ORIGINAL ARTICLE



The Italian version of the Quebec Back Pain Disability Scale: cross-cultural adaptation, reliability and validity in patients with chronic low back pain

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Abstract

Background and aim Growing attention is being given to physical functioning measures to assess interventions for low back pain (LBP). The Quebec Back Pain Disability Questionnaire (QBPDS) has never been validated in Italian patients, and the aim of the study was culturally adapting and validating the Italian version of the QBPDS (QBPDS-I), to allow its use with Italian-speaking patients with chronic LBP.

Methods The QBPDS-I was developed by means of forward–backward translation, a final review by an expert committee and a test of the prefinal version to evaluate its comprehensibility. The psychometric testing included structural validity by exploratory factor analysis (EFA), reliability by internal consistency (Cronbach's alpha) and test–retest reliability (intraclass correlation coefficient, ICC 2.1), measurement error by calculating the minimum detectable change (MDC), construct validity by assessing hypotheses of QBPDS correlations with the Roland Morris Disability Scale (RMDQ), the Oswestry Disability Questionnaire (ODI) and a pain numerical rating scale (NRS) (Spearman's correlations).

Results It took one month to develop a consensus-based version of the QBPDS-I. The questionnaire was administered to 201 subjects with chronic LBP and was well accepted. EFA suggested a one-factor 20-item solution (first factor variance explained = 54.7%). Internal consistency (α =0.95) and test–retest reliability (ICC=0.90) were excellent. The MDC was 12 scale points. Construct validity was good as all of the hypotheses were met; correlations: RMDQ (r=0.40), ODI (r=0.48) and NRS (r=0.44).

Conclusions The QBPDS-I is unidimensional, reliable and valid in patients with chronic LBP. Its use is recommended for clinical and research purposes.

Graphic abstract



Keywords Chronic low back pain · Cross-cultural adaptation · Reliability · Validity · Sensitivity to change

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Extended author information available on the last page of the article

Introduction

Low back pain (LBP) is one of the most common and burdensome problems in primary and secondary care as it causes disability, reduces the quality of life and prevents participation in usual activities [1, 2]. Chronic LBP has a prevalence of about 23%, with 11-12% of the population being disabled, and it tends not to improve with time and consumes most resource [3]. With such a high epidemiological and clinical burden, it is of importance to apply evidence-based, validated and comprehensive outcome measures to help clinicians to monitor quality of care and effectiveness of interventions [4]. There is consensus among experts and patients that physical functioning (intended as the patient's ability to carry out physical daily activities) is the most important outcome domain to measure in patients with LBP [5, 6] The most frequently recommended and used questionnaires to measure this domain are the Roland Morris Disability Questionnaire (RMDQ) and the Oswestry Disability Index (ODI) [7, 8]. However, the former does not provide any questions asking specifically about lifting, carrying, pulling or pushing objects, and the latter does not have any questions pertaining to bending or body movement [9, 10]; additionally, both RMDQ and ODI contain various items measuring domains other than physical functioning (e.g. pain intensity, sleep, social functioning) [11].

The Quebec Back Pain Disability Scale (QBPDS) is another frequently used physical functioning measure in patients with LBP [7], and it was specifically developed to cover all daily activities relevant to patients with LBP to establish a more accurate physical functioning questionnaire [12, 13]. The 48 original items investigating physical limitations due to LBP were reduced through classical test and item response psychometric methods to the final 20-item questionnaire [12, 13]. The psychometric properties of the original version demonstrated acceptable degree of internal consistency, test-retest reliability, as well as face, content, concurrent and construct validity [12-15]. The QBPDS has already been cross-culturally adapted and validated in Dutch, French, Persian, Turkish, Brazilian Portuguese, Greek, Polish, Arabic, Korean, European Portuguese, Chinese, Hindi, German, Moroccan and Tswana [16–30].

These studies contributed to confirm reliability, validity and responsiveness of the translated forms of the questionnaire, allowing comparison of results and investigating the impact of LBP on physical functioning across different countries [31].

While RMDQ and ODI have already been adapted into Italian [9, 10], an Italian version of the QBPDS has not been cross-culturally adapted and psychometrically analysed; therefore, Italian researchers and clinicians are limited from using this instrument. The aim of this study was to develop and to assess an Italian version of the QBPDS for use in patients with LBP.

Methods

This cross-sectional study was approved by our Institutional Review Board (approved on 7/04/2016) and conducted in accordance with ethical and humane principles of research of the Declaration of Helsinki.

Patients

The study involved patients attending the Physical and Rehabilitation Units at the University Hospital in Cagliari (Italy), and at the University Hospital in Rome (Italy) between September 2016 and July 2018. The inclusion criteria were chronic non-specific LBP (i.e. a pain lasting more than 12 weeks with no diagnosable cause), an age of > 18 years and fluency in Italian. Exclusion criteria were acute (up to 4 weeks) and subacute (up to 12 weeks) non-specific LBP, specific causes of LBP (e.g. disc herniation, lumbar stenosis, spinal deformity, fracture, spondylolisthesis) with or without peripheral neurological signs, non-mechanical causes of low back pain (e.g. systemic illness, such as tumour and rheumatologic diseases) and mental health/psychiatric deficits (mini-mental state examination scale of < 24).

Outpatients visiting the two involved centres during the study period were evaluated by two physiatrists, one for each centre, coordinated by the principal investigator. Those satisfying the inclusion criteria were asked to sign a written informed consent. Once the patients had given their approval to participate to the study, their demographic and clinical characteristics were recorded by research assistants.

Cross-cultural adaptation

Adaptation of the QBPDS was done in accordance with the protocol issued by the American Association of Orthopaedic Surgeon Outcomes Committee [32]. Further, principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures based on the report of the ISPOR task force were taken into account [33].

Step 1: Translation into Italian The items taken from the original QBPDS [12] were translated into Italian with the aim of retaining the concepts of the original while using culturally and clinically fitting expressions. Two translations were made independently by two Italian professional translators experienced in biomedical field. The translators were given a clear explanation of the concepts in the QBPDS, in order to capture the conceptual meaning of the items, by keeping the language colloquial and compatible with a

reading age of 12 years. Discrepancies between the translators were resolved by means of consensus; step 1 ended when a common adaptation was agreed.

Step 2: Back Translation into English Two bilingual translators, English native speakers without biomedical background, independently back-translated the initial translation. The principal investigator reviewed these translations and, with the help of the back translators, made sure that the Italian version reflected the same item content as the original version and was conceptually equivalent.

Step 3: Expert committee To achieve harmonization of the adaptation process, the translations were submitted to a bilingual committee of clinicians, methodologists and translators, chaired by the principal investigator. To identify any discrepancy or mistake, the committee explored the semantic, idiomatic and conceptual equivalence of the items and response options. This phase ended when a prefinal version was agreed.

Step 4: Test of the prefinal version A test of the prefinal version was performed to assess the level of comprehensibility and cognitive equivalence of the translation, to highlight any items that may be inappropriate at a conceptual level and to identify any other issues that cause confusion. Cognitive interviews were therefore conducted by a trained psychologist by administering the QBPDS to 20 patients with chronic LBP. The Expert Committee reviewed the results from cognitive debriefing with the aim of identifying any modification necessary for improvement of the Italian form.

Sample size

Sample size was based on the "rule of thumb" of ten subjects per item [34].

Psychometric properties

Acceptability

The time needed to answer the questionnaire was recorded. The subjects were asked about any problems they encountered, and the data were checked for missing or multiple responses.

Structural validity

The QBPDS dimensionality was explored by principal component factor analysis [35]. An eigenvalue criterion of 1.0 and a scree plot analysis were used to select relevant factors. The scale was considered unidimensional if the explained variance of the first factor was > 50% and if the ratio between the first and second eigenvalues was greater than 4 [35]. The results were given in terms of the percentage and the cumulative percentage of variance explained by the factors. Items were accepted on the final factors if they loaded 0.40 or higher on the corresponding factor.

Reliability

Internal consistency (Cronbach's alpha, with values of > 0.70 being considered acceptable) was investigated; data from item–item and item-total correlations were estimated to complement the analysis. Test–retest reliability (intraclass correlation coefficient, ICC 2.1, with good and excellent reliability, respectively, indicated by values of 0.70–0.85 and > 0.85) [34] was examined; the test–retest interval was ten days.

Measurement error

It was estimated by means of the minimum detectable change (MDC) calculated by multiplying the standard error of the measurements (SEM) by the z-score associated with the desired level of confidence (95% in our case) and the square root of 2, which reflects the additional uncertainty introduced by using difference scores based on measurements made at two time points (in our case on days 1 and 10). The SEM was estimated using the formula: SEM = SD[(1 - R)1/2], where SD is the baseline standard deviation of the measurements and R the test-retest reliability coefficient [34].

Construct validity

For construct validity [34], it was hypothesized a priori the QBPDS would achieve positive correlations ≥ 0.40 with: (a) the Italian versions of RMDQ [9], and of the ODI [10]; and $0.30 \leq 0.60$ with (b) pain intensity measured with the 0–10 Numerical Rating Scale (NRS) [36]. Spearman's correlations were calculated and construct validity was considered good if $\geq 75\%$ of the hypotheses was met.

Floor/ceiling effects

Descriptive statistics were calculated to identify floor/ceiling effects, which were considered to be present when > 15% of the subjects obtained the lowest or highest possible scores [34].

Measures

QBPDS The questionnaire includes 20 items and refers primarily to the main daily living activities that are frequently affected by LBP. These items allow subjects to rate their degree of restriction in activities from 0 ('not difficult at all') to 4 ('unable to do'). The responses to the items are added and total score ranges from 0 to 100, with higher scores indicating greater disability [12, 13].

RMDQ The Italian 24-item version displayed consistency Cronbach's alpha equal to 0.82 and ICC of 0.92. The total score varies from 0 (no disability) to 24 (maximum disability) [9].

ODI The Italian self-reported ten-item version was used. The total score ranges from 0 (no disability) to 100 (maximum disability). Cronbach's alpha was 0.86 and ICC for test–retest reliability 0.96; high correlations were found with pain (r=0.73) and physical functioning (r=0.82) [10].

NRS This is an 11-point rating scale ranging from 0 ('no pain at all') to 10 ('the worst imaginable pain') [36]. The ICC for test–retest reliability was equal to 0.92 in patients with LBP [37]. Subjects were asked to evaluate the pain they felt in the last week.

The analyses were made using R software, version 3.4.4 [38].

Results

Subjects

The study involved 201 patients with chronic LBP; 60.2% were female and mean age was 48.20 ± 11.76 years old. The median duration of complaints was 56 months (range 6–80).

Table 1	General characteristics
of the sa	mple $(n=201)$

Variable	N (%)
Gender	
Male	80 (39.8)
Female	121 (60.2)
Marital status	
Married	140 (69.7)
Not married	52 (25.9)
Missing	9 (4.4)
Employment	
Employee	165 (82.1)
Self-employed	8 (4.0)
Housewife	27 (13.4)
Pensioner	1 (0.5)
Education	
Elementary school	9 (4.5)
Middle school	33 (16.4)
High school	96 (47.8)
University	61 (30.3)
Missing	2 (1.0)
Smoking status	
Smoker	41 (20.4)
Non-smoker	160 (79.6)

The mean body mass index was 24.26 ± 3.67 . Table 1 shows socio-demographic characteristics.

Translation and cross-cultural adaptation

The translation procedure took 1 month to reach a culturally adapted version, and all the items were easily forward- and back-translated; no difficulties were evidenced during the review of the back translations. The correctness of the process, the content of the items and the concepts expressed were confirmed by the experts. The cognitive interviews confirmed the comprehensibility and the cognitive equivalence of the translation; no other issues were pointed out. Finally, the principal investigator and the Expert Committee confirmed the work performed. The Italian version of the QBPDS (QBPDS-I) is reproduced in "Appendix".

Scale properties

Structural validity

The Bartlett test of sphericity was statistically significant (p < 0.001), and the value found for Kaiser–Meyer–Olkin measure of sampling adequacy was 0.925, and therefore, an exploratory factor analysis was performed. This analysis showed the existence of one dominant factor that explained 54.7% of the variance, with two factors exhibiting an eigenvalue larger than 1 (Table 2). The ratio between the eigenvalues of the two factors was larger than 4; also, the additional factor led only to a moderate improvement in the explained variance (9.6%) in the unrotated model, suggesting the relational structure of QBPDS-I items was explained by a predominant common factor, thus reflecting the substantial unidimensionality of the scale (Table 2).

Loadings were more than 0.40 on each items. The subsequent analyses were therefore conducted considering a one-factor 20-item solution as "sufficiently unidimensional".

Acceptability

All of the questions were well accepted. The questionnaire was completed in 8.4 ± 1.6 min. No missing responses or multiple answers were found. There were no further problems in comprehension.

Reliability

Cronbach's α was 0.95. The item-total correlation of the individual items with the total scale ranged from 0.37 to 0.83, showing moderate-to-strong correlations of the single items with the total scale (Table 3). The lowest estimate observed was 7 (rated by one patient, 0.7% out of 201 subjects), and the highest one was 83 (rated by one patient,

Table 2Total varianceexplained

PC	Initial eigenvalues			Extraction sums of squared loadings			Rotation sums of squared loadings	
	Total	% Variance	Cumulative %	Total	% Variance	Cumulative %	Total	% Variance
1	8.957	54.670	54.670	8.957	54.670	54.670	7.117	43.440
2	1.574	9.605	64.275	1.574	9.605	64.275	3.413	20.835
3	0.854	5.211	69.486					
4	0.617	3.767	73.253					
5	0.548	3.348	76.601					
6	0.502	3.062	79.663					
7	0.434	2.648	82.311					
8	0.415	2.533	84.845					
9	0.363	2.216	87.061					
10	0.277	1.690	88.751					
11	0.273	1.663	90.415					
12	0.250	1.525	91.939					
13	0.240	1.466	93.405					
14	0.207	1.264	94.669					
15	0.189	1.154	95.824					
16	0.176	1.072	96.896					
17	0.155	0.947	97.843					
18	0.146	0.891	98.734					
19	0.120	0.735	99.468					
20	0.087	0.532	100.000					

PC principal component

0.7%). Test-retest reliability was excellent (ICC = 0.90; 95% CI 0.86-0.93).

Measurement error

The MDC was 11.7, reflecting the smallest changes in score that are likely to reflect a true change rather than a measurement error.

Construct validity

It was good as all of the a priori hypotheses were confirmed (Table 4). The correlations among the QBPDS-I and the other physical functioning measures were as expected (RMDQ: r=0.40; ODI: r=0.48), as well as pain intensity (NRS: r=0.44).

Distribution and floor/ceiling effects

The QBPDS-I had no significant floor/ceiling effects.

Discussion

This study describes the process of cross-cultural adaptation, structural validity, reliability, measurement error and construct validity of the QBPDS in Italian-speaking subjects with chronic LBP. While the scale was unidimensional, it displayed good reliability measurement error and construct validity.

Cross-cultural adaptation required a process of translation, backward translation, expert committee revision and testing of the prefinal version in order to guarantee the meaning of the original items was adequately captured in the Italian language: all of the steps indicated its development was successful and followed recommended guidelines. The experts played an important role during the evaluation of the cross-cultural adaptation and confirmed the work done. The on-field text confirmed the comprehensibility of the translated items, thus leading to a valid measure of another culture's conception of health, allowing data comparability and cross-national studies.

The questionnaire was highly acceptable, easily understood and capable of being self-administered and required less than ten minutes to complete. It therefore seems to be

 Table 3
 Reliability analysis

Item	Test mean (SD)	Retest mean (SD)	Correlation with QBPDS- I
1	1.96 (0.9)	1.97 (0.9)	0.75
2	2.00 (1.0)	2.02 (0.9)	0.70
3	2.06 (1.0)	1.99 (0.9)	0.74
4	2.02 (1.0)	2.09 (1.1)	0.83
5	1.93 (0.9)	1.91 (0.9)	0.81
6	1.63 (1.0)	1.76 (1.0)	0.73
7	2.01 (0.8)	2.00 (0.9)	0.70
8	2.05 (0.9)	2.05 (0.9)	0.75
9	2.19 (1.1)	2.10 (1.1)	0.79
10	2.13 (0.9)	2.11 (0.9)	0.83
11	1.80 (0.8)	1.81 (0.9)	0.67
12	2.22 (0.9)	2.19 (1.0)	0.77
13	0.65 (0.9)	0.95 (1.0)	0.50
14	1.89 (0.9)	1.90 (1.0)	0.69
15	0.73 (0.9)	1.05 (1.0)	0.37
16	1.45 (0.7)	1.45 (0.9)	0.65
17	0.60 (0.9)	1.02 (1.0)	0.40
18	0.67 (0.9)	1.13 (1.0)	0.48
19	1.11 (0.9)	1.22 (1.0)	0.77
20	1.07 (0.8)	1.11 (1.0)	0.79
QBPDS-I	32.15 (13.2)	33.85 (11.9)	_

Distributions and Spearman's correlations between QBPDS-I and its items

QBPDS-I Quebec Back Pain Disability Scale, Italian version

Table 4 Construct validity

Outcome measures	QBPDS-I	Test mean (SD)	Floor/ceil- ing effects (%)
RMDQ	0.40	13.6 (3.7)	0/0 (0/0)
ODI	0.48	15.9 (4.9)	0/0 (0/0)
NRS	0.44	7.0 (1.4)	0/1 (0/0.5)

Spearman's correlations between the QBPDS -I and RMDQ, ODI and NRS

QBPDS-I Quebec Back Pain Disability Scale, Italian version, *RMDQ* Roland Morris Disability Questionnaire, *ODI* Oswestry Disability Index, *NRS* pain intensity Numerical Rating Scale

applicable in everyday clinical practice. However, among various content validity aspects, only the comprehensibility of the QBPDS was assessed in this study, whereas its relevance and comprehensiveness to measure physical functioning in patients with LBP were not assessed; this research gap should be filled by future studies conducting a thorough assessment of content validity, possibly following the recently published COSMIN methodology [39]. The use of exploratory factor analysis helped to evaluate the factorial structure of the Italian version. A one-factor solution provided the best balance between clinical significance and explained variance, as also found in Portuguese subjects [25]. The original developers as well as Greek researchers showed a six-factor solution, and Hindi and German researchers found a four-factor solution, probably due to different cultures concerning disability impact on activities of daily living [12, 21, 27, 28].

The close correlations among the items showed the Italian QBPDS was internally consistent and in line with the original version results (i.e. 0.96) [12]. Our findings are also consistent with Dutch (0.90), Iranian (0.86), Turkish (0.92), Brazilian (0.93), Greek (0.92) Polish (0.93), Arabic (0.86–0.98), Korean (0.91), Portuguese (0.95), Chinese (0.99), Hindi (0.96), German (0.94), Moroccan (0.98) and Tswana (0.95) estimates [16, 18–30] and higher than French (0.55, higher retest interval) estimate [17].

Test–retest reliability was indicated by the excellent agreement between the results on days 1 and 10, as shown by the original scale (i.e. 0.92) [12]. Our findings are in line with Dutch (0.95), Iranian (0.92), Turkish (0.93–0.94), Brazilian (0.97), Polish (0.92), Arabic (0.92), Korean (0.95), Portuguese (0.95), Chinese (0.98), Hindi (0.98), Moroccan (0.96) and Tswana (0.91) estimates [16, 18–20, 22–27, 29, 30].

As for construct validity, the correlations with the RMDQ and the ODI were as expected (Table 4). However, it should be noted the QBPDS is a 20-item questionnaire that is designed to assess the day-to-day impact of LBP disability on physical functioning. It differs from the RMDQ and the ODI because it is much more focused on physical activity rather than the global functioning of a patient with LBP. Therefore, we expected not very high hypotheses between the QBPDS and these other tools, as correlations > 0.60 or 0.70 would be normally expected for questionnaires measuring the same construct.

Our correlations were in line with German findings (RMDQ: 0.54). However, all of other studies found correlations > 0.60 with these instruments: original developers (RMDQ: 0.77; ODI: 0.80), Dutch (RMDQ: 0.80), Turkish (ODI: 0.68), Brazilian (RMDQ: 0.85), Greek (RMDQ: 0.70; ODI: 0.78), Polish (RMDQ: 0.82), Arabic (ODI: 0.67), Korean (ODI: 0.72), Portuguese (ODI: 0.62), Chinese (ODI: 0.91), Hindi (RMDQ: 0.77) and Moroccan estimates (RMDQ: 0.64) [12, 16, 19–27, 29]. It is possible that in the Italian clinical context some QBPDS items are interpreted differently than in other countries; these could be the items displaying a correlation < 0.50 with the total score (i.e. 15, 17 and 18).

The remaining existing versions introduced other measure of disability, and therefore, comparisons with our data are not possible (French: Dallas Pain questionnaire; Turkish and German: Pain Disability Index, and Tswana: Disability Rating Index) [17, 19, 30].

As for correlation with pain intensity, our results were higher than Moroccan (0.01), in line with the original developers (0.54), French (0.49), Persian (0.46), Turkish (0.44–0.47), Portuguese (0.38), German (0.46) studies, and lower than Dutch (0.74), Brazilian (0.75), Arabic (0.61), Korean (0.65), Chinese (0.77), Hindi (0.68) and Tswana (0.68) reports [12, 16–20, 23–30].

The QBPDS-I also proved to display an acceptable measurement error. Given the high degree of repeatability of our results, the SEM and MDC were reduced and ensured that it could identify changes in the scores exceeding the threshold of instrument noise. At a 95% confidence level, the MDC indicates that, if an individual shows a change of more than 12 points after a given intervention, it would not be a measurement error.

This study has some limitations. Firstly, it is a cross-sectional study and responsiveness of the QBPDS could not be assessed. Secondly, the relationships between back-related physical functioning and physical tests were not considered because only questionnaires were used. Thirdly, correlations with other measures including psychological factors (e.g. Tampa Scale of Kinesiophobia, Pain Catastrophizing Scale or Pain Self-Efficacy Questionnaire) and quality of life issues (e.g. Short-Form Health Survey 36-items) were not analysed. Fourthly, our study was restricted to patients with non-specific chronic LBP and it is uncertain whether these findings can be extended to patients with (sub)acute LBP or specific causes for LBP, such as disc herniation or stenosis. Future studies in these populations are recommended.

Conclusions

The Italian version of QBPDS shows a one-factor structure, and it is reliable and valid and has an acceptable measurement error. This adapted QBPDS can be recommended for clinical and research purposes in order to improve the assessment of disability of chronic LBP.

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Compliance with ethical standards

Conflicts of interest The authors declare that they have no conflict of interest.

IRB approval The study was approved by our hospital's Institutional Review Board and was conducted in accordance with ethical and humane principles of research.

Appendix: Quebec Back Pain Disability Scale

Il presente questionario intende valutare in che modo il mal di schiena influenza la tua vita quotidiana. Soggetti con problemi alla schiena possono trovare difficoltà a svolgere alcune attività di ogni giorno. Pertanto, vorremmo sapere se a causa della tua schiena hai difficoltà a svolgere alcune delle attività descritte di seguito. Per ogni attività è possibile rispondere da 0 a 5. Per cortesia, scegli una risposta per ogni attività (senza saltarne nessuna) cerchiando il numero corrispondente.

Oggi, hai difficoltà a svolgere le seguenti attività a causa della tua schiena?

Oggi, hai difficoltà a svolgere le seguenti attività a causa della tua schiena?

	0.Non ho nessuna difficoltà	1.Ho un po' di difficoltà	2.Ho abbastanza difficoltà	3.Ho difficoltà	4.Ho molta difficoltà	5.Non riesco a compiere l'attività
1. Alzarsi dal letto						
2. Dormire di notte						
3. Girarsi nel letto						
4. Viaggiare in macchina						
5. Stare in piedi per 20-30 minuti						
6. Sedere su una sedia per alcune ore						
7. Salire una rampa di scale						
8. Camminare per 300-400 metri						
9. Camminare per alcuni chilometri						
10. Raggiungere gli scaffali più alti						
11. Lanciare una palla						
12. Correre per 100 metri						
13. Tirare fuori gli alimenti dal frigorifero						
14. Rifare il letto						
15. Infilarsi le calze						
16. Piegarsi in avanti per pulire la vasca da						
bagno						
17. Spostare una sedia						
18. Tirare o spingere porte pesanti						
19. Trasportare due borse della spesa						
20. Sollevare e trasportare una valigia pesante						

Punteggio totale:____/100

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