Portuguese-language version of the COPD Assessment Test: validation for use in Brazil*

Validação do Teste de Avaliação da DPOC em português para uso no Brasil

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Abstract

Objective: To validate a Portuguese-language version of the COPD assessment test (CAT) for use in Brazil and to assess the reproducibility of this version. **Methods:** This was multicenter study involving patients with stable COPD at two teaching hospitals in the city of Fortaleza, Brazil. Two independent observers (twice in one day) administered the Portuguese-language version of the CAT to 50 patients with COPD. One of those observers again administered the scale to the same patients one week later. At baseline, the patients were submitted to pulmonary function testing and the six-minute walk test (6MWT), as well as completing the previously validated Portuguese-language versions of the Saint George's Respiratory Questionnaire (SGRQ), modified Medical Research Council (MMRC) dyspnea scale, and hospital anxiety and depression scale (HADS). **Results:** Inter-rater and intra-rater reliability was excellent (intraclass correlation coefficient [ICC] = 0.96; 95% CI: 0.93-0.97; p < 0.001; and ICC = 0.98; 95% CI: 0.96-0.98; p < 0.001, respectively). Bland & Altman plots showed good test-retest reliability. The CAT total score correlated significantly with spirometry results, 6MWT distance, SGRQ scores, MMRC dyspnea scale scores, and HADS-depression scores. **Conclusions:** The Portuguese-language version of the CAT is a valid, reproducible, and reliable instrument for evaluating patients with COPD in Brazil.

Keywords: Pulmonary disease, chronic obstructive; Questionnaires; Validation studies; Quality of life; Reproducibility of results.

Resumo

Objetivo: Realizar a validação e verificar a reprodutibilidade da versão em português do Brasil do *COPD Assessment Test* (CAT). **Métodos:** Estudo multicêntrico, no qual foram selecionados pacientes com DPOC estável em dois hospitais de ensino na cidade de Fortaleza, CE. A versão do CAT foi aplicada duas vezes a 50 pacientes com DPOC por dois observadores independentes no mesmo dia. Após uma semana, esse mesmo questionário foi aplicado novamente aos mesmos pacientes por um dos observadores. No primeiro dia, os pacientes foram submetidos à prova de função pulmonar e ao teste de caminhada de seis minutos (TC6) e responderam as versões validadas de *Saint George's Respiratory Questionnaire* (SGRQ), escala de dispneia *Modified Medical Research Council* (MMRC) e *hospital anxiety and depression scale* (HADS). **Resultados:** As reprodutibilidades interobservador e intraobservador foram excelentes (coeficiente de correlação intraclasse [CCI] = 0,96; IC95%: 0,93-0,97; p < 0,001; e CCI = 0,98; IC95%: 0,96-0,98; p < 0,001, respectivamente). As disposições gráficas de Bland & Altman demonstraram boa confiabilidade teste-reteste. Houve correlações significativas do escore total do CAT com os resultados de espirometria, TC6, SGRQ, escala de dispneia MMRC e HADS-depressão. **Conclusões:** A versão brasileira do CAT é um instrumento válido, reprodutível e confiável para a avaliação dos pacientes com DPOC na população brasileira.

Descritores: Doença pulmonar obstrutiva crônica; Questionários; Estudos de validação; Qualidade de vida; Reprodutibilidade dos testes.

Introduction

Classically, COPD is defined as chronic progressive airflow limitation that is partially reversible and causes significant extrapulmonary effects, culminating in a reduction in the functional capacity, social interaction, and well-being of the patients, negatively affecting their health-related quality of life (HRQoL).[1,2]

The literature indicates that the chronic symptoms of COPD associated with the systemic manifestations of the disease are the major factors responsible for the worsening of HRQoL. Although the airflow obstruction is partially reversible, the disease control interventions are primarily aimed at improving the HRQoL of patients, which thereby becomes an important measure to be assessed.[3,4]

The administration of questionnaires to assess the HRQoL of patients with COPD has been widely discussed in the literature. The results inferred by the use of these instruments generate reliable, valid, and reproducible evidence.[5]

Disease-specific questionnaires designed to assess COPD impact are widely used in clinical studies. However, these questionnaires are still considered complex and extensive, requiring a substantial amount of time to completion. Chief among them are the Saint George's Respiratory Questionnaire (SGRQ),[6] the Chronic Respiratory Questionnaire (CRQ),[7] the Breathing Problems Questionnaire,[8] and the Airways Questionnaire 20 (AQ20),[9] all of which have been validated for use in Brazil.

Recently, a group of researchers in the United Kingdom developed and validated the COPD Assessment Test (CAT), which is a short, simple instrument for quantifying COPD impact during routine clinical practice, in addition to aiding health status assessment and facilitating communication between patients and health professionals.[10] However, this questionnaire has not been validated for use in Brazil. Therefore, the objective of the present study was to validate a Portuguese-language version of the CAT for use in Brazil and to assess the reproducibility of this version.

Methods

This was a cross-sectional study, conducted between January and November of 2012, involving patients treated at the Pulmonology Outpatient Clinic of the Federal University of Ceará Walter Cantídio University Hospital and patients eligible for pulmonary rehabilitation at the Dr. Carlos Alberto Studart Gomes Messejana Hospital, both of which are located in the city of Fortaleza, Brazil.

The present study was conducted in accordance with Brazilian National Health Council Resolution 196/96, which sets out the ethical principles for human research, and was approved by the ethics committees of the two hospitals (Ruling no. 108.10/11 and Ruling no. 880/12, respectively). All patients gave written informed consent prior to their inclusion in the study.

The inclusion criteria were as follows: having been clinically diagnosed with COPD with moderate to severe airflow obstruction and having an FEV_1/FVC ratio < 0.7 (as measured by spirometry), in accordance with the recommendations of the Global Initiative for Chronic Obstructive Lung Disease[1]; being between 40 and 80 years of age; being clinically stable (no hospitalizations or infections in the three months prior to the study); and being a smoker or former smoker with a smoking history greater than 10 pack-years.

The exclusion criteria were as follows: experiencing an exacerbation of COPD requiring therapeutic intervention; and having other nonpulmonary diseases that are considered disabling, severe, or difficult-to-control.

The CAT consists of eight items, designated cough, phlegm, chest tightness, breathlessness, activity limitations at home, confidence leaving home, sleep, and energy. For each item, the patient chooses only one response option, which is scored from zero to five (Appendix 1). At the end of the test, all response scores are summed, and then the clinical impact of COPD is determined on the basis of the stratification scoring of the study that developed and validated the CAT.[10] The results vary according to the range within which the scores obtained lie, being classified by clinical impact as follows: 6-10 points, mild; 11-20, moderate; 21-30, severe; and 31-40, extremely severe.

In order to test the inter-rater reliability of the CAT, the patients were administered the questionnaire twice by two observers, 30 minutes apart, during the first visit (V1). The second visit (V2) occurred 7 days after the first one, and the CAT was again administered to the same patients

by only one of the observers in order to test the intra-rater reliability.

Also at baseline, the patients underwent the six-minute walk test (6MWT) and spirometry, as well as being administered the previously validated Portuguese-language versions of the SGRQ,[6] hospital anxiety and depression scale (HADS), and modified Medical Research Council (MMRC) dyspnea scale.

Spirometry was performed with a Respiradyne II Plus spirometer (Sherwood Medical, St. Louis, MO, USA), in accordance with Brazilian guidelines,[11] using the reference values for the Brazilian population established by Pereira et al.[12]

The 6MWT was performed in accordance with guidelines established by the American Thoracic Society,[13] with the patient being encouraged to walk as far as possible, in six minutes, on a 30-m level corridor. At the end of the test, the examiner recorded the distance covered.

The HADS consists of 14 items, of which 7 focus on the assessment of anxiety (HADS-A) and 7 focus on the assessment of depression (HADS-D). Each item can be scored from zero to three, the maximum score on each subscale being 21 points. We adopted the cut-off points recommended for both subscales: 0-8 points, absence of anxiety and/or depression; and ≥ 9 points, presence of anxiety and/or depression.[14]

Dyspnea was assessed with the MMRC dyspnea scale.[11]

Data were statistically analyzed with the Statistical Package for the Social Sciences, version 17.0 (SPSS Inc., Chicago, IL, USA) and GraphPad Prism, version 6.0 (GraphPad Software Inc., San Diego, CA, USA). For the analysis of the reliability of the administration of the CAT (V1 vs. V2), we used the intraclass correlation coefficient (ICC). The Wilcoxon test was used to compare the scores obtained from the administration of the CAT by the observer in V1 and V2. In order to assess the agreement between V1 and V2, we used Bland & Altman plots. The instruments were tested for internal consistency by Cronbach's alpha coefficient. In order to validate the CAT, we assessed the correlations (Spearman's correlation test) of its scores with those obtained on the SGRQ (gold standard questionnaire), HADS, and MMRC dyspnea scale, as well as with 6MWD and spirometry values. The level of significance was set at 5%.

Results

The study sample comprised 50 patients with COPD, 26 of whom were female (52%). The mean age of the patients was 62.2 ± 8.4 years, whereas the mean height and weight were 1.58 ± 0.08 cm and 65.8 ± 15.9 kg, respectively (Table 1).

There were no significant differences between the total scores obtained from the administration of the CAT by the same observer in V1 and V2 (20.7 ± 9.8 vs. 20.1 ± 9.4; p = 0.8). The ICC for intra-rater reliability (V1 vs. V2) was 0.96 (95% CI: 0.93-0.97).

Table 1 – Characteristics of the sample of 50 COPD patients studied.[a]

Variable	Result
Age, years	62.4 ± 8.4
Gender[b]	
Male	24 (48)
Female	26 (52)
Level of education[b]	
Illiterate	34 (68)
> 9 years of schooling	6 (12)
9 years of schooling	3 (6)
High school (incomplete)	4 (8)
High school (complete)	2 (4)
College (complete)	1 (2)
Height, cm	1.58 ± 0.08
Weight, kg	65.8 ± 15.9
BMI, kg/cm^2	26.0 ± 4.9
Post-BD FEV$_1$, L	1.05 ± 0.41
Post-BD FEV$_1$, % of predicted	44.0 ± 13.8
Post-BD FVC, L	2.19 ± 0.78
Post-BD FVC, % of predicted	72.3 ± 18
Post-BD FEV$_1$/FVC	0.48 ± 0.10
MMRC dyspnea scale score	1.8 ± 1.0
6MWD, m	344 ± 97

BMI: body mass index; BD: bronchodilator; MMRC: modified Medical Research Council; and 6MWD: six-minute walk distance. [a]Values expressed as mean ± SD, except where otherwise indicated. [b]Values expressed as n (%).

Table 2 – Correlations (Spearman's correlation test) of the COPD Assessment Test scores with the Saint George's Respiratory Questionnaire scores, spirometry values, six-minute walk distance, modified Medical Research Council dyspnea scale scores, and hospital anxiety and depression scale scores.
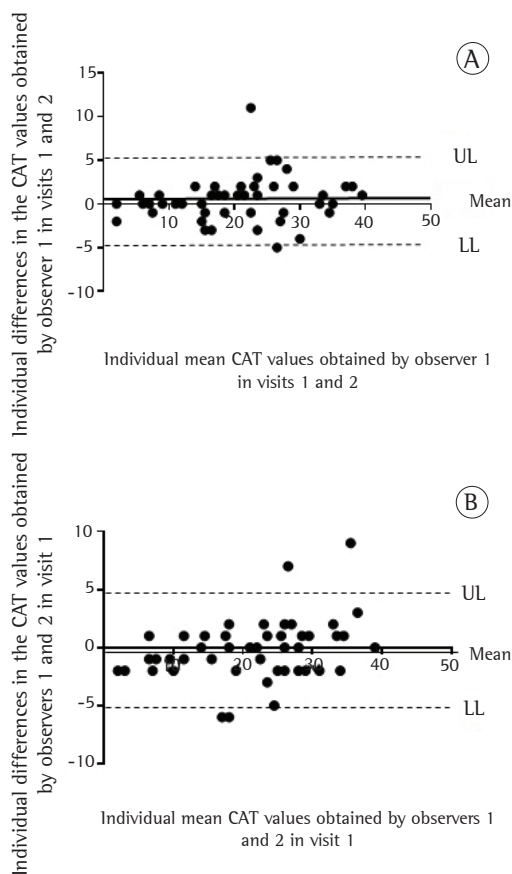
Variable	r	p
SGRQ		
Symptoms	0.60	< 0.001
Activity	0.59	< 0.001
Impact	0.51	< 0.001
Total	0.64	< 0.001
FEV_1, L	−0.38	0.006
FEV_1, % of predicted	−0.25	0.07
FVC, L	−0.39	0.005
FVC, % of predicted	−0.30	0.03
FEV_1/FVC	0.01	0.9
6MWD	−0.37	0.008
MMRC dyspnea scale score	0.48	< 0.001
HADS-A score	0.03	0.7
HADS-D score	0.39	0.001

SGRQ: Saint George's Respiratory Questionnaire; 6MWD: six-minute walk distance; MMRC: modified Medical Research Council; HADS-A: hospital anxiety and depression scale-anxiety subscale; and HADS-D: hospital anxiety and depression scale-depression subscale.

Figure 1 – Bland & Altman plots. In A, intra-rater analysis: mean = 0.64; upper limit (UL) = 5.69 and lower limit (LL) = −4.41. In B, inter-rater analysis: mean = −0.26; UL = 4.80 and LL = −5.32.

There were also no significant differences in the scores between the two observers of the study (20.7 ± 8.5 vs. 21.2 ± 9.0; p = 0.4). The ICC for inter-rater reliability was 0.98 (95% CI: 0.96-0.98). The Cronbach's alpha coefficient for the CAT was 0.98 (p < 0.001).

Bland & Altman plots showed good test-retest reliability and good inter-rater reliability (Figure 1).

There were significant correlations between the CAT score and the SGRQ total and domain scores (0.51 < r < 0.64). The CAT score correlated better with the MMRC dyspnea scale score than with the HADS-D score (r = 0.48 vs. r = 0.39; p < 0.05 for both). The CAT scores correlated negatively with 6MWD (r = −0.37) and with some pulmonary function measurements, such as FEV_1 in L (r = −0.38);

FVC in L (r = −0.39); and FVC as % of the predicted value (r = −0.30; Table 2).

The mean administration time was 104.00 ± 0.69 seconds.

Discussion

The present study showed that the Portuguese-language version of the CAT had excellent reliability when administered by different observers and when administered by the same observer at two distinct time points. Bland & Altman plots showed that the CAT has good test-retest reliability, as well as a high Cronbach's alpha coefficient and a good correlation with the SGRQ (total and domain scores).

The process of development and preparation of the CAT arose from the need for new instruments for evaluating COPD impact on HRQoL and clinical practice in a simple, fast, and effective way.[10]

Various studies conducted in countries such as Spain,[15] China,[16] South Korea,[17] and Saudi Arabia[18,19] have validated versions of the CAT in their language and reported the instrument to have good reproducibility. We found no studies validating a Portuguese-language version of the CAT for use in Brazil or assessing the reproducibility of the CAT.

During test-retest, the ICC was found to be 0.98. Jones et al.[10] found high ICC values and high Cronbach's alpha coefficients when they performed the first validation of the CAT in a multicenter study. The Cronbach's alpha coefficient of 0.98 found in the present study shows that the questionnaire has excellent internal consistency.

The questionnaires used for the validation of the CAT were the SGRQ, MMRC dyspnea scale, and HADS. These instruments were used because they are related to some specific items of the CAT, such as those concerning respiratory symptoms and limitations in activities of daily living (which are also addressed in the SGRQ and MMRC dyspnea scale) and those concerning self-confidence and energy (which are also addressed in the HADS and SGRQ).

In general, there were high and significant correlations between the CAT scores and the SGRQ total and domain scores.

Previous studies have demonstrated that the CAT can measure the impact of COPD on the lives of patients, showing correlations with standard questionnaires other than the SGRQ, such as the CRQ and the Clinical COPD Questionnaire.[20-24]

Regarding the pulmonary function variables, the present study showed that there was a weak but significant correlation of the CAT scores with some spirometry values and 6MWD. This might represent a discrepancy between patient experiences and perspectives and the degree of respiratory dysfunction. Other studies have also shown weak correlations between the CAT scores and pulmonary function values, especially FEV_1.[17,20,21,25]

Regarding the sensation of dyspnea, the CAT scores correlated significantly with MMRC dyspnea scale scores and SGRQ symptom scores, showing that the CAT can detect the patient's respiratory complaints.

There was no significant correlation between the CAT scores and the anxiety scores. However, for the depression scores, the correlation was found to be weak. This might have occurred because, among the CAT questions, only the items concerning energy and confidence leaving home address issues that are more directly related to the psychological component of the patient.

The administration time of the CAT in the present study was, on average, 104 s; this occurred because of the simplicity of the questions and response options. While administering the CAT to patients with COPD, Ringbaek et al.[26] found that it required a shorter administration time than did the SGRQ and CRQ (107 s, 134 s, and 578 s, respectively).

There was no back-translation analysis of the CAT, since there is already a Portuguese-language version, written in congruent, easy-to-understand language, ready for use. None of the items in the present version sounded odd in Brazilian Portuguese or seemed to be alien to the Brazilian culture and society, and therefore there was no need for any significant adaptations.

Since the present study was cross-sectional in design, it was not possible to evaluate the responsiveness of the Portuguese-language version of the CAT to interventions, such as pulmonary rehabilitation. This can be considered a limitation of the study; however, other studies have used the same approach.[15,21,23,26] Following this line of thought and knowing that the Portuguese-language version of the CAT proved to be valid and reproducible, we believe that, in future studies, it will prove to be responsive.

In conclusion, the Portuguese-language version of the CAT is a valid, reproducible, and reliable instrument for assessing the impact of COPD on the lives of patients in Brazil.

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Appendix 1 – Portuguese-language version of the COPD Assessment Test.