Original Article

Psychometric Analysis of the Bengali Clinical Chronic Obstructive Pulmonary Disease Questionnaire

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Abstract

Background: The Clinical Chronic Obstructive Pulmonary Disease Questionnaire Bengali version (CCQ-B) is a prevalidated, patient-administered, 10-item questionnaire assessing symptom severity (SS) and quality of life in adults suffering from chronic obstructive pulmonary diseases (COPDs). To date, no validated Bengali version of the questionnaire is available. We aimed to translate it into Bengali and examine its psychometric properties. **Methods:** The CCQ-B was produced by standardized forward–backward translations. A cross-sectional study was conducted to gather responses by consecutive sampling. Reliability was examined using internal consistency ($n = 110$) and test–retest reliability ($n = 30$) analyses, concurrent validity by comparing with COPD Assessment Test questionnaire scores, while construct validity by exploratory principal component analysis (varimax rotation; $n = 110$). Subsequently, confirmatory factor analysis (CFA; $n = 110$) was performed to verify the model fit of the *a priori* identified scales. **Results:** The internal consistency (Cronbach's α) for overall CCQ-B was 0.746, indicating acceptable reliability. Satisfactory values of test–retest reliability and concurrent validity were found. On factor analyses, all the items loaded above the prespecified value of 0.3. Varimax rotation identified three components (SS, health and social life, and depression and limitation of activities), explaining 58.2% of variation. The Kaiser–Meyer–Olkin was 0.734 and Bartlett's test of sphericity was also significant. Goodness-of-fit of the three-component model in CFA was mediocre, but acceptable. **Conclusion:** The CCQ-B, consisting of 10 items and framed within three components, is a valid and reliable questionnaire but measured different dimensions from the English version.

Keywords: Clinical chronic obstructive pulmonary diseases questionnaire, confirmatory factor analysis, principal component analysis, reliability, validity

Introduction

In industrialized and developing countries, chronic obstructive pulmonary disease (COPD) has emerged as one of the leading causes of morbidity and mortality. Health-related quality of life (HRQoL) is an important outcome measure in COPD and increasingly being used to measure the symptom burden and to steer treatment.[1] The Clinical COPD Questionnaire (CCQ) is a 10-item (scored between 0 and 6), self-administered, HRQoL questionnaire, consisting of three domains (symptoms, functional, and mental), taking <2 min to complete, and having good psychometric properties.[2] Its conciseness and ease make it suitable for routine use in clinical practice. The scores of the 10 individual items are summed up to erect the total score and divided by 10, thus giving a total score between 0 and 6 with higher scores signifying worse HRQoL. It has three components – (1) symptoms (items 1, 2, 5, and 6); (2) functional state (items 7, 8, 9, and 10); and (3) mental state (items 3 and 4).

Although COPD Assessment Test (CAT) questionnaire remains the most frequently used questionnaire in COPD studies, there are some circumlocutory indications that the CCQ may have some additional advantages. Patients need lesser assistance to complete the CCQ than CAT.[3] Similarly, in a study evaluating

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the psychometric properties of the CCQ, CAT, and St. George's respiratory questionnaire, >60% of patients favored CCQ over others for assessing health status of patients suffering from COPD.[4] In addition, in another study, CCQ revealed better responsiveness than CAT.[5] In another review, CCQ was identified as the most suitable questionnaire in primary care.[6]

As no valid Bengali version of the CCQ was available, we aimed to develop a Bengali version of the questionnaire through standardized forward–backward translation and thereafter evaluate whether the CCQ Bengali version (CCQ-B) is a psychometrically sound tool to measure the construct and to examine its cross-cultural adaptation considering linguistic equivalence.

Methods

Study design

This noninterventional, cross-sectional, validation study was multifaceted; it consisted of standardized translation procedures, face validation by pilot testing, and field testing and psychometric assessment of the CCQ-B.

Study setting

It was conducted at National Institute of Homoeopathy, Kolkata, under the Ministry of AYUSH, Government of India. Institutional Ethics Committee approved the protocol before initiation (Ref. No. 5-023/NIH/PG/Ethical Comm. 2009/Vol. III/1964 [A/S]; dated March 27, 2017).

Questionnaire translation stages

1. Forward translation: An expert committee was constructed, consisting of pulmonologists, linguistic experts, and research methodologists. First, two Bengali speakers, one pulmonologist and one linguistic expert, translated the English version of CCQ into Bengali (T_1 and T_2)
2. Synthesis of $T_{1,2}$: The two translators then agreed upon a consensus version of the translation ($T_{1,2}$). Then, the expert committee verified the version
3. Back translation: Two English language translators (BT_1 and BT_2; one pulmonologist and one linguistic expert), blinded to the original English version, translated $T_{1,2}$ back into English independently
4. Committee review: All the translations (T_1 and T_2, $T_{1,2}$, and B_1 and B_2) were reviewed by the committee and a written report was prepared comparing the back-translations with the forward translations. Based on these, the prefinal version was developed
5. Face validation: The prefinal version of the questionnaire was tested on randomly chosen ten patients visiting outpatient clinics of the hospital for the purpose of testing contextual clarity, layout, language transparency, ease of understanding the content and use, comprehensibility of the instructions, and response scales. Difficulties, if any, were noted. A written report was prepared by the interviewers, including detected insufficiencies and recommended changes, and was then submitted back to the committee
6. Committee appraisal: The final version of the CCQ-B was developed by the committee based on the inputs from face validity (supplementary file). The different translation stages and the complete study flow are presented in Figure 1.

Field testing and validation

During development of the original English version, content validity of the CCQ questionnaire was already evaluated, and we refrained from repeating so.

Inclusion criteria

Patients aged 18–65 years and with mild-to-severe form of COPD[7] (ICD-10 code J44.9): mild forced expiratory volume-1 s (FEV_1) ≥80% predicted, FEV_1/forced vital capacity (FVC) <0.7, moderate FEV_1 50%–79% predicted, FEV_1/FVC <0.7, and severe FEV_1 30%–49% predicted, FEV_1/FVC <0.7, ability to read Bengali, and written consent to participate were included. Patients undergoing any therapy for COPD were also included after a washout period of 15 days.

Exclusion criteria

Patients with very severe COPD, FEV_1/FVC <0.7, and FEV_1 <30% predicted or <50% predicted in addition with chronic respiratory failure, psychiatric diseases, pregnancy and lactation, cases suffering from uncontrolled systemic illness or life-threatening infections or any vital organ failure, and substance abuse and/or dependence were excluded.

Of 127 eligible patients approached, 110 (response rate 86.7%) returned the questionnaire and these responses were subjected to exploratory factor analysis (EFA) and 110 further responses (response rate 93.2%) were subjected to confirmatory factor analysis (CFA).

Sample size

Recommendations for adequate sample size to conduct factor analysis are between 50 and 250, with most authors recommending at least 100 subjects.[8] Subject-to-item ratio (5:1 or 10:1) was used to calculate the sample size based on Gorsuch's formula, thus indicating a sample size of 50–100.[9] By keeping provision for assumed 10% missing data, the sample size was enhanced to 110 participants.

Sampling

Patients suffering from COPD who attended the outpatients of the hospital on the days of data collection were approached by consecutive sampling and were invited to participate in the study.

Data collection

Before obtaining responses on the CCQ-B, all the participants were provided with patient information sheets in local vernacular Bengali and written informed consents were obtained. Patients' privacy was maintained by concealing all the identifiable information. Another section in the questionnaire sought information regarding patients' sociodemographic

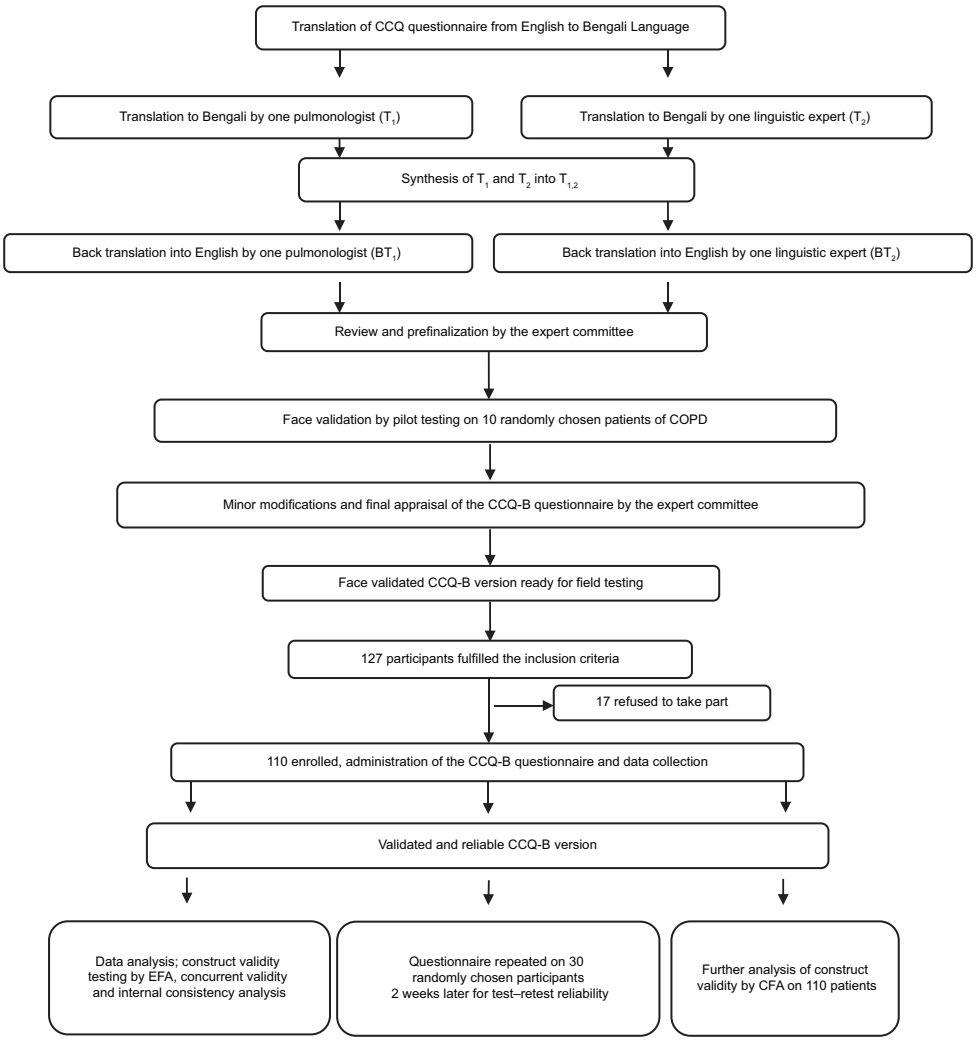

Figure 1: Study flow

features. The filled-in CCQ-B questionnaires were put inside envelops and sealed at the study site. Thirty randomly chosen participants were selected for retest visits at approximately 2–3 weeks' interval to fill the same questionnaire again. All the data were extracted in a specially designed Microsoft Excel spreadsheet and that was analyzed statistically.

Statistical analysis

It was conducted using IBM® Statistical Package for the Social Sciences (SPSS)® software, version 20.0 and SPSS Amos® version 20.0 (IBM Corp., Armonk, NY, USA). First, adequacy of sample was checked using Kaiser–Meyer–Olkin (KMO) value and data appropriateness for principal component analysis (PCA) was checked using Bartlett's test of sphericity. The KMO value of 0.50 and above[10] with significant Bartlett's test of sphericity ($P < 0.05$) was considered appropriate for factor analysis. Then, EFA using PCA with varimax rotation (eigenvalue >1) was conducted to examine the CCQ-B unidimensionality of the construct. Only factors with loadings of 0.30 and above were retained. Weak loadings, that is, failure to load >0.29 on any component and general loadings of 0.30 on more than one component would lead to exclusion of the items from the matrix. Next, CCQ-B reliability was evaluated by analyses of internal inconsistency and test–retest reliability. High internal consistencies were denoted by Cronbach's alpha of 0.5–0.7[11] and average item-total correlation in a moderate range of 0.3–0.9. Alpha value of 0.9 and above was considered as excellent, while no meaningful construct was indicated by a correlation near 0.[12] Intraclass correlation coefficient (ICC) values above 0.7 indicated that CCQ-B was stable over time, 0.4–0.7 indicated fair reliability, while poor reliability was demonstrated by values <0.4.[13] Paired *t*-test was used on randomly chosen 30 patients' responses to evaluate whether change in scores on the CCQ-B between the test–retest evaluations were statistically significant. Correlation statistics was used to assess the interitem correlations between domains (item discriminant validity) and the overall CCQ-B (internal item convergence). The instrument was considered to be internally consistent if the correlation value was found to be 0.4 or higher. Concurrent validity was examined using Pearson's *r* statistics comparing the total CCQ-B scores with simultaneously measured CAT scores ($n = 110$). Correlation coefficients of 0.10 were considered being small,

0.30 as moderate, and 0.50 as large.[14] Finally, a CFA model was developed to verify the goodness-of-fit of the *a priori* detected scales as suggested by EFA. The goodness-of-fit of the CFA models was evaluated utilizing the following multiple fit indices: comparative fit index (CFI), normed fit index (NFI), Tucker Lewis index (TLI), root mean square error of approximation (RMSEA), standardized root mean square residual (SRMR), Bayesian information criterion (BIC), and Hoelter index. The recommendations for cutoff values indicating a good model fit are CFI/TLI ≥0.95, RMSEA ≤0.6, and SRMR ≤0.8.[15,16] Statistical tests were two-tailed and were conducted with α fixed at 0.05.

Results

Descriptive statistics

These were presented in terms of means, standard deviations, medians, interquartile ranges, skewness, and kurtosis of each individual item. The details are presented in Table 1.

Exploratory factor analysis

The average communalities after extraction was 0.582, that is above the preferred cut-off of 0.5, thus ensuring adequacy of sample size of 110 for running PCA. Sample was adequate as evidenced by the KMO = 0.734 (Chi-square: 252.061, $P < 0.001$), much greater than the minimum Kaiser criterion of 0.5. A significant Bartlett's test of sphericity (degrees of freedom [df] = 45, $P < 0.001$) also signified that the *R*-matrix was not an identity matrix. We performed extraction using principal component method for determining how many factors best explained the observed covariation matrix within the data set. The Scree plot revealed high eigenvalue for the first three components, and thereafter, the curve began to tail off gradually before the final plateau was reached [Figure 2]. The factor component matrix also supported the Scree plot by representing information from initial unrotated solution and extracting three components explaining 58.2% of the total variance [Table 2]. Each of the components with their respective eigenvalues and percentage of total variances explained are presented in Table 2. The values were weights that related the item (or variable) to the respective factor. Display of coefficients was sorted by size. Factor loadings were similar to regression weights (or slopes) and represented the strength of the association between the variables and the factors. Next, the correlation matrix was searched for values >0.9 to identify multicolinearity and

Table 1: Descriptive statistics of the clinical chronic obstructive pulmonary disease questionnaire responses subjected to exploratory principal component analysis (*n*=110)

Items	Mean (SD)	Median (IQR)	Skewness	Kurtosis
1	2.8 (1.6)	3.0 (2.0, 4.0)	0.184	−0.598
2	4.5 (1.4)	5.0 (4.0, 6.0)	−1.183	1.451
3	4.3 (1.6)	5.0 (3.0, 5.0)	−0.990	0.354
4	3.2 (1.4)	3.0 (2.0, 4.0)	−0.007	−0.211
5	3.7 (1.4)	4.0 (3.0, 5.0)	−0.323	−0.098
6	3.3 (1.8)	3.0 (2.0, 5.0)	0.131	−1.073
7	4.4 (1.5)	5.0 (3.8, 6.0)	−1.129	0.907
8	3.1 (1.6)	3.0 (2.0, 4.0)	−0.333	−0.338
9	1.7 (1.5)	2.0 (0.0, 3.0)	0.660	0.087
10	1.4 (1.3)	1.0 (0.0, 2.0)	1.129	1.006

SD: Standard deviation, IQR: Interquartile range

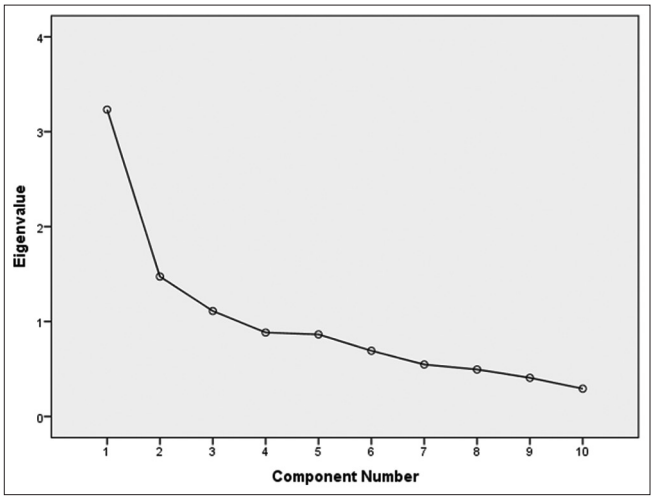

Figure 2: Scree plot

Table 2: Total variances explained (*n*=110; principal component analysis)

Component	Initial eigenvalues			Extraction sums of squared loadings			Rotation sums of squared loadings[a]
	Total	Percentage of variance	Cumulative (%)	Total	Percentage of variance	Cumulative (%)	Total
1	3.233	32.330	32.330	3.233	32.330	32.330	2.719
2	1.474	14.738	47.068	1.474	14.738	47.068	1.964
3	1.111	11.112	58.180	1.111	11.112	58.180	2.162
4	0.884	8.841	67.021				
5	0.864	8.641	75.663				
6	0.692	6.917	82.579				
7	0.548	5.475	88.055				
8	0.495	4.947	93.001				
9	0.407	4.071	97.072				
10	0.293	2.928	100.000				

singularity. Determinant of the correlation matrix was 0.090. Thus, multicolinearity was not a problem for the dataset. All the items correlated well and none of the correlation coefficients were predominantly large, thus contradicting elimination of any item at this stage. The rotated (promax) component matrix was a matrix of factor loadings for each variable onto each factor. The absolute values <0.3 were suppressed, ensuring that factor loadings within ± 0.3 were not displayed in the output. After conducting factor rotation, those items were eliminated that loaded onto the same factor. Three subcomponents of the main construct were identified and named as below [Table 3]:

1. Items 2, 7, 9, 1, and 3: "Symptom severity" (SS)
2. Items 6, 5, and 10: "Health and social life" (HSL)
3. Items 4 and 8: "Depression and limitation of activities" (DLA).

Internal consistency

The Cronbach's alpha value for the overall CCQ-B was 0.746 and α for the three subscales were 0.679, 0.548, and 0.541, respectively, indicating acceptable to good reliability [Table 4].

Correlation statistics

The correlations between the overall and CCQ-B subscales were identified to be higher than correlations between subscales [Table 5].

Test–retest reliability

CCQ-B subscale scores were largely stable with insignificant mean differences, thus indicating acceptable test–retest reliability [Table 6].

Concurrent validity

CCQ-B total score had a significantly strong correlation with CAT (CCQ-B: 32.3 ± 8.3 vs. CAT: 25.6 ± 6.4, Pearson's $r = 0.699$, $P < 0.001$) scores, thus ensuring acceptable concurrent validity.

Confirmatory factor analysis

The indices of CFA that confirmed model fit (Chi-square = 49.843, df = 32, probability level = 0.023) were as follows: CFI = 0.688, NFI = 0.512, TLI = 0.562, RMSEA = 0.072, SRMR = 0.275, BIC = 157.954, and Hoelter index (at α 0.05) = 102, indicating a mediocre model fit and three distinct components [Figure 3].

Discussion

The English version of the CCQ is an already validated questionnaire comprised of 10 questions, framed within 3 components, and assessing SS and QoL in patients with COPD; however, until now, no validated Bengali version of the questionnaire was available. The English questionnaire underwent standardized forward–backward translation to produce the CCQ-B. In similarity with the original three subscales of English version, EFA using PCA of the CCQ-B identified three components but different from the original version, while the overall model goodness-of-fit was further confirmed by CFA. Thus, CCQ-B was valid and reliable with Cronbach's α, ICC, concurrent validity, and test–retest reliability within acceptable limits.

One of the major strengths of this study was to apply EFA and CFA on two different samples as recommended.[17-19] Our study shows that the overall and individual subscales of CCQ-B were similar to other studies. Unlike other validation studies, there was no control (normal/healthy) group; hence, assessment of item discriminant validity was

Table 3: Principal component analysis with rotated component matrix - Factor loadings revealing three-component structures

Items	Components		
	1 (SS)	2 (HSL)	3 (DLA)
2	0.965		
7	0.824		
9	0.382		
1	0.362		
6		0.732	
5		0.617	
10		0.593	
3	0.469		
4			0.950
8			0.596

SS: Symptom severity, HSL: Health and social life, DLA: Depression and limitation of activities

Table 4: Internal consistency of the clinical chronic obstructive pulmonary disease questionnaire-Bengali version questionnaire (n=110, principal component analysis)

	Cronbach's alpha	ICC coefficient (95% CI)
Overall CCQ-B	0.746	0.746 (0.668-0.811)
CCQ-B components		
Symptom severity	0.679	0.679 (0.574-0.765)
Health and social life	0.548	0.548 (0.379-0.677)
Depression and limitation of activities	0.541	0.541 (0.330-0.685)

ICC: Intraclass correlation coefficient, CI: Confidence interval, CCQ: Clinical COPD questionnaire, COPD: Chronic obstructive pulmonary disease

Table 5: Correlations matrix between the clinical chronic obstructive pulmonary disease questionnaire-Bengali version components and the overall score (n=110, principal component analysis)

	SS	HSL	DLA	Overall score
SS	1.000	0.328	0.458	0.868
HSL	0.328	1.000	0.309	0.682
DLA	0.458	0.309	1.000	0.698
Overall score	0.868	0.682	0.698	1.000

Determinant=0.000. SS: Symptom severity, HSL: Health and social life, DLA: Depression and limitation of activities

Table 6: Test-retest reliability analysis of the clinical chronic obstructive pulmonary disease questionnaire-Bengali version questionnaire ($n=30$)

Components	Mean (SD)		Pearson's *r*	Score difference Mean (95% CI)	*P**
	Test score	Retest score			
SS	17.2 (5.1)	17.3 (5.0)	0.999	−0.053 (−0.153-0.047)	0.284
HSL	8.4 (3.6)	8.4 (3.7)	0.996	−0.040 (−0.160-0.080)	0.501
DLA	6.5 (2.7)	6.5 (2.6)	0.993	0.033 (−0.086-0.153)	0.573
Overall score	32.1 (7.7)	32.1 (7.5)	0.998	−0.060 (−0.257-0.137)	0.539

*Paired *t*-test. SD: Standard deviation, CI: Confidence interval, SS: Symptom severity, HSL: Health and social life, DLA: Depression and limitation of activities

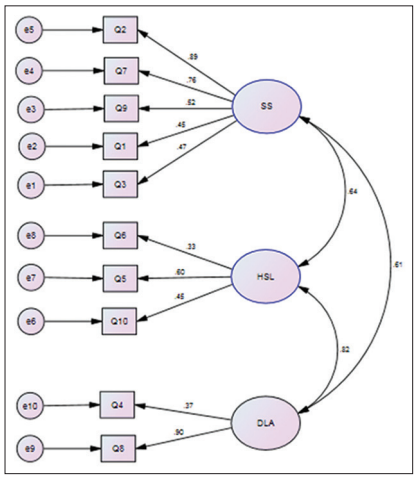

Figure 3: The confirmatory factor analysis model; SS: Symptom severity, HSL: Health and social life, DLA: Depression and limitation of activities

not possible. Besides, responsiveness of the questionnaire was not assessed because the treatment offered by the study site was homeopathy exclusively and that was not an accepted standard treatment for COPD. Our findings revealed that the internal consistency was overall reasonable and comparable to the existing versions. However, the individual Health and Social Life (HSL) and DLA components showed a fairly low Cronbach's alpha. This fact was also reflected on the lower correlation between subscales shown in Table 5. Alpha measure depends on the number of items and covariances between items. A score <0.70 suggests that the items within the tool may not be measuring the same underlying construct and poorly correlated items need to be deleted. However, as the number of items was not too many, correlation coefficients with the "social activities" and overall score were higher than 0.30, and retaining all the items revealed a fair fit in the CFA model, we decided not to eliminate any items. It should also be kept in mind that alpha has very strict assumptions including unidimensionality, uncorrelated errors, and identical covariances between the items (tau equivalence). In most of the cases, these assumptions are violated and thus over- or under-estimate the true reliability. Thus, alpha may not be the best choice for measuring reliability. The probable alternative may be Guttman's lambda or McDonald's omega which are not based on tau-equivalence.[20] There were satisfactorily high interitem correlations among the subscales. While running PCA, sample size achieved by us was similar to the original CCQ development and validation study and other translations, but we achieved more 120 samples to perform CFA. Fifty percent (5/10) of the items had strong factor loadings of 0.60 and above.[21] Second, the CCQ-B was administered to the patients who were competent in reading and understanding the Bengali language. Therefore, the study findings are generalized to Bengali population only. Finally, the three-component model had an acceptable model fit in CFA. Thus, further translation and validation of the questionnaire aew warranted into other Indian languages and on larger sample for better and large-scale utilization in a multi-ethnic Indian population. Another drawback was the consecutive sampling used that might have introduced sampling bias into the study.

Thus, the validated CCQ-B served as an important patient-administered outcome questionnaire to measure the SS and QoL in patients suffering from COPD. Future research should include utilization of the CCQ-B as outcome measure in clinical trials. Hence, the responsiveness and sensitivity to change of the CCQ-B to measure symptoms and treatment effects need to be determined in future investigations. Finally, to confirm that CCQ-B can measure the impact of clinical treatment, the final step in this development will be to define a minimally important difference of change reflecting a clinically meaningful difference.

Conclusion

The developed CCQ-B contains 10 items which are constructed within three-component model. It is a reasonably valid and reliable tool, enabled to measure the QoL in Bengali patients suffering from COPD. However, to strengthen the validity of the CCQ-B, further analyses are recommended.

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Conflicts of interest

There are no conflicts of interest.

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