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REVIEW ARTICLE

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# Immune response to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination in patients receiving secukinumab: a literature review

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**ABSTRACT**

**Purpose:** There is a paucity of evidence on the impact of immune-mediated inflammatory disease (IMID) treatments on the immunogenicity of SARS-CoV-2 vaccination. The purpose of this literature review is to address the question of whether patients with IMIDs receiving secukinumab, a fully human anti–interleukin-17A monoclonal antibody, have an adequate immune response after SARS-CoV-2 vaccination. **Materials and Methods:** Clinical studies that evaluated the effect of secukinumab on immune responses in patients with IMIDs after SARS-CoV-2 vaccination were searched in publication databases, including Medline and Embase, until May 2022. **Results:** From the 53 articles identified, a total of 11 articles were included. Overall, the majority of the patients treated with secukinumab elicited an adequate immune response to SARS-CoV-2 vaccines. Patients receiving secukinumab for IMIDs developed cellular immune responses following vaccination with the BNT162b2 vaccine, and there were no significant differences in the overall humoral and cellular immune responses between patients and healthy individuals. The third dose of the BNT162b2 mRNA vaccine resulted in a positive antibody response in secukinumab-treated patients. **Conclusion:** The available data provide no evidence of impairment in immunological response to SARS-CoV-2 vaccines by secukinumab in patients with IMIDs.

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**KEYWORDS**
COVID-19; immune-mediated inflammatory diseases; SARS-CoV-2 vaccination; secukinumab

## Introduction

The emergence of novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and the subsequent coronavirus disease 2019 (COVID-19) pandemic has resulted in a global public health crisis (1). Intense research efforts have resulted in the rapid development of effective vaccines against SARS-CoV-2 (1).

The SARS-CoV-2 vaccines authorized for use in the United States (US), European Union (EU), and Canada include the messenger RNA (mRNA) vaccines BNT162b2 (Pfizer-BioNTech) and mRNA-1273 (Moderna) and the nonreplicating viral vector vaccines Ad26.COV2.S (Janssen) and ChAdOx1 (Oxford or AstraZeneca; only in the EU and Canada) (2). Evidence suggests that SARS-CoV-2 vaccination confers protective immunity in the general population by eliciting the production of specific antibodies against SARS-CoV-2–encoded epitopes (2,3). However, various medical conditions and therapies may interfere with the immune system function, and impair the development of protective immunity after SARS-CoV-2 vaccination (3).

Immune-mediated inflammatory disorders (IMIDs) such as psoriasis, psoriatic arthritis (PsA), and axial spondyloarthritis (axSpA) result in innate immune dysregulation and altered immunological function (4). In addition, immunosuppressive or immunomodulatory agents administered for the treatment of IMIDs may decrease the protective immunological response after SARS-CoV-2 vaccination (3,5,6). Notably, nonspecific immunosuppressants such as corticosteroids (7,8), methotrexate (9,10) and Janus kinase inhibitors (11) have the potential to decrease the broader host immune response in a dose-dependent manner. On the other hand, anti-cytokine biologics target specific immune system components and thus have a lower risk of causing immunological dysfunction (12,13). Limited evidence exists on how the treatments for IMIDs affect the immune response after SARS-CoV-2 vaccination. A deeper understanding of the immune response to SARS-CoV-2 vaccination in patients treated with immunosuppressants or immunomodulators for IMIDs may help physicians to enhance patient care and address patients' concerns.

Secukinumab, a fully human monoclonal antibody that selectively neutralizes interleukin (IL)-17A, has shown long-lasting efficacy and a favorable safety profile in a broad spectrum of plaque psoriasis manifestations (including the scalp, nails, palms and soles), PsA, ankylosing spondylitis, and non-radiographic axSpA (14–18). Nevertheless, it is essential to determine whether patients receiving secukinumab still mount an adequate immunological response after SARS-CoV-2 vaccination, because vaccine-induced host protection is thought to be mediated by a complex interplay of innate, humoral and cellular immunity.

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## Literature screening

A literature search was performed to identify clinical studies that reported immune responses after SARS-CoV-2 vaccinations in patients with IMIDs receiving secukinumab. A manual search was initially performed on the topic of secukinumab and SARS-CoV-2 vaccines, and after reading the identified articles, a search string was developed based on the following terms: “secukinumab”, "interleukin 17 inhibitor", "interleukin 17 A inhibitor", "COVID 19 vaccines" and "SARS-CoV-2 vaccines". Next, the following electronic databases were searched: Ovid, Biosis, Embase, Medline, EBM Reviews, and Cochrane Database of Systematic Reviews. The search was conducted until May 2022. The bibliography of the articles identified was also screened for relevant studies. Articles published in languages other than English and those reporting the results of nonhuman research, editorials, or commentaries, were not considered. A total of 53 articles were identified. After excluding duplicates and irrelevant articles based on screening, a total of 11 articles were considered for this review.

## Overview of the literature

### *Immunogenic response after vaccination with mRNA SARS-CoV-2 vaccines in patients with IMIDs or healthy individuals*

A 6-week prospective, observational, multicenter study compared the BNT162b2 mRNA SARS-CoV-2 vaccine immunogenicity between adult patients with autoimmune inflammatory rheumatic disorders (AIIRDs; $n = 686$) and healthy individuals ($n = 121$) (19). After vaccination, immunogenicity was assessed by levels of serum immunoglobulin (Ig) G anti-trimeric S1/S2 spike glycoprotein antibodies measured 2–6 weeks after the second vaccine dose (19). The seropositivity rates were 97% (160/165) in the PsA group and 99% (67/68) in the axSpA group, compared with 100% (121/121) in the control group (19). An IL-17 inhibitor (such as secukinumab) was given to 48 patients (40 with PsA and 8 with axSpA) (19). Most of the IL-17 inhibitor-treated patients (47/48; 98%) showed an immunogenic response, with no significant difference compared with healthy individuals (19). The seropositivity rate was 100% (37/37) for IL-17 inhibitor monotherapy and 86% (6/7) for IL-17 inhibitor plus methotrexate (19) (Table 1).

Another study characterized humoral and cellular immune responses after the first dose of the BNT162b2 vaccine in healthy individuals and patients with psoriasis treated with methotrexate or biologics targeting tumor necrosis factor-alpha (TNF-α), IL-17A (secukinumab or ixekizumab) or IL-23, without concurrent glucocorticoids (6). Assessments were performed immediately before and 28 days (±2 days) after the single vaccine dose (6). Of the 84 patients with psoriasis, 17 (20%) received methotrexate, 27 (30%) received TNF-α inhibitors, 15 (18%) received IL-17A inhibitors, and 25 (30%) received IL-23 inhibitors (6). The seroconversion rate was 100% (95% confidence interval [CI]: 80–100; 17/17) in healthy individuals and 78% (95% CI: 67–87) in patients receiving methotrexate or biologics (60/77), with methotrexate-treated patients having the lowest rate (47% [95% CI: 21–73]; 7/15). Seroconversion rates in patients receiving biologics were 79% (95% CI: 58–93) in the TNF-α inhibitor group (19/24), 100% (95% CI: 78–100) in the IL-17A inhibitor group (15/15), and 83% (95% CI: 61–95) in the IL-23 inhibitor group (19/23) (6). Patients receiving methotrexate had substantially lower neutralization activity against wild-type SARS-CoV-2 than healthy individuals, with a median 50% inhibitory dilution of 129 (interquartile range [IQR]: 40–236) versus 317 (IQR: 213–487; $p = 00032$); conversely, patients receiving targeted biologics maintained this activity (269 [IQR: 141–418]) (6). All individuals had low neutralizing titers against the B.1.α.7 variant of SARS-CoV-2 (6). Although functional humoral immunity was attenuated by methotrexate, cellular immune responses were elicited and maintained. Of note, targeted biologics did not impair functional humoral immunity or T cell responses.

In a follow-up to the longitudinal cohort study by Mahil et al. (6), monotherapy with methotrexate or targeted biologics did not substantially affect serological or functional humoral responses 14 days after the second dose of the BNT162b2 vaccine in patients with psoriasis (20). All participants developed seroconversion after the second vaccination dose (20). Whereas all healthy individuals showed detectable total T cell responses after the second vaccine dose, 18 (29%) of 63 people on methotrexate or targeted biologics had no detectable T cell responses (20). Notably, after the first ($n = 14$) and second ($n = 13$) vaccine doses, all patients (100%) receiving IL-17 inhibitors developed an anti–SARS-CoV-2 IgG (serological) vaccine response. T cell response to the vaccine was reported in 93% (13/14) and 62% (8/13) of IL-17 inhibitor-treated patients after the first and second vaccine doses, respectively (20). These data show that the second dose of the BNT162b2 vaccine, given at regular intervals, elicits antibody responses in patients taking methotrexate and targeted biologics. However, as compared to healthy individuals (14/14 [100%] [95% CI: 77–100], $p = .022$), a reduced percentage of patients receiving immunosuppressants (45/63 [71%] [95% CI: 59–82]) showed detectable T cell responses or signs of an increase in T cell immunity after the second dose (20).

Another study investigated the response to SARS-CoV-2 mRNA vaccines in 26 patients with chronic inflammatory diseases (including two patients treated with secukinumab) and 42 healthy control subjects (21). SARS-CoV-2 mRNA vaccines led to the development of antibodies in treated patients with IMIDs (21). Safety events in treated patients were comparable with those in healthy individuals, with systemic adverse effects being less frequent (21). No flares of the underlying IMIDs could be observed in the context of the vaccination in this study (21).

The immune responses after BNT162b2 mRNA SARS-CoV-2 vaccination in 84 people with IMIDs (IL-17 inhibitors, $n = 7$) and 182 healthy individuals were analyzed in a longitudinal study (3). Most patients with IMIDs had spondyloarthritis [SpA, including axSpA and PsA]) (32.1%), followed by rheumatoid arthritis (29.8%), inflammatory bowel disease (9.5%), psoriasis (9.5%), and systemic IMIDs. All healthy individuals who received at least one dose of the BNT162b2 mRNA SARS-CoV-2 vaccine developed anti–SARS-CoV-2 IgG antibodies as early as 11 days after the first vaccine dose. SARS-CoV-2 vaccination also produced an immune response in patients with IMIDs, although at a delayed and diminished rate than the control individuals (3). Notably, vaccination did not produce an immunogenic response in five patients with IMIDs (including one secukinumab-treated patient with SpA). Even after the second vaccine dose, a small proportion (9.5%) of patients with IMIDs remained unresponsive to the vaccine, suggesting that monitoring antibody levels after vaccination may be beneficial in certain cases to assess immunity development (3). Overall, 1 in 10 patients with IMIDs did not develop neutralizing antibodies after SARS-CoV-2 vaccination, compared with 1 in 100 healthy individuals (3).

**Table 1.** Overview of studies assessing response to SARS-CoV-2 vaccines in patients treated with secukinumab.

| Author and citation | Population | Number of patients | Type of vaccine administered | Summary |
|---|---|---|---|---|
| Furer et al. (19) | Patients with autoimmune inflammatory rheumatic diseases ($n = 686$); general population ($n = 121$) | IL-17 inhibitor (includes secukinumab) ($n = 48$) | BNT162b2 mRNA vaccine | Most of the IL-17 inhibitor-treated individuals (47/48; 97.92%) showed an immunogenic response. |
| Mahil et al. (6) | Patients with psoriasis ($n = 84$) and healthy individuals ($n = 17$) | Secukinumab or ixekizumab ($n = 15$) | BNT162b2 mRNA vaccine | Seroconversion rate in patients receiving an IL-17 inhibitor was 100% |
| Mahil et al. (20) | Patients with psoriasis ($n = 82$) and healthy individuals ($n = 15$) | IL-17 inhibitor ($n = 14$)[a] | BNT162b2 mRNA vaccine | The overall humoral response was not significantly impaired after BNT162b2 vaccination in patients with PsA treated with secukinumab |
| Damiani et al. (24) | Patients with psoriasis ($n = 4$) | Secukinumab ($n = 2$) | BNT162b2 mRNA vaccine | The vaccine was effective; all patients developed anti–S1-receptor-binding domain IgG against SARS-CoV-2 |
| Geisen et al. (21) | Patients with chronic inflammatory diseases ($n = 26$) and healthy individuals ($n = 42$) | Secukinumab ($n = 2$) | SARS-CoV-2 mRNA vaccines | SARS-CoV-2 mRNA vaccination showed effective immune response in patients treated with immunosuppressive therapies, including secukinumab without significant adverse effects or flares |
| Braun-Moscovici et al. (25) | Patients with inflammatory rheumatic diseases ($n = 264$) | Secukinumab or ixekizumab ($n = 5$) | BNT162b2 mRNA vaccine | Four of five patients receiving an IL-17 inhibitor mounted an immune response after vaccination |
| Simon et al. (3) | Patients with immune mediated inflammatory diseases ($n = 84$) and healthy control subjects ($n = 182$) | IL-17 inhibitor (includes secukinumab) ($n = 7$) | BNT162b2 mRNA vaccine | Overall, patients with immune-mediated inflammatory diseases responded to SARS-CoV-2 vaccination |
| Elkayam et al. (22) | Patients with PsA or AS ($n = 162$) | Secukinumab ($n = 37$) | BNT162b2 mRNA vaccine | Secukinumab did not impair humoral immunity within short-term after a second dose, 6 months after a first dose, and after a third dose of the BNT162b2 mRNA vaccine |
| Smetanova et al. (23) | Patients with AS ($n = 17$) | Secukinumab ($n = 7$) | BNT162b2 mRNA vaccine | After vaccination with the BNT162b2 vaccine, secukinumab-treated patients were able to develop cellular immune responses, and the overall humoral and cellular immune response did not differ significantly between patients and healthy individuals |
| Al-Janabi et al. (26) | Patients with immune-mediated inflammatory diseases ($n = 120$) | Secukinumab ($n = 6$) | BNT162b2 mRNA vaccine or AZD1222 | Compared to biologics, the likelihood of a detectable antibody response was lower with nonbiologic immunomodulators such as methotrexate. Not all patients on immunomodulators mounted a detectable humoral response after a single dose of the BNT162b2 or AZD1222 vaccine |
| Benucci et al. (27) | Patients with PsA ($n = 110$) | Secukinumab ($n = 37$) | BNT162b2 mRNA vaccine | Patients with PsA treated with secukinumab had a detectable humoral response. No significant differences in anti–SARS-CoV-2 Spike RBD IgG antibodies were observed between secukinumab and healthy controls |

[a]Includes secukinumab or ixekizumab [based on interim analysis, Mahil et al. (6)]. AS: ankylosing spondylitis; CI: confidence interval; IgG: immunoglobulin gamma; IL: interleukin; mRNA: messenger ribonucleic acid; PsA: psoriatic arthritis; RBD: receptor-binding domain; SARS-CoV-2: severe acute respiratory syndrome coronavirus 2.

A prospective study examined humoral immune responses to the BNT162b2 mRNA vaccine in patients with PsA or AS receiving secukinumab or a TNF-α inhibitor, as well as healthy controls (22). The analysis included 162 individuals with SpA receiving secukinumab ($n = 37$) or a TNF-α inhibitor ($n = 125$), and 122 healthy controls. The rate of seropositivity at 6 months after the second vaccine dose was 96% in both the secukinumab and healthy control groups but declined to 79% in TNF-α inhibitor-treated patients. Within 6 months of the second vaccine dose, the decrease in spike-specific S1/S2 IgG titers was quantitatively higher in patients taking TNF-α inhibitor compared with controls and the secukinumab group. The third dose considerably enhanced anti-S1/S2 IgG titers in all groups. The anti-S1/S2 IgG titers were comparable in secukinumab-treated patients and healthy controls at all time periods, but quantitatively lower in TNF inhibitor-treated patients (22).

Another study evaluated antibody and T cell responses after two doses of the BNT162b2 vaccine in 17 patients with AS who had not been exposed to SARS-CoV-2 and were being treated with either adalimumab ($n = 10$) or secukinumab ($n = 7$), compared with six healthy controls (23). All study participants had a high level of seroconversion. Vaccination also resulted in proinflammatory cytokine-producing CD4+ and CD8+ T cells, with no statistically meaningful differences in the proportion of SARS-CoV-2–reactive T cells across study groups. The second dose of the BNT162b2 vaccination did not induce CD8+ T cell degranulation in patients receiving adalimumab or secukinumab (23).

### *Immunogenicity of the BNT162b2 or AZD1222 vaccines in patients with IMIDs receiving biologics and/or oral nonbiologic immunomodulators*

In a case study of four patients receiving biologics for the treatment of psoriasis (secukinumab, $n = 2$; ixekizumab, $n = 1$; risankizumab, $n = 1$), the BNT162b2 vaccine was found to be effective based on the development of anti-S1 receptor binding domain IgG against SARS-CoV-2 (24). In a single-center study, humoral response after two doses of SARS-CoV-2 mRNA vaccine was assessed in 264 patients with inflammatory rheumatic diseases treated with immunomodulatory agents (including five patients on IL-17 inhibitors) (25). After the second vaccine dose, 227 patients (86%) mounted IgG production against SARS-CoV-2 (mean [standard deviation]: 5830.8 [8937] arbitrary units/mL), while the remaining 37 patients (including one patient on an IL-17 inhibitor) did not elicit any response (25).

In a single-center study, a total of 120 patients (73 treated with biologics including secukinumab) with IMIDs were enrolled, including 107 patients with psoriasis, 25 with PsA, 10 with rheumatoid arthritis, 1 with systemic lupus erythematosus, and 3 with Crohn's disease (26). According to the study findings, 15% of patients with IMIDs receiving immunomodulators failed to develop a detectable antibody response to a single dose of the BNT162b2 or AZD1222 vaccine, and 41% had no detectable anti-S1 IgG. Methotrexate decreased the likelihood of a detectable antibody response versus biologics (adjusted odds ratio [95% CI]: 0.31 [0·08–1.17] versus 0.18 [0.06–0.59]).

In another single-center study, the overall humoral response was not significantly impaired after BNT162b2 vaccination in patients with PsA treated with secukinumab ($n = 37$). There were no significant differences in anti–SARS-CoV-2 spike IgG antibody levels between PsA patients (median: 928.00 binding antibody units [BAU]/mL [IQR: 329.25, 1632.0]) and controls (healthy healthcare workers; median: 1562.00 BAU/mL [IQR: 975.00, 1632.00]) (27). The median of anti–SARS-CoV-2 spike receptor-binding domain IgG antibodies level in patients treated with secukinumab was 928.00 BAU/mL (IQR 329.25, 1632.0).

## Discussion

Biologic treatments, including secukinumab, have become essential components of the treatment armamentarium against many IMIDs (4), the effective treatment of which requires targeting the TNF–IL-23–Th17 inflammatory pathways. The same pathways, however, are involved in the control of infections, and may interfere with the vaccine-induced immune protection of the host.

Evidence from the literature (Table 1) suggests that secukinumab did not decrease the anti–SARS-CoV-2 antibody response after vaccination in individuals with IMIDs. Along with serological responses to SARS-CoV-2 vaccines, individuals with IMIDs have maintained cellular immunogenicity across biologic classes, including IL-17A inhibitors (3,6,19,21,24–26). A systematic review and meta-analysis concluded that patients with IMIDs had a reduced incidence of seroconversion after SARS-CoV-2 vaccination; treatments such as TNF inhibitors, anti-integrin, IL-17 inhibitors, IL-6 inhibitors, and anti–IL-12/IL-23 agents, however, may not affect seroconversion rates (28).

Vaccine-induced cellular responses are considered to be essential for the development of long-term humoral immune responses and SARS-CoV-2 clearance (29,30). In a longitudinal cohort study, methotrexate or targeted biologics did not impair the functional humoral immune response to the second dose of BNT162b2 vaccine in patients with psoriasis; some patients on immunosuppression, however, had no detectable T cell responses (20). The lack of boosting of T cell responses in some patients receiving immunosuppressants indicates a disparity in long-term cellular and humoral immunity. These findings contrast with the study by Smetanova et al. which showed no significant difference between cellular and humoral immune responses to vaccination in patients treated with secukinumab or adalimumab (23). Decreased cellular immune response was observed in a small percentage of patients; nevertheless, further research on the longevity/kinetics of the complex humoral and cellular response to subsequent vaccine doses, including against newer variants of concern, is warranted to assess the clinical implications (6,20).

Numerous studies have shown a decline in anti-spike antibody levels following the two-dose BNT162b2 mRNA vaccine regimen in individuals with or without an IMID (31–33). A decline in anti-S1/S2 IgG titers within 6 months following the second vaccine dose, similar to that in immunocompetent controls, was observed in patients treated with secukinumab; the third vaccine dose restored the levels of anti-S1/S2 IgG titers, however, supporting the recommendation of booster vaccination in all individuals with an IMID (22). Evidence also suggests that SARS-CoV-2 vaccination did not appear to be a major driver of disease flare-ups and was not associated with severe adverse effects in patients receiving disease-modifying antirheumatic drugs, such as secukinumab, for chronic inflammatory diseases (21).

According to a real-world study based on social media data, psoriasis was the most discussed condition online by patients with psoriasis and PsA, while secukinumab and adalimumab

were the most discussed biologics, along with SARS-CoV-2 vaccines (34). Almost 60% of patients with psoriasis reported no change in their condition following vaccination, and those who did experience side effects reported that they were manageable (34). Patients with PsA experienced more severe vaccine-related side effects such as significant pain, weakness, and fatigue (34).

Overall, immune responses to SARS-CoV-2 vaccination in patients receiving biologics such as IL-17 inhibitors including secukinumab are aligned with and supporting the respective clinical guidance provided by scientific societies and regulatory agencies. The American College of Rheumatology COVID-19 Vaccine Clinical Guidance Task Force recommends (moderate level of consensus) that there should be no modifications to either the IL-17 inhibitor therapy, including secukinumab, or the timing of the SARS-CoV-2 vaccination. Similarly, the National Psoriasis Foundation COVID-19 Task Force recommends that patients receiving an mRNA-based or adenovirus vector-based vaccine should continue their biologic for psoriasis and/or PsA in most cases and that shared decision-making between the clinician and the patient should guide discussion about the use of systemic therapies during the pandemic (35,36). On 12 August 2021, the United States Food and Drug Administration expanded the emergency use authorization of both mRNA SARS-CoV-2 vaccines "to allow for the use of an additional dose in certain immunocompromised individuals" (37).

Although a thorough literature search of all the available evidence about the effect of secukinumab on immunogenicity after SARS-CoV-2 vaccination was conducted, the limitation of this review is that most studies were conducted on a small number of patients and were different in terms of the study concepts, design and settings. Nevertheless, the results were mostly consistent among the studies, despite the identified studies having limited power.

The available data suggest that secukinumab does not impede immunological response to SARS-CoV-2 vaccines, although larger cohort studies are needed to determine the response to SARS-CoV-2 vaccines and, more importantly, the long-term SARS-CoV-2 infection rates in secukinumab-treated patients with IMIDs.

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## Data availability statement

All data included in this review are available in the articles listed in references.

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