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LETTER

Safety of omalizumab treatment in patients with chronic spontaneous urticaria and COVID-19

Dear Editor,

Omalizumab is a recombinant, humanized, monoclonal IgG1 anti-IgE antibody. It is approved for the treatment of chronic spontaneous urticaria (CSU) in H1-antihistamine refractory individuals aged 12 years and older. Omalizumab treatment results in a significant improvement in CSU activity and quality of life, and is well tolerated.[1] The treatment does not seem to be associated with an increased incidence of respiratory tract infections.[2] Rather, it seems to promote restoration of responses to both rhinovirus and influenza viruses.[3] Data on the use of omalizumab during severe acute respiratory syndrome Coronavirus 2 (SARS-CoV-2) pandemic are limited. However, it has been suggested that continuing treatment with omalizumab is advisable in patients affected with mild-to-moderate Coronavirus disease 2019 (COVID-19); in severe disease, prolongation of the dosing interval or treatment interruption should be considered.[4] We herein report the data regarding seven CSU patients in whom omalizumab treatment was continued at standard dosage (300 mg every 4 weeks) while suffering from COVID-19. A signed informed consent was obtained from patients to allow extracting data from their clinical records. All the patients (four males; mean age 49.7 ± 17.01; range 28–74 years) had a clinical history of CSU, ranging from 1 to 5 years (mean duration: 2.9 years). Mean baseline urticaria activity score on 7 days (UAS7) score (range 0–42) was 27.1, ranging from 18 to 39. In all the cases, second-generation antihistamine treatment (up to 4-folds the basic dosage) had been inefficacious. The patients, therefore, received omalizumab at standard dosage. All the patients achieved UAS7 score of 0 after an average of 8 weeks (range 1–12 weeks). At the moment of COVID-19 onset, the seven patients were on omalizumab treatment on average for 70.8 weeks (range 26.1–156.4 weeks). COVID-19 symptoms were mild in four (57.1%) patients, while three (42.9%) of them were asymptomatic. No patient discontinued omalizumab treatment. None of the seven patients experienced relapse of CSU during the viral infection. CSU symptoms seem worse in SARS-CoV-2 infected patients, especially in severe COVID-19[5]; therefore, an effective treatment is needed in these subjects. On the other hand, the use of immunosuppressive drugs for chronic inflammatory skin disease during SARS-CoV-2 pandemic and in patients affected with COVID-19 is debated in literature. The use of biologic drugs such as anti-IL17, anti-IL12/ IL23, and anti-IL23 appears to be safe in psoriasis patients.[6] Moreover, the use of anti-IL4/13 in atopic dermatitis patients is not contraindicated, though a careful assessment is mandatory for each subject and further studies are necessary to characterize the immunologic responses in COVID-19.[7] Few data exist regarding omalizumab therapy in CSU patients with COVID-19. Lommatzsch et al. described a man suffering from asthma and treated with omalizumab, who developed mild COVID-19 that was not influenced by omalizumab treatment.[8] Instead, two of three CSU patients hospitalized for COVID-19 described by Ayhan et al. discontinued omalizumab.[9] Our data seem to suggest that omalizumab does not worse COVID-19 course in CSU patients. However, no definitive conclusions can be drawn since our data are from a group of only seven patients affected with asymptomatic or mild COVID-19.

CONFLICT OF INTEREST

Cataldo Patruno acted as investigator, and/or speaker, and/or consultant, and/or advisory board member for AbbVie, Eli Lilly, Leo Pharma, Novartis, Pfizer, Pierre Fabre, and Sanofi. Maddalena Napolitano acted as speaker, and/or consultant, and/or advisory board member for Sanofi, Abbvie, Leo Pharma and Novartis. Gabriella Fabbrocini acted as investigator, and/or speaker, and/or consultant, and/or advisory board for AbbVie, Abiogen, Almirall, Celgene, Eli-Lilly, Leo Pharma, Novartis, Sanofi, and UCB.

AUTHOR CONTRIBUTIONS

Conceptualization: Cataldo Patruno and Maria Passante. *Methodology*: Cataldo Patruno. *Software*: Maddalena Napolitano. *Formal analysis*: Cataldo Patruno, Maria Passante. *Data curation*: Luigi Bennardo, Stefano Dastoli, Maddalena Napolitano, Maria Passante. *Writing-original draft preparation*: Maria Passante, Cataldo Patruno. *Writing-review and editing*: Luigi Bennardo, Stefano Dastoli, Gabriella Fabbrocini, Maddalena Napolitano, Steven Paul Nisticò. *Visualization*: Gabriella Fabbrocini, Steven Paul Nisticò. *Supervision*: Gabriella Fabbrocini, Steven Paul Nisticò.

ETHICS STATEMENT

The study was conducted according to the guidelines of the Declaration of Helsinki and approved by The Ethics Committee of University Magna Graecia of Catanzaro (Regione Calabria-Comitato Etico Sezione Area Centro) no. 325/2020. Informed consent was obtained from all subject involved in the study.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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