Construct Validity and Reliability of the 2-Minute Step Test in Patients with Fibromyalgia

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Abstract

Background: The aim of this study was primarily to assess the validity and reliability of the 2-minute step test (2MST) in patients with fibromyalgia; and secondly, to explore its relationship with the 2-minute walk test (2MWT), the 6-minute walk test (6MWT), as well as fatigue severity and quality of life.
Methods: This cross-sectional study involved 55 female patients aged 18-65 diagnosed with fibromyalgia according to the American College of Rheumatology 2010 Diagnostic Criteria. Pain intensity was measured using the Visual Analog Scale, quality of life impact was assessed with the Fibromyalgia Impact Questionnaire, and fatigue severity was evaluated using the Fatigue Severity Scale. Patients underwent initial assessments using the 2MST, 2MWT, and 6MWT. Test–retest reliability of the 2MST was determined with a 7-day interval between assessments.
Results: The study included a cohort of participants with an average age of 45.3 ± 7.7 years. The mean score for the 2MST was 51.9 ± 15.6, with a second 2MST yielding a mean score of 56.1 ± 16.4. The reliability of the 2MST was found to be good (ICC = 0.925) in patients with fibromyalgia. The 2MST exhibited significant correlations with the 2MWT (ρ = 0.633) and 6MWT (ρ = 0.703).
Conclusion: In conclusion, this study demonstrates that the 2MST is a reliable tool for evaluating exercise capacity in individuals with fibromyalgia, showing a negative association with age and pain severity.
Keywords: Exercise, exercise test, fatigue, fibromyalgia, physical fitness

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Introduction

Fibromyalgia syndrome (FMS) is a chronic condition characterized by widespread pain and sensitivity in the body, accompanied by fatigue, sleep disturbances, and cognitive problems. The prevalence of FMS in the general population varies between 0.2% and 6.6%. The incidence of FMS tends to increase with age, and the majority of the patient population is composed of women.[1] Fatigue, reported to affect 100% of patients, is one of the most significant symptoms of FMS.[2]

Assessing aerobic exercise capacity in individuals with musculoskeletal problems is important for determining the impact of the disease on the individual. Additionally, it is beneficial in designing personalized exercise programs, tracking the response to physical therapy modalities, and medical treatment. In this context, various methods are available for assessing an individual's exercise capacity. The 6-minute walk test (6MWT) is a method used to assess exercise capacity and physical performance in FMS patients.[3] The 2-minute walk test (2MWT) is among the objective tests used for this purpose.[4] In addition to these tests, there are many other methods used to assess physical capacity, such as the 10-meter walk test, self-paced walking test, 5-repetition getting up from a chair and sitting, treadmill walking test, 30-second chair stand, and timed up-and-go test.[4,5] Both the 6MWT and 2MWT are advantageous in clinical practice because they can be easily performed and repeated by patients and do not require special equipment. However, their disadvantages include the need for a long corridor of at least 30 meters and a longer cardiopulmonary loading time for patients, making the application time-consuming in clinical settings. In 1999, as an alternative to these tests, Rikli and colleagues developed the 2-minute step test (2MST).[6] In their study, they reported that the 2MST had good reliability intraclass correlation coefficient (ICC: 0.90) and conducted a validation study.[7] Furthermore, the 2MST has been subject to validity studies in knee arthroplasty,[8] low back pain,[9] and gonarthrosis[10] among others.

According to our knowledge, there has been no prior study investigating the validity and reliability of the 2MST in FMS patients. The purpose of this study was to explore the validity and reliability of the 2MST as an

objective and practical test for assessing exercise capacity in FMS patients.

Material and Methods

Study Design
This prospective cross-sectional research study obtained ethical approval (protocol no: 2023/357) from the Bakırköy Dr. Sadi Konuk Training and Research Hospital Clinical Research Ethics Committee. Between October 1, 2023, and November 1, 2023, 55 female patients aged 18-65, diagnosed with fibromyalgia according to the American College of Rheumatology 2010 Diagnostic Criteria, were consecutively included in the study at the Health Science University,Istanbul Physical Medicine and Rehabilitation Training and Research Hospital outpatient clinics. Prior to commencing the study, all participants were provided with informed consent forms and signed them. Exclusion criteria for the study encompass uncontrolled hypertension, the presence of degenerative disease or arthritis in the lower extremities, prior lower extremity surgical procedures, neurological diseases that could create balance problems, decompensated heart failure, systemic diseases affecting lower extremity functions, peripheral artery disease, psychiatric disorders, cognitive impairment, pregnancy, and cognitive impairment. Demographic data of the patients, including age, height, weight, body mass index (BMI), marital status, education level, and occupation, were recorded. Duration of symptoms and pain localization were also investigated. The impact of fibromyalgia on patients' quality of life was assessed using the Turkish version of the Fibromyalgia Impact

Main Points
- Fibromyalgia is a commonly encountered syndrome characterized by widespread body pain, fatigue, and tender points.
- Numerous studies have identified that pain, mental state, and fatigue in fibromyalgia patients contribute to a decrease in exercise capacity.
- There are various methods available to assess exercise capacity, and the 2-minute step test (2MST) is one of the options that can be utilized to evaluate aerobic and functional capacity.
- Given that there is a lack of studies in the literature investigating the validity and reliability of the 2MST in the lumbar spinal stenosis patient group, we decided to address this topic in our research.

Questionnaire (FIQ), which has demonstrated validity and reliability.[11] The level of fatigue in patients was determined using the Fatigue Severity Scale (FSS).[12] Pain levels were measured using a linear scale known as the 100 mm Visual Analog Scale (VAS).[13]

During the assessment of exercise capacity, the 2MST, 6MWT, and 2MWT were administered. It was ensured that the patient had rested for at least 30 minutes before the tests and that there was a minimum of 30 minutes of rest between the tests. Before starting the tests, the patient's vital signs were checked. Relative contraindications include resting heart rate more than 120, systolic blood pressure more than 180 mm Hg, and diastolic blood pressure more than 100 mm Hg.[14] One week after the evaluation, the 2MST was repeated for each patient by the same examiner.

Sample Size
Our study's primary outcome variable is the 2MST. Based on data from the research conducted by Jesus et al in 2022,[9] with a significance level (alpha) of 0.05 and research power of 0.98, the minimum required sample size was calculated to be 49. The sample size for the study included 55 patients and was determined using G*Power version 3.1.9.4 (Franz Faul, University of Kiel, Germany) software.

Outcomes

Fibromyalgia Impact Questionnaire
In our study, to assess the impact on the quality of life of FMS patients, the Turkish version of the FIQ, with proven validity and reliability, was used.[11] The FIQ is a 10-item scale. The first item includes 10 sub-items that assess the ability to perform daily life activities. Responses to these 10 activities are in Likert format, with 0 indicating "I can always do it," 1 indicating "I can mostly do it," 2 indicating "I can do it occasionally," and 3 indicating "I can never do it." The next 2 items are related to how many days in a week the person felt good and was unable to work. The final 7 items include inquiries about how pain affects the functional status, the intensity of pain and fatigue, the level of feeling good in the morning, the level of morning stiffness, and questions related to mood. According to this scoring system, the highest possible score is 100, indicating severe impairment, and the minimum score is 0.

Fatigue Severity Scale
In our study, to determine the level of chronic fatigue, the Turkish version of the FSS, with proven validity and reliability in FMS patients,

was used.[12] This scale consists of 9 items that inquire about the intensity and impact of fatigue on patients. Each item is scored from 0 (completely disagree) to 7 (completely agree) on a scale from 0 to 7. The total score is calculated by taking the arithmetic mean of the scores given to the items. The minimum score that can be obtained is 0, and the maximum score is 7. The higher the total score, the higher the level of fatigue is considered.

6-Minute Walk Test
The 6MWT was conducted following the American Thoracic Society (ATS) guidelines.[14] A straight corridor, 30 meters in length and 3 meters in width, was used for the test. The patient was instructed to walk back and forth in the corridor as quickly as possible for a total of 6 minutes, avoiding unnecessary delays when making turns. If the patient felt the need to rest due to fatigue or pain, they were allowed to do so, but the time continued to elapse. Encouraging statements were provided to the patient at the end of each minute, and the total distance covered in 6 minutes was measured and recorded. The patient was then instructed to sit in a chair and rest for 30 minutes. Afterward, the 2MWT was conducted.

2-Minute Walk Test
The 2MWT is a modified version of the 6MWT as described in the ATS guideline.[14] In the 2MWT, the patient walks for a duration of 2 minutes in a 30-meter long corridor as quickly as possible without running. At the end of the 2 minutes, the distance covered is measured and recorded.

2-Minute Step Test
The 2MST was developed by Rikli and Jones in 1990 as an alternative for measuring exercise capacity.[6] Before commencing the test, the patient was provided with necessary information about the test. The midpoint between the anterior superior iliac spine and the patella was measured, and its level was marked on the wall.[15] The patient was then asked to lift their knees as many times as possible within a 2-minute duration, reaching at least to the marked level. The number of times the right knee was raised during the 2 minutes was recorded. Steps that didn't reach the designated level were not included. The patient was allowed to rest when they felt too fatigued or in pain to continue, but the timer continued. The test was repeated 7 days after the initial test.

Visual Analog Scale
To determine the level of chronic pain experienced by the patient, the VAS was used.[13]

According to the VAS scale, 0 represents no pain at all, and 100 represents the most severe level of pain. It is a linear scale ranging from 0 to 100 points. Patients were asked to indicate their level of pain on this scale.

Statistical Analysis

Quantitative data were presented using mean and standard deviation values, while qualitative data were represented by count and percentage values. Test–retest reliability, conducted at a 1-week interval, was evaluated using the ICC method, with respective 95% CIs, minimum detectable change (MDC$_{95}$), and standard error of measurement (SEM) values provided, following the approach by Bassi et al.[16] Interpretation of the ICC values was based on the study by Fleiss et al.[17] Higher ICC values indicate greater reliability of the tested variable. According to this study, ICC values less than 0.40 indicate low reliability, values between 0.40 and 0.74 indicate moderate reliability, values between 0.75 and 0.90 indicate high reliability, and ICC values greater than 0.90 signify excellent reliability. Standard error of measurement was calculated using the formula SEM = standard deviation × $\sqrt{(1-ICC)}$, while MDC was determined using the formula $1.96 \times SEM \times \sqrt{2}$.[18] The calculated overall SEM value is the average of the SEM values calculated based on the test and retest measurements. The SEM and MDC values were reported as absolute values identical to the 2MST scores and also as a percentage of the grand mean to facilitate comparison with other studies. The grand mean represents the average of subsamples (test and retest).[19]

The normality of the data distribution was assessed using the Kolmogorov–Smirnov test. The relationship between the 2-MST and the 2-MWT, 6-MWT, and FIQ scores was evaluated using Spearman correlation coefficients. A correlation coefficient of ≥0.50 was considered indicative of similar constructs, between 0.30 and 0.50 suggested related but different constructs, and below 0.30 implied unrelated constructs.[16] A multiple linear regression analysis was performed to evaluate the predictors of 2MST performance. Independent variables included in the model were age, BMI, symptom duration, 6MWT, FIQ, VAS, and FSS. Two-minute walk test was not included in the regression model to avoid redundancy with the 6MWT, as these 2 measures are highly correlated and evaluate similar aspects of physical performance. The regression model aimed to determine the relationship between these predictors and the 2MST scores. The adjusted R^2 value was calculated to assess the proportion of variance in the dependent variable explained by the predictors.

Results

Descriptive statistics for the patients are detailed in Table 1. Among the patients, 83.6% experienced widespread pain throughout their entire body (Table 1).

All of the test results are summarized in Table 2. During the initial assessment, the average values for the 2MST were 51.9 ± 15.6, and in the second application, these values were 56.1 ± 16.4. The mean values for the 2MWT and the 6MWT were calculated as 147 ± 22.1 and 430 ± 62.9, respectively (Table 2).

Table 3 displays the test–retest reliability of the 2MST conducted with a 7-day interval. The ICC value was found to be 0.925, indicating a high level of reliability (ICC > 0.90) (Table 3).

Table 4 shows the correlations between the 2MST and demographic data, 2MWT, 6MWT, VAS, FIQ, and FSS scores. Upon examining the values in the table, it was observed that as age increased, 2MST scores decreased, showing a weak negative correlation ($\rho = -0.271$, $P = .045$). There was no significant relationship between BMI and symptom duration with 2MST. Additionally, there was a high-level correlation between 2MST and 2MWT ($\rho = 0.633$, $P < .001$) and 6MWT ($\rho = 0.703$, $P < .001$) scores. A significant negative relationship was present between VAS values and 2MST ($\rho = -0.366$, $P = .006$). There were no statistically significant correlations found between 2MST and FIQ or FSS scores (Table 4).

According to the results of the multiple regression analysis, the positive effect of 6MWT on 2MST performance was particularly strong ($P = .000$, $\beta = 0.668$). However, no significant relationships were found between 2MST and age, BMI, symptom duration, 2MWT, FIQ, VAS, or FSS. The adjusted R^2 value of 0.469 indicates that approximately 46.9% of the variance in the 2MST scores can be explained by the predictors included in the model (Table 5).

Discussion

In this study, the aim was to demonstrate that the 2MST can be a valid and reliable tool for assessing functional capacity in FMS patients. It was found that the 2MST has high reliability and internal consistency, with an ICC value of 0.925 in women with FMS. Additionally, a significant and strong positive correlation was found between the 2MST and 6MWT, as well as between the 2MST and 2MWT.

Previous studies conducted in healthy individuals and different patient groups have also reported the reliability of 2MST.[10,18,24,25] In 1999, Rikli and Jones suggested that 2MST could be used as an alternative aerobic test under the title "Senior Fitness Test Items."[10] In the following years, this test has been used to assess functional capacity in various disease groups. Nogueira et al[20] conducted a study in active or sedentary participants aged 18-44, and they found that 2MST had high interrater reliability and test–retest reliability levels (ICC ≥ 0.83). In a study conducted in patients with

Table 1. Descriptive Statistics

		Mean (SD) / n (%)			Median (Min-Max)
Age		45.3	±	8.72	46 (21-65)
Marital status	Married	50		90.9	
	Single	5		9.1	
BMI		27.62	±	4.84	26.8 (17.85-40.37)
Education (years)		8.65	±	4.21	8 (0-16)
Occupation	Employed	15		27.3	
	Retired	6		10.9	
	Housewife	34		61.8	
Symptom duration (months)		77.8	±	95.6	48 (1-480)
Sportive activity	Yes	7		12.7	
	No	48		87.3	
Treatment	Yes	16		29.1	
	No	39		70.9	

BMI, body mass index.

Table 2. Scores of Objective and Subjective Tests

	Mean (SD)		Median (Min-Max)
2MWT	147	± 22.1	145 (100-200)
6MWT	430	± 62.9	427 (285-596)
VAS	82.8	± 16.9	90 (40-100)
FIQ (score)	70.7	± 16.2	72.6 (25.2-97.1)
FSS	5.47	± 1.4	5.77 (2.33-7)
2MST	51.9	± 15.6	48 (25-96)
Second 2MST	56.1	± 16.4	52 (19-98)

2MST, 2-minute step test; 2MWT, 2-minute walk test; 6MWT, 6-minute walk test; FIQ, fibromyalgia impact questionnaire; FSS, fatigue severity scale; VAS, visual analog scale.

Table 3. Test–Retest Reliability of the Measurement of the 2-Minute Step Test in Individuals with FMS

	ICC	95% CI SEM	SEM (%)	MDC	MDC_{95}
2MST	*0.925*	0.669-0.971 4.38	8.11	6.20	12.15

ICC, intraclass correlation coefficient; MDC, minimum detectable change; SEM, standard error of measurement.

Table 4. Correlations Between 2-Minute Step Test (2MST) and Other Tests and Parameters

	ρ	P
Age	- 0.271*	*.045*
BMI	- 0.235	.084
Symptom duration	- 0.061	.657
2MWT	0.633**	*<.001*
6MWT	0.703**	*<.001*
FIQ	- 0.264	.052
VAS	- 0.366**	*.006*
FSS	- 0.123	.372

Spearman's Rho. 2MST, 2-minute step test; 2MWT, 2-minute walk test; 6MWT, 6-minute walk test; BMI, body mass index; FIQ, fibromyalgia impact questionnaire; FSS, fatigue severity scale; VAS, visual analog scale.*. Correlation is significant at the 0.05 level (2-tailed). **. Correlation is significant at the 0.01 level (2-tailed).

knee osteoarthritis, the test–retest and inter-rater reliability levels of 2MST were evaluated, and the ICC values were found to be 0.94 and 0.97, respectively.[14] McCain et al[21] investigated the online applicability of gait speed, 30-second chair stands, and 2MST for determining physical function in adults aged over 65. In the same study, they reported an average ICC value of 0.89 (0.79-0.94) and found it to be highly reliable. Ricci et al[22] compared 2MST with a cardiopulmonary exercise test in individuals with obesity and comorbidities (BMI ≥ 35 kg/m²) and morbidly obese individuals (BMI ≥ 40 kg/m²). They concluded that 2MST is a simple, easily applicable, and valid test for assessing functional capacity. Braghieri et al[23] conducted a reliability study of 2MST in individuals with peripheral artery disease and reported an ICC value of 0.945. Consistent with the literature, the result of this study showed that 2MST is a valid and highly reliable method in FMS patients, with an ICC value of 0.925.

An important finding of this study is the high-level, significant correlation of 2MST with 2MWT (ρ=0.633, P=.000) and 6MWT (ρ=0.703, P = .000). Braghieri et al[23] conducted a reliability study of 2MST in peripheral artery disease and reported an ICC value of 0.945. Additionally, they reported a significant correlation between 2MST and 6MWT (ρ=0.55). They evaluated the 6MWT in terms of both step count and distance walked, suggesting that the relationship between step count and 2MST is stronger, which they indicated could be related to differences in patients' step lengths and heights.

In a study conducted by Berlanga et al[24] with a mean age of 72.9 ± 4.6 in healthy adults, a high-level positive correlation between 2MST and 6MWT scores was reported (r=0.696, P < .001). In patients diagnosed with systolic heart failure, a statistically significant relationship between 2MST and 6MWT was found.[25] In a study conducted on elderly hypertensive patients, a low-to-moderate positive correlation (r=0.36; P=.04) was demonstrated between 2MST and 6MWT scores.[26] In another study, a cutoff value of 60 for the 2MST score was determined to assess exercise capacity in older individuals with hypertension, with reported sensitivity of 87.50% and specificity of 70.59%. Moreover, a positive correlation between 2MST and 6MWT was identified.[27]

To the best of our knowledge, there has been no previous research investigating the validity and reliability of 2MST in individuals with FMS. However, this study has several limitations. First, the single-center nature of the study prevented the examination of potential variations arising from diverse environmental conditions or healthcare settings, which may limit the generalizability of the findings. Second, the study included only female participants, excluding male FMS patients, who may exhibit different functional characteristics. Additionally, the potential effects of the menstrual cycle, which could influence functional performance, were not considered. Another limitation is the relatively small sample size, which may have reduced the statistical power to detect significant correlations or regression relationships between the 2MST and disease-specific features such as FSS and FIQ. This could explain the lack of significant associations between the 2MST and these FMS-specific measures. Larger sample sizes in future studies could provide a more accurate evaluation of these relationships. Lastly, while the study employed a cross-sectional design, longitudinal data would provide deeper insights into the utility of the 2MST in monitoring disease progression or response to

Table 5. Multiple Regression Analysis Predicting 2-Minute Step Test (2MST) Performance

	Unstandardized B	SE	β	P	95% CI
Age	- 0.375	0.195	- 0.209	.060	(- 0.767, 0.017)
BMI	0.027	0.376	0.008	.942	(- 0.729, 0.784)
Symptom duration	0.006	0.017	0.035	.742	(- 0.029, 0.041)
6MWT	0.166	0.028	0.668	*.000*	(0.111, 0.221)
FIQ	0.049	0.129	0.051	.706	(- 0.211, 0.309)
VAS	- 0.077	0.112	- 0.083	.496	(- 0.301, 0.148)
FSS	- 0.479	1.349	- 0.043	.724	(- 3.193, 2.235)

Multiple regression analysis. Adjusted R^2 = 0.469. 2MST, 2-minute step test; 6MWT, 6-minute walk test; BMI, body-mass index; FIQ, fibromyalgia impact questionnaire; FSS, fatigue severity scale; SE, standard error; VAS, visual analog scale.

treatment over time. Future research should also aim to include a broader population with diverse demographic and clinical characteristics to enhance the generalizability of the findings.

In conclusion, 2MST proves to be a practical and easily applicable method for assessing aerobic capacity in individuals with FMS. Moreover, it correlates with objective methods assessing physical capacity such as 6MWT and 2MWT, indicating its potential as an alternative to these tests.

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