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Cross-cultural adaptation and validation of Leicester Cough Questionnaire in sarcoidosis: the persian version

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Abstract. *Background and aim:* Cough is a common symptom among patients with sarcoidosis, and the Leicester Cough Questionnaire, a cough-specific quality-of-life measure, evaluates the impact of cough across physical, psychological, and social domains in patients with chronic cough. The aim of this study was cross-cultural adaptation and validation of Persian version of Leicester Cough Questionnaire (LCQ) in pulmonary sarcoidosis in Iran. *Methods:* Psychometric analyses included translation and back translation of the questionnaire, face validity, content validity, construct validity, criterion-related validity, internal consistency, and test –retest reliability were performed. *Results:* Twenty-five participants demonstrated no major language barriers or difficulties in completing the questionnaire and adequate face validity of ≥1.5. Twelve experts confirmed the content validity was good (CVR>0.56, I-CVI≤0.79, S-CVI/Ave>0.80). Totally, 190 patients were included in the study. The Pearson's coefficients and their significance's (*P<0.05*) showed an acceptable agreement between the LCQ and the SF-36 questionnaire. The goodness-of-fit of the conceptual model including psychological, physical, and social domains, obtained from EFA, was confirmed throughout the RMSEA of 0.09 (<0.1), NFI of 0.9, NNFI of 0.91, and CFI of 0.92 which all were ≥0.9. The Persian LCQ showed an excellent internal consistency regarding Cronbach's alpha of 0.974 and ICC (95%CI) value of 0.983 (0.977, 0.987). *Conclusions:* The psychometric properties showed that the Persian version of LCQ is a valid and reliable measure to evaluate cough-specific quality of life and is a fit-for-purpose measure for use in patients with pulmonary sarcoidosis and the results can guide clinicians in treatment decisions.

Key words: health-related quality of life, reliability, validity

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Introduction

Sarcoidosis is a multisystem disorder characterized by the infiltration of non-necrotizing granulomas in various organs (1,2). Impairments can adversely influence patients' quality of life (QoL) and disrupt critical life areas (1,3,4). Influence of cough as a significant symptom in sarcoidosis with a prevalence of 30 to 50%, on patients' QoL has not been adequately addressed so far (5). Leicester Cough Questionnaire (LCQ) is a self-administered tool and has been validated in several diseases (6–9) and languages (10–16). The aim of this study was cross-cultural adaptation and validation of Persian version of LCQ in pulmonary sarcoidosis in Iran.

Material and methods

In this cross-sectional study, 190 pulmonary sarcoidosis were recruited by a non-random convenience sampling method from March 2022 to March 2023 in the outpatient sarcoidosis clinic of Dr. Masih Daneshvari Hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran. Inclusion criteria were definitive diagnosis of pulmonary sarcoidosis by a pulmonologist based on the patient's signs and symptoms and paraclinics, being literate and completion of the consent form; Exclusion criteria were smoking, gastroesophageal reflux disease, chronic rhinosinusitis, allergic rhinitis, angiotensin-converting enzyme (ACE) inhibitors drugs and other pulmonary diseases. Psychometric analyses, forward-backward translation, face validity, content validity, construct validity (including exploratory factor analysis (EFA) and confirmatory factor analysis (CFA)), criterion-related validity, as well as reliability (internal consistency and test–retest reliability) were performed (Figure 1). First, the patients referring to the clinic were visited by a pulmonologist, and after explaining the study objectives and informed consent obtaining, the questionnaires were given to the patients. In the construct validity phase, EFA was used to achieve the highest amount of variance with the least number of factors throughout the eigenvalues≥1. Afterward, CFA was used to confirm the conceptual model for 190 patients. Ten subjects per item of the instrument were applied for the sample size determination (17). The study was approved by the ethics committee of Dr. Masih Daneshvari hospital (IR.SBMU.MSP.REC.1400.335) and according to the principles of the 1975 declaration of Helsinki.

Questionnaires

Data collection included three sections; demographic and medical information, LCQ, and 36-Item Short Form General Quality of Life Survey (SF-36).

The medical parameters assessed included underlying diseases, drug history, Scadding criteria, spirometry, and 6-min walk distance (6MWD) test.

LCQ is a 19-item, self-completed, disease-specific, quality-of-life measure of chronic cough including physical (eight items), psychological (seven items), and social (four items) domains. Items 1,2,3,9,10,11,14, and 15 are related to physical domain; 4,5,6,12,13,16, and 17 items related to psychological; and social domain includes items 7,8,18, and 19 (18). To calculate the LCQ score, mean scores for each domain (ranging from 1 to 7) and a total score are calculated as the sum of the domain scores (ranging from 3 to 21) (19). Each LCQ item assesses symptoms, or the impact of symptoms, on Health-related quality of life (HRQoL) over the past 2 weeks using a 7-point Likert-type scale ranging from all the time to none of the time. Higher scores indicate better HRQoL (18). Clinicians may consider a≥1.3-point increase in the LCQ total score as clinically meaningful in patients with refractory or unexplained chronic cough (19).

SF-36 as a valid and internationally accepted self-report measure of functional health and well-being is a general questionnaire with 36 questions and eight domains (physical function, social function, pain, functional limitation affected by physical health, functional limitation due to emotional health, energy/fatigue, general health, and mental health) (20).

Formation of a specialized working group

A focus group of twelve experts consisting of eight pulmonologists, one epidemiologist, one Ph.D. in public health, and two English language experts was formed.

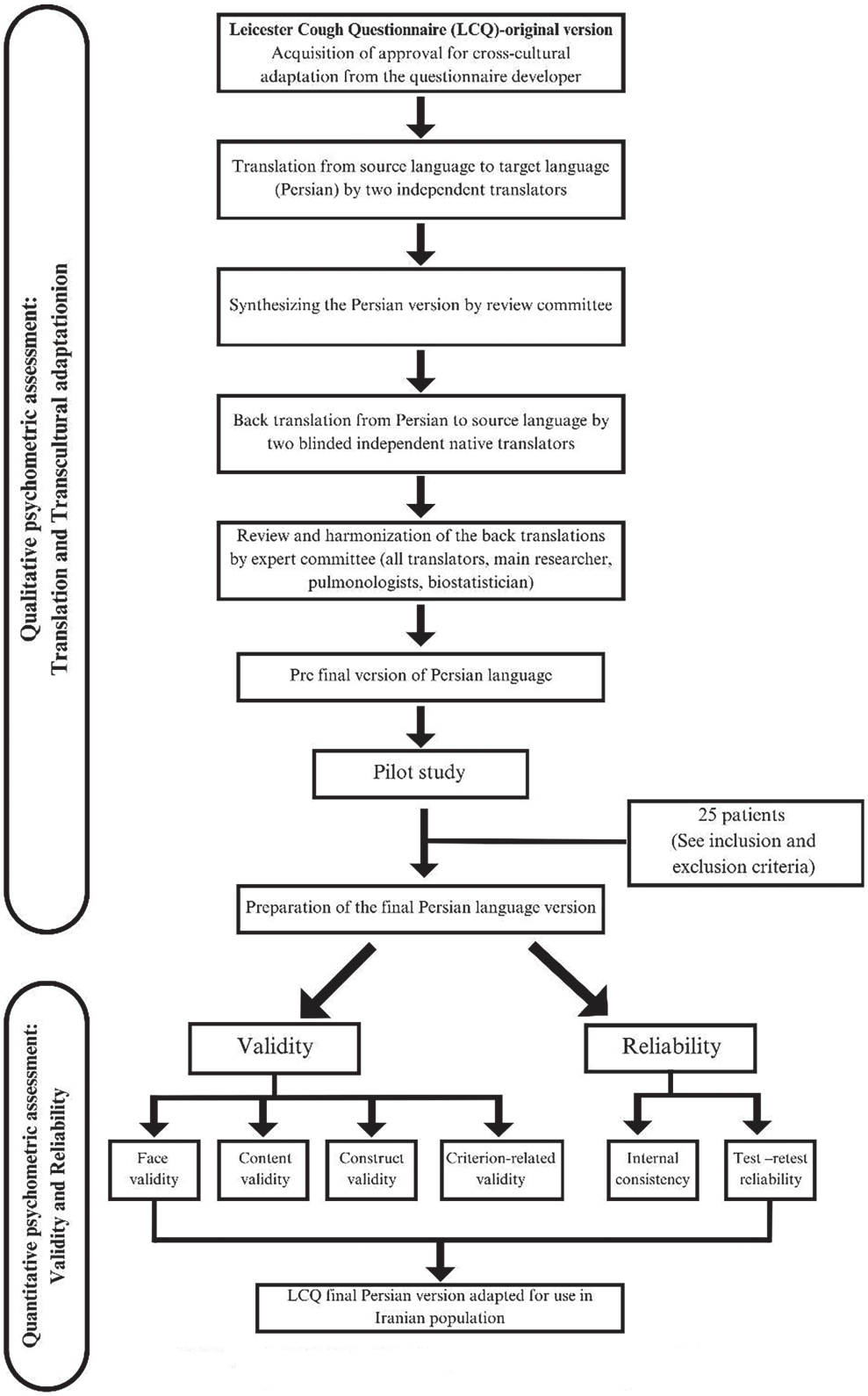

Figure 1. Summary of the process of translation and cross-cultural adaptation of the Leicester Cough Questionnaire (LCQ) for use in Iran.

Translation and back translation of the questionnaire

After approval from the questionnaire developer, Professor Surinder Birring, the World Health Organization's standard forward-backward translation method was used (21). At first, the original English version of the questionnaire was translated into Persian as the target language by two independent bilingual and bicultural seniors including a healthcare expert familiar with English and an English language expert. A third independent translator compared translations and a synthesis version was generated. The preliminary initial Persian translation was re-translated into English by two well-qualified independent native speakers separately that were blind to the original version of instrument. The first translator was knowledgeable about healthcare terminology and the second translator was familiar with colloquial phrases, idiomatic *expressions*, and emotional terms of the source language. The original English version was compared with the re-translated version by the expert working group and the differences were discussed to resolve ambiguities and discrepancies and decided finally. The final English version was sent to the instrument developer, Professor Surinder Birring, to be qualitatively matched with the original version and finally, the proposed amendment was approved (18).

Validity

Content validity

Content validity as an index for comprehensiveness assessment was confirmed by calculating content validity ratio (CVR) to ensure that the most important and correct content (necessity of the question) was selected and content validity index (CVI) to ensure that the instrument questions were designed in the best way to measure the content. CVR= (ne - N/2)/ (N/2), CVI= (Number of responses adequate or very adequate)/ (Total number of responses) were calculated. The minimum acceptable value for CVR was 0.56 based on the Lawshe table (22), and minimum required amount of CVI for each item was 0.79 (23).

To calculation of CVI, the experts were asked to rate each item on a 4-point scale of relevance: 4 = very relevant and succinct; 3 = relevant but needs minor alteration; 2 = unable to assess relevance; and 1 = not relevant. Items classified as 1 (not relevant) or 2 (unable to assess relevance) were revised. Content validity index at the item level (I-CVI) and at the scale level (S-CVI) by averaging calculation (S-CVA/Ave) method were calculated. As a general criterion, I-CVI should be ≥ 0.70. (24) The minimum acceptable value of S-CVI/Ave should be 0.80 (25,26). Items that do not achieve the minimum acceptable indices were revised and re-evaluated. New content validity indices were calculated. The process continues until acceptable indices of content-related validity or content equivalence were achieved. The face and content validity method were selected based on the consensus-based standards for the selection of health measurement instrument (COSMIN) (27).

Face validity

For face validity, pilot testing of the pre-final Persian version of the instrument by 25 Iranian sarcoidosis patients was conducted to further support the conceptual, and content equivalency of the translated questionnaire and improve the structure of sentences to be easily understood by the target population prior to psychometric testing. Some minor final modifications based on these structured interviews were implemented and documented to improve the comprehensibility of the questionnaire. The face validity was calculated using formula: Importance Score= Σ (f×importance)/N; (28) and values ≥1.5, were retained.

Construct validity

In construct validity phase, EFA was used for construct validity for a sample of 102 patients, considering the Varimax rotation. Thereafter, CFA was used to confirm the goodness of fit of EFA results including 190 patients. Root Mean Square Error of Approximation (RMSEA), Normed Fit Index (NFI), Non-Normed Fit Index (NNFI), and Comparative Fit Index (CFI) statistics were performed to assess the goodness-of-fit model.

Criterion-related validity

Criterion-related validity is the degree of agreement between the newly-developed instrument and a standard valid instrument in the same field. SF-36 as a general well-studied measure of quality of life was utilized for criterion-related validity.

Reliability

Internal consistency

Cronbach's alpha was used to determine internal consistency considering that values above 0.9 are considered excellent, between 0.7 - 0.9 indicate good, between 0.6 - 0.7 are acceptable, between 0.5 - 0.6 are weak, and less than 0.5 indicate unacceptable internal consistency (29–31).

Test-retest reliability

Test-retest reliability measures the consistency of results when we repeat the same test on the same sample at a different point in time. Test–retest reliability was used to determine intraclass correlation coefficient (ICC). Based on the 95% confidence interval 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 (32).

Statistical analysis

Note that quantitative data are presented as mean±SD, and qualitative data were evaluated as percentages. A significance level of less than 0.05 was considered. The data description and EFA was performed using IBM SPSS 22.0. CFA was performed using Lisrel software version 8.8.

Results

Demographic characteristics

Ninety-three (48%) patients from 190 patients were male. Their mean±SD age was 50.27±10.06 years. The most underlying diseases were diabetes, hypertension, and lymphadenopathy reported in 33 (17.6%), 30 (16%), and 146 (78.1%) patients, respectively. Assessment of the Scadding criteria (33) showed stage II (hilar enlargement plus interstitial lung disease) in most of the patients (52%). Pulmonary function analyses disclosed that 95 patients were normal. The mean 6MWD for all patients was 534 m. Most of the patients (42%) accomplished 400–500 m. Demographic and clinical data are summarized in Table 1.

Table 1. N (%) of the symptoms and Underlying diseases in the studied sarcoidosis patients.

Sing and Symptoms		**N (%)**
	Fatigue	131 (70.10)
	Shortness of breath	103 (71.70)
	Cough	103 (55.10)
	Skin lesions	86 (45.20)
	Blurred vision	85 (44.70)
Underlying Diseases		
	Diabetes mellitus	33 (17.60)
	Hypertension	30 (16)
	Ischemic heart diseases	22 (11.50)
	Liver diseases	2 (1.05)
	Cerebrovascular diseases	1 (0.52)
Drug history		
	Prednisolone	166 (88.8)
	Methotrexate	98 (52.4)
	Hydroxychloroquine	66 (35.3)
	Leflunomide	10 (5.3)
	Azathioprine	6 (3.2)
	Mycophenolate mofetil	3 (1.6)
	Infliximab	2 (1.1)
	Thalidomide	2 (1.1)
	Rituximab	1 (0.5)
	Other drugs	17 (9.1)
Scadding criteria		
	Stage I: hilar enlargement alone	76 (40)
	Stage II: hilar enlargement plus interstitial lung disease	97 (52)
	Stage III: interstitial lung disease alone	17 (8)
Pulmonary function test		
	Normal	95 (50)
	Obstructive defect	48 (25)
	Restrictive defect	28 (15)
	Mixed defects	19 (10)
Six min walk distance (6MWD)		
	>500 m	38 (20)
	400-500 m	80 (42)
	<400 m	72 (38)

Validity

Content validity

Table 2 illustrates the 19 questions that had the minimum acceptable score for CVR, I-CVI, S-CVI, and S-CVI/Ave which were retained in the questionnaire.

Table 2. I-CVI, S-CVI, CVR, Cronbach's Alpha, and ICC of the LCQ

Domain	Item	Question	I-CVI	CVR	Cronbach's Alpha if item deleted
Physical	1		0.85	0.71	0.983
	2		1	1	0.984
	3		0.71	0.72	0.983
	9		0.85	0.71	0.983
	10		0.85	0.71	0.985
	11		1	1	0.983
	14		0.72	0.74	0.983
	15		0.72	0.74	0.984
	S-CVI=0.855 Cronbach's Alpha =0.955 ICC= 0.959, 95% CI:(0.947,0.97) F=12.575, P<0.001				
Psychological	4		0.82	0.73	0.985
	5		0.74	0.86	0.983
	6		0.85	0.71	0.983
	12		0.74	0.62	0.983
	13		0.85	0.62	0.982
	16		0.85	0.62	0.983
	17		0.75	0.62	0.983
	S-CVI=0.800 Cronbach's Alpha =0.965 ICC= 0.945, 95% CI:(0.927,0.96) F=21.790, P<0.001				
Social	7		0.85	0.71	0.983
	8		0.85	0.72	0.983
	18		0.85	0.71	0.983
	19		0.85	0.71	0.983
	S-CVI=0.850 Cronbach's Alpha =0.974 ICC= 0.96, 95% CI:(0.955,0.967) F=2.303, P<0.001				
LCQ	S-CVI/Ave=0.835 Cronbach's Alpha =0.984 ICC= 0.984, 95% CI:(0.98, 0.987) F=62.76, P<0.001				

Abbreviations:CVR: content validity ratio, I-CVI: item content validity index, S-CVI: scaled CVI, S-CVI/Ave: S-CVI Average, ICC: Intra-class correlation coefficient, F: F-value for probable bias, P: P value for F test.

Face validity

Regarding the Importance score ≥1.5, all 19 questions were retained in the questionnaire.

Construct validity

EFA revealed three factors due to three eigenvalues of 15.061, 2.2, and 1.068 greater than 1 explaining 85% of the total variance. None of the questions were removed from the questionnaire because all the factor loading values were>0.5.

The goodness-of-fit of the conceptual model including psychological, physical, and social domains, obtained from EFA, was confirmed throughout the RMSEA of 0.09 (<0.1), NFI of 0.9, NNFI of 0.91, and CFI of 0.92 which all were ≥0.9. Figure 2 shows the standardized effect size of each item related to

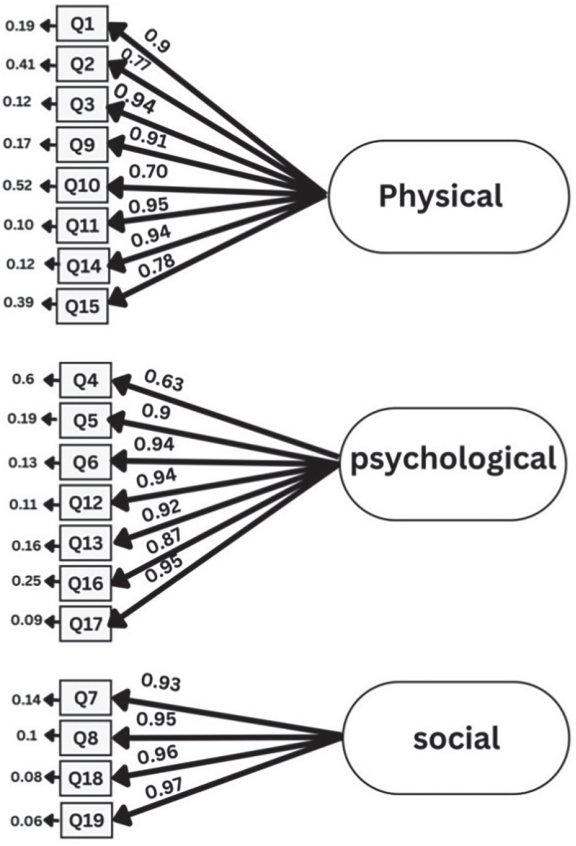

Figure 2. The standardized effect size of each item related to the corresponding factor and item error variances.

the corresponding factor, in addition to the error variances for each item.

Criterion-related Validity

Table 3 approved the criterion-related validity of the translated instrument. Pearson correlation coefficient of each of the domains of the LCQ with the domains of the SF-36 showed a significance (*P<0.05*) or a high significance (*P<0.001*) demonstrating an acceptable agreement between the LCQ and the SF-36.

Reliability

Internal consistency

The results of Cronbach's alpha index indicated that the internal consistency of the questionnaire was excellent (≥0.9) for each scale (0.955, 0.965, and 0.974) and LCQ (0.984). Cronbach's alpha if an item is deleted is presented in Table 2 showing excellent internal consistency.

Table 3. Pearson correlation for criterion-related validity between LCQ and SF-36.

	LCQ domains		
SF-36 domains	**Social**	**Psychological**	**Physical**
1. Role limitations due to physical functioning (role functioning-physical)	0.632**	0.649**	0.654**
2. Physical Functioning	0.514**	0.55**	0.646**
3. Bodily Pain	0.722**-	0.724**-	0.711**-
4. General health perception	0.095*-	0.12*-	0.22*-
5. Vitality (energy and fatigue)	0.199*-	0.226*-	0.29*-
6. Social Functioning	0.196*-	0.205*-	0.12*-
7. Role limitations due to emotional functioning (role functioning-emotional)	0.697**	0.718**	0.679**-
8. General mental health	0.199*-	0.277*-	0.37**-

P<0.05*P<0.001**

Test-retest reliability

ICC (95%CI) values in Table 2 indicated excellent stability for three scales as well as ICC for the total score of 0.983 (0.977, 0.987). F-values of 12.575, 21.79, 2.303, and 62.76 (*P < 0.001*) for the three factors and whole LCQ, respectively, showed the probable existence of bias in the test-retest.

Discussion

This study established the satisfactory validity, and reliability of the LCQ questionnaire in Iranian pulmonary sarcoidosis patients. In this study, the LCQ was translated into the Persian language, and its psychometric properties were examined in a cross-sectional design. Based on the obtained results from the CVI and CVR calculations in addition to face validity scores, all the questions had at least the minimum required score and were not excluded from the

study. The internal consistency of the Persian LCQ was excellent, with both Cronbach's Alphas and ICC greater than 0.9 for the total score and the three scales.

There are three cough-specific quality-of-life questionnaires including the Leicester Cough Questionnaire, Cough Quality of Life Questionnaire, and Chronic Cough Impact Questionnaire which have been validated so far (34). The LCQ is the shortest with the minimal important difference of 1.3 for the original version that has been validated in several languages (12–15,34).

Polley et al. (35) have compared the LCQ and the Cough specific Quality of life Questionnaire (CQLQ) with the EUroQol, a generic health status questionnaire, in different chronic respiratory diseases, including bronchiectasis, Chronic Obstructive Pulmonary Disease (COPD) or asthma; and suggested the LCQ may be able to provide useful information about the impact of cough (36,37). The LCQ itself is more concise than other cough specific HRQoL questionnaires which may imply greater patient acceptance of the questionnaire (18).

Haukeland-Parker S et al. in a psychometric assessment of the Norwegian version of the LCQ in COPD used the COPD Assessment Test (CAT) and Dartmouth Primary Care Cooperative Research Network/World Organization of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians (COOP/WONCA) questionnaires as there were no other measures in Norwegian for assessing subjective cough symptoms. The results showed poor construct validity and these outcomes may be due to the construct in these two measures being too different from what the LCQ domains aim to capture (38). These results are in contrast with our construct validity data which final model based on EFA and CFA clearly demonstrated the relationship between questions and factors. Our study has special strengths with some other previous studies which have validated the LCQ and reported acceptable construct validity for the domains but did not perform factor analysis (7,14,39).

In Berkhof FF et al. study, correlation coefficients for the LCQ and most of the corresponding domains of the SF-36 were low and almost nonexistent for the psychological domain; except the correlations between the social domain of the LCQ and the social functioning domain of the SF-36; in contrast with our study with acceptable agreement between the LCQ and the SF-36 (7).

The excellent internal consistency of the Persian LCQ was in line with the Korean version of the LCQ in patients with chronic cough; the Cronbach's alpha coefficients for all three domains, and the total questionnaire were more than 0.8 (40).

In this study, all domains and the total LCQ score had excellent test-retest reliability (ICC >0.90). The ICC results were higher than other studies ranging from 0.84 to 0.93, which strengthens this study (6,7,12,14,18,39).

The significance of F-values in the test-retest analysis implies the existence of bias, which is likely due to a short duration between the test and retest, or a small sample size of the cases in this phase.

To the best of our knowledge, there is no valid and reliable instrument to measure the impact of cough-specific quality of life among Iranian pulmonary sarcoidosis patients, so it can be applied in both clinical practice and research in Persian-speaking countries.

Conclusion

The diversity of the population worldwide shows a great need for cross-culturally validated instruments or scales. In conclusion, the psychometric properties showed that the Persian version of LCQ is a valid and reliable measure to evaluate cough-specific quality of life and is a fit-for-purpose measure for use in patients with pulmonary sarcoidosis and the results can guide clinicians in treatment decisions.

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

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