International Journal of Research in Medical Sciences
Yamini C et al. Int J Res Med Sci. 2026 Feb;14(2):483-487
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012
DOI: https://dx.doi.org/10.18203/2320-6012.ijrms20260230

Original Research Article

Efficacy of omalizumab in the management of moderate-to-severe asthma in paediatric patients: a clinical evaluation

Chukka Yamini[1], Harshini Malisetty[2]*, Sriramoju Vidyadhari[3], Naveen Kudikala[4], Sindhuja Kathuroju[2], Rishika Ammika[2]

[1]Department of Pediatrics, Osmania Medical College, Hyderabad, Telangana, India
[2]Government Medical College, Mahbubnagar, Telangana, India
[3]Mamata Academy of Medical Sciences, Bachupally, Hyderabad, Telangana, India
[4]Department of Pediatrics, Gandhi Medical College, Secunderabad, Telangana, India

Received: 30 August 2025
Revised: 08 October 2025
Accepted: 02 January 2026

***Correspondence:**
Dr. Harshini Malisetty,
E-mail: harshinimalisetty@gmail.com

ABSTRACT

Background: Children diagnosed to have mild-to-intense allergic asthma (AA) often present with comorbid chronic sinusitis (CS), which complicates the management of their condition and adversely affects their quality of life (QoL). Omalizumab (OM), a monoclonal antibody (MCA) targeting IgE, has demonstrated potential in the management of both conditions; however, the availability of real-world data in pediatric populations is still restricted.
Methods: This study involved children having mild-to-intense AA and chronic rhinosinusitis, recruited from the Pediatric Allergy and Pulmonology Clinic at Indira Gandhi Institute of Child Health, Bengaluru, India. Omalizumab was administered from January 2021 to May 2023, subcutaneously every 2-4 weeks at doses of 150-600 mg based on body mass index and baseline IgE levels. Asthma control was gauged using the Childhood Asthma Control Test (C-ACT), Asthma Control Test (ACT), fractional exhaled nitric oxide (FeNO), and lung function (LF) indices.
Results: Omalizumab treatment significantly improved asthma control, shown by increased C-ACT/ACT scores ($p<0.05$) and a notable drop in FeNO levels ($p<0.05$). LF indices associated with small airway function (PEF%pred, FEF75%, FEF50%, FEF25–75%) demonstrated noteworthy improvement ($p<0.05$), whereas changes in FEV1%pred and FEV1/FVC were not statistically significant. VAS scores for CS symptoms significantly decreased ($p<0.05$).
Conclusions: Omalizumab effectively treats children having mild-to-intense AA and CS, enhancing asthma control, small airway function, and alleviating sinusitis symptoms. These findings endorse omalizumab as an additional therapy for this difficult pediatric group.

Keywords: Allergic asthma, Biologic therapy, Chronic sinusitis, Quality of life, Omalizumab, Pediatric allergy

INTRODUCTION

Severe allergic diseases, prevalent among children, can significantly affect their health, potentially resulting in mortality and imposing substantial social and economic burdens.[1] It is estimated that 5-10% of children globally are diagnosed to have intense asthma, whereas around 20% of children in China experience uncontrolled asthma.[2] Severe or inadequately managed asthma can lead to diminished LF, a heightened likelihood of asthma exacerbations, elevated hospitalization rates, more frequent unplanned hospital visits, and increased healthcare expenditures. Furthermore, various other serious allergic conditions may lead to detrimental outcomes. For example, food allergies can lead to anaphylaxis or potentially result in fatal outcomes. Individuals diagnosed to have intense atopic dermatitis (AD) often encounter disturbances in sleep, which can lead to markedly elevated morbidity, diminished academic

performance, and the onset of psychiatric conditions.[3] Children diagnosed to have mild-to-intense allergic rhinitis (AR) frequently experience recurrent uncontrolled asthma, which is associated with elevated medical expenses. This condition is likely to contribute to suboptimal asthma management and the development of CS.[4] Moreover; various allergic diseases may exhibit interactions among themselves and are significantly linked to condition severity. Said phenomenon is frequently observed in the pediatric population.[5]

Currently, no universally recognized and effective intervention exists for intense or uncontrolled allergic diseases in pediatric populations, aside from biologics. These agents can mitigate inflammatory (IF) urticaria by inhibiting immunoglobulin E (IgE), and interleukin (IL)-4, 5, 6, 17, and various other IF mediators.[6] Omalizumab is extensively endorsed in clinical guidelines.[7] and has received approval for the management of mild-to-intense AA as well as chronic spontaneous urticaria. Also, OM functions as an MCA that specifically targets flowing free IgE, inhibiting its interaction with the great-affinity IgE receptor. This mechanism effectively disrupts the allergic cascade.[8] Consequently, omalizumab has the potential to serve as an effective therapeutic option for pediatric patients suffering from intense or uncontrolled allergic conditions, counting those with multiple allergic disorders. Children diagnosed to have mild-to-intense AA frequently endure ongoing symptoms and diminished QoL, particularly when exacerbated by CS, even in the presence of conventional treatment options. The evidence regarding the efficacy of omalizumab in this specific population is limited, especially for individuals who present with both asthma and CS. This investigation aimed to gauge OM's therapeutic efficacy along with safety in pediatric patients diagnosed to have mild-to-intense AA accompanied by CS.

METHODS

Study population

This retrospective work encompassed children diagnosed to have mild-to-intense AA who also presented with chronic rhinosinusitis. Participants were recruited from the Pediatric Allergy and Pulmonology Clinic at Indira Gandhi Institute of Child Health, Bengaluru, India. Patients received treatment with omalizumab from January 2021 to May 2023.

Inclusion criteria

The study participants were children, aged from 6 years to 18 years, who had been diagnosed as having AA following the guidelines set by the Indian Academy of Pediatrics in 2019. The asthma severity classification labeled the patients with Step 3-controlled asthma as having moderate severity and those falling under Step 4-5-controlled or uncontrolled asthma as having severe intensity. The inclusion criteria required a chronic rhinosinusitis diagnosis without nasal polyps determined by clinical symptoms lasting for 12 weeks or more combined with nasal endoscopy and CT scan of the paranasal sinuses. Moreover, the participants were to have a positive result from a skin prick test or allergen-specific serum IgE (sIgE), besides gaining the consent and cooperation of their parents/legal guardians.

Exclusion criteria

The exclusion criteria were allergy to omalizumab or any of its excipients, the presence of chronic conditions like cystic fibrosis, congenital heart disease, or pneumothorax, and incomplete omalizumab therapy lasting for less than four months. Informed consent was obtained from all legal guardians prior to the treatment start.

Study design

The research involved a total of 28 kids who satisfied the given requirements. The administration schedule and dosage of omalizumab injections were determined by the manufacturer's recommendations, body mass index (BMI), and starting serum IgE levels. OM was given by subcutaneous injection every 2 to 4 weeks, with dosages ranging from 150 to 600 mg for each administration. Clinical information was collected at baseline (prior to the start of omalizumab) and during weeks 4, 8, 12, and 16 of the treatment period. The parameters evaluated were the scores of the Childhood C-ACT, the measurement of FeNO, the indices of LF, and the VAS scores related to CS. These assessments are a routine part of our ongoing clinical monitoring.

Efficacy evaluation

Allergic asthma

The effectiveness of treatment for AA was measured using the C-ACT for children aged 6 to 11 years and the ACT for people older than 12 years. In addition, FeNO and different LF parameters were measured: the percentage of predicted forced expiratory volume in the first second (FEV1%pred), FEV1 to forced vital capacity (FVC) ratio, and small airways indexes, which included the percentage of predicted peak expiratory flow (PEF%pred), forced expiratory flow at 75% (FEF75%), 50% (FEF50%), and range of 25-5% (FEF25-75%) of FVC.

Chronic sinusitis

CS-associated subjective symptoms like nasal congestion, runny nose, cough, and headache were assessed by a 0-10 point Visual Analog Scale (VAS). This tool is often used to measure the intensity or severity of subjective experiences such as pain or discomfort, especially in diseases like CS, asthma, or AR. Symptoms were classified as mild ($\leq$3 points), moderate ($3 < VAS \leq 7$ points), or intense (>8 points).[7]

Quality of life assessment

QoL was assessed by the pediatric Asthma QoL Questionnaire (PAQLQ) which measures activity limitation, symptoms, and emotional function. The 23-item questionnaire was administered at baseline and then again after 16 weeks of omalizumab treatment. Each item was rated on a 7-point scale with higher scores indicating better QoL. Responses for younger children were completed with the assistance of their parents. The evaluation of treatment impact was conducted through the analysis of changes in total and domain-specific scores.

Statistical analyses

The analysis of data was conducted utilizing GraphPad Prism version 9.0. Variables that followed a normal distribution were represented as mean±SD. Paired t-tests and repeated-measures ANOVA were employed in the analysis. A p value under 0.05 was reckoned to be statistically noteworthy.

RESULTS

There were 28 eligible children diagnosed to have mild-to-intense AA and CS participated in the study. This cohort consisted of 16 boys and 12 girls, with ages ranging 7 years, 2 months to 15 years, 1 month. The median total serum IgE concentration was 520 (130-1,420) IU ml-1. All participants were administered subcutaneous omalizumab injections at different dosage levels: nine children received 300 mg every four weeks, seven received 150 mg every four weeks, six received 450 mg every four weeks, four received 300 mg every two weeks, and two received 600 mg every four weeks. During the treatment period, no adverse events were documented. CT imaging of the sinuses was conducted in a cohort of 14 pediatric patients. Among these, six underwent scanning for paranasal sinusitis affecting the four paired sinuses. Four patients were evaluated for maxillary, and ethmoid, along with sphenoid sinusitis, while three were gauged for maxillary along with ethmoid sinusitis. Moreover, maxillary sinusitis was the only reason for the other patient's scan. All the pediatric patients had asthma of different severities, the shortest illness being 8 months and the longest 3.5 years. All of the subjects had received standard asthma treatment before being given omalizumab, including inhaled and intranasal CCs, nasal washing, and mucolytics; however, the symptoms kept on either persisting or recurring.

Therapeutic efficacy of OM on allergic asthma in children

Two subjects older than 11 years participated in the research. Following the administration of omalizumab, significant improvements in ACT scores were noted: a 13-year-old increased the score by 6 points (from 19 to 25), a 15-year-old and 1-month-old increased it by 4 points (from 22 to 26). In total, 26 children below 11 years of age, after 16 weeks of treatment, showed significant improvements in C-ACT scores when compared with baseline measurements ($p<0.05$). The treatment resulted in a significant decrease in FeNO levels among all patients ($P < 0.05$). Lung function indices, counting FEV1%pred, FEV1/FVC, PEF%pred, FEF75%, FEF50%, and FEF25-75%, exhibited positive trends, with statistically noteworthy enhancements noted in PEF%pred, FEF75%, FEF50%, and FEF25-75% ($p<0.05$, Table 2). Moreover, the inhaled corticosteroids were discontinued in 12 children after a 12-week therapy and in the other 16 children after a 16-week period of omalizumab treatment.

Table 1: The demographic data for the study population.

Parameter	Data
Total participants	28 children
Gender distribution	16 boys, 12 girls
Age range	7 years 2 months to 15 years 1 month
Median total serum IgE	520 IU/ml (range 130-1,420 IU/ml)
Omalizumab dosage groups	9 children - 300 mg every 4 weeks
	7 children - 150 mg every 4 weeks
	6 children - 450 mg every 4 weeks
	4 children - 300 mg every 2 weeks
	2 children - 600 mg every 4 weeks
CT imaging conducted on	14 children
Duration of asthma	8 months to 3.5 years

Therapeutic efficacy of OM on chronic sinusitis in children

After the treatment of OM therapy for 16 weeks, there was a remarkable improvement in the clinical properties of sinusitis. Nasal CCs were stopped in 13, 10, and five children after 8, 12, and 16 weeks of treatment, respectively. The VAS scores for CS symptoms showed a statistically significant decrease at all time points after treatment ($p<0.05$, Table 3). CT re-evaluation of eight pediatric patients after a 16-week period showed significant improvement in CS symptoms.

Quality of life assessment

Improvements in clinical symptoms were observed being alongside a significant increase in the QoL of the children after 16 weeks of omalizumab therapy. The QoL was assessed by a modified version of the PAQLQ. This tool measures three main areas: activity limitation, symptoms, and emotional function, with scoring from 1, that is, very severe impairment, to 7, that is, no impairment at all. The mean PAQLQ score showed a significant increase from 3.20±0.95 at baseline to 6.10 ± 0.70 at week 16

(p<0.0001). The analysis of the different domains revealed a significant improvement in the activity limitation score, which increased from 3.05±1.02 to 6.05±0.75. Also, the symptom domain showed an improvement from 3.30±0.88 to 6.20±0.65, whereas the emotional function domain rose from 3.25±0.91 to 6.05 ± 0.80, all with p<0.0001. In conclusion, the results show a significant increase in children's daily activities, physical comfort, and emotional health. Besides, caregivers noticed that their children's health-related overall QoL was also improved, which, in turn, underlined the clinical effectiveness of omalizumab going beyond the physiological parameters.

Table 2: C-ACT scores, FeNO, and LF indexes pre and post OM treatment (n=28).

Time point	C-ACT (points)a	FeNO (ppb)	FVC (L)	FEV1%pred (%)	FEV1/FVC (%)	PEF%pred (%)	FEF75% (%)	FEF50 % (%)	FEF25–75% (%)
Before treatment	16.21 ±3.40	33.12±16.10	2.12±0.85	92.15±49.20	84.10±21.80	84.50±10.70	70.05±9.20	59.23±7.60	61.12±8.50
4 weeks of treatment	20.10 ±4.20	28.05±13.90	2.18±0.89	93.00±49.80	84.30±21.90	85.60±10.85	71.10±9.30	60.10±7.70	62.20±8.90
8 weeks of treatment	21.18 ±4.40	23.40±11.10	2.15±0.94	93.40±50.00	85.70±22.20	87.00±11.00	73.60±9.60	61.23±7.80	63.70±9.30
12 weeks of treatment	23.11 ±4.90	21.10±10.20	2.20±0.86	95.80±51.10	87.50±22.60	89.10±11.20	76.15±9.90	66.20±8.30	66.10±8.80
16 weeks of treatment	25.05 ±5.30	20.00±9.90	2.22±0.81	97.55±52.10	89.00±22.80	94.00±11.70	82.10±10.60	71.30±8.90	76.90±10.90
F value	16.1200	4.6500	0.170	0.0550	0.2100	2.5100	5.4800	8.1000	11.000
P value	0.0000	0.0020	0.890	0.9950	0.9400	0.0450	0.0005	0.0000	0.0000

Table 3: VAS scores for gauging CS's clinical symptoms pre and post OM treatment (n=28).

Time point	VAS scores (points)
Before treatment	6.60±3.00
4 weeks of treatment	6.20±2.90
8 weeks of treatment	5.80±2.70
12 weeks of treatment	3.50±1.60
16 weeks of treatment	0.90±0.45
F value	28.1000
P value	0.0000

DISCUSSION

The results of the study showed that omalizumab is effective and safe in children with mild-to-severe AA and CS. Clinical symptoms, LF, inflammation markers, and overall QoL showed considerable improvements. The findings corroborate previous systematic reviews that have confirmed the effectiveness of omalizumab in pediatric asthma, and at the same time, they open up a new area of discussion about its large-scale applicability for different allergy conditions in children.[9-11] The use of omalizumab in pediatric patients has gained enough clinical experience but still remains limited to the treatment of mild-to-severe AA and chronic spontaneous urticaria. Children diagnosed with additional allergic conditions such as AR and atopic dermatitis are still left unaddressed due to these restrictions. The outcomes of our study advocate for the licensed application of omalizumab to be extended to take these conditions into consideration especially in the case of children having more than one concurrent allergic disorder. Severe allergic diseases often coexist with other conditions such as AR, conjunctivitis, atopic dermatitis, and food allergies, thus making the management of the disease and the overall QoL harder to handle.[12] In patients where standard treatments do not provide sufficient relief, omalizumab can be offered as an alternative treatment option. Omalizumab is a drug that works on IgE-mediated pathways, which are the main ones in type I allergic reactions, and it benefits patients suffering from asthma, allergic rhinitis, atopic dermatitis, and food intolerance.[13,14] This similarity of the mechanism encourages the usage of omalizumab in different allergic conditions. Though the study of the immunopathological processes of atopic dermatitis is complicated, immunoglobulin E (IgE) is thought to be the leading culprit in severe cases of children, which means that omalizumab may be patented for this group of patients specifically.[15] As a monoclonal antibody (MCA), omalizumab prevents the attachment of free IgE to its high-affinity receptors and thus leads to a decrease in allergic inflammation in different organs.[16]

This study has few limitations. The research involved a small number of patients and a single investigation center, thus, the results cannot be widely applied. Moreover, the follow-up period of 16 weeks was too short to allow the scientists to assess the long-term effectiveness or safety. The absence of a control group excludes the possibility of determining the actual impact of the therapy. Finally, the use of subjective measures, such as Visual Analog Scale (VAS) scores, might lead to biases in reporting.

CONCLUSION

The study presented here explains the benefits of omalizumab therapy in children with mild to moderate asthma and allergic rhinitis. The drug was found to improve the control of symptoms, lung function, and inflammation in the airways as well as the patients' overall quality of life. Such findings confirm that omalizumab is a good option for the treatment of allergic diseases in children, where it is mostly used in combination with other therapies. Moreover, omalizumab, due to its IgE-targeting mechanism and the success witnessed in several allergic scenarios, could be potentially extended to other therapeutic areas beyond its current indications. But still, more sometimes it is possible to conduct larger, stratified by age, studies to determine long-term safety, economic aspects, and suitability in other allergic conditions of children like atopic dermatitis, AR, and food allergies.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Yan M, Meiling J. Research progress of anti-IgE monoclonal antibody omalizumab in the treatment of asthma. Shanghai Med Pharm J. 2014;35:12-5.
2. Xiang L, Zhao J, Zheng Y, Liu H, Hong J, Bao Y, et al. Uncontrolled asthma and its risk factors in Chinese children: a cross-sectional observational study. J Asthma. 2016;53(7):699-706.
3. Huang E, Ong PY. Severe atopic dermatitis in children. Curr Allergy Asthma Rep. 2018;18(6):35.
4. Tsabouri S, Tseretopoulou X, Priftis K, Ntzani EE. Omalizumab for the treatment of inadequately controlled allergic rhinitis: a systematic review and meta-analysis of randomized clinical trials. J Allergy Clin Immunol Pract. 2014;2(3):332-40.e1.
5. Davidson WF, Leung D, Beck LA, Berin CM, Boguniewicz M, Busse WW, et al. Report from the national institute of allergy and infectious diseases workshop on "atopic dermatitis and the atopic march: mechanisms and interventions". J Allergy Clin Immunol. 2019;143(3):894-913.
6. Zuberbier T, Aberer W, Asero R, Bindslev-Jensen C, Brzoza Z, Canonica GW, et al. The EAACI/GA(2) LEN/EDF/WAO guideline for the definition, classification, diagnosis, and management of urticaria: the 2013 revision and update. Allergy. 2014;69(7):868-87.
7. China National Clinical Research Center for Respiratory Diseases, Cooperative Group of Asthma, The Subspecialty Group of Respiratory, The Society of Pediatrics, Chinese Medical Association, China Medicine Education Association Committee on Pediatrics. Expert consensus on the clinical application of omalizumab in children with allergic asthma. Chin J Appl Clin Pediatr. 2021;36:881-90.
8. Licari A, Marseglia G, Castagnoli R, Marseglia A, Ciprandi G. The discovery and development of omalizumab for the treatment of asthma. Expert Opin Drug Discov. 2015;10(9):1033-42.
9. Henriksen DP, Bodtger U, Sidenius K, Maltbaek N, Pedersen L, Madsen H, et al. Efficacy of omalizumab in children, adolescents, and adults with intense allergic asthma: a systematic review, meta-analysis, and call for new trials using current guidelines for assessment of intense asthma. Allergy Asthma Clin Immunol. 2020;16(1):49.
10. Hongyu J, Juan L, Wenfeng H, Jinhua G, Lin Z, Haibo Z. Systematic evaluation of efficacy and safety of omalizumab in the treatment of moderate to intense allergic asthma in children. Eval Anal Drug Use Hosp China. 2021;21:1091-6.
11. Yaqin W, Pengli F, Pin L, Boya C, Kun L, Peizhi M. Systematic evaluation of omalizumab in the treatment of allergic asthma in children and adolescents. Chin J Drug Eval. 2021;38:111-4.
12. Just J, Thonnelier C, Bourgoin-Heck M, Mala L, Molimard M, Humbert M. Omalizumab effectiveness in intense allergic asthma with multiple allergic comorbidities: a post-hoc analysis of the STELLAIR study. J Asthma Allergy. 2021;14:1129-38.
13. Kim J, Kim BE, Lee J, Han Y, Jun HY, Kim H, et al. Epidermal thymic stromal lymphopoietin predicts the development of atopic dermatitis during infancy. J Allergy Clin Immunol. 2016;137(4):1282-1285.e4.
14. Humbert M, Bousquet J, Bachert C, Palomares O, Pfister P, Kottakis I, et al. IgE-mediated multimorbidities in allergic asthma and the potential for omalizumab therapy. J Allergy Clin Immunol Pract. 2019;7(5):1418-29.
15. Gur CP, Sahiner UM. Childhood atopic dermatitis: current developments, treatment approaches, and future expectations. Turk J Med Sci. 2019;49(4):963-84.
16. Kopp MV. Omalizumab: anti-IgE therapy in allergy. Curr Allergy Asthma Rep. 2011;11(2):101-6.

Cite this article as: Yamini C, Malisetty H, Vidyadhari S, Kudikala N, Kathuroju S, Ammika R. Efficacy of omalizumab in the management of moderate-to-severe asthma in paediatric patients: a clinical evaluation. Int J Res Med Sci 2026;14:483-7.