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Original Research Article

Prescription pattern of inhalational medications for chronic obstructive pulmonary disease in India: insights from cross-sectional survey of pulmonologists across India

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ABSTRACT

Background: Treatment of COPD depends on disease severity, phenotype and exacerbation risk. Inhaled medications are the treatment of choice in COPD. We undertook this survey to find the most commonly prescribed inhalational medication in COPD as per the severity of the disease.
Methods: It was a cross-sectional questionnaire-based survey of pulmonologists in real-world clinical practice settings conducted across India.
Results: The participants included 806 pulmonologists across India. Seventy-five per cent of pulmonologists ranked symptom relief, reduction in the frequency of exacerbations and improvement in lung function as the most important treatment targets. In COPD patients falling under GOLD group A, the treatment choice by pulmonologists in descending rank order was fomroterol/glycopyrronium (32%), ipratropium (38%), and tiotropium (30%) and for gold group B, this was fomroterol/glycopyrronium (34%), followed by indacaterol/glycopyrronium (26%) and tiotropium/formoterol (40%). In the GOLD group E, triple therapy (formoterol/glycopyrronium/budesonide) was preferred by 41% of pulmonologists. In the frequent exacerbator, predominant emphysema, chronic bronchitis and concomitant asthma phenotype, 44%, 38%, 46% and 32% of pulmonologists ranked formoterol/ glycopyrronium/budesonide as their preferred 1st therapy, respectively. Among COPD patients with cardiovascular disease (CVD) comorbidity, 31% of pulmonologists selected formoterol/glycopyrronium/budesonide as 1st-preference drug therapy. Similar results were obtained for COPD patients with metabolic syndrome comorbidity.
Conclusions: For the management of COPD patients, pulmonologists predominantly preferred a triple drug combination of formoterol/glycopyrronium/budesonide in GOLD group E and also in patients with cardiovascular and metabolic comorbidities. Fomroterol/glycopyrronium was the most preferred combination for GOLD group A and GOLD group B.

Keywords: COPD, Inhalational medications, Prescription pattern, Survey, Triple drug therapy

INTRODUCTION

The GOLD guidelines define chronic obstructive pulmonary disease (COPD) as a heterogeneous lung condition characterized by chronic respiratory symptoms (dyspnea, cough, sputum production) due to abnormalities of the airways (bronchitis, bronchiolitis) and/or alveoli (emphysema) that cause persistent, often progressive, airflow obstruction.[1] Two recent systematic reviews and meta-analyses of data from a total of 88,000 patients yielded a pooled estimate of >7% prevalence in India.[2,3] The estimated mortality attributed to COPD as per the global burden of disease (GBD, 1990-2019) is twice as high in India compared to global proportions (9.57% versus 5.8% of total deaths).[4] It also accounts for nearly 4.55% of disability-adjusted life years (DALYs) in the Indian population compared to 2.94% of the global population.[4] Thus, as per these estimates compared to the global figures, India has nearly double the mortality rate and DALYs.[4] In India, a considerable proportion of patients with COPD may delay seeking medical attention and present at advanced stages of COPD.[5] This may be attributed to poor perception of symptom severity and restricted use of spirometry, which in turn delays diagnosis and worsening of the lung function.[6] These factors should be considered when implementing guideline recommendations in the Indian context.

Long- or short-acting bronchodilators should be prescribed to patients with COPD categorized as group A depending on their effectiveness on breathlessness and continued based on improvement of symptoms. Long-acting bronchodilators should be the preferred choice unless the frequency of breathlessness is too low. In patients categorized as group B, the treatment should be initiated with a dual bronchodilator (LABA+LAMA) combination. Compared to LAMA monotherapy, dual therapy has demonstrated superior improvements in group B patients.[7] Also, in patients categorized as group E, the treatment should be initiated with a dual bronchodilator (LABA+LAMA) combination. In group E patients with eosinophil (eos) ≥300 cells/µl or concomitant asthma, triple drug therapy (LABA+LAMA+ICS) is superior to LABA+ICS.[8,9] Therefore the approach towards managing COPD in a real-world in-clinic setting would be interesting since evidence-based guidelines usually follow the findings of randomized studies conducted in controlled settings. Hence, we undertook a questionnaire-based survey across India with the primary objective of exploring the prescription pattern of pulmonologists in patients with COPD.

METHODS

Design and participants

The current study was a cross-sectional survey of pulmonologists conducted across all states of India between August and December 2022. The participating pulmonologists were in the age range of 40-60 years having 10-25 years of clinical experience. The questionnaire was developed to provide unbiased observations of real-world in-clinic settings from a pulmonologist's perspective to understand factors affecting current practices and standards of care. It was developed by reviewing the published literature on a knowledge-attitude-practice survey of COPD among doctors.[10,11] The pulmonologists were chosen based on their educational qualifications and clinical experience in the field of respiratory disease management. The validated questionnaire was then shared with the pulmonologist through an online platform.

Variables

The pulmonologists ranked their preferred pharmacological therapy in patients with COPD belonging to various GOLD groups and phenotypes.

Statistical analyses

The data was analyzed and expressed as percentages for all the parameters using the Microsoft Excel program 2016.

Ethics committee approval

The study was conducted as a survey and comprises real-world in-clinic observational research. It does not involve any intervention or patients. Therefore, no ethics committee approval was applicable.

RESULTS

The survey included responses from 806 pulmonologists across India. The maximum participation was from the South zone (34%), followed by the north zone (21%) and the least from central zone (11%) (Table 1). Pulmonologists from the east zone comprised 15% of the total, while those from the west zone accounted for 18%.

Table 1: Distribution of participant pulmonologists across India.

Zone	Proportion
South	34%
North	21%
West	18%
East	15%
Central	11%

According to the data obtained, 75% of pulmonologists ranked symptom relief, reduction in the frequency of exacerbations and improvement in lung function as their 1st priority, 16% ranked reduction in the frequency of exacerbations alone as their 2nd and only 9% ranked symptom relief alone as their 3rd priority while selecting a treatment option for patients with COPD (Figure 1).

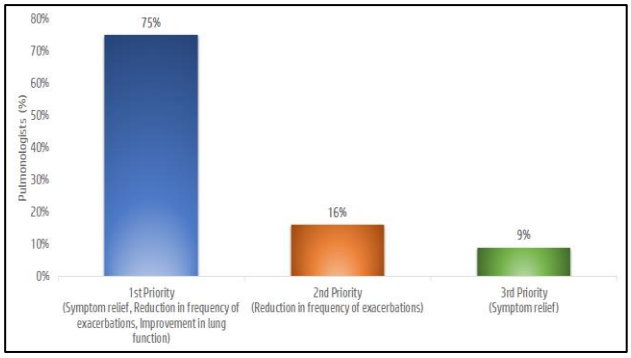

Figure 1: Priorities while selecting a treatment for COPD patients.

In COPD patients categorized as GOLD A, 32% of pulmonologists ranked formoterol/glycopyrronium as a 1st preferred therapy, 38% ranked ipratropium as 2nd, and 30% ranked tiotropium as 3rd. In COPD patients categorized as GOLD B, 34% of pulmonologists ranked formoterol/glycopyrronium as a 1st preferred therapy, 26% ranked indacaterol/glycopyrronium as 2nd, and 40% ranked formoterol/tiotropium as 3rd. In COPD patients categorized as GOLD E, 41% of pulmonologists ranked formoterol/glycopyrronium/budesonide as a 1st preferred therapy, 32% ranked formoterol/glycopyrronium as 2nd, and 27% ranked indacaterol/glycopyrronium as 3rd (Figure 2).

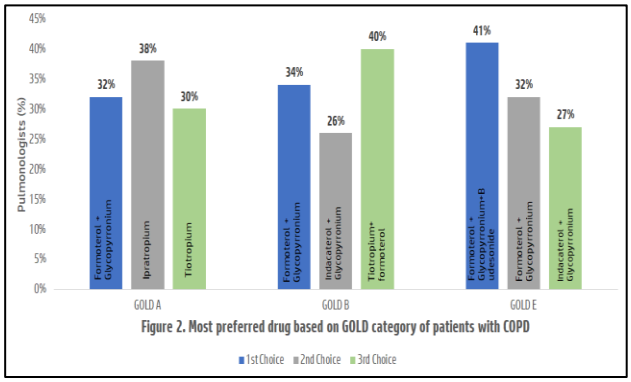

Figure 2: Most preferred drug based on GOLD category of patients with COPD.

Based on the COPD phenotype, the survey sought responses on preferred therapies. In the frequent exacerbator phenotype, 44% of pulmonologists ranked formoterol/glycopyrronium/budesonide as a 1st preferred therapy, 30% ranked ICS/LABA as 2nd and 26% ranked formoterol/glycopyrronium as 3rd. Among patients with acute exacerbations, 46% of pulmonologists ranked LABA/LAMA as a 1st preferred therapy and an equal proportion ranked SABA-SAMA and LAMA alone as 2nd and 3rd, respectively. For chronic bronchitis and concomitant asthma phenotype, the ranking order was the same as for frequent exacerbators phenotype. For the emphysema-predominant phenotype, 38% of pulmonologists ranked formoterol/glycopyrronium/budesonide as a 1st preferred therapy, 32% ranked formoterol/glycopyrronium as 2nd, and 30% ranked tiotropium/formoterol as a 3rd preferred therapy (Figure 3). Among the COPD patients with the eosinophilic phenotype (>300 cells/µl), the preferred ICS/LABA were formoterol/budesonide (40%), followed by vilanterol/fluticasone (36%) and formoterol/fluticasone (24%).

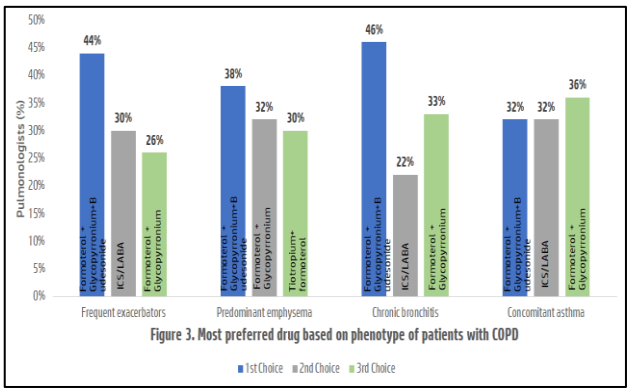

Figure 3: Most preferred drug based on phenotype of patients with COPD.

Based on the pulmonologists' experience with the overall efficacy of the various treatment options available, 38% ranked formoterol/glycopyrronium/budesonide as a 1st preferred therapy, 38% ranked formoterol/glycopyrronium as 2nd and 25% ranked indacaterol/formoterol as 3rd preferred therapy. Similar rank order was observed for the overall safety parameter (Figure 4).

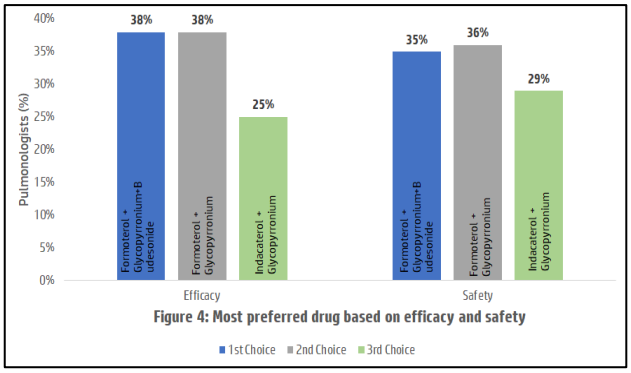

Figure 4: Most preferred drug based on efficacy and safety.

Among the various comorbidities in patients with COPD, 38%, 23%, 21% and 18% pulmonologists ranked CVD as 1st, metabolic syndrome as 2nd, osteoporosis as 3rd and depression and anxiety as fourth. Among COPD patients with CVD, 31% of pulmonologists preferred formoterol/glycopyrronium/budesonide as a 1st preferred therapy, 38% preferred formoterol/glycopyrronium as 2nd preferred therapy and 31% preferred indacaterol/glycopyrronium as 3rd. Even in patients with metabolic syndrome, the rank order remained the same, with 32%, 38% and 30% preferring formoterol/glycopyrronium/

budesonide as 1st, formoterol/glycopyrronium as 2nd and indacaterol/glycopyrronium as 3rd (Figure 5).

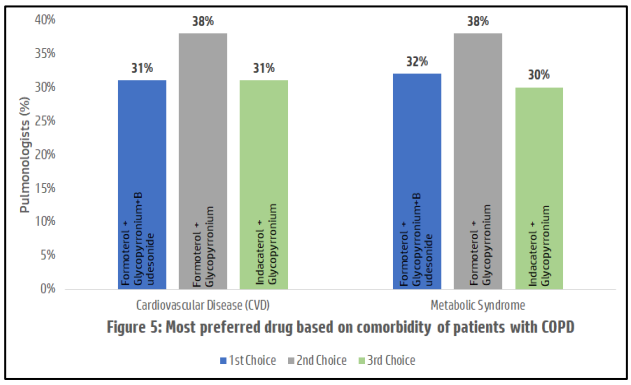

Figure 5: Most preferred drug based on comorbidity of patients with COPD.

According to the participant pulmonologists, the major challenges COPD patient deals with are inspiratory flow with dry powder inhaler (46%), hand-breath coordination with metered-dose inhaler (29%) and inhalation duration (25%).

DISCUSSION

The main treatment goals recommended as per the GOLD 2023 guideline are reduced symptoms and future exacerbations in patients with stable COPD.[1] The participating pulmonologists also regard these priorities highly, recognizing that while lung function alone may not dictate the need for pharmacological intervention, it remains a crucial treatment outcome.[12]

The GOLD guidelines recommend treatment based on ABE groups. Single or dual bronchodilators are recommended for the GOLD A and B groups who are less symptomatic and are at low risk of exacerbations. The survey showed that pulmonologists rank dual long-acting bronchodilators (formoterol/glycopyrronium) as their first choice over short-acting ones, followed by LAMA (ipratropium and tiotropium) alone in GOLD group A patient. For group B, due to higher symptom burden, preferences shift to dual bronchodilators including formoterol/glycopyrronium, indacaterol/ glycopyrronium, and formoterol/tiotropium. The choice of LABA may be affected by their pharmacological characteristics. Formoterol and Indacaterol have a higher intrinsic efficacy at the β_2-adrenoceptor (95% and 86%, respectively) than vilanterol (70%). Additionally, their faster onset of action is advantageous, especially for patients with suboptimal treatment adherence.[13] Formoterol is more selective for β_2 over β_1 and β_3 with affinities greater than indacaterol.[14,15] These may translate into desired efficacy in terms of quicker symptomatic relief and, therefore, are preferred amongst various LABAs.[16]

Glycopyrronium has an advantageous M_3:M_2 receptor residence duration time compared to Tiotropium, which may underlie the difference in their onset of action. Glycopyrronium, therefore, appears to have a faster onset of action. The onset of the effect may be expressed in terms of improvement in FEV1 from baseline. A 100 ml difference in pre-dose or trough FEV1 has been considered the minimum clinically important difference noticeable to patients.[17] Glycopyrronium increased FEV1 by 105 ml, while tiotropium increased by 100 ml on day 1, slightly increased or maintained for up to a year.[17] Hence, it may be argued that glycopyrronium is slightly superior to tiotropium in terms of onset of action and measure of bronchodilation.

Compared to tiotropium, glycopyrronium has superior receptor specificity regarding M3:M2 activity, potentially resulting in enhanced cardiovascular safety and tolerability. Conversely, tiotropium is linked to a higher prevalence of anticholinergic adverse events such as urinary retention, dry mouth and constipation.[18-20] The quicker onset, improved FEV1, and better adverse event profile may have led pulmonologists to prefer glycopyrronium over tiotropium.

In the GOLD E group of patients with a high risk of exacerbation, most pulmonologists ranked the triple combination of formoterol/glycopyrronium/budesonide as 1st and LABA/LAMA formoterol/glycopyrronium and indacaterol/glycopyrronium as 2nd and 3rd, respectively. GOLD guidelines recommend ICS only in those with exacerbations associated with hospitalization or high eosinophil counts. However, it is worth mentioning that the preference for initial triple drug therapy may be due to the peculiar characteristics of COPD patients in India. Patients lack awareness regarding the disease symptoms and severity, so they neglect seeking medical advice. Additionally, restricted use of spirometry in primary care centres, especially in rural areas, hinders appropriate management, accelerating the decline of pulmonary function.[6] Therefore, most patients may present at advanced GOLD stages and need intensive treatment by triple drug therapy (ICS/LABA/LAMA).

With improved insights into COPD pathology, clinical features and genetic characteristics, the approach to phenotyping of COPD has considerably improved. The elucidation of COPD phenotypes has permitted more tailored therapeutic strategies that offer greater benefits and better tolerability. Finally, it may be argued that the phenotypic approach to COPD significantly influences the clinical practice and treatment of COPD patients. Therefore, we sought ranking for the treatment of specific phenotypes. For all four phenotypes, the triple drug combination was ranked 1st, followed by ICS/LABA and dual bronchodilators (formoterol/glycopyrronium), except for cases of emphysema predominance, where dual bronchodilators were ranked 2nd and 3rd. The role of triple drug therapy in the exacerbator phenotype and asthma-COPD phenotype (with high eosinophil counts)

has been widely recommended and accepted. In the emphysema and chronic bronchitis phenotype, dual bronchodilators with or without ICS and PDE inhibitors are usually preferred; however, pulmonologists probably prefer triple drug therapy due to high eosinophil counts commonly found in the Indian population. These findings strongly suggest that pulmonologists are switching towards triple drug combination therapies.

Cardiovascular diseases and COPD commonly coexist in up to 17-29% of patients.[21] In studies from India, the incidence is even higher, up to 60%.[22] The prevalence of diabetes, a key component of metabolic syndrome in various studies of COPD, ranges from 3 to 12%.[23,24] Studies from India have shown that the incidence of metabolic syndrome in those with COPD is twice that of non-COPD control cases.[25] Therefore, pharmacotherapeutic agents such as LABAs and LAMAs have to be highly selective for the target receptors. LABA should be specific to the β_2 receptor to avoid β_1 agonistic adverse effects such as tachycardia and increased oxygen demand of the heart.[26] Slightly lower incidences of tremor and tachycardia are reported in patients treated with formoterol than indacaterol.[27] Among the LAMAs, higher incidences of dry mouth and blood glucose elevations were reported with tiotropium than with glycopyrronium.[28] The differences in receptor specificity may underlie the variations in the adverse event profile of LABA and LAMAs. Therefore, pulmonologists may have considered formoterol over indacaterol and glycopyrronium over tiotropium.

This study sheds light on the prevailing preferences among pulmonologists regarding the pharmacological management of COPD patients. The findings of the survey clearly demonstrate that the triple drug combination of formoterol/glycopyrronium/budesonide is the most preferred treatment regimen. This choice is driven by considerations of disease severity, phenotypic characteristics, and the presence of cardiovascular or metabolic comorbidities, reflecting a comprehensive approach to patient care.

The observed inclination towards triple drug therapy underscores the importance of addressing multiple aspects of COPD pathophysiology, including bronchodilation, inflammation, and mucus production, in order to achieve optimal disease control and improve patient outcomes. Furthermore, the widespread adoption of this triple drug combination regimen suggests a growing recognition among pulmonologists of the need for personalized treatment approaches tailored to individual patient needs and characteristics.

Additionally, our study highlights a secondary preference among pulmonologists for dual combinations of LABA/LAMA, providing insight into alternative treatment options for COPD management. Dual LABA/LAMA combinations offer a simplified regimen while still addressing key aspects of COPD pathophysiology, particularly bronchodilation.

Apart from bronchodilators and inhaled corticosteroids, other pharmacological drugs for COPD treatment includes methylxanthines, (e.g. theophylline), which can be used as adjunctive therapy, although their role is limited due to a narrow therapeutic index and potential side effects. Phosphodiesterase-4 inhibitors, like roflumilast, are recommended for patients with severe COPD associated with chronic bronchitis and a history of exacerbations, as they help reduce inflammation and frequency of exacerbations. Mucolytic agents, such as N-acetylcysteine and carbocysteine, may benefit patients with viscous sputum by reducing mucus viscosity and improving airway clearance. Finally, patient education and self-management are vital for optimizing overall COPD management.[1]

Alternative treatment options for COPD, according to the GOLD 2023 guidelines, include several non-pharmacological and pharmacological interventions. Pulmonary rehabilitation is a key component, offering comprehensive programs that improve exercise capacity, symptoms, and quality of life. Long-term oxygen therapy is recommended for patients with severe resting hypoxemia to improve survival. Non-invasive ventilation (NIV) may be beneficial for select patients, particularly those with chronic hypercapnic respiratory failure. Smoking cessation remains the most crucial intervention for altering disease progression. Additionally, lung volume reduction surgery (LVRS) and bronchoscopic interventions can be considered for patients with severe emphysema and hyperinflation, providing symptomatic relief and enhancing lung function.[1]

Overall, these findings underscore the importance of considering multiple factors, including disease severity, phenotype, and comorbidities, in the pharmacological management of COPD patients. Future research should continue to explore the comparative effectiveness and safety of different treatment regimens, as well as the impact of personalized approaches on long-term outcomes in COPD management. By addressing the diverse needs of COPD patients through evidence-based and individualized treatment strategies, we can strive towards improved quality of life and better disease control for this challenging condition.

CONCLUSION

For the management of COPD patients, pulmonologists predominantly preferred a triple drug combination of formoterol/glycopyrronium/budesonide in GOLD group E and also in patients with cardiovascular and metabolic comorbidities. Fomroterol/glycopyrronium was the most preferred combination for GOLD group A and GOLD group B.

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