

HINDI TRANSLATION AND PSYCHOMETRIC EVALUATION OF THE OSWESTRY DISABILITY INDEX (ODI) VERSION 2.1a

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ABSTRACT

Study Design: Methodological Study, translation

Objective: To translate the original English version of Oswestry Disability Index Version-2.1a into Hindi language and to assess its content validity, Internal Consistency and Test-Retest reliability.

Summary of Background Data: ODI has been validated, and used as an outcome measure for various Low Back Pain conditions and its Hindi version is not available.

Methods: The translation was carried out in accordance with the Linguistic validation of a Patient Reported Outcomes Measure, provided by the Mapi institute. Content validity was evaluated through Qualitative (Wallace & McKenzie) and Quantitative methods (Lawshe). Internal Consistency and Test-retest Reliability was examined on 50 patients.

Results: Internal consistency for Hindi ODI version 2.1a was excellent with Cronbach s alpha=0.947. The intraclass correlation coefficient of test–retest reliability was 0.900.

Conclusion: The results of this study indicate that the Hindi version of the ODI 2.1a is a reliable and valid instrument for the measurement of disability in patients with low back pain.

KEYWORDS: Oswestry Disability Index, translation, reliability, validity, low back pain.

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INTRODUCTION

Low back pain is an important clinical, social, economic, and public health problem that affects the population indiscriminately. Low back pain is a disorder with many possible etiologies, occurring in many groups of the population, and with many definitions.¹ Low Back Pain (LBP) is a common health problem worldwide. It imposes enormous cost on the community and is also a common reason for sick leave from employment.² On any given day, an estimated 6.5 million people in the United States are bed-ridden

because of back pain and approximately 1.5 million new cases of low back pain are seen by physicians in each month. There has been growing concern about the low back disability in western society. In India, occurrence of low back pain is also alarming; nearly 60% of the people in India have significant back pain at some or the other point of time in their lives.³ The measurement of disability is an important part of Low Back Pain (LBP) assessment and management. The choice of the most appropriate outcome measure should rely on the nature

of the condition, the type of data desired by the clinician, and environmental factors.⁴ Clinical decision making relies on valid and reliable outcome measures. Outcome measures help in determining client's disability and impairment, choice of therapy, and degree of change over time. To be clinically significant, an outcome measure must be easy to complete and score, valid, reliable, and responsive.⁴ It's usually classified into generic or disease specific. Disease-specific instruments are often found to be more responsive to the target condition when compared to generic measure⁵ Among these disease-specific measures, an international group of researchers, Deyo et al, recommended two measures: the Roland-Morris Disability Questionnaire (RMDQ) or the Oswestry Disability Questionnaire (ODI).⁶ The need for a condition-specific health disability questionnaire for use in everyday clinical practice as an outcome measurement of various treatment modalities, to compare the results of clinical studies of similar treatments and for research purposes, has been recognized by several authors.⁶ The ODI is a disease-specific self-administered questionnaire designed to assess the baseline functional status and its change over time for patients with back pain, it also assesses disability in LBP. It has been found to be reliable, valid and responsive in particular in patients with a higher level of disability.⁷⁻¹⁰ The ODI score has less notable ceiling effects than the RMDQ score, indicating that the ODI has a better discriminative property when the score reaches the maximum on the RMDQ that is at high levels of disability, the ODI may still show change when RMDQ scores are maximal. The authors therefore recommend use of the ODI in patients who are likely to have persistent severe disability and the RMDQ in patients who are likely to have relatively little disability. However, for most patient groups, both instruments function satisfactorily in groups with severe disability.⁷ ODI exists in many versions, the developer of ODI Dr. Jeremy Fairbank recommended version 2.1a as the most updated version of the ODI for translation.

MATERIALS AND METHODS

Subjects

Inclusion Criteria: Age above 18year, Presence of LBP with or without radicular pain², Able to

read and understand Hindi.

Exclusion criteria: Patients diagnosed with any of these conditions (Spinal infections, Malignancy, Recent fracture, Cauda equina, Ankylosing spondylitis, Spinal deformity, Rheumatoid arthritis, Osteoarthritis)^{11, 12}, Any known pregnancy¹¹, Patients who demonstrated inability for effective communication as a result of neurologic or psychiatric alterations.^{5,11} Patients suffering from pain in area(s) other than Low Back area, and those who refused to participate in the investigation.¹¹

10 patients were included in Hindi translation phase of the study, 10 in Content Validity phase, and 50 patients for internal consistency & test-retest reliability evaluation. Patients were recruited from Indian Spinal Injury Centre, and Deen Dayal Upadhyaya Hospital, New Delhi.

The study was approved by the ethical committee and written informed consent was obtained from all the participants.

Procedure

The procedure was divided into two phases. **Phase I** involved Translation of the scale to Hindi language. **Phase II** Evaluation of the psychometric properties of Hindi Oswestry Disability Index Version 2.1a.

Prior to the initiation of Hindi translation process, due permission was taken from the author of original English version of Oswestry Disability Index, Dr.Jeremy Fairbank and Mapi Research Institute, through an e-mail

Phase I: Translation of the scale to Hindi language.

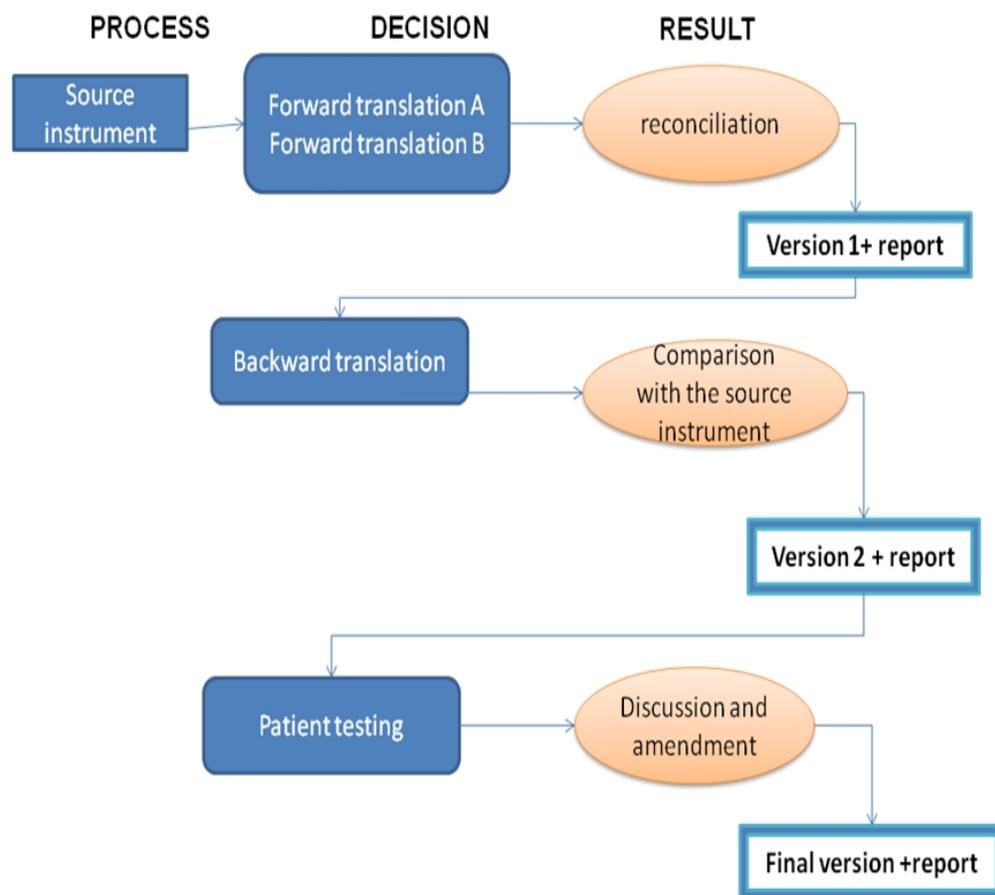
The translation was carried out in accordance with the Linguistic validation of a Patient Reported Outcomes Measure, provided by the Mapi institute, it consisted of three steps forward translation, Backward translation and Patient testing.¹³

In Forward translation step, 2 local professional translators, native Hindi language speakers, bilingual in English language translated questionnaire from English to Hindi individually. Only after discussion between the two translators and the local project manager agreement was made on one reconciliation version. Which was conceptually equivalent

translation of the original English questionnaire and the Hindi language used was colloquial and easy to understand. At the end a report was produced outlining the translation issues and how settlement was made. In case of interpretation problems of the original English questionnaire, the author was contacted and according to his explanation, the reconciliated Version 1 (in Hindi language) was modified. Backward translation step required a local professional translator, native speaker of the English language, bilingual in Hindi language, but it was difficult to find a professional translator with English as his native language, so with the author's and Mapi research institute's permission an experienced professional translator with Hindi mother tongue, and bilingual in English language was chosen. He translated the scale back to English which was then compared with the original English version by the local project manager (researchers of the Hindi ODI version) and the backward translator, in order to detect any misunderstandings, mistranslations or inaccuracies in the intermediary forward version of the questionnaire.

A report in English was produced on the issues which were discussed item-by-item and how the final decisions were made.

In Patient testing step the translated questionnaire was tested on 10 Low Back Pain patients who gave their consent, in order to determine whether it was acceptable or not, and was understood in a correct way, and whether the language used was simple, comprehensible and appropriate. A comprehension test was performed through face to face interviews during which a set of questions was used to inquire whether the patient had any difficulty in understanding instructions, items or the response choices and patient's interpretation of all items and responses were checked. Problems detected were reported, patients were asked to propose alternatives and suggestions. A report on the interviews conducted on patients was produced in English. A third version of the questionnaire after proof-reading, and making changes, which was considered to be as the final, was produced.



Phase II: Evaluation of the psychometric properties of Hindi Oswestry Disability Index Version 2.1a.

Content validity was evaluated through Qualitative and Quantitative methods. For qualitative review criteria given by McKenzie and colleagues¹⁴ and Wallace et al¹⁵ were used and for Quantitative review Content Validity Ratio Method by Lawshe was used.¹⁶

The panel of experts or jury of experts is the initial and critical step in establishing the content validity. In this step, 10 experts were approached, of which 5 were experienced physiotherapist, 5 were experienced spine surgeons, and also 10 subjects with Low Back Pain i.e. the target group with same inclusion and exclusion criteria as in Stage 3 (Patient Testing). The surgeons and physiotherapist were experienced in dealing with Low Back Pain patients. The experts were invited via face to face contact, covering letter was provided and all the participants were explained about the purpose of the study. Their consent for participation in the validation phase along with their demographics and experience details were obtained.

An inventory of questions and copy of translated Hindi version of questionnaire was given to the experts. The experts were requested to provide their feedback on the overall questionnaire including directions, content areas, and items of the questionnaire, need for revision of items, additions of items, deletion of items and any additional suggestions. The reviews given by all the expert panel members were collected by hand and appropriate changes were made after a thorough discussion between the local project manager and translators. The changes were again discussed with the experts, and consensus was achieved at last that led to development of the final Hindi version of the ODI version 2.1a questionnaire.

After the completion of qualitative review, all the members of the expert panel were asked to quantitatively evaluate the final Hindi version of the questionnaire. Lawshe's method was used to quantitatively evaluate content validity.¹⁶ The panel of experts were asked to rate the appropriateness of the 10 items of the scale by stating whether each item was "essential," "useful but not essential," "not necessary," or "not useful."

After receiving each expert's ratings, values were entered into a Microsoft excel spread sheet and the researcher sums up the responses marked for each item, by each panel member. The Content Validity Ratio (CVR) was calculated by applying the formula developed by C. H. Lawshe (1975).¹⁵

$$CVR = \frac{Ne - N/2}{N/2}$$

Keys,

CVR= CVR value for the l'th measurement item
Ne= No. of subject matter experts indicating a measurement item as "essential"

N= Total number of subject matter experts in the panel

The calculated CVR is then compared to the levels required for statistical significance. A minimum CVR value of 0.42 was necessary for statistical significance at p = 0.05 based on 20 panellist.¹⁶ A master chart can be reviewed for the individual item ratings by the expert panel.

Instruments

The ODI is a disease-specific self-administered questionnaire designed to assess the baseline functional status and its change over time for patients with back pain has an advantage of easy patient comprehension and compliance. This self-assessment test takes less than 5 min to complete and 1 min to score, with no training, equipment or cost requirements; and it covers a wide range of function, pain and role limitation.²

Statistical Analyses

Content Validity: Refers to the extent an instrument measures what it is intended to measure, also the extent to which the instrument provides adequate coverage of the items under study.¹⁷ It was calculated using the Content Validity Ratio Formula given by C.H. Lawshe.

Internal consistency: Alpha was developed by Lee Cronbach in 1951 to provide a measure of the internal consistency of a test or scale; it is expressed as a number between 0 and 1. Internal consistency describes the extent to which all the items in a test measure the same concept or construct and hence it is connected to the inter-relatedness of the items within the test.¹⁸

Test-Retest reliability: Reliability is the estimate of the precision or consistency of a measure determined by the variance of repeated measurements; the extent to which a test is free of random error. Test-retest reliability relies on two separate measures of the test and assumes there is no underlying change that has occurred between test periods. Its purpose is to establish that an instrument is capable of measuring a variable consistency.¹⁹

RESULTS

Demographic Data: A total of 50 subjects were purposively sampled for reliability analysis of the study with mean age of 36.6 years. Total number of subjects was 50, out of which there are 20 males and 30 females.

Content validity: Content validity ratio was calculated for each item according to the formula given by C.H.Lawshe method.¹⁶ Results reveals content validity ratio for each items. As mentioned in methodology, at significance level of p = 0.05, the item having content ratio more than 0.42 were retained. In total, no item was found to be content wise valid out of initial 10 items (Table 1). Thus, the final scale constituting 10 items was having good content validity.

Table 1: Content validity ratio of 10 items.

Item number (N)	CVR
1	1.00 (S)
2	1.00 (S)
3	1.00 (S)
4	1.00 (S)
5	1.00 (S)
6	1.00 (S)
7	1.00 (S)
8	1.00 (S)
9	1.00 (S)
10	1.00 (S)

Key, CVR = Content Validity Ratio, N = Item number, (S) = Significant

Internal consistency reliability: Internal consistency was evaluated by Cronbach's alpha coefficient. The Cronbach's alpha for community Hindi ODI Version 2.1a was found to be 0.947 which indicate excellent internal consistency of ODI.

Test-retest reliability: To evaluate test-retest reliability, the Hindi questionnaire was re-admin

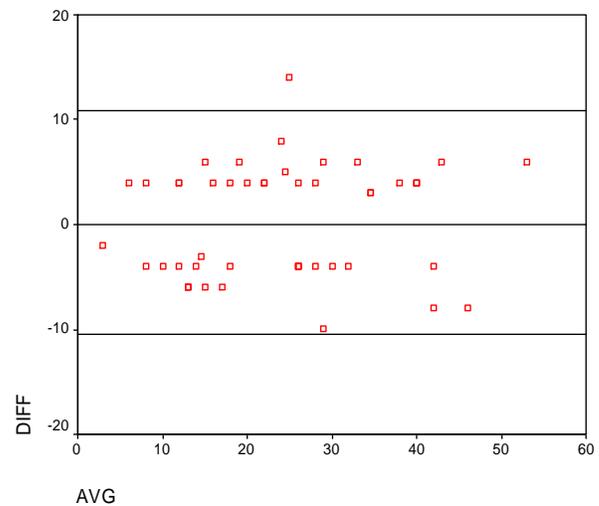
istered after 24 hours was found to be 0.900, at 95% Confidence Interval. The test-retest reliability was calculated by evaluating intraclass correlation coefficient (ICC) for the scale. Table 2 reveals the ICC value. The ICC obtained indicates excellent test-retest reliability.

Table 2: ICC for Hindi ODI v2.1a.

Variable	ICC	95% Confidence Interval
Measurement 1 Vs Measurement 2	0.9	0.8303-0.9420

The plot indicates the differences between measures from the two test sessions against the mean of the two sessions for each participant. The dashed line shows 95% (± 1.96 SD) limits of agreement. The Bland Altman plot between the individual difference between two measurements against the average of two measurements showed very high reliability as more than 95% of values were lying between the limits (Graph 1)

Graph 1: Bland-Altman plot for test retest reliability for Hindi ODI Version 2.1a



DISCUSSION

The aim of the study was to translate original English Oswestry Disability Index Version 2.1a to Hindi and evaluate its psychometric properties.

The Oswestry is a common condition-specific tool that has been used in over 200 published articles since its inception in 1980. It can be argued that the condition-specific measure most sensitive to change in patients with low function

should be used and the National Spine Network (NSN) has chosen to utilize the ODI over the RMQ.²⁰

The analyses reveal that of the two disease-specific measures, the RMDQ may be more suitable for patients with less limitation in function and the ODI may be more suitable for patients with greater limitation and appeared to be more sensitive in the severely disabled patients.²⁰

Translation procedure as given by Mapi Research Institute was followed, which involved two forward translators and one backward translator.

In Forward Translation phase meaning of the word "extra pain" in the questionnaire was confirmed with the author, whether it is related to "back pain" or not, in reply the author had confirmed that "it is most likely to be back pain".

In Stage-3 (patient testing) 10 patients were interviewed regarding clarity, whether they were able to understand each item, its responses and instruction, put it in his/her own words. Also patients were asked to report any difficult words encountered and provide alternatives or suggestions for the same.

Patients were unable to judge the distance unit "mile" in Section-4 (Walking). When asked on understanding of distance in mile they were not very clear but when, kilometre equivalent for mile was told it became more comprehensible about the same. With author's permission "kilometres" and "meters" equivalent were used instead of "mile" and "yards" as per Mapi institute's directions.

In Content Validity phase, meaning of words "extra pain" in the Questionnaire was confirmed with the author that whether it is the pain over or above the resting pain or it is a new pain which is originating with the activities. Author replied that "the questions/responses mentioning "extra pain" cover both, those with no pain at all and also those with some pain which is not made worse by particular activity"

The Content Validity evaluation phase had been divided into two phases, Qualitative and Quantitative phase. A Jury of 10 experts and 10 patients, in total 20, was established for Qualitative and Quantitative Review. In Qualitative Review 7 experts including 2

patients pointed out that in response no. 2, 3 and 4 in Section-1 (Pain Intensity) gradation of pain intensity was overlapping and not clearly differentiated. After a meeting between Local Project Managers and all the translators, a better alternative was chosen for the word "moderate" in Hindi and an acceptable gradation of pain intensity was made.

In Section-3 some experts suggested to add examples of objects or mention in "Kilograms" for "light to medium weights", as it would be easier for the patients to understand and quantify. Author was contacted for the same issue, in his reply Dr Jeremy Fairbank explained that there are cultural issues, and perception of light, medium and heavy weights would vary from gender to gender, small to larger frame, and age of an individual, therefore it must not be quantified, so this question asks the subject to decide for themselves. Keeping all directions in mind the words "light to medium weights" were not replaced by any examples, either of "objects or in any unit of weight.

One of the experts suggested deletion of Section-9 (Social Life) as the questionnaire covers activities like standing, sitting, walking, travelling, etc individually which if put together makes the social life. But after a detailed discussion of all the components of Social Life, the expert was convinced with the importance of the Section 9.

After Qualitative Review changes were made in the questionnaire, all the experts gave their consent to these changes and appreciated the work.

The Quantitative Review involved calculating content validity ratio (CVR) was using

Lawshe's method in which all the 20 experts had to rate each of the 10 items as "essential", "useful but not essential" or "not necessary", it came out to be 1.00 for each item at $p = 0.05$.

The internal consistency of Hindi ODI version 2.1a estimated by Cronbach's alpha was found to be 0.94 indicating excellent internal consistency of Hindi ODI to assess functional disability in low back pain population. Strong et al (using version 1.0) found Cronbach's alpha to be 0.71, Fisher and Johnson (using version 2.0) 0.76, and Kopec et al 0.87. All these investiga-

tions show an acceptable degree of internal consistency.⁸ Brazilian Portuguese version of ODI version 2.0 had excellent internal consistency, indicated by Cronbach's coefficient alpha = 0.87.¹¹

There are different reports about the acceptable values of alpha, ranging from 0.70 to 0.95. Items with low correlations (approaching zero) are deleted. If alpha is too high it may suggest that some items are redundant as they are testing the same question but in a different guise. A maximum alpha value of 0.90 has been recommended.¹⁸

The Intraclass Correlation Coefficient was calculated for establishing test-retest reliability. Different guidelines exist for the interpretation of ICC, but one reasonable scale is that an ICC value of less than 0.40 indicates poor reproducibility; ICC values in the range 0.40 to 0.75 indicate fair to good reproducibility, and an ICC value of greater than 0.75 shows excellent reproducibility.²¹

Patients with low back pain were tested twice in a 24-hour interval, under similar conditions. The ICC value for single measures is 0.900, indicating excellent test-retest reliability. In the original study, Fairbank et al found ICC=0.99 (n=22,) at a 24hr interval (Fairbank 1980). Brazilian Portuguese version of ODI version 2.0 had excellent agreement between the scores (ICC = 0.99) when evaluated twice at a 24-hour interval. This may include a memory effect. In another study, Kopec et al found the agreement ICC=0.91, with a mean interval of 4 days for the test-retest, which varied from 1 to 14 days. Gronblad et al, evaluating test-retest reliability using the ICC, found a lower value (n=20, ICC=0.83), with a 1-week interval.¹¹

Bland Altman plot is a measure of within-subject variation and the limits of agreement were examined using the Bland and Altman plot. The plot (Graph 1) shows the difference between the first and the second sum scores against the mean of both sum scores. The Limits of Agreement ranged from -10.44 to 10.92.

In paired-t test the difference between the two readings taken at 24hour interval was not significant as p-value was more than 0.05.

Hindi version of ODI Version 2.1a is a valid and

reliable tool for assessing disability in patients with low back pain.

Limitations of the study:

- The Hindi version questionnaire has not been adapted cross-culturally.
- Sample population for the phase I and II was predominantly taken from Delhi.
- The questionnaire has been not been validated in the populations like lumbar canal stenosis, surgical stabilization, lumbar discectomy, spinal thrust manipulation, decompression surgeries, pedicle subtraction osteotomy, Posterior Interbody Lumbar fusion, kyphoplasty, etc.

Future recommendations:

- Establishing criterion and concurrent validity of the Hindi ODI Version 2.1a.
- Measuring the responsiveness of Hindi ODI Version 2.1a.
- To find out the utility of Hindi ODI Version 2.1a to other populations like lumbar canal stenosis, surgical stabilization, lumbar discectomy, spinal thrust manipulation, decompression surgeries, pedicle subtraction osteotomy, Posterior Interbody Lumbar fusion, kyphoplasty, etc.

Conflicts of interest: None

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