Reliability and validity of the Shoulder Pain and Disability Index in a sample of patients with Frozen Shoulder

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Abstract

Background: The Shoulder and Pain Disability Index (SPADI) is a broadly used outcome measure. The aim of this study is to explore its psychometric properties in a sample of idiopathic frozen shoulder patients.

Methods: The SPADI was administered to 124 patients with idiopathic frozen shoulder. The SPADI scores were compared with Disabilities of the Arm, Shoulder and Hand Questionnaire (DASH), Numerical Pain Rating Scale (NPRS), and 36-item Short Form Health Survey (SF-36). Structural validity, internal consistency, test-retest reliability, measurement error, and construct validity were analyzed.

Results: The CFA showed good values of all indicators for both pain and disability subscale (CFI=0.999; TLI=0.997; RMSEA=0.030). A remarkably good internal consistency (α for pain=0.859; α for disability=0.895) was shown for both the subscales. Moreover, high test-retest reliability value was found (ICC for pain=0.989 [95% CI=0.975-0.995]; ICC for disability=0.990 [95% CI=0.988-0.998], together with SEM value of 4.52% and 2.82% and MDC value of 12.54% and 7.81% for pain and disability subscale, respectively. Construct validity was satisfactory, as ≥75% of the expected correlations were met for each subscale.

Conclusion: The SPADI demonstrated satisfactory psychometric properties and resulted to be reliable and valid in a sample of idiopathic frozen shoulder patients.

1. Background

Frozen Shoulder (FS) is a condition characterized by a *functional restriction of both active and passive motions and by X-rays of the glenohumeral joints essentially unremarkable*[1].

Two types of shoulder stiffness can be recognized. If it develops without any trauma or specific disease, it is called primary or idiopathic FS[2]; on the other hand, it is defined secondary stiff shoulder if it is linked directly to a trauma, a surgery or any known cause[2]. This condition has a female preponderance[3], with an incidence that begins to increase around the age of 50[4] and that is significantly influenced by other comorbidities as obesity or diabetes[5].

There is no gold standard test to diagnose FS[2]. A correct diagnostic process should be based on clinical findings as: a restriction of both active and passive ROM in multiple planes, especially in external rotation at variable degrees of shoulder abduction[6], and a normal shoulder X-ray (to exclude other pathologies) [7].

This condition, marked by pain and reduced mobility, influences multiple aspects of the every-day life highly: from hobbies to work, everything is modified to suit related disabilities[8]. The lack of a standard plan of treatment, delays in the diagnostic process and incomplete or vague prognostic information by

the clinicians are also elements that increase the patients' frustration, and the socio-cultural impact FS has in their life[9].

Clear and valid information, taken from the best available evidence, should be the basis for building an efficient therapeutic alliance, with the advantage of creating a rehabilitation program tailored-made for the patient's necessity and fears. Health indicators as the Patient Reported Outcome Measures system (PROMs)[10] could be used to get over the mismatch between clinicians' and patients' perception[11] of this disabling condition. PROMs *measure patients' perceptions of their health status, clinical outcomes, mobility and quality of life*[12]. Through this survey-based instruments it is possible to assess the patients' point of view systematically, by improving the symptom management, promoting communication and allowing a personalized care approach[13]. Despite there are a lot of questionnaires that investigate shoulder disability, none of these might be considered valid scientifically for the FS[11].

The FS research lacks of studies that prove a good reliability and validity for one of these PROMs in the assessment of the two main aspects of this disorder: pain and disability linked to stiffness[7].

Keeping in mind these priorities, the Shoulder Pain and Disability Index (SPADI), could be an appropriate PROMs to evaluate FS patients' prospective[14].This self-administered index consists in 13 items divided into two subscales: 5 items for pain and 8 items for disability[11]. SPADI is quite fast to be completed (less than 5 minutes) by the patient and it's easy to be administered and scored by the clinicians[15]. SPADI has shown to have excellent reliability and construct validity in the assessment of shoulder impairments[16], mostly in patients showing up at the primary care level with shoulder pain[17].

To our best knowledge, only one study assessed the responsiveness in a sample of patients with FS[14].

Pain and Disability are the two domains that assess SPADI[18], but they are also the two aspects that concern FS patients' mostly[12]. Moreover, in the available literature, the SPADI is one of the most used PROMs to assess these two aspects in samples of FS patients[19], even if it has not gone through any specific scientific validation for the FS.

For all these reasons, the aim of this study was to explore the psychometric properties of the SPADI in a sample of Italian patients with FS.

2. Methods

2.1 Inclusion and exclusion criteria

Patients were recruited through convenience sampling from 2 private physical therapy clinics in Italy, over a 3-year period between 2019 and 2021. They have meet the following inclusion criteria: 1) aged over 18 years, 2) with clinically diagnosis of idiopathic FS by orthopaedic surgeons and physiotherapists, 3) a restriction of both active and passive ROM in multiple planes, especially in external rotation at variable degrees of shoulder abduction[6], and 4) a normal shoulder X-ray[7]. Subject were excluded if they presented red flags[20], a secondary stiff shoulder, an history of trauma[2], serious disease[21], positive

history of cognitive impairments or they were unable to understand Italian. All procedures involving human participants were in accordance with the 1964 Helsinki declaration and its later amendments. Personal information and informed consent were obtained from all of the patients to participate the study.

2.2 Outcome measures

Shoulder and Pain Disability Index: The Italian version of the SPADI (SPADI-I) was administered in this study[22]. The Italian validation of SPADI (SPADI-I) has already been performed for the assessment of shoulder dysfunction in patients treated for neck cancer[22], in patients after shoulder surgery to solve an anterior instability[23] and in patients with non-specific shoulder pain[24]. Before the compilation process, the patient has to be instructed to place a mark on the NRS (Numeric Rating Scale): a 0-10 scale where the patient circles the number that describes pain or disability[22] in a better way. The results of each subscale are summed and converted to a score out of 100: the closer the score is to a hundred, the greater pain and disability[22] are. Patients may mark one only item as not applicable in each subscale and the item is omitted from the total score. If a patient marks more than two items as non-applicable, no score is calculated[25].
The minimal clinically important difference (MCID) is 8 points[25], instead, the Minimal Detectible Change (MDC) is 18 points[25].

Disability of Arm, Shoulder and Hand Questionnaire (DASH): The DASH is an outcome measure that assess the ability of an upper extremity to perform daily activities regardless of the site(s) and nature of musculoskeletal pathology[26]. Thirty items regarding disability and symptoms (DASH-DS), and two optional modules compose the DASH questionnaire: the work one (DASH-W) and the sport/performing art one (DASH-SA), made up by 4 items each one. Items of DASH-DS tests the degree of difficulty when performing various physical, social and work-related daily activities together with the impact on sleep routine and the patient's perception of him or herself in the light of upper extremity problems[27]. The other two modules are optional and contains activity-specific items that rate the ability to work and to perform sports or play musical instruments[27]. For each question, patients rates difficulty on a five-point Likert scale that ranges from "no difficulty or no symptoms" (scores 1 point) to "unable to perform activity or severe symptoms" (scores 5 points)[26]. The DASH-DS score ranges from 0 (no disability) to 100 (severest disability) and cannot be calculated if there are more than 3 missing items[27]. The other two modules are scored separately but in a similar way. In this study has been used the longer form: translated, cross-cultural adapted and validated in Italian[28].

Numerical Pain Rating Scale (NPRS): NPRS is an eleven-point measure of pain in which patients rate their pain ranging from 0 (no pain) to 10 (worst imaginable pain)[29]. It has already shown good responsiveness in shoulder pain[30] and in this study has been used to assess the patient's pain perception in the last week.

36-Item Short Form Health Survey questionnaire (SF-36): SF-36 is an instrument that evaluates Health-

Related Quality of Life.[31] The SF-36 measures eight scales: physical functioning (PF), role physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional (RE), and mental health (MH).[32] It has been chosen in this study to assess patient's general health because off his widely recognized properties in the evaluation of the shoulder disorders[33] and has been used the Italian version[34].

2.3 Procedures

SPADI was contextually administered to each subject with the Italian version of the DASH scale, the SF-36 and the NRPS. A private questionnaire was also administered to acquire clinic and demographic data. A sub-group of 29 participants have been re-tested after 7 days.

2.4 Statistical analysis

This study has followed the definitions and procedures proposed by the COSMIN initiative[35] in the evaluation process of the SPADI' s psychometric properties.

The structural validity was assessed by a Two-Factors Confirmatory Factor Analysis (CFA)[36] using the following indicators[37] :

- The Comparative Fit Index (CFI) and the Tucker-Lewis Index (TLI) ≥ 0.95
- The Root Mean Square Error of Approximation (RMSEA) ≤ 0.06
- The Standardized Root Mean Square Residual (SRMR) ≤ 0.08

Reliability was assessed as internal consistency, test-retest reliability and measurement error. These analyses were undertaken on both the two subscales, separately: Pain and Disability subscale. Internal consistency was valuated according to these criteria:

- Cronbach's Alpha (α)[38], where values are recommended between 0.70 and 0.95.[39]
- α if an item was deleted, where the alpha was calculated after removing each item in turn; values below the total Cronbach's alpha are expected[40].
- item to total correlation, which are the nonparametric correlations (based on Spearman's ϱ) between each item and its rest score (i.e. the total score minus the item score); values≥ 0.40 were considered satisfactory[41].

To examine the test-retest reliability, the intraclass correlation coefficient ($ICC_{2,1}$) with 95% confidence intervals (CI)[42] was calculated. The minimal ICC value that is requisite for a reliable measure on groups is >0.75[43], but value >0.90 are considered essential to reach excellent reliability in a clinical measurement at the individual level[44]. The Standard Error of Measurement (SEM) and Minimum Detectable change (MDC) were used to test the measurement error[45]. SEM was calculated with the following formula: $SD*\sqrt{(1-ICC)}$, where SD is the baseline standard deviation of the measurements, and the ICC value is the one of intra-rater reliability. MDC was calculated by multiplying the SEM by 1.96, i.e. the z-score associated with the 95% confidence level and the square root of 2.

The administrated scales have been used for a comparative analysis to study the construct validity. To analyse the pain construct, the authors compared SPADI with NPRS, while, to analyse shoulder disability, compared SPADI with DASH questionnaire, despite it refers to a disability of the arm, shoulder and hand and has been shown not be specific for shoulder disorders[46].
Construct validity has been tested though hypothesis testing by the means of the Spearman's rank correlation (r_s) coefficients between the two subscales of the SPADI and the other three scales (DASH, NPRS and SF-36). Based on the obtained r_s coefficients, an Hypothesis Testing of the following assumption was made (Table 4):

1. the correlation between the Pain subscale and the NPRS scores is > 0.60 because they measure the same construct, and this value of correlation has be found in another SPADI validation study[47];
2. the correlation between the Pain subscale and the DASH total scores is > 0.60 as found in other SPADI validation studies[48, 49];
3. the correlation between the Pain subscale and the physical functioning (PF) subscale of the SF-36 scores is > 0.30, because shoulder pain globally compromises physical health status[50];
4. the correlation between the Pain subscale and the bodily pain (BP) subscale of the SF-36 scores is > 0.30 and < 0.60, based on the weak values found in the literature, together with the consciousness that they measure similar constructs;
5. the correlation between the Disability subscale and the DASH total scores is > 0.60, as reported in other SPADI validation studies[23, 48, 49];
6. the correlation between the Disability subscale and the NPRS scores is between >0.30 and < 0.60, because pain showed a strong correlation with disability in affine patients[18, 47];
7. the correlation between the Disability subscale and the role physical (RP) subscale of the SF-36 scores is > 0.30[47, 51];
8. the correlation between the Disability subscale and the social functioning (SF) subscale of the SF-36 scores is > 0.30[47, 51].

The cut-offs of $r_s > 0.60$, $0.30 < r_s < 0.60$, and $r_s < 0.30$ represent strong, moderate, and weak correlations, respectively[52]. Construct validity was considered satisfactory, moderate, or low if ≥75%, >50% but <75%, and <50% of expected hypotheses were met, respectively[53].

R-package lavan was used to run the CFA, while SPSS package, version 21 for Windows (SPSS Inc., Chicago, IL; 2004) was used for all other statistical analyses. The *p*-value was set for $\alpha<0.05$ for all analyses.

3. Results

3.1 Subjects

One hundred and twenty-four (mean ± SD age = 55.2 ± 7.7 years, 46.8% male) subjects with FS were included in this study. Detailed demographic and clinical characteristic are presented in Table 1.

Table 1
Demographic and clinical characteristics of the sample (N = 124)

Variable	Mean ± SD	Frequency (%)
Age, *years*	55.2 ± 7.7	
Gender		
Male		58 (46.8%)
Female		66 (53.2%)
Affected shoulder		
Right		55 (44.4%)
Left		69 (55.6%)
Dominant side		
Right		100 (80.6%)
Left		24 (19.4%)
Pain duration, *days*	217.7 ± 231.3	
SPADI Pain Score	57.0 ± 22.2	
SPADI Disability Score	50.2 ± 22.6	
NPRS	6.9 ± 2.0	
DASH	38.7 ± 18.9	
SF-36		
Physical Activity	76.1 ± 16.6	
Physical Role Functioning	41.3 ± 37.2	
Bodily Pain	38.7 ± 19.2	
General Health Perceptions	66.8 ± 19.7	
Vitality	53.8 ± 18.5	
Social Role Functioning	62.2 ± 26.3	
Emotional Role Functioning	59.4 ± 42	
Mental Health	67 ± 18.5	

Abbreviations: SPADI, Shoulder Disability and Pain Index; NPRS, Numeric Pain Rating Scale: DASH, Disability of the Arm Shoulder and Hand; SF-36, Short Form Health Survey questionnaire.

3.2 Structural Validity

Considering the results of the CFA made on the two subscales that composes SPADI, pain and disability scale, good values of all indicators have been found. Results of CFA revealed a two-factors structures (CFI = 0.999; TLI = 0.997; RMSEA = 0.030; SRMR = 0.051).

3.3 Reliability

The data regarding reliability are reported in Tables 2 and 3. A remarkably good internal consistency (α for pain = 0.859 and α for disability = 0.895) was shown for both the subscales (Table 2). Likewise, good results were obtained with the analysis of the item-to-total correlations, values are always positive and higher than 0.40 whether in Pain and in Disability subscale. The deleting of almost every item did not increase α in both subscales except for the item#9 of the Disability subscale in accord with the Cronbach's alpha-if-item-deleted data (Table 2). Test-retest reliability (studied in 29 subjects) showed an $ICC_{2,1}$ (95% CI) of 0.989 (0.975–0.995) for the Pain subscale and of 0.990 (0.988–0.998) for the Disability subscale. The results of measurement error reported for the Pain subscale a SEM of 2.26 and a MDC of 6.27, while for the Disability subscale was registered a SEM of 2.26 and a MDC of 6.25.

Table 2
Item descriptive statistics and internal consistency results (N = 124)

N	*Item*	*Mean ± SD*	*Item-to-total-correlation*	*Cronbach Alpha if item deleted*
	Pain subscale (α = 0.859)			
1	At its worst	6.8 ± 2.1	0.604	0.850
2	Lying on the involved side	5.7 ± 2.7	0.679	0.828
3	Reaching for something high	6.6 ± 2.7	0.649	0.836
4	Touching the back of the neck	4.5 ± 3.0	0.704	0.822
5	Pushing with the involved arm	5.1 ± 3.1	0.768	0.804
	Disability subscale (α = 0.895)			
6	Washing the hair	4.3 ± 3.1	0.798	0.869
7	*Washing the back*	7.4 ± 2.4	0.687	0.882
8	Putting on an undershirt or jumper	6.0 ± 2.7	0.709	0.879
9	Putting on a shirt that buttons down the front	3.4 ± 3.2	0.457	**0.902**
10	Putting on pants	2.8 ± 3.0	0.748	0.874
11	Placing an object on a high shelf	6.7 ± 2.8	0.721	0.877
12	Carrying a heavy object	4.5 ± 3.3	0.650	0.884
13	Removing something from your back pocket	5.1 ± 3.4	0.684	0.881
	Recommended value	*N/A*	*> 0.40*	*<α*

Abbreviations: *α, Cronbach's alpha; N/A, not appropriate; SD, standard deviation.*

Note: *statistics values beyond the recommended cut-off are in bold.*

Table 3
Results of the Test retest reliability and the measurement error (N = 29)

Scale	Test-retest reliability	Measurement error			
	$ICC_{2,1}$ (95% CI)	SEM	SEM%	MDC	MDC%
Pain	0.989 (0.975–0.995)	2.26	4.52	6.27	12.54
Disability	0.990 (0.988–0.998)	2.26	2.82	6.25	7.81

Abbreviations*: CI, Confidence Interval, ICC, Intraclass Coefficient Correlation; MDC, Minimal Detectable Change; p, p-value; SEM, Standard Error Measurement; %, percentage.*

3.4 Construct Validity

The *a-priori* hypothesis and the relatives correlation coefficients between the SPADI subscales and the other scales administered to patients are reported in Table 4.

Table 4. Hypothesis testing for Spearman's rank correlations between the Italian version of the Shoulder Pain and Disability Index (SPADI) and comparator instruments (N =124).

Hypothesis testing	Estimated Correlation	Hypothesis met?
Pain subscale		
1. **The correlation between the Pain subscale and the NPRS scores is > 0.60**	0.65**	Yes
2. **The correlation between the Pain subscale and the DASH total scores is > 0.60**	0.62**	Yes
3. **The correlation between the Pain subscale and the physical functioning (PF) subscale of the SF-36 scores is > 0.30**	-0.32**	Yes
4. **The correlation between the Pain subscale and the bodily pain (BP) subscale of the SF-36 scores is > 0.30 and < 0.60**	-0.37**	Yes
Disability subscale		
1. **The correlation between the Disability subscale and the DASH total scores is > 0.60**	0.77**	Yes
2. **The correlation between the Disability subscale and the NPRS scores is between >0.30 and < 0.60**	0.49**	Yes
3. **The correlation between the Disability subscale and the role physical (RP) subscale of the SF-36 scores is > 0.30**	-0.40**	Yes
4. **The correlation between the Disability subscale and the social functioning (SF) subscale of the SF-36 scores is > 0.30**	-0.26**	No

Abbreviations: SPADI-I, Italian version of the Shoulder Disability and Pain Index; DASH, Disability of the Arm Shoulder and Hand; SF-36, Short Form Health Survey questionnaire; NPRS, Numeric Pain Rating Scale.

***. p<0,01.*

**.p<0,05*

The construct validity for each subscale was satisfactory. Four out of four (100%) for the Pain subscale and three out of four for the Disability subscale (75%) of the *a-priori* hypotheses resulted positive for each subscale.

4. Discussion

Considering Pain and Disability as the aspects that mostly concern FS patients [12], the current study suggest the SPADI as a useful tool in the assessment of these constructs. Indeed, the SPADI proved a good reliability and validity of both its subscales in a sample of 124 patients with Idiopathic FS.

CFA showed well-fitting values with a CFI of 0.999, a TLI of 0.997, and a low error value with a RMSEA of 0.030 and a SRMR of 0.051. The good structural validity, highlighted in the current study, is supported by the existing literature (In the SPADI Italian version[22], like in the Spanish one[47]) that presents similar fitting indicators, but worst RMSEA values.

The internal consistency of this PROMs was satisfactory in the Pain subscale ($\alpha = 0.859$) as like in the Disability subscale ($\alpha = 0.895$). These values are coherent with those found in the English original version[11] and with those obtained in the other Italian similar studies[22, 23] together with the Spanish[47] and Chinese[51] ones. The strong accordance between our Pain and Disability α value and the ones found in the original version highlights the efficacy of this questionnaire in the assessment of the FS. Despite the good general data, the α if-item-is-deleted of item #9 in the Disability subscale, reported a discordant value and reveals the redundancy of the item in relation to the questionnaire consistency[43]. This value could be explained by the fact that the item #9 investigates an action (putting on a shirt that buttons down the front) that barely involves the shoulder movements characterized by restriction in a FS patient[6]. Contrariwise, the item with the higher value of α if-item-is-deleted is the #6 :washing the hair; this action fully involves shoulder abduction and external rotation, and results to be one of the most provocative action in a FS patient[9].

Our results showed an excellent test-retest reliability with values of 0.989 (0.975–0.995) for the Pain subscale and 0.990 (0.988–0.998) for the Disability subscale, both solid values considering the re-test administration period of 7 days in a condition that can last more than 24 months[54] and can unlikely change in a so short period of time.

The construct validity of each subscale was remarkable, with 4/4 (100%) hypothesis met for the Pain subscale and 3/4 (75%) hypothesis met for the Disability subscale.

The construct validity analysis brings to light similar knowledge to what could be found in the literature[23, 47, 49, 51]; indeed, while the correlation hypothesis with NPRS and DASH were met, the ones regarding the SF-36 were not always met and showed a lower r_s values.. This lacking relation between SPADI and SF-36 brings us to think that the SPADI alone fails to evaluate the complexity of FS implications in patient's quality of life. The implicit limit of this index is that is not fully able to evaluate this condition, where the continuous nociceptive solicitation could bring to Peripheral and subsequently

long-lasting Central Sensitization, with an altered health status perception of patient[55]. Consequently, the two PROMs should be administered together.

The Italian SPADI is complete and provide valid and responsive data on shoulder disability[23]. The present study confirms the good psychometric properties, observed in the available literature, and validates them in FS patients' assessment. In addition, the credit of this work is that results to be the first one that can be defined complete in the validation process of the SPADI in the FS. In fact, the only other study found by the authors with a similar construct[14] has a smaller sample (n = 76) and only examine the responsiveness, comparing the SPADI with the shoulder ROM changes.

The limitations of this study are worth nothing: the results may lack of generalizability, as this study was targeted only on subjects with Frozen Shoulder pain. Further investigation should evaluate other psychometric properties like responsiveness, interpretability and content validity.

5. Conclusion

In conclusion, the SPADI has good internal consistency, reliability and validity in a sample of FS patients. Future studies should confirm construct validity in other shoulder diseases and investigate psychometric properties as responsiveness, interpretability and content validity.

Abbreviations

SPADI, Shoulder Disability and Pain Index
NPRS, Numeric Pain Rating Scale
DASH, Disability of the Arm Shoulder and Hand
SF-36, Short Form Health Survey questionnaire.

Declarations

Ethics approval and consent to participate

All procedures involving human participants were in accordance with the 1964 Helsinki declaration and its later amendments. Written informed consent was obtained from all of the patients to participate the study. The study protocol was approved by the ethics committee of Local health company of Lecce (Italy) (protocol number 20, June 4th, 2018).

Consent for publication

Not appropriate

Availability of data and materials

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors report no conflicts of interest.

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Authors' contributions

Conceptualization: DV, AP; Data Curation: DV, GG; Formal analysis: LP, MG; Data collection: DV, AR, DP, AP; Writing – Original Drat: DV, GG, All authors read and approved the final version of the manuscript.

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