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Monoclonal Antibody in Treatment of Severe Allergic Asthma: A Meta-Analysis on The Effectiveness of Omalizumab

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Abstract
Background: Asthma is a chronic obstructive pulmonary disease that has persistent symptoms with intermittent periods of exacerbation, representing the reduction in health status. Chronic obstructive pulmonary disease has become fourth leading cause of death in 2021, responsible for approximately 5% of total deaths[1,2,3,4]]. Frequent, recurring periods of exacerbation may reach significant severity, and advanced therapy may become necessary, including the prescription of omalizumab, the anti-IgE monoclonal antibody. This meta-analysis aims to determine and systematically review the effect of omalizumab compared with the placebo in the control of severe asthma.
Methods: A systematic review and meta-analysis were conducted following PRISMA guidelines. Data were extracted from randomized controlled trials (RCTs) comparing omalizumab with placebo. RevMan 5.4 was used for statistical analysis, applying a fixed-effect inverse variance model. The primary outcomes were FEV1% improvement, severe asthma exacerbations over 48 weeks, and ACT scores. Heterogeneity was assessed using Chi^2, I^2 statistics, with significance set at $P < 0.05$.
Results: Omalizumab significantly improved ACT scores ($Z = 8.06$, $P < 0.00001$) with low heterogeneity ($I^2 = 0\%$). It significantly reduced severe asthma exacerbation rates ($Z = 6.08$, $P < 0.00001$), with no heterogeneity ($I^2 = 0\%$). However, there was no significant improvement in FEV1% ($Z = 0.22$, $P = 0.83$), with moderate heterogeneity ($I^2 = 49\%$).
Conclusion: Omalizumab is highly effective in reducing exacerbation rates and improving asthma control in severe asthma patients. However, it does not significantly enhance FEV1%, suggesting its primary benefit lies in symptom relief rather than lung function improvement. These findings support omalizumab's role in severe asthma management, warranting further investigation into long-term lung function outcomes.
Keywords: Asthma, Monoclonal Antibody, Omalizumab

Introduction

Asthma severity describes the condition that presents particular challenges in management, affecting around 5-10% of the patients suffering from asthma and causing significant hindrances to effective control and treatment. Even though inhaled corticosteroids (ICS) and long-acting β2-agonists (LABA) are given to the patients, there are still many who find it difficult to achieve adequate control of the symptoms of severe asthma despite the therapy. Omalizumab, as recognized as the anti-IgE monoclonal antibody, has been studied intensively in numerous clinical studies and has proven capable of alleviating the frequency of asthmatic attacks, improving the general management of asthma, and enhancing global pulmonary function. Its specific effect, however, with regard to the measurement of FEV1% has raised questions regarding its assessment [6,7,8,9]. This current meta-analysis aims to assess the effect of omalizumab towards the values of FEV1, the decrease in the frequency of severe asthmatic attacks, and thus, the enhancement of the control of the asthmatic symptoms. This purpose will be achieved by performing complete analysis of data taken from multiple randomized controlled trials (RCTs) [10,11,12,13, 14].

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Material and methods

A meta-analysis and systematic review were conducted following PRISMA guidelines. The databases used for this study included PubMed, Scopus, Embase, and the Cochrane Library, https://clinicaltrials.gov/ ,targeting randomized clinical trials comparing omalizumab with a placebo. The inclusion criteria included RCTs with a follow-up of at least 48 weeks, studies reporting FEV1%, asthma exacerbation incidents, and ACT scores, and patients with severe persistent asthma.The data analysis for the meta-analysis was done using RevMan software version 5.4, where a fixed-effect inverse variance method was applied. In this systematic review, the effect estimates that were derived and calculated were the mean difference (MD) for both the FEV1% and the ACT score, as well as the risk ratio (RR) for the incidence of asthma exacerbation. To determine the heterogeneity of the studies included in the analysis, the Chi^2 test, in addition to the I^2 statistic, was used, where the level of statistical significance was set at $P < 0.05$ to consider the results statistically significant. A total of 12 studies, involving N = 3891 patients, were successfully included based on the predefined inclusion criteria for this analysis. In the omalizumab cohort, 584 patients had their ACT score assessed, 831 patients had documented exacerbations, and 1160 patients had their FEV1% assessed. In contrast, in the placebo cohort, 450 patients had their ACT score assessed, 525 patients had documented exacerbations, and 814 patients had their FEV1% assessed.

Results

Omalizumab also caused significant reduction in severe asthmatic exacerbation incidence, as reflected by the Z score of 6.08 and the P value that also fell below the figure of 0.00001, with the notable finding that this result showed zero degree of heterogeneity, as the I^2 value was not available but zero, by all likelihood implying zero heterogeneity as depicted in fig 1.

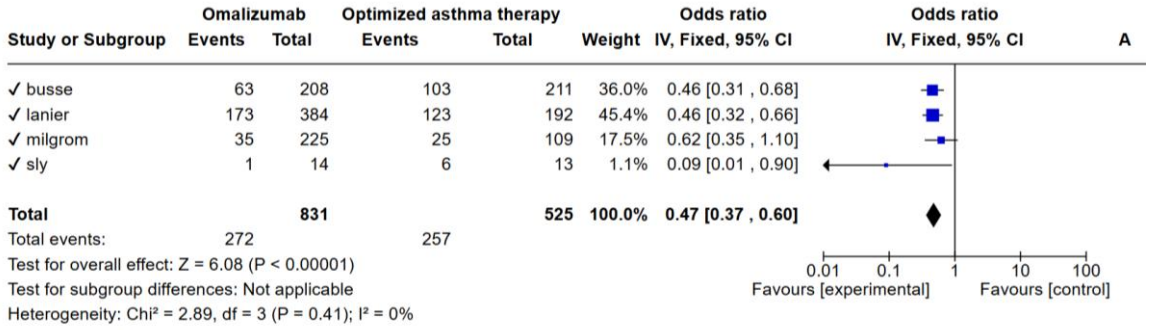

Figure 1. Asthma exacerbation events over 48 weeks post treatment period

Omalizumab therapy caused significant improvement in ACT scores, as reflected by the Z score of 8.06 and the statistically significant P value of less than 0.00001, with the added finding of an insignificant degree of heterogeneity, as quantitated by the I^2 value of 0% as shown in fig 2.

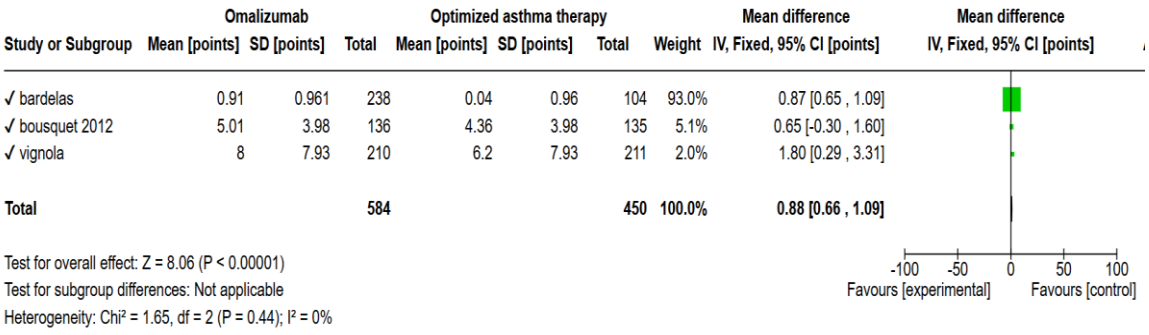

Figure 2. ACT scores variation in different studies

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On the contrary, there were no statistically significant changes in FEV1%, as this showed the Z score of merely 0.22 with the P value of 0.83, with the additional finding of the moderate degree of heterogeneity, as represented by the I^2 value of 49%.

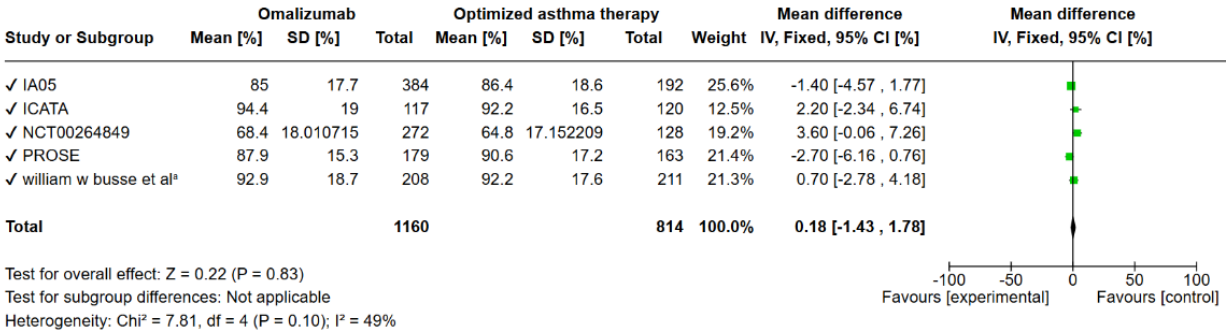

Figure 3. Fev1(%) post treatment

Discussion

The data of this study evidently point to the fact that omalizumab has an important function in improving the management of asthma, while also having the effect of reducing the number of exacerbations in patients with severe asthma. It has, however, been discovered that the drug does not bring with it any significant increase in FEV1% that would show its main benefit to be in improving the pulmonary function, but simply in the reduction of asthmatic symptoms. The conclusions of this study have broad implications for patient management and the implementation of clinical practice. Most importantly, it is imperative to take into account the treatment with omalizumab in patients with severe asthma with persistent symptoms despite the therapy with ICS-LABA. Further research efforts should also aim to explore differences in long-term FEV1% values and the predictors that could predict the improvements in pulmonary function over the long term.Limitations include moderate heterogeneity ($I^2 = 49\%$) for FEV1% outcomes, lack of individual patient-level data, and variations in baseline asthma severity among included studies.

Conclusion

This meta-analysis supplies persuasive evidence that omalizumab, a monoclonal antibody, widely employed in asthma care, significantly decreases the frequency of severe asthma exacerbations and augments overall symptom control. These significant results highlight the crucial role of omalizumab in symptom relief from asthma and prevention of exacerbations, thus further solidifying the drug's crucial role as a therapeutic option in the treatment of severe asthma.

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