LETTER TO THE EDITOR

Management of biological therapies for chronic plaque psoriasis during COVID-19 emergency in Italy

Dear Editor,

The coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, is creating an unprecedented global public health emergency with the continuous growth of infected individuals worldwide.[1] Italy was one of the first European countries to face the first wave of infection outside mainland China.[2] The first case of COVID-19 was confirmed in Lombardy on 20 February 2020, and subsequently, a rapid increase in the number of detected cases was observed, spreading through Italy and the rest of Europe.[3] As of 22 April, confirmed COVID-19 cases in Italy were 183 957.[2,4]

Because of the impaired immunologic status of patients with psoriasis, their clinical management is challenging in the pandemic, particularly for those using biologics inhibiting key pathogenic cytokines such as TNF-α, IL-17, IL-12/23 or IL-23.[5–6]

To date, there is neither an agreement nor a study sustaining the impact of continuing or stopping biologics in psoriatic patients during the COVID-19 pandemic.[7–10]

The PSO-BIO-COVID is an observational, multicentric study, supported by the Italian Society of Dermatology (SIDeMaST), aimed at evaluate the impact of SARS-CoV-2 infection on the management of patients with psoriasis in Italy, during the first year of the pandemic.

Patients with moderate-to-severe chronic plaque psoriasis, aged >18 years, undergoing treatment with any biological agent as of 22 February 2020, were eligible.

Data on biological agent used for treatment and any suspension and/or lengthening of time intervals (LTIs) for treatment administration between 22 February and 22 April 22 2020 have been collected in a standardized data collection system through face-to-face, remote visits or via email. Frequency and percentages on the total number of centres and patients were the analyses performed.

The study was approved by the National Ethical Committee for COVID-19-related studies at INMI Lazzaro Spallanzani IRCCS, with the Dermatology Unit-Fondazione Policlinico Tor Vergata as the coordinating centre.

A total of 12 807 psoriatic patients from 33 specialized dermatologic centres were included in the study. 328 patients (2.6%) stopped treatment during the observation period without consulting their dermatologist mainly because of fearing high contagious risk; 233 (1.8%) interrupted their therapy after consulting their dermatologist mainly because of suspected infection or contact with the SARS-CoV-2 as they were professional healthcare providers or they have had a contact with SARS-CoV-2+ subjects (Table 1). Discontinuation rates ranged from 1.4% for patients using guselkumab to 5.5% for those treated with infliximab, when the decision was taken by the patients, while ranged between 0.5% for ixekizumab-treated patients and 2.8% for adalimumab-treated when the decision was taken after dermatological consultation.

Table 1 Number and percentage of psoriatic patients treated with a biological agent in Italy. Period: 22 February 2020–22 April 2020

	ADA	ETA	INF	UST	SEC	IXE	BRO	GUS	TIL	RIS	Total
Total patients	**3045**	**1645**	**343**	**2638**	**2417**	**1586**	**297**	**628**	**16**	**192**	**12 807**
Mean % of treated patients for each biological drugs	23.8%	12.8%	2.7%	20.6%	18.9%	12.4%	2.3%	4.9%	0.1%	1.5	100%
Patients stopping therapy autonomously†	90 (3.0%)	49 (3.0%)	19 (5.5%)	72 (2.7%)	49 (2.0%)	32 (2.0%)	5 (1.7%)	9 (1.4%)	0	3 (1.6%)	**328 (2.6%)**
Patients stopping therapy after consulting with the physician†	85 (2.8%)	30 (1.8%)	10 (2.9%)	21 (0.8%)	36 (1.5%)	8 (0.5%)	5 (1.7%)	13 (2.1%)	0	4 (2.1%)	**233 (1.8%)**
Patients' LTIs of therapy autonomously†	47 (1.5%)	61 (3.7%)	5 (1.5%)	28 (1.1%)	27 (1.1%)	9 (0.6%)	2 (0.7%)	4 (0.6%)	0	2 (1.0%)	**185 (1.4%)**
Patients' LTIs of therapy after consulting with the physician†	25 (0.8%)	6 (0.4%)	11 (3.2%)	26 (1.0%)	10 (0.4%)	26 (1.6%)	1 (0.3%)	5 (0.8%)	0	4 (2.1%)	**114 (0.9%)**

ADA, adalimumab; BRO, brodalumab; ETA, etanercept; GUS, gusesslkumab; INF, infliximab; IXE, ixekizumab; LTIs, lengthening of time intervals; RIS, risankizumab; SEC, secukinumab; TIL, tildrakizumab; UST, ustekinumab.
†Percentages are calculated on the total number of patients.

An additional 185 (1.4%) patients have autonomous LTIs of their therapy, and further 114 (0.9%) did the same but after consulting their reference centre. The risk and fear of the contagious were the most frequently reported reasons for LTIs the treatment.

This observational study included patients across Italy having a large variability of SARS-CoV-2 infection incidence. Centres were highly representative of the Italian distribution of SARS-CoV-2 during the observation period, ranging from cities like Bergamo or Milan, in Lombardy, having more than 20,000 confirmed diagnoses of COVID-19, to Cagliari (Sardinia) and Palermo (Sicily) where less than 500 cases were observed in the period when this observation was performed.[4]

The low number of patients who have interrupted treatment or have LTIs for their treatment at the peak of the infection seems a clear signal that neither the patient nor their reference physician felt this as an option ensuring a satisfactory balance between the risks and potential benefits.

This outcome highlights the importance of a continuous and trusting relationship between the patient and the medical staff who is taking care of his/her psoriasis. Patients and dermatologists are satisfied using biologics for psoriasis treatment. Thus, both are reluctant to interrupt biological therapy if no contraindications occurred.

Further details on the incidence of COVID-19 disease in patients with chronic plaque psoriasis treated with biological agents, clinical course and outcomes of patients who developed SARS-CoV-2 infection or who have been exposed to someone with laboratory-confirmed COVID-19 will be obtained by the ongoing investigation by the PSO-BIO-COVID study group.

Conflicts of interest

L. Bianchi reports personal fees from speaker and as consultant for AbbVie, Novartis, Janssen-Cilag, Pfizer, UCB and Leo Pharma, outside the submitted work. SP Cannavò has served as speaker or board member for AbbVie, Celgene, Eli Lilly, Leo Pharma, Janssen, Novartis and Sanofi Genzyme. A. Chiricozzi served as advisory board member and consultant and has received fees and speaker's honoraria or has participated in clinical trials for AbbVie, Almirall, Biogen, Fresenius Kabi, Leo Pharma, Lilly, Janssen, Novartis, Sanofi Genzyme and UCB Pharma. A. Conti served as advisory board member and consultant, and has received fees and speaker's honoraria or has participated in clinical trials for AbbVie, Leo Pharma, Eli Lilly, Novartis, UCB Pharma, Pfizer, Sandoz, Celgene, Biogen and Janssen-Cilag. M.C. Fargnoli has served on advisory boards, received honoraria for lectures and research grants from Almirall, AbbVie, Galderma, Leo Pharma, Mylan, Medac Pharma, Celgene, Pierre Fabre, UCB, Eli Lilly, Pfizer, Janssen, Novartis, Sanofi Genzyme, Roche, Sun Pharma and MSD. P. Gisondi has been a consultant and/or speaker for AbbVie, Almirall, Celgene, Janssen, Leo pharma, Eli Lilly, Novartis, Pfizer, Sandoz and UCB. K. Peris reports personal fees for advisory board meeting from Almirall, AbbVie, Biogen, Janssen, Eli Lilly, Celgene, Galderma, Leo Pharma, Novartis, Pierre Fabre, Sanofi, Sandoz and Sun Pharma outside the conduct of the work. I. Zalaudek has been a consultant and/or speaker for Novartis, Celgene and Amgen.

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Appendix

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