The Use of High-Dose Omalizumab in the Treatment of Resistant Chronic Urticaria: A Case Series

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Dear Editor,

The approved dose of omalizumab in the treatment of chronic spontaneous urticaria is 150 mg or 300 mg as a subcutaneous injection every 4 weeks (300 mg in Europe, 150 mg in the USA).[1] Flexible treatment regimens, such as narrowing the dose interval or increasing the dose according to the patient's symptoms, are likely to provide better symptom control.[2,3] In this letter, we would like to share our clinical experience by presenting a case series using 450 mg and 600 mg doses in patients with chronic urticaria refractory to omalizumab 300 mg. Patient information, treatment initiationtime and laboratory tests are summarized in Tables 1 and 2.

Our first case was a 58-year-old male patient treated with omalizumab 300 mg for 7 months. There was no adequate clinical response, and his attacks became severe. Three steroid injections were needed in 1 month. After 3 doses of 450 mg omalizumab, he is being followed up without attacks.

Our second case was a 38-year-old woman who had an angioedema attack 3 months after receiving omalizumab 300 mg. She had recurrent angioedema attacks and was investigated for hereditary angioedema. The C1 inhibitor level was normal. She was then switched to omalizumab 450 mg and has been on treatment for 2 months and is being followed up without urticaria and angioedema attacks.

Our third case was a 47-year-old woman whose attacks were controlled with omalizumab 300 mg for 6 months. It was administered every 6 weeks. When urticaria attacks increased, it was administered once a month. In the 10th month of treatment, it was increased to 450 mg when the attacks became severe. When there was no urticaria attack with 450 mg for 6 months, it was switched to 300 mg. Afterwards, she had a severe attack and needed a systemic steroid. She was switched back to omalizumab 450 mg and has been on treatment for 9 months without an urticaria attack.

Our fourth case was a 51-year-old woman who experienced an increase in attacks after 8 months on omalizumab 300 mg. Her dose was increased to 450 mg, and the attacks subsided after one month. The patient has been on treatment for 4 months without attacks.

Our fifth case was a 37-year-old woman. When 300 mg of omalizumab failed to suppress her attacks, she was switched to 450 mg. Despite this, urticaria and angioedema attacks continued and omalizumab 450 mg was continued. Methotrexate (15 mg/week) was added to the treatment plan. Our patient, who received 6 doses of omalizumab 450 mg and continued methotrexate treatment at a dose of 15 mg/week for 3 months, is being followed up without attacks.

Our sixth case is a 60-year-old woman. She was treated with 300 mg of omalizumab for 7 months. When urticaria attacks became severe, the dose of omalizumab was increased to 600 mg. She was followed up for 2 months and her attacks regressed. No side effects developed.

Our seventh case is a 36-year-old woman with a history of atopic dermatitis. She developed chronic urticaria. When no response was obtained with antihistamines, she was treated with 3 doses of 300 mg omalizumab. Her attacks were unresponsive, and she experienced an angioedema attack. Omalizumab was increased to 450 mg and treatment continued for 4 months. Urticaria attacks decreased, but atopic dermatitis lesions exacerbated, so dupilumab treatment was initiated. She has been treated with dupilumab for 2 months. Urticaria attacks and eczematous lesions have regressed.

In patients receiving a 300 mg/month dose of omalizumab without adequate clinical response, increasing the dose to 450 mg may control the attacks. Salman et al[4] reported the efficacy and safety of omalizumab 450 mg in a retrospective cohort study including 72 patients treated with

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Table 1. Demographic Characteristics of the Patients and the Transition Periods to Omalizumab 300 mg/month Treatment after the Onset of Urticaria Attacks. Patients Who did not Respond to 300 mg Omalizumab Treatment were Switched to the 450 mg Dose without Interruption

Patient	Age/Gender	Omalizumab 300 mg Starting Time	Omalizumab 300 mg Dose Count	Omalizumab 450 mg Dose Count
1	58/M	18 month	7	5
2	38/F	6 month	4	2
3	47/F	6 month	10	9
4	51/F	4 month	8	4
5	37/F	6 month	5	6[a]
6	60/F	6 month	7	2
7[b]	36/F	unknown	6	6

[a]Methotrexate 15 mg/week was added to the treatment of the patient who did not achieve a sufficient clinical response with 450 mg omalizumab for 3 months, and the attacks were suppressed.
[b]The patient also has atopic dermatitis.

Table 2. Table Indicating the Patients' Total IgE, Eosinophil, Thyroid Function Test, Thyroid Autoantibodies, and History of Angioedema

Patient	Total IgE (IU/mL)	Eosinophil (10^3/μL)	TSH (μIU/mL)	Anti-tpo/anti-thyroglobulin	History of Angioedema
1	707	0.13	2.94	negative	+
2	182	0.9	1.63	negative	+
3	159	0.8	2.08	negative	–
4	343	1.16	5.83	negative	–
5	<10	0.32	1.8	Positive[(a)]	+
6	77	0.1	1.01	unknown	–
7	1206	0.4	1.72	unknown	+

IgE, Immunoglobulin E; TSH, thyroid-stimulating hormone.
[a]The patient with positive anti-TPO has normal thyroid function tests and is clinically asymptomatic, being followed up without treatment.

omalizumab 300 mg and 450 mg. In our case series, 6 patients had a clinically significant response to omalizumab 450 mg, and 1 patient to omalizumab 600 mg. One patient required the addition of methotrexate at a dose of 15 mg/week. Another patient was switched to dupilumab treatment due to concomitant atopic dermatitis. 450 mg of omalizumab was used safely in all 6 patients and no side effects were observed. At the 600 mg dose, no adverse effects were detected in our patient. Written informed consent was obtained from patients who participated in this study.

In conclusion, the use of omalizumab in a flexible treatment regimen for patients unresponsive to conventional doses shows clinically significant responses. We would like to present our case series demonstrating that increasing the dose or adjusting the dose intervals according to the frequency of attacks is effective in controlling the attacks.

Data Availability Statement: The data that support the findings of this study are available on request from the corresponding author.

Informed Consent: Written informed consent was obtained from patients who participated in this study.

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