Association Between Clinical Variables and Health-Related Quality of Life in Patients with Chronic Obstructive Pulmonary Disease

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Purpose. Treatment strategies of chronic obstructive pulmonary disease (COPD) are often based on clinical data, such as lung function and physical symptoms, and neglect patients' quality of life. The health- related quality of life (HRQL) measurement can often reflect patients' self-perceived well-being, such as psychological state, social relationships and environmental health. The relationship among clinical variables and HRQL were investigated in order to optimize the appropriate treatment for patients with COPD.

Methods. Clinical data and HRQL (WHOQOL-BREF questionnaire) were collected from 132 COPD patients (age range, 44.2 to 88.4 yr) from 2001 to 2003. Correlation, crude regression and multiple regression analysis were used to determine the factors that influenced HRQL.

Results. Mean HRQL scores were significantly lower among patients with lower predicted FEV1 and lower scores for fatigue and breathing difficulties in the physical domain, and breathing difficulties in the environmental domain. None of the clinical variables correlated significantly with the psychological and social domains.

Conclusions. The HRQL yields additional information about patients' health status, such as psychological well-being, social relationships and perception of environment. These data may provide health care providers with a much more detailed picture of the disease. **(Mid Taiwan J Med 2006;11:155-63)**

Key words

chronic obstructive lung disease, clinical symptoms, quality of life

INTRODUCTION

The reference global initiative for obstructive lung disease (GOLD) workshop report [1] defines chronic obstructive pulmonary disease (COPD) as a disease state characterized by airflow limitation that is not fully reversible. The airflow limitation is usually both progressive and associated with an abnormal inflammatory response of the lungs to noxious particles or gases. This definition excludes asthma (reversible airflow limitation) and does not use the terms chronic obstructive bronchitis and emphysema. This debilitating disease is the fifth leading cause of death worldwide and it is predicted that its prevalence and mortality will rise in the coming

decades [2]. According to an official report, COPD was the 11th leading cause of death in 2002 in Taiwan; however, this figure is an underestimation because of the different classification criteria used in Taiwan compared with that used in western countries [3].

The main symptoms of COPD include cough, sputum production, and dyspnea on exertion. Acute worsening of these symptoms often occurs episodically [1]. The physical effects of COPD include chronic shortness of breath and dyspnea, which reduces energy and vitality and can lead to anxiety, dependency, loss of self-esteem, and other psychiatric problems [4]. Smoking is an important risk factor for COPD [5]. The morbidity due to COPD increases with age and is greater in men than women [6]. The average survival time of COPD patients after diagnosis is about 15 years and mortality 10 years after diagnosis is above 50 percent [7,8]. However, COPD is not fully reversible and cannot be "cured". It can be managed using a combination of management strategies. The primary goals of COPD management are reduction of airflow obstruction, prevention or treatment of complications associated with the disease, and improvement of quality of life [9].

Quality of life is defined by the World Health Organization as an individual's perception 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 [10]. It is a broad ranging concept, incorporating in a complex way the persons' physical health, psychological state, level of independence, social relations, personal briefs, and relationship to salient features of environment. The World Health Organization QOL (WHOQOL) measurement is a multidimensional, multi-lingual profile that has been designed for cross-cultural subjective assessment [11,12]. The WHOQOL-BREF questionnaire used in this study includes 24 facets and 2 global WHOQOL items from the WHOQOL conceptual constructs, as well as two additional facets specifically designed for the Taiwan WHOQOL-BREF version [13]. HRQL questionnaires, such as the WHOQOL-BREF, are increasingly being used as outcome measurements in clinical trials, effectiveness research, and research on quality of care [14]. The WHOQOL-BREF has been shown to have good internal reliability, test-retest reliability, content validity, discriminant validity and construct validity when applied to COPD patients [15].

Because COPD often affects older people, task performance may be less important than the ability to enjoy life. There is growing awareness that health status is better characterized by HRQL than standard physiologic outcomes [16-18]. Previous studies have shown that the relationship between respiratory impairment reflected by pulmonary functions such as the forced expiratory volume in one second (FEV_1), forced vital capacity (FVC), and the FEV_1/FVC ratio and HRQL measures in patients with COPD is only weakly significant [19-21]. Therefore, it is not possible to determine the impact of the disease on a patient by only examining the physiological index. The HRQL in elderly outpatients with chronic disease is a multidimensional construct which evaluates patients' health, psychological well-being, social relationships and their environment. Physicians may misinterpret patients' health status if they rely too heavily on physical symptoms and clinical variables [17].

Quality of life (QOL) is becoming an increasingly important outcome measure for physicians to evaluate the effectiveness of treatment strategies [22]. This type of self-perceived health outcome measure yields useful and relevant information because it reflects patients' experiences and perspectives. Physical symptoms alone may not accurately reflect patients' QOL. In order to gain a better understanding of the relationship between QOL and clinical parameters, we assessed the correlations between HRQL and clinical parameters of COPD patients, such as lung function (% predicted FEV_1; FEV_1/FVC), disease duration, and various medical symptoms as diagnosed by a physician.

Table 1. Patients' characteristics

Characteristics	Subjects (n = 132)
Female (%)	9.1
Age, mean (SD), age range	69.7 (8.2), 44.2-88.4
Duration of disease, mean (SD), age range	3.7 (3.3), 0-14.6
Current smoking status (% yes)	30.5

MATERIALS AND METHODS

Patient selection

A total of 132 COPD patients (12 females and 120 males) aged from 44 to 88 years (mean = 69.7 ± 8.2), whose conditions had been diagnosed according to WHO GOLD guidelines [1] were enrolled in the study. Patients were recruited from outpatient clinics of the China Medical University Hospital (CMUH) and Changhua Christian Hospital (CCH) in central Taiwan from 1 August 2001 to 31 April 2003. Written informed consent was obtained from all participants in this study. Criteria for inclusion were as follows: 40 years of age or older; an $FEV_1/FVC < 70\%$, or an FEV_1/FVC greater or equal to 70% associated with chronic bronchitis, or the presence of cough and sputum production for at least 3 months in each of two consecutive years. Subjects with cancer were excluded from our study.

Lung function variables

FEV_1 and FVC were evaluated on the same day as the questionnaire assessments. A diagnosis of COPD was confirmed by spirometry. Spirometric lung function parameters were determined by measuring FVC and FEV_1 and calculating the ratio between FEV_1 and FVC. Spirometric results were expressed as a predicted percentage using appropriate normal values for the person's gender, age, and height. Historically, patients with COPD typically show a decrease in both FEV_1 and FEV_1/FVC. The degree of spirometric abnormality generally reflects the severity of COPD. Disease stage of COPD was determined using the GOLD criteria [1].

Clinical symptom variables

Patients' symptoms, including loss of appetite, fatigue, coughing frequency, and breathing difficulties, were assessed by the physician during the physical examination using a self-developed questionnaire; the questionnaire had been validated by 3 physicians and 1 biostatistian. Each of the four symptoms was evaluated using a scale ranging from 0 to 100. For example, for appetite, 0 represented no appetite and 100 represented normal appetite. In the multiple regression analysis, each symptom score was divided into three groups (mild, moderate, and severe) by the 33.3 and the 66.7 percentiles.

WHOQOL-BREF and other variables

WHOQOL-BREF questionnaire data were collected by interviewing patients in person at outpatient departments. All interviewers were well trained prior to data collection. Patients' demographic data and other basic information such as smoking status were collected during the interview. In addition, physicians attempted to determine the approximate duration of COPD. The Taiwan version of the WHOQOL-BREF was developed in compliance with WHO guidelines [23,24], and good reliability and validity of this version have been reported [25]. All items were rated on a five-point Likert scale with a higher score indicating a higher QOL. The scoring procedure was performed according to WHOQOL guidelines [26]. In WHOQOL-BREF, a score transformation was done for the "negative phrasing" items; so higher scores always indicated better HRQL. Each item score was transformed to a 0-100 score.

Analysis of data

Pearson's correlation coefficients were determined to examine the degree of association among lung function parameters, clinical symptoms, and HRQL. To further examine the magnitude of each clinical variable on HRQL, we

Table 2. Clinical variables and HRQL of the study population

	Subjects (n = 132)
Lung function: Mean (SD)	
FEV$_1$ (% predicted)	56.0 (20.1)
FEV$_1$/FVC ratio	61.4 (10.6)
Disease stages of severity*: n (%)	
Stage 0: at risk	12.0 (9.1)
Stage I: mild	6.0 (4.6)
Stage II: moderate	61.0 (46.2)
Stage III: severe	40.0 (30.3)
Stage IV: very severe	13.0 (9.9)
Clinical symptoms scores: Mean (SD)	
Loss of appetite	84.9 (19.5)
Fatigue	73.4 (21.0)
Coughing frequency	68.7 (16.9)
Breathing difficulties	60.8 (19.7)
HRQL: Mean (SD)	
Physical	59.4 (13.5)
Psychological	60.7 (13.5)
Social	67.8 (8.8)
Environmental	66.8 (9.8)

Each symptom was evaluated using a scale of 0-100 (0 = most severe; 100 = normal). Each HRQL domain ranged from 0 to 100 (0 = very bad; 100 = very good). *Disease stage of COPD was determined using the GOLD criteria.

divided the clinical symptoms into three groups of severity (mild, moderate and severe). The stages of COPD were also combined to form three groups (stage 0 and I, stage II and III, and stage IV). We then applied multiple regression analysis to assess the relationship between each clinical variable and HRQL after adjusting for age and gender. SAS software [27] was used for all statistical analyses. A *p* value of < 0.05 was regarded as statistically significant.

RESULTS

Patients

The characteristics of the 132 COPD patients are presented in Table 1. About 91% of patients were men and 9% were women with an average age of 69.7 years (SD = 8.2 yr, range = 44.2 to 88.4 yr). Duration of COPD ranged from 0 (recent diagnosis) to 14.6 years (mean = 3.7 yr; SD = 3.3 yr). Most patients stated that they were non-smokers (69.5%).

Clinical variables and HRQL

The clinical variables and HRQL of the study population are presented in Table 2. Mean FEV$_1$% predicted was 56.0% and the FEV$_1$/FVC ratio was 61.4. For clinical symptoms, the lowest score was for breathing difficulties (60.8), followed by coughing frequency (68.7), fatigue (73.4), and loss of appetite (84.9). Most patients (46.2%) were in lung function stage II, followed by stage III (30.3%), stage IV (9.9%), stage 0 (9.0%) and stage I (4.6%). For HRQL, the lowest scores were in the physical domain (59.4), followed by the psychological (60.7), environmental (66.8) and social (67.8) domains.

Correlation between clinical variables and HRQL

The Pearson's correlation coefficients for clinical variables and HRQL in the four domains are presented in Table 3. FEV$_1$ (% predicted) correlated significantly with the physical domain (*p* = 0.0034). Fatigue and breathing difficulties were significantly related to the physical domain (*p* = 0.0062 and 0.0059, respectively). Breathing difficulties were also significantly related to the environmental domain (*p* = 0.0052). None of the other parameters (FEV$_1$/FVC ratio, loss of appetite and coughing frequency) correlated with

Table 3. Pearson's correlations coefficients between clinical variables and HRQL

	Pearson's correlation coefficients			
	Physical	Psychological	Social	Environmental
Lung function				
FEV$_1$ (% predicted)	0.25**	0.15	0.04	0.01
FEV$_1$/FVC ratio	0.15	−0.02	−0.01	−0.04
Clinical symptom scores				
Loss of appetite	0.14	0.08	0.001	0.11
Fatigue	0.26**	0.07	−0.01	0.13
Coughing frequency	−0.05	−0.14	0.11	−0.002
Breathing difficulties	0.26**	0.17	0.12	0.27**

Each symptom was evaluated using a scale of 0-100 (0 = most severe; 100 = normal). Each HRQL domain ranged from 0 to 100 (0 = very bad; 100 = very good). **$p < 0.01$.

Table 4. Multiple regression analysis of each clinical variable on HRQL

	Regression coefficients (adjusted for age and gender)			
	Physical	Psychological	Social	Environmental
Disease stages of severity[†]				
Stage II & III *vs* stage 0 & I	−6.64*	−2.22	−2.94	−1.51
Stage IV *vs* stage 0 & I	−14.15**	−9.17	−4.67	−3.26
Clinical symptom scores[†]				
Loss of appetite				
Moderate *vs* mild	−1.04	−1.21	0.27	0.17
Severe *vs* mild	−4.18	−4.79	−1.01	−3.89
Fatigue				
Moderate *vs* mild	−6.08*	−5.92	−2.18	−3.15
Severe *vs* mild	−10.03**	−5.83	−1.42	−5.06
Coughing frequency				
Moderate *vs* mild	−5.60	−3.54	−4.64	−5.30
Severe *vs* mild	−0.77	2.82	−4.23	−3.18
Breathing difficulties				
Moderate *vs* mild	−1.36	−0.49	−1.18	−4.40*
Severe *vs* mild	−10.09**	−7.82	−3.21	−6.17*

Each HRQL domain ranged from 0 to 100 (0 = very bad; 100 = very good). [†]For disease severity, stages 0 and I are combined to comprise the reference group. For clinical symptoms, scores of 0-100 were divided into three groups, mild, moderate and severe, based on the 33.3 and 66.7 percentiles, and the mild group served as the reference group. *$p < 0.05$, **$p < 0.01$.

any of the four domains.

Multiple regression analysis of HRQL

Table 4 shows the regression coefficients from the multiple regression analysis between each clinical variable and each of the four HRQL domains after adjustment for age and gender. The results are similar to those in Table 3. The results revealed that severity of the disease, fatigue and breathing difficulty were significantly related to physical quality of life, and that breathing difficulty was significantly related to environmental quality of life. With disease stages 0 and I serving as the reference group for the physical domain, there were significant differences in physical QOL scores in disease stages II and III group ($p = 0.0030$) and in disease stage IV group ($p = 0.0447$), respectively. Similarly, the physical quality of life decreased with worsening fatigue and breathing difficulty; and the environmental quality of life decreased with worsening breathing difficulty.

DISCUSSION

The present study reveals that, for patients with chronic obstructive pulmonary disease (COPD), clinical variables are well related to the physical domain. This result was expected. Measurements of patients' clinical variables may

not reflect their quality of life. Quality of life is a considerably more comprehensive measure than health status and includes other experiences that may or may not be affected by health or treatment [28]. Furthermore, our findings from both correlation and multiple regression analysis revealed that clinical variables were unrelated to the social and psychological domains, and only breathing difficulty was related to the environmental domain.

In assessing patients' health status, physicians generally only measure basic physical clinical variables using a simple, self-designed questionnaire. However, such assessments do not measure non-physical characteristics such as psychological well-being, social relationship, and perception of environment. Increasingly, it has been recognized that health-related quality of life (HRQL) is an important outcome of medical care [28,29] and is a powerful predictor of hospitalization and all-cause mortality [7,30]. There are a number of well established health related quality of life questionnaires which have been shown to be useful in a clinical setting. For example, HRQL can markedly increase in COPD patients even when lung function variables remain unchanged, which demonstrates that HRQL can sensitively measure the influence of intervention programs on patients' prognosis independent of the physical domain [13,28,31,32]. A better understanding of the relationships between clinical variables and the measures of HRQL will enable physicians to conduct a more comprehensive evaluation of their patients.

Breathing difficulty and coughing are two major symptoms of COPD [1,5]. In our study population, breathing difficulty and coughing were the two most bothersome symptoms followed by fatigue and loss of appetite. Breathing difficulty and fatigue correlated well with the physical domain, but coughing frequency and loss of appetite did not, possibly because of the nature of these symptoms. For example,

coughing in COPD patients is a very common symptom but HRQL was assessed during the day when coughing may be less severe. In addition, coughing symptom is readily influenced by other factors such as air pollutants and allergens which may induce intermittent episodes of coughing. It was therefore difficult to establish a strong link between coughing frequency and HRQL. Dyspnea though was strongly related to HRQL because it represents a worsening of health status and is a much more unpleasant physical symptom than coughing. Recent studies have shown that differences in health status may not be detected until the later stages of the disease [2]. As such, physical HRQL in COPD patients is better correlated with dyspnea than with coughing.

A methodological limitation of the study was its cross sectional design, which does not allow for much scope to make predictions or generalizations. Most COPD patients in this study were in disease stages II and III, so the data did not adequately represent patients in stages 0, I and IV. The only QOL questionnaire used in this study was the generic WHOQOL-BREF; we did not use a disease-specific QOL questionnaire. Smoking is an important risk factor for COPD patients but in this study we only measured current smoking status. We did not collect detailed data, such as age at smoking commencement and total packs smoked per year. In addition, most patients had quit smoking by the time the disease was diagnosed. Therefore current smoking status did not yield any significant trend with regard to QOL in the analysis. Duration of disease is often difficult to determine because many patients at diagnosis are already at disease stage II or III. Because duration of disease is often underestimated, it is not a good predictor of HRQL [2,33]. Hence, in our regression analysis, smoking status and duration of disease were not included because these factors were problematic.

In conclusion, COPD patients' clinical variables only give the physician limited information about their health status. Assessment

of patients' health-related quality of life may provide additional, useful information relevant to the patients' psychological, social, environmental as well as physical needs. It is necessary for healthcare workers to measure and promote QOL because for this group of patients enhancement of self-perceived well-being is as important as managing the physical aspects of the disease.

ACKNOWLEDGMENTS

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慢性阻塞性肺部疾病患者臨床因子與健康相關生活品質之相關性探討

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目的　　慢性阻塞性肺部疾病(COPD)患者的治療常著重於身體症狀與生理層面，而忽略了患者的心理、社會等層面的問題。健康相關生活品質(HRQL)經常能有效地反應患者的自覺健康狀況。本研究探討COPD患者的臨床因子與其健康相關生活品質之相關性。

方法　　共計收案132名COPD患者，年齡介於44.2至88.4歲，收案期間為2001年至2003年。主要測量患者的臨床資料及以世界衛生組織生活品質問卷(WHOQOL-BREF)所測得的健康相關生活品質。相關分析及複迴歸分析用以評估影響健康相關生活品質的臨床因子。

結果　　若患者的第一秒最大呼氣量($FEV_1\%$預測值)值較低，且在疲倦與呼吸困難症狀的得分較低，則患者於生理範疇的健康相關生活品質得分亦顯著較低，若患者呼吸困難症狀的得分較低亦於環境範疇有顯著較低的得分。臨床症狀與心理範疇及社會範疇的得分無顯著相關性。

結論　　健康相關生活品質對患者健康狀況能提供更全面的訊息如心理健康、社會關係及對環境的感受性等，使健康照護者能更加瞭解疾病對患者的影響層面。（中台灣醫誌2006;11:155-63）

關鍵詞
慢性阻塞性肺部疾病，臨床症狀，生活品質