

DISABILITY IN PATIENTS WITH CHRONIC NON-SPECIFIC LOW BACK PAIN: VALIDATION OF THE SLOVENE VERSION OF THE OSWESTRY DISABILITY INDEX

OVIRANOST BOLNIKOV S KRONIČNO ENOSTAVNO BOLEČINO V KRIŽU: OVREDNOTENJE SLOVENSKE RAZLIČICE VPRAŠALNIKA OSWESTRY DISABILITY INDEX

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Abstract

Aim: To validate the Slovene version of the Oswestry Disability Index.

Method: A case series study of 129 adult patients with non-specific chronic low back pain attending a 10-day physical therapy programme. Visual Analog Pain Scale (VAS), Euroqol questionnaire (EQq), and Oswestry Disability Index (ODI) were used at the beginning and at the end of the physical therapy programme.

Results: Cronbach's α of the Slovene ODI was 0.876 at the beginning of the physical therapy programme and 0.901 at the end of the programme. All items of the questionnaire loaded on the same factor. A significant positive correlation existed between the Slovene ODI and VAS, EQ-5D and EQ-VAS at the beginning of the physical therapy programme ($r=0.630$, $p<0.001$; $r=0.657$, $p<0.001$; $r=-0.510$, $p<0.001$, respectively), as well as at the end of the programme ($r=0.491$, $p<0.001$; $r=0.725$, $p<0.001$; $r=-0.648$, $p<0.001$, respectively). The difference between ODI scores obtained at the first and at the second interview was 2.7 ± 5.2 ($p<0.001$), and the difference between ODI disability scores was 5.4 ± 10.5 ($p<0.001$). The effect size of the Slovene ODI questionnaire was 0.30.

Conclusions: The Slovene ODI questionnaire is a reliable and valid instrument for assessing outcomes of physical therapy in patients with chronic non-specific low back pain.

Key words: disability evaluation, low back pain, physical therapy, validation studies, questionnaire

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Izvleček

Namen: Z raziskavo smo želeli ovrednotiti slovensko različico vprašalnika Oswestry Disability Index.

Metode: Izvedli smo raziskavo na 129 odraslih bolnikih s kronično enostavno bolečino v križu, ki so se udeležili 10-dnevne ambulantne fizioterapije. Prvi in zadnji dan fizioterapije so izpolnili bolečinsko lestvico VAS, vprašalnik EuroQol (EQ) in vprašalnik Oswestry Disability Index (ODI).

Rezultati: Cronbachov koeficient α pri slovenski različici ODI na začetku fizioterapije je znašal 0,876, na koncu pa 0,901. Vsa vprašanja vprašalnika so tvorila en sam faktor. Korelacija med ODI in VAS, EQ-5D ter EQ-VAS na začetku fizioterapije je bila statistično značilna: $r=0,630$, $p<0,001$; $r=0,657$, $p<0,001$; $r=-0,510$, $p<0,001$. Korelacija med ODI in VAS, EQ-5D in EQ-VAS na koncu fizioterapije je bila prav tako statistično značilna: $r=0,491$, $p<0,001$; $r=0,725$, $p<0,001$; $r=-0,648$, $p<0,001$. Razlika med seštevkom točk na vprašalniku ODI na začetku in na koncu fizioterapije je bila $2,7 \pm 5,2$ točk ($p<0,001$); med točkami, ki označujejo oviranost na vprašalniku ODI, pa $5,4 \pm 10,5$ točk ($p<0,001$). Ocena učinka slovenske različice vprašalnika ODI je bila 0,30.

Sklepi: Slovenska različica vprašalnika ODI je zanesljivo in veljavno orodje za ugotavljanje učinka fizioterapije pri bolnikih s kronično enostavno bolečino v križu.

Ključne besede: oviranost, bolečina v križu, fizioterapija, vrednotenje, vprašalnik

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1 Introduction

A disability is any restriction or lack (resulting from impairment) of the ability to perform an activity in the manner or within the range considered normal (1). Any existing disability seriously affects the functional ability and working status of the young and adult population (2, 3). Studies have shown that low back pain limits the ability of disabled individuals to perform the activities of daily living, reduces health-related quality of life and causes important health care expense (4). While in patients with acute low back pain disability improves within one month, in patients with chronic pain it is ongoing (5) and therefore hard to manage (6). In patients with acute low back pain, disability is mainly associated with the pain itself, whereas in patients with chronic low back pain, psychological factors (7) rather than biomedical or biomechanical factors have a substantial impact on the disability (8). In order to quantify their functional limitations and assess treatment outcomes, it is important to assess not only the intensity of pain but also the level of disability in these patients (9).

One way to assess the level of disability is to use questionnaires. Their suitability for clinical use is determined by psychometric characteristics, including validity, reliability and responsiveness. A tool is considered valid if it measures what it intends to measure, and reliable if it produces consistent results, has little measurement errors, and differentiates among patients. A valid and reliable tool is clinically relevant only if it is able to assess change over time (sensitivity to change), or to assess change over time that is important to patients responsiveness (9, 10). The Oswestry Disability Index (ODI) is one of the instruments for measuring disability caused by low back pain (9). The first ODI 1.0, published in 1980 (11), was followed by several other versions (12-15). It consists of 10 items: pain intensity, personal care, lifting, walking, sitting, standing, sleeping, sex life, social life and travelling. Each item can be answered with one of six answers. The level of disability is calculated from the composite score of the questionnaire: minimal disability, moderate disability, severe disability, crippled, and bedbound or exaggerating (13). Good reliability and validity of the questionnaire justify its wide use in patients with low back pain (16), and its good responsiveness makes it clinically relevant (11). It is easy to administer and score, objectifies patients' complaints, and monitors effects of therapy (11). Because of the lack of validated Slovene language scales for measuring disability in patients with low

back pain the aim of our study was to validate the Slovene version of ODI (hereafter referred to as the Slovene ODI).

2 Patients and methods

2.1 Type of study

This case series study was conducted at the physical therapy department of the health resort Topolsica, one of the providers of physical therapy in the northeast region of Slovenia. The study was approved by the National Medical Ethics Committee.

2.2 Study population

We enrolled 129 adult patients, aged 18 years or older, referred to physical therapy for treatment of low back pain by their family doctor. We excluded patients with low back pain that lasted less than 12 weeks (not chronic pain), patients with underlying pathology of chronic back pain (infection, tumor, osteoporosis, rheumatoid arthritis, fracture, inflammation, previous vertebral surgery, intervertebral disc herniation) and patients who refused to participate in the study.

2.3 Data collection

A questionnaire was given to all eligible patients upon their admission to the physical therapy department. The questionnaire consisted of a visual analog pain scale (VAS) (17), Slovene version of the EuroQol questionnaire (18), Slovene ODI 2.0 (16), and a demographic data sheet including questions about sex, age, education (primary, secondary, university) and employment status (employed, unemployed, retired). The patients were asked to complete the questionnaire and return it to the nurse. After a 10-day course of physical therapy, the doctor asked the patients to complete another questionnaire and return it to a nurse. The second questionnaire consisted of VAS (17), Slovene version of the EuroQol questionnaire (18), and Slovene ODI 2.0 (16). The doctor recorded the number and the type of physical therapy procedures for each patient.

VAS is a 10-point pain intensity scale from 1 (no pain) to 10 (worst pain imaginable) (17). The EuroQol questionnaire is a widely used tool for the measurement of health-related quality of life. It consists of two components: one component, EQ-5D, comprises five dimensions (mobility, self-care, usual activity, pain/discomfort, anxiety/depression). For each dimension there are three answer categories (no problem-scored

0/moderate problems – scored 1/extreme problems – scored 2). The composite score ranges from 0 to 10 points. Another component of the questionnaire is a visual analogue scale (EQ-VAS), providing the respondents with the option to describe their current overall health status on a thermometer-type scale, ranging from 0 (the worst health imaginable) to 100 (the best health imaginable) (18). ODI consists of 10 items with six available answers scored from 0 to 5, the composite score ranging from 0 points (minimum) to 50 points (maximum). A disability score is calculated using the following equation: total score/50x100. The result is given in %, the minimum value being 0% and the maximum value 100%. Disability scores of 0% to 20% are rated as minimal disability, scores of 21 to 40% as moderate disability, scores of 41 to 60% as severe disability, scores of 61 to 80% as crippled, and scores from 81 to 100% as disability of patients who are either bed-bound or exaggerating their symptoms (16). The original English version of ODI was translated into Slovene language according to the Guillemin criteria (19).

2.4 Statistical analysis

Data were analysed in SPSS 13.0 (SPSS Inc., Chigaco, IL, USA) and descriptive statistics were calculated. Reliability (internal consistency) of ODI was assessed with Cronbach's α and criterion-related validity (concurrent validity using correlations between ODI and EQ-5D, EQ-VAS and VAS. In univariate analysis, paired samples t-test and linear correlation were used. Statistical significance was set at $p < 0.05$. For calculating changes in ODI scores, a new variable was defined, based on the following equation: ODI (difference) = ODI (beginning) – ODI (end). The effect size (ES) for each instrument was calculated using the mean change from pre-physical therapy to post-physical therapy scores, divided by the pooled standard deviation of this change.

3 Results

3.1 Patient demographics and clinical data

We enrolled 129 patients of whom 61 (47.3%) were men. Their mean age \pm SD was 50.1 ± 10.2 years (minimum 24, maximum 77). The majority of patients had secondary education (83, 64.3%), followed by primary (23, 17.8%), and higher (education 17, 13.2%). Six patients (4.7%) did not answer this question. The majority of patients were employed (91, 70.5%); there

followed the retired (35, 27.1%), and unemployed (3, 2.3%).

The mean duration of low back pain was 115.6 ± 110.0 months (minimum 3, maximum 480). The mean VAS score at the first interview was 6.2 ± 1.9 points (minimum 1, maximum 10). The mean score on the EQ-5D visual analog scale at the first interview was 53.4 ± 16.1 points (minimum 10, maximum 90) and the mean score of the 5-dimension EQ-5D at the first interview was 3.8 ± 1.5 points (minimum 0, maximum 8).

At the second interview conducted after ten days of physical therapy, the following mean scores were obtained: VAS: 4.4 ± 2.0 points (minimum 0, maximum 10), EQ-5D: 3.0 ± 1.5 points (minimum 0, maximum 8), and EQ-VAS: 63.8 ± 15.5 points (minimum 25, maximum 95).

The patients had 3.7 ± 0.7 different physical therapy procedures per day (minimum 2, maximum 5). These included: group exercise (75, 58.1%), electrotherapy (148, 79.1%), magnetotherapy (14, 10.9%), ultrasound (14, 10.9), thermotherapy (61, 47.3%), massage (107, 82.9%), lumbar traction (22, 17.1%), and thermal water gymnastics (45, 34.9%).

3.2 Analysis of the Slovene ODI questionnaire

The mean ODI score at the first interview was 15.6 ± 8.6 points (minimum 1, maximum 41) (Table 1), and the mean disability score was 31.0 ± 17.3 (minimum 2, maximum 82). According to the disability the patients were assigned to the following five groups according to the level of their disability: minimal disability (38, 27.0%), moderate disability (43, 30.5%), severe disability (27, 19.1%), crippled (5, 3.5%), and bed-bound (1, 0.7%). Data were not available for 27 (19.1%) patients. Cronbach's α for the Slovene ODI at the first interview was 0.876 (Table 1). A good correlation was established between the Slovene ODI and VAS, EQ-5D, and EQ-VAS ($r=0.630$, $p < 0.001$; $r=0.657$, $p < 0.001$; $r=-0.510$, $p < 0.001$, respectively).

The mean score obtained at the second interview was 12.9 ± 9.0 points (minimum 0, maximum 43) (Table 1) and the mean disability score was 25.8 ± 18.0 points (minimum 0, maximum 86). The patients were assigned to five groups according to their disability level: minimal disability (55, 39.0%), moderate disability (32, 22.7%), severe disability (21, 14.9%), crippled (4, 2.8%), and bed-bound (1, 0.7%). Data were not available for 28 (19.9%) patients. Cronbach's α for the Slovene ODI at the second interview was 0.901 (Table 2). A good correlation existed between the Slovene ODI and VAS, EQ-5D, and EQ-VAS ($r=0.491$, $p < 0.001$; $r=0.725$, $p < 0.001$; $r=-0.648$, $p < 0.001$, respectively).

Table 1. Scores for individual and all ODI items.

Tabela 1. Točke pri posameznih vprašanjih in seštevku točk vprašalnika ODI.

Item Vprašanje	Mean (first interview) Povprečje (prvi intervju)	Mean (second interview) Povprečje (drugi intervju)	SD (first interview) Standardni odklon (prvi intervju)	SD (second interview) Standardni odklon (drugi intervju)
Pain intensity Jakost bolečine	2.4	1.5	1.5	1.6
Personal care Osebna nega	0.8	0.6	1.0	0.9
Lifting Dvigovanje bremen	2.6	2.1	1.5	1.4
Walking Hoja	0.8	0.7	1.1	1.0
Sitting Sedenje	2.1	2.1	1.1	1.3
Standing Stanje	2.0	1.7	1.1	1.1
Sleeping Spanje	1.2	0.8	1.5	1.3
Sex life Spolno življenje	1.0	0.9	1.3	1.3
Social life Družabno življenje	1.7	1.3	1.3	1.3
Travelling Potovanje	1.4	1.3	1.1	1.1

Table 2. Item-total statistics – the Slovene version of the ODI questionnaire.
Tabela 2. Statistika vseh vprašanj slovenske različice vprašalnika ODI.

Item Vprašanje	Corrected item-total correlation R Popravljen korelacija vseh vprašanj R		Squared multiple correlation R ² Multipla korelacija na kvadrat R ²		Cronbach's α if item deleted Vrednost Cronbachovega koeficienta α , če vprašanje izločimo	
	First interview Prvi intervju	Second interview Drugi intervju	First interview Prvi intervju	Second interview Drugi intervju	First interview Prvi intervju	Second interview Drugi intervju
Pain intensity Jakost bolečine	0.499	0.672	0.286	0.501	0.874	0.891
Personal care Osebna nega	0.634	0.627	0.432	0.438	0.864	0.894
Lifting Dvigovanje bremen	0.580	0.618	0.398	0.403	0.867	0.893
Walking Hoja	0.614	0.594	0.458	0.474	0.864	0.895
Sitting Sedenje	0.546	0.698	0.344	0.552	0.868	0.888
Standing Stanje	0.513	0.583	0.356	0.395	0.870	0.895
Sleeping Spanje	0.554	0.580	0.399	0.414	0.869	0.896
Sex life Spolno življenje	0.732	0.710	0.598	0.582	0.854	0.887
Social life Družabno življenje	0.724	0.764	0.563	0.652	0.854	0.883
Travelling Potovanje	0.708	0.751	0.552	0.626	0.857	0.886

Item analysis of the results obtained at the first interview showed that item-total correlations (discriminative indices) ranged from $r=0.499$ (pain intensity) to $r=0.732$ (sex life) (Table 2). At the second interview, they ranged from $r=0.580$ (sleeping) to $r=0.765$ (social life). Explorative factor analysis revealed only one factor which accounted for 49.2% of the total variance at the first interview, and for 54.1% of the total variance at the second interview (Table 3).

3.3 Sensitivity to change

The difference between ODI scores of the first interview and ODI scores obtained at the second interview was 2.7 ± 5.2 ($p<0.001$); for ODI disability

scores the difference was 5.4 ± 10.5 ($p<0.001$). ES was 0.30. Significant improvements were observed for the following items: pain intensity, personal care, lifting, standing, sleeping, sex life, and social life. The first item exhibited the greatest change (Table 4). The intensity of pain on the VAS scale reported after ten days of physical therapy decreased by an average of 1.7 ± 1.8 points ($p<0.001$). ES was 0.85. After a 10-day course of physical therapy, overall health on the EQ-VAS improved by an average of 10.3 ± 15.2 ($p<0.001$). ES was 0.64. An average decrease in EQ-5D scores after a 10-day programme of physical therapy was 0.8 ± 1.2 points ($p<0.001$). ES was 0.53.

Table 3. Results of explorative factor analysis of the Slovene ODI*.
Tabela 3. Rezultati eksplorativne faktorske analize slovenske različice vprašalnika ODI.

Item Vprašanje	Component 1 Komponenta 1	
	First interview Prvi intervju	Second interview Drugi intervju
Pain intensity Jakost bolečine	0.579	0.743
Personal care Osebna nega	0.719	0.699
Lifting Dvigovanje bremen	0.663	0.690
Walking Hoja	0.716	0.682
Sitting Sedenje	0.629	0.770
Standing Stanje	0.610	0.664
Sleeping Spanje	0.648	0.653
Sex life Spolno življenje	0.812	0.781
Social life Družabno življenje	0.806	0.831
Traveling Potovanje	0.784	0.814

* Extraction method: principal component analysis

* Metoda ekstrakcije: temeljna komponentna analiza

4 Discussion

Our study showed that the Slovene version of ODI is a reliable and valid instrument for measuring disability in patients with chronic non-specific low back pain. It has good sensitivity to change and is therefore a good tool for measuring outcomes of physical therapy in patients with chronic non-specific low back pain.

The Slovene ODI demonstrated good reliability (internal consistency), which is in accordance with the results of the original study (12) and other investigations (20-25). In some studies, the sex life item proved problematic and was therefore eliminated to assure better internal consistency (20). In our study, item analysis showed good internal consistency of all items. Explorative factor analysis revealed only one factor inconsistent with the findings of Chow and co-workers (20). Their study revealed two factors indicating that the patients perceived their disability level as high when they

engaged in sexual activity. The authors attributed this different perception of sex life to different cultural beliefs (20). In our study, the item-total correlation for the majority of items exceeded 0.6 (Table 2), an observation indicating that each item forms a single factor with other items. This finding is consistent with other studies (12) and justifies the use of the 10-item Slovene ODI.

A good correlation with VAS, EQ-5D and EQ-VAS in both interviews indicates good criterion-related validity (concurrent validity) of the Slovene ODI. A good correlation with VAS was reported also in other studies, with correlation coefficients ranging from 0.62 to 0.82 (17, 24, 26, 27). We found no reports on the correlation between EQ-5D and ODI. In one study, a good correlation, with a correlation coefficient of $r=0.78$, was established between ODI and Short Form 36 (SF-36), another instrument for measuring patients' quality of life (28).

Table 4. Sensitivity to change for individual items of the Slovene version of ODI.

Tabela 4. Občutljivost na spremembo pri posameznih vprašanih slovenske različice vprašalnika ODI.

Item Vprašanje	Mean difference in pre- and post-physical therapy ODI scores \pm SD Povprečje razlik v seštevku točk na začetku in na koncu fizikalne terapije \pm standardni odklon (SD)	p
Pain intensity Jakost bolečine	1.0 \pm 1.4	<0.001
Personal care Osebna nega	0.2 \pm 0.9	0.002
Lifting Dvigovanje bremen	0.4 \pm 1.1	<0.001
Walking Hoja	0.1 \pm 0.7	0.096
Sitting Sedenje	-0.1 \pm 0.9	0.569
Standing Stanje	0.2 \pm 0.7	<0.001
Sleeping Spanje	0.3 \pm 1.1	0.002
Sex life Spolno življenje	0.2 \pm 0.9	0.014
Social life Družabno življenje	0.4 \pm 1.0	<0.001
Traveling Potovanja	0.1 \pm 0.8	0.427

In our study, the effect size for the Slovene ODI after the completion of physical therapy was similar to that in the Brazilian-Portuguese version (26), but lower than in other studies (29-32). Various factors, such as differences in subject population, study design, type of intervention, and others, may be responsible for this discrepancy (11). However, considering that clinically irrelevant changes may occur in function scale scores, the concept of specificity is also important in the assessment of sensitivity (29). In our study, ESs for VAS, EQ-5D, and EQ-VAS were moderate or high, which indicates good sensitivity of these instruments to clinical change. A highly significant correlation between the ODI score and scores of the above mentioned instruments suggests that the Slovene ODI has satisfactory sensitivity to change, even though its ESs were lower than those obtained with VAS, EQ-5D, and EQ-VAS. Since the consensus calls for a minimal change of 10 points to be clinically significant (13, 14), our results should be interpreted with caution. The strengths of our study include its prospective design, enrollment of all consecutive patients

according to the inclusion criteria, use of valid and reliable instruments sensitive to clinical change, and use of standard methods of questionnaire translation. Also, our group of patients is similar to a national sample of family practice attendees in terms of age and sex (32). There are also limitations to this study: patients were recruited from only one physical therapy department, which may contribute to a selection bias. Test-retest reliability and responsiveness of the Slovene ODI were not determined

5 Conclusions

Our study showed that the Slovene ODI is a reliable and valid instrument for assessing outcomes of physical therapy in patients with chronic non-specific low back pain. It has a satisfactory sensitivity to clinical change, which justifies its use in clinical settings. Further studies should address its test-retest reliability and responsiveness, and test its validity in different subject populations.

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