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博 士 論 文

Development and Preliminary Testing of a Questionnaire for Assessment of Patients' Self-monitoring of Exacerbation of Chronic Obstructive Pulmonary Disease

（慢性閉塞性肺疾患患者の増悪のセルフモニタリングに関する質問紙の開発と予備的検討）

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Abstract

This study aimed to develop a questionnaire assessing patients' self-monitoring of exacerbations of chronic obstructive pulmonary disease (QASM-ECOPD) and model the causal relationships of its factors using structural equation modeling. The QASM-ECOPD was divided into domain 1, "awareness of exacerbations," and domain 2, "interpreting symptoms and signs as cues to seek medical care." Factor analysis showed that domain 1 comprised 22 items across 3 factors and domain 2 comprised 18 items across 3 factors. Confirmatory factor analysis showed that the two domains had reasonable model fit. The internal consistency and stability were at an acceptable level. The QASM-ECOPD correlated with the score of external criterion. The structural model of QASM-ECOPD exhibited a sequential relationship between the factors and the fact that a domain 2 factor, "recognizing hesitation before seeking medical care" is at its basis. COPD patients showed reluctance to seek treatments, and even if they noticed the onset of signs, they did not take action to seek medical care until general symptoms appeared. The QASM-ECOPD is reliable and valid to assess patients' self-monitoring of exacerbation. The structural model of QASM-ECOPD provides important suggestions for encouraging COPD patients to take action to seek medical care in early stages of exacerbation.

Key Words

Chronic obstructive pulmonary disease, Exacerbation of COPD, Self-monitoring, Assessment, Instrument development, Structural equation modeling

INTRODUCTION

COPD patients typically experience acute episodes of exacerbations, which are characterized by worsening of respiratory symptoms—beyond the normal daily variations—and require additional medication. Severe exacerbation of COPD that requires hospitalization has an adverse effect on prognosis [1-3]. Frequent exacerbations are associated with a more rapid decline in lung function [4] and impaired health-related quality of life [5,6]. Most of the cost for COPD patients is related to the treatment of acute exacerbation, with the hospitalization cost being the major component [7].

It has been suggested that early treatment improves exacerbation recovery, and reduces risks of hospitalization [8]. In recent years, based on this evidence, action plans for exacerbations have been incorporated into self-management programs targeting COPD patients [9]. It has been reported that use of COPD exacerbation action plans with a single short educational component along with ongoing support, directed patients to take self-initiated actions, such as changing medication regimens or visiting the hospital, that could reduce hospital-based healthcare utilization and increase appropriate treatment of COPD exacerbations [10]. In contrast, even in the setting of randomized controlled trials with systematic educational interventions, only about 40% of patients adhered to the action plan during exacerbations [11,12], which demonstrates that individual patients require support to initiate an action plan appropriately.

The COPD patients' perceptions and reaction toward exacerbations are complex and varied. A previous report has identified the following three different patterns in recognition of exacerbation among COPD patients: (a) early recognition, (b) late recognition, and (c) difficulties with recognition [13]. Additionally, while there are some patients who take prompt action to seek treatment for signs and symptoms of exacerbation, there are also patients who postpone consulting with their health care professional until a crisis point is reached where they cannot cope anymore [13-15]. Symptoms are subjective experiences of a patient [16] and their meaning can be understood and interpreted by patients [17]. Based on these factors, it is essential to ascertain the status of the patients' self-monitoring before they decide to seek medical care. Assessing what individual COPD patients focus on when becoming aware of changes associated with exacerbation and how to interpret these findings can help encourage them to initiate an action plan.

Self-monitoring in the context of chronic illness has been defined as awareness of symptoms or bodily sensations that is enhanced through periodic measurements, recordings, and observations to provide information for improved self-management. This concept consists of the following major attributes: (a) awareness, (b) measurements, recordings, and observation, and (c) interpretation of the information [17,18]. Self-monitoring may help patients recognize symptoms and common triggers, and improve self-care and regulation of the disease [17,18]. Therefore, the success of early detection of exacerbation and self-initiated action as prescribed depends on the status of the patients' self-monitoring.

There have been several patient-reported outcome measures developed to date that can be used to predict and evaluate COPD exacerbation. The COPD Assessment Test (CAT) is a representative questionnaire, which can be used as a complementary tool in a patients' clinical assessment for predicting COPD

exacerbation, acute deterioration of health status, depression, and mortality [19]. Exacerbations of Chronic Obstructive Pulmonary Disease Test-Patient-Reported Outcome (EXACT-PRO) is an instrument to detect and measure the severity, duration, and frequency of exacerbations of COPD [20]. However, there are no instruments to ascertain individual patients' subjective perspective of their exacerbation episodes.

Hence, an instrument to measure patients' self-monitoring of COPD exacerbation is necessary to identify efficacious forms of self-monitoring, leading to adequate self-management behavior during exacerbation. Therefore, this study aimed to develop a new questionnaire for assessment of patients' self-monitoring of exacerbations of chronic obstructive pulmonary disease (QASM-ECOPD) and examine the causal or temporal relationships between component factors of the QASM-ECOPD.

METHODS

Development of the questionnaire involved three steps: item generation and selection, content and face validity of the initial questionnaire, and psychometric evaluation of the new questionnaire.

Step 1: Item Generation and Selection

The QASM-ECOPD was based on the definition of self-monitoring and its attributes presented by previous concept analyses [17,18]. In this study, we operationally defined self-monitoring of COPD exacerbation as having awareness of the changes in symptoms and signs caused by exacerbation through regular measurements, recordings, and observations, and interpreting this information as a cue to seek medical care. We also included domain 1 "awareness of exacerbations" and domain 2 "interpreting symptoms and signs as cues to seek medical care" in the QASM-ECOPD, referencing attributes of self-monitoring [17, 18]. To generate the items of the questionnaire, we conducted a semi-structured interview with 20 patients with a COPD history of >1 year who had either visited the hospital or had been hospitalized for COPD exacerbation. The responses to the following questions were obtained via a standardized interview: (a) "what would you usually measure, record, or observe to become aware of a change in your respiratory symptoms or condition?" and (b) "what kind of change would you interpret as cues to seek medical care?" We selected certain key factors from among the responses, and an initial pool of potential items was generated.

Step 2: Content and Face Validity of the Questionnaire

The potential items were then reviewed by a panel of experts to evaluate the content validity of the questionnaire. The review panel comprised twelve nurses certified in chronic respiratory nursing and a pulmonologist. The experts were asked to comment on the relevance, comprehensiveness, and clarity of the items. In addition, to evaluate the face validity of the items, eight COPD patients were invited to pilot test the questionnaire for comprehension, ease of response, and time required to respond. This process led to the establishment of a prototype of the questionnaire with domain 1 "awareness of exacerbations" (29 items) and domain 2 "interpreting symptoms and signs as cues to seek medical care" (25 items). The answers were measured using a 5-point Likert scale: (a) strongly disagree, (b) disagree, (c) neutral, (d)

agree, and (e) strongly agree, where a higher score was indicative of more valid self-monitoring.

Step 3: Psychometric Evaluation

We implemented cross-sectional descriptive studies to evaluate the construct validity, internal consistency, stability, and criterion-related validity of the questionnaire. The development of the questionnaire was based on the traditional psychometric theory used in the development of many clinical scales [21].

Participants and Procedure

The study participants were recruited from outpatients who had visited the department of respiratory medicine in 3 public hospitals or 1 clinic, or from among those who had used visiting nursing services in the western region of Japan. The recommended sample size was at least 5 respondents for each variable [22]. Thus, the study required responses from >150 participants. The inclusion criteria were a confirmed diagnosis of COPD and a disease duration of ≥1 year. Patients with malignant disease, dementia, or psychiatric disorders were excluded. Physicians and visiting nurses were asked to select the participants. A questionnaire sheet was distributed to patients who met the abovementioned criteria, and was returned via mail. The questions were answered anonymously.

Data Collection

The participants were asked to complete the Self-Care Agency Questionnaire (SCAQ) for patients with chronic illness for use as an external criterion, in addition to completing the QASM-ECOPD. The SCAQ consists of the following 5 sub-scales: (a) health awareness, (b) health choices, (c) ability to adjust one's own physical condition, (d) ability to perform activities of daily living, and (e) having people around for support, where a higher score was indicative of higher self-care ability [23].

Various participant background factors were also investigated, including age, gender, disease duration, history of receiving long-term oxygen therapy (LTOT) or non-invasive positive pressure ventilation (NPPV), number of unexpected hospitalizations due to COPD exacerbation over the past year, and presence of family members. Furthermore, the modified British Medical Research Council (mMRC) questionnaire was used to assess the participants' level of dyspnea in daily living.

To assess the stability of the QASM-ECOPD, test-retests were used. The QASM-ECOPD survey was conducted twice at 2-week intervals. The questionnaires were distributed to the participants from April 2014 to March 2016.

Data Analysis

Descriptive statistics were used to present the participant characteristics. The homogeneity of each domain was evaluated using item-total correlation analysis, with an acceptance r level of ≥0.3 [24].

The construct validity of each domain was first confirmed via exploratory factor analysis (EFA) using the principal factor method and promax rotation, and then via confirmatory factor analysis (CFA). Before performing the factor analyses, data were examined with Bartlett's test of sphericity and the Kaiser-Meyer-Olkin index (KMO) measure of sampling adequacy. In the EFA, the following criteria were used to retain

the factors and items: the scree-plot, eigenvalues of >1, factor loadings of ≥0.4, no cross-loadings, and theoretical interpretability of the resulting factor structure. The CFA was performed to confirm the degree of model fit for the EFA results.

Thereafter, structural equation modeling (SEM) was used to assess several hypothetical models that explained the paths of the relationships between component factors of the QASM-ECOPD. By clarifying the paths, we aimed to obtain insights into the causal or temporal relationships as an expression of the order of COPD patients' self-monitoring of exacerbations.

We applied the following indices to assess model fit: comparative fit index (CFI), root mean square error of approximation (RMSEA), and standardized root mean square residual (SRMR). The CFI is one of the most popularly reported fit indices as it is one of the measures least affected by sample size; a value of ≥0.95 is indicative of good fit and a value of >0.90 is needed to ensure that misspecified models are not accepted [25]. The RMSEA is regarded as one of the most informative fit indices due to its sensitivity to the number of estimated parameters in the model. RMSEA values <0.07 represent the acceptable threshold levels [26]. An SRMR <0.08 is indicative of a good fit [25].

The reliability of the questionnaire was assessed via internal consistency and test-retest stability. Internal consistency was evaluated by calculating Cronbach's α coefficient. An α value ≥0.80 is generally considered to indicate a reliable measure [27]. Stability was assessed by calculating the intraclass correlation coefficient (ICC) between the 2 datasets collected over a 2-week interval. An ICC value >0.70 is considered satisfactory [27]. Spearman's correlation coefficients for the QASM-ECOPD and the SCAQ were determined to evaluate criterion-related validity.

Statistical analyses were performed using SPSS version 22.0 and Amos version 22.0 (IBM Corp., Tokyo, Japan).

Ethical Considerations

Ethical approval for the study was obtained from the Ethics Committee of Kobe University (approval no. 263 and no. 371). Participants were informed about the purpose and procedure of the study, voluntary nature of participation, measures to protect participant anonymity, and confidentiality of the data. Written consent was obtained from all participants.

RESULTS

Participant Characteristics

The questionnaires were distributed to 244 participants, and responses were received from 224 (response rate, 91.8%). Of the 51 participants with missing data in the responses to each QASM-ECOPD domain, 16 participants with >10% of missing data were excluded; in the responses of 35 participants with <10% of missing data, the mean values were imputed and used for data analysis (valid rate, 92.9%). The demographic and clinical characteristics of the participants are shown in Table 1.

Table 1. Participant Demographics and Clinical Characteristics (n = 208)

Variables	
Age (mean ± SD)	72.3 ± 7.8
Age group, n (%)	
50-59	12 (5.8)
60-69	60 (28.8)
70-79	96 (46.2)
80-89	38 (18.3)
90<	2 (1.0)
Gender, n (%)	
Male	180 (86.5)
Female	28 (13.5)
Duration of COPD years, n (%)	
1-5	51 (24.5)
6-10	67 (32.2)
11-15	51 (24.5)
16-20	26 (12.5)
20<	13 (6.3)
Regular COPD treatment, n (%)	
LTOT use	75 (36.1)
NPPV use	11 (5.3)
mMRC dyspnea score (mean ± SD)	1.6 ±1.1
mMRC dyspnea score, n (%)	
0	32 (15.4)
1	70 (33.7)
2	44 (21.2)
3	48 (23.1)
4	6 (2.9)
No response	8 (3.8)
Number of unscheduled hospitalization for exacerbations in the past 12 months, n (%)	
0	128 (61.5)
1	39 (18.8)
2	16 (7.7)
3	2 (1.0)
4	1 (0.5)
No response	22 (10.6)
Living status, n (%)	
Alone	24 (11.5)
With families	183 (88.0)
No response	1 (0.5)
Work status, n (%)	
Employed	56 (26.9)
Unemployed	150 (72.1)
No response	2 (1.0)

COPD: chronic obstructive pulmonary disease, LTOT: long term oxygen therapy, NPPV: non-invasive positive pressure ventilation, mMRC: modified British Medical Research Council, 0 = "I only get breathless with strenuous exercise," 1 = "I get short of breath when hurrying on the level or walking up a slight hill," 2 = "I walk slower than people of the same age on the level because of breathlessness or have to stop for breath when walking at my own pace on the level," 3="I stop for breath after walking about 100 yards or after a few minutes on the level," 4 = "I am too breathless to leave the house" or "I am breathless when dressing"

Item Analysis

In each QASM-ECOPD item, there were 0–3 cases of missing data (0–1.4%), and none of the items had an extremely high ratio of missing data. For the domain 1 "awareness of exacerbations," the item-total correlation varied between 0.333 and 0.687, except for the following 2 items: "I think it is difficult to notice warning signs when flare-ups occur" (r = 0.040); "I think my condition can suddenly worsen without any warning" (r = -0.029). For the domain 2 "interpreting symptoms and signs as cues to seek medical care," the item-total correlation varied between 0.419 and 0.738, except for 1 item: "I sometimes cannot distinguish between daily COPD symptom variations and exacerbation symptoms" (r = 0.116).

After removing these 3 items, the 27 items from domain 1 and 24 items from domain 2 were further refined via EFA.

Factor Analysis

The KMO measure of sampling adequacy for domain 1 "awareness of exacerbations" and domain 2 "interpreting symptoms and signs as cues to seek medical care" were 0.879 and 0.904, respectively, indicating that the sample size was adequate for performing EFA. Bartlett's test of sphericity for each domain showed statistical significance (χ^2 = 2482.424, df = 351, p<0.01; χ^2 = 2738.385, df = 276, p<0.01, respectively), indicating that there were significant correlations among the variables, and that the data were appropriate for EFA.

Domain 1 "Awareness of Exacerbations." EFA was conducted using the 27 items of domain 1. Five items were eliminated from further analysis because of the presence of factor loadings <0.40. Finally, the 3-factor solution for the 22 remaining items provided the most meaningful factor pattern (Table 2). The 3-factor solution explained 47.4% of the total variance. Each factor was interpreted with the following labels: first factor, "giving attention to the causes and triggers of exacerbation"; second factor, "objectively monitoring degrees of variation of respiratory condition and physical condition"; and third factor, "monitoring degrees of variation of cough and sputum." CFA was performed to test the validity of the correlated 3-factor measurement model based on the EFA. For the results of the CFA, the fit indices of the model were as follows: CFI = 0.927, RMSEA = 0.060, and SRMR = 0.064. All standardized coefficients (path coefficients) in the model were significant (p<0.01).

Domain 2 "Interpreting Symptoms and Signs as Cues to Seek Medical Care." EFA was conducted using the 24 items of domain 2. Six items were eliminated from further analysis because of the presence of factor loadings <0.40 or a cross-factor loaded item. Finally, the 3-factor solution for the 18 remaining items provided the most meaningful factor pattern (Table 3). The 3-factor solution explained 53.2% of the total variance. Each factor was interpreted with the following labels: first factor, "assessing general symptoms and signs," second factor, "assessing the signs of a respiratory infection," and third factor, "recognizing hesitation before seeking medical care." In the CFA results, the fit indices of the model were as follows: CFI = 0.946, RMSEA = 0.064 and SRMR = 0.062. All standardized coefficients (path coefficients) in the model were significant (p<0.01).

Table 2. Exploratory Factor Analysis of Domain 1 "Awareness of Exacerbations" of the QASM-ECOPD

Items		Factor loading		
		Factor 1	Factor 2	Factor 3
Factor 1: Giving attention to the causes and triggers of exacerbation				
1	I pay attention to changes in my respiratory symptoms and physical condition related to heat, humidity, and cold.	**0.762**	0.183	-0.133
2	I pay attention to changes in my respiratory symptoms and physical condition after feeling the first signs of a cold or a sore throat.	**0.757**	-0.112	-0.057
3	I pay attention to effects that the changing of the season has on my respiratory symptoms and physical condition.	**0.750**	0.079	0.014
4	I pay attention to any cold symptoms such as sneezing, runny nose, nasal congestion, or chills.	**0.731**	-0.169	0.154
5	I pay attention to changes in my respiratory symptoms and physical condition after visiting places where the air is smoky, dusty, or stuffy.	**0.698**	0.011	-0.015
6	I pay attention to the appearance of a sore throat or throat irritation.	**0.697**	-0.125	0.193
7	Whenever I do an activity, I am concerned how my actions will affect my respiratory symptoms and physical condition.	**0.645**	0.183	-0.153
8	I am concerned about the recurrence of flare ups of my symptoms.	**0.561**	0.068	0.211
Factor 2: Objectively monitoring degrees of variation of respiratory condition and physical condition.				
9	I regularly check my pulse rate and my heart rhythm.	-0.024	**0.688**	0.102
10	I record my temperature every day.	0.012	**0.659**	-0.216
11	I pay attention to changes in my appetite and food intake.	0.058	**0.621**	0.054
12	Every day, I record my symptoms, measurements, and daily events in my diary and monitor any changes.	-0.004	**0.613**	-0.132
13	I monitor any swelling in my ankles or legs.	0.013	**0.593**	0.105
14	I regularly weigh myself and pay attention to any weight changes.	-0.313	**0.564**	0.183
15	I have my own signs to check whether my respiratory condition or physical condition is good or bad	0.099	**0.527**	0.041
16	I frequently take my temperature when I feel the slightest problem.	0.157	**0.512**	0.002
17	I recognize that my energy levels or mood is tied to my respiratory condition.	0.089	**0.454**	0.054
18	There is someone around me who can quickly notice any changes in my respiratory condition.	0.017	**0.411**	0.143
Factor 3: Monitoring degrees of variation of cough and sputum				
19	I can recognize changes in the color, consistency, and amount of sputum.	-0.139	0.043	**0.910**
20	When I have sputum, I check its color, consistency, and amount.	0.08	0.068	**0.674**
21	I pay attention to an increase of coughing.	0.291	-0.117	**0.634**
22	I can recognize any changes in my cough.	0.162	0.072	**0.503**
Cumulative contribution rate (%)		34.5	43.0	47.4
Inter-factor correlations	Factor 1	1.00		
	Factor 2	0.50	1.00	
	Factor 3	0.63	0.47	1.00

Model fit examined using CFI = 0.927, RMSEA = 0.060, SRMR = 0.064

QASM-ECOPD: Questionnaire for assessment of patient self-monitoring of acute exacerbations of chronic obstructive pulmonary disease;

CFI = comparative fit index; RAMSEA = root mean square error of approximation; SRMR = standardized root mean square residual

Items eliminated from further analysis because of the presence of factor loadings <0.40: "I notice what causes my condition to be exacerbated," "I notice that my condition is exacerbated by a cold, influenza, and the like," "I believe that a decrease in my body weight is a sign or trigger of exacerbation of my condition," "I can recognize changes in my breathing difficulty (shortness of breath)," and "I monitor my physical activity including moving and walking in my own way."

Table 3. Exploratory Factor Analysis of Domain 2 "Interpreting Symptoms and Signs as Cues to Seek Medical Care" of the QASM-ECOPD

	Items	Factor loading		
		Factor 1	Factor 2	Factor 3
Factor 1: Assessing general symptoms and signs				
1	If I lacked energy and had difficulty doing something, I would consult my health care professionals.	**0.860**	0.009	-0.089
2	If I had a sudden loss of appetite, I would consult my health care professionals.	**0.817**	-0.077	-0.188
3	If I had a continuously fast or irregular pulse, I would immediately consult my health care professionals.	**0.779**	-0.104	0.028
4	If my feet or legs became unusually swollen or I gained more than 2 kilograms in a few days, I would immediately consult my health care professionals.	**0.657**	0.109	0.041
5	If I had a headache, felt drowsy, or had tremors, I would immediately consult my health care professionals.	**0.644**	0.028	0.117
6	If I had unusual shortness of breath, I would either take the emergency medicine prescribed by my doctor, or consult my health care professionals.	**0.605**	0.088	0.112
7	If I felt in any way concerned or worried about my condition, I would consult my health care professionals.	**0.510**	0.236	0.04
Factor 2: Assessing the signs of a respiratory infection				
8	If the amount of sputum increased or became hard to expectorate, I would either take the emergency medicine prescribed by my doctor, or consult my health care professionals.	-0.041	**0.864**	-0.053
9	If I noticed any changes in the color of sputum, I would either take the emergency medicine prescribed by my doctor, or consult my health care professionals.	-0.021	**0.839**	-0.053
10	If my coughing got more severe or more frequent than usual, I would either take the emergency medicine prescribed by my doctor, or consult my health care professionals.	0.056	**0.777**	0.037
11	If I had cold symptoms such as sneezing, runny nose, nasal congestion, or chills, I would either take the emergency medicine prescribed by my doctor, or consult my health care professionals.	-0.08	**0.722**	0.072
12	If I had a sore throat or throat irritation, I would either take the emergency medicine prescribed by my doctor, or consult my health care professionals.	0.182	**0.586**	0.031
Factor 3: Recognizing hesitation before seeking medical care				
13	Even if I didn't feel well, I would tend to endure as much as I could until my next doctor appointment. †	0.061	-0.077	**0.869**
14	I would consult my health care professionals if I reached a point where I could no longer endure my symptoms. †	-0.173	0.002	**0.716**
15	I couldn't decide to consult my health care professionals unless I was confident that a flare-up had occurred. †	-0.047	0.041	**0.69**
16	Whenever I don't feel well, I am inclined to think that I am going to feel better soon. †	0.059	-0.015	**0.664**
17	If I had a fever, I would endure unless it exceeded 38°C. †	-0.077	0.107	**0.504**
18	Even if I noticed a change in my condition, I would find it troublesome to visit the hospital. †	0.239	-0.062	**0.436**
Cumulative contribution rate (%)		38.3	47.2	53.2
Inter-factor correlations	Factor 1	1.00		
	Factor 2	0.65	1.00	
	Factor 3	0.55	0.45	1.00

† Reverse-scored item

Model fit examined using CFI = 0.946、 RMSEA = 0.064, SRMR = 0.062

QASM-ECOPD: Questionnaire for assessment of patient self-monitoring to acute exacerbations of chronic obstructive pulmonary disease;
CFI = comparative fit index; RMSEA = root mean square error of approximation; SRMR = standardized root mean square residual

Items eliminated from further analysis because of the presence of factor loadings <0.40: "If I had symptoms of a cold, I would take over-the-counter cold medicine and see how it goes for a while," "If I had symptoms that I cannot judge by myself, I would consult my health care professionals," and "If I postpone consulting health care professionals by one day when I have a hard symptom, my condition will get even worse."
Items eliminated because of the presence of a cross-factor loaded item: "If my wheezing gets worse, I would either take the emergency medicine prescribed by my doctor, or consult my health care professionals," "If I developed a fever of 37.5 °C, I would either take the emergency medicine prescribed by my doctor, or consult my health care professionals," and "If I had discomfort or a strange sensation in my chest, I would immediately consult my health care professionals."

Reliability

The internal consistency and stability of the questionnaire are shown in Table 4. Cronbach's α for domain 1 was 0.909 and those for its factors ranged from 0.840 to 0.897. Cronbach's α for domain 2 was 0.908 and those for its factors ranged from 0.810 to 0.886; they all met the criterion of ≥0.80.

The ICCs (two-way mixed effect model, perfect agreement) were calculated by using the data from the 26 valid respondents on the test-retest. The ICC for domain 1 was 0.910, and those for its factors ranged from 0.817 to 0.860. Moreover, the ICC for domain 2 was 0.900, and those of its factors ranged from 0.834 and 0.905; they all met the criterion of >0.70.

Criterion-Related Validity

Spearman's correlation coefficients for the QASM-ECOPD and SCAQ are shown in Table 5. The correlation coefficient of domain 1 with the SCAQ was 0.650, which was statistically significant ($p<0.01$). The correlation coefficients for each factor and the SCAQ subscale ranged from 0.303 to 0.591, which were all statistically significant ($p<0.01$). The correlation coefficient of domain 2 with the SCAQ was 0.556, and the correlation coefficients for each factor and the SCAQ subscale ranged from 0.263 to 0.488, which were all statistically significant ($p<0.01$).

Table 4. Internal consistency and test-retest stability of the QASM-ECOPD

	Cronbach's α	Intra-class correlation coefficient (n = 26)
Domain 1: Awareness of exacerbations		
Giving attention to the causes and triggers of exacerbation	0.897	0.841** (95% CI, 0.677–0.925)
Objectively monitoring degrees of variation of respiratory condition and physical condition	0.84	0.817** (95% CI, 0.604–0.917)
Monitoring degrees of variation of cough and sputum	0.841	0.860** (95% CI, 0.709–0.935)
Entire	0.909	0.910** (95% CI, 0.803–0.959)
Domain 2: Interpreting symptoms and signs as cues to seek medical care		
Assessing general symptoms and signs	0.886	0.834** (95% CI, 0.658–0.923)
Assessing the signs of a respiratory infection	0.883	0.905** (95% CI, 0.802–0.956)
Recognizing hesitation before seeking medical care	0.81	0.875** (95% CI, 0.744–0.942)
Entire	0.908	0.900** (95% CI, 0.787–0.955)

** $p<0.01$

QASM-ECOPD: Questionnaire for assessment of patient self-monitoring to acute exacerbations of chronic obstructive pulmonary disease

CI, confidence interval.

Table 5. Spearman's rank correlations between the QASM-ECOPD and the SCAQ (n = 181)

	SCAQ subscales					
	Health awareness	Health choices	Ability to adjust one's own physical condition	Ability to perform activities of daily living	Having people around for support	Total
Domain 1: Awareness of exacerbation						
Giving attention to the causes and triggers of exacerbation	0.528**	0.322**	0.436**	0.395**	0.386**	0.486**
Objectively monitoring degrees of variation of respiratory condition and physical condition	0.532**	0.591**	0.476**	0.481**	0.524**	0.637**
Monitoring degrees of variation of cough and sputum	0.513**	0.421**	0.303**	0.344**	0.374**	0.473**
Total	0.613**	0.542**	0.499**	0.499**	0.524**	0.650**
Domain 2: Interpreting symptoms and signs as cues to seek medical care						
Assessing general symptoms and signs	0.454**	0.360**	0.470**	0.405**	0.462**	0.531**
Assessing the signs of a respiratory infection	0.488**	0.402**	0.488**	0.421**	0.461**	0.555**
Recognizing hesitation before seeking medical care	0.287**	0.263**	0.288**	0.287**	0.269**	0.327**
Total	0.486**	0.412**	0.481**	0.434**	0.469**	0.556**

**. p<0.01

QASM-ECOPD: Questionnaire for assessment of patient self-monitoring to acute exacerbations of chronic obstructive pulmonary disease
SCAQ: the Self-Care Agency Questionnaire for Patients with Chronic Illness

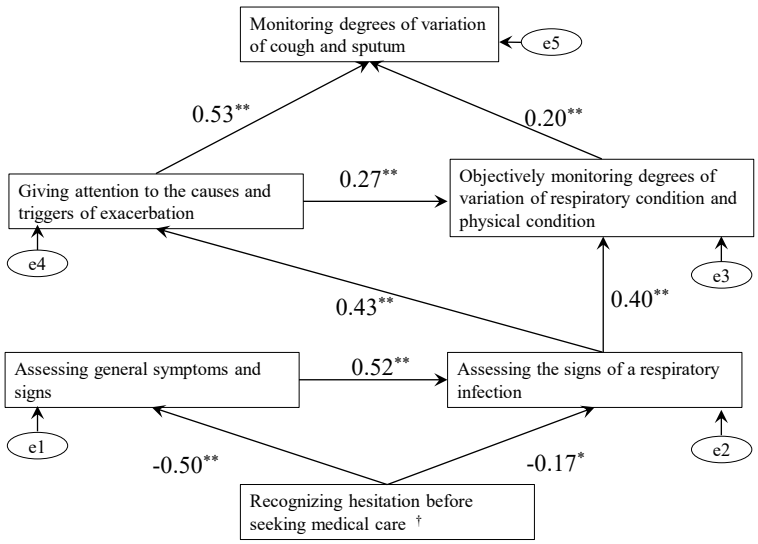

Figure 1. Structural Equation Modeling of Component Factors of the QASM-ECOPD

A path analysis was conducted to show the relationship between the six factors that were obtained by the structural equation modeling.

Model fit examined using CFI = 0.986, RMSEA = 0.061, SRMR = 0.038

The numbers represent the path coefficients. *p<0.05, **p<0.01, † Reverse-scored factor

QASM-ECOPD: Questionnaire for assessment of patient self-monitoring to acute exacerbations of chronic obstructive pulmonary disease;

CFI = comparative fit index; RAMSEA = root mean square error of approximation; SRMR = standardized root mean square residual

Structural Equation Modeling

We explored several hypothesized models, particularly the direction of the relationships. A path analysis was performed to show the relationship between the six factors that were obtained by the factor analysis. We observed sequential relationships between the factors. Figure 1 shows the model with the best fit. The fit indices of the model were as follows: CFI = 0.986, RMSEA = 0.061, SRMR = 0.038. All standardized coefficients (path coefficients) in the model were significant ($p<0.01$, $p<0.05$).

"Recognizing hesitation before seeking medical care" was the most foundational factor in COPD patients' self-monitoring of COPD exacerbation and had a negative effect on "assessing general symptoms and signs" (path coefficient = -0.50) and "assessing the signs of a respiratory infections" (path coefficient = -0.17). Moreover, only "assessing the signs of a respiratory infection" had a significant effect on "giving attention to the causes and triggers of exacerbation" and "objectively monitoring degrees of variation of respiratory condition and physical condition," and the structure showed no direct path stemming from "assessing general symptoms and signs."

DISCUSSION

In this study, we developed a questionnaire to assess the individual COPD patients' focus to enable them to become aware of signs and symptoms of exacerbation and how to interpret these findings; we also examined the causal or temporal relationships between component factors of the QASM-ECOPD. The QASM-ECOPD comprised domain 1, "awareness of exacerbations," and domain 2, "interpreting symptoms and signs as cues to seek medical care," based on attributes of self-monitoring that were clarified through previous concept analysis [17,18].

EFA was used to identify an appropriate factor structure, and then CFA was used to verify the factor structure of the QASM-ECOPD and to confirm items that reflected its attributed factors. The final models of the two domains of the QASM-ECOPD attained reasonably appropriate model fit and had statistical power. Thus, the construct validity of the QASM-ECOPD was supported. The Cronbach's α value for both domains and for those factors indicated were over 0.80, indicating good internal consistency. The results of the test-retest procedure indicated that stability of both domains was good, as the ICC reached the recommended values ≥ 0.70. In the examination of criterion-related validity, we found moderate correlations between each domain in the QASM-ECOPD, and the external criterion (the SCAQ) was statistically significant. Those factors showed low to moderate significant correlations with the subscales of the SCAQ. In previous studies, efficacious self-monitoring led to improvements in the adequacy of self-care [17,18]. These findings support the criterion-related validity of the QASM-ECOPD. Consequently, the QASM-ECOPD was confirmed as a valid and reliable instrument for assessing self-awareness and self-interpretation of exacerbations in COPD patients.

Domain 1, "awareness of exacerbations", assesses whether COPD patients are aware of their own causes and triggers of exacerbation, whether they are paying attention to the consequence of these factors, and

whether patients have the viewpoints and means to detect diverse changes associated with exacerbation. Previous studies have reported that the onset of exacerbation could vary from gradual to sudden, and the types and severity of symptoms are not always consistent, and such heterogeneity was an important barrier to patients' recognition of exacerbation[13]. Therefore, it is essential to evaluate whether patients have the viewpoints and means to detect diverse changes associated with exacerbation in order to increase patients' awareness of COPD exacerbation. Domain 2, “interpreting symptoms and signs as cues to seek medical care”, assesses an individual’s assessment of signs and symptoms commonly experienced by many COPD patients [14,20,28]. Symptoms are private, and even symptoms that are generated through the same mechanism can present with very different experiences depending upon how the individual interprets them [16]. Reports show that the threshold for seeking medical care for symptom deterioration varies among individuals with COPD [13,14]. Conducting assessment using domain 2 will enable health care professionals to understand patients’ subjective interpretations of signs and symptoms, which are considered difficult to observe. Thus, the QASM-ECOPD emphasized the patients’ perspective of exacerbation episodes. This new questionnaire can be used to assess individual patients’ awareness and interpretation of exacerbation in the background of self-management behavior during exacerbation. Better understanding individual patients’ perspective of exacerbation will guide the development of future individualized and tailored exacerbation-related self-management interventions.

Our study results also provide insights into the status of self-monitoring that COPD patients actually perform by assessing the relationships between QASM-ECOPD factors. The SEM results indicate a sequential relationship between factors and identified “recognizing hesitation before seeking medical care” as its basis. Patients were hesitant to seek medical care, and even if they became aware of the onset of symptoms and signs, they failed to consult until general symptoms and signs such as dyspnea and lack of energy appeared. A previous study suggested that some patients with COPD were reluctant to consult a physician, and therefore postponed contacting their health care professionals until feeling an urgent need for medical care. It has been reported that such reluctance arises from patients’ beliefs such as “it will get well soon” and “their social responsibilities are more important than their own feeling” and barriers in the patient-professionals relationship such as “they don’t want to bother their professionals” [13,14]. Moreover, patients’ experience of having their suffering and anxiety underestimated by health care professionals also leads to reluctance to consult their health care professional [14,29,30]. The results of SEM showed how important it is for health care professionals to be aware of COPD patients’ reluctance to seek medical care, to establish a patient-professional relationship in which patients feel free to seek medical help as needed, and to pay sincerely attention to patients’ symptom experience during their visits.

Furthermore, in the structural model, “assessing the signs of a respiratory infection” was the only factor associated with behavior for awareness of exacerbation, such as monitoring degrees of variation of a respiratory and physical condition, and paying attention to the causes and triggers of exacerbation. This factor focuses on patients’ assessment of symptoms and signs that deteriorated during the prodromal phase

or on the day of onset of exacerbation, such as increased sputum volume, sputum color change, increased coughing, sore throat, and symptoms of a cold [31]. Helping patients understand the implications of these signs and symptoms is important in encouraging patients' observations and measurements, leading to the awareness of the onset of exacerbation.

These results should be viewed as preliminary and some limitations in the current study should be considered. First, this study used a convenience sampling method, and so the proportion of LTOT users was higher than in the general patient population. In addition, patients with a history of asthma or with comorbidities including heart disease could not be completely excluded. Thus, the results of this study may have been influenced by sampling bias. Second, this study merely developed a questionnaire for understanding the self-monitoring performed by COPD patients. Our examination of validity only focused on the model fit of factor structure of the new questionnaire and correlations with the SCAQ based upon traditional psychometric theory. In the future, it is necessary to determine the relationship between patients' self-monitoring and self-management behaviors during COPD exacerbation, through further examination of the construct validity using a more rigorous sampling method.

CONCLUSION

In this study, we developed a questionnaire to assess COPD patients' self-monitoring of exacerbation, and we investigated the construct validity (including CFA), the internal consistency, stability, and criterion-related validity of the questionnaire. We also examined the causal or temporal relationships between component factors of the QASM-ECOPD. Confirmatory factor analysis showed that the two domains ("awareness of exacerbations" and "interpreting symptoms and signs as cues to seek medical care") had reasonable model fit. The Cronbach's α value indicated good internal consistency. The results of the test-retest procedure indicated that stability of both domains was good. In the examination of criterion-related validity, the score of each domain in the QASM-ECOPD was significantly correlated with the SCAQ scores. These findings support the criterion-related validity of the QASM-ECOPD. The QASM-ECOPD can be used to ascertain the status of the individual COPD patient's self-monitoring of exacerbation at a stage before they initiate action to seek medical care. Therefore, it might be a useful questionnaire to guide the development of future individualized and tailored exacerbation related self-management intervention. The structure model of QASM-ECOPD indicated that elimination of "recognizing hesitation before seeking medical care" is the first support needed for COPD patients to seek treatment in the early stages of COPD exacerbation. Furthermore, reinforcement of "assessing the signs of a respiratory infection" is crucial for COPD patients to pay attention to the onset of exacerbation.

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