

Impact of changing GOLD guidelines (2007–2011–2017) on assignment of a COPD patient to disease severity category

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Abstract

Introduction: The international standard for the recognition and treatment of chronic obstructive pulmonary disease (COPD) is guided by a regularly updated set of criteria developed by the Global Initiative for Chronic Obstructive Lung Disease (GOLD).

Aim: To investigate the impact of updated COPD management guidelines from 2007 to 2017 (GOLD 2007, GOLD 2011 and GOLD 2017) on the assignment of patients into individual therapeutic groups, examining both individual and population dimensions.

Material and methods: Each of 500 randomly chosen primary care physicians in Poland provided information on 10 individual COPD patients (disease history, clinical status, treatment and pharmacotherapy). This data was used to simulate the consequences of the implementation of the GOLD 2007, 2011 and 2017 guidelines.

Results: A group of 298 physicians of 500 approached provided information on 2597 patients (64.2% males) aged 29–96 (61.6 ±11.1 years). Based on GOLD 2007 guidelines, most patients (56.7%) presented a severe stage of COPD. GOLD 2011 updates would significantly increase the proportion of patients with the most severe stage of disease, and this group would be predominantly classified as moderate or severe in GOLD 2007. The implementation of GOLD 2017 guidelines would result in a significant migration of patients towards the lightest (category A) form of the disease.

Conclusions: Updates to the GOLD 2007 COPD guidelines for GOLD 2011 and 2017 would have a significant impact on the classification of patients for particular therapeutic groups. As a result of the migration of patients to particular therapeutic groups, the pharmacological treatment would also change.

Key words: chronic obstructive pulmonary disease, GOLD guidelines, treatment, pharmacotherapy.

Introduction

Chronic obstructive pulmonary disease (COPD) is one of the most common chronic non-infectious diseases, with a continuously growing prevalence [1]. It is estimated that, by 2020, COPD will be the third most common cause of death in the world [2]. The results of the international multicentre BOLD (Burden of Obstructive Lung Disease) study of COPD showed that COPD may affect 8.7% of the adult population over 40 years old [3]. The world standard for the recognition and treatment of chronic obstructive pulmonary disease is outlined by the regularly updated recommendations developed by the Global Initiative for Chronic Obstructive Lung Disease (GOLD) [4–6]. Assignment of the severity stage of

the disease according to the GOLD recommendation determines clinical management. Every few years the methods used to classify COPD severity and treatment guidelines are significantly revised and published, like three GOLD documents published, in the years 2007, 2011 and 2017 [4–6].

Aim

The aim of this study was to determine to what extent the changes between the 2007, 2011 and 2017 GOLD guideline schemes affected the assignment of a COPD patient to a specific category of clinical severity of disease.

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Material and methods

The study was performed in 2017. Subjects were COPD patients registered with 500 primary care health providers in Poland, randomly selected from a national registry. Invited physicians were asked to provide information on 10 consecutive patients with diagnosed COPD. Questionnaires were used to collect data on disease history and the condition of the patient during the visit. The questions also addressed history of smoking, diagnostic procedures, clinical management, hospitalization, ambulance intervention, adverse drug reactions, disease control, current values of spirometry and presence of respiratory symptoms. A COPD exacerbation was defined as the presence of a history of: emergency intervention and/or hospitalization due to COPD and/or systemic steroid use (oral, intramuscular or intravenous) and/or deterioration recorded during a follow-up visit.

Assignment of the COPD severity stage

Using individual, questionnaire-derived data, we classified the COPD severity stage for each subject using three classification schemes provided by GOLD 2007, 2011 and 2017 guidelines. Severity of dyspnea was assessed using modified Medical Research Council dyspnea scale (mMRC).

The GOLD 2007 classification [4] was based on the degree of airway obstruction and depended on the forced expiratory volume in 1 s (FEV_1) value after the use of a bronchodilator. In every case, proportion of a person's vital capacity that they are able to expire in the first second of forced expiration (FEV_1) to the full, forced vital capacity (FVC) was less than 70% of the expected value. Category I included patients with mild COPD, where the value of post-bronchodilator FEV_1 was $\geq 80\%$ of predicted value; in category II (moderate) the values of FEV_1 reached from ≥ 50 to $< 80\%$ of predicted; category III (severe) included patients with FEV_1 from ≥ 30 to $< 50\%$ of the predicted value; in category IV (very severe) FEV_1 values were less than 30% of the predicted or FEV_1 below 50% predicted and coexisting chronic respiratory failure [4].

The GOLD 2011 classification was composed of four ABCD categories [5]. Category A included patients with $FEV_1 \geq 80\%$ of predicted, an mMRC score below 2 and less than 2 exacerbations during the last year. Category B included patients with values of FEV_1 from ≥ 50 to $< 80\%$ of predicted, an mMRC score two or more, and less than 2 exacerbations in a year. Category C included patients with FEV_1 from ≥ 30 to $< 50\%$ of predicted, an mMRC score below 2 or occurrence of at least two COPD exacerbations or one hospitalization for COPD during the year. The most severe category D included patients with FEV_1 values less than $< 30\%$ of the predicted, an mMRC score two or more and occurrence of at least two COPD exacerbations or one hospitalization for COPD during the year.

The GOLD 2017 guidelines [6] do not rely on spirometric assessment. Assignment of patients to specific therapeutic groups (ABCD) is based on the presence and severity of symptoms and COPD exacerbations. Category A includes patients with an mMRC score below 2 and less than 2 exacerbations during the last year. Category B included patients with an mMRC score of at least 2, and less than 2 exacerbations in a year. Category C includes patients with an mMRC score below 2 or occurrence of at least two COPD exacerbations or one hospitalization for COPD during the year. Category D includes patients with an mMRC score of 2 or above and occurrence of at least two COPD exacerbations or one hospitalization for COPD during the year.

Statistical analysis

Data analysis was performed using the procedures available in the Statistica 12 package. Descriptive statistics were used to present the distributions of the analyzed quantitative (arithmetic mean, standard deviation) and qualitative (frequency of analyzed variables) variables. Distribution of categorical variables was presented by frequencies and proportions, together with 95% confidence intervals. The normality of the distributions of quantitative variables were assessed using the Shapiro-Wilk test. Statistical significance of differences in between-group distributions of quantitative variables were assessed using the *t*-Student test or nonparametric *U* Mann-Whitney test and in case of qualitative variables χ^2 test of independence. The criterion of statistical significance was $p < 0.05$.

Results

A group of 298 GPs (59.6% of invited) provided information on 2756 patients with COPD. Incomplete information resulted in exclusion of data from 159 (5.8%) patients. The final analysis included 2597 patients (women 35.3%) aged 29–96 years (mean: 61.6 ± 11.1 years). During last 12 months, 19.8% of patients needed ambulance intervention due to COPD-related events. This proportion mainly depended on the gender (Table 1) and increase with the severity of the disease ($p = 0.00001$). Hospitalization due to COPD in the last year was necessary in 29.4% of patients, and the rate was dependent on the gender ($p < 0.001$) (Table 1) and increase with the severity of the disease. The COPD exacerbations without hospitalization in the last year were observed in 40.9% of the patients and the frequency depends on the gender ($p < 0.001$) ranging from 27.3% among men to 65.9% among women (Table 1). Frequency of COPD exacerbation without hospitalization in the last 12 months also depended on the gender ($p < 0.001$). The impact of COPD on life activity was assessed according to the mMRC scale: 25.0% of the patients declared no impact of COPD on life activity, 29.5% declared a slight reduction, 25.7%

large, 14.5% very large, and 5.2% declared a maximal limitation of live activity caused by COPD. Detailed characteristics of the study group are presented in Table 1.

The COPD severity stage

According to the GOLD 2007 classification guidelines, in this group of 2597 COPD patients, 13.1% of patients fulfill the criteria for mild, 26.7% moderate, 56.7% severe, and 3.4% very severe stage of COPD (Table 2). Men and women differed significantly in terms of disease severity ($p < 0.001$).

According to GOLD 2011 guidelines in the same group of 2597 patients, 14.8% would be classified as A, 10.4% as B, 39.7% as C and 35.1% as D category COPD severity

stage. Men and women differed significantly in terms of disease severity ($p < 0.001$) (Table 3).

The GOLD 2017 criteria assigned 46.8% patients to category A, 23.8% to category B, 7.7% to category C, and 21.6% to category D, with significant differences ($p < 0.001$) between men and women (Table 4).

The differences between COPD guidelines on patients' severity classifications are presented in Tables 5–7. Among patients with mild COPD according to GOLD 2007, the vast majority (82%) would be assigned to group A according to GOLD 2011 and GOLD 2017. Only 34% of patients classified as moderate under the GOLD 2007 criteria would enter group B under the GOLD 2017 criteria. Out of patients with severe COPD by GOLD 2007 criteria, only 9% would be classified as group

Table 1. Characteristics of 2597 patients with COPD participating in the study

Variable	Total N = 2597 (100%) 95% CI	Men n = 1667 (100%) 95% CI	Women n = 917 (100%) 95% CI	P-value*
Smoking history: pack-years (mean ± SD)	33.6 ±16.2	36.0 ±16.0	29.0 ±15.4	0.001*
Active smoking on the day of the study	51.2% (49.3–53.1)	51.6% (49.2–54.0)	51.0% (47.8–54.3)	0.7**
Ambulance intervention during last 12 months	19.8% (18.3–21.4)	22.1% (20.2–24.2)	15.5% (13.3–18.0)	< 0.001**
Hospitalization during last 12 months	29.4% (27.7–31.2)	20.8% (18.9–22.8)	8.6% (7.0–10.6)	< 0.001**
Frequency of exacerbation without hospitalization in the last 12 months:				
0	59.1% (57.2–61.0)	72.7% (70.5–74.8)	34.1% (31.1–37.3)	< 0.001**
1	14.1% (12.8–15.5)	15.1% (13.5–16.9)	12.3% (10.4–14.6)	
2	18.7% (17.3–20.3)	9.4% (8.1–10.9)	35.5% (32.5–38.7)	
More than 2	8.1% (7.1–9.2)	2.8% (2.1–3.7)	18.1% (15.8–20.7)	
Severity of dyspnea according to mMRC dyspnea scale:				
0	25.0% (23.4–27.0)	22.9% (21.0–25.0)	28.8% (26.0–31.8)	< 0.001**
1	29.5% (27.8–31.3)	29.5% (27.4–31.8)	29.6% (26.8–32.7)	
2	25.7% (24.1–27.4)	25.3% (23.3–27.5)	26.6% (23.9–29.6)	
3	14.5% (13.2–15.9)	16.6% (14.9–18.5)	10.6% (8.8–12.7)	
4	5.2% (4.4–6.1)	5.7% (4.7–6.9)	4.3% (3.1–5.8)	

SD – standard deviation; 95% CI – 95% confidence interval; *results of U Mann-Whitney test, **results of χ^2 test.

Table 2. COPD severity stage according to the GOLD 2007 guidelines

COPD severity stage according to the GOLD 2007	Total N = 2597 (100%)	Men n = 1667 (100%)	Women n = 917 (100%)	P-value*
Mild ($FEV_1 \geq 80\%$ predicted)	340 (13.1)	169 (10.1)	168 (18.3)	0.000001
Moderate ($FEV_1 50\text{--}80\%$ predicted)	693 (26.7)	499 (29.9)	190 (20.7)	
Severe ($FEV_1 30\text{--}50\%$ predicted)	1474 (56.7)	928 (55.7)	540 (58.9)	
Very severe ($FEV_1 < 30\%$ predicted)	90 (3.4)	71 (4.2)	19 (2.1)	

*Results of χ^2 test.

Table 3. COPD severity stage according to the GOLD 2011 guidelines

COPD severity stage according to the GOLD 2011	Total N = 2597 (100%)	Men n = 1667 (100%)	Women n = 917 (100%)	P-value*
A	385 (14.8)	210 (12.6)	172 (18.8)	0.0001
B	270 (10.4)	183 (11.0)	86 (9.4)	
C	1031 (39.7)	663 (39.8)	364 (39.7)	
D	911 (35.1)	611 (36.6)	295 (32.2)	

*Results of χ^2 test.

Table 4. COPD severity stage according to the GOLD 2017 guidelines

COPD severity stage according to the GOLD 2017	Total N = 2597 (100%)	Men n = 1667 (100%)	Women n = 917 (100%)	P-value*
A	1215 (46.8)	735 (44.1)	474 (51.7)	0.0001
B	619 (23.8)	394 (23.6)	222 (24.2)	
C	201 (7.7)	138 (8.3)	62 (6.8)	
D	562 (21.6)	400 (24.0)	159 (17.3)	

*Results of χ^2 test.

Table 5. Assignment of the COPD severity stage according to GOLD 2007 and GOLD 2011 in a group of 2597 patients

		GOLD 2011			
		A N = 385 n % column % line	B N = 270 n % column % line	C N = 1031 n % column % line	D N = 911 n % column % line
GOLD 2007	Mild N = 340	280 72.73 82.35	31 11.48 9.12	18 1.74 5.29	11 1.21 3.24
	Moderate N = 693	105 27.27 15.15	239 88.52 34.49	46 4.46 6.64	303 33.26 43.72
	Severe N = 1474	–	–	960 93.11 65.13	514 56.42 34.87
	Very severe N = 90	–	–	7 0.68 7.78	83 9.11 92.22

C under GOLD 2017 criteria, the other 91% patients would be classified into the remaining 3 groups, including 56% of patients assigned to category A. In patients with very severe COPD according to GOLD 2007 criteria, only 62% would be classified as category D by GOLD 2017 criteria (Figure 1).

Discussion

The Global Initiative for Chronic Obstructive Lung Disease (GOLD) was initiated in 1998 as a result of co-

operation between US institutions such as the National Heart, Lung and Blood Institute and the National Institutes of Health with the World Health Organization [4–6]. The main goal of this initiative was to raise awareness about COPD and to reduce the morbidity and mortality associated with COPD. The GOLD guidelines currently define the “gold standard” of clinical management and treatment of patients with COPD [6]. Due to the growing number of research on COPD, these guidelines require constant monitoring and updating. Every 5 years, the

Table 6. Assignment of the COPD severity stage according to GOLD 2007 and GOLD 2017 in a group of 2597 patients

		GOLD 2017			
		A N = 1215	B N = 619	C N = 201	D N = 562
		n	n	n	n
		% column	% column	% column	% column
		% line	% line	% line	% line
GOLD 2007	Mild N = 340	280 23.05 82.35	31 5.01 9.12	18 8.96 5.29	11 1.96 3.24
	Moderate N = 693	105 8.64 15.15	239 38.61 34.49	46 22.89 6.64	303 53.91 43.72
	Severe N = 1474	825 67.90 55.97	322 52.02 21.85	135 67.16 9.16	192 34.16 13.03
	Very severe N = 90	5 0.41 5.56	27 4.36 30.00	2 1.00 2.22	56 9.96 62.22

Table 7. Assignment of the COPD severity stage according to GOLD 2011 and GOLD 2017 in a group of 2597 patients

		GOLD 2017			
		A N = 1215	B N = 619	C N = 201	D N = 562
		n	n	n	n
		% column	% column	% column	% column
		% line	% line	% line	% line
GOLD 2011	A N = 385	385 31.69 100.00	–	–	–
	B N = 270	–	270 43.62 100.00	–	–
	C N = 1031	830 68.31 80.50	–	201 100.00 19.50	–
	D N = 911	–	349 56.38 38.31	–	562 100.00 61.69

method of classification of COPD severity and the treatment guidelines are radically revised.

The magnitude of changes in assignment to GOLD categories are unknown. There are limited data assessing impact of GOLD guideline updates on assignment of a COPD patients to specific therapeutic groups. We wanted to determine what consequences were brought about for the same patients during a 10 year span due to shifts in severity classification standards. To our best knowledge, our study is the first available study comparing distribution of the COPD patients according to the GOLD 2007, 2011 and 2017 guidelines, which is based on a “real life scenario”.

Our study found that according to GOLD 2007 classification, among the 2597 COPD patients under the care

of a primary care physician, more than half of the subjects (56.7%) presented severe COPD. Those proportions differ from some observed in outpatient specialist care and GP's, where 47–55% of patients had moderate COPD severity stage [7–9]. In cross-sectional studies, the proportion of patients presenting a particular severity stage of the disease depended on the study population as well as the study protocol. Our data were collected between September and November 2009 with a higher probability of GP visits in patients with more severe stages of disease.

Changing the classification criteria for COPD raises serious consequences. Upon adoption of the GOLD 2011 guidelines, nearly a tenfold increase in the number of pa-

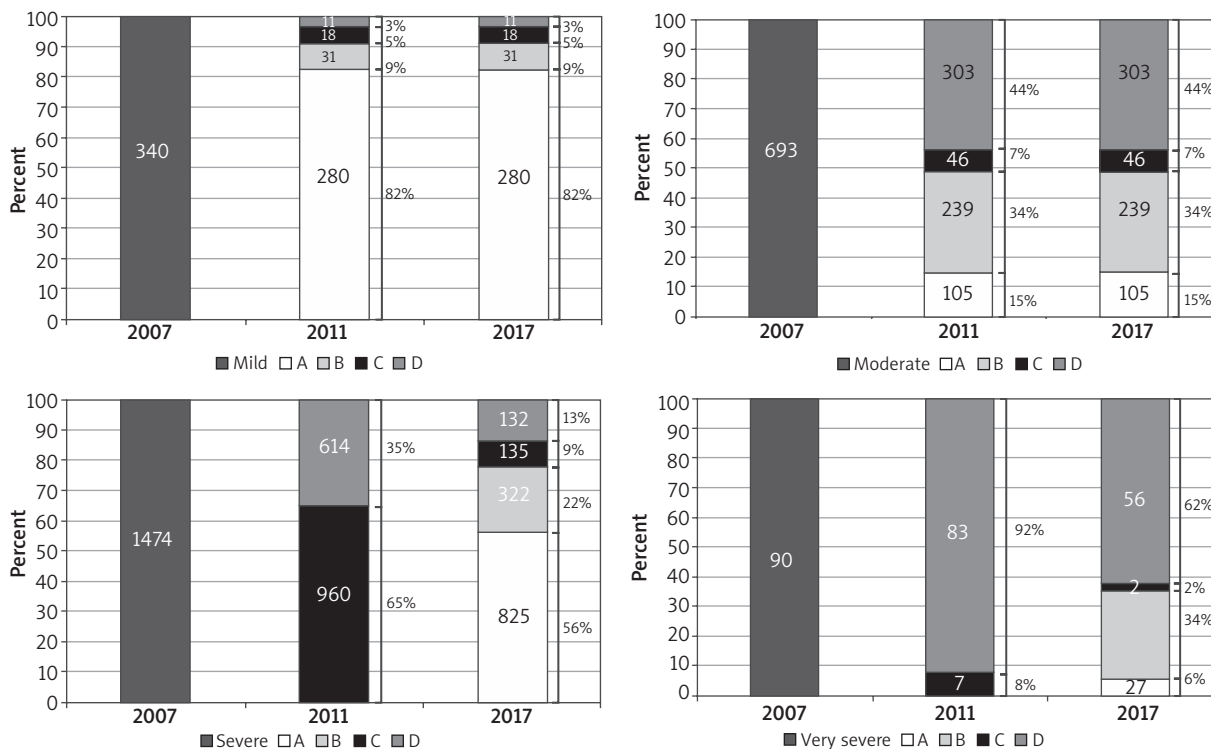


Figure 1. Changes in the structure of patients assigned to specific therapeutic groups depending on the GOLD 2007–2011–2017 guidelines

tients with very severe COPD was observed. Among patients in category D according to the GOLD 2011 criteria, almost 44% would be patients who were previously classified as having moderate COPD according to the GOLD 2007 criteria. Grzelewska-Rzymowska *et al.* also observed this increase in the number of patients assigned to category D after the implementation of the GOLD 2011 guidelines [10]. The proportion of patients assigned to category D would have increased tenfold – from 5.4% according to GOLD 2007 to 53.5% after introduction of the GOLD 2011 guidelines, wherein 78% of those in category D would consist of patients with severe COPD, according to GOLD 2007 guidelines [10]. A study of a group of 2271 patients with COPD under the care of 411 pulmonology and allergy specialists from all over Poland performed by Wesółowski *et al.* also showed uneven distribution of patients into individual categories due to the GOLD 2011 update [11]. In that study the most numerous group were the patients who were classified as category D (40.7%) or A (30.3%); only one tenth (11.3%) were assigned to category C, and 17.7% patients presented moderate COPD severity stage [11]. In addition, the authors showed that patients who were assigned to categories B and D and presented more severe symptoms were older and smoked more cigarettes compared to patients in categories A and C [11]. The risk of exacerbation was the major cause of assignment to category C or D [11]. Likewise, Hernández *et al.* analyzed the changes between the

GOLD 2007 and 2011 standards and concluded that classifying patients using the GOLD 2011 criteria reassigned a relevant proportion of patients to a different risk category and identified larger proportions of patients in the mildest and more severe groups compared to the GOLD 2007 classification [12].

Significant differences in patient assignments to individual therapeutic groups were also reported when comparisons between the GOLD 2007 and 2017 guidelines were analyzed. Classifying 2597 patients into categories based on the GOLD 2017 guidelines, we observed a significant migration of patients to the lightest form of COPD (46.8% vs. 13.1%). Interestingly, mild or moderate severity COPD according to the GOLD 2007 guideline were equally attributed to individual ABCD groups according to both the GOLD 2011 and the GOLD 2017 guidelines. A study performed by Marçõa *et al.* in a group of 200 patients with COPD also showed differences in patients assignment to individual therapeutic groups depending on the GOLD 2011 and 2017 guidelines [13]. All the patients classified to category A or B according to the GOLD 2011 guidelines would remain in these groups after reclassification based on the GOLD 2017 updates, which is a comparable result to that obtained in our study. Approximately half of the patients assigned to group D according to the GOLD 2011 criteria migrated to group B in the GOLD 2017 update. After implementation of the GOLD 2017 guidelines, the lowest proportion of patients

would be classified into group C (4.5% of COPD patients), which is similar to results obtained in our study (7.7% of patients in group C according to GOLD 2017) [13]. Moreira *et al.* evaluated the distribution of patients to particular therapeutic groups, depending on the used GOLD 2001–2011–2017 guidelines (Moreira *et al.*, ERS International Congress 2017, Milan). In the study by Moreira *et al.* significant migration towards groups of lighter COPD severity after introduction of newer grades according to GOLD was observed, which is similar to results presented in our study. Mathioudakis *et al.* observed that applying the GOLD 2017 recommendations in UK primary care will significantly reduce the cost of COPD pharmacotherapy (Mathioudakis *et al.*, ERS International Congress 2018, Paris).

The update of the GOLD guidelines has important clinical implications affecting everyday clinical practice. Classification of patients into disease severity categories according to the GOLD recommendation determines the clinical management of their disease. Due to this fact, assignment of patients to a specific disease severity category depending on the used GOLD 2007–2011–2017 guideline resulted in a significant migration, which dramatically changed the structure of patients assigned to specific therapeutic groups. The detailed analysis of the clinical implications of GOLD guideline updates as well as the economic consequences of GOLD guideline updates will be presented in the separate publications.

Sets of drugs recommended in the pharmacotherapy of COPD according to GOLD 2007–2011–2017 are significantly different, depending on used GOLD criteria. The changes in assignment of patients into individual COPD severity stage, are associated with the need for a different approach to clinical management and treatment regimes in regards to individual patients, and previously used pharmacotherapy require adaptation to these new recommendations. Therefore, it is advisable to promote the most up-to-date GOLD guidelines to physicians dealing with COPD patients on a daily basis.

We are aware of several limitations regarding this study. First of all, our study does not reflect the full population of patients diagnosed with COPD. Our study was based on a population of the patients attending primary care health centers in Poland. Nevertheless, it is one of the largest cross-sectional studies carried out in a group of patients with COPD under the care of family doctors from all over Poland. In addition, it should be noted that in Poland, the majority of patients with COPD remain under the care of a primary care physician and primary care physicians' actively manage the pharmacotherapy of patients with COPD. It cannot be ruled out that the method of recruitment of the subjects could have had an effect on the distribution of the severity of the disease. The authors are aware that the use of the CAT testing might involve a different distribution of patients to particular therapeutic groups, but nevertheless at the time of performing this study, the CAT test was not widely available.

It should be noted that the GOLD 2011 and 2017 guidelines mention both tests as equivalent without prioritizing any of them.

Conclusions

Updates on GOLD 2007 COPD guidelines for GOLD 2011 and 2017 have a significant impact on the classification of patients for particular treatment groups. Compared to patients stratified according to GOLD 2007, patients assignments guided by GOLD 2011 criteria significantly increased the proportion of patients with the most severe stage of disease (D).his group was predominantly classified as moderate or severe in GOLD 2007. The implementation of GOLD 2017 guidelines resulted in a significant migration of patients towards the lightest (category A) form of the disease. The migration of the same patients to particular therapeutic groups set by different GOLD updates would result in serious changes in the recommended pharmacological treatment. The major consequence of the current GOLD 2017 update is that more patients are using less intensive pharmacological therapies compares to the GOLD 2007 and 2011 recommendations.

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Conflict of interest

The authors declare no conflict of interest.

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