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Validation of the COPD Assessment Test (CAT) in patients with idiopathic pulmonary fibrosis

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ABSTRACT

Introduction: Idiopathic pulmonary fibrosis (IPF) is a chronic disease with high morbidity and mortality. A reliable and manageable questionnaire that assesses patients' quality of life is needed to help to improve the content of clinical consultations. The chronic obstructive pulmonary disease (COPD) Assessment Test (CAT) is used in clinical practice; therefore, the aim of this study was to investigate correlations among the CAT, St. George's Respiratory Questionnaire (SGRQ) and clinical parameters among patients diagnosed with IPF.

Methods: A retrospective cohort design was employed in which 87 patients diagnosed with IPF who were receiving treatment at an outpatient clinic were included.

Results: The CAT was found to be significantly correlated with SGRQ (p < 0.001). Furthermore, the CAT was significantly correlated with all of the included physiological variables.

Conclusions: This add to support the validity of the COPD Assessment test (CAT) as a measure of symptoms in patients with IPF which in clinical practice in combination with dialogue between healthcare professionals and the patient, can help to improve the content of a clinical consultation.

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KEYWORDS

CAT; idiopathic pulmonary fibrosis; quality of life

Introduction

Idiopathic pulmonary fibrosis (IPF) is a chronic, progressive disease that is associated with increased morbidity and mortality [1], and is the most common type of idiopathic interstitial pneumonia (IIP). It accounts for approximately 55% of all new cases [2,3]. It is characterized by fibrotic scarring in the lung tissue subsequent to lung injury that remains poorly understood [1]. The incidence of IPF has been shown to be between 6.8 and 7.4 pr. 100.000 person-years [4,5], and seems to increase due to the ageing population and increased awareness of the disease among both patients and healthcare professionals [6,7]. IPF predominantly occurs in older adults, as it is uncommon under the age of 50 years, with a peak among people in their 80s [8].

Pulmonary fibrosis results in reduced lung volume and impaired diffusion capacity. The cardinal symptoms are increased exertional dyspnoea and dry cough. Progression of fibrosis leads to respiratory insufficiency and death [1,7,9–11]. Disease progress is often slow and occurs gradually over a few years. However, some patients experience an accelerated decline, with acute respiratory worsening and exacerbations [12,13]. It is the type of lung fibrosis with the highest mortality rate, as the median length of survival is 3–5 years [8–11,14], which means that IPF has a poorer prognosis than a number of malignant diseases [7,15]. In 2006, Gribbin and colleagues reported a 43% 5-year survival rate among patients with IPF, and Navaratnam later estimated a 5-year survival rate of 37% in 2011 [4,16].

It is known from patients with other life-threatening diseases that a relationship exists between the patients' experience of symptoms and quality of life [17] and that many patients experience symptoms that are under-treated [18]. A validated test that measures the impact of IPF on health as it is experienced in the patients' everyday life, therefore, is needed and may potentially contribute to improving future treatment and palliation for the single patient by more precisely targeting treatment and care.

The St. George's Respiratory Questionnaire (SGRQ) was originally developed to measure health-related quality of life among patients diagnosed with chronic obstructive pulmonary disease (COPD) and later was validated for use among patients with IPF [19]. However, this questionnaire is a research tool and too complex to use in daily clinical practice. Several validated tests are available for use with patients with

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COPD, a disease with symptoms that are similar to IPF. One of those is the COPD Assessment Test (CAT), which is a short instrument to quantify COPD's impact in practice [20]. The CAT has previously been tested and shown good psychometric properties among patients with a mixed group of ILD [21] but has not been tested among patients diagnosed with IPF. Given the overlap in symptoms between IPF and COPD and due to the lack of a short IPF-specific tool for symptom screening, we applied the CAT questionnaire in our daily clinical practice as an aid to improve systematically the content of clinical consultations of IPF patients.

The aim of this study was to investigate whether CAT score correlates with the SGRQ score and clinical parameters in patients with IPF.

Materials and methods

Study design

The study was designed as a retrospective cohort study.

Participants

Included in the study were patients diagnosed with IPF who were referred to the outpatient clinic at the Department of Respiratory Medicine at Gentofte University Hospital. The diagnosis was based on predetermined clinical, radiological, and histological criteria based on current international guidelines [1]. Consecutive patients with a definitive diagnosis of IPF were included if they had a consultation from October 2015 to April 2016 and had completed CAT questionnaire at the time of consultation.

Ethics

Approval to perform the study was obtained from the Danish Data Protection Agency (journal no. HGH-2016–049) and the Danish Health Authority (journal no. 3-3013-1586/1/).

Data

The demographic data that were collected from the patients' medical records were gender, age, and treatment with antifibrotic drugs. Furthermore, completed CAT, SGRQ, and the Medical Research Councils (MRC) scales were collected.

CAT

The CAT was developed in 2009. It is a self-administered QOL questionnaire that measures the impact of COPD on health status. It is relatively easy to complete and has been shown to be suitable for clinical use. It consists of eight items, each of which is scored on a scale from 1 to 5. The total score ranges from 0 to 40. Higher scores indicate a greater impact on the patient's life. The score is divided into four impact levels, with associated examples of how the patient is affected by the disease and proposals of management considerations [20]. The CAT questionnaire is provided in a Danish translation by the Danish Society of Respiratory Medicine and can be downloaded from https://www.lungemedicin.dk/fagligt/skemaer/143danishcatest.html. The English version is available from http://www.catestonline.org/images/pdfs/CATest. pdf. The CAT was validated for use with patients with COPD. The Cronbach's alpha value is excellent, and the instrument has good test-retest reliability and a high correlation with the SGRQ in American patients [20]. Positive correlations among the CAT, SGRQ, and MRC were found in Korean and Asian COPD patients [22,23] and in patients with ILD in a Japanese study with 55 patients, 15 of whom had IPF [21].

SGRQ

The SGRQ is a self-administered instrument. It consists of 50 items that can be divided into three categories: symptoms (8 items), activity (16 items), and impact (26 items). Scores are weighted; therefore, every domain score and the total score range from 0 to 100. Higher scores indicate poorer health-related quality of life. The scores are calculated after filling in an Excel file developed by the creators of the questionnaire [24,25]. The SGRQ is a validated tool for patients with airflow limitations [24]. Swigris and colleagues reviewed the literature and found that the SGRQ was useful for measuring HRQL in patients with IPF [25].

MRC

The MRC dyspnoea scale is a short scale with item scores ranging from 1 to 5, where the degree of dyspnoea is reported by the patient. A higher score indicates a larger impact of breathlessness on daily activities. In an English study with COPD patients, there were significant associations between the MRC and SGRQ [26]. Correlations between the MRC dyspnoea scale and lung function parameters have been found in patients with IPF [27].

Physiological variables

Phsychological variables were forced vital capacity (FVC), forced expiratory volume in 1 sec (FEV1), and diffusion capacity of the lung for carbon monoxide (DLCO). The 6 Minutes' Walking Distance (6 MWD) test was performed indoors in a long, straight corridor according to international guidelines [28] without oxygen or with the patient's current oxygen flow if he or she was receiving home oxygen therapy. SpO₂ was measured before and immediately after walking for 6 min, and the difference was calculated.

Gender, age, and physiology GAP index

The GAP index is a staging system for IPF based on a point score that is calculated based on the patient's gender, age and physiological variables (FVC and DLCO). Ley and colleagues found that GAP index correlated well with 1-year mortality among patients with IPF [29,30].

Statistical analysis

The data were analysed using SPSS (version 19) (SPSS Inc., Chicago, IL, USA). The characteristics of participants are presented as numbers or means and using descriptive statistics to include percentages or standard deviations. The correlation between the CAT and SGRQ was initially inspected using a scatterplot. This was followed by an analysis of the correlation between the scores on the CAT and SGRQ and the other outcome measures using Spearman's correlations coefficients.

Results

Patient characteristics

The study included 87 patients with IPF who had a mean age of 70.1 years (SD = 10.1). Table 1 shows the characteristics of the included patients. There were slightly more men (62%) than women. When the data were collected, 42 patients were treated with pirfenidone, 5 patients were treated with nintedanib, and 40 patients were not on treatment, either because they were assessed before treatment start or they have declined antifibrotic therapy. The severity of IPF was graded according to the GAP score, 37 patients had mild IPF (GAP 1), 38 had moderate IPF (GAP 2) and only 7 had severe IPF (GAP 3). Figures 1 and 2 show the distribution of the SGRQ and CAT scores in relation to the GAP index. Assessing both figures visually, patients who belong to GAP index 2 had scorings covering almost all

Table 1. Characteristics of the study	population, 87 patients
with idiopathic pulmonary fibrosis.	

	N (%) or Mean (SD)
Male	54 (62 %)
Age (years)	70.1 (10.1)
Treatment	
Pirfenidone	42 (48.3 %)
Nintedanib	5 (5.7 %)
None	40 (46.0 %)
FVC (litre) ¹	2.88 (0.85)
FEV1 (%) ²	84.21 (19.76)
CAT	16.76 (6.83)
DLCO (%) ³	45.01 (13.16)
6 MWD (m) ⁴	424.6 (108.1)
Saturation before 6 MWD ⁴	95.23 (2.37)
Saturation after 6 MWD ⁴	84.39 (7.99)
GAP Index ⁵	1.63 (0.64)
MRC ⁶	2.69 (1.08)
SGRQ Symptoms ⁷	54.05 (21.18)
SGRQ Activity ⁸	57.45 (24.12)
SGRQ Impact ⁹	33.88 (19.57)
SGRQ Total score ¹⁰	45.09 (19.76)

¹6 values missing; ²7 values missing; ³7 values missing; ⁴31 values missing;
 ⁵5 values missing; ⁶32 values missing; ⁷41 values missing; ⁸40 missing;
 ⁹43 missing; ¹⁰46 values missing.

possible values in both the CAT score and the SGRQ score. Univariate analysis showed a significant increase in disease impact in the different GAP grades, whether assessed by SGRQ (p = 0.013) or CAT score (p = 0.03).

Correlations

The correlation between the CAT score and SGRQ score was initially inspected visually in a scatterplot to look for a possible relationship between the two variables (Figure 3). The Spearman's correlation coefficient was r = 0.8 (p < 0.001), indicating that the two scores shared approximately 64% of the variance. Table 2 shows the Spearman's correlation coefficients between the CAT and SGRQ scores in combination with the physiological variables. The CAT score was significantly correlated with all physiological variables. The SGRQ total score was significantly correlated with the FVC, FEV1 (%), 6 MWT distance and MRC. The SGRQ did not show significant correlation with FEV1, DLCO and Desaturation at 6 MWD, as did the CAT score. Neither the CAT nor the SGRQ was significantly correlated with age.

Discussion

In this study, we found a strong correlation between the CAT score and SGRQ score, indicating that it is feasible to use the test to measure health-related quality of life among patients with IPF. The CAT score generally showed higher correlations with physiological parameters than the SGRQ score, supporting its validity as a test to assess the impact of IPF on health status. Interestingly,

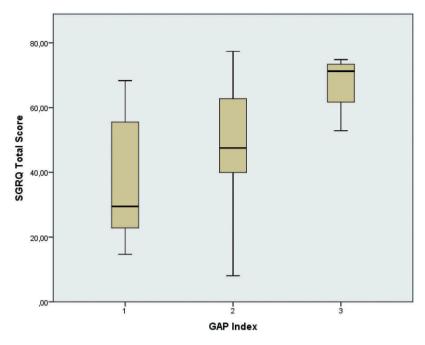


Figure 1. Distribution of the SGRQ total score according to the GAP index in patients with IPF (GAP index 1 n = 37, GAP index 2 n = 38, GAP index 3 n = 7). SGRQ – The St. George's Respiratory Questionnaire, IPF- Idiopathic Pulmonary Fibrosis, GAP Index – Gender, age and physiology.

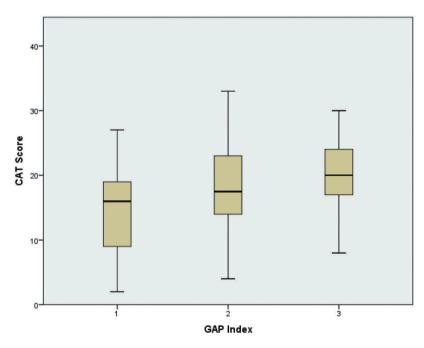


Figure 2. Distribution of the CAT score according to the GAP index in patients with IPF. (GAP index 1 n = 37, GAP index 2 n = 38, GAP index 3 n = 7) SGRQ – The St. George's Respiratory Questionnaire, IPF- Idiopathic Pulmonary Fibrosis, GAP Index – Gender, age and physiology.

desaturation at 6 MWT, which is a prognostic parameter in IPF, only showed significance in relation to CAT.

The results are supported in a recent study from Japan, where Matsudo and colleagues also found that the CAT was significantly correlated with SGRQ score in a group of patients with IPF [31].

Symptoms such as dyspnoea [32] and physiological parameters such as DLCO [33] and 6 MWD [34] have been shown to correlate with quality of life among patients with IPF. In our study, the CAT score correlated to more physiological parameters than the SGRQ score did, indicating that it may provide a better

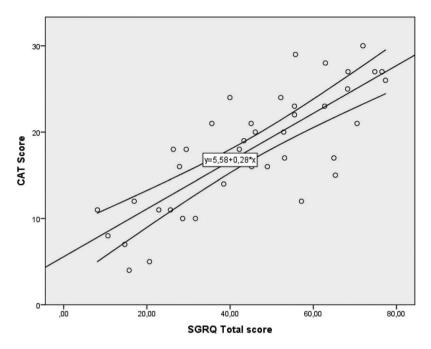


Figure 3. Correlation between the CAT and SGRQ total scores in patients with IPF. Pearson correlation 0.8

SGRQ – The St. George's Respiratory Questionnaire, IPF- Idiopathic Pulmonary Fibrosis, GAP Index – Gender, age and physiology.

 Table 2. Spearman correlations between the CAT and SGRQ scores and physiological variables in patients with IPF.

	CAT	SGRQ total score
Age	053	008
FVC	338**	339*
FVC (%)	425**	433**
FEV1	252*	127
FEV1 (%)	323**	367*
FEV1/FVC	.0162	.229
DLCO	346**	299
DLCO (%)	348**	280
6 MWD	582**	796**
MRC	.646**	. 805**
CAT		.8**
Desaturation at 6 MWD	.679**	.06

**Correlation is significant at the 0.01 level (2-tailed).

*Correlation is significant at the 0.05 level (2-tailed).

picture of patients' health-related quality of life, even though it is short and simple.

Patients with IPF are highly affected by the chronic, progressive disease, given its high morbidity and mortality. The lung tissue changes irreversibly, which results in symptoms such as dyspnoea and dry cough, which again affect patients' everyday life. It has been shown that patients have a clear understanding of their prognosis but lack assistance with understanding how their disease will progress [35]. Exploring the patients' perspective, Overgaard and colleagues found that the fatality of the disease was overwhelming for patients and, therefore, the dose and timing of information are tricky [36]. Sampson and colleagues showed that the patients' initial relief associated with not being diagnosed with cancer was replaced by shock associated with the prognosis of IPF [35]. Clinical encounters, timely identification of changes in health status and functional activity and understanding of symptoms influence patients' experiences of care. Therefore, the use of a standardized questionnaire such as the CAT score cannot stand alone. Instead, it must be accompanied with dialogue among the patient, patient's family and health care professionals.

Given the lack of a disease-specific questionnaire for IPF, other health-related quality of life tools have been tested among patients with IPF. The Patient-Reported Outcome Measurement Information System (PROMIS), with the exception of sleep disturbance, has shown the ability to generate scores with a high level of sensitively in relation to the MRC [37]. Other available questionnaires are the Tool to Assess Quality of Life in Idiopathic Fibrosis (ATAQ-IPF) [38]. The SGRQ-I, which is an IPF-specific version of the SGRQ [19], and King's Brief Interstitial Lung Disease (K-BILD) questionnaire [39] also exist. However, they have not been independently validated and are not widely used, and the K-BILD does not include questions about cough, a cardinal symptom in IPF patients. Currently, studies are needed to evaluate and validate all four questionnaires, although the reliability and validity of the SGRQ-I were found to be acceptable and comparable to the original SGRQ.

In addition to assessing health status and quality of life in IPF research, there is an urgent need for a reliable and valid tool for use in routine clinical practice. We needed a short and simple questionnaire that is available in Danish to facilitate our clinical evaluation of IPF patients. CAT is translated into many different languages, and therefor available in many cultural contexts. The focused information on daily symptoms, activity limitations, and disease impact guides consultations on patient-related outcomes and the optimal management plan in the time available for consultation. Nevertheless, whereas it was originally a COPD questionnaire, we chose the CAT for the aforementioned reasons. In fact, the CAT includes items that are valuable for assessing IPF, including fatigue and sleep quality, which are not available in diseasespecific questionnaires [39].

There are some limitations in the present study. The CAT score was assessed using a Danish translation and even though it seems as though the scores across other European countries showed no significant difference in reporting [40], a published study of the validity and reliability of the Danish translation was not found. A relatively high number of values related, to SGRQ, to 6 MWD (and saturation before and after the test), and the MRC were missing. Although this was anticipated due to the poor physical condition of some of the included patients, it obviously influenced the strength and quality of our findings. The results from this study must be further validated before they can be considered generalizable due to limited number of patients with severe symptoms.

Conclusions

In conclusion, results support the validity of the CAT as a measure of symptoms in patients with IPF and correlates both to SGRQ and important physiological parameters in this group of patients.

Geolocation

The study was performed in the capital region in Denmark.

Disclosure statement

No potential conflict of interest was reported by the authors.

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