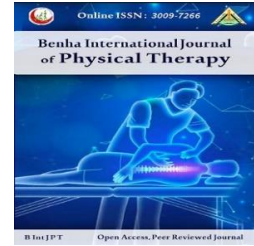


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Original research

Cross cultural adaptation, validity and reliability test of the arabic version of rotator cuff quality of life questionnaire.

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Abstract

Background: Shoulder pain is a common problem in orthopedic clinics. The Rotator Cuff Quality of Life Index (RC-QOL) questionnaire covers pain, frequency, severity, symptoms, quality of life, and activities of daily living affected by shoulder disorders and has no Arabic version. **Purpose:** To find out the validity and reliability of the translated version of RC-QOL among the Arab population in Egypt. **Methods:** The questionnaire translated into Arabic according to recent guidelines by Tsang. Four experts panels and 340 patients with rotator cuff disorders (RCD) participated in this study. Test-retest was measured by interclass correlation (ICC) with confidence interval (CI) 95% and internal consistency analysis were measured by Cronbach's alpha value to test reliability. Face, content, and construct validity were evaluated for the RC-QOL. Factor analysis and internal construct validity were assessed, and convergent and divergent validity were tested by the correlation between RC-QOL, Disabilities of The Arm, Shoulder and Hand (DASH) and Western Ontario Shoulder Instability Index (WOSI) questionnaires. **Results:** The study showed that the scale index of clarity was 90% to 100% and the mean index of clarity was 98.82%, the item content validity index (CVI) ranged from 0.7 to 1, the scale CVI (S-CVI) was 0.97 (97%), the experts proportion of relevance ranged from 91.18 to 100% and the mean was 97.94%. The questionnaire items were filled out 100% on all sheets and it needed less than 13 min maximum and a minimum 3 min to be answered. Cronbach's alpha was 0.998, ICC was 0.928 to 0.953 with 95%. **Conclusion:** The Arabic version of the RC-QOL questionnaire is a reliable and valid tool to assess Rotator Cuff Disorder in the Egyptian population.

Keywords: Translation, Validity, Reliability, Rotator Cuff Quality of Life questionnaire

Introduction

Shoulder pain is a common musculoskeletal problem. It can hinder the individual's life, activities, and work^{1, 2, 3}. The third most common cause of musculoskeletal pain is Rotator Cuff Disorder (RCD) which is the primary source of shoulder pain^{4, 5}.

Standardized tools, in the form of self-administered questionnaires, have been utilized more clinically and in research in recent years, these tools measure outcomes of relevance to patients (as symptoms, function, satisfaction with treatment outcomes, and quality of life)^{6, 7}.

The RC-QOL questionnaire is a disease-specific Health-related patient-reported outcome measure (HR-PROM) intended for usage in individuals suffering from "full spectrum of RCD."⁸ It can determine the effect of treatment, report pain, function, determine the prognosis, severity, irritability, and nature of a patient's condition⁹.

It contains 34 questions distributed in 5 sub-scales: symptoms, work, sports, life-style and social concerns. Questions were scored on a 100-mm visual analog scale (0 to 100). Patients have the option of answering "not applicable" on 14 questions only and answers were not imputed but were treated as if these questions had never been offered to the patient. RC-QOL is calculated by taking an average of answered questions. When the score denotes 0% (indicates the worst quality of life, 100% indicates the best quality of life)¹⁰.

Patient-based questionnaires should be translated and validated in the language and culture of the target population and community before using for clinical outcome evaluations¹¹. Although RC-QOL questionnaire has been translated into various languages and validated (as English [8, 10], Italian [12], Chinese [13], Turkish [14], Spanish [15] and German language [16]), no adapted Arabic version has been published. This research set out to assess the translated Arabic version of RC-QOL questionnaire's validity as well as reliability in a group of Egyptian patients who speak Arabic and have RCD in Egypt.

Methods

Design of study

This is prospective observational research. Before the study, participants were required to submit written agreements after being fully

informed, and ethical approval was obtained from the institutional review board of the Faculty of Physical Therapy at Cairo University (with the reference number P.T.REC/012/03834).

Study participants and recruitment criteria:

The adaptation and translation of the questionnaire were finished in accordance with the established standards by Sousa, Borsa and Tsang^{17, 18, 19}. The study was conducted from July 2023 to January 2024. A sample of 340 patients with RCD conducted the RC-QOL questionnaire and then repeated it after 7-10 days to assess its test-retest reliability. All of the participants were recruited from Qasr El Ainy and Atfal Masr Hospitals. The following were the inclusion requirements: Being from 18 to 59 years, literate, speaking Arabic, diagnosed as chronic partial thickness rotator cuff tear or shoulder impingement by an orthopaedist and the diagnosis was confirmed by ultrasonography or magnetic resonance imaging, and patients with pre-existing rotator cuff pathology who experienced an injury to the ipsilateral shoulder¹⁰.

Patients with cognitive impairment, who were unable or unwilling to complete study outcomes or provide informed consent, who have concomitant symptomatic pathology of the affected shoulder (i.e., instability, osteoarthritis), cervical spine pathology or radiculopathy or both, or autoimmune disease, inflammatory joint disease, bankart lesion, previous surgery on the affected shoulder and patients with full-thickness rotator cuff tear were excluded from recruitment Ebank and papalia^{10, 12}.

Procedures:

The RC-QOL questionnaire was translated with the author's consent. It is originally written in English and was translated into Arabic according to the forward-backward translation principles established by Sousa, Borsa and Tsang^{17, 18, 19}. The original scale was initially translated into two Arabic variants, followed by the development of a preliminary translated version. This version was then backwardly translated into two English versions, leading to the development of a pre-final version. The pre-final version was tested by professionals and found there is a need to modify the preliminary initial Arabic version so, a secondary Arabic version was produced. Then the last form was done among patients to test reliability and feasibility. Three experts panels were tasked

with assessing the scale's clarity by evaluating the instructions, items, and face validity. They were also requested for improving clarity (clear-unclear) to calculate the clarity index of the questionnaire. Following this, a separate set of 10 experts was given a scale to use in determining whether or not each item on the instrument had content equivalent (content-related validity or relevance) using the provided scale. 1 = not relevant; 2 = unable to assess relevance; 3 = relevant but requires minimal alteration; 4 = extremely relevant and succinct. Following the successful completion of expert face as well as content validity tests the research team took all the comments from the four expert panels and modified the pre-final version to the most clear and equivalent formula; it was known as the last version. The assessment was done with patients to fill out the final form of the scale to assess the feasibility and internal consistency reliability using Cronbach's coefficient, then the patients were assessed to fill out the scale again after 7-10 days to calculate test-retest reliability via mean scores and the ICC. Also, Patients filled out DASH, and WOSI questionnaires to test concurrent validity.

Statistical analysis:

Descriptive statistical analysis of the sample was performed using means and standard deviations for numerical data and using frequency and percentage for categorical data. The clarity index and expert proportion of the clearance were used to test face validity. CVI, S-CVI, and expert proportion of relevance were used to test the content validity. Concurrent validity was investigated through the correlation between RC-QOL, DASH, and WOSI questionnaires using Pearson correlation coefficients. Cronbach's alpha was used to measure the internal consistency reliability. Test-retest reliability was measured using the two-way mixed ICC with 95% CI. Feasibility is measured by the calculation of the missed item index and the average time needed to answer the questionnaire. The level of significance for all statistical tests was set at $p < 0.05$. All statistical measures were performed through the Statistical Package for Social Studies (SPSS) version 25 for Windows.

Results

Subject characteristics:

340 subjects with RCD (as rotator cuff tendonitis or tendinopathy, Shoulder impingement,

chronic partial thickness rotator cuff tear) participated in this study. Their mean \pm SD age, weight, height, and BMI were 37.62 ± 10.95 years, 81.46 ± 11.03 kg, 168.68 ± 6.83 cm and 28.60 ± 2.83 kg/m². 157 (46%) of the subjects were females and 183 (54%) were males. 260 (76%) had the right side affected and 80 (24%) had the left side affected (**Table 1**).

Table 1: General characteristics of the subjects:

	Mean \pm SD	Minimum	Maximum
Age (years)	37.62 \pm 10.95	18	59
Weight(kg)	81.46 \pm 11.03	55	110
Height (cm)	168.68 \pm 6.83	149	179
BMI (kg/m ²)	28.60 \pm 2.83	19.79	34.89
Sex distribution	N	%	
Females	157	46	
Males	183	54	
Affected side	N	%	
Right side	260	76	
Left side	80	24	

Expert panel:

The four expert panels have the same individuals where the 10 experts participated in this study to investigate the validity of the Arabic version of the RC-QOL questionnaire. One expert holds Ph.D., 4 with master's degree, and 5 with BSC. Their mean \pm SD experience years of the expert panel for face validity was 12.67 ± 2.74 years with a minimum of 10 years and a maximum of 17 years.

Face validity:

The mean index of clarity of the Arabic version of RC-QOL questionnaire was 98.82% which is excellent. The index of clarity of the Arabic version of RC-QOL questionnaire ranged from 90% to 100%. The mean expert proportion of clearance was 99.11% which is excellent. The expert proportion of clearance ranged from 97.06% to 100%. Seven experts had 100% proportion of clearance and three experts had 97.06% proportion of clearance.

Content validity:

The Arabic version of RC-QOL demonstrated excellent content validity. The item CVI ranged from 0.7 to 1. The S-CVI was 0.97 (97%). The mean expert proportion of relevance was 97.94%, which is excellent. The expert's proportion of relevance ranged from 91.18 to 100%.

Concurrent validity:

The correlation between DASH and total score of RC-QOL questionnaire was strong negative

significant correlation ($r = -0.976, p = 0.001$). Also, the correlation between DASH and RC-QOL subscales was moderate to strong negative significant correlation (**Table 2**).

The correlation between WOSI total score and total score of RC-QOL questionnaire was strong negative significant correlation ($r = -0.969, p = 0.001$). The correlation between WOSI and RC-QOL subscales was a strong negative significant correlation (**Table 2**).

Table 2. Correlations between RC-QOL questionnaire, DASH and WOSI:

RC-QOL questionnaire	DASH	WOSI				
		Physical symptoms	Sports/recreation/work	Lifestyle	Emotion	Total WOSI
Symptoms	-0.974**	-0.968**	-0.952**	-0.958**	-.957**	-.967**
Work	-0.970**	-0.963**	-0.954**	-0.959**	-.958**	-.964**
Sports	-0.392**	-0.393**	-0.407**	-0.393**	-.386**	-.392**
Lifestyle	-0.969**	-0.96**	-0.950**	-0.961**	-.957**	-.962**
Social/Emotional	-0.962**	-0.952**	-0.940**	-0.951**	-0.956**	-.954**
Total Score	-0.976**	-0.969**	-0.956**	-0.963**	-0.962**	-0.969**

r value: Pearson correlation, p value: Probability value, **: Significant at $p < 0.001$

Reliability:

Internal consistency of the Arabic version of RC-QOL:

Cronbach's alpha for the Arabic version of RC-QOL was 0.998 that means it had excellent internal consistency.

Test-retest reliability of the Arabic version of RC-QOL:

The Arabic version of RC-QOL questionnaire showed high test-retest reliability in all items (ICC:

0.928 to 0.953). ICC for total score was 0.946, with 95% CI 0.933-0.957. (**Table 3**)

RC-QOL	ICC	(95% CI)		P value
		Lower bound	Upper r	

			boun d	
Ques. 1	0.936	0.921	0.948	0.001
Ques. 2	0.939	0.924	0.951	0.001
Ques. 3	0.937	0.922	0.949	0.001
Ques. 4	0.947	0.935	0.958	0.001
Ques. 5	0.938	0.923	0.950	0.001
Ques. 6	0.939	0.925	0.951	0.001
Ques. 7	0.928	0.911	0.942	0.001
Ques. 8	0.935	0.919	0.947	0.001
Ques. 9	0.943	0.929	0.954	0.001
Ques. 10	0.929	0.901	0.949	0.001
Ques. 11	0.938	0.923	0.950	0.001
Ques. 12	0.939	0.924	0.951	0.001
Ques. 13	0.93	0.911	0.944	0.001
Ques. 14	0.937	0.921	0.949	0.001
Ques. 15	0.935	0.918	0.948	0.001
Ques. 16	0.945	0.932	0.955	0.001
Ques. 17	0.946	0.933	0.957	0.001
Ques. 18	0.943	0.929	0.955	0.001
Ques. 19	0.945	0.932	0.956	0.001
Ques. 20	0.945	0.931	0.955	0.001

Ques. 21	0.951	0.930	0.965	0.001
Ques. 22	0.95	0.929	0.964	0.001
Ques. 23	0.947	0.925	0.962	0.001
Ques. 24	0.95	0.929	0.964	0.001
Ques. 25	0.947	0.934	0.957	0.001
Ques. 26	0.944	0.931	0.955	0.001
Ques. 27	0.945	0.931	0.956	0.001
Ques. 28	0.94	0.926	0.952	0.001
Ques. 29	0.953	0.941	0.962	0.001
Ques. 30	0.949	0.937	0.959	0.001
Ques. 31	0.936	0.921	0.948	0.001
Ques. 32	0.952	0.940	0.961	0.001
Ques. 33	0.939	0.922	0.952	0.001
Ques. 34	0.949	0.937	0.959	0.001
Symptoms	0.941	0.927	0.952	0.001
Work	0.946	0.933	0.956	0.001
Sports	0.982	0.978	0.986	0.001
Lifestyle	0.946	0.933	0.956	0.001
Social / Emotional	0.944	0.931	0.955	0.001
RC-QOL	0.946	0.933	0.957	0.001

Feasibility:

The questionnaire needed an average of 7.15 ± 2.34 min to be answered with maximum of 13 min and minimum of 3 min. There were no missing

items. The frequency and percentage of time taken to answer the questions in minutes showed in (Table 4).

Table 4. Frequency distribution of time needed to fill the questioner in minutes:

Time (min)	Frequency	Percent
3	9	2.6
4	33	9.7
5	46	13.5
6	55	16.2
7	37	10.9
8	55	16.2
9	38	11.2
10	40	11.8
11	12	3.5
12	8	2.4
13	7	2.1

Discussion

The self-administered questionnaire is appropriate when its purpose is easily explained in print. The instructions and questions asked are straightforward, relatively cheap (compared with interviews), allow a larger sample as well as a wider geographical distribution of the sample, also it is simple to administer, easy to analyze, and collect a large amount of data in a relatively short time. They are therefore useful in quantitative research, for example, if the researcher wants a breadth of data from a random sample from which to make generalizations about a population²⁰.

The Arabic version of RC-QOL has excellent face validity as the questionnaire index of clarity was 90% to 100%, the mean index of clarity (clear responses) was 98.82%, the expert proportion of clearance ranged from 97.06% to 100% and the mean expert proportion of clearance was 99.11%. Also, it had excellent CVI ranging from 0.7 to 1 and S-CVI was 0.97 (97%), the expert's proportion of relevance ranged from 91.18 % to 100% and the mean was 97.94%.

The concurrent validity of the total score in RC-QOL questionnaire with DASH questionnaire was strong negative significant correlation ($r = -0.976$, $p = 0.001$), the correlation between DASH and RC-QOL sub-scales was strong negative significant correlation with symptoms ($r = -0.974$, $p = 0.001$), work ($r = -0.970$, $p = 0.001$), and with social/ emotional sub-scale ($r = -0.962$, $p = 0.001$); while the sport was moderate negative significant correlation ($r = -0.392$, $p = 0.001$).

The concurrent validity of the total score in RC-QOL questionnaire with WOSI questionnaire was strong negative significant correlation ($r = -0.969$, $p = 0.001$), the correlation between physical symptoms of WOSI and symptoms sub-scale of RC-QOL questionnaire was strong negative significant correlation ($r = -0.968$, $p = 0.001$), the correlation between sports/ recreation/ work of WOSI was strong negative significant correlation with work subscale of RC-QOL questionnaire ($r = -0.954$, $p = 0.001$) and was moderate negative significant correlation with sports sub-scale of RC-QOL questionnaire ($r = -0.407$, $p = 0.001$), the correlation between lifestyle sub-scale of WOSI and RC-QOL questionnaire was strong negative significant correlation ($r = -0.961$, $p = 0.001$); while the emotion sub-scale was strong negative significant correlation ($r = -0.956$, $p = 0.001$).

Among the 340 subjects who participated in the study, 157 (46%) subjects were female and 183 (54%) were males, their mean \pm SD age, weight, height and BMI were 37.62 ± 10.95 years, 81.46 ± 11.03 kg, 168.68 ± 6.83 cm and 28.60 ± 2.83 kg/m², 260 (76%) subjects were right side affected and 80 (24%) subjects were left side affected.

The results of the current study came in agreement with Polit and Beck²¹ who stated that a scale to be judged as having excellent content validity, it would be composed of items with I-CVI that meet the following criteria (I-CVI of 1.00 with three to five experts and a minimum I-CVI of 0.78 for 6 to 10 experts) and it would have S-CVI of 0.90 or higher. The recommended standards may necessitate two rounds of expert review if the final assessment suggests the need for substantial item improvements.

Also, this came in agreement with Waltz²² who stated that S-CVI/Ave of 0.90 or above is the minimum acceptable index, and items that don't achieve the minimum acceptable indices are revised and re-evaluated.

The Arabic version of RC-QOL had excellent internal consistency as Cronbach's alpha was 0.998 (Cronbach's alpha of sub-scales were 0.995 for symptoms, 0.985 for work, 0.989 for sports, and 0.986 for lifestyle and social/ emotional subscale).

The Arabic version of RC-QOL had excellent test-retest reliability and was measured using the two-way mixed ICC with 95% CI was 0.928 to 0.953 (the ICC for symptoms sub-scale was 0.941 with 95% CI 0.927 – 0.952, the ICC for work sub-scale was 0.946 with CI 95% 0.933 – 0.956, the ICC for sports sub-scale was 0.982 with 95% CI 0.978 – 0.986, the ICC for lifestyle sub-scale was 0.946 with 95% CI 0.933 – 0.956, the ICC for social/ emotional subscale was 0.946 with 95% CI 0.933-0.956 and the ICC for total score was 0.946 with 95% CI 0.933-0.957).

So, according to Koo and Li 23 the 95% CI of the ICC estimate, values less than 0.5, between 0.5 and 0.75, between 0.75 and 0.9, and greater than 0.90 are indicative of poor, moderate, good, and excellent reliability, respectively.

The Arabic version of RC-QOL had high feasibility because the scale items were filled out by 100% in all sheets and it needed an average of 7.15 ± 2.34 min to be answered with a maximum 13 min and a minimum 3 min. There were no missing items .

So, the results came in agreement with Van 24 who stated that the missing rate on the item level was considered acceptable if no single item had a missing rate exceeding 10% and completion time was considered acceptable if 95% of sheets were completed in less than 15 minutes.

This study came in agreement with the English version of RC-QOL that provides additional reliability, validity, and responsiveness testing in accordance with the Consensus-Based Standards for the Selection of Health Measurement Instruments (COSMIN) guidelines 10. Where the Cronbach alpha was 0.96 (95% CI, 0.89-0.99; range, 0.72-0.94). The ICC for the RC-QOL was 0.87 (95% CI, 0.79-0.85; range, 0.77-0.88). Content validity was confirmed through standardized patient interviews. All a priori hypotheses were confirmed .

Another study aimed to translate and culturally adapt the Chinese version of RC-QOL and validate its use for assessing Chinese patients with RCD Wang 13 where Cronbach's alpha and internal consistency scores were high for all parts of the RC-QOL with Cronbach's alpha-ranging between

0.89 and 0.98. Internal consistency scores range from 0.82 to 0.92, which can be regarded as an excellent correlation. Test-retest reliability was excellent for all parts of the RC-QOL with good absolute reliability. RC-QOL correlates the CS score, UCLA Shoulder Rating Scale and the WORC score, with all being statistically significant .

Also, these results came in agreement with similar results obtained by (Papalia 12 who conducted a study to adapt the RC-QOL to the Italian version, to Turkish version by Çınar-Medeni 14, to Spanish version by Rodríguez 15, and to German version by Huber 16) with all being statistically significant.

Conclusion

Based on the results obtained from this study RC-QOL questionnaire is a valid, reliable, and feasible questionnaire for assessing RCD and it is applicable in both therapeutic application and academic studies to evaluate the severity and disability in people with RCD.

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Conflict of interest

The authors say they have no competing interests.

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