

The examination of decreased function due to
low back pain with validated, self-reported
questionnaires

Doctoral theses

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Introduction

Low back pain (LBP) is defined as the pain experienced between the lower ribs and the lower gluteal folds. Its symptoms can occur with or without pain radiating down the lower extremities.

The LPB is a symptom which affects a wide range of the population. LBP causes a severe health care and socio-economic problem for the society due to its high lifetime prevalence, the recrudescence nature of its symptoms, the frequent development of chronic condition, as well as due to the decrease in function and the handicap it can result in. The pathological reasons underlying the complaints cannot always be unequivocally identified, as radiological findings show only weak to moderate correlation with the symptoms. These paradoxes of the LPB highlight the importance of other tools next to the physical examination and diagnostic imaging in assessing the patients' conditions.

In the musculoskeletal practice – as a result of the last decades’ developmental work, experience and various scientific researches with high levels of evidence – patient reported outcome measures (PROM) have become the primary tools for clinical assessment and therapeutic follow-up. Due to the self-reported style, they are suitable to collect data from a large number of patients. Their cost is negligible. Their application is fully accepted in the international clinical practice and they have become essential measurement tools in scientific researches.

The original language of PROMs used in the international practice is usually English. These English language questionnaires cannot be scientifically used in other languages after a simple translation. At first, the cultural adaptation and translation process, then a repeated clinical validation process in the target language must be carried out, so that the versions of target language are also going to yield accurate, comparable results.

Purpose

The purpose of our study was to create the validated, scientifically proved Hungarian versions of the most essential, internationally widespread low back specific, self-reported questionnaire. By reason of their international acknowledgement, we undertook to carry out the adaptation and validation process of the Oswestry Disability Index (ODI), Quebec Back Pain Disability Scale (QDS), Roland-Morris Disability Questionnaire (RMQ) and the Core Outcome Measures Index (COMI).

To achieve our purpose, four cross-sectional and one prospective studies were carried out and answers were searched for the following questions:

Are the Hungarian PROMs (ODI, QDS, RMQ, COMI), after the cultural adaptation and translation process, comprehensible and suitable – from a linguistic point of view – to collect data from a large number of divergent patients.

- Do the internal consistency data of the Hungarian questionnaires show, in all four cases (ODI, QDS, RMQ, COMI), scientifically acceptable results?
- Is the repeatability of the newly created Hungarian versions suitable?
- What is the value of the standard error of measurement as well as that of the minimal detectable change of the Hungarian PROMs?
- Do the scientific studies of the Hungarian versions verify their construct validity?
- Do the validated questionnaires reflect the efficiency of the therapeutic intervention during prospective clinical follow-up?

Methods

As a first step of our research, we created the Hungarian versions of the questionnaires and studied the clinicometric properties of the PROMs by applying it in LBP patients. As a second step, we aimed to present the practical application of self-reported questionnaires through the examination of therapeutic outcome in degenerative LBP patients. Thus, two closely connected researches are brought forward:

- **Validation study:** the making of the Hungarian versions of the ODI, QDS, RMQ and COMI.
- **Prospective study of therapeutic outcome:** the introduction of the practical application of the validated Hungarian questionnaires through the follow-up examination of patients with lumbar disc herniation.

Method of the validation studies

To create the Hungarian versions of all four questionnaires, two work phases followed each other. In the first phase, the cultural adaptation and linguistic validation of the ODI, QDS and RMQ were carried out. In the second phase, the clinicometric properties of these Hungarian questionnaires were defined.

The cultural adaptation and linguistic validation consisted of 5 steps: translation from English to Hungarian, synthesis, reverse translation, consensus, pretesting.

On testing the questionnaires with the patients, the ODI and QDS were examined together. Later, the validation study of the RMQ was carried out, to which the validated Hungarian version of the ODI was used as well. Finally, the Hungarian version of the COMI was certified and the valid Hungarian version of the ODI was also used in this process.

During statistical analysis, the distribution of the received data, then the presence of the floor and ceiling effect were checked.

The internal consistency of the Hungarian versions was checked as well. To do so, at first the factor analysis was used in case of the ODI and QDS. After assessing the factor structure, the characteristic value of internal consistency, the Cronbach-alpha, was calculated. In case of the RMQ and COMI, the Cronbach-alpha was directly determined.

The examination of the repeatability was carried out by test-retest method. The presence of accidental differences between the two data acquisition was analyzed by paired t-test. The Interclass correlation coefficient (ICC) was calculated by the two-way random ANOVA model.

Finally, in case of every studied questionnaire, the standard error of measurement (SEM) was calculated, as well as we also determined the minimal detectable change (MDC) at a confidence level of 95%.

During the testing of construct validity – in the absence of a gold standard- patients were assigned into

subgroups according to clinical severity: surgical/ non-surgical, with/ without neurological deficit. Two-sample t-test was used to find out, whether the studied questionnaires can detect any significant, clinical differences between the subgroups.

To test construct validity, we also examined the correlation of the spine specific questionnaires with the physical subscale of the previously validated general quality of life questionnaire, WHOQoL, as well as with the pain. Data measuring pain intensity were taken by visual analogue scale in case of the ODI, QDS, RMQ and COMI. To examine the correlation during the validation process of the RMQ and COMI, the already validated Hungarian version of the ODI was used.

The method for prospective examination of the therapeutic outcome

The practical application of the validated Hungarian questionnaires was demonstrated through the prospective follow-up of patients with mono-segmental lumbar disc herniation.

To measure therapeutic outcome, the National Center for Spinal Disorders, Budapest, introduced the everyday application of the ODI and COMI. In accordance with that, the questionnaire booklet created for the purpose of our study contained these two PROMs.

Values of the maximal pain, which were assessed by a Visual Analogue Scale (VAS) in the questionnaire, acquired from the subdimensions of COMI were analyzed separately, too. Patients filled out the questionnaire booklet prior to their treatment, then 3, 6, 12 and 24 months after it as well.

Patients received surgical or non-surgical treatment depending on which group they were assigned into. The intervention for the surgical group was the removal of those disc fragments compressing the nerve

(microdiscectomy), as well as mono-segmental stabilization (fusion).

The therapy of the non-surgical subgroup consisted of NSAID or i.v. steroid, McKenzie therapy and stabilization training.

During statistical calculation, we first checked the distribution of the acquired data as well as the incidental presence of the floor and ceiling effect. To examine the efficiency of therapeutic interventions, the ODI, COMI and VAS scores acquired on five different occasions were analyzed with the repeated measures analysis of variance (ANOVA).

The statistical analysis of both validation studies and the follow-up were executed by SPSS 21.0 program and $p < 0,05$ was considered significant.

Results

The ODI and QDS showed a one-factor and four-factor structure, respectively. The Cronbach-alpha value was between 0,86 and 0,95. All four questionnaire showed significant difference between the subgroups ($p < 0,001$). Correlation studies brought strong and significant results ($p < 0,001$, rho, $r > 0,5$) in all cases. The ICC results were between 0,91 - 0,93. Results of the standard error of measurement were 4,8 (ODI), 5,2 (QDS), 1,7 (RMQ), 0,6 (COMI) as well as the minimal detectable change (MDC) results were 13, 14, 5 and 1,6, respectively. The prospective follow-up examination proved the ODI and COMI suitable for demonstrating the therapeutic outcome both in the surgical and non-surgical group ($p < 0,01$).

During our validation study, we followed the latest, international, consensus-based nomenclature and methodical recommendations. The quality criteria for medical questionnaires, regarding the Hungarian versions, are listed in figure 1.

Figure 1: Quality criteria for the validated questionnaires.

PROM	Cultural adaptation, lingual validation					Reliability			Validity	Responsiveness
	1.	2.	3.	4.	5.	6.	7.	8.	9.	
ODI	+	+	+	+	+	+	+	+	+	0
QDS	+	+	+	+	+	+	+	+	+	0
RMQ	+	+	+	+	+	+	+	+	+	0
COMI	+	+	+	+	+	+	+	+	+	0

1. translation, 2. synthesis, 3. reverse translation, 4. consensus, 5. pretesting, 6. internal consistency, 7. repeatability, 8. error of measurement, 9. constructive validity

+: examined criterion with positive result

-: examined criterion with negative result

0: non-examined criterion

Conclusion

We can draw the following conclusions based on the results of our study:

- After the cultural adaptation and translation process, the Hungarian PROMs (ODI, QDS, RMQ, COMI) came to have a plain language and are suitable for collecting data from a large number of distinctive patients.
- Internal consistency data showed scientifically acceptable results in all of the Hungarian versions ($0,75 \leq \text{Cronbach alfa} \leq 0,95$).
- Repeatability index of the Hungarian versions is adequate ($\text{ICC} > 0,70$).
- The standard error of measurement in case of the ODI, QDS, RMQ and COMI were 4,8; 5,2; 1,7; 0,6, respectively. The minimal detectable change scored 13 (ODI), 14 (QDS), 5 (RMQ) and 1,6 (COMI).

- Our scientific studies proved the constructive validity of the Hungarian questionnaires, as a substantive difference between the clinical subgroups was demonstrated. Moreover, the correlation studies brought adequate results regarding both the physical function and the pain ($r, \rho > 0,50$).
- The validated questionnaires were proved to be suitable to demonstrate the efficiency of therapeutic interventions and to follow up patients' condition during prospective examination ($p < 0,01$).

List of my own publications

Publications in connection with the subject of my doctoral thesis:

Valasek T, Varga PP, Szoverfi Z, Kumin M, Fairbank J, Lazary A. (2013) Reliability and validity study on the Hungarian versions of the Oswestry disability index and the Quebec back pain disability scale. *Eur Spine J*, 22: 1010-1018.

Valasek T, Varga PP, Szovérfi Z, Bozsodi A, Klemencsics I, Fekete L, Lazary A. (2014) Validation of the Hungarian version of the Roland-Morris disability questionnaire. *Disabil Rehabil* (*first online published*)

Publications not connected with the subject of my doctoral thesis:

Kovács E, Tóth K, Dénes L, **Valasek T**, Hazafi K, Molnár G, Fehér-Kiss A. (2012) Effects of exercise programs on balance in older women with age-related visual problems: a pilot study. Arch Gerontol Geriatr, 55: 446-452.