J Bras Pneumol. 2018;44(3):213-219
http://dx.doi.org/10.1590/S1806-37562017000000149

ORIGINAL ARTICLE

# Is the COPD Assessment Test sensitive for differentiating COPD patients from active smokers and nonsmokers without lung function impairment? A population-based study

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**Submitted:** 5 May 2017.
**Accepted:** 30 October 2017.

Study carried out at the Núcleo de Pesquisa em Asma e Inflamação das Vias Aéreas – NUPAIVA – Universidade Federal de Santa Catarina – UFSC – Florianópolis (SC) Brasil.

## ABSTRACT

**Objective:** To assess COPD Assessment Test (CAT) scores in adults with and without COPD, as well as to compare the CAT scores for nonsmokers, former smokers, and smokers without COPD with those for patients with COPD. **Methods:** This was a cross-sectional population-based study (the *Respira Floripa* study). The study included adults ≥ 40 years of age residing in the city of Florianópolis, Brazil. A total of 846 households were surveyed. In addition to completing the *Respira Floripa* questionnaire and the CAT, participants underwent pulmonary function testing. **Results:** We analyzed data on 1,057 participants (88.1% of the predicted sample size). A functional diagnosis of COPD was made in 92 participants (8.7%). Of those, 72% were unaware that they had COPD. The mean CAT score was higher in the group of COPD patients than in that of individuals without COPD (10.6 [95% CI: 8.8-12.4] vs. 6.6 [95% CI: 6.1-7.0]; $p < 0.01$). Individual item scores were significantly higher in the patients with COPD than in the individuals without COPD ($p < 0.001$), the exception being the scores for the items related to sleep ($p = 0.13$) and energy ($p = 0.08$). The mean CAT score was higher in the group of COPD patients than in nonsmokers (5.8 [95% CI: 5.3-6.4]) and former smokers (6.4 [95% CI: 5.6-7.2]; $p < 0.05$). However, there were no significant differences in the mean CAT score between the group of COPD patients and smokers without COPD (9.5 [95% CI: 8.2-10.8]; $p > 0.05$), the exception being the mean scores for confidence leaving home ($p = 0.02$). **Conclusions:** CAT scores were higher in the group of patients with COPD than in nonsmokers and former smokers without COPD. However, there were no significant differences in CAT scores between COPD patients and smokers without COPD. Smokers with an $FEV_1/FVC$ ratio > 0.70 have impaired health status and respiratory symptoms similar to those observed in COPD patients.

**Keywords:** Respiratory function tests; Pulmonary disease, chronic obstructive; Smoking.

## INTRODUCTION

COPD is an inflammatory lung disease characterized by chronic, progressive and not fully reversible airflow limitation.[1] Although COPD is primarily a lung disease, it also produces significant systemic effects that might result in impaired functional capacity, exercise capacity, quality of life, and health status.[1,2]

According to the 2011 update of the Global Initiative for Chronic Obstructive Lung Disease (GOLD)[3] strategy document, COPD management and treatment should consider disease impact (as determined by symptom burden) and the risk of exacerbation (as determined on the basis of airflow limitation and exacerbation history) rather than functional findings alone.[3] Since the publication of the 2011 GOLD guidelines, the COPD Assessment Test (CAT) has been increasingly used in clinical and research settings. The CAT has proved to be a reliable, valid, and responsive tool for health status assessment in patients with COPD.[4] Nonresponse rates, as well as floor and ceiling effects, together with the minimum clinically important difference for the CAT, are currently known.[5] In addition to studies examining the psychometric properties of the CAT, studies exploring other characteristics of the CAT in different scenarios and for different purposes are on the rise.[6] A recent systematic review showed that the CAT can be used as a complementary tool to predict COPD exacerbations, depression, acute deterioration of health status, and mortality.[6]

Although there is a growing body of evidence on the CAT and its features, the cross-sectional validity of the CAT

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Financial support: This study received financial support from the *Núcleo de Pesquisa em Asma e Inflamação das Vias Aéreas* (NUPAIVA, Center for Research on Asthma and Airway Inflammation). Manuela Karloh and Simone Aparecida Pereira Vieira were recipients of doctoral scholarships from the *Coordenação de Aperfeiçoamento de Pessoal de Nível Superior* (CAPES, Office for the Advancement of Higher Education).

in specific population subgroups and its discriminatory properties in such groups (e.g., smokers and former smokers) have yet to be adequately studied.[7] Another gap in the literature regarding the CAT is related to its use in the general population. The parameters thus obtained are important because they allow comparisons between specific populations and the normative data obtained from population-based studies.

To our knowledge, there have been only two studies reporting the use of the CAT in the general population.[8,9] In Brazil, there have been no population-based studies examining the CAT, despite the fact that the CAT is considered to be valid and reliable for patients with COPD.[10]

The objective of the present study was to assess CAT scores in a sample of adults ≥ 40 years of age with and without COPD. A secondary objective was to compare the CAT scores for nonsmokers, former smokers, and smokers without COPD with those for patients with COPD.

## METHODS

### Study design and sample selection

This was a cross-sectional population-based study. The study was part of the *Respira Floripa* study, in which the methodology employed in the Latin American Project for the Investigation of Obstructive Lung Disease (PLATINO) study was used,[11] albeit with modifications.

A representative sample of individuals ≥ 40 years of age residing in the greater metropolitan area of Florianópolis, Brazil, was randomly obtained by cluster sampling of census tracts and households. The study sample was stratified by socioeconomic class and location in the metropolitan area. Given that the population of Florianópolis residents ≥ 40 years of age was estimated at 157,450 inhabitants and that the number of ≥ 40-year-old residents per household was estimated at 1.42, 68 of the 419 census tracts in the area were randomly assigned to the study, a total of 846 households being included.

The study consisted of one or more household visits in which the participants answered the *Respira Floripa* questionnaire. The questionnaire contains questions regarding demographic characteristics and respiratory symptoms, among others. Participants underwent anthropometric and vital sign measurements, as well as pulmonary function testing. The inclusion criteria were as follows: being 40 years of age or older, residing in the greater metropolitan area of Florianópolis, and agreeing to participate in the study. The exclusion criteria were as follows: being institutionalized; being nonautonomous; having undergone thoracic, abdominal, or ophthalmologic surgery in the last three months; having had angina, acute myocardial infarction, or both in the last three months; having tuberculosis; having an HR > 120 bpm or < 60 bpm; having a systemic blood pressure > 180/90 mmHg; being pregnant; having had a respiratory infection in the three weeks preceding the assessment; being unable to perform spirometry; and failing to complete the CAT. The study was approved by the Research Ethics Committee of the Federal University of Santa Catarina (Protocol no. 766/2010), located in the city of Florianópolis, and all participants gave written informed consent. All household interviews were conducted between April of 2012 and July of 2013.

### Study procedures

#### The Respira Floripa questionnaire

Participants answered the *Respira Floripa* questionnaire, a standardized questionnaire based on the PLATINO study questionnaire[11] with minor modifications, which were based on the following: the American Thoracic Society (ATS) Division of Lung Diseases questionnaire,[12] the European Community Respiratory Health Survey II,[13] the Lung Health Study questionnaire,[14] and the 12-Item Short-Form Health Survey.[15] Demographic and socioeconomic data were collected, as were data on respiratory symptoms, respiratory diseases, medication use, medical diagnosis of respiratory diseases and other comorbidities, smoking history, and quality of life, among others. Questions regarding reasons for continued smoking,[16] sinonasal symptoms,[17] symptoms of depression and anxiety,[18] quality of sleep,[19] and health status[20] were added to the interview.

#### CAT

The CAT[20] assesses the health status of patients with COPD by quantifying the impact of common COPD symptoms (including cough, phlegm, chest tightness, breathlessness going up hills/stairs, activity limitations at home, confidence leaving home, sleep, and energy) on the lives of patients.[21] Individual question scores range from 0 to 5, total CAT scores therefore ranging from 0 to 40; a higher CAT score translates to a poorer health status.[20] A cut-off point ≥ 10 indicates impaired health status. The impact of COPD symptoms on the lives of patients can be divided into four categories, on the basis of the CAT score: low (i.e., CAT scores of 1-10), medium (i.e., CAT scores of 11-20), high (i.e., CAT scores of 21-30), and very high (i.e., CAT scores of 31-40).[22] The Portuguese version of the CAT has been validated for use in Brazil, and its reproducibility has been established.[10]

#### Pulmonary function testing and anthropometry

Spirometry was performed in accordance with ATS/European Respiratory Society standards,[23] with the use of an ATS-certified, portable, ultrasound-based spirometer (EasyOne®; ndd Medical Technologies, Inc., Andover, MA, USA). The following spirometric parameters were assessed: $FEV_1$, FVC, and $FEV_1$/FVC. The diagnosis of COPD was based on a post-bronchodilator $FEV_1$/FVC ratio of < 0.70. The reference values were those from the third National Health and

Nutrition Examination Survey.[24] Height was measured with a portable stadiometer (Seca®; Hamburg, Germany), and weight was measured with an electronic scale (Tanita Corporation of America, Inc., Arlington Heights, IL, USA). Height and weight were measured with participants barefoot and wearing light clothing.

### *Statistical analysis*

Descriptive statistics were used in order to summarize the demographic characteristics of the study participants. Continuous variables were summarized as mean and 95% confidence interval. Categorical variables were expressed as absolute and relative frequencies. The Kolmogorov-Smirnov test was used. Between-group differences were determined by the Student's t-test for independent samples and by analysis of variance (one-way ANOVA or the Kruskal-Wallis test) with post hoc Bonferroni correction. Within-group differences were determined by the Student's t-test for paired samples. The significance level was set at 95%. All statistical analyses were performed with the IBM SPSS Statistics software package, version 20.0 (IBM Corporation, Armonk, NY, USA).

### *Sample size*

The sample size calculation was based on the primary objective of the *Respira Floripa* study, which was to determine the prevalence of COPD in Florianópolis. The sample size was calculated by using parameters that were similar to those of the PLATINO study.[11] The required sample size was initially calculated to be 432. However, on the basis of the assumption that the prevalence of COPD might be lower than hypothesized and of the need for a higher number of COPD patients to allow between-group comparisons, the required sample size was calculated to be 1,200.

## RESULTS

Of a total of 1,184 eligible adults residing in Florianópolis, 102 declined to participate. The response rate was 91.3%. A total of 23 interviews were subsequently excluded because the interviewees were unable to perform reproducible flow-volume loops during spirometry, and another 2 were excluded because the interviewees did not complete the CAT (Figure 1).

We analyzed data on 1,057 participants, which accounted for 88.1% of the predicted sample size. The mean age was 58 years (95% CI: 57-59), the mean body mass index was 28.0 kg/m$^2$ (95% CI: 27.7-28.3), the mean $FEV_1$/FVC ratio was 79.6 (95% CI: 79.1-80.0), the mean percent predicted $FEV_1$ was 92.2% (95% CI: 91.0-93.5), and the mean percent predicted FVC was 89.0% (95% CI: 87.9-90.0). A functional diagnosis of COPD was made in 92 participants (8.7%). Of those, 72% were unaware that they had COPD. Patients with a diagnosis of COPD had a mean smoking history of 29.6 pack-years (95% CI: 23.7-35.6). Approximately half of the sample (52.9%) had never smoked, 18.0% were smokers, and 29.1% were former smokers (Table 1).

The mean CAT score was higher in the group of patients with COPD than in that of individuals without COPD (10.6 [95% CI: 8.8-12.4] vs. 6.6 [95% CI: 6.1-7.0]; $p < 0.01$). Individual item scores were significantly higher in the patients with COPD than in the individuals without COPD ($p < 0.001$), the exception being the scores for the items related to sleep ($p = 0.13$) and energy ($p = 0.08$).

The mean CAT score was higher in the group of COPD patients than in nonsmokers (5.8 [95% CI: 5.3-6.4]) and former smokers (6.4 [95% CI: 5.6-7.2]; $p < 0.05$; Figure 2). However, there were no significant differences in the mean CAT score between the group of COPD patients and smokers without COPD (9.5 [95% CI: 8.2-10.8]; $p > 0.05$). In addition, there were no significant differences between those two groups regarding individual item scores, the exception being the scores for the question regarding confidence leaving home ($p = 0.02$; Figure 3).

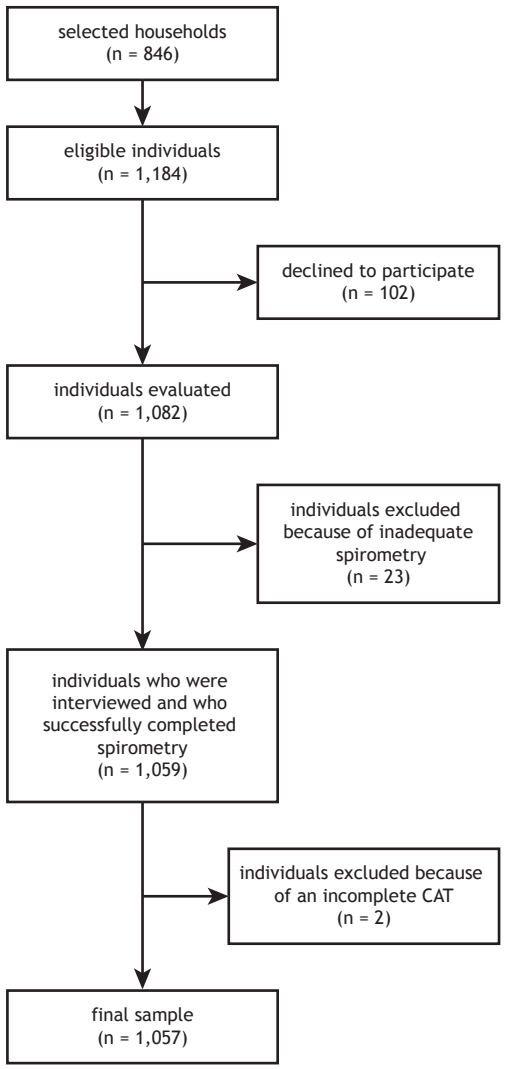


**Figure 1.** Flow chart of the sample selection process. CAT: COPD Assessment Test.

**Table 1.** Characteristics of the sample of individuals with and without COPD, the latter being stratified by smoking status.[a]

| Characteristic | Individuals without COPD | | | Individuals with COPD | p |
|---|---|---|---|---|---|
| | Nonsmokers | Former smokers | Smokers | | |
| | n = 539 | n = 274 | n = 152 | n = 92 | |
| Age, years | 57.8 (56.8-58.9) | 58.8 (57.5-60.1) | 53.4 (52.0-54.8)*,† | 65.0 (62.8-67.3)*,†,‡ | < 0.01 |
| Smoking history, pack-years | - | 23.4 (20.7-26.2) | 30.9 (37.4-24.5) | 29.6 (23.7-35.6)*,† | < 0.01 |
| Sex, n (%) | | | | | < 0.01 |
| Female | 362 (67.2) | 136 (49.6) | 95 (62.5) | 40 (43.5) | |
| Male | 177 (32.8) | 138 (50.4) | 57 (37.5) | 52 (56.5) | |
| Self-reported race[b] | | | | | < 0.01 |
| White | 465 (86.3) | 245 (89.4) | 117 (77.0) | 73 (79.3) | |
| Other | 74 (13.7) | 29 (10.6) | 35 (23.0) | 19 (20.7) | |
| Level of education, no. of years of schooling[b] | | | | | < 0.01 |
| 0-4 | 129 (23.9) | 56 (20.5) | 35 (23.0) | 37 (40.2) | |
| 5-8 | 85 (15.8) | 51 (18.6) | 39 (25.7) | 15 (16.3) | |
| ≥ 9 | 325 (60.3) | 167 (60.9) | 78 (51.3) | 40 (43.5) | |
| Socioeconomic class[b] | | | | | 0.03 |
| A and B | 81 (15.0) | 42 (15.3) | 19 (12.5) | 12 (13.0) | |
| C | 409 (75.9) | 208 (75.9) | 105 (69.1) | 66 (71.7) | |
| D and E | 49 (9.1) | 24 (8.8) | 28 (18.4) | 14 (15.3) | |
| BMI, kg/m$^2$[b] | | | | | 0.02 |
| < 25 | 139 (25.8) | 73 (26.7) | 58 (38.2) | 36 (39.1) | |
| 25-29 | 228 (42.3) | 116 (42.3) | 56 (36.8) | 36 (39.1) | |
| ≥ 30 | 172 (31.9) | 85 (31.0) | 38 (25.0) | 20 (21.8) | |
| Lung function | | | | | |
| $FEV_1$, % predicted | 96.6 (94.9-98.3) | 95.1 (93.1-97.2) | 88.8 (86.0-91.5)*,† | 63.7 (59.5-68.0)*,†,‡ | < 0.01 |
| FVC, % predicted | 91.0 (89.6-92.4) | 90.1 (88.2-91.9) | 87.6 (85.3-90.0) | 76.1 (72.0-80.1)*,†,‡ | < 0.01 |
| $FEV_1$/FVC | 82.0 (81.6-82.4) | 80.7 (80.0-81.3)* | 79.8 (79.0-80.6)* | 61.8 (60.3-63.4)*,†,‡ | < 0.01 |

BMI: body mass index. [a]Data expressed as mean (95% CI), except where otherwise indicated. [b]Data expressed as n (%). *vs. nonsmokers. †vs. former smokers. ‡vs. smokers.

## DISCUSSION

The results of the present study confirm that the CAT is sensitive for differentiating the health status of patients with COPD from that of individuals without the disease, even when it is administered to a sample of individuals without a previous diagnosis of COPD. In addition, the present study shows that the degree of health status impairment is similar between smokers without COPD and COPD patients.

This is the first population-based study in which the CAT score obtained during household interviews was followed by functional assessment to confirm the presence of COPD. Although the CAT was originally developed for patients with COPD, the data obtained by administering it to the general population (i.e., individuals without COPD) contribute to improving the interpretation of the CAT, especially regarding the magnitude, severity, and relevance of the symptoms on the rating scale,[9] as well as contributing to a deeper understanding of the impact of diseases such as COPD on patient health status.

Jones et al.[8] assessed the CAT in a large, random population-based survey conducted in 11 countries in the Middle East and northern Africa. Mean CAT scores were 6.99 ± 6.91 for the participants who answered the Arabic version and 9.88 ± 9.04 for those who answered the Turkish version.[8] Limitations of the study included data obtained by telephone interview and the fact that no functional evaluation was performed.[8]

In a cohort study designated the Canadian Cohort Obstructive Lung Disease (CanCOLD) study and investigating 1,500 individuals residing in nine urban/suburban areas in Canada,[9] the CAT was administered to a sample of 500 individuals without COPD, and the mean score was 6.00 ± 5.09. As in the present study, all CanCOLD study participants underwent pulmonary function testing by spirometry.[9] In another study,[25] which was part of the CanCOLD study, 481 individuals without COPD were evaluated, and the mean CAT score was similar to that observed in the present study (6.9 ± 6.2).

Several studies have shown that the CAT is sensitive to changes in health status in various groups of individuals. In agreement with other studies,[8,25-28] the present study showed that the mean CAT score for the general population of individuals without COPD was nearly half that for patients with COPD. This finding confirms the known-group validity of the CAT, mean CAT scores being significantly higher in patients with COPD than in individuals without the disease.

The magnitude of differences between individuals with and without COPD regarding the CAT score varies widely across studies. Among the Arabic-speaking participants of the BREATHE study,[8] mean CAT scores

were 16.6 (95% CI: 15.5-16.8) for those with COPD and 5.4 (95% CI: 5.2-5.6) for those without COPD; among Turkish-speaking respondents, mean scores were 20.9 (95% CI: 19.6-22.2) for those with COPD and 8.1 (95% CI: 7.6-8.6) for those without COPD. In a study by Nishimura et al.,[27] mean CAT scores were 7.3 ± 5.2 for the COPD group and 5.8 ± 4.4 for the non-COPD group. Raghavan et al.[25] reported mean scores of 9.2 ± 6.6 for the COPD group and 6.9 ± 6.2 for the non-COPD group. The three aforementioned studies evaluated individuals from the general population. In contrast, Miyazaki et al.[28] and Gao et al.[26] investigated individuals selected from among those treated at tertiary care centers. Miyazaki et al.[28] and Gao et al.[26] reported mean scores of 12.4 ± 8.3 and 10.3 ± 5.3 in the COPD groups and 9.4 ± 6.6 and 4.0 ± 2.1 in the non-COPD groups, respectively. This variability among studies involving different populations suggests the need for local scoring systems and emphasizes the relevance of our study.

We found significant differences between individuals with and without COPD regarding total CAT scores and individual item scores, the latter being higher in the COPD group than in the non-COPD group (the exception being the scores for sleep and energy). Although analysis of individual item scores is not recommended,[29] we decided to include it in the present study in order to provide a more detailed understanding of the behavior of the questionnaire and a qualitative analysis of the data. Of the eight items that constitute the CAT, sleep and energy are the only items that do not refer specifically to signs, symptoms, or limitations that are characteristic of patients with COPD. The item related to energy reads "I have lots of energy"/"I have no energy at all"; there is no mention of lung disease. However, the item related to sleep quality reads "I sleep soundly"/"I don't sleep soundly because of my lung condition". Nevertheless, although the item states that the reason for not sleeping soundly is the presence of a lung disease, increased scores are common among individuals without COPD because they perceive the sentence "I don't sleep soundly" as applying to them. Rating scales, such as CAT, can be interpreted in different ways depending on the content of the anchors (e.g., "I sleep soundly"/"I don't sleep soundly because of my lung condition"). It has been argued that the aforementioned items might require refinement depending on the population being evaluated.[25] In addition, because they are the most comprehensive items on the questionnaire, they might be unable to differentiate between patients with COPD and individuals without the disease, given that sleep and energy changes are important findings in other diseases.[28,30]

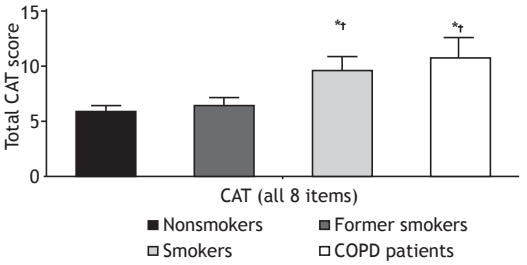


**Figure 2.** Total COPD Assessment Test (CAT) scores for each group of individuals in the study sample. *p < 0.05 vs. nonsmokers. †p < 0.05 vs. former smokers. ‡p < 0.05 vs. smokers.

In the individuals without COPD, CAT scores were found to be significantly higher in smokers than in nonsmokers and former smokers. The same was true for the items cough, phlegm, chest tightness, and breathlessness going up hills/stairs. These findings are important because they show that smokers have impaired health status and respiratory symptoms characteristic of chronic respiratory diseases despite the absence of changes in the fixed $FEV_1$/FVC ratio as assessed by spirometry, their CAT scores being similar to those observed in COPD patients.

The results of the present study are consistent with those of a recent nonpopulation-based study[31] showing that the presence of respiratory symptoms, as determined by the CAT, is common in approximately 50% of current and former smokers, despite their having preserved lung function (as assessed by spirometry).

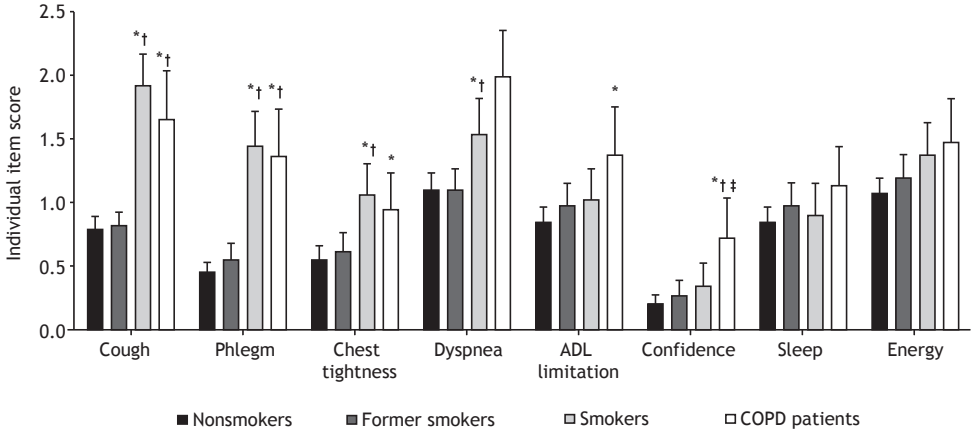


**Figure 3.** Individual COPD Assessment Test (CAT) item scores for each group of individuals in the study sample. ADL: activities of daily living. *p < 0.05 vs. nonsmokers. †p < 0.05 vs. former smokers. ‡p < 0.05 vs. smokers.

Although the prevalence of respiratory symptoms is slightly lower in current and former smokers than in patients with GOLD stage I or II COPD (65%), it is much higher in ever smokers (current or former) than in never smokers (16%).[31] In addition, ever smokers with preserved lung function and a CAT score ≥ 10 are more likely to have respiratory exacerbations, worse performance on the six-minute walk test, and radiological evidence of bronchiolitis than are individuals with a CAT score of < 10.[31] Other studies have reported similar findings for the CAT[8,26] and the Saint George's Respiratory Questionnaire.[32]

In a recent study,[33] 54.1% of all smokers or former smokers with post-bronchodilator $FEV_1/FVC > 0.70$ and $FEV_1 \geq 80\%$ of the predicted value reported one or more limitations related to respiratory disease. According to Fabbri,[34] the results of the aforementioned studies[31,33] indicate that individuals with respiratory symptoms without changes in lung function suffer the same consequences as do patients with spirometric changes consistent with mild to moderate airflow obstruction. In addition, he suggests that $FEV_1$ might not be a sensitive marker for COPD diagnosis in most individuals who smoke. According to Woodruff et al.,[31] the use of spirometry to establish a diagnosis of COPD might not adequately cover the breadth of symptomatic smoking-related lung disease. Therefore, it could be argued that a fixed $FEV_1/FVC$ ratio should be used as a screening tool rather than a diagnostic tool for COPD, given that it is unable to detect early changes in lung function.

Although the CAT is a disease-specific tool developed to complement the evaluation of patients with COPD, its score seems to be influenced by the presence of comorbidities. Although the CAT has a "COPD-centric" origin, three of its items (cough, phlegm, and breathlessness going up hills/stairs) address symptoms that are very common in, but not exclusive to, patients with COPD. The remaining five items (chest tightness, activity limitations at home, confidence leaving home, sleep, and energy) are even less exclusive to COPD. Therefore, it is possible that the attempt to create a multidimensional instrument capable of reflecting the complexity of COPD resulted in a nonspecific tool.

One potential limitation of the present study is the use of a fixed post-bronchodilator $FEV_1/FVC$ ratio of < 70% for the diagnosis of COPD; a post-bronchodilator $FEV_1/FVC$ ratio of < 70% tends to underestimate the presence of COPD in younger individuals and overestimate it in older individuals.[35,36] In addition, a post-bronchodilator $FEV_1/FVC$ ratio of < 70% is not exclusive to patients with COPD. It can be found in asthma patients with airway remodeling,[35] in the asthma-COPD overlap syndrome, and in other chronic respiratory diseases characterized by airflow obstruction.[23,36] Furthermore, in patients with severe COPD and decreased FVC due to lung hyperinflation, the $FEV_1/FVC$ ratio could be falsely increased,[37] contributing to underdiagnosis. However, the use of the $FEV_1/FVC$ ratio for the diagnosis of COPD is a simple method that does not depend on reference equations and has been widely used in numerous studies worldwide, some of which have provided the basis for COPD guidelines.

Another potential limitation is the sample size calculation. It was based on the primary objective of the *Respira Floripa* study, which was to determine the prevalence of COPD in Florianópolis. However, in order to support the results obtained by comparing the groups, the statistical power of the study was calculated and was found to be > 85% for the main comparisons.

In summary, CAT scores were higher in the group of patients with COPD than in nonsmokers and former smokers without COPD. However, there were no significant differences in CAT scores between COPD patients and smokers without COPD. Despite the apparent absence of changes in lung function on spirometry, smokers have impaired health status and respiratory symptoms similar to those observed in COPD patients. Symptomatic smokers with CAT scores above the cut-off point should undergo further pulmonary function tests for a better evaluation of their lung function.

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