Health Status Assessment in Routine Clinical Practice: The Chronic Obstructive Pulmonary Disease Assessment Test Score in Outpatients

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\textbf{Abstract}

\textbf{Background:} The chronic obstructive pulmonary disease (COPD) assessment test (CAT) is a simple, self-completion questionnaire developed to measure health status in patients with COPD, which is potentially suitable for routine clinical use. \textbf{Objectives:} The purpose of this study was to establish the determinants of the CAT score in routine clinical practice. \textbf{Methods:} Patients attending the clinic completed the CAT score before being seen. Clinical data, including, where available, plethysmographic lung volumes, transfer factor and arterial blood gas analysis, were recorded on a pro forma in the clinic. \textbf{Results:} In 224 patients (36% female), mean forced expiratory volume in 1 s (FEV\textsubscript{1}) was 40.1% (17.9) of predicted (%pred); CAT score was associated with exacerbation frequency [0–1/year 20.1 (7.6); 2–4/year 23.5 (7.8); >4/year 28.5 (7.3), p < 0.0001; 41/40/19% in each category] and with Medical Research Council (MRC) dyspnoea score ($r^2 = 0.26$, $p < 0.0001$) rising approximately 4 points with each grade. FEV\textsubscript{1} %pred had only a weak influence. Using stepwise regression, CAT score = 2.48 + 4.12 [MRC (1–5) dyspnoea score] + 0.08 (FEV\textsubscript{1} %pred) + 1.06 (exacerbation rate/year)] ($r^2 = 0.36$, $p < 0.0001$). The CAT score was higher in patients (n = 54) with daily sputum production [25.9 (7.5) vs. 22.2 (8.2); $p = 0.004$]. Detailed lung function (plethysmography and gas transfer) was available in 151 patients but had little influence on the CAT score. \textbf{Conclusion:} The CAT score is associated with clinically important variables in patients with COPD and enables health status measurement to be performed in routine clinical practice.

\textbf{Introduction}

It is well established that in patients with chronic obstructive pulmonary disease (COPD), airflow obstruction causes breathlessness, exercise limitation and difficulty in performing daily activities [1]. COPD patients may experience a considerable symptom burden and poor quality of life (QOL) [2]. The COPD assessment test (CAT) was introduced in 2009 as a tool to assess the impairment in health status associated with the condition [3, 4]. It is a self-completion questionnaire that includes 8 items that address a range of different COPD symptoms. It is quick and easy to complete and does not require any
specialist software to score. This potentially makes it suitable for routine clinical use, both to track changes in patients’ overall health status and to aid communication between patients and healthcare professionals.

The CAT has been developed and validated in patients taking part in clinical trials [3]. The purpose of this study was to establish, in an unselected clinical population, which features of COPD were most strongly associated with health status. There are previous data to suggest that there is only a limited correlation between QOL and spirometry measurements [5]. There are few data to show whether other lung function parameters might be more relevant.

### Methods

**Ethics Statement**

The Research Ethics Committee of the Royal Brompton Hospital has determined that approval is not required for observational studies of routinely collected clinical data.

The study involved a prospective investigation of patients attending COPD hospital clinics between October 2009 and November 2010. The CAT score was adopted into routine clinical practice, with patients completing it on paper in the waiting room before being seen. It comprises 8 items scored 1–5 relating to cough, phlegm, chest tightness, breathlessness, confidence, sleep quality and energy, to give a total score of 40 [3]. Categories of mild, moderate, severe and very severe health status impairment have been proposed for the CAT score, representing scores of 1–10, 11–20, 21–30 and 31–40 [6].

Spirometry was performed by a respiratory clinical nurse specialist in accordance with guidelines of the American Thoracic Society and the European Respiratory Society. In addition, Medical Research Council (MRC) dyspnoea score (rated 1–5 with increasing dyspnoea) [7], body mass index (BMI), oxygen saturation and exacerbation rate were recorded as well as smoking status and medication. Exacerbations were defined as episodes of worsening symptoms requiring treatment with antibiotics and/or oral corticosteroids, and the number was based on patient self-report in the clinic. The number of episodes was recorded and exacerbation rates were categorized a priori as 0–1, 2–4 or 4 per year. The presence of daily sputum production was also documented. The clinical physician entered the patient’s history, including the items specified above, onto a standard pro forma while seeing the patient, and this information was subsequently entered into a clinical audit database.

Where patients had had other lung function parameters, including arterialised capillary blood gas, plethysmographic lung volumes (total lung capacity, TLC, residual volume, RV, functional residual capacity, FRC) and gas transfer (carbon monoxide transfer factor, TLCO, and carbon monoxide coefficient, Kco), performed within 12 months of the clinic date, these parameters were also used for comparison. These measurements were made using a Jaeger CompactLab system (Jaeger, Germany).

### Statistical Analysis

Analysis of data was performed using StatView (1992–1998, SAS Institute, USA).

Simple regression or ANOVA was used to determine independent correlates of the CAT score. Backward stepwise regression, including anthropometric and demographic measures, spirometry and exacerbation rate, were used as exploratory variables to develop models for prediction of the CAT score and MRC dyspnoea score in the whole population. In the subgroup with more detailed lung function tests available, lung volumes, gas transfer and arterial blood gas parameters were also included in the model. Results are presented as means (SD) unless specified otherwise, and significance was accepted at p < 0.05.

### Results

Data were recorded for 224 patients (36% female) attending the clinic with a diagnosis of COPD consistent with GOLD (Global Initiative for Chronic Obstructive Lung Disease) guidelines [1] of whom 41 (18.3%) were attending the clinic for the first time, the rest being under follow-up. Patient demographic and clinical characteristics are displayed in table 1. All patients had airflow obstruction characterised by a ratio of forced expiratory volume in 1 s (FEV1)/forced vital capacity <70%. Mean FEV1 was 40.1% (17.9) of predicted (%pred) with GOLD stages

### Table 1. Patient characteristics

<table>
<thead>
<tr>
<th>Mean ± SD</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>63.5 ± 10.3</td>
</tr>
<tr>
<td>Males, n (%)</td>
<td>144 ± 64.3</td>
</tr>
<tr>
<td>Smoking, pack years</td>
<td>41.7 ± 23.2</td>
</tr>
<tr>
<td>BMI</td>
<td>25.2 ± 5.4</td>
</tr>
<tr>
<td>MRC dyspnea score (1–5)</td>
<td>3.5 ± 0.9</td>
</tr>
<tr>
<td>CAT score</td>
<td>23.1 ± 8.2</td>
</tr>
<tr>
<td>Exacerbations/year</td>
<td>2.6 ± 2.5</td>
</tr>
<tr>
<td>FEV1, liters</td>
<td>1.08 ± 0.51</td>
</tr>
<tr>
<td>FEV1, %pred</td>
<td>40.1 ± 17.9</td>
</tr>
<tr>
<td>FVC, liters</td>
<td>2.96 ± 0.95</td>
</tr>
<tr>
<td>FVC, %pred</td>
<td>36.7 ± 12.9</td>
</tr>
<tr>
<td>TLC, %</td>
<td>122.6 ± 17.8</td>
</tr>
<tr>
<td>RV/TLC, %</td>
<td>55.6 ± 9.9</td>
</tr>
<tr>
<td>FRC, %pred</td>
<td>163.7 ± 35.7</td>
</tr>
<tr>
<td>TLCO, %pred</td>
<td>42.4 ± 17.3</td>
</tr>
<tr>
<td>KCO, %pred</td>
<td>53.8 ± 20.9</td>
</tr>
<tr>
<td>PaO2, kPa</td>
<td>9.40 ± 1.39</td>
</tr>
<tr>
<td>PaCO2, kPa</td>
<td>5.14 ± 0.70</td>
</tr>
<tr>
<td>SaO2, %</td>
<td>94.1 ± 3.3</td>
</tr>
</tbody>
</table>

FVC = Forced vital capacity; PaO2/PaCO2 = partial pressure of oxygen/carbon dioxide in arterialised earlobe capillary sample; SaO2 = oxygen saturation.
The mean CAT score in this clinic population was 23.1 (8.2), with 15 (6.7%), 55 (24.6%), 103 (46.0%) and 51 (22.8%) in the mild, moderate, severe and very severe health status impairment groups, defined by CAT scores of 0–10, 11–20, 21–30 and 31–40, respectively. Patients scored across the whole available range from 1–40. The exacerbation frequency category in the year preceding the clinic appointment was significantly associated with the CAT score; 0–1/year 20.2 (7.6); 2–4/year 23.5 (7.8); >4/year 28.5 (7.3), (ANOVA p < 0.0001) with 41, 40 and 19% of patients in each category, respectively (fig. 1). If exacerbation rate was treated as a continuous variable it was also significantly associated with CAT score (r² = 0.18, p < 0.0001). Consistent with this, the CAT score was higher in patients (n = 54) where daily sputum production was documented [25.9 (7.5) vs. 22.2 (8.2); p = 0.004].

CAT score was also significantly associated with MRC dyspnoea score (r² = 0.26, p < 0.0001; fig. 2). There was no significant difference in CAT score between smokers [n = 30 (13.4%)] 23.8 (10.1) and non-smokers 22.9 (7.9). In univariate analysis, CAT score was not significantly associated with FEV₁ %pred (r² = 0.02, p = 0.06) and only weakly with gas trapping, as represented by the RV/TLC ratio (r² = 0.03, p = 0.04) in the subgroup (n = 151) where more detailed lung function had been performed. There was no correlation between CAT score and gas transfer, other measures of lung volume, arterial blood gases, pack years of smoke exposure, gender or BMI (table 2). Most patients were taking regular long-acting inhaled corticosteroids as well as long-acting β₂ agonists and antimuscarinic agents, and no association between medication and CAT score was identified.

Using stepwise regression in the whole population (n = 224), demographics, BMI and oxygen saturation were not retained, but MRC dyspnoea score, exacerbation rate and FEV₁ %pred were independent predictors of CAT score giving the equation: CAT score = 2.48 + 4.12 [MRC (1–5) dyspnoea score] + 0.08 (FEV₁ %pred) + 1.06 (exacerbation rate/year), with r² = 0.36, p < 0.0001.

Stepwise regression was conducted in the 151 patients in whom detailed lung function testing was available, including lung volumes and gas transfer as possible correlates. In this group, TLC %pred replaced FEV₁ %pred in the regression model, which again explained 36% of the variance in the CAT score; CAT score = 19.5 + 1.02 (exacerbation rate/year) + 3.46 [MRC (1–5) dyspnoea score] – 0.092 (TLC %pred), with p < 0.0001.
There was no difference between CAT scores in new and follow-up patients, and this parameter was not retained in any regression model for CAT score.

### MRC Dyspnoea Score

MRC dyspnoea score was significantly correlated with lung volumes, gas transfer and hypoxia (table 2). A stepwise regression model including FEV₁ %pred, age and exacerbation rate explained 30% of the variance in the MRC score. Gender, oxygen saturation and BMI were not retained in the model. In the subgroup of patients with detailed lung function, MRC score was independently associated with RV/TLC, TLCO and exacerbation rate ($r^2 = 0.32$); MRC (1–5) dyspnoea score = 2.7 + 0.024 (RV/TLC %) − 0.18 (TLCO %pred) + 0.07 (exacerbation rate).

### Discussion

#### Main Findings

The present study investigated the use of CAT, which has recently been developed as a tool to assess health status of COPD patients in routine clinical practice, aiming to identify its associations with clinical features in patients with the condition. CAT score was most strongly associated with exacerbation frequency and breathlessness during daily activities, with only minimal additional contribution from lung function parameters, although TLC %pred was retained in the regression model. The determinants of the CAT score did not differ between new and follow-up patients. In addition, the study also illustrates the feasibility of using the CAT score in routine clinical practice.

### Significance of Findings

#### Exacerbations

Acute exacerbations of COPD (AECOPD) are a key feature of the disease, and have been found to be associated with worse health status, more rapid deterioration in lung function, muscle wasting and impaired survival [8–11] as well as to cause prolonged further reductions in physical activity and time spent outdoors, which are likely to impact significantly on patients’ QOL [9, 12–16]. The acute deterioration in health-related QOL may be persistent and may not recover if exacerbations recur [17]. Daily sputum production has been shown to be associated with worse health status [9]. Recent data from the ECLIPSE cohort suggest that the ‘frequent exacerbator’ is a stable phenotype with prior exacerbation rate as a powerful predictor of future exacerbations [18].

AECOPD have been identified, together with inability to perform daily activities, as having major impacts on patients’ lives in surveys [16] and may contribute to depression, an important co-morbidity in COPD [19]. Interestingly, recently it has been demonstrated that raised levels of CRP, a marker of systemic inflammation, are associated with worse QOL in COPD [20].

In the present study, exacerbation rate was identified as an important contributor to impaired QOL. The initial validation paper for CAT found a mean difference of 5 points between stable and exacerbating patients [3]. CAT score rose by approximately 1 point per reported exacerbation per year and differed by 8 points between the prespecified low (0–1 per year) and high (>4 per year) exacerbation rate groups. A further related finding is the increased CAT score seen in patients reporting daily sputum production. Daily sputum production has previously been shown to be associated with increased exacerbation frequency [9].

#### Breathlessness and Pulmonary Function

The inability to perform daily activities because of breathlessness is a fundamental aspect of the experience...
in COPD for patients with the condition [1, 16]. It arises from airflow limitation and dynamic lung volume changes which increase the work of breathing, worsening with exercise, where dynamic hyperinflation is strongly associated with daily physical activity [21] and during acute exacerbations [22, 23]. In the population studied here, there were significant relationships between breathlessness assessed using the MRC dyspnoea score and airflow obstruction, gas transfer impairment and increased lung volumes. Increasing MRC score was also associated with worsening QOL, with a 1-point increase in MRC score equivalent to an approximately 4-point increase in CAT score. COPD is a heterogeneous condition; patients may have varying degrees of airway disease, emphysema and pulmonary vascular involvement, which impact on different lung function parameters to a varying extent. Lung function impairment is experienced by patients largely as breathlessness, but chest tightness is also an important symptom which is incorporated into the CAT score. The retention of TLC %pred in the regression models for CAT score may thus reflect a perception of chest tightness as lung volumes expand as well as the fact that the MRC score is a relatively crude measure of dyspnoea.

A poor correlation between spirometry and aspects of COPD, including breathlessness, exercise capacity, co-morbidity and exacerbation frequency as well as health-related QOL, has been described most recently in the ECLIPSE cohort of more than 2,000 patients [24]. In the present study, FEV₁ %pred was retained in the regression model but an absolute reduction of 10% produced less than a 1-point change in CAT score. RV/TLC was weakly associated with CAT score in univariate analysis and TLC %pred replaced FEV₁ %pred in stepwise analysis in the subgroup with additional lung function, consistent with the role of hyperinflation in the development of breathlessness and activity limitation in COPD [21, 25].

Spirometry and MRC score have both been incorporated into multidimensional scores that predict survival in COPD [26, 27], and there is also evidence that some health-related QOL tools are predictive of mortality [28]. It remains to be established whether the CAT score will be associated with survival. It is likely that TLCO was not retained in the model, because the parameters it is determined by are less directly linked to symptoms than measures of airflow obstruction or lung volume. This does not mean that gas transfer need not be measured as gas transfer measurements can help to quantify the presence of emphysema and are also prognostic [29].

Introducing the CAT within a busy outpatient clinic was simple and unproblematic, being administered to patients while they were waiting to be seen. We did not formally assess its acceptability, but no patient complained about filling it in and some remarked that they found it helpful. Development of its use as an outcome measure in clinical practice, including pulmonary rehabilitation and adoption into primary care, has the potential to improve communication between different arenas of healthcare provision and provide a tool to identify the burden of symptoms present in COPD patients, particularly those who would be defined as having ‘less severe disease’ by spirometry. Although an attractive prospect, further work is needed to establish how responsive the CAT score is to interventions. Recent data in pulmonary rehabilitation suggest that a change of 1.3 points following the program corresponds to feeling ‘a little better’ and 3.8 points to ‘much better’ [30].

A further issue is that the data recorded, including lung function, exacerbation rate, breathlessness, treatment and anthropometrics, explain only 38% of the variation in health status in this COPD population. Other factors such as limitation during daily physical activity may be important, and further work is needed to identify these other factors.

Methodological Issues
Since the present study was performed in a hospital clinic, the patients by definition had disease of sufficient severity to warrant referral, and caution must therefore be exercised in extrapolating to a population with milder disease. Ideally, a walking test would have been performed to allow further stratification of our patients according to a multidimensional score such as the BODE index [26].

As well as looking at exacerbation rate as a continuous variable, the data are also presented according to pre-specified categories – a rate of 2 or more per year was considered important as this is the level at which the addition of inhaled corticosteroids has been recommended [1]. Exacerbation rate was identified by direct questioning when patients attended the clinic. Based around events requiring a change in treatment, the definition has the advantage of clinical relevance. Although the use of diary cards might have produced different results, recent data suggest that patient recall of exacerbations is accurate [31].
Conclusion

The most important associations of health status in outpatients with COPD, assessed using the CAT score, are exacerbation rate and breathlessness during daily activities rather than lung function parameters. These findings are consistent with data in COPD obtained using other health status measures in a research context and support the validity of the tool. The CAT score has the advantage of being suitable for use in normal clinical practice, and these data should promote the routine assessment of health status in clinical encounters with COPD patients. A systematic approach to health status assessment is likely to drive up standards of care.

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Financial Disclosure and Conflicts of Interest

The authors declare that they have no conflicts of interest.

References


The CAT Score in COPD

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