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Guselkumab effectiveness in real-world settings: observations from an Italian multicentre study

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Abstract

Objectives: Guselkumab is a biologic disease-modifying antirheumatic drug (bDMARD) with proven efficacy for psoriatic arthritis (PsA) in randomized controlled trials. Evidence of its effectiveness from clinical practice remains limited. We evaluated the real-world effectiveness of guselkumab for PsA (primary objective) and identified factors influencing clinical outcomes.

Methods: This retrospective, observational, multicentre study enrolled consecutive patients with PsA prescribed guselkumab for joint involvement at 26 Italian rheumatology referral centres. Baseline data included patient history, PsA subtype, treatment history and disease activity. Treatment effectiveness was assessed with Kaplan–Meier curves; Cox proportional hazards analysis identified factors associated with treatment persistence.

Results: The study included 278 patients (median age: 57 years [interquartile range, IQR: 50–63]; 64.4% female); median observation 10.7 months (IQR: 5.3–15.9; total: 3332.6 patient-months). Retention rates at 6, 12 and 24 months were 90.4%, 80.0% and 67.8%, respectively. Reasons for discontinuation included primary inefficacy (48% of 54 cases), secondary inefficacy (41%) and skin/mucosal intolerance (4%). Statistically significant factors ($P < 0.05$) influencing treatment persistence included sex, smoking, concurrent conventional synthetic DMARDs (csDMARDs), corticosteroid use, year of prescription and axial or enthesitic involvement.

Conclusions: Approximately two-thirds of PsA patients treated with guselkumab remained on therapy after 2 years. Adverse events motivated <10% of discontinuations. Effectiveness was higher in patients with enthesitic or axial PsA and in those without concurrent corticosteroids or csDMARDs, confirming the effectiveness and safety of guselkumab as an optimal choice for monotherapy, particularly in PsA patients with enthesitis, with or without joint impairment, and/or axial involvement.

Lay Summary

What does this mean for patients?

This study looked at how well the biologic drug guselkumab works in everyday clinical practice for people living with psoriatic arthritis (PsA), a chronic inflammatory disease that affects the joints and skin. We collected data from 278 patients treated at 26 rheumatology centres in Italy. Unlike clinical trials, which enrol patients who meet selective criteria, this study reflects what happens in the real world. We found that most patients had continued taking guselkumab over time: after 1 year, 80% were still on treatment, and after 2 years, about 68% remained on it. The main reasons people stopped the drug were because it did not work well enough initially, or it stopped working over time. Side effects were rare and mild. Patients with inflammation near tendons or ligaments (enthesitis), or those with spinal involvement (axial PsA) had the best results. In contrast, those taking other medications like steroids or methotrexate along with guselkumab were more likely to stop treatment early. These findings suggest that guselkumab is a safe and effective long-term treatment option for people with PsA, especially those with enthesitis or spinal involvement. The findings support its use as a standalone therapy in appropriate patients and help guide real-world treatment decisions.

Keywords: psoriatic arthritis, guselkumab, drug retention rate, real-world effectiveness.

Key messages

- Guselkumab was efficacious for PsA in controlled trials, but evidence of real-world effectiveness remains limited.
- We evaluated the real-world effectiveness of guselkumab for PsA and identified factors influencing clinical outcomes.
- Two-year treatment retention was approximately two-thirds, with adverse events motivating <10% of discontinuations.

Introduction

Guselkumab is a biologic disease-modifying antirheumatic drug (bDMARD) that inhibits interleukin-23 (IL-23) signalling by selectively targeting the p19 subunit, blocking its interaction with the IL-23 receptor. It has been available to rheumatologists for the treatment of psoriatic arthritis (PsA) since December 2021 [1], and its use has progressively spread in this clinical context. Registrational clinical trials have demonstrated significant efficacy in most of the domains, such as joint and enthesitis, across a wide range of patients [2–4]. Approximately half of the patients with articular involvement in the DISCOVER 1 and 2 trials achieved low disease activity at 100 weeks of treatment [5], while resolution of enthesitis was observed in nearly 58% of enrolled subjects at 52 weeks [6].

However, the generalizability of these findings to real-world settings is limited by relatively short observation periods for a chronic condition, adherence to rigid treatment protocols, reliance on surrogate endpoints and the selected

study populations that may not represent the broader clinical population [7, 8].

Initial real-world evidence on patients with PsA was primarily derived from studies on PsA patients in psoriasis (PsO) registries or real-life observational studies [9–11]. While these studies provide valuable insights into specific patient subsets, they lack the breadth to draw conclusions applicable to the broader PsA population encountered in routine clinical practice. Furthermore, existing real-world studies focusing on PsA populations are often limited by either short follow-up durations [12–15] or small sample sizes [16, 17]. Thus, there remains a critical need for studies that evaluate the medium- to long-term (≥2 years) performance of guselkumab in large cohorts of PsA patients treated in routine clinical practice.

This study assessed the effectiveness of guselkumab through its retention rate in patients with PsA treated in a real-world setting. Secondary objectives included recording the reasons for discontinuation and identifying predictors of treatment persistence.

Methods

Study design

This retrospective observational study assessed the 2-year retention rate of guselkumab. The study was conducted in accordance with the Declaration of Helsinki and approved by the Area Vasta Emilia Nord (AVEN) Ethics Committee, protocol code 34713.

Patients

Participating centres included both hospital and university rheumatology units, representing a diverse range of healthcare facilities, including local centres. This heterogeneity was incorporated to ensure a comprehensive representation of PsA management in real-world clinical practice across Italy. Consecutive patients with PsA from 26 Italian centres were screened between October 2019 and December 2024. The inclusion criteria were: (a) diagnosis of PsA according to CASPAR criteria [18], (b) prior exposure to guselkumab and (c) availability of complete data. Patients receiving guselkumab exclusively for dermatological indications were excluded.

Data collection

Demographic and clinical characteristics were recorded for each patient, including age, sex, smoking status, BMI, HLA-B27 positivity and disease duration. PsA domains involved were categorized as oligoarthritis, polyarthritis, axial disease, enthesitis and/or dactylitis. PSO severity: PsO extent was classified based on body surface area as 0%, <10%, 10–20% or >20%. Comorbidities of interest included inflammatory bowel disease, fibromyalgia and other conditions relevant for calculating the modified Rheumatic Disease Comorbidity Index (mRDCI) [19].

Data on treatment history included guselkumab start and discontinuation dates, as well as any use in the preceding 6 months of conventional synthetic DMARD (csDMARDs), bDMARDs, oral corticosteroids and/or intra-articular corticosteroid injections.

Assessment of disease activity at baseline and follow-up visits included tender/swollen joint count, number of painful entheses on the Leeds Enthesitis Index (LEI), Disease Activity Index for Psoriatic Arthritis (DAPSA), patient global assessment, dactylitis count [20], as well as the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) [21], C-reactive protein levels and a 10-point visual analogue scale for pain, as appropriate.

The reasons for treatment discontinuation were categorized as lack of efficacy, loss of efficacy, infections, malignancies or adverse cutaneous/mucosal reactions. Discontinuations because of remission, pregnancy or dermatological issues related to worsening of PsO were censored.

Statistical analysis

The non-parametric distribution of data was assessed using the Pearson-D'Agostino normality test. Data are presented as median and interquartile range (IQR) or percentages, as appropriate.

The Kaplan–Meier method was used to graphically represent therapy retention rates. Cox proportional hazards analysis was performed to compute guselkumab retention rates and to identify factors associated with treatment persistence, including sex, age, BMI, concomitant csDMARD or corticosteroid use, PsA subtype, smoking status, treatment line and year of guselkumab prescription. A *P-value* <0.05 was considered statistically significant.

Results

A total of 278 patients were enrolled in the study, with a median observation period of 10.7 months [IQR 5.3–15.9], corresponding to 3332.6 patient-months of follow-up. Baseline patient characteristics are summarized in Table 1. Overall, approximately one-third of patients had previously used at least two csDMARDs, and nearly half (49.6%) initiated guselkumab after failing at least two bDMARDs. Only 21.2% of patients received guselkumab as first-line therapy.

The guselkumab retention rates at 6, 12 and 24 months were 90.4%, 80.0% and 67.8%, respectively (Fig. 1). Reasons for treatment discontinuation included primary inefficacy (48% of interruptions), secondary inefficacy (41%) and skin/mucosal intolerance (4%). Other reasons included infections, palpitations and cancer onset, each reported in one patient.

Multivariate analysis was initially performed considering all risk factors with minimal missing data, including age, concomitant csDMARD or corticosteroid use, PsA subtype, smoking status, treatment line and year of guselkumab prescription. The factors significantly influencing retention were sex, smoking status, year of prescription,

Factors significantly associated with longer guselkumab retention included male sex, and axial or entheseal involvement, while current smoking, more recent guselkumab prescription, concomitant csDMARD use and concomitant corticosteroid use were associated with shorter retention (Fig. 2).

In the subgroup of patients with available BMI data ($n = 259$), the same significant factors were identified except for year of prescription (data not shown). After 6 months of treatment, most patients maintained their baseline csDMARD (78.4%) and corticosteroid (79.5%) regimens.

Discussion

To the best of our knowledge, this observational study is one of the largest and longest to assess the retention rate of guselkumab in a real-world PsA cohort. Accumulating evidence indicates that guselkumab is associated with a high retention rate, with pooled data from two guselkumab clinical trials

Table 1. Patient characteristics at baseline ($N = 278$)

Characteristic		
Male prevalence, %		35.6
Age, median (IQR), years		57 (50–63)
Smokers, %	Current	18.7
	Former	10.4
	Never	69.1
	Unknown	1.8
BMI, median (IQR), kg/m^2[a]		26.0 (23.2–29.4)
PsA duration, median (IQR), months		75 (38–126)
mRDCI, median (IQR)[a]		1 (0–3)
Inflammatory bowel disease prevalence, %		4.3
Fibromyalgia prevalence, %		20.1
Human leukocyte antigen B27, %	Yes	3.6
	No	55.0
	Unknown	41.4
MRI sacroiliitis, %	Yes	28.8
	No	60.1
	Unknown	11.2
Swollen joint count, median (IQR)		2 (1–5)
Tender joint count, median (IQR)		7 (4–10)
LEI, median (IQR)		0 (0–2)
Dactylitis severity score, median (IQR)		0 (0–0)
C-reactive protein, median (IQR), mg/dl		1.0 (0.4–3.0)
10-point visual analogue scale pain, median (IQR)		8 (6–8)
Patient global assessment, median (IQR)		7 (5–8)
DAPSA, median (IQR)		26.3 (19.3–31.4)
BASDAI, median (IQR)[b]		6.7 (5.5–7.6)
PSO body surface area involvement, %	0	32.0
	<10%	36.0
	10–20%	17.3
	>20%	13.7
	unknown	1.1
Subset prevalence, %	Oligoarticular	25.5
	Polyarticular	72.3
	Dactylitis	21.9
	Enthesitis	46.4
	Axial	35.3
Line of treatment, median (IQR)		2 (2–4)
Prior conventional synthetic DMARD use, %	Methotrexate	75.5
	Sulfasalazine	19.1
	Leflunomide	17.6
	Cyclosporin	16.2
Prior biological DMARD use, %	TNF inhibitor	68.7
	IL17 inhibitor	42.1
	IL12/23 inhibitor	11.2
	IL23 inhibitor	1.4
	CD80 inhibitor	1.8
Prior targeted synthetic DMARD use, %		9.5
Prior locoregional treatment, %		13.0
Concomitant conventional synthetic DMARD, %	Methotrexate	25.9
	Sulfasalazine	1.8
	Leflunomide	3.6
	Cyclosporin	0.4
	None	68.3
Concomitant corticosteroids, %		21.6

DAPSA, Disease Activity Index for Psoriatic Arthritis; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; LEI, Leeds Enthesitis Index; mRDCI, modified rheumatic disease comorbidity index; SJC, swollen joint count; PsA, psoriatic arthritis; IQR, interquartile range; TJC, tender joint count.
Data were missing in 19 ([a]) and 25 ([b]) patients.

showing that over 80% of patients complete at least 1 year of treatment per protocol [22].

The low frequency of severe adverse events observed in our cohort is consistent with pooled safety data on guselkumab from more than 4000 patients (>10 000 patient/years) in 11 phase II/III studies [23]; however, the excellent safety profile and low rate of adverse events [23] may only partially explain this high retention rate. Guselkumab is emerging as a drug that is associated with long-term improvement of multiple PsA domains [17, 24, 25]. The high retention rate may be considered an indicator of its effectiveness, more than its safety and tolerability.

Observational studies in patients with PsO have demonstrated that guselkumab exhibits a higher retention rate compared with other biologics, such as IL-17 inhibitors and TNF inhibitors [26]. Notably, the presence of arthritis does not appear to diminish treatment response in patients with primarily cutaneous disease [27]. Data from the BADBIR registry revealed that more than 90% of patients with PsA receiving guselkumab for PsO remained on treatment for 2 years [28]. However, among patients with both active PsA and PsO, the retention rate modestly decreases to just below 85% [10]. In patients with severe PsA who were diagnosed early and monitored within a dermatological cohort, the 1-year retention rate exceeded two-thirds [16]. These findings highlight differences in patient populations treated by dermatologists and rheumatologists, as the former typically encounter patients with predominant skin involvement, whereas rheumatologists more frequently manage cases where articular manifestations predominate, and skin involvement is less severe.

Previous studies primarily focused on PsO patients with concomitant arthritis, while investigations targeting PsA populations treated with guselkumab for joint disease are more recent and limited in sample size or follow-up duration. Data from the CorEvitas registry [15] showed high short-term (6-month) retention of ∼80%. Longer-term data from U.S. insurance registries indicate that guselkumab retention rates at 1 year surpass those of TNF inhibitors (∼70% vs 45%) [14] and IL-17 inhibitors (67% vs 50%) [15]. However, it is challenging to extrapolate these observations to different healthcare settings, as the reasons for treatment discontinuation are not always clear.

A multicentre study of a small, real-world PsA cohort managed directly by rheumatologists demonstrated a 12-month retention rate of ∼70% [17]; however, the long-term retention rate and factors influencing it remain poorly defined. Our study aimed to address these unmet needs.

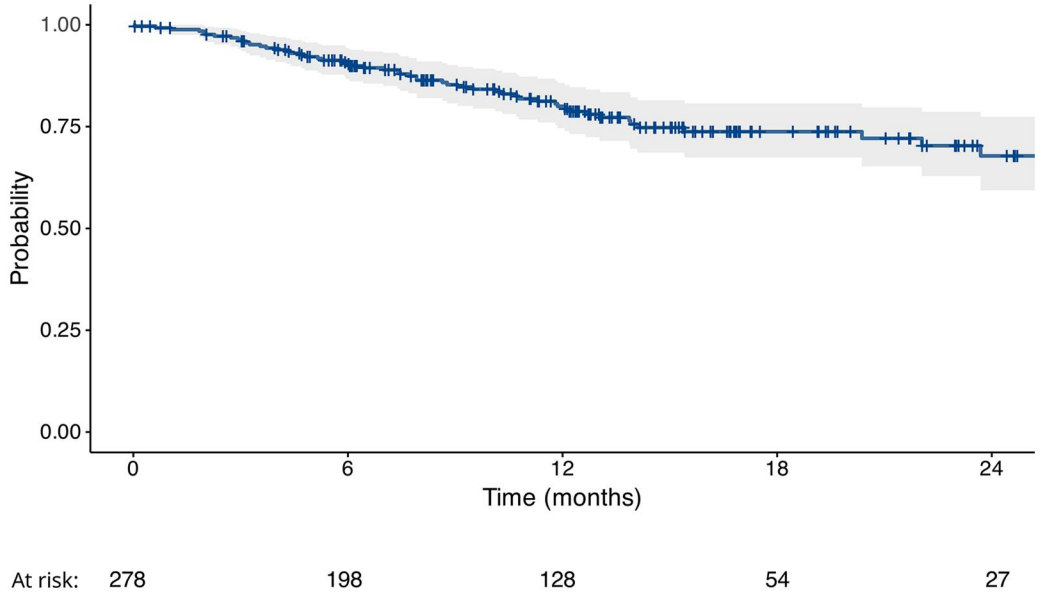

Figure 1. Kaplan–Meier estimates of the guselkumab retention rate over 24 months

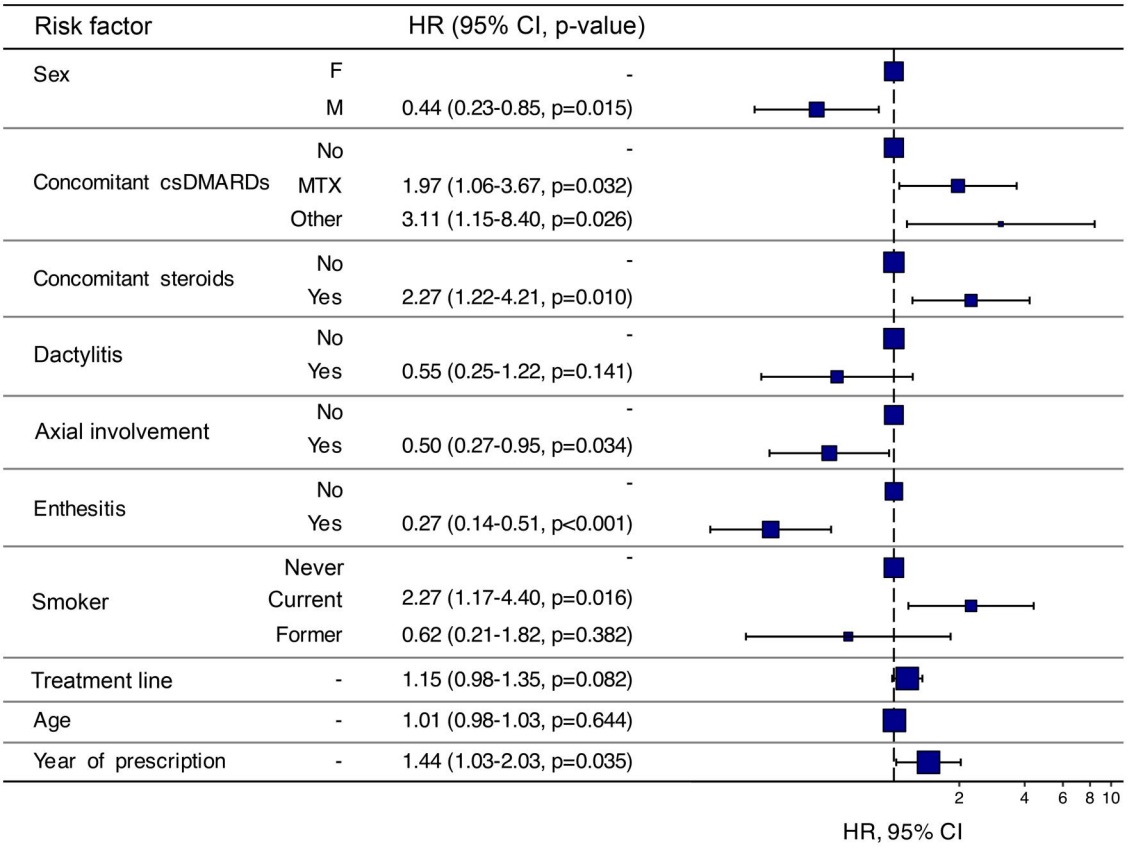

Figure 2. Cox proportional hazards analysis of covariate factors associated with guselkumab treatment persistence over 24 months

The investigated cohort showed no significant differences in baseline characteristics such as BMI, disease duration, age, PsA subsets or disease activity compared with previously described cohorts [14, 15], except for the fact that nearly half of the patients had been treated with at least two prior bDMARDs, suggesting that this was a *difficult-to-treat* PsA population [29]. Guselkumab retention in our cohort after 1 year exceeded rates reported in clinical trials and aligned with other observational studies. At 2 years, there was a reduction in the incidence of treatment discontinuation (80% retained at 1 year vs just under 69% at 2 years).

The main factors influencing retention were consistent with the literature for other agents [30]. These included sex, smoking and year of guselkumab prescription. Concomitant corticosteroid or csDMARD use was associated with lower retention, while entheseal and axial involvement positively influenced

retention. Corticosteroids are generally discouraged by EULAR guidelines [31] due to their potential rebound effects on PsO and PsA. The role of csDMARDs remains unclear [31], but our findings suggest that any concomitant csDMARD use (e.g. methotrexate, sulfasalazine, leflunomide or ciclosporin) might reduce guselkumab effectiveness.

Although this is the first report of such an observation for IL-23 inhibitors, a similar effect has been noted for other bDMARDs. For example, the PsABio study reported that methotrexate co-administration with ustekinumab (an IL-12/23 inhibitor) reduced its retention rate [31]. This may reflect a bias, as patients requiring combination therapy are often deemed at high risk of failure due to unmeasured clinical factors. Furthermore, variations in concomitant therapy during follow-up (e.g. NSAID use) were not systematically recorded. At the 6-month follow-up, however, 80% of patients had not altered their baseline concomitant treatment [31].

Guselkumab's good performance in patients with entheseal involvement aligns with its mechanism of action, as IL-23 is highly expressed in entheses [32], and is supported by experimental studies [6]. Surprisingly, patients with axial PsA responded favourably to guselkumab. The axial involvement in these patients could have a different subtype of inflammation (i.e. enthesitis affecting the spine and pelvis), in contrast to patients with axial spondylarthritis who do not have concomitant PsO. For this reason, a novel score for the evaluation of axial involvement in PsA could be useful for to optimize disease management, as reported elsewhere [17]. Finally, we note that prior use of bDMARDs did not influence guselkumab effectiveness.

In addition to the limitations inherent to observational research, interpretation of the results of this study must consider several caveats. It was not possible to collect uniform detailed information on corticosteroids and NSAID dosages and changes over time; however, medical and legal restrictions likely limited long-term use of these agents. Disease subsets were classified by different evaluators across centres. Enthesitis was assessed using clinical or ultrasound criteria, while axial forms were frequently confirmed by MRI of the sacroiliac joints (in ∼90% of cases), suggesting that objective methods were commonly used. The lack of uniform disease activity measures across patients (e.g. LEI vs MASES index for enthesitis) precluded a unified analysis of disease activity as a retention factor. Finally, 7% of patients lacked BMI or mRDCI data, necessitating Cox regression analyses with and without BMI, which revealed minimal differences in the results.

In conclusion, this real-world study demonstrates the sustained effectiveness of guselkumab over time, even in patients previously treated with two bDMARDs. Key factors influencing retention included corticosteroid and/or csDMARD use (disadvantageous) and entheseal and/or axial involvement (advantageous). Considering its favourable safety profile, comparable to that observed in clinical trials, guselkumab is a viable treatment option for a broad range of PsA patients.

Data availability

Data available on request.

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