



Lack of Evidence for an Increased Risk of Severe COVID-19 in Psoriasis Patients on Biologics: A Cohort Study from Northeast Italy

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Dear Editor,

Uncertainties exist about the risk of psoriasis patients being treated by biologics during the COVID-19 pandemic. Some data point to an increased risk of respiratory infections in patients being treated with antagonists of interleukin (IL)-17 and tumor necrosis factor-alpha (TNF α) [1, 2]. On the other hand, these same drugs have been used to treat the sometimes deadly ‘cytokine storm’ of COVID-19 [3, 4].

In this study, we evaluated the incidence of COVID-19 in a population of patients with plaque psoriasis receiving biologic therapies compared with the general population.

All patients were observed at the out-patient clinics of three Dermatology Units uniformly covering the Veneto region in Italy, namely Verona, Padua and Vicenza.

General statistics and data on comorbidities in the underlying regional population were retrieved from ISTAT census data [8] and the Italian Observatory on Healthcare Report 2018 [9]. Data on COVID-19 confirmed cases, including demographics, hospitalizations and deaths, were extracted from the Regional Health Agency [10] as well as from the National Health Institute (ISS) [11].

From February 20 to June 1, 2020, a total of 1830 patients were included in the main analysis, with a total of 6199.5 patient-months of follow-up.

The characteristics of the studied population are outlined in Table 1. Most of them (55.3%) were treated with TNF

inhibitors. Over the period analyzed, all patients were recommended not to modify their treatment regimen.

The COVID-19 incidence rate (IR) was 9.7 (95% CI 3.9–20.1) per 10,000 person-months in our cohort and 11.5 (95% CI 11.4–11.7) per 10,000 person-months in the general regional population, resulting in an incidence rate difference (IRD) of – 1.8 (95% CI – 7.6 to 8.6).

The IR of hospitalization for COVID-19-related pneumonia and COVID-19-related death were 6.5 (95% CI 2.0–15.6) and 0 (95% CI 0–10.4) per 10,000 person-months in our cohort and 9.6 (95% CI 9.4–9.7) and 1.16 (95% CI 1.10–1.21) per 10,000 person-months in the general population, resulting in an IRD of – 3.1 (95% CI – 7.5 to 6.0) and – 1.2 (95% CI – 2.6 to 3.7), respectively. There were only six cases of COVID-19 among 1830 psoriatic patients compared with 19,154 cases among 4,905,854 individuals (16,601,409.94 person-months) from the general population. Out of the six cases of COVID-19, four were admitted to hospital because of interstitial pneumonia. None of them died. The patients were treated with etanercept, ustekinumab, ixekizumab, secukinumab, and guselkumab.

In our large cohort of psoriatic patients, no signal emerged for an increased risk of COVID-19 or COVID-19-related respiratory or life-threatening complications associated with biologics.

Our analysis was flawed by low numbers of patients with COVID-19 in our cohort.

Nonetheless, our cohort of psoriatic patients had a higher prevalence of comorbidities compared with the general population, including hypertension (25.9% vs 17%), diabetes mellitus (13.8% vs 4.5%), and cardiovascular diseases (12.2 vs 4.3%). All of these conditions have been associated with a significantly increased rate of hospitalization and fatal course in COVID-19 patients [5]. Therefore, a higher incidence of COVID-19-related hospitalization and death would have been expected in our psoriasis patients.

This further corroborates the hypothesis of at least similar or lower risk of COVID-19 pneumonia and death in our

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Table 1 Characteristics of the 1830 studied patients and the general population from Veneto

Variable	Study population (<i>n</i> = 1830)	General population from Veneto (<i>n</i> = 4,905,854)
Age, years (mean ± SD)	55 ± 14.8	45.1 ± 23.4
Male gender, <i>n</i> (%)	1208 (66)	2,399,783 (48.9)
Presence of psoriatic arthritis, <i>n</i> (%)	606 (33.1)	
Biologic therapy used		
TNF inhibitor	1112 (55.3)	
IL-17 inhibitor	527 (28.8)	
IL-12/IL-23 or IL-23 inhibitor	291 (15.9)	
Presence of obesity, <i>n</i> (%)	512 (27.9)	495,491 (10.1)
Presence of hypertension, <i>n</i> (%)	474 (25.9)	833,995 (17.0)
Presence of cardiovascular disease, <i>n</i> (%)	223 (12.2)	210,952 (4.3)
Presence of diabetes, <i>n</i> (%)	252 (13.8)	220,763 (4.5)
COVID-19 incidence rate per 10,000 person-months (95% CI)	9.7 (3.9–20.1)	11.5 (11.4–11.7)
COVID-19-related hospitalizations per 10,000 person-months (95% CI)	4 (2.0–15.6)	9.6 (9.4–9.7)
COVID-19-related deaths per 10,000 person-months (95% CI)	0 (0–10.4)	1.16 (1.10–1.21)

CI confidence interval, IL interleukin, SD standard deviation, TNF tumor necrosis factor

psoriatic patients treated with biologics compared with the general population.

Accordingly, some preliminary data on TNF inhibitors and IL-12/23 inhibitors in inflammatory bowel disease patients showed that these therapies do not worsen the clinical course of COVID-19 compared with sulfasalazine/mesalamine [6]. On the other hand, they seem to be associated with a better outcome, even though there are insufficient data to make definite statements [6].

Our data confirms the findings of a recent paper from Northern Italy [7]. In our study, however, we focus on the Veneto Region where one of the first Italian outbreaks of COVID occurred. Moreover, we extended the follow-up time to 1 June, 2020. We could therefore perform a comparison with the general population of the same region, calculating incidence rate differences, which were not assessed in the previous paper.

This study has some limitations. Despite a reasonably-sized cohort of 1830 psoriatic patients receiving biologic treatment, we collected very few COVID-19 cases, with wide CIs. Given the small event count, we could not stratify the analysis by type of biologic therapy.

While awaiting evidence directing the treatment of COVID-19, we have to make decisions on our patients undertaking biological therapies. The data available so far do not indicate an increased risk of COVID-19 infection or COVID-19-related pneumonia and death in these patients.

Declarations

Conflict of Interest Stefano Piaserico has been a consultant and/or speaker for Abbvie, Ammirall, Celgene, Janssen, Leo-pharma, Eli Lilly, Merck Sharp & Dohme, Novartis, Pfizer, Sandoz, and UCB. Paolo Gisondi has been a consultant and/or speaker for Abbvie, Ammirall, Celgene, Janssen, Leo-pharma, Eli Lilly, Novartis, Pfizer, Sandoz, and UCB. Simone Cazzaniga has nothing to declare. Luigi Naldi has been a consultant and/or speaker for Abbvie, Ammirall, Celgene, Janssen, Eli Lilly, and Novartis.

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Ethics Approval Not applicable.

Consent to Participate Not applicable (data were anonymized).

Consent for Publication Not applicable (data were anonymized).

Availability of Data and Materials The datasets generated during the current study are available from the corresponding author on reasonable request.

Code Availability Not applicable.

Author Contributions Stefano Piaserico conceived and planned the study, interpreted the data and drafted the manuscript. Paolo Gisondi conceived and planned the study, interpreted the data and critically reviewed the manuscript. Simone Cazzaniga analyzed the data and drafted the manuscript. Luigi Naldi conceived and planned the study, interpreted the data and critically reviewed the manuscript.

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