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HEALTH SERVICES RESEARCH

Validation in Colombia of the Oswestry Disability Questionnaire in Patients With Low Back Pain

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Study Design. Observational study to validate a scale.

Objective. To translate, culturally adapt, and validate the Oswestry Disability Index (ODI), version 2.1a.

Summary of Background Data. The ODI is one of the most frequently used tools to evaluate disability in patients with low back pain. Its psychometric properties have shown to be highly reliable. Currently, no validated Colombian version is available.

Methods. The ODI (2.1a) was translated into Spanish and this translated version was analyzed in terms of semantic and linguistic equivalence. Then, the Spanish version was translated back into English. The first time, the ODI was administered to a total of 111 patients with back pain. Internal consistency, construct validity, content validity and criterion validity were evaluated for the scale. The inter-rater reliability was evaluated by 2 different observers a day apart from each other and the intra-rater reliability was determined by the same observer, 7 days apart. A sensitivity-to-change analysis was performed on 81 patients.

Results. Of the sample, 67.6% were women, with a mean (SD) age of 44.88 (16.38) years. Cronbach alpha coefficient was 0.86. Inter-rater reliability yielded an intraclass correlation coefficient (ICC) of 0.94 whereas intrarater reliability yielded an ICC of 0.95. Pearson correlation between ODI and each of the 8 domains of SF-36, was statistically significant. Construct validity, when comparing extremely acute and chronic groups, did not show any differences ($P = 0.409$). Concurrent criterion validity between ODI and Roland–Morris Disability Questionnaire (RMQ) was $r = 0.75$; between ODI and the Visual Analog Scale (VAS) was $r = 0.540$. For patients who received an intervention, the value of this change was 1.2.

Conclusion. ODI-C is a helpful, reliable and valid tool in Colombia for back pain patient follow-up and assessment, regardless the stage of the evolution. It is an observational study to validate the Oswestry disability index (ODI) in the Spanish language. ODI is the most used tool in evaluating disability related to low back pain.

The psychometric properties were evaluated in Colombia and the results were very good, similar to other studies.

Key words: oswestry disability index, low back pain, validation, outcome measurement, rehabilitation. **Spine 2011;36:E1730–E1735**

Moderate back pain of moderate duration occurs with an annual incidence ranging from 10% to 15% in an adult population and prevalence between 15% and 30%. Out of the total acute episodes, 90% subside spontaneously during the first 3 months, but the remaining 10% show a slow recovery and require long-term treatment with the consequent economic demand of the health system.[1]

The most frequently studied outcomes in back pain research and clinical practice are: pain, disability, work resumption, and life quality. These variables are evaluated through patient-centered scales. They have been used in studies of back pain treatment with nonsteroidal anti-inflammatory (NSAID),[2] comparing NSAI drugs,[3] opioids,[4] muscle relaxants,[5] different routes of administration of medication, nonpharmacological treatment,[6–8] alternative therapies,[9,10] educational programs,[11] and physical means, among others.

For a general pain assessment, the most commonly used measurement instrument is the visual analog scale (VAS).[12] A reduction of at least 20 mm[13] is considered statistically significant. Two of the most commonly used self-report questionnaires to assess back pain are the Oswestry Disability Index (ODI) and the Roland–Morris Disability Questionnaire (RMDQ).[14]

Four versions of the ODI are available in English. Version 1.0 was published in 1980 by its author Jeremy Fairbank[15] and it was extensively distributed by the International Society for the Study of the Lumbar Spine (ISSLS) in Paris. A new ODI version was adapted in 1989 by the Chiropractic College in England. The American Academy of Orthopedic Surgeons and other spine associations adapted the ODI 1.0 version in 1996 omitting categories 1, 8, and 9. This version is included in the assessment protocol proposed by the Musculoskeletal Outcomes Data Evaluation and Management System (MODEMS), which brings together the main international spine associations. Version 2.0 was modified by the Medical Research Council Group in the United Kingdom in 1996[16] and they omitted the word "painkillers" in the first category. Version 2.1a is the most recent and recommended

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by its author. In this version a section called previous treatment appears, which is not taken into account for scoring.

The ODI has been translated with validation into 9 languages and it has been translated without validation in 5 languages.[17,18] In 1995, version 1.0 was translated into Spanish, validated and culturally adapted.[19] The ODI meets the requirements set by the International Classification of Functioning, Disability and Health (ICF). Validity, reliability and sensitivity to change have been tested in the various ODI validations and this has been used in criterion validity for other instruments. The authors of a recently published research article claim that a difference of 10 points is considered clinically significant for back pain.[20]

The Roland–Morris Questionnaire (RMQ) is a 24-item scale in which the impact of back pain on daily activities is assessed. The measure does not evaluate psychological or social aspects. This questionnaire was validated in Spanish by Kovacs Foundation, located in Palma de Mallorca, Spain.[21,22] This study aimed at translating the ODI, version 2.1a, culturally adapting it and validating it in Colombia with back pain patients.

MATERIALS AND METHODS

An observational study to validate a scale carried out with Colombian people older than 18 years who have back pain. The study involved 3 phases. First, the tool was translated into Spanish and adapted to the Colombian culture. Second, a pilot test was carried out to test the proper understanding and reproducibility of the Spanish version. The final stage involved the validation of the study to determine its psychometric properties.

Participants

The questionnaire was administered to 111 patients who met the inclusion criteria and signed a written informed consent. The sample consisted of males (32.4%) and females (67.6%) with a mean (SD) age of 44.88 (16.38) years. A percentage of 97.3% of the sample lived in an urban area. A total of 83% of the sample was interviewed and the remaining 17% completed the self-report.

Methods

Translation: Dr. Jeremy Fairbank authorized and recommended validating ODI 2.1a. Two translations into Spanish were made by 2 freelance certified translators whose native language is Spanish. A three-people committee evaluated the Spanish translations. An orthopedist, a neurosurgeon and a physiatrist, which were familiar with the original version, chose the best. Some semantic changes were performed to improve patient's comprehension. Next, the Spanish version was translated again into English by a third translator who had not participated in this process. This version was compared with the original English version and both were found to be equivalent. The experts committee reviewed the obtained versions, came up with the final version, which was compared again with the original.

A pilot test was carried out with a sample of 20 back pain patients older than 18, who signed an informed consent form in different health centers of Medellin, Colombia.

Different aspects were evaluated including comprehension, ambiguous meaning, confusing phrasing, emotional words, range of answers, presence of end-aversion bias and frequency of answer and answer percentages higher than 80% for the same question.

The Oswestry Disability Index, version 2.1a, is a questionnaire made up of 10 categories: (1) pain intensity, (2) personal care, (3) lifting, (4) walking, (5) sitting, (6) standing, (7) sleeping, (8) sex life, (9) social life, and (10) traveling. Each category consists of 6 items scored from 0 to 5 with the first statement scoring 0 to the last statement scoring 5. A check at the highest levels means the person is in the worst state. The questionnaire includes an additional question about previous treatments. If more than one answer is selected, the highest score is considered. If all 10 sections are completed, the score is calculated as follows:

$$\frac{(\text{Score Section 1} + \text{Score Section 2} \ldots\ldots\ldots + \text{Score Section 10}) \times 100}{\text{Maximal Score of the Sections}}$$

Maximum Score

The maximum score for all 10 sections is 50 points. If all sections are completed, this number becomes a percentage with a total of 100. This figure is equivalent to the most severe disability. If a section is omitted, the patient's total score is calculated over 45 points and if 2 or more sections are omitted the percentage is obtained by the same method.

Reliability

Internal consistency was used to evaluate reliability. The scale was administered to all patients (n = 111). The statistical analysis was done by Cronbach alpha coefficient. The acceptable reliability coefficient value of this measure ranges from 0.7 to 0.90.

For the inter-rater reliability, a sample size of 46 patients was calculated. Twenty-four hours after the first scale was administered, a second rater administered a second scale, blinding the results from the first one. For the intra-rater reliability the scale was administered 2 times (with a gap of 7 days between the 2 scales) by the same rater to 45 patients. The statistical analysis was done by correlation intra-class coefficient. The acceptable reliability coefficient value of this measure ranges from 0.7 to 0.8, higher than 0.8 is excellent.

Validity

To establish the content validity the sample size was calculated with 10 patients per section. The scale is made up of 10 sections and an additional item, for a total of 110 patients.[23] An exploratory factor analysis of main components was performed to determine the scale dimensions (domains or factors). The graphic criterion and the Kaiser criterion were considered (value > 1). An orthogonal Varimax rotation was employed. To determine the construct validity 2 extreme groups were compared. Forty-four patients with

chronic back pain with more than 12 weeks of evolution were selected. Forty-four patients with acute back pain with less than 4 weeks of evolution were also selected. The sample size was calculated according to data obtained from the original validation study. ODI averages were obtained for each group. Next, the Kolgomorov-Smirnov test was applied and normality of the distribution was found for the scale. The Student *t* test was used for unrelated samples. The ODI was compared with the visual analog scale. Subgroups were compared according to the pain stage of evolution. The scale was also compared with the SF-36 dimensions by Pearson coefficient. For the criterion validity, the ODI was compared with the Roland–Morris Questionnaire ranging from 1 to 24, with 24 being maximum disability. The calculated sample size was 66 patients. However, the comparison was made with all 111 patients. Because data were found to be normally distributed, the analysis was performed by Pearson correlation coefficient.

SENSITIVITY TO CHANGE

Both patients with acute low back pain and with a new episode of chronic low back pain were sequentially included. These patients received a pharmacological and/or a physical rehabilitation treatment. Two assessments were performed—at the beginning and 1 month after. A sample size of 81 patients was calculated. The statistical analysis was done through comparison of means between the first and second assessments, and a T-paired test was used because the variables had normal distribution. The effect size was calculated with the Cohen d coefficient. SPSS 15 software was used for the analysis.

RESULTS

A total sample of 111 patients were included in the study, 44.1% had acute low back pain, 16.2% had subacute low back pain, and 39.6% had chronic low back pain. The sample was composed of 63% of low socioeconomic level patients and 37% of high socioeconomic level patients. No differences were found for ODI average in both levels. Disability severity was determined according to the score range proposed by Osthus *et al*.[24] A minimal or moderate disability was observed in 78.3% of patients, with a score lower than 40. There were no patients with a score higher than 80 (Table 1).

Items were 100% completed, except for the sex life section, which was not completed by 23% of patients. This is due to the fact that a high percentage of the administration was done either by an interviewer or self-administered but with the presence of an interviewer. A Cronbach alpha of 0.86 was obtained for internal consistency. This value indicates high internal consistency reliability for all parts of the questionnaire. Regarding inter-rater reliability, an average of 26.5 (12.3) was found in the first assessment whereas an average of 26.12 (13.2) was obtained in the second one, with an intraclass correlation coefficient (ICC) of 0.94 (0.89–0.97), a value considered excellent. The analysis of intra-rater reliability yielded an average of 28.8 (12.8) in the first assessment whereas an average of 30.9 (13.7) was found in the second one, with an ICC of 0.95 (0.91–0.97).

TABLE 1. Classification of Patients in Colombia According to the Severity or Disability

No. Patients (%)	Group No.	Score (%)	Severity
36 (32.4%)	1	0–20	Minimal disability
51 (45.9%)	2	21–40	Moderate disability
23 (20.7%)	3	41–60	Severe disability
1 (0.9%)	4	61–80	Extremely severe disability
0	5	81–100	Confined to bed or exacerbated symptoms

The factor analysis yielded 2 components. Lifting, walking, and standing were related to the first factor. Pain intensity, personal care, sitting, sleeping, and traveling were related to the second one. Sex life and social life were related to both factors. Both components would account for 55.6 of variance (Table 2).

When comparing acute patients to chronic patients no meaningful differences were found regarding construct validity. The acute group showed an average of 27.7 (12.3) in the ODI whereas the chronic group showed an average of 30 (12.3) with $P = 0.409$. This scale does not show discrimination between patients based on the stage of the evolution. The correlation ODI/VAS for the 3 subgroups (acute, subacute, and chronic) was positive, $r >$ of 0.475 with $P < 0.05$ (Table 3).

The correlation ODI/SF36 was found significant for each domain. Pearson correlation coefficient was above 0.7 for Physical Functioning (PF), 0.6 for Social Functioning (SF),

TABLE 2. Analysis of Principal Components of ODI

		Principal Component Coefficients ≥ 0.4	
	Item	F 1	F 2
Section 1	Pain intensity		0.681
Section 2	Personal care		0.607
Section 3	Lifting	0.612	
Section 4	Walking	0.617	
Section 5	Sitting		0.665
Section 6	Standing	0.887	
Section 7	Sleeping		0.585
Section 8	Sex life	0.423	0.683
Section 9	Social life	0.435	0.752
Section 10	Traveling		0.713

F indicates factor.

TABLE 3. Correlation of ODI and VAS in Patients With Low Back Pain in Colombia

	ODI			VAS			
	n	Mean	(SD)	Mean	(SD)	Coefficient*	*P*
Acute	49	27.66	12.33	45.35	24.95	0.584†	0.000
Subacute	18	27.21	13.64	46.63	21.63	0.475‡	0.047
Chronic	44	30.02	15.06	45.50	23.04	0.532†	0.000
Total	111	28.5	13.6			0.540	0.000

SD indicates standard deviation.

**Pearson correlation.*

†Correlation is significant at the 0,01 level.

‡Correlation is significant at the 0,05 level.

0.57 for Bodily Pain (BP) and 0.4 for Role-Physical (RP), General Health (GH) and Vitality (VT) and above 0.3 for Mental Health (MH) and Role-Emotional (RE). These last 2 domains are not assessed by the ODI (Table 4).

When the SF-36 was initially evaluated, the RP domain showed the lowest average for the total number of patients average = 21.4 (3.2), followed by the BP domain 40.1 (1.73), RE 51.4 (3.3), and PF 51.9 (2.4). In terms of the condition stage of the evolution, RP was the most affected domain in the 3 subgroups, in the subacute group the average was 13.8 (2.6); the second most affected domain was BP in the subacute group with an average of 35.9 (1.4), followed by PF = 46.6 (2.5).

Concurrent criterion validity was obtained comparing the ODI results with the Roland–Morris Questionnaire. The ODI average for the whole population was 28.5 (13.6) and the RMQ average was 8.9 (5.0). Pearson correlation coefficient was 0.75, which indicates a very good correlation.

The sensitivity-to-change analysis showed that the disability index improved in the 81 patients who were intervened. The ODI went from 26.6 (13.5) to 9.8 (13.7), a statistically significant change ($P = 0.0001$). Cohen coefficient was 1.2, which indicates a very large effect size.[25]

DISCUSSION

Contrary to what is found in the general population in which there is a homogeneous distribution of sexes, there were more women than men in this study.[26] In terms of the distribution regarding the stage of the evolution, this is similar to the information from the national and global epidemiological data-similar distribution for acute and chronic groups and lower for sub acute groups.

The results for this study for the ODI Colombian version show good reliability and validity. The scale was properly understood and completed; similar to what is found in the Turkish,[14] German[24] and Japanese[27] validations. The question about sex life was not answered by 23% of the patients; the remaining questions were answered by 100% of patients. And 78.3% was in the minimum and moderate disability category. This finding agrees with what was reported in the German validation, where 84.6% of patients were in the same category.[24]

Cronbach alpha coefficient of 0.86 was higher than the coefficient of the English version, 0.76,[28] similar to the findings of Kopec of 0.87[29] and to the Korean version of 0.84,[30] a little lower than the German validation of 0.90. This value is considered to be good for internal consistency. If could be used not only for group analysis but for an individual score as well.[31]

Interrater reliability (CCI = 0.94) was equivalent to that found in the ODI Turkish validation[14] and similar to that found in Japan (0.93).[27]

This high correlation is common to all studies and it indicates a highly reliable scale to be used by different interviewers for clinical purposes.

Regarding intra-rater reliability, intraclass correlation was 0.95, a higher value than the one obtained by Gronblad, 0.83

TABLE 4. Pearson Correlation Coefficient of the ODI With Scales of the SF-36

		ODI	
SF-36	n	Coefficient*	*P*†
RE	111	–0,351	0,000
MH	110	–0,377	0,000
VT	110	–0,422	0,000
GH	107	–0,436	0,000
RP	111	–0,452	0,000
BP	111	–0,57	0,000
SF	111	–0,603	0,000
PF	111	–0,758	0,000

**Pearson correlation.*

†Correlation is significant at the 0.01 level.

on day 7.[32] This finding indicates that the scale is reliable for repeated administrations to the same subject if health conditions remain unchanged.

The ODI factor analysis yielded 2 components, a highly similar result to the German version. Only the sitting category and the social life category were different in both studies.[24] Other validations do not include a description of factor analysis. Unlike other studies, we found that the scale does not discriminate between acute and chronic patients.[33] It is necessary to carry out further analyses to evaluate differences based on socioeconomic levels or sex.

When compared with the Roland–Morris Questionnaire, Pearson correlation ($r = 0.75$) was very good and similar to the Greek: $r = 0.73$,[34] Iranian: $r = 0.76$,[35] Brazilian: $r = 0.81$,[36] and Argentinean: $r = 0.81$ versions.[37] For the Turkish ODI validation[14] a correlation of $r = 0.367$ ($P = 0.01$) with the VAS was found at the first assessment. A correlation of $r = 0.392$ ($P = 0.01$) was found on day 7. The correlation found for the Colombian version indicates good criterion validity.

SF36 and ODI convergent validity has been evaluated by different authors. In Fujiwara's study in Japan[27] with 97 patients with degenerative spine disease, the correlation coefficient was higher for the PF domain, $r = –0.824$, and lower for the SF domain, $r = – 0.524$. In the German assessment the correlations were[24] higher both for the PF domain, $r = –0.78$ and the BP domain, $r = –0.72$, and the lowest correlations were found for MH, $r = –0.52$, and RE, $r = –0.48$. Grevitt *et al* reported[38] a significant correlation between the English ODI version and SF-36, particularly for the PF domain. These results are similar to our findings and they show that unlike SF36, which assesses the emotional component, ODI assesses the physical component.

The effect size yielded by the Cohen *d* in this study validates the scale as a helpful tool to assess changes in the health status and differences in interventions. This ability to assess changes has been proven in several studies. Osthus *et al*[24] demonstrated a large effect size. In Japan, Hirotaka[39] evaluated the effect of decompression surgery for degenerative lumbar canal stenosis, just like Yukawa,[40] and Gunzburg.[41] The scale is sensitive to changes after an intervention. Likewise, ODI has proved to be able to assess disability perception in both patients under different workout programs[42] and different pharmacological interventions.[3]

CONCLUSIONS

The results yielded by this study indicate that the validated Spanish ODI version for the Colombian population is a transculturally equivalent, reliable and valid tool to assess disability in low back pain patients.

The psychometric properties of this study are very good. In some cases they are better than the various validation studies done in different countries.

ODI-C is a helpful and reliable tool for low back patient assessment and follow ups, regardless of the stage of the evolution. It allows assessing changes in the health status and can be used in research studies.

➢ Key Points

- ❑ The Oswestry Disability Index (ODI) version 2.1a was translated, transculturally adapted and validated into Spanish language.
- ❑ The Colombian version of the ODI has proven to have very good concurrent validity, construct validity, internal consistency, reliability, and sensitive to change.
- ❑ The results of this study indicate that the validated Spanish ODI version is a reliable and useful instrument for the assessment of disability and follow-up to patients regardless of the stage of the evolution caused by low back pain.

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