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Development and Validation of a Chronic Obstructive Pulmonary Disease Self-Management Scale

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Conflict of Interest

None Declared.

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Abstract

Background: Although self-management reportedly can improve the health and quality of life of patients with chronic obstructive pulmonary disease (COPD), there is no validated instrument for evaluating the status of patients' self-management on COPD. **Methods**: A 51-item COPD Self-Management Scale (CSMS) including five domains (symptom management, daily life management, emotion management, information management, and self-efficacy) was developed and validated using data from 413 COPD patients. **Results**: The CSMS showed good reliability and validity in the validation study. The test-retest correlation coefficient (CC) and the Cronbach's alpha coefficient of the CSMS were 0.87 and 0.92, respectively. The content validity index of the CSMS was 0.90. The correlations of the CSMS with established COPD Self-Efficacy Scale (CSES), Chronic Disease Self-Management Behavior Scale (CDSMBS) and Chronic Disease Self-Efficacy Scale (CDSES) were 0.71, 0.61 and 0.66, respectively. The self-efficacy domain in the CSMS was highly correlated with the total score of the CSES (CC=0.82) and the CDSES (CC=0.76). Moreover, the total score of the CSMS were negatively correlated with the percentage of predicted values of forced expiratory volume in one second (FEV1 % Predicted), with a CC of -0.55. CSMS domain 1 (symptom management) and domain 2 (daily life management) had relatively high CCs (-0.57 and -0.64, respectively) with FEV1 % Predicted, indicating good criterion validity of the scale. **Conclusions**: The CSMS is reliable, valid and sensitive for evaluating the self-management status of COPD patients. It is the first dedicated scale for evaluating the self-management status of COPD patients, and will serve as an important instrument for

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assessing and improving the self-management of COPD patients, particularly, those in the Hunan region of China.

Keywords: chronic obstructive pulmonary disease; self-management; validity; reliability; validation study; self-efficacy

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Introduction

Chronic obstructive pulmonary disease (COPD) is characterized by a progressive deterioration of lung function and associated with mental and physical comorbidities such as depression, muscle wasting, and heart failure.[1] COPD imposes an enormous burden on patients, health-care professionals, and the society.[2-3] The burden of COPD in China is currently greater than that found in developed countries. A population-based, cross-sectional survey of COPD conducted between 2002 and 2004 showed that the overall prevalence of the disease in people aged > 40 years was 8.2%,[4] which would result in a COPD patient population of more than 43 million in China in that time period. It has been reported that patient self-management for COPD can change the patients' life style, reduce costs of hospitalization and improve the patients' depression and quality of life (QOL).[5-7] However, there is no dedicated scale for evaluating the status of patients' self-management on COPD. In the present study, we developed and validated a self-management scale for COPD patients, which provides an important instrument for assessing and improving the self-management of COPD patients.

Methods

Patients

From August 2008 to December 2008, a source-stratified (inpatient and outpatient) random sample of subjects, who required treatment or a physical examination in different hospitals of Hunan Province, were drawn from eligible COPD patients. The inclusion criteria were as follows: (1) With confirmed diagnosis of COPD according to standard criteria[8]; (2) with a disease duration of 1 year or more. The exclusion criteria were as

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follows: (1) With severe cognitive impairment; (2) With concurrent oncologic or psychiatric diseases; (3) With drug or alcohol abuse. Of 413 COPD Self-Management Scale (CSMS) forms distributed, 274 (66.3%) were returned from inpatients (mean age 67.5 years, SD 13.28), 139 (33.7%) from outpatients (mean age 66.9 years, SD 11.71). Of the 413 patients, 120 were randomly selected to complete a second test with the CSMS two weeks later, and 150 were randomly selected to completed tests with a COPD Self-Efficacy Scale (CSES), a Chronic Disease Self-Management Behavior Scale (CDSMBS) and a Chronic Disease Self-Efficacy Scale (CDSES)[9-11]. Basic characteristics of the patients are shown in Supplementary Table S1.

Conceptual Framework

Based on the definition of self-management by Corbin and Straus[12] and the description of self-management contents for COPD patients by Worth et al.,[13] COPD self-management was defined as the process in which COPD patients change their life styles and develop self-efficacy through managing COPD symptoms, treatments, and physiological and psychological changes. Five conceptual domains of COPD self-management were identified: symptom management, daily life management, emotion management, information management, and self-efficacy. Symptom management refers to the COPD patient seeking medication and others' help to deal with COPD symptoms such as dyspnea, cough and sputum. Daily life management refers to the COPD patient taking appropriate amount of exercises and avoiding activities that exacerbates COPD. Emotional management refers to the COPD patient managing emotional changes such as anxiety and depression associated with COPD. Information management refers to the

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COPD patient communicating with clinicians or accessing media to gain information about COPD. Self-efficacy refers to the confidence of the COPD patient in self-management of COPD symptoms, daily life, emotions and information.

Scale Development

Programmed decision processing, a method to develop a scale by a nominal group and a focus group, was used. A pool of 90 items was drafted by interviewing the nominal group consisting of 20 COPD patients. The focus group consisting of nine experts in psychology, nursing, social science, pulmonary medicine, biostatistics and epidemiology reviewed and discussed the pool of items. Individual questions were edited to ensure that problematic items were identified and redundant questions eliminated before an initial pool of 67 items was drafted. The responses to each item were graded on a 5-point scale (1=never, 2=rarely, 3=sometimes, 4=often, and 5=always). A pilot test was conducted in 30 patients and the scale items were readjusted according to the answers received. Then a test was conducted in 413 COPD patients as mentioned above, in which the scale items were selected by the following statistical methods. First, subjects were ranked by the score on the scale to derive a high- and low-score group, comprising 27% of those with the highest and lowest scores, respectively. The score of each item was then compared using Student's *t*-test. Items with no significant difference ($a = 0.01$) between the groups were eliminated. Second, any item with a Pearson correlation coefficient (CC) <0.30 with the total scale score was eliminated. Any item correlating with more than two domains with a CC >0.40 were also eliminated. After the screening tests, 11 items were discarded. The remaining 56 items were subject to principal components analysis, which was used

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to eliminate items with a factor loading <0.4. A 51-item COPD Self-Management Scale (CSMS) was finally derived after the factor analysis (Supplementary Table S2).

Scale Validation

CCs were calculated for the first and the third week tests for test-retest reliability. Internal consistencies for the instrument and its domains were calculated with Cronbach's α coefficient. The validity of the CSMS was tested in three aspects. Content validity was evaluated using the standard proposed by Lynn for content validity index (CVI >0.78).[14] We used principal components analysis and correlation analysis to test construct validity. For criterion validity, four criteria were used, including the CSES, the CDSMBS, the CDSES, and the percentage of predicted values of forced expiratory volume in one second (FEV1 % Predicted). All statistical analyses in this study were performed with SPSS 13.0 for Windows. The statistical significance level of this study was set at two-sided α=0.05. The main procedure of the study is shown in Fig. 1.

Ethical Considerations

The study was approved by the Ethics Committee of Central South University. Written informed consent was obtained from all participating patients before the start of the study.

Results

As mentioned in *Methods*, after screening with Student's *t*-tests and correlation analyses, 11 items were eliminated from the initial draft pool of 67 items. Principal components analysis with varimax rotation was subsequently performed to determine the underlying

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factor structure of the 56-item CSMS and whether items should be removed. The Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy was 0.85, which would be considered meritorious by Kaiser.[15] The results of Bartlett's test indicated that there were significant correlations among the 56 items (χ^2=11389.61, $p<0.01$), supporting the factorability of the correlation matrix. Criteria for inclusion of an item on a factor were a minimum loading of 0.40 and at least 0.10 difference from other loadings. Alpha values and item-total correlation were determined to evaluate the effects of item deletion. The initial principal components analysis yielded 16 factors with eigenvalues >1. All 16 components accounted for 69.60% of the entire variance. Upon examining the Scree plot (Fig. 2), a clear "elbow" was seen at five factors, which directed the subsequent analysis: Solutions between four and six factors were examined. After examination of the three solutions, the five-factor solution was determined to be the best solution because all of the loadings on factors were high (>0.40) (Table 1), and there were fewer double loadings than the other solutions. Of the 56 items put to factor analysis, 51 items comprised the five factors, which explained 46.20% of the total variance. Based on the item contents, the five factors were named as the following domains: symptom management (8 items), daily life management (14 items), emotion management (12 items), information management (8 items), and self-efficacy (9 items) (Table 1). The results fit the initial conceptual framework,

The construct validity of the 51-item CSMS was further assessed by correlation analysis of scores among items, domains and the total scale. The item-total CCs of the domains varied bewteen 0.45 and 0.85. As shown in Table 2, the inter-domain CCs varied between

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0.36 and 0.65, and the domain-total CCs varied between 0.81 and 0.92, confirming the construct validity of the scale.

CVI of the CSMS was 0.90, higher than the standard proposed by Lynn for content validity index (CVI >0.78).[14] The criterion validity of the scale is summarized in Table 3. As shown in Table 3*A*, the CC of the total scores of the 51-item CSMS and the CSES was 0.71. Domain 5 (self-efficacy) in the CSMS was highly correlated with the total score of the CSES (CC=0.82). Correlation between domain scores of the 51-item CSMS and the total score of the CDSMBS varied between 0.46 and 0.60, and the CC of the total scores of the two scales was 0.61 (Table 3*B*). The CC of the total scores of the 51-item CSMS and the CDSES was 0.66. Domain 5 (self-efficacy) in the CSMS was highly correlated with the total score of the CDSES (CC=0.76) (Table 3*C*). Moreover, the total score of the CSMS were negatively correlated with FEV1 % Predicted, with a CC of -0.55 (Table 3*D*). The CCs of CSMS domain 1 (symptom management) and domain 2 (daily life management) with FEV1 % Predicted were -0.57 and -0.64, respectively (Table 3*D*).

As shown in Table 4, test-retest CCs of domains in the 51-item CSMS varied between 0.72 and 0.87, and Cronbach's α varied between 0.82 and 0.92. The test-retest CC of the total score was 0.87 and Cronbach's α 0.92, providing evidence that the 51-item CSMS was stable and reliable according to generally accepted criteria[16] and if good reliability is based on a test-retest CC >0.7 and a Cronbach's α>0.8.

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Discussion

Although self-management reportedly can improve COPD patients' health and quality of life, there is no validated instrument for evaluating the status of patients' self-management on COPD. To fill that gap, in the present study, we developed and validated a scale to assess COPD self-management. The 51-item CSMS described in this article showed good content, construct and criterion validity, as well as test-retest reliability and internal consistency in a large sample of COPD patients including both in and outpatients. Items and hypothesized scales were selected based on a comprehensive literature review and a concept analysis of COPD patients' behavior related to self-management of COPD. Our findings suggest that the instrument captures multiple important domains of COPD patients' self-management.

The results of factor analysis identified five domains of the CSMS, providing evidence in support of the conceptual framework. These factors accounted for 46.20% of the total variance, suggesting good construct validity. The reliability of the instrument is supported by good internal consistency. The satisfactory levels of item-total and domain-total correlations suggest that the items are sufficiently related. With Cronbach's α values between 0.87 and 0.92, internal consistency of the CSMS was well above the minimum recommended level for reliability of Cronbach's coefficient α (>0.70).[17]

As there is no standard reference measure for COPD self-management, the test of criterion validity is difficult. Wigal et al. developed a 34-item CSES to assess self-efficacy in COPD patients. The CSES has good test-retest reliability (r =0.77), excellent

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internal consistency (Cronbach's alpha =0.95), and a five-factor structure (negative affect, intense emotional arousal, physical exertion, weather/environmental, and behavioral risk factors.[19] Thus, this established CSES was used in the present study for criterion test. An established questionnaire on chronic disease self-management developed by Lorig et al. includes four primary classifications of outcome variables (health behaviors, health status, self-efficacy, and health service utilization), which enable a description of how well people are managing their chronic disease.[10, 11] The four subscales of 20 outcome variables are: (1) self-management behavior change; (2) self-efficacy; (3) health status; and (4) health service utilization. The "self-management behavior change" and the "self-efficacy" subscales in the questionnaire were respectively employed as the CDSMBS and the CDSES in the present study for criterion tests. FEV1 % Predicted is a widely used indicator for evaluating the severity of COPD.[18] Our results showed that the total score of the CSMS were negatively correlated with FEV1 % Predicted, with a CC of -0.55. Particulaly, CSMS domain 1 (symptom management) and domain 2 (daily life management) had relatively high CCs with FEV1 % Predicted, indicating good criterion validity of the scale.

COPD is now well recognized as placing a heavy burden on patients and on the health-care system.[19] Numerous studies have demonstrated the benefits of self-management intervention for COPD.[5-7] Efraimsson et al. showed that self-care education could motivate COPD patients for life-style changes.[5] Bourbeau et al. demonstrated that self-management intervention would be cost saving relative to usual care for COPD patients, thereby holding positive economic benefits.[6] Nguyen et al. reported that dyspnea self-

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management could help improve depression in COPD patients.[7] However, there is no dedicated scale for evaluating patients' self-management on COPD. The CSMS developed and validated in the present study is the first dedicated scale for evaluating the status of patients' self-management on COPD. Therefore, it may serve as an effective tool to assess the effects of various self-management interventions on COPD patients, thereby helping change COPD patients' life style, reduce costs of hospitalization and improve the patients'' depression and QOL. Nevertheless, as the CSMS was developed and validated only in the Hunan Region of the Chinese population, further studies may need to evaluate its applicability to other ethnicities or countries.

In conclusion, the CSMS is a reliable, valid and sensitive for evaluating the self-management status of COPD patients. It will serve as an important instrument for assessing and improving the self-management of COPD patients, at least in China.

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Figure Legends

Fig. 1 Flow Chart for the Development Process of the COPD Self-Management Scale.

Fig. 2 Scree Plot for Principal Components Analysis of the COPD Self-Management Scale.

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Tables

Table 1. Variance Explained by the 51-Item COPD Self-Management Scale

Domain	Number of Items	Domain Loading	% of Variance	Cumulative %
Symptom management	8	0.45 – 0.77	25.38	25.38
Daily Life Management	14	0.43 – 0.69	7.51	32.89
Emotion Management	12	0.46 – 0.74	5.06	37.95
Information Management	8	0.46 – 0.69	4.62	42.57
Self-Efficacy	9	0.44 – 0.63	3.63	46.20

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Table 2. Inter-Domain and Domain-Total Correlations of the COPD Self-Management Scale (n=413)

	Domain 1	Domain 2	Domain 3	Domain 4	Domain 5	Total
Domain 1	1.00					
Domain 2	0.42**	1.00				
Domain 3	0.46**	0.51**	1.00			
Domain 4	0.36**	0.56**	0.53**	1.00		
Domain 5	0.65**	0.56**	0.64**	0.53**	1.00	
Total	0.92**	0.86**	0.81**	0.83**	084**	1.00

Note: Domain 1=Symptom Management; Domain 2=Daily Life management; Domain 3= Emotion Management; Domain 4= Emotion Management; Domain 5=Self Efficacy; ***P*<0.01.

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Table 3*A*. Correlations between Scores of the COPD Self-Management Scale and the COPD Self-Efficacy Scale (n=150)

	Total Score (CSES)
Domain 1	0.33**
Domain 2	0.29**
Domain 3	0.57**
Domain 4	0.35**
Domain 5	0.82**
Total Score (CSMS)	0.71**

Table 3*B*. Correlations between Scores of the COPD Self-Management Scale and the Chronic Disease Self-Management Behavior Scale (n=150)

	Total Score (CDSMBS)
Domain 1	0.60**
Domain 2	0.46**
Domain 3	0.48**
Domain 4	0.48**
Domain 5	0.53**
Total Score (CSMS)	0.61**

Table 3*C*. Correlations between Scores of the COPD Self-Management Scale and the Chronic Disease Self-Efficacy Scale (n=150)

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	Total Score (CDSES)
Domain 1	0.25**
Domain 2	0.20*
Domain 3	0.61**
Domain 4	0.58**
Domain 5	0.76**
Total Score (CSMS)	0.66**

Table 3*D*. Correlations between Scores of the COPD Self-Management Scale and FEV1 % (n=150)

	FEV1 % Predicted
Domain 1	-0.57**
Domain 2	-0.64*
Domain 3	-0.18**
Domain 4	-0.29**
Domain 5	-0.25**
Total Score (CSMS)	-0.55**

Note: Domain 1=Symptom Management; Domain 2=Daily Life management; Domain 3= Emotion Management; Domain 4= Emotion Management; Domain 5=Self Efficacy; CSMS, COPD Self-Management Scale; CSES, COPD Self-Efficacy Scale; CDSMBS, Chronic Disease Self-Management Behavior Scale; CDSES, Chronic Disease Self-Efficacy Scale; FEV1, forced expiratory volume in first second; FEV1 % predicted, FEV1% of the patient divided by the average FEV1% in the population for any person of similar age, sex and body composition. *P<0.05; **P<0.01.

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Table 4. Three-Week Test-Retest Reliability and Cronbach's α Coefficients of the COPD Self-Management Scale

Domain	Pearson CCs for Two Tests	Cronbach's α
Total Score	0.87	0.92
Symptom Management	0.72	0.83
Daily Life management	0.87	0.86
Emotion Management	0.84	0.87
Information Management	0.78	0.82
Self-Efficacy	0.76	0.83

Note: All Pearson CCs were significant at $P < 0.01$; CC, correlation coefficient.

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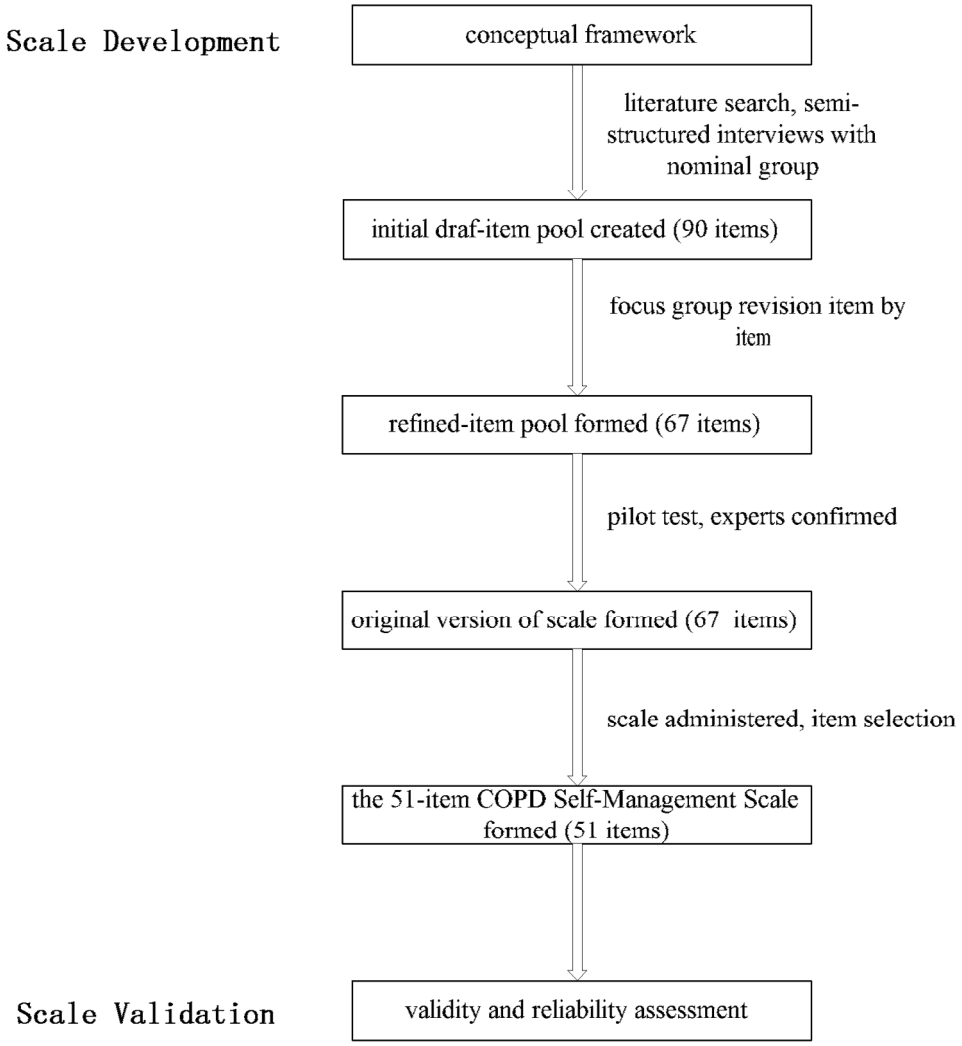

Fig. 1

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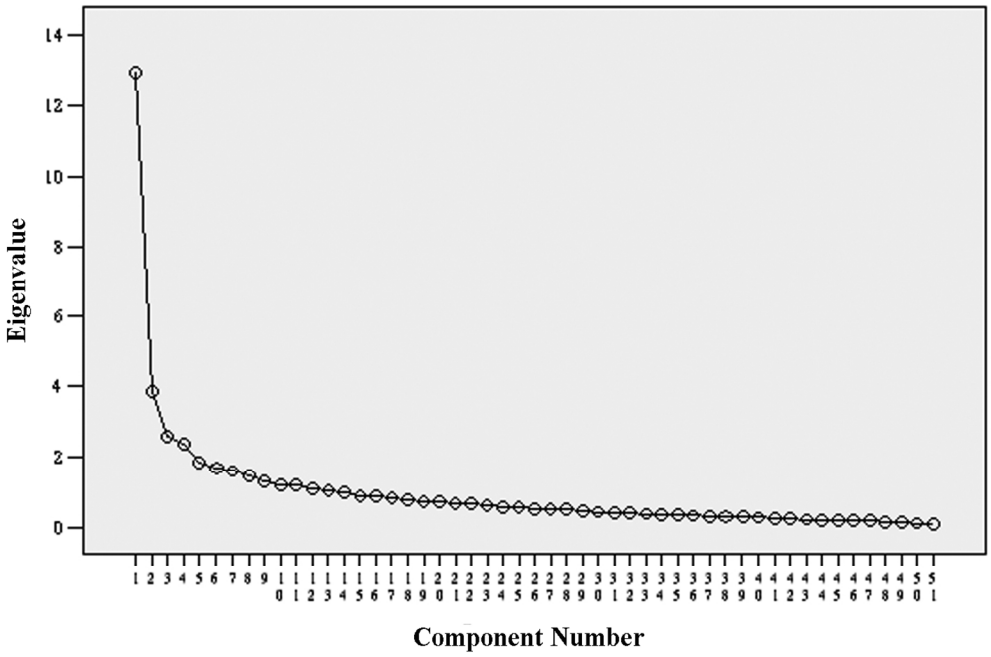

Fig. 2

121x92mm (300 x 300 DPI)