Original Article

New combined assessment of chronic obstructive pulmonary disease: Utilization, pitfalls, and association with spirometry

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ABSTRACT

Introduction: Classification of chronic obstructive pulmonary (COPD) disease has changed from being solely based on spirometric variables to combined assessment including symptom scores and history of exacerbations/ hospitalizations. There is both lack of awareness regarding change in its assessment as well as underutilization due to time constraints and seeming complexity. Moreover, treatment of COPD needs to be tailored according to the new combined assessment. **Aims:** Current study was planned to look at current stratification of patients according to new revised combined assessment (Global Initiative for Chronic Obstructive Lung Disease GOLD 2017) in comparison to old(GOLD 2011) as well as its incorporation in clinical practice. Co-relation between revised combined assessment and spirometric staging was also assessed. **Methods:** 418 consecutive COPD patients were enrolled, their dyspnea scores in terms of modified medical research council scale (mMRC), preceding history of hospitalization/ exacerbation over preceding one year and spirometric variables were recorded. Their stratification according to old and new classification recorded. Their past treatment records were reviewed and combined assessment if done recorded. **Results:** Substantial shift of categories is seen from C and D respectively to stage A and B on applying the new classification compared to old i.e more severe to less severe. Secondly, revised combined assessment is still highly underutilized. Revised combined assessment has positive co-relation with spirometry and post bronchodilator forced expiratory volume in 1 second(FEV_1). **Conclusions:** Management of substantial number of stable COPD patients may need to be stepped down in accordance with revised combined assessment. There is a need to disseminate information regarding change in COPD classification and stress on its incorporation in our day-to day clinical practice. Revised combined assessment has positive co-relation with spirometry, stressing its utility even in peripheral centers without spirometry facilities.

KEY WORDS: COPD, Combined assessment, stratification

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INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is a common preventable and treatable respiratory disease leading to substantial morbidity and mortality. COPD classification has changed drastically with time from being solely based on lung functions to the incorporation of symptom scores and a history of exacerbations/hospitalizations as

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part of its combined assessment. Combined assessment is still an evolving field with changes being incorporated continuously. In 2017, the combined assessment was further modified with spirometric staging being done separately and symptom scores along with a history of exacerbations/hospitalizations being utilized as part of combined assessment. In spite of more than 7 years of this paradigm shift in the assessment of stable COPD patient's, studies regarding categorization among patients and incorporation in the Indian scenario have been lacking. The current study was planned to see the stratification of patients according to the new combined assessment (Global Initiative for Chronic Obstructive Lung Disease [GOLD] 2017) in comparison to the old (GOLD 2011) along with its incorporation in practice and its correlation with spirometric staging.

MATERIALS AND METHODS

All consecutive consenting patients of COPD attending the Outpatient Department at AIIMS, Rishikesh, from September 2015 to 2017 were enrolled. Patients >70 years of age and with comorbidities, for example, moderate-to-severe hypertension, diabetes mellitus, ischemic heart disease, chronic liver, or renal disease, and any associated significant restrictive lung disease were excluded from the study. Spirometry was performed through the American Thoracic Society and European Respiratory Society guidelines compliant spirometer, and COPD was diagnosed on the basis of clinical history, and the ratio of postbronchodilator forced expiratory volume in 1 s (FEV_1) to forced vital capacity <0.70.[1]

Spirometric variables including FEV1 postbronchodilator were recorded. Baseline parameters including age, sex, and smoking status were recorded using a questionnaire. The previous history of any hospitalization/exacerbation leading to change in oral medication, use of injectable, or emergency room visits over preceding 1 year was also recorded. Exacerbation was defined as increase in two or more symptoms including dyspnea/cough/expectoration for more than 3 days which led to a change in medication/injectable utilization, emergency room visits, or hospitalization. Symptom scores regarding dyspnea scores as Modified Medical Research Council (mMRC) scores from 0 to 4 were recorded. We have only utilized mMRC scores for assessment of symptoms in the current study. Treatment records of patients, which were available, were reviewed and treatment was recorded. Combined assessment/classification if mentioned in previous treatment records was assessed. A total of 418 consenting patients were enrolled in the study, and previous treatment records of 300 patients were available for review. The research was approved by the Institutional Ethics Committee.

Data analysis

Data were entered into Microsoft Excel and analyzed using IBM SPSS statistics v23 (IBM Corporation., Chicago, IL, USA). For comparison of means, one-way ANOVA was used, and for comparison of proportions, Chi-square test was used. $P < 0.05$ was considered statistically significant. Cramer's V value and corresponding P value was reported to measure the strength of association between categorical variables having more than two categories.

RESULTS

A total of 418 patients were enrolled in the study with a mean age of 60.4 + 7.25 years. Of these, 91.9% were male, while rest 8.1% were female. About 63.2% of the patients in the study were exsmokers, 33.5% current smokers, and only 3.3% were never smokers. Demographic details along with the distribution of patients according to the spirometric severity, old combined assessment (GOLD 2011), and new revised combined assessment (GOLD 2017) are shown in Table 1. While according to the spirometric severity, most patients were classified as moderate and severe COPD, i.e., Stage 2 and 3; according to the GOLD 2011, 29.5% were in Group A, 18.7% in Group B, 25.4% in Group C, and 26.3% in Group D, respectively. GOLD 2011 using mMRC scores shows more equitable distribution. According to the GOLD 2017, 48.9% were in Group A, 36.9% in Group B,

Table 1: Sociodemographic details and classification of patients enrolled in the study

Variables	Mean (SD)/*n* (%)
Age	60.4 (7.25)
Gender	
Male	384 (91.9)
Female	34 (8.1)
Smoking history	
0=No	14 (3.3)
1=Current	140 (33.5)
2=Ex	264 (63.2)
Spirometric stage	
1	35 (8.4)
2	191 (45.7)
3	157 (37.6)
4	35 (8.4)
COPD classification (GOLD 2011)	
A	123 (29.4)
B	79 (18.9)
C	106 (25.4)
D	110 (26.3)
COPD classification (GOLD 2017)	
A	204 (48.8)
B	154 (36.8)
C	25 (6.0)
D	35 (8.4)
mMRC	
0	64 (15.3)
1	165 (39.5)
2	121 (28.9)
3	60 (14.4)
4	8 (1.9)
FEV1%	52.85 (18.4)

mMRC: Modified Medical Research Council scale, FEV_1: Forced expiratory volume in 1 s, COPD: Chronic obstructive pulmonary disease, GOLD: Global Initiative for Chronic Obstructive Lung Disease, SD: Standard deviation

Table 2: Association between age, gender, smoking status, forced expiratory volume in 1 s %, and Global Initiative for Chronic Obstructive Lung Disease 2017 combined assessment

Variables	Mean (SD)/*n* (%)				*F* value for ANOVA/χ^2
	GOLD A (204)	GOLD B (154)	GOLD C (25)	GOLD D (35)	
Age	59.9 (7.7)	60.9 (6.9)	61.2 (5.6)	60 (6.8)	0.64
Gender					
Female	18 (52.9)	11 (32.3)	2 (5.9)	3 (8.8)	0.34
Male	186 (48.5)	143 (37.1)	23 (6.0)	32 (8.4)	
Smoker					
Non	4 (28.6)	7 (50.0)	3 (21.4)	0 (0.0)	13.42*
Current	74 (52.9)	53 (37.9)	6 (4.3)	7 (5.0)	
Ex	126 (47.7)	94 (35.6)	16 (6.1)	28 (10.6)	
FEV1% (post)[a]	55.2 (18.6)	51.7 (18.6)	49.2 (17.5)	42.1 (13.9)	7.75**

*$P<0.05$, **$P<0.001$, [a]FEV_1: Postbronchodilator forced expiratory volume in 1 s. FEV: Forced expiratory volume, GOLD: Global Initiative for Chronic Obstructive Lung Disease, SD: Standard deviation

6% in Group C, and 8.4% in Group D with more patients in less severe groups [Table 1].

While age and gender had no significant association with GOLD 2017 assessment, a significant association was observed between GOLD 2017 assessment and smoking status and postbronchodilator FEV1% [Table 2]. A significant but weak association was also seen between spirometric staging and new assessment [Table 3].

A substantial shift of patients is seen from more severe categories to less severe on applying new assessment. About 76.4% of patients falling in Stage C according to the old classification shifted to Stage A on applying the new classification. About 68.2% of patients falling in Stage D according to the old classification shifted to Stage B on applying the new classification. Kappa statistic of 0.497 with a $P < 0.001$ indicates a moderate agreement between the two classifications [Table 4].

Treatment records of 300 patients were available to assess if stratification regarding combined assessment was done and in none was it mentioned, showing poor incorporation at the community level.

Table 3: Association between spirometric staging and Global Initiative for Chronic Obstructive Lung Disease 2017 combined assessment

Variables	GOLD 2017 combined assessment			
	A	B	C	D
Spirometric stage[a]				
1	22 (62.9)	10 (28.6)	3 (8.6)	0 (0.0)
2	100 (52.4)	67 (35.1)	14 (7.3)	10 (5.2)
3	67 (42.7)	62 (39.5)	8 (5.1)	20 (12.7)
4	15 (42.9)	15 (42.9)	0 (0.0)	5 (14.3)
Total	204 (48.8)	154 (36.8)	25 (6.0)	35 (8.4)

Pearson χ^2: 18.31, df: 9, $P<0.03$, Phi statistic: 0.209. Cramer's V value 0.121, P: 0.032. Spirometric stage1: FEV_1 >80%, 2: FEV_1 50%-80%, 3: FEV_1 30%-50%, 4: FEV_1 <30%. GOLD: Global Initiative for Chronic Obstructive Lung Disease, FEV_1: Forced expiratory volume in 1 s

Table 4: Stratification of Copd patients according to GOLD 2011 and GOLD 2017

Variables	GOLD 2017 new COPD classification, *n* (%)			
	A (204)	B (154)	C (25)	D (35)
GOLD 2011 COPD classification				
A (123)	123 (100.0)	0 (0)	0 (0)	0 (0)
B (79)	0 (0)	79 (100.0)	0 (0)	0 (0)
C (106)	81 (76.4)	0 (0)	25 (23.6)	0 (0)
D (110)	0 (0)	75 (68.2)	0 (0)	35 (31.8)

Pearson χ^2: 545.66, df: 9, $P<0.001$, Kappa statistic: 0.497.
COPD: Chronic obstructive pulmonary disease, GOLD: Global Initiative for Chronic Obstructive Lung Disease

DISCUSSION

In 2011, the GOLD guidelines for COPD recommended a change in the assessment of COPD patients.[1] Previously, postbronchodilator FEV1 was utilized as the sole criteria for COPD severity, classification, and treatment. GOLD 2011 devised a new combined assessment incorporating spirometry, symptom scores in terms of mMRC, or COPD assessment test (CAT) scores with cutoff of ≥2 of mMRC score and CAT scores of >10 being equivalent and previous history of any hospitalization/exacerbation over preceding 1 year. In 2017, GOLD guidelines combined assessment was further modified and spirometry was not included as part of this combined assessment rather spirometric staging is to be done separately, while symptom scores and exacerbation/hospitalization history were used for combined assessment.[2]

Classification as per all three, i.e., spirometric, old (GOLD 2011), and new (GOLD 2017) varies. According to spirometric severity, Stages 2 and 3, i.e., moderate and severe COPD, are more common consistently across studies which are also corroborated in our study.[3-5] According to studies using GOLD 2011 guidelines, Group C was the least common and the most common group varied according to the study population from D to A.[3-7] Hence, a few studies also concluded that GOLD 2011 shifted the overall COPD severity distribution to more severe categories with more patients in Stage D than previous Stage 4 spirometric classification.[7]

Concerns have also been raised about the equivalence of GOLD mMRC versus GOLD CAT classification. A few studies

concluded that while mMRC resulted in more equitable distributions, CAT system put most in either B or D.[8-10] Among 87 stable COPD patients using CAT, 65.5% of patients were in high-symptom groups (B and D). With mMRC, only 37.9% were in B and D groups.[9,10] As part of the current study, we have only utilized mMRC scores for the assessment of symptoms as the use of simple 5-point mMRC score is practically feasible in outpatient department (OPD) practice and can be easily incorporated in day-to-day practice. In our study, it is a possible reason for more equitable distribution seen among A–D groups with 29.5% in Group A, 18.7% in Group B, 25.4% in Group C, and 26.3% in Group D, respectively, according to the GOLD 2011.

According to the GOLD 2017, in our study, 48.9% were in Group A, 36.9% in Group B, 6% in Group C, and 8.4% in Group D with Group A being the most common and Group C least common. How the classification has changed stratification of COPD patients according to the 2017 guidelines has been reported by few studies. A prospective multicentric study on 200 COPD patients to evaluate how COPD patients are reclassified by the 2017 GOLD system (vs. GOLD 2011) reported that approximately half of the patients classified as GOLD D (2011) changed to GOLD B (2017). The extent of agreement between GOLD 2011 and GOLD 2017 was moderate (Cohen's Kappa = 0.511; $P < 0.001$) and the ability to predict exacerbations was similar (69.7% and 67.6%, respectively).[11] Similarly, we also found moderate agreement between the two classifications. In a study on 571 participants with physician-diagnosed and spirometry-verified COPD found, 53% of the participants from Group C would be reclassified to the lower-risk Group A, and from Group D, 47% of the participants would be reclassified to the lower-risk Group B, when using GOLD 2017 instead of GOLD 2014. Compared to the subjects who would remain in Group D, those who would change to Group B were more often men, of an older age, had more primary care contact, had lower levels of blood neutrophils, geometrical mean, reported less anxiety/depression, experienced less asthma, and had fewer symptoms according to the CAT.[12] In our study, 76.4% of patients falling in Stage C according to the old classification (GOLD 2011) shifted to Stage A on applying the new classification (GOLD 2017). Furthermore, 68.2% of patients falling in Stage D according to the old classification shifted to Stage B on applying the new classification. Hence, the substantial shift of categories is seen when utilizing GOLD 2017 from more severe-to-less severe categories.

Not only this, but change in classification of COPD also raises a very important question for patient's downstaged from D and C Class to A and B. Does the treatment also need to be stepped down, especially in the context of inhaled corticosteroid?[13] Potentially, a large number of patients who shift from D and C to A and B may need to have their treatment to be stepped down.

There are few studies regarding utilization of spirometric and combined assessment. In a study from Germany, among pulmonologists and primary care physicians, the GOLD classification of moderate and severe COPD based on the spirometry was used by 36.2% and 23.4% of the pulmonologists, respectively, and by 32.1% and 20.2% of the primary care physicians (PCPs) and concluded deficits exist among these groups with respect to diagnosis and treatment of COPD and practical implementation of educational measures.[14] In the present study we observed that none of the 300 previous available treatment records of patients mentioned combined assessment indicating no incorporation at community level. It is highly underutilized possibly both on account of lack of awareness or seeming complexity though 2017 guidelines have simplified it to some extent. As the treatment of COPD is based on this, combined assessment underutilization of it would also result in prescription errors. Other studies have also found low levels of treatment appropriateness with both under and overtreatment being common.[15,16]

Correlation between spirometric severity and combined classification according to the new GOLD 2017 was evaluated, and a weak but significant positive correlation between spirometric severity and 2017 GOLD combined assessment was seen. A significant association with postbronchodilator FEV1 is also seen.

The utility of new combined assessment lies in the fact that categorization does not need spirometry and appropriate treatment can be initiated based on the revised combined assessment using symptom scores and history of exacerbations/hospitalizations. This can be done at the most peripheral health-care institutions, especially in developing countries like ours where spirometric facilities may not be available at remote peripheries.

CONCLUSION

COPD is a disease with systemic manifestations as is being increasingly recognized. Similarly, its stratification has undergone a change since 2011 with spirometry being replaced as the sole determinant of its severity. A combined assessment including symptom scores and risk of exacerbations and hospitalizations needs to be incorporated in our day-to-day OPD practice. This study highlights distribution according to the combined classification (GOLD 2017) among patients of COPD as well as shows its underutilization in our clinical practice possibly leading to prescription errors. This study highlights the fact that there is urgent need to disseminate information about new GOLD classification of COPD to ensure appropriate management of COPD patients and also raises an important question regarding further management of substantial number of patients reclassified according to the 2017 guidelines. The use of inhaled corticosteroids has been documented to cause increased risk of pneumonia and tuberculosis. Adequate utilization of combined classification and appropriate use of inhaled corticosteroid only where indicated is what is needed.

There are few limitations of our study that it is a single-center trial and we have used only mMRC scales and not CAT scores for symptom assessment, and this being a more implementable approach in busy clinical practice.

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Conflicts of interest

There are no conflicts of interest.

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