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## **RESEARCH ARTICLE**

# Predicting Quality of Life in Chronic Obstructive Pulmonary Disease Patients Living in the Rural Area of Chiang Mai Province, Thailand

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### Abstract:

### Background:

Chronic Obstructive Pulmonary Disease (COPD) becomes burdensome and reduces the quality of life in COPD patients and their families. Understanding the factors affecting the quality of life could improve the process of care and treatment of these patients. Therefore, this study aimed to investigate the factors that influence and can predict the quality of life in COPD patients.

#### Methods:

A total of 281 COPD patients were included and analyzed by spirometry measurement, BODE index and its components (body mass index; BMI, forced expiratory volume in one second % predicted; FEV<sub>1</sub>%predicted, dyspnea score of the modified Medical Research Council; mMRC, and distance in the six-minute walking test; 6MWT).Quality of life was assessed by the St. George's Respiratory Questionnaire (SGRQ).

### Results:

The total SGRQ score was 42.1 $\pm$ 17.4. The mMRC dyspnea score, ABCD group classification of COPD and BODE index moderately correlated with the total SGRQ score. Weak correlations were found between BMI, FEV<sub>1</sub>%predicted and 6MWT. Multiple regression analysis showed that the mMRC dyspnea score, BODE index, age, and COPD group D were important predictors of quality of life in COPD patients with R<sup>2</sup> of 0.467.

### Conclusion:

The mMRC dyspnea score, BODE index, age, and COPD group D could predict the quality of life in the COPD patients in this study.

Keywords: Quality of life, Chronic obstructive pulmonary disease, Pulmonary disease, BODE index, Rural community, St. George's Respiratory Questionnaire.

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## 1. INTRODUCTION

Chronic Obstructive Pulmonary Disease (COPD) is one of the most important diseases, which affects more than 200 million people worldwide [1]. The World Health Organization predicts that COPD will be 3.8% of total Disability-adjusted Life Years (DALYs) [2] and the third-leading cause of global death by 2030 [3]. COPD is a preventable and treatable disease characterized by persistent respiratory symptoms and airflow limitation [4]. These characteristics lead to deconditioning, poor functional capacity and poor quality of life [5, 6]. Hence, COPD treatments aim to control symptoms, improve physical function, exercise tolerance and health status, and decrease the psychological impact of COPD and hospital re-admission, with the ultimate goal of improving quality of life [4, 7 - 10].

Quality of life is important in measuring the impact of chronic diseases [11]. The objectives of measuring the quality of life for the patients are to improve the process and planning of care and assist physicians and patients in deciding the appropriate treatment [12]. Evaluation of quality of life is necessary in COPD patients because the association between measures of airway obstruction and exercise impairment were

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poor, and the cause of breathlessness could not be summarized by only the lung function test [11]. The St. George's Respiratory Questionnaire (SGRQ) is an instrument for measuring quality of life, and was specially designed for COPD patients. It shows the impact of disease on everyday life [13, 14] and includes 3 components; symptoms, activity and impact [15 - 18]. The SGRQ score represents the association with health resource utilities and decreased survival [19, 20]. Moreover, it responds to either pharmacological or nonpharmacological intervention [21, 22]. Previous studies have investigated the correlation and impact between quality of life and many variables, including the BODE index, Global Initiative for Chronic Obstructive Lung Disease (GOLD) grade classification, and ABCD group classification of COPD [23 -26]. Sarkar et al. [24] found that the BODE index, including its individual components, strongly correlated with quality of life, and it was shown to be better than the GOLD grade classification in predicting the health status in stable COPD patients. Nonato et al. [23] reported that COPD patients in early stages, with a BODE index score of 0 could have impaired quality of life. Martin et al. [27] revealed that quality of life correlated better with the BODE index than with forced expiratory volume in one second % predicted (FEV<sub>1</sub> %predicted), while no correlation with body mass index (BMI) was found. Boland et al. [26] found that the ABCD group classification associated more closely with quality of life than the GOLD grade classification. Nevertheless, findings in the ABCD group and GOLD grade classification have been inconclusive, as shown in previous studies [26, 28, 29]. Thus, it was unknown whether the BODE index, GOLD grade, or ABCD group could predict the quality of life in COPD patients.

Chiang Dao district has an area of approximately 1,882 km<sup>2</sup>, in the north of Chiang Mai province, Thailand, and is surrounded by high mountains. The prevalence of COPD in Chiang Dao district was higher at 6.8% than that in municipal areas of Chiang Mai (3.7%) [30], which leads to major health problems [4]. Previous study found that outdoor air pollution affects quality of life in COPD patients in Chiang Dao [31], but other factors are inconsistent. It is important to identify the factors that influence and can predict quality of life. Therefore, this study aimed to investigate the variables that influence and can predict the quality of life in COPD patients, which could improve their process of care and treatment.

### 2. MATERIALS AND METHODS

This cross-sectional study was approved by the Research Ethics Committee of the Faculty of Medicine, Chiang Mai University (No. 497/2015). A total of 281 COPD patients, who attended the COPD clinic at Chiang Dao Hospital (60-bed community hospital), Chiang Mai, Thailand between December 2015 and November 2016 were recruited into this study. The inclusion criteria comprised patients clinically diagnosed with COPD according to the GOLD report [4], aged 40 years or older and able to walk independently. The exclusion criteria consisted of acute exacerbation within 4 weeks before the assessment, tuberculosis, asthma, cognitive impairment, and psychological and musculoskeletal disorders.

All of the patients completed the SGRQ - Thai version,

which was permitted by Professor Paul Jones, Professor of Respiratory Medicine, St. George's University of London. The SGRQ - Thai version is considered a gold standardized questionnaire for measuring impaired health and perceiving quality of life in chronic respiratory diseases. It contains 50 items with 76 weighted responses that are divided into three domains: symptoms - distress due to respiratory symptoms, activity - disturbances of physical activity, and impact - overall impact on daily life and well-being. Items were scored from zero (no impairment) to 100 (maximum impairment) [14].

The BODE index is a multidimensional scoring system and capacity index used for assessing COPD patients. It is calculated by the scores obtained from BMI, measurement of airflow obstruction using spirometry (FEV<sub>1</sub>%predicted), exercise capacity by distances in the six-minute walking test (6MWT) and dyspnea scale from the modified Medical Research Council (mMRC). Scoring from 0 to 10 points in further quartiles was as follows: quartile 1 (0 to 2 points), quartile 2 (3 to 4 points), quartile 3 (5 to 6 points), and quartile 4 (7 to 10 points) [32].

The severity of COPD in the patients was classified according to the GOLD report [4] by the level of airflow limitation (post-bronchodilator FEV<sub>1</sub> %predicted) into GOLD grades 1-4: GOLD 1 (mild COPD): FEV<sub>1</sub>> 80%predicted, GOLD 2 (moderate COPD): FEV<sub>1</sub> 50-79%predicted, GOLD 3 (severe COPD): FEV<sub>1</sub> < 30%predicted. The symptoms (mMRC dyspnea scale or COPD assessment test; CAT) and the risk of future exacerbation (prior history of moderate to severe COPD exacerbation) were put into the GOLD groups A-D group: Group A: low risk, fewer symptoms, Group B: low risk, more symptoms, Group C: high risk, fewer symptoms and Group D: high risk, more symptoms.

#### 2.1. Statistical Analysis

The results were analyzed as mean  $\pm$  standard deviations or percentages. Pearson's correlation coefficient and Spearman's correlation coefficient were used to screening the correlation between variables. Multiple regression analysis was used to analyze all variables for predicting. The statistical model was validated using the coefficient of determination (R<sup>2</sup>). A p-value of <0.05 (2-sided) was set as the level of statistical significance.

### **3. RESULTS**

A total of 281 COPD patients were included for analyses. All of the patients were smokers with a mean smoking history of  $39.0\pm18.1$  years; 50.9% of them were male with a mean age of  $68.9\pm10.2$  years and mean income of approximately  $139.9\pm218.2$  USD (US dollar) per month; and 48.8% had an occupation; 87.5% stayed with a caregiver; and 43.1% had comorbidity. The mean post-bronchodilator FEV<sub>1</sub> was  $63.5\pm28.3\%$  predicted. Mean SGRQ scores were as follows: total score  $42.1\pm17.4$ , symptom score  $39.9\pm21.5$ , activity score  $49.8\pm25.6$  and impact score  $38.2\pm16.3$ . Demographic data and clinical characteristics of the participants are presented in Table **1**.

Table 1.	Characteristics	of COPD	patients.
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Variables (N=281)	n (%) or mean±SD
Sex	
male	143 (50.9)
Age (years)	68.9±10.2
Income (USD/month)	139.9±218.2
Smoking (years)	39.0±18.1
Occupation Yes	137 (48.8)
Caregiver Yes	246 (87.5)
Comorbidity Yes	121 (43.1)
BODE Index (score of 10)	3.3±2.1
BMI (kg/m <sup>2</sup> )	19.1±3.9
mMRC (score)	1.6±1.1
FEV <sub>1</sub> % predicted	63.5±28.3
6MWT (meters)	341.7±102.1
GOLD stage	
GOLD 1	66 (23.5)
GOLD 2	109 (38.8)
GOLD 3	83 (29.5)
GOLD 4	23 (8.2)
ABCD assessment groups	
Group A	133 (47.3)
Group B	107 (38.1)
Group C	14 (5.0)
Group D	27 (9.6)

SD: Standard deviation, COPD: Chronic obstructive pulmonary disease, BMI: Body massindex, FEV<sub>1</sub>: Forced expiratory volume in one second, mMRC:modified medical research council dyspnea score, 6MWT: six-minute walking test. USD: US dollar.

Table 2 shows the SGRQ score of each component with each variable. Table 3 shows the correlation between the SGRQ score and each factor.

The total SGRQ score was at a moderate level for both males and females, with no significant difference between genders when compared with the mean difference.

Age was associated with the symptom (R = -0.16; p < 0.05) and activity score (R = 0.14; p < 0.05), but not with the impact or total score. Having occupation was associated with activity score (R = -0.28; p < 0.001), impact score (R = -0.10; p < 0.001), and total score (R = -0.18; p < 0.001), but not with the symptom score.

Table 2. Mean SGRQ scores in COPD	patients according to the individual components of the BODE index.
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Variables		SGRQ score (mean±SD)				
		Symptoms score	Activity score	Impact score	Total scores	
Overall	281	39.9±21.5	49.8±25.6	38.2±16.3	42.1±17.4	
BMI (kg/m <sup>2</sup> )						
>21	201	40.5±21.0	51.6±25.0	39.2±15.1	43.3±16.3	
≤21	80	38.3±22.6	45.4±26.7	35.5±18.7	39.1±19.5	
p value		0.231	0.051	0.030	0.027	
FEV <sub>1</sub> %predicted						
$\geq 65$	110	38.7±21.9	43.3±23.6	34.3±17.4	37.8±17.4	
50-65	65	40.6±23.9	54.8±27.0	41.2±15.2	45.4±18.0	
36-49	66	40.2±19.0	49.2±25.6	38.5±13.9	42.2±15.7	
≤35	40	41.1±20.7	60.6±24.2	43.4±16.2	48.5±16.4	
p value		0.906	0.001	0.005	0.002	
mMRC grade						
Grade 0-1	147	33.6±21.6	34.5±19.7	30.2±14.0	32.1±14.0	

#### 360 The Open Public Health Journal, 2020, Volume 13

(Table 2) cont....

Variables	n	SGRQ score (mean±SD)			
Grade 2	60	43.5±17.9	57.1±17.5	42.6±11.8	47.3±11.5
Grade 3	71	49.6±20.3	74.4±19.1	50.4±14.6	57.8±13.8
Grade 4	3	42.7±5.6	72.9±19.5	48.3±21.9	55.1±17.1
p value		< 0.001	< 0.001	< 0.001	< 0.001
6MWT (meters)					
≥350	157	39.3±22.4	42.2±24.3	36.3±16.5	38.6±17.4
250-349	74	38.4±18.7	54.1±23.2	39.2±15.6	43.7±15.5
150-249	34	42.5±22.5	63.6±23.1	40.9±16.4	48.2±17.4
<150	16	46.2±21.8	75.5±21.3	46.5±13.8	55.5±15.9
p value		0.505	< 0.001	0.055	< 0.001
Quartile BODE	index			31.6±16.4 37.9±14.5 45.9±14.6	
Quartile 1	101	36.4±21.6	36.4±21.8		33.9±16.5
Quartile 2	89	39.6±21.0	48.3±23.8 68.1±20.0		41.4±15.6
Quartile 3	58	43.5±19.6			52.5±14.2
Quartile 4	21	51.4±20.4	76.1±19.0	49.9±13.8	58.3±13.5
p value		< 0.001	< 0.001	< 0.001	< 0.001
ABCD grou	p				
Group A	107         45.7±18.9         64.7±19.8         45           14         33.9±24.8         37.7±22.4         27			30.5±13.9 45.9±13.6 27.8±14.9	32.2±13.9
Group B					51.8±13.4
Group C			37.7±22.4		31.9±15.9
Group D			50.8±15.1	58.2±14.2	
p value		< 0.001	< 0.001	< 0.001	< 0.001

\*p < 0.05, \*\*p< 0.01

SD: Standarddeviation, SGRQ: St George's respiratory questionnaire, COPD: Chronic obstructive pulmonary disease, BMI: Body mass index, FEV<sub>1</sub>: Forced expiratory volume inonesecond, mMRC:modified medical research council dyspnea score, 6MWT: six-minute walking test.

Table 3. Correlations	with p	p values	) for the SGRQ and factors.

Factors	Symptoms	Activity	Impact	Total
Sex <sup>b</sup>	-0.05 (p = 0.393)	0.07 (p = 0.234)	0.06 (p = 0.333)	0.06 (p = 0.290)
Age <sup>a</sup>	-0.16 (p = 0.006)*	0.14 (p = 0.020)*	-0.08 (p = 0.155)	-0.01 (p = 0.880)
Income <sup>a</sup>	-0.03 (p = 0.605)	-0.09 (p = 0.139)	-0.06 (p = 0.360)	-0.07 (p = 0.224)
Smoking <sup>a</sup>	-0.05 (p = 0.531)	0.07 (p = 0.299)	0.03 (p = 0.597)	0.04 (p = 0.535)
Occupational <sup>b</sup>	-0.01 (p = 0.847)	-0.28 (p <0.001)**	-0.10 (p <0.001)**	-0.18 (p = 0.002)*
Caregiver <sup>b</sup>	-0.00 (p = 0.954)	-0.03 (p = 0.623)	-0.02 (p = 0.788)	-0.02 (p = 0.696)
Comorbidity <sup>b</sup>	0.03 (p = 0.665)	-0.02 (p = 0.798)	-0.01 (p = 0.902)	0.00 (p = 0.545)
BODE index <sup>a</sup>	0.21 (p <0.001)**	0.58 (p <0.001)**	0.42 (p <0.001)**	0.52 (p <0.001)**
BMI <sup>a</sup>	-0.04 (p = 0.491)	-0.18 (p = 0.002)*	-0.12 (p = 0.042)*	-0.15 (p = 0.010)*
mMRC <sup>a</sup>	0.30 (p <0.001)**	0.72 (p <0.001)**	0.54 (p <0.001)**	0.66 (p <0.001)**
FEV <sub>1</sub> %predicted <sup>a</sup>	-0.09 (0.143)	-0.25 (p <0.001)**	-0.22 (p <0.001)**	-0.24 (p <0.001)**
6MWT <sup>a</sup>	-0.03 (0.587)	-0.36 (p <0.001)**	-0.12 (p <0.041)*	-0.23 (p <0.001)**
Quartile BODE index <sup>b</sup>	0.19 (0.002)*	0.52 (p <0.001)**	0.35 (p <0.001)**	0.45 (p <0.001)**
ABCD group <sup>b</sup>	0.28 (p <0.001)*	0.54 (p <0.001)*	0.42 (p <0.001)*	0.52 (p <0.001)**

<sup>a</sup> = Pearson's correlation, <sup>b</sup> = Spearman's correlation, \*p < 0.05, \*\*p < 0.001.

SGRQ: StGeorge's respiratoryquestionnaire, BMI: Body massindex, mMRC:modified medical research council dyspnea score, FEV<sub>1</sub>: Forced expiratory volumeinonesecond, 6MWT: six-minute walking test.

The total SGRQ score in patients with BMI <21 kg/m<sup>2</sup> and  $\geq$ 21 kg/m<sup>2</sup> was 43.3±16.3 and 39.1±19.5, respectively. The mean difference between the two groups was statistically significant (p<0.05). Even if BMI associated with total SGRQ scores, the correlation was weak (R = -0.15; p < 0.05).

FEV<sub>1</sub>%predicted and the total SGRQ score of at least one pair were statically significant (p<0.05). The total SGRQ score was highest in patients with FEV<sub>1</sub>  $\leq$ 35%predicted (48.5±16.4)

and lowest in those with  $FEV_1 \ge 65\%$  predicted (37.8±17.4). The correlation between  $FEV_1\%$  predicted and total SGRQ score was weak (R = -0.24; p< 0.001).

The mMRC dyspnea score and total SGRQ score of at least one pair were statistically significant (p<0.001). The total SGRQ score was highest in patients with mMRC grade 3 (57.8 $\pm$ 13.8) and lowest in those with mMRC grade 0-1 (32.1 $\pm$ 14.0). The mMRC dyspnea score showed strong correlation with the activity (R = 0.72; p < 0.001) and total score (R = 0.66; p < 0.001), but moderate and mild correlation with the impact (R = 0.54; p < 0.001) and symptom score (P = 0.30; p < 0.001), respectively.

The 6MWT and total SGRQ score of at least one pair were statistically significant (p<0.001). The total SGRQ score was highest in patients with a walking distance <150 meters ( $55.5\pm15.9$ ) and lowest in those with a walking distance  $\geq 350$  meters ( $38.6\pm17.4$ ). Mild negative correlations were found in the activity score (P = -0.36; p < 0.001), impact score (P = -0.12; p < 0.001), and total SGRQ score (P = -0.23; p < 0.001), but no correlation was shown in the symptom score.

The Quartile BODE index and total SGRQ score of at least one pair were statistically significant (p<0.001). The mean total SGRQ score gradually increased with increasing quartile BODE index. The highest total SGRQ score was in quartile 4 (58.3±13.5) and lowest in quartile 1 (33.9±16.5). The quartile BODE index showed moderate correlation with the activity (R = 0.52; p < 0.001) and total score (R = 0.515; p < 0.001), but mild correlation with the symptom (R = 0.19; p < 0.01) and impact score (P = 0.35; p < 0.01).

The ABCD group classification and total SGRQ score of at least one pair were statistically significant (p<0.001). The total SGRQ score was highest in group D (58.2±14.2) and lowest in group C (31.9±15.9). The ABCD group showed moderate correlation with the activity (R = 0.54; p < 0.01) and total score (R = 0.52; p < 0.01), but mild correlation with the symptom (R = 0.28; p < 0.01) and impact score (R = 0.42; p < 0.01).

Multiple regression analysis was applied to identify independent variables that could predict quality of life in COPD patients (Table 4). The coefficient of determination ( $\mathbb{R}^2$ ) was 0.467, which showed that this model was capable of predicting the total SGRQ score of 46.7%, while the mMRC dyspnea and BODE index score, age, and COPD group D were important predictors of degenerating quality of life, as assessed by the total SGRQ score.

The equation of multiple regression models is as follows:

 $Y_{SGRQ} = 38.194 + 8.935 \text{ (mMRC)} + 1.160 \text{ (BODE index)} - 0.214 \text{ (Age)} + 6.175 \text{ (Group D)}$ 

When the mMRC dyspnea score increases 1, the total SGRQ score increases 8.935. When the BODE index score

increases 1, the total SGRQ score increases 1.160. When the age increases 1 year, the total SGRQ score decreases 0.214. COPD group D had a greater SGRQ score than the other groups, with a score of 6.175.

### 4. DISCUSSION

Quality of life for the rural COPD patients in this study was at a moderate level, which was better than that of patients living in the urban and rural areas in a previous study [33]. Equation multiple regression models could predict quality of life at 46.7%, and it was found that the mMRC dyspnea score, BODE index, age and COPD group D could predict quality of life in COPD patients. Although occupation, FEV<sub>1</sub>%predicted, 6MWT, and BMI had significant correlations with the SGRQ, these variables could not predict quality of life in the model of this study.

This study achieved several important findings. First, it showed a strong correlation between the ABCD group classification and total SGRQ score. Second, it confirmed that quality of life in COPD group D was worse than that in group A, B and C. Third, a negative correlation was found between age and the total SGRQ score. Finally, this study confirmed the correlation between BODE index and the SGRQ score.

The ABCD classification correlated with the total SGRQ score. Due to ABCD classification being classified by exacerbating history and dyspnea symptoms [34], a moderate to strong correlation was found between dyspnea score and total SGRQ score (R=0.66). This confirms the results of previous studies that showed a significant association between ABCD classification and quality of life in COPD patients [26, 28]. Moreover, this study found that group D of the ABCD classification could predict quality of life in COPD patients. Group D had a higher total SGRQ score than the other groups, which indicated the worst quality of life. This study found that quality of life in group C (high risk, fewer symptoms) and group A (low risk, fewer symptoms) was similar. Either group A or C had a better quality of life than group B (low risk, more symptoms) and D (high risk, more symptoms). This confirmed that group B had a lower survival rate and worse quality of life than group C in a previous study [26, 35]. Therefore, the authors assumed that the quality of life in COPD patients depended on symptoms more than risk.

	Variables	В	SE	t	95% CI
	Constant	38.194	5.255	7.269	27.85, 48.54
	mMRC	8.935	1.008	8.868	6.95, 10.92
	BODE index	1.160	0.502	2.308	0.17, 1.15
	Age	-0.214	0.078	-2.757	-0.37, -0.06
	ABCD groups				
	Group D	6.175	2.720	2.270	0.82, 11.53

Table 4. Factors predicting the SGRQ score in COPD patients by multiple regression analysis.

 $R^2 = 0.467$ , SEE = 12.78846, F = 60.461, Sig. of F = 0.000, \*p < 0.05, \*\*p< 0.001

mMRC:modified medical research council dyspnea score.

#### 362 The Open Public Health Journal, 2020, Volume 13

This study found a negative correlation between age and symptoms, and positive correlation between age and activity in the SGRQ score, but no correlation between impact and total SGRQ score. It showed that older COPD patients had a better quality of life than younger ones in aspects of symptoms. This result supported Martinez et al. [36], who found that older COPD patients reported better quality of life than younger ones. Whereas, previous studies revealed that age could decrease the level of quality of life [33]. The BODE index correlated significantly with the SGRQ score. This finding confirmed the results from the previous studies [23, 24, 27, 37, 38], which showed modest to strong correlation between them. Among components of the BODE index, the higher mMRC score, and lower BMI, FEV<sub>1</sub>%predicted and 6MWT, correlated with worsening quality of life in COPD patients [24]. The mMRC score was the only component of the BODE index that could predict the total SGRQ score in the equation model.

The mMRC score, which measured dyspneic symptoms, had good correlation with the total SGRQ score (R = 0.66; p <0.01), and was an important predictor of quality of life in COPD patients. The pathology of COPD causes airway obstruction [39] that leads to air trapping, hyperinflation [40] and subsequently dyspneic symptoms. Dyspnea is associated with daily activities. COPD patients were deconditioned, due to inactivity from dyspnea, causing decreased functional capacity [5, 6] that leads to poor quality of life in the future. This study also demonstrated the correlation between mMRC score and SGRQ score as published [23, 24], and showed that perception of dyspnea could explain 25% to 54% of the quality of life score in COPD patients [41]. Thus, the evaluation of quality of life can be used for the assessing dyspnea, which is simple and clear, easy to apply, and practical, particularly in the rural areas of Thailand, where the SGRQ is complex and the communication difficult, especially with minority groups and elderly people.

This study found that the mMRC dyspnea score, BODE index, age and COPD group D could predict quality of life in rural COPD patients.Hence, combined center-and home-based pulmonary rehabilitation programme, which includes exercise training and breathing exercise, can alleviate the dyspnea, increase functional capacity and improve quality of life in rural COPD patients [42].

The strengths of this study include the large sample size and number of COPD patients that was equal between men and women, which helped to decrease bias. However, the limitations in this study include only 8.2% of COPD patients at a very severe GOLD stage level, which made it impossible to generalize results from that stage. However, this seemed to be a general format, which has been seen in several other studies of COPD [24, 26, 33, 35, 43]. This study did not evaluate psychological health, which is known to affect quality of life in COPD patients.

### CONCLUSION

The mMRC dyspnea score, BODE index, age, and COPD group D were the major predictors of quality of life in the COPD patients in this study.

#### ETHICAL APPROVAL AND CONSENT то PARTICIPATE

The study protocol was approved by the Research Ethics Committee, Faculty of Medicine, Chiang Mai University, Thailand (Ethics approval number: 497/2015).

#### HUMAN AND ANIMAL RIGHTS

No animals were used in this study. All human research procedures were followed in accordance with the ethical standards of the committee responsible for human experimentation (institutional and national), and with the Helsinki Declaration of 1975, as revised in 2013.

#### **CONSENT FOR PUBLICATION**

Informed consent was obtained from all the participants.

### AVAILABILITY OF DATA AND MATERIALS

The datasets generated and/or analyzed during the current study are available at Bagiyatallah University of Medical Sciences.

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#### **CONFLICT OF INTEREST**

The author declares no conflict of interest, financial or otherwise

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