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Original Research Article

Evaluation of severity of chronic obstructive pulmonary disease using bronchial obstruction, dyspnea, exercise index and global initiative for chronic obstructive lung disease classification and it's correlation with physical quality of life measured by St. George's respiratory disease questionnaire score

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ABSTRACT

Background: The Global initiative for chronic Obstructive Lung Disease (GOLD) criteria classified chronic obstructive pulmonary disease (COPD) by severity into four stages. Recently, Body mass index (BMI), Bronchial Obstruction, Dyspnea, Exercise (BODE) index, was proposed to provide useful prognostic information of COPD patients. Health-related quality of life (HRQOL) is measured by St. George's Respiratory disease Questionnaire (SGRQ). Study was undertaken to assess correlations between BODE index and GOLD classification with SGRQ score.

Methods: Fifty five COPD patients were included. Spirometry was performed in all patients. Modified Medical Research Council (mMRC) scale was used to label severity of dyspnea. Six-minute walking distance (6 MWD) was performed. BODE index was calculated by giving points to BMI, forced expiratory volume in one minute (FEV1), 6 MWD, and mMRC. SGRQ was used to determine HRQOL. Correlation analysis was done using Pearson's method.

Results: Mean symptoms, mean activity, mean impacts and mean total SGRQ score were significantly higher in patients having mMRC scale 0-1, patients who could walk ≤149 meters, and in patients who had GOLD III and IV class. Lesser the FEV1, higher the mMRC grade, and lesser the 6 MWD, worse was the quality of life. BODE index (r = 0.72) and GOLD classification (r =0.59) were significantly and positively correlated with symptoms score, activity score, impacts score and total SGRQ score.

Conclusions: BODE index correlated better than the Gold classification with SGRQ score implying that apart from the airflow limitation, functional impairment measured by the 6MWT and mMRC also affect HRQOL.

Keywords: Chronic obstructive pulmonary disease, Global initiative for chronic Obstructive Lung Disease criteria, Body mass index, Bronchial obstruction dyspnea exercise index, Health-related quality of life, St. George's Respiratory disease questionnaire correlation

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is a slow, progressive, and largely irreversible airways disease resulting in breathlessness, cough and sputum production. Smoking, other air pollutants, biomass fuel, and pesticides are well established risk factors for COPD. The Global initiative for chronic Obstructive Lung Disease

(GOLD) criteria classified COPD by severity into four stages; this constitutes the basis of treatment recommendations. The GOLD classification has already demonstrated its usefulness in longitudinal studies in which higher GOLD stages were found to be associated with increased mortality risk.[1,2] Nevertheless, doubts exist about the appropriateness of the GOLD classification to categorise the impact of the disease on health status adequately.[3] Consequently, the clinical utility of the GOLD classification for pulmonary rehabilitation may be questioned.[4]

Recently, a new multidimensional grading system, the Body mass index (BMI), Bronchial Obstruction, Dyspnea, Exercise (BODE) index, was proposed to provide useful prognostic information of COPD patients.[5] This multidimensional grading system incorporates four parameters: assessment of symptoms, nutritional state, exercise capacity, and spirometric measures such as forced expiratory volume in one second (FEV1), all aimed to include both respiratory and systemic manifestations of COPD.[5]

The concept of health-related quality of life (HRQOL) combines some of the main aspects of health, disease, and adaptation that make an integral part of the patient and his or her treatment. The measurement of HRQOL in these patients mainly covers the following dimensions related to their subjective experience: difficulties in physical mobility, psychological and social status, and general perception of health and well-being in relation to the disease.[5] HRQOL has become an important outcome in respiratory patients as proved by the development of several respiratory disease-specific questionnaires like the St. George's Respiratory disease Questionnaire (SGRQ).

Although the BODE index has been shown to be a predictor of the risk of death, its utility has been seen in the evaluation of pulmonary rehabilitation programs and prediction of hospitalizations in COPD patients.[6,7] But there are not enough studies to show whether this index is a useful indicator of patients' health status. Using the BODE index in COPD patients will help in detecting the disease early and to start treatment early. Therefore, a study was undertaken to assess the correlations between the BODE index and GOLD classification with SGRQ score and to find which was better index for predicting the impact of COPD on physical quality of life.

METHODS

This observational study was conducted between May 2016 and September 2017. After approval from the scientific advisory committee and institutional ethics committee, written informed consent was obtained from all patients. Fifty-five patients who attended outpatient department of chest diseases or admitted in Poona Hospital and Research Centre, Pune were included. The criteria for diagnosis of COPD was based on the symptoms of the patient and spirometry tests the patient had undergone, which has FEV1/Forced expiratory capacity (FVC) <0.7) and post bronchodilator no reversibility/partial reversibility.

Inclusion criteria

- Patients aged ≥18 years of either sex.
- Stable COPD patients.

Exclusion criteria

- Patients with respiratory tract infection, interstitial lung disease, bronchial asthma, walking disability.
- Patients with history of cardiac event like acute coronary syndrome/ heart failure in last two months.

Demographic features and medical history of the patients including the disease duration, smoking history was recorded. Weight, height was measured and BMI was calculated. Spirometry was performed as per American Thoracic Society (ATS)/ European Respiratory Society (ERS) recommendations using Spirometer RMS MEDSPIROR (Recorders and Medicare Systems Pvt. Ltd., Chandigarh, India) and software "HELIOS".[8] The procedure was repeated at least three times until three acceptable readings were obtained. After that a short acting beta-2 agonist salbutamol 400 µgm was administered and repeat reading was obtained after 10 minutes. At end of the test post bronchodilator FEV1, FVC and the FEV1 /FVC was obtained. Using the post bronchodilator FEV1, COPD staging was done according to GOLD 2017.

The Modified Medical Research Council (mMRC) scale was used to label severity of dyspnea. Six-minute walking distance (6 MWD) was performed in a 30 m long, flat and straight corridor. Patients were motivated to walk at the fastest speed they can for 6 minutes. Pulse and oxygen saturation was measured before and after the test and the distance walked was recorded by counting the number of laps. During the test if the participant experienced chest pain, intolerable dyspnea, leg cramps or SpO_2 fell below 80%, patient was asked to stop and discontinue and was excluded from the study.

BODE index was calculated by giving points to BMI, FEV1 (Post bronchodilator), 6 MWD, and mMRC. SGRQ was used to determine the quality of life.

The result of the questionnaire was entered into MS excel, SGRQ calculator and the symptom, activity, impact and total score was calculated. All positive responses were entered as 1 and all negative responses were entered as 0. The total score calculated summarized the impact of the disease on overall health status. Scores were expressed as a percentage of overall impairment where 100 represents worst possible health status and 0 indicated best possible health status. Primary outcome measure was to calculate BODE index and GOLD

classification and correlate with total SGRQ score and its components.

On the basis of a previously published study, a sample size of 55 patients was calculated by a formula with 80% power and 5% probability of Type I error to reject null hypothesis.[9,10]

Data collected were entered in Excel 2007 and analysis of data was done using Statistical package for social sciences (SPSS) version 21, IBM Corporation, USA for MS Windows. The data on categorical variables is shown as n (% of cases) and data on continuous variables is shown as mean±standard deviation (SD). The inter-group statistical significance of difference of categorical variables and continuous variables between two groups was tested using Chi-Square test/Fisher's exact test and unpaired 't' test. Inter-group statistical significance of difference of means of continuous variables more than two groups was tested using one-way analysis of variance (ANOVA) or F test. The correlation analysis was done using Pearson's method. The confidence limit for significance was fixed at 95% level with p-value <0.05.

RESULTS

Of 55 patients studied, 6 (10.9%), 20 (36.4%), 14 (25.5%), 12 (21.8%) and 3 (5.5%) were between 45- 54 years, 55-64 years, 65-74 years, 75-84 years and >84 years respectively. The mean±standard deviation of age of the patients was 66.5±10.6 years. Twenty eight (50.9%) patients were males and 27 (49.1%) were females. Of 55 patients, 21 (38.2%) were smokers and 34 (61.8%) were non-smokers. One (1.8%), 18 (32.7%), 22 (40.0%), and 14 (25.5%) patients had duration of disease less than 12 months, 12 <60 months, 60 - 120 months and >120 months respectively. Of 55 patients, 12 (21.8%), 29 (52.7%), 12 (21.8%), 1(1.8%) and 1 (1.8%) had no annual exacerbation, 1, 2, 3 and 4 annual exacerbations respectively. Nine (16.4%), 32 (58.2%) and 14 (25.4%) patients had BMI <21.0 kg/m^2, 21.0 - 25.0 kg/m^2 and >25.0 kg/m^2 respectively. The mean±SD of BMI in the study group was 23.7±4.5 kg/m^2. Of 55 patients, 11 (20.0%), 19 (34.5%), 13 (23.6%) and 12 (21.8%) had FEV1 ≥65%, 50 - 64%, 36 - 49% and ≤35% respectively. The mean±SD of FEV1 in the study group was 50.4±15.8%.

Ten (18.2%), 18 (32.7%), 14 (15.5%) and 13 (23.6%) patients had BODE index 0 - 2, 3 - 4, 5 - 6 and 7 - 10 respectively. Of 55 patients, 1 (1.8%), 30 (54.5%), 18 (32.7%) and 6 (10.9%) had GOLD index stage I, stage II, stage III and stage IV respectively. Thirteen (23.6%), 24 (43.6%), 17 (30.9%) and 1 (1.8%) patients had Grade 1, Grade 2, Grade 3 and Grade 4 mMRC respectively. Of 55 patients, none, 23 (41.8%), 28 (50.9%), and 4 (7.3%) had 6 MWD ≥350, 250 - 349, 150 - 249 and ≤150 metres respectively. The mean±SD of 6 MWD in the study group was 235.8±46.8 metres.

There was no statistically significant difference in distribution of mean BODE Index and total SGRQ score between male and female patients. There was no statistically significant difference in distribution of mean BODE Index and total SGRQ score between smokers and non-smokers. The distribution of mean BODE Index and total SGRQ score did not differ significantly between groups of patients who had <2 co-morbidities and group of patients who ≥2 co-morbidities. The distribution of mean BODE index and mean total SGRQ score did not differ significantly in patients whose BMI were <21.0 kg/m^2, 21.0 - 25.0 kg/m^2 and > 25.0 kg/m^2.

Distribution of mean symptoms score and mean impacts score did not differ significantly between the patients who were <60 years and ≥60 years. Mean activity and mean total score was significantly higher in patients who were ≥60 years (Table 1).

Table 1: Distribution of mean SGRQ scores by age.

	Symptom	Activity	Impacts	Total
Age in years	**Mean±SD**	**Mean±SD**	**Mean±SD**	**Mean±SD**
<60	51.97±14.15	59.13±13.65	28.23±13.92	41.52±12.24
≥60	59.03±12.62	67.75±12.74	35.57±13.73	49.02±11.92
p-value	0.080	0.033	0.084	0.044
Unpaired t test was used.				

SGRQ - St. George's Respiratory disease Questionnaire

As depicted in Table 2, distribution of mean total SGRQ score was significantly higher among the patients with duration of disease ≥60 months compared to patients with <60 months duration of disease. The distribution of mean total SGRQ score was significantly higher among patients with annual exacerbations compared to patients with no annual exacerbations. Table 3 shows that the mean symptoms, mean impacts score and mean total SGRQ score were significantly higher in patients having FEV1 ≤35%. The mean symptoms, mean activity score, mean impacts score and mean total SGRQ score were significantly lower in patients having mMRC scale 0-1.

Table 2: Distribution of mean total SGRQ according to disease duration and annual exacerbations.

Variables		N	Mean total SGRQ score±SD	p value
Disease duration	<60 Months	19	40.7±10.8	0.005
	≥60 Months	36	50.3±12.0	
Annual exacerbations	No exacerbation	12	39.6±9.9	0.018
	exacerbation	43	49.0±12.3	

Unpaired 't' test was used.
SGRQ- St. George's Respiratory disease Questionnaire

Table 3: Distribution of mean SGRQ scores by components of BODE index.

BODE index components	FEV1				p value	mMRC scale				p value
	≤35%	36 - 49%	50 - 64%	≥65%		0-1	2	3	4	
Mean Symptoms±SD	68.9± 12.9	64.6±8.7	51.8± 9.6	45.8± 8.1	0.001	44.7± 6.3	56.0± 10.9	66.6±11.4	83.7± 12.8	0.001
Mean Activity±SD	72.0± 12.9	75.0±9.7	58.2± (11.6)	59.4± 11.2	0.001	53.6± 13.8	63.5± 8.6	75.8±9.9	86.6± 10.9	0.001
Mean Impact±SD	45.6± 13.1	40.5±10.0	27.2± 10.9	23.3± 10.5	0.001	21.3± 10.2	34.6± 12.9	40.0±11.6	60.0± 11.9	0.001
Mean Total±SD	57.4± 11.3	54.8±7.7	40.4± 9.5	37.6± 7.9	0.001	34.7± 8.6	46.7± 10.0	55.3±9.2	72.0± 10.5	0.001

ANOVA test was used
SGRQ-St. George's Respiratory disease Questionnaire
BODE-Body mass index (BMI), Bronchial Obstruction, Dyspnea, Exercise
FEV1 -forced expiratory volume in one second
mMRC- Modified Medical Research Council

Table 4: Distribution of mean SGRQ scores by components of BODE index.

BODE Components	6 MWD in meters			p value	BMI in kg/m^2		p value
	≤149	150-249	250 - 349		≤21	>21	
Mean Symptoms±SD	83.4±1.1	60.2±9.5	48.7±10.6	0.001	57.5±13.4	55.0±10.9	0.609
Mean Activity±SD	84.9±3.4	69.3±10.5	57.3±12.2	0.001	65.7±13.0	64.1±16.5	0.761
Mean Impact±SD	49.0±15.8	39.2±11.1	24.0±10.9	0.001	33.9±14.0	31.9±15.1	0.705
Mean Total±SD	65.6±8.7	51.7±9.2	38.1±9.3	0.001	47.3±12.3	45.3±13.4	0.668

ANOVA test was used.
SGRQ -St. George's Respiratory disease Questionnaire
BODE- Body mass index (BMI), Bronchial Obstruction, Dyspnea, Exercise
6 MWD-Six-minute walking distance

Table 5: Distribution of mean SGRQ scores by GOLD classification.

SGRQ score	GOLD Classification				p value
	GOLD I	GOLD II	GOLD III	GOLD IV	
Mean Symptoms±SD	39.1±5.7	50.1±9.8	66.7±9.5	66.4±16.2	0.001
Mean Activity±SD	55.2±8.9	59.0±11.3	75.7±8.7	68.1±16.9	0.001
Mean Impacts±SD	19.0±3.6	26.4±10.9	43.0±11.2	43.9±14.9	0.001
Mean Total±SD	33.3±6.2	40.0±9.1	56.7±7.5	55.0±15.3	0.001

ANOVA test was used
SGRQ -St. George's Respiratory disease Questionnaire
GOLD-Global initiative for chronic Obstructive Lung Disease

Mean symptoms, mean activity score, mean impacts score and mean total SGRQ score were significantly higher in patients who could walk ≤149 meters. The distribution of mean symptoms score, mean activity score, mean impacts score and mean total SGRQ score did not differ significantly between patients whose BMI ≤21 and >21 (Table 4). The mean symptoms, mean activity score, mean impacts score and mean total SGRQ score were significantly higher in patients who had

GOLD III and IV class (Table 5). As shown in Table 6, lesser the FEV1, higher the mMRC grade, and lesser the 6 MWD worse was the quality of life. BMI did not show significant correlation with symptoms score, activity score, impacts score and total SGRQ score.

Table 6: Correlation between SGRQ scores and BODE index.

BODE components	Symptoms	Activity	Impacts	Total
FEV1				
r-value	-0.626	-0.418	-0.535	-0.579
p-value (Correlation)	0.001	0.001	0.001	0.001
mMRC				
r-value	0.667	0.654	0.540	0.667
P-value (Correlation)	0.001	0.001	0.001	0.001
6 MWD				
r-value	-0.669	-0.641	-0.626	-0.709
p-value (Correlation)	0.001	0.001	0.001	0.001
BMI				
r-value	-0.093	-0.099	-0.160	-0.151
p-value (Correlation)	0.500	0.474	0.244	0.272

Pearson's correlation test was used.
SGRQ -St. George's Respiratory disease Questionnaire
BODE- Body mass index (BMI), Bronchial Obstruction, Dyspnea, Exercise
FEV1 - forced expiratory volume in one second
MMRC- Modified Medical Research Council
6 MWD- Six-minute walking distance

Table 7: Correlation between 2 COPD staging systems and SGRQ scores.

	Symptoms		Activity		Impacts		Total	
COPD Staging	r value	p value	r value	p value	r value	p value	r value	p value
BODE Index	0.727	0.001	0.581	0.001	0.650	0.001	0.720	0.001
GOLD class	0.585	0.001	0.438	0.001	0.567	0.001	0.594	0.001

Spearman rank correlation test was used.
COPD- Chronic obstructive pulmonary disease
BODE- Body mass index (BMI), Bronchial Obstruction, Dyspnea, Exercise
SGRQ -St. George's Respiratory disease Questionnaire
GOLD- Global initiative for chronic Obstructive Lung Disease

As depicted in Table 7, BODE index was significantly and positively correlated with symptoms score, activity score, impacts score and total SGRQ score. GOLD classification was significantly and positively correlated with symptoms score, activity score, impacts score and total SGRQ score. Bode index correlated better (r values more) than Gold classification to health related quality of life as it is a multidimensional index to determine severity of COPD and its systemic consequences.

DISCUSSION

This study was conducted in 55 patients attending Poona hospital and research centre. In the present study we have calculated BODE index, GOLD classification and SGRQ score and found correlation with each other. Total SGRQ score was 49.02 and 41.52 in patients aged ≥60 years and <60 years respectively (p-value<0.05). Corlateanu et al, also reported that the total SGRQ score was higher in the elderly patients than in the younger patients (69.7 vs. 57.4, p <0.0001).[11] But Martinez et al, stated that older subjects with COPD report better HRQOL than do younger COPD patients and that this age-related difference involved a lower impact of dyspnea with increasing age.[12] They suggested that the younger population had more negative perception or the elderly population adjusted by restricting their activities or having minimal expectations.

The prevalence, hospitalization and mortality for COPD in women is increasing. The biggest risk factor for disease development in the developed world is tobacco smoke. For women in the developing world, where fuels such as coal and biomass are used for indoor cooking and heating, several studies have reported an association between exposure to biomass smoke and COPD.[13] In the present study, there was no statistically significant difference in distribution of mean BODE Index and total

SGRQ score between male and female patients. Katsura et al, and Skumlein et al, reported that women had greater deterioration in health related quality of life.[14,15]

In this study 21/55 (38.2%) were smokers and 34 (61.8%) were non-smokers implying that other noxious particles like dust, biomass fuel, pesticides were responsible for the airway obstruction in 61.8% cases. However, history of smoking did not affect the HRQOL and BODE index. The distribution of mean BODE index and total SGRQ score did not differ significantly between smokers and non-smokers in the study group. In India approximately two-thirds of the population uses biomass fuel for cooking purposes. On the contrary, just one-third of the Indian subset comprises the smoking population.[16] Thus, exposure to biomass fuel is a greater hazard for COPD in India.

COPD is a systemic disease and co morbidities that occur frequently in COPD patients include cardiovascular disease, skeletal muscle dysfunction, metabolic syndrome, osteoporosis, depression and lung cancer. In the present study mean BODE Index and total SGRQ score did not differ significantly between group of patients with <2 co-morbidities and group of patients with ≥2 co-morbidities. A study conducted in Europe by Jones et al, reported that co morbidities >3 resulted in worse SGRQ score unlike our study.[17]

In the present study, the distribution of mean total SGRQ score was significantly higher among the patients with higher duration of disease (>60 months) compared to group of cases with lesser duration of disease (<60 months). Longer the duration of the disease, worse was the quality of life. Similar finding were reported by Ahmed et al, and by Miravitlles et al.[18,19]

Total SGRQ score was significantly higher among patients with annual exacerbations compared to group of patients with no annual exacerbations. David et al, and Jones et al, reported positive correlation between frequent exacerbations and total SGRQ scores.[20,17] Mean symptoms, mean impacts score and mean total SGRQ score were significantly higher in patients having FEV1 ≤35%. These findings are consistent with the studies conducted by Jones et al, Antonelli-Incalzi et al, and Sarkar et al.[17,21,9]

mMRC dyspnea grade was significantly and positively correlated with symptoms score, activity score, impact score and total SGRQ score. Hsu et al, concluded that the mMRC dyspnoea scale is a concise and practical tool to assess the HRQOL of patients with COPD in daily clinical practice.[22] Similar positive correlation were reported in studies conducted by Marin et al, and Sarkar et al.[23,9] In the present study, 6MWD was significantly and negatively correlated with symptoms score, activity score, impact score and total SGRQ score. Various previous studies have reported statistical significant correlation between SGRQ and 6MWD.[24-26]

The distribution of mean BODE Index and total SGRQ score did not differ significantly across three BMI groups. De et al, reported that mean BMI reduced significantly with progression of COPD severity.[27] Meta-analysis by Cao et al, and Guo et al, concluded that there was a significant non-linear relationship between BMI and mortality of COPD patients.[28,29] Lower BMI had higher risk of death and therefore BMI forms an important component of BODE index.

In the present study SGRQ total correlated better with BODE index than with GOLD class (r = 0.72, vs r =0.594). Overall, we found that the SGRQ scores worsened exponentially as disease severity increased by BODE quartiles. Previous studies by Sarkar et al, Marin et al, Huijsmans et al, Medinas et al, Nonato et al, and Ong et al, concluded that BODE index positively correlated with SGRQ score.[9,23,4,5,30,31]

Total SGRQ score and all of its 3 domains showed a significant worsening in GOLD stages III and IV. In previous studies, it has been suggested that the boundary between GOLD stages II and III (FEV1 <50%) marks a threshold for dramatic worsening of health status and an increased mortality risk.[1,21] Huijsmans et al, reported that the largest reduction in exercise capacity and quality of life was found in the transition from GOLD III to GOLD IV.[4] Health related quality of life should be evaluated when planning interventions as it better expresses the composite effect of the intervention on patient's well-being. The BODE index reflects stages of COPD better and should emerge as a tool to assess disease modification and future disease outcome. GOLD and BODE indices can be used express the complex nature of COPD better.

There are few limitations to the present study. Authors have not included data regarding occupational exposure history, socioeconomic status, medication use, or previous hospitalization. This study only evaluated the SGRQ and the results may not extend to other instruments of HRQOL. Authors have not assessed anxiety and depression which are known to affect the quality of life in COPD patients. Multi-centric studies with large sample size is needed to validate our findings.

CONCLUSION

The multidimensional BODE index and all its 4 components except BMI had a positive correlation for health related quality of life measured by the SGRQ. BODE index correlated better than the Gold classification with SGRQ score implying that apart from the airflow limitation, functional impairment measured by the 6MWT and mMRC also affect the health related quality of life. The activity component was a major contributor to total health related quality of life. Age of the patient statistically and positively correlated with total SGRQ and activity domain of it. There was no gender differences and females were almost equally affected.

Smoking was not the only cause of COPD in this study. Majority were due to other noxious particles. Duration of disease and annual exacerbations positively correlated with quality of life.

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