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Italian version of the Roland Disability Questionnaire, specific for low back pain: cross-cultural adaptation and validation

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Abstract Over the last 10 years, patient-oriented evaluations using questionnaires have become an important aspect of clinical spinal outcome studies. Any questionnaire must be translated and culturally adapted in order to be used with different language groups, and the translated version must then be evaluated for reliability and validity, which are fundamental attributes of any measurement tool. The Roland Disability Questionnaire, a low back pain disease-specific tool, was submitted to translation into Italian and to cross-cultural adaptation following the Guillemin criteria. It was then validated on 70 patients (37 male and 33 female; mean age 58, range: 28–67) suffering from low back pain as assessed by clinical examination, imaging and also electromyography in cases of suspected neurological impairment. The test-retest reliability, assessed with intraclass correlation, was 0.92 and the internal consistency reached a Cronbach's alpha of 0.82. The Italian version of the Roland Disability Questionnaire sat-

isfied the validation criteria, showing characteristics of reliability and validity similar to previously published versions translated and adapted for other countries.

Keywords Low back pain · Questionnaire · Spine · Outcome assessment

Introduction

Orthopedic outcome measurements have usually focused on objective parameters such as radiographic measures or other technical aspects [8, 12, 17]. However, these parameters are weakly related with the outcomes that are most

relevant to patients, such as functional status and symptoms [2, 18]. Over the past 10 years, patient-oriented measures have become an important aspect of spinal clinical outcome evaluation [1, 5, 7, 13]. The most common instruments used to assess the patient's perspective are self-administered questionnaires, which must be subjected to a validation process to evaluate reliability and validity,

which are fundamental attributes for any instrumental measure [13, 17].

In the literature, the proposed questionnaires are often published in English. These tools must be translated and culturally adapted if they are to be used with different language groups and in different countries.

Currently, low back pain is one of the clinical conditions most intensely studied. A number of disease-specific questionnaires have been developed to assess low back pain [7, 16]. We chose the Roland Disability Questionnaire to translate and submit to a validation process, because it has been translated into a number of different languages [4, 6, 9, 11, 20] and is widely used in the literature. The purpose of this study is to validate the Italian cross-culturally adapted version of the Roland Disability Questionnaire.

Materials and methods

As has been previously described in literature [10, 13, 14], we have submitted the Roland Disability Questionnaire (RDQ) to validation through a process involving translation, cultural adaptation and testing. The RDQ assesses low back pain through 24 items, providing a numerical score (ranging from 0=no disability to 24=severe disability).

Translation and cultural adaptation

The RDQ was translated and culturally adapted for use with Italian speaking people during a previously published study [15]. In order to validate the questionnaire, three new translations were obtained by two independent professional mother tongue translators and one physician. These new versions did not show substantial differences from the earlier version, and we therefore decided to submit our original translation for validation. A back-translation was obtained and checked for inconsistencies. After the clinical phase of the study, we discovered the existence of a second non-validated Italian version [6]. We therefore compared the two versions, and as no meaningful differences were noted, we decided to proceed with the validation of our original translation.

Testing

The study was carried out on 70 patients (37 male and 33 female; mean age 58, range: 28–67) suffering from low back pain, as assessed by clinical examination (either orthopedic or neurologic), imaging (radiographic analysis, computed tomography and/or magnetic resonance imaging), and electromyography in cases of suspected neurological impairment.

Each patient filled in:

1. Our Italian version of the RDQ
2. The SF-36 official Italian version [3]
3. A visual analogue scale (VAS)

The questionnaires were administered in waiting rooms by paramedic staff, before meeting the physicians, as proposed in the literature [13, 19].

The SF-36 consists of 36 questions inquiring about the general health status of patients. This questionnaire provides eight specific

categories of physical and emotional scores: Physical functioning (PF), Role-physical (RP), Bodily pain (BP), General health (GH), Vitality (VT), Social functioning (SF), Role-emotional (RE), Mental health (MH), collapsed into two main scores: Physical composite score (PCS) and Mental composite score (MCS). Very low scores for PCS indicate severe physical dysfunction, distressing bodily pain, frequent tiredness and an unfavourable evaluation of the health status. Very low scores for MCS indicate frequent psychological distress, and severe social and role disability due to emotional problems [19].

Statistical analysis was performed to assess reliability and validity, using Cronbach's alpha for internal consistency, the ICC for reproducibility, and Pearson's correlation coefficient for correlation between the subjective assessments. Reproducibility was tested by administering the questionnaire twice to a subsample of 30 patients. We used a 48-h interval, on the assumption that during this period the clinical situation would not change (no drugs were administered to patients). No significant differences were found between the two patient groups (the whole population and the 30 patients used for the test-retest). The validity was tested by comparing the RDQ scores with the VAS, as was performed in the validation of the original English language RDQ [16], and with the SF-36, as performed in literature [20].

Results

The patients found no difficulty in filling in the questionnaires (mean time required: 5 min).

The test-retest reliability, assessed with intraclass correlation (ICC), was 0.92, and the internal consistency reached a Cronbach's alpha of 0.82.

As regards the correlation between SF-36, RDQ and VAS scores, summarized in Table 1, high levels of correlation appear from statistical analysis. In particular, analy-

Table 1 Correlation of the Italian version of the Roland Disability Questionnaire (RDQ) with a visual analogue pain scale (VAS) and with scores on the eight domains of the SF-36 – Physical functioning (PF), Role-physical (RP), Bodily pain (BP), General health (GH), Vitality (VT), Social functioning (SF), Role-emotional (RE), Mental health (MH) – as well as with the SF-36 Physical composite score (PCS) and Mental composite score (MCS). Mean (SD) scores, Pearson's correlation coefficient (R) and statistical significance (P-value) are presented

	Mean score (SD)	Correlation with RDQ	P-value
RDQ	15.4 (5.7)	–	–
VAS (100 mm)	42.2 (20.8)	R=0.79	P<0.001
SF-36 (PF)	40.3 (20.5)	R=0.68	P<0.001
SF-36 (RP)	21 (28.5)	R=0.62	P<0.001
SF-36 (BP)	35.1(20.8)	R=0.61	P<0.001
SF-36 (GH)	42.8 (20.7)	R=0.55	P<0.002
SF-36 (VT)	44.1 (21.2)	R=0.53	P<0.005
SF-36 (SF)	56.5 (27.2)	R=0.50	P<0.005
SF-36 (RE)	49.1 (40.2)	R=0.25	n.s.
SF-36 (MH)	62.7 (22.9)	R=0.32	n.s.
SF-36 (PCS)	31.2 (10.1)	R=0.65	P<0.001
SF-36 (MCS)	45.1 (14.2)	R=0.39	n.s.

sis of the eight domains of the SF-36 and composite scores shows statistically significant results for all domains except for RE, MH and MCS. The correlation with the VAS results also shows good results ($R=0.79$ and $P<0.001$). All these data are similar with the results published in a previous paper on another cross-cultural validation of the RDQ (German-language version) [20].

Discussion

The development of tools to measure patients' symptoms has been mainly carried out by the English mother tongue scientific community. Therefore, most of the questionnaires are written in English and tailored for the Anglo-Saxon culture. The need to include the patient's perspective in scientific papers puts an onus on the European scientific community to adopt such types of analysis. The process of spreading such evaluation systems throughout Europe requires either the elaboration of new questionnaires or the adaptation of those already in existence in countries with a different language and culture. The former solution implies a complex procedure, whereas the latter demands a linguistic and cultural adaptation process and a statistical validation of the new version. The transcultural adaptation procedure, which was described by Guillemin in 1993 with regard to non-specific questionnaires, is without doubt more challenging than a mere linguistic translation. However, the development of disease-specific questionnaires is slightly more simple. Whereas the transcultural adaptation of generic health status questionnaires requires a complex analysis of psychological and cultural aspects, the analysis of symptoms shared in specific pathologies is simpler. In the latter case, the subjective complaints are investigated through specific questions, without fundamental interference of cultural influences. A further element favouring the translation of existing questionnaires over the development of new ones is that the diffusion of a single questionnaire into the international scientific community will allow the performance of meta-analysis studies and the standardization of outcome measurement. The RDQ has already been translated into a number of different languages [4, 6, 9, 11, 20], and is widely used in the spinal literature. For these reasons, the validation process of the Italian version is of great importance.

The Italian version of the RDQ showed levels of reliability and validity comparable to the English and German versions. The strong correlation between the RDQ and the SF-36 physical domains and VAS scores must particularly be underlined. The non-significant results regarding the SF-36 mental domains (RE, MH and MCS), and the higher probability value ($P<0.005$) regarding the other mental domains are consistent, because these SF-36 domains analyse mental health, which is not directly correlated to LBP. The behaviour of correlation between the

RDQ and SF-36 domains appears similar in the Italian and German versions. The results of this validation study also confirm the results of a previous study that used this Italian version of the RDQ [15].

Hence, we can state that the Italian RDQ version proved to have equivalent evaluation capacities to published versions in other languages. Furthermore, the basic features of any measuring tool, such as reproducibility, consistency and validity satisfied the statistical requirements.

Appendix

Questionario autocompilato dal paziente
per la valutazione del lombalgia

Quando avete mal di schiena trovate difficile eseguire alcune abituali attività. Questa lista contiene alcune frasi che la gente utilizza per descrivere cosa prova quando ha mal di schiena. Leggendole potrete notare che alcune di esse ben descrivono come vi sentite *oggi*. Leggendo la lista pensate a come vi sentite oggi. Se una frase descrive bene il modo in cui vi sentite oggi segnate con un cerchio il numero della frase. Se invece la frase non descrive il vostro stato, lasciatela in bianco e passate alla successiva.

Importante: segnate solo le frasi che ben descrivono il modo in cui vi sentite oggi

1. Per il mio dolore alla mia schiena rimango la maggior parte del tempo a casa
2. Cambio frequentemente posizione per trovare e mantenere una posizione comoda per la mia schiena
3. Per il mio dolore alla schiena io cammino più lentamente che al solito
4. Per il mio dolore alla schiena io non faccio alcun lavoro che normalmente facevo per la casa
5. Per il mio dolore alla schiena io uso il corrimano per salire le scale
6. Per il mio dolore alla schiena io mi stendo per riposare più spesso
7. Per il mio dolore alla schiena devo appoggiarmi a qualcosa per alzarmi da una poltrona
8. Per il mio dolore alla schiena io cerco di far fare le cose ad altri per me
9. Io mi vesto più lentamente per il dolore alla schiena
10. Per il mio dolore alla schiena riesco a stare in piedi solo per breve tempo
11. Per il mio dolore alla schiena evito di piegarli o di inginocchiarsi
12. Per il mio dolore alla schiena trovo difficoltà nell'alzarmi da una sedia
13. Ho dolore alla schiena quasi sempre
14. Ho difficoltà nel girarmi nel letto
15. Per il mio dolore alla schiena ho uno scarso appetito
16. Per il mio dolore alla schiena faccio fatica a mettere le calze

17. Per il mio dolore alla schiena posso percorrere a piedi solo brevi distanze
18. Per il mio dolore alla schiena dormo meno
19. Per il mio dolore alla schiena posso vestirmi solo con l'aiuto di qualcuno
20. Per il mio dolore alla schiena resto seduto per gran parte della giornata
21. Per il mio dolore alla schiena sono costretto ad evitare lavori domestici pesanti
22. Per il mio dolore alla schiena sono più irritabile e di cattivo umore del normale
23. Per il mio dolore alla schiena salgo le scale più lentamente del normale
24. Per il mio dolore alla schiena rimango a letto quasi tutto il tempo

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