Expert Opinion on Biological Therapy

ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/iebt20

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To cite this article: Marina Talamonti & Marco Galluzzo (2021): Safety of COVID-19 vaccines in patients with psoriasis undergoing therapy with anti-interleukin agents, Expert Opinion on Biological Therapy, DOI: 10.1080/14712598.2021.1965985

To link to this article: https://doi.org/10.1080/14712598.2021.1965985

Published online: 17 Aug 2021.

EXPERT OPINION ON BIOLOGICAL THERAPY
https://doi.org/10.1080/14712598.2021.1965985

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LETTER TO THE EDITOR

Safety of COVID-19 vaccines in patients with psoriasis undergoing therapy with anti-interleukin agents

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ABSTRACT

Introduction: There is very limited kn3e safety of COVID-19 vaccines in patients with psoriasis who are being treated with biological agents. We present our experience in 369 patients with moderate-to-severe psoriasis undergoing therapy with anti-IL agents who were vaccinated against SARS-CoV-2.

Areas covered: None of the 369 patients referred to any serious adverse event related to vaccination against COVID-19, while about one-third reported mild adverse events similar to those seen in the general population that were resolved within 48 hours. No patient discontinued biological therapy to receive a COVID-19 vaccine.

Expert opinion: Our observations provide evidence that COVID-19 vaccines can be considered safe in patients with moderate-to-severe psoriasis who are receiving anti-IL therapy.

KEYWORDS
Anti-interleukin; coronavirus; COVID-19; psoriasis; vaccine

Dear Editor,

The ongoing COVID-19 pandemic has significantly changed dermatological practice worldwide [1]. Vaccinations against COVID-19 give the possibility to provide protection against the virus and gradually allow for a progressive return to pre-pandemic conditions. Currently, several vaccines based upon adenoviral vectors or mRNA technology have received regulatory authorization [2]. In general, it is believed that biological agents such as anti-interleukin (anti-IL) inhibitors are not associated with a lower antibody response to vaccines and thus do not need to be discontinued [3]. However, there has been some concern about the safety of COVID-19 vaccines in patients undergoing therapy with biological and immunomodulatory drugs [4]. At present, there is very limited knowledge about the safety of COVID-19 vaccines in patients with psoriasis who are being treated with biological agents. In addition, patients on immunosuppressive therapy were excluded from Phase 3 trials with the mRNA and adenovirus-based COVID-19 vaccines [5,6].

We report our experience in a cohort of 369 patients with moderate-to-severe psoriasis undergoing therapy with anti-IL agents who were vaccinated against COVID-19 during the period from January to May 2021. The mean age of patients was 52.5 ± 14.8 years (range 22–90 years); there were 165 women and 204 men. Vaccinations were carried out in accordance with national guidance for employment (20% were healthcare workers/military personnel/teachers) and age. Patients had been receiving anti-IL therapy for a mean of 245.6 ± 171.2 weeks (range: 8.1–581.4 weeks); 192 (66 women) with an anti-IL12/23 agent, mean treatment time 373.2 ± 140.1 weeks (range 40.4–581.4 weeks); 93 (39 women) with an anti-IL-17 agent, mean treatment time 141.2 ± 71.2 weeks (range 8.4–291.3 weeks); 84 (60 women) with an anti-IL-23 agent, mean treatment time 76.3 ± 38.0 weeks (range 14.4–131 weeks). In this cohort, during the 5-month period, treatment was not discontinued in any patient. In nine patients (9.4%) undergoing therapy with an anti-IL-17 agent and in 8 patients (9.2%) undergoing therapy with an anti-IL-23 agent the vaccination was carried out at the time of induction (patients did not disclose to physicians that they were starting biological therapy for psoriasis). None of the 369 patients referred to any serious adverse event related to vaccination against COVID-19. About one-third of patients reported mild adverse events seen in the general population such as injection site pain, fever, fatigue, and muscle pain on the day of or day after the vaccination that resolved within 48 hours.

However, there is very limited data on the safety of COVID-19 vaccines in patients with psoriasis being treated with biological agents, and to our knowledge only a single small case series has been published. In this report, the results of four healthcare workers with moderate-to-severe psoriasis who were being treated with various biologics and who underwent vaccination for COVID-19 were presented [7]. No safety issues were documented and all patients developed IgG antibodies toward SAR-CoV-2. Krajweski et al. recently published a case report of a patient experiencing a psoriasis flare-up at 5 days following the second injection with an mRNA-based vaccine [8]. Prior to the second vaccination, the patient was being treated with deucravacitinib as part of a clinical trial and was completely clear of lesions. Other authors have noted

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that while there is a theoretical possibility that immunosuppressive treatment may lead to a less effective immune response to the vaccine, a biological would need to be discontinued for several weeks during which time there would be a reasonable probability that there would be disease recurrence [9]. Thus, while there may be some doubts about the ability of an immunosuppressed patient to mount an optimal immunological response to COVID-19 vaccines, vaccination is nonetheless considered to provide some degree of protection against SARS-CoV-2 [9].

Indeed, both the National Psoriasis Foundation and the American College of Rheumatology have recommended that such patients receive COVID-19 vaccination, consistent with age restrictions, since the benefits outweigh the possible risk of a new-onset autoimmunity [10,11]. At the same time, the lack of evidence for the safety of COVID-19 vaccines in patients with psoriasis who are receiving biological therapy has also been acknowledged and that a theoretical risk for disease flares is present with COVID-19 vaccination [10,11]. Our results substantially expand the available information in this regard, and provide evidence that COVID-19 vaccines can be considered safe in patients with moderate-to-severe psoriasis and receiving anti-IL therapy. In our cohort, no serious adverse reactions were observed and therapy was not discontinued in any patient.

Lastly, our results also reinforce a prior assumption that there are presently no contraindications to the administration of COVID-19 vaccines in patients with psoriasis undergoing therapy with anti-IL agents, other than age in accordance with national guidelines and hypersensitivity to the active substance or to any of the excipients [12]. In our opinion, clinicians can have additional confidence that this group of patients should receive a COVID-19 vaccine and that an anti-IL agent need not be discontinued prior to vaccination, which would also risk disease flare-up.

Regarding the hypothesis that immunosuppressive therapies used to treat psoriasis can reduce the immune response to COVID-19 vaccines, we would like to underline that biological drugs are immunomodulating agents that act on a specific molecular target (e.g. TNF-α, IL-17, IL-23, etc.), unlike traditional systemic drugs such as cyclosporine, methotrexate, and systemic corticosteroids, which are immunosuppressants in a broad sense. Furthermore, to date, it has not been possible to fully understand the immunological protection that the vaccine creates in patients with psoriasis in immunosuppressive therapy. Indeed, at present, there are no firm conclusions on the utility of serological tests following vaccination, and there are no methods that can formally confirm protection against SARS-CoV-2. When a subject is infected, or when one is vaccinated, a dual response is created. The first consists of an antibody response, which can be estimated by measurement of blood samples, while the second is a cellular response that is more difficult to estimate. In fact, antibodies do not necessarily protect from infection, since immunological memory controls persistent infections and distinguishes them from primary ones, preventing them from replicating. Accordingly, the concept of immune memory forms the biological basis for vaccination programs. After vaccination (with either a vaccine based on mRNA or adenovirus), T cells and memory B cells specific for the spike protein develop and circulate together with high-affinity SARS-CoV-2 antibodies, helping prevent SARS-CoV-2 infection. At any rate, our results affirm that there also appear to be no safety issues in patients with moderate-to-severe psoriasis and that there is no need to discontinue anti-IL therapy prior to the administration of any approved COVID-19 vaccines.

Declaration of interest

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

Reviewer disclosures

Editorial board members who peer-reviewed this manuscript have no relevant financial relationships or otherwise to disclose.

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Funding

This paper is not funded.

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