

The Shoulder Activity Level: an Italian Translation, Cross-Cultural Adaptation and Validation

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SUMMARY

Introduction. In this study we aimed to cross-culturally translate the Shoulder Activity Level (SAL) into Italian language and assess its clinimetric properties including reliability, validity, and responsiveness. The objective was to evaluate activity level in patients with shoulder disorders.

Methods. Italian version of the SAL was obtained after forward-backward translation. Three questionnaires were completed by the participants: SAL, SST and SPADI. Fifty patients completed the SAL again, 1 week after the first administration to evaluate the test-retest reliability. Then was evaluated construct validity using Spearman's rank correlation, test-retest reliability and internal consistency were assessed using Intraclass Correlation Coefficient (ICC) and Cronbach's alpha, respectively.

Results. No language difficulties were reported during translation process. Test-retest reliability of the SAL was good with an ICC of 0.896 and a Cronbach's alpha level of 0.739 was also obtained. The correlation between the SAL and the SPADI was moderate, proving divergent validity ($r_s = -0.235$), even the correlations between the SAL and the SST were moderate proving convergent validity ($r_s = 0.247$).

Conclusions. The study provides statistically significant results of test-retest reliability, internal consistency, construct validity, and responsiveness of the Italian version of the SAL in patients with shoulder disorders. Therefore, it seems that this instrument is a useful measure of shoulder activity level in research setting and clinical practice.

KEY WORDS

Shoulder; questionnaire; physiotherapy; activity; disorders.

INTRODUCTION

Shoulder joint disorders are the second most common musculoskeletal disorders following the low back pain (1) and it can cause significant difficulty in performing a majority of activities daily living (2). Nowadays the use of outcome measure that assess the patient's condition is very common in orthopaedics (3); however, most of them are designed to quantify only symptoms and/or functional disability (4). Although closely correlated, function and activity level must be assessed separately. In fact, function reflects how well a patient does certain task, while activity level measures how much a patient does (5). Therefore,

the measurement of activity level should play a key role in patient evaluation.

After the same injury, two individuals with different levels of activity may have similar limitations and pain conditions. However, after a period of rehabilitation, their results may be different for various reasons. The patient's activity level before injury could influence the success of the therapeutic intervention and patient's perception of treatment success.

If a treatment relieves night pain, it may be considered satisfactory by a patient with a low level of activity. In reverse, a more active individual expects the return to pre-injury activity level to achieve a similar degree of satisfaction.

Thus, the activity level could be an important prognostic factor related to outcomes of rehabilitation treatment and it should be measured in addition to outcome measures of symptoms and functions in patients with different musculoskeletal disorders including shoulder joint disorders (5). In recent years the use of instruments capable of measuring the level of activity has increased and many of them are already used in subjects with problems affecting different body districts such as shoulder, knee (6) and ankle (7). In Italy no study has yet investigated the outcome measure related to activity level in this specific patient population.

After a revision of the literature we found that the only two previous papers that evaluated the psychometric properties of the scale were the original article (Brophy 2005) (5) and Persian adaptation (Negahban 2015) (17).

In the original article the scale was developed using: item generation, item reduction, pretesting, and reliability and validity testing (5). Test-retest reliability was excellent with an ICC of 0.92. The scale was also significantly correlated with self-reported activity score ($r = 0.52$), Simple Shoulder Test ($r = 0.46$) and the Knee Activity Rating Scale ($r = 0.66$). In the Persian study was assessed reliability, validity and responsiveness with an ICC of 0.98, a Cronbach's Alpha level of 0.64. The scale was significantly correlated with SF-36 ($r = 0.21$). Moreover, low negative correlations were found between SAL and SPADI ($r = -0.09$).

Therefore the aim of this study is to cross-culturally translate the Shoulder Activity Level (SAL) into Italian language and to determine its clinimetric properties including reliability, validity and responsiveness in a group of patients with different shoulder disorders.

The SAL was developed by Prof. Brophy *et al.* and it is a rating scale that measures how much patients suffering from the most common shoulder pathologies, have been able to use shoulder joint in their healthiest and most active state in the past year, during activities of daily living and sport⁵. This choice is justified by the conciseness of the scale (made up of only seven items) completed within 1 minute, its schematic structure and the simplicity of understanding which make it a useful and practical measurement tool to use by clinicians.

MATERIALS AND METHODS

The research group who conducted the study was composed of rehabilitation experts from University of Rome "La Sapienza" and experts from the Department of Italian Air Force Aerospace Medicine. Authors certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research. All procedures followed were

in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008. Informed consent was obtained from all participants for being included in the study. Ethics Committee Sapienza approval was not required because the administration of these tool was part of the usual process of assessment of these individuals in clinical practice, the research involved the analysis of data collected such that individual subjects cannot be identified in any way.

Translation and cultural adaptation process

Cross-cultural translation of the SAL was performed following the "Guidelines for the process of cross-cultural adaptation of self-report measures" by Beaton *et al.* (8) and "Principles of good practise for the translation and cultural adaptation process for the patient-reported outcomes (PRO) measures: report of the ISPOR Task Force for Translation and Cultural Adaptation" by Wild *et al.* (9).

Permission for translating the questionnaire has been obtained from the developer.

The translation and cultural adaptation of the original version of the SAL into the Italian version was done using a forward and backward method as summarized in **figure 1**. In the first step two independent Italian-language translators with good knowledge of English language and not familiar with the SAL have translated the original version of SAL producing two different independent versions in Italian. In the second step, an Italian native speaker and out-of-work translator, who had not been involved in any of the previous translations, optimized the two translations and produced a single one in Ital-

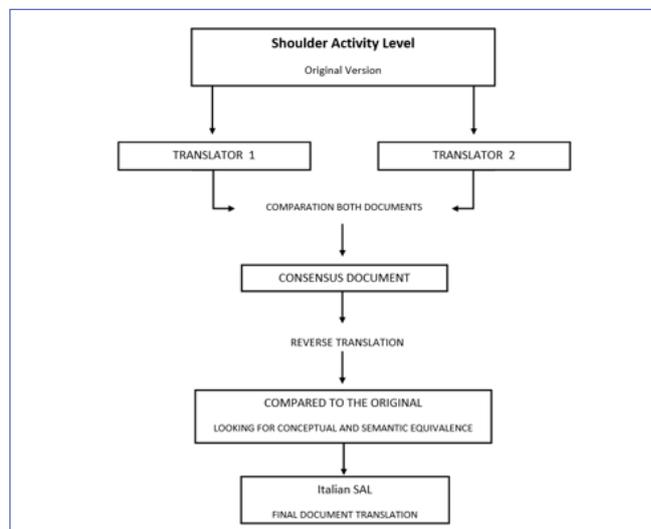


Figure 1. Translation and cultural adaptation process.

ian. In the third phase, the version obtained from the optimization process was then independently translated into the original language by two bilingual translators who were not aware of the original version of the questionnaire. In the last phase, the two backward translated versions of the questionnaire were compared with the original by a focus group composed of three physiotherapists who corrected some spelling, grammar or other errors to minimize the differences from the original version by creating a single version, in order to reach a consensus on the semantic, idiomatic, and conceptual equivalence between the Italian version and the original version of the SAL.

Patients

During a 4-month period, a sample of 100 Italian patients was recruited to participate in this project. If they agreed to participate in this study, they were informed about it and signed an informed consent form. All questionnaires were administered using Google Forms platform due to the Covid-19 pandemic which did not allow the questionnaire to be administered in person.

A link was sent to all participants that included informed consent form and three rating scales that is SAL, SST and SPADI.

The patients included in this study had different diagnosis including rotator cuff tendonitis, impingement syndrome, frozen shoulder, bursitis, and shoulder instabilities. The most common diagnosis was rotator cuff tendonitis ($n = 47$). Patients were excluded if they had: shoulder pain that caused by impairment in a region other than shoulder complex such as cervical joints dysfunction; radicular pain from cervical disc herniation; involvement of other joints affecting upper extremity such as elbow and wrist; systemic inflammatory rheumatic diseases, neurological, or psychiatric disorders; history of shoulder fracture or surgery (5).

All patients completed the Shoulder Activity Level (SAL), the Shoulder Pain And Disability Index (SPADI) and the Simple Shoulder Test (SST), during test session. The patients were asked to complete the SAL, 1 week after the first visit to evaluate test-retest reliability. Between test and retest intervals, no treatments were permitted for their shoulder problems. In the retest session, patients were asked to answer whether their shoulder function has changed since the test session. Reliability was analyzed on those patients who stated that their health status has not changed between test and retest sessions, *i.e.*, 50 patients.

To assess responsiveness, data were collected in the first visit and then again after 4-weeks (10 sessions) of physiotherapy intervention or home exercises program. The sample recruited for the responsiveness study was a separate sample of test-retest reliability. Physiotherapy program consisted

of shoulder mobilization techniques, shoulder stabilization, strengthening exercises with theraband and instrumental physical therapies. Moreover, the SAL was completed by the patients at 4 weeks and served as a reference standard of perceived magnitude of change in shoulder function from the 50 patient's perspective.

Instruments

The SAL score is a numerical sum of scores for five activities rated on a five point frequency scale from never performed (0 points) to daily performed (4 points). Patients were scored on the following criteria: carrying objects by hands, handling objects overhead, weight lifting or training with arms, swinging motion (*i.e.*, hitting tennis or golf ball), and lifting heavy objects. Two additional multiple-choice questions provide a score assessing participation in contact and overhead sports. This instrument evaluates the activity level of participants at their most active state over the previous 12 months. Each activity has a scoring range of 0–4: 0 point indicates performing the activity never or less than once a month, 1 point indicates activity for once a month, 2 points indicate activity for once a week, 3 points indicate activity for more than once a week, and 4 points indicate daily activity. The total score ranges from 0 (least active) to 20 (most active). Moreover, for descriptive evaluation of activity level, two questions regarding the participation in contact sports and overhead throwing sports were included in a multiple choice format. The possible answers are A) no; B) yes, without organized officiating; C) yes, with organized officiating; or D) yes, at a professional level. It can be completed quickly and used to assess activity level as a prognostic factor in patients with shoulder disorders.

The SPADI was developed to measure pain and disability related to shoulder disorders. This instrument is a self-reported questionnaire that consists of two dimensions (pain and disability), required 5–10 min to complete. All items were scored based on a visual analogue scale from 0 (no pain and disability) to 10 (most pain and disability). The range of possible scores for the pain and disability dimensions lies between 0 and 100, with higher scores indicate greater amount of pain and disability. The total score of the SPADI was achieved by averaging the pain and disability scores and the score ranges from 0 to 100 (10).

The Simple Shoulder Test (SST) consists of 12 questions about physical function with dichotomous (yes or no) response options. For each item, patients indicate whether or not they are able to carry out specific activities and if the shoulder problem allows them to sleep peacefully and to carry out their work full time. The scores ranges are reported as the percentage of items that a person answers in the affirmative (10, 11).

Assessment of clinimetric properties

Reliability

Test–retest reliability was measured using the two-way random effect’s model of Intraclass Correlation Coefficient (ICC) with 95% confidence intervals (CI) (12). An ICC equal to or greater than 0.75 was considered as good test–retest reliability and a value greater than 0.90 indicates excellent reliability so that the using an instrument is reasonable for clinical implications (5). The internal consistency is a measure of item homogeneity of a scale and measures the extent to which items are inter-correlated (13). The internal consistency of the SAL was evaluated by calculating Cronbach’s alpha using the data obtained from the entire group of 100 patients in the test session. An acceptable internal consistency will be obtained when Cronbach’s alpha is higher than 0.90 (13).

Validity

Due to the absence of gold standard to determine activity level, the validity of the SAS was evaluated from the aspect of construct validity. Construct validity means how well an instrument evaluate the construct it is intended to measure (5). Construct validity in this study was evaluated by examining the associations between the scores on the SAS and the scores obtained from the SST and SPADI. The SAL has a positive correlation with the SST and negative correlation with the SPADI. The latter is because of the fact that patients with higher shoulder activity levels were expected to have lower shoulder pain/disability. However, due to the conceptual differences between activity and function, we expected weak correlation between the SAL and the SPADI. Due to the ordinal data, Spearman’s rank correlation was used for all correlations. Spearman’s correlation coefficients less than 0.20, 0.20–0.60, and greater than 0.60 were considered low, moderate, and strong, respectively.

Dimensionality

Dimensionality of the Italian SAL was assessed through the factor analysis with principle component analysis and varimax rotation (14). If the SAS is a uni-dimensional measure of shoulder activity level, it was expected that all items should be loaded on only one factor. To decide how many factors to select, an eigenvalue greater than 1 was used as a conventional method for factor extraction. Only factor loadings ≥ 0.40 were considered as indicative of item loading (figure 2).

RESULTS

Because sports participation questions do not alter the overall score of the SAL, we report the descriptive results

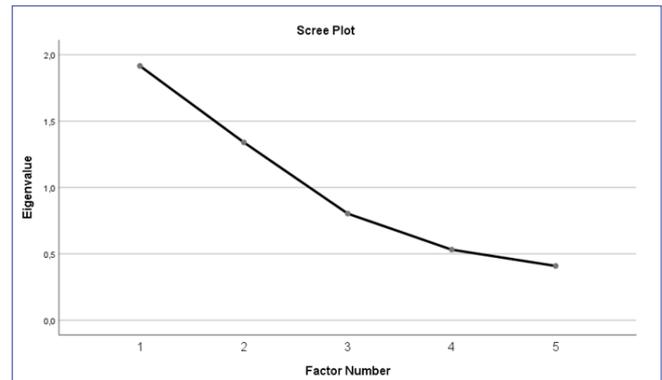


Figure 2. Scree plot.

of these questions. For question 1 (participation in contact sports), 71% answered A, 24% answered B, 4% answered C, and 1% answered D. For question 2 (participation in overhead throwing sports), 82% answered A, 13% answered B, 5% answered C and 0% answered D. Therefore, the present study showed that the patients participated in this study had low sports participation.

Translation process and cultural adaptation

Forward and backward translations of the SAS showed no problem or language difficulties. Cultural adaptations were made because the units of measurement reported in the questionnaire, *i.e.*, pounds for mass and gallons for volume, are not used in Italy; therefore, they have been replaced, respectively, by kilograms and liters by making the appropriate equivalences: 1 lb = 0.45 kg; 1 gal = 3.79 L.

Statistical analysis

Following the checklist “Consensus-Based Standards for the Selection of Health Status Measurement Instrument” (COSMIN), the reliability and construct validity of the culturally adapted scale were evaluated (15, 16).

The descriptive analysis was used to analyze the data obtained from the sample and the administration of the scales: the average and the standard deviation (DS) of the variables were calculated (table I).

Table I. Descriptive analysis.

	Mean	Standard Deviation	N
Total SAL	7.8400	3.88000	100
Total SST	7.12	2.851	100
Total SPADI	60.65	25.839	100

Mean and Standard Deviation of SAL and scales used for comparison.

Reliability

The results of test–retest reliability of the SAL (table II) was excellent with an ICC of 0.896 (95% CI), the Cronbach’s alpha level of 0.739 was also obtained in this study (table III).

Validity

The SAL was significantly correlated with the SST ($r_s = 0.247$, $p < 0.05$). Also, the SAL had a significant moderate

negative correlation with the SPADI ($r_s = -0.235$, $p < 0.05$) (table IV).

DISCUSSION

The results of this study provided evidence for the test–retest reliability of the SAL based on the data obtained from 50 patients (ICC = 0.896). Internal consistency was acceptable, with Cronbach’s alpha of 0.739. The findings provided

Table II. Reliability.

	Intraclass Correlation ^b	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.812 ^a	.692	.888	9.494	50	50	.000
Average Measures	.896 ^c	.818	.941	9.494	50	50	.000

Intraclass Correlation Coefficient (ICC) between the test and the retest of 50 participants. Two-way mixed effects model where people effects are random and measures effects are fixed. ^aThe estimator is the same, whether the interaction effect is present or not; ^bType A intraclass correlation coefficients using an absolute agreement definition; ^cThis estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.

Table III. Internal consistency.

Cronbach’s Alpha	N of Items
.739	6

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach’s Alpha if Item Deleted
Item 1	12.8700	51.872	.495	.715
Item 2	14.0600	49.491	.477	.709
Item 3	14.5600	46.916	.614	.681
Item 4	14.9600	51.150	.515	.711
Item 5	14.1100	52.038	.373	.730
Total SAL	7.8400	15.206	1.000	.579

Cronbach’s α , Mean and Variance if the item is deleted and for each individual item.

Table IV. Validity.

			Total SAL	Total SST	Total SPADI
Spearman’s rho	Total SAL	Correlation Coefficient	1.000	.247*	-.235*
		Sig. (2-tailed)	.	.013	.019
		N	101	100	100
	Total SST	Correlation Coefficient	.247*	1.000	-.703**
		Sig. (2-tailed)	.013	.	.000
		N	100	100	100
	Total SPADI	Correlation Coefficient	-.235*	-.703**	1.000
		Sig. (2-tailed)	.019	.000	.
		N	100	100	100

Spearman Correlation Coefficient between SAL SST and SPADI. *Correlation is significant at the 0.05 level (2-tailed); **Correlation is significant at the 0.01 level (2-tailed).

some evidence to support the construct validity of the SAL. Factor analysis indicated that all items strongly loaded on one factor, and this supports that the SAL measures a single construct known as the shoulder activity level. Finally, the SAL was, to some extent, responsive to changes following physiotherapy intervention. Therefore, the Italian version of the SAL is an appropriate instrument for assessing activity level of patients with different shoulder disorders.

The questions of this instrument are short, easy to understand, and requires two minutes to complete. This allows clinicians to evaluate other outcome measurements related to patients with shoulder disorders. Including a reliable, valid, and responsive measure of shoulder activity would improve the quality of clinical outcome studies performed on patients with different shoulder disorders (5).

Matching the outcomes of our work, the values are in line with previous reports. The reliability of the Italian version of the SAL (ICC = 0.896) was similar to that of the original English version (ICC = 0.92) (5) and to the Persian version (ICC = 0.98) by Negahban *et al.* (17). The results of validity provide some support for our hypotheses related to convergent and divergent validities of the SAL. As expected, because of differences in symptoms and activity constructs, the correlation between the SAL and the SPADI was negative moderate.

Our study is not without limitation. First, the responsiveness study was performed on small sample size, and this may explain the marginal level of AUC index achieved in this study. Second, the results of the present study may be more generalized to rotator cuff tendonitis that constituted a significant proportion of participants (n = 47).

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CONCLUSIONS

In conclusion, the current study provides some evidences to support the test–retest reliability, internal consistency, construct validity, and responsiveness of the Persian version of the SAS in a group of patients with different shoulder disorders. Therefore, it seems that this instrument is a useful measure of shoulder activity level in research setting and clinical practice.

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None.

DATA AVAILABILITY

Data are available under reasonable request to the corresponding author.

CONTRIBUTIONS

All authors contributed equally to the manuscript and read and approved the final version of the manuscript.

CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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