

SHORT REPORT

Safety of SARS-CoV-2 vaccines in psoriatic patients treated with biologics: A real life experience

Maria Letizia Musumeci | Giuliana Caruso | Andrea Calogero Trecarichi |
Giuseppe Micali 

Dermatology Clinic, University of Catania,
Catania, Italy

Correspondence

Giuseppe Micali, Dermatology Clinic,
University of Catania, Via Santa Sofia
78, 95123 Catania, Italy.
Email: cldermct@gmail.com

Abstract

Vaccination is the most effective method to prevent and control the SARS-CoV-2 infection and biologics are not considered a contraindication for vaccination. The burning question is that safety data are lacking since patients taking drugs affecting the immune system were excluded from clinical trials leading to vaccine approbation. Moreover, it seems that vaccination could worsen psoriasis. We conducted a survey to investigate the safety of SARS-CoV-2 vaccines in psoriatic patients treated with biologics. A total of 150 patients with stable plaque psoriasis treated with biologics for at least 2 months were evaluated in a 3 months period. Fifty patients (22 F/28 M; age: 33–83 years) only underwent the first and second doses of SARS-CoV-2 vaccines. All patients discontinued their biological agents 10 days before and 10 days after each dose of vaccine. Of these, 24 patients were treated with anti-TNF, 14 with anti-IL17, 7 with anti-IL12-23, and 5 with anti-IL23. After the vaccines, all patients were evaluated at day 2, 7, and 14 for local and/or systemic side effects and/or adverse drug reactions to SARS-CoV-2 vaccines. None of the patients experienced any side effects or a psoriatic flare. Only one patient treated with infliximab biosimilar referred an exacerbation of psoriasis after vaccine. The remaining 100 patients reported that they did not get the vaccine yet. Our preliminary data confirm that SARS-CoV-2 mRNA vaccines are safe for patients with chronic plaque psoriasis treated with biologics and did not trigger psoriasis, although these data should be validated in a larger population. We encourage an early SARS-CoV-2 vaccines administration in all psoriatic patients on immunosuppressant drugs.

KEYWORDS

biologics, psoriasis, SARS-CoV-2 vaccine

The impact of COVID-19 in psoriasis is still not adequately known, and there is no evidence that psoriatic patients are at high-risk and that biologics alter the risk of contracting SARS-CoV-2 infection or cause a worse outcome of COVID-19 disease.^{1–3} Biological agents

target the immune system and are contraindicated in patients with chronic viral infections, as HIV or active hepatitis. In general, in patients under immune-modulating treatments, including biological agents, it is recommended to continue their therapy during COVID-19

This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.

© 2021 The Authors. *Dermatologic Therapy* published by Wiley Periodicals LLC.

pandemic.^{2,4} On the contrary, it is reasonable to interrupt systemic therapy in psoriatic patients with positive test for SARS-CoV-2 or with COVID-19 disease because potentially negative effects of the therapy cannot be fully excluded.⁵

These patients should monitor the symptoms and discuss the management of their diseases with health care providers.⁴

Vaccination is the most effective method to prevent and control the COVID-19 infection and biologics are not considered a contraindication for vaccination.¹ The Italian Society of Medical, Surgical, Aesthetic Dermatology and Sexually Transmitted Diseases (Società Italiana di Dermatologia medica, chirurgica, estetica e delle Malattie Sessualmente Trasmesse—SIDeMaST) along with other dermatologic societies and task forces (International Psoriasis Council, Italian National Psoriasis Foundation) strongly recommends vaccination in all psoriatic subjects^{1,4}; only in selected patients with potential contraindications, the decision to do the vaccination should be personalized and shared between the patient and the physician.⁶ The burning question is that safety data are lacking since patients taking drugs affecting the immune system were excluded from clinical trials leading to vaccine approbation. Moreover, it seems that vaccination could worsen psoriasis considering that vaccination may induce the T helper 1 stimulation producing high level of TNF α , IFN γ , and IL2. In the summary of product characteristic of the biological drugs, it is recommended to avoid the use of live or live-attenuated vaccines. Among vaccines, mRNA ones are based on liposome-formulated uracil-modified mRNA decreasing the toll-like receptor 7 stimulation, and therefore potentially attenuate the risk of autoimmune disease flare.¹ A potential but uncommon association between some vaccinations (influenza, BCG, tetanus diphtheria, pneumococcal polysaccharide) and the onset or the exacerbation of psoriasis was previously documented,⁷ but SARS-CoV-2 vaccines data are limited in psoriatic patients and the all vaccine instructions delegate to clinicians the decision to vaccinate such patients.⁸ Only one Italian study is available on safety and efficacy of SARS-CoV-2 vaccines in four psoriatic patients treated with biologics without experiencing any psoriatic flare and/or cutaneous and systemic manifestations.⁸ Similar results were observed in three patients treated with apremilast undergoing SARS-CoV-2 vaccine.⁹ Successively, another Italian experience reported 11 cases of psoriasis exacerbation within 14 days from the vaccination (Pfizer mRNA BNT162b2, Moderna mRNA-1273 or AstraZeneca-Oxford AZD1222), mainly (81.8%) after the 2nd dose.¹⁰ Interestingly, six cases (54.5%) of them were observed in subjects under biologic treatment.¹⁰

We conducted a survey to investigate the safety of SARS-COV-2 vaccines in psoriatic patients treated with biologics. A total of 150 patients with stable plaque psoriasis treated with biologics for at least 2 months were evaluated in a 3 months period (February–April 2021). Fifty patients (22 F/28 M; age: 33–83 years) only underwent the first and second doses of Pfizer mRNA BNT162b2 (49 patients) or Moderna mRNA 1273 (1 patient) vaccines. All patients discontinued their biological agents 10 days before and 10 days after each dose of vaccine. Of these, 24 patients were treated with anti-TNF (17 with adalimumab biosimilar, 2 with etanercept biosimilar, 2 with infliximab

biosimilar, 3 with certolizumab pegol), 14 with anti-IL17 (9 with ixekizumab, 5 with secukinumab), 7 with anti-IL12-23 (ustekinumab), and 5 with anti-IL23 (guselkumab). After the vaccines, all patients were evaluated at day 2, 7, and 14 for local and/or systemic side effects and/or adverse drug reactions to SARS-CoV-2 vaccines.¹¹ None of them experienced any side effects or a psoriatic flare. Only one patient treated with infliximab biosimilar referred an exacerbation of psoriasis after Pfizer vaccine. The remaining 100 patients (45 F/55 M; age: 42–75 years), independently from age and sex, reported that they did not get the vaccine yet. Forty percent of them has booked the vaccination and the remaining ones reported SARS-CoV-2 vaccine-phobia or side effects-phobia. Moreover, 20% of all patients referred lack of information by their general practitioners.

Our preliminary results confirm that SARS-CoV-2 mRNA vaccines are safe for patients with chronic plaque psoriasis treated with biologics¹² and did not trigger psoriasis, conferring a sort of protection against vaccine-related psoriatic flares,⁸ although these data should be validated in a larger population.¹⁰ We encourage an early SARS-CoV-2 vaccines administration in all psoriatic patients under immunosuppressant drugs,¹³ even if the vaccination is underperformed in certain geographic areas as shown in our real life experience. In this regard, educational campaigns targeting the general population and physician counseling of patients under biologics are essential to improve disinformation on SARS-CoV-2 vaccines.¹⁴

ACKNOWLEDGEMENT

Open Access Funding provided by Università degli Studi di Catania within the CRUI-CARE Agreement. [Correction added on May 23, 2022, after first online publication: CRUI funding statement has been added.]

CONFLICT OF INTEREST

The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in this manuscript. Maria Letizia Musumeci MD, PhD, served as advisory board member and consultant, and has received fees and speaker's honoraria or has participated to clinical trials for Abbvie, Ammirall, Biogen, Eli-Lilly, Janssen Cilag, Leo Pharma, Novartis.

DATA AVAILABILITY STATEMENT

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

ORCID

Giuseppe Micali  <https://orcid.org/0000-0002-5157-3939>

REFERENCES

1. Stingeni L, Bianchi L, Peris K, et al. Board Members of SIDeMaST. SARS-CoV-2 vaccines and biological treatments: dermatological perspectives. *Ital J Dermatol Venerol*. 2021;156(2):118-120.
2. Talamonti M, Galluzzo M, Chiricozzi A, et al. PSO-BIO-COVID study group. Management of biological therapies for chronic plaque

- psoriasis during COVID-19 emergency in Italy. *J Eur Acad Dermatol Venereol.* 2020;34(12):e770-e772.
3. Talamonti M, Galluzzo M, Chiricozzi A, et al. Characteristic of chronic plaque psoriasis patients treated with biologics in Italy during the COVID-19 pandemic: risk analysis from the PSO-BIO-COVID observational study. *Expert Opin Biol Ther.* 2021 Feb;21(2):271-277.
 4. Gelfand JM, Armstrong AW, Bell S, et al. National Psoriasis Foundation COVID-19 task force guidance for management of psoriatic disease during the pandemic: version 2-advances in psoriatic disease management, COVID-19 vaccines, and COVID-19 treatments. *J Am Acad Dermatol.* 2021 May;84(5):1254-1268.
 5. Gisondi P, Bellinato F, Chiricozzi A, Girolomoni G. The risk of COVID-19 pandemic in patients with moderate to severe plaque psoriasis receiving systemic treatments. *Vaccines (Basel).* 2020;8(4):728.
 6. Stingeni L, Bianchi L, Zalaudek I, et al. Board Members of SIdEMaST. Adverse cutaneous and mucous reactions from anti SARS-CoV-2 vaccines: recommendations from the Italian Society of Dermatology (SIdEMaST). *Ital J Dermatol Venerol.* 2021;156(2):115-117.
 7. Munguía-Calzada P, Drake-Monfort M, Armesto S, Reguero-Del Cura L, López-Sundh AE, González-López MA. Psoriasis flare after influenza vaccination in Covid-19 era: a report of four cases from a single center. *Dermatol Ther.* 2021;34(1):e14684.
 8. Damiani G, Allocco F. Young Dermatologists Italian Network, Malagoli P. COVID-19 vaccination and patients with psoriasis under biologics: real-life evidence on safety and effectiveness from Italian vaccinated healthcare workers. *Clin Exp Dermatol.* 2021;46:1106-1108. doi:10.1111/ced.14631
 9. Pacifico A, d'Arino A, Pigatto PDM, Malagoli P. Young Dermatologists Italian Network, Damiani G. COVID-19 vaccine does not trigger psoriasis flares in psoriatic patients treated with apremilast. *Clin Exp Dermatol.* 2021;46:1344-1346.
 10. Megna M, Potestio L, Gallo L, Caiazzo G, Ruggiero A, Fabbrocini G. Reply to "psoriasis exacerbation after COVID-19 vaccination: report of 14 cases from a single Centre" by Sotiriou E et al. *J Eur Acad Dermatol Venereol.* 2021. doi:10.1111/jdv.17665
 11. Stingeni L, Bianchi L, Tramontana M, et al. Skin tests in the diagnosis of adverse drug reactions. *G Ital Dermatol Venereol.* 2020 Oct;155(5):602-621.
 12. Chiricozzi A, Gisondi P, Bellinato F, Girolomoni G. Immune response to vaccination in patients with psoriasis treated with systemic therapies. *Vaccines (Basel).* 2020 Dec 16;8(4):769.
 13. Gisondi P, Geat D, Naldi L, Piaserico S. Insights into Sars-CoV-2 vaccination in patients with chronic plaque psoriasis on systemic treatments. *J Eur Acad Dermatol Venereol.* 2021;35(6):e361-e362.
 14. Le H, Vender RB. A psoriatic patient-based survey on the understanding of the use of vaccines while on biologics during the COVID-19 pandemic. *J Cutan Med Surg.* 2021;25(3):298-302.

How to cite this article: Musumeci ML, Caruso G, Trecarichi AC, Micali G. Safety of SARS-CoV-2 vaccines in psoriatic patients treated with biologics: A real life experience. *Dermatologic Therapy.* 2022;35(1):e15177. doi:10.1111/dth.15177