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Evaluation of omalizumab therapy in pediatric patients with severe asthma

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Abstract
Aim: Severe asthma affects 2–5% of children and often remains uncontrolled despite high-dose inhaled corticosteroids (ICS) and long-acting β_2-agonists. Omalizumab, an anti-IgE monoclonal antibody, is approved for patients aged ≥ 6 years, yet evidence in younger children remains limited. This study assessed the efficacy, safety, and treatment satisfaction of omalizumab in pediatric patients aged 4–17 years with severe allergic asthma, emphasizing preschoolers.
Methods: A retrospective cohort of 21 children with GINA-defined severe asthma who received ≥ 9 months of omalizumab (May 2023–December 2024) was evaluated. Data on exacerbations, hospitalizations, systemic corticosteroid use, ICS dose, lung function (FEV_1, reversibility), and asthma control (ACT/C-ACT) were compared between baseline and month 9.
Results: Median exacerbations decreased from 8 to 2 per 6 months ($p < 0.01$), hospitalizations from 2 to 1 ($p < 0.001$), and systemic steroid use from 18 to 3 days ($p < 0.001$). FEV_1 improved from 55% to 82% ($p < 0.001$), and bronchodilator reversibility declined from 16% to 5% ($p = 0.009$). The median ICS dose decreased from 500 mcg to 125 mcg ($p < 0.001$). ACT/C-ACT scores rose from 7 to 22 ($p \leq 0.03$). Two preschoolers (ages 4–5) achieved complete symptom control without adverse effects.
Conclusion: Omalizumab markedly improved control, lung function, and steroid dependence across pediatric ages, including preschoolers. These findings support the potential value of early biologic intervention in improving short-term disease control in children who do not respond to conventional therapy.

Keywords
asthma management, pediatric severe asthma, omalizumab treatment

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Introduction

Asthma is the most prevalent chronic inflammatory respiratory disease in children, characterized by reversible airway obstruction.[1] Although severe asthma affects only 2–5% of pediatric cases, it carries a substantial public health burden due to reduced quality of life, increased healthcare utilization, and high treatment costs.[2] According to the Global Initiative for Asthma (GINA) guidelines, asthma that remains symptomatic despite a stepwise treatment plan is classified as "difficult-to-treat asthma," often due to modifiable factors such as incorrect inhaler technique, poor adherence, environmental triggers, or comorbidities like obesity.[1] Severe asthma is a subset of this group and refers to cases that remain uncontrolled despite optimized high-dose inhaler corticosteroid (ICS) plus long-acting β2 agonist (LABA) therapy and strict management of contributing factors.[1-3]

Asthma comprises two main inflammatory endotypes: type 2 (T2-high) and non–type 2 (T2-low). T2-high asthma, the predominant form in children, is characterized by eosinophilic inflammation mediated by IgE and Th2 cytokines (IL-4, IL-5, IL-13) and responds well to biologics targeting these pathways. This endotype is particularly responsive to biological therapies targeting IgE or Th2 pathways.[4] Omalizumab, a humanized anti-IgE monoclonal antibody, is an approved treatment for severe asthma in children aged 6 years and older, as well as in adolescents and adults. By binding to free IgE, omalizumab prevents interaction with FcεRI receptors on mast cells and basophils, inhibiting downstream inflammatory cascades and allergen-triggered responses.[5]

Current GINA guidelines recommend omalizumab as a Step 5 add-on therapy for patients aged ≥ 6 years with severe allergic asthma, elevated serum IgE levels, and confirmed sensitization to perennial aeroallergens.[1] Although asthma is more common in school-aged children, preschoolers experience a disproportionately high number of severe exacerbations leading to emergency visits and hospitalizations.[6] ICS often provides inadequate control in this age group, contributing to poor quality of life, increased future exacerbation risk, and higher healthcare costs.[7] Management is further complicated by the limited availability of high-quality clinical trials in preschoolers.[8] Consequently, evidence for the use of omalizumab in children under 6 remains scarce, largely limited to isolated case reports and small series.[9,10]

In this study, we evaluated the clinical efficacy, safety profile, and treatment satisfaction of omalizumab in pediatric patients with severe asthma aged 4 to 17.

Materials and Methods

Study Design and Data Collection

This retrospective observational cohort study was conducted at the Pediatric Allergy and Immunology Clinic and included 21 children aged 4–17 years with severe allergic asthma, diagnosed according to the 2024 GINA guideline.[1] Patients who received omalizumab for at least nine months between May 2023 and December 2024 were included, and none discontinued treatment for adverse effects or other reasons. Patients were excluded if they had chronic lung disease unrelated to asthma (e.g., bronchopulmonary dysplasia, cystic fibrosis), known primary or secondary immunodeficiency, a history of prematurity with persistent respiratory morbidity, concomitant respiratory disorders that could confound asthma assessment (such as congenital airway anomalies or vocal cord dysfunction), or incomplete medical records preventing confirmation of baseline or follow-up clinical data.

In December 2024, clinical and demographic data were retrospectively extracted from medical records, including age, sex, aeroallergen sensitization, comorbid atopic diseases, total IgE levels, eosinophil counts, and asthma medications. ICS dosages were standardized by converting all prescribed preparations (fluticasone propionate, budesonide, and beclomethasone dipropionate) into equivalent microgram doses according to GINA 2024 potency adjustment Supplementary Tables. Daily doses were calculated based on each patient's prescribed regimen and categorized as low, medium, or high according to guideline-defined cutoffs. For analysis, all ICS doses were expressed as µg/day of fluticasone-propionate equivalent to ensure comparability across patients. Additional variables extracted included exacerbation frequency, asthma-related hospitalizations, school absenteeism, and details of omalizumab treatment. Follow-up assessments provided data on asthma control and omalizumab dosing. Clinical, laboratory, and asthma-control parameters obtained before and after omalizumab therapy were compared to evaluate treatment efficacy.

Two patients under six years of age, for whom omalizumab is not approved, were evaluated individually. Both had severe asthma characterized by multiple aeroallergen sensitizations and inadequate control despite high-step standard therapy. A comprehensive differential diagnostic work-up was performed, including detailed laboratory testing and appropriate imaging, and no underlying chronic disease, immunodeficiency, or structural lung abnormality was identified. For both patients, off-label use authorization for omalizumab was obtained from the Ministry of Health.

Omalizumab Administration

Omalizumab treatment was initiated for all patients according to clinical guidelines.[1] Before starting omalizumab treatment, patients were assessed for adherence to their current medications, proper inhaler techniques, potential comorbidities, and control of these factors.

Assessment of Asthma Control

Asthma control was evaluated using spirometric measurements in patients able to perform acceptable spirometry, together with age-appropriate asthma control tests (ACT). All spirometric assessments were performed using a calibrated spirometer and interpreted according to ATS/ERS 2019 standardized criteria. Measurements included FEV_1, FVC, and bronchodilator reversibility. Only maneuvers that met acceptability and reproducibility requirements (e.g., at least three acceptable curves with < 150 mL variability) were included. Predicted FEV_1 values were automatically calculated using age-, sex-, height-, and ethnicity-adjusted reference equations. Airway obstruction and bronchodilator responsiveness were assessed using FVC and FEV_1 values. Measurements ≥ 80% of predicted were considered normal, while lower values indicated airflow

limitation. Reversibility was defined as an increase of ≥ 12% or ≥ 200 mL in FEV_1 or FVC following administration of a rapid-acting β_2-agonist.

The ACT consists of five items scored 1–5, with total scores of 25 indicating full control, 20–24 partial control, and ≤ 19 uncontrolled asthma. The Childhood ACT (C-ACT) includes seven items (four child-reported, three parent-reported), scored 0–27, with scores ≤ 19 reflecting uncontrolled asthma.

Ethical Approval

This study was approved by the Ethics Committee of Harran University, School of Medicine (Date: 2024-06-10, No: HRÜ/24.08.22).

Statistical Analyses

Statistical analyses were performed using Jamovi (v2.2.26, The Jamovi Project, Sydney, Australia), and figures were generated with GraphPad Prism (v9.5.1, GraphPad Software, Boston, MA, USA) and Adobe Illustrator 2023 (v27.9.0, Adobe Inc., CA, USA). Data normality was assessed using the Shapiro–Wilk test and visually confirmed with histograms due to the sample size (< 50). Categorical variables were presented as frequencies and percentages, while continuous variables were reported as mean ± SD (normal distribution) or median (IQR, 25th–75th%) (non-normal distribution). Dependent categorical variables were compared using the McNemar test, and independent categorical variables using the chi-square (x^2) test. For continuous data, dependent groups underwent paired sample t-tests for normally distributed data and Wilcoxon signed-rank tests for non-normally distributed data. A p-value < 0.05 indicates statistical significance. Repeated-measures comparisons across time points were performed using the Friedman test, with Durbin–Conover pairwise analyses and Bonferroni correction for multiple testing. Spearman's correlation analysis was used to evaluate associations between non-normally distributed variables, with coefficients ranging from –1 to +1. Correlation significance was also determined using a p-value < 0.05.

Reporting Guidelines

This retrospective observational cohort study was reported in accordance with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines.

Results

Patient Demographics, Clinical and Laboratory Characteristics

The study included 21 children with severe asthma who remained symptomatic despite high-dose ICS and LABA therapy. The mean age was 10.2 ± 3.98 years, with a median age at diagnosis of 7 years (IQR 25-75%: 4–8). Most of the cohort was male (61.9%, n = 13). All patients showed sensitivity to at least one aeroallergen. The most commonly identified allergens included pollen (66.7%), house dust mites (47.6%), and molds (42.9%). Fourteen patients (66%) had concurrent comorbid allergic diseases, such as allergic rhinitis and chronic urticaria. The median total IgE level was 650 IU/ml (IQR 25-75%: 300–996), and the median eosinophil count was 100/μL (IQR 25-75%: 20–400). All patients received high-dose ICS for a median of 7 months (IQR 25-75%: 5-11) and were treated with ICS + LABA combinations (71.4% budesonide–formoterol, 28.6% fluticasone–salmeterol). Additionally, 66.7% used leukotriene receptor antagonists, and 9.6% required systemic steroids. Supplementary Table 1 summarizes the demographic, clinical, and laboratory features.

We had two severe asthma patients under 6 years old (a 4-year-old girl and a 5-year-old boy); both had high IgE levels and sensitization to house dust mites, and they had no concomitant allergic comorbidities. Despite high-dose ICS + LABA and LTRA therapy, their asthma remained uncontrolled, and they frequently required systemic steroids. After excluding alternative diagnoses, reinforcing trigger avoidance, and confirming inhaler technique, off-label omalizumab approval was obtained from the Ministry of Health for patients under 6 years old. Omalizumab treatment was initiated based on the weight and IgE levels indicated in the package insert. Treatment led to marked improvement, with full symptom control, reduced exacerbations, and decreased ICS requirements. No systemic or local adverse effects were observed, and both patients have been on omalizumab for 12 months.

Treatment Characteristics of Omalizumab

The median dosage of Omalizumab was 300 mg (IQR, 25-75%: 300–450) per injection, with median dose interval of 4 weeks (IQR, 25-75%: 2-4) in accordance with weight- and IgE-based dosing Supplementary Tables, and the median treatment duration was 10 months (IQR, 25-75%: 9-12). No systemic adverse reactions were reported. However, two patients experienced mild local swelling and pain at the injection site, which resolved with continued treatment (Supplementary Table 2).

The Efficacy of Omalizumab Treatment

Clinical and laboratory parameters before and after 9 months of omalizumab therapy were compared. There was a significant decrease in median asthma attacks over the previous 6 months, decreasing from 8 (IQR, 25-75%: 6-10) to 2 (IQR, 25-75%: 1-3) (p < 0.01). Hospitalizations also declined significantly, from a median of 2 (IQR, 25-75%: 1-3) to 1 (IQR, 25-75%: 0-1) (p < 0.001). The median ICS dose decreased from 500 mcg (IQR, 25-75%: 320-600) to 125 mcg (IQR, 25-75%: 80-160) (p < 0.001), and systemic steroid use dropped from 18 days (IQR, 25-75%: 10-30) to 3 days (IQR, 25-75%: 0-5) over 9 months (p < 0.001). Asthma control improved substantially. Median FEV_1 increased from 55% (IQR, 25-75%: 50-60) to 82% (IQR, 25-75%: 80-85) (p < 0.001). While reversibility on spirometry decreased from 16% (IQR, 25-75%: 15-20) to 5% (IQR, 25-75%: 0-10) (p = 0.009). ACT scores increased from 7 (IQR, 25-75%: 6-7) to 22 (IQR, 25-75%: 21-23) (p = 0.03), while C-ACT scores increased from 7 (IQR, 25-75%: 6-8) to 22 (IQR, 25-75%: 21-23) (p < 0.001). A comparison of clinical and laboratory parameters before and after omalizumab treatment is shown in Supplementary Table 2. We evaluated changes in clinical and spirometric parameters before treatment and at the 3rd and 9th months of omalizumab therapy. Significant improvements were observed after treatment initiation, including increased FEV1 and reductions in reversibility, ICS dosage, and asthma attacks per 3 months (all p < 0.001). Detailed pairwise comparisons confirmed early improvements in FEV1 levels (Supplementary Figure 1 A) and

reductions in reversibility on spirometry (Supplementary Figure 1 B), ICS dosage (Supplementary Figure 1 C), and asthma attacks per 3 months (Supplementary Figure 1 D) from baseline to the 3rd month ($p = 0.03$, $p = 0.007$, $p = 0.004$, $p = 0.04$). No significant differences were detected between the 3rd and 9th months, indicating stabilization of treatment effects.

Correlation analysis showed a strong negative correlation between the ACT scores at the 9th month of omalizumab treatment and the duration of high-dose ICS use ($p = 0.012$, $r = -0.9$) (Supplementary Figure 2 A). C-ACT scores at the 9th month showed a significant negative correlation with the FEV_1 change during omalizumab treatment ($p = 0.003$, $r = –0.8$) (Supplementary Figure 2 B) and a moderate negative correlation with the number of hospitalizations in the six months before treatment ($p = 0.04$, $r = –0.5$) (Supplementary Figure 2 C). Additionally, FEV_1 change during omalizumab therapy showed a moderate negative correlation with baseline FEV_1 ($p = 0.02$, $r = –0.55$) (Supplementary Figure 2 D) and a moderate positive correlation with the number of asthma attacks ($p = 0.03$, $r = 0.53$) (Supplementary Figure 2 E) and prior hospitalizations ($p = 0.02$, $r = 0.55$) (Supplementary Figure 2 F).

Discussion

This study demonstrates the effectiveness and tolerability of add-on omalizumab in children aged 4–17 years with severe allergic asthma, supporting and extending findings from real-world cohorts, systematic reviews, and long-term observational studies.[10-17]

We observed a marked reduction in exacerbations after initiating omalizumab, consistent with the ~50% decrease reported in previous research.[10,12,13,15] Hospitalizations and emergency visits also declined, aligning with clinical trials showing significantly lower hospitalization rates in omalizumab-treated pediatric patients.[10,11] These improvements translate into meaningful clinical benefits, including better quality of life for children with severe asthma receiving anti-IgE therapy. Our cohort additionally showed improvements in lung function and a reduction in maintenance ICS requirements. This steroid-sparing effect echoes randomized trials in which omalizumab enabled a mean daily ICS reduction of about 100 µg compared with placebo.[18,19] Although some controlled studies did not show significant changes in FEV_1, multiple real-world studies have reported improvements in FEV_1 over longer follow-up periods.[10,20] In our cohort, gains in FEV_1 were modest but evident, suggesting that omalizumab helps stabilize or enhance lung function.

Asthma control significantly improved in our cohort, reflected by higher ACT and C-ACT scores after omalizumab treatment. These findings are consistent with previous studies: meta-analyses have shown significant improvements in ACT in children with severe asthma, and a prospective study demonstrated a rapid rise in C-ACT from approximately 15.6 to 25.0 within 16 weeks.[21] Omalizumab also demonstrated a favorable safety profile in our cohort. No systemic adverse events occurred, including in preschool-aged children, aligning with large registries such as EXCELS, which reported no increased risk of anaphylaxis or malignancy in pediatric populations.[22] Mild injection-site reactions resolved spontaneously, consistent with previous observations.[11,12]

A notable strength of our study is the inclusion of two patients aged 4–5 years, in whom omalizumab was used off-label. Both achieved full symptom control without adverse events, suggesting that some preschoolers with severe allergic asthma may benefit from omalizumab when standard therapies fail. Although omalizumab is officially approved from age 6 onward due to limited trial data in younger children, existing evidence supports its potential in this age group. The efficacy and safety of omalizumab in managing severe asthma in children under the age of 6 have been demonstrated in the literature as a case report and notably in the ANCHOR study, which reported a remarkable 95% reduction in the rate of severe exacerbations among 16 young patients, without any significant side effects.[16] Additionally, the ongoing PARK study is formally exploring its use in toddlers.[23]

We observed a negative correlation between baseline FEV_1 and post-treatment improvement, indicating that children with poorer initial lung function gained greater benefit, supporting omalizumab's role in reducing inflammation-driven airway dysfunction. This severity-response pattern is consistent with prior studies; for example, Szefler et al. reported greater reductions in exacerbations in children with lower baseline lung function or prior hospitalizations.[24] These findings suggest that omalizumab should be considered for pediatric patients with frequent exacerbations, prior hospitalizations, or persistently low lung function despite standard therapy. Conversely, the strong negative correlation between ACT scores and prior duration of high-dose ICS use suggests that delaying biologic therapy may diminish responsiveness, underscoring the importance of early initiation in severe asthma.

Limitations

This study has several limitations. As a retrospective cohort analysis, it is vulnerable to biases such as incomplete data and the absence of a control group. Reliance on medical records and caregiver reports for exacerbation history and medication use may introduce information bias. The small sample size, particularly the under-six subgroup, reduces the statistical power and limits the strength of our conclusions. Being a single-center study also affects generalizability, as our population may not represent all children with severe asthma. Additionally, the average follow-up of approximately one year does not allow assessment of long-term outcomes beyond 12–24 months. Although no major safety concerns were observed, the limited sample size may not detect rare adverse events such as anaphylaxis, underscoring the need for continued monitoring during treatment. These limitations highlight the importance of future multicenter, randomized controlled trials with larger cohorts and longer follow-up to validate and expand on our findings.

Conclusion

Our study demonstrates that omalizumab is an effective add-on therapy for severe allergic asthma in children, significantly reducing exacerbations and healthcare use. Early initiation aligns with GINA recommendations and improves daily asthma control while providing a steroid-sparing benefit that limits exposure to high-dose ICS and systemic corticosteroids.

Encouraging outcomes in children under six also suggest that early biological treatment may positively influence disease progression during key periods of lung development. Overall, omalizumab offers strong efficacy and safety, underscoring its value as a core component of pediatric severe asthma management.

Ethics Declarations
This study was approved by the Ethics Committee of Harran University, School of Medicine (Date: 2024-06-10, No: HRÜ/24.08.22)

Animal and Human Rights Statement
All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed Consent
All patients and parents were informed about the study, and informed consent was obtained from parents of children under eight years and from both patients and parents for those aged eight and older.

Data Availability Statement
The datasets used and/or analyzed during the current study are not publicly available due to patient privacy reasons but are available from the corresponding author on reasonable request.

Conflict of Interest
The authors declare that there is no conflict of interest.

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None.

Author Contributions (CRediT Taxonomy)
Conceptualization: A.P.S., M.Ş.K.
Methodology: A.P.S.
Formal Analysis: A.P.S.
Investigation: A.P.S., M.Ş.K.
Data Curation: A.P.S.
Writing – Original Draft Preparation: A.P.S.
Writing – Review & Editing: M.Ş.K.
Supervision: M.Ş.K.

Scientific Responsibility Statement
The authors declare that they are responsible for the article's scientific content, including study design, data collection, analysis and interpretation, writing, and some of the main line, or all of the preparation and scientific review of the contents, and approval of the final version of the article.

Abbreviations
ACT: Asthma Control Test
C-ACT: Childhood Asthma Control Test
FEV_1: Forced Expiratory Volume in 1 Second
FVC: Forced Vital Capacity
GINA: Global Initiative for Asthma
ICS: Inhaled Corticosteroid
IgE: Immunoglobulin E
LABA: Long-Acting $Beta_2$-Agonist
LTRA: Leukotriene Receptor Antagonist

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