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EMERGING THERAPIES IN THE TREATMENT OF COPD: EFFICACY AND FUTURE PROSPECTS

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Abstract: Objective: To analyze the updates of the GOLD 2025 guidelines in the management of Chronic Obstructive Pulmonary Disease (COPD), highlighting the proposed changes and the new emerging therapies recommended, in addition to evaluating the theoretical and practical implications of these innovations in the treatment of the disease. **Methodology:** A literature review based on articles indexed in the PubMed database. The descriptors used in the search included "Chronic Obstructive Pulmonary Disease" AND "Ensifentrine" OR "Dupilumab" OR "Newtreatment" OR "Global Initiative for Chronic Obstructive Lung Disease". Twenty--two articles were selected for detailed analysis, considering their relevance to the topic. **Discussion:** The GOLD 2025 guidelines incorporated new diagnostic methods, such as impulse oscillometry and inflammatory biomarkers, as well as innovative therapies, such as Ensifentrine and Dupilumab, promoting a more personalized and effective approach. It was also noted that, despite advances, challenges such as limited access to technologies and the need for additional studies remain. **Final considerations:** The updates to the GOLD 2025 guidelines reflect significant advances in the approach to COPD, promoting a more individualized management based on recent evidence. The new recommendations aim to improve risk stratification, therapeutic efficacy and patients' quality of life, highlighting the importance of continuous monitoring of the evolution of the guidelines and the development of new therapeutic strategies.
Keywords: COPD, GOLD 2025, Biomarkers, Personalized Management.

INTRODUCTION

Chronic Obstructive Pulmonary Disease (COPD) is one of the leading causes of morbidity and mortality globally and represents a significant challenge for health systems. The disease is characterized by persistent airflow limitation associated with chronic inflammation of the airways, often resulting in dyspnea, chronic cough and sputum production. Given the debilitating impact of the disease, effective diagnostic and therapeutic approaches are essential to improve patients' clinical outcomes and in recent years, scientific and technological advances have transformed the management of COPD, from more refined diagnostic methods to innovative therapeutic interventions.

Van der Veer *et al.* (2025) demonstrated that artificial intelligence (AI) can be used to automatically quantify obstructive airway mucus plugs, a metric associated with all-cause mortality in COPD patients. In addition, the use of new drugs such as Ensifentrine, which simultaneously provide bronchodilation and an anti-inflammatory effect, have shown good results (Yappalparvi *et al.*, 2024; Hanania; Celli, 2024). According to Singh et al. (2024), pre- and post-bronchodilator spirometry remains the standard method for diagnosing the disease, excelling in early identification and personalized patient management. These findings highlight the potential of emerging technologies to improve risk stratification and reduce disease complications.

Despite recent advances, significant gaps remain in research into the management of COPD. The application of AI in the treatment of the disease is still in its early stages, and more studies are needed to validate its effectiveness in different populations and clinical settings. Additionally, the standardization of spirometry is not always feasible in regions with limited resources, hindering equity in diagnosis and treatment. These gaps justify the need for research that addresses not only the efficacy of emerging therapies, but also strategies to overcome implementation barriers and expand access to innovative technologies. A relevant example is the COPD Assessment Test (CAT), which has demonstrated good sensitivity and specificity as a complementary tool in the early detection of COPD, especially in contexts with limited access to spirometry (Al Wachami et al., 2024).

The need to improve risk stratification criteria is also evident. Waeijen-Smit *et al.* (2024) point out that the historical exacerbation categories of the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines have moderate performance in predicting future exacerbations and mortality, suggesting that a single previous episode of moderate exacerbation may be a better predictor of risk. In addition, Kim *et al.* (2024) point out that broadening the definition of COPD can pose a clinical challenge by including conditions such as bronchiectasis with airflow limitation, which can compromise diagnostic accuracy. Finally, Al Wachami *et al.* (2024) show that although the Moroccan version of the CAT has shown high internal consistency and good diagnostic accuracy, it should be used as a complementary tool to spirometry, and not as a definitive substitute.

Against this backdrop, this study aims to analyze the updates to the GOLD 2025 guidelines on COPD management, with an emphasis on the proposed changes and the new emerging therapies recommended. The aim is to understand the theoretical and practical implications of these changes, assessing their impact on risk stratification, personalization of treatment and improvement of clinical outcomes. This in-depth study will help to optimize the management of COPD, promoting a more effective and accessible approach to the disease.

METHODOLOGY

A literature review developed according to the criteria of the PVO strategy, which stands for: population or research problem, variables and outcome. This strategy was used to develop the research question What are the main updates to the GOLD 2025 guidelines for the management of COPD and new emerging treatment therapies, and what are the potential theoretical and practical implications of these changes in the approach to the disease? The searches were carried out using the PubMed - MEDLINE (Medical Literature Analysis and Retrieval System Online) databases. The search terms were used in combination with the Boolean terms "**AND" and "OR"** using the following search strategy: (Chronic Obstructive Pulmonary Disease) AND ((Ensifentrine) OR (Dupilumab) OR("Newtreatment") OR (GOLD) OR ("Global Initiative for Chronic Obstructive Lung Disease")). From this search, **305** articles were found, which were then submitted to the selection criteria. The inclusion criteria were: articles in English published between 2024 and 2025 and which addressed the themes proposed for this research, narrative review-type studies, systematic review, meta-analysis, observational studies, experimental studies. The exclusion criteria were: duplicate articles, articles available in abstract form, articles that did not directly address the proposal studied and articles that did not meet the other inclusion criteria. After applying the search strategy to the database, a total of **38** articles were found. After applying the inclusion and exclusion criteria, **21** articles were selected from the PubMed database to make up this study's collection.

DISCUSSION

The GOLD 2025 guidelines introduce significant changes in the management of Chronic Obstructive Pulmonary Disease (COPD), reflecting diagnostic and therapeutic advances aimed at more individualized and effective care. COPD is one of the most common chronic lung diseases and, due to its complexity, is constantly being updated. The traditional classification of patients was based on spirometry, using the ratio of forced expiratory volume in the first second (FEV1) to forced vital capacity (FVC) of less than 0.7 as the diagnostic criterion. However, this criterion has prognostic limitations, as it is not directly associated with arterial blood gas analysis, a relevant factor for disease prognosis (Hwa; Kim, 2024). To overcome this limitation, the most recent edition of the GOLD guidelines incorporates complementary diagnostic methods, such as impulse oscillometry (IOS), which assesses respiratory mechanics using sound waves, plethysmography, which detects pulmonary hyperinflation, and helium dilution, which can measure functional residual capacity. Although these tests provide valuable information, their access is still limited, reinforcing the need for early and accessible diagnosis for all patients (Hwa; Kim, 2024). In addition to the changes in diagnostic criteria, the GOLD 2025 guidelines also present new therapeutic approaches aimed at more effective control of the disease.

MAIN UPDATES TO THE GOLD 2025 GUIDELINES

Pharmacological recommendations have also undergone major revisions. The use of beta-agonist and anticholinergic bronchodilators, together with inhaled corticosteroids, remains the mainstay of treatment, ensuring symptom control, reduced exacerbations and improved quality of life (Yappalparvi *et al.,* 2024). However, it has been observed that a significant proportion of patients maintain

uncontrolled symptoms, requiring frequent hospitalizations and compromising their quality of life. Given this scenario, Ensifentrine has emerged as a promising new therapeutic option, being a dual inhibitor of phosphodiesterase 3 (PDE3) and phosphodiesterase 4 (PDE4), simultaneously providing bronchodilation and an anti-inflammatory effect. This innovative approach differentiates Ensifentrine from conventional treatments, which usually focus on only one of these aspects, arousing great interest as a possible pharmacological recommendation in the GOLD 2025 guidelines (Yappalparvi *et al*., 2024; Hanania; Celli, 2024). If confirmed in new studies, the benefits of this approach could represent a milestone in the treatment of COPD, reducing hospitalizations and improving patients' quality of life.

Despite therapeutic advances, the prolonged use of oral corticosteroids remains a challenge due to their adverse effects and the financial impact on health systems. This makes the statement more objective and clear

. In addition, its use can lead to various adverse effects, such as hyperglycemia, weight gain, insomnia, anxiety, depression, cataracts, osteoporosis, peptic ulcers and pneumonia, making it necessary to re-evaluate its indication (Tse *et al.,* 2024). Another relevant issue in the update of the GOLD 2025 guidelines concerns exercise-induced oxygen desaturation (EID), which is an important marker of COPD severity. Studies show that reduced blood oxygenation during physical exertion is associated with a high mortality rate due to cardiovascular complications resulting from systemic hypoxia. The systemic inflammation resulting from hypoxia can aggravate extrapulmonary manifestations, such as vascular dysfunction and the formation of atherosclerotic plaques, making a more targeted therapeutic approach necessary for these patients. However, studies still differ on the direct relationship between inflammation and arterial stiffness in COPD, which requires further investigation (Wang *et al.*, 2024).

New strategies for managing exacerbations are also gaining prominence, with emphasis on the use of phosphodiesterase inhibitors, which have been shown to reduce tissue inflammation and promote greater bronchodilation. Recent studies suggest that the combination of PDE3 and PDE4 in nebulized therapy can progressively improve patients' quality of life. However, research is still needed to assess the safety and efficacy of this approach in conjunction with other drugs (Hanania; Celli, 2024). With these updates, the GOLD 2025 guidelines reaffirm their commitment to innovation and scientific advancement, guaranteeing increasingly evidence-based care that is accessible to patients.

DIFFERENCES BETWEEN PREVIOUS AND CURRENT RECOMMENDATIONS

GOLD has long established the ratio between forced expiratory volume in the first second (FEV1) and forced vital capacity (FVC) as a diagnostic criterion, using a fixed cut-off point of less than 0.7. However, this approach has limitations, especially in elderly patients, where the physiological reduction in the index can result in incorrect diagnoses and, consequently, inadequate therapeutic approaches (Bohadana *et al.,* 2025).

Furthermore, although spirometry is considered the gold standard for diagnosing COPD, its application faces challenges in settings such as primary care, where the test can be difficult to access and its execution depends on the patient's cooperation (Shen *et al.,* 2024). Faced with these limitations, more recent guidelines have started to consider complementary methods in screening for the disease, such as the **Chronic** Obstructive Pulmonary Disease Population Screener (COPD-PS)

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and Chronic Obstructive Pulmonary Disease Screening Questionnaire (COPD-SQ), as well as the peak expiratory flow (PEF) test. According to Shen *et al.* (2024), the association between the COPD-SQ and the PEF has shown superior performance in identifying COPD at different degrees of severity, allowing for more accessible and effective screening.

The revision of the guidelines also brought changes to the classification of COPD. Recent studies have compared the GOLD guideline with the Global Lung Initiative (GLI) approach, which uses the LMS (lambda, mu, sigma) method to adjust spirometric parameters according to age. The findings of Bohadana *et al.* (2025) showed that 15% of patients previously classified as severe phenotype by GOLD were reclassified as less severe by GLI, while 32% of individuals considered possible COPD patients by GOLD were reclassified as normal according to the new criteria. These discrepancies reinforce the need for more comprehensive assessments that integrate spirometry with clinical criteria, smoking history and structural findings. This approach aims to reduce diagnostic errors that can negatively impact both the therapeutic approach and the costs and quality of life of patients.

In addition to changes in diagnostic criteria, the most recent guidelines emphasize the personalization of COPD treatment, considering inflammatory biomarkers and strategies to optimize therapeutic adherence. Previous guidelines widely recommended the use of inhaled corticosteroids in combination therapy; however, recent evidence indicates that this treatment should be targeted at patients with high eosinophil counts (≥300 cells/μL) and a history of frequent exacerbations (Jacques, Kuhn and Albertson, 2024). Another significant advance is the prioritization of single-dose combination inhalers, aimed at improving adherence to treatment and reducing errors in drug administration.

New therapeutic strategies are also being incorporated. Macrolides, such as azithromycin, have shown benefits in reducing exacerbations, while PDE3/4 inhibitors, such as enfisentrin, show promise in promoting sustained bronchodilation (Bhatt *et al.,* 2025). Advances in knowledge about the inflammatory pathophysiology of COPD have also prompted research into biological therapies, such as dupilumab, a monoclonal antibody that blocks the IL-4 and IL-13 pathways, demonstrating efficacy in reducing exacerbations and improving lung function, regardless of the presence of emphysema (Bhatt *et al*., 2025).

The updates to the guidelines reflect the ongoing need to adapt diagnostic and therapeutic criteria in the light of new scientific evidence. Replacing a fixed criterion with approaches that take into account individual factors, such as age and biomarkers, aims to minimize diagnostic errors and improve therapeutic management. In addition, the introduction of alternative screening strategies allows for the early detection of COPD, especially in contexts where spirometry is less accessible. The refinement of inhalation therapy, with the more targeted use of corticosteroids and the transition to once-daily combination inhalers, seeks to improve treatment adherence and efficacy. At the same time, the incorporation of new biological therapies expands the therapeutic possibilities for different patient profiles.

Given these changes, the importance of constantly updating the guidelines is evident, ensuring that clinical decisions are in line with the latest advances in science and enabling more precise and effective management of COPD.

ADVANCES IN UNDERSTANDING THE PATHOPHYSIOLOGY AND MANAGEMENT OF COPD

The recent updates to the COPD guidelines reflect advances in understanding the pathophysiology of the disease, allowing for more individualized and effective management. The introduction of inflammatory biomarkers in diagnosis and the revision of spirometry criteria demonstrate a more refined approach, avoiding errors in the classification of disease severity and enabling more accessible screening (Pan *et al*., 2024). In addition, new biological therapies, such as Dupilumab, represent a milestone in the personalization of treatment, targeting interventions according to the inflammatory profile of patients (Pan *et al*., 2024). The identification of type II inflammation in many COPD patients, characterized by the elevation of interleukins IL-4, IL-5 and IL-13, has allowed the transition from generalized treatment to more specific strategies, optimizing clinical results (Pan *et al*., 2024).

In terms of diagnosis, the traditional reliance on spirometry has been reviewed, as its applicability can be limited by operational difficulties and the need for qualified professionals. Pan et al. (2024) indicate that the accuracy of this test is not always sufficient to correctly detect COPD, especially in places with less access to specialized resources. As an alternative, capnography has emerged as an auxiliary method, providing a more detailed assessment of lung function and allowing for a more accurate classification according to the GOLD 1 to GOLD 4 criteria (Hu *et al.,* 2025). This advance demonstrates a more dynamic and comprehensive approach to diagnosis, expanding the possibilities for early screening and appropriate management.

From a therapeutic point of view, the most recent recommendations consolidate triple therapy (ICS/LABA/LAMA) as the basis of COPD treatment, but recognize its limitations in certain inflammatory profiles. The introduction of targeted therapies, such as the use of Dupilumab, represents an important step in modulating the immune response, blocking IL-4 and IL-13 and reducing exacerbations in patients with type II inflammation (Pan *et al.,* 2024). This advance reinforces the trend towards precision medicine, in which therapeutic choice is guided by specific biomarkers, allowing for a more effective and personalized approach.

In addition to developments in the treatment of lung inflammation, the relationship between COPD and lung cancer has been increasingly studied, since both diseases share similar risk factors and immunological mechanisms. Chronic inflammation in COPD creates a favorable environment for tumor progression, promoting angiogenesis and immunosuppression, processes mediated by the expression of the PD-1 protein, which reduces the immune response against neoplastic cells (Dong *et al*., 2024). Given this relationship, new therapies have been explored to treat both conditions in an integrated manner. Pembrolizumab, a monoclonal antibody that acts on the PD-1 pathway, has shown benefits in progression-free survival in patients with non-small cell lung cancer (NSCLC), reducing the risk of death by up to 19% (Dong *et al.*, 2024). This approach reinforces the need to consider the impact of COPD on other associated diseases and to explore combined therapeutic strategies.

Recent updates reflect significant progress in understanding the pathophysiology of COPD and its intersection with other inflammatory and neoplastic conditions. The incorporation of biomarkers in diagnosis and the transition to biological therapies demonstrate an advance in the individualization of treatment, promoting better clinical outcomes and reducing exacerbations. In addition, the integration of new therapeutic strategies for

associated diseases, such as lung cancer, points to a future in which COPD management will be increasingly targeted and personalized. These changes underscore the continuing need for research that deepens understanding of the disease and contributes to the formulation of increasingly effective guidelines tailored to patients' needs.

EMERGING THERAPIES

The growing understanding of the disease's pathophysiology has allowed for the development of more targeted strategies aimed at optimizing therapeutic efficacy and minimizing complications. These innovations include new pharmacological approaches, the incorporation of biomarkers to guide treatment and the adoption of advanced diagnostic tools, which together promise to redefine the way COPD is managed in clinical practice.

Triple inhaled therapy (LABA/LAMA/ICS) has been shown to be one of the most effective interventions in reducing disease burden, especially in patients classified in groups C and D of the GOLD classification. This approach has shown benefits in improving lung function and reducing exacerbations, although its impact on cost-effectiveness and adherence to treatment still requires further long-term investigation. Observational studies indicate that, after statistical adjustments, significant differences between patients treated with this therapy were minimized, indicating the need for further research to establish its real clinical impact (Zader *et al*., 2024).

Innovative approaches include the role of molecular biomarkers in the prognosis and treatment stratification of COPD. The lncRNA SNHG5, for example, has been associated with inflammatory processes in the disease, and evidence indicates that reduced levels of this biomarker are related to greater systemic inflammation and increased mortality in patients with frequent exacerbations (Yao *et al*., 2024). The modulation of biomarkers such as SNHG5 may represent a promising strategy for personalized therapeutic interventions aimed at controlling inflammation and mitigating disease progression.

In addition to pharmacological therapies, the introduction of new diagnostic tools has enabled a more precise assessment of COPD and a more individualized therapeutic approach. Impulse oscillometry (IOS) has emerged as a promising alternative to traditional spirometry, allowing early detection of changes in lung function, particularly in patients with peripheral airway involvement. This method has the potential to help in the early diagnosis of the disease and to optimize the choice of therapy based on more detailed physiological parameters (Sarkar *et al.*, 2024).

Comparative studies between the GOLD classification and the STaging of Airflow obstruction by Ratio (STAR) indicate that GOLD remains one of the best predictors of mortality and clinical impact. However, there is a growing trend to integrate detailed functional assessments and biomarkers into the disease classification, with a view to more precise and effective management (Nishimura *et al*., 2024). This approach could help to better tailor treatment to the individual characteristics of each patient, promoting more effective control of COPD.

Another significant advance in understanding the pathophysiology of the disease involves the relationship between the lung microbiome and the progression of COPD. Recent studies indicate that patients with an accelerated decline in lung function show changes in mucus composition and microbial colonization, including increased expression of the mucins MUC5AC and MUC5B, as well as a greater presence of bacteria such as Achromobacter and Klebsiella (Meldrum *et al.*, 2024). These findings suggest therapeutic potential in the modulation of the pulmonary microbiome,

as well as in the development of interventions aimed at controlling mucus hypersecretion and the exacerbated inflammatory response.

The personalization of COPD treatment must integrate both new pharmacological therapies and the incorporation of biomarkers and innovative diagnostic tools. The combination of these approaches allows for the early identification of patients at high risk of exacerbation and disease progression, enabling the implementation of targeted therapeutic strategies (Yao *et al.*, 2024; Nishimura *et al.*, 2024). However, more studies are needed to validate the clinical applicability of these innovations and assess their long-term impact.

Given these new perspectives, the future of COPD management is moving towards a personalized and multidimensional treatment model, in which different aspects of the disease - including biomarkers, microbiome, lung function and inflammatory response - will be considered to optimize patient prognosis. Incorporating these findings into clinical guidelines could transform medical practice, reducing the morbidity and mortality associated with the disease, as well as significantly improving patients' quality of life (Meldrum *et al.,* 2024; Nishimura *et al.*, 2024).

FINAL CONSIDERATIONS

The GOLD 2025 guidelines represent a significant advance in the management of COPD, incorporating diagnostic innovations such as impulse oscillometry and inflammatory biomarkers, as well as the introduction of emerging therapies such as Ensifentrine and Dupilumab, which expand the possibilities for more precise and personalized treatment. However, challenges remain, including unequal access to advanced technologies and the need for further studies to consolidate the efficacy and safety of these new approaches. It is therefore essential to continually update the guidelines, ensuring that clinical practices are based on the latest scientific evidence, with a focus on optimizing risk stratification, maximizing therapeutic benefits and improving patients' quality of life.

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