ORIGINAL RESEARCH

Validation of the Sinhalese version of the Oswestry Disability Index for low back pain

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Abstract

Introduction: Low back pain (LBP) is a major cause of disability. Oswestry Disability Index (ODI) is used to evaluate the impact of LBP) on daily activities. The objective of the current study was to validate and culturally adapt the ODI to the Sinhalese speaking Sri Lankan population. **Methods:** The study was conducted at National Hospital, Sri Lanka, including an 18-65 years aged cohort of 100 patients with chronic LBP. The Sinhalese ODI version 2.1a was validated by assessing the test-retest reliability (Intraclass correlation coefficient), internal consistency (Cronbach α) and constructs validity comparing the ODI with the Roland Morris Disability Questionnaire (RDQ) and Visual Analog Scale for pain intensity (Pearson correlation coefficient). **Results:** The mean age (±SD) of the study participants was 50.17 ± 11.20 years and mean duration of LBP among participants were 34.00 ± 43.58 months. The ODI had an overall Cronbach α coefficient of 0.811 (95% CI 0.746- 0.865). An excellent agreement was detected between test and re-test ODI scores, indicated by an ICC of 0.983 (95% CI: 0.975-0.989. The Pearson's correlation test revealed a significant strong positive correlation between ODI and RDQ ($r=0.989$, $p<0.001$) and a moderate positive correlation between ODI and VAS pain intensity ($r=0.568$, $p<0.001$). **Conclusion:** The Sinhalese translation of the ODI version 2.1a had good reliability, temporal stability, and validity when assessed compared to other standard measures. The ODI can be employed in future studies assessing LBP disability in Sri Lanka.

Introduction

Low back pain (LBP) is generally defined as the pain, discomfort, muscle tension or localized stiffness below the costal margin and above the inferior gluteal folds with or without leg pain (sciatica) [1].

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It is one of the leading causes of pain and disability in the world [2] and is known to affect 80-85% of individuals across the globe at some point in their life [3]. Between 1990-2015, years lived with disability due to LBP has increased by 54% worldwide, with the largest escalation reported in low-income and middle-income countries [4]. Lower back was the most common site of pain in the Sri Lankan population [5]. In line with the Global Health Data Exchange statistics, the healthy life lost per 100,000

individuals with regard to LBP in Sri Lanka has increased by 20.3% since 1990.

LBP is commonly categorized based on the onset or duration of pain as; acute (<4 weeks), sub-acute (4-12 weeks) and chronic (>12 weeks) [6]. Restoration and facilitation of normal functions is one of the main goals of physiotherapy in treating patients with chronic LBP, hence, physiotherapists utilize various measurement tools to assess the functions and to monitor the progression of chronic LBP [7]. Standardized self-reported measures provide quantitative information which is obtained directly from patients and they are frequently used in clinical application [8]. The Oswestry Disability Index (ODI) and the Roland-Morris Disability Questionnaire (RDQ) are two of the most commonly used measures to evaluate the severity of chronic LBP [9].

The ODI, is a simple and inexpensive tool which is used to determine the permanent functional disability of a patient with low back pain. It is a self-administered questionnaire based on patients' current functional status, which could be completed in approximately 5 minutes and scored in less than a minute, with a total score ranging from 0-100, where a higher score implies greater disability [10]. The ODI is widely used by healthcare professionals, researchers and disability evaluators as the test is considered as the 'gold standard' of low back functional outcome tools [11]. It is convenient to use and score with minimal respondent and administrator burden.

The ODI version 1.0 was published in 1980 and it was intended to be utilized as a tool for both assessment and outcome [12]. Different versions of ODI has been introduced since then, with modifications in sections, individual questions and instructions. Version 2.1b is the most recent and updated version of ODI. However, Version 2.1a is well recommended by the developers for research and clinical use [13]. The ODI was initially developed in English and it has been translated and culturally adapted in a range of foreign languages [11,14].The ODI has also been validated for use in several countries [15] including Brazil, Norway, India, Saudi Arabia, China, Canada, Finland, Switzerland, Italy, and Iran. It has been reported to be valid and reliable tool to measure LBP severity. Sinhala is the language spoken by majority (>70%) of the Sri Lankans [16]. A translated Sinhalese version of ODI 2.1a is currently available in the Mapi Research Trust website [13]. However, it has not been validated to be utilized among the Sinhalese population. Thus, the objective of the current study was to assess its validity among Sinhalese individuals with chronic LBP.

Methods

Study population and sampling

The study was conducted at the Department of Rheumatology and Rehabilitation at National Hospital of Sri Lanka (NHSL), Colombo, Sri Lanka. The study was approved by the Ethics Review Committee of National Hospital, Sri Lanka and Ethics Review Committee of Faculty of Medicine, General Sir John Kotelawala Defense University. A subject-item ratio of 10 was used to calculate the sample size. Since the ODI contains 10 questions the required sample size was estimated to be 100 (10 items * 10 subjects). The final sample size was calculated as 100 patients satisfying the inclusion/exclusion criteria given below. A systematic random sampling method of eligible patients was used to select participants until the required sample size was achieved. Informed written consent was

obtained from all participants prior to recruitment. To be included in the study the participants had to be; a) 18-65 years of age and b) diagnosed with chronic LBP (>12 weeks) by a Rheumatologist. Patients who were unable to read and/or understand Sinhala, diagnosed with neurological disorders, with fractures in spine/hip/knee/pelvis, history of spinal or abdominal surgery within last year, pregnant, with leg length discrepancy of more than 10mm and those with any systemic diseases were excluded. Once the eligibility was confirmed, back pain severity was measured using Oswestry Disability Index.

Study Instrument and definitions
The ODI is a self-administered questionnaire, which includes 9 items on daily activities (lifting, walking, social life, personal care, sitting, standing, sleeping, travelling and sex life) and 1 item on pain. The total ODI score is calculated by multiplying the scores obtained in each item by 2 and which is converted into a percentage [10]. The total possible ODI score is from 0-100, with a higher ODI score implying greater disability. The LBP disability is interpreted based on the final ODI score, which is categorized as follows: a) Minimal disability (0-20%), b) Moderate disability (21%-40%), c) severe disability (41%-60%), d) crippling LBP (61%- 80%) and e) confined to bed; indicating excessive incapacity (>80%) [7]. In addition we also collected socio-demographic data of study participants, including age, gender, level of education and occupation. To evaluate the performance of the ODI, Roland-Morris disability questionnaire (RDQ) and Visual Analog Scale (VAS) for pain were used. The RDQ was initially designed in 1983 to assess physical disability due to LBP. It is a 24-item

scale with no subgroups and is extensively used in clinical practice to monitor the progression of LBP. The RDQ scores range from 0 (no disability) to 24 (maximal disability) [17]. The original 24-item RDQ was interviewer administered and used to gauge the LBP disability. VAS was used as a uni-dimensional measure for evaluating pain intensity, where a continuous horizontal scale of 10 cm (100mm) indicated no pain (score of 0) to worst possible pain (score of 100). This was self-completed by the respondents, in which they are instructed to rate their current pain [18].

Statistical analysis and validation
The questionnaire validation included evaluation of internal consistency, temporal stability and performance with regards RDQ and VAS pain intensity. It was assumed that content validity was performed by the authors of the original study. In the analysis of internal consistency, the correlation of each item with the sum of the items and inter item correlation, calculating a Cronbach α coefficient for each questionnaire. For the analysis of temporal stability, 100 patients with stable therapeutic schemes were retested at an interval 14 days. Test-retest reliability was evaluated using the intraclass correlation coefficient (ICC) (range 0-1). An ICC values of 1 indicates perfect reliability, 0.90-0.99 very high correlation; 0.70-0.89 high correlation; 0.50-0.69 moderate correlation; 0.26-0.49 low correlation and 0-0.25 little reliability [19]. The Bland-Altman plot of with-in subject variation and the limits of agreement were used to assess the agreement between the ODI scores obtained during test and re-test. This was created by plotting mean difference in the ODI scores for the 2 occasions against the baseline ODI scores. 95% confidence interval around the mean

difference was calculated and limits of agreement were also plotted. Construct validity was assessed by calculating Pearson's correlation coefficients (*r*). Based on previous studies with similar objectives, it was expected that the ODI and RDQ would have high correlation, while VAS would have moderate to high correlations with ODI. SPSS version 22.0 was used in the analysis of data. In all analyses, p < 0.05 was considered as statistically significant.

Results

Socio-demographic and disease characteristics

The total number of subjects recruited for the study was 100. The mean age (±SD) of the subjects was 50.17±11.20 years (range 18-65 years) and 66.0% (n=66) were females. Majority of the study participants (60.0%, n=60) were either unemployed or retired at the time of data collection and were educated up to GCE ordinary level (52%, n=52). Mean duration (±SD) of chronic LBP among study participants were 34.00±43.58 months (range 3 months – 20 years). Approximately, half of the study participants had back pain for 3-12 months (52%, n=52). Considering the chronic LBP location, 31% (n= 31) of the study participants had LBP in either sides as well as in the center, while approximately one fourth (24%, n=24) of the participants had LBP limited only to the center. Most of the subjects had a gradual onset LBP (81%, n=81). Mean ODI (± SD) value of the study populations was 30.30±13.86. Socio-demographic and LBP related characteristics are depicted in Table 1.

Validation of translated questionnaire

In the analysis of temporal stability after 2 weeks in the 100 patients with chronic LBP the

questionnaire demonstrated an excellent agreement between test and re-test ODI scores, indicated by an interclass correlation coefficient of 0.983 with very narrow confidence intervals (95% CI: 0.975-0.989). Mean ODI (±SD) value of test and re-test studies were 30.30 (±13.86) and 30.27 (±13.26) respectively (p-NS).

The Bland and Altman plot indicated that the bias was very minimal as the mean difference was close to zero [mean difference (d) = 0.342] and the limits of agreement were excellent (-4.49 to 5.17) with just six outliers (Figure 1). Analysis of the internal consistency was performed in the 100 patients recruited for the study. The ODI had a Cronbach α coefficient of 0.811 (95% CI 0.746-0.865), which suggest adequate internal consistency. The Pearson's correlation test revealed a significant strong positive correlation between ODI and RDQ scores (r=0.989, p<0.001). There was also a significant moderate positive correlation between ODI score and VAS pain intensity (r=0.558, p<0.001).

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Table 1: Socio-demographic and low back pain related characteristics of the sample

Variables	Number (%)		
	All adults	**Males**	**Females**
Mean age (years)	50.17 ± 11.20	48.94 ± 13.46	50.80 ± 9.90
Gender			
Males	34 (34.0)	N/A	N/A
Females	66 (66.0)		
Employed			
Yes	60 (60.0)	10 (29.4)	16 (24.2)
No	40 (40.0)	24 (70.6)	50 (75.7)
Education			
No formal education	6 (6.0)	1 (2.9)	5 (7.6)
Grade 1-5	15 (15.0)	8 (23.5)	7 (10.6)
Grade 6-12	10 (10.0)	1 (2.9)	9 (13.6)
Up to GCE Ordinary Level	52 (52.0)	19 (55.9)	33(50.0)
Up to GCE Advanced Level	8 (8.0)	3 (8.8)	5 (7.6)
Higher Education	9 (9.0)	2 (5.9)	7 (10.6)
LBP duration (in months)			
3-12	52 (52.0)	20 (58.8)	32 (48.5)
13- 48	27 (27.0)	8 (23.5)	19 (28.8)
>48	21 (21.0)	6 (17.6)	15 (22.7)
LBP onset			
Gradual onset	81 (81.0)	29 (85.3)	52 (78.8)
Sudden onset	19 (19.0)	5 (14.7)	14 (21.2)
LBP location			
Center only	24 (24.0)	7 (20.6)	17 (25.8)
Center and bilateral	31 (31.0)	11 (32.4)	20 (30.3)
Right side only	21 (21.0)	9 (26.5)	12 (18.2)
Left side only	14 (14.0)	6 (17.6)	8 (12.1)
Bilateral	10 (10.0)	1 (2.9)	9 (13.6)

LBP - Low Back Pain.

Table 2: Mean values of Oswestry Disability Index, Visual Analogue Scale and Roland Morris Disability Questionnaire.

Variable	Mean (SD)
Oswestry Disability Index (ODI) - Test	30.30 (13.86)
Oswestry Disability Index (ODI) - Retest	30.27 (13.26)
Visual Analog Scale (VAS)	42.53 (19.63)
Roland Morris Disability Questionnaire (RDQ)	7.72 (3.34)

Discussion

The aim of current study was to validate the Sinhalese version of Oswestry Disability Index version 2.1a. Validation and translation of ODI into other languages is strongly motivated by previous studies [20].

The ODI version 2.1a was tested on 100 participants and all the participants completed the retest questionnaire within 1-2 weeks after the initial assessment. The results of the current study indicated that the Sinhalese version 2.1a of ODI is a reliable and a valid instrument which could be used for LBP severity measurement in Sinhala speaking patients.

The Mean ODI value of the current study was 30.61±13.78, which was similar to a previous study done in Iran (Mean ODI=30.1±12.4) [21] and Switzerland (Mean ODI=30.5 ±17.0) [22]. The consistency of the survey results were evaluated using internal consistency and test-retest reliability. In a reliability analysis of a questionnaire, it is considered ideal when the Cronbach α coefficient is greater than 0.7 [23]. The Cronbach α coefficient was 0.811 for the overall ODI questionnaire, which indicated good internal consistency. This finding was similar to previous studies investigating the translated version of ODI, in Canada (α = 0.88) [24], in Saudi Arabia (α= 0.886) [25] and India (α = 0.94) [26]. Test-retest reliability could be evaluated using the intraclass correlation coefficient (ICC) [27]. Values more than 0.8 implied good reliability [28]. The test-retest reliability (temporal stability) of the current study resulted in an ICC of 0.983 (95% CI: 0.975-0.989), indicating an excellent agreement between test and retest values. This was in consistent with the previous studies conducted in Canada (ICC=0.92) [24], India (ICC=0.943) [26], China (ICC=0.99) and Germany (ICC=0.96).

The performance of ODI Sinhalese version was evaluated in compared with RDQ and VAS pain intensity. The Pearson's correlation coefficient (r) value were interpreted as follows: 0.00 to 0.19 = very weak correlation; 0.20 to 0.39 = weak correlation; 0.40 to 0.69 = moderate correlation; 0.70 to 0.89 = strong correlation; and 0.90 to 1 = very strong correlation [29]. RDQ has been shown to correlate to ODI in previous studies [30]. In the current study, the Pearson's correlation test revealed a significant strong positive correlation between ODI and RDQ (r=0.989, p<0.001), which was better than previous research findings in countries such as Saudi Arabia (r = 0.656) [25], Canada (r = 0.84) [24] and Germany (r=0.80) [22]. The VAS which is used to assess the pain intensity and has been employed in many other translation research of the ODI and they have indicated to have a significant correlation with ODI [9,31]. The current study results demonstrated a significant moderate positive correlation between ODI and VAS pain intensity (r=0.558, p<0.001). Low correlation between ODI and VAS pain intensity score has been previously reported in India (r=0.325) [26]. However, better correlation between ODI and VAS has also been reported in Germany (r=0.78,) [22], Saudi Arabia (r = 0.708) [25], Finland (r= 0.62) [32] and China (r =0.69) [33]. The present study has several limitations that need to be acknowledged. The results of the study are not generalizable to all previous versions of the ODI questionnaire or to patients with definite causes for their LBP.

Conclusion

The Sinhalese version of ODI questionnaire demonstrated a good reliability (internal consistency), test- retest reliability (temporal stability) and validity when compared with similar standard measures. The Sinhalese version of Oswestry Disability Index version 2.1a (ODI) can be employed in future studies assessing LBP disability in Sri Lanka which would be beneficial for physiotherapists and health care professionals in assessing and treating individuals with low back pain.

Conflicts of interest

Authors declare no conflicts of interest.

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