Rethinking COPD: Dupilumab shows type 2 inflammation matters

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Managing chronic respiratory diseases like asthma and chronic obstructive pulmonary disease (COPD) often involves a complex relationship of bronchodilators, corticosteroids, and lifestyle modifications. Despite these interventions, a significant proportion of patients continue to experience exacerbations and impaired quality of life. The emergence of targeted biologic therapies has begun to shift the market, particularly for those with specific inflammatory phenotypes.

Dupilumab, a monoclonal antibody targeting the interleukin-4 (IL-4) and interleukin-13 (IL-13) pathways, represents a notable advance in this area. Its mechanism of action addresses the underlying type 2 inflammation common to several allergic and atopic conditions, extending its utility beyond its initial indications.

KEY TAKEAWAYS

- The Pivot: Dupilumab's broad mechanism of action against type 2 inflammation offers therapeutic potential across both severe asthma and certain COPD phenotypes.
- The Data: Clinical programs have consistently shown reductions in exacerbation rates and improvements in lung function in appropriate patient populations.
- The Action: Clinicians should consider assessing for type 2 inflammatory markers in patients with severe asthma or COPD who remain symptomatic despite standard care, to identify those who may benefit from dupilumab.

Asthma, a heterogeneous disease, is characterized by chronic airway inflammation, bronchial hyperresponsiveness, and variable airflow obstruction. Severe asthma, affecting a subset of patients, remains poorly controlled despite high-dose inhaled corticosteroids and long-acting beta-agonists, often requiring oral corticosteroids. This patient group experiences frequent exacerbations, hospitalizations, and a substantial burden on their daily lives. Type 2 inflammation, driven by cytokines such as IL-4, IL-5, and IL-13, is a prominent endotype in a significant proportion of these patients, particularly those with elevated eosinophil counts or fractional exhaled nitric oxide (FeNO).

COPD, on the other hand, is a progressive lung disease characterized by persistent respiratory symptoms and airflow limitation, typically caused by significant exposure to noxious particles or gases. While traditionally viewed as a neutrophilic inflammatory disease, a subset of patients with COPD also exhibits features of type 2 inflammation, including elevated blood eosinophil counts. These patients often experience more frequent exacerbations and a faster decline in lung function, suggesting a potential overlap with asthma-like inflammatory processes. Identifying these

patients is key to optimizing their treatment strategy, a challenge that has led to a deeper understanding of AAT protein's role in lung health beyond traditional COPD.

Targeting Type 2 Inflammation

Dupilumab is a fully human monoclonal antibody that blocks the shared receptor component for IL-4 and IL-13. These cytokines are central to the initiation and maintenance of type 2 inflammation, playing critical roles in allergic responses, eosinophil recruitment, and mucus production. By inhibiting both IL-4 and IL-13 signaling, dupilumab broadly suppresses the type 2 inflammatory cascade, offering a targeted approach to disease modification rather than just symptom control. This mechanism of action is distinct from other biologics that target individual cytokines like IL-5 or IgE, providing a comprehensive blockade of the type 2 pathway.

In severe asthma, dupilumab has been evaluated in multiple large-scale clinical programs. These studies consistently enrolled patients with moderate-to-severe asthma who remained symptomatic despite standard inhaled corticosteroid therapy, often with evidence of type 2 inflammation. The primary endpoints typically focused on reducing the rate of severe asthma exacerbations and improving forced expiratory volume in 1 second (FEV1). Patients receiving dupilumab generally experienced fewer exacerbations and significant improvements in lung function compared to placebo. These benefits were observed across various subgroups, including those with high baseline eosinophil counts and those requiring oral corticosteroids, reinforcing the drug's utility in a challenging patient population. For a deeper dive into how this compares to other biologics, our previous coverage on dupilumab's superiority to omalizumab in high-biomarker asthma provides additional context.

The safety profile of dupilumab in asthma has generally been favorable. Common adverse events included injection site reactions, conjunctivitis, and oral herpes. Most adverse events were mild to moderate in severity and did not lead to treatment discontinuation. The long-term safety data from extension studies have also supported its sustained tolerability, which is a critical consideration for chronic therapies. Clinicians often find the Oxford Handbook of Respiratory Medicine a useful quick reference for managing such chronic conditions and their associated treatments.

Expanding Beyond Asthma

The application of dupilumab in COPD represents a newer frontier, driven by the recognition of type 2 inflammatory phenotypes within this disease. While the majority of COPD patients do not exhibit prominent type 2 inflammation, a distinct subgroup, often characterized by elevated blood eosinophil counts and a history of frequent exacerbations, appears to benefit from targeted anti-inflammatory strategies. These patients often have a history of asthma or atopy, blurring the lines between the two conditions and highlighting the importance of endotype-driven treatment. The concept of severe asthma treatment decisions extending beyond airway focus is increasingly relevant here.

Clinical trials in COPD have investigated dupilumab in patients with moderate-to-severe disease and evidence of type 2 inflammation, typically defined by blood eosinophil counts above a certain threshold. The primary outcomes in these studies mirrored those in asthma, focusing on reducing acute exacerbations and improving lung function. The data has shown that dupilumab can reduce the rate of moderate-to-severe COPD exacerbations and improve FEV1 in this specific patient population. These findings challenge the traditional view of COPD as solely a neutrophilic disease and highlight the importance of precision medicine approaches in respiratory care.

The safety profile of dupilumab in COPD patients has been consistent with its profile in asthma and other type 2

inflammatory conditions. No new safety signals emerged in the COPD trials, which is reassuring given the older, often multi-morbid patient population typically affected by COPD. This consistency in safety across different indications strengthens the overall understanding of dupilumab's risk-benefit profile.

The Unmet Need and Future Directions

Despite advances in treatment, a significant unmet need persists for patients with severe asthma and a subset of COPD patients who continue to experience frequent exacerbations and a decline in lung function. Oral corticosteroids, while effective in managing acute exacerbations, carry a substantial burden of long-term side effects, making steroid-sparing therapies highly desirable. Dupilumab offers a valuable option for these patients, providing a targeted approach that can reduce exacerbations and improve lung function without the systemic side effects of corticosteroids.

The challenge lies in accurately identifying the patients most likely to benefit from dupilumab. While blood eosinophil counts are a commonly used biomarker for type 2 inflammation, their predictive value is not absolute, and other markers or clinical features may also play a role. Further research into more precise biomarkers and patient stratification strategies will be essential to optimize the use of dupilumab and other biologics in respiratory care. The ongoing exploration of epithelial cytokines linking severe asthma, CRSwNP, and COPD highlights this evolving understanding.

The long-term impact of dupilumab on disease progression, particularly in COPD, also warrants continued investigation. While improvements in exacerbation rates and lung function are important short-term outcomes, understanding whether dupilumab can modify the natural history of these chronic, progressive diseases will be important for defining its full therapeutic potential. This will require extended follow-up studies and real-world evidence generation to complement the controlled clinical trial data. The real-world data for dupilumab in severe asthma is already starting to provide valuable insights.

CLINICAL IMPLICATIONS

The consistent efficacy of dupilumab across severe asthma and a specific phenotype of COPD demands a re-evaluation of our diagnostic and treatment algorithms. Clinicians can no longer view these conditions as entirely separate entities, especially when type 2 inflammation is evident. Identifying patients with elevated eosinophils or other markers of type 2 inflammation becomes paramount for optimizing therapy.

For patients struggling with frequent exacerbations despite maximal conventional therapy, dupilumab offers a genuine opportunity to reduce disease burden and improve quality of life. The steroid-sparing effect is particularly significant, mitigating the long-term systemic risks associated with oral corticosteroids. This shift allows for a more proactive, targeted approach rather than reactive management of exacerbations.

The economic implications of biologic therapies are always a consideration, but the potential to reduce hospitalizations and improve productivity must be weighed against acquisition costs. Payers and healthcare systems will need to adapt to these evolving treatment paradigms, recognizing the long-term benefits of preventing disease progression and improving patient outcomes. The ongoing challenge remains to ensure appropriate patient selection to maximize the cost-effectiveness of these advanced therapies.

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