https://skinallergyjournal.com/

Indian Journal of Skin Allergy

Article in Press

Letter to Editor

Long-term control of chronic spontaneous urticaria with omalizumab: A case of refractory urticaria managed for 8 years

Abhilasha Negi[1], Prashant Verma[1]

Department of Dermatology, Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi, India.

Dear Editor,

Urticaria comprises a group of disorders characterized by wheals, angioedema, or both, and usually an episode lasts for <24 hours. Chronic spontaneous urticaria (CSU) is defined as recurring urticaria on most days of the week and persisting beyond 6 weeks. CSU is a potentially debilitating disorder that can significantly impact patients, as seen in our case, due to persistent pruritus, recurrent episodes, and sleep deprivation. The currently recommended treatments are in the order of first-line treatment (antihistamine), second-line treatment (omalizumab), and third-line treatment (cyclosporine). First-line therapy with antihistamines may not result in satisfactory control in 5–50% of patients with CSU.

Hereby, we present a case of a 55-year-old woman who presented to our outpatient department 8 years ago with CSU. Her review of systems was unremarkable, and she tested negative for anti-thyroid peroxidase antibodies. Serum immunoglobulin E (IgE) levels were found to be elevated (210 IU/mL). Initially, she was started on levocetirizine 5 mg orally once daily, but there was no significant improvement. The dose was subsequently increased to 20 mg daily, resulting in minimal response. Other antihistamines, including hydroxyzine, loratadine, fexofenadine, and bilastine, were introduced, but she only experienced partial relief. Further therapies, including dapsone, sulfasalazine, hydroxychloroquine, cyclosporine A, and tranexamic acid, were also administered without success.

At this stage, her dermatology life quality index (DLQI) score was 20, indicating a very large impact on quality of life. Subsequently, omalizumab was started at a dose of 300 mg subcutaneously once a month, alongside continued hydroxyzine 25 mg nightly. This regimen led to a complete resolution of the wheal and pruritus. Her DLQI score improved to 2 within the initial months of omalizumab therapy, reflecting rapid and near-complete resolution of disease impact, though continued monthly dosing remained essential for sustained control. For the past 8 years, she has remained on the same regimen, maintaining complete control of her urticaria without any interruptions, even during the COVID-19 pandemic. Any delay in omalizumab administration results in a flare of symptoms, but there have been no reported side effects during the entire course of treatment.

Our patient had failed to respond to various first- and second-generation antihistamines, as well as immunomodulators, including cyclosporine, hydroxychloroquine, tranexamic acid, and methotrexate. Omalizumab, a humanized anti-IgE monoclonal antibody, is now considered second-line therapy in cases of CSU that are refractory to treatment with maximum doses of second-generation antihistamines for 2–4 weeks, or even earlier if symptoms are severe. Omalizumab selectively binds to the C3 domain of the IgE heavy chain, where IgE binds to high-affinity IgE receptor (FχεRI), inhibiting the interaction between anti-IgE and IgE-sensitized mast cells, thereby improving CSU symptoms. Omalizumab is effective in 50–70% of patients with CSU.[1,2] Serum IgE levels are the most reliable predictor of treatment response to omalizumab in CSU. Non-responders usually have a baseline IgE level of <20 IU/mL.[3] It may take 4 weeks to as long as 24 weeks for a complete response to the treatment.[4] Long-term treatment of CSU with omalizumab is still debatable, and tapering attempts, decreasing dosage, prolonging dose intervals, and individualized discontinuations have been attempted. On the other hand, symptom remission was observed in approximately 50% of patients over up to 4 years following either a single omalizumab course or 2 consecutive 24-week courses.[5] In a retrospective analysis of 80 patients, complete response was achieved in 86.3%, while late response was observed in 27.5% of the patients. Adverse events were reported in 15% during treatment.[6]

In another retrospective analysis of 41 patients, omalizumab was administered for an average of 41.93 months

***Corresponding author:** Prashant Verma, Department of Dermatology, Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi, India. drprashantderma@gmail.com

Received: 21 February 2025 **Accepted:** 26 April 2025 **EPub Ahead of Print:** 28 May 2025 **Published:** XXXXXX **DOI:** 10.25259/IJSA_13_2025

(mean 31.68 injections/patient). There was no loss of efficacy of omalizumab. In 16 patients (39%), omalizumab had been restarted after a mean discontinuation time of 24 weeks. Mild and transient adverse effects were reported in five patients (12.2%).[7]

In an observational open-label study of 52 weeks duration, the mean duration of the observation period was 330.3 ± 86.2 days. Relapse was seen in 65 of the patients, and serious adverse events were reported in 11.8% of patients. Urticaria (1.8%) and eczema (1.1%) were the most common adverse events. About 92.8% of patients improved in the Physician's Global Impression of Change. About 81.3%, 75.0%, and 95.1% of patients achieved urticaria control test (UCT) score ≥ 12, weekly urticaria activity score (UAS7) ≤ 6, and dermatology life quality index (DLQI) ≤ 5 up to week 52, respectively.[8]

In our case, any attempt to increase the time interval between omalizumab doses, even by a few days, resulted in a recurrence of urticaria. Consequently, a supervised tapering schedule could not be attempted. The patient has been symptom-free on omalizumab in the standard dose of 300 mg/month. A meta-analysis reported an adverse event rate of 4% with omalizumab in CSU.[9] Long-term treatment with omalizumab of up to 9 years was found to be remarkably safe and well tolerated in a real-life setting in bronchial asthma.[10]

To the best of our knowledge, this case represents the longest reported treatment of CSU with omalizumab, extending over 8 years. It underscores the importance of individualized treatment duration in patients with CSU and highlights the need for further real-world studies to better define the long-term safety, efficacy, and optimal discontinuation strategies for omalizumab therapy.

Ethical approval: The Institutional Review Board approval is not required.

Declaration of patient consent: The authors certify that they have obtained all appropriate patient consent.

Financial support and sponsorship: Nil.

Conflicts of interest: There are no conflicts of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation: The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

REFERENCES

1. Kaplan AP, Joseph K, Maykut RJ, Geba GP, Zeldin RK. Treatment of chronic autoimmune urticaria with omalizumab. J Allergy Clin Immunol 2008;122:569-73.
2. Saini S, Rosen KE, Hsieh HJ, Wong DA, Conner E, Kaplan A, *et al*. A randomized, placebo-controlled, dose-ranging study of single-dose omalizumab in patients with H1-antihistamine-refractory chronic idiopathic urticaria. J Allergy Clin Immunol 2011;128:567-73.e1.
3. Ertas R, Ozyurt K, Atasoy M, Hawro T, Maurer M. The clinical response to omalizumab in chronic spontaneous urticaria patients is linked to and predicted by IgE levels and their change. Allergy 2018;73:705-12.
4. Kaplan A, Ferrer M, Bernstein JA, Antonova E, Trzaskoma B, Raimundo K, *et al*. Timing and duration of omalizumab response in patients with chronic idiopathic/spontaneous urticaria. J Allergy Clin Immunol 2016;137:474-81.
5. Di Bona D, Nettis E, Bilancia M, Ridolo E, Minenna E, Nizi MC, *et al*. Duration of chronic spontaneous urticaria remission after omalizumab discontinuation: A long-term observational study. J Allergy Clin Immunol Pract 2021;9:2482-5.e2.
6. Apalla Z, Sidiropoulos T, Kampouropoulou E, Papageorgiou M, Lallas A, Lazaridou E, *et al*. Real-life, long-term data on efficacy, safety, response and discontinuation patterns of omalizumab in a Greek population with chronic spontaneous urticaria. Eur J Dermatol 2020;30:716-22.
7. Ornek S, Kocaturk E. A patient-oriented approach to long-term use of omalizumab in chronic spontaneous urticaria. Cutan Ocul Toxicol 2021;40:305-11.
8. Hide M, Fukunaga A, Suzuki T, Nakamura N, Kimura M, Sasajima T, *et al*. Real-world safety and effectiveness of omalizumab in Japanese patients with chronic spontaneous urticaria: A post-marketing surveillance study. Allergol Int 2023;72:286-96.
9. Tharp MD, Bernstein JA, Kavati A, Ortiz B, MacDonald K, Denhaerynck K, *et al*. Benefits and harms of omalizumab treatment in adolescent and adult patients with chronic idiopathic (spontaneous) urticaria: A meta-analysis of "real-world" evidence. JAMA Dermatol 2019;155:29-38.
10. Di Bona D, Fiorino I, Taurino M, Frisenda F, Minenna E, Pasculli C, *et al*. Long-term "real-life" safety of omalizumab in patients with severe uncontrolled asthma: A nine-year study. Respir Med 2017;130:55-60.

How to cite this article: Negi A, Verma P. Long-term control of chronic spontaneous urticaria with omalizumab: A case of refractory urticaria managed for 8 years. Indian J Skin Allergy. doi: 10.25259/IJSA_13_2025