Psoriasis: Targets and Therapy

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ORIGINAL RESEARCH

Long-Term Efficacy and Safety of Guselkumab for Moderate to Severe Psoriasis: A 3-Year Real-Life Retrospective Study

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Introduction: Guselkumab safety and efficacy profiles in psoriasis have been showed by VOYAGE (1 and 2) trials. Although trial results have been already previously confirmed by real-life studies, long-term real-life data, and drug survival data about guselkumab are still poor.

Patients and Methods: We performed a 3-year retrospective study, with the aim of assessing guselkumab efficacy and safety profile in the management of plaque psoriasis in a real-life setting.

Results: Thirty-one patients completed the study. Both Psoriasis Area Severity Index (PASI) and Body Surface Area (BSA) statistically improved since week 16, and up to week 144 [PASI reduction from 16.4 ± 6.2 to 0.6 ± 0.9 ($p < 0.0001$) at week 144 while BSA from 33.2 ± 14.6 to 1.9 ± 1.4 ($p < 0.0001$)]. At week 12 PASI90 and PASI100 were achieved by 19 (61.3%) and 11 (35.4%) patients, respectively, as well as 24 (77.4%) and 18 (58.1%) subjects reached PASI 90 and PASI 100 at week 144. As regards the safety, no cases of injection site reaction, candida, serious AEs, malignancy, or major cardiovascular events were reported. Of note, mild AEs were collected with pharyngitis as the main one (7, 22.6%), followed by headache (5, 16.1%) and flu-like illness (5, 16.1%), all without requiring treatment discontinuation.

Conclusion: Our experience confirmed the efficacy and safety of guselkumab in daily clinical practice up to 3 years, suggesting this drug as an effective treatment option in psoriasis long-term management.

Keywords: psoriasis, guselkumab, IL-23, anti-IL-23, real life, biologic, IL-23, IL-17A

Introduction

Psoriasis is an inflammatory chronic skin diseases with a reported prevalence of 1–3% in the global population, which may have a high negative impact on patients' quality of life, especially in its moderate to severe forms.[1,2] Even if the exact pathogenesis of psoriasis has not been fully clarified, recent research advantages lead to understand the central role played by interleukin (IL)-23 and IL-17 pathways, resulting in the development of high efficacy therapies.[3–5] IL-23 inhibitors represent the latest biologic class approved for psoriasis.[6] Guselkumab is a humanized antibody which acts by binding p19 subunit of IL-23, resulting in the inhibition of intracellular signalling of IL-23.[7] It was the first IL-23 inhibitors to receive the EMA and FDA approval for the treatment of moderate-to-severe plaque psoriasis.[7] Guselkumab safety and efficacy were evaluated by two Phase III clinical trials (VOYAGE-1 and −2), which reported promising results in terms of both PASI 90 and PASI 100 responses, linked with a good safety profile.[8,9] Phase-III trials also compared guselkumab efficacy to placebo, and different biologic classes, including anti-Tumour necrosis factor (TNF)-α, adalimumab (VOYAGE-1-2), anti-IL-17, secukinumab (ECLIPSE), and anti-IL-12/23, ustekinumab (NAVIGATE).[8–11] Moreover, recent data from real-world practice confirmed trial results, showing guselkumab efficacy also in multifailure, and elderly patients.[1,2,12–18] Although trials results have been already previously confirmed by real-life studies, long-term real-life data, and drug survival data about guselkumab are still poor. Herein, we report the results of a long-term real-life (3 years) study, with the aim of assessing guselkumab safety and efficacy profiles in psoriasis management.

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Methods

We performed a retrospective study enrolling patients affected by moderate-to-severe psoriasis, from October-2018 to March-2022. The aim of the study was to assess the long-term guselkumab efficacy and safety in a real-life setting. Patients affected by moderate-to-severe plaque psoriasis starting guselkumab were included in the study. At baseline, we registered: i) psoriasis and psoriatic arthritis (PsA) (if present) history; ii) demographic data;; iii) comorbidities; iv) previous received treatments for psoriasis; v) Psoriasis severity. At each follow-up visit, we evaluated and registered: eventual adverse events (AEs), psoriasis severity scores (PASI, BSA), routine blood tests, and safety assessment [physical examinations, and laboratory monitoring treatment-emergent AEs]. The present study has been approved by local Ethics Committee (University of Naples Federico II, Naples, Italy). The present study was performed respecting the Declaration of Helsinki.

Statistical Analysis

t-test and Chi-squared test were used to compare the quantitative and qualitative characteristics of the populations. A p-value of <0.05 was considered statistically significant. All statistical analyses were performed using GraphPad-Prism 4.0 (GraphPad Software Inc., La Jolla, CA, USA).

Results

A total of 95 patients undergoing treatment with guselkumab were screened. Among these, 56 (59.0%) patients respected the inclusion criteria. However, only 31 (32.6%) subjects (18 male, 58.1%; mean age 55.0 ± 6.9 years, range 32–70 years, mean psoriasis duration 18.3 ± 9.7 years) completed the study period (Table 1). Among these, PsA was assessed in 17 (54.8%) patients. As regards comorbidities, hypertension was the most frequently reported (17, 54.8%), followed by dyslipidemia (15, 48.4%) and depression (8, 25.8%) (Table 1). All of the patients have been treated with a conventional systemic treatment before starting guselkumab, with methotrexate (21, 67.7%) and cyclosporine (16, 51.6%) as the mains (Table 1). Moreover, 26 (83.9%) patients were previously treated with a biologic treatment, while 5 (16.1%) subjects did not receive any biologic before starting guselkumab. In particular, an anti-tumour necrosis factor (TNF)α, anti-IL17 and ustekinumab were previously administered in 22, 16 and 10 subjects, respectively (Table 1) (Table 1).

Table 1 Patients' Demographics and Clinical Characteristics Features at Baseline

Patients, n	31
Sex, M/F; n (%)	18/13 (58/42)
Age, years	55 ± 6.9
Psoriasis duration, years	18.3 ± 9.7
Psoriatic arthritis, n (%)	17 (54.8)
Comorbidities, n (%)	
Hypertension	17 (54.8)
Diabetes	5 (16.1)
Cardiopathy	6 (19.3)
Dyslipidaemia	15 (48.4)
Depression	8 (25.8)
Prostatic hyperplasia	1 (3.2)
Latent TB infection	1 (3.2)
Other	5 (16.1)

(*Continued*)

Table 1 (Continued).

Previous conventional systemic treatments, n (%)	
Ciclosporin	16 (51.6)
Methotrexate	21 (67.7)
Acitretin	9 (29)
NB-UVB phototherapy	6 (19.3)
Previous biologic treatments, n (%)	
Anti-TNF	22 (70.9)
Adalimumab	10 (32.2)
Etanercept	6 (19.3)
Infliximab	2 (6.4)
Certolizumab	4 (12.9)
Golimumab	3 (9.6)
Anti-IL-12/23	10 (32.2)
Ustekinumab	10 (32.2)
Anti-IL-17	16 (51.6)
Secukinumab	9 (29)
Ixekizumab	10 (32.2)
Brodalumab	0 (0)
Bio-naïve patients	5 (16.1)

At baseline, a mean PASI of 16.4 ± 6.2 and a mean BSA of 33.2 ± 14.6 were reported. A statistically significant improvement of PASI and BSA were assessed at week 12 [(PASI: 3.1 ± 1.8 ($p < 0.0001$); BSA: 7.5 ± 2.6 ($p < 0.0001$)], with 19 (61.3%) patients reaching PASI 90 response and 11 (35.4%) patients achieving PASI100, respectively. Psoriasis improvement was confirmed at week 28 [PASI: 1.6 ± 1.6 ($p < 0.0001$); BSA: 4.2 ± 2.3 ($p < 0.0001$)] and at each follow-up visit up to week 144 [PASI: 0.6 ± 0.9 ($p < 0.0001$), BSA: 1.9 ± 1.4 ($p < 0.0001$)]. Moreover, 22 (71.0%) and 16 (51.6%) patients reached PASI90 and PASI100 response at week 28, respectively, as well as PASI 90 and PASI 100 were evaluated in 24 (77.4%) and 18 (58.1%) patients at week 144. Psoriasis severity at baseline and each follow-up visit is reported in Table 2.

A total of 6 (19.3%) patients discontinued guselkumab for primary (1, 16.7%) or secondary (5, 83.3%) inefficacy. However, no predictive factors for guselkumab discontinuation were assessed.

As regards the safety, no cases of serious AEs, injection site reaction, candida, major cardiovascular events, or malignancy, were reported. Of note, mild AEs were collected with pharyngitis as the main one (7, 22.6%), followed by headache (5, 16.1%) and flu-like illness (5, 16.1%), all without requiring treatment discontinuation. Furthermore, 1 case (3.2%) of new-onset PsA development was reported. The patient was treated combining methotrexate to guselkumab, avoiding treatment discontinuation.

Routine blood tests showed mild alterations in 5 (16.1%) subjects [2 patients (6.5%) showed mild transient hyperglycemia (135 and 127 mg/dl, n.v. 60–100 mg/dl); 2 patients (6.5%) showed hypertriglyceridemia (186 and 202 mg/dl; n.v. 45–175 mg/dl), and 1 patient (3.2%) showed an elevation of liver enzymes (GPT: 77 U/l n.v. 0–46 U/L, GOT: 152 n.v. 0–39 U/l, and γ-GT: 44 n.v. 11–40 U/l)], without requiring treatment interruption.

Table 2 Patients' Feature at Baseline (Week 0) and at Each Follow-Up Visit (Week 12, Week 28, Week 48, Week 72, Week 96, Week 120) Up to Week 144. PASI: Psoriasis Activity Severity Index. BSA: Body Surface Area

Baseline	
Mean PASI	16.4 ± 6.2
Mean BSA	33.2 ± 14.6
Week 12	
Mean PASI	3.1 ± 1.8
Mean BSA	7.5 ± 2.6
PASI90	19 (61.3)
PASI100	11 (35.4)
Weeks 28	
Mean PASI	1.6 ± 1.6
Mean BSA	4.2 ± 2.3
PASI90	22 (71)
PASI100	16 (51.6)
Weeks 48	
Mean PASI	1.2 ± 1.7
Mean BSA	3.4 ± 1.6
PASI90	23 (74.2)
PASI100	17 (54.8)
Weeks 72	
Mean PASI	1.3 ± 1.2
Mean BSA	4.0 ± 1.9
PASI90	23 (74.2)
PASI100	16 (51.6)
Weeks 96	
Mean PASI	0.9 ± 1.1
Mean BSA	2.2 ± 1.9
PASI90	24 (77.4)
PASI100	17 (54.8)

(*Continued*)

Table 2 (Continued).

Baseline	
Weeks 120	
Mean PASI	1.0 ± 1.1
Mean BSA	2.8 ± 1.8
PASI90	24 (77.4)
PASI100	17 (54.8)
Weeks 144	
Mean PASI	0.6 ± 0.9
Mean BSA	1.9 ± 1.4
PASI90	24 (77.4)
PASI100	18 (58.1)
Discontinuation rate n (%)	6 (19.3)
Adverse events n (%)	10 (32.3%)
Pharyngitis	7 (22.6)
Flu-like illness	5 (16.1)
Headache	5 (16.1)
Diarrhoea	4 (12.9)

Finally, 3 (9.7%) subjects precautionarily suspended guselkumab treatment (week range 1–5) due to Covid-19 infection or for "at-risk" contact with a subject positive to SarsCov-2 infection.

Discussion

The IL-23/Th17 axis seems to have a key role in psoriasis pathogenesis, particularly IL-23.[3] Thus, drugs selectively targeting IL-23 have been recently approved for the management of psoriasis.[6] Among these, guselkumab was the first IL-23 inhibitors to receive the EMA and FDA approval for the treatment of moderate-to-severe plaque psoriasis.[7] Its efficacy and safety have been reported by both clinical trials and real-life studies. However, long-term data about the use of guselkumab in patients affected by psoriasis are scant.[9–18] Thus, the aim of our study was to report long-term data on the efficacy and safety of guselkumab in a real-life setting which is more complicated than trials for several factors, including patients with a higher previous biologic failure frequency, a higher rate comorbidities and polypharmacy, etc.[19,20] In our cohort, 31 (32.6%) patients (18 male, 58.1%; mean age 55.0 ± 6.9 years, range 32–70 years, mean psoriasis duration 18.3 ± 9.7 years) completed the study. A statistically significant improvement of both PASI and BSA was observed since week 16 up to week 144 [PASI reduction from 16.4 ± 6.2 to 0.6 ± 0.9 ($p < 0.0001$) at week 144 while BSA from 33.2 ± 14.6 to 1.9 ± 1.4 ($p < 0.0001$)] (Table 2). Of note, at week 12 PASI90 and PASI100 were achieved by 19 (61.3%) and 11 (35.4%) patients, respectively, as well as 24 (77.4%) and 18 (58.1%) subjects reached PASI 90 and PASI 100 at week 144.

The long-term safety of guselkumab was confirmed as well with no serious AEs reported and mild AEs collected in 10 patients (32.3%). Finally, treatment discontinuation for primary or secondary inefficacy was assessed in 1 (16.7%) and 5 (83.3%) patients.

No statistically significant differences in terms of efficacy and safety were found between bio-experienced and bio-naïve patients as well as the presence of comorbidities does not seem to affect the effectiveness of guselkumab. Moreover, no predictive factors for treatment discontinuation were assessed.

In literature, long-term data on the efficacy and safety of guselkumab have been reported by the trials VOYAGE 1 and VOYAGE 2. Reich et al reported the results at the three years follow-up of both trials showing that 11.1% (86/774) and 16.1% (152/947) patients discontinued the study in VOYAGE 1 and VOYAGE 2, respectively, through week 156, mainly for AEs (3.4% and 4.5%) and withdrawal by patient (3.2% and 5.0%).[21] Differently from Reich et al, we did not report cases of treatment discontinuation for AEs in our study period. As regards the efficacy, 82.1% and 82.8% in VOYAGE 1 and 79.1% and 77.2% in VOYAGE 2 reached PASI90 at week 100 and 156, respectively, as well as 50.8% and 48.4% of patients achieved PASI100 at week 156 in VOYAGE 1 and VOYAGE 2. Similarly, IGA 0/1 was reached by 83.3% and 82.1% in VOYAGE 1 and 83.1% and 83.0% in VOYAGE 2 at week 100 and week 156, respectively. Patients previously treated with adalimumab in VOYAGE 2 and switched to guselkumab showed the same results in terms of effectiveness at 3 years follow-up visit. Our real-life experience showed a lower percentage of patients achieving PASI90 at week 96 compared to VOYAGE 1 and VOYAGE 2 at week 100 (77.4% vs 82.1% and 79.1%). Moreover, similar results in terms of PASI90 response were assessed also comparing our data at week 144 to VOYAGE 1 and VOYAGE 2 at week 156 (77.4% vs 82.8% vs 77.2%). However, in our cohort 58.1% of patients reached PASI100 at week 144 compared to 50.8% and 48.4% of patients in VOYAGE and VOYAGE 2 at week 156. Regarding the safety, no serious AEs were reported up to week 156.[21] In our study, no serious AEs were reported up to week 144 as well.

The effectiveness of guselkumab was confirmed in a 4-year analysis of VOYAGE 2 reporting that 79.7% and 51.0% of patients achieved PASI100 at week 204 with 81.9% reaching an IGA score of 0/1.[22] Finally, at week 204 PASI 90 was reached by 84.1% and 82.0% of patients in VOYAGE 1 and VOYAGE 2, respectively, with 82.4% and 85.0% reaching IGA 0/1.[23]

Iznardo et al investigated the drug survival in psoriasis patients treated with guselkumab (n = 43), ixekizumab (n = 60) and secukinumab (n = 78).[24] As regards the guselkumab cohort, median duration of follow-up was 1145 days. The authors reported that ixekizumab and secukinumab showed lower probabilities of survival compared to guselkumab (HR 0.16, 95% CI 0.05–0.53, P = 0.003 and HR 0.49, 95% CI 0.27–0.89, respectively; P = 0.018).[24] Moreover, 4 patients in the guselkumab group interrupted the treatment due to poor control of psoriatic arthritis symptoms (n = 3: 2 switched to ixekizumab and 1 to adalimumab) and lost to follow-up (n = 1).[24] No serious AEs were collected.[24]

An overall survival of 94% after 93.4 weeks of treatment with guselkumab was reported by Ruiz-Villaverde et al in an observational, longitudinal retrospective study as well.[25]

Furthermore, a 2-years multicenter study enrolling 264 patients undergoing treatment with guselkumab for moderate-to-severe plaque psoriasis showed a reduction in overall survival rate from 0.989 to 0.674 at week 104. The lack of efficacy (30, 11.4%) and incomplete lesion clearance or residual arthralgia (10, 3.8%) were the main reason for treatment discontinuation.[26] Lytvyn et al showed that the survival was lower for patients who previously failed at least 2 biologics and higher for bio-naive patients (P = 0.0274).[26]

Maliyar et al reported the results of a retrospective study showing that 58 out of 79 patients (73.3%, median duration of treatment 1.2 years, range 2.4 months - 2.7 years) achieved a body surface area involvement of <1%. Guselkumab was shown to be well tolerated and no serious AEs were reported.[27]

Finally, Bardazzi et al showed that 96.8%, and 83.9% of patients reached PASI90 and PASI100 at week 60, respectively, in a 60-week retrospective study. Moreover, PASI reduction does not seem to be influenced by the presence of ≥3 comorbidities, BMI >30, the involvement of difficult-to-treat areas, smoking, and a previous failure to ≥2 biologic treatments (p > 0.05).[28]

The IL inhibitors represented an important advancement in the treatment of moderate to severe psoriasis, leading to the achievement of higher rates of PASI90 and PASI100 responses, and with a better safety profile than anti-TNFα, which represented the first biological class to be approved for psoriasis.[29] The introduction of biologic therapies has revolutionized psoriasis management. Among the armamentarium of the biologics, guselkumab seems to be effective and safe.[30] Furthermore, guselkumab also showed to be a safe and effective treatment option during the ongoing pandemic era, during which several concerns have been raised about the treatment with biologic drugs.[31–37]

However, studies with a long follow-up are needed to confirm these data also in the long term.[38,39]

Conclusion

To the best of our knowledge, this is the first study evaluating the use of guselkumab in a real-life setting with a follow-up period of 3 years. Our experience confirmed the efficacy and safety of guselkumab in a real-life setting up to 3 years, suggesting this anti-IL-23 as a valuable option in psoriasis management also in the long term. Certainly, further studies are needed to confirm our results to create a tailored-tail approach in the therapeutic landscape of psoriasis treatment.

Ethics Statement

The present study was approved by local ethics committees (University of Naples Federico II). The study was conducted in compliance with the protocol approved by the local Ethics Committee (University of Naples Federico II, Naples, Italy). Written informed consent was obtained from all the patients prior to participation in the study. This study was performed in accordance with Good Clinical Practices and the Declaration of Helsinki 1996.

Disclosure

The authors report no conflicts of interest in this work.

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