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Translation and Validation Study of the Persian Version of the Oxford Shoulder Instability Score

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ARTICLE INFORMATION	ABSTRACT
	Introduction: Assessing quality of life for patients with shoulder instability may be essential because of the negative impacts of the disease on patient's life. The aim of the present study, therefore, was to assess the internal validity and consistency, test-retest reliability, and convergent validity of the Persian version of the Oxford Shoulder Instability Score (OSIS). **Material and Methods:** A total of 150 patients with shoulder instability completed the Persian OSIS, Disabilities of the Arm, Shoulder, and Hand (DASH), and visual analog scale (VAS) to test convergent validity. 50 randomly selected patients completed the OSIS, 48 hours later, for the second time.
Corresponding Author: Gholam Reza Olyaei **Emial:** olyaeigh@sina.tums.ac.ir **Tel:** +982177528469 **Fax:** +982177534134	**Results:** Cronbach's alpha coefficient for the Persian OSIS was 0.90. The Persian OSIS showed excellent test-retest reliability with intraclass correlation coefficient 0.94 (P < 0.01). The Pearson's correlation coefficient between the Persian OSIS and DASH and VAS was 0.84 and 0.79, respectively (P < 0.01), indicating a good convergent validity. **Conclusion:** The Persian OSIS is a reliable and valid instrument to measure health-related quality of life and functional disability in Persian-speaking patients with shoulder instability in Iran. **Keywords:** Shoulder instability; Oxford Shoulder Instability Score; Reliability; Validity; Quality of life; Functional disability; Persian Oxford Shoulder Instability Score

Introduction

Shoulder instability is among the prevalent shoulder disorders affecting adults (1-6). Shoulder instability and dislocation/subluxation have negative impacts on the patient's activities of daily living, work status, and sport activities, consequently influence health-related quality of life (HRQOL) (1, 2, 7). Objective measures, such as range of motion and muscle strength, have been conventionally used to assess the impact of shoulder disorders on the level of functional health status as well as to measure outcome in clinical practice and research (8-11). However, in some settings, these measures are poorly associated with outcomes that are more relevant to patients and society such as symptom relief, daily functional ability, and work status (9, 12, 13). The aim of treatment in shoulder disease, including shoulder instability disorders, is often improving the functional abilities and quality of life of the patient; hence, HRQOL should be considered as an important outcome in

clinical trials investigating disorders of the rotator cuff (9, 10, 13).

Several region, joint, and disease-specific disability and quality of life instruments have been developed for patients with shoulder disorders and commonly used as outcome measures in research and clinical settings (11, 14-17). It has been argued that joint- or disease-specific measures are more sensitive to detect small but important changes related to specific disorders than generic measures (9, 18). The Oxford Shoulder Instability Score (OSIS) is a newly developed self-administered diseases-specific instrument that was designed to measure HRQOL in patients with shoulder instability (18-20). The psychometric properties of original OSIS have been tested and shown good reliability and convergent validity (16, 21, 22).

At present, no disease-specific quality of life and functional disability measure is available for Persian-speaking patients with shoulder instability. The use of generic and specific subjective measures in different

countries must follow certain guidelines for translation, cross-cultural adaptation, and validation. Hence, the aims of the present study were two-folds: (1) Translation and cultural adaptation of the OSIS for use by Persian-speaking patients with shoulder instability in Iran and (2) Investigate the internal validity and consistency, test-retest reliability, and convergent validity of the Persian version of the OSIS.

Materials and methods

The original version of the OSIS was used for cultural translation and validation in the present study. The Persian versions of the Disabilities of the Arm, Shoulder, and Hand (DASH) (23) and visual analog scale (VAS) of pain were used to test convergent validity of the Persian OSIS.

The OSIS (15)

The OSIS is a condition-specific questionnaire developed for patients with shoulder instability. It contains 12 items to be answered by the patient independently. There are five categories of response for every question, corresponding to a score ranging from 1 to 5. Scores are combined to give a single score, with a range from 12 (the best) to 60 (the worst).

The DASH (22)

It is a 30-items questionnaire that measures the patient's functional status during the preceding week. The questionnaire designed to evaluate the degree of difficulty in performing several physical activities because of an arm, shoulder, or hand problem (21 items), the severity of each of the symptoms of pain, activity-related pain, tingling, weakness, and stiffness (5 items), as well as the effects of the condition on social activities, work, and self-image impact (4 items).We used the Persian DASH, which has been recently translated and validated for Iranian people (23).

VAS

VAS is a horizontal line, 100 mm in length, anchored by word descriptors at each end (no pain to worst pain). The patient selects the point on the line that best represents his/her perception of pain level.

A total of 250 native Persian-speaking patients with rotator cuff disorders, who were referred to orthopedics surgery, rheumatology, and physical therapy clinics, were consequently enrolled in the study over a period of 12-month. Face validity was carried out with the first 50 patients (pilot group). Content, internal, and convergent validity were conducted on the next 150 patients (original group). To carry out the test-retest reliability, a total of 50 patients, randomly selected from the original group, completed the questionnaire again 48 hours later, in the same manner as the first time. All patients underwent a comprehensive history taking, clinical examination, and radiological evaluations if indicated. Patients with recent history of

fracture and operation of the affected shoulder, inflammatory arthritis (e.g., rheumatoid arthritis), clinical signs of a cervical syndrome, systematic inflammatory disease, and relevant co-morbidities such as cancer, infectious disease, heart attack, or clinically recognizable cognitive impairment were excluded from the study. All patients signed an informed consent approved by the Ethics Committee of our University Review Board (No. 8710).

Translation and cultural adaptation

The translation and cultural adaptation process followed the previously published guidelines (24, 25). Two independent professional translators produced two forward translations of the OSIS into the Persian language. One translator was aware of the questionnaire concept, and another translator was not. Both translators were instructed to aim for conceptual rather than literal translation. Together with one of the authors, the translators compared their translations and produced a single consent version of the questionnaire. Totally blind to the original version, two other professional translators translated the last Persian questionnaire back into the original English language. The two translators were not aware of the questionnaire concept. Finally, an expert committee consisted of the translators, the researchers, two orthopedic surgeons, and one outcome methodologist reviewed all the translation and cultural adaptation processes. Consensus in terms of semantic, idiomatic, experiential, and conceptual equivalence was reached, and a pre-final version of the translated OSIS (the Persian OSIS) was obtained.

Face and content validity

Face validity is concerned with whether a measurement seems to be assessing the intended parameters (26). Along with one of the authors, the pre-final Persian OSIS was completed by 50 patients to establish that the Persian version could be understood and that the questions measured what they were intended to measure. Each participant was then asked to answer the questionnaire and was encouraged to point out and discuss any item that was difficult to understand. All findings from this phase of the adaptation process were evaluated by the authors, and then, the final Persian OSIS was developed and subjected to further psychometric testing. Content validity examines the completeness of item responses, the distribution of the scores, and the magnitudes of ceiling and floor effects (26). Floor and ceiling effects were considered to be present if more than 15% of the respondents achieved the highest or lowest possible score, respectively.

Scale internal validity and reliability

The internal validity of the scale was evaluated by computing the correlation of the items with the respective scales corrected for overlap to avoid the bias

of self-correlation. Item-discriminate validity indicated to what extent an item measures what it is not supposed to measure, that is, the degree of discriminatory power. It was tested by computing the correlation of each item with the other scales. To support the high discriminatory power of scales, there should not be a high correlation for item discriminance. Reliability of measurement refers to the extent to which the measured variance in a score reflects the true score rather than random error; that is, the extent to which measures give consistent or accurate results (26). Two common forms of reliability are internal consistency method (Cronbach's alpha) and test-retest reliability (27). To evaluate test-retest reliability, 45 randomly selected patients completed the Persian OSIS twice with a time interval of 48 hours.

Convergent validity

Convergent validity examines the extent to which a particular measure relates to other measures that are believed to be assessing the same construct (26, 28). In the absence of a true "gold standard" against which to assess criterion validity of the Persian OSIS, we compared this questionnaire with commonly used external measures likely to reflect the impact of rotator cuff disease. To test convergent validity, correlations between domains and total score of the Persian OSIS and the Persian versions of the DASH and VAS questionnaires were measured.

Kolmogorov–Smirnov test was used to assess the distribution of the Persian OAI, DASH, and VAS scores. The interval measurements were normally distributed, and therefore, several parametric tests were employed to analyze data. A Pearson's correlation of at least 0.4 was assumed as the standard for supporting scale internal validity. The coefficient of internal consistency was assessed with the Cronbach's alpha that ranges from 0 to 1, and values ≥ 0.7 indicate adequate internal consistency for scale (28). The test-retest reliability was tested using intraclass correlation coefficient (ICC). Values of ICC vary from 0 (totally unreliable) to 1 (perfectly reliable). Values above 0.80 were considered as evidence of excellent reliability (26). The Pearson's correlation coefficient was used to test convergent validity of the Persian OSIS. Correlation values of 0.40 or above were considered satisfactory ($r \geq 0.81$ to 1.0 as excellent, 0.61 to 0.80 as very good, 0.41 to 0.60 as good, 0.21 to 0.40 as fair, and 0 to 0.20 as poor) (26, 28). SPSS (version 21; SPSS Inc., Chicago, IL., USA) was used for analyses. The critical values for significance were set at P < 0.05.

Results

Table 1 summarizes the demographic and clinical characteristics of the participants.

Scale reliability and validity

Regarding the scale internal validity, the computed correlations of single items with the referring scale indicated high scale internal validity. Regarding discriminatory power, Pearson's coefficient for correlation between the items of a scale and the other scales were > 0.4. Overall, the values indicated the high discriminatory power of scales. The Cronbach's alpha and ICC value for the OSIS were 0.90 and 0.94, respectively (P < 0.01), which indicate excellent test-retest reliability for the questionnaire. The correlations between the Persian OSIS domains and the DASH and VAS were 0.84 and 0.79, respectively (P < 0.01).

Table 1. Demographic and clinical characteristics of the participants

Characteristics	Mean ± SD	Min	Max
Age (years)	28.5 ± 8.4	18	40
Education (years)	11.1 ± 2.8	6	18
Pain duration (years)	2.8 ± 4.0	0.01	20
DASH (0-100)	56.0 ± 18.2	8	97.4
VAS (0-100)	49.2 ± 32.6	5	89
OSIS (12-60)	38.3 ± 19.8	14	52

DASH: Disabilities of the Arm, Shoulder, and Hand outcome measure, VAS: Visual analog scale, OSIS: Oxford Shoulder Instability Score, SD: Standard deviation

Discussion

The results of the present study showed satisfactory internal validity and consistency, reliability, and convergent validity of the Persian OSIS in patients with shoulder instability. It is easy to use for patients and covers most important areas of health status that are influenced by shoulder disorders. With the growing number of multinational and multi-center studies, the need to culturally adapt health status measures for use in other than the source language has grown rapidly (24, 27). The presence of an internationally validated disease-specific instruments for shoulder instability would allow direct comparison across countries as well as it would simplify the problems of meta-analysis for clinical studies (25). The findings of the present study suggest satisfactory internal validity and consistency of the Persian OSIS. In the present study, the Persian OSIS showed excellent test-retest reliability, with ICC of 0.94. Our results show high agreement between measurements recorded on 2 occasions over a 48-hour period.

Convergent validity

The Persian OSIS showed good significant convergent validity as assessed with the Persian versions of the DASH and the VAS. The significant very good correlation was found between the Persian versions of the OSIS and the DASH total scores. In the analysis for convergent validity, a good significant correlation was found between the domains and total score of the Persian OSIS and VAS. The correlation between upper extremity disability and pain ratings is expected to be good, but it is not expected to be extremely high. These findings are in accordance with the recent opinion that indicated there is a moderate significant correlation

between pain and functional disability (29).

To our knowledge, the Persian OSIS is the only disease-specific outcome measure for shoulder instability in Iran. In addition, as far as we know, this article describes the first attempt at translation and validation of a disease-specific shoulder instability measure in Asia. Given the population of Iran (over 70 million) and high complaint of shoulder instability disease, the Persian OSIS might provide both clinicians and patients with numerous advantages. HRQOL was rarely assessed as a primary endpoint in studies of shoulder disorders in Iran, and indeed should be included as an important outcome in the future studies. This might help to better understand the impact of disorders of shoulder instability on HRQOL and functioning in these patient populations.

Conclusion

We recommend the Persian OSIS as an efficient clinical measure because the Persian OSIS is a reliable and valid instrument to measure HRQOL and functional disability in Persian-speaking patients with shoulder instability.

Conflict of Interests

Authors have no conflict of interests.

Acknowledgement

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