Cross-cultural adaptation and validation of the Romanian Oxford Shoulder Score

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Abstract

Background: The use of validated patient reported outcome scores is critical to the reporting and monitoring of the effectiveness of clinical treatment. The aim of this study was to translate and culturally validate the English Oxford Shoulder Score (OSS) to Romanian.

Methods: Approximately, 125 patients with disorders of the rotator cuff and proximal humerus fractures completed the translated Oxford Shoulder Score (OSS_RO), the Disabilities of the Arm, Shoulder, and Hand (QuickDASH) and EuroQol 5-Dimension (EQ-5D-5L). The patients repeated the evaluation using the OSS_RO after 2 days.

Results: The OSS_RO had a high degree of internal consistency and reliability with a Cronbach’s α of 0.954 at the initial completion and 0.945 at the second testing. The intraclass correlation coefficient (ICC, 2-way mixed effects model) was 0.953 (single measures) and 0.976 (average), P < .001. The OSS_RO was reproducible (Pearson’s r = 0.95; P < .001). The OSS_RO was divergently valid with QuickDASH score (Pearson’s r = 0.633 first and r = 0.672 second; P < .001) and convergent with the EQ-5D VAS (Pearson’s r = 0.627 first and r = 0.640 second; P < .001) and the EQ-5D Index (Pearson’s r = 0.759 first and r = 0.771 second; P < .001).

Conclusion: Our study showed that the Romanian translation of the OSS is a reliable, reproducible and valid measure of shoulder function in patients with variable shoulder pathology.

Abbreviations: CONSORT = Consolidated Standards of Reporting Trials, EQ-5D-5L = EuroQol 5-Dimension, 5 level instrument of health related quality of life, ICC = intraclass correlation coefficient, ISPOR = International Society for Pharmacoeconomics and Outcomes Research, OSS = Oxford Shoulder Score, PROs = patient reported outcomes, QuickDASH = Disabilities of the Arm, Shoulder, and Hand.

Keywords: clinical treatment, Oxford Shoulder Score, Romania Shoulder Program, rotator cuff

1. Introduction

Shoulder pathology is among the most common orthopedic conditions seen by family practitioners, hospital specialists, and orthopedic surgeons. The shoulder is the second most common joint affected by painful pathology after the knee, reported in 18.7 million people of the adult population in the United States. The prevalence of shoulder pathology increases with age but the distribution based on gender is equal. Patient reported outcomes (PROs) are self-reported measurements of a patient’s health status. These measurement tools are scores based on a series of questions answered by the patient without clinician interference. The Oxford Shoulder Score (OSS), administered by Oxford University Innovation, is a validated PRO used to assess the patient’s perception of shoulder function and pain. It was originally developed in English and has been adapted for use in several other languages and cultures in Europe and Asia. To date, there has been no translation of the OSS in Romanian.

The aim of this project was to perform translation and cultural adaptation of the OSS to Romanian. We performed psychometric testing of the Romanian translation of the OSS to determine if it can be used as a valid outcome measure for evaluation of shoulder pain and outcome in clinical practice.

2. Methods

2.1. Translation

The original questions used for the translation and validation were provided by Oxford University Innovation (previously known as Isis Innovation Ltd., Oxford, United Kingdom) as the ‘English’ version for the United Kingdom (1996). The English OSS form was translated and culturally validated using the instrument developer’s translation and linguistic validation
guidelines (2010, 2013) and following the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) principles of good practice for the translation and cultural adaptation process.\[10\] The subsequent Oxford Hip Score translation has been compared and contrasted to this initial OSS translation.\[11\] The Consolidated Standards of Reporting Trials (CONSORT) flow diagram is available as supplemental material (Chart 1, http://links.lww.com/MD/C262). Copyright of the translated form is owned by Oxford University Innovation.

One hundred and fifty seven patients with documented shoulder pathology based on clinical complaints and examination from 4 medical centers in Romania were recruited to the study. During this evaluation, patients completed the OSS_RO (Romanian translation of the OSS), Disabilities of the Arm, Shoulder, and Hand (QuickDASH), and EuroQol 5-Dimension, 5 level instrument of health related quality of life (EQ-5D-5L). Time required to fill the OSS_RO was recorded. The patients completed a second OSS_RO at home after 2 days from the office visit. OSS_RO scoring was performed as instructed by Oxford University Innovation. Each question has a 5 point Likert scale. Answers for the OSS_RO are scored 0 to 4. When the 12 items were summed, this produced overall scores that could run from 0 to 48.\[2\] EQ-5D-5L scoring was performed as stated by the Euroqol guide version 2.1 April 2015.\[12\] The QuickDASH is a shortened version of the DASH Outcome Measure. Instead of 30 items, the QuickDASH uses 11 queries (Institute for Work and Health 2006, Romanian translation developed by Oxford Outcomes Ltd, Oxford, UK under contract by GlaxoSmithKline, United Kingdom).\[13\] QuickDASH scoring was performed as stated by the developer’s guidelines.\[14\]

Of the initial 157 patients, 125 patients completed the second form and were included in the final analysis. Sixty patients were from Timisoara, 36 from Sibiu, 24 from Craiova, and 5 from Cluj. The average age was 52.8 years (range, 17–89 years). The design at the time of clinical evaluation were as follows: 73 patients with subacromial impingement/cuff tear, 12 patients with proximal humerus fracture, 7 patients with anterior glenohumeral instability, 5 patients with calcific tendinitis, 4 patients with adhesive capsulitis, 4 patients with clavicle fracture, and 3 patients with glenohumeral osteoarthritis. The remaining 17 cases complained of atraumatic shoulder pain but no clear diagnosis was available at the time of evaluation.

2.2. Statistical analysis

Data were collected and analyzed using SPSS v17 statistical software package (SPSS Inc, Chicago, IL) and are presented as average ± standard deviation (numerical variables with Gaussian distribution), median, and interquartile range (numerical variables with non-parametric distributions) respectively percentage from the sub-group total and (number of individuals).

To evaluate the strength of the association between 2 continuous variables with Gaussian distribution we used Pearson’s correlation coefficient; the statistical significance of the correlation was evaluated using t-distribution test. A P < 0.05 was considered to reflect a Gaussian distribution of variables using Shapiro-Wilk test. A P < 0.05 was the threshold for statistical significance.

The internal consistency of the questionnaire was evaluated using the Cronbach’s alpha coefficient and the intraclass correlation coefficient (ICC, 2-way mixed effects model). The reproducibility of the test was evaluated using Pearson’s correlation coefficient. Agreement between the PROs was assessed with Pearson’s correlation coefficient.

2.3. Statement of ethics

The study was conducted in accordance with the Declaration of Helsinki. Participants consented voluntarily to data collection. The study protocol was approved by our Emergency Clinical County Hospital ethics committee.

3. Results

The average time needed to complete the form was 2 minutes and 53 seconds (range 21–390 seconds). Initial average OSS_RO scores were 24.3 (range 1–47) at the initial evaluation and 24.1 (range 1–47) 2 days later. For the EQ-5D-5L subscales the summary is presented in the table below (Table 1). The average VAS was 63.48 (min. 10 to max. 100).

3.1. Reliability: the internal consistency of the questionnaire.

The questionnaire had a high degree of reliability, at the initial completion of the questionnaire we obtained a Cronbach’s α = 0.954 respectively at the second testing a Cronbach’s α = 0.945. The ICC was 0.953 (single measures) and 0.976 (average), P < .001.

3.2. Reproducibility

All studied patients filled once again the questionnaire 2 days later, aiming to assess the reproducibility of the questionnaire’s results. The 2 results were strongly, positive, and significantly correlated (Pearson’s r = 0.953; P < .001). This correlation denotes a strong reproducibility of the questionnaire’s score (Table 2).

3.3. Validity

The OSS_RO was strongly, negatively, and significantly correlated with QuickDASH score (Pearson’s r = −0.633 first and r = −0.672 second; P < .001) and strongly, positively, and significantly correlated with the EQ-5D VAS (Pearson’s r = 0.627 first and r = 0.640 second; P < .001) and the EQ-5D Index (Pearson’s r = 0.759 first and r = 0.771 second; P < .001) (Table 2, Figs. 1 and 2).

4. Discussions

The clinometric properties of the OSS_RO are comparable to previous translations of the OSS to other European and Asian languages. In our analysis, the internal consistency determined by the Cronbach’s α coefficient was 0.95 and 0.94 respectively. This is comparable to the translation of the OSS to Korean (0.91),
The reliability of the OSS_RO for the test/retest reliability demonstrated a Pearson’s correlation coefficient of 0.95. This compares favorably to other translation of the OSS. The Pearson’s correlation coefficient for the French translation of the OSS is 0.93, 0.95 for the Korean, 0.97 for the Italian, and 0.98 for simplified Chinese. During translation and cultural adaptation there were no significant linguistic issues. The entire translation report can be made available upon request. The score was completed by people with a wide range of social and educational background. The time needed to fill out the form was comparable to that recorded for other European countries. However, it was slightly longer than what would be expected for the English form.

There are many patient and clinician based outcome scores available in both paper and electronic based formats. For its proven validity, versatility, and ease of use we favored the OSS versus DASH or clinician based evaluations like the Constant-Murley score. Both our subject sample and target population include many shoulder conditions but the majority were diagnosed with disorders of the rotator cuff and proximal humerus fractures. A strong correlation was demonstrated between OSS, DASH, and the Constant score for cuff tears, as well as between OSS and Constant score for proximal humerus fractures.

Most studies compared the translated version of the OSS against the DASH or a clinician based score such as the Constant-Murley score. Both our subject sample and target population include many shoulder conditions but the majority were diagnosed with disorders of the rotator cuff and proximal humerus fractures. A strong correlation was demonstrated between OSS, DASH, and the Constant score for cuff tears, as well as between OSS and Constant score for proximal humerus fractures.

In conclusion, this study demonstrates that the OSS_RO is a reliable, reproducible, and valid measure of shoulder function in patients from several areas of Romania with variable diseases.

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| The Correlation matrix between the 2 OSS_RO scores, QuickDASH, and EQ-5D. |
|-----------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Correlation matrix          | First OSS       | Second OSS      | EQ-5D VAS       | EQ-5D Index     | Quick DASH      |
| First OSS                   |                | 0.953 P<.001    | 0.627 P<.001    | 0.759 P<.001    | −0.633 P<.001  |
| Second OSS                  | 0.953 P<.001   |                | 0.640 P<.001    | 0.771 P<.001    | −0.672 P<.001  |
| EQ-5D VAS                   | 0.627 P<.001   | 0.640 P<.001    |                | −0.469 P<.001   | −0.469 P<.001  |
| EQ-5D Index                 | 0.759 P<.001   | 0.771 P<.001    | −0.469 P<.001   |                | −0.469 P<.001  |
| Quick DASH                  | −0.633 P<.001  | −0.672 P<.001   | −0.469 P<.001   | −0.469 P<.001   |                |

OSS=Oxford Shoulder Score, QuickDASH=Disabilities of the Arm, Shoulder, and Hand. EQ-5D-5L=EuroQol 5-Dimension, 5 level instrument of health related quality of life.

Table 2

Figure 1. Correlation between the first OSS_RO score and QuickDASH; OSS=Oxford Shoulder Score, QuickDASH=Disabilities of the Arm, Shoulder, and Hand.

Figure 2. Correlation between the first OSS_RO score and EQ-5D Index; OSS=Oxford Shoulder Score, EQ-5D Index=EuroQol 5-Dimension Index.
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