

Towards the Validation of the Persian Translation of the Revised Cystic Fibrosis Quality of Life Questionnaire in Adolescents and Adults (CFQ-R 14+)

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Abstract

Background: the present study aimed to translate the cystic fibrosis questionnaire for adolescents and adults (CFQ-R 14+) into Persian, and assess its validity and reliability.

Methods: In total, 35 patients with cystic fibrosis (CF) completed the Persian version of CFQ-R 14+, and Forced Expiratory Volume in one second (FEV1) and body mass index (BMI) were measured. In addition, the Pediatric Quality of Life inventory (PedsQL) was completed by the subjects. The validity of the CFQ-R 14+ was assessed using the face validity, Content Validity Ratio (CVR), and Content Validity Index (CVI), along with concurrent and know-group validities for checking its construct validity. The scale's reliability was also estimated by test-retest and Cronbach's alpha coefficients.

Results: After forward-backward translation, the values of the total CVR and CVI and their sub-items were higher than 0.8 and 0.49 respectively. Most of the scales had strong internal consistency (Cronbach's Alpha \geq 0.70), and the test-retest correlations were within the range of 0.72-0.95, considered significant for all the scales. Moreover, strong correlations were observed between the total CFQ-R and PedsQL 4.0 ($r=0.9$; $P<0.001$), as well as moderate-to-strong incomparable domains ($r=0.4-0.8$). A significant correlation was denoted between the total CFQ-R scale and FEV1 ($r=0.42$; $P=0.01$), while a reverse correlation was observed between the total CFQ-R scale and age group discrimination ($r=-0.35$; $P=0.03$).

Conclusion: According to the results, the Persian version of the CFQ-R 14+ is a reliable and valid instrument for measuring the health-related quality of life among Iranian adolescent and adult patients with CF.

Key Words: Cystic Fibrosis, Adolescent, Adult, Quality of Life, validation.

* Please cite this article as: Talebi S, Sayedi J, Khadem Rezaiyan M, Ranjbar G, Barghchi H, Safarian M, Kianifar H. towards the Validation of the Persian Translation of the Revised Cystic Fibrosis Quality of Life Questionnaire in Adolescents and Adults (CFQ-R 14+). Int J Pediatr 2022; 10 (1):15313-15322. DOI: 10.22038/IJP.2021.60865.4694

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Received date: Nov.11,2021; Accepted date:Dec.5,2021

1- INTRODUCTION

Quality of life (QoL) is defined as the conscious cognitive judgment of satisfaction with one's life⁽¹⁾ and an individual's perception of their status in life in the context of the culture and value systems in which they live in regards to their goals, expectations, standards and concerns (2).

Health-Related Quality of Life (HRQoL) is an indicator of overall health and provides data on the physical and mental health status of individuals, as well as the impact of the health status on the QoL (3). In fact, QoL is an inclusive concept encompassing all the factors that impact an individual's life, while HRQoL only encompasses the factors that are involved in the individual's health (4). Another definition of HRQoL is the aspects of self-perceived wellbeing that are related to or affected by the presence of disease or treatment (5).

QoL could be evaluated using several approaches. Self-assessment is a method frequently used for the measurement of QoL based on the subjective feelings of an individual. Furthermore, the measurement instruments of QoL are classified as global and specific (6). Global HRQoL tools are designed to assess various dimensions of health-related issues and compare the treatment options for the same health condition, as well as various chronic diseases. On the other hand, disease-specific HRQoL instruments are designed to evaluate the impact of a specific condition and its treatment on the patient's life. These questionnaires often contain a list of symptoms that are associated with specific diagnoses and treatments, and their aim is to monitor changes in terms of treatment efficacy and provide important follow-up information to clinicians (7, 8).

The Cystic Fibrosis Questionnaire (CFQ) is an instrument consisting of both disease-specific and generic domains. The CFQ

was first developed in France in three versions appropriate for children aged 6-13 years (CFQ-child), parents of the children with CF aged 6-13 years (CFQ-parent), adolescents and adults with CF aged 14 years (CFQ-teen/adult) (9). After the psychometric testing of the original version, a revised version, named CFQ-R, was developed with slight revisions (10).

To the best of our knowledge, no Persian version of the CFQ is currently available. The present study, thus, aimed to translate and psychometrically assess the Persian Revised CFQ (CFQ-R) for adolescents and adults.

2- MATERIALS AND METHODS

2-1. Participants and Procedures

In total, 35 adolescent and adult patients with cystic fibrosis (CF) were selected from the referrals to the clinic of Akbar Hospital, affiliated to Mashhad University of Medical Sciences in Mashhad, Iran. In the routine visits during 2019-2020, with consecutive methods, all the known CF patients aged ≥ 14 years were enrolled in the study and provided informed consent to complete the QoL questionnaires of CFQ-R 14 and the pediatric quality of life inventory (PedsQL). Patients who had difficulty understanding the Persian language or were unlettered and those with severe pulmonary exacerbation were excluded from the study.

Data were collected on the demographic characteristics and anthropometric indices with a standard position using SECA instruments for height and weight, as well as the pulmonary function test by spirometry indices with spirometer (CHESTGRAPH HI-105) of the selected patients. To obtain an unbiased perception of the HRQoL, the physical examinations and laboratory procedures were performed after the completion of the questionnaires. In addition, the patients were asked to complete the CFQ-R14 in about 10-14

days after the study with the same clinical status. The study protocol was approved by the Institutional Medical Ethics Committee of Mashhad University of Medical Sciences (IR.MUMS.MEDICAL.REC.1399.415).

2-2. Translation

The translation process initiated with backward-forward translations. The English CFQ-R was translated into Persian by two translators. In the second step, two native and non-native English translators carried out a backward translation of the scale into English. In addition, a third expert compared the original English questionnaire with the backward English translation. The final version of the instrument was prepared after the agreement of the editors.

2-3. Content Validity

Content validity was used after consultation with the experts in this field. To this end, 11 experts with specialties and subspecialties in various fields, i.e., gastroenterologists, pulmonologists, nutritionists, psychiatrists, pediatrics and general physicians were asked to evaluate the content validity of the translated questionnaire. Lawshe's content validity ratio (CVR) was also used to quantify the validity of an assessment tool with various items (Essential, Useful but Not Essential, Not Essential); the CVR of ≥ 0.49 confirmed the proper content validity of the instrument (11). Furthermore, we used Waltz and Bausell quantitative measures to determine the content validity index (CVI) of the questionnaire, and the experts graded the items based on a four-point rating scale (Not Relevant, Partially Relevant, Quite Relevant, and Very Relevant). Face validity was determined based on the comments of the experts and patients the scale's ability to assess the desired concept and its feasibility for the Iranian population, particularly CF patients (12).

2-4. CF Questionnaire-Teen/Adult

CFQ-R14 consists of 49 items, which are divided into the domains of physical functioning (eight items), vitality (four items), emotional functioning (five items), social functioning (six items), role function (four items), body image (three items), eating disorders (three items), and treatment burden (three items). Also, it consists of symptom scales including respiratory (six items), digestive (three items), weight (one item), and overall health perception (three items). The participants can score these items based on a four-point Likert scale and express whether they agree or disagree with a particular statement. The score range of the instrument is 0-100, with the higher scores indicating the high QoL of the respondent. The questionnaires were completed within an average of 10-15 minutes, and a minimum 80% of the items had to be answered, so that the score of each domain could be calculated. (13)

2-5. Pediatric Quality of Life Inventory (PedsQL) 4.0 Generic Core Scales

The 23-item PedsQL™ generic core scales have been designed to measure the core dimensions of health as delineated by the World Health Organization (WHO), as well as the role (school) function. The scale has four multidimensional scales, including physical functioning (eight items), emotional functioning (five items), social functioning (five items), and school functioning (five items). The scale could also be classified into the physical health summary score (eight items) and psychosocial health summary score (15 items). The questionnaires were completed within approximately four minutes. The items were scored based on a five-point Likert scale (Never=0, Almost Always=4). In addition, the items were scored in reverse and linearly transformed to a scale of 0-100 (0=100, 1=75, 2=50, 3=25, 4=0). If more than 50% of the items in the scale were missing, the scale scores could not be

computed; and the mean score was the sum of the items over the number of the answered items (14, 15).

2-6. Homogeneity

The internal consistency of each domain was estimated, using Cronbach's alpha coefficients, to be 0.7 or higher.

2-7. Reproducibility

Test-retest reliability was used to measure the stability of the CFQ-R scores over time. In total, 18 patients with stable clinical conditions (no hospitalization or pulmonary exacerbation) re-completed the CFQ-R after 10-14 days. Notably, the length of the period was determined as such to control memory effect as a confounding factor, while it was also short enough to prevent the deterioration of the disease status.

2-8. Concurrent Validity

We used PedsQL 4.0 generic core scales as a validated questionnaire for comparison with the CFQ-R and assessment of the concurrent validity of the CFQ-R. In addition, correlation-coefficients were obtained for the total score and comparable domains of the CFQ-R and PedsQL 4.0.

2-9. Construct Validity

To assess whether the measure could discriminate between the patients with varying degrees of disease severity, the patients were categorized based on their level of pulmonary impairment as normal-to-mild ($FEV1 \geq 70\%$ predicted) and moderate-to-severe ($FEV1 < 70\%$ predicted). In addition, construct validity was assessed by correlating the CFQ-R scores with the pulmonary functioning domain. The comparison of the age groups and nutritional status was also performed based on the BMI and CFQ-R scores.

2-10. Statistical Analysis

Data analysis was performed in SPSS version 26 using descriptive statistics to

determine the mean and standard deviation of the domain scores. Inter-group comparisons were performed using independent t-test, and the correlations between the CFQ-R scores; and clinical outcomes (BMI, FEV1% predicted, and age) were determined using Pearson's correlation-coefficient.

3- RESULTS

3-1. Study Population

In total, 35 CF patients were recruited, and the mean age of the adolescents and adults who completed the CFQ-R questionnaire was 18.34 ± 4.27 years (age range: 14-46 years). The subjects were 51% males and 48% females. The mean FEV1 prediction rate was $72.74 \pm 24.93\%$, and the mean BMI was 18.41 ± 3.79 kg/m². **Table 1** represents the demographic characteristics of the patients.

3-2. Content Validity

In the present study, Lawshe's method was used to assess the necessity of each item in the scales, and the items were observed to have a high average. Furthermore, the Waltz and Bausell method was applied to evaluate the clarity, simplicity, and relevance of the items, all of which had acceptable scores.

3-3. Face Validity

According to the obtained results, the CF experts and CF patients had a positive view toward the relevance and simplicity of the questionnaire items, confirming their acceptability and face validity. Notably, the CFQ-R was completed within an average of 10-15 minutes.

3-4. Reliability

In the current research, the internal reliability of the scales was observed to be strong based on Cronbach's alpha value (0.94). **Table 2** shows the correlations of the items with the domains and Cronbach's alpha coefficients.

Table-1: Clinical and demographic characteristics of the patients from cystic fibrosis registry

Variables	N, %, mean (SD)
Number of case	35
Age(year); Mean± SD(min-max)	18.34±4.27(14-46)
Gender	
Male (Number, Percentile)	18(51%)
female	17(48%)
BMI(kg/m ²); Mean± SD	18.41±3.79
BMI Z score; Mean± SD	-1.34(1.82)
FEV1 prediction(percentage)	72.74±24.93%
Sweat chloride test(meq);Mean± SD	98.77±56.64
CFTR mutation	R117H: Homozygote (22), Heterozygote (7) G542: Homozygote (2), Heterozygote (3) W1282X: Heterozygote (3) Δ F508: Homozygote (3)

CFTR: Cystic Fibrosis Transmembrane conductance Regulator, BMI: Body Mass Index, FEV1: Forced Expiratory Volume is measured during the forced vital capacity test, SD: Standard Deviation

Table-2: CFQ-R scales, mean, and standard deviation of each domain

Descriptive Statistics			
	Items (N)	Mean±SD	Cronbach's Alpha
Physical Functioning	8	77.04±19.17	0.91
Emotional Functioning	5	70.11±22.34	0.84
Vitality	4	74.04±15.36	0.5
Health Perception	3	74.28±20.32	0.71
Eating Disorders	3	80.95±23.59	0.74
Weight	1	66.41±29.51	-
Treatment Burden	3	67.85±14.73	0.18
Body Image	3	66.42±23.43	0.74
Social Functioning	6	69.23±13.31	0.14
Role Functioning	4	72.85±21.95	0.74
Respiratory Symptoms	6	76.92±16.20	0.83
Digestive Symptoms	3	77.38±16.49	0.52
Total CFQ-R	49	72.16±11.34	0.94

CFQ-R; Cystic Fibrosis Questionnaire-Revised

3-5. Test-retest Reliability

In total, 18 patients had stable health conditions and completed the CFQ-R again after 15 days. The mean age of this subgroup was 18.72±4.77 years, their mean FEV1 was 70.03±24.80%, and their mean BMI was 19.70±3.67 kg/m². Additionally, strong correlations were

observed between the mean total scores and each domain of the scale. **Table 3** shows the correlation-coefficients and P-values of the domains.

3-6. Concurrent Validity

According to the results, the comparable domains of the CFQ-R and PedsQL 4.0

were properly correlated, and the mean total correlation of the CRQ-R with the PedsQL 4.0 was estimated as $r=0.85$ ($P<0.001$). Furthermore, the correlations were moderate-to-strong in the domains of physical functioning ($r=0.77$; $P<0.001$),

social functioning ($r=0.42$; $P=0.01$), emotional functioning ($r=0.8$; $P<0.001$), and role function ($r=0.39$; $P=0.01$), indicating the acceptable concurrent validity of the CFQ-R.

Table-3: Correlation-coefficients of mean scores of the total scale and the domains before and after two weeks

Domains	Test-Retest Analysis		
	Number of Answers	Correlation-coefficient	P-value
Physical Function	18	0.94	≤ 0.001
Emotional Functioning	18	0.89	≤ 0.001
Vitality	18	0.98	≤ 0.001
Health Perception	18	0.87	≤ 0.001
Eating Disorders	18	0.74	≤ 0.001
Weight	18	0.8	0.01
Treatment Burden	18	0.72	≤ 0.001
Body Image	18	0.92	≤ 0.001
Social Functioning	18	0.84	≤ 0.001
Role Functioning	18	0.85	≤ 0.001
Respiratory Symptoms	18	0.89	≤ 0.001
Digestive Symptoms	18	0.72	≤ 0.001
Total CFQ-R	18	0.9	≤ 0.001

3-7. Construct Validity

A significant correlation was observed between the mean total CFQ-R score and FEV1 prediction ($r=0.42$; $P=0.01$). Furthermore, the comparison of the domains between the two FEV1 groups demonstrated significant differences in physical functioning ($P=0.01$), health perception ($P=0.003$), treatment burden ($P=0.02$), role function ($P=0.03$), and respiratory symptoms ($P=0.02$). The CF patients with a mild disease status also achieved significantly higher scores compared to those with moderate-to-severe disease status, indicating the discriminating power of the scale in terms of the disease severity.

To further evaluate clinical utility of the scale, the correlations of factors such as age, gender, BMI, and FEV1 with the CFQ-R results were also estimated. Our

findings revealed a significant reverse correlation between the mean CFQ-R scores and age groups ($r=-0.35$; $P=0.03$). The comparison of the domains between the two age groups of adolescents (aged up to 18 years) and adults (aged more than 18 years) indicated that the adults had a lower QoL compared to the adolescents, particularly in terms of physical functioning ($P=0.05$), health perception ($P=0.03$), and respiratory symptoms ($P=0.02$).

The comparison of the domains between various BMI groups revealed that the patients with malnutrition obtained lower body image scores compared to those with a normal BMI ($P=0.01$). However, no correlation was observed between the CFQ and gender. **Tables 4** and **5** show the comparison of the mean CFQ-R domain scores between the study groups.

Table-4: Comparing the Means of CFQ-R domain scores based on different grouping variables

Groups variable	Number of Patients	Total CFQ-R (Mean±SD)	Mean Difference (P-value)
FEV1 <70% Prediction	13	66.87±11.59	0.66
>70% Prediction	22	75.28±10.19	
Age (year)			0.1
14-18	23	74.73±8.62	
>18	12	67.22±14.43	
Gender			0.82
Male	18	71.72±12.34	
Female	17	72.62±10.53	
BMI Z-score			0.93
<-1 SD	18	68.73±10.68	
>-1	17	75.79±11.17	

CFQ-R: Cystic Fibrosis Questionnaire-Revised, FEV1: Forced Expiratory Volume in one second, BMI: Body Mass Index

Table 5: Total CFQ-R score and correlation coefficients with FEV1, age, gender and BMI Z-Score

	Correlation coefficient	Physical Function	Emotional Functioning	Vitality	Health Perception	Eating Disorder	Weight	Treatment Burden	Body Image	Social Function	Role Function	Respiratory Symptom	Digestive Symptom
Total CFQL	Pearson Correlation	.802**	.676**	.703**	.765**	.766**	-.120	.554**	.717*	.469*	.771**	.636**	.461**
	P value	.000	.000	.000	.000	.000	.512	.001	.000	.005	.000	.000	.005
FEV1	Pearson Correlation	.512**	.183	.268	.525**	.273	-.139	.456**	.291	.195	.436**	.406*	.104
	P value	.002	.293	.119	.001	.112	.448	.006	.095	.261	.009	.016	.553
Age	Pearson Correlation	-.383*	-.410*	-.193	-.407*	-.233	.087	-.291	-.145	-.081	-.223	-.451**	-.154
	P value	.023	.015	.268	.015	.177	.636	.090	.413	.644	.198	.006	.376
BMI Z-Score	Pearson Correlation	.271	-.088	.081	.153	.073	.032	.184	.432*	.263	.334	.103	-.205
	P value	.115	.616	.645	.379	.678	.863	.291	.011	.127	.050	.556	.238

CFQ-R: Cystic Fibrosis Questionnaire-Revised, FEV1: Forced Expiratory Volume in one second, BMI: Body Mass Index

** P<0.001; * P<0.05

4- DISCUSSION

In the present study, we translated the English version of the CFQ-R for adolescents and adults into Persian and psychometrically evaluated the revised Persian version of it. According to our findings, the Persian version of the CFQ-R

had an acceptable structure, reliability, and validity for the Iranian CF patient population. Reliability refers to the agreement of two attempts to measure the same underlying construct using similar methods, while validity is the extent to which a concept is accurately measured in a quantitative study. The Cronbach's alpha

is commonly used for reliability assessment and measurement of internal consistency, while it also evaluates the correlations between the items of a scale and determines whether set items hang together to form a scale (12).

In the present study, all the items had an acceptable Cronbach's alpha coefficient, with the exception of the treatment burden and social functioning domains. Previous studies have also reported the low reliability of the treatment burden (13, 16) and body image items (16). Since this questionnaire is embedded in the CF patients with the most involvement diagnosed in the lungs, it may be able to assess the effects of disease severity on the QoL.

To evaluate clinical utility in the current research, the contributing factors to the disease severity of the CF patients were considered, including the pulmonary function test (FEV1), BMI, and age. Our findings demonstrated that the mean FEV1 prediction, respiratory symptoms, and physical functioning had the most significant correlations. After the classification of the patients based on their disease severity by the FEV1 percentage, our findings indicated that the QoL scores diminished with the increased disease severity. This is consistent with the previous studies in this regard (16, 17), denoting that the instrument has acceptable concurrent validity for patients with respiratory involvement.

Disease progression often increases with age, thereby significantly affecting the QoL of patients with CF. Several studies have confirmed the lower QoL scores of elderly patients. Consistent with the previous studies (16, 18), the current research also indicated the significantly lower QoL scores in the elderly patients, as well as the negative correlations between the domains of physical activity, perceived health, and respiratory symptoms.

With regard to gender, we observed that no significant differences were denoted in the total mean values of scale domains. Other studies have confirmed the decreased QoL of women and the significant gender differences in the perceived body image and weight scales, suggesting that female CF patients are more satisfied with their thinness than male CF patients (16, 17, 19).

Malnutrition is an important influential factor in the disease severity and QoL of patients with CF (20, 21). Since the BMI is considered to be the optimal component for anthropometric assessment in CF patients (22), it is highly recommended that its correlation with the QoL be further investigated. Our findings demonstrated that the subjects with malnutrition had a poor impression of their appearance.

The main limitation of this study was the small sample size due to the fact that cystic fibrosis is a genetic rare disease with low incidence, and its prevalence is, likewise, low due to the high mortality rate in adults. So the number of the available CF patients aged more than 14 years is rather limited. In this regard, we could not perform complete validation tools like factor analysis. This issue could be overcome through multi-center studies across different universities. To the best of our knowledge, this was the first study designed for the translation and psychometric evaluation of the CFQ-R for adolescents and adults.

5- CONCLUSION

According to the results, the Persian translation of the CFQ-R has sufficient reliability and validity to be used in the Iranian CF patient population.

6- ABBREVIATIONS

Body Mass Index (BMI), Cystic Fibrosis (CF), Content Validity Index (CVI), Content Validity Ratio (CVR), Cystic Fibrosis quality of life

Questionnaire (CFQ), Cystic Fibrosis quality of life Questionnaire-Revised (CFQ-R), Forced Expiratory Volume in one second (FEV1), Health-Related Quality of Life (HRQoL), Pediatric Quality of Life inventory (PedsQL), Quality of Life (QoL)

7- FUNDING SOURCE: None

8- CONFLICT OF INTEREST: None

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