The reliability and validity of the Turkish version of fibromyalgia survey diagnostic criteria and symptom severity scale

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Abstract.

BACKGROUND: The fibromyalgia survey diagnostic criteria and severity scale (FSDC) is a self-reported version of 2010 preliminary diagnostic criteria for fibromyalgia syndrome (FMS). FSDC not only facilitates to diagnose FMS, it measures pain (the Widespread Pain Index (WPI)/FSDC Section 3), the Symptom Severity (SS)/FSDC Sections 1 and 2, and provides a score, polysymptomatic distress (PSD)/FSDC Total score in patients with FMS. The purpose of our study is to evaluate the reliability and validity of Turkish version of FSDC in Turkish patients with FMS.

METHODS: The Turkish version FSDC was obtained by two forward translations of the instrument into Turkish by two bilingual Turkish individuals, one of them was a physician. They were then back translated into English by two different bilingual individuals; another Turkish physician and a backtranslator whose mother tongue was English. The original version of FSDC, the two Turkish forward translations, and English back translations were then reviewed by the individuals involved in translations, and the last experimental Turkish version was created. This last version of Turkish FSDC studied on patients with newly diagnosed FMS by using American College of Rheumatology (ACR) 1990 classification criteria. Patients filled validated Turkish revised fibromyalgia impact questionnaire (rFIQ), our nonvalidated experimental Turkish FSDC; marked Visual Analog Scale (VAS) for pain and the disease severity. In 7 to 15 days, they have filled the nonvalidated Turkish FSDC for the second time.

RESULTS: In 132 patients, by the test to retest reliability analysis of nonvalidated Turkish FSDC, for the 25 single items, correlation coefficients ranged 0.383 to 0.818 (all \( p < 0.01 \)). There were significant correlations between nonvalidated Turkish FSDC assessment 1 and assessment 2 for Section 1 + 2 (SS) \( (r = 0.748) \), Section 3 (WPI) \( (r = 0.775) \), and the total scores (PSD) \( (r = 0.821) \) (all \( p < 0.01 \)). Cronbach alpha was 0.766 for the nonvalidated Turkish FSDC assessment 1 total score, and 0.77 for the Turkish FSDC assessment 2 total score. There were significant correlations between nonvalidated Turkish FSDC assessment 1 total score and total rFIQ \( (r = 0.576) \), VAS pain \( (r = 0.443) \), VAS disease severity \( (r = 0.342) \) (all \( p < 0.01 \)). Our results indicated that 94.7% to 96% of our patients satisfying 1990 FMS criteria also satisfied 2010 modified diagnostic criteria.

CONCLUSIONS: The Turkish experimental version of FSDC is a reliable and valid instrument in Turkish FMS patients. It is easily completed, simple to score providing valuable instrument to diagnose and follow FMS.

Keywords: Fibromyalgia, validation of measures, Turkish, validity, reliability

1. Introduction

Fibromyalgia Syndrome (FMS) is a very common disorder which accounts for about 10% of all outpa-

tient visits in rheumatology, and have a prevalence rate of 2–4.7% around the globe [1–4]. Until 2010, diagnosis of FMS based on 1990 American College of Rheumatology (ACR) classification criteria which requires lengthy tender point examinations which would come up with different results by different physicians for the same patient, especially in the absence of training, and did not cover all somatic symptoms making diagnoses and follow-up of this common entity com-
In 2010, the ACR published different preliminary diagnostic criteria for FMS that in addition to chronic widespread pain, fatigue, unrefreshing sleep, cognition, and somatic symptoms were taken into consideration without the requirement to perform a tender point examination [7]. These criteria were later modified to a self-reported questionnaire format [Fibromyalgia Survey Diagnostic Criteria and Severity Scale (FSDC)] to allow their use in epidemiologic and survey studies [8]. Two components of the 2010 criteria, the widespread pain index (WPI/FSDC Section 3) and the symptom severity (SS/FSDC Sections 1+2) score, could be combined by addition into a index, “polysymptomatic distress” scale (PSD/FSDC total score) [9,10], so the key symptoms of FMS could be measured. FSDC is one page questionnaire, could easily filled by a patient, simple to score that makes to diagnose FMS with ease. FSDC with all these features has a potential not only to be used in research settings but also to be used in the clinical settings. In our study, we aimed to create Turkish version of this practical instrument, FSDC, to allow its use in our FMS patients and to show its reliability and the validity in Turkish patients with FMS.

2. Material and methods

2.1. Study procedure

We studied patients who were born and raised in Turkey and the main language is Turkish, or born and raised abroad but had Turkish ancestors. The patients presented to Outpatient Clinic with complaint of chronic widespread pain and were evaluated for the presence of FMS. FMS was diagnosed using American College of Rheumatology (ACR) 1990 classification criteria [5]. Manual Tender Point Survey was used for tender point examination [11]. At the time of the first assessment, demographic information including family origin, education, work, and the medical history were taken from the patients. Physical examinations were done in addition to Manual Tender Point examinations. Patients who reported serious internal and psychiatric disorders, who had uncontrolled thyroid problems were excluded from the study. We included patients who were having symptoms in spite of therapy for FMS. Patients were then asked to fill Turkish revised Fibromyalgia Impact Questionnaire (rFIQ), the nonvalidated Turkish FSDC form that we had created, marked a Visual Analog Scale for pain and the disease severity, and informed that they would ask help anytime. Some patients needed help to fill the forms, and all forms were checked by examiners to see if any information missing. Patients asked to fill Turkish nonvalidated FSDC for the second time, about 7 to 15 days later, when they come back to present their laboratory results which were ordered as a part of their diagnostic work-up for FMS. An ethical approval was obtained from the institutional review board of our institution and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

2.2. Assessment tools

The Turkish rFIQ was validated to Turkish language by Ediz et al. and has 21 individual questions as in the original rFIQ [12,13]. All questions are based on an 11-point numeric rating scale of 0 to 10, with 10 denoting the worst possible condition. The Turkish rFIQ is divided into three linked sets of sections as in the original rFIQ: (a) First section evaluate functional status and contains 9 questions, (b) second section is related to overall impact of disease on functioning and symptom severity and contains 2 questions, and (c) contains symptoms evaluation (contains 10 questions, with the same order in section, related to pain, energy level, stiffness level, sleep quality, depression level, memory problems, anxiety level, tenderness to touch, balance, and environmental sensitivity). The summed score for function (range 0 to 90) is divided by 3, the summed score for overall impact (range 0 to 20) is not changed, and the summed score for symptoms (range 0 to 100) is divided by 2. The total rFIQ Turkish version score is the sum of the three modified domain scores (0–100).

Patients’ global assessment of disease severity (0 being not a problem, 10 being severe problem) and pain severity (0 being no pain, 10 being very severe pain) for the last week were assessed by a 10 cm VAS.

Fibromyalgia Survey Diagnostic Criteria and Severity Scale has 3 sections. The first section contains 3 questions on symptoms of fatigue, cognitive problems, and unrefreshing sleep during the past week, each of which is scored by a Likert format from 0 (no problem) to 3 (severe: continuous, life-disturbing problems) [8,14]. The second section comprises 3 questions with a positive or negative response for the following somatic complaints occurring during the past 6 months; abdominal pain or cramps, depression, and headache, with a maximum score of 3. The sum of section 1 and 2 provides a Symptom Severity (SS) Score,
1. Aşağıdaki her bir şıkayetin **gecen haftaki** ciddiyet derecesini, aşağıda verilen ölçüge göre değerlendirerek uygun kutuyu işaretleyiniz.

0: sorun yok
1: az veya hassas derecede sorun; genellikle haif veya aralıklı
2: orta şiddet; dikkate değer sorun; siklikla mevcut ve/veya orta düzeyde
3: Şiddetli; sürekli, yaşamı etkileyecik derecede sorun

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- Karnın alt tarafında ağrı veya kramp □ Evet □ Hayır
- Depresyon □ Evet □ Hayır
- Baş ağrısı □ Evet □ Hayır

3. Lütfen, geçtiğiniz **son 7 günde** aşağıdaki listelenen bölgelerden her birinde ağrı veya hassasiyet yaşadığınız belirtin. Ağır veya hassasiyet yaşadıysanız lütfen kutuya bir X işaretini koyun. Hem sağ taraf, hem de sol taraf için ayrı ayrı işaretlediğinizden emin olun.

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4. Yukarda 1-3. sorularda listelenen şıkayetleriniz **en az 3 aydır** bulunamakta midir? □ Evet □ Hayır

Fig. 1. The Turkish version of Fibromyalgia survey diagnostic criteria and severity scale.

with a range from 0–12 [8,14]. The third section is a measurement of the Widespread Pain Index (WPI) and is completed by identifying body areas where pain or tenderness was felt during the previous 7 days, with a total of 19 body areas identified as follows: shoulder girdle (left and right), upper arm (left and right), lower arm (left and right), hip (left and right), upper leg (left and right), lower leg (left and right), jaw (left
and right), chest, abdomen, upper back, lower back, and neck. The maximum score for the WPI section is 19 [8,14]. The PSD is defined as the sum of the (0–19) WPI and the 6-item (0–12) SS scale ranged between 0–31 [9,10]. Patients who satisfy the 2010 criteria to diagnose FMS, defined by either 1) WPI at least 7/19 pain sites positive and SS score at least 5/12 (Type A), or 2) WPI between 3–6/19 and SS score 9/12 (Type B), will always have a score on the PSD scale of at least 12 [9,14].

2.3. Translation of the FSDC

With the permission of Frederick Wolfe, MD (National Data Bank for Rheumatic Diseases and University of Kansas School of Medicine, Wichita) by e-mail correspondence, the FSDC was translated into Turkish as follows. We obtained two initial forward translations of the instrument into Turkish by two bilingual individuals, one of them was a physician, whose mother tongue was Turkish. The two forward translations were then backtranslated into English by two different bilingual individuals, blinded to original English version. One of them was another physician whom mother tongue was Turkish. The second backtranslator’s mother tongue is English. All translators work for the a Sworn Translator Office. The original version of FSDC, the two Turkish forward translations, and English back translations were then reviewed by a committee composed of two bilingual study investigators whose mother tongues were Turkish, and the individuals involved in translations, and the last experimental Turkish version was created (Fig. 1). The last Turkish version of FSDC was tested on 5 bilingual physicians filling English and Turkish versions, and 10 hospital staff filling only Turkish version indicating if they found any instructions or items difficult or ambiguous.

2.4. Statistical analysis

IBM SPSS Statistics 22 (IBM SPSS, Turkey) was used for statistical analysis. Test-retest reliability of the FSDC was assessed with Pearson’s correlation coefficients. An analysis of internal consistency using Cronbach’s coefficient α was performed with measurement of α ≥ 0.7 considered as representing a good internal consistency [15]. To test construct validity, we hypothesized a relationship between the FSDC and other measures of pain and symptom severity in FMS including the rFIQ, V AS for pain, and V AS for the disease severity using Spearman’s rho correlation analys-

| Table 1 | Tender point and control point counts; revised fibromyalgia impact questionnaire total score; fibromyalgia survey diagnostic criteria and severity scale assessment 1 scores; and visual analog scores for the pain and the disease severity |
|---|---|---|---|---|
| Tender point counts (0–18) | 11–18 | 16.17 ± 2.04 |
| Control point counts (0–3) | 0–4 | 1.83 ± 1 |
| rFIQ total score (0–100) | 5.5–100 | 70.34 ± 19.18 |
| Pain, V AS (0–10) | 2.4–10 | 8.03 ± 1.76 |
| Disease severity, V AS (0–10) | 0–10 | 8 ± 2.1 |
| FSDC1 total (PSD: 0–31) | 9–31 | 22.61 ± 4.64 |
| FSDC1 Section 1 (SS: 0–12) | 3–12 | 9.26 ± 2.07 |
| FSDC1 Section 3 (WPI: 0–19) | 4–19 | 13.35 ± 3.53 |


sis. Strength of correlation was graded according to the recommendation of Cohen as follows: 1. Moderate correlation coefficient (0.30–0.49), 2. Strong correlation coefficient (0.50–1) [14], p < 0.05 was considered significant.

3. Results

3.1. Characteristics of the cases

We had 132 female patients with newly diagnosed FMS who aged between 23 and 67 years, with a mean age of 42.78 ± 8.58 year. Family origin of the cases were as follows: 5 (3.8%) from the Mediterranean region of Turkey, 34 (25.8%) from Eastern Anatolia region, 12 (9.1%) from South-eastern Anatolia region, 22 (16.7%) from Central Anatolia region, 38 (28.8%) from the Black Sea region, 19 (14.4%) from Marmara region, 2 (1.6%) from abroad (Turks live in Yugoslavia). Ninety-six of the cases (72.7%) were housewives, and 36 of them (27.3%) were working in a variety of jobs. Sixteen cases (12.1%) did not finish any training but able to read and write; 83 of the cases (62.9%) were primary or secondary school graduates, and 33 (25%) graduated from high school or higher.

Patients’ tender point counts were between 11 and 18, with a mean of 16.17 ± 2.04 (Table 1). rFIQ total score of the patients were between 5.5 and 100, with a mean of 70.34 ± 19.18. V AS for pain scores were between 2.4 and 10, with a mean of 8.03 ± 1.76. V AS for the disease severity scores ranged from 0 to 10, with a mean of 8 ± 2.1. The nonvalidated Turkish version of FSDC assessment 1 total scores (PSD scores) were between 9 and 31, with a mean of 22.61 ± 4.64. The non-
validated Turkish FSDC first assessment Sections 1 and 2 (SS) scores were between 3 and 12, with a mean of 9.26 ± 2.07; Section 3 (WPI) scores ranged from 4 to 19, with a mean of 13.35 ± 3.53.

All 132 cases had FMS according to 1990 FMS ACR classification criteria, whereas by the nonvalidated Turkish version of FSDC assessment 1 only 125/132 patients (94.7%), by the Turkish version of FSDC assessment 2 only 119/124 (96%) had FMS according to ACR 2010 diagnostic criteria.

3.2. Reliability analysis

Only 124 patients filled the Turkish nonvalidated version of FSDC for the second time. By the test to retest reliability analysis of Turkish FSDC, for the 25 single items, correlation coefficients ranged 0.383 to 0.818 indicating that the correlation is not from chance ($p < 0.01$) (Table 2). There were statistically significant correlations between Sections 1 and 2 (SS) scores ($r = 0.748$, $p < 0.01$), Section 3 (WPI) scores ($r = 0.775$, $p < 0.01$), and the total scores (PSD) ($r = 0.821$, $p < 0.01$). Internal consistency Cronbach’s alpha coefficients for the nonvalidated Turkish version of FSDC assessment 1 were 0.526 for SS, 0.777 for WPI and 0.766 for total score. For the FSDC assessment 2, it was found 0.535 for SS, 0.775 for WPI, 0.777 for total score.

3.3. Validity analysis

Tender point counts were correlated FSDC 1 ($r = 0.376$, $p < 0.01$), rFIQ ($r = 0.337$, $p < 0.01$), VAS pain (0.210, $p < 0.05$), and not correlated with VAS disease severity ($r = 0.073$, $p > 0.05$) (Table 3). There were significant correlations between the nonvalidated Turkish version of FSDC assessment 1 total (PSD) score and total rFIQ ($r = 0.576$), VAS pain ($r = 0.443$), VAS disease severity ($r = 0.342$) (Table 3) (all $p < 0.01$). rFIQ total score also correlated with VAS pain ($r = 0.482$) and VAS disease severity ($r = 0.436$) (all $p < 0.01$). Turkish unvalidated version of FSDC assessment 1 Section 1 item Fatigue was best correlated with rFIQ Section 3 Energy level ($r = 0.317$) and Sleep quality ($r = 0.428$) (all $p < 0.01$); Cognition was best correlated with rFIQ Section 3 Memory problems ($r = 0.598$, $p < 0.01$); Sleep disturbance was best correlated with rFIQ Section 3 Sleep quality ($r = 0.367$, $p < 0.01$); Depression was best correlated with rFIQ Section 3 Depression ($r = 0.652$, $p < 0.01$) (Table 4).

4. Discussion

In our study, we have studied female FMS patients with high average pain, the disease severity, rFIQ total,
and FSDC total (PSD) scores. In this group of patients, we have demonstrated that the Turkish version of the FSDC is a reliable instrument for FMS, with strong test-retest reliability correlation coefficients ranging from 0.748 to 0.821 for SS, WPI and PSD total scores. Internal consistency analysis was also showed a good internal consistency for Turkish version of FSDC with a Cronbach’s alpha 0.766–0.777 for the FSDC total scores.

We have also obtained construct validity of the Turkish version of FSDC by observing statistically significant moderate to strong correlations between SS, WPI, and PSD total scores of the Turkish version of FSDC and rFIQ total, VAS pain and VAS disease severity scores. Similarly, rFIQ total and its subscale scores correlated significantly with VAS pain and VAS disease severity scores with moderate correlations.

Although the specific questions regarding pain, fatigue, sleep disturbance, mood, and memory are nuanced differently in the rFIQ and FSDC, we have found that the rFIQ total score and individual measures of pain, fatigue, sleep, mood and memory in rFIQ Section 3 correlated well with the Turkish version FSDC individual items as well as total scores indicating construct validity of Turkish version of FSDC for the assessment of Turkish patients with FMS. We have further obtained moderate correlation between pain component of the FSDC (WPI) and VAS pain, although their construction is different.

The FSDC has also been validated in several languages [14,16,17]. In a French speaking fibromyalgia cohort, French version of FSDC had a test-retest reliability between 0.600 and 0.888 for the 25 single items of the FSDC, and 0.912 for the total FSDC [14]. Internal consistency measured by Cronbach’s alpha was also good (0.846 for FSDC assessment 1, and 0.867 for FSDC assessment 2). Construct validity of French version of FSDC was obtained with significant correlations between the FSDC and FIQ 0.670. Health Assessment Questionnaire 0.413, McGill Pain Questionnaire 0.562, global disease severity VAS 0.591, and pain VAS 0.663. They have concluded that French version of FSDC performed well in French patients with FMS.

In a study by Usui et al. seventy-seven of 94 (82%) Japanese FMS patients in the fibromyalgia group met the ACR 2010 preliminary diagnostic criteria for FMS, whereas 9% (4/43) of the non-fibromyalgia group did so, with a sensitivity of 82%, specificity of 91%, positive predictive value of 95%, negative predictive value of 70%, and positive likelihood ratio of 8.8 [16]. Mean total scores on the Fibromyalgia Symptom Scale (PSD) also significantly differentiated the fibromyalgia (18 ± 5.8) from the nonfibromyalgia group (4.9 ± 4.4). Internal consistency was high, with a Cronbach’s alpha of 0.846 and variances of 0.562, global disease severity VAS 0.591, and pain VAS 0.663. They have concluded that French version of FSDC performed well in French patients with FMS.
lidity (Total FSDC score was correlated well with VAS pain 0.493, VAS Health state 0.406, and FIQ total score 0.716). In addition, the Spanish FSDC proved to be useful in differentiating FMS severity subgroups.

In our study, we also found high concordance between ACR 1990 Classification criteria and ACR 2010 modified Diagnostic criteria by Turkish version of FSDC assessments as in Carrillo-de-la-Penã et al. study. In the study by Wolfe et al. the ACR 2010 criteria correctly classified 88.1% of cases that met the 1990 criteria [7]. In a recent editorial by Frederich Wolfe [6], he stated that primary studies were always optimized for best agreement, so that in practice, 80% agreement between two criteria might be reasonable, and the ACR 2010 and modified 2010 criteria drew strong support from clinical studies and were useful in clinical practice and research.

5. Conclusion

In conclusion, we have shown that the Turkish version of FSDC is a reliable and valid instrument in Turkish FMS patients. This scale is a beneficial tool to diagnose FMS with ease as we found important majority of our patients who were diagnosed by 1990 criteria also satisfied 2010 modified ACR diagnostic criteria, and has the potential to become the standard for measurement of symptom severity in FMS and other chronic pain conditions in both clinical as well as study settings.

Conflict of interest

The authors have no conflict of interest to declare.

References
