

Properties of the COPD Assessment Test (CAT) in a cross-sectional European study

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ABSTRACT

A short, easy-to-use health status questionnaire is needed in the multidimensional assessment of chronic obstructive pulmonary disease (COPD) in routine practice.

The performance of the 8-item COPD Assessment Test (CAT) was analysed in 1817 patients from primary care in seven European countries. The CAT has a scoring range from 0-40 (high score representing poor health status).

Mean CAT scores indicated significant health status impairment that was related to severity of airway obstruction, but within each GOLD Stage (I to IV) there was a wide range of scores (I: 16.2 ± 8.8 ; II: 16.3 ± 7.9 ; III: 19.3 ± 8.2 ; IV: 22.3 ± 8.7 . I vs. II, $p=0.88$; II vs. III, $p<0.0001$; III vs. IV, $p=0.0001$). CAT scores showed relatively little variability across countries (within $\pm 12\%$ of the mean across all countries). Scores were significantly better in patients who were stable (17.2 ± 8.3) vs. those suffering an exacerbation (21.3 ± 8.4) ($p<0.0001$); and in patients with zero (17.3 ± 8.1) or 1-2 (16.6 ± 8.2) vs. ≥ 3 (19.7 ± 8.5) comorbidities ($p<0.0001$ for both). The CAT distinguished between classes of other impairment measures and was strongly correlated with the St George's Respiratory Questionnaire ($r=0.8$, $p<0.0001$).

The CAT is a simple and easy-to-use questionnaire that distinguishes between patients of different degrees of COPD severity and appears to behave the same way across countries. (Study number: 111749)

Keywords: Chronic obstructive pulmonary disease; COPD Assessment Test; CAT; health-related quality of life; primary care

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is an inflammatory disease of the lungs characterised by progressive and partially reversible airflow obstruction associated with an abnormal inflammatory response of the lungs to noxious particles or gases, primarily caused by cigarette smoking [1,2]. The prevalence of COPD and associated mortality is predicted to increase in the coming decades [3] and with it a considerable economic and social burden. Whilst COPD has traditionally been associated with older (> 50 years) males, recent evidence suggests that the disease is already present in 20-45 year olds and that gender differences are becoming less pronounced [4].

Effective management of COPD involves an overall approach that aims to relieve symptoms, improve exercise tolerance, health status and survival, and to prevent complications and exacerbations [1, 2]. It is now recognised that the assessment of dyspnoea, exercise performance and health status provides important additional information to pulmonary function measures [5].

Current COPD-specific health status measurements, including the St George's Respiratory Questionnaire (SGRQ) [6,7] and Chronic Respiratory Disease Questionnaire (CRD) [8] have been validated and used extensively in clinical trials. Such questionnaires are complex and time-consuming to complete. There is a requirement in clinical practice for a simple, short questionnaire that would allow routine assessment of patients' health status in all healthcare settings but particularly in primary care where the majority of COPD patients are managed.

The COPD Assessment Test (CAT) is a short, easy-to-complete health status tool that has been developed to help patients and their clinicians assess and

quantify the symptoms and impacts of COPD and enable better communication between patients and physicians about these consequences of their disease. During the development of the CAT, an initial qualitative survey involved interviews with both patients and physicians, and identified 21 items covering all aspects of COPD that affect a patient's health [9].

Subsequent item-reduction and validation studies (partly using data from this survey) resulted in the final 8-item CAT questionnaire with good sensitivity and reliability [10].

This paper describes the properties of the CAT, tested in a European, cross-sectional health status study in a large population of COPD patients from primary care.

METHODS

Full details of the study design for this survey have been reported previously [11] and are summarised here.

This health related quality of life survey in COPD in Europe was a cross-sectional, epidemiological, non-randomised study, conducted by primary care practitioners (PCP) from Belgium, France, Germany, Italy, the Netherlands, Spain and the United Kingdom (UK). Patients with an established history of COPD (aged ≥ 30 years at diagnosis of COPD with a smoking history ≥ 10 pack years) were eligible. Patients with COPD, presenting at their PCP practices for any reason and who fulfilled the entry criteria, were invited to participate. Patients completed four health-related quality of life (HRQL) questionnaires at a single study visit including the St George's Respiratory Questionnaire – COPD specific (SGRQ-C) [6], the generic Short Form health survey (SF-12) [12], the Functional Assessment of Chronic Illness Therapy

(FACIT) Fatigue scale [13] and the 21 CAT candidate items. The investigator scored the patient's reported breathlessness using the Medical Research Council (MRC) Dyspnoea Scale [14]. Severity of COPD was assessed clinically by the PCP as mild, moderate, severe or very severe. GOLD stage severity was calculated retrospectively using lung function data obtained at or within six months of the assessment. An exacerbation was defined as a worsening of symptoms that required oral corticosteroids and/or antibiotics and/or hospitalization. The type and number of comorbidities were recorded. Patients with cardiovascular co-morbidities were defined as those with at least one of: myocardial infarction, stroke, heart failure, treated hypertension, treated angina pectoris or treated arrhythmia. All study related assessments, including completion of the HRQL questionnaires, were completed at the single study visit in the primary care practice. The questionnaires were completed after all other assessments had been conducted.

Only the results related to CAT will be further discussed in this paper as other results have been previously reported [11].

CAT Questionnaire

In this study, the 21 candidate CAT items were administered to all patients. Data from a sample of these patients, together with data from patients in the US were used to identify the 8 items that form the CAT [10]. The analysis presented here is confined to the eight items that now form the CAT. These 8 items cover: cough, phlegm, chest tightness, breathlessness going up hills/stairs, activity limitations at home, confidence leaving home, sleep and energy.

Each item is scored from 0 to 5 giving a total score-range from 0 to 40, corresponding to the best and worst health status in patients with COPD respectively. The CAT is designed to assess current health and does not specify a recall period. All translations of the CAT items from English were carried out with careful translation and back translation, followed by full linguistic and cultural validation and finally international harmonisation to ensure that the concepts contained in the items were the same regardless of language.

Statistical analysis

Sample size calculations for this study have been presented elsewhere [11]. Descriptive statistics, analysed using Statistical Analysis Systems version 9.1.3 software (SAS Inc, Cary, USA), were used to report baseline characteristics and distribution of HRQL questionnaire scores for the whole study population and subgroups split by country, demographic factors, COPD clinical status, GOLD Stage and reported comorbidities.

Comparisons between classes of other impairment measures were tested using Student's t-test. A two factor analysis of variance (ANOVA) was performed to check differences in CAT scores across countries.

Correlations between CAT score and other impairment measures were calculated using Spearman's rank correlation coefficient. Scatter plots and regression equations were also presented to further interpret these relationships. Tests for an effect of country on the relationship between CAT score and other HRQL measures were performed using a general linear model. These multivariate models were re-run excluding the data from Italy

and UK to check for the potential influence of these two smallest-recruiting countries on the power of the related statistical tests in these models.

For all statistical tests, the applied comparison-wise significance level was 0.05.

RESULTS

Patient characteristics

Patient flow through the survey is shown in Figure 1. Results for this manuscript are based on the 1817 patients who had an age at diagnosis of COPD ≥ 30 years, smoking pack years > 10 , had completed at least one health outcomes questionnaire and who fulfilled the GOLD criterion by demonstrating $FEV_1/FVC < 70\%$.

The clinical characteristics of this population have been described previously [11], and are summarised in Table 1. In brief, the majority of patients were male with a mean age of 65 years, mean smoking pack years of 40 and mean FEV_1 of 1.6L (56.7% of predicted). The proportion of patients reporting an exacerbation at the study visit, increased with increasing COPD severity, based on GOLD staging. There was no difference in the numbers of exacerbations reported in the 6 months before the study between GOLD Stages I and II, however, there was a stepwise increase between Stages III and IV.

COPD Assessment Test (CAT) scores

CAT scores showed significant impairment in health status across all COPD severities, even in patients with mild disease, regardless of whether severity was assessed by PCP or classified by GOLD Stage (Figure 2). There was

wide variation in health status impairment within each severity group, demonstrated by large standard deviations around the mean score.

There were no differences in CAT scores between males: 17.6 (95% CI 17.2, 18.1) and females: 18.0 (95% CI 17.3, 18.8), or between younger (≤ 65 years): 18.0 (95% CI 17.4, 18.5) vs. older: 17.5 (95% CI 17.0, 18.1) patients (see online supplementary table).

Effect of exacerbations and comorbidities on CAT scores

At the time of the study, 237 patients were experiencing an exacerbation; in these patients CAT scores were significantly higher (i.e. worse health status) than in patients who were stable (Figure 3). The presence of ≥ 3 reported comorbidities was associated with significantly worse health status (higher CAT scores) compared with none or 1-2 comorbidities (Figure 3). There was no difference in CAT scores between patients with or without cardiovascular comorbidities (Figure 3).

CAT scores by country

CAT scores in all countries showed an approximately normal distribution, as evidenced by the similarity between mean and median values in Table 2.

There was relatively little difference between countries, since the difference between the country with the highest mean score and that with the lowest was only 23% of the mean across all the countries (Table 2). It should be noted that the analyses in this paper were re-run after excluding patients from Italy and UK since these formed $<5\%$ of the total, but the results were no different, so we have reported the intention-to-study population.

Association between CAT scores and other COPD impairment measures

The difference in CAT score between GOLD Stages I and II was small and not statistically significant (Table 3). By contrast, the difference between PCP-judged clinical severity grades mild and moderate was significant (Table 3). CAT score differences between GOLD Stages II-III and III-IV were significant. For PCP-rated clinical severity, there was a consistent difference in CAT score between all stages of severity (Figure 2). The relationship between CAT score and GOLD stage, was similar across countries, as shown by a non-significant ($p=0.40$) effect of country as an interaction term in an ANOVA that tested the relationship between CAT and GOLD stage. This finding remained unchanged when the models were re-run without the data from Italy and UK. CAT scores clearly distinguished between SGRQ score categories (quartiles); the differences between all categories was statistically significant (all $p<0.0001$) (Table 3). CAT scores also showed significant differences between MRC dyspnoea scale grades (Table 3).

The CAT score was strongly correlated with SGRQ total score ($r=0.84$) (Figure 4) and showed moderate to strong correlations with generic HRQL questionnaires: SF-12 PCS: $r= -0.65$; SF-12 MCS: $r= -0.58$ and FACIT: $r= -0.77$. In contrast, the CAT score had only a weak negative correlation with FEV₁ percent predicted (Figure 4).

The strength of these correlations varied between countries, however when tested in a general linear model, the slope of these relationships did not differ significantly between countries

DISCUSSION

This paper summarises the performance of the disease-specific CAT questionnaire in a large population of COPD patients from primary care,

across all severities of airway obstruction. Results showed significant impairment in health status that was related to COPD severity, whether based on GOLD spirometric staging, clinician-judged severity, MRC Dyspnoea score, or disease-specific or generic health status scores. The study also confirmed an observation made in a much smaller number of patients in secondary care [10], that patients presenting to their primary care physician with an exacerbation have worse health scores than those who are stable. The proportion of patients presenting with an exacerbation, and the relative frequency of severe exacerbations within those patients was higher in patients with higher CAT scores.

The CAT scores were the same in males and females and were not influenced by age. This suggests that symptoms and health status impairment are the main drivers for patients' attendance in primary care, rather than demographic factors. This would also explain the high CAT scores seen in patients with GOLD Stage I. The presence of ≥ 3 comorbidities was associated with higher scores, compared with patients with two or less comorbidities, but the difference in score was relatively small (approx 2.5 units or $<15\%$ of the score of patients with 0-2 comorbidities). These findings suggest that the CAT is not affected by low levels of comorbidity. The relationship between high levels of comorbidity and higher CAT scores is consistent with the observation that comorbidity rates are similar in GOLD stages I and II but are higher in GOLD III and IV disease [15]. Cardiovascular comorbidity, as defined here, did not influence the CAT score, even though 50% of patients were diagnosed with either a cardiovascular comorbidity that

was potentially symptomatic or multiple cardiovascular comorbidities simultaneously.

One of the most notable findings of the current survey was the small difference in health status impairment between patients in GOLD Stages I and II, seen with the CAT. Similarly, only small differences between these two GOLD stages were seen with the SGRQ-C, SF-12, proportion of patients with high MRC grades and frequency of exacerbations [11]. It is noteworthy, however, that the CAT scores were clearly different between patients rated by their physicians to be mild or moderate, suggesting that physicians take more than just the degree of airway obstruction into account when assessing COPD severity. These results suggest that the CAT provides a standardised assessment of the severity of the patient's disease that is complementary to spirometry, which may be especially important in patients who have mild-moderate airflow limitation. Spirometry is clearly insufficient for a precise phenotyping of COPD patients, as recently demonstrated by studies using cluster analysis [16-18], highlighting the need for a multidimensional assessment of COPD. Short questionnaires such as the CAT are likely to offer relevant alternatives to complex tools such as the SGRQ, providing PCPs with a comprehensive and objective, but not time-consuming, assessment.

One of the limitations of the current survey is that the 8 items that form the CAT were presented to the patients along with 13 other candidate items that were eventually excluded from the final questionnaire. It is possible that the responses may be slightly different when the eight items are presented alone, but this effect is likely to be small. The extremely strong correlation between

CAT and SGRQ, reported in this and an earlier analysis [10] suggest that the patients' responses to these 8 items were valid. Indeed, the high correlation between SGRQ and CAT is remarkable considering the fact that they were developed using entirely different methodologies and have very different structures, layouts and response formats. This suggests that the underlying construct that they were both designed to test i.e. 'health status impairment due to COPD', is a valid entity. Perhaps the most important contribution of the CAT is that it brings this type of assessment into the arena of routine practice. A further limitation was that this was a cross-sectional study, so it provides no indication of the responsiveness of the CAT over time and there is as yet, no study derived information on a minimally important clinical difference for CAT. Another limitation of the study is that countries were chosen on the basis of representing large COPD populations, and were all from Western Europe, so not all European countries are reflected in the dataset. There were also some differences between countries in patient numbers. However the results of the between-country comparisons are encouraging and suggest that with careful translation into other languages, the measurement properties of the CAT described here should be reliable.

Unlike the physician's judgement of clinical severity, the CAT provides a standardised assessment and a numerical estimate of disease impact which appears to be reliable across languages and countries. It is, however, only one part of the clinician's toolkit, to be used alongside spirometry, exacerbation history and an assessment of comorbidity. Like any clinical assessment technique, its utility will only become fully apparent with time, but this study provides some evidence that the CAT will provide the practising

physician with a reliable tool with which to measure the impact of COPD on their patients.

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Table 1. Demographic and Clinical Characteristics of COPD Patients

Characteristic	GOLD Staging ¹				Reported Population (N=1817)
	I (N=223)	II (N=868)	III (N=551)	IV (N=144)	
Age (years)	65.3±9.7	65.0±9.8	65.0±9.5	63.3±9.5	64.9±9.6
Male sex, n (%)	144 (64.6)	610 (70.3)	413 (75.0)	122 (84.7)	1305 (71.8)
Duration COPD (years)	8.4±6.6	8.8±6.7	10.4±7.5	10.3±6.4	9.4±7.0
Smoking pack years	36.9±21.2	39.2±21.6	42.4±27.7	43.8±29.6	40.4±24.4
Exacerbations on study day, n (%):					
Stable disease	204 (91.5)	777 (89.5)	461 (83.7)	110 (76.4)	1580 (87.0)
Exacerbation	19 (8.5)	91 (10.5)	90 (16.3)	34 (23.6)	237 (13.0)
Exacerbations in last 6 months, n (%), requiring:					
Antibiotics	117 (52.5)	458 (52.8)	318 (57.7)	93 (64.6)	1005 (55.3)
Oral corticosteroids	66 (29.6)	276 (31.8)	205 (37.2)	70 (48.6)	632 (34.8)
Hospitalisation	15 (6.7)	56 (6.5)	72 (13.1)	31 (21.5)	175 (9.6)
FEV ₁ (L)	2.4 (0.5)	1.8 (0.4)	1.1 (0.3)	0.7 (0.2)	1.6 (0.6)
FEV ₁ % of predicted	92.2 (11.8)	63.3 (8.3)	40.6 (5.5)	24.1 (4.6)	56.7 (20.1)
SGRQ ² Total score	38.5±19.3	40.4±18.1	50.2±18.6	58.6±17.7	44.7±19.4
SF-12 ³					
PCS	39.8±8.8	39.3±8.7	35.7±8.7	31.7±8.8	37.7±9.1
MCS	47.4±11.8	47.9±11.3	47.0±12.0	43.7±12.9	47.2±11.8
FACIT ⁴	36.4±11.0	36.3±10.8	32.5±12.1	28.7±12.1	34.5±11.6
MRC dyspnoea scale ⁵ , n (%):					
1	65 (29.1)	207 (23.8)	55 (10.0)	15 (10.4)	344 (18.9)
2	88 (39.5)	392 (45.2)	180 (32.7)	23 (16.0)	694 (38.2)
3	42 (18.8)	181 (20.9)	166 (30.1)	29 (20.1)	427 (23.5)
4	25 (11.2)	70 (8.1)	125 (22.7)	43 (29.9)	271 (14.9)
5	3 (1.3)	17 (2.0)	24 (4.4)	34 (23.6)	79 (4.3)

Data presented as mean±SD unless otherwise stated; ¹FEV₁ (% predicted) is missing for 31 patients, therefore they are not classifiable into GOLD stages.

Abbreviations: FEV₁=forced expiratory volume in one second. FVC=forced vital capacity; SGRQ=St George's Respiratory Questionnaire; SF-12=Short Form health survey; PCS=Physical component score; MCS=Mental component score; FACIT-F=Functional Assessment of Chronic Illness Therapy Fatigue scale; MRC=Medical Research Council. Scoring: ²SGRQ total score: a lower score represents a better QoL; ³SF-12 scores: a higher score represents a better QoL; ⁴FACIT fatigue scores: a higher score indicates less fatigue; ⁵MRC scale: a lower score indicates less breathlessness

Table 2. CAT scores by country

CAT score	Belgium (N=199)	France (N=383)	Germany (N=621)	Italy (N=11)	NL (N=139)	Spain (N=393)	UK (N=71)	Reported Population (N=1817)
Mean±SD	18.8±9.2	18.5±8.5	18.8±7.7	19.9±8.2	14.6±7.7	15.9±8.7	17.8±8.2	17.7±8.4
P25	11.0	12.0	14.0	14.0	8.0	9.0	12.0	11.0
Median	18.0	18.0	18.0	18.0	15.0	15.0	16.0	17.0
P75	25.0	24.0	24.0	25.0	20.0	21.0	24.0	24.0

CAT=COPD Assessment Test; P25= 25th percentile; P75= 75th percentile

Table 3. Differences in CAT scores between classes of other COPD impairment measures

	Mean CAT score±SD	Mean difference between classes	p-value
GOLD Stage			
I	16.2±8.8	-0.1	ns
II	16.3±7.9	-3.0	<0.0001
III	19.3±8.2	-3.0	0.0001
IV	22.3±8.7		
PCP-rated COPD severity			
Mild	13.2±7.5	-3.4	<0.0001
Moderate	16.6±7.6	-4.7	<0.0001
Severe	21.3±8.1	-3.5	<0.0001
Very severe	24.8±8.9		
Mean total SGRQ score¹		-5.6-4.9	
≥0 and <30	9.4 ± 5.0	-7.8	<0.0001
≥30 and <45	15.0 ± 4.7		<0.0001
≥45 and <60	19.9 ± 5.3		<0.0001
≥60	27.7 ± 5.7		<0.0001
MRC dyspnoea grade			
1	11.7±6.8	-4.0	<0.0001
2	15.7±7.0	-4.8	<0.0001
3	20.5±7.5	-2.9	<0.0001
4	23.5±7.4	-3.9	<0.0001
5	27.3±8.3		

¹by SGRQ quartiles ; PCP=primary care physician; ns=statistically non-significant; SGRQ=St George's Respiratory Questionnaire; MRC=Medical Research Council.

Figures Legend

Figure 1: Patient Flow through the European HRQL survey [11]. ¹Health Outcomes Population consisted of patients with: (1) Age at diagnosis of COPD ≥ 30 (2) Number of pack years > 10 , and (3) At least one health outcomes questionnaire completed. ²Reported Population consisted of the Health Outcomes Population and demonstrating a FEV₁/FVC ratio $< 70\%$

Figure 2: CAT score by PCP-rated COPD severity and GOLD Staging.

Figure 3:

- a) CAT score by COPD status on study day (mean + SD) (stable disease [n=1580] versus exacerbation [n=237])
- b) CAT score by number of comorbidities (mean + SD) (0 [n=350], 1-2 [n=870], 3+ [n=597])
- c) CAT score by cardiovascular comorbidities (present¹ [n=1061] or absent [n=756]) (mean + SD). CV=cardiovascular.

¹defined as the patient having myocardial infarction, stroke or heart failure or patient being treated for hypertension, angina pectoris or arrhythmia

Figure 4:

- a) Scatter plot of correlation between SGRQ total score and CAT score.
Regression equation: CAT score = 1.54 + 0.36*total SGRQ (r= 0.84; p<0.001)
- b) Scatter plot of correlation between FEV₁ percent predicted and CAT score.
Regression equation: CAT score = 22.6 - 0.09*percent predicted FEV₁ (r= -0.23; p<0.001)

Figure 1: Patient Flow through the European HRQL survey

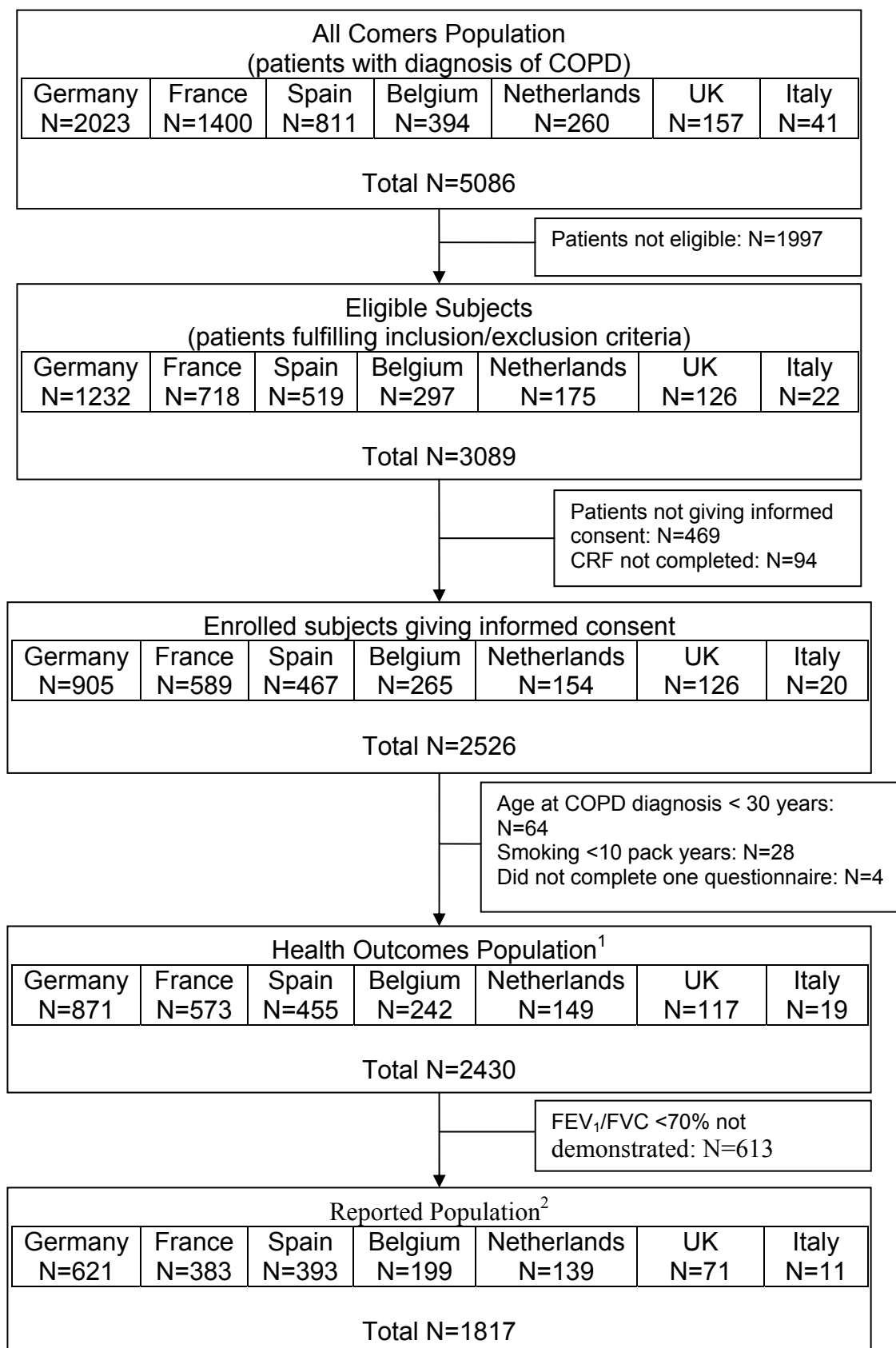


Figure 2: CAT score by PCP-rated COPD severity and GOLD Staging

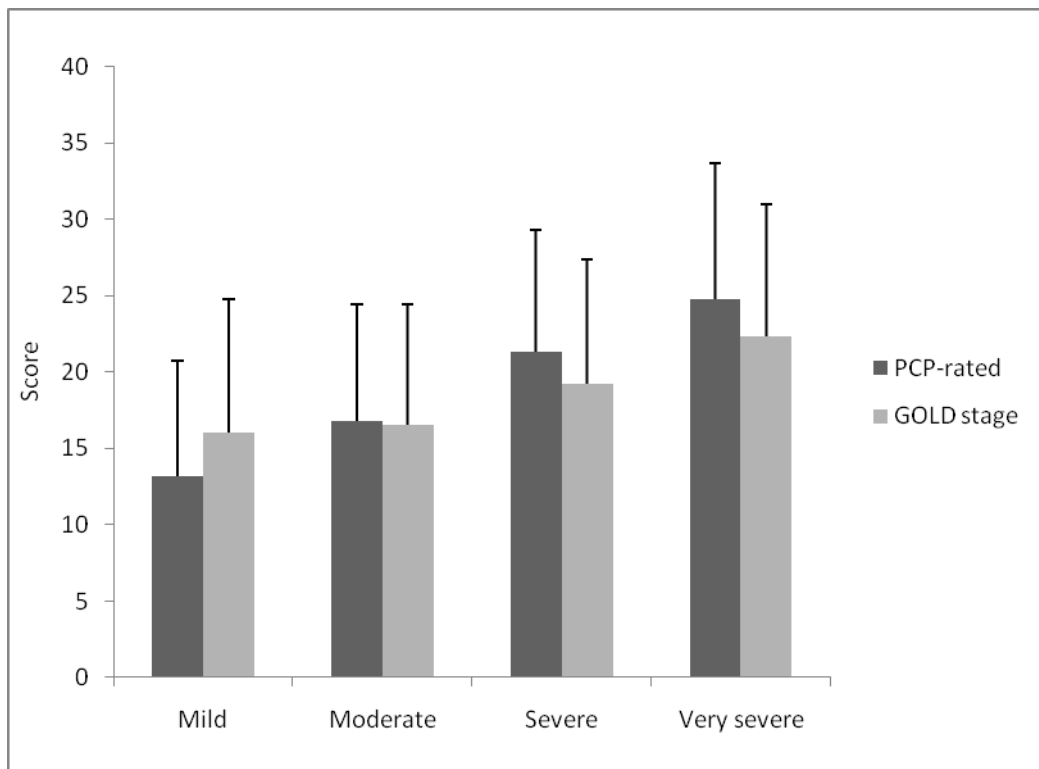
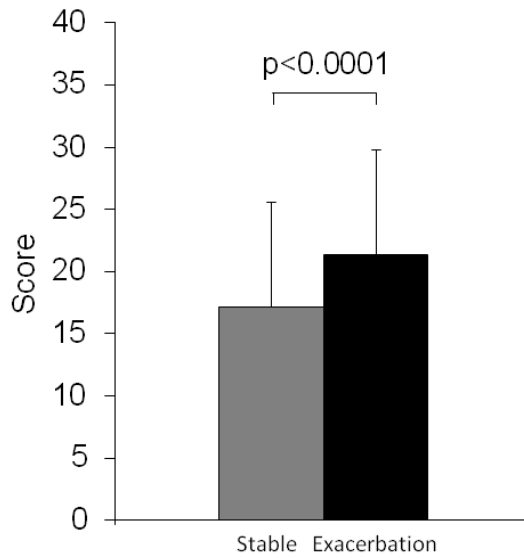
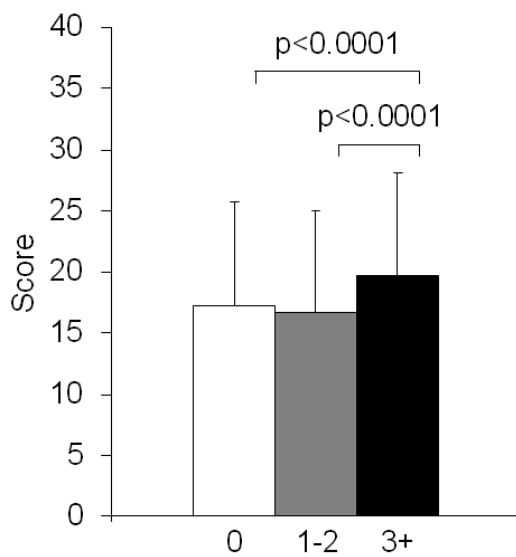


Figure 3

a) CAT score by COPD status on study day (mean + SD) (stable disease versus exacerbation)



b) CAT score by number of comorbidities (mean + SD)



C) CAT score by CV comorbidities

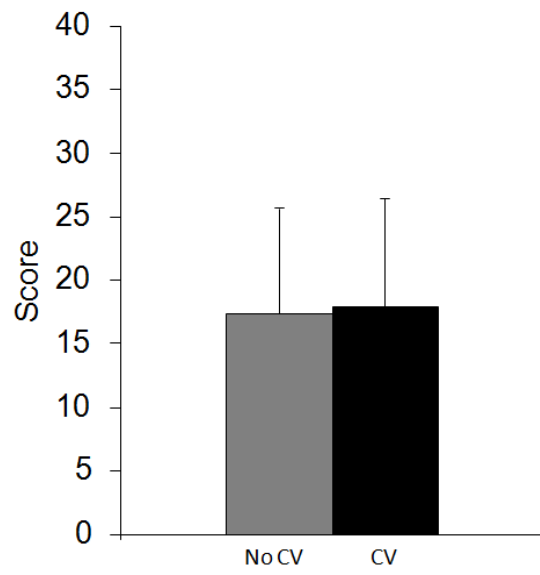


Figure 4a: Scatter plot of correlation between SGRQ total score and CAT score

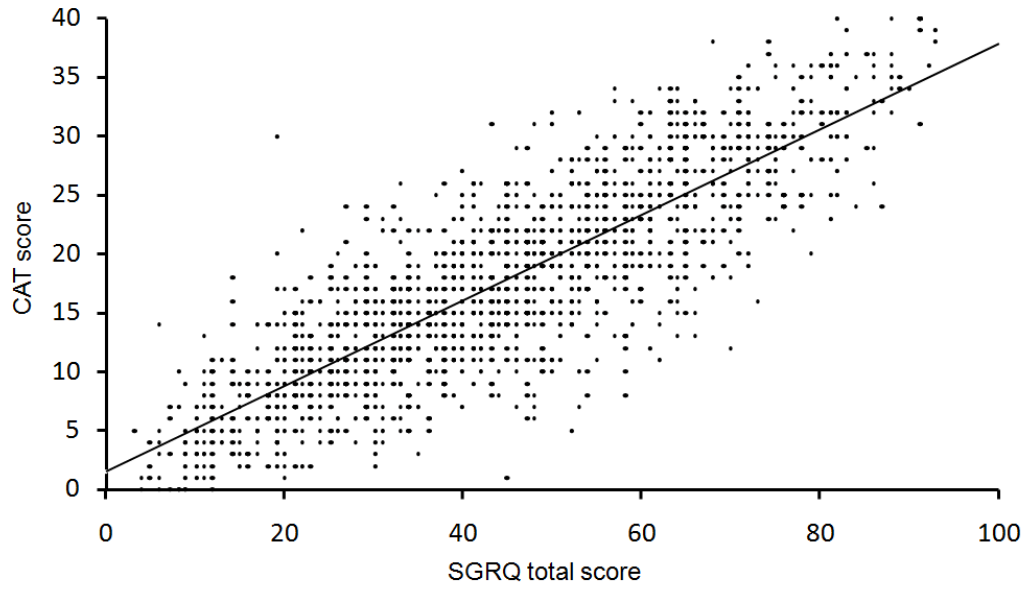


Figure 4b: Scatter plot of correlation between FEV1 percent predicted and CAT score

