Real-world clinical experience with secukinumab in psoriatic arthritis: an observational study and a literature review

Eleonora Celletti,[1] Giulio Gualdi,[2] Emanuela Sabatini,[1] Francesco Cipollone,[1] Fabio Lobefaro,[2] Paolo Amerio[2]

[1]Rheumatology Service, Medical Clinic, ASL 2 Abruzzo, G. d'Annunzio University, Chieti; [2]Unit of Dermatology, Department of Medicine and Aging Science, G. d'Annunzio University, Chieti, Italy

Correspondence: Paolo Amerio, Unit of Dermatology, Department of Medicine and Aging Science, G. d'Annunzio University, Chieti, Italy.
E-mail: paolo.amerio@unich.it

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Summary

Objective. Psoriatic arthritis (PsA) can be treated with biological drugs targeting IL-17A, such as secukinumab, with good responses and long-term positive outcomes in clinical studies.

Methods. An observational study was conducted on adult subjects with PsA and comorbidities treated with secukinumab after prior therapy with conventional disease-modifying anti-rheumatic drugs or biological agents that were discontinued due to lack of efficacy or adverse drug reactions. Patients were followed up with clinical visits at 3, 6, 9, and 12 months and evaluated for disease activity, pain, and quality of life compared to baseline. Moreover, a narrative review of the literature was performed on secukinumab's use for PsA in real life.

Results. Fifteen patients completed 6 months of follow-up, eleven patients completed 9 months, and six patients were followed for 12 months. The major comorbidities recorded were fibromyalgia (33% of patients), recurrent bilateral anterior uveitis, and autoimmune thyroiditis with hypothyroidism (both 13% of the patients). A significant improvement in Disease Activity Score-28 was recorded at 6 and 9 months, while a significant difference *vs.* baseline was seen at 3, 6, and 9 months for the Psoriasis Area Severity Index. The Bath Ankylosing Spondylitis Disease Activity Index showed significant differences *vs.* baseline at 9 and 12 months. There was an improving trend at 9 and 12 months for pain scores and a significant improvement at 6 and 9 months for the physical component and at 12 months for the social component (Short Form 36 Health Survey quality of life scores). For the review of the literature, 35 articles were identified, but only 17 papers were eventually considered.

Conclusions. Secukinumab has demonstrated effectiveness for PsA treatment in several real-world studies. Both patient-oriented and clinician-oriented outcomes showed a significant improvement with this treatment. The present real-world evaluation adds further evidence on the use of secukinumab for PsA treatment, showing the rapid, safe, clinically significant, and sustained responses of PsA patients affected by co-morbidities.

Introduction

Psoriatic arthritis (PsA) is a chronic, systemic immune-mediated inflammatory disease characterized by musculoskeletal involvement and dermatological manifestations (1). It most commonly affects subjects around 40-50 years of age, frequently involving peripheral and axial joints, skin, and nails (2). Recent evidence has indicated that several comorbidities are frequently observed in patients with PsA. These include cardiovascular disease, metabolic syndrome, overweight, diabetes, bowel inflammation, obesity, osteoporosis, renal disease, and ophthalmologic conditions, as well as psychological symptoms like anxiety and depression (1-3). PsA, and especially its disabling articular manifestations, are responsible for substantial clinical burden. Considering these elements and their chronic nature, early diagnosis, together with prompt and effective treatment, is needed to limit structural damage and minimize the detrimental health effects and adverse socioeconomic consequences (1, 2).

In recent years, PsA treatment has progressed substantially through the availability of new biological disease-modifying anti-rheumatic drugs (bDMARDs) and novel targeted synthetic DMARDs. In this regard, in addition to inhibitors of tumor necrosis factor (TNF)-α, many of these agents target the interleukin (IL)-23/IL-17A and Janus kinase/signal transduction and transcription activation pathways and can be considered a valid therapeutic approach for PsA (4). There is now solid evidence that IL-17A is an important effector cytokine in the pathogenesis of PsA and has also been implicated in several autoimmune diseases (5). Therapies targeting the IL-17 axis have been shown to be highly effective in PsA. (6). Among these, secukinumab is a fully human monoclonal antibody that exhibits a high-affinity, selective binding to IL-17A, leading to its neutralization (7). In clinical trials, secukinumab has shown good efficacy on the key domains of PsA and has now been approved for its treatment (8). Secukinumab has been studied in Phase 3 FUTURE trials, where, compared to placebo, it led to significant improvement of Psoriasis Area Severity Index (PASI) and American College of Rheumatology (ACR) responses as well as radiographic progression, with long-term outcomes sustained for up to 2 years (9-13).

While randomized clinical trials of secukinumab have demonstrated its efficacy in PsA treatment after inadequate response to TNF or as a first biological treatment, real-world evidence (RWE) of the drug's efficacy still provides new insights. RWE is important since it is complementary to the data from controlled trials, wherein the findings may not always be generalizable to real-world practice (14). In this paper, we reviewed different studies using secukinumab in PsA and analyzed the results in terms of drug retention rate, efficacy, and patients' reported outcomes. To add to the RWE of the use of secukinumab in PsA, we report our experience in a cohort of patients with PsA who had inadequate response to anti-TNF and/or traditional agents that were observed for a maximum period of 1 year. In addition to clinical parameters, quality of life (QoL) was also evaluated.

Materials and Methods

Study design and patients

In this observational study, patients with PsA, diagnosed with ClASsification criteria for Psoriatic ARthritis (CASPAR) criteria, were enrolled among those attending the Rheumatology Service at the "SS.ma Annunziata" Hospital in Chieti. Patients were studied over a period of 18 months, from April 2018 to October 2019, and evaluated from time 0, prior to the start of therapy, for up to 12 months, with clinical visits at 3, 6, 9, and 12 months. Since subjects were enrolled at different times, the duration of the observation was different for each one. The cohort was divided into four groups based on the observation time achieved by the individual subjects: T1=3 months, T2=6 months, T3=9 months, and T4=12 months. T0 is defined as the baseline of the study. There were no strict enrollment criteria other than a prior therapy with conventional DMARDs or biological agents, which was discontinued due to lack of efficacy or adverse reactions. Secukinumab was administered at 300 mg each week for 5 weeks, followed by 300 mg every month, and was not associated with methotrexate in any patient. All procedures were in accordance with the ethical standards of the Helsinki Declaration and its later amendments. Written informed consent was obtained from all individual participants included in the study.

Study endpoints

The following clinical outcomes were evaluated: Disease Activity Score 28 (DAS28-CRP); visual analog scale (VAS) pain score, PASI score; Bath Ankylosing Spondylitis Disease Activity Index (BASDAI); Bath Ankylosing Spondylitis Functional Index (BASFI). The Short Form 36 Health Survey (SF-36) was used to evaluate the effects of treatment on QoL. Clinical evaluation was performed before initiation of therapy with secukinumab and after 3, 6, 9, and 12 months.

Statistical analysis

For the efficacy analysis, the mean, standard deviation, mean difference, and significance (p-value) were individually analyzed for each parameter for each of the four groups. The mean was calculated separately considering data at time 0 and those at 3 months, 6 months, 9 months, and 12 months to evaluate the differences before initiation of therapy and during treatment. Statistical analysis was performed with SPSS for Statistics v.20 software (IBM, Armonk, NY, USA). Continuous variables were analyzed with the t-test or Wilcoxon test based on data distribution. A p-value ≤ 0.05 was considered statistically significant.

Literature review

Electronic research was performed on the PubMed database using the following string: "real-word" AND "secukinumab" AND "psoriatic arthritis". The publications included were in the English language, published from 2018 to 2023, with studies performed at least on 50 patients. Case reports and small case series were excluded as robust studies were already available, and we aimed to provide the appropriate perspective for the present study.

Results

Demographic and baseline clinical characteristics

From April 2018 to October 2019, a total of 20 patients were enrolled in the study.

The main clinical characteristics at baseline are shown in Table 1. Five patients dropped out of the study due to the inability to comply with the scheduling of the treatment. Of the 15 patients, 12 were women and 3 men, with a mean age of 56.0 and 59.5 years, respectively. Three patients were obese. A total of 15 patients completed 6 months of follow-up, 11 patients completed 9 months, and 6 patients were followed for 12 months. Dropouts occurred before follow-up due to transfers to other cities (n=5), secondary failures (n=2), and the patient's decision to stop therapy (n=2).

The type of PsA and prior therapies are detailed in Table 1. All patients had experienced multiple treatment failures with various conventional and bDMARDs (range 2-8 prior therapies). Treatment had been discontinued due to lack of efficacy or adverse reactions and included patients who had contraindications to the common agents used to treat PsA. Different articular patterns were present according to the classification of Moll and Wright (15): there were four cases of asymmetric peripheral polyarthritis, five cases of spondylitis, and six cases of mixed involvement of the spine and peripheral joints. No formal clinical score for enthesitis was conducted in the study group; however, dactylitis was present in 5 patients (3 in the hands and 2 in the feet). Regarding cutaneous involvement, 9 patients had psoriasis at baseline: of these, 3 were affected by a severe form (PASI 15), of which 2 cases with classic involvement (extensor surfaces of the forearms and legs, scalp) and 1 case with palm-plantar involvement; the remaining 6 patients had a mild-moderate form (PASI <10), all patients had nail involvement. The 6 patients who did not present skin involvement at baseline had a family history and/or previous clinical history of mild psoriasis. The participants within the cohort were also affected by multiple comorbidities that included fibromyalgia (n=5), two cases of recurrent bilateral anterior uveitis, which failed to respond to adalimumab, and autoimmune thyroiditis with hypothyroidism, and one instance each of arterial hypertension, myasthenia gravis, dyslipidemia, multiple sclerosis (treated with glatiramer acetate), antiphospholipid antibody syndrome, obesity, and obstructive sleep apnea. Two patients also had depressive symptoms and were being administered antidepressants. None of the patients presented signs or symptoms of inflammatory bowel disease. Therefore, the cohort was highly heterogeneous and could be considered equally difficult to treat as the common real-life setting.

Clinical endpoints

Changes in DAS28, PASI, BASDAI, and BASFI scores are shown in Tables 2 and 3. For DAS28 significant differences were seen at 6 and 9 months of therapy. For PASI, a significant difference *vs.* baseline was seen at 3, 6, and 9 months. For BASDAI, as

Table 1. Type of psoriatic artrhitis and prior therapies in the cohort.

Patient	Type of PsA	Prior therapies
1	Mixed	MTX, IFX, ETA, ADA, UST
2	Spondylitis	MTX, IFX, ADA, ETA, CERT
3	Mixed	MTX, ETA, ADA, GOL
4	Peripheral polyarthritis	MTX, ETA, GOL, IFX
5	Peripheral polyarthritis	MTX, LFN
6	Spondylitis	MTX, LFN
7	Central	MTX, IFX, ADA
8	Peripheral polyarthritis	MTX, CSA, SLF, LFN, HCQ, ETA, ADA, APR
9	Spondylitis	MTX, ADA, ETA
10	Spondylitis	MTX, GOL
11	Mixed	MTX, HCQ
12	Mixed	MTX, IFX, ADA
13	Peripheral polyarthritis	MTX, CSA, GOL, ADA, ETA, IFX
14	Spondylitis	MTX, SLF, LFN, ADA, ETA, IFX
15	Mixed	MTX, ADA, ETA

ETA, etanercept; MTX, methotrexate; ADA, adalimumab; IFX, infliximab; GOL, golimumab; CERT, certolizumab; CSA, ciclosporin; LFN, leflunomide; APR apremilast; UST, ustekinumab; HCQ, hydroxychloroquine; SLF, sulfasalazine; PsA, psoriatic arthritis.

Table 2. Changes in Disease Activity Score 28 and Psoriasis Area Severity Index score.

	N	Mean ± SD	Mean difference DAS28	p	Mean ± SD	Mean difference PASI	p
T_0	15	4.2±1.57	1.2	0.08	3.2±6.39	1.2	**0.05**
T_1	15	3.0±1.16			2±5.34		
T_0	15	4.2±1.57	2.2	**0.05**	3.2±6.39	1.2	**0.05**
T_2	15	2.00±1.80			2±4.81		
T_0	11	4.2±1.83	2	**0.02**	3.5±7.2	2.5	**0.02**
T_3	11	2.2±2.11			1±5.99		
T_0	6	4.9±2.25	2.6	0.05	2.2±4.26	1.2	0.06
T_4	6	2.3±2.36			1±2.15		

SD, standard deviation; DAS28, Disease Activity Score 28; PASI, Psoriasis Area Severity Index; T0 indicates baseline value at enrollment, while T_1, T_2, T_3, and T_4 indicate values at 3, 6, 9, and 12 months, respectively. Significant p-values are indicated in bold.

Table 3. Changes in Bath Ankylosing Spondylitis Disease Activity Index and Bath Ankylosing Spondylitis Functional Index scores.

	N	Mean ± SD	Mean difference BASDAI	p	Mean ± SD	Mean difference BASFI	p
T_0	15	4.5±1.9	1.2	0.07	6.3±1.9	2.8	0.07
T_1	15	3.3±19			3.5±19		
T_0	15	4.53±1.9	1.3	0.06	6.3±1.9	3.1	0.06
T_2	15	3.2±1.1			3.2±1.1		
T_0	11	4.7±2.2	1.9	**0.05**	6.3±2.2	3,4	0.05
T_3	11	2.8±1.0			2.9±1.0		
T_0	6	5.0±1.5	2.2	**0.02**	7.3±1.5	4.5	**0.05**
T_4	6	2.8±1.4			2.8±1.4		

BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; BASFI, Bath Ankylosing Spondylitis Functional Index; SD, standard deviation.T_0 indicates baseline value at enrollment, while T_1, T_2, T_3, and T_4 indicate values at 3, 6, 9, and 12 months, respectively. Significant p-values are indicated in bold.

well as for BASFI, significant differences *vs.* baseline were seen at 9 and 12 months, although an improving trend of the score was already present at 3 months. Axial involvement was also assessed using radiography and MRI. However, no formal analysis was conducted at any time point because the study group with this type of involvement was too small, with only 2 patients at the 9-month time point.

Changes in pain and quality of life

For VAS pain, differences *vs.* baseline were observed at 6 months, although they were significant only after 9 months of treatment and confirmed at 12 months (Table 4). Considering the results of the SF-36 physical scores, significant differences were observed at 6 and 9 months but not at 12 months, possibly due to the low number of patients (Table 5). Lastly, a significant improvement at 12 months was seen for the social component of the SF-36 (Table 5).

Safety

The safety profile of secukinumab was very good, despite the extreme heterogeneity and the numerous comorbidities of the studied population. In fact, no adverse reactions were observed in this cohort.

Literature review

A total of 35 articles were identified. Nineteen were excluded as they were not pertinent to the aim of the study (PsA patients were not the only patients in the study population). A total of 17 papers were finally selected for the review. Of those, the majority were published in 2022 (8), 3 in 2020, three in 2021, 2 in 2019, and 1 in 2023. Most of the studies were observational and either retrospective or prospective population studies; instead, two were observational analyses from biological registries such as the Spanish BIOBADASER (16). Among the observational studies, the largest was the SERENA study (17), collecting data on patients treated with secukinumab from 438 sites across Europe.

Most of the studies focused on drug retention rates as well as on the clinicians' and patients' reported outcomes.

One of the first papers on the RWE of secukinumab was a letter to the editor by Elliot *et al*. in 2019 where the authors presented their retrospective data on secukinumab's use for PsA and ankylosing spondylitis in 45 patients. Patients with peripheral disease experienced a decrease in pain VAS, baseline tender 68 joint score, and swollen 66 joint score. Additionally, 52% of patients achieved a modified ACR 20 score, while 38% and 14% achieved an ACR50 and ACR70 respectively (18). The study from Klavadianou *et al.* in 2020 was larger (19), and the authors conducted a retrospective, observational study to assess the efficacy, drug survival, and safety of secukinumab on 75 biologically experienced patients (*i.e.*, patients treated previously with another biological drug) patients with PsA (who fulfilled the CASPAR criteria) in the real-life setting. Most of the patients had peripheral arthritis (97%), 42% of them had axial involvement, 22% had enthesitis and 12% had dactylitis. Two-thirds of the patients were bio-experienced (TNF inhibitor or anti-IL-12/IL-23). The median drug survival for secukinumab was 26.8 months with 64 % of patients continuing therapy at the 1-year follow-up. All clinimetric indexes [DAS28-C-reactive protein (CRP) and Disease Activity index for PSoriatic Arthritis] improved and dactylitis resolved in 56 % of patients. In addition, patients with axial involvement experienced a significa-

Table 4. Changes in visual analog scale pain.

	N	Mean ± SD	Mean difference	p
T_0	15	6.9±1.8	1.9	0.37
T_1	15	5±2.3		
T_0	15	6.9±1.8	2.9	0.06
T_2	15	4±2.4		
T_0	11	7.0±2.1	3.5	**0.05**
T_3	11	3.5±3.0		
T_0	6	7.6±1.8	4.6	**0.05**
T_4	6	3±3.1		

SD, standard deviation. T_0 indicates baseline value at enrolment, while T_1, T_2, T_3, and T_4 indicate values at 3, 6, 9, and 12 months, respectively. Significant p-values are indicated in bold.

Table 5. Changes in Short Form 36 Health Survey physical and social scores.

	N	Mean ± SD SF-36 Physical	Mean difference	p	Mean ± SD SF-36 Social	Mean difference	p
T_0	15	29.67±24.96	-19.08	0.00	37.87±34.94	-10.73	0.08
T_1	15	48.75±22.06			48.60±32.18		
T_0	15	29.67±24.96	-14.93	0.03	37.87±34.94	-9.00	0.23
T_2	15	44.60±26.25			46.87±35.49		
T_0	11	31.82±26.01	-20.45	**0.05**	36.73±39.27	-9.45	0.36
T_3	11	52.27±34.09			46.18±39.54		
T_0	6	30.00±23.45	-19.00	0.06	10.33±25.31	-18.67	**0.05**
T_4	6	49.00±27.64			29.00±37.66		

SF-36, Short Form 36 Health Survey; SD, standard deviation. T_0 indicates baseline value at enrollment, while T_1, T_2, T_3, and T_4 indicate values at 3, 6, 9, and 12 months, respectively. Significant p-values are indicated in bold.

tive improvement: BASDAI score decreased from a mean of 5.53 to 4.12 (p=0.047) as did the BASFI score (19).

Data from a larger Japanese open-label, multicentric observational study confirmed the improvement in secukinumab-treated PsA patients (20). The mean Health Assessment Questionnaire-Disability Index decreased from 0.72 (at baseline) to 0.37 at week 4 and 0.47 at week 24; the mean DAS28-CRP score decreased from 3.43 (at baseline) to 2.3 after week 2. The mean BASDAI score was 5.04 at baseline, decreased to less than 4 by week 4, and remained in the range of 2.85-2.25 from week 12 to week 24.

In the overall assessment of changes in joint symptoms, response rates were 86.49% at week 4, 80.77% at week 12, 90.70% at week 16, and 87.50% at week 24, demonstrating a consistently positive trend. The study showed a good retention rate (20). Secukinumab was found to be associated with a lower risk of non-persistence in the group of biologic-naïve patients [hazard ratio (HR) 0.65; 95% confidence interval (CI) 0.49, 0.86] while it was linked to a higher risk of non-persistence in biologically-experienced patients [HR 1.20 (95% CI 1.03, 1.40)] in a Swedish study published in 2020 (21). These data were further supported by a retrospective nationwide Spanish study in which drug survival rates of 97.1%, 89.0%, 81.1%, and 74.3%, respectively at 6, 12, 18, and 24 months were observed (22).

Secukinumab retention rate as a first-line treatment was higher in bio-naïve patients, as demonstrated by Evitair *et al.* in 2021. In this subgroup of patients, the drug retention rate was 86% at 3 years (23).

These data were supported by later studies from Spain in 2022, where the presence of peripheral arthritis and an evolution time >6 years were the only two variables that showed a significant probability of a higher secukinumab retention rate (24).

Evitar *et al.* results were also supported by a later analysis of the Spanish BIOBADASER biological drugs patient population registry. The data collected suggested that secukinumab is effective in both naïve and non-responder patients. Moreover, the retention rates were higher when secukinumab was used as the first-line biological treatment, although they were also adequate in the second and third lines of treatment (16).

A positive retention rate was also reported by Moskal et al. and Garcia Dorta *et al.* (25, 26).

Most of the RWE data for secukinumab in PsA came from the SERENA registry (17). This is an ongoing, longitudinal, real-world observational study involving patients with moderate-to-severe psoriasis, PsA, or ankylosing spondylitis who received at least 16 weeks of secukinumab. Interim analysis on several hundred patients showed secukinumab's sustained effectiveness in PsA for at least 2 years after enrolment (27, 28).

Larger patient cohorts (2017 PsA patients) were studied by Michelsen *et al*. in 13 European countries. The authors concluded that although the clinimetric indexes such as DAS28-CRP and CDAI improved at 12-month follow-up, the remission was significantly higher in biologics-naïve patients, as was for the response rate outcomes measured with ACR20/50/70 (29). CHRONOS was a multicentric, non-interventional, retrospective Italian real-world study assessing the 6-month and 1-year effectiveness of biological drugs for PsA treatment, which was conducted in 20 Italian hospital rheumatology clinics. The study included 399 patients who fulfilled the inclusion criteria (56.9% were females), with a mean (standard deviation) duration of PsA of 7.2 (6.9) years. Secukinumab was the most frequently prescribed biologic (40.4%) and was followed by adalimumab (17.8%) and etanercept (16.5%). The proportion of secukinumab responders according to EULAR DAS28 criteria was 73.4% (95% CI: 65.8-81.1%) and 69.6% (95% CI: 61.5-77.7%) at 6 months and 1 year, respectively. Additionally, the percentage of secukinumab-treated patients who achieved an ACR20/50/70 response at 6 months was 45.3%, 33.3%, and 18.2%, while at 1 year was 35.1%, 29.3%, and 17.1%, respectively. These data confirmed the efficacy of secukinumab in the real-world setting (30). The improvement in patient reported outcomes (PRO) in secukinumab-treated PsA patients was the main focus of the retrospective cohort study conducted by Mease *et al.* (31). One hundred patients were included in the study and 17% were biologically naïve. According to previous data, improvements in PRO measures and clinical manifestation were observed after 6 months among patients who initiated and maintained secukinumab (31). Symptoms such as joint pain or tenderness, ankle or heel pain, morning stiffness, fatigue, pain disrupting sleep, and toe swelling were also evaluated in a US cross-sectional, web-based survey of PsA secukinumab-treated patients. Two hundred PsA patients were included in the analysis, with 12.5% being biologically naïve. After secukinumab initiation, 79.9% of patients reported an overall PsA symptom improvement. Additionally, 52.2% of patients reported an overall improvement in PsA symptoms within 4 weeks after secukinumab initiation, 25.2% within 1-2 months, and 21.4% after 3 months. Furthermore, more than 90% of patients reported an improvement in symptoms within 6 months. Finally, the majority of patients (≥ 96%) expressed overall satisfaction with the drug (32).

Discussion

In our real-life observational study, secukinumab can be considered an effective PsA therapy. Significant improvements were seen in PASI scores at 3, 9, and 12 months, and in BASDAI at 9 and 12 months. Significant differences compared to the baseline were observed in DAS28. Improvements in VAS pain scores were seen at 9 months, as well as a benefit in physical scores at most time points and in social scores at 1 year. Randomized clinical trials showed that secukinumab was associated with meaningful improvements in clinical and radiological parameters (9-13), and recent real-life evidence supports the efficacy of secukinumab in PsA. In 2018, Nicola *et al.* published a small case series of 13 patients with PsA treated with secukinumab and reported a rapid remission of psoriatic lesions and an improvement of arthritis at 4 and 16 weeks (33). Pinto Tasende *et al.* published a real-life series of 76 PsA patients who were treated with secukinumab, documenting high retention rates at 12 months (90.9% in naïve and 81.5% in non-naïve patients) (34). It was also noted that the safety profile was in agreement with that observed in clinical trials.

More recently, Chiricozzi *et al.* published the results of a retrospective, European, real-world study on secukinumab treatment in 330 patients with moderate-to-severe plaque psoriasis (35). Patients who were naïve to biological treatment had a greater probability of achieving PASI scores of ≤1, ≤2, ≤3, and ≤5 at week 12, compared to those previously treated with a biologic agent. Moreover, secukinumab was associated with greater efficacy in naïve patients up to week 52. The results may help to better identify the characteristics of patients who show better responses to secukinumab. That study suggested that lower body mass index, shorter disease duration, less severe arthritis, and younger age may be associated with a better response to secukinumab.

More recently, a study on 178 patients from 12 clinical centers demonstrated that, in a real-life setting, secukinumab was effective in improving DAS28 scores, dactylitis skin lesions, and enthesitis

at 24 months. In this study, secukinumab was used as a third-line biological treatment in 42% of the patients. This finding closely aligns with our study, where 12 out of 15 patients were treated with secukinumab as a second-line therapy (36).

In the review of the literature, we tried to collect evidence about the effectiveness of secukinumab in patients with PsA in a real-world setting. Current literature about real-world experience provided evidence of a good retention rate of secukinumab and a low risk of drug discontinuation in PsA patients. Reports of clinician-oriented and patient-oriented measures showed a marked improvement during secukinumab administration. In line with the evidence collected, secukinumab represents a reliable and effective therapeutic option for patients with PsA. Our real-life study largely confirms the results of these previous reports, documenting that secukinumab induces a rapid improvement of symptoms with an excellent efficacy duration. Moreover, QoL with secukinumab therapy, evaluated with the SF-36 form, also showed significant improvement in the social and physical subdomains, albeit not at all time points. The lack of statistically significant results may also be due to the low number of patients, especially at later time points. Patient-reported pain, which imposes a remarkable burden, also seemed to mildly improve during treatment, although no significant differences were observed. However, it must be highlighted that our patients had failed multiple therapies and that many were affected by comorbidities. In fact, the high heterogenicity of our cohort could be seen as the real spectrum of patients seen in the clinics. The improved QoL scores during the treatment may suggest that even in these difficult-to-treat patients secukinumab could be a valid choice.

The safety profile of secukinumab was also favorable, confirming the results of clinical and other real-world studies. In fact, we did not observe any adverse effects in our cohort.

Our study has some limitations such as the small number of patients enrolled and the limited number of patients who were followed for 12 months. Nevertheless, the IL-17 inhibitor secukinumab provided rapid, clinically significant, and sustained responses in patients with PsA. Our real-world data show that secukinumab is moderately effective in difficult-to-treat PsA patients and provides beneficial effects for up to 1 year. This study adds to current knowledge of the real-life use of secukinumab in PsA.

Conclusions

This observational study confirmed the rapid, safe, clinically relevant, and sustained positive responses to secukinumab treatment in PsA patients with co-morbidities, who were previously subjected to alternative therapies. Further investigations are needed to better evaluate the role played by the comorbidities in the response to this biological agent.

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