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BRIEF REPORT

Multicenter Retrospective Study of Secukinumab Drug Survival in Psoriasis Patients in a Daily Practice Setting: A Long-Term Experience in Spain

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ABSTRACT

Introduction: There is limited and conflicting evidence over the real-world drug survival of secukinumab (SEC) in patients with psoriasis, especially in the long term. Our objective was to analyze the short- and long-term survival of SEC (S-SEC) and its predictive factors for the treatment of psoriasis.

Methods: Patients clinically diagnosed with plaque psoriasis and under treatment with secukinumab (n = 384) in a daily practice setting were analyzed in a retrospective, multicenter study performed in a nationwide cohort and followed up for a period of 2 years. Kaplan–Meier curve was plotted to analyze drug

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survival time, and log-rank test was performed to compare several groups. Factors related to speed of treatment discontinuation were studied with a Cox regression model.

Results: The overall cumulative secukinumab drug survival rates observed at 6, 12, 18, and 24 months were 97.1%, 89.0%, 81.1%, and 74.3%, respectively. Obesity [hazard ratio (HR), 1.809, CI 95% 1.114–2.962; $p = 0.004$] and previous experience with biological therapies, particularly those who had been treated with ≥ 2 biologicals with different mechanisms of action (HR 3.476, CI 95% 1.875–6.444; $p = 0.017$) were associated with an early discontinuation, whereas psoriatic arthritis was associated with delayed discontinuation, (HR 0.493, CI 95% 0.265–0.917; $p = 0.025$).

Conclusions: In our study, we found that cumulative secukinumab drug survival for psoriasis patients for the period 6–18 months was in the range of real-world evidence studies. Additionally, we observed a relatively high long-term survival rate at 24 months (74.3%).

Keywords: Anti IL-17; Drug survival; Psoriasis; Secukinumab

Key Summary Points

To date, there is limited and conflicting evidence over the real-world drug survival of secukinumab in patients with psoriasis, especially in the long term.

The overall cumulative secukinumab drug survival rates observed at 6, 12, 18, and 24 months were 97.1%, 89.0%, 81.1%, and 74.3%, respectively. Drug ineffectiveness was the main reason for discontinuation.

Obesity and previous experience with biological therapies, particularly those who had been treated with ≥ 2 biologicals with different mechanisms of action, were associated with an early discontinuation, whereas psoriatic arthritis was associated with a higher persistence.

INTRODUCTION

Secukinumab (SEC) is a fully human monoclonal IgG1/κ isotype antibody that selectively binds to and neutralizes interleukin 17A (IL-17A), a proinflammatory cytokine with key involvement in the clinical manifestation of psoriasis [1]. Despite its high effectiveness and safety profile demonstrated in the treatment of moderate-to-severe plaque psoriasis, there is limited and conflicting evidence over the real-world drug survival of secukinumab in patients with psoriasis [2–15], especially in the long term [16–18]. Moreover, there is also a great variability in the results related to the predictors of a greater or lesser survival. Our objective was to analyze the short- and long-term survival of SEC (S-SEC) and its predictive factors for the treatment of psoriasis in a retrospective, multicenter study performed in a nationwide cohort of psoriasis patients in Spain followed up for a period of 2 years.

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METHODS

The study was a collaboration between 20 Spanish hospitals following patients in an uncontrolled, daily practice cohort, non-interventional and observational manner between February 2014 and March 2018. It was approved by the Ethics Committee of Hospital La Princesa (EDT-SIA-2017–01), and written informed consents were obtained from patients.

As requirements of the study, the patients had been clinically diagnosed with plaque psoriasis and were under treatment with SEC in a daily practice setting. The subjects were followed up for a minimum of 3 months and a maximum of 24 months. Patients under concomitant treatment with systemic or topical antipsoriatic drugs were also included in the study.

In agreement with the officially approved regimen recommended for the treatment of plaque psoriasis with SEC, 300 mg of the drug was subcutaneously administered to patients weekly during the first 4 weeks and then on a monthly basis. Cohort monitoring was performed immediately before beginning the treatment (baseline) and then at 1, 3, 6, 12, 18, and 24 months after the therapy start date.

Drug survival (roughly, the time from starting the treatment until drug withdrawal) was calculated by plotting Kaplan–Meier curves. Log-rank test was used to compare survival time of naïve versus biologically experienced patients, no obese patients [body mass index (BMI) < 30 kg/m^2] versus obese patients (BMI ≥ 30 kg/m^2), and patients starting treatment with baseline Psoriasis Area Severity Index (PASI) < 10 versus those who presented PASI ≥ 10 at initial visit. Furthermore, Cox regression models were used to explore possible relation between SEC survival and several factors, including patient's gender, age, psoriasis evolution time, obesity (BMI < 30 versus BMI ≥ 30 kg/m^2), presence of psoriatic arthritis, baseline PASI (PASI ≥ 10 versus PASI < 10), and concomitant treatment. Previous exposure to other biologic treatments was unfolded in two variables: number of prior biological treatments [naïve or single biological experienced versus multiexperienced (≥ 2 prior biologicals)], and mechanism of action of biological experienced [none, anti-tumor necrosis factor (TNF), anti-IL12/23, or both]. Hazard ratios (HR) with their 95% confidence interval (CI) are shown, and p-values < 0.05 were considered as significant. Analyses were performed with IBM SPSS package 23.0 (Armonk, NY, USA).

RESULTS

A total of 384 patients were included in the study (241 males and 143 females). Among those, 278 (72.4%) started the study with a baseline PASI ≥ 10 (median baseline PASI was 14.3 ± 8.4). The mean age $\pm$ standard deviation was 47.6 ± 12.5 years, and 30% of the patients presented psoriatic arthritis. Furthermore, 42.6% of the patients were obese (BMI ≥ 30), and the total accumulated exposure time among the patients was 347.3 patient-years. The proportion of naïve patients and those who received ≥ 2 biologics was 31% and 49%, respectively.

The overall drug survival for secukinumab was analyzed using data from the 384 patients, of which 83 (21.6%) discontinued the treatment at different moments of the study owing to drug ineffectiveness (16.7%), side effects (3.4%), or patient decision (1.6%). The observed cumulative drug survival rate at 6, 12, 18, and 24 months was 97.1%, 89.0%, 81.1%, and 74.3%, respectively (Fig. 1).

Survival rates for different groups were plotted and compared with log-rank test. Comparing survival rates for separate groups based on treatment history (Fig. 2A), we found that naïve patients were more likely to continue the treatment than patients who experienced other previous biologic treatments (log rank, $p = 0.015$). The cumulative S-SEC for bio-naïve patients at 6, 12, 18, and 24 months was 97.5%, 93.0%, 86.4%, and 84.0% respectively, while S-SEC for bio-experienced patients was 96.9%, 87.1%, 78.5%, and 69.4%, respectively.

We compared S-SEC between obese and non-obese patients (Fig. 2B), finding that shorter drug survival was associated with obesity (log rank, $p = 0.004$). The cumulative S-SEC for non-

obese patients at 6, 12, 18, and 24 months was 98.5%, 93.5%, 85.7%, and 80.0%, respectively. In contrast, patients with BMI ≥ 30 presented survival rates of 95.9%, 83.1%, 75.8%, and 66.5% respectively. Additionally, no significant difference was found regarding drug survival rates between the group of patients who started with baseline PASI ≥ 10 and those who started with PASI < 10 (Fig. 2C).

The multivariate analysis of factors related to S-SEC (Table 1) showed that obesity (HR 1.809, CI 95% 1.114–2.962; $p = 0.004$) and prior experience with anti-TNF and anti-IL12/23 (HR 3.476, CI 95% 1.875–6.444; $p = 0.017$) were associated with a reduced S-SEC, whereas psoriatic arthritis was associated with increased S-SEC (HR 0.493, CI 95% 0.265–0.917; $p = 0.025$). The other variables analyzed (gender, age, psoriasis evolution time, baseline PASI ≥ 10, and concomitant treatment) were not significantly associated with drug survival.

DISCUSSION

Although some real-world evidence (RWE) studies reporting the rates of S-SEC in psoriasis patients are available [2–15], scarce evidence about survival ≥ 2 years has been collected

Fig. 2 Kaplan–Meier plots representing how drug survival relates to patient's treatment history (**A**), body mass index (**B**), or baseline PASI (**C**). Data show all-cause discontinuation

[16–20]. In most of the RWE studies included in two meta-analyses [6, 13], the patients were followed for a period shorter than 1 year. To the best of our knowledge, this is the second-largest RWE cohort study ($n = 384$) reporting S-SEC after 24-month follow-up. The reported results of S-SEC are very variable, probably because drug survival may be determined by multiple factors. The rates of overall survival that we have found at 6, 12, 18, and 24 months, 97%, 89%, 81%, and 74% respectively, are consistent with those described in the meta-analysis (90% and 80% at 6 and 12 months) [6], and remarkably higher than those previously reported by multicenter studies in the Netherlands [3] (76% and 67% at 12 and 18 months) and in Denmark (45% at 24 months) [19]. This discrepancy could be explained by the fact that the proportion of naïve patients in our study, 31%, was higher than in Dutch or Danish studies, 17% and 21%, respectively; and the proportion of patients

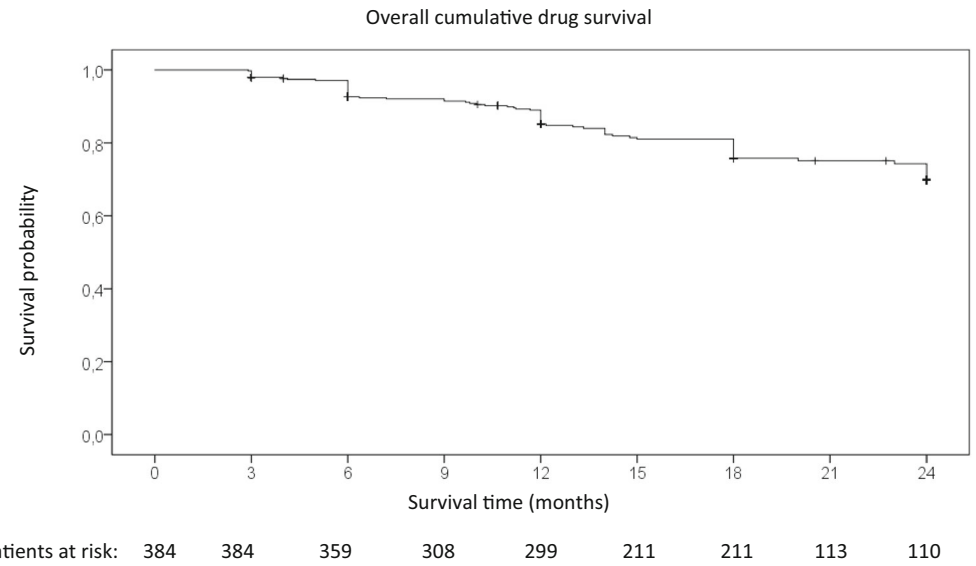
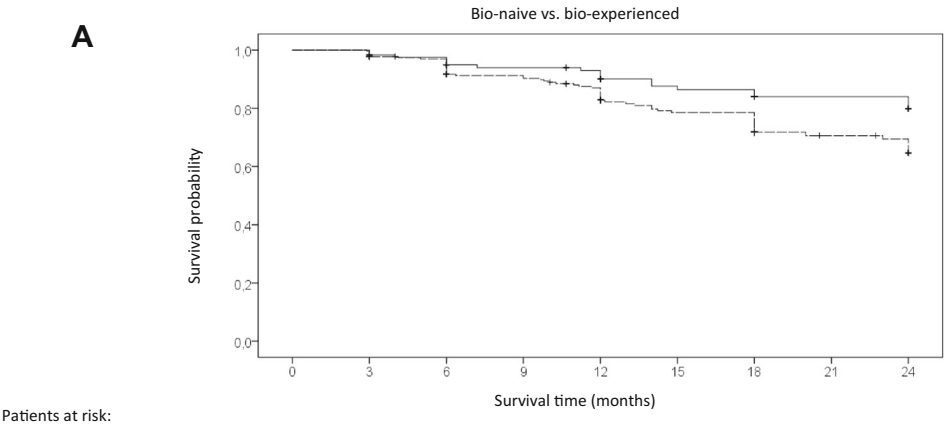
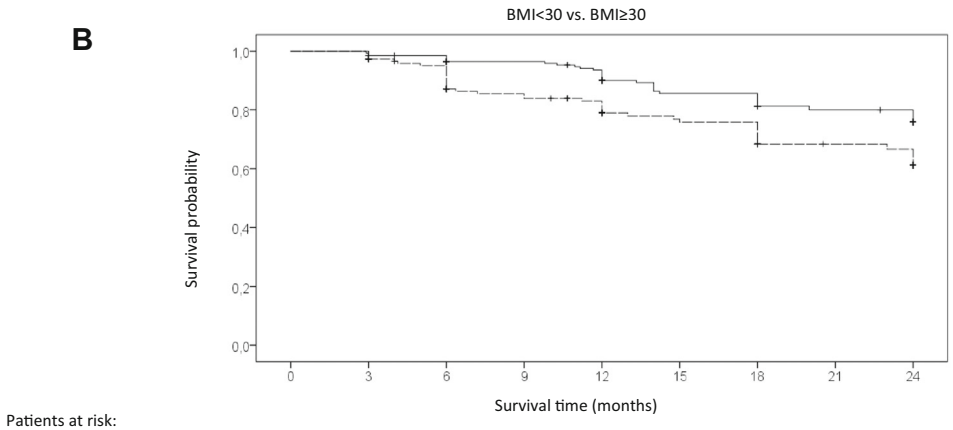


Fig. 1 Overall cumulative drug survival of secukinumab in psoriasis patients represented by Kaplan–Meier plot. Data show all-cause discontinuation



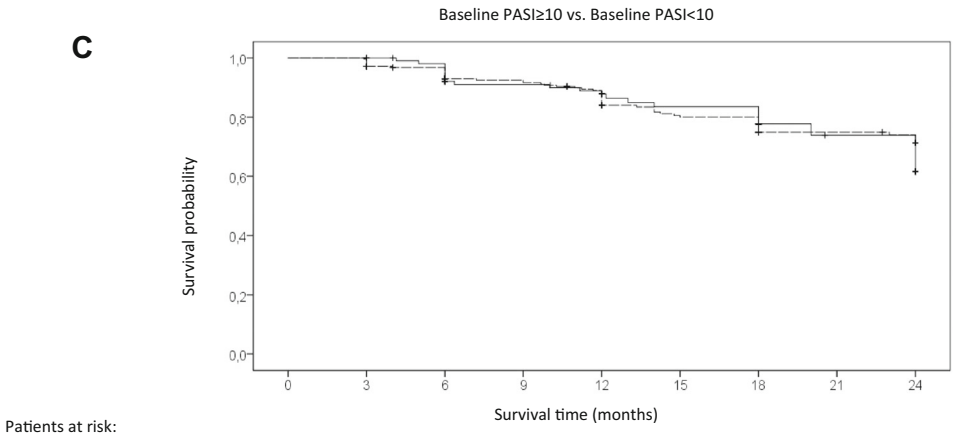
Patients at risk:

Bio-naive	120	120	116	103	99	76	76	45	45
Bio-experienced	264	264	243	205	200	135	135	68	65



Patients at risk:

BMI<30	201	201	192	166	159	118	118	60	59
BMI≥30	149	149	131	107	100	73	72	38	36



Patients at risk:

Baseline PASI≥10	278	278	259	219	211	149	149	92	89
Baseline PASI<10	106	106	100	89	88	62	62	21	21

multiexperienced with two or more biologicals was lower in our study, 49%, than in Dutch or Danish studies, 64% and 63%, respectively [3, 19].

Although not universally confirmed, but consistent with most of the previous RWE studies, we have found that patients who presented obesity [5, 14] or were previously exposed to biologic treatments (versus naïve patients) [3–5, 7, 10, 11, 14–16] showed an increased risk of discontinuing SEC. Moreover, in our study, patients who received two or more biologicals with different mechanisms of action before SEC discontinued treatment before naïve patients. On the contrary, in our study, coinciding with the case series by Yiu et al. [10], but in disagreement with other studies [4, 5, 15, 17], psoriatic arthritis was associated with a longer S-SEC.

Interestingly, no significant difference was found regarding drug survival rates between the group of patients who started with baseline PASI $\geq$ 10 and those who started with PASI $<$ 10, which is commonly overlooked in other drug survival studies in a real-world setting. On the other hand, in several studies it has been observed that the female gender was significantly associated with a poorer persistence [3, 12, 14, 15]. This was not observed in our cohort of patients or in other studies [4, 5]. The other variables analyzed (age, psoriasis evolution time, and concomitant treatment) were not significantly associated with S-SEC.

Limitations include the lack of assessment of deviations from the standard treatment regimen throughout the follow-up, and those derived from the multicenter and retrospective nature of the study. The influence on survival of difficult-to-treat localizations (nails, palms and soles, scalp) was not included in the analysis.

Table 1 Analysis of several factors that can potentially relate to drug survival (Cox regression model)

Method	Forced introduction				Forward stepway			
	p	HR	95% CI for HR		*p*	HR	95% CI for HR	
Variable			Lower	Upper			Lower	Upper
Age	0.330	1.012	0.988	1.035				
Gender	0.992	0.997	0.591	1.683				
Obesity (ref. BMI $<$ 30)	0.035	1.734	1.038	2.896	0.019	1.809	1.104	2.962
Baseline PASI (ref. PASI $\geq$ 10)	0.842	1.059	0.605	1.853				
Psoriasis evolution time	0.250	0.985	0.961	1.010				
Psoriatic arthritis	0.010	0.430	0.226	0.818	0.025	0.493	0.265	0.917
BT type (ref. no BT)	0.100				$<$ 0.001			
Anti TNF	0.153	0.349	0.082	1.480	0.574	0.760	0.291	1.982
Anti IL12/23	0.613	1.392	0.386	5.018	0.503	1.533	0.439	5.357
Both	0.976	0.976	0.196	4.855	$<$ 0.001	3.476	1.875	6.444
Concomitant systemic treatment [a]	0.592	1.277	0.522	3.120				
Previous BT (ref. 0–1)	0.092	3.742	0.805	17.387				

BMI body mass index, *BT* biologic treatment, *CI* confidence interval, *HR* hazard ratio, *IL* interleukin, *PASI* Psoriasis Area and Severity Index, *ref* reference, *TNF* tumor necrosis factor

[a] Concomitant treatment: methotrexate, acitretin, leflunomide, steroids, nonsteroidal antiinflammatory drugs, or phototherapy

CONCLUSION

In conclusion, in this multicenter, daily practice, nationwide, long-term study, we found that overall cumulative drug survival for SEC at 24 months was 74%. Furthermore, obesity, previous exposure and multiexperience with two or more biological drugs with different mechanisms of action were associated with a higher risk for SEC withdrawal. Drug ineffectiveness and adverse events were the main reasons for drug discontinuation. This results provide valuable information in the context of daily clinical practice and may play a role in the clinical decision-making to choose the most appropriate biological.

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Compliance with Ethics Guidelines. The study design, data collection and analysis were approved by the Ethics Committee of H. Princesa (EDT-SIA-2017–01) Individually written informed consents were obtained from patients at the beginning of the study.

Data Availability. The data provided for the analysis and writing of this manuscript are available in an anonymized database accessible at Hospital Universitario de La Princesa (Madrid, Spain).

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