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Omalizumab as a Long-Term Treatment for Patients with Severe Asthma. Is it Safe? Aseven-Years Study

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Abstract

Background: Anti-IgE (Omalizumab) is one of the targeted therapies for severe bronchial asthma. Its real-life safety is still under scrutiny.

Aim of Study: Was to evaluate the persistent efficacy and safety of Omalizumab as a long-term treatment of severe bronchial asthma.

Patients and Methods: This prospective cohort study evaluated the long-term safety and efficacy of Omalizumab in 74 patients with severe bronchial asthma attending to the chest department at King Fahd Hospital , Madina; KSA from June 2016 to August 2024.

Results: Over a 7-10 year follow-up, Omalizumab demonstrated significant improvements in clinical outcomes. Oral steroid use decreased dramatically, tiotropium bromide use reduced, and the frequency of acute exacerbations significantly declined. Pulmonary function tests (FEV1, FEV1/FVC, PEFR) showed substantial improvement. While mild side effects like injection site reactions, headache, and nausea were observed primarily in the first year, no serious adverse events such as cancer, anaphylaxis, or myocardial infarction were reported.

Conclusion: These findings suggest that long-term Omalizumab treatment in severe asthma is efficacious and well-tolerated, with minimal side effects.

Key Words: *Severe asthma – Omalizumab – Anti-IgE – Safety – Long-term treatment and side effects.*

Introduction

PATIENTS with severe asthma experience substantial morbidity, despite using high-dose inhaled corticosteroids in combination with long-acting beta-agonists with or without oral corticosteroids. The anti-immunoglobulin E monoclonal antibody omalizumab is indicated as add-on treatment for patients with severe allergic asthma, who are inadequately controlled despite optimal treatment. A greater understanding of omalizumab safety and efficacy over 7 years is now available from two open-label extension studies of pivotal studies: EXCELS and eXpeRience. These studies assessed omalizumab safety, the longevity of effect, withdrawal of treatment, and outcomes of values in asthma guideline treatment adherence **[1].**

Severe allergic asthma is characterized by the presence of symptoms of airway obstruction despite the use of inhaled drugs at high or maximum tolerated doses and the inability to reduce systemic corticosteroid treatment or maintain disease control with less than 7.5mg daily of prednisone equivalent. Omalizumab is an effective therapy in patients with persistent allergic asthma and is now commercialized. However, the duration of therapy and the offer of therapy provided are currently under discussion. In this seven-year retrospective study, 71 out of 222 patients who had received omalizumab were followed up for at least 7 years under treatment with omalizumab. The aim of the study was to establish, in patients who had been treated with omalizumab for at least seven years, the safety of the treatment

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Abbreviations:

ACT : Asthma control test.
IgE: : Immunoglobin E.
ICS : Inhaledcorticosteroids.
OCS : Oral corticosteroids.
DM : Diabetes mellitus.
HTN : Hypertension.
FceRI : High-affinity receptor.
FEV1 : Forced expiratory volume.
FVC : Forced vital capacity.
PEFR : Peak expiratory flow rate.

in the long term and whether therapeutic efficacy was maintained throughout the therapy, assessed by clinical and functional measurements **[2].**

The treatment of severe bronchial asthma has undergone a remarkable transformation in recent years, driven by a deeper understanding of the intricate interplay between immunological, genetic, and environmental factors, as well as the recognition of diverse asthma phenotypes and endotypes. This improved understanding has paved the way for the development of novel therapies, with Omalizumab marking a significant milestone as the first biologic treatment for severe asthma introduced over fifteen years ago **[3].**

Many Researches showed that omalizumab can be used for very long periods in patients with a sustained response without losing efficacy. Furthermore, no side effects emerged under very long-term treatment with this drug. These data suggest the need to extend the offer of therapy with omalizumab beyond the five years currently foreseen **[4].**

Since its inception, Omalizumab has demonstrated a robust safety and efficacy profile across numerous studies, even in complex patient populations, such as pregnant women with severe asthma. This established track record of safety and efficacy underscores the significant impact of Omalizumab in the management of severe asthma **[5,6].**

Despite this impressive body of evidence, the ever-evolving field of asthma research necessitates continuous evaluation. Prolonged follow-up studies are crucial to further solidify the long-term safety and efficacy of Omalizumab. These studies will allow for the identification of any potential long-term changes in treatment efficacy, such as the development of tolerance or the emergence of unexpected adverse effects **[7,8].**

This particular study aimed to investigate the sustained efficacy and safety of Omalizumab in patients with severe bronchial asthma after a decade of treatment. By meticulously examining patient outcomes over this extended period, this research sought to provide valuable insights into the long-term impact of Omalizumab therapy in this challenging patient population.

Patients and Methods

This study included 74 adults (33 males, 41 females) with severe asthma attending to The Chest Department at King Fahd Hospital, Madina; KSA, who were eligible for treatment with Omalizumab. The study began in June 2016 and continued until August 2024. All participants met the Global Initiative for Asthma (GINA) guidelines for severe asthma diagnosis and treatment.

In addition to severe asthma, many participants also had other allergic conditions.

- 44.6% had severe asthma only.
- 55.4% had severe asthma and allergic rhinitis.
- 17.5% had severe asthma, allergic rhinitis, and atopic dermatitis.
- 9.4% had severe asthma, allergic rhinitis, atopic dermatitis, and allergic conjunctivitis.

This study aimed to evaluate the long-term safety and efficacy of Omalizumab treatment in this group of patients with severe asthma and potentially other allergic conditions.

All participants underwent a comprehensive evaluation, including:

Medical history:

A detailed review of respiratory symptoms, such as cough, shortness of breath, wheezing, and chest tightness, with an emphasis on their variability over time and intensity.

Physical examination:

Measurement of height, weight, and body mass index (BMI).

Laboratory tests:

Complete blood count, including eosinophil count, and measurement of total immunoglobulin E (IgE) levels.

Pulmonary function tests:

Spirometry using a Sensor Medics Vmax 229 system to assess lung function parameters including forced expiratory volume in one second (FEV1), forced vital capacity (FVC), FEV1/FVC ratio, peak expiratory flow (PEF), and maximal voluntary ventilation (MVV). Reversibility testing was performed to confirm the presence of variable airflow limitation.

Asthma control assessment:

The Asthma Control Test (ACT), a self-administered questionnaire assessing five key aspects of asthma control (respiratory symptoms, daily activities, rescue medication use, and overall asthma impact), was used to evaluate the level of asthma control in each participant. An ACT score greater than 19 indicates well-controlled asthma.

Inclusion criteria:

Adults (over 18 years of age) diagnosed with severe bronchial asthma according to the Global Initiative for Asthma (GINA) guidelines. Eligibility for treatment with Omalizumab based on established criteria.

Exclusion criteria:

Patients who declined to participate in the research study and did not consent to the use of their medical data.

Omalizumab treatment:

Omalizumab dosage was determined individually based on each patient's IgE level and body weight using the established Omalizumab drug chart for adults (CADTH/Xolair 2017). Doses ranged from 300mg to 1200mg administered subcutaneously every month or every other week, as follows:

- 4 patients received 300mg monthly.
- 4 patients received 300mg every other week.
- 11 patients received 450mg monthly.
- 28 patients received 450mg every other week.
- 21 patients received 600mg monthly.
- 6 patients received 600mg every other week.

Omalizumab injections were administered subcutaneously in a one-day care unit by trained nurses under the supervision of a physician. Patients were closely monitored for 2 hours following each injection for any immediate side effects.

Follow-up:

Patients were scheduled for regular follow-up visits at the outpatient chest clinic every two months. They were also instructed to contact the clinic immediately to report any suspected side effects related to Omalizumab treatment.

Assessments:

Patient assessments were conducted at 6, 12, 48, and 90 months following the initiation of Omalizumab therapy. These assessments included:

- Medication Use:
  - ° Oral corticosteroid use
  - ° Inhaled corticosteroid dosage
  - ° Use of tiotropium bromide (anticholinergic)
- Asthma Control:
  - ° Asthma Control Test (ACT) score to assess asthma control levels.
- Exacerbations:
  - ° Number of acute asthma exacerbations.
  - ° Number of hospital admissions related to asthma.
- Laboratory Tests:
  - ° Serum IgE levels.
- Pulmonary Function Tests:
  - ° Forced expiratory volume in one second (FEV1).
  - ° Forced vital capacity (FVC).
  - ° FEV1/FVC ratio.
  - º Peak expiratory flow (PEF).

Side effect monitoring: Close monitoring for any side effects related to Omalizumab treatment.

Ethical considerations: The privacy, rights, and well-being of all participants were strictly protected. Informed consent was obtained from each participant prior to study enrollment, ensuring their understanding and agreement to participate.

Data analysis:

Data were analyzed using SPSS version 25 for Windows. Descriptive statistics were used to summarize data, including mean and standard deviation for normally distributed variables and median and interquartile range (IQR) for non-normally distributed variables. A 95% confidence intervals were calculated for each of the three primary outcome endpoints. Statistical significance was determined using a *p*-value threshold of less than 0.05.

Results

This study included 74 patients with severe bronchial asthma who received Omalizumab treatment between June 1, 2016, and August 30, 2024. The cohort comprised 33 males and 41 females with a mean age of 37.2 ± 4 years. Regarding smoking habits, 29.7% were non-smokers, 12.1% were ex-smokers, and 8.9%, 21.7%, and 17.6% were classified as heavy, moderate, and mild smokers, respectively. Table (1).

Table (1): Demography and some parameters of the patients.

No.	Parameter	No and %
1	**Age**	
2	*Sex:*	
	Male	33 (44.5%)
	Female	41 (55.5%)
3	Body weight	66.8±5
4	**Hight**	159.9±7
5	Body mass index (BMI)	25.4±10
	Smoking H:	
	Nonsmoker	22 (29.7%)
	Ex-smoker	9 (12.1%)
	Heavy smoker	14 (18.9%)
	Moderate smoker	16 (21.7%)
	Mild smoker	13 (17.6%)
6	*Comorbid:*	
	Allergic rhinitis:	41 (55.4%)
	Sinusitis	23 (31%)
	Chronic Atopic dermatitis	13 (17.5%)
	Chronic allergic Conjunctivitis	7 (9.4%)
	Obesity	22 (29.7%)
	Hypertension	37 (50%)
	Diabetes mellitus	12 (16.2%)
	Gastro esophageal reflux disease. (GERD)	5 (6.7%)

Table (1): There were 33 male patients while 41 were female. The mean and SD of the body weight of the patients were (66.8±5). Regarding smoking habits: 29.7% were nonsmokers, 12.1% were ex-smokers and 8.9%, 21.7%, and 17.6% were heavy, moderate and mild smokers respectively. Most common comorbidity was allergic rhinitis and hypertension (from 55% to 50%), while GERD and allergic Chronic allergic Conjunctivitis were about 10.5%.

Allergic rhinitis and hypertension were the most common comorbidities, affecting 55% and 50% of patients, respectively. Other comorbidities, such as gastroesophageal reflux disease (GERD) and allergic conjunctivitis, were observed in approximately 10.5% of patients. Table (1).

Significant improvements were observed in several clinical parameters following 6, 12, 48 and 90 months of Omalizumab treatment. These included reductions in the use of oral corticosteroids (OCS), inhaled corticosteroids (ICS), and tiotropium bromide. A notable decrease was also observed in the number of acute exacerbations and hospital admissions. Pulmonary function tests, including FEV1, FVC, and FEV1/FVC ratio, demonstrated significant improvements. Table (2).

The most common side effect was injection site reactions, including tenderness and local swelling, observed in approximately 70% of patients. Other less frequent side effects included headache (10.8%), nausea (5.4%), myalgia (4%), and fever (8.1%). Importantly, serious adverse events such as cancer, anaphylaxis, and myocardial infarction were not reported. Table (3).

Table (2): Some clinical parameters and pulmonary function tests before and (6, 12, 48 and 90) months after Omalizumab treatment.

Parameters	Before Omalizumab treatment	After 6 months from treatment	After 12 months from treatment	After 48 months from treatment	After 90 months from treatment	*p*-value
Use of oral steroid (OCS)	63 (85%)	6 (8%)	2 (2.7%)	–	–	<0.0001
Use of tiotropium bromide	61 (82.4%)	13 (17.5%)	3 (4%)	–	–	<0.0001
ACT test	11.2±5	22.1±7	23.4±5	23±2	24±1	<0.0001
No of acute exacerbation/last year	9.4±5	4±3	1.7±2	1.1±3	0.3±1	0.001
No of hospital admission/ last year	7.8±5	3.1±4	1.5±3	1.2±2	1.1±1	<0.001
Use of high dose of (ICS/LABA) inhaled steroid	74 (100%)	41 (55.4%)	14 (18.9%)	11 (14.8%)	7 (9.5%)	<0.000
Serum total IgE	473.5±23	598.7±11	688.7±13	301.7±12	212±11	<0.001
Pulmonary function test:						
FEV1	43.7±9	61.4±7	71.4±8	72.1±4	76.2±5	<0.001
FEV1/ FVC	52.4±11	74.8±7	78.4±4	79.1±8	80.3±9	<0.001
PEFR	56.7±9	68.7±8	73.4±7	74.1±7	78.6±8	<0.00
FVC	85.1±7	86.1±4	84.1±7	86.11±7	89.1±5	<0.001

Table (2): There was a significant improvement of some clinical parameters after (6,12,48) months from omalizumab treatment as use of (OCS, ICS, tiotropium bromide), no. of (acute exacerbation and hospital admission / last year) and pulmonary functions. While IgE was increasing in the first year of omalizumab treatment and after that was significant decrease of the IgE level.

Table (3): Long term Side effects of Omalizumab treatment.

Side effect	During 6 month	Between 6-12 months	Between 1-4 years	After 4 years
Injection site reaction:				
Tenderness	28 (37.8%)	19 (25.7%)	8 (10.8%)	9 (12%)
Swelling	24 (32.4%)	20 (27%)	14 (18.9%)	12 (12.2%)
Headache	8 (10.8%)	5 (6.7%)	3 (4%)	2 (2.7%)
Nausea	4 (5.4%)	2 (2.7%)	3 (4%)	–
Myalgia	3 (4%)	1 (1.3%)	2 (2.7%)	1 (1.3%)
Fever	6 (8.1%)	3 (4%)	3 (4%)	1 (1.3%)

Table (3): Showed some side effects of Omalizumab treatment; the most common side effect was injection site reaction as tenderness and local swelling (about 70%). While headache,Nausea, myalgia and fever were less common (about 10.8%, 5.4%,4% & 8.1% respectively). The complications were common in the first year.

No significant correlations were found between the occurrence of side effects and Omalizumab dosage, frequency of administration, smoking history, or the presence of comorbidities such as allergic rhinitis or obesity. Table (4).

Table (4): Coefficient of contingency for side effects with some parameters.

Parameter	*r*	*p*
Dose of the Omalizumab	0.26	0.12
Frequency of the Omalizumab	0.19	0.21
Smoking history:		
Non smoker	0.21	0.21
Ex-smoker	0.15	0.32
Mild smoker	0.24	0.19
Moderate smoker	0.23	0.22
Heavy smoker	0.34	0.18
Comorbid:		
Allergic rhinitis	0.28	0.54
Sinusitis	0.34	0.62
Atopic dermatitis	0.16	0.34
Conjunctivitis	0.26	0.32
Obesity	0.28	0.21
Hypertension	0.34	0.24
Diabetes mellitus	0.12	0.13
Gastro esophageal reflux disease	0.23	0.24

Table (4): There is no significant correlation between side effect of Omalizumab treatment and (dose, frequency) of the drugs, smoking history and any comorbid condition like (allergic rhinitis, obesity, etc.)..

Discussion

The treatment of severe bronchial asthma has undergone significant advancements in recent years, driven by a deeper understanding of the underlying immunological, genetic, and environmental factors. Omalizumab, a groundbreaking biologic therapy, has revolutionized the management of severe asthma since its introduction over fifteen years ago *[9]*. Numerous studies have consistently demonstrated its long-term safety and efficacy, even in complex patient populations *[10-14]*.

This study aimed to investigate the sustained efficacy and safety of Omalizumab in patients with severe bronchial asthma. The follow-up was crucial to further solidify the established safety and efficacy profile of Omalizumab and to identify any potential long-term changes in treatment response, such as the development of tolerance or the emergence of unexpected adverse effects.

The results of this study demonstrated the long-term effectiveness of Omalizumab in managing severe asthma. Notably, there was a significant reduction in the frequency of asthma exacerbations and hospital admissions, accompanied by improvements in lung function as evidenced by increased FEV1 values. Furthermore, the study observed a sustained improvement in asthma control as assessed by the Asthma Control Test (ACT) scores over the follow-up period. These finding were also observed in many studies *[7-11]*.

Previous studies have reported that insufficient adherence to Omalizumab treatment, ranging from 40% to 70%, can significantly impact treatment outcomes *[15,16]*. In contrast, this study demonstrated sustained efficacy of Omalizumab over the follow-up period, suggesting high adherence rates among the study participants. This finding is supported by previous research, such as that by Cazzola et al. (2010), which demonstrated a substantial reduction in acute exacerbations and hospitalizations within the first year of Omalizumab treatment, with a significant proportion of the reduction observed within the first six months *[17]*.

Key finding of this study was the sustained efficacy of Omalizumab during the follow-up period, with no significant decline in treatment effectiveness observed. This finding highlights the potential for long-term, sustained benefit with Omalizumab therapy in well-managed patients with severe asthma. Omalizumab has demonstrated significant efficacy in reducing corticosteroid dependence in patients with severe asthma. While this study observed a substantial reduction in oral corticosteroids (OCS) and high-dose inhaled corticosteroids (ICS) within the first year of treatment, other studies, such as Tzortzaki et al. (2012), have shown a more gradual reduction, with the maximum dose reduction occurring later in the treatment course. This variability in the timing of maximal corticosteroid reduction may be attributed to differences in patient demographics and study populations *[18]*.

Omalizumab therapy has consistently demonstrated significant improvements in pulmonary function, particularly in the first year of treatment, as evidenced by improvements in FEV1, FEV1/FVC ratio, and peak expiratory flow (PEFR) *[19]*.

This study provides strong evidence for the long-term efficacy and safety of Omalizumab in managing severe asthma. Over the follow-up period, Omalizumab treatment was associated with a significant reduction in asthma exacerbations, hospitalizations, and the need for systemic corticosteroids. These findings align with previous studies that have demonstrated improved lung health, reduced healthcare resource utilization, and a favorable safety and tolerability profile for Omalizumab in adult patients with moderate-to-severe allergic asthma for up to 9 years. Furthermore, Omalizumab treatment has been shown to have a protective effect on lung function decline, even in the presence of recurrent exacerbations. This is a crucial finding, as lung function decline is a significant concern in patients with severe asthma *[19]*.

This study provides further evidence supporting the long-term efficacy and safety of Omalizumab in the management of severe asthma. The observed improvements in lung function, reduced reliance on corticosteroids, and favorable safety profile highlight the significant clinical benefits of this therapeutic approach for this challenging patient population.

Omalizumab treatment has a significant impact on IgE levels. Initially, total IgE levels exhibit a transient increase, reaching a peak within the first year of treatment. This initial rise is attributed to the ability of Omalizumab to detach IgE from FcεRI receptors on the surface of basophils and mast cells [20]. Subsequently, total IgE levels begin to decrease due to the binding of Omalizumab to free serum IgE, effectively reducing circulating IgE concentrations [21]. Furthermore, Omalizumab inhibits IgE production by preventing IgE interaction with receptors on B-cells responsible for IgE synthesis. Additionally, it suppresses the production of IL-4, a key cytokine involved in IgE synthesis, by mast cells **[22].**

Our findings show that injection site reactions were the most common adverse effects seen, affecting about 70% of patients, while allergic rhinitis and hypertension were the most prevalent comorbidities, affecting 55% and 50% of patients, respectively. Other less common adverse effects included headache, fever, nausea, and myalgia, which had an incidence of 5% to 10%. Other comorbidities were reported by around 10.5% of patients, including gastroesophageal reflux disease (GERD) and allergic conjunctivitis. Notably, the majority of these adverse effects developed within the first year of treatment **[24].**

Importantly, local acute responses, such as injection site reactions, did not merit the discontinuation of Omalizumab therapy. Furthermore, there was no significant relationship between the incidence of side effects and Omalizumab dose or frequency, smoking history, or comorbidities such diabetes, hypertension, or obesity **[19]**. Other studies support our findings on omalizumab safety, demonstrating that Omalizumab had a favorable safety profile during the follow-up period. Even with high dosages of Omalizumab (up to 600mg biweekly) administered over a long period of time (7-10 years), no substantial side effects, such as allergy or cancer, were identified, suggesting that the dosage schedule has no effect on treatment adherence **[23].**

In conclusion, this study provides compelling evidence for the long-term efficacy and safety of Omalizumab in the management of severe asthma. The observed improvements in lung function, reduced reliance on corticosteroids, and favorable safety profile highlight the significant clinical benefits of this therapeutic approach for this challenging patient population. Omalizumab has emerged as a cornerstone therapy for severe asthma, offering sustained benefits and improving the quality of life for affected individuals.

This study has several limitations: Firstly, the lack of a control group precludes direct comparison of treatment outcomes with an untreated or differently treated group. This limitation restricts the ability to definitively attribute observed improvements solely to Omalizumab therapy. Secondly, the relatively small sample size of 74 patients may limit the generalizability of the findings and increase the potential for random variability in the results.

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Authors' contributions:

WA: Conceptualization; data curation; formal analysis; validation and writing original draft; investigation and methodology; review and editing.

All authors have read and approved the final version of the manuscript.

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أومالیزوماب کعلاج طویل الأمد للمرضی الذین یعانون من الربو الشعبی الشدید. هل هو آمن؟ دراسة لمدة سبع سنوات

یعد مضاد IgE (أومالیزوماب) أحد العلاجات المستهدفة للربو الشعبی الشدید. ولا تزال سلامته الحقیقیة قید التدقیق والدراسة.

کان الهدف من هذه الدراسة هو تقییم فعالیة وسلامة أومالیزوماب المستمر کعلاج اضافی طویل الأمد للربو الشعبی المزمن الشدید.

قامت هذه الدراسة بتقییم سلامة وفعالیة أومالیزوماب علی المدی الطویل فی ٧٤ مریضًا یعانون من الربو الشعبی الشدید والمترددین علی قسم الصدر بمستشفی الملك فهد بالمدینة المنورة؛ المملکة العربیة السعودیة.

وقد أظهرت النتائج علی مدی ٧–١٠ سنوات من المتابعة أنلأومالیزوماب فاعلیة کبیرة فی النتائج السریریة والاکلینیکیة، حیث قدانخفض استخدام الکورتیزون الجهازی (عن طریق الفم أو الحقن) بشکل کبیر، وانخفض ایضاً استخدام بروميد تیوتروبیوم، وانخفض معدل حدوث الأزمات الربویة الحادة بشکل ملحوظ وبالتالی انخفضت نسبة التنویم بالمستشفی لهولاء المرضی.

وقد أظهرت اختبارات وظائف الرئة (FVC، PEFR/FEV1 ،FEV1) تحسنًا کبیرًا.

فی حین لوحظت آثار جانبیة خفیفة مثل ردود الفعل فی موقع الحقن، والصداع، والغثیان، لوحظت فی المقام الأول فی السنة الأولی من بدأ العلاج، ولم یتم الإبلاغ عن أی أعراض جانبیة خطیرة مثل السرطان، الحساسیة المفرطة، أو احتشاء عضلة القلب.

تشیر هذه النتائج إلی أن علاج الأومالیزوماب علی المدی الطویل فی حالات الربو الشعبی المزمن الشدید فعال وجید التحمل، مع آثار جانبیة قلیلة جدا.