Omalizumab in chronic spontaneous urticaria refractory to conventional therapy: an Italian retrospective clinical analysis with suggestions for long-term maintenance strategies

Mandel Victor Desmond, MD,[1] Guanti Mario Bruno, MD,[1] Liberati Serena, MD,[1] Demonte Antongiulio, MD,[1] Pellacani Giovanni, MD,[1] Pepe Patrizia, MD,[1]

[1]Dermatology Unit; Surgical, Medical and Dental Department of Morphological Sciences related to Transplant, Oncology and Regenerative Medicine; University of Modena and Reggio Emilia, Modena, Italy.

Introduction: Omalizumab is indicated for the treatment of patients affected by chronic spontaneous urticaria (CSU) refractory to antihistamines. The aim of this study was to assess the efficacy, safety and recurrence of symptoms in a real life experience of omalizumab as an add-on therapy for H1-antihistamine refractory CSU patients (refractory CSU).

Material and Methods: A retrospective review of the clinical record of all refractory CSU treated with omalizumab at our Dermatology Centre from June 2014 to April 2017 was performed. Patients previously treated with second-generation antihistamines at a four-fold increased dose without clinical responses at 4 weeks of treatment were selected. Omalizumab was administered at a single dosage of 300 mg every 4 weeks for 6 months. Disease severity was assessed using the 7-day Urticaria Activity Score (UAS7) index.

Results: Eighteen patients (14 females; mean age 51 years, range 25-74) were enrolled. Mean UAS7 at baseline was 27.3 (range 15-38). Symptoms improved in all patients at 4 weeks (UAS7 = 16.1, range 0-36). Treatment was completed in 17 patients (94.4%), and among these, a complete response (UAS7 = 0) was registered in 10 patients (58.8%). Adverse events included thrombocytopenia in 1 patient (5.6%) at 16 weeks; therapy was suspended at 21 weeks and the complication was resolved, resulting in a freedom from major adverse events of 94.4%. Symptom recurrence occurred in 3 patients (17.6%) at 4, 5 and 7 months from the end of the primary therapy. Retreatment with omalizumab was successful without any adverse effects. Mean follow-up was 9.5 months (range 1-28).

Discussion: Add-on omalizumab therapy for refractory CSU in a real life setting seems to be effective and safe with a relatively low incidence of symptom recurrence. Further research should investigate personalized omalizumab treatment dosages and administration intervals, and the identification of biomarkers for future treatment algorithms.