Article published online: 2022-09-22

ORIGINAL ARTICLE

An outcome measure of functionality and pain in patients with low back disorder: A validation study of the Iranian version of Core Outcome Measures Index

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ABSTRACT

Background: Lumbar Disc Herniation (LDH) and Lumbar Spinal Stenosis (LSS) are the most common diagnoses of low back and leg pain symptoms. This study aimed to cross-culturally translate, and validate the Core Outcome Measures Index (COMI) in Iran.

Methods: The translation and cross-cultural adaptation of the original questionnaire were performed in accordance with published guidelines. A total of 121 patients with LDH or LSS were asked to respond to the questionnaire at two points in time: Pre and postoperative assessments (6 months follow-up). The Oswestry Disability Index (ODI) also was completed. To test the reliability, the internal consistency was assessed by Cronbach's alpha coefficient, and validity was assessed using convergent validity. Responsiveness to change also was assessed for comparing patients' pre and postoperative scores.

Results: The Cronbach's alpha coefficients for the COMI at pre and postoperative assessments ranged from 0.79 to 0.82, indicating a good internal consistency. The change in the ODI after surgery was strongly correlated with change in the COMI, lending support to its good convergent validity ($r = 0.79$ for LDH and $r = 0.77$ for LSS; $P < 0.001$). In addition, the correlation of each item with its hypothesized subscale of the COMI showed satisfactory results suggesting, that the items had a substantial association with the subscale, representing the concept. Further analysis also indicated that the questionnaire was responsive to change ($P < 0.0001$).

Conclusion: The Iranian version of COMI performed well, and the findings suggest that it is a reliable and valid measure of back pain treatment evaluation among LDH and lumbar canal stenosis patients.

Key word: Core Outcome Measures Index, Iran, low back pain, validity

Introduction

Low back pain is the most common type of back pain,[1] mainly caused by lumbar disc herniation (LDH) and lumbar spinal stenosis (LSS). The term LDH refers to the nucleus in the center of the disc pushes out of its normal space whereas the term LSS refers to the anatomic narrowing of the spinal canal in the anterior-posterior axis.[2] Symptoms for LDH include back and leg pain, which may spread out into the hand.[3] LSS can lead to increasing weakness and loss of function of the legs.[2]

In 1998, an international group designed the Core Outcome Measures Index (COMI) to assess pain, function, well-being, disability, and satisfaction for evaluating the treatment for low back pain.[4] The main goal for developing the COMI was to provide a standardized outcome assessment without an excessive burden of instruments, or questions that make it difficult for patients to complete the instruments of evaluation.[5] The COMI allows an appropriate assessment, but faster and simpler than other questionnaires.[6] With slight modifications, it has been validated as an outcome measure in low back pain in many countries.[7,5,8-14]

Access this article online	
Quick Response Code:	Website: www.asianjns.org
	DOI: 10.4103/1793-5482.151511

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The aim of this study is to translate the COMI into Persian (Iranian language), validate and use the questionnaire in studies of quality-of-life in LDH or lumbar canal stenosis (LCS) patients in Iran. Currently, there is no such questionnaire available in Iran.

Methods

The questionnaire

The COMI is a short, self-administered and multidimensional outcome instrument. It consists of 5 subscale including 7 questions that evaluate pain (2 items), function (1 item), well-being (1 item), disability (2 items) and satisfaction (1 items). The possible score on the questionnaire ranges from 1 to 5, with 1 being the best possible result. The total COMI score is the average of the 5 subscales [Appendix1].[4,6]

Translation

The "forward-backward" procedure was applied to translate the COMI from English into Persian (Iranian language). Two general practitioners translated the questionnaire into Persian. One translator was aware of the project and the other translator was not the same. Both translators were instructed to aim for conceptual rather than a literal translation.[15] Together with the main investigator (PA) the translators compared translations and produced a single provisional version of the questionnaire. Then, two other professional translators translated the provisional Persian questionnaire back into the English language.[16] Finally, an expert committee consisting of the translators, the researchers, one outcome methodologist reviewed the translation and cultural adaptation processes. After a careful review, few changes have been made, and the prefinal Persian version of the questionnaire was produced.

Face validity

The number of patients with low back pain completed the prefinal Persian version of the COMI to establish, that this version could be understood, and that the questions measured what they were intended to measure. For each item, patients were asked to respond to the following questions: "Do you understand what this means?" and "What does this mean to you by your own words?" Most patients correctly understood the questions and the concept of each item. However, their general comments on the difficulty in completing the questionnaire or understanding the texts were examined, and after a consensus by authors the final version was developed and used in this study.

Patients and data collection

The final draft of the Iranian version was administered to a sample of newly diagnosed LDH or LCS patients attending the neurosurgery clinic of a large teaching hospital in Tehran, Iran. There were no restrictions on patient selection with regard to types of LDH or LSS, age or other characteristics. A trained neurosurgery resident during one complete calendar year collected the data. Patients were assessed at two points in time: Pre and postoperative (6 months follow-up).

Additional measure

The Iranian version of Oswestry Disability Index (ODI): This is a measure of functionality, and contains 10 items. The possible score on the ODI ranges from 0 to 50, with higher scores indicating worst conditions. The psychometric properties of Iranian version of the questionnaires are well-documented.[17] A questionnaire was used to examine criterion validity.

Statistical analysis

The following analyses were performed to assess psychometric properties of the COMI.

Reliability

To test the reliability, the internal consistency of the questionnaire was measured using the Cronbach's alpha coefficient and alpha equal to or >0.70 was considered as satisfactory.[14]

Validity

Validity was assessed performing item-scale correlations. Correlations were calculated using the Pearson's correlation coefficient (r). It was expected that item scores would correlate higher with own hypothesized scale than other scales. Correlation values of 0.40 or above were considered satisfactory ($r \geq 0.81$–1.0 as excellent, 0.61–0.80 very good, 0.41–0.60 good, 0.21–0.40 fair and 0.20 poor).[18] In addition, the correlation between the COMI and the ODI was assessed using Pearson's correlation coefficient in order to assess criterion validity (convergent validity). Values of 0.40 or above were considered satisfactory ($r \geq 0.81$–1.0 as excellent, 0.61–0.80 very good, 0.41–0.60 good, 0.21–0.40 fair, and 0.0–0.20 poor).[18]

Responsiveness to change

Responsiveness as a psychometric property of the questionnaire also was assessed. As such patients', pre and postoperative scores were compared using a paired t-test in order to examine whether the COMI was able to capture the change after intervention (surgery).

Ethics

The Ethics Committee of the Shahid Beheshti University of Medical Sciences approved the study.

Results

In all 121 patients, we completed the questionnaire. The characteristics of patients and their scores on the COMI are shown in Table 1. The mean age of patients was 51.2 (standard deviation = 9.8) years; most were married (74.4%), and had completed primary or secondary education (71.9%). Almost all patients (99%) found the Iranian version of the COMI acceptable.

The internal consistencies of the COMI for patients with LDH and LSS as measured by the Cronbach's alpha coefficient were respectively, 0.79 and 0.78 at preoperative assessment and 0.81 and 0.82 at postoperative evaluation, indicating a satisfactory reliability.

Validity of the COMI was examined using item-scale correlations. The item-scale correlation matrix between each item and the five COMI subscales based on the type of disease are shown in Tables 2 and 3. All correlations between items and its hypothesized scale showed satisfactory results suggesting that the items had a substantial association; with the subscale representing the concept. Pearson correlation coefficient exceeded the 0.40 level recommended ranging from 0.67 (Q1-a) to 0.8 (Q1-b and Q6) for patients with LDH and 0.67 (Q3) to 0.79 (Q5) for patients with LSS.

Table 1: Characteristics of the study sample (*n*=121)

Characteristics	Number	Percentage
Age groups (years)		
Mean (SD)	51.2 (9.8)	-
Range	22-83	-
Gender		
Male	53	43.8
Female	68	56.2
Educational status		
Illiterate	19	15.7
Primary	56	46.3
Secondary	31	25.6
College/university	15	12.4
Marital status		
Single	19	15.7
Married	90	74.4
Divorced/widowed	12	9.9
Type of disease		
Lumbar disc herniation	71	58.7
Lumbar canal stenosis	50	41.3
ODI		
Lumbar disc herniation		
Preoperative		
Mean (SD)	31.9 (10.2)	
Range	21-50	
Postoperative		
Mean (SD)	14.8 (11.5)	
Range	0-23	
Lumbar canal stenosis		
Preoperative		
Mean (SD)	28.4 (11.0)	
Range	19-50	
Postoperative		
Mean (SD)	16.5 (11.8)	
Range	0-27	
COMI		
Pain, mean (SD)	3.98 (0.79)	-
Function, mean (SD)	3.89 (1.1)	-
Well-being, mean (SD)	4.3 (0.3)	-
Disability, mean (SD)	3.26 (1.4)	-
Satisfaction, mean (SD)	2.9 (1.1)	-
Total, mean (SD)	3.67 (1.2)	-

SD – Standard deviation; COMI – Core outcome measures index; ODI – Oswestry disability index

The change in the ODI is correlated strongly, with the change in the COMI; lending support to its good convergent validity ($r = 0.79$; $P < 0.001$) for patients with LDH and ($r = 0.77$; $P < 0.001$) for patients with LSS.

Responsiveness to change was assessed by paired *t*-test. In all instances, the COMI was able to detect the changes after intervention (surgery), indicating the improvements in all subscales as expected. The results are shown in Tables 4 and 5.

Discussion

This study is the first to report on translation and validation of the COMI in Iran. The results of the current study showed that the Persian version of the COMI is a reliable measure to evaluate the back pain in Iranian patients with LDH and LSS. The Persian version of COMI had excellent internal consistency. Lozano-Álvarez *et al*. reported similar findings, where they reported that the instrument had desirable internal consistency. Values for the Cronbach's alpha were 0.81 and 0.91 respectively, at pre and postoperative assessments.[19] Ferrer *et al*.[15] showed that the Cronbach's alpha was 0.92 among patients with chronic low back pain and 0.64 for patients with subacute osteoporotic fracture at preoperative.

The change in the ODI is good correlated with the change in the COMI, as in the study by Lozano-Álvarez *et al*. ($r = 0.73$; $P < 0.01$),[15] and Deyo *et al*. ($r = 0.60$; $P < 0.01$).[3] Furthermore, the COMI showed excellent item-scale correlation. The findings from the current study suggest that the Persian version of the questionnaire has a good construct, and could be regarded as a valid measure.

Although psychometric evaluation was different in many studies, however, as just in the Spanish,[5] German,[6] Polish,[12] French,[8] Norwegian,[13] Italian,[9] and Brazilian-Portuguese[7] psychometric studies, the results of our studies have indicated similarly good, construct validity, sensitivity to change and internal consistency.

The results of the current study showed that this instrument seems to be a reliable and valid outcome measure for back pain evaluation of patients with LDH or LSS in Iran. As suggested, the COMI is a quick and effective alternative in daily clinical practice to assess the condition of patients.[19]

This study has some limitations. The sample size was small, and a larger study population is very essential. We carried out a number of limited tests to perform this validation study. In

Table 2: Item-scale correlation matrix for the five COMI subscales* (lumbar disc herniation)

Items (item number)	Pain	Function	Well-being	Disability	Satisfaction
Duration the past week, how bothersome have each of the following symptom been?					
Low back pain	0.67	0.22	0.12	0.23	0.11
Leg pain (sciatica)	0.80	0.14	0.15	0.13	0.13
Duration the past week, how much did pain interfere with your normal work (including both work outside the home and housework)	0.22	0.68	0.18	0.08	0.17
If you had to spend the rest of your life with the symptoms you have right now, how would you feel about it?	0.19	0.14	0.73	0.14	0.16
During the past 4 weeks, about how many days did you cut down on the things you usually do for more than half the day because of back pain or leg pain (sciatica)	0.24	0.12	0.27	0.75	0.24
During the past 4 weeks, how many days did low back pain or leg pain (sciatica) keep you from going to work or school?	0.29	0.23	0.23	0.80	0.21
Over the course of treatment for your low back pain or leg pain (sciatica) how satisfied were you with your overall medical care?	0.15	0.27	0.18	0.18	0.72

*Pearson correlation (*r*) equal to or >0.40 was considered satisfactory (correlation ≥0.81-1.0 as excellent, 0.61-0.80 very good, 0.41-0.60 good, 0.21-0.40 fair, and 0.0-0.20 poor).[18]
COMI – Core outcome measures index

Table 3: Item-scale correlation matrix for the five COMI subscales* (lumbar canal stenosis)

Items (item number)	Pain	Function	Well-being	Disability	Satisfaction
Duration the past week, how bothersome have each of the following symptom been?					
Low back pain	0.69	0.24	0.13	0.22	0.12
Leg pain (sciatica)	0.78	0.11	0.15	0.11	0.13
Duration the past week, how much did pain interfere with your normal work (including both work outside the home and housework)	0.23	0.72	0.17	0.11	0.21
If you had to spend the rest of your life with the symptoms you have right now, how would you feel about it?	0.17	0.14	0.67	0.15	0.12
During the past 4 weeks, about how many days did you cut down on the things you usually do for more than half the day because of back pain or leg pain (sciatica)	0.22	0.15	0.21	0.77	0.22
During the past 4 weeks, how many days did low back pain or leg pain (sciatica) keep you from going to work or school?	0.27	0.21	0.23	0.79	0.21
Over the course of treatment for your low back pain or leg pain (sciatica) how satisfied were you with your overall medical care?	0.17	0.23	0.18	0.23	0.75

*Pearson correlation (*r*) equal to or >0.40 was considered satisfactory (correlation ≥0.81-1.0 as excellent, 0.61-0.80 very good, 0.41-0.60 good, 0.21-0.40 fair, and 0.0-0.20 poor).[18]
COMI – Core outcome measures index

Table 4: Responsiveness to change for lumbar disc herniation

Subscales	Mean (SD)		*P**
	Preoperative	Postoperative	
Pain	4.04 (0.81)	2.46 (1.3)	<0.0001
Function	3.83 (1.1)	2.6 (1.3)	<0.0001
Well-being	4.5 (0.36)	3.2 (1.2)	<0.0001
Disability	3.34 (1.4)	1.8 (1.1)	<0.0001
Satisfaction	2.8 (1.1)	1.9 (1.0)	<0.0001
Total	3.7 (1.1)	2.39 (1.0)	<0.0001

*Derived from paired samples *t*-test. SD – Standard deviation

Table 5: Responsiveness to change for lumbar canal stenosis

Subscales	Mean (SD)		*P**
	Preoperative	Postoperative	
Pain	3.92 (0.78)	2.44 (1.2)	<0.0001
Function	3.95 (1.1)	2.8 (1.2)	<0.0001
Well-being	4.1 (0.32)	3.0 (1.2)	<0.0001
Disability	3.18 (1.4)	1.6 (1.1)	<0.0001
Satisfaction	3.0 (1.1)	2.1 (1.0)	<0.0001
Total	3.63 (1.1)	2.38 (1.0)	<0.0001

*Derived from paired samples *t*-test. SD – Standard deviation

future, it might be necessary to perform other tests to establish stronger psychometric indexes for the COMI.

Conclusion

The findings from this validation study indicate that the Iranian version of COMI is a reliable and valid instrument for back pain evaluation in patients with LDH or LCS.

Acknowledgment

The authors would like to thank the staff of the Neurosurgery Unit at Imam-Hossain Hospital, Tehran, Iran.

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How to cite this article: Mohammadi HR, Azimi P, Zali A, Montazeri A. An outcome measure of functionality and pain in patients with low back disorder: A validation study of the Iranian version of Core Outcome Measures Index. Asian J Neurosurg 2015;10:46.

Source of Support: Nil, **Conflict of Interest:** None declared.

Appendix 1: Core measures outcome index

Subscales	1	2	3	4	5
Pain					
Duration the past week, how bothersome have each of the following symptom been?	Not at all bothersome	Slightly bothersome	Moderately bothersome	Very bothersome	Extremely bothersome
Low back pain					
Leg pain (sciatica)					
Function					
Duration the past week, how much did pain interfere with your normal work (including both work outside the home and housework)	Not at all	A little bit	Moderately	Quite a bit	Extremely
Well-being					
If you had to spend the rest of your life with the symptoms you have right now, how would you feel about it?	Very dissatisfied	Somewhat dissatisfied	Neither satisfied nor dissatisfied	Somewhat satisfied	Very satisfied
Disability					
During the past 4 weeks, about how many days did you cut down on the things you usually do for more than half the day because of back pain or leg pain (sciatica)	None	Between 1 and 7 days	Between 8 and 14 days	Between 15 and 21 days	More than 21 days
During the past 4 weeks, how many days did low back pain or leg pain (sciatica) keep you from going to work or school?	None	Between 1 and 7 days	Between 8 and 14 days	Between 15 and 21 days	More than 21 days
Satisfaction					
Over the course of treatment for your low back pain or leg pain (sciatica) how satisfied were you with your overall medical care?	Very dissatisfied	Somewhat dissatisfied	Neither satisfied nor dissatisfied	Somewhat satisfied	Very satisfied