

RESEARCH ARTICLE

Oswestry Disability Index, Roland-Morris Disability Questionnaire, and Quebec Back Pain Disability Scale: Responsiveness and Minimal Clinically Important Changes in Iranian People with Lumbar Disc Herniation Following Physiotherapy

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Abstract

Objectives: The present study aimed to investigate the responsiveness of the Persian version of the Oswestry Disability Index (ODI), Roland-Morris Disability Questionnaire (RMDQ), and Quebec Back Pain Disability Scale (QBPDS) and detect minimal clinically important changes (MCICs) of these questionnaires in people with lumbar disc herniation.

Methods: Ninety-two patients with lumbar herniated disc completed the Persian version of the ODI, RMDQ, and QBPDS before and after the physiotherapy intervention. Additionally, they completed a global rating of change scale after the final physiotherapy session to give an account of non-improved and improved outcomes. The responsiveness of these three disability questionnaires was represented by Receiver Operating Characteristic (ROC) and correlation analyses. The MCIC was defined as the best cut-off when sensitivity and specificity were optimally balanced.

Results: Area under the ROC curves are in the acceptable range for ODI and QBPDS (0.78 and 0.70, respectively). Moreover, ODI, RMDQ, and QBPDS have significant positive fair to moderate correlation with the external anchor ($P < 0.001$). The MCIC values for ODI, RMDQ, and QBPDS were 13, 5.5, and 14.5 points, respectively.

Conclusion: Our results revealed that the ODI and QBPDS questionnaires have adequate responsiveness to detect improvements in the functional status of lumbar herniated disc patients following a physiotherapy treatment. Therefore, the ODI and QBPDS seem to be superior to the RMDQ for use in randomized clinical trials and clinical settings in patients with herniated lumbar discs. The MCIC scores of 13 and 14.5 obtained for the ODI and QBPDS can help to identify important changes in the clinical status of an individual patient and treatment efficacy.

Level of evidence: IV

Keywords: Clinimetric properties, Disability questionnaires, Low back pain, Persian

Introduction

More than half of people who experience musculoskeletal disorders are diagnosed with low back pain (LBP).^{1,2} One of the specific sources of LBP is lumbar disc herniation, in which displacement of intervertebral disc contents may cause inflammation and/or nerve root compression, leading to LBP with or

without radicular pain to the lower extremities. This is a potentially disabling symptom resulting in serious socio-economic costs for patients, health services, and society.²

Since disability is an important patient outcome, several questionnaires are developed to determine patients' level of disability.^{3,4} Among disability questionnaires used in LBP

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patients, the Oswestry Disability Index (ODI), Roland-Morris Disability Questionnaire (RMDQ), and Quebec Back Pain Disability Scale (QBPDS) have been the most comprehensive and common.⁵⁻¹⁰ These outcome measures were translated into numerous languages, including Persian, and their good validity and reliability have been reported.¹¹⁻¹⁵ However, other clinically important clinimetric properties like responsiveness and interpretability have not been investigated for all translations of these questionnaires, particularly the Persian version.^{16,17}

Responsiveness is described as the capability of an outcome measure to identify change through time in the intended construct and is usually measured by means of anchor-based methods.¹⁸ Interpretability is frequently reported as the minimal clinically important change (MCIC) represented by the lowest change considered significant to a patient.¹⁹ Therefore, it is considered the change score which can best distinguish improved from non-improved patients, according to an external anchor.²⁰ Thus, it could be viewed as a threshold above which change scores indicate improvement in patients.²¹ The MCIC threshold could be considered as a reference score for significant improvement and is an appreciated value of the clinical importance of a change in the patients' functional status.^{22,23}

Several studies have evaluated the responsiveness of the English version of the ODI, RMDQ, and QBPDS in patients with LBP and other spinal conditions.^{14,18,19,24} However, the responsiveness of the ODI, RMDQ, and QBPDS has not been determined yet in Iranian patients with lumbar herniated discs. Therefore, the present research aimed to investigate the responsiveness and interpretability of the Persian version of the ODI, RMDQ, and QBPDS. We hypothesized that the Persian version of ODI, RMDQ, QBPDS have an acceptable responsiveness in this population, and we may find specific MCICs in LBP patients with lumbar disc.

Materials and Methods

Patients

From November 2017 to February 2019, ninety-two patients with LBP related to lumbar disc herniation who were referred to the Physiotherapy Department of Ardabil Sabalan Hospital and a private clinic participated in this study. The participants were included in the study if they were aged 18 or older, diagnosed with lumbar disc herniation via MRI confirmed by a neurosurgeon, and had LBP with or without leg radiculopathy for a minimum of six weeks. In addition, they needed to be able to read and speak Persian fluently. The exclusion criteria were pregnancy, spinal surgery in the past 12 months, specific spinal pathology (tumor or local infection), osteoarthritis, spondylolysis, spondylolisthesis and spinal stenosis, cauda equine syndrome, ankylosing spondylitis, fracture, and progressive paresis. This study was approved by the Ethics Committee of the Tabriz University of Medical Sciences, Iran. All patients filled out an informed consent form. To calculate the sample size, G*Power 3.1® program was applied. According to the global rating of change scale, two improved and non-improved groups of patients were considered to measure the MCIC on the receiver operator characteristic (ROC) curve. Considering an effect size of $d=0.8$, $\alpha=0.05$, and

power $(1-\beta) = 0.8$, a total sample size of 92 patients was calculated.

Procedure

The questionnaires were given to the patients before and after a 10-session physiotherapy intervention by one of the research team members. The reliability and validity of the questionnaires have been broadly investigated and shown to be excellent.¹¹⁻¹⁵

The physiotherapy was done for all patients in 10 sessions over four weeks, which included manual therapy, electrotherapy, precise exercises of lumbar stabilization, and exercises of strengthening and stretching. On the final physiotherapy occasion, the patients achieved the global rating of the change scale, as well. In this study, the patients were received the physiotherapy recognized to make a change on the intended construct; therefore, the applied physiotherapy over the time serves as the construct for change.^{22,25} On the other hand, since patients with chronic lumbar herniated disc could show less improvement, we anticipated some patients would improve and some ones would not improve through this time. Thus, patients can be expected to experience different changes.^{22,25} The physiotherapy program was not controlled in the present study since the purpose of our study was to investigate the responsiveness of these questionnaires rather than the effectiveness of physiotherapy intervention.^{26,27} Additionally, examining responsiveness by the anchor-based method is not dependent on the types of interventions.^{28,29}

Instruments

Oswestry Disability Index (ODI)

The ODI is a ten-item questionnaire that assesses the disabling effects of LBP on activities of daily living (ADL). It is a reliable and valid self-reported questionnaire that lasts 5 min for the patient to complete the measure and a few minutes for the examiner to calculate the scores. Each item is scored from 0 to 5, and the summation of the ten scores is stated as a percentage of the maximum score; therefore, it ranges from 0 (no disability) to 100 (maximum disability).^{5,30}

Roland-Morris Disability Questionnaire (RMDQ)

The RMDQ is also a self-reported measure including 24 items that evaluate the effects of the LBP on normal ADL. Each marked statement is equal to one point, with the values varying from 0 to 24 (no disability to extremely severe disability).⁸

Quebec Back Pain Disability Scale (QBPDS)

The QBPDS contains twenty daily activities classified into six types of activities relevant to LBP, including bed/rest, sitting/standing, ambulation, movement, bending/stooping, and handling large or heavy objects, and asks the patient to score the amount of difficulty in doing each activity from 0 ("not difficult at all") to 5 ("unable to do"). The overall score is determined by a summary of the values for each item and ranges from 0 ("not being disabled") to 100 ("being maximally disabled").¹²

Global rating of change scale

The global rating of change scale we applied as an external anchor in our study was a Likert scale, which asks the patients to numerically rate the degree of improvement or deterioration of their condition during a predefined period of time. It is an interesting tool in research and clinical settings, having seven levels of change in condition of patient, including three improvement levels (very much better, much better, and slightly better), one no change level and three worsening levels (slightly worse, much worse, and very much worse). The scores of the patient's condition on the global rating of change scale are used to offer a dichotomous variable outcome: non-improved (including slightly better, no change, slightly worse, much worse, and very much worse) and improved (including very much better, much better, and better).^{29,31} Consistent with the latest conclusions of the Consensus-based Standards for the Development of Measurement Instruments (COSMIN), using the global rating of change scale as a judicious golden standard to evaluate responsiveness is recommended.²⁵ The COSMIN group concluded such a global rating of change scale shows high face validity and could be regarded as a judicious gold standard for outcome measures if the global rating scale evaluates a similar construct as the intended outcome. According to this recommendation, since in this study, the global rating of change scale evaluated a similar construct as our intended outcome measures, we used the global rating of change scale as the golden standard and followed the criterion approach.²⁵ As a criterion approach, the experienced improvement after therapeutic intervention was applied as a gold standard for significant improvement in functional status.³² Therefore, the global rating of change scale from patient perspectives is commonly applied as a reference standard in studies.^{28,33,34}

Statistical analysis

We applied the Kolmogorov–Smirnov test to investigate the data distribution normality. We also used paired t-test to compare before- and after-intervention scores. Responsiveness was assessed by the ROC method, with a 95% confidence interval (CI) and correlation analysis. For calculating the change scores of the ODI, RMDQ, and QBPDS, the baseline scores were subtracted from the follow-up scores. Therefore, we considered negative change scores as a decrement in the clinical condition of the patients, while positive change scores were considered as an improvement in patients' clinical condition. In the next step, a correlation

analysis was performed to find out the correlations between the global rating of the change scale (i.e., the external anchor) and the change scores of each questionnaire. According to the ordinal data obtained from global rating of change scale, Gamma correlation coefficient was used. Correlation coefficients were described as little or no relationship (<0.25), fair (0.25–0.50), moderate to good (0.50–0.75), and good to excellent (>0.75) relationship. Based on the scores attained from the global rating of change scale, the patients were classified in two groups of improved (scored 6 and 7) and unimproved (scored 1 to 5).

In the ROC method, the sensitivity and specificity were calculated for different change scores as cutoff points. The vertical axis was labeled as sensitivity, and the horizontal axis indicated 1-specificity. Then, the ROC was designed for all probable cutoff points. The area under the curve (AUC) was considered to show the capability of the assessment instruments (i.e., ODI, RMDQ, and QBPDS) to distinguish between the improved patients and non-improved ones. The AUC larger than 0.70 indicated an acceptable responsiveness. The MCIC was calculated as the greatest cutoff point with the largest sensitivity and specificity.^{35,36} Data analysis was done by the SPSS version 18.0 (SPSS Inc., Chicago, IL), and a $P < 0.05$ was considered statistically significant.

Results

Firstly, 106 patients were considered as possible participants. Those who did not come in this study had spinal surgery in the past 12 months ($n=3$), were pregnant ($n=4$), or were reluctant to participate ($n=7$). Thus, 92 patients entered into this study. All patients gained physiotherapy through the time between the first and second assessments.

Descriptive clinical characteristics and demographic information of the participants are demonstrated in Table 1 [Table 1]. The results of the paired t-test for comparing pre- and post-intervention scores of ODI, RMDQ, and QBPDS are summarized in Table 2 [Table 2]. Table 3 presents the results of the ROC analysis, as well as Gamma correlation coefficients indicating the association between the scores of the three disability questionnaires and the external anchor [Table 3]. The AUC values are in the acceptable range for ODI and QBPDS (0.78 and 0.70, respectively). Moreover, ODI, RMDQ, and QBPDS have significant positive fair to moderate correlation with the external anchor ($P<0.001$). The MCIC values for ODI, RMDQ, and QBPDS were 13, 5.5, and 14.5 points, respectively.

Table 1. Demographic and clinical characteristics of patients completing the Questionnaires (n=92)

Demographic data	n (%) unless stated
Age (year), mean (SD)	41.54 (9.37)
Height (cm), mean (SD)	166.12 (8.04)
Weight (kg), mean (SD)	76.67 (12.15)
BMI, mean (SD)	27.69 (3.97)

Table 1. Continued	
Sex:	
Men	34 (37.00)
Women	58 (63.00)
Education:	
Elementary school	25 (27.20)
Secondary school	34 (37.00)
Higher education	33 (35.90)
Pain duration, month, Mean (SD)	25.85 (43.51)

SD: Standard Deviation; BMI: Body Mass Index

Table 2. Mean (SD) of pre-intervention, following and change scores of ODI, RMDQ, and QBPDS (n=92)					
Questionnaires		Pre-intervention Mean (SD)	Follow-up Mean (SD)	Change Mean (SD)	P-value
ODI	Total (n=92)	37.02 (16.49)	24.64 (15.70)	12.38 (12.18)	<0.01
	Improved (n=40)	36.33 (18.32)	17.18 (12.19)	19.14 (12.18)	<0.01
	Not improved (n=52)	37.56 (15.08)	30.38 (15.78)	7.18 (9.37)	<0.01
RMDQ	Total (n=92)	11.10 (4.80)	7.58 (4.80)	3.52 (3.81)	<0.01
	Improved (n=40)	10.50 (5.04)	5.70 (3.82)	4.80 (4.38)	<0.01
	Not improved (n=52)	11.57 (4.60)	9.03 (5.01)	2.53 (2.99)	<0.01
QBODQ	Total (n=92)	37.67 (19.81)	24.36 (16.33)	13.30 (14.89)	<0.01
	Improved (n=40)	57.70 (88.86)	18.72 (14.13)	38.97 (87.14)	<0.01
	Not improved (n=52)	36.98 (17.55)	28.71 (16.71)	8.26 (11.37)	<0.01

ODI: Oswestry Disability Scale, RMDQ: Roland-Morris Disability Questionnaire, QBPDS: Quebec Back Pain Disability Scale

Table 3. Gamma correlation coefficient and area under the receiver operating characteristic area under curve (AUC) for ODI, RMDQ, and QBPDS Questionnaires according to external, dichotomized measure of global rating of change scale (improved versus unimproved) (n=92)						
Questionnaires	Gamma coefficient	P-value	AUC (95% CI)	Optimal cutoff value	Sensitivity (95% CI)	Specificity (95% CI)
ODI	0.55	<0.01	0.78 (0.68-0.87)	13.00	0.70 (0.53-0.82)	0.73 (0.58-0.84)
RMDQ	0.36	<0.01	0.66 (0.55-0.77)	5.50	0.40 (0.25-0.56)	0.86 (0.73-0.93)
QBPDS	0.44	<0.01	0.70 (0.60-0.81)	14.50	0.60 (0.43-0.74)	0.70 (0.54-0.80)

ODI: Oswestry Disability Scale, RMDQ: Roland-Morris Disability Questionnaire, QBPDS: Quebec Back Pain Disability Scale, CI: Confidence Interval, AUC: Area under Curve, equal or greater than 0.70 are in bold

Discussion

Our study aimed to investigate the responsiveness and interpretability of three LBP disability-related questionnaires, including ODI, RMDQ, and QBPDS in Iranians with lumbar disc herniation following 10 sessions of physiotherapy. Overall, our results revealed that ODI and QBPDS attained acceptable responsiveness, while the RMDQ was poorly responsive after receiving physiotherapy treatment.

Oswestry Disability Index (ODI)

The ODI showed good responsiveness and moderate relationship with the external anchor (i.e., the 7-item Likert questionnaire) in people with lumbar disc herniation. To our knowledge, all the prior studies in this field support our findings on the acceptability of the responsiveness of the ODI.^{14,17,18,37-39} The ODI is developed to evaluate disability in acute, sub-acute, and chronic patients with LBP, and it could be used to evaluate the effectiveness of conservative, surgical, and behavioral treatments.^{5,30} Additionally, the possibility of omitting unanswered items when calculating its total score as well as scoring on the scale of 0-5, may make ODI a highly responsive tool for evaluating the effects of various treatments in LBP patients.³⁰

Roland-Morris Disability Questionnaire (RMDQ)

While several studies similar to ours found the RMDQ as a non-responsive instrument in people with LBP,^{17,40} Coelho, Lauridsen and Walsh reported an acceptable responsiveness for this questionnaire.^{14,19,38} The RMDQ is a popular questionnaire for evaluating the disability of LBP patients because the completion of this questionnaire is simple (by just marking the appropriate statement), and it needs a short time to be completed (less than five minutes).⁸ However, there are several issues that make a large diversity in its reported responsiveness throughout different studies. This questionnaire is not able to evaluate low disability levels. It also does not consider two important tasks that are highly affected by the LBP, including sitting and picking up obstacles while it assesses standing up from a chair twice. Additionally, it is not capable of distinguishing between 'no' and possible 'forgotten to be marked' when facing an unmarked statement. Moreover, the way of answering the RMDQ items may result in a loss of information about slight changes in patients' disability as a result of intervention. It has been demonstrated that by replacing the binary answering system of the RMDQ with a 0-10 Likert scale, the responsiveness improvements. Therefore, when assessing the amount of change for the individuals, the MCIC threshold should be considered as a reference value demonstrating improvements in the patient's clinical status.

Limitations

Recruitment of 92 patients to evaluate the responsiveness of assessment tools in a specific LBP condition (i.e., herniated lumbar disc) is a strength point of our study; however, this point decreased the generalizability of our results to other types of LBP, e.g.,

could be increased significantly. Furthermore, the type of external anchor, the interval between two assessments, and the baseline scores may affect the responsiveness of the RMDQ. Kuijer et al. stated that using different external anchors to investigate the responsiveness of this questionnaire results in the AUC ranging between 0.76 to 1.⁷

Quebec Back Pain Disability Scale (QBPDS)

In the same line with our findings on the responsiveness of the QBPDS, Vieira and Demoulin also reported a fair responsiveness for this questionnaire.^{9,16} Similar to the ODI, the items of the QBPDS could be answered on the 6-level scale, and it may be a potential reason for QBPDS usefulness in distinguishing slight changes in the disability as a result to physiotherapy intervention in these patients.

The results of our study could rationalize the application of the ODI and QBPDS for clinical settings and aid clinical decision-making in selecting appropriate outcome measures in individuals with lumbar disc herniation. Thus, we recommend using the ODI and QBPDS when evaluating the effects of physiotherapy interventions in clinical settings as well as planning clinical trials.

Interestingly, the reported MCICs for the three questionnaires in our study are higher than the ones in all previous studies. The value of MCIC in a study depends on several issues. First, the external reference and the method of classifying patients into groups of improved and non-improved may change the amount of MCIC. Recent studies revealed no significant difference between before- and after-intervention scores of disability questionnaires in patients who choose "I am slightly improved". Thus, it is suggested that these patients are better to be classified as non-improved. In such studies in which slightly improved patients are considered as improved, the values of MCIC are lower.²⁶ On the other hand, chronicity of LBP, type, cause of pain, presence of leg pain, and the severity of pain may lead to different basic scores and subsequently different MCIC values.

Another issue is the implication of obtained MCIC scores in the clinical and research settings.^{28,41-43} The MCIC scores strongly reveal the needed scores for important changes in the clinical status of chronic lumbar herniated disc patients. The MCIC scores were 13 points for the ODI and 14.5 points for QBPDS after 10 sessions of physiotherapy in this study. It means that a patient with chronic lumbar herniated disc has to change at least 13 points on the ODI, and 14.5 points on the QBPDS to be considered as having clinically important non-specific LBP, spine fractures, and zygapophysial problems. It is suggested to conduct studies on the responsiveness of these disability outcome measures in other types of LBP in the future. Another limitation is that using the global rating of change scale as an external standard may be challenging due to recall bias.^{29,44} However, selecting the intervention period of four weeks in our study could decrease the likelihood of recall bias.

Conclusion

The results of ROC and correlation analyses

demonstrated that the ODI and QBPDS questionnaires have adequate responsiveness to detect improvement in the functional status of lumbar herniated disc patients after physiotherapy treatment. Therefore, the Persian version of ODI and QBPDS seems to be superior to the RMDQ for use in randomized clinical trials and clinical settings in patients with herniated lumbar discs. The MCIC scores of 13 and 14.5 obtained for the ODI and QBPDS can help to identify important changes in the clinical status of an individual patient and treatment efficacy.

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