Dermatology Practical & Conceptual

Long-Term Persistence with Guselkumab: A 5-Year Multicenter Retrospective Study across 14 Dermatology Centers in Italy

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ABSTRACT

Introduction: Psoriasis is a chronic systemic inflammatory disease that requires long-term treatment strategies to maintain sustained disease control. Treatment persistence is an important real-world indicator of therapeutic effectiveness and tolerability. Guselkumab, an IL-23 inhibitor, has shown favorable persistence in several studies, but extended long-term data remain limited.

Objectives: To assess 3- and 5-year drug survival rates of guselkumab in patients with moderate-to-severe plaque psoriasis and to examine the relationship between persistence and clinical variables such as PASI, BMI, prior biologic exposure, and involvement of difficult-to-treat areas.

Methods: This was a multicenter retrospective observational study conducted across 14 dermatology centers in Italy. Adult patients with moderate-to-severe plaque psoriasis who started guselkumab were included. Data collected included demographics, clinical history, disease severity, comorbidities, and treatment details. Drug survival was analyzed using Kaplan–Meier curves and Cox proportional hazards models.

Results: A total of 247 patients were included. At three years, 80.2% of patients remained on guselkumab, and at five years, 72.8% continued treatment. Persistence was not significantly influenced by BMI, PASI, or age. However, prior biologics exposure was associated with a higher risk of discontinuation (hazard ratio (HR): 1.84; *P*=0.0208), especially in those previously treated with IL-17 inhibitors (HR:2.14; *P*=0.0150). The involvement of difficult-to-treat areas did not significantly affect persistence, although a trend toward reduced discontinuation was observed in patients with genital involvement (*P*=0.0539).

Conclusions: Guselkumab demonstrated high long-term persistence in real-world clinical practice. Drug survival remained consistently high across various subgroups, with prior IL-17 inhibitor exposure being the main predictor of decreased persistence.

Introduction

Psoriasis is a chronic systemic inflammatory condition that affects both the skin and multiple organ systems and is frequently associated with comorbidities such as metabolic syndrome, cardiovascular disease, and inflammatory bowel disorders [1-4]. The pathogenesis of psoriasis involves complex interactions between genetic predispositions and environmental triggers, leading to an inflammatory response mediated by dendritic cells, T cells, keratinocytes, and cytokines such as TNFα and the IL-23/IL-17 pathways [1,5]. This inflammatory cascade not only affects the skin, causing characteristic erythematous, indurated, and scaly plaques, but also contributes to systemic inflammation, which is implicated in the development of the above-mentioned comorbidities [1,2].

Moderate-to-severe psoriasis significantly impacts patients' quality of life and creates a substantial long-term disease burden, necessitating ongoing disease management. The chronic nature of psoriasis leads to considerable physical, social, and psychological impairments, affecting not only patients but also their families [6,7].

The introduction of biologics targeting interleukin pathways (IL-12/23, IL-17, IL-23) has revolutionized the management of psoriasis and psoriatic arthritis. IL-12/23 inhibitors like ustekinumab, and IL-23 inhibitors such as guselkumab, tildrakizumab, and risankizumab have demonstrated varying levels of treatment persistence, which is an essential measure of long-term efficacy and safety and an essential feature leading to patient satisfaction in real-world settings [8].

Guselkumab has demonstrated high drug survival rates in the treatment of moderate-to-severe psoriasis across various real-world studies [9-13]. However, real-life evidence regarding guselkumab persistence over extended follow-up and the factors influencing it remains limited.

The aim of this work was to retrospectively assess the long-term persistence of guselkumab in a cohort of patients with psoriasis as well as to explore the associations between persistence and key variables such as BMI, PASI, previous biologic treatments, and the involvement of difficult-to-treat areas.

Materials and Methods

Study Design and Population

This multicenter retrospective observational study was conducted across 14 dermatology centers in Italy (listed in Table S1). It included adult patients (aged 18 years or older) with moderate-to-severe plaque psoriasis who initiated guselkumab treatment as a part of routine clinical practice.

Both bio-naïve and bio-experienced patients were eligible. Clinical data were collected retrospectively from medical records, starting from the initiation of treatment. Follow-up was assessed at three years (primary endpoint) and five years (secondary endpoint), as specified in the study protocol.

Data Collection

Collected variables included demographic (age, sex) and anthropometric variables (weight, height, BMI), clinical history (age at disease onset, disease duration, family history), comorbidities (especially cardiometabolic and gastrointestinal), and previous biologic therapies. Psoriasis characteristics included baseline PASI scores and involvement of difficult-to-treat areas (scalp, nails, genital, and pretibial regions). Data on treatment discontinuation, including timing and documented reasons, were also collected.

Outcome Measures

The primary endpoint was the survival of the drug guselkumab, defined as persistence in treatment over time, evaluated for up to three years after treatment initiation.

Secondary endpoints included evaluating the drug survival with guselkumab for up to five years after treatment initiation, based on baseline PASI, BMI, prior biologics exposure (overall and by drug class), and involvement of difficult-to-treat anatomical sites.

Statistical Analysis

Descriptive statistics were used to summarize baseline characteristics. Continuous variables are reported as means and standard deviations (SD), and categorical variables as counts and percentages.

Kaplan–Meier curves were used to assess drug survival over time. Factors associated with treatment discontinuation were evaluated using multivariate Cox proportional hazards models, including age, sex, BMI, PASI, bio-experience, prior biologics exposure (overall and by drug class), and site-specific involvement. A p-value of <0.05 was considered statistically significant. Analyses were performed using R (version 4.0.5) and GraphPad Prism 4.0 (GraphPad Software Inc., La Jolla, CA, USA).

Ethics Statement

The study was conducted in accordance with the principles outlined in the Declaration of Helsinki. The Ethics Committees of the participating centers waived the requirement for formal approval and informed consent as the study was non-interventional and based on retrospective, anonymized data collection.

Results

Patients' Baseline Characteristics

A total of 247 patients with moderate-to-severe plaque psoriasis who received guselkumab treatment were included in the analysis. The mean age was 53.2 years (SD: 13.9), with a slight predominance of males (57.5%). The average weight was 78.8 kg (SD: 15.2), and mean BMI was 27.2 kg/m² (SD: 4.9). According to BMI classification, 1.2% of patients were underweight, 32.8% had normal weight, 39.3% were overweight, and 23.1% were classified as obese. The mean PASI index was 14.51 (SD: 8.76). Approximately half of the cohort (53%) had prior exposure to biologic therapies. Other baseline characteristics of the study population are detailed in Table 1.

Overall Drug Survival

A total of 247 patients treated with guselkumab were included in the persistence analysis. As shown in Figure 1, at three years, 198 of the 247 patients (80.2%) were still receiving treatment, while 49 patients (19.8%) had discontinued. At five years, 67 patients (27.1%) had discontinued treatment for various reasons, while 180 patients (72.8%) continued the therapy.

Drug Survival based on BMI

Treatment persistence with guselkumab was analyzed according to baseline weight, stratifying patients into two groups: ≤90 kg and >90 kg, as shown in Figure 2A.

At 12 months, the persistence rates were 97.0% for patients weighing ≤90 kg and 95.0% for those >90 kg (P=0.556). At 24 months, persistence declined slightly to 92.0% and 89.0%, respectively (P=0.244). At 36 months, the rates were 88.0% and 82.0% (P=0.656), followed by 84.0% and 75.0% at 48 months (P=0.999) and 80.0% and 70.0% at 60 months (P=0.998). No statistically significant difference was observed.

Treatment persistence with guselkumab was also evaluated according to baseline body mass index (BMI), as shown in Figure 2B. Patients were categorized into three groups: BMI <20, BMI 21–30, and BMI >30. At 12 months, persistence rates were 95.0% in the BMI <20 group, 96.0% in the BMI 21–30 group, and 94.0% in the BMI >30 group. The differences between groups at this time point were not statistically significant (BMI 21–30 vs <20: P=0.098; BMI >30 vs 21–30: P=0.098). Over time, persistence rates declined gradually across all BMI categories. At 24 months, persistence was 91.0% in both the <20 and 21–30 BMI groups, and 87.0% in the >30 group. At 36 months, persistence reached 85.0%, 87.0%, and 80.0%, respectively, with no statistically significant difference observed (e.g., P=1.000 for <20 vs 21–30; P=0.9731 for >30 vs 21–30).

Table 1. Patients' Baseline Characteristics.

Characteristic	Count	%	Mean ± SD
Age (years)			53.2 ± 13.9
Sex: Male	142.0	57.5	
Weight (kg)			78.8 ± 15.2
BMI (kg/m²)			27.2 ± 4.9
BMI Underweight	3.0	1.2	
BMI Normal weight	81.0	32.8	
BMI Overweight	97.0	39.3	
BMI Obese	57.0	23.1	
PASI			14.51 ± 8.76
Bio-experienced: Yes	131.0	53.0	
Cardiometabolic comorbidities	76.0	30.8	
Gastrointestinal comorbidities:	4.0	1.6	
Nail involvement:	70.0	28.3	
Scalp involvement:	144.0	58.3	
Genital involvement:	66.0	26.7	
Pretibial involvement:	134.0	54.3	

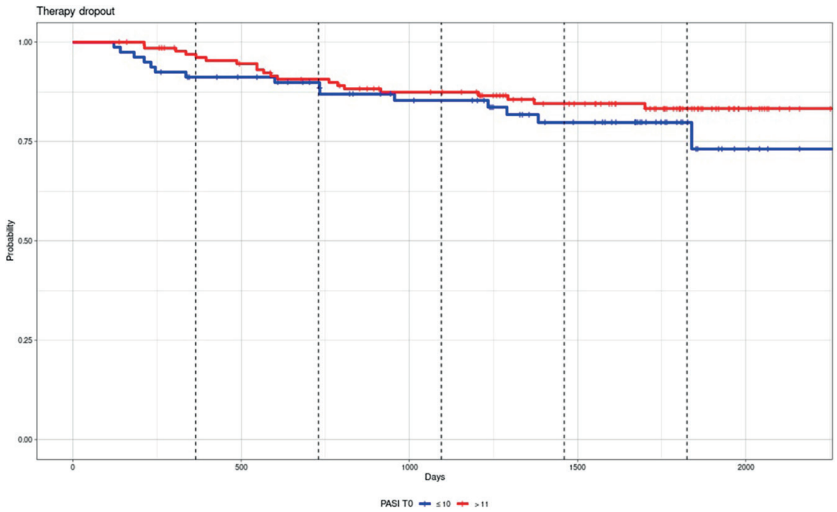

Figure 1. Kaplan-Meier curve showing treatment persistence with guselkumab in the overall study population (N=247). The analysis includes all reasons for discontinuation, both clinical and non-clinical. At three years, 198 patients (80.2%) remained on treatment; at five years, 180 patients (72.8%) continued therapy, while 67 patients (27.1%) had discontinued.

By 48 months, rates were 78.0%, 83.0%, and 72.0%, respectively, and at 60 months, they were 72.0%, 78.0%, and 66.0%, again with all comparisons showing P>0.3. No statistically significant difference in treatment persistence was observed between BMI groups at any time point.

Drug Survival based on Disease Severity

Treatment persistence with guselkumab was assessed according to baseline PASI score, as shown in Figure 3. Patients were stratified into two groups: PASI <10 and PASI >11. At 12 months, persistence rates were 95.5% in the PASI <10 group and 95.3% in the PASI >11 group, with no statistically significant difference (*P*=0.051). Over time, persistence declined similarly across both groups. At 24 months, persistence was 90.9% for PASI <10 and 91.0% for PASI >11 (*P*=0.539). At 36 months, rates were 86.4% and 86.6%, respectively (*P*=0.715). At 48 months, persistence reached 84.1% and 83.6% (*p*=0.998) and at 60 months, 79.5% and 78.4% (*P*=0.998), again with no statistically significant difference observed.

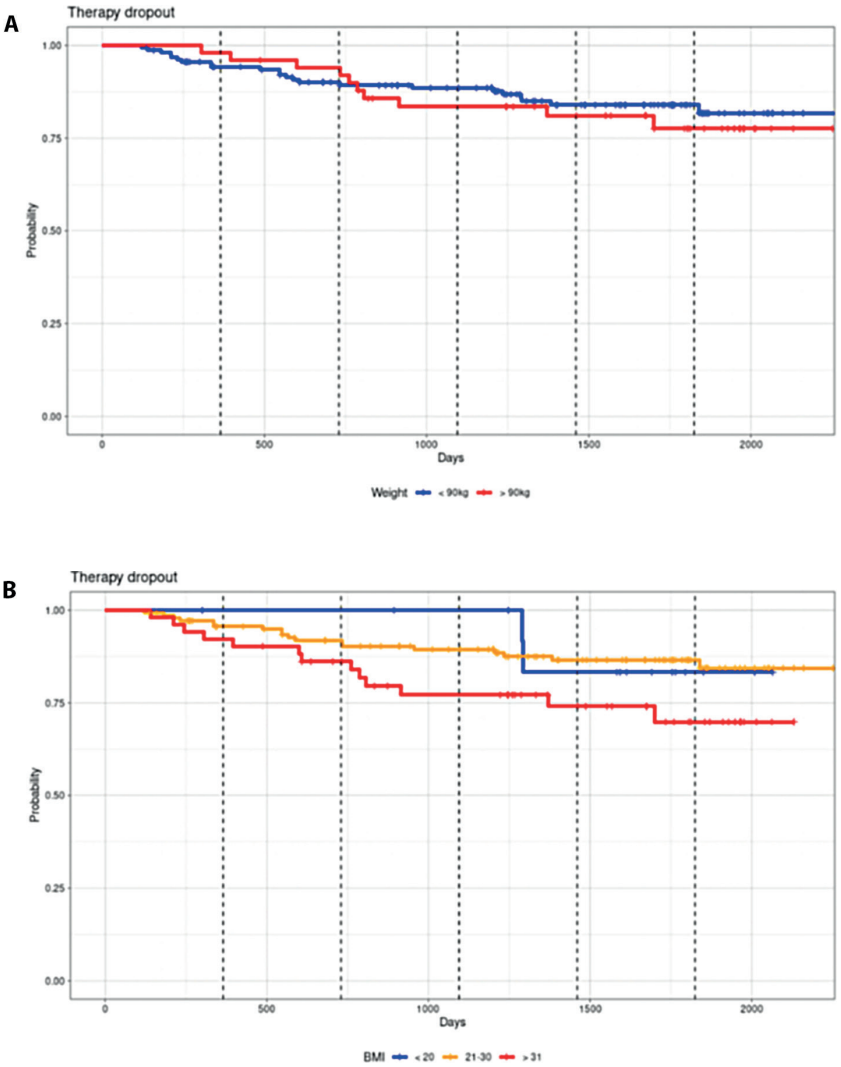

Figure 2. Treatment persistence with guselkumab stratified by baseline weight (A) and BMI (B). (A) Patients were categorized into two weight groups: <90 kg and >90 kg. (B) Patients were stratified by BMI into three categories: (<20), (21-30), and (≥31).

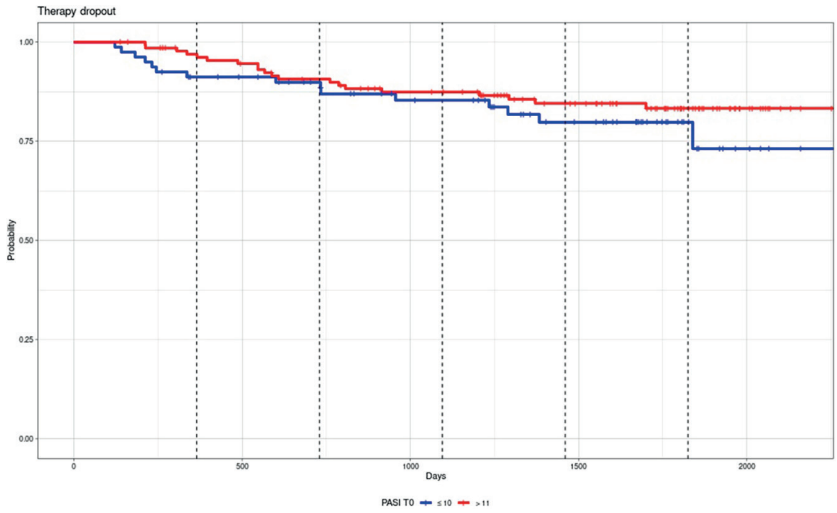

Figure 3. Treatment persistence with guselkumab stratified by baseline PASI score. Patients were grouped into three categories according to disease severity at baseline: PASI <10 and PASI >11.

Drug Survival based on Prior Exposure to Biologic Therapies

Treatment persistence with guselkumab was evaluated according to prior exposure to biologic therapies, as illustrated in Figure 4. Patients were classified as either bio-naïve or bio-experienced. At 12 months, persistence was 95.7% in the bio-naïve group and 90.8% in the bio-experienced group (*P*=0.960). At 24 months, 91.3% of bio-naïve patients and 82.4% of bio-experienced patients remained on therapy (*P*=0.411), and at 36 months, the rates were 87.8% and 77.9%, respectively (*P*=0.340). By 48 months, persistence declined to 85.2% in the bio-naïve group and 73.3% in the bio-experienced group (*P*=0.999), and at 60 months, it reached 82.6% and 68.7%, respectively (*P*=0.999). These differences were not statistically significant.

Multivariate Analysis

A multivariate Cox regression analysis was performed to assess factors associated with treatment discontinuation (Table 2). Variables included in the model were age, sex, BMI, baseline PASI, and prior exposure to biologic therapies (bio-experience).

Among these, prior biologic experience emerged as the only statistically significant predictor of discontinuation (HR = 1.84, coefficient=0.6101; SE=0.2640; z=2.311; *P*=0.0208), indicating a higher risk of treatment interruption in bio-experienced patients.

Other variables, including BMI (coefficient: 0.0330; *P*=0.1628), age (coefficient: –0.0059; *P*=0.5238), sex (coefficient: 0.4376; *P*=0.0828), and PASI (coefficient: –0.0038; *P*=0.8394) were not significantly linked with persistence outcomes.

A separate model evaluated the impact of previous biologic class exposure (Table 3). Prior use of IL-17 inhibitors was significantly associated with an increased risk of discontinuation (coefficient: 0.7613; SE=0.3128; z=2.433; *P*=0.0150), corresponding to an HR of 2.14. No statistically significant association was found for prior exposure to anti-TNF-α agents (coefficient: 0.3182; HR: 1.37; *P*=0.2190), IL-12/23 inhibitors (coefficient: 0.2939; HR:

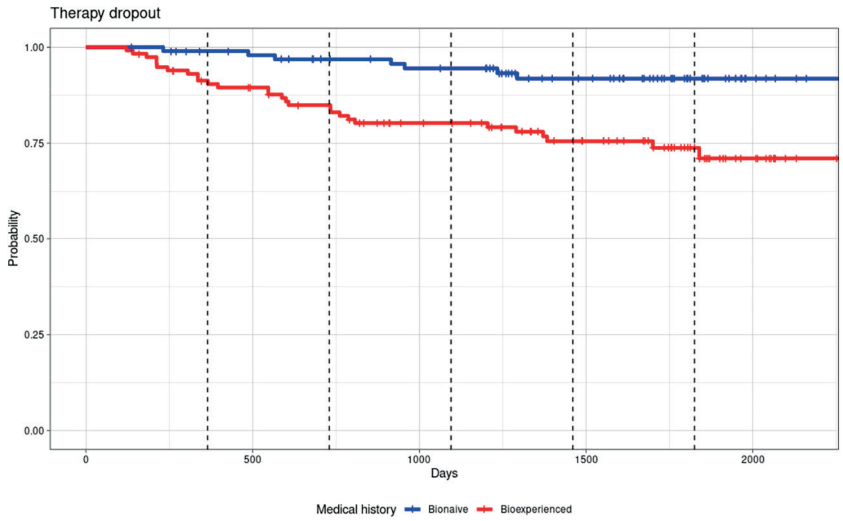

Figure 4. Treatment persistence with guselkumab stratified by prior exposure to biologic therapies. Patients were categorized as bio-naïve (no previous biologic treatment) or bio-experienced (previously treated with one or more biologics).

Table 2. Multivariate Cox Regression Analysis of Factors associated with Treatment Discontinuation. The model included baseline BMI, age, sex, PASI, and previous exposure to biologic therapies.

Variable	coef	exp(coef)	SE(coef)	z	p-value	
BMI	0.032964	1.033514	0.023617	1.396	0.1628	
Age	-0.005853	0.994164	0.009181	-0.637	0.5238	
Sex	0.437617	1.549012	0.252292	1.735	0.0828	
PASI	-0.003767	0.996240	0.018592	-0.203	0.8394	
Bio-experience	0.610064	1.840549	0.263955	2.311	0.0208	*

Table 3. Multivariate Cox Regression Analysis Evaluating the Impact of Prior Biologic Drug Classes on Treatment Discontinuation with Guselkumab.

Variable	N patients (y/n)	Coef	exp(coef)	se(coef)	z	p	
Anti-TNF-α	82/165	0.3182	1.3750	0.258800	1.2290	0.2190	
IL12/IL23 Inhibitor	45 / 202	0.2939	1.3420	0.303500	0.9680	0.3330	
IL17 Inhibitor	38 / 209	0.7613	2.1410	0.312800	2.4330	0.0150	*
IL23 Inhibitor	2 / 242	-1.5120	0.0000	0.244292	-0.0060	0.9950	

1.34; *P*=0.3330), or IL-23 inhibitors (coefficient: –1.5120; HR: ≈ 0.22; *P*=0.9950).

A further multivariate analysis investigated the association between psoriasis involvement in difficult-to-treat areas and the treatment persistence. Genital involvement was associated with a trend toward reduced discontinuation (estimate: –0.1173; SE: 0.0605; t = –1.938; *P*=0.0539). Nail (estimate: 0.0595; *P*=0.3253), scalp (estimate: 0.0744; *p*=0.1755), and pretibial involvement (estimate: –0.0560; *p*=0.2799) were not significantly associated with treatment persistence.

Discussion

Psoriasis is a clinically heterogeneous lifelong skin disease characterized by various forms, including plaque, flexural, guttate, pustular, and erythrodermic. It affects approximately 60 million people globally [14], and its prevalence in Italy ranges from 1.8% to 4.8%, with an incidence between 107.742 and 230.62 per 100,000 person-years [15]. Guselkumab is a monoclonal antibody that targets interleukin (IL)-23, approved for treating adults with moderate-to-severe plaque psoriasis [16]. It has demonstrated sustained efficacy and safety over five years, with significant improvements in Psoriasis Area and Severity Index (PASI) scores and Dermatology Life Quality Index (DLQI) scores [17,18].

Additionally, guselkumab has demonstrated significant drug survival in patients with moderate-to-severe psoriasis across various real-world settings. An Australian multicenter retrospective study aimed to determine the drug survival rates of biologics available in Australia for treating chronic plaque psoriasis, analyzing data from 306 patients and 566 treatment courses collected from two outpatient dermatology clinics between April 2006 and December 2020. Results indicated that guselkumab had the longest drug survival rates at 94.2% at both one and five years, followed by ixekizumab with rates of 87.2% at one year and 59.4% at five years [19]. Mastorino et al. evaluated the drug survival, effectiveness, and safety of guselkumab for treating moderate-to-severe psoriasis over 208 weeks, involving 202 patients. The estimated drug survival rate at almost four years (208 weeks) was 68.5%, with factors such as being a super responder and having cardiovascular comorbidities associated with a reduced risk of drug interruption [20]. A retrospective study analyzed real-world data from the Czech Republic BIOREP registry involving 333 patients treated with guselkumab for psoriasis. Drug survival remained high at 91.6%, 87.0%, and 85.5% after 12, 24, and 36 months, respectively [21].

In our study, we observed a high long-term treatment persistence, with 80.2% of patients still receiving treatment after three years. This result aligns with the findings reported by Torres et al., who noted 3-year persistence rates of over 80% for guselkumab in a large international real-world cohort [22]. After five years, 72.8% continued the therapy. This high long-term persistence rate matches previous reports in the literature and reflects the favorable tolerability and sustained effectiveness of guselkumab in real-life clinical practice [19-21,23]. The analysis considers all causes of discontinuation, including both clinical and non-clinical factors, providing a comprehensive overview of treatment retention.

Treatment persistence with guselkumab was evaluated based on baseline weight and BMI. In the present cohort, patients were stratified by body weight into two categories: ≤90 kg and >90 kg. Persistence rates at 12 months were high in both groups (97.0% and 95.0%, respectively) and gradually declined over time. At 24 months, persistence was 92.0% in the ≤90 kg group and 89.0% in the >90 kg group; at 36 months, 88.0% and 82.0%; at 48 months, 84.0% and 75.0%; and at 60 months, 80.0% and 70.0%, respectively.

In the analysis by body mass index (BMI), patients were classified into three categories: BMI <20, BMI 21–30, and BMI >31. At 12 months, persistence rates were 95.0% in the BMI <20 group, 96.0% in the BMI 21–30 group, and 94.0% in the BMI >31 group. These rates declined progressively over time: at 24 months, persistence was 91.0%, 91.0%, and 87.0%, respectively; at 36 months, 85.0%, 87.0%, and 80.0%; at 48 months, 78.0%, 83.0%, and 72.0%; and at 60 months, 72.0%, 78.0%, and 66.0%, respectively, for the BMI <20, BMI 21–30, and BMI >31 categories. These findings indicate that treatment persistence with guselkumab was

consistently high and did not appear to be significantly influenced by baseline weight or BMI. These results align with findings from other studies, which have shown that drug survival is not affected by patient weight or BMI [21,24].

Chiricozzi et al. investigated how age affects the drug survival of IL-17 and IL-23 inhibitors in patients with moderate-to-severe plaque psoriasis, analyzing 4,178 patients and 4,866 treatment lines in a large retrospective multicenter cohort. The results showed that aging negatively affects overall treatment persistence, but this impact was notably stronger for IL-17 inhibitors. Conversely, IL-23 inhibitors maintained high drug survival even in elderly patients, indicating greater resilience to age-related discontinuation [25]. These findings suggest that, unlike IL-17 inhibitors, the persistence of IL-23 inhibitors is minimally influenced by patient age. This age-related trend was also confirmed in our study, where patient age did not significantly affect the long-term drug survival of guselkumab.

In the Australian Psoriasis Registry, guselkumab demonstrated high drug survival rates, with 93.1% at nine months for bio-experienced patients, compared to 100% for bio-naïve patients. Overall drug survival was 99.0%, 83.3%, and 77.1% at three, 15, and 27 months, respectively. The study found that bio-naïve patients had more prolonged drug survival than those with prior biologic therapy [26]. Li et al. conducted a retrospective analysis of 386 patients with plaque psoriasis treated with biologics (ixekizumab, secukinumab, guselkumab, and adalimumab) over a 52-week period, revealing that guselkumab had the highest drug survival rate at 72.2%. Additionally, results showed that, among bio-naive patients, drug survival rates tended to be higher compared to bio-experienced patients, although these differences were not statistically significant [27]. According to these studies, in our work, treatment persistence with guselkumab was analyzed based on previous exposure to biologic therapies. Patients were categorized as bio-naïve or bio-experienced. At 12 months, persistence was 95.7% in the bio-naïve group and 90.8% in the bio-experienced group. This difference remained evident over time: at 60 months, 82.6% of bio-naïve patients were still on treatment, compared to 68.7% of bio-experienced patients. These data suggest a higher long-term persistence among patients who had not previously received biologic therapies, indicating that a previous exposure to biologics may be associated with an increased likelihood of treatment discontinuation. The multivariate analysis investigating the impact of previous biologic drug classes on guselkumab persistence revealed that the prior use of IL-17 inhibitors was significantly associated with a higher risk of treatment discontinuation (coefficient: 0.7613; P=0.0150). No statistically significant association was observed for prior exposure to anti-TNF-α agents (P=0.2190), IL-12/23 inhibitors (P=0.3330), or IL-23 inhibitors (p=0.9950). These findings suggest that, as already reported for other biological treatments, being bio-experienced lowers the likelihood of retaining the current drug; moreover, in our cohort, we demonstrated that specifically a history of treatment with IL-17 inhibitors may predict reduced persistence with guselkumab, whereas prior use of other biologic classes does not appear to have a significant impact.

Interestingly, the involvement of difficult-to-treat areas did not appear as a significant predictor of treatment discontinuation in the multivariate analysis, except for genital psoriasis, which showed a trend toward a lower dropout risk (P=0.0539). This observation may reflect a higher observed benefit among patients with diseases in sensitive or high-impact locations, potentially improving treatment adherence.

This study presents some limitations. First, the retrospective design may have introduced selection and information biases, and some clinical data, such as patient-reported outcomes or reasons for discontinuation, may be incomplete or have been recorded inconsistently across centers. Moreover, the lack of formal diagnostic assessment for comorbid psoriatic arthritis may have affected persistence estimates in certain cases.

Future prospective studies integrating clinical, patient-reported, and biomarker data are necessary to better characterize long-term treatment trajectories with guselkumab.

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