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ARTICLE

Lack of reactivation of tuberculosis in patients with psoriasis treated with secukinumab in a real-world setting of latent tuberculosis infection

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ABSTRACT

Background: Some biologics for psoriasis, especially anti-tumor necrosis factor (TNF)-α therapies, may re-activate latent tuberculosis (TBC) infection with consequent morbidity and mortality. However, there is a low reported incidence of conversion to positive TBC status among patients with psoriasis treated with second-generation biologic therapies, particularly anti-interleukin (IL)-17 therapies such as secukinumab.

Objectives: To evaluate the safety profile of secukinumab in psoriasis patients with latent TBC infection.

Methods: Real-life data were collected by retrospective chart review on patients with moderate-to-severe psoriasis who showed positivity for TBC screening at baseline and underwent secukinumab treatment for psoriasis at six Italian centers. Patients received secukinumab 300 mg at week 0/1/2/3/4, then every 4 weeks.

Results: Fifty-nine patients were enrolled; 30.5% also had psoriatic arthritis and other comorbidities were common. At baseline, the mean psoriasis duration was 14.5 years. Ten (17%) patients did not undergo prophylaxis before starting secukinumab. Conversely, isoniazid ± rifampicin or rifampicin alone prophylaxis was administered in 49/59 (83.1%) patients. After a mean treatment duration of 84 weeks, there were no cases of TBC reactivation and no unexpected safety signals.

Conclusions: Secukinumab use over an extended period was safe in psoriasis patients with latent TBC, even in patients who did not receive chemoprophylaxis.

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Biologics; chemoprophylaxis; latent tuberculosis infection; psoriasis; reactivation; secukinumab

Introduction

In recent years, biologic therapies have transformed the treatment of immune-mediated inflammatory diseases, including rheumatoid arthritis, inflammatory bowel diseases, plaque psoriasis and psoriatic arthritis (PsA) (1–4). However, it has been reported that some biologics for psoriasis, especially anti-tumor necrosis factor (TNF)-α therapies, may re-activate latent tuberculosis (TBC) infection with consequent morbidity and mortality (5–8). Hence, in the clinical management of psoriasis, screening for tuberculosis infection is mandatory before starting biologic therapy (3,9–12).

Active TBC infection is a contraindication for biologic treatment. Therefore, psoriasis patients candidate for such treatment and with latent TBC infection (a state of persistent immune response to *Mycobacterium tuberculosis* antigens, with no evidence of clinically manifest active TB) must undergo prophylactic treatment with isoniazid and/or rifampicin prior to the initiation of biologic therapy (3,9–13). This is also true for the newer biologics [anti-interleukin (IL) 17 and 23], despite a low reported incidence of conversion to positive TBC status among patients with psoriasis treated with these drugs (14). Of note, there is increasing evidence to support the safety of anti-IL-17 agents for patients with latent TBC (15–20). Indeed, no cases of TBC reactivation have been observed in phase III clinical trials of anti-IL-17 therapies (15,18,21).

Secukinumab is a fully human monoclonal antibody targeting IL-17A. It selectively binds and neutralizes IL-17A as both homodimer and heterodimer dimeric ligands of IL-17 (22). Secukinumab has been shown to be highly effective and safe in clinical trials (19,23–27). Furthermore, there have been reports of psoriasis patients with latent TBC treated with secukinumab without reactivation of TBC, despite not receiving TBC prophylaxis. These included a case series of 12 patients who underwent secukinumab without receiving TBC prophylaxis because of

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clinical contraindications or patient refusal (28), and three patients with comorbidities that made TBC prophylaxis impractical who were successfully treated with secukinumab following the failure of conventional disease-modifying antirheumatic drug (DMARD) therapy (29). None of the 15 patients experienced TBC reactivation. Other studies have shown that latent TBC infection reported as an adverse event after secukinumab treatment is very uncommon, further supporting the safe use of secukinumab in chronic systemic inflammatory conditions (16,28,30–35). Of particular interest, a recent analysis of the long-term safety of secukinumab from pooled data of 28 clinical trials and post-marketing safety surveillance in 12,637 patients with psoriasis, psoriatic arthritis, and ankylosing spondylitis treated with secukinumab for up to 5 years found an incidence of opportunistic infections of less than 0.2 cases per 100 patient-years (35). On the other hand, there are numerous reports of TBC reactivation during treatment with TNF-α inhibitors and a small number of cases with IL-12/23 inhibitors (16).

Hence, we collected real-life data on psoriasis patients with latent TBC infection who underwent secukinumab treatment for psoriasis to evaluate its safety profile in this cohort of patients.

Patients and methods

Study participants

This was a multicenter retrospective study conducted between 2018 and 2021 at the following Italian centers: Department of Dermatology, University of Naples Federico II, Naples; Dermatology Unit, University of Campania Luigi Vanvitelli, Naples; Department of Medicine, Surgery and Dentistry, 'Scuola Medica Salernitana' University of Salerno, Salerno; Department of Health Sciences, University Magna Graecia of Catanzaro, Catanzaro; Department of Biomedical Sciences and Human Oncology, Section of Dermatology, University of Bari, Bari; Department of Clinical and Experimental Medicine, Section of Dermatology, University of Messina, Messina; Section of Dermatology, Department of Health Promotion, Mother and Child Care, Internal Medicine and Medical Specialties 'G. D'Alessandro' (PROMISE), University of Palermo.

A retrospective chart review was performed at each participating institution to identify adult patients with moderate-to-severe psoriasis treated with secukinumab who had clinical suspicion of latent TBC infection at baseline. All patients who showed positivity for TBC screening (QuantiFERON TB test) underwent thoracic X-ray examination to exclude active TBC and infectivological or pulmonological consultation to confirm a diagnosis of latent TBC infection and for the prescribing of appropriate prophylactic therapy. Secukinumab was administered at the standard dose for psoriasis in Italy, 300 mg at week 0, 1, 2, 3, and 4, then 300 mg every 4 weeks.

The study received institutional ethics approval from the local Ethics Committee or Institutional Review Board at each participating institution and was conducted following the principles of the 1975 Declaration of Helsinki and its amendments, the International Conference of Harmonization Good Clinical Practice, and all applicable laws and regulations. Patients were not required to give informed consent to the study because the analysis used anonymous data obtained after each patient agreed to be followed up when prescribed secukinumab and for clinical records to be collected by the institutions.

Table 1. Baseline demographic and clinical characteristics.

Characteristic	$N = 59$
Age, mean ± SD, year	55 ± 11.2
Gender, *n* (%)	
Female	21 (35.6)
Male	38 (64.4)
Psoriasis duration, mean ± SD, year	14.5 ± 10.8
Psoriatic arthritis, *n* (%)	18 (30.5)
Duration, mean ± SD, year	7.4 ± 4.8
Comorbidities, *n* (%)	
Hypertension	28 (47.5)
Dyslipidemia	22 (37.3)
Diabetes	17 (28.8)
Cardiopathy	15 (25.4)
Others[a]	9 (15.3)
Prior conventional systemic treatment for psoriasis, *n* (%)	59 (100)
Cyclosporine	28 (47.5)
Phototherapy	23 (39.0)
Methotrexate	20 (33.9)
Acitretin	7 (11.9)
Fumarates	3 (5.1)
Prior biologic use	24 (40.7)
Adalimumab	16 (27.1)
Ustekinumab	12 (20.3)
Etanercept	5 (8.5)
Ixekizumab	2 (3.4)
Infliximab	1 (1.7)
Latent TBC infection	59 (100)
Anti-tuberculosis prophylaxis therapy, *n* (%)	49 (83.1)
Isoniazid	43 (72.9)
Isoniazid plus rifampicin	3 (5.1)
Rifampicin	3 (5.1)
Duration of prophylactic therapy, mean ± SD, weeks	23.1 ± 3.2

[a]Autoimmune disease ($n = 2$), chronic obstructive pulmonary disease (3), and chronic gastritis, encephalopathy, renal failure, and peptic ulcer in 1 patient each.
SD: standard deviation; TBC: tuberculosis.

Data collection

Data were anonymously collected in each center and were assembled in an electronic database for analysis. For each patient, demographic, clinical and standard laboratory data were extracted, including age, gender, psoriasis duration, comorbidities including PsA, previous treatment for psoriasis, TBC prophylaxis (if any), TBC prophylaxis duration and type, duration of secukinumab therapy, and TBC reactivation (if present).

Outcome

The primary study outcome was the reactivation of latent TBC infection. The diagnosis of TBC reactivation was determined by signs or symptoms of TBC (fever, chronic cough, weight loss, fatigue, night sweats) and thoracic X-ray examination findings. Response to, or adverse events (other than TBC reactivation) with, secukinumab were not aims of the study and were not recorded. Data were analyzed with descriptive statistics.

Results

A total of 59 patients with moderate-to-severe plaque psoriasis were enrolled. They were 38 males and 21 females, with a mean age of 55 ± 11.2 years. Patient demographic and clinical characteristics at baseline are summarized in Table 1. The mean psoriasis duration was 14.5 ± 10.8 years, and 18 patients (30.5%) were also affected by PsA with a mean disease duration of 7.4 ± 4.8 years. Comorbidities were prevalent in our sample (Table 1); almost half of the patients had hypertension, and

dyslipidemia, diabetes, and cardiopathy were also relatively common. The most common previous systemic treatments for psoriasis are shown in Table 1. Twenty-eight (47.4%) patients had received cyclosporine, 23 (39%) phototherapy, 20 (33.9%) methotrexate, 16 (27.11%) adalimumab, and 12 (20.3%) ustekinumab. Other treatments included acitretin, etanercept, fumarates, ixekizumab, and infliximab.

All 59 patients had latent TBC infection, confirmed by QuantiFERON TB test positivity and negative thoracic x-ray prior to starting secukinumab. Prophylactic TBC treatment, mainly consisting of isoniazid ($n = 43$, 72.9%), followed by isoniazid plus rifampicin (3, 5.1%), and rifampicin (3, 5.1%), was administered for a mean of 23.1 ± 3.2 weeks in 49 of the 59 (83.1%) patients (Table 1). Of note, 10 (17%) patients with latent TBC infection did not undergo any prophylactic treatment for TBC before starting secukinumab. There were no statistically significant differences in baseline demographic and clinical characteristics between patients who did versus did not receive TBC prophylaxis. Among the 49 (72.9%) patients who underwent TBC prophylaxis, secukinumab was started after a mean of 5.2 ± 4.1 weeks (range 0–24 weeks) after prophylaxis. In the 10 (17%) patients who refused or had contraindications to prophylaxis, secukinumab was started directly without any prophylactic therapy.

Overall, the mean duration of secukinumab treatment for the 59 patients was 84 ± 62.4 weeks. There were no cases of TBC reactivation during secukinumab treatment, and no unexpected safety signals were identified during the secukinumab treatment period of up to 84 weeks. No clinical, safety related to TBC, or other noteworthy differences were reported between patients who underwent TBC prophylaxis and those who did not undertake TBC prophylaxis.

Discussion

Active TBC infection is an absolute contraindication for biologic therapy, and TBC screening is mandatory prior to initiation of biologic therapy for immune-mediated inflammatory diseases such as psoriasis. Prophylactic treatment is needed if latent TBC is detected, with regular monitoring for symptoms indicative of active TBC infection during treatment with biologics (1–3,10,15). Anti-TBC prophylaxis therapies, which may need to be continued for 3–4, and up to 9 months, are associated with a significant risk of adverse events such as hepatic side effects and elevation of transaminases (10,36–38). In addition to issues of patient compliance associated with long-term prophylactic therapy, the concomitant presence of comorbidities (e.g. hepatitis) may be a contraindication for TBC prophylaxis. Hence, it is helpful to understand if some biologics are safe in terms of TBC reactivation with or without TBC prophylaxis in real-life. The potential to avoid chemoprophylaxis before starting biologic therapy would constitute an advantage over other biologic agents approved for the treatment of moderate-to-severe psoriasis that are known to increase the risk of reactivation of TBC infection.

In our study, there were no cases of active TBC or TBC reactivation among 59 psoriasis patients with latent TBC treated with secukinumab for a mean time of 84 weeks of therapy. Of note, the sample also included 10 (17%) patients who did not undergo TBC prophylaxis prior to secukinumab treatment. Hence, our real-life data further supports data from phase III clinical trials, which showed no cases of TBC reactivation with secukinumab (15,18,21). Secukinumab is not likely to induce TB reactivation probably because, unlike TNF-α, IL-17 is not involved in the pathogenesis of *M. tuberculosis* infection reactivation. Indeed, it appears that, as the target of IL-17A antibody treatments, such as secukinumab, is downstream of the immune pathway, reactivation of latent TBC or other opportunistic infections is minimized (16,28,31). These data are also all supported by an *in vitro* study of Kammuller et al. (33), who examined the effect of the anti-TNF-α monoclonal antibody, adalimumab, and secukinumab on dormant *M. tuberculosis* H37Rv in a novel human three-dimensional microgranuloma model. In particular, they showed that secukinumab was comparable to control treatment, indicating a lack of effect on *M. tuberculosis* dormancy. In contrast, adalimumab showed increased staining for Auramine-O, decreased Nile red staining and decreased rifampicin resistance, indicative of mycobacterial reactivation (33).

Our study has some potential limitations, including the retrospective design and the lack of a comparison group of patients with latent TBC who were not treated with secukinumab or other biologics. Therefore, conclusions about the precise effect of secukinumab on the incidence of TBC reactivation cannot be inferred from this analysis. We also acknowledge the relatively small sample size related to the limited number of psoriasis patients with latent TBC. However, a strength of our study is that it included a patient population that may be excluded from or underrepresented in clinical trials, analyzing data from a cross-section of patients with a range of comorbidities representative of patients seen in real-world clinical practice and previously treated with a range of systemic treatments for psoriasis.

Conclusions

Our study supports other analyses indicating that secukinumab may be used safely over an extended duration (up to 84 weeks) in psoriatic patients with latent TBC, even in patients who do not receive prior chemoprophylaxis, and adds to the data supporting its use in patients with chronic inflammatory-mediated diseases. We recommend using IL-17A-targeted biologics as first-line therapy in psoriasis patients with latent TBC infection.

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Disclosure statement

Megna M has acted as speaker or consultant for Abbvie, Amgen, Eli Lilly, Leo Pharma, Janssen, Novartis, UCB; Fabbrocini G has acted as speaker or consultant for Abbvie, Almirall, Amgen, Eli Lilly, Leo Pharma, Janssen, Novartis, Sanofi, UCB; Patruno C has acted as an advisor, consultant, speaker and/or investigator for AbbVie, Amgen, Eli Lilly, Leo Pharma, Novartis, Pfizer, Pierre Fabre, Sanofi; Guarneri C has received consultation fees and/or grants for research projects, advisory panels and giving educational lectures from Wyeth-Pfizer, Abbott Immunology-Abbvie, Janssen-Cilag, Novartis, LEO-Pharma, Ely-Lilly, Celgene, Merck-Serono, Sanofi-Aventis, Amgen and Almirall. The other authors report no conflicts of interest.

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