

Safety of omalizumab administration in chronic spontaneous urticaria during COVID-19 infection: a case report.

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Dr. Marisa Paulino has nothing to disclose.

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To the Editor:

COVID-19 pandemic affected millions of people worldwide since was first reported in December 2019¹. As the pandemic expanded around the world medical practice suffered substantial changes. Healthcare systems worldwide had to adapt to provide the best and safest care for patients as well as ensure the safety of medical personnel. Patients with severe allergic disease provide the major challenge for allergists². Biologicals are widely used in the management of severe allergic diseases and have long become part of our daily practice, however, SARS-CoV-2 infection risks in these patients lacks evidence². Recent reports regarding Dupilumab (anti-IL3 and IL-4) administration in infected patients with chronic rhinosinusitis with nasal polyps³ and severe atopic dermatitis^{4,5} showed no increase in risk of severe COVID-19.

Omalizumab is a monoclonal antibody targeting IgE approved for the treatment of severe asthma, chronic spontaneous urticaria (CSU)⁶. We report a case of a 45-year-old female with CSU treated with omalizumab that contracted COVID-19.

Urticaria symptoms began at 42 years-old, 1 year prior to the first appointment, initially with only symptomatic dermographism: wheeling and itching 5-10 minutes after scratching the skin or in areas of friction from clothes. After six months she had an episode of generalized maculopapular, itching lesions with individual duration of less than 24hours that worsened after sun exposure developing areas of angioedema. She recurred to her general practitioner that prescribed bilastine 20mg/day, topical corticosteroid and referred her to our urticaria Unit.

At first appointment she was medicated with bilastine 20mg/day maintaining daily wheals with a weekly urticaria activity score (UAS7) between 24-25 for the following 12 weeks. H₁-Antihistamine dosage was increased until a maximum dosage of 4/day was achieved. Skin prick tests for aeroallergens and food allergens were negative. Autologous serum skin test (ASST) was negative. Blood workup was clear. She had a positive

respiratory test for *Helicobacter pylori* that required two eradication treatments to achieve a negative result but without influence on the urticaria activity.

The patient quality of life deteriorated further as the disease progressed with an increased absenteeism from work (health care assistant), strained personal and social relationships and reduced self-esteem.

After failure of the second line of treatment (H_1 -Antihistamine 4/day), omalizumab was proposed. She started treatment in November 2019 with 300mg subcutaneously every 4 weeks at our day care unit. At first administration she was medicated with bilastine 20mg 4/day. The UAS7 was 21, urticaria control test (UCT) was 7 and Dermatology Life Quality Index (DLQI) was 7. At the fourth administration she had her CSU controlled: UAS7 0, UCT 16 and DLQI 0, and reduced the dose of bilastine 20mg to 2/day.

Due to the COVID-19 pandemic, the patient chose not to take omalizumab in March 2020, imposing an 8-week interval between administrations. At that time she reported only a slight increase in pruritus (UAS7 7). Omalizumab was resumed on April 28th. Triage was performed before administration excluding COVID-19 symptoms, fever or contact with infected individuals.

Her husband started exhibiting COVID-19 symptoms on May 3rd (fever, cough, dyspnea, diarrhea) and 1 day later she noticed anosmia and arthralgia, both were positive to SARS-CoV-2 (RT-PCR of nasopharyngeal exudate) on May 5th. CSU was controlled and she reported only a slight increase in pruritus with the need for increasing H_1 -Antihistamine dosage from 2 to 4/day. She maintained mild symptoms and tested negative after 3.5 weeks. Only anosmia persisted but with a slight improvement. As she was quarantined at the time, she was unable to attend treatment in May but maintained the scheduled treatments in June 23rd as CSU was controlled.

No worsening of CSU symptoms or increase in COVID-19 severity was observed in this case despite the administration of omalizumab in the week prior to SARS-CoV-2 infection.

Viral infections are known as triggers or eliciting factors for chronic urticaria⁶, SARS-CoV-2 infection as also been reported to manifest with acute urticaria⁷. The effects of COVID-19 in CSU control are unknown, in the reported case, no worsening of symptoms was observed.

According to the EAACI consensus on biologicals, patients with severe allergic disease should maintain treatment with biologicals if there is a safe environment, and at-home administration should be encouraged. Regardless of disease severity, patients with COVID-19 should interrupt treatment until recovery is established².

More evidence is needed to assert the safety of biologicals during COVID infection and effect of the disease in severe allergic patients.

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