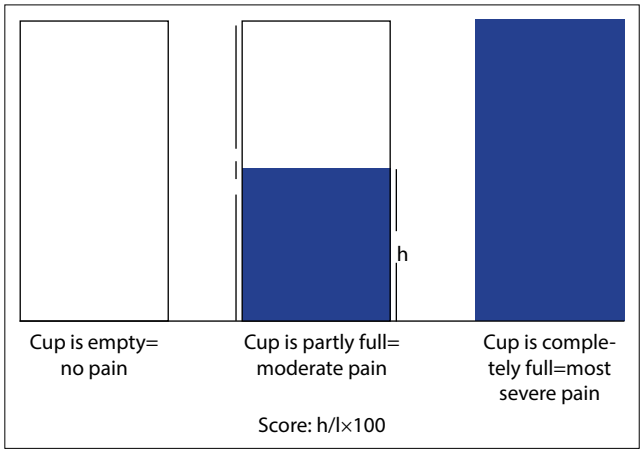

Figure 1. Full cup test.

back pain on the 10 cm line. The higher scores mean higher pain intensity.[14]

Scales to assess functional level and quality of life

ODI

It was specifically developed to evaluate functional impairment in low back pain. This index with proven Turkish validity and reliability consists of 10 items. It questions intensity of pain, self-care, lifting, walking, sitting, standing, sleeping, sexual life, social life, and traveling. Every item has six sub-statements one of which fitting the patient's condition best should be marked by the patient. The first statement is scored 0 and the 6th statement is scored 5 points. The overall score ranges between 0 to 100, higher scores indicating worse disability.[15]

NHP

It is a generic quality of life scale evaluating patients in terms of physical, emotional, and social aspects. It has six domains including pain, physical activity, energy, sleep, social isolation, and emotion with a total of 38 items. Questions are dichotomously answered as "yes" or "no." Every domain is scored from 0 to 100. Zero indicates best health status while 100 corresponds to worst. Higher scores indicate poorer health status.[16]

Design of the study

Reliability

To investigate the interobserver agreement, two independent researchers (G1 and G2) performed the FCT to 100 patients on the 1st day. FCT was applied to all patients 3 days later to evaluate test-retest reliability (G1). Patients did not get any treatment for low back pain during this period.

Validity

To determine the external construct validity, VAS, ODI, and NHP were applied to all patients by G1 on the 1st day.

Statistical analysis

G-Power package program was used to determine the power and sample size of this study. With the power analysis, the power of the study was determined to be 85% for the sample size of 100 units with 95% confidence level (α=0.05) and effect size d=0.45.

The statistical pocket program IBM SPSS v20 was used for statistical analysis. Descriptive statistics (mean, standard deviation, frequency, and percentage) were used for the evaluation of demographic characteristics.

Reliability

To test reliability, test-retest, inter- and intraobserver agreement, and internal consistency were investigated. The intraclass correlation coefficient (ICC) was calculated for test-retest and interobserver reliability. Cronbach's alpha was used to determine internal consistency. The ICC ranges from 0.00 to 1.00 and 0.60 to 0.80 indicate good reliability while >0.80 corresponds to excellent reliability. Test-retest scores were assessed using the Pearson correlation analysis. The extent and direction of the relationship between variables were evaluated by Pearson correlation coefficient.

Validity

To determine the construct validity, relationships between FCT and VAS, ODI, and NHP subscales were evaluated using the Pearson correlation coefficient. The correlations between variables were investigated with the Pearson correlation test.

Independent samples t-test was used to evaluate the effect of gender on the scales used, while the effects of age and education were analyzed by one-way variance analysis (ANOVA). $P<0.05$ was considered statistically significant.

Results

The mean age of 70 women and 30 men was 56.04±12.33 years, respectively, and the mean BMI of patients was 27.7±4.3 kg/m^2. The demographic and clinical characteristics of patients are presented

in Table 1 and data regarding pain, functionality, and quality of life are given in Table 2.

Reliability

The ICC score showing the intraobserver reliability was 0.989, and the ICC for interobserver reliability was 0.984. The internal consistency coefficient Cronbach's α was 0.994 which seems rather high (Table 3).

Validity

When the validity of the FCT is tested, there were strong correlations between FCT and VAS, ODI, and all subscales of the NHP (pain, mood, sleep, functional activity, and energy) except for social isolation ($p<0.01$) (Table 4).

When the effect of several factors including age, gender, and educational status on FCT and VAS scores was evaluated, it was determined that gender did not affect FCT and VAS ($p=0.582$) (Fig. 2). FCT and VAS scores were significantly higher in patients over 50 years compared to other age groups ($p<0.01$) (Fig. 3). The mean FCT scores were higher than mean VAS scores in patients over 70 years, without statistically significance ($p=0.553$). FCT and VAS scores were significantly higher in illiterate people ($p<0.01$), whereas there was no significant difference between mean FCT and VAS scores ($p=0.566$) (Fig. 4).

Table 1. The demographic and clinical characteristics of patients

Demographical data	n	%	Mean±SD
Age (year)	100		56.04±12.33
BMI (kg/m^2)	100		27.7±4.3
Sex			
Female	70	70	
Male	30	30	
Occupation			
Housewife	66	66	
Retired	15	15	
Officer	10	10	
Self-employer	9	9	
Education			
Illiterate	17	17	
Primary school	47	47	
Secondary school	16	16	
High school	13	13	
University	7	7	
Marital status			
Married	75	75	
Single	25	25	
Clinical characteristics			
Etiology			
Discopathy	34	34	
Spinal stenosis	14	14	
Spinal degeneration	20	20	
Myofascial pain	32	32	
Spinal surgery			
Yes	7	7	
No	93	93	

SD: Standard deviation; BMI: Body mass index.

Discussion

The FCT which is accepted as a simple test to assess pain severity was developed by Ergün et al.[9] We evaluated validity and reliability of this test in patients with low back pain in the present study.

We found that the FCT test has significantly high inter- and intraobserver reliability. We detected significant relationships between FCT and VAS, ODI, and NHP which were performed to assess pain severity, functionality, and quality of life. In a study on patients with toothache, weaker reliability compared to ours was reported (Cronbach's alpha=0.85).[13]

In another study by Ergün et al.[9] on rheumatologic patients with pain, there was a significant correlation between FCT and VAS (r=0.95) which is compatible with our results.

In a study by Say et al.[17] on patients with diabetic neuropathic pain evaluating pre- and post-treatment VAS and FCT scores, high correlation was detected between VAS and FCT in both pre- and post-treatment assessments (r=0.86, r=0.84) which is lower than our correlation rate.

In studies comparing VAS and FCT on patients with toothache[13] or pain following dental surgery,[11,12] authors reported high correlation between two scales which are in accordance with our results.

In recent years, there has been a trend to supplement objective assessment of treatment outcomes in patients with LBP, with measurements of functional status and quality of life.

Table 2. Scores of questionnaires regarding pain, functionality, and quality of life

Data	Mean±SD
FCT	60.52±22.65
VAS	5.88±2.16
ODI	25.80±12.21
NHP-P	55.02±27.16
NHP-E	20.86±25.67
NHP-S	32.56±32.99
NHP-SI	8.60±20.02
NHP-FA	50.42±23.22
NHP-E	37.69±43.86
NHP-T	202.23±123.32

FCT: Full cup test; VAS: Visual analog scale; ODI: Oswestry Disability Index; NHP-P: Nottingham Health Profile-Pain; NHP-E: Nottingham Health Profile-Emotion; NHP-S: Nottingham Health Profile-Sleep; NHP-SI: Nottingham Health Profile-Social Isolation; NHP-FA: Nottingham Health Profile-Functional Activity; NHP-E: Nottingham Health Profile-Energy; NHP-T: Nottingham Health Profile-Total.

In recent years, there has been a trend to supplement objective assessment of treatment outcomes in patients with LBP, with measurements of functional status and quality of life. Many instruments are available for measuring health-related quality of life. Although most of these instruments measure physical functioning and can be used as condition-specific quality of life instruments, in majority of back pain studies, the authors did not directly refer to health related quality of life. ODI is a comprehensive scale developed specifically for low back pain evaluating self-care, mobilization, sitting, walking, traveling, sleeping, and social life. In our study, we have found significantly high correlation between FCT and ODI scores suggesting that FCT assesses not only pain but also functionality. There are no other studies evaluating FCT and functional status in the literature.

In another study, Say et al.[18] assessed symptoms of patients with carpal tunnel syndrome using the Boston Carpal Tunnel Syndrome Questionnaire (BCTQ) and FCT. Furthermore, they compared FCT results with electromyography. They reported high correlation between FCT and BCTQ symptom scale and function scale (r=0.60 and r=0.65). Furthermore, there was significant relationship between FCT and electrodiagnostic test results.

In the present study, quality of life was assessed using the NHP revealing high correlations between the FCT and total NHP scores and all subscales of the NHP except for social isolation. As far as we are concerned, there is no study evaluating the relationship between FCT and quality of life in the literature.

In a review evaluating pain severity in patients recovering from oral and maxillofacial surgery, 10 scales including the FCT were used: McGill Pain Questionnaire, Short form of the McGill Pain Questionnaire, Wisconsin Brief Pain Questionnaire, VAS, Verbal De-

Table 3. Reliability analysis of the FCT

Data	Mean±SD		ICC
	1st evaluation	2nd evaluation	
Intraobserver reliability	60.52±22.65	60.06±21.92	0.989
Interobserver reliability	60.52±22.65	60.64±21.89	0.984

FCT: Full cup test; ICC: Intraclass correlation coefficient; SD: Standard deviation.

Table 4. Correlation between FCT and VAS, ODI, and NHP total/subscales

Data	VAS	ODI	NHP-P	NHP-E	NHP-S	NHP-SI	NHP-FA	NHP-E	NHP-T
FCT									
r	0.941**	0.702**	0.776**	0.440**	0.406**	0.158	0.607**	0.385**	0.623**
p	0.000	0.000	0.000	0.000	0.000	0.116	0.000	0.000	0.000

Spearman correlation analysis; *: Correlation was significant at 0.05 level; **: Correlation was significant at 0.01 level; FCT: Full cup test; VAS: Visual analog scale; ODI: Oswestry Disability Index; NHP-P: Nottingham Health Profile-Pain; NHP-E: Nottingham Health Profile-Energy; NHP-S: Nottingham Health Profile-Sleep; NHP-SI: Nottingham Health Profile-Social Isolation; NHP-FA: Nottingham Health Profile-Functional Activity; NHP-T: Nottingham Health Profile-Total.

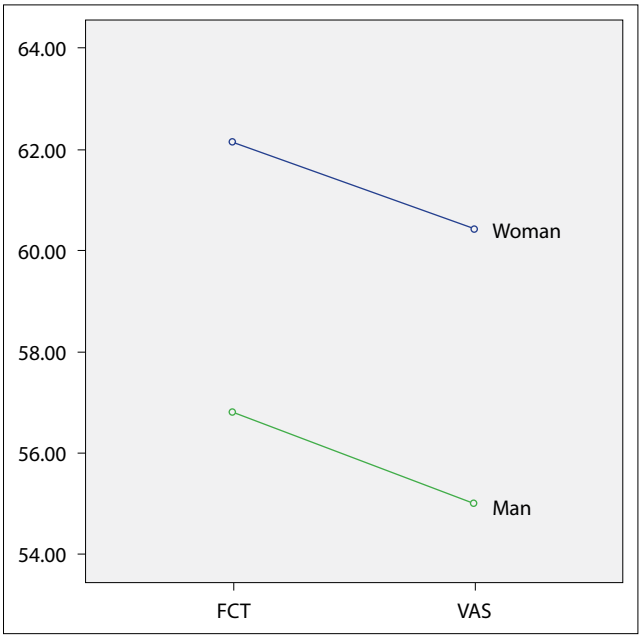

Figure 2. Comparison of full cup test and visual analog scale scores according to gender.
FCT: Full cup test; VAS: Visual analog scale.

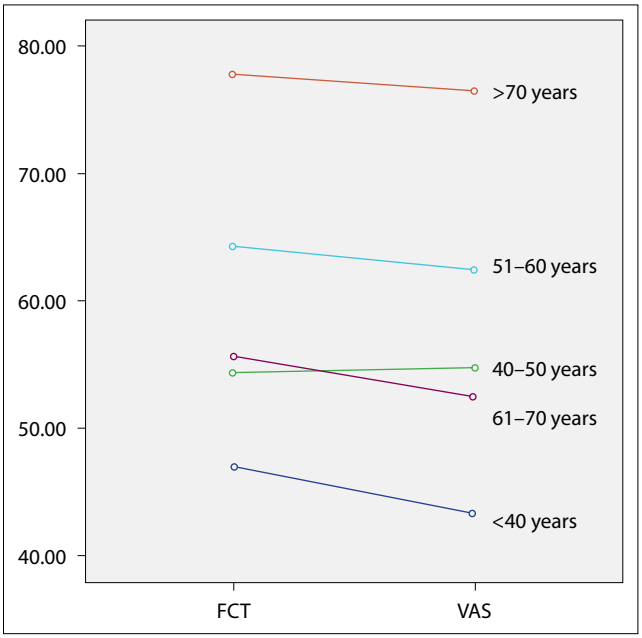

Figure 3. Comparison of full cup test and visual analog scale scores according to age.

scriptor Scale, VRS, Numerical Rating Scale, Faces Pain Scale, Wong-Baker Faces Pain Rating Scale, and FCT. Along with advantages and disadvantages of each scale, FCT was emphasized to be more easy to apply in the acute term.[19]

A proper pain scale is expected not to differ according to gender. We determined no difference in FCT scores in both sexes. This is an important result, indicating that FCT is perceived and answered in the same way by female and male patients. There is no study investigating gender differences in FCT.

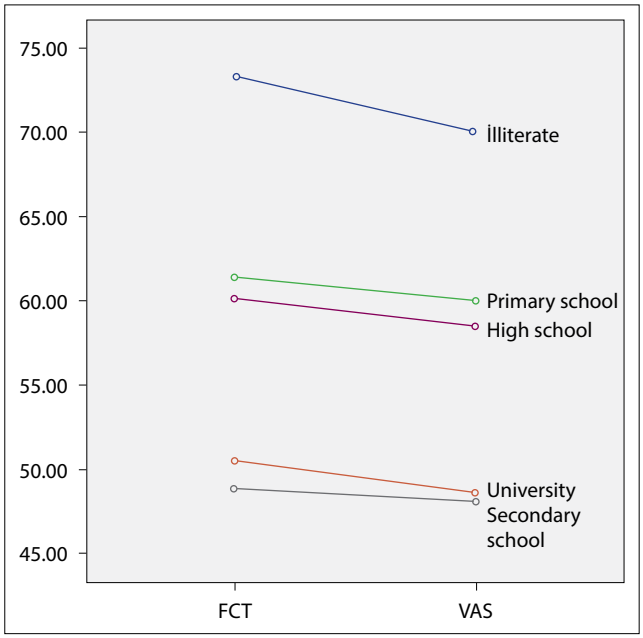

Figure 4. Comparison of full cup test and visual analog scale scores according to the educational status.

In the present study, patients over 50 years had elevated FCT and VAS scores which were also correlated with each other without significant differences within. The reason behind that may be the fact that patients over 50 years more commonly experience low back problems. In another study, 11% of the elderly were reported not to complete VAS and 2% not to cope with a numeric scale.[20]

In a review investigating the pain scales among adolescents from Italy in 2018, FCT was depicted to be an applicable test over 7 years.[21] While there are studies on feasibility of the FCT on adult population, studies regarding pediatric patients are required.

It has been reported in several articles that educational level is significant for the comprehensibility of questionnaires.[9,22] In our study, FCT and VAS scores were similar without a significant difference. While the illiterate had highest FCT scores, secondary school graduates (8 years of education) had the lowest scores. Other educational levels did not differ significantly. The reason why illiterate persons had higher FCT scores may be the fact that they could express themselves better by this method or they had higher levels of pain.

Similar to our results, another study in the literature reported that people with lower educational status experienced more difficulty in VAS despite not being statistically significant. Furthermore, it was depicted that these difficulties in vocabulary scales may be associated to educational level.[23]

In a study by Ergün et al.,[9] FCT and VAS scores were compared in patients with low educational status. While 21.4% of these patients could not complete the VAS, all of them were able to finish the FCT. The average time to explain VAS was approximately 2 times longer than the FCT. These data suggest that the FCT is easier to comprehend and respond compared to VAS. In another study evaluating pain status following dental surgery, the easiest scales to apply were listed as NPRS, FCT, and VAS, respectively. When patients were questioned why they preferred the FCT, they expressed that it was easier to indicate pain and the cup image was simple.[11]

Similarly, in another study evaluating five pain scales (faces pain scale, NRS, verbal rating scale, VAS, and FCT), patients stated that FCT is the simplest scale to understand and to apply ($p<0.001$).[12] In a systemic review assessing pain scales in 2019, VAS, VRS, and NRS were evaluated. VAS was considered as the most difficult scale among them.[24] Therefore, we propound that the FCT may be preferred as an alternative over VAS, which is commonly used in the daily practice but harder to apply than predicted.

In the present study, we concluded that the FCT is a valid and reliable tool in the assessment of low back pain. The strong element of this study is employing quality of life and daily living activity scales in addition to pain scales when evaluating low back pain. The FCT has been found to be able to assess the functional burden of low back pain, which was evaluated for the 1st time in the literature. We consider that the FCT may be used more frequently in routine practice due to being easier to understand and to apply compared to VAS, not containing numeric values, and being compatible with other instruments regarding daily living activities and quality of life.

Ethical Approval: The study was approved by The Kirikkale University Clinical Research Ethics Committee (Date: 27/11/2018, No: 20/07).

Conflict-of-interest issues regarding the authorship or article: None declared.

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