RESEARCH ARTICLE

Translation, Cross-Cultural Adaptation and Psychometric Properties of the Persian Version of Patient-Specific Functional Scale in Patients with Chronic Low Back Pain

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Abstract

Objectives: The major emphasis of physical therapy in patient evaluation is the assessment of physical function, and the Patient-Specific Functional Scale (PSFS) is one of the most commonly used instruments for this purpose. Therefore, the present study aims to translate and cross-culturally adapt the PSFS into Persian and test its psychometric properties in patients with chronic low back pain (CLBP).

Methods: The PSFS was translated from English to Persian and cross-culturally adapted in accordance with the study by Beaton et al. Psychometric properties of 100 CLBP patients were assessed. Reliability (internal consistency and test-retest) was examined for 32 participants who completed the Persian version of the PSFS (PSFS-P) twice with one week interval. Construct validity was assessed against the Persian versions of the Oswestry Disability Index (ODI-P) and the Numerical Pain Rating Scale (NPRS-P).

Results: The PSFS-P showed excellent reliability (Cronbach's alpha=0.88, intraclass correlation coefficient [ICC $_{3,1}$] =0.95, 95% CI [0.87 to 0.98]). The construct validity analysis revealed a moderate negative correlation between PSFS-P and NPRS-P (r=-0.47) and a high negative correlation between PSFS-P and ODI-P (r=-0.61). The PSFS-P showed no floor and ceiling effects.

Conclusion: The PSFS-P has adequate psychometric properties and is applicable in both clinical settings and research involving the Iranian population with CLBP.

Level of evidence: IV

Keywords: Low back pain, Patient reported outcome measures, Psychometrics

Introduction

Measuring physical function is among the most important components in evaluating patients with low back pain (LBP) in clinical and research settings.[1,2] Self-report instruments, including generic, disease-specific, region-specific, domain-specific, and patient-specific instruments are commonly used to measure the activity component.[3,4]

Patient-specific outcome measures have advantages compared to other measures of physical function or disability. They are short and easy to administer, use patient-generated items, and can be completed verbally and used in various clinical conditions and body regions.[2] One of the most commonly used patient-specific instruments is the Patient-Specific Functional Scale (PSFS), developed by Stratford et al.[5-7] In addition to its robust measurement properties,[7,8] the PSFS has been cross-culturally adapted for several languages and cultures.[2,3,9-14]

Considering the high prevalence of back pain in

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musculoskeletal disorders, the PSFS questionnaire has been often used to evaluate various types of back pain.[2,3,5,9,1516] Although a number of instruments for measuring the physical function of LBP patients have been cross-culturally adapted to Persian, such as the Roland-Morris Disability Questionnaire (RMDQ) and the Oswestry Disability Index (ODI), the PSFS has yet to be translated into Persian.[17] Questionnaires, such as the RMDQ and ODI, consist of several items, resulting in extended completion and scoring times, making them less practical in clinical settings.[3] Therefore, using PSFS instead of or in addition to other self-report instruments in clinical settings have been recommended.[5,11]

To date, there is no cross-culturally adapted and tested version of the PSFS in Persian. By adapting the PSFS to Persian, this possibility is given to Persian-speaking patients to capture activity limitations that are unique and specific to their culture, experience, and lifestyle. Consequently, the present study aimed to translate and cross-culturally adapt the PSFS into Persian and examine its psychometric properties in patients with chronic LBP (CLBP). We hypothesized that Persian PSFS would exhibit evidence substantiating its reliability, including good to excellent test-retest reliability and acceptable measurement error. Additionally, it was expected to show construct validity and avoid any floor or ceiling issues.

Materials and Methods

The present research was executed in two phases. Stage 1 entailed the translation and cross-cultural adaptation of PSFS into Persian, using recommended guidelines.[18] Stage 2 included testing the psychometric properties of the Persian version of PSFS (PSFS-P) in 100 patients with CLBP. We tested the following psychometric properties: ceiling and floor effects, internal consistency, test-retest reliability, standard error of measurement (SEM), minimal detectable change (MDC), and construct validity.

Participants

A total of 100 Persian-speaking patients aged 18-80 years were enrolled. They were diagnosed with CLBP by specialist doctors from different Orthopedic Clinics in Tehran, Iran, from February to July 2022. The patients had experienced CLBP for at least three months. Patients with serious spinal pathologies (e.g., tumors, fractures, infections, and radiculopathy), previous spinal or abdominal surgery, recent history of trauma, spinal deformity, and current pregnancy were excluded.

Measures

Sociodemographic characteristics, PSFS-P, and Persian versions of the Numeric Pain Rating Scale (NPRS-P) and the ODI (ODI-P) were evaluated at baseline. PSFS-P, NPRS-P, and ODI-P were repeated again at a one-week follow-up, along with the Persian version of the 7-item Global Rate of Change (GROC-P). A brief description of each questionnaire is provided below.

The PSFS-P was used to measure physical function. In PSFS, patients are asked to select and prioritize up to three important activities that they are having difficulty with or cannot accomplish owing to their condition (e.g., CLBP). Furthermore, patients are requested to assess their present level of difficulty on an 11-point scale, from 0 (unable to perform activity) to 10 (able to perform activity at the pre-injury level). The PSFS total score ranges from 0 to 30, with increased scores signifying enhanced functional capability.[5] the administration and recording of the PSFS can often be completed within a time frame of around four minutes.[19]

The ODI-P was used to measure the degree of disability linked to LBP. It comprises 10 sections of questions that evaluate the activities of daily living (ADL) and pain. Each section contains six statements, rated from 0 (the lowest level of difficulty) to 5 (the highest level of difficulty). The total score is obtained by summing the results from all parts, yielding a maximum of 50 points, which is then multiplied by two to get the percentage of disability. A higher percentage signifies a greater disability as reported by the patient.[17,19]

Pain intensity was also measured with NPRS-P, ranging from 0 (no pain) to 10 (the most severe pain imaginable). Individuals with CLBP were requested to assess their pain intensity on an 11-point scale.[19]

In addition the GROC-P was used to measure the changes in the symptoms of LBP participants in the second measurement. The GROC is a 7-point scale that extends from +3 (completely recovered) through 0 (no change) and down to -3 (vastly worse). Patients were asked, "How would you describe your situation today compared to the first assessment session?" A high score in a positive direction indicates improvement, a low score in a negative direction indicates a worsening situation, and zero indicates no change.[20]

Translation and Cross-Cultural Adaptation

The translation of the PSFS into Persian followed the guidelines established by Beaton et al. for the process of cross-cultural adaptation of self-report measures.[18]

Initial translation: Two independent translators, whose native language is Persian, translated the original PSFS items from English into Persian.

Synthesis of the translation: The two translators evaluated their translations against one another, and after a reconciliation meeting, a singular translation was derived from the first two translations.

Back translation: The version was subsequently back-translated into English by two distinct translators who were unaware of the original version.

Expert committee: To ensure concept equality, two back translators compared the backward translation.

Pre-final version: A pre-final version test of the PSFS-P was conducted with 10 patients suffering from CLBP to evaluate the instrument's clarity and interpretability.

Approval: The back translation was sent to the PSFS developer, Professor Paul Stratford, and received approval.[18]

Data Collection

The CLBP patients completed ODI-P, PSFS-P, and NPRS-P at baseline. To minimize potential bias, PSFS-P was completed first to ensure that the activity items mentioned in ODI-P did not influence the patients' selection of activities for PSFS-P. After one week, participants were asked to answer a question about the change in symptoms during the past week (GROC). Patients who had no change in their symptoms

answered the questionnaires for the second time (32 participants).

Measurement Properties and Statistical Analysis

Data analysis was conducted using SPSS version 20 (IBM Corp., Armonk, NY, USA), and graphs were depicted using GraphPad Prism Version 8.0.1 (GraphPad Prism Software Inc., San Diego, CA, USA). A P-value < 0.05 was considered statistically significant.

Reliability

The internal consistency of the PSFS-P was assessed by Cronbach's alpha, average inter-item correlation, and corrected item-total correlation. A Cronbach's alpha value of 0.7 or greater was considered satisfactory.[21] the corrected item-total correlation refers to the correlation between each item and the total scale score, calculated using the remaining items. Values below 0.3 signify that a particular item exhibits a weak correlation with other items.[22]

The one-week test-retest reliability was evaluated using a 2-way mixed-effects model and a single measurement intraclass correlation coefficient 3, 1 ($ICC_{3,1}$), line of equality, and Bland-Altman plot.[23] For a line of equality, if the measurements agree closely, the scatter plot points will line up near the 45° line through the origin. Values for ICC were classified as poor, moderate, good, and excellent reliability, respectively, at <0.5, 0.5-0.75, 0.75-0.9, and >0.9.[24]

The time interval between the two test administrations impacts the test-retest reliability. While a longer period increases the chance of a change in status occurring, a shorter interval enhances the possibility of carryover effects brought on by memory, practice, or mood.[25]A one-week time period appears to be appropriate for minimizing the carryover effects. Furthermore, given the chronic nature of the symptoms, significant changes within a week are not expected. Based on this matter and prior research of a similar nature, a one-week gap between two assessment sessions was selected.[2,11-13]

SEM was calculated using the equation $\boldsymbol{SEM = SD_{Baseline} \times \sqrt{1 - ICC}}$.[26] the equation $\boldsymbol{MDC_{95} = 1.96 \times SEM \times \sqrt{2}}$ was employed to compute MDC, which established the authenticity of a patient's change score at a 95% confidence interval.[27]

Validity

Construct validity pertains to the degree to which scores from a specific instrument correlate with other measures.[26,28,29] Therefore, construct validity was evaluated by comparing PSFS-P scores with ODI-P and NPRS-P scores at baseline.[26] We hypothesized a moderately significant negative correlation. Construct validity was calculated by Pearson correlation coefficients. Correlation values were determined to be low for $r < 0.30$, moderate for $0.30 \leq r < 0.60$, and high for $r \geq 0.60$.[28]

Floor or Ceiling Effects

Floor or ceiling effects are deemed present if over 15% of respondents attain the minimum (floor) or maximum (ceiling) attainable score.[26,28] These values were determined by calculating the percentage of patients who achieved the lowest (score of 0) or highest (score of 10) mean scores for three activities, respectively.[28]

Estimation of sample size

The sample size was established according to the recommendations of the consensus-based standards for the selection of health measurement instruments (COSMIN).[26,30] The COSMIN advises that a minimum of 50 patients is required to adequately assess construct validity. Additionally, the COSMIN criteria determined that a minimum sample size of 30 (fair rating) is necessary to assess the test-retest reliability and measurement error.[31]

Ethical statements

Written informed permission was completed by each patient, and ethical approval was secured from the Ethics Committee of Iran University of Medical Sciences (IR.IUMS.REC.1402.037).

Results

Translation and Cross-Cultural Adaptation

The translation and cross-cultural adaptation of PSFS into Persian were successfully completed. After reaching the pre-final version, during the reconciliation meeting, two words were replaced with a better equivalent to make it easier and more understandable. During the pilot study, 10 patients with CLBP were enlisted to evaluate the pre-final version of the PSFS-P. The Cronbach's alpha of the pilot study data was 0.89, which indicates good homogeneity of the items.

Participants

A total of 105 eligible patients were enrolled in this study, of whom five did not answer the questions completely. Therefore, the final analysis included 100 patients. The number of female and male participants was almost equal (51 vs. 49), and 68% of them were married. Table 1 shows the patients' demographic and baseline characteristics [Table 1].

Reliability

Table 1 presents the means, SDs, and internal consistency for the PSFS-P. The item means ranged from 5.10 (for item 3) to 5.34 (for item 2). The mean PSFS-P total score was 5.28 ± 2.24 (range, 0 to 8.70) [Table 1].

The Cronbach's alpha and the average inter-item correlation were 0.878 and 0.706, respectively. The corrected item-total correlations ranged from 0.748 to 0.774, above the minimum threshold of 0.3. The Cronbach's alpha value did not increase if an item was deleted from the scale.

Test-retest data were collected from 32 patients over a one-week interval. The ICC was 0.952 (95% CI [0.871 to 0.980]). The SEM and MDC for the PSFS-P were 0.53 (95% CI) and 1.47, respectively. In addition, the agreement between the test and retest measures of the total PSFS scores was examined via visual inspection of the Bland-Altman plot and line of equality. As presented in [Figure 1a], the scatter plot shows that the data points fell on or near the line of equality. The Bland-Altman plot [Figure 1b] indicates that all points, with the exception of one, fall within the established lower and higher bounds of agreement. Furthermore, no significant

trend or bias was seen in the distribution of data.

Construct Validity

A moderate and negative correlation was determined between the PSFS-P and NPRS-P at baseline (r=-0.470, P<0.001). Moreover, PSFS-P and ODI-P were strongly correlated (r=-0.606, P<0.001) [Table 2].

Floor and Ceiling Effects

In PSFS-P, only 1 (1%) participant reached the minimum score, while none reached the maximum score. Therefore, PSFS-P did not exhibit floor and ceiling effects.

Table 1. Characteristics of participants (n=100)

Variable	
Age (years)	42.70(14.99)
Gender	
Female (%)	51(51)
Male (%)	49(49)
BMI (kg/m^2)	25.9(3.89)
Education	
Middle school	23(23.0)
Diploma	35(35.0)
Bachelor's	28(28.0)
Master's	12(12.0)
Doctor	2(2.0)
Pain duration (months)	28.29(43.55)
NPRS-P (0–10)	5.28(2.18)
ODI-P (0-100)	33.56(19.56)
GROC (-3 to +3)	3.31(0.78)
PSFS (0-10)	5.28(2.23)

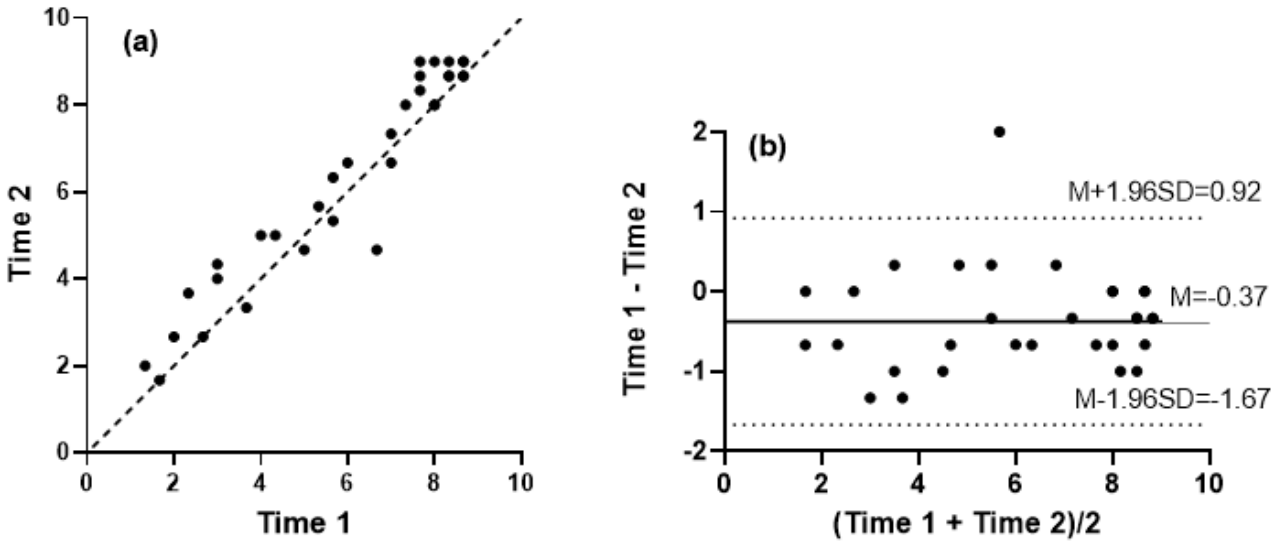

Figure 1. (a) Scatter plot of PSFS score at Time 2 versus Time 1; (b) Bland and Altman plot for assessing agreement between Time 1 and Time 2 on PSFS scores

Table 2. Descriptive statistics and internal consistency reliability of the PSFS among 32 participants

	Inter-item correlation			Corrected item-total correlation	Alpha if item deleted	Cronbach' alpha	Average inter-item correlation
	Q1	Q2	Q3				
Q1	1	---	---	0.748	0.842	0.878	0.706
Q2	0.694	1	---	0.772	0.821	---	---
Q3	0.697	0.728	1	0.774	0.819	---	---
Mean	5.30	5.34	5.10	---	---	---	---
SD	2.42	2.49	2.48	---	---	---	---

SD: Standard Deviation

Discussion

The present study aimed to translate and cross-culturally adapt the PSFS from English into Persian and to test its psychometric properties in CLBP patients. Overall, the results indicated that the PSFS-P performs well with good psychometric properties and correlates with both ODI-P and NPRS-P, confirming its reliability and validity as a measure for evaluating CLBP patients.

Ceiling and floor effects were not present in PSFS-P, showing that this measure is suitable for CLBP patients. Ceiling and floor effects of a questionnaire can affect responsiveness, as patients with the highest or lowest possible scores remain undetectable.[12,26] Therefore, the lack of floor and ceiling effects in the present study indicates the responsiveness of PSFS-P.[31] The current research did not assess the responsiveness of the PSFS-P, as it was not an intervention trial. Therefore, a more detailed evaluation of its responsiveness is essential. In some studies, the possibility of a floor effect has been mentioned as a potential problem with PSFS.[10,32] Since in PSFS, patients are asked to identify activities that they are not able to do or that they do with difficulty, low average scores are expected. If such a possibility is assumed to be true, the sensitivity and responsiveness of the instrument will be reduced. However, recently, a systematic review indicated that the PSFS demonstrates sufficient responsiveness (moderate-to-high certainty) in numerous musculoskeletal conditions.[7]

The PSFS-P demonstrated extremely high reliability with an ICC value of 0.952. The results of the test-retest reliability showed that patients with CLBP and stable conditions will have similar scores when they take the test more than once over time. The reliability estimate of the PSFS-P reported in the present study is consistent with previous reports in the PSFS reliability literature. Nazari et al. showed in a systematic review that the test-retest reliability of the PSFS in patients with low-back pathology ranged from 0.59-0.97.[8] Only one of five studies reported a lower ICC (0.59 for patients with lumbar spinal stenosis),[33] and one reported a higher ICC (0.97 for mechanical back pain).[5] Additionally, in translated versions, ICC values have been reported between 0.79 and 0.98 for test-retest reliability, of which the highest ICC belongs to the Japanese version (0.98 for patients with neck pain) [2,3,9-14]. Three types of studies have shown high reliability. First, studies in which patients were informed of their initial test scores during the retest.[5, 11] Second, studies that involved participants with chronic pain.[15,34] Third, studies that had a short time interval between the two evaluation sessions.[3] The high reliability observed in the present study is likely attributed to the chronic pain experienced by the participants. In cases of chronic pain, there is typically not much-expected change in the nature of activities or the severity of symptoms in a week.

In the current study, SEM and MDC were used to calculate the PSFS-P measurement error. The SEM value discovered in this study (0.53) is in line with those reported for the PSFS in patients with LBP (ranging between 0.41 and 1.03 PSFS points on a scale of 0-10).[8] Furthermore, the MDC value of PSFS-P was 1.47, indicating that a shift in the PSFS-P score of more than 1.47 points can be regarded as beyond measurement error or chance variation. The MDC for PSFS-P found in this study is within the range of values reported in the literature for other PSFS languages (range, 0.64 to 1.49), supporting the findings of this investigation.[2,11,12,14] Furthermore, in patients with low back pathology, PSFS had an MDC value ranging from 1.46 to 2.4 points.[2,32]

The construct validity of the PSFS-P as a measure of activity limitation was confirmed by significant correlations between PSFS-P, ODI-P, and NPRS-P. There is a strong correlation between PSFS-P and ODI-P compared to a moderate correlation between PSFS-P and NPRS-P. Although it seems that higher pain intensity correlates with higher level of activity limitation, it should be noted that these two concepts are different and not necessarily directly related to each other. Therefore, as expected, the relationship between PSFS-P and ODI-P was stronger than the relationship between PSFS-P and NPRS-P. These findings are consistent with the pattern of correlation observed in previous studies. In patients with LBP, the relationship between PSFS and patient-reported outcome measures (PROMs) that measure activity limitation (such as RMDQ,[3,5,9] ODI,[2,4] Functional Rating Index [FRI],[3] and GROC[33]) is usually stronger than the relationship between PSFS and pain (such as NPRS[2, 3] and Visual Analog Scale [VAS][9]). Since PSFS and other PROMs quantifying activity limitation measure the same construct, this stronger relationship is predictable, while measures of pain do not directly assess the construct of physical function.

One of the appealing aspects of the PSFS is that patients can indicate activities that are very important to them, especially in other cultures, compared to the culture in which the questionnaire was established. Due to differences in culture

and lifestyle, these activities might not be included in questionnaires with fixed items. Given the fact that many PROMs for evaluating activity limits have been established in Western cultures and do not accurately represent Eastern lifestyles, this issue is particularly crucial in Eastern cultures. The PSFS is also shorter and simpler to learn, may be administered verbally, and can be used in a range of conditions compared to existing instruments. Therefore, PSFS-P seems to be a suitable tool for use in routine clinical practice and research purposes.

This study has some limitations that should be noted. First, PSFS can be used in a wide range of musculoskeletal diseases, while in this study, the psychometric properties of the Persian version in CLBP patients were examined. To generalize the results, the psychometric properties of the PSFS-P should be evaluated in other musculoskeletal diseases as well. Second, the current study did not examine the sensitivity of the PSFS-P to changes in the clinical setting; thus, conclusions about predictive validity or responsiveness could not be drawn. Such an issue could be the next step in research on the PSFS-P.

Conclusion

Based on the findings of the present research, PSFS-P is a reliable and valid instrument for assessing physical function in patients with CLBP. Although the responsiveness of PSFS-P has not been investigated, the obtained results justify using PSFS-P in clinical trials for CLBP patients.

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Authors Contribution:

Afshin Aghazadeh devised the study, conducted data collection, and authored the initial manuscript.

Soheil Mansour Sohani designed and supervised the study, in addition to reviewing and editing the manuscript.

Reza Salehi conceptualized and critically reviewed the manuscript.

Mohamad Parnianpour designed and supervised the study, in addition to reviewing and editing the manuscript.

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Declaration of Informed Consent: That there is no information (names, initials, hospital identification numbers, or photographs) in the submitted manuscript that can be used to identify patients.

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