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ORIGINAL PAPER

Translation, cross-cultural adaptation, and validation of the Italian version of the Oxford Shoulder Instability Score

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Abstract

Purpose The Oxford Shoulder Instability Score (OSIS) is self-reported outcome measurement developed to evaluate shoulder instability taking into account also adaptive strategies. Valid, reliable, reproducible, and user-friendly translations of outcome measure instruments are needed to allow comparisons of international study results.

Methods The Italian translation and cultural adaptation of the OSIS were completed using a "translation–back translation" method and the final version was administered to a sample of 25 consecutive Italian-speaking patients. The psychometric properties of this adaptation were evaluated in terms of feasibility, reliability, construct validity, and responsiveness.

Results No major differences occurred between the OSIS translations into Italian and back into English, and no content- or linguistic-related difficulties were reported. The Cronbach's alpha for the total OSIS was 0.897. Intraclass correlation coefficient value for inter-rater reliability was 0.805, while for intra-rater reliability was 0.586. Spearman rank correlation coefficient between the OSIS and the Rowe score was 0.548 ($p = 0.005$) and between OSIS-I and SF-12 was 0.488 ($p = 0.013$).

Conclusions The Italian version of the OSIS is a reliable, valid, and reproducible outcome measure for clinical evaluation of patients affected by shoulder instability, which remains simple and user-friendly as the original version.

Level of evidence Prospective cohort study, Level II.

Clinical relevance *The availability of a validated translation of the OSIS will help surgeon to share their data on shoulder instability diagnostic and treatment in a more reproducible and comparable fashion.*

Keywords Shoulder instability · Patient reported outcome measurements · Translation · Cross-cultural adaptation · Validation · Oxford shoulder instability score · OSIS

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Introduction

Shoulder instability is defined as an excessive translation of the humeral head in relation to the glenoid, responsible for symptoms in the conscious patient [1]. Shoulder instability is a common problem in the orthopaedic practice, generally affecting young, active subjects [2]. In order to allow comparisons of national and international study results, valid, reliable, reproducible, and user-friendly outcome measure instruments are needed. Translation, cross-cultural adaptation, and validation of health status measures are therefore mandatory to ensure that the instruments used in large multicentre international studies or epidemiologic and therapeutic studies are culturally equivalent [3–5]. The Oxford Shoulder Instability Score (OSIS) is a short, simple, self-reported outcome measurement for patients with shoulder instability, which has been developed to evaluate shoulder instability taking also adaptive strategies into account, which can be difficult to investigate in the clinical setting [6]. It is one of the most common patient reported outcome measures for shoulder instability and it has been shown to be valid, reliable, and reproducible [6, 7]. A validated translation is currently available only in Dutch language [8], and no Italian validated version of the OSIS exists.

The aim of this study was to translate and cross-culturally adapt the OSIS in Italian and to evaluate the psychometric properties of this adaptation, in terms of feasibility, reliability, construct validity, and responsiveness.

Materials and methods

Translation and cross-cultural adaptation

The Italian translation and cultural adaptation of the scale were completed according to the stages recommended by Beaton et al. using a "translation–back translation" method [4].

The original English version of the scale was translated into Italian language by two independent native Italian speakers, fully competent in both languages: a professional Italian translator informed on medical and surgical procedures and a professional Italian translator working at the Italian Translation Unit of the European Union. These two versions were summarized to obtain a best fitting translation. Back translation was performed by a third professional Italian translator, not involved in the creation of the first version. Finally, an expert panel of Italian physicians with special interest in shoulder surgery and an Italian linguist evaluated the definitive translation to validate content, semantic, technical, criterion, and conceptual equivalence.

After this step, the committee decided that the original OSIS and its Italian version could be considered equivalent and a pre-test to confirm the comprehensibility of the final Italian version was performed on 15 healthy subjects, with no previous history of shoulder trauma or shoulder diseases.

Patients

The final Italian version of OSIS (OSIS-I) was administered to a sample of consecutive Italian-speaking patients affected by shoulder instability who were admitted to the Accident & Emergency Department or to the Department of Orthopaedics and Traumatology of our institution with a diagnosis of shoulder dislocation and clinically and radiologically confirmed instability.

Subjects were excluded if they had other shoulder-associated pathologies (e.g., rotator cuff injury, humerus fracture, acromion-clavear diseases, shoulder stiffness or impingement). Participants gave their written informed consent for collection, storage, and use of personal data.

The OSIS-I was administrated to each patient and the time necessary to complete the questionnaire and any difficulty encountered in answering a question were recorded. Immediately after this first interview, a second examiner re-administrated the same questionnaire to evaluate inter-rater reliability. The OSIS-I was then re-administrated between five and ten days after the first administration (average test–retest interval: 8 days); this interval was considered long enough to forget prior answers, and short enough to assume an unchanged shoulder condition.

Psychometric properties of the OSIS-I

Reliability

All questionnaires were administrated by two independent physiotherapists with special interest in treatment and rehabilitation of shoulder pathologies, who were instructed on how to administer the OSIS-I prior to study begin. The two raters independently examined all patients. To explore the test–retest reliability, one of them assessed again all patients at a distance of no more than ten days apart.

Validity

Comparisons of the OSIS-I with the Rowe Scores for instability [9], and SF-12 [10] was performed in order to estimate construct validity.

The first version of the Rowe Scores for instability contains three items (stability, motion, function) and final score ranges from 0 to 100 points and include possible ratings of excellent, good, fair, and poor [9].

SF-12 is a shortened form (12 items) of the SF-36 Health Survey. This is a generic assessment of health-related quality of life (HR QOL) from the client/patient's perspective. The validated Italian version of the scale was used for this study [10].

Statistical analyses

Data analyses were performed using the SPSS statistical package 20.0 for Windows. For reliability analysis, the inter- and intra-rater reliability was estimated by calculation of the single measure intraclass correlation coefficient (ICC), using a two-way fixed model. The standard error of measurement (SEM) and the minimal detectable change (MDC) were also calculated. The ICC values were interpreted according to the guidelines of Fleiss [11]: values less than 0.4 indicate poor reliability, values between 0.4 and 0.75 indicate good reliability, values greater than 0.75 indicate excellent reliability. Clinical applications were interpreted according to the guidelines of Buxton et al. [12]: an ICCs ≥ 0.70 should be considered suitable for studies on groups of subjects and an ICCs of 0.90 should be considered the minimum level acceptable for measures to be used in individuals.

Cronbach's alpha was calculated to check for internal consistency of the subscales and total scale.

Correlation of the OSIS-I with Rowe score for instability and SF-12 were performed in order to estimate construct validity. All correlations between different scales were performed using the Spearman rank correlation coefficient.

Floor and ceiling effects were determined by calculating the number of patients who obtained the best or worst scores possible. Floor or ceiling effects were considered to be present if more than 15% of subjects achieved the lowest or highest possible score, respectively [13].

Results

No major differences occurred between the OSIS translations into Italian and back into English, and no content- or linguistic-related difficulties were reported. The final version was considered free of cross-cultural inconsistencies, so that we can consider all questions applicable to the Italian population. No critical aspects were observed in the pre-test phase. The OSIS-I is shown in Appendix 1.

The OSIS-I was administered to a population of 25 subjects: fivefemales (20%), mean age 26.1 years; 84% of them was available for retest. Additional demographic characteristics of the enrolled population are presented in Table 1. There were no missed answers, multiple responses or problems of comprehension for any item. Average time to completion was ten minutes.

Table 1 Patients' demographics

F/M ratio	0.20/.080
L/R ratio	0.48/0.52
Age groups: ≤ 35	78%
36–45	13%
> 46	9%

Psychometric properties of the OSIS-I

Reliability Cronbach's alpha for the total OSIS-I was 0.897. ICC values for inter-rater reliability was 0.805 (CI = 0.606 to 0.909), while for intra-rater reliability was 0.586 (CI = 0.257 to 0.794). SEM and MDC values were 2.8 and 7.9 points respectively for the intra-rater analysis, and 2.9 and 8.0 respectively, for the inter-rater analysis.

Construct validity Spearman rank correlation coefficient between the OSIS-I and the Rowe score was 0.548 ($p = 0.005$) and between OSIS-I and SF-12 was 0.488 ($p = 0.013$).

Floor and ceiling effects No patients scored minimum scores, whereas two scored maximum scores; no floor effect could be observed, whereas a ceiling effect was observed, with 68.4% of the patients scoring in the MDC-range for the highest possible score.

Table 2 summarizes the results of the statistical analysis.

Discussion

The main finding of this study is that the OSIS-I score is reliable, internally consistent and well accepted by patients. Moreover, analogous psychometric properties to the original English version were detected. This study does make a new contribution to the literature as, to our knowledge, there is no other study on the issue of translation and cross-cultural validation into Italian of the OSIS.

Shoulder instability is a common problem in the orthopaedic practice, generally affecting young, active subjects. Research in the fields of conservative and surgical management of shoulder instability are increasingly expanding, and therefore valid, reliable, reproducible and user-friendly outcome measure instruments are needed to allow comparisons of international study results [3–5, 14]. The cross-cultural adaptation of a clinical score may require not only translation but also adjustment of cultural words, idioms, and colloquialism. This process may involve substantial transformation of some items to fully capture the essence of the original concepts.

The OSIS was developed in 1999 as tool to investigate changes in quality of life related to shoulder instability. This score includes 12 questions: these items were originally developed from a prospective interview of 20 patients with unstable shoulders: each patient was asked to list his recurrent daily-life problems, which led to a list of 18 items. The same cohort and, subsequently, a different group of 20 patients, were finally asked to review and comment the proposed items which led to a reduction of the original questionnaire to 12

Table 2 Summary of the psychometric properties investigated and results

Properties	Test used		Result	*p* value or (CI95%)
Consistency	Internal consistency	Chronbach's Alpha	0.897	–
Test–retest reliability and measurement error	Intra-rater reliability	ICC	0.805	(0.606–0.909)
	Intra-rater error	SEM (MDC)	2.9 (8.0)	–
	Inter-rater reliability	ICC	0.586	(0.257–0.794)
	Inter-rater error	SEM (MDC)	2.8 (7.9)	–
Construct validity	Correlation with Rowe	Spearman's Rho	0.548	$p = 0.005$
	Correlation with SF-12	Spearman's Rho	0.488	$p = 0.013$

items. This definitive version of the OSIS was tested on 92 patients and published [6]. In the original version, answers were scored from 1 to 5 points for a total score that ranged from 12 (least impaired) to 60 (most impaired). An alternative version of the OSIS was subsequently described, in which answers are scored from 0 to 4, and the score is reversed, with the total score ranging from 0 (most impaired) to 48 (least impaired) [15]. This last version is the currently most frequently used and was adopted also in this study.

The OSIS questions are simple and straightforward, which makes this questionnaire very well accepted by patients and easy to complete. Moreover, usually the patient does not require detailed additional explanations or instructions and is able to independently answer the questions. With a Cronbach's α of 0.92, a Pearson correlation coefficient of 0.97 and a SEM of 5.7 [6], the OSIS has already proven to be valid and reliable, making it clinically important and frequently used as outcome measure in clinical studies on patients with shoulder instability [16, 17].

The innovative aspect of the OSIS score was its ability to take also adaptive strategies into account, which can be difficult to investigate in the clinical setting. Awareness of the unstable shoulder and self-confidence with the injured limb may, in fact, produce subtle subjective differences among patients affected by similar diseases.

To allow direct comparisons of national study results, translation of internationally used scores is mandatory and validation or adaptation are needed to ensure that the instruments used are culturally equivalent [3–5].

The OSIS-I is a new precious tool to be added to the already available Italian translated and validated shoulder scores [18–27]. This Italian translation was obtained after a rigorous translation–back translation process involving three different professional translators, a panel of physicians with expertise in shoulder pathology and a pre-test cohort of 15 healthy subjects. When validated on patients affected by recurrent shoulder instability, the OSIS-I proved to be well accepted and without any critical problem concerning lexical and semantic interpretation.

The ICC proved to be moderate for intra- and high inter-rater reliability, confirming therefore the high reproducibility of this instrument recently documented in the Dutch translation of the OSIS [8].

The high Cronbach's alpha coefficient (0.897) indicates a high level of internal consistency and a certain redundancy in the translated score, which is however also reported in the original version.

Only one group investigated SEM and MDC for the OSIS, obtaining comparable results [8].

A moderate correlation was obtained when comparing the OSIS-I with the Rowe and SF-12 scores. The Rowe rating scale was originally devised to assess outcomes after surgical repair for recurrent dislocation of the shoulder and is nowadays frequently used as simple, observer-based measurement instrument. The SF-12, rather than being disorder specific, is related to the general health condition and is useful for quality of life assessment.

Limitations of this study are the lack of a power analysis and the choice of a relatively small sample size, which was referred to similar studies already available in the literature [22, 24, 28, 29]. A larger sample size of patients could have provided a more stable ICC analysis. Even with these limitations, we can conclude that the OSIS-I has equivalent properties to the English version.

Conclusions

The Italian version of the OSIS, translated according to international standardized guidelines, is a reliable, valid, and reproducible outcome measure for clinical evaluation of patients affected by shoulder instability (intra-rater ICC 0.586, inter-rater ICC 0.805, Cronbach's alpha: 0.897). The OSIS-I remains simple and user-friendly as the original version and can be easily administered to Italian-speaking patients.

Authors contributions BM: study design, patient enrollment, and data collection
DC: original draft preparation
TG: patient enrollment and data collection
MP: statistical analysis and manuscript correction
PA: manuscript correction
SN: study design, and manuscript correction

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

The study protocol was approved by the University of Florence – Università degli Studi di Firenze, Scuola di Scienze della Salute Umana (ID03062015).

Informed consent Informed consent was obtained from all individual participants included in the study.

References

1. Tonino PM, Gerber C, Itoi E et al (2009) Complex shoulder disorders: evaluation and treatment. J Am Acad Orthop Surg 17:125–136
2. Galvin JW, Ernat JJ, Waterman BR et al (2017) The epidemiology and natural history of anterior shoulder instability. Curr Rev Musculoskelet Med 10:411–424. https://doi.org/10.1007/s12178-017-9432-5
3. Wild D, Grove A, Martin M et al (2005) Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures: report of the ISPOR task force for translation and cultural adaptation. Value Health 8:94–104. https://doi.org/10.1111/j.1524-4733.2005.04054.x
4. Beaton DE, Bombardier C, Guillemin F, Ferraz MB (2000) Guidelines for the process of cross-cultural adaptation of self-report measures. Spine (Phila Pa 1976) 25:3186–3191
5. Guillemin F, Bombardier C, Beaton D (1993) Cross-cultural adaptation of health-related quality of life measures: literature review and proposed guidelines. J Clin Epidemiol 46:1417–1432
6. Dawson J, Fitzpatrick R, Carr A (1999) The assessment of shoulder instability. The development and validation of a questionnaire. J Bone Joint Surg Br 81:420–426
7. Wylie JD, Beckmann JT, Granger E, Tashjian RZ (2014) Functional outcomes assessment in shoulder surgery. World J Orthop 5:623–633. https://doi.org/10.5312/wjo.v5.i5.623
8. van der Linde JA, van Kampen DA, van Beers LWAH et al (2015) The Oxford shoulder instability score; validation in Dutch and first-time assessment of its smallest detectable change. J Orthop Surg Res 10:146. https://doi.org/10.1186/s13018-015-0286-5
9. Rowe CR, Patel D, Southmayd WW (1978) The Bankart procedure: a long-term end-result study. J Bone Joint Surg Am 60:1–16
10. Kodraliu G, Mosconi P, Groth N et al (2001) Subjective health status assessment: evaluation of the Italian version of the SF-12 health survey. Results from the MiOS Project. J Epidemiol Biostat 6:305–316
11. Fleiss JL (1999) The design and analysis of clinical experiments. https://doi.org/10.1002/9781118032923
12. Fitzpatrick R, Davey C, Buxton MJ, Jones DR (1998) Evaluating patient-based outcome measures for use in clinical trials. Health Technol Assess 2:i–iv 1–74
13. McHorney CA, Tarlov AR (1995) Individual-patient monitoring in clinical practice: are available health status surveys adequate? Qual Life Res 4:293–307
14. Randelli P, Cucchi D, Butt U (2016) History of shoulder instability surgery. Knee Surg Sports Traumatol Arthrosc 24:305–329. https://doi.org/10.1007/s00167-015-3947-3
15. Dawson J, Rogers K, Fitzpatrick R, Carr A (2009) The Oxford shoulder score revisited. Arch Orthop Trauma Surg 129:119–123. https://doi.org/10.1007/s00402-007-0549-7
16. Blonna D, Bellato E, Caranzano F et al (2016) Arthroscopic Bankart repair versus open Bristow-Latarjet for shoulder instability: a matched-pair multicenter study focused on return to sport. Am J Sports Med 44:3198–3205. https://doi.org/10.1177/0363546516658037
17. Venkatachalam S, Storey P, Macinnes SJ et al (2016) The Sheffield bone block procedure: a new operation for the treatment of glenoid bone loss in patients with anterior traumatic shoulder instability. Should Elb 8:106–110. https://doi.org/10.1177/1758573215622614
18. Murena L, Vulcano E, D'Angelo F et al (2010) Italian cross-cultural adaptation and validation of the Oxford shoulder score. J Shoulder Elb Surg 19:335–341. https://doi.org/10.1016/j.jse.2009.07.068
19. Cacchio A, Paoloni M, Griffin SH et al (2012) Cross-cultural adaptation and measurement properties of an Italian version of the Western Ontario Shoulder Instability Index (WOSI). J Orthop Sports Phys Ther 42:559–567. https://doi.org/10.2519/jospt.2012.3827
20. Marchese C, Cristalli G, Pichi B et al (2012) Italian cross-cultural adaptation and validation of three different scales for the evaluation of shoulder pain and dysfunction after neck dissection: University of California - Los Angeles (UCLA) Shoulder Scale, Shoulder Pain and Disability Index (SPADI). Acta Otorhinolaryngol Ital 32:12–17
21. Padua R, Padua L, Ceccarelli E et al (2010) Italian version of ASES questionnaire for shoulder assessment: cross-cultural adaptation and validation. Musculoskelet Surg 94(Suppl 1):S85–S90. https://doi.org/10.1007/s12306-010-0064-9
22. Papalia R, Osti L, Leonardi F et al (2010) RC-QOL score for rotator cuff pathology: adaptation to Italian. Knee Surg Sports Traumatol Arthrosc 18:1417–1424. https://doi.org/10.1007/s00167-009-0943-5
23. Sartorio F, Moroso M, Vercelli S et al (2015) Cross-cultural adaptation, and validity of the Italian version of the Upper Limb Functional Index (ULFI-I). G Ital Med Lav Ergon 37:115–119
24. Corona K, Cerciello S, Morris BJ et al (2016) Cross-cultural adaptation and validation of the Italian version of the Western Ontario Osteoarthritis of the Shoulder index (WOOS). J Orthop Traumatol 17:309–313. https://doi.org/10.1007/s10195-016-0400-4
25. Merolla G, Corona K, Zanoli G et al (2017) Cross-cultural adaptation and validation of the Italian version of the Kerlan-Jobe Orthopaedic Clinic Shoulder and Elbow score. J Orthop Traumatol 18:415–421. https://doi.org/10.1007/s10195-017-0467-6
26. Calistri A, Di Martino L, Gurzì MD et al (2014) Italian version of University of California at Los Angeles (UCLA) activity score: cross-cultural adaptation. J Arthroplast 29:1733–1735. https://doi.org/10.1016/j.arth.2014.04.028
27. Padua R, Padua L, Ceccarelli E et al (2003) Italian version of the disability of the arm, shoulder and hand (DASH) questionnaire. Cross-cultural adaptation and validation. J Hand Surg Br 28:179–186
28. Alvarez-Nemegyei J, Puerto-Ceballos I, Guzmán-Hau W et al (2005) Development of a Spanish-language version of the shoulder disability questionnaire. J Clin Rheumatol 11:185–187
29. Marcondes FB, de Vasconcelos RA, Marchetto A et al (2012) Translation and cross-cultural adaptation of the Rowe score for Portuguese. Acta Ortop Bras 20:346–350. https://doi.org/10.1590/S1413-78522012000600007