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Effectiveness and safety of secukinumab in Italian patients with psoriasis: an 84 week, multicenter, retrospective real-world study

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ABSTRACT

Background: Long term data on the real-life use of secukinumab are scant. The aim of this study was to investigate the real-life effectiveness, safety and treatment persistence of secukinumab in patients with moderate-to-severe psoriasis.

Research design and methods: This 84-week, multicenter (n = 7) retrospective study analyzed data from patients who initiated and received at least 6 months of secukinumab treatment between June 2016 and June 2018 in the Campania region of Italy. Patient demographic and treatment characteristics, duration of treatment and reasons for discontinuation as well as Psoriasis Area and Severity Index (PASI), Body Surface Area (BSA), and Dermatology Life Quality Index (DLQI) scores were assessed.

Results: 324 patients (63% male, mean age 50.2 years) were enrolled and received a mean 11.7 months of secukinumab treatment. Overall, 9.5% discontinued secukinumab, including 5.2% who discontinued due to secondary inefficacy and 1.8% due to adverse events. PASI, BSA and DLQI scores were significantly improved from baseline at every follow-up visit ($p < 0.001$) and mean PASI decreased from 15.3 ± 6.3 at baseline to 0.5 ± 1.0 at week 84. Secukinumab had comparable effectiveness in biologic naïve and non-naïve patients.

Conclusions: This study confirmed the effectiveness and safety of secukinumab in real-world patients with psoriasis.

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KEYWORDS
Anti-IL-17; biologic drugs; PASI; psoriasis; real life; secukinumab

1. Introduction

Psoriasis is one of the most common inflammatory skin diseases affecting up to 3% of population worldwide [1]. In the last decades, major discoveries in the pathogenesis of psoriasis have shown that it is a chronic multifactorial inflammatory disease, which is founded on the dysregulated interplay between keratinocytes and immune cells (Th1 and Th17 above all) through the production of inflammatory cytokines [2]. In this context, interleukin (IL)-17A plays a key role, increasing the expression by keratinocytes of chemokines involved in recruiting myeloid dendritic cells, Th17 cells, and neutrophils in psoriatic skin lesions and leading to inflammation, neutrophilic chemotaxis and angiogenesis [3,4]. Therefore, IL-17A has been shown to be a new therapeutic target for psoriasis treatment.

Secukinumab is a fully human immunoglobulin G1 kappa monoclonal antibody targeting IL-17A, and was the first anti-IL 17 approved by the US Food and Drug Administration and European Medicines Agency for the treatment of moderate-to-severe psoriasis and psoriatic arthritis (PsA) in adult patients in 2015 [5]. The approved regimen for plaque psoriasis is 300 mg subcutaneously every week for 4 weeks and once every 4 weeks thereafter. Phase III trials of secukinumab have shown high response rates for this regimen, with 76–91% of patients achieving a 75% reduction in Psoriasis Area and Severity Index (PASI) score (PASI75) and 54–73% achieving a 90% reduction in PASI (PASI90) after 12 weeks of therapy [6–8].

In the Campania region of Southern Italy, secukinumab has been available for the treatment of psoriasis since June 2016. As it was only recently introduced to the market, data on the performance of secukinumab in daily practice is still scarce, particularly regarding long-term effectiveness and safety, secondary inefficacy and drug persistence. Although data regarding the efficacy and safety of secukinumab when administered for up to 5 years are now accessible [9], there is a need for real-world studies on this topic. Indeed, real-world patients with psoriasis are very different from those enrolled in clinical trials, often presenting with comorbidities and/or polypharmacotherapy, which can strongly influence biologic treatment choice and outcomes as well as disease course [10]. To address these issues, a multicenter, retrospective study was conducted to determine the long-term effectiveness, safety, and drug persistence of secukinumab in patients with psoriasis attending routine clinical practices in Campania.

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2. Patients and methods

2.1. Patients

Data from adult (≥18 years old) patients with moderate-to-severe plaque psoriasis with or without PsA of >1 year's duration who initiated and received at least 6 months of treatment with secukinumab between June 2016 and June 2018 were analyzed. The study population consisted of patients attending the dermatologic outpatient clinics of the seven participating centers (University of Naples Federico II, Naples; University of Campania 'Luigi Vanvitelli', Naples; 'Gaetano Rummo' Hospital, Benevento; Dermatology Unit, 'Ospedale del Mare', Naples; University of Salerno, Salerno; 'Sant'Anna and San Sebastiano' Hospital, Caserta; 'Sacro Cuore di Gesù Fatebenefratelli' Hospital, Benevento). The protocol of this study was approved by the Ethic Committee for Biomedical Activities of the University of Naples 'Federico II' and the study was conducted following the principles of the Declaration of Helsinki. All patients provided their informed consent for participation.

2.2. Outcomes

For each patient the following data were collected through computer-based database or electronic registries: i) personal and demographic data; ii) duration of psoriasis and PsA (if available); iii) comorbidities; iv) previous psoriasis systemic treatments; v) duration of secukinumab therapy and eventual reason for its discontinuation (if available); vi) Psoriasis Area and Severity Index (PASI), Body Surface Area (BSA), and Dermatology Life Quality Index (DLQI) scores at initiation of secukinumab (baseline) and at all available follow-up appointments (particularly at 4, 24, 48, 60, 72, and 84 weeks of secukinumab treatment, if available).

Safety was assessed by treatment-emergent adverse events, physical examinations and laboratory monitoring.

2.3. Statistical analysis

Effectiveness data were analyzed using a last observation carried forward (LOCF) method, where if a patient dropped out of the study the last available value was 'carried forward' until the end of the treatment. Having a clinical response less than a PASI75 after 12 weeks was considered a primary lack of efficacy whereas the development of an inadequate response (<PASI75) after an initial clinical response at 12 weeks was considered as treatment inefficacy (secondary inefficacy). Data were presented as mean ± standard deviation (continuous variables) or as number and proportion of patients (categorical variables). The significance of differences in mean values obtained at the different time points of treatment was assessed by unpaired Student's t-test, where p-values <0.05 were considered to be statistically significant. All statistical analyses were performed using GraphPad Prism 4.0 (GraphPad Software Inc., La Jolla, CA, USA).

3. Results

3.1. Participants

Of the 385 patients with moderate-to severe plaque psoriasis screened at the seven dermatology centers, 61 were excluded from the survey since they did not meet inclusion criteria of having a secukinumab treatment duration of at least 6 months. In 50 of these patients (82.0%), secukinumab treatment was still on-going at the time of study enrollment, whereas seven patients had stopped treatment after week 12 due to a primary lack of efficacy. Therefore, a total of 324 patients (63.6% male; mean age 50.18 years) were enrolled in the study (Table 1). These patients had a mean psoriasis duration of 18.16 years and 36.1% of patients also had PsA, with a reported mean articular disease duration of 9.45 years. One or more comorbidities were present in the majority of patients (66.7%), the most frequent of which were hypertension (32.1%), dyslipidemia (14.8%) and diabetes (13.9%; Table 1).

All patients had previously received at least one conventional systemic treatment for psoriasis, with cyclosporine being the most common (67.9%), followed by methotrexate (46.6%) and phototherapy (narrowband

Table 1. Baseline characteristics and demographics.

Characteristic	N = 324
Male, n (%)	206 (63.6)
Age, years	50.18 ± 13.67
Duration of psoriasis, years	18.16 ± 10.53
PsA, n (%)	117 (36.1)
Duration of PsA, years	9.45 ± 8.1
Previous treatments, n (%)	324 (100.0)
Acitretin	113 (34.9)
Cyclosporine	220 (67.9)
Methotrexate	151 (46.6)
Phototherapy	123 (38.0)
Biologics	222 (68.5)
Adalimumab	121 (37.3)
Certolizumab pegol	12 (3.7)
Etanercept	118 (36.4)
Golimumab	33 (10.2)
Infliximab	26 (8.0)
Ustekinumab	80 (24.7)
Naïve to biologic drugs, n (%)	102 (31.5)
Comorbidities, n (%)	216 (66.7)
Anxiety-depression disorder	12 (3.7)
Arthrosis	7 (2.2)
Asthma	4 (1.2)
Benign prostatic hyperplasia	8 (2.5)
Chronic gastritis	5 (1.5)
Celiac disease	1 (0.3)
Congestive heart failure	4 (1.2)
Coronary artery disease	15 (4.6)
Depression	7 (2.2)
Diabetes	45 (13.9)
Dyslipidemia	48 (14.8)
GERD	4 (1.2)
Hepatitis B	6 (1.9)
Hepatitis C	4 (1.2)
Hypertension	104 (32.1)
Latent tuberculosis	10 (3.1)
Obesity	30 (9.2)
Thyroid disease	10 (3.1)
Ulcerative colitis	2 (0.6)
Uveitis	1 (0.3)

Values are presented as mean ± standard deviation unless stated otherwise.
GERD, gastroesophageal reflux disease; PsA, psoriatic arthritis.

ultraviolet B [NB-UVB] or psoralen plus ultraviolet A; 38.0%). The majority of patients had also received previous biologic treatments (68.5% of patients), including adalimumab (37.3%), etanercept (36.4%) and ustekinumab (24.7%; Table 1).

3.2. Secukinumab treatment and persistence

Secukinumab was administered for a mean duration of 11.7 ± 4.4 months. No dose or frequency modifications of secukinumab were performed; however, concomitant use of another anti-psoriatic drug was initiated in 8 patients (2.5%; methotrexate, n = 7; NB-UVB, n = 1). Thirty-one (9.5%) patients discontinued secukinumab therapy. The most common reasons for treatment discontinuation were secondary inefficacy (at a mean secukinumab treatment duration of 10.2 months, range 6–16 months; n = 17, 5.2%) and adverse events (n = 6, 1.8%), whereas the remaining patients (n = 8, 2.5%) discontinued secukinumab therapy due to other reasons such as loss to follow-up, personal preference, decision to become pregnant or scheduled surgical intervention. The proportion of patients discontinuing secukinumab treatment because of lack of efficacy was similar in patients who had prior exposure to biologic therapies and those who were naïve to biologic therapies (11/222, 5.0% vs 6/102, 5.9%, respectively). Moreover, the proportion of patients discontinuing secukinumab treatment because of lack of efficacy did not differ significantly between obese and non-obese patients (2/30, 6.7% vs 15/294, 5.1%, respectively, P = 0.66).

3.3. Effectiveness

PASI, BSA and DLQI scores were all improved from baseline with secukinumab treatment (Table 2); mean PASI scores decreased from 15.3 at baseline to 0.5 after 84 weeks of treatment, BSA decreased from 21.4 to 0.7 and DLQI decreased from 11.7 to 0.2. In particular, a statistically significant improvement for all disease and quality of life severity indexes (PASI, BSA and DLQI) was seen after only 4 weeks of therapy (all p < 0.001 vs baseline; Table 2). The significant improvements in PASI were highlighted by the percentage change from baseline in PASI score results, which were 55.5% at week 4, 84.3% at week 24, 89.5% at week 48, 93.4% at week 60, 97.4% at week 72 and 96.7% at week 84 (Figure 1).

When effectiveness was assessed by baseline biologic therapy, the change in PASI, BSA and DLQI scores from baseline with secukinumab was comparable between patients who had prior exposure to biologic therapies and those who were naïve to biologic therapies. While numerically greater reductions in mean PASI, BSA and DLQI scores was observed in patients who were naïve to biologic therapies, no significant difference was observed between the patient subgroups except for the mean reduction in PASI at week 24 and 48 (Table 3).

Obese patients had a significantly higher mean PASI score at baseline and at every follow up than non-obese patients (Table 4). However, in both obese and non-obese patients, mean PASI scores were numerically lower at each follow up than at baseline.

Table 2. Mean PASI, BSA and DLQI scores at baseline and at week 4, 24, 48, 60, 72 and 84.

Assessment	Baseline	W4	W24	W48	W60	W72	W84
PASI	15.3 ± 6.3	6.8 ± 5.0*	2.4 ± 2.8*	1.6 ± 2.6*	1.0 ± 2.4*	0.4 ± 1.2*	0.5 ± 1.0*
BSA	21.4 ± 14.4	9.3 ± 8.9*	3.4 ± 4.3*	2.7 ± 4.5*	1.5 ± 2.7*	0.8 ± 1.7*	0.7 ± 1.9*
DLQI	11.7 ± 2.8	4.0 ± 3.6*	1.7 ± 2.5*	0.5 ± 1.0*	0.6 ± 2.3*	0.3 ± 0.8*	0.2 ± 0.5*

Values are presented as mean ± standard deviation. *p < 0.001 vs baseline (assessed by unpaired Student's t-test). BSA, Body Surface Area; DLQI, Dermatology Life Quality Index; PASI, Psoriasis Area Severity Index; W, week.

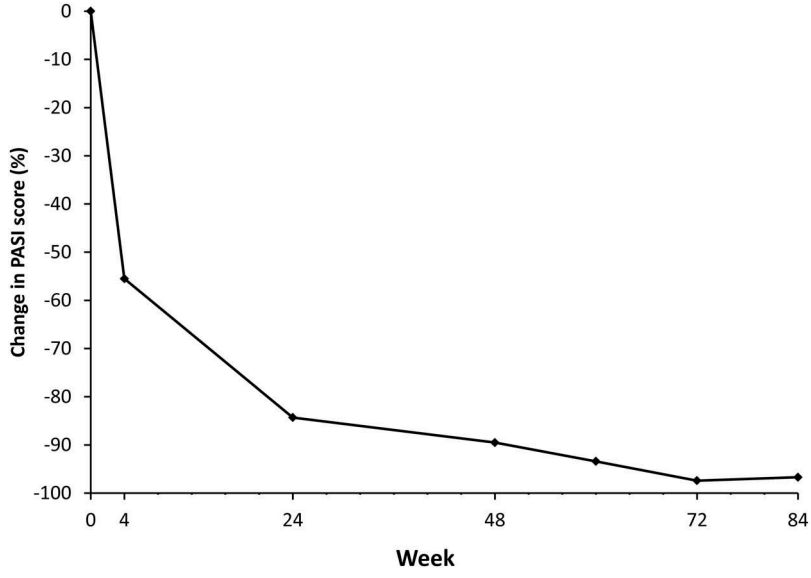

Figure 1. Mean percentage change from baseline in Psoriasis Area Severity Index (PASI) score.

Table 3. Mean PASI, BSA and DLQI scores at baseline and at week 4, 24, 48, 60, 72 and 84 in patients who were naïve to biologic therapies (n = 102) and those with prior exposure (n = 222).

Assessment	Baseline	W4	W24	W48	W60	W72	W84
PASI							
Naïve pts	15.5 ± 7.2	6.1 ± 5.7	1.6 ± 2.0	1.0 ± 1.7	0.4 ± 1.6	0.4 ± 1.3	0.5 ± 0.8
Non-naïve pts	15.2 ± 6.0	7.2 ± 4.7	2.8 ± 3.1	1.9 ± 3.0	1.4 ± 2.9	0.5 ± 1.6	0.7 ± 1.9
P	0.83	0.62	<0.001	<0.05	0.10	0.62	0.55
BSA							
Naïve pts	23.1 ± 16.1	9.5 ± 10.6	2.8 ± 4.5	1.6 ± 3.0	1.1 ± 2.0	1.5 ± 2.9	0.7 ± 1.4
Non-naïve pts	21.0 ± 13.9	9.4 ± 8.5	3.7 ± 4.8	2.9 ± 4.7	1.7 ± 3.0	1.4 ± 2.1	1.1 ± 2.1
P	0.28	0.95	0.13	0.16	0.46	0.06	0.22
DLQI							
Naïve pts	12.2 ± 4.6	3.0 ± 2.8	1.0 ± 1.5	0.3 ± 0.5	0.4 ± 0.8	0.4 ± 0.5	0.2 ± 0.6
Non-naïve pts	11.6 ± 2.9	4.2 ± 3.8	1.9 ± 2.7	0.6 ± 1.2	0.8 ± 2.8	0.3 ± 1.1	0.3 ± 0.9
P	0.42	0.19	0.14	0.38	0.29	0.36	0.52

Values are presented as mean ± standard deviation. BSA, Body Surface Area; DLQI, Dermatology Life Quality Index; PASI, Psoriasis Area Severity Index; pts, patients; W, week. p-values are assessed by unpaired Student's t-test.

Table 4. Mean PASI scores at baseline and at week 4, 24, 48, 60, 72 and 84 in patients who were obese (n = 30) and non-obese (n = 294) at baseline.

Assessment	Baseline	W4	W24	W48	W60	W72	W84
PASI							
Obese pts	17.6 ± 7.2	8.7 ± 5.6	4.1 ± 4.8	2.8 ± 3.1	2.8 ± 2.2	1.4 ± 1.3	1.6 ± 2.1
Non-obese pts	15 ± 6.2	6.6 ± 4.9	2.1 ± 2.3	1.2 ± 1.8	1.0 ± 2.4	0.4 ± 1.1	0.7 ± 1.7
P	<0.05	<0.05	<0.001	<0.01	<0.01	<0.05	<0.05

Values are presented as mean ± standard deviation. PASI, Psoriasis Area Severity Index; pts, patients; W, week.

3.4. Safety

Adverse events which led to secukinumab discontinuation were reported in 1.8% of patients and included perianal abscess, fever and tremor, PsA worsening, eczematous skin eruption, candida infection, and latent tuberculosis infection [n = 1 each].

4. Discussion

Over the past few decades, major advances in the understanding of the pathogenesis of psoriasis have led to the development of biologic drugs, completely revolutionizing the treatment of moderate-to-severe psoriasis [10]. In this context, as IL-17A has been shown to be a key cytokine in psoriasis pathogenesis, biologics targeting this cytokine have demonstrated rapid improvement of psoriasis with high levels of skin clearance maintained over time and manageable safety profiles [11]. In particular, secukinumab, a fully human monoclonal antibody that selectively neutralizes IL-17A, has been shown to have significant efficacy and safety in the treatment of moderate-to-severe plaque psoriasis and PsA [5,6]. Secukinumab introduced a new era in the management of psoriasis, shifting possible psoriasis treatment outcomes from PASI75 to a 90% reduction of PASI score (PASI90) or complete response (100% reduction in PASI scores; PASI100), which are now recognized goals for the treatment of psoriasis in Italian guidelines [12,13]. Numerous factors must be considered when selecting appropriate treatment for a patient with psoriasis, including commonly-associated comorbidities (such as psoriatic arthritis, obesity and cardiovascular disease), patient age and concomitant infections [14,15]. Secukinumab appears to represent a step forward in the disease management due to its efficacy and safety in different patient populations with numerous comorbidities (including elderly patients and those with PsA), its low immunogenicity potential, as well as its efficacy in typically difficult-to-treat areas such as scalp, palmo-plantar area, lower limbs and nails [14,16–21]. As patients with psoriasis have an increased risk of cardiovascular comorbidity, we note with interest the results of a recent study in patients with plaque psoriasis which suggested that secukinumab may improve endothelial function and thus have a beneficial effect on cardiovascular risk [22]. Further studies in this area are necessary.

However, while a real-world Danish registry study of patients with psoriasis receiving biologic therapy has shown that secukinumab had the highest number of PASI100 respondents, it also had the lowest rate of drug persistence among all the biologics assessed (adalimumab, etanercept, infliximab, ustekinumab and secukinumab), with 29.2% of patients discontinuing secukinumab [23]. The fact that most patients receiving secukinumab in the registry had received a prior biologic therapy may be a confounding factor for this outcome [23], but the results of the registry showed that there was a lower long-term efficacy observed with secukinumab compared with data from clinical trials, a high drop-out rate (predominantly because of lack of efficacy), as well as a higher frequency of adverse events, mainly infections, with secukinumab [23]. These results are consistent with a single center report of 90 patients with psoriasis treated with secukinumab, in which 30% of patients discontinued therapy before 32 weeks of treatment, with 18.9% of patients treated with secukinumab exhibiting loss of efficacy at 24–32 weeks [24]. Conversely, data from a clinical trial have shown a high sustained long-term efficacy and a favorable safety profile with secukinumab when administered to patients with moderate-to-severe psoriasis for up to 5 years [9], while an additional real-life survey in 107 patients with psoriasis reported long-term maintenance of clinical improvement over up to 52 weeks of observation as well as good safety, with only 9.3% of patients experiencing adverse events [25]. As the current literature on the long-term efficacy of secukinumab as well as its secondary inefficacy are controversial, we decided to

perform this multicenter, retrospective real-life study involving psoriasis care centers located in Campania, a region in the South of Italy, where secukinumab had been available since June 2016.

This multicenter, retrospective study analyzed a large cohort of patients with moderate-to-severe psoriasis (n = 324) treated with secukinumab for a maximum follow-up period of 84 weeks, showing rapid and high clinical responses, which were comparable to those reported in phase III trials [6,9]. In line with what was observed in clinical trials [6,8], secukinumab appeared to have a rapid action in this study, with significant improvements in psoriasis disease and quality of life severity indexes reported after only 4 weeks of therapy. Furthermore, in this study secukinumab had a high persistence, with only 31 (9.5%) patients discontinuing secukinumab therapy during the 84 weeks of assessment. In particular, 17 (5.2%) patients stopped treatment for secondary inefficacy with only 1.8% of the total initial population stopping secukinumab for primary lack of efficacy at week 12. This rate of discontinuation is much lower than that observed in other publications, such as the 32-week single center study conducted by Huang and colleagues (10/53, 18.9% [24]), the 52-week retrospective multicenter study conducted by Georgakopoulos and colleagues (10/41, 24% [26]) and the 52-week multicenter study conducted by Notario and colleagues (29/136, 21.3% [27]) and somewhat similar to that seen in the 52-week retrospective real-life study conducted by Galluzzo and colleagues (12/107, 11.2% [25]). However, the rate of secukinumab discontinuation due to secondary inefficacy observed in this study (5.2%) seems to be in line with the result of the 5-year SCULPTURE trial extension study reported by Bissonette and colleagues (7/168, 4.3%) [9]. These results highlight that the rate of secukinumab discontinuation is very variable in current literature, even if the studies with larger study populations, such as our study (n = 324) and the study conducted by Bissonette and colleagues (n = 168 [9]), suggest that the rate of secukinumab discontinuation due to inefficacy is low, ranging from 4.2 to 5.2%. The higher percentages of primary or secondary inefficacy with secukinumab may be explained by the fact that the majority of secukinumab-treated patients had previous exposure to a biologic therapy, as was the case in the publications by Egeberg and colleagues [23] (where patients treated with secukinumab were typically receiving their third or fourth biologic drug), Huang and colleagues [24] (where all of the discontinuations were observed in patients who were not naïve to biologics), Notario and colleagues [27] (where 72.1% of patients had failed treatment with at least one biologic drug) and Galluzzo and colleagues [25] (who observed that multidrug-treated patients who received more than 2 biologic drugs more frequently reported a loss of efficacy). It is not always easy to evaluate the real impact of previous biologic treatment on secukinumab therapy since possible confounding factors and involved variables are very numerous. In this study, we also performed a comparison between the subgroup of patients who were naïve to biologic therapy and those had previous exposure and showed that the effectiveness of secukinumab was almost comparable between these two groups, which is partially in line with data reported by Blauvelt and colleagues [28] where a difference in PASI90 of only 13% at week 16 was observed between these patient populations. In addition, our subgroup analysis showed that the rate of patients discontinuing secukinumab for treatment inefficacy was similar between patients who had prior exposure to biologic therapies and those who did not (5.0% vs 5.9%, respectively). However, previous biologic treatment appears not to be the only reason for the high variability of the reported secukinumab inefficacy rate; other possible factors may be represented by patient dissatisfaction following minor disease relapse (achieving PASI90 or PASI100 has become more common, driving higher rates of discontinuation in real-world clinical practice), as well as clinicians' high expectations of the performance of secukinumab [29]. In addition, another factor to consider could be suggested by the high proportion of patients returning to their previous therapy upon failing on secukinumab in the study conducted by Egeberg and colleagues [23]; these data may suggest that these patients were controlled with an acceptable, but not complete, skin clearance and were consequently switched to secukinumab in an attempt to obtain a lower absolute PASI score. This tendency may also explain higher and/or variable percentages of secukinumab inefficacy reported in different real-life studies. As regarding data coming from the DERMBIO Danish psoriasis registry, secukinumab lack of efficacy percentages may be higher in real practice because a subgroup of patients has been treated off-label with a lower dosage of the drug (150 mg instead of 300 mg) as reported by Schwensen and colleagues [30]. Previous studies have shown that obesity may be linked to lower response rates to secukinumab over 52 weeks of treatment [25, 27.] In our study, although the rate of patients discontinuing secukinumab for treatment inefficacy did not differ significantly between obese and non-obese patients (6.7% vs 5.1%, P = 0.66), obesity appeared to be linked to a higher disease severity and a lower response to secukinumab. Mean PASI values were significantly higher in obese patients than non-obese ones at baseline and at every follow-up visit up to week 84.

Long-term treatment discontinuation due to adverse events represents another matter of debate. Indeed, data form the DERMBIO Danish registry showed that among all biologics the highest rate of infections occurred with secukinumab (incidence rate 19.1 per 100 person-years) with 2% of patients treated with this drug also reporting cardiovascular adverse events [23]. In contrast, the safety of secukinumab has been confirmed in numerous clinical trials [6–9], with real-life studies also reporting that adverse events following secukinumab treatment are uncommon and the frequency of treatment discontinuation due to adverse events is low (ranging from 1.5–4.7%) [25–27,31]. In this context, our results are in line with the majority of studies reported above which show a low rate of secukinumab discontinuation due to adverse events, with only 1.8% of patients stopping treatment for safety concerns. Interestingly, we also had one case of PsA worsening with secukinumab treatment, which was also seen by Galluzzo and colleagues in their study [25]. This is a topic which indubitably needs to be further investigated.

Our study presents some limitations, such as the relatively small sample size (324 patients), together with the retrospective design and the use of LOCF as the main drug effectiveness measure. The inclusion criterion of at least 6 months

treatment with secukinumab may be viewed as a limitation, however this criterion was chosen in order to focus on secondary rather than primary inefficacy; it has been reported previously that secondary inefficacy generally occurs after 6 months of treatment [24].

5. Conclusions

In conclusion, even with the limitations inherent in a retrospective design, the results of this study demonstrated the effectiveness and safety of secukinumab in psoriatic patients, as well as its rapid action, confirming the results of clinical trial data in a more complicated set of patients with comorbidities, polypharmacy, multi-drug failure, etc. To our knowledge, this study has the longest follow-up duration for a real-life study of secukinumab reported so far (84 weeks). Moreover, our real-life survey also showed the almost comparable efficacy of secukinumab in patients who were naïve to biologic therapies and those with prior exposure as well as the low rate of secukinumab discontinuation during an 84-week treatment period due to both lack of efficacy or adverse events. Despite the relatively recent approval of secukinumab, the current real-world analysis appears to confirm its effectiveness and safety, as well as high survival and treatment maintenance. Undoubtedly, additional studies are needed to further confirm and extend to longer periods these observations.

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Author contributions

Matteo Megna contributed to the study design, enrolled patients, read and approved each draft of the manuscript and performed some of the analyses; Luisa Di Costanzo contributed to the study design, enrolled patients, read and approved each draft of the manuscript and performed some of the analyses; Giuseppe Argenziano contributed to the study design, enrolled patients, read and approved each draft of the manuscript; Anna Balato enrolled patients, read and approved each draft of the manuscript, performed some of the analyses, and performed statistical analysis of the data; Paola Colasanti enrolled patients and read and approved each draft of the manuscript; Francesco Cusano enrolled patients and read and approved each draft of the manuscript; Antonia G. Galluccio enrolled patients and read and approved each draft of the manuscript; Alessio Gambardella enrolled patients and read and approved each draft of the manuscript; Serena Lembo enrolled patients, read and approved each draft of the manuscript and performed statistical analysis of the data; Raffaele Mozzillo enrolled patients and read and approved each draft of the manuscript; Genoveffa Scotto Di Luzio enrolled patients and read and approved each draft of the manuscript; Gabriella Fabbrocini enrolled patients and read and approved each draft of the manuscript; Nicola Balato contributed to the study design, enrolled patients and read and approved each draft of the manuscript. All authors drafted and/or critically revised the manuscript and approved the final draft for submission.

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