

Available online on 15.12.2022 at <http://jddtonline.info>

Journal of Drug Delivery and Therapeutics

Open Access to Pharmaceutical and Medical Research

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Research Article

A Pilot Study of Omalizumab to Treat Severe Allergic Asthma in South Indian Population

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Article Info:



Article History:

Received 09 Oct 2022
Reviewed 13 Nov 2022
Accepted 29 Nov 2022
Published 15 Dec 2022

Cite this article as:

Harshidha D, Dinesh Kumar G, Ektha PK, Dinesh T, Divya T, A Pilot Study of Omalizumab to Treat Severe Allergic Asthma in South Indian Population, Journal of Drug Delivery and Therapeutics. 2022; 12(6-s):21-23

DOI: <http://dx.doi.org/10.22270/jddt.v12i6-s.5855>

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Abstract

Background: Asthma is a respiratory disease that affects your lungs. In asthma, airways of the lungs constrict due to swelling and accumulation of mucus. Newer remedies known as targeted therapies have evolved as a result of advancements in medical research, greatly relieving these patients. The biologics used in the severe allergic asthma is Omalizumab.

Purpose: Demonstrating the clinical efficacy of Omalizumab in severe allergic asthma by reducing exacerbation rates and increasing quality of life.

Methods: A single-arm prospective pilot study of omalizumab in severe allergic asthma was conducted in a tertiary care hospital for the duration of one year with the help of Asthma Quality of Life Questionnaire (AQLQ).

Results and discussions: On an initial dose of omalizumab of 150 mg in 2 vials subcutaneously every month for 6 months, among our study population, 45% of the patients had their symptoms improve more than they had with prior medications. Results show that the patient's overall score has improved by nearly 50%. This shows that omalizumab improves the quality of life of severe asthmatic patients.

Conclusion: Patients treated with omalizumab have improved their clinical conditions and quality of life, and it can prevent exacerbations by controlling the severity of the condition.

Keywords: AQLQ, Allergic asthma, Exacerbation, IgE, Omalizumab.

INTRODUCTION:

Asthma is a respiratory disease that affects your lungs ¹. Asthma prevalence varies greatly between nations, regions, and even within nations with diverse geographies and socioeconomic strata ^{2,3}. According to the Indian Study on Epidemiology of Asthma, Respiratory Symptoms, and Chronic Bronchitis in Adults (INSEARCH), there are 17.23 million asthma sufferers in the country, with a prevalence rate of 2.05% ⁴. According to the most current Global Burden of Disease report (GBD, 1990-2019), 34.3 million Indians are predicted to have asthma, which represents 13.09% of the global burden. In addition, it stated that asthma was to account for 13.2 thousand fatalities in India ⁵. In Indians, asthma accounted for 27.9% of DALYs (disability-adjusted life years). Overall, compared to the worldwide burden of asthma, India has three times the mortality rate and more than twice the DALYs ⁵. In asthma, airways of the lungs constrict due to swelling and accumulation of mucus ¹. It results in recurrent episodes of coughing at night or in the early morning, as well as dyspnea, chest tightness, and wheezing. Taking medication and avoiding the triggers in your surroundings that might manage your asthma ⁶. Allergic asthma is classically diagnosed with allergenic triggering, complete blood count, sputum test, positive skin prick test, and elevated Immunoglobulin E(IgE), which is a biomarker ⁷. Newer remedies known as targeted therapies have evolved as a result of advancements in medical research, greatly relieving these

patients. These specialized treatments stop particular proteins from activating (IgE or interleukin 5). These medications are Biologics or respiratory biologics ¹. The biologics used in the severe allergic asthma is Omalizumab. It is a monoclonal, recombinant, anti-human immunoglobulin E antibody and was created by humanizing a murine monoclonal antibody, from which it was derived ⁸. Omalizumab was formulated to bind to free IgE with great affinity and inhibit allergen-specific IgE from adhering to FcεRI. They do not directly stimulate mast cells or basophils because it does not bind to cell surface IgE. The number of FcεRI receptors on mast cells, basophils, and antigen presenting cells decreases when free IgE levels decline ⁹.

METHODS:

A single-arm prospective pilot study of omalizumab in severe allergic asthma was conducted in a tertiary care hospital. Face-to-face interviews were done using the AQLQ questionnaire. The AQLQ has 32 questions divided into four areas (symptoms, activity limitation, emotional function, and environmental stimuli). Patients are asked to recollect on their past two weeks and reply to each of the 32 questions on a 7-point scale (7 = not impaired at all, and 1 = seriously impaired). The overall AQLQ score is the average of all 32 replies, whereas the individual domain scores are the means of the questions in that domain. Thus, AQLQ scores range from 1 to 7, with higher scores suggesting a better quality of life.

Patient Selection:

- Patients with known case of wheezing.
- Patients who had an exposure to dust.
- Patients with elevated IgE level.
- Patient with normal Absolute Eosinophil Count (AEC).

Data Collection:

The study was conducted from November 2021 to November 2022. All the patients were sent to the interviewers by their pulmonary department physicians at a tertiary care hospital in Southern India. Before recommending patients to the interviewers, the physicians described the objective of the study to them. If the patients refused to participate in the interview, the doctor would respect their decision.

Before conducting the interview, all participants provided written informed Consent. Patients who did not know what their diagnosis were not referred to us by their doctor and hence were not enrolled for this study interview.

Statistics:

Using descriptive statistical techniques, information on sociodemographic variables, medical history, and responses to questions about symptoms, activity limitation, emotional function, and environmental stimuli were condensed. Means, frequencies (n) and percentages (%) were used to display the results.

RESULTS AND DISCUSSION:**Treatment period:**

Mean omalizumab duration in our study was 24 weeks with a recommended dosing scheme according to total IgE level and weight. The Omalizumab was generally prescribed 150 mg in 2 vials subcutaneously per month. All patients were non-smokers and had no other lung pathology present at the same time.

Outcomes:

In our study, we included 9 patients receiving omalizumab injection for severe allergic asthma. Demographics of these patients were included in (Table -1). Among our study population, 56% were male and 44% were female patients. 33% were under the age 30. All the patients completed six doses of omalizumab.

The AQLQ questionnaire was divided into 4 domains: symptoms, activity limitation, emotional function, and environmental stimuli. The symptom domain includes 12 questions; activity limitation includes 11 questions; emotional function includes 5 questions; and environmental stimuli includes 4 questions.

The AQLQ questionnaire was taken from the patients prior to the treatment, which is tabulated in table-2. Patient experienced acute exacerbations, breathing difficulty, frequent hospitalization, and a lag in their daily activities prior to the treatment. On initiation of omalizumab, many patients experienced the treatment's clinical improvements within a few doses, and there were no adverse effects noted. On completion of all doses 45% patients felt symptomatic relief.

The AQLQ questionnaire was repeated, and the results are shown in Table 3. Results show that the patient's overall score has improved by nearly 50%, which was greater than the study conducted by Hanania NA et al ¹⁰. This shows that omalizumab improves the quality of life of severe asthmatic patients.

Treatment with omalizumab was associated to significantly lower mean daily doses of OCS, asthma flare-ups, inpatient hospitalizations, outpatient visits (apart from those for omalizumab administration), hospital bed days, and sick days from work/school. In our study, the asthma exacerbation rate decreased by 60% after using omalizumab, which was greater than the study conducted by Barnes N et al ¹¹.

Table 1 Demographics

Patient	Age	Gender	IgE level before treatment IU/ml	No of doses taken
1	41	Male	612	6
2	24	Male	676	6
3	50	Male	1026	6
4	32	Female	858	6
5	11	Female	750	6
6	35	Male	742	6
7	35	Female	792	6
8	11	Male	1833	6
9	52	Female	715	6

Table 2: AQLQ Scores Prior Omalizumab Administration

Patient	Activity Limitation	Symptoms	Emotional Function	Environmental Stimuli	Overall Quality
1	3.18	3.25	3.00	2.50	11.93
2	3.27	3.33	2.60	2.25	11.45
3	2.72	3.16	3.40	3.00	12.28
4	3.45	3.50	3.20	2.75	12.90
5	3.01	3.00	2.80	2.00	10.84
6	3.09	2.91	2.60	2.50	11.10
7	2.63	2.66	2.00	1.75	09.04
8	2.81	2.58	2.40	2.00	09.79
9	2.54	2.50	2.20	1.50	08.74

Table 3: AQLQ Scores after Omalizumab Treatment

Patient	Activity Limitation	Symptoms	Emotional Function	Environmental Stimuli	Overall Quality
1	5.45	5.66	5.8	5.75	22.66
2	5.63	6.00	6.0	6.25	23.88
3	4.36	5.16	5.7	5.50	20.72
4	4.81	5.33	5.6	5.00	20.03
5	4.72	5.50	6.0	5.25	21.47
6	4.45	5.25	5.2	5.00	19.90
7	4.36	5.08	5.0	4.75	19.19
8	4.54	4.91	4.8	4.50	18.75
9	4.27	4.83	4.4	4.50	18.00

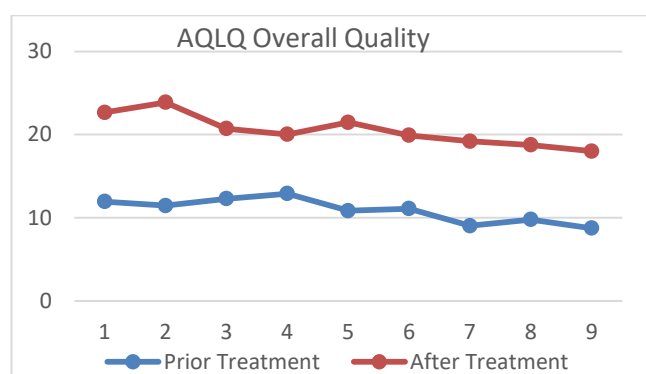


Figure 1 AQLQ Overall Quality

CONCLUSION:

Asthma that is caused by allergens like pollen, pets, and dust mites is known as allergic (or atopic) asthma. Patients with elevated IgE levels are more likely to begin receiving biologics, which reduce the need for frequent hospitalization. Patients treated with omalizumab have improved their clinical conditions and quality of life, and it can prevent exacerbations by controlling the severity of the condition. Since asthma can only be managed, it is necessary to avoid triggers and have a healthy lifestyle.

PATIENT'S CONSENT

Written informed consent was obtained from the patients for the publication of this study.

ACKNOWLEDGMENT

Firstly, we would like to thank the Pulmonology department for guiding us throughout the study period. We would like to thank the patients and their family for their cooperation and full support.

AUTHORS CONTRIBUTION

All authors equally contributed.

AUTHORS FUNDING

This study received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

ETHICAL APPROVAL

Not applicable.

CONFLICT OF INTEREST

The authors have no conflicts of interest.

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