INTRODUCTION

The prevalence of shoulder disorders in Pakistan conforms to the international prevalence and the shoulder joint is the third frequently affected among musculoskeletal conditions. Its prevalence is high in occupations engaged in the repeated use of the shoulder joint such as nurses, dentists, teachers, housewives, and others and not uncommon in persons with sedentary lifestyles. Shoulder-related pain affects the quality of life and activities which constitute the quality of life such as housekeeping, overhead activities, recreational activities, and sleep. It leads to disability due to the impairment of functional movements of the shoulder.

Several methods are being used in this connection to evaluate the impact of a disease, of which most conventionally used is the objective assessment; focussed on measuring the range of motion and strength of the muscle by using a goniometer and manual muscle testing, respectively. However, these measures are not associated with the interventional outcomes, as the pain and pain-related disability are subjective feelings, which must be reported by patients themselves; therefore, the use of well-structured subjective questionnaires have been emphasized; known as the patient-reported outcome (PRO) measures. These PRO measures are the only and helpful way to collect the specific information regarding the pain and disability related to the specific condition or the region of the body. Thus making it necessary for clinicians and researchers to practice the use of a reliable and accurate questionnaire to evaluate the interventional outcomes related to the functional status of patients.

SPADI is one of the thirty plus shoulder-specific PRO measures developed in the English language and is the most commonly used, valid, reliable, brief, and subjective tool to evaluate the pain and functional status related to shoulder joint conditions. Its initial English version was developed by Roach et al. (1991) and validated in visual analogue scale (VAS) which was later established as a numeric scale for telephonic use and reliable results. Well, ahead Williams et al. (1995) modified it as a numeric rating scale (NRS). Realizing its significance, SPADI is validated in all the major languages. Chines, German, Turkish, Arabic, Slovene, and Hindi are few to mention.

ABSTRACT

Background: Shoulder-related pain leads to disability due to the impairment of functional movements of the shoulder and affects the quality of life. Realizing the importance of cultural adaptation and validation, Shoulder Pain and Disability Index (SPADI) is need to be translated and validated in the Urdu language. Objective: to determine the validity and evaluate the reliability of the Urdu version of the Shoulder pain and disability index (SPADI-U) in the Urdu-speaking population with shoulder pathologies in Pakistan. Methodology: The SPADI-U was administered to 135 respondents; of which 105 were subjects with shoulder pathology and the remaining 30 were healthy individuals for determination of its discriminant (Construct) validity. Visual analogue scale (VAS) and active range of motion were used to evaluate its convergent (construct) and criterion validity, respectively. It's internal and intra-rater reliability was also evaluated and a retest was conducted after 2-3 days of first administration and was completed by 50 patients. The data were analysed in SPSS version 21. Results: Cronbach’s alpha value for SPADI-U was 0.920, and intraclass coefficient (ICC, 95% CI)) value ranged between 0.700 and 0.938 for individual items. High values of 0.935 (0.887-0.963) for a total SPADI score were observed. The Pearson’s correlation coefficient showed moderately negative correlation (range r = -0.457 to -0.683) with SPADI-U indicating its acceptable criterion validity. Whereas, the high positive correlation of VAS with SPADI; for pain (r=0.871, 0.910, 0.893) and disability (r= 0.817, 0.915 and 0.813), showing good convergent validity. Mann-Whitney U-test was used for discriminant validity with significant difference (p<0.05) between the groups. No floor and ceiling effect was found. Conclusion: SPADI-U is valid and reliable tool for use in Urdu speaking individuals.

Key words: Psychometrics, reliability and validity, shoulder, SPADI-U, Urdu version.
Urdu is the National language of Pakistan, and is vocal in about 65 million people of specifically two countries of Asia; India and Pakistan, in a total population of 224 Million people Pakistan about 67% use it as their first and second language. \(^{23-25}\)

Realizing the importance of cultural adaptation and validation, several outcomes measuring tools have been translated and validated in the Urdu language \(^{26-30}\), and so the SPADI have been translated and culturally adapted as SPADI-U in the Urdu Language. \(^{31}\) The reliability and validity of the SPADI-U were not determined. It is in this context that this study was carried out to determine the validity and reliability of the culturally adopted SPADI-U.

**METHODOLOGY**

The data was collected from May 2019 to July 2019. The setting of the present study included shoulder patients from outpatient department of Helping Hand Institute of Rehabilitation Sciences. The Sample size was selected according to the recommendations to include 2-20 respondents per variable with a minimum sample size of 100 subjects to ensure steadiness for exploratory factor analysis. \(^{32}\) According to respondent-to-item ratio 8:1, SPADI being 13 items questionnaire, sample size suggested was 104 patients with shoulder pain or disability. The SPADI-U was administered to 105 shoulder patients and 30 physically healthy subjects. Shoulder patients were recruited through convenience sampling whereas, randomization approach was used for the recruitment of healthy subjects. Every 7th, 11th, and 17th roll number was selected from each semester of DPT students. At the first visit, the recruited respondents were assessed for eligibility. Those with cognitive and communication problems; scored with >2 errors on the short portable mental status questionnaire, cervical joint dysfunction, radicular pain, systemic diseases, neurological disorders, or disorders other than shoulder joint involvement were excluded. Those with age above 18 years and below 70 years, able to read, write and understand Urdu, any painful shoulder condition or Shoulder pain or functional limitations persisting more than 1 month were included in the study and were given consent form and information about the research topic, having the choice to participate or withdraw.

Agreed to participate respondents were then handed the booklet composed of SPADI-U, VAS\textsubscript{pain}, and VAS\textsubscript{disability} as well as, their demographics characteristics and active ROM were recorded. Of these 105 patients, 60 were requested to refill the SPADI-U after 48 -72 hours with no treatment session taken for the next 2 days. Out of 60, only 51 patients filled follow-up questionnaire without treatment.

Shoulder Pain And Disability Index: Roach et al proposed a self-reported shoulder-specific outcome questionnaire to evaluate subjective clinical outcome measures in an outpatient setting. \(^{11}\) It is a 13 item tool with two subscales measuring the different dimensions of pain and disability. Five items are designed to quantify pain and eight-item cover the disability measures of a patient with shoulder pathology. The total pain score is the sum of all five questions divided by the total maximum score x 100 results in %age of pain. Whereas total disability score is the sum of all questions attempted divided by total possible maximum score x 100, and the sum of all questions divided by total maximum possible score x 100 results in total SPADI score in percentage. A questionnaire with more than 2 items not answered was excluded, and with 1 -2 items missing the percentage was generated from the maximum possible score.

**Visual Analogue Scale For Pain:** VAS\textsubscript{pain}, was a single measure of pain intensity on a straight line of 100cm, from 0 indicating no pain to the other end 10 indicating the most severe pain. This was asked to fill according to the pain experienced in the last 1 week. Visual analogue Scale is a valid and reliable tool. \(^{33}\)

**Visual Analogue Scale For Disability:** VAS\textsubscript{disability} was a single measure severity of disability on a straight line of 100cm from 0 indicating no difficulty to the other end 10 indicating severe disability. This was asked to fill according to the difficulty experienced in last 1 week. The patient was asked to mark a line on the horizontal line of 100 mm (10cm). The distance from 0 to the mark point was measured in mm which was then categorized as 1-4mm = no difficulty, 5-44mm as mild difficulty, 45-75 mm as moderate difficulty, and 76-100 mm as severe disability.
Range Of Motion: Shoulder active range of motions was measured using a bubble inclinometer, using standard positioning. Flexion, extension, external rotation, internal rotation, and abduction were measured to compare and evaluate the criterion validity of SPADI-U.

The collected data were analysed by using IBM SPSS version 21. The statistical significance level was set at $p<0.05$. The descriptive statistics of demographics and diagnosis were analysed. The construct validity was analysed by principal component analysis for factor analysis and factor loading determined by the principal component coefficient more than 0.4. The discriminative construct validity was assessed by applying Mann Whitney U Test, determined by the difference between the score of patients and healthy respondents. Convergent construct validity was analyzed by measuring the correlation between total SPADI score, $\text{VAS}_{\text{pain}}$, and $\text{VAS}_{\text{disability}}$ by using Pearson’s correlation coefficient. Criterion validity was assessed by determining the relationship and correlation between active ROM of shoulder and total SPADI score, total pain score, and total disability score. The reliability of SPADI-U was assessed in different parameters, the internal consistency was assessed by Cronbach’s $\alpha$ score ($>0.70$), and test-retest reliability was measured by intra-class coefficient by two-way analysis of variance with absolute agreement. Standard error of measurement (SEM) was detected by formula $\text{SD} \times \sqrt{1-\text{ICC}}$ and small detectable change (SDC) was measured by applying formula as $1.96 \times \sqrt{2 \times \text{SEM}}$.

RESULTS

The mean ($\pm SD$) age of shoulder patients ($n=105$) was 42.7($\pm13.63$), participants of test retest $n=61$ was 38.5($\pm13.36$) and healthy participants was 21.2($\pm1.58$) years. Sixty five out of the total 105 were males and 40 females. Twelve males and 18 females.

The descriptive statistics for VAS at three levels and AROM presented in table 1. The mean for SPADI-U recorded at first assessment was 50.24($\pm16.22$)% with a range of 21-89% and the retest score was about 48.29 ($\pm13.12$) %, with a range of 17-80%.

Reliability: The internal reliability of SPADI-U was found in terms of the Cronbach’s alpha (CA); Cronbach value for total SPADI score was 0.920, while for the subscales pain and disability it was 0.82 and 0.906 respectively (significant at $<0.001$). The test retest reliability or stability over time for total SPADI score was ICC= 0.935 with absolute agreement at 95% confidence interval range from 0.887-0.963. The table 2 shows ICC (95%CI) and mean $\pm SD$ for every individual item and total pain disability and total score. Table 2 also shows calculated SEM and SDC.
Table 1: Descriptive statistics

<table>
<thead>
<tr>
<th>Variables</th>
<th>Mild n(%)</th>
<th>Moderate n(%)</th>
<th>Severe n(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAS (pain)</td>
<td>30(28.6%)</td>
<td>65(61.5%)</td>
<td>10(9.5%)</td>
</tr>
<tr>
<td>VAS (disability)</td>
<td>35(33.3%)</td>
<td>66(62.9%)</td>
<td>4(3.8%)</td>
</tr>
</tbody>
</table>

Table 2: Intraclass correlation coefficient (ICC)

<table>
<thead>
<tr>
<th>Item</th>
<th>ICC</th>
<th>95% CI</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean</th>
<th>±SD</th>
<th>SDC***</th>
<th>SEM**</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1</td>
<td>0.938</td>
<td>0.89-0.97</td>
<td>2(1.9%)</td>
<td>10(7.6%)</td>
<td>6.47</td>
<td>±2.05</td>
<td>1.42</td>
<td>0.51</td>
</tr>
<tr>
<td>P2</td>
<td>0.846</td>
<td>0.73-0.91</td>
<td>1(1%)</td>
<td>10(1.9%)</td>
<td>5.64</td>
<td>±2.14</td>
<td>2.33</td>
<td>0.84</td>
</tr>
<tr>
<td>P3</td>
<td>0.830</td>
<td>0.70-0.90</td>
<td>1(1%)</td>
<td>10(1.9%)</td>
<td>6.19</td>
<td>±1.87</td>
<td>2.13</td>
<td>0.77</td>
</tr>
<tr>
<td>P4</td>
<td>0.894</td>
<td>0.81-0.94</td>
<td>0(1.9%)</td>
<td>10(1.9%)</td>
<td>5.47</td>
<td>±2.24</td>
<td>2.02</td>
<td>0.73</td>
</tr>
<tr>
<td>P5</td>
<td>0.700</td>
<td>0.48-0.83</td>
<td>0(3.8%)</td>
<td>10(2.9%)</td>
<td>5.84</td>
<td>±2.28</td>
<td>3.09</td>
<td>1.25</td>
</tr>
<tr>
<td>D1</td>
<td>0.870</td>
<td>0.77-0.93</td>
<td>0(4.8%)</td>
<td>10(2.9%)</td>
<td>3.97</td>
<td>±2.42</td>
<td>2.41</td>
<td>0.87</td>
</tr>
<tr>
<td>D2</td>
<td>0.91</td>
<td>0.84-0.95</td>
<td>0(1%)</td>
<td>10(2.9%)</td>
<td>5.01</td>
<td>±2.24</td>
<td>1.87</td>
<td>0.68</td>
</tr>
<tr>
<td>D3</td>
<td>0.91</td>
<td>0.84-0.95</td>
<td>0(1.9%)</td>
<td>10(3.7%)</td>
<td>4.25</td>
<td>±2.41</td>
<td>1.02</td>
<td>0.73</td>
</tr>
<tr>
<td>D4</td>
<td>0.800</td>
<td>0.65-0.89</td>
<td>0(11.4%)</td>
<td>9(5.7%)</td>
<td>2.48</td>
<td>±2.07</td>
<td>2.56</td>
<td>0.92</td>
</tr>
<tr>
<td>D5</td>
<td>0.797</td>
<td>0.65-0.89</td>
<td>0(15.2%)</td>
<td>9(1.9%)</td>
<td>2.71</td>
<td>±2.29</td>
<td>1.87</td>
<td>1.03</td>
</tr>
<tr>
<td>D6</td>
<td>0.862</td>
<td>0.75-0.92</td>
<td>0(1.0%)</td>
<td>10(2.9%)</td>
<td>5.84</td>
<td>±2.05</td>
<td>2.11</td>
<td>0.76</td>
</tr>
<tr>
<td>D7</td>
<td>0.879</td>
<td>0.79-0.93</td>
<td>0(1.9%)</td>
<td>10(9.5%)</td>
<td>5.74</td>
<td>±2.09</td>
<td>1.01</td>
<td>0.73</td>
</tr>
<tr>
<td>D8</td>
<td>0.840</td>
<td>0.72-0.91</td>
<td>0(1.9%)</td>
<td>10(1%)</td>
<td>4.72</td>
<td>±2.19</td>
<td>2.43</td>
<td>0.88</td>
</tr>
</tbody>
</table>

Significance level: p<0.05*, p<0.01**, p<0.001***
P= Pain subscale, D= Disability subscale

Validity: The “discriminant validity” was evaluated by equating the scores of SPADI-U between patients (n=105) and normal individuals by applying Mann Whitney –u test for between the group analyses since the Kolmogorov Smirnov and Shapiro Wilk test revealed a significant difference between 2 groups in ages. A significant difference between the two groups (p<0.001) was found on Mann Whitney–U test showed for subgroup analysis between the patient (n=20) and normal/healthy controls group (n=30) of matching age. A significant difference between two groups (p<0.001) on independent sample T-test. The questionnaire was filled independently by all respondents and reported that it is easy to understand and took 8 to 10 minutes to complete the questionnaire. The Pearson's correlation of SPADI score for both VAS (pain) and VAS (disability) was highly positive. The criterion validity was evaluated by finding a correlation between the AROM of the shoulder and SPADI scores were a moderately negative correlation, indicating good criterion validity as shown in table (Table 3).

Factor Analysis: The Kaiser-Meyer-Olkin for sample adequacy was Bartlett’s sphericity test was significant (p<0.001) and reasonably high (0.933). A 2-factor structure was established based on Eigen value>1, with a total explained variance of 83.138% for two factors (Table 4). The screen plot supported the structure factor as the line straightens out after the 2-factors, with the eigenvalue for factor 1 is 9.769 and factor 2 is 1.039. (Figure 2)
Table 4 Factor Analysis with and without varimax rotation

<table>
<thead>
<tr>
<th>Item</th>
<th>PC Loading (Unrotated)</th>
<th>PC loading after Varimax rotation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PC1</td>
<td>PC2</td>
</tr>
<tr>
<td>P1</td>
<td>0.872</td>
<td>-</td>
</tr>
<tr>
<td>P2</td>
<td>0.878</td>
<td>-</td>
</tr>
<tr>
<td>P3</td>
<td>0.899</td>
<td>-</td>
</tr>
<tr>
<td>P4</td>
<td>0.870</td>
<td>-</td>
</tr>
<tr>
<td>P5</td>
<td>0.888</td>
<td>-</td>
</tr>
<tr>
<td>D1</td>
<td>0.897</td>
<td>-</td>
</tr>
<tr>
<td>D2</td>
<td>0.891</td>
<td>-</td>
</tr>
<tr>
<td>D3</td>
<td>0.880</td>
<td>-</td>
</tr>
<tr>
<td>D4</td>
<td>0.693</td>
<td>0.540</td>
</tr>
<tr>
<td>D5</td>
<td>0.766</td>
<td>0.594</td>
</tr>
<tr>
<td>D6</td>
<td>0.938</td>
<td>-</td>
</tr>
<tr>
<td>D7</td>
<td>0.885</td>
<td>-</td>
</tr>
<tr>
<td>D8</td>
<td>0.883</td>
<td>-</td>
</tr>
</tbody>
</table>

P=Pain subscales, D=Disability subscale

DISCUSSION

The SPADI-U was translated and culturally adapted into Urdu 31, but it was never validated in the Pakistani Urdu-speaking population. The goal of this study was to validate and assess the reliability of the SPADI-U, which was accomplished. The present study validated the SPADI-U in the Numerical Rating Scale version, which was strongly recommended and supported by Jeldi et al. 34. The psychometrics analysis revealed excellent reliability of SPADI-U 35, the Cronbach score of the current study was slightly lower than the findings of other versions including the original version. 11, 15, 18, 20, 36

The Cronbach’s score was stable with the results of Gadam and Yao et al. 8, 9 Although Cronbach’s alpha value was greater than 0.90 is present as a result of a redundant item 15, 18 which indicates homogeneity among items. Therefore, Cronbach’s score from 0.70 to 0.95 is considered as good and reliable. 8, 13, 37

The results for intra-rater reliability were substantially good as shown by the ICC for total SPADI score. These results were concurrent and consistent with some versions of SPADI 15, 18, 21, whereas it was somewhat lesser than the findings of Gadam and Alsawani et al 9, 20 and higher than other versions of SPADI. 8, 22, 38-40 The ICC score higher than >0.9 allows a reliable assessment of the individual patient. 15, 41

Only a few articles provided information regarding the duration of test-retest reliability check. Spanou et al. used the duration similar to ours as 2-3 days gap 15, which is enough to reduce the memory effects and change of patient functional and pain status over time. The time duration of test-retest for the Danish version was 8 days 42 while the Chinese version and Italian version reported 7 days interval for retest. 8, 43

The SEM for Urdu SPADI total score was 4.14, which is consistent with the results of Wang and Rodey et al. 17, 44 and lower than the outcomes of, Spanou, Angst, and Sharma et al., respectively. 15, 18, 22 The weighted average for SEM reported by Roy in the systematic review of four questionnaires is 6.8. 45

The SDC measured for SPADI-U was 11.4, indicating that for a true detectable change the 11.4 points are required, similar findings are reported by Wang et al (11.56) 17, whereas SDC reported for original (13 points), Greek SPADI (13.2), 15 Hindi version (14.2) 22 and Danish SPADI (19 points) 42; reported are higher than SPADI-U. These measures could be helpful for the clinician to detect the change in a repeated and re-administered questionnaire in a clinical setting. That is, 11 point change would reflect a real change in the status of the patient’s function and pain in Urdu speaking population. Whereas, SDC reported by the Norwegian population was about 20 points in patients with impingement syndrome 42 and 17 for adhesive capsulitis patients. 46

There was not a single item unanswered by the respondents, which strongly reflects good content validity and floor and ceiling effect, which were
counted to be less than 15% except for item 10 (putting on your pants) demonstrating the flooring effect to be 15.2%. The literature review revealed ceiling effects for two items of SPADI, item 9 and 10 in German versions reporting as 54 and 61%, and Chinese version reported 58.33 and 55.83%, respectively. The findings of the present study showed good convergent validity by a high positive correlation. These results were higher than those conducted by Yao min et al. Whereas, other studies compared the SPADI with DASH, SPF36, HAQ, and ASES, indicating a poor to high convergent validity. This variance may be due to differences in the construct and structure of different questionnaires. The VAS only determines one dimension of pain and disability whereas, questionnaires like SPADI, measures the quality and functional status from different dimensions. None of the above mention scales were available in Urdu to be administered in Urdu speaking population, therefore VAS was used for convergent validity. The reliability and validity reported for VAS for disability are moderate to good as compared to other scales used to assess disability.

The exploratory factor analysis revealed that all components strongly on factor 1 while two components; items 9 and 10 were cross-loaded on factor 2, and after varimax rotation, some of the components were cross-loaded on factor 2, and items 9 and 10 were strongly loaded on factor 2 only. These findings are comparable to those of Jamnik et al. The original version; where only one factor was loaded without rotation and with rotation the components of disability were strongly loaded on the first factor, while most of the pain components were loaded on the second factor. While some versions showed the single factor loading, and the three-factor dimension. This variance in findings is due to the wording of the SPADI item that the people responding to the questions are unable to differentiate between the pain and disability items. Such disability components ask how much difficulty one has performing a task exception of pain and one might respond to it as pain while performing the activity. Later suggest that though there is a variance of factor loading of items for each version of SPADI, all versions come together to the same conclusion.

Because there was no gold standard for comparability, the criterion validity was assessed by correlating SPADI with active range of motions of the shoulder joint. Pearson’s correlation coefficient revealed a moderately negative correlation, indicating that SPADI-U has acceptable criterion validity. These findings were nearly identical to those of Gadam and Jeldi et al. Whereas, correlation of active ROM with the original scale reported by Roach et al. reflected a highly negative correlation.

The current study emphasises the significance of self-reported patient outcome measures from both a clinical and a research standpoint. This tool will not only aid in assessing the level of subjective shoulder-related measures in the Urdu-speaking population, but will also aid in pre and post-therapeutic management, as well as clinical decision-making based on true change detected by the smallest detectable change. However, it will also be an important research tool for Urdu-speaking physicians, rheumatologists, orthopaedic surgeons, neurologists, physical therapists, occupational therapists, community nurses, and other health professionals. Due to time constraint the responsiveness of the questionnaire is not validated. This could be a recommendation for future researches.

CONCLUSION

The SPADI-U has been shown to be reproducible and valid for use as a research and clinical outcome measuring tool for self-reported outcomes. Every aspect of psychometric analysis provided evidence for its reliability. The use of the Urdu version in clinical settings and outpatient departments has been validated as a research tool.

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Disclaimer: None to declare.
Conflict of Interest: None to declare.
Funding Sources: None to declare.