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Riccardo Asero

To cite this article: Riccardo Asero (2018) Omalizumab treatment in patients with severe chronic spontaneous urticaria: consideration from real-life experience in Italy, Journal of Dermatological Treatment, 29:sup3, 1-2, DOI: [10.1080/09546634.2018.1557886](https://doi.org/10.1080/09546634.2018.1557886)

To link to this article: <https://doi.org/10.1080/09546634.2018.1557886>



Accepted author version posted online: 07 Dec 2018.
Published online: 03 Jan 2019.



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EDITORIAL

Omalizumab treatment in patients with severe chronic spontaneous urticaria: consideration from real-life experience in Italy

Chronic urticaria is a clinical condition characterized by spontaneous or inducible recurrent wheals, frequently associated with angioedema, occurring for more than 6 weeks, as acknowledged by current guidelines (1). Lesions of chronic spontaneous urticaria (CSU) appear unpredictably, are frequently present most days of the week, can occur on virtually any part of the body, and are associated with angioedema (but not laryngeal oedema) in 40% of patients (2). Antihistamines remain the initial step of the therapy and approximately 50% of patients respond and do not require further treatment. Second-generation antihistamines are effective and carry fewer side effects, such as sedation and mucosal dryness, compared to first-generation drugs. After resolution induced by effective treatment, CSU relapse often occurs within 1–3 months, and most patients can be safely re-treated. Nevertheless, approximately 50% of patients are unresponsive to antihistamines and need an add-on therapy (2). Current guidelines suggest the use of corticosteroids as possible second-line, add-on drugs during exacerbations. Long-lasting treatment with corticosteroids may induce well-known adverse events such as psychological effects, fluid retention, glaucoma, hyperglycaemia, immune suppression, and osteoporosis. Third line therapy may be needed in almost half of patients, and guidelines suggest adding omalizumab (1).

Xolair® (omalizumab; Novartis Pharmaceuticals Corp., East Hanover, NJ, USA) is an effective agent for CSU, with good tolerability profile. A placebo controlled and single-blind study demonstrated efficacy in severe, autoimmune-associated CSU (3) and three phase III trials with over 900 patients had a response rate of 60%–70%, and a complete response rate of 33.7%–44.3% (4). Effective doses were found to be 150 or 300 mg per injection independently of body weight or IgE level (5–7). Omalizumab is recommended by current guidelines for the treatment of chronic spontaneous urticaria in patients resistant to antihistamines at a dose of 300 mg/month (1).

At present, experience from daily clinical practice suggests that some issues are still to be faced for optimal use of omalizumab in patients with CSU who have inadequate response to H1-antihistamines. As an example, management of re-treatment, long-term therapy, use of omalizumab during concurrent immunomodulatory therapy, and criteria to predict response to omalizumab treatment were recently discussed in the literature (8–14). Twenty-five CSU patients treated with 300 mg/month omalizumab (median duration = 6 months) were retrospectively analysed. At the end of treatment, 15 patients were partial responders, and 8 were complete responders. After discontinuation of omalizumab therapy, 11/18 patients experienced relapse and 10 of them received retreatment with omalizumab. Half of the patients had complete response, and half had partial response (UAS = 1–4) after retreatment. No treatment related adverse events were documented (8). A retrospective study from the United States suggested that omalizumab was effective and safe in patients with refractory CU who used omalizumab for longer than 1 year (9). The XTEND-CIU study provided additional evidence on the efficacy and safety of long-

term use of omalizumab in patients with CSU. Continued omalizumab treatment prevented return of symptoms and achieved sustained control through 48 weeks of treatment. Furthermore, the percentage of patients experiencing clinical worsening during the 12 weeks after withdrawing treatment was identical in patients treated for 24 weeks before withdrawal and those treated for 48 weeks before withdrawal, suggesting the need to treat beyond 48 weeks (10). Syrigos et al. described the case of a female patient with relapsing-remitting multiple sclerosis, under treatment with interferon beta-1a, azathioprine and gabapentin, who was successfully treated with omalizumab for refractory CSU (11). Straesser and co-authors stated that low serum IgE (15.2 IU/ml) in patients with chronic urticaria correlated with significantly lower omalizumab treatment response, underlined the importance of biomarkers in predict the patient response to treatment (12). Moreover, Marzano et al. supported the hypothesis that CSU duration before omalizumab and baseline UAS7 may be clinical markers of relapse risk (13). Tharp and colleagues, analyzing available data from literature and real-life experiences, found that benefits and safety of omalizumab in the real-world treatment of CIU meet or exceed results gleaned from clinical trials, helping to inform both clinical treatment expectations and policy decision-making (14).

Accordingly, real life experience may promote a better knowledge in omalizumab use and help readers to challenging with these kinds of patients. In this supplement was reported the Italian dermatologists experiences in the effective use of omalizumab in patients affected by CSU, even in challenging situations. Malara et al. and Gatta et al. reported experience in a real life setting; the authors showed that omalizumab might be safely used in subjects resistant to antihistamines, for prolonged treatment, when corticosteroids would not be tolerated. At the same time, Grieco et al. and Maggio et al. stated efficacy of omalizumab in patients with CSU and severe comorbidity, as well as Morrone et al. Excellent tolerability was confirmed by the experience of Leonardi et al. in a 9-year old child with atopic dermatitis and chronic urticaria.

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Riccardo Asero

*Ambulatorio di Allergologia, Clinica San Carlo, Paderno Dugnano,
Milan, Italy*

 <mailto:r.asero@libero.it>