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# Translation, cross-cultural adaptation and validation of the Persian version of selected PROMIS measures for use in lumbar canal stenosis patients

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## Abstract:

**BACKGROUND:** The National Institutes of Health (NIH) developed a new measurement system called the Patient-Reported Outcomes Measurement Information System (PROMIS) which can be used for multiple health conditions. The 29-item short form (PROMIS-29) with seven domains was more often used by clinical researchers to measure the physical function, mood and sleeping status of patients with low back pain (LBP). Translation of the PROMIS into multiple languages and adaptation of its application in different cultural diversities can help to further standardize clinical research studies and make them comparable to each other. This study aimed to cross-culturally adapt the PROMIS-29 into Persian (P-PROMIS-29) and evaluate the construct validity and reliability of the translated questionnaire among patients with lumbar canal stenosis.

**MATERIALS AND METHODS:** The translation was conducted by using the multilingual translation methodology guideline. Construct validity, internal consistency, and test–retest reliability at a two-week interval for the P-PROMIS-29 were calculated. Construct validity was assessed by calculating correlations between the P-PROMIS-29 with Oswestry Disability Index (ODI) and Roland–Morris results.

**RESULTS:** The study sample included 70 participants with lumbar canal stenosis. Internal consistencies were moderate to good with Cronbach's alpha ranging from 0.2 to 0.94. The test–retest reliability evaluation was excellent with intraclass correlation coefficients (ICCs) ranging from 0.885 to 0.986. Construct validity of different domains of P-PROMIS-29 were moderate to good, with Pearson's correlation coefficient results ranging from 0.223 to 0.749.

**CONCLUSION:** Our results showed that P-PROMIS-29 is a valid and reliable measurement tool for evaluation of patients with lumbar canal stenosis.

## Keywords:

Cross cultural adaptation, lumbar canal stenosis, PROMIS, reliability, validation

## Introduction

To collect patient reports on their functioning and well-being in a standardized manner in daily clinical practice and to encourage physicians to use patient reports along with other information sources such as imaging and lab data in the

clinical decision-making circumstances, the wider use of patient-reported outcomes (PROs) has been emphasized by many health institutes.<sup>[1]</sup> This issue has been further supported by research studies that have shown that implementation of PROs in routine practice not only improves patient–doctor communication but also

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leads to enhancement of the patient's clinical and health outcomes.<sup>[1-3]</sup> However, low rate of responsiveness, incomprehensibility, being too long and time consuming, large measurement errors and inaccuracy (particularly in patients with severe disability or those who are extremely functional, which leads to floor and ceiling effects, respectively) are some of the challenges of common current PROs.<sup>[4,5]</sup> Furthermore, the scores achieved from each of the PROs are often not easy to interpret and incomparable with other ones, which limits the possibility of comparison between different health systems and care providers<sup>[6]</sup>

In order to deal with these challenges, the National Institutes of Health (NIH) developed a new measurement system, the Patient-Reported Outcomes Measurement Information System (PROMIS) which can be used for multiple health conditions.<sup>[7,8]</sup> This standardized scale was developed based on adapting major health domains into several item banks to target physical, mental and social health of the respondents. Although the primary aim of the NIH task force was to administer PROMIS in a tailored manner and its application as computerized adaptive tests (CATs), some fixed or short forms of PROMIS were developed as well.<sup>[9,10]</sup> It has been shown that the short forms have greater measurement errors compared to CATs.<sup>[11]</sup> However, the feasibility of the use of these fixed forms (which have acceptable correlation with standard computer forms) in areas with no access to internet and computers make them further valuable in research and clinical studies.

Along with many other conditions, NIH recommended the use of short or computer form of PROMIS for measurement of baseline and follow-up characteristics of patients with low back pain (LBP).<sup>[12]</sup> In this regard, the 29-item short form (PROMIS-29) with seven domains was more often used by clinical researchers to measure the physical function, mood and sleeping status of patients with LBP. In 2009, Deyo *et al.*<sup>[12]</sup> suggested a new scale called "Impact score". This was calculated by incorporating pain intensity into nine items from PROMIS-29 (physical function and pain interference constructs); it showed higher correlation with clinical outcome of patients with chronic LBP and other musculoskeletal conditions<sup>[13]</sup>

The PROMIS-29 and its subdomains and modifications such as impact score have been validated to a host of legacy measures in different populations such as Roland-Morris Disability Questionnaire,<sup>[14]</sup> Oswestry Disability Questionnaire (ODI),<sup>[15]</sup> the EuroQol five-dimensions (EQ-5D) instrument,<sup>[16]</sup> Brief Pain Inventory<sup>[17]</sup> and quality-adjusted life year (QALY) scales.<sup>[18]</sup> Translation of the PROMIS into multiple languages and adaptation of its application in different

cultural diversities, can help to further standardize clinical research studies and make them comparable to each other. The aim of the present study was to evaluate the validity of a cross-culturally adapted Persian version of PROMIS-29 measures (physical function, pain intensity, pain interference, fatigue, anxiety, sleep disturbance and depression domains) among patients with lumbar canal stenosis. This would provide a platform for accurate assessment of health-related quality of life impairments among patients with lumbar canal stenosis. In this study, the validity of the Persian version of PROMIS questionnaire was tested through a previously validated Persian version of ODI and Roland-Morris questionnaires.<sup>[19]</sup> Also, to measure the reliability of the questionnaire, a test-retest technique was used.

## Materials and Methods

### Study design and setting

In the translation process of the PROMIS-29 questionnaire, the multilingual translation methodology was used.<sup>[6,20,21]</sup> According to this protocol, the following forward and backward translations, assessment of translation quality, and pilot testing were done:

- a- Two parallel forward translations were carried out from English to Persian. The translators were native Persian speakers with high academic studies in English literature who were not familiar with the questionnaire and the purpose of the study.
- b- The translation team set a meeting with the principal investigators and evaluated the translations, reconciled the two forward translations, and generated a merged Persian version.
- c- Back-translation was done by a bilingual English-Persian speaker. He didn't have access to the original PROMIS-29 version.
- d- The translation manager compared the back-translated English version and the original version and highlighted the discrepancies between the texts. For each of the differences, the two forward translations and the hybrid version were examined to assess whether the problem was related to the forward or the backward translations.
- e- Three independent native Persian-speaking experts (a linguist, an expert in the development of questionnaires, and one expert in PROMIS) evaluated all of the preceding steps and suggested recommendations.
- f- The final Persian version of the PROMIS-29 (P-PROMIS-29) was developed and it was confirmed by all the research team members.

### Study participants and sampling

A cross-sectional study was carried out on 70 Persian language patients with lumbar canal stenosis who were recruited consecutively from the spine outpatient clinic

at our university hospital. The inclusion and exclusion criteria of the subjects were as follows: Those of an age between 18 and 75 who were able to read and speak Persian and had LBP (defined as having pain in the region between the lower posterior margin of the rib cage and the horizontal gluteal fold<sup>[22]</sup>) due to lumbar spinal stenosis were included. The diagnosis of lumbar spinal stenosis was made based on spinal magnetic resonance imaging (MRI), which was interpreted by two spine surgery specialists. Patients having serious medical conditions or complications that might interfere with the participant's ability to respond to the study questionnaires or those with history of debilitating disease like chronic rheumatic diseases (e.g., rheumatoid arthritis, osteoarthritis, lupus), chronic kidney or liver disease, history of psychiatric illness and malignancy were excluded.

### Data collection tool and technique

At the clinic, demographic information as well as clinical data were obtained by an attending spine surgeon, according to the previously designed checklists. In this regard, a comprehensive history was taken and physical examination was carried out on all participants.

The psychometric properties of PROMIS-29 were evaluated in different methods. Firstly, floor and ceiling effects (individuals who had lowest and highest scale scores) were assessed. To test the homogeneity of the questionnaire, internal consistency of the P-PROMIS was assessed through the use of Cronbach's alpha coefficient. In this regard, the minimum acceptable value for Cronbach's alpha was considered as 0.70. To measure the questionnaire reproducibility, the test-retest reliability of the questionnaire was measured. To do this, two weeks after the first measurements, 55 of the subjects were invited to our center and were asked to fill the same P-PROMIS questionnaire. Test-retest reliability was measured using intraclass correlation coefficient (ICC, one-way random-effects model), and values more than 0.8 were considered as excellent. To measure the construct validity of the questionnaire, at the first meeting, all of the participants fulfilled the previously validated Persian version of the ODI<sup>[19]</sup> and Roland-Morris questionnaire.<sup>[19]</sup> The results achieved from these tests were compared with the results of P-PROMIS using Pearson's correlation coefficient.

Pain impact score (PIS) was defined and validated previously by the NIH research task force committee on LBP.<sup>[13,22]</sup> PIS in PROMIS-29 was calculated by the sum of pain interference (PI-1), pain intensity (PI-2), and physical function (PF) scores. The higher scores of PIS are related to more severe pain and physical dysfunction and shows higher correlation with clinical outcome of patients with chronic LBP and other musculoskeletal

conditions. Therefore, in addition to seven domains of the PROMIS-29 questionnaire, the PIS was calculated for participants of the study. Data of P-PROMIS for all participants were uploaded to the Health Measures Scoring Service software,<sup>[23]</sup> and the T-score for each domain was calculated (except pain intensity domain, which has only one question in the original PROMIS-29 and thereby, calculation of T-score for this domain is not possible). For further analysis of data, the Statistical Package for the Social Science (SPSS) version 27 was used. For quantitative variables, the descriptive analysis was carried out using mean, standard deviation (SD), range, and variance. The questionnaire's internal consistency was evaluated by measuring Cronbach's alpha coefficient for each dimension.

### Ethical consideration

Informed consent which was approved by the Ethics Committee of our institution was obtained from all participants.

## Results

### Participants

A total of 70 individuals with lumbar canal stenosis participated in the survey. The mean  $\pm$  SD age of the participants was  $49.9 \pm 16.13$  (range: 18–75). Sociodemographic data of participants in this study are shown in Table 1.

### Distribution of scores

The scores of subjects after filling the P-PROMIS-29, ODI, and Roland-Morris questionnaires at the baseline are shown in Table 2. The higher scores in each questionnaire

**Table 1: Demographic information**

	n (%)
Age (years)	
<40	18 (25.71)
40-49	12 (17.14)
50-59	20 (28.57)
60-69	13 (18.57)
>69	7 (10)
Sex	
Male	36 (51.43)
Female	34 (48.57)
Education	
Under diploma	24 (34.28)
High school diploma	26 (37.14)
BS/master	18 (25.71)
Doctorate level	2 (2.86)
Symptom Duration (years)	
<1	14 (20)
1-5	28 (40)
6-10	18 (25.71)
>10	10 (14.29)

indicates less wellbeing and poorer health condition. As it is shown in Table 2, in addition to seven domains of PROMIS-29 questionnaire, the PIS was calculated for participants of the study.

The distributions of scores [Table 2] demonstrate floor and ceiling effects for variety of PROMIS-29 scales, especially Depression (30% of individuals had the maximal score) and Pain interference (8.57% with the minimal score).

### Psychometric validation and reliability of P-PROMIS-29

Construct validity of P-PROMIS was measured by analyzing the correlation between the different PROMIS-29 domains and ODI and Roland–Morris questionnaires. The results of Pearson’s correlation analysis between different domains of the P-PROMIS and previously validated Persian version of ODI and Roland–Morris are shown in Table 3. There was a significant and acceptable correlation between all PROMIS-29 domains and PIS with ODI and Roland Morris questionnaires [Table 3]. To measure the homogeneity of the questionnaire, Cronbach’s alpha was calculated for different P-PROMIS domains and showed an acceptable internal consistency in each P-PROMIS domains [Table 4].

Out of all the participants, 55 were invited to our center and asked to re-fill the questionnaire to check the reliability of their responses. As shown in Table 5, using ICC, an excellent test–retest reliability between the first and second responses of those 55 participants was found.

## Discussion

The results of the present study showed that the Persian version of PROMIS-29 (P-PROMIS-29) was a valid and reliable measurement tool for use among patients with lumbar canal stenosis in both clinical and

research settings. Our findings showed that T-scores achieved from most of the domains of P-PROMIS-29 were in parallel to that of US adults with chronic musculoskeletal pain<sup>[8,13]</sup> and Thai patients with chronic LBP,<sup>[24]</sup> although there are some insignificant differences between the domains. For instance, our sample showed a lower mean score of physical function and a greater mean score of anxiety than those of the Thai and US studies (38.6 and 61.07 versus 43.6 and 57 versus 50 and 48.5, respectively).<sup>[8,24]</sup> This dissimilarity could be due to differences in age (49.9 vs 46.2 vs 50, respectively), gender distribution (48.57% vs 71% vs 52 female subjects, respectively) as well as severity and durations of the symptoms of the participants in different studies. As mentioned previously by Rawang *et al.*,<sup>[24]</sup> these differences in demographic and clinical baseline variables might influence the T-score of different domains of P-PROMIS-29. Older patients with severe symptoms might be more likely to have floor effects for physical function and less likely to have ceiling effects for participation in social activity domains.

To measure the floor and ceiling effects, the number of patients receiving the lowest and highest possible scores for each domain were counted, respectively. The floor and ceiling effects are less evident with PROMIS domains compared to Roland–Morris and ODI. A possible reason for this is that PROMIS uses fewer questions with greater accuracy to update longer form legacy instruments. The PROMIS researchers developed a procedure that PROMIS item banks are optimized and upgraded over time.<sup>[25,26]</sup> In general, the results regarding ceiling and floor effects for the P-PROMIS-29 are similar to those of the original English PROMIS-29 scales in adults with chronic musculoskeletal pain. The results showed that the ceiling effect of the translated P-PROMIS-29 in depression and anxiety domains are 30% and 15.7%, respectively. These findings are consistent with the

**Table 2: The PROMIS domains, ODI, and Roland-Morris questionnaire in lumbar stenosis patients (n=70)**

Parameter	Mean	Range	Ceiling effect (%)	Floor effect (%)
PROMIS-29 (T-scores)				
Physical function	38.67 (6.92)	22.6-70	4.28	1.43
Anxiety	61.07 (11.59)	40.3-81.4	5.71	15.71
Depression	55.65 (10.89)	41-79.3	4.28	30
Fatigue	53.10 (9.35)	33.7-69	0	7.14
Sleep disturbance	51.20 (7.41)	32-65.5	0	2.86
Social roles	44.64 (8.83)	27.5-64.2	2.85	5.71
Pain interference	62.42 (6.93)	41.6-75.6	8.57	4.28
PROMIS-29				
Pain impact score (0-50)	32.47 (8.82)	13-48	5.71	2.86
Pain intensity (0-10)	6.41 (2.01)	2-10	0	0
ODI	20.5 (9.36)	2-44		
Roland-Morris	11.82 (5.37)	2-21		

ODI: Oswestry disability index

percentage of ceiling effect among individuals with musculoskeletal pain from the USA (42%).<sup>[13]</sup>

The reliability of the P-PROMIS-29 was measured using the ICC. The results showed an excellent coefficient when the questionnaire was refilled by the subjects with a 14-day interval. The measured reliability of the P-PROMIS-29 is higher than the reported scores of the Arabic,<sup>[27]</sup> French,<sup>[28]</sup> Thai<sup>[24]</sup> and original version<sup>[7]</sup> of the P-PROMIS-29 questionnaire. The 14-day interval between two records of the patients in this study was higher than the Thai study (7 days), and it was shown previously that coefficients would decrease substantially with the increase in time between evaluations.<sup>[29]</sup> On this basis, the higher ICC of the P-PROMIS-29 comparing to

the Thai version might imply on the excellent reliability of the newly developed PROMIS-29 questionnaire among participants with lumbar canal stenosis.

The PROMIS-29 has 29 questions that assess mental health, physical health, and social health, including physical function, anxiety, depression, fatigue, sleep disturbance, ability to participate in social roles and activities, and pain interference.<sup>[30]</sup> It is vital to remember that PROMIS-29 is an instrument to assess different domains of quality of life. It is not only a back pain questionnaire and need not just be used on persons with LBP. This is an essential strength of the measure and makes it possible to be used for comparison of quality-of-life domains among samples with different conditions (e.g., back pain, heart disease). Moreover, as populations become older, the number of individuals with comorbid conditions increases, so generic function measures are more necessary. The PROMIS scales were developed to support this need for generic measures of important health-related function domains. These scales can replace disease-specific instruments because they assess the exact domains with equal responsiveness and reliability.<sup>[31-33]</sup> The PROMIS-29 scales do not assess function (e.g., physical function) in a way that specific back pain questionnaires like Roland-Morris,<sup>[34]</sup> the ODI,<sup>[35]</sup> and the Quebec back pain disability scale (QPDS)<sup>[36]</sup> do. Nonetheless, one study among patients with spinal complaints showed that PROMIS physical function scale has better performance with a lower assessment burden than ODI and 36 items short

**Table 3: Correlations of PROMIS domains with ODI and Roland-Morris in lumbar stenosis patients**

PROMIS-29	Oswestry disability index (ODI)		Roland-Morris (RM)	
	Correlation*	P	Correlation*	P
Physical function	0.749	<0.01	0.577	<0.01
Anxiety	0.542	<0.01	0.490	<0.01
Depression	0.525	<0.01	0.591	<0.01
Fatigue	0.223	<0.01	0.312	<0.01
Sleep disturbance	0.287	<0.01	0.292	<0.01
Social roles	0.334	<0.01	0.341	<0.01
Pain interference	0.553	<0.01	0.607	<0.01
Pain intensity	0.533	<0.01	0.366	<0.01
Pain impact score	0.723	<0.01	0.650	<0.01

ODI: Oswestry disability index, Correlation: Pearson's correlation

**Table 4: Interclass correlations of PROMIS domains in lumbar stenosis patients**

PROMIS-29 domain	PF	A	D	F	SD	SR	PI-1	PI-2	PIS
Physical function (PF)	1	0.603	0.582	0.017	0.286	0.548	0.661	0.658	0.876
Anxiety (A)		1	0.905	0.722	0.199	0.642	0.624	0.547	0.664
Depression (D)			1	0.79	0.279	0.574	0.721	0.566	0.709
Fatigue (F)				1	0.154	0.637	0.612	0.52	0.501
Sleep disturbance (SD)					1	0.388	0.287	0.031	0.222
Social roles (SR)						1	0.6	0.371	0.603
Pain interference (PI-1)							1	0.767	0.935
Pain intensity (PI-2)								1	0.871
Pain impact score (PIS)									1

**Table 5: Means (standard deviations) and the test-retest reliability coefficients of the P-PROMIS-29 scores at initial assessment and two weeks later for participants who participated in test-retest (n=55)**

PROMIS-29 scale	Baseline	2 weeks	ICC
Physical function (PF)	38.92 (6.52)	35.09 (4.45)	0.885 (0.797-0.935)
Anxiety (A)	61.59 (10.67)	62.69 (9.37)	0.986 (0.975-0.992)
Depression (D)	56.41 (9.97)	57.72 (9.25)	0.985 (0.973-0.991)
Fatigue (F)	52.34 (8.99)	52.65 (8.67)	0.985 (0.973-0.991)
Sleep disturbance (SD)	51.88 (7.59)	51.98 (6.68)	0.972 (0.95-0.984)
Social roles (SR)	45.32 (7.72)	44.59 (7.16)	0.977 (0.96-0.987)
Pain interference (PI-1)	62.37 (6.59)	62.30 (5.89)	0.981 (0.967-0.989)
Pain intensity (PI-2)	6.46 (2.06)	6.62 (1.84)	0.964 (0.938-0.98)
Pain impact score (PIS)	32.68 (8.36)	33.07 (7.17)	0.97 (0.947-0.983)

ICC: Intraclass correlation coefficient

form survey (SF-36).<sup>[37]</sup> However, more studies are needed to compare legacy measures with PROMIS to declare the PROMIS scales that can be used instead of legacy instruments. Pain impact score (PIS) in PROMIS-29 is calculated by the sum of pain interference, pain intensity, and physical function scores. It was previously shown that higher scores of PIS were related to more severe pain and physical dysfunction, especially among patients with musculoskeletal complaints. Deyo *et al.*<sup>[22]</sup> showed the strong correlation between PROMIS-29 domains and PIS by calculating standardized Cronbach's alpha of PIS with other domains of PROMIS-29 in participants with LBP (0.91).<sup>[13]</sup> Similarly, we found a satisfactory correlation between the PIS and other domains of P-PROMIS-29 [Table 4].

### Limitation and recommendation

This study has some limitations that should be disclosed when explaining the results. First, as mentioned previously, the study sample was limited to individuals with low back pain due to lumbar stenosis. Thus, we cannot generalize these results to samples of individuals with other health conditions or who are otherwise healthy. Prospective studies are required to be carried out in individuals with other health conditions. Second, we evaluated participants before a treatment program designed to improve quality of life. We were unable to assess any improvements in the quality-of-life domains by the P-PROMIS-29 scales. Future research to address this vital issue would be helpful. Third, the scoring protocols for computing the standardized T-scores used in this study were based on normative samples from USA. Scores based on a normative model from Iran might differ to some extent. Fourth, in this study confirmatory factor analysis was not conducted for evaluating the psychometric properties of PROMIS-29. Further studies are recommended to perform the confirmatory factor analysis. Finally, this study didn't conduct tests for differential item functioning (DIF) to determine if the P-PROMIS-29 items have the same properties in the current sample versus samples from other countries.

### Conclusion

Despite the study's limitations, the findings provide preliminary support for the cultural appropriateness, reliability, and initial validity of the P-PROMIS-29 for assessing multiple health-related domains in individuals with low back pain due to lumbar stenosis from Iran.

### Consent to participate

Informed consent was obtained from all the participants.

### Consent for publication

The authors all agree for submission and publication of the manuscript.

### Authors' contribution

All authors have contributed to

- 1- Conception and design of the study
- 2- Analysis and interpretation of data
- 3- Provision of study material or patients
- 4- Collection, assembly, possession of raw data (doing experiments)
- 5- Statistical analysis
- 6- Critical revision of the article for important intellectual content
- 7-Final approval of the study
- 8-Guarantee of integrity of the entire study

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### Conflicts of interest

There are no conflicts of interest.

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