

# European Portuguese Language and Cultural Validation of the Chronic Obstructive Pulmonary Disease Assessment Test

## Validação e Adaptação Cultural para o Português Europeu do Teste de Avaliação da Doença Pulmonar Obstrutiva Crónica



Margarida PIMENTA VALÉRIO<sup>1</sup>, Soraia RIBEIRO<sup>2</sup>, Carlos SEIÇA CARDOSO<sup>2</sup>, João MACHADO<sup>1</sup>, José COSTA<sup>1</sup>, Cidália RODRIGUES<sup>1</sup>, Alexandre REBELO-MARQUES<sup>3,4,5</sup>

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### ABSTRACT

**Introduction:** The chronic obstructive pulmonary disease assessment test (CAT) is a self-administered questionnaire that measures health-related quality of life. GOLD proposes using this questionnaire, since it provides thorough coverage of the impact of chronic obstructive pulmonary disease (COPD) on well-being. This questionnaire has been widely used in daily clinical practice in Portugal, but it lacks validation for European Portuguese. The aim of this study was to carry out the cultural adaptation and validation of the CAT questionnaire so that the most appropriate version can be made available to Portuguese researchers and clinicians.

**Material and Methods:** A cross-sectional descriptive study was performed involving 65 patients with COPD aged 40 years or older. CAT and the previously validated Portuguese-language version of the Clinical Questionnaire for COPD were applied between January 2019 and June 2019. The agreement between the two questionnaires was determined with Kappa agreement with a 95% confidence interval. Spearman correlation was used to find the correlation between two scores.

**Results:** The 65 patients included in the study were observed in a hospital-based pulmonology clinic [aged  $68 \pm 7$  years; forced expiratory volume in 1 sec (FEV1)  $49.86\% \pm 16.5\%$  predicted]. CAT correlated significantly with all the domains and the overall score of the CCQ ( $0.47 < r < 0.75$ ;  $p < 0.001$ ). The bilingual patient interclass correlation coefficient was 0.922; Pearson's  $r = 0.928$ ;  $p < 0.001$ . The Cronbach's alpha coefficient was 0.96 ( $p < 0.001$ ).

**Conclusion:** The European Portuguese version of the COPD Assessment Test is a valid instrument for measurement of health-related quality of life in COPD patients. The use of validated questionnaires is of great importance since it generates reliable and reproducible evidence for use either in research or clinical practice.

**Keywords:** Portugal; Pulmonary Disease, Chronic Obstructive; Reproducibility of Results; Surveys and Questionnaires; Translating

### RESUMO

**Introdução:** O teste de avaliação da doença pulmonar obstrutiva crónica (CAT) é um questionário autoaplicável que mede a qualidade de vida relacionada com a saúde. As normas internacionais GOLD propõem o uso deste questionário, uma vez que traduz o impacto da doença pulmonar obstrutiva crónica (DPOC) no bem-estar. Este questionário tem sido amplamente utilizado na prática clínica diária em Portugal, mas carece de validação para o português europeu. Assim, o objetivo deste estudo foi realizar a adaptação cultural e validação do questionário CAT para que a sua versão mais adequada possa ser disponibilizada a investigadores e clínicos portugueses.

**Material e Métodos:** Foi realizado um estudo transversal descritivo com 65 doentes com DPOC com 40 anos ou mais. O CAT e a versão em português previamente validada do questionário clínico para DPOC foram aplicados entre janeiro de 2019 e junho de 2019. A concordância entre os dois questionários foi determinada com o teste de concordância de Kappa com intervalo de confiança de 95%. A correlação de Spearman foi usada para avaliar a presença de uma correlação entre os dois scores.

**Resultados:** Os 65 doentes incluídos no estudo foram observados em consulta de pneumologia hospitalar [idade  $68 \pm 7$  anos; volume expiratório máximo no 1º segundo (FEV1)  $49,86\% \pm 16,5\%$  do previsto]. O CAT correlacionou-se significativamente com todos os domínios e com a pontuação geral do CCQ ( $0,47 < r < 0,75$ ;  $p < 0,001$ ). O coeficiente de correlação interclasse de doentes bilingues foi de 0,922;  $r$  de Pearson = 0,928;  $p < 0,001$ . O coeficiente alfa de Cronbach foi de 0,96 ( $p < 0,001$ ).

**Conclusão:** A versão em português europeu do CAT é um instrumento válido para medir a qualidade de vida relacionada com a saúde em doentes com DPOC. A aplicação de questionários validados é fundamental, visto que gera evidência confiável e reprodutível para uso em ensaios clínicos ou na prática clínica.

**Palavras-chave:** Doença Pulmonar Obstrutiva Crónica; Inquéritos e Questionários; Portugal; Reprodutibilidade dos Testes; Tradução

### INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is a common, preventable, and treatable disease characterized by persistent respiratory symptoms and airflow limitation due to airway and/or alveolar abnormalities, usually caused by significant exposure to noxious particles or gases.<sup>1</sup> According to the WHO Global Health Estimates, COPD is cur-

rently the third leading cause of death in the world. A study in 2013 estimated the prevalence of COPD in the Lisbon region (Portugal) to be 14.2% in adults aged 40 or older, although it is often underdiagnosed.<sup>2</sup>

The diagnosis of COPD requires spirometry in subjects with a history of exposure to known risk factors (cigarette

1. Pulmonology Department. Centro Hospitalar e Universitário de Coimbra. Coimbra. Portugal.

2. Unidade de Saúde Familiar Condeixa. Administração Regional de Saúde Centro. Coimbra. Portugal.

3. Faculty of Medicine. University of Coimbra. Coimbra. Portugal.

4. Coimbra Institute for Clinical and Biomedical Research (iCBR). Faculty of Medicine. University of Coimbra. Coimbra. Portugal.

5. Clinical Academic Center of Coimbra (CACC). Coimbra. Portugal.

✉ **Autor correspondente:** Margarida Pimenta Valério. [mvalerio@campus.ul.pt](mailto:mvalerio@campus.ul.pt)

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smoking and other environmental hazards) and symptoms such as dyspnea and/or chronic cough with sputum production.<sup>3</sup>

The management strategy for stable COPD should be predominantly based on the individualized assessment of symptoms and future risk of exacerbations.<sup>1</sup> One of the key issues in understanding the symptoms is to value them according to their impact on the health status of the patient. Therefore, when evaluating these individuals, we must obtain reliable and valid information on daily symptoms, activity limitation, and other manifestations of the disease. This is also important because symptom burden and health status increase the probability of future exacerbations.<sup>4</sup> A standardized patient-centered assessment tool covering key attributes of COPD facilitates information gathering on specific areas of greater severity to serve as a focal point for targeted management.<sup>5</sup>

According to the Global Initiative for Chronic Obstructive Pulmonary Disease (GOLD), as compared with the modified British Medical Research Council (mMRC) dyspnea scale, the COPD assessment test (CAT) represents the impact of the disease on well-being to a greater extent and therefore should be used preferentially.<sup>6</sup> The CAT is a self-administered questionnaire that measures health-related quality of life and how it changes over time. It comprises eight items, each classified between 0 and 5, representing the increasing severity of the symptoms. The patients should mark the value that best describes their present situation. The total score ranges from 0 to 40, and it can be divided into four groups – 1) mild, 2) medium, 3) high, and 4) very high – representing the repercussions of the symptoms on the patient's life.<sup>6</sup> The Clinical Questionnaire for COPD (CCQ) is a clinical tool for evaluating the health status (symptomatology, functional status, and mental status) of people with COPD. The questionnaire comprises three domains and 10 items with an overall score: symptoms (four items), functional state (four items), and mental state (two items). Patients should answer the CCQ questions based on their experience in the last seven days on a Likert-based scale that assumes the following values: 0) never, 1) hardly ever, 2) a few times, 3) several times, 4) many times, 5) a great many times, and 6) almost all the time. The total score ranges from 0 to 60. The primary outcome measure of the CCQ is the mean total score (divided by 10 items), with higher scores representing worse health status and quality of life.<sup>7</sup> The CCQ was validated in 2012 for the Portuguese language.<sup>7</sup> The CAT has been validated for use in Brazilian Portuguese through a study that showed it to be a reproducible and reliable instrument for the assessment of COPD patients in the Brazilian population.<sup>8</sup> And even though this questionnaire has been widely used in daily clinical practice in Portugal, it lacks validation for European Portuguese. Thus, the aim of this study is to carry out the cultural adaptation and validation of the CAT questionnaire so that the most appropriate version can be made available to Portuguese researchers and clinicians.

## MATERIAL AND METHODS

### Translation

The Portuguese version of the CAT was obtained using a translation, back-translation, and comparison methodology carried out by a committee specially created for this purpose. The original version of CAT was translated into Portuguese by three independent translators, and three other independent translators performed the back-translation process. Five of the six translators recruited to find the final version of the questionnaire were from other institutions. The final versions were merged into one by a committee whose members were fluent in English, and it was compared with the original version. The committee did all the adjustments, converged them, and approved a unique and final European Portuguese language version (A.1). The equivalence between the two versions (English and European Portuguese) was also evaluated. Twelve bilingual individuals completed both versions, first the original version and the European Portuguese translation after a week. Correlations between the scores obtained with both versions were calculated.

### Study design and data collection

This cross-sectional descriptive study was performed at the COPD clinic in Centro Hospitalar e Universitário de Coimbra between January 2019 and June 2019.

The inclusion criteria of the study were as follows: a) COPD diagnosis confirmed by spirometry [with a post-bronchodilator forced expiratory volume in 1 sec / forced vital capacity (FEV1/FVC) ratio < 0.7] at least six months before the study period; b) age of 40 years or above; c) attendance of the COPD consultations at the Centro Hospitalar e Universitário de Coimbra – Hospital Geral during the study period.

The following exclusion criteria were applied: a) history of medical conditions that could influence the dyspnea-related disability, such as asthma, active pulmonary tuberculosis, lung cancer, or pulmonary resection; b) non-pulmonary diseases considered to be incapacitating, severe, or difficult to control; c) infections or hospitalization within the last three months; d) history of COPD exacerbation (defined as an acute worsening of respiratory symptoms that results in additional therapy) within the last six weeks; e) medication change within the last four weeks; f) cognitive deterioration with inability to understand the questionnaire.

This protocol was approved by the competent human research ethics committee (Administração Regional de Saúde do Centro), and every patient was provided informed consent before being enrolled in the study.

The Portuguese version of CAT was given to the patient, who was instructed to read the descriptive statements in each item and select the number between 0 and 5 which best fits his or her symptoms. The CCQ for the Portuguese language, validated in 2012, was also applied to analyze the correlation between the two questionnaires.<sup>7</sup>

Patient demographics and disease related data (including FEV1% predicted and exacerbation history) were also obtained.

### Statistical analysis

We summarized the characteristics of study populations using descriptive statistical methods with percentage, mean, and standard deviation (SD).

The agreement between these two questionnaires was determined with Kappa agreement with a 95% confidence interval. Spearman correlation was used to find the correlation between two scores. To evaluate the questionnaire's reliability, the Cronbach's alpha coefficient was determined. We performed all calculations using SPSS Statistics version 26®.

### Outcome measures

The primary outcome was to determine the concordance of the GOLD classification while using these tools: the CAT and the CCQ. The cut-off points at CAT 10 and CCQ 2 were used to allocate patients into each GOLD classification.

### RESULTS

The characteristics of the 65 participants of the study are represented in Table 1. Patients were predominantly male

(86.15%) and had exposure to tobacco smoke (76.92%). This group was characterized by moderate to severe obstruction, as well as a small rate of exacerbations.

As represented in Table 2, most patients (58.46%) had CAT scores between 10 and 20. Comparing the results from both questionnaires, there were only three respondents (4.62%) who had a CAT score < 10 that had a CCQ score  $\geq 2$ . On the other hand, 21.54% ( $n = 14$ ) of the respondents who had a CAT score  $\geq 10$  had a CCQ score < 2 (Table 3).

Test-retest agreement was not performed, since the participants were enrolled in the setting of a medical appointment and were not hospitalized.

The CAT score correlated significantly with all the domains separately and the overall score of the CCQ ( $0.47 < r < 0.75$ ;  $p < 0.001$ ) (Table 4).

The mean administration time for the CAT questionnaire was  $101 \pm 1.1$  seconds. The bilingual patient inter-class correlation coefficient was 0.922; Pearson's  $r = 0.928$ ;  $p < 0.001$ . The Cronbach's alpha coefficient was 0.96 ( $p < 0.001$ ), showing high internal consistency, and the obtained kappa was 0.91 ( $p < 0.001$ ) with a 95% confidence interval,

Table 1 – Demographic and disease-related characterization

| Characteristics                            | n         | %     | Mean ( $\pm$ SD) |
|--|-----------|-------|------------------|
| Age (years)                                |           |       | 68 (7)           |
| Sex (male)                                 | 56        | 86.15 |                  |
| Weight (kg)                                |           |       | 66.98 (9.55)     |
| BMI (kg/m <sup>2</sup> )                   |           |       | 23.4 (3.9)       |
| FEV <sub>1</sub> % predicted               |           |       | 49.86 (16.5)     |
| Gold A/B/C/D                               | 23/26/7/9 |       |                  |
| Smoking history                            | 46        | 70.77 |                  |
| Current smoker                             | 4         | 6.15  |                  |
| <b>Exacerbations in the last 12 months</b> |           |       |                  |
| 0  | 28        | 43.08 |                  |
| 1  | 21        | 32.31 |                  |
| $\geq 2$                                   | 16        | 24.62 |                  |

Table 2 – CAT and CCQ scores

| Scores  | n  | %     | Mean (SD)    |
|---|----|-------|--------------|
| <b>CAT</b>  |    |       | 15.17 (6.78) |
| Mild < 10   | 14 | 21.54 |              |
| Medium 10 - 20  | 38 | 58.46 |              |
| High 21 - 30  | 13 | 20.00 |              |
| Very high > 30  | 0  | 0     |              |
| <b>CCQ total</b>                                      |    |       | 2.13 (0.89)  |
| <b>CCQ Symptoms</b>                                   |    |       | 2.33 (1.15)  |
| <b>CCQ Functional State</b>                           |    |       | 2.40 (1.20)  |
| <b>CCQ Mental State</b>                               |    |       | 1.20 (1.20)  |
| Acceptable (CCQ < 1)                                  | 6  | 9.23  |              |
| Acceptable for moderate disease ( $1 \leq$ CCQ < 2)   | 19 | 29.23 |              |
| Unstable – severely limited ( $2 \leq$ CCQ < 3)       | 27 | 41.54 |              |
| Very unstable – very severely limited (CCQ $\geq 3$ ) | 13 | 20.00 |              |

**Table 3** – Categorization of patients in both scores

|                | CCQ < 2 (n/%) | CCQ ≥ 2 (n/%) |
|----------------|---------------|---------------|
| CAT < 10 (n/%) | 11/16.92      | 3/4.62        |
| CAT ≥ 10 (n/%) | 14/21.54      | 37/56.92      |

**Table 4** – Correlation of CAT with CCQ

| CCQ domains vs CAT          | r    | p       |
|-----------------------------|------|---------|
| Symptoms CCQ vs CAT         | 0.62 | < 0.001 |
| Functional state CCQ vs CAT | 0.64 | < 0.001 |
| Mental State CCQ vs CAT     | 0.47 | < 0.001 |
| CCQ Total vs CAT            | 0.75 | < 0.001 |

which also shows excellent agreement. There were also no absent answers.

## DISCUSSION

The CAT questionnaire correlated significantly with all the domains and the overall score of the CCQ questionnaire, showing that the translated version is valid. Also, the intraclass correlation coefficient and the Cronbach's alpha coefficient obtained showed the reproducibility and the reliability of this questionnaire.

Even though CAT is widely recommended for the evaluation of patients with COPD, we found no studies of validation and cultural adaptation of the Portuguese version of CAT.

The CCQ was chosen as the validation criterion for the Portuguese language version and cultural adaptation of CAT because it is an instrument with proven validity and is widely used in scientific research.<sup>7</sup> There is previous evidence that CAT and the CCQ are both measuring similar factors and can be used reliably and interchangeably.<sup>9</sup>

In the study concerning the development and first validation of CAT, internal consistency was excellent with Cronbach's alpha = 0.88, which is higher than the acceptable value of 0.70 and the correlation between the CAT and St George's Respiratory Questionnaire-C (SGRQ-C) in stable patients was very good (r = 0.8) and equally good (r = 0.78) in acute patients with an exacerbation.<sup>5</sup> Posterior adaptations and validations for other languages also showed high reliability and good correlation with other validated scores,<sup>7,10,11</sup> as demonstrated in our study.

According to GOLD, classifying COPD patients into four subgroups by considering symptoms and exacerbations allows the stratification of therapy and prognosis.<sup>1</sup> These two dimensions should also be assessed in the follow-up of these patients and are crucial for their ongoing management. In order to achieve this, symptomatic evaluation through validated scores such as CAT and mMRC is essential. Therefore, when treating these patients, individualization of therapy is a core concern, and this can only be accomplished by the correct assessment of symptom impact on COPD patients, which further strengthens this validation study.

On the other hand, even though CAT and mMRC are useful for clustering patients into groups with therapeutic

and prognostic implications, these two scores evaluate different dimensions of symptoms in COPD patients.<sup>12</sup> Future studies should address this issue in order to allow physicians to choose the most suitable tool to assess each patient.

As this study was performed in a hospital outpatient clinic, it included mostly patients with moderate to severe airflow obstruction and with small rates of exacerbation. We believe that further validation studies should include larger and more representative samples, bearing in mind that an individualized approach is essential to reduce symptoms and exacerbations and improve health status.

An important limitation in this process of cultural validation and adaptation is the lack of test-retest assessment, given the clinical context in which the questionnaires were provided to patients. Despite this limitation, we believe that it is not a critical error in our methodology, considering all the other positive findings mentioned above. According to the type of study we conducted, we were unable to evaluate the responsiveness of the Portuguese-language version of the CAT in interventions such as pulmonary rehabilitation or bronchiectasis.<sup>13</sup> This may also be considered a limitation of the study. However, other studies have used the same approach,<sup>14-17</sup> and we have done so previously.<sup>18,19</sup> We also recognize that the sampling method is not entirely free of bias, even though there was always a great effort by everyone, and the patients included are patients who attend the clinic and who agreed to participate in the study.

The importance of the validation of this questionnaire in our language is the possibility to use a reliable tool in evaluating COPD patients in various scenarios from primary care to hospitalized patients. Previous studies performed have showed the utility of CAT in these two settings.<sup>20,21</sup>

The validation and cultural adaptation of CAT to patients based in Portugal is therefore of significant importance, and the present study showed this version of CAT to be valid, reproducible, and reliable questionnaire.

The administration of validated questionnaires is essential since it generates reliable and reproducible evidence for use in either research or clinical practice. Questionnaires that are validated for a specific population help to collect better quality data with high comparability increasing its credibility.<sup>22</sup> Since both therapeutic stratification and follow-up decisions are strongly based on symptom burden and this information is more objectively collected by validated symptom questionnaires, the future use of this European Portuguese version should improve care for these patients and boost evidence-based research in our country.

In the future we ought to continue the work in different settings and with further follow up, ensuring the stability over time and contexts of the Portuguese version of CAT.

## CONCLUSION

The cultural adaptation of the European Portuguese version of the COPD Assessment test was validated by this study since this translated version correlated significantly with the CCQ and displayed feasibility and external validity

when compared with a traditional and previously validated instrument. We showed this version of CAT to be valid, reproducible, and reliable questionnaire. The lack of test-retest assessment was a limitation to consider since it would provide us the stability coefficient of this questionnaire, showing whether individuals responses would change over different time periods. Nevertheless, and considering all other findings, the European Portuguese version of the CAT is a valid instrument for measurement of health-related quality of life in COPD patients.

#### AUTHORS CONTRIBUTION

MPV: Data collection and treatment, manuscript outline, review and final approval

SR, CSC: Study design, review and correction of the manuscript, final approval.

JM, JC: Collection and treatment of data, review and correction of the manuscript, final approval.

CR: Manuscript review and correction, final approval

ARM: Statistical study. Review of the manuscript, final approval.

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#### PROTECTION OF HUMANS AND ANIMALS

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the Helsinki Declaration of the World Medical Association updated in 2013.

#### DATA CONFIDENTIALITY

The authors declare having followed the protocols in use at their working center regarding patients' data publication.

#### COMPETING INTERESTS

The authors have declared that no competing interests exist.

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