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ORIGINAL RESEARCH

Real-World Long-Term Effectiveness and Safety of Secukinumab in Psoriasis: Up to 7 Years of Evidence from the Italian Landscape Psoriasis (IL PSO) Multicenter Retrospective Study

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ABSTRACT

Introduction: Secukinumab, approved in 2015 for the treatment of moderate-to-severe psoriasis, has demonstrated sustained efficacy and safety in pivotal randomized controlled trials. However, real-world data on its long-term effectiveness and safety are limited. We conducted a multicenter retrospective study involving 15 Italian dermatology units to assess the long-term effectiveness and safety of secukinumab in routine clinical practice over a period of up to 7 years.

Methods: A total of 769 adult patients with moderate-to-severe psoriasis who received continuous secukinumab treatment for at least 4 years were included. We assessed effectiveness

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in terms of the Psoriasis Area and Severity Index (PASI) 90 and 100 (complete skin clearance) and an absolute PASI score of ≤ 2 at various time points from week 16 to 7 years. We performed subgroup analyses to evaluate the impact of different comorbidities. Safety was assessed by recording all adverse events (AEs) reported during follow-up visits.

***Results*:** PASI 90 was achieved by 36.0% of patients at week 16, increasing to 71.0% at year 1, 84.1% at year 4, 87.0% at year 5, and 90.0% at year 6. PASI 100 rates rose from 27.4% at week 16 to 67.1% at year 4 and 80.2% at year 7. Patients with concomitant psoriatic arthritis (PsA) showed significantly higher PASI 100 rates at years 5 and 6 ($p \leq 0.05$). The overall incidence of AEs was low, with serious AEs occurring in a small number of patients. Treatment was permanently discontinued due to adverse drug reactions in five patients (three due to de novo malignancies, one due to eosinophilic pneumonia, and one due to massive pulmonary embolism).

***Conclusions*:** In this selected cohort of long-term responders, secukinumab demonstrated sustained and progressively increasing effectiveness with a favorable safety profile over up to 7 years of treatment.

Keywords: Anti-IL17; Biologics; Psoriasis; Real-Life; Secukinumab

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Key Summary Points

Why carry out this study?

Secukinumab has demonstrated solid short- and medium-term efficacy in RCTs and effectiveness in real-world studies; however, real-world evidence on treatment effectiveness beyond 3–4 years of continuous therapy remains limited.

Multicenter long-term observational studies are essential to characterize the durability of response, the impact of comorbidities, and the safety profile of secukinumab under conditions of routine clinical practice.

What was learned from the study?

In a large cohort of 769 patients treated for at least 4 years across 15 Italian dermatology units, PASI 90, PASI 100, and PASI ≤ 2 response rates increased progressively over time, reaching 90.0%, 75.3%, and 94.4%, respectively, after 6 years of treatment.

Secukinumab demonstrated a consistently favorable safety profile over up to 7 years of treatment.

Patients with concomitant PsA showed significantly higher rates of complete skin clearance at years 5 and 6.

INTRODUCTION

Psoriasis is a chronic, immune-mediated inflammatory skin disease affecting approximately 40 million people worldwide, with a steadily increasing incidence reported between 1990 and 2019 and a global prevalence settled around 4–5% [1, 2].

Plaque psoriasis, also referred to as psoriasis vulgaris, is the most prevalent clinical subtype, representing almost 90% of cases [3]. The term "plaque" refers to its classic presentation with well-demarcated, erythematous plaques often covered with silvery-white scales and varying degrees of infiltration [4, 5]. Lesions most commonly involve the extensor surfaces of the body although other anatomical sites may also be affected [4].

Instead of the primitive cutaneous nature of the onset of this disease, in the modern era, the concept of psoriasis as an exclusively skin pathology is outdated and no longer scientifically accepted [6]. Indeed, psoriasis is now recognized as a complex, systemic inflammatory disorder with cutaneous signs that represent only the visible component of a much broader pathological process. In this context, the skin involvement can be conceptualized as the "tip of the iceberg," reflecting an underlying multisystem inflammatory disease driven by immune dysregulation [7, 8]. Genetic studies further support this multisystemic inflammation model, with early evidence implicating interleukin (IL)–10 family cytokines, particularly IL-19, IL-20, and IL-24, in psoriasis susceptibility, later confirmed and expanded by genome-wide association studies identifying novel risk loci and therapeutic targets [9–11].

Recent studies describe the progression of inflammation from the skin to systemic involvement as the "psoriatic march," characterized by a systemic inflammatory state linked and shared with multiple extracutaneous comorbidities, including cardiometabolic disorders, psoriatic arthritis (PsA), and mental health disorders [12–14]. Due to this proinflammatory link, early treatment with an effective and safe option, sustained over time, is essential to ensure long-term physical and mental well-being [15].

In daily clinical practice, psoriasis severity is assessed by combining objective measures evaluated throughout the Psoriasis Area and Severity Index (PASI) score and the calculation of the percentage the affected body surface area (BSA), with patient-reported impact on quality of life, evaluated through the Dermatology Life Quality Index (DLQI), and by considering the involvement of difficult-to-treat or high-impact areas (e.g., face, scalp, palms, soles, nails, and genitals) [16]. On this basis, psoriasis is generally classified as mild, usually manageable with topical therapies, or moderate-to-severe, which requires systemic treatment [17].

According to the Italian adaptation of the European guidelines, patients affected by

moderate-to-severe psoriasis are those defined by a PASI > 10 and/or a DLQI > 10 and/or a BSA > 10% [18, 19]. These thresholds reflect not only the extent and clinical severity of cutaneous involvement but also the burden of disease on patients' quality of life [20].

Over the past decade, the advent of targeted biologic agents has significantly reshaped the management of moderate-to-severe psoriasis, offering higher effectiveness, improved safety profiles, and sustained long-term disease control [21]. Beyond clinical response, biologics have led to substantial improvements in health-related quality of life, enabling many patients to regain daily functioning, social confidence, and psychological well-being [22].

Biologic therapies available are classified according to their molecular targets, which include tumor necrosis factor (TNF)-α, as well as the interleukin (IL)–17, IL-12/23, and IL-23 pathways [23–27].

Within the anti-IL-17 class, the currently available agents are secukinumab (a fully human monoclonal antibody that selectively targets IL-17A), ixekizumab (which similarly inhibits IL-17A), brodalumab (a fully human monoclonal antibody targeting the IL-17 receptor A [IL-17RA]), and bimekizumab (a human monoclonal antibody designed to provide dual and selective inhibition of both IL-17A and IL-17F) [27].

Among IL-17 inhibitors, secukinumab was first approved in January 2015 by both the Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for the treatment of moderate-to-severe plaque psoriasis in adults aged 18 years and older, with the indication subsequently extended to pediatric patients aged 6 years and older by the EMA in July 2020 and by the FDA in 2021 [28]. In November 2015 (EMA) and January 2016 (FDA), secukinumab was further approved for the treatment of active PsA in adults aged 18 years and older, based on the pivotal phase-3 FUTURE 1 and FUTURE 2 trials. This indication was later extended to pediatric patients aged 2 years and older (FDA, December 2021) and aged 6 years and older (EMA, 2022) [29, 30]. Most recently, secukinumab received regulatory approval for the treatment of moderate-to-severe hidradenitis suppurativa (HS) in adults aged 18 years and older, based on the results of the pivotal phase-3 SUNSHINE and SUNRISE trials [31]. Given this broad regulatory timeline spanning adult and pediatric populations across multiple immune-mediated inflammatory diseases, secukinumab represents the anti-IL-17 biologic with the longest and most extensive real-world data in terms of effectiveness, safety, and drug survival rates [32].

Despite the efficacy, safety, rapid onset of action, and sustained disease control of secukinumab in moderate-to-severe plaque psoriasis having been well investigated and documented through long-term extensions of randomized clinical trials (RCTs), data from real-world settings on its long-term effectiveness and drug survival remain limited in the current literature [33–37].

In this context, we conducted a multicenter real-world retrospective study to assess the effectiveness and safety of secukinumab in patients with moderate-to-severe plaque psoriasis, with a follow-up period of up to 7 years, making this one of the longest real-world observational experiences reported to date for this biologic in the treatment of psoriasis.

METHODS

Study Design and Population

We conducted a multicenter retrospective real-world study by collecting data from the electronic databases of 15 Italian dermatology units from January 2017 to December 2025. We enrolled 769 adult patients (≥ 18 years) with moderate-to-severe plaque psoriasis who had received secukinumab for at least 4 years. Patients' eligibility for secukinumab treatment was assessed according to the Italian Adaptation of the EuroGuiDerm Guideline on the systemic treatment of chronic plaque psoriasis [18]. All

patients received secukinumab at the approved dosing schedule for moderate-to-severe plaque psoriasis (300 mg by subcutaneous injection at weeks 0, 1, 2, 3, and 4, followed by 300 mg every 4 weeks thereafter), in accordance with the Summary of Product Characteristics [32].

Data Collection

Patients' clinical and demographic characteristics, including age, gender, weight, height, body mass index (BMI), disease duration, cardiometabolic comorbidities (CMD; defined as the presence of at least one of the following: arterial hypertension, hypercholesterolemia, type-2 diabetes mellitus [T2DM], obesity, or a history of major adverse cardiovascular events [MACE]), concomitant PsA, previous exposure to other biological agents, involvement of difficult-to-treat areas (scalp/face, nails, genitalia, and palms/soles), and PASI score at baseline, were obtained from electronic medical records. Due to the retrospective design of the study, missing data could not be recovered or retrieved.

Effectiveness Assessment

The primary effectiveness outcome was the proportion of patients achieving a PASI 90 response (reduction of at least 90% in PASI score from baseline), PASI 100 (complete skin clearance), and an absolute PASI score ≤ 2, evaluated at weeks 16 and 32, and after 1, 2, 3, 4, 5, 6, and 7 years. Additionally, subgroup analyses were performed to compare treatment effectiveness according to the involvement of at least one difficult-to-treat area, the presence of at least one CMD and the presence of concomitant PsA.

Safety Assessment

Safety was assessed by analyzing all AEs reported in the medical records at each follow-up visit.

AEs were classified according to clinical severity. Particular attention was given to serious AEs and to adverse drug reactions (ADRs) leading to treatment discontinuation.

Statistical Analysis

Categorical variables were summarized as absolute numbers and percentages, while continuous variables were reported as mean and standard deviation (SD). Statistical differences between groups were analyzed using the Chi-squared test for categorical variables; Fisher's exact test was applied when expected cell frequencies were fewer than five in any cell. Student's *t*-test was used for continuous variables. A *p*-value of ≤ 0.05 was considered statistically significant. Given the exploratory nature of the subgroup analyses, no correction for multiple comparisons was applied. All analyses were conducted on an "as-observed" basis using Stata/SE 18.0. Figures were generated using GraphPad Prism (version 10.2.3) and tables using Microsoft Excel.

Ethical Consideration

Institutional review board approval was exempted as the study protocol did not deviate from standard clinical practice. All patients received secukinumab as in good clinical practice, in accordance with Italian guidelines. All included patients had provided written consent for retrospective study of data collected during routine clinical practice (demographics, clinical scores). The study was performed in accordance with the Helsinki Declaration of 1964 and its later amendments. Data collection and handling complied with applicable laws, regulations, and guidance regarding patient protection, including patient privacy.

RESULTS

Baseline Characteristics

A total of 769 patients with moderate-to-severe psoriasis were included in this multicenter retrospective study and received secukinumab for at least 4 years across 15 Italian dermatology units. All patients completed 4 years of treatment; 669, 231, and 101 patients were followed for 5, 6, and 7 years, respectively.

The mean age of our cohort of study was 56.6 years (SD 13.7), with a mean disease duration of 20.2 years (SD 12.7). The mean BMI was 26.6 kg/m^2 (SD 4.4), and the mean baseline PASI score was 15.3 (SD 5.9). Most patients were male (494, 64.2%), and 461 (59.9%) presented with involvement of at least one difficult-to-treat area (including scalp/face, genitalia, palms/soles, and nails).

Regarding baseline comorbidities, 249 patients (32.4%) presented a prior diagnosis of PsA. Furthermore, at least one cardiometabolic comorbidity was present in 396 patients (51.5%). More specifically, among these comorbidities, arterial hypertension was the most prevalent (33.8%), followed by obesity (14.8%), T2DM (14.2%), hypercholesterolemia (10.8%), and a prior positive history of MACE (7.4%).

Thyroid disorders were observed in 48 (6.2%) patients, and anxiety or depressive disorder was reported in 13 (1.7%) patients. A previous diagnosis of neoplasm was documented in 27 (3.5%) patients. Of the patients, 26 (3.4%) had a chronic infection: 4 patients had chronic hepatitis B (HBV), 7 had chronic hepatitis C (HCV), 1 had human immunodeficiency virus (HIV) infection with an undetectable viral load under antiretroviral therapy, and 15 had latent tuberculosis infection (LTBI). At baseline, 447 (58.1%) patients were bio-naïve. Complete baseline characteristics are provided in Table 1.

Table 1 Baseline demographic and clinical characteristics of the study population at baseline ($N = 769$)

Characteristic	$N = 769$
Age (years), mean ± SD	56.6 ± 13.7
Male, *N* (%)	494 (64.2)
Female, *N* (%)	275 (35.8)
BMI (kg/m^2), mean ± SD	26.6 ± 4.4
Disease duration (years), mean ± SD	20.2 ± 12.7
Baseline PASI, mean ± SD	15.3 ± 5.9
Bio-naïve, *N* (%)	447 (58.1)
PsA, *N* (%)	249 (32.4)
Difficult-to-treat area involvement, *N* (%)	461 (59.9)
Face/scalp	272 (35.4)
Nails	201 (26.1)
Genitalia	126 (16.4)
Palmoplantar	115 (15.0)
At least one CMD, *N* (%)	396 (51.5)
Arterial hypertension	260 (33.8)
T2DM	109 (14.2)
Obesity	114 (14.8)
Hypercholesterolemia	83 (10.8)
MACE	57 (7.4)
MAFLD	9 (1.2)
Chronic infections, *N* (%)	26 (3.4)
HBV	4 (0.5)
HCV	7 (0.9)
HIV	1 (0.1)
LTBI	15 (2)
Prior neoplasm, *N* (%)	27 (3.5)
Thyroid disease, *N* (%)	48 (6.2)
Anxiety/depressive disorder, *N* (%)	13 (1.7)

Data are presented as mean ± SD for continuous variables and *N* (%) for categorical variables. *BMI* body mass index, *SD* standard deviation, *PASI* Psoriasis Area and Severity Index, *PsA* psoriatic arthritis, *CMD* cardiometabolic comorbidity, *T2DM* type 2 diabetes mellitus, *MACE* major adverse cardiovascular events, *MAFLD* metabolic-associated fatty liver disease, *HBV* hepatitis B virus, *HCV* hepatitis C virus, *HIV* human immunodeficiency virus, *LTBI* latent tuberculosis infection

Effectiveness

Effectiveness outcomes at all time points are summarized in Table 2 and illustrated in Fig. 1.

At week 16, PASI 90 was achieved by 277 (36%) patients, complete skin clearance (PASI 100) was achieved by 211 (27.4%), and an absolute PASI ≤ 2 was reached by 356 (46.3%). Response rates improved substantially by week 32: 420 (54.6%) patients achieved PASI 90, 318 (41.4%) achieved PASI 100, and 538 (70.0%) reached an absolute PASI ≤ 2.

At year 1, PASI 90, PASI 100, and PASI ≤ 2 were achieved by 546 (71.0%), 414 (53.8%), and 621 (80.8%) of patients, respectively, confirming the durability of early responses. Response rates continued to increase throughout long-term

follow-up: at year 2, PASI 90, PASI 100, and PASI ≤ 2 were reached by 72.4%, 53.6%, and 82.6% of patients, respectively; at year 3, by 78.2%, 57.6%, and 87%; and, at year 4, by 84.1%, 67.1%, and 91.4%, respectively.

Among the 669 patients who completed 5 years of treatment, PASI 90 was maintained or further improved in 582 patients (87%), PASI 100 in 484 (72.3%), and PASI ≤ 2 in 617 (92.2%). Among the 231 patients followed for 6 years, response rates were 90% for PASI 90, 75.3% for PASI 100, and 94.4% for PASI ≤ 2. In the 101 patients with 7 years of follow-up, PASI 90 was achieved by 89.1%, PASI 100 by 80.2%, and PASI ≤ 2 by 95.0%.

Subgroup analyses are presented in Table 3 and illustrated in Fig. 2. Regarding the impact of comorbidities, no statistically significant differences in terms of PASI 90, PASI 100, or PASI ≤ 2 response rates were observed between patients with and without CMD or between patients with and without involvement of difficult-to-treat areas at any of the analyzed time points.

In contrast, patients with concomitant PsA achieved significantly higher rates of complete skin clearance (PASI 100) compared with those without PsA after 5 (77.9% versus 69.8%, $p < 0.05$) and 6 (85.7% versus 71.4%, $p < 0.05$) years of follow-up, respectively. PASI 90 rates were also significantly higher in patients with PsA at year 6 (96.8% versus 87.5%, $p < 0.05$).

Safety

The overall safety profile was favorable throughout the entire study period. A total of 54 (7%) patients experienced at least one nonserious AE during the follow-up period. The most commonly reported AE was upper respiratory tract infections (URTIs) in 36 patients followed by candida infections (10 patients) and headache (3 patients). These events were all mild in severity and did not lead to treatment modification.

Regarding serious AEs, five patients permanently discontinued treatment: three patients (0.4%) developed de novo malignancies (one breast cancer, one endometrial carcinoma, and one carcinoma of the thyroid). Additionally, one patient experienced a massive pulmonary embolism (0.1%), and one developed eosinophilic pneumonia (0.1%).

Finally, among the 15 patients with pre-existing LTBI, no reactivation of tuberculosis was detected during the study period, as confirmed by annual chest radiography and pulmonological follow-up visits. Similarly, no virological reactivation was observed among the 11 patients with pre-existing chronic viral hepatitis (4 patients with HBV and 7 with HCV) or the 1 patient with HIV infection. The complete safety profile is summarized in Table 4.

Table 2 Secukinumab effectiveness throughout the entire study period in terms of PASI 90, PASI 100, and PASI ≤ 2

Time point	*N*	PASI 90, *N* (%)	PASI 100, *N* (%)	PASI ≤ 2, *N* (%)
Week 16	769	277/769 (36)	211/769 (27.4)	356/769 (46.3)
Week 32	769	420/769 (54.6)	318/769 (41.4)	538/769 (70)
Year 1	769	546/769 (71)	414/769 (53.8)	621/769 (80.8)
Year 2	769	557/769 (72.4)	412/769 (53.6)	635/769 (82.6)
Year 3	769	601/769 (78.2)	443/769 (57.6)	669/769 (87)
Year 4	769	647/769 (84.1)	516/769 (67.1)	703/769 (91.4)
Year 5	669	582/669 (87)	484/669 (72.3)	617/669 (92.2)
Year 6	231	208/231 (90)	174/231 (75.3)	218/231 (94.4)
Year 7	101	90/101 (89.1)	81/101 (80.2)	96/101 (95)

PASI Psoriasis Area and Severity Index

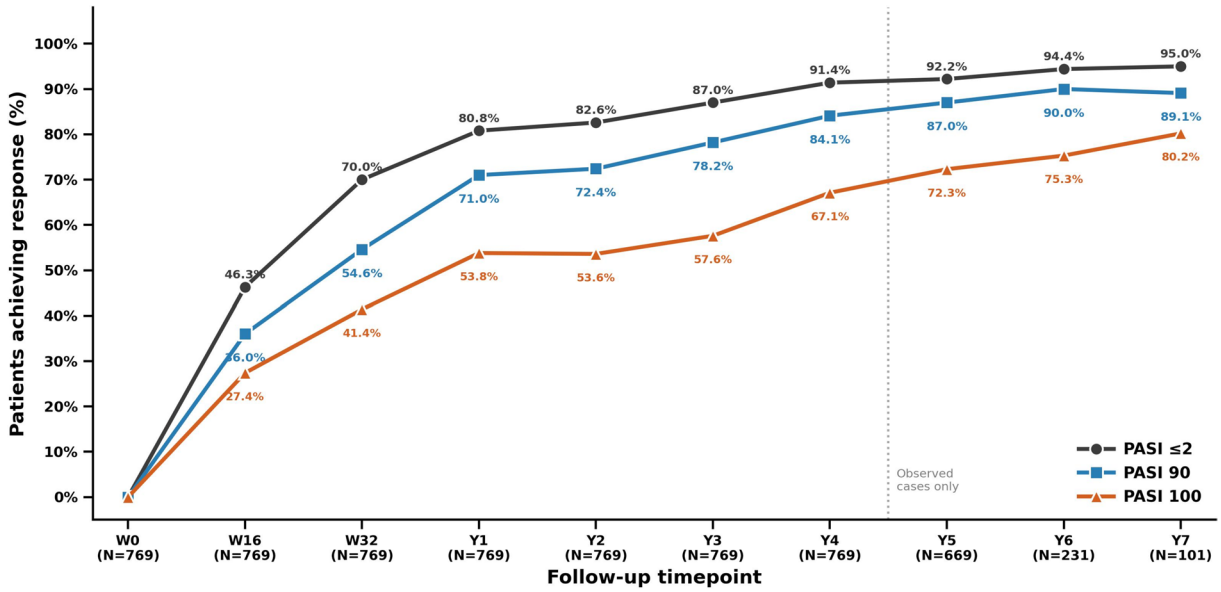

Fig. 1 Secukinumab effectiveness in terms of PASI 90, PASI 100, and PASI ≤ 2 from baseline to year 7. *PASI* Psoriasis Area and Severity Index

DISCUSSION

In this large multicenter retrospective real-world study, we assessed the long-term effectiveness and safety of secukinumab in 769 patients with moderate-to-severe plaque psoriasis over up to 7 years of continuous treatment across 15 Italian dermatology units. To the best of our knowledge, this represents one of the largest and longest real-world experiences reported to date for this biologic in psoriasis. Our data demonstrate that, among patients who maintained continuous treatment for at least 4 years, clinical responses are sustained and show a progressive increase over time, with PASI 90, PASI 100, and PASI ≤ 2 response rates reaching 90.0%, 75.3%, and 94.4% at year 6, respectively, and remaining stable after 7 years of treatment.

The sustained effectiveness observed in our cohort is broadly consistent with the long-term data reported from the extensions of the pivotal RCTs. In the SCULPTURE extension study, Bissonnette et al. demonstrated that secukinumab maintained high and stable skin clearance through 5 years of treatment in the controlled trial setting [30]. Similarly, the 5-year extension of the ERASURE and FIXTURE trials reported by Langley et al. confirmed the durability of PASI responses [31]. The response rates observed in our real-world cohort at years 4 and 5 are comparable or marginally superior to those reported in these RCT extensions. This is at least partly attributable to the survivor effect inherent in long-term real-world observational studies, in which only patients who maintain an adequate clinical response and tolerate the drug well are carried forward to later time points; those who discontinue treatment for any reason, whether for ineffectiveness, AEs, or patient preference, are no longer represented.

Among published real-world studies, Mastorino et al. recently reported a multicenter Italian real-world experience with secukinumab over up to 5 years in patients with psoriasis and psoriatic arthritis, demonstrating favorable drug survival rates and sustained skin clearance [35]. Our study extends this experience to 7 years with a larger cohort, further reinforcing the long-term value of secukinumab in routine clinical practice. In particular, Galluzzo et al. conducted a multicenter real-world study documenting secukinumab's sustained effectiveness over 6 years, while Dastoli et al. reported

Table 3 Subgroup analyses at long-term follow-up (years 4–7) according to the presence of concomitant PsA, cardiometabolic comorbidities, and involvement of difficult-to-treat areas

Comparison	Year	Outcome	Exposed, *N* (%)	Control, *N* (%)	*p*-Value	Test
PsA versus no PsA	4	PASI 90	207/249 (83.1)	440/520 (84.6)	0.598	χ^2
		PASI 100	167/249 (67.1)	349/520 (67.1)	0.990	χ^2
		PASI ≤ 2	230/249 (92.4)	473/520 (91)	0.514	χ^2
	5	PASI 90	186/208 (89.4)	396/461 (85.9)	0.210	χ^2
		PASI 100	**162/208 (77.9)**	**322/461 (69.8)**	**0.031***	**χ^2**
		PASI ≤ 2	196/208 (94.2)	421/461 (91.3)	0.194	χ^2
	6	**PASI 90**	**61/63 (96.8)**	**147/168 (87.5)**	**0.035***	**χ^2**
		PASI 100	**54/63 (85.7)**	**120/168 (71.4)**	**0.025***	**χ^2**
		PASI ≤ 2	62/63 (98.4)	156/168 (92.9)	0.121	Fisher
	7	PASI 90	22/24 (91.7)	68/77 (88.3)	1.000	Fisher
		PASI 100	20/24 (83.3)	61/77 (79.2)	0.776	Fisher
		PASI ≤ 2	24/24 (100)	72/77 (93.5)	0.335	Fisher
CMD versus no CMD	4	PASI 90	331/396 (83.6)	316/373 (84.7)	0.667	χ^2
		PASI 100	257/396 (64.9)	259/373 (69.4)	0.181	χ^2
		PASI ≤ 2	358/396 (90.4)	345/373 (92.5)	0.301	χ^2
	5	PASI 90	290/327 (88.7)	292/342 (85.4)	0.204	χ^2
		PASI 100	243/327 (74.3)	241/342 (70.5)	0.266	χ^2
		PASI ≤ 2	302/327 (92.4)	315/342 (92.1)	0.904	χ^2
	6	PASI 90	101/113 (89.4)	107/118 (90.7)	0.742	χ^2
		PASI 100	87/113 (77)	87/118 (73.7)	0.565	χ^2
		PASI ≤ 2	106/113 (93.8)	112/118 (94.9)	0.714	χ^2
	7	PASI 90	39/43 (90.7)	51/58 (87.9)	0.755	Fisher
		PASI 100	36/43 (83.7)	45/58 (77.6)	0.444	χ^2
		PASI ≤ 2	41/43 (95.3)	55/58 (94.8)	1.000	Fisher
Difficult areas versus none	4	PASI 90	388/461 (84.2)	259/308 (84.1)	0.978	χ^2
		PASI 100	305/461 (66.2)	211/308 (68.5)	0.497	χ^2
		PASI ≤ 2	423/461 (91.8)	280/308 (90.9)	0.681	χ^2
	5	PASI 90	347/398 (87.2)	235/271 (86.7)	0.859	χ^2
		PASI 100	285/398 (71.6)	199/271 (73.4)	0.605	χ^2
		PASI ≤ 2	371/398 (93.2)	246/271 (90.8)	0.247	χ^2

Table 3 continued

Comparison	Year	Outcome	Exposed, *N* (%)	Control, *N* (%)	*p*-Value	Test
	6	PASI 90	120/131 (91.6)	88/100 (88)	0.365	χ^2
		PASI 100	99/131 (75.6)	75/100 (75)	0.920	χ^2
		PASI ≤ 2	125/131 (95.4)	93/100 (93)	0.429	χ^2
	7	PASI 90	53/59 (89.8)	37/42 (88.1)	1.000	Fisher
		PASI 100	50/59 (84.7)	31/42 (73.8)	0.174	χ^2
		PASI ≤ 2	57/59 (96.6)	39/42 (92.9)	0.647	Fisher

Bold values indicate statistically significant difference ($p < 0.05$). *PsA* psoriatic arthritis, *CMD* cardiometabolic disease, *PASI* Psoriasis Area and Severity Index, *Fisher* Fisher's exact test (two-tailed), *MACE* major adverse cardiovascular events

*$p \leq 0.05$

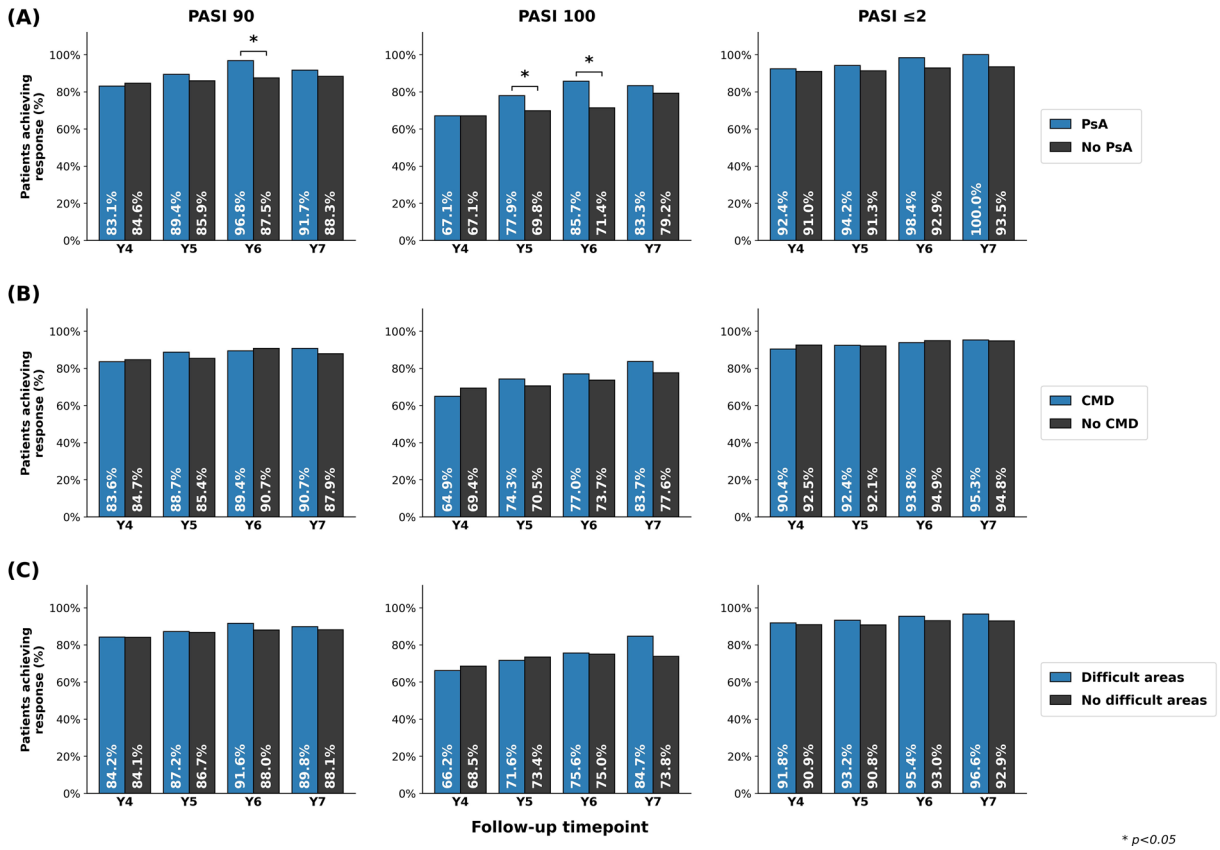

Fig. 2 Long-term effectiveness by patient subgroup at years 4–7. Grouped bar charts illustrating PASI 90, PASI 100, and PASI ≤ 2 response rates stratified by: (A) concomitant PsA, (B) presence of at least one cardiometabolic comorbidity, or (C) involvement of at least one difficult-to-treat area. *$p < 0.05$; *PASI* Psoriasis Area and Severity Index, *PsA* psoriatic arthritis, *CMD* cardiometabolic comorbidity

Table 4 Safety profile of secukinumab during follow-up ($N = 769$)

Adverse event	*N* (%)
Nonserious adverse events	54 (7)
URTIs	36 (4.7)
Candida infections	10 (1.3)
Headache	3 (0.4)
Eczematous reaction	2 (0.3)
Asthenia	2 (0.3)
Arthralgia	1 (0.1)
Serious adverse events	5 (0.7)
De novo malignancies	3 (0.4)
Breast cancer	1
Endometrial cancer	1
Carcinoma of the thyroid	1
Massive pulmonary embolism	1 (0.1)
Eosinophilic pneumonia	1 (0.1)

AE adverse event, *URTI* upper respiratory tract infection

comparably favorable outcomes over 240 weeks of follow-up in a Southern Italian multicenter setting [38, 39]. Moreover, the meta-analysis conducted by *Augustin* et al., comprising 43 studies, confirmed effectiveness rates across heterogeneous patient populations consistent with our findings [36].

In our study, secukinumab demonstrated long-term response rates comparable to those of other real-world studies on other IL-17 inhibitors, particularly ixekizumab, in terms of PASI 90 and PASI 100 [40, 41].

Regarding the subgroup analyses, no significant differences were found in most of the variables analyzed in terms of effectiveness, consistent with other real-life studies reporting similar outcomes with different anti-IL-17 and anti-IL-23 agents [40, 42].

An exploratory finding of our study was the observation of a higher rate of complete skin clearance in patients with concomitant PsA compared with those without PsA, which reached statistical significance at years 5 and 6. The mechanism underlying this observation remains speculative. A possible, though unproven, pathophysiological explanation may relate to the central role of the IL-17A pathway in both cutaneous and articular inflammation in PsA: the dual immunological burden in these patients may create a context in which sustained IL-17A inhibition exerts particularly pronounced anti-inflammatory effects across both compartments [29, 30, 43]. This hypothesis, however, is exploratory and requires dedicated prospective studies to be confirmed.

In contrast, the presence of cardiometabolic comorbidities did not significantly affect PASI response rates at any time point. This evidence could suggest that the approved dosing regimen of secukinumab provides adequate therapeutic drug exposure even in patients with altered metabolic profiles, including obesity and insulin resistance, unlike other biologic drugs approved for the treatment of psoriasis, which require dose adjustment in this patient population [44–47]. Similarly, the involvement of difficult-to-treat areas, such as the scalp, nails, genitalia, and palmoplantar regions, did not negatively impact response rates at any analyzed time point. These results are in line with previous reports on the effectiveness of anti-IL-17 and anti-IL-23 therapies in patients with difficult sites, and reinforce the use of secukinumab as a reliable long-term option regardless of the distribution of skin involvement [16, 48, 49].

The safety profile of secukinumab in our cohort remained consistently favorable across the entire observation period. Nonserious AEs were reported in fewer than 10% of patients, and the rates of serious events, including malignancies and thromboembolic events, are consistent with the background incidences expected in a population of middle-aged patients with moderate-to-severe psoriasis and a substantial prevalence of cardiometabolic comorbidities [50, 51].

Regarding chronic infections, no reactivation of LTBI, viral hepatitis, or HIV was observed throughout the study period, confirming previous studies on other anti-IL-23 and anti-IL-17 used for the treatment of psoriasis [52, 53].

Our study has several limitations. First, the retrospective nature of the data collection introduces inherent risks of information bias

and selection bias, and missing data cannot be recovered. Second, the inclusion criterion of at least 4 years of continuous secukinumab treatment introduces an inherent survivor bias, which excludes patients who discontinued the treatment early. Consequently, the progressively increasing response rates observed over time should not be interpreted exclusively as evidence of improving treatment effectiveness, but they must also reflect cohort attrition, with nonresponders progressively absent from later time points. Additionally, the use of an "as-observed" statistical approach, which includes only patients with available data at each time point, may further complicate this overestimation of effectiveness.

Moreover, the lack of a formal drug survival analysis represents an additional limitation of this study. Without it, we cannot fully evaluate how long patients stay on treatment or which factors are linked to early discontinuation, which may have contributed to the overestimation of long-term effectiveness in this cohort. It is also important to note that the statistical analysis was limited to univariate methods. Consequently, it is not possible to rule out confounding baseline variables, and the differences observed in the subgroup analysis should be interpreted with caution. Lastly, the multicenter design may introduce inter-center variability in clinical assessment practices and data collection standards, which may influence both effectiveness and safety outcomes. Despite these limitations, the large sample size, the extended follow-up period, and the multicenter real-world setting represent significant strengths of this study.

CONCLUSIONS

This large multicenter real-world study confirms the effectiveness and safety of secukinumab in the treatment of moderate-to-severe psoriasis throughout a period of 7 years of continuous treatment. Among patients who maintained continuous treatment, PASI 90, PASI 100, and PASI ≤ 2 response rates progressively increased, regardless of the presence of CMD or involvement of difficult-to-treat areas. Patients with concomitant PsA showed superior complete skin clearance rates at years 5 and 6, suggesting a potential immunological benefit of sustained IL-17A inhibition in this subgroup. These findings represent one of the longest real-world follow-up experiences reported for secukinumab in psoriasis to date.

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Author Contributions. All authors contributed to the conception and design of the study. Material preparation and data analysis were conducted by Luciano Ibba, Mario Valenti, Sara Di Giulio, and Alessandra Narcisi. Data collection was performed by Piergiorgio Malagoli, Anna Balato, Federico Bardazzi, Massimo Travaglini, Giampiero Girolomoni, Martina Maurelli, Martina Burlando, Stefano Caccavale, Carlo G. Carrera, Andrea Carugno, Paolo Dapavo, Eugenia V. Di Brizzi, Valentina Dini, Francesca M. Gaiani, Claudio Guarneri, Claudia Lasagni, Francesco Loconsole, Angelo V. Marzano, Matteo Megna, Alessandra Michelucci, Luca Potestio, Simone Ribero, Lidia Sacchelli, Nicola Zerbinati, and Luca Mastorino. Luciano Ibba and Sara Di Giulio wrote the first draft of the manuscript, and all authors commented on previous versions of the manuscript. Alessandra Narcisi and Mario Valenti performed the review and the editing of the final draft of the manuscript. Alessandra Narcisi and Antonio Costanzo supervised the study. Mario Valenti, the corresponding author attests that to the best of their knowledge, Dr. Dapavo met the definition of authorship through his contribution to the work, and all co-authors agree with retaining him in the author list. All authors read and approved the final manuscript.

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Data Availability. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Conflict of Interest. Luciano Ibba has been a consultant and/or speaker and has served as an advisory board member for Almirall and LEO Pharma. Piergiorgio Malagoli has been a speaker for AbbVie, Eli Lilly, Novartis, Janssen-Cilag, Celgene, Leo Pharma, and Almirall. Anna Balato has received honoraria for participation in advisory boards, in meetings, or as a speaker for AbbVie, Celgene, Janssen-Cilag, Eli Lilly, Novartis Pharma, Pfizer, Sanofi-Genzyme, and UCB Pharma. Federico Bardazzi has been a consultant adviser and clinical study investigator for Eli Lilly, AbbVie, Novartis, Leo Pharma, Sandoz, Bristol Myers, Abiogen-Pharma, Celgene, and Janssen. Giampiero Girolomoni has received personal fees from AbbVie, Almirall, Amgen, Boehringer-Ingelheim, Bristol-Myers Squibb, Eli-Lilly, Janssen-Cilag, Leo Pharma, Merck Serono, Novartis, Pfizer, Pierre Fabre, Samsung Bioepis, and Sanofi. Martina Burlando has acted as a speaker and consultant for AbbVie, Janssen, Amgen, Novartis, Eli Lilly, and UCB Pharma. Carlo G. Carrera has served as a board participant or speaker for AbbVie, Eli Lilly, Janssen, Novartis, Celgene, Almirall, and Leo Pharma. Andrea Carugno has been a consultant and/or speaker for AbbVie, Leo Pharma, Eli Lilly, Novartis, Janssen-Cilag, Amgen, Almirall, UCB Pharma, and Boehringer Ingelheim. Paolo Dapavo has been a speaker for Novartis, AbbVie, Sanofi, UCB, Janssen, Eli Lilly, and Leo Pharma. Claudio Guarneri has been a scientific consultant, speaker, and clinical study investigator for AbbVie, Celgene, Janssen, Eli Lilly, Novartis, Pfizer, Sanofi, Almirall, and Leo Pharma. Claudia Lasagni declares a conflict of interest with AbbVie, Novartis, Eli Lilly, and Almirall. Francesco Loconsole served on advisory boards and/or received honoraria for lectures from AbbVie, Janssen-Cilag, Novartis, Lilly, and Sanofi. Angelo V. Marzano reports consultancy/advisory boards disease-relevant honoraria from AbbVie, Amgen, Boehringer-Ingelheim, Bristol Myers Squibb, Incyte, Leopharma, Novartis, Pfizer, Sanofi, and UCB. Matteo Megna acted as a speaker or consultant for AbbVie, Eli Lilly, Janssen, Leo Pharma, and Novartis. Simone Ribero has served as an advisory board member and/or consultant and has received fees and speaker's honoraria or has participated in clinical studies for AbbVie, Almirall, Leo Pharma, Eli Lilly, Novartis, Pfizer, and Sanofi Genzyme. Antonio Costanzo has served as an advisory board member, consultant, and has received fees and speaker's honoraria or has participated in clinical trials for AbbVie, Almirall, Biogen, Leo Pharma, Eli Lilly, Janssen, Novartis, Pfizer, Sanofi Genzyme, and UCB Pharma. Alessandra Narcisi has served on advisory boards, received honoraria for lectures, and research grants from Almirall, AbbVie, Leo Pharma, Celgene, Eli Lilly, Janssen, Novartis, Sanofi Genzyme, Amgen, and Boehringer Ingelheim. Mario Valenti has been a consultant and/or speaker for Sanofi, Leo Pharma, Eli Lilly, Novartis, Janssen, AbbVie, Boehringer Ingelheim, Almirall, UCB, and Difa Cooper. Sara Di Giulio, Martina Maurelli, Stefano Caccavale, Eugenia V. Di Brizzi, Valentina Dini, Francesca M. Gaiani, Luca Mastorino, Alessandra Michelucci, Lidia Sacchelli, Nicola Zerbinati, Luca Potestio, and Massimo Travaglini have nothing to declare. Mario Valenti is an Editorial Board Member of *Dermatology and Therapy*. Mario Valenti was not involved in the selection of peer reviewers for the manuscript nor any of the subsequent editorial decisions.

Ethical Approval. Institutional review board approval was exempted, as the study protocol did not deviate from standard clinical practice. All patients received secukinumab as in good clinical practice, in accordance with Italian guidelines. All included patients had provided written consent for a retrospective study of data collected during routine clinical practice (demographics, clinical scores). The study was performed in accordance with the Helsinki

Declaration of 1964 and its later amendments. Data collection and handling complied with applicable laws, regulations, and guidance regarding patient protection, including patient privacy.

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