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# Efficacy and Safety of Omalizumab in the Treatment of Allergic Rhinitis

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## ABSTRACT

This meta-analysis was conducted to investigate the efficacy and safety of omalizumab in the treatment of allergic rhinitis in adults.

Randomized controlled trials (RCTs) on omalizumab in the treatment of allergic rhinitis in adults were collected by searching PubMed, Cochrane Library, Embase, Web of Science, CNKI, VIP, and Wanfang Data. The search period was from the establishment of each database to October 2024. Stata 15.0 software was used for data analysis. The control group received a placebo or other anti-allergy drugs, while the experimental group received omalizumab, with or without specific immunotherapy.

A total of 8 RCTs were involved in this meta-analysis. The combined analysis exhibited that the effective rate was higher in the omalizumab group than in the control group (RR=1.15; 95% CI, 1.06–1.24) for allergic rhinitis. IgE levels (SMD=−2.82; 95% CI, −4.03 to −1.62) and DNSS (SMD=−1.99; 95% CI, −3.04 to −0.94), DOSS (SMD=−2.95; 95% CI, −4.65 to −1.25) were lower in the omalizumab group compared with the control group. No significant difference was observed in the incidence of adverse events between the two groups (RR=1.15; 95% CI, 0.69–1.93).

Omalizumab is effective and safe in the treatment of adult allergic rhinitis.

**Keywords:** Allergic rhinitis; Efficacy; Omalizumab

## INTRODUCTION

Allergic rhinitis (AR) occurs when an atopic individual is exposed to allergens, and later, non-infectious inflammatory diseases of the nasal mucosa are mainly mediated by immunoglobulin E (IgE), involved by a variety of immune cells and factors.[1] Typical clinical manifestations include paroxysmal sneezing, watery rhinorrhea, nasal pruritus, and nasal congestion, and may be accompanied by ocular symptoms such as eye itching, tearing, conjunctival redness, and a burning sensation.[2] AR has become a global health problem, influencing 10% to 40% of the world's population.[3] AR could reduce the quality of life, affecting the learning and work efficiency of patients.[4] Patients with AR may also have sleep disorders and even mental disorders such

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as depression and anxiety.[4,5] AR may not seem serious compared to other diseases, but the costs and burdens are huge.[3] Currently, the main first-line drugs are new antihistamines and nasal glucocorticoids.[6]

Omalizumab is a recombinant humanized anti-IgE monoclonal antibody that blocks IgE binding to high-affinity IgE receptors on mast cells and basophils, thereby inhibiting the release of histamine and other mediators and preventing downstream allergic reactions, ultimately relieving patients' clinical symptoms.[7,8] The US Food and Drug Administration approved omalizumab for the treatment of moderate to severe asthma in 2003, expanding the indication for chronic idiopathic urticaria in 2014. There are numerous records on the treatment of nasal polyps and allergic asthma with omalizumab.[9–11] However, limited research on omalizumab for allergic rhinitis emerges. Yu et al[12] and Tsabouri et al[13] both used meta-analysis to study the efficacy of omalizumab in the treatment of allergic rhinitis. Nevertheless, their studies involved both children and adults.

Therefore, this study adopted the method of meta-analysis to explore the efficacy and safety of omalizumab in treating adult AR, in order to provide evidence-based medical evidence for clinical omalizumab in the treatment of AR.

## MATERIALS AND METHODS

### Retrieval Strategy

Randomized controlled trials (RCTs) of omalizumab for adult AR were collected through PubMed, Cochrane Library, Embase, Web of Science, CNKI, VIP, and Wanfang Data from the establishment of each database to October 2024. The search terms were "omalizumab," "anti-IgE," "anti-immunoglobulin E," and "Allergic rhinitis." Besides, we consulted the relevant reviews and citations manually as supplements. The languages were limited to English and Chinese. The search was conducted independently by two researchers and finally cross-checked. Any differences were settled through discussion.

### Inclusion and Exclusion Criteria

Inclusion criteria: (1) Study design: RCTs; (2) Participants: patients with AR (ages >18 years). (3) Intervention and control: The control group was treated with a placebo or other anti-allergy drugs, while the test group with or without specific immunotherapy (SIT). (4) Outcomes: effective rate, IgE level, daily nasal symptom score (DNSS), daily ocular symptom score (DOSS), and incidence of adverse reactions.

Exclusion criteria: (1) Insufficient data; (2) Full-text research not available; (3) Studies involving children.

### Literature Quality Evaluation

The risk of bias for RCTs was rated using the Cochrane Manual of Systematic Evaluators 5.1 recommended tool. The quality of the included literature was assessed independently by two reviewers. In case of disagreement, an agreement was reached through discussion.

### Data Extraction

After reviewing the full texts, two researchers independently extracted data including the first author, publication year, country, follow-up duration, sample size, age, control treatment, patient population, dosage and frequency, and outcomes. Any discrepancies were resolved by a third researcher through discussion until consensus was reached.

### Statistical Analysis

Stata 15.0 software was used for data analysis. The heterogeneity among the results was evaluated by the Q test and $I^2$ statistics. If the tested $p<0.1$, or $I^2 \geq 50\%$, it indicates high heterogeneity among studies. On the contrary, when low heterogeneity ($p \geq 0.1$ and $I^2<50\%$) was found, the fixed-effects model was used for pooled analysis. For DNSS, DOSS, and IgE levels, the standardized mean difference (SMD) with 95% CI was used as the effect indicator. For effective rate and incidence of adverse reactions, the relative risk (RR) with 95% CI was applied as the effect size. If the number of outcomes included in the study was greater than 5, Egger's Test was used to detect publication bias.

## RESULTS

### Results of the Search and the Basic Characteristics of the Included Literature

After preliminary screening, 824 records were identified, and 8 RCTs14 – 21 were ultimately included in this meta-analysis (Figure 1). A total of 472 patients were assigned to the experimental group and 425 to the control group. The baseline characteristics of the included studies are summarized in Table 1, and the risk-of-bias assessment is presented in Figure 2.

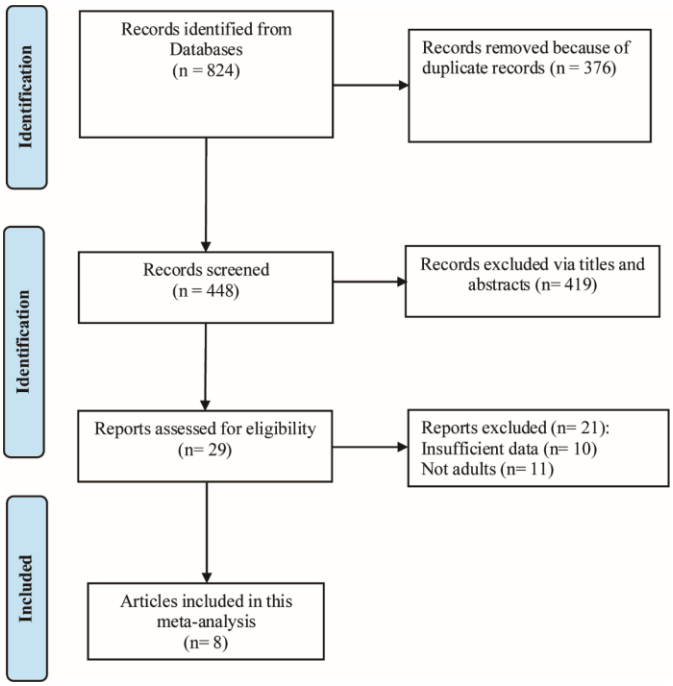



**Figure 1. Records retrieval flow chart**

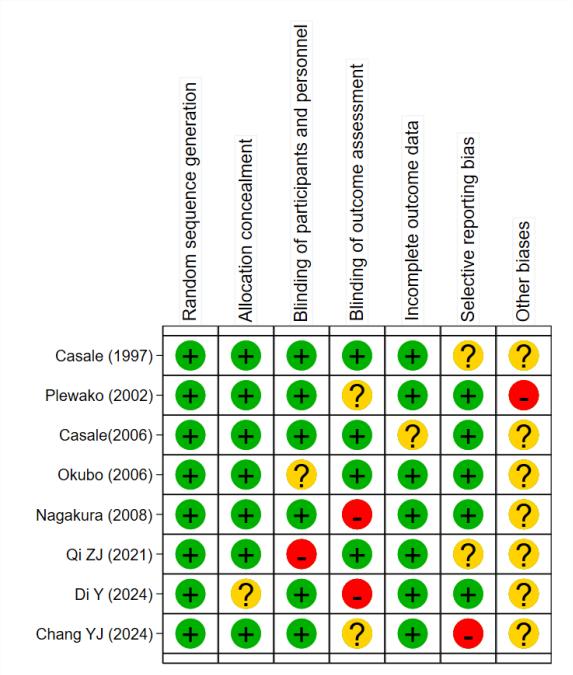



**Figure 2. Assessment of the risk of bias in included studies**

**Table 1. Characteristics of the included studies.**

| Study | Year | Country | Follow-up, wk | Sample size | Age, y | | Control | Patient type | Dosage and frequency | Outcomes |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Experimental | Control | | | | |
| Casale | 1997 | USA | 12 | 240 | 18–66 | 20–59 | placebo | SAR | 0.15 mg/kg, once every 2 wk | DNSS |
| Plewako | 2002 | Nordic | 6 | 30 | 20–48 | 20–48 | placebo | SAR | 300 mg, once every 3 wk | IgE level |
| Casale | 2006 | USA | 21 | 159 | 33.8±9.7 | 33.8±9.7 | placebo+SIT | SAR | 0.016 mg/(kg·Total IgE IU per mL of serum), once every 4 wk | Incidence of adverse reactions, DNSS |
| Okubo | 2006 | Japan | 24 | 100 | 32.2±12.1 | 31.5±12.3 | placebo | SAR | 150, 225, 300, 375 mg, once every 2 to 4 wk | Incidence of adverse reactions, DNSS, DOSS |
| Nagakura | 2008 | Japan | 12 | 308 | 35.3±13.0 | 34.9±12.0 | Mesulast | SAR | 150, 225, 300, 375 mg, once every 2 to 4 wk | Incidence of adverse reactions, DNSS, DOSS |
| Qi ZJ | 2021 | China | 16 | 150 | 33.2±8.2 | 31.5±8.3 | CT | AR | 0.016 mg/kg, once every 4 wk | Effective rate, incidence of adverse reactions, IgE level |
| Di Y | 2024 | China | 12 | 80 | 35.2±4.4 | 35.0±4.3 | CT | AR | Dosage determined based on body weight and total IgE, once every 2 wk | Effective rate, incidence of adverse reactions, IgE level, DNSS, DOSS |
| Chang YJ | 2024 | China | 8 | 90 | 42.7±11.8 | 41.9±12.2 | CT | AR | 150 mg, once every 4 wk | Effective rate, incidence of adverse reactions, IgE level, DNSS |

AR: allergic rhinitis; CT: conventional treatment; DNSS: daily nasal symptom score; DOSS: daily ocular symptom score; IgE: immunoglobulin E; SAR: seasonal allergic rhinitis; SIT: specific immunotherapy.

**Meta-analysis Results**

***Heterogeneity Analysis***

In the efficient analysis ($I^2$=0%, $p$=0.639), the heterogeneity was not obvious, so the fixed-effects model was adopted. Significant heterogeneity was found in IgE ($I^2$=93.7%, $p$<0.001), DNSS ($I^2$=97.1%, $p$<0.001), DOSS ($I^2$=96.9%, $p$<0.001), and incidence of adverse reactions ($I^2$=61.5%, $p$=0.023). Therefore, a random-effects model was utilized (Figures 3–7).

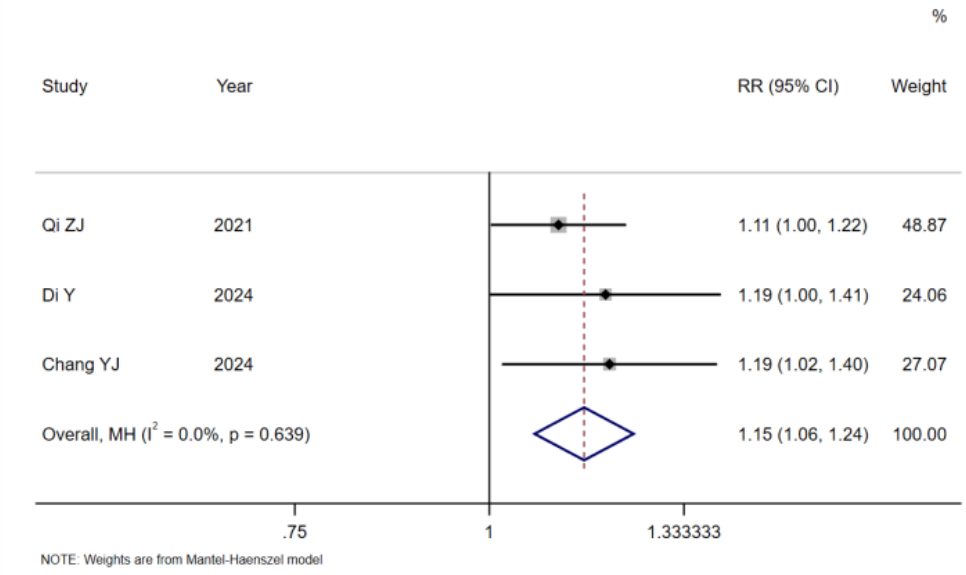



**Figure 3. Forest plot of the efficacy of omalizumab for allergic rhinitis**

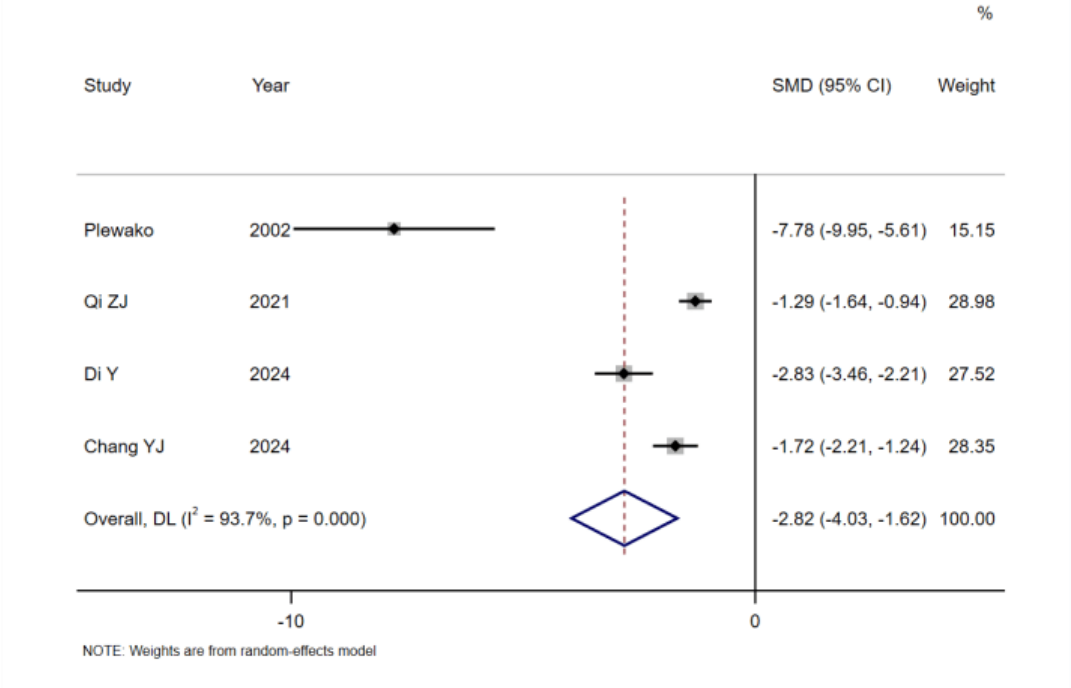



**Figure 4. Forest plot of IgE levels of omalizumab for allergic rhinitis**

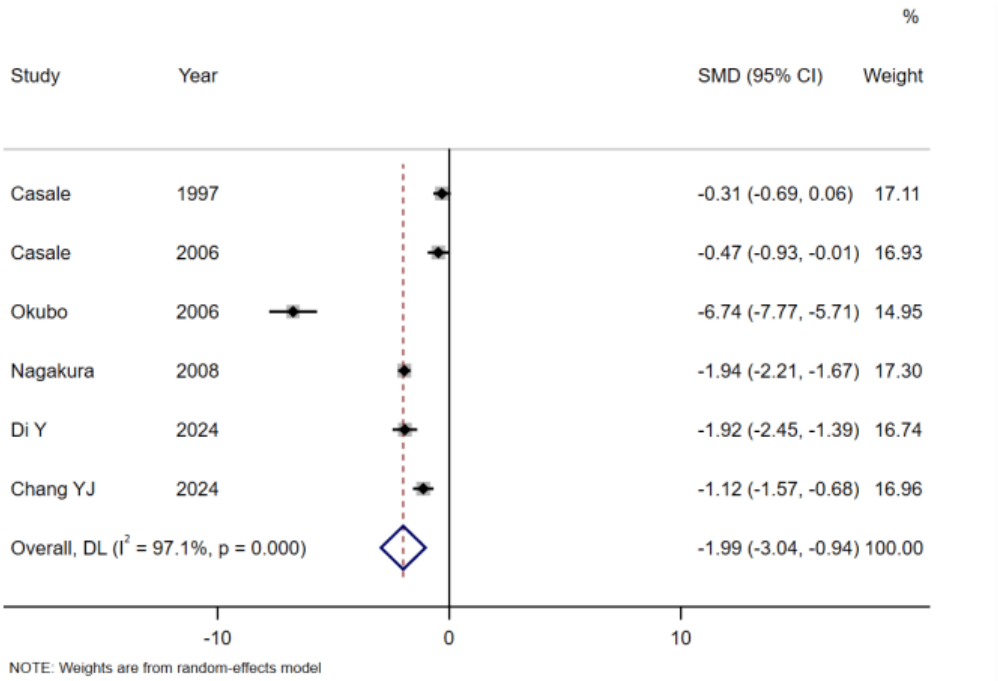



**Figure 5. Forest plot of DNSS of omalizumab for allergic rhinitis**

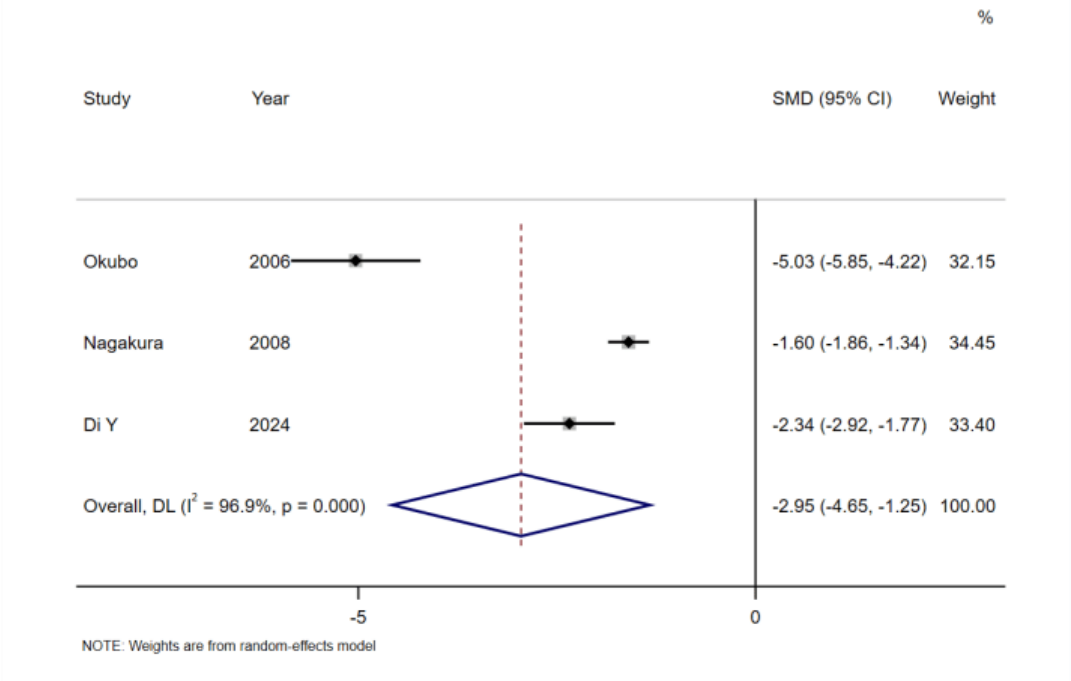



**Figure 6. Forest plot of DOSS of omalizumab for allergic rhinitis**

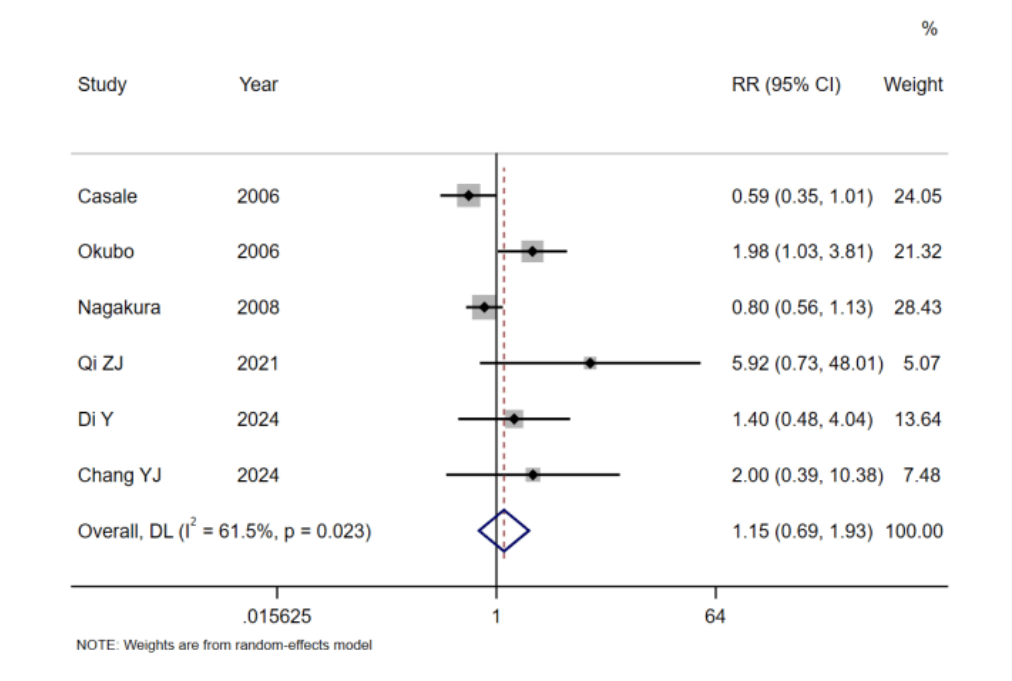



**Figure 7. Forest plot of incidence of adverse reactions of omalizumab for allergic rhinitis**

***Efficiency Comparison***

Effective rates were reported in three studies. The results showed (Figure 3) that compared with the control group, omalizumab had a higher effective rate in the treatment of AR (RR=1.15; 95% CI, 1.06–1.24; $p$<0.001), and the difference was statistically significant.

***IgE Comparison***

IgE was reported in four records. The results showed (Figure 4) that IgE levels in the omalizumab group were lower than those in the control group (SMD=−2.82; 95% CI, −4.03 to −1.62; $p$<0.001), and the difference was statistically significant.

***DNSS Comparison***

Six trials were entered into the DNSS analysis. The results showed (Figure 5) that DNSS in the omalizumab group was lower than that in the control group (SMD=−1.99; 95% CI, −3.04 to −0.94; $p$<0.001), with a statistically significant difference.

***DOSS Comparison***

Three trials were included in the DOSS analysis. The results showed (Figure 6) that DOSS in the omalizumab group was lower than that in the control group (SMD=−2.95; 95% CI, −4.65 to −1.25; $p$=0.001), and the difference was statistically significant.

***Comparison of the Incidence of Adverse Reactions***

The comparison of the incidence of adverse reactions was included in six articles. The results showed (Figure 7) no statistically significant difference between the two groups (RR=1.15; 95% CI, 0.69–1.93; $p$=0.587).

***Publication Bias Detection***

In the analysis of DNSS and the incidence of adverse reactions, the $p$ value of Egger's test was 0.401 and 0.124, respectively, indicating no significant publication bias in this meta-analysis.

## DISCUSSION

To explore the efficacy and safety of omalizumab in the treatment of adult patients with AR, we conducted this meta-analysis. Its pathogenesis is similar to that of allergic asthma. Inhalation of allergens induces local nasal mucosa and regional drainage lymph nodes to produce specific IgE, which binds to high-affinity IgE receptors on the surface of mast cells, basophils, and other effector cells to form sensitivities.[6] When the allergens are exposed again, the allergen binds to IgE on the surface of mast cells and basophils, activates the cells, releases a large number of leukotrienes, histamine, and

other inflammatory mediators, mediates the inflammatory response, causes nasal mucosal vascular dilation and glandular secretion, and causes nasal catarrhal symptoms such as runny nose, nasal itching, and sneezing.[1]

In patients with seasonal allergic rhinitis, compared with standard pharmacotherapy, a single dose of omalizumab administered two weeks before the onset of the pollen season more effectively controls symptoms and reduces the need for rescue medications.[22] In a prospective study of omalizumab in patients with severe persistent AR combined with incomplete control of severe asthma, 11 patients received subcutaneous omalizumab every 4 weeks for 36 months, with a total of 10 patients completing the study, and nasal symptoms, asthma control test tables, and lung function were significantly improved.[23] The meta-analysis by Tsabouri et al[13] revealed that omalizumab can significantly improve the nasal and ocular symptoms of AR in children and adults, reduce the dose of other therapeutic drugs, and improve the quality of life.

Several mechanisms have been proposed to explain how omalizumab works in allergic rhinitis (AR). First, omalizumab exerts its effects primarily by inhibiting IgE-mediated pathways, thereby reducing basophil activation, alleviating symptoms, and improving disease control.[24] Second, the rapid onset of omalizumab in allergic rhinitis may be related to its competitive binding to free IgE, forming immune complexes that reduce circulating IgE available to bind Fc ε RI and thereby quickly attenuate IgE-mediated effector responses.[25] Thirdly, omalizumab acts on the membrane IgE (mIgE) on the surface of IgE+ B cells, inducing B-cell non-responsiveness and reducing IgE synthesis, thus achieving the effect of controlling inflammation.[26]

The results of this meta-analysis showed that, compared with the control group, omalizumab significantly enhanced the effective rate in the treatment of adult AR, and improved DNSS and DOSS scores. In addition, no statistically significant difference was observed in adverse reactions between the omalizumab and control groups. After the marketing of omalizumab, according to the follow-up of 57 300 patients treated, about 0.2% of the patients had allergic reactions, with most of the adverse reactions consisting of fever, joint pain, rash, and lymph node enlargement,[27] and about 60% of the patients had allergic reactions within 2 hours after intramuscular injection.[28]

This meta-analysis has several limitations. First, heterogeneity across the included studies − such as differences in rhinitis severity, drug formulations, follow-up duration (with some studies not meeting ideal follow-up requirements), and varying rates of allergic comorbidities−may have reduced the precision of the pooled estimates. Second, because relatively few studies of adult allergic rhinitis have been published, only a limited number of trials were eligible, resulting in a small overall sample size and potentially reduced robustness of the findings. Third, only English- and Chinese-language publications were included; potentially high-quality studies in other languages were not assessed, which may have introduced publication bias.

In conclusion, omalizumab is effective in the treatment of adult AR and has good safety. Given the limitations of this study, the findings of this meta-analysis need to be verified by more trials with larger sample sizes in the future.

## STATEMENT OF ETHICS

Not applicable.

## FUNDING

Not applicable.

## CONFLICT OF INTEREST

The authors declare no conflicts of interest.

## ACKNOWLEDGMENTS

Not applicable.

## DATA AVAILABILITY

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

## AI ASSISTANCE DISCLOSURE

Not applicable.

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