Cross-Cultural Adaptation, Reliability and Validity Study of the Persian Version of the Clinical COPD Questionnaire

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Received: 21 Nov. 2015; Accepted: 02 Feb. 2016

Abstract- The clinical COPD questionnaire (CCQ) has been developed to measure the health status of COPD patients. The aim of this study was to translate CCQ into the Persian language and assess the validity and reliability of the translated version. We used a forward-backward procedure to translate the questionnaire. In a cross-sectional study 100 COPD patients and 50 healthy subjects over 40 years old were selected to assess the reliability and construct validity of the instrument. The face and content validity were used for the questionnaire validity. Validity was examined in a population of patients with COPD, using the Persian validated version of the St George's Respiratory Questionnaire (PSGRQ). In order to assess the questionnaire's reliability, the Intraclass correlation coefficient (ICC) and Cronbach's alpha were calculated. Test-retest reliability was tested by re-administering the Persian version of the CCQ (PCCQ) after 1 week. Test-retest carry out of data demonstrates that the PCCQ has excellent reliability (ICC for all 3 domains were higher than 0.9). Internal consistency was found by Cronbach's alpha to be 0.96, 0.94, 0.97, and 0.98 for the symptom, mental state, functional state and total scores respectively. In addition, the correlation between the components of PCCQ and PSGRQ showed satisfactory construct validity. Analyzing the data from healthy subjects and patients divulged that the PCCQ has acceptable discriminant validity. In general, the PCCQ had satisfactory reliability and validity for assessing health-related quality of life status of Iranian COPD patients.

Acta Med Iran, 2016;54(8):518-524.

Keywords: Chronic obstructive pulmonary disease; Health-related quality of life; Clinical COPD questionnaire; Reliability; Validity

Introduction

Evidence suggests that chronic obstructive pulmonary disease (COPD) is the only cause of death from a chronic disease that will grow everywhere until 2020 (1).

COPD imposes a significant burden on patients, including medical emergencies, hospitalizations, work absenteeism, and activity limitations. Ultimately, this has a significant physical and psychological impact on patients (2,3). The main aim of COPD management is to prevent or treat symptoms, improve pulmonary function and functional status/health-related quality of life (HRQoL) (4-5).

More recently, the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines revised and goals of effective COPD management introduced: These goals include relieve symptoms, improve exercise tolerance, improve health status, prevent disease progression and prevent and treat exacerbations (6).

The quality of life measurements to evaluate disease burden have become an important outcome measure in COPD management (7).

The use of HRQoL status as an outcome measure is becoming more widespread in COPD research and management. There are a number of health status measures that the CCQ and SGRQ are two of disease-specific HRQoL questionnaires for measuring respiratory health status. Lately, SGRQ has been translated into the Persian language (8).

CCQ is the first questionnaire specifically developed and validated to measure Clinical efficacy in the management of patients with COPD (9).

This tool would encourage therapists not to focus

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entirely on the condition of the airways and to become more aware of the patients' functional needs.

Although the CCQ has been developed mainly for use in clinical practice, it was detected that a simple carefully developed and validated instrument would also, be helpful in clinical trials and other research works to evaluate the performance of clinical management and to assess the impact of treatment on the overall goals of the GOLD guidelines (9).

The CCQ made up of ten items divided into three domains: symptoms (4 items), functional state (4 items) and mental state (2 items), graded on a 7 point scale from 0 to 6. Lower scores indicate better health status.

The CCQ is available in a week (7 days) version and a 24-hour version. Patients are asked to record their experiences during the last seven days (week version) or during the last 24 hours (24-hour version) (10).

The CCQ has an advantage over SGRQ because the CCQ takes about two minutes to complete. Another advantage of CCQ is that the CCQ is practical, simple, and easy to administer and therefore is useful in clinical control as a prognostic instrument on COPD patients that help to prevent COPD exacerbations.

Research shows that there is a need for a simple clinical tool to help therapists identify the clinical status of COPD patients. The CCQ is available in over 60 languages, most of them translated, and Validity assessed. The CCQ has been cross-culturally adapted in Italy, Sweden, Netherlands, Greek, and Indian populations (11-14). But in Iran, the CCQ has not been translated and validated, so there is a need to validate the PCCQ to identify the HRQoL status of those with COPD in Iranian population.

Therefore, this study carried out to translate the CCQ and assess the validity and reliability of the Persian (Farsi) version of the CCQ (PCCQ) for Farsi-speaking COPD patients.

Materials and Methods

Translation and cross-cultural adaptation

The translation and cultural adaptation of CCQ were performed by the forward and backward translation procedure according to recommended guidelines (15).

The original English version of the CCQ was forward translated independently by two bilingual translators. After translation, the two translators, a physiotherapist and a pulmonologist who participated in the study committee discussed and synthesized a PCCQ. Then one person, who was blinded to the study and had no previous knowledge of the original CCQ, back translated the questionnaire into the original language. Translation process went well without any serious problem. A backward version of the questionnaire was reviewed by developers, and fortunately, it was consistent with the original version of the questionnaire.

In the next step accomplished committee to achieve cross-cultural equivalence was established. The original developers of the questionnaire were in close contact with the accomplished committee during this part of the process. The group consolidated all the versions of the questionnaire and created a pre-final version of the questionnaire for face validity stage. Upon the advice of the developers of the questionnaire, it was decided to investigate the face validity of the PCCQ to collect votes from patients at different stages of the illness. A pretest was carried out with the pre-final version for face and content validity, with the questionnaire being administered to 30 patients with COPD at different stages of the disease. It was found that 12 patients in item 2, the term "physical activity" to misinterpret and knew it was wrong to exercise. It was decided to avoid errors of interpretation, the phrase “All activities during the day are done" replace the term "physical activity." Finally, based on the feedback from the physiotherapists and patients in the perception of the items and its equivalence in an applied situation, a review was made for the final version to help better describe the items.

Subjects

A group of COPD patients participated in the study who was attending the specialized hospital clinics in Tehran and Qazvin cities in Iran.

Subjects had the following inclusion criteria: a) met the diagnostic criteria for COPD; b) had an age of 40 years or older; c) Iranian Persian-speaking peoples and d) had been clinically stable for 2 months before entering the study (no hospital admissions).

COPD patients excluded with disease exacerbation in the previous four weeks asthma, chronic heart failure, obstructive sleep apnea syndrome, cancer or other disabling diseases except for COPD.

Fifty healthy subjects over 40 years of age were selected in social meeting places. Healthy subjects who had no any disease symptoms, or any limitation in daily activities for any reason, or who did not mention suffering from disabling chronic diseases (COPD, asthma, arthritis, angina or heart insufficiency) volunteered to participate in the study.

Stage of COPD was determined by the spirometric classification. Patients were clinically examined and then completed the PCCQ. In addition to the PCCQ,

patients filled up the Persian validated version of the St George's Respiratory Questionnaire (PSGRQ) (8). The PSGRQ is a standardized self-administered airway disease-specific questionnaire (16-18).

PSGRQ contains 50 items (covering 76 levels) divided into three subscales: "Symptoms" (8 items), including several respiratory symptoms, their frequency and severity; "Activity" (16items), concerned with activities that cause or are limited by breathlessness; and "Impacts" (26 items), which covers a range of aspects concerned with social functioning and psychological airways disease resulted in disturbances (18,20).

To assess the reliability of the PCCQ, test-retest method applied and 50 patients completed the instrument twice (with 1-week interval). In the test-retest the Intra-class Correlation Coefficient (ICC) analysis, the sample was limited to patients who were no variation of the previous therapy or introduction of new therapy.

This study was approved by the Ethics Committee of the Tehran University of medical science.

Statistical analysis

The criteria presented by Terwee *et al*., for assessing measurement properties of HRQoL questionnaires including construct validity, concurrent criterion validity, internal consistency and test-retest reliability were applied as proper for testing the PCCQ (21).

The data were analyzed using the SPSS software, version 18 (SPSS, Inc, Chicago, IL). Internal consistency was evaluated by calculating Cronbach's alpha coefficient (for the three domains and total). The independent samples t-test was used to determine the discriminant validity of the PCCQ to differentiate between healthy subjects and COPD patients. Test-retest reliability analysis was done by calculating the ICC. The construct validity of the questionnaire was tested by Pearson's correlation coefficient. A value of $P<0.05$ was considered as statistically significant.

Results

Demographics

Baseline characteristics of participants (one hundred patients and fifty healthy subjects) are shown in table 1.

Table 1. Demographic characteristic of the participant's frequency

		Healthy subjects	Patients
Male		38(76%)	76(76%)
Female		12(24%)	24(24%)
Total		50	100
Age [yrs]	**Mean**	57.68	62.47
	std.deviation	6.6	8.91
	range	45-71	40-88
Educational level	**Just reading and writing**	2	19
	Primary school	14	42
	High school	27	35
	university	7	4
Smoking habit	**Non-smoker**	45	28
	Ex-smoker*	0	65
	smoker	5	7
Stage of COPD in patients	**Mild**	--	6
	Moderate	--	34
	Severe	--	49
	Very severe	--	11
Drug type in patients	**No drug**	--	22
	Bronchodilator	--	28
	Bronchodilator and corticosteroids	--	34
	Bronchodilator and corticosteroids and oxygen	--	16

*Ex-smoker: Who had quit smoking

Floor and ceiling effects

The PCCQ scores were well distributed. None of the patients had a maximum or minimum score for the PCCQ. The total scores of the PCCQ ranged between 1.00 and 5.50 (3.4350±1.2884).

Discriminative validity

The PCCQ scores between the two groups of patients with COPD and healthy subjects were statistically significant (P<0.0001). Healthy subjects had significantly lower (better) PCCQ scores than patients with COPD in total score (P<0.001), symptom domain (P<0.000), mental state domain (P<0.005) and functional state domain (P<0.005).

Distribution of the quality of life scores in different stages of COPD

The differences between mean scores of quality of life in patients at different stages of the disease were compared using ANOVA. The results of these tests showed that the average quality of life measures in three domains (*symptoms*, *mental* and *functional state*) and total score are significantly different in various stages of the disease.

Patients with mild COPD had better PCCQ values compared with patients with Moderate COPD only in mental state (P<0.05), but in total score, functional state, and symptom domain there was no significant difference. Patients with moderate COPD had better PCCQ values compared with patients with severe COPD in total scores and within domains (P<0.05). Patients with severe COPD had lower scores than patients with very severe COPD only in symptom state domain (P<0.05) and in total score, functional state, and mental domain there was no significant difference (Table 2).

Table 2. Distribution of the quality of life scores in different stages of COPD patients and healthy subjects

	Mild	Moderate	Severe	Very severe	Total	Healthy subjects
N	6	34	49	11	100	50
Symptom	2.12±0.44	2.21±0.45	3.69±0.76*↑	4.32±0.45*↑□	3.16±1.01	0.29±0.26
Mental state	2.08±0.66	3.06±0.87*	5.11±0.89*↑	5.68±0.51*↑	4.29±1.43	0.04±0.13
Functional state	0.87±0.41	1.67±0.83	4.36±0.93*↑	4.75±0.56*↑	3.27±1.65	0.2±0.25
Total	1.62 ±00.35	2.16±0.58	4.24±0.72*↑	4.76±0/35*↑	3.43±1.28	0.2±0.16

*Significant difference compared with patients in the mild stage (P<0.05)
↑Significant difference compared with patients in the moderate stage (P<0.05)
□Significant difference compared with patients in the severe stage (P<0.05)

Reliability

The internal consistency of the test using Cronbach's alpha was 0.96 for symptom domain, 0.94 for the mental domain, 0.97 for the functional domain and 0.98 for total scores. For test-retest reliability, the ICCs were found to be 0.96 for symptom domain, 0.94 for the mental domain, 0.97 for the functional domain and 0.98 for total scores (Table 3).

Table 3. Internal consistency and test-retest reliability of PCCQ and original version

	T1* mean±SD	T2** mean±SD	Chronbach's alpha coefficient (T1, T2)	ICC	Chronbach's alpha in the original version
Symptom domain	3.09 ± 0.99	3.2 ± 1.01	0.914, 0.918	0.96	0.78
Mental state domain	4.00 ± 1.16	4.38 ± 1.21	0.942, 0.924	0.949	0.80
Functional state domain	3.10 ± 1.4	3.09 ± 1.30	0.975, 0.950	0.978	0.89
Total	3.43 ± 1.3	3.38 ± 1.05	0.956, 0.935	0.982	0.91

T1. First questionnaire completion attempt (test); ** T2. Second questionnaire completion after 1 week(retest)

Factor Analysis

The Kaiser-Meyer-Olkin (KMO) measure created a coefficient of 0.91, the qualifier of sampling adequacy (P<0.001). A principal component analysis with varimax rotation was performed. Factor analysis supports 3 factors structure of scale, but item loadings on the three factors in the Persian version of the questionnaire was different. Three factors were named based on the content of each area: Impact of disease, Symptom, and Anxiety. The first factor (impact of disease) included 7 items, which explained 74.04% of the total variance. The second factor (symptom)

included 2 items, which explained 11.86% of the total variance, and third factor (anxiety) included 1 item, which explained 5.01% of the total variance. The results are shown in Table 4.

Table 4. The Factor Structure of the PCCQ

PCCQ Items	Factors		
	Anxiety	Symptom	Impact of disease
1. Short of breath at rest?			0.82
2. Short of breath doing physical Activities?			0.8
3. Concerned about getting a cold or your breathing getting worse?	0.86		
4. Depressed (down) because of your breathing problems?			0.85
5. Did you cough?		0.87	
6. Did you produce phlegm?		0.94	
7. How limited were you in Strenuous physical activities ?			0.82
8. How limited were you in Moderate physical activities?			0.82
9. How limited were you in Daily activities at home?			0.93
10. How limited were you in Social activities?			0.9

Construct validity

The Pearson's correlation coefficients showed a significant relationship between the PCCQ and the PSGRQ (r=0.94, *P*<0.001). Table 5 shows correlations between the PCCQ score and the PSGRQ scores.

Table 5. Correlations between PCCQ and PSGRQ scores in patients with COPD (n=100)

PSGRQ	PCCQ			
	symptom	Functional state	Mental state	Total
Symptom	0.86	0.88	0.82	0.91
Activity	0.78	0.88	0.81	0.88
Impact	0.80	0.91	0.85	0.91
Total	0.84	0.94	0.87	0.94

Discussion

This study investigated the psychometric properties of the PCCQ in the Iranian COPD patients. To evaluate the reliability of the PCCQ in patients with COPD, internal consistency and test-retest reliability were tested. In our study high internal consistency was obtained in the 3 dimensions of the PCCQ. All the values achieved were above the acceptable values recommended by the original authors (9). The acceptable high internal consistency for the PCCQ showed the homogeneity of items and confirmed that PCCQ items describe a homogeneous variable, in line with results from the original version of the CCQ. The test-retest reliability in this study was excellent in accordance with the original English version (ICC=0.94) (9). In the original version, CCQ was correlated with SF-36 and SGRQ. The total score of the CCQ and SGRQ were significantly correlated (r=0.72; *P*<0.01). Cronbach's α was 0.91 for the total score. Internal consistencies of the symptom, functional state, and mental state domain were 0.78, 0.89 and 0.80, respectively. The value for ICC to assess test-retest reliability was determined 0.94 (9). In our study, construct validity was tested by calculating a Pearson's correlation between the PCCQ and PSGRQ. In the evaluation of concurrent validity, a significantly high correlation between the PCCQ and the PSGRQ was found, which supports the concurrent criterion validity of the PCCQ. Previous studies with the different

translated versions of the CCQ also demonstrated a high positive correlation when it was compared with the SGRQ. The notion that the functional state domain of CCQ corresponds to the activity domain of SGRQ was supported. There was also a good correlation between the Impacts and Mental State domains (11-14).

Discriminative validity is defined as the ability of a measure to distinguish between populations of patients and healthy subjects. According to the discriminative validity test result, the PCCQ score for COPD patients was significantly higher than healthy group. This confirms that the PCCQ is capable of distinguishing COPD patients from healthy subjects. This finding is consistent with the results reported in the Italian version. A study using validated Italian version of the CCQ in subjects with COPD also found that healthy subjects had significantly lower (better) CCQ Score (11). In general, in the other studies that analyzed the evaluative properties of the CCQ such as Italian version (11), Swedish version (12), Greek version (13) and South Indian population version (14) have supported the reliability and validity of the CCQ in COPD patients.

Compared to a recent validation of the SGRQ (8) into the Persian language as a disease-specific HRQoL questionnaire, our results suggest that PCCQ has more benefit. The PCCQ is easy to score, allows data to be quickly collected and processed, and is thus suitable for use in everyday practice for clinical trials or quality of care monitoring. While PSGRQ is not adapted for everyday use in primary care and therapists, do not routinely use PSGRQ in the clinical practice because of the longer time administration.

This study found that patients completed all items of the PCCQ with no missing response to an item, indicating the acceptability of the instrument, but the scoring system of the PSGRQ is complicated, and some patients were unable to complete the PSGRQ acceptably. An instrument with missing responses cannot accurately assess the patients' health status. There were no floor and ceiling effects for the total score of PCCQ. In this study, the absence of floor and ceiling effect indicate sensitivity and content validity of the PCCQ. Structural validity has not been evaluated using factor analysis in previous studies and adapted versions of the CCQ (11-14). In our investigation with PCCQ in a population with COPD, factor analysis supports 3 factors structure of scale, but item loadings on the three factors in the Persian version of the questionnaire was different. Item loadings on the three factors in the Persian version of the questionnaire, based on cultural conditions are justified. This finding confirmed that the PCCQ is a multidimensional instrument for patients with COPD as proposed by developers of the original CCQ. Three factors were named based on the content of each area: Impact of disease, Symptom, and Anxiety.

In conclusion, the results support reliability and validity of the Persian (Farsi) version of CCQ in the sample of Iranian COPD patients and provide evidence to use of the PCCQ as a reliable and valid instrument to assess HRQoL.

The PCCQ is practical, simple, and easy to administer and therefore is appropriate in clinical control as a prognostic instrument on COPD patients that help to prevent COPD exacerbations.

It can be used by Iranian therapists and researchers working in the field of pulmonary rehabilitation to assess the short-term effects of pulmonary rehabilitation on HRQoL.

Acknowledgement

This project was supported by a grant from the Postgraduate Studies, Tehran University of Medical Sciences, Tehran, Iran. The authors declare that they have no Conflict of Interests.

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