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# Characteristics of patients with increasing COPD assessment test scores within 3 years



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#### ABSTRACT

*Background:* The chronic obstructive pulmonary disease (COPD) Assessment Test (CAT) is a subjective measure of quality of life. The aim of this study was to examine the characteristics of COPD patients with increasing CAT scores within 3 years.

*Methods:* Keio University and its affiliate hospitals conducted an observational COPD cohort study over 3 years. St. George's Respiratory Questionnaire (SGRQ) and CAT were completed at baseline and annually thereafter. Patients who had at least 3 CAT scores were included (n = 315). The  $\Delta$ CAT score/year and  $\Delta$ SGRQ score/year were calculated by the slope between each of the measures and the date of measurement.

*Results*: The median  $\Delta$ CAT score/year was 0.4, and  $\Delta$ CAT score/year was significantly correlated with  $\Delta$ SGRQ total score/year. Using an annual cut-off CAT score of +2 points, patients who deteriorated (n = 79) were older, had lower %FEV<sub>1</sub>, and more severe emphysema on computed tomography scan at baseline than patients who did not deteriorate. The baseline value was not a determinant of subsequent changes in the CAT score. Longitudinal changes in the CAT score were positively correlated with those in the SGRQ score.

*Conclusions:* Old age and severe COPD, not the CAT score at one time point, predicted worsening quality of life.

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Abbreviations: COPD, chronic obstructive pulmonary disease; CAT, COPD assessment test;  $\Delta$ CAT, rate of change in CAT; SGRQ, St. George's Respiratory Questionnaire;  $\Delta$ SGRQ, rate of change in SGRQ; FEV<sub>1</sub>, forced expiratory volume in one second; %FEV<sub>1</sub>, ratio of predicted FEV<sub>1</sub>; GOLD, The Global Initiative for Chronic Obstructive Lung Disease; mMRC, the modified British Medical Research Council; K-CCR, the Keio COPD Comorbidity Research; LAA%, ratio of low attenuation area; WA %, ratio of airway wall area; SF-36, medical outcomes study short-form 36-item; ICS, inhaled corticosteroids; LAMA, long-acting muscarinic antagonist; LABA, long-acting  $\beta_2$  agonist;  $\Delta$ SF-36, rate of change in SF-36; GERD, gastroesophageal reflux disease; BMI, body mass index; FVC, forced vital capacity; LTOT, long-term oxygen therapy; HAD-A, seven items for anxiety of hospital anxiety and depression; HAD-D, seven items for depression of hospital anxiety and depression; SD, standard deviation.

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#### 1. Introduction

Chronic obstructive pulmonary disease (COPD) is defined by the presence of poorly reversible airflow limitation [1,2]. Although COPD is primarily a lung disease, it also produces significant systemic effects that can reduce functional status, exercise capacity, and health status [3,4]. The COPD Assessment Test (CAT) was developed to meet the perceived need for a simple instrument that could provide reliable measurements of COPD health status in routine clinical practice [5,6]. It is a self-completion questionnaire that includes 8 items that address a range of different COPD symptoms, and it is known that %FEV<sub>1</sub> had only a weak correlation with CAT score [6,7]. The Global Initiative for Chronic Obstructive Lung Disease (GOLD) strategy proposed the use of the CAT or the

modified British Medical Research Council (mMRC) dyspnea scale for assessment of symptoms in COPD patients [1,2].

Recent studies showed that exacerbations may temporarily worsen the CAT score [8,9], and that the effects of rehabilitation were reflected in the improvement of the CAT score [9,10]. De Torres et al. reported that, among patients with stable COPD, the one-year CAT changes varied and were best predicted by changes in mMRC scale scores [11]. However, annual changes in CAT scores have not been assessed in COPD patients. We have been conducting a multicenter, observational cohort study, called the Keio COPD Comorbidity Research (K-CCR), to longitudinally examine the comorbidities of COPD in Japan.

We hypothesized that the annual change of the CAT score correlated to the annual change of other health-related quality of life (QOL) scores, and that COPD patients with an increasing CAT score have unique clinical characteristics. The aim of this study was to investigate the variability in CAT score changes and their correlation with changes in other health-related quality of life (QOL) scores, as well as the clinical characteristics of Japanese COPD patients with increasing CAT scores over 3 years.

#### 2. Methods

#### 2.1. Study population

The overall design of the K-CCR has been previously published [12,13]. In brief, this study was a 3-year, prospective observational study that enrolled 572 men and women aged 40-91 years who had been diagnosed as having COPD (n = 440) or being at risk for COPD (n = 132) by pulmonary physicians from April 2010 to December 2012. For the purpose of this study, data only from COPD patients with at least 3 CAT scores over 3 years (n = 315) were selected and analysed. The data of the remaining 257 patients were not analysed. All patients were clinically stable and had no exacerbations for at least 1 month prior to recruitment. The ethics committees of Keio University and its affiliated hospitals approved the study protocol. Each patient provided written, informed consent to analyse and present their data. All aspects of the study conformed with the principles in the Declaration of Helsinki adopted by the 59th WMA General Assembly, Seoul, Republic of Korea, October 2008.

#### 2.2. Assessment of clinical parameters

Complete medical and smoking histories, as well as information about current pharmacologic treatment, were obtained on enrolment and annually [14]. All patients were assessed by spirometry and chest computed tomography (CT) imaging. The extent of emphysema was quantified as the ratio of low attenuation area (LAA%) and the percentage of airway wall area (WA%) on CT images using custom-made software (AZE Ltd. Tokyo, Japan) [13]. Independent investigators judged the number and severity of exacerbations based on reviews of physicians' medical records, as previously reported [15]. Comorbid diagnoses were established by clinical history and examination findings based on review of available medical records [12,13,16].

#### 2.3. Questionnaires on health-related quality of life

All patients were clinically stable and had no exacerbations for at least 1 month before study enrollment and on the day of the annual examination. The Japanese version of CAT was used for assessment of COPD-specific health status [5,17], together with the St. George's Respiratory Questionnaire (SGRQ) in Japanese for assessment of disease-specific health status of COPD [18–20]. In addition, the Medical Outcomes Study Short-Form 36-Item (SF-36) version 2 was used to assess general health status [21]. All of the following questionnaires were completed by the patients themselves at home. The annual rates of change in the CAT, SGRQ, and SF-36 scores were measured over 3 years; Excel (Microsoft Inc. Redmond, WA, USA) was used to calculate the derived slope between each of the above measures and the date of data collection [22].

#### 2.4. Statistical analysis

Data are presented as means  $\pm$  standard deviation (SD) or as medians (interquartile range (IQR)). The Shapiro-Wilk test was used to verify if the data followed a normal distribution, in order to justify the use of a parametric test. Data were compared between two groups using Welch's *t*-test, the Mann-Whitney *U* test, and the  $\chi^2$  test. Correlations between continuous variables were evaluated by Spearman's rank correlation coefficient. Univariate and multivariate logistic regression analyses were performed in order to assess the effects of factors on increasing CAT score. Differences in rates of change over time and in levels of CAT scores among the 3 groups classified according to the severity of exacerbation were estimated using mixed-effects modeling with Bonferroni correction. For all tests, two-sided p values < 0.05 were considered significant. Data were analysed using JMP 10 software (SAS Institute, Cary, NC, USA). A mixed-effect model was applied using SPSS 23 (IBM Corporation, Armonk, NY, USA).

#### 3. Results

#### 3.1. Clinical features of the study populations

Table 1 shows the baseline characteristics of the study participants. The average age of the COPD patients was  $72.3 \pm 7.7$  years, 93.3% were men, and only 9.2% were current smokers. The overall median CAT score was 11; 56.8% had a CAT score  $\geq$ 10. Of the 315 COPD patients, 36.2% were treated with inhaled corticosteroids (ICS), and 78.4% were treated with bronchodilators (63.1% on long-acting muscarinic antagonist and 47.3% on long-acting beta agonist). Patients who dropped out from the study were more female, were more current smoker, had worse airflow limitation and lower body mass index compared to those who completed the 3-year follow-up (Supplemental Table S1).

Table 1
Baseline characteristics of the study participants.

	1
Gender, female, n (%)	21 (6.7)
Age, years	$72.3 \pm 7.7$
Smoking Index, pack-years	57.3 ± 30.3
Current smoking, n (%)	29 (9.2)
BMI, kg/m <sup>2</sup>	$22.8 \pm 3.0$
FEV <sub>1</sub> , L	$1.69 \pm 0.62$
FEV <sub>1</sub> /FVC, %	52.7 ± 12.2
%FEV1, %	$63.3 \pm 21.0$
GOLD grade 1/2/3/4, n (%)	76/146/77/16 (24.1/46.4/24.4/5.1)
Baseline CAT score	11 (6-17)
Baseline CAT score $\geq 10$ , n (%)	175 (56.8)
LAMA, n (%)	198 (63.1)
ICS, n (%)	114 (36.2)
LABA n (%)	149 (47.3)

Data are shown as mean  $\pm$  SD and median (interquartile range).

CAT, COPD assessment test; BMI, body mass index; FEV<sub>1</sub>, forced expiratory volume in 1 s; FVC, forced vital capacity; %FEV<sub>1</sub>, ratio of predicted FEV<sub>1</sub>; LAA%, ratio of low attenuation area; WA%, ratio of airway wall area.

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