

The Development and Validation of a New Questionnaire to Address the Gap between the Actual and Desired States in COPD Patients

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Abstract

Background: Numerous quality of life (QOL) assessment tools are available for patients with chronic obstructive pulmonary disease (COPD); however, most only focus on the patient's actual state, and very few assess the patient's desired state.

Objective: To develop a questionnaire that can assess COPD patients' desired states and to verify the usefulness of the findings.

Methods: We interviewed COPD patients to identify components that best reflected the patients' desired movement/activities. Two types of questionnaires were created with each component intended for self-assessment by actual and desired states. The revised questionnaire included the appropriate components based on the results of the preliminary survey. A multicenter study was performed using the final questionnaire.

Results: We selected 32 components of the patients' desired movement/activity from interviews with 22 COPD patients. The final questionnaire consisted of eight components and had a sufficiently high internal consistency (Cronbach's $\alpha > 0.8$). Three hundred and sixty two COPD patients participated in the validation study. The gap score (the difference between actual and desired scores) was significantly correlated with the predicted percentage of the forced expiratory volume in 1 s, dyspnea scale, and the COPD assessment test (CAT) ($p < 0.0001$). Oxygen therapy and frequent exacerbations exhibited unfavorable gap scores ($p < 0.001$). Multiple regression analysis on actual scores identified dyspnea scale, CAT, oxygen use, unemployment, exacerbation and heart failure to be independent explanatory variables (adjusted $R^2=0.63$). Whereas only dyspnea scale and CAT were significant predictors in gap score (adjusted $R^2=0.32$).

Conclusion: The gap and actual scores evaluate the different aspect of the patients' state. Evaluating the gap scores in patients might be useful in the assessment of the suitability of ongoing medical interventions and in the determination of future therapeutic goals.

Keywords: COPD; QOL; Gap; Questionnaire

Abbreviations:

HRQOL: Health Related Quality of Life; COPD: Chronic Obstructive Pulmonary Disease; CAT: COPD Assessment Test; PROs: Patient-Reported Outcomes; FEV₁: Forced Expiratory Volume in 1 Second; FVC: Forced Vital Capacity; mMRC: Modified Medical Research Council; 6MWT: 6-Minute Walking Test; LTOT: Long-Term Oxygen Therapy; CHF: Chronic Heart Failure; SDs: Standard Deviations

Introduction

Chronic Obstructive Lung Disease (COPD) is a global health problem and Japan is no exception. The incidence rate of COPD in

Japan is 0.81 per 100 person-years for males and 0.31 per 100 person-years for females, and increases significantly with age. Its incidence rate in Japan is similar to those reported in Europe [1]. The population of Japan is expected to shrink from 128 million in 2005 to 95 million in 2050, while the proportion of people aged 65 years or older is expected to rise to 40% [2]. Because of this expected increase in the number of older adults, it is necessary to maintain good communication with elderly patients to continue the treatment of chronic diseases. Humanistic approach, respect, and people-focused attitude are critical for good communication with COPD patients [3].

Furthermore, the importance of improving health related quality of life (HRQOL) and preventing future risks has been emphasized for the management of patients with COPD in the Global Initiative for Chronic Obstructive Lung Disease (GOLD) document and the Japanese Respiratory Society guidelines [4,5]. Therefore, it is

imperative to evaluate the HRQOL of patients with COPD in common practice.

The term QOL covers a wide variety of concepts and there is no consensus on its definition. QOL is dependent on the similarity of the patient's desires to their actual experience and can be improved by reducing the gap between the desired state and the actual state [6]. Furthermore, the World Health Organization defined QOL as the "individuals' perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns" [7]. Numerous QOL assessment methods are based on this basic concept, from generic types to disease-specific types, and such methods for COPD are presently close to becoming established.

To assess the HRQOL in COPD patients, the St. George's Respiratory Questionnaire [8] and the Chronic Respiratory Disease Questionnaire [9] have been established as disease-specific tools. These have been utilized in the assessment of not only the pharmacological effects of new drugs, but also a variety of other aspects including the effects on disease worsening [10], rehabilitation [11], and correlation with the outcomes [12]. More recently established tools include those that are universally simple and easy-to-use, such as the COPD assessment test (CAT) [13]. These HRQOL assessment tools provide important information concerning the patient-reported outcomes (PROs) and objectively present one aspect of the patient's condition.

However, these tools do not generally focus on the extent to which the patients want to improve their well-being or their desired health condition [14]. Studies that focus on the patient's desires are limited. The desired physical condition of a COPD patient will be dependent on various factors, including disease severity and living conditions. Furthermore, setting a therapeutic goal by incorporating an individual's unique desires would be useful in planning specific actions in daily life.

In the present study, we developed a new-approach questionnaire for the evaluation of patients' desires to help determine a COPD therapy goal from the patient's perspective.

Methods

Two studies were performed. Study I involved the development and validation of a new questionnaire, and Study II involved a large-scale validation of the new questionnaire in related facilities. Patients with COPD from authors' institutions and from the institutions participating in the Japan Asthma and COPD management Forum (JASCOM) were recruited in the present study. The inclusion criteria were the medical diagnosis of COPD, post-bronchodilator forced expiratory volume in 1 second (FEV₁)/forced vital capacity (FVC) <70%, at least 40 years of age, and history of smoking for at least 10 pack-years.

Study I: The questionnaire development

A flow chart representing the questionnaire development process is presented in Figure 1. We initially conducted a survey on COPD patients under routine practice to understand their desired living conditions. Based on these results, we selected the appropriate components to create an initial version of the questionnaire where each component had to be answered considering both the actual and desired states. After conducting a preliminary survey using the initial version, we created a modified version of the questionnaire by limiting

it to a smaller set of components and by adopting a five-point assessment scale. Subsequently, cluster analysis was performed to finalize the questionnaire.

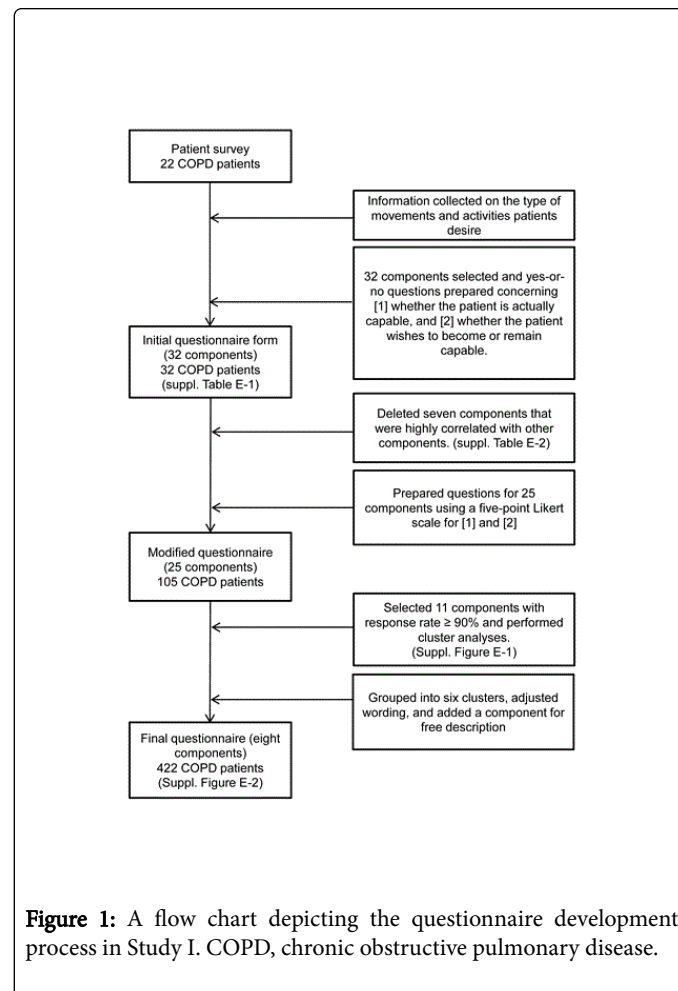


Figure 1: A flow chart depicting the questionnaire development process in Study I. COPD, chronic obstructive pulmonary disease.

Initial patient interview: A qualitative focus-group interview was conducted among a sample population of symptomatic adults with COPD. Twenty-two subjects aged 55-77 years were recruited from the Tokyo metropolitan or Kansai regions. The patients were divided into 5 age groups containing 4 or 5 patients each (3 groups in Tokyo: 50s, 60s, and 70s; 2 groups in Kansai: 50-60s and 60-70s). Each interview was conducted over a period of 2 h. Patients were asked to speak freely about their desired activities and daily living conditions. The patients were particularly questioned on their present concerns and what they wanted to do in the future. The interviews were audio-recorded and content analysis was applied to the transcripts in order to derive the item pool. Based on the information obtained from the audio recordings, we extracted the movements and activities desired by the patients. These interviews were carried out based on the advice of the Japan Management Association.

Initial questionnaire: The first version of the questionnaire consisted of the initial patient interview components involving two types of questions: 1) 'yes' or 'no' questions relating to the ability of the patient to perform a specific movement/activity, and 2) 'yes' or 'no' questions relating to the patient's desire to perform a specific movement/activity or the maintenance of performing that movement/activity. Using the first version of the questionnaire, we subsequently conducted a

preliminary survey among COPD patients treated as outpatients at the Tohoku Medical and Pharmaceutical University Wakabayashi Hospital.

The modified questionnaire: The modified questionnaire contained some of the first version components that were selected based on the results of the preliminary survey. Each component was answered according to a 5-point Likert scale for actual and desired states (completely capable–0 point, highly capable–1 point, somewhat capable–2 points, poorly capable–3 points, not capable–4 points). Using this modified version, we conducted another preliminary survey on the COPD patients from the authors' five institutions.

Preparation of the final questionnaire: To reduce the number of items in the modified questionnaire, we selected the components that achieved at least a 90% response rate (thereby allowing high discrimination). After item selection, cluster analysis was performed using the Ward method [15]. We created a final questionnaire based on this result. The difference between the actual state score and the desired state score was defined as the gap score.

Study II: Cross-sectional survey

Using the final version of the questionnaire, we conducted a cross-sectional survey of outpatients diagnosed with COPD at 25 institutions participating in the JASCOM between January and March 2013. We also investigated the lung function (FEV_1/FVC and $FEV_1\%$ predicted), CAT scores, modified Medical Research Council (mMRC) dyspnea scale scores, 6-min walking test (6MWT) results, co-morbidities, long-term oxygen therapy utilization, frequency of exacerbations in the previous year, employment status, and family composition of each patient surveyed. The severity of airflow obstruction was classified as stage I, II, III, or IV depending on the percentage of the predicted post-bronchodilator $FEV_1\%$. Exacerbation was defined as "an acute event characterized by the worsening of the patient's respiratory symptoms that is beyond the normal day to day variation and leads to a change in medication", in the Japanese Respiratory Society COPD guidelines [5]. Data regarding exacerbations were collected using chart-review at each institution.

The diagnosis of any comorbidity was confirmed by either reviewing the patient's medication list, or when feasible by confirmatory tests available from their medical records. Ten comorbidities were identified in all patients: Hypertension, diabetes mellitus, ischemic heart disease, chronic heart failure (CHF), cerebrovascular disease, any malignant disease, gastrointestinal disease, osteoporosis, and depression. All patients provided written informed consent before participating in the study.

Statistical analysis

Cronbach's alpha coefficient was computed to assess the internal consistency within the questionnaire components. A high internal consistency suggests that the scale or subscale measures a single construct. A value <0.70 indicates that individual items provide an inadequate contribution to the overall scale. Descriptive analysis included calculating means and standard deviations (SDs). We tested the relationship between the questionnaire score and clinical parameters using the Spearman correlation test. Non-parametric tests for independent samples (The Mann-Whitney U Test for two groups and Kruskal-Wallis Test for three or more groups) were employed to test for differences.

For the prediction of the actual, desired, and gap scores, a stepwise multiple regression analysis was performed using variables that were identified to be significant in the single regression analysis. All variables with p-values <0.25 were entered into the regression model according to the stepwise approach, while all variables with p-values >0.10 were removed. Data were analyzed using the JMP v.10 (Japanese version) software and p-values <0.05 were considered statistically significant.

Results

Study I

From the initial patient interview, we selected 32 components of the patients' desired movements and activities for the initial version of the questionnaire. Using this questionnaire, a preliminary survey was conducted with 32 COPD patients at the Tohoku Medical and Pharmaceutical University Wakabayashi Hospital (Supplementary Table E-1). Based on these results, we modified the questionnaire by selecting 25 components through the exclusion of seven that were highly correlated with other components (Supplementary Table E-2). The Cronbach's alpha coefficient for the 25 components was 0.883, indicating satisfactory internal consistency. Using the 25-component questionnaire, a second preliminary survey was conducted with 105 COPD patients from five affiliated institutions. Based on this questionnaire outcome, we selected 11 components that achieved at least 90% response rates. Finally, cluster analysis was conducted using these 11 components.

At the end of the cluster analysis, 11 components were grouped into six clusters: 1) Going-out activities (Q12 and Q14); 2) Moderate activities (Q8, walking on stairways); 3) Vigorous activities (Q9, carrying a heavy item); 4) Pace of activity (Q16, performing an activity at a pace similar to unaffected individuals in the same age group); 5) Activities of daily living (Q1, 2, & 4; sleeping and eating); and 6) Activities of daily living (Q5, 6, & 3; bathing and using the toilet) (Supplementary Figure E-1).

Taking this as reference, we added an extra component for the patient to freely describe a specific desired hobby/sport, and adjusted the questions and overall wording. Finally, we prepared the final version of the questionnaire comprised of eight components (Supplementary Figure E-2).

In the final version, the total score range could be 0-32 points for both the actual and desired states; larger scores indicated a more unfavorable state.

Study II

We retrieved the completed questionnaires from 422 patients. Among them, 24 exhibited normal FEV_1/FVC levels; 36 had incomplete information (8 patients forgot to fill out the forms while the data of the remaining 24 patients were missing); and the remaining 362 patients were included in the final analysis.

Overall patient characteristics: The overall patient characteristics are summarized in Table 1. The majority of patients were aged in their 70s, 74% had $\%FEV_1$ of 30–80, and the mean patient CAT score was 14.6 points. At the time of the survey, 22% of the patients were employed and 31% did not have a spouse.

Variables	n = 362
Male/Female/unknown	328/31/3
Age, Y	73.2 (8.1)
FEV _{1.0} L	1.35 (0.58)
%FEV _{1.0} %	57.7 (23.5)
≥80	64 (17.7)
50-79	133 (36.7)
30-49	134 (37)
<30	31 (8.6)
Modified MRC dyspnea scale	2.6 (1.0)
0	50 (14)
1	136 (38)
2	104 (29)
3	56 (15.6)
4	12 (3.3)
Unknown	4 (0.1)
6MWD, m (n = 110)	358 (150.6)
CAT	14.6 (8.3)
Exacerbation rate/year	0.53
0-1	310 (85.6)
2	44 (12.2)
Unknown	8 (2.2)
LTOT use, yes	62 (17.2)
Currently employed, yes	77 (22.5)
Marital status-single	114 (31.5)
Data are presented as number, mean (SD), or number (%)	
6MWD: 6 Minutes Walking Distance; CAT, COPD assessment test; Exacerbation rate, previous exacerbation rate; FEV _{1.0} : Forced Expiratory Volume in 1 s; MRC: Medical Research Council; LTOT: Long-term Oxygen Therapy; SD: Standard Deviation	

Table 1: Patient characteristics.

The score distribution patterns: The mean scores (±SD) of the actual state scores, desired state scores, and gap scores were 10.8 (±10.0), 5.0 (±4.0), and 5.7 (±4.7), respectively. The Cronbach's alpha coefficient was favorable at 0.887, 0.870, and 0.846 for the actual state scores, desired state scores, and gap scores, respectively. The distribution pattern for the gap scores is plotted as bar charts in Supplementary Figures E-3 and E-4.

The mean actual and desired state scores indicated a relatively small gap between the actual and desired states for components related to the basic activities of daily living, such as eating and bathing (Q4 and Q5). The data revealed a greater gap for components related to activities more vigorous than the activities of daily living (Figure 2).

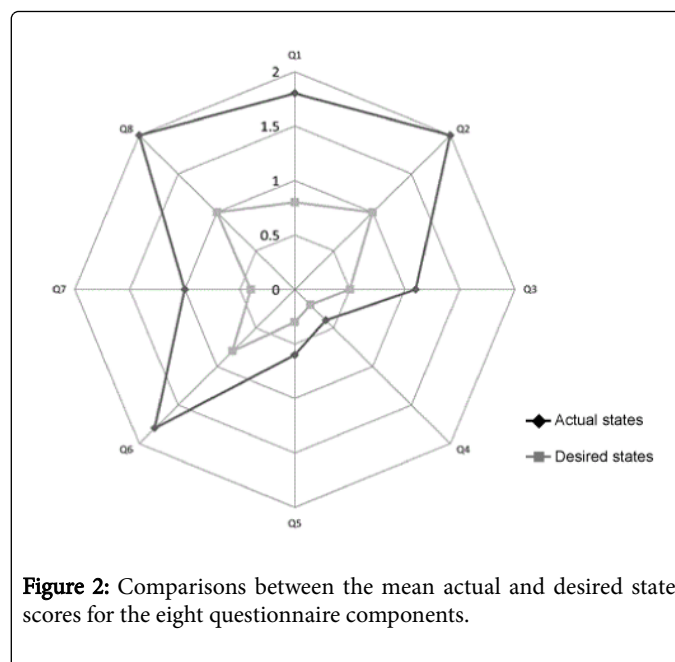


Figure 2: Comparisons between the mean actual and desired state scores for the eight questionnaire components.

The relationship between each component score and clinical parameters: The actual state scores, desired state scores, and gap scores significantly correlated with %FEV₁ (rho = -0.436, -0.313, and -0.315, respectively; all p < 0.0001), mMRC dyspnea scale scores (rho = 0.674, 0.451, and 0.508, respectively; all p < 0.0001), and CAT scores (rho = 0.654, 0.430, and 0.512, respectively; all p < 0.0001) (Table 2).

	Actual state score		Desired state score		Gap score	
	rho	p-value	rho	p-value	rho	p-value
Age	0.166	0.002	0.183	0.0005	0.041	0.443
%FEV ₁	-0.436	<0.0001	-0.313	<0.0001	-0.315	<0.0001
6MWD	-0.587	<0.0001	-0.544	<0.0001	-0.276	0.005
mMRC	0.674	<0.0001	0.451	<0.0001	0.508	<0.0001
CAT	0.654	<0.0001	0.43	<0.0001	0.512	<0.0001

6MWD: 6 Minutes Walking Distance; CAT: COPD Assessment Test; FEV₁: Forced Expiratory Volume in 1 s; mMRC: Modified Medical Research Council

Table 2: The correlation between each questionnaire score and clinical parameters.

Patient age was weakly correlated with actual scores (rho = 0.166; p = 0.0016) and desired state scores (rho = 0.183; p = 0.0005), but not with gap scores. Employment status had an impact on the gap score; working patients exhibited a smaller gap score, indicating a favorable state (p = 0.0016). Patients utilizing long-term oxygen therapy, and those with frequent exacerbation showed a greater gap, indicating an unfavorable state (p < 0.0001 and p = 0.0009, respectively). In contrast, patient sex and being married did not correlate with any of the scores. In co-morbidities, CHF and osteoporosis were significantly higher for the actual and desired scores, and depression was significantly higher for only the desired scores. However, there were no comorbidities that caused significant differences in the gap score (Table 3).

Clinical character		Actual state score	Desired state score	Gap score
Sex	Male (n = 328)	10.6 (6.8)	4.9 (4.7)	5.6 (4.8)
	Female (n = 31)	12.5 (7.8)	5.4 (5.1)	7.1 (5.2)
LTOT	Yes (n = 62)	18.0 (6.5) ^a	9.6 (5.0) ^a	8.4 (5.3) ^a
	No (n = 298)	9.2 (5.9) ^a	4.1 (4.1) ^a	5.2 (4.6) ^a
Exacerbation rate	0–1 (n = 310)	9.9 (6.5) ^a	4.6 (4.5) ^a	5.4 (4.7) ^a
	≥2 (n = 52)	16.2 (7.5) ^a	8.2 (5.3) ^a	8.0 (5.4) ^a
Employed	Yes (n = 77)	7.9 (5.8) ^a	3.6 (3.6) ^a	4.3 (4.2) ^a
	No (n = 265)	12.0 (6.9) ^a	5.7 (4.9) ^a	6.3 (5.0) ^a
Single	Yes (n = 42)	11.0 (7.6)	5.1 (5.1)	6.0 (4.9)
	No (n = 320)	10.6 (6.6)	5.0 (4.6)	5.6 (4.8)
Co-morbidity				
Ischemic heart disease	Yes (n = 30)	11.3 (7.5)	5.1 (5.1)	6.1(5.4)
	No (n = 332)	10.7 (6.8)	5.0 (4.7)	5.7 (4.8)
Chronic heart failure	Yes (n = 18)	16.1 (7.2) ^a	9.8 (5.9) ^a	6.3 (4.0)
	No (n = 344)	10.4 (6.8) ^a	4.8 (4.5) ^a	5.7 (4.9)
Hypertension	Yes (n = 99)	11.5 (7.2)	5.3 (4.9)	6.1 (4.8)
	No (n = 263)	10.5 (6.8)	4.9 (4.7)	5.6 (4.9)
Cerebrovascular disease	Yes (n = 12)	13.1 (5.8)	5.7 (6.1)	7.4(3.9)
	No (n = 350)	10.7 (6.9)	5.0 (4.7)	5.7 (4.9)
Diabetes mellitus	Yes (n = 33)	12.9 (7.6)	6.0 (6.2)	6.9 (5.6)
	No (n = 329)	10.6 (6.8)	4.9 (4.6)	5.6 (4.8)
Gastrointestinal disease	Yes (n = 55)	10.5 (6.9)	4.1 (4.0)	6.4 (4.8)
	No (n = 307)	10.8 (6.9)	5.2 (4.9)	5.6 (4.9)
Bronchial asthma	Yes (n = 58)	11.8 (7.9)	6.1 (5.8)	5.7 (5.1)
	No (n = 304)	10.6 (6.7)	4.8 (4.5)	5.8 (4.8)
Malignant disease	Yes (n = 31)	10.5 (7.5)	4.8 (4.8)	5.7 (5.5)
	No (n = 331)	10.8 (6.8)	5.0 (4.7)	5.7 (4.8)
Osteoporosis	Yes (n = 20)	15.4 (8.2) ^a	9.1 (5.5) ^a	6.4 (4.0)
	No (n = 342)	10.5 (6.7) ^a	4.8 (4.6) ^a	5.7 (4.9)
Depression	Yes (n = 13)	13.0 (5.3)	7.8 (4.5) ^b	5.1 (3.6)
	No (n = 349)	10.7 (6.9)	4.9 (4.7) ^b	5.7 (4.9)
Data are expressed as mean (SD), ^a p < 0.01, ^b p < 0.05				
Exacerbation rate = Previous COPD exacerbation rate per year; LTOT: Long-term Oxygen Therapy; Gastrointestinal disease = Peptic ulcer, chronic gastritis				

Table 3: Comparison of each questionnaire score according to clinical characteristics.

The comparison of gap scores stratified by disease severity (based on %FEV₁) indicated a significant increase in the gap scores with increasing disease severity (Mean gap score (±SD); Stage I = 3.6 (±3.5), II = 5.3 (±4.7), III = 6.4 (±4.7), IV = 9.0 (±6.2)). Similarly, gap scores increased with increasing CAT score or mMRC dyspnea scale score (Figure 3).

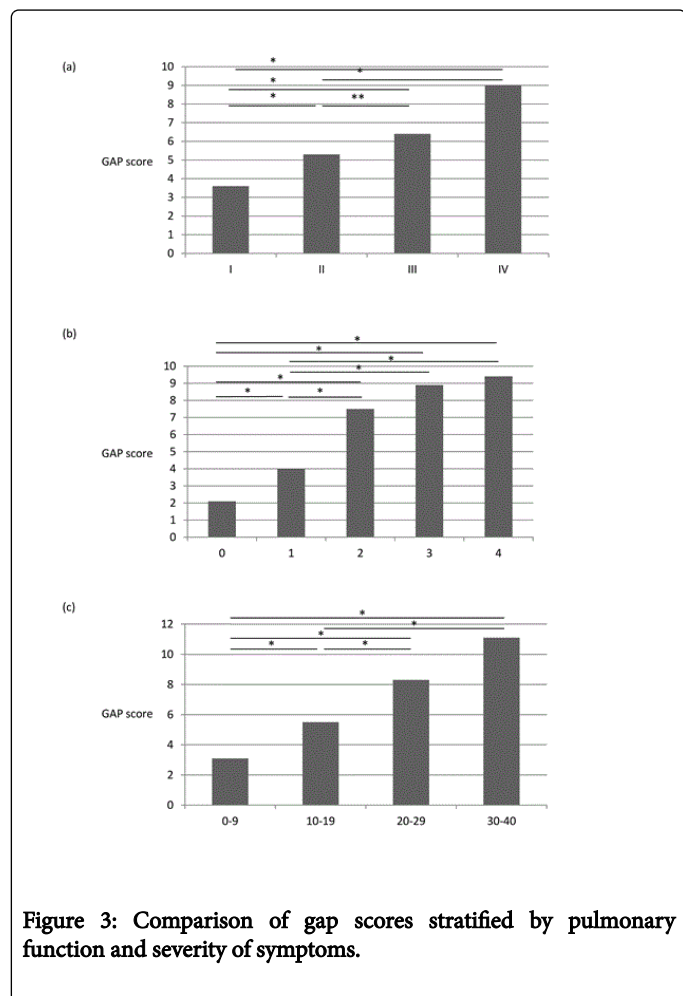


Figure 3: Comparison of gap scores stratified by pulmonary function and severity of symptoms.

Regression analysis: Multiple regression analyses were conducted to identify the factors significantly associated with the actual, desired, and gap scores. To predict the actual and desired scores as dependent variables, 10 independent variables (age, sex, mMRC dyspnea scale, CAT score, %FEV₁, oxygen consumption, frequent exacerbation, employment status, CHF, and osteoporosis) were included in the regression model. The significant predictors of actual scores were identified to be mMRC, CAT, oxygen consumption, unemployment, frequent exacerbation, and CHF (adjusted R² = 0.629; Table 4).

The results for the desired score were similar to those for the actual score excluding the contribution of the exacerbation and employment status to the regression model. Furthermore, eight independent variables (age, sex, mMRC dyspnea scale, CAT score, oxygen use, frequent exacerbation, and employment status) were included in the regression model to predict the gap score. Although the gap score identified mMRC and CAT as independent explanatory variables, the adjusted R² of the regression model was a quite low value (R² = 0.317; Table 4).

Scores/variables	Beta	Standard error	p value	F	Adjusted R ²
Actual score				82	0.629
mMRC	2.219	0.298	<0.0001		
CAT	0.34	0.033	<0.0001		
LTOT use, yes	1.332	0.344	0.0001		
Employment status, Yes	-0.909	0.286	0.0016		
Frequent exacerbation	-0.786	0.332	0.0185		
CHF, Yes	-1.134	0.514	0.0281		
Desired score				34.4	0.366
CAT	0.131	0.029	<0.0001		
LTOT use, Yes	1.472	0.306	<0.0001		
mMRC	0.985	0.258	0.0002		
CHF, Yes	-1.321	0.472	0.0054		
Osteoporosis, Yes	-1.196	0.438	0.0067		
Age	0.057	0.026	0.0294		
Gap score				39.8	0.317
mMRC	1.135	0.263	<0.0001		
CAT	0.215	0.031	<0.0001		
Employment status, Yes	-0.522	0.27	0.0539		
Frequent exacerbation	-0.341	0.31	0.2732		

mMRC: Modified Medical Research Council; CAT: COPD Assessment Test; LTOT: Long-Term Oxygen Therapy; Frequent exacerbation, previous COPD exacerbation rate per year 2; CHF: Chronic Heart Failure

Table 4: Multiple regression analysis of the actual, desired, and gap scores.

Discussion

The currently available HRQOL assessment tools generally focus on the present state of a patient. In contrast, our questionnaire, in addition to assessing the patient's present state, evaluated the patient's desired state by quantitatively assessing the gap between the actual and desired states. This type of approach is not part of the conventional evaluation of COPD patients and therefore represents the most important feature of our questionnaire.

Some studies have investigated the relationship between patients' QOL and desires, primarily in the field of cancer research [16,17]. Wan et al. conducted a survey of QOL in cancer patients using the Functional Assessment of Cancer Therapy-General questionnaire and reported that the gap between the desired level and actual level for each patient significantly correlated with the HRQOL. Based on this finding, the authors emphasized the importance of providing sufficient

information on the risk, efficacy, and outcome of therapies beforehand and to have each patient set a realistic goal [16].

Welham et al. evaluated the difference between reality and desire using the "QOL gap" in psychiatric patients and found that the QOL gap was more correlated with the patient's satisfaction level than with QOL alone. The authors suggested that the QOL gap assessment could aid in therapeutic and research fields because it has the potential to focus on the patient's desired therapeutic goal [18]. Furthermore, a recent report applied the concept of gap evaluations to the interview-based QOL assessment of children with chronic diseases; however, its clinical significance has not been established [19]. Our gap scoring system is also likely to play a similar role to previously reported methods, and the evaluation of its clinical significance in future studies is required.

In our cross-sectional survey, the gap score significantly correlated with the parameters related to the severity of COPD, including %FEV₁, mMRC dyspnea scale scores, CAT scores, home oxygen therapy, and frequent exacerbations. Our results revealed that these parameters were not only associated with the actual state of the COPD patients, but also with the gap between the desired and the actual states. Furthermore, multivariate analysis demonstrated that CAT and breathlessness were more significant explanatory variables than the frequency of disease worsening or employment status. These two measures have been emphasized in the symptom assessment of COPD patients following the revision of GOLD 2011 [3]. It has been reported that CAT can appropriately evaluate disease worsening [20] and progress in rehabilitation [21]. A close correlation between the mMRC dyspnea scale score and prognosis has also been reported [22]. Since these two parameters are highly associated with the gap score, medical interventions that improve these parameters are expected to achieve the therapeutic goals of patients to some extent. In the future, we recommend conducting a longitudinal study to follow the changes in gap evaluations before and after intervention.

As expected, multiple regression analysis was able to predict 63% of the actual score by conventional clinical factors (e.g. dyspnea severity, hypoxia, exacerbation). However, only 32% of the gap scores could be explained by similar clinical factors. In other words, these results suggest that predicting the patient's desire using standard clinical information is difficult. At the same time, our results confirm that this questionnaire evaluates a new aspect of patient data.

It was speculated that patient satisfaction was associated with the gap score. According to a study conducted by Fan et al., disease severity assessed by physical limitations and symptom burden was only weakly associated with general satisfaction. In contrast, factors such as education, coping skills, or disease perception were consistently associated with greater general satisfaction concerning the care provided [23]. A large gap score was attributed to the severity of COPD and it could be an indication of unsatisfactory medical intervention. This suggests that intervention has to be increased if the patient QOL is unfavorable and if the gap score is large. In addition, it is possible to attribute unfavorable QOL to the differences between medical facilities; therefore, assessment of the quality of facilities might be useful in evaluating the quality of care from the perspective of the patient, in order to meet the patient's standards.

Clinician-patient communication is one of the elements that contribute to patient satisfaction. The enhancement of communication helps develop treatment goals for patients with COPD [24]. Our new questionnaire allows the assessment of patient feelings, which can be

used to improve the communication between the clinician and the patient. Because patient satisfaction was not assessed in this study, future studies should aim to focus on the gap score and its relationship with patient satisfaction.

Although comorbidities had no effect on the gap score, some were significantly higher for the actual or desired state scores. If a difference is reflected on the actual and desired state scores in the presence or absence of complications, this indicated that there was no difference in the patient's desire level. It should be noted that the meaning of these results is completely different compared to that for the oxygen using/exacerbation rate affected gap scores. It is imperative to conduct further studies to interpret the differences in these three scores.

The GAP score was significantly poor for unemployed patients. A study conducted in Netherlands by Orbon et al. showed that patients with paid employment developed equal severity of airflow obstruction, but had a better QOL compared to patients who were unable to work [25]. Another study from Sweden showed that the self-reported QOL of patients with COPD was associated with social support and economic problems [26]. In the United States, employed adults with COPD reported significantly lower QOL and work productivity, and increased healthcare resource utilization than employed adults without COPD [27]. This suggests that working could serve as rehabilitation and may improve the QOL of patients with COPD [28]. The effect of employment status should be compared between the developed and developing countries.

The present study has several limitations. First, these results might be biased because the surveys were limited to Japanese patients with different lifestyles, religious beliefs, and attitudes towards hobbies and sports compared to patients from different countries. Therefore, these findings need to be verified in patients from different countries and ethnic groups. Second, the variation in the gap score attributable to the therapeutic intervention is unknown because we only performed a cross-sectional survey. The next research step should be to evaluate whether this gap can be reduced by therapeutic intervention.

Conclusion

We developed a new questionnaire style for the evaluation of the gap between the actual and desired states of COPD patients. The evaluation of differences between the desired and actual states of a patient is likely to aid the assessment of the suitability of ongoing medical intervention and might help determine future therapeutic goals.

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Author Contributions

TM, TT, and HK were involved in the design of the study, data collection, and interpretation. MI and AN were involved in the design and interpretation of the study. TM was involved in data analysis. All authors contributed to the writing of the manuscript and they have approved the final version for submission.

Disclosures

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