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ORIGINAL RESEARCH

The Evaluation of Effectiveness and Safety of Guselkumab in Patients with Psoriatic Arthritis in a Prospective Multicentre "Real-Life" Cohort Study

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ABSTRACT

Introduction: Guselkumab is an interleukin-23 (IL-23) inhibitor licensed for the treatment of psoriatic arthritis (PsA). This study aimed to evaluate the 6-month effectiveness of guselkumab in patients with PsA in a "real-life" multicentre patient cohort. We also estimated the drug retention rate (DRR) of gusulkumab, also assessing the impact of comorbidities and patient clinical characteristics, in a collective 18-month prospective follow-up.

Methods: Between December 2021 and September 2023, consecutive patients with PsA were evaluated if treated at least for 6 months with guselkumab in a prospective multicentre study to evaluate the effectiveness of the drug by means of disease activity index for psoriatic arthritis (DAPSA) and cumulative DRR.

Results: A total of 111 patients with PsA were evaluated and treated with guselkumab (age 56.8 ± 9.9, male sex 20.7%). These patients were mainly characterised by active and long-standing PsA with median disease duration of 6.0 (7.0) years (55.9% disease duration ≥ 5 years), 55.0% showed comorbidities, 78.4% of patients were previously treated with biologic disease-modifying anti-rheumatic drugs (bDMARDs), and 60.4% concomitantly with conventional synthetic DMARDs (csDMARDs). After 6 months, a significant reduction of DAPSA was observed (β − 15.47, $p = 0.001$, 95% CI − 23.15 to − 9.79) with 39.6% of patients achieving a DAPSA ≤ 14.At the end of cumulative follow-up, 71.2% of patients were still treated with guselkumab whereas 24.3% discontinued the drug because of inefficacy. An 18-month DRR of guselkumab of 66.7% was estimated with a mean time of administration of 9.8 ± 4.1 months. The results of the DRR were stratified according to patient clinical characteristics. The DRR of guselkumab appeared to be not influenced by long disease duration, comorbidities, obesity, concomitant csDMARDs, and previous bDMARDs.

Conclusion: The "real-life" 6-month effectiveness of guselkumab was shown in patients with PsA, mainly characterised by active long-standing disease, previously treated with bDMARDs,

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and with comorbidities. Furthermore, a good DRR of guselkumab was estimated in the cumulative 18 months of follow-up and appeared to be not influenced by long disease duration, comorbidities, obesity, and previous bDMARDs.

Keywords: Psoriatic arthritis; Guselkumab; Therapy

Key Summary Points

Why carry out this study?

On the basis of the pathogenic role of interleukin-23 (IL-23), IL-23 inhibitors have been developed to treat psoriatic arthritis (PsA); among these drugs, guselkumab is a monoclonal antibody specifically targeting the p19 subunit of the cytokine.

Despite evidence in randomised controlled trials in the context of PsA, few studies investigated the effectiveness of guselkumab in "real-life" settings.

A total of 111 patients with active and long-standing PsA were evaluated and treated with guselkumab.

What was learned from the study?

After 6 months, a significant reduction of disease activity index for psoriatic arthritis (DAPSA) was observed with 39.6% of patients achieving a DAPSA $\leq$ 14.

The 18-month drug retention rate of guselkumab was estimated to be 66.7% with a mean time of administration of 9.8 $\pm$ 4.1 months.

The drug retention rate of guselkumab appeared not to be influenced by long disease duration, comorbidities, obesity, concomitant conventional synthetic disease-modifying anti-rheumatic drugs, and previous biologic disease-modifying anti-rheumatic drugs.

INTRODUCTION

Psoriatic arthritis (PsA) is a chronic disease characterized by inflammatory musculoskeletal manifestations in patients with psoriasis [1]. This disorder is associated with heterogeneous clinical manifestations variously involving peripheral joint, enthesis, and spine [1–3]. A destructive form of arthritis, linked with a clinically relevant disability, and extra-articular manifestations may occur in a patient subgroup characterised by a more aggressive disease [4, 5]. In addition, an enhanced rate of comorbidities is observed in patients with PsA, complicating their management and worsening their outcome over time [6, 7]. As far as the pathogenesis of PsA is concerned, a multilayer mechanistic model based on the interplay among genetic background, environmental triggering factors, and deregulated inflammatory response has been recently suggested [8, 9]. In this regard, multiple lines of evidence show the importance of interleukin (IL)-23 since it may induce and perpetuate the activity of Th17 cells [10–12]. This heterodimeric cytokine is composed of IL-12B (IL-12p40) and IL-23A (IL-23p19) subunits [8]. Given this pathogenic background of IL-23, IL-23 inhibitors have been successfully used to treat PsA [11]. Thus, both European League Against Rheumatism (EULAR) and Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) recommendations for treatment of PsA suggest the administration of these drugs in patients who are identified as non-responders to the first-line therapies [13, 14]. Among IL-23 inhibitors, guselkumab has been licensed for the treatment of PsA; this drug specifically targets the p19 subunit of the cytokine [15]. In support of drug efficacy, randomized clinical trials showed the improvement of clinical manifestations in patients with PsA following the administration of guselkumab [16–18]. However, patients enrolled in randomised clinical trials are often not fully representative of the "real-life" population in daily clinical practice. In fact, the strict enrolment criteria may limit the generalization of the derived results to daily clinical practice [19]. Therefore, real-world evidence data may

provide relevant information about the management of patients encountered in daily clinical settings, who may have multiple comorbidities or other clinical features influencing their management [20, 21]. The drug retention rate (DRR) is a widely accepted metric to study the effectiveness in cohorts of patients from clinical practice by the assessment of the persistence of therapy over time. In the context of PsA, few studies investigated the effectiveness of guselkumab in "real-life" studies [23–25].

On these bases, we aimed to evaluate the 6-month effectiveness of guselkumab in patients with PsA in a "real-life" multicentre patient cohort. Furthermore, we estimated the DRR of guselkumab in these patients with PsA, also assessing the impact of comorbidities and patient clinical characteristics, in a collective 18-month prospective follow-up.

METHODS

Study Design, Patients, and Settings

Between December 2021 and September 2023, consecutive patients with PsA and fulfilling CASPAR criteria [26] were evaluated if treated at least for 6 months with guselkumab in a prospective multicentre study to evaluate the effectiveness of the drug. Patients with moderate-to-active PsA were selected among those attending rheumatologic outpatient clinics of involved centres. All the units were characterised by experience in the management of PsA as well as by high-volume clinical activity. Data of patients were recorded during the scheduled visits. In this study, two guselkumab dose regimens were employed according to clinical judgement (100 mg every 4 weeks (Q4W) or every 8 weeks (Q8W) dosing intervals) following drug datasheet.

The local ethics committee (Comitato Etico Azienda Sanitaria Locale 1 Avezzano/Sulmona/L'Aquila, L'Aquila, Italy; protocol number 0204194/22) approved the study, which was performed according to the Good Clinical Practice guidelines and the Declaration of Helsinki. Each patient provided written informed consent. Consent for publication was not required as all patient data were de-identified. In reporting the results, we followed the STROBE guidelines.

Effectiveness of Guselkumab in Patients with PsA

The main objective of the present study was the evaluation of the effectiveness of guselkumab in patients with PsA after 6 months in a "real-life" setting. Disease activity index for psoriatic arthritis (DAPSA) was calculated at baseline and after 3 and 6 months of therapy. Furthermore, the achievement of DAPSA $\leq$ 14 was recorded exploiting possible predictive factors among clinical features. In addition, the values of Leeds Enthesitis Index (LEI), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), tender and swollen joints, and C-reactive protein (CRP) were analysed following the administration of guselkumab to further assess the activity of these patients with PsA. Furthermore, visual analogue scale (VAS) pain, physician global assessment, and patient global assessment were evaluated before and after the administration of guselkumab.

Persistence of Guselkumab Therapy in Patients with PsA

After the first 6 months of therapy, the DRR of guselkumab was evaluated by assessing the months of therapy. The reasons for discontinuation of guselkumab due to inefficacy and/or side effects were also registered in a cumulative 18-month follow-up. The impact of selected clinical manifestations on DRR was also evaluated; specifically, male/female sex, disease duration, presence of comorbidity, obesity, previous and concomitant therapies.

Clinical Variables, Data Sources, Bias, and Study Size

During scheduled visits demographic and disease features were also collected including age, sex, body mass index (BMI) to codify patients with obesity (BMI $\geq$ 30), disease duration, and clinical manifestations. The presence of

comorbidities was recorded and defined as coexisting medical conditions distinct from the principal diagnosis for which the patient was included in this study. Previous biologic disease-modifying anti-rheumatic drug (bDMARD) therapy, concomitant glucocorticoids (GCs), conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs), and non-steroidal anti-inflammatory drugs (NSAIDs) were also registered in our patient cohort. Side effects related to guselkumab administration were registered.

Considering the "real-life" design, our study could be subject to a number of possible biases but these were minimised by a careful definition of each variable to be assessed. Furthermore, patients with significant missing data, meaningful for the analyses, were removed. No specific sample size was estimated because of our study design.

Statistics

Statistics firstly provided a descriptive evaluation of assessed patients with PsA; according to their distribution, continuous variables were presented as mean and standard deviation (SD) or median and interquartile range (IQR). DAPSA and other indexes of disease activity were firstly compared before and after the administration of guselkumab, adjusting for multiple comparisons. Concerning the overall 6-month reduction of DAPSA, an age- and male sex-adjusted linear mixed model was set up as random intercept and random slope model, assuming an unstructured covariance matrix. After that logistic regression models were built to exploit possible clinical predictive factors of the achievement of DAPSA $\leq$ 14 after 6 months of follow-up. In addition to age and male sex, these logistic regression models were adjusted for disease manifestations, long disease duration, concomitant, and previous therapies, smoking habit, the presence of comorbidity and obesity. In addition, Kaplan–Meier curves were also plotted to estimate the cumulative DRR of guselkumab with the event being drug discontinuation due to inefficacy. Furthermore, Kaplan–Meier curves were carried plotted to evaluate the impact of selected clinical manifestations and compared by using long-rank test. Two-sided *P* values less than 0.05 were considered as being statistically significant. The Statistics Package for Social Sciences (SPSS for Windows, version 20.0, SPSS Inc., Chicago, IL, USA) and GraphPad for Windows (version 8.0, San Diego, USA) were used for all analyses.

RESULTS

Clinical Features of Assessed Patients with PsA

In this study, 111 patients with PsA were evaluated (mean age 56.8 $\pm$ 9.9, male sex 20.7%), as reported in Table 1. These patients were mainly characterised by active and long-standing PsA, considering the median disease duration of 6.0 (7.0) years and that 55.9% had a disease duration $\geq$ 5 years. Peripheral involvement was mainly recognised in these patients (86.5%) in association with skin disease (75.9%). Axial features (64.3%), enthesis involvement (51.4%), and dactylitis (29.7%) were also recognised. Comorbidities were reported in 55.0% of patients, mainly high blood pressure (36.2%), dyslipidaemia (33.3%) and obesity (20.7%). Regarding therapies, 78.4% of patients were previously treated with bDMARDs, mainly tumour necrosis factor (TNF) inhibitors, and 60.4% concomitantly with csDMARDs. Guselkumab was mainly administered according to Q8W dosing interval (65.8%).

6-Month Effectiveness of Guselkumab

After 6 months of follow-up, a significant reduction of DAPSA was observed in patients with PsA treated with guselkumab ($p < 0.001$), as reported in Fig. 1. A significant effect of the drug was also observed on the overall 6-month reduction of DAPSA after adjusting the linear mixed model for age and male sex (β − 15.47, $p = 0.001$, 95% CI − 23.15 to − 9.79). After 3 months, 29.7% of patients achieved a DAPSA $\leq$ 14. This percentage increased to 39.6% at 6-month assessment. Such clinical

Table 1 Descriptive statistics of assessed patients with PsA

Clinical characteristics	111 patients with PsA
Demographic characteristics	
Age, years, mean ± sd	56.8 ± 9.9
Male sex (%)	20.7
Weight, kg, mean ± sd	72.2 ± 12.6
Height, m, mean ± sd	1.7 ± 0.4
BMI, mean ± sd	25.5 ± 5.1
Smoking habit (%)	37.8
Disease characteristics	
Peripheral involvement (%)	86.5
Skin and/or nail involvement (%)	75.9
Axial involvement (%)	64.3
Enthesis involvement (%)	51.4
Dactylitis features (%)	29.7
Extra-articular manifestations (%)	8.9
Disease duration, years, median (IQR)	6.0 (7.0)
Disease duration ≥ 5 years (%)	55.9
DAPSA, median (IQR)	25.6 (15.2)
LEI, median (IQR)	2.0 (3.0)
Tender joints, median (IQR)	9.0 (5.0)
Swollen joints, median (IQR)	1.0 (2.0)
VAS pain, median (IQR)	7.0 (6.0)
Physician global assessment, median (IQR)	6.0 (6.0)
CRP, mg/dL, median (IQR)	0.7 (1.9)
BASDAI, median (IQR)	5.8 (4.6)
Comorbidity features	
Comorbidities (%)	55.0
High blood pressure (%)	36.2
Dyslipidaemia (%)	33.3
Obesity, BMI ≥ 30 (%)	20.7
Clinical atherosclerosis (%)	12.6
Type 2 diabetes (%)	10.8
Other comorbidities (%)	27.8
Guselkumab features	
Ongoing at the last observation (%)	71.2
Discontinuation due to inefficacy (%)	24.3
Discontinuation due to side effects (%)	4.5
Previous therapy with bDMARDs (%)	78.4
Previous therapy with TNF inhibitor (%)	63.5
Concomitant therapy with csDMARDs (%)	60.4
Concomitant therapy with MTX (%)	52.3
Concomitant therapy with NSAIDs (%)	45.9
Concomitant therapy with GCs (%)	12.8

PsA psoriatic arthritis, *BMI* body mass index, *bDMARDs* biologic disease-modifying anti-rheumatic drugs, *csDMARDs* conventional synthetic disease-modifying anti-rheumatic drugs, *NSAIDs* non-steroidal anti-inflammatory drugs, *GCs* glucocorticoids, *DAPSA* disease activity index for psoriatic arthritis, *LEI* Leeds Enthesitis Index, *IQR* interquartile range, *VAS* visual analogue scale, *CRP* C-reactive protein, *BASDAI* Bath Ankylosing Spondylitis Disease Activity Index, *TNF* tumour necrosis factor, *MTX* methotrexate

target was chosen considering that the majority of patients had a long-term disease and were previously treated with bDMARDs [13]. By age- and male sex-adjusted logistic multivariate regression models, no significant results were retrieved exploiting possible clinical predictive factors of the achievement of DAPSA ≤ 14. Specifically, disease manifestations (i.e. axial

disease, enthesis involvement, dactylitis), disease duration ≥ 5 years, concomitant csDMARDs, previous bDMARDs, smoking habit, obesity (BMI ≥ 30), and comorbidities did not appear to influence the achievement of DAPSA ≤ 14. These findings are reported in Table 2.

In addition, during the 6-month follow-up, the administration of guselkumab was associated with a significant reduction of LEI ($p < 0.001$), and BASDAI ($p < 0.001$). Furthermore, tender joints ($p < 0.001$), swollen joints ($p < 0.001$), and CRP ($p = 0.002$) significantly reduced. In addition, VAS pain ($p < 0.001$), patient global disease assessment ($p < 0.001$) and physician global disease assessment ($p < 0.001$) decreased following the administration of guselkumab. These results could suggest the effectiveness of guselkumab for the heterogeneous manifestations of patients with PsA. These findings are represented in Fig. 2.

DRR of Guselkumab in 18-Month Follow-up

At the end of follow-up 71.2% of patients were still treated with guselkumab whereas 24.3% discontinued the drug because of inefficacy in our patient cohort. Thus, a cumulative 18-month DRR of guselkumab of 66.7% was estimated with a mean time of administration of 9.8 ± 4.1 months (median 9.0 [IQR 5.0] months), as reported in Fig. 3. After that, we analysed the results of the DRR of guselkumab according to patient clinical characteristics. These data are summarized in Fig. 4. Male sex ($p = 0.941$) and disease duration ≥ 5 years ($p = 0.959$) did not influence the DRR of guselkumab in our cohort. The presence of comorbidities, considering any concomitant disorder ($p = 0.824$), and obesity ($p = 0.444$) did not affect the DRR of guselkumab in assessed patients. Finally, the DRR of guselkumab appeared to be not influenced by concomitant therapy with csDMARDs ($p = 0.854$) or previous bDMARDs ($p = 0.293$).

Safety Profile of Guselkumab During the Study

In this study, 4.5% of patients discontinued guselkumab because of side effects. No life-threatening events were observed. The discontinuation of the drug was mainly due to gastrointestinal features, including diarrhoea and dyspepsia, and respiratory tract infections,

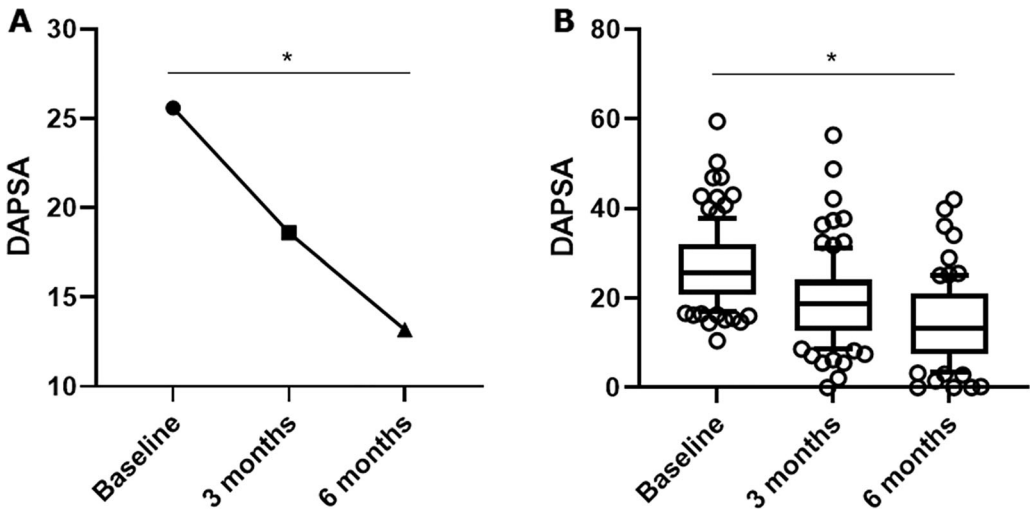

Fig. 1 6-month effectiveness of guselkumab on disease activity index for psoriatic arthritis (DAPSA). A significant reduction of DAPSA was observed in patients with psoriatic arthritis (PsA) treated with guselkumab ($p < 0.001$); **a** median values, **b** median values and 10–90 percentiles

Table 2 Multivariate regression analyses exploiting the possible predictive role of selected clinical variables on the likelihood of DAPSA $\leq$ 14 following guselkumab administration

Clinical variables	OR	95% CI	*P* value
Achievement of DAPSA $\leq$ 14			
Multivariate analysis			
Age	0.97	0.92–1.02	0.289
Male sex	2.81	0.75–10.52	0.996
Axial disease	0.44	0.16–1.17	0.100
Enthesitis	1.23	0.47–3.62	0.617
Dactylitis	1.32	0.45–3.92	0.611
Multivariate analysis			
Age	0.98	0.93–1.03	0.549
Male sex	2.86	0.80–10.30	0.106
Disease duration $\geq$ 5 years	0.91	0.34–2.44	0.856
csDMARDs	0.92	0.35–3.56	0.719
Previous bDMARDs	0.65	0.18–2.21	0.623
Multivariate analysis			
Age	0.96	0.91–1.02	0.224
Male sex	2.01	0.51–8.03	0.313
Smoking habit	0.39	0.31–2.88	0.091
Obesity	0.46	0.13–1.16	0.461
Comorbidity	1.58	0.46–5.41	0.924

OR odds ratio, *95% CI* 95% confidence interval, *DAPSA* disease activity index for psoriatic arthritis, *bDMARDs* biologic disease-modifying anti-rheumatic drugs, *csDMARDs* conventional synthetic disease-modifying anti-rheumatic drugs

$P < 0.05$ is considered statistically significant

which needed antibiotic therapies. These reactions were resolved without long-term consequences and led to the discontinuation of guselkumab. In addition, minor transient side effects were reported during the study, mainly injection site reactions, which did not lead to the stoppage of the drug.

DISCUSSION

This study demonstrated the 6-month effectiveness of guselkumab in patients with PsA, mainly with active long-standing disease, previously treated with bDMARDs, and with comorbidities. Furthermore, a DRR of guselkumab was estimated in the cumulative 18 months of follow-up and appeared to be not influenced by patient clinical characteristics. These findings may suggest the clinical usability of guselkumab in the heterogeneous "real-life" clinical setting of patients with PsA.

In the first 6 months of follow-up, a significant progressive decrease of DAPSA was reported in our cohort. Furthermore, almost 40% of patients reached a low disease activity achieving a DAPSA $\leq$ 14. This clinical target was considered acceptable in our setting since we assessed a majority of patients with a long disease duration and previously treated with bDMARDs [13]. Our data may parallel that reported in clinical trials, in which efficacy of guselkumab was observed in patients with PsA who were inadequate responders to previous bDMARDs and independently of csDMARD background [16–18, 27]. These results may further reinforce the findings about the effectiveness of guselkumab in patients with active long-standing disease, previously treated with bDMARDs, and with comorbidities, as reported in the CorEvitas Psoriatic Arthritis/Spondyloarthritis (PsA/SpA) Registry [25, 28]. In addition, assessing possible predictive factors, we did not find specific associations with the 6-month achievement of good clinical response. Thus, further studies are needed to fully evaluate the clinical profile of patients with PsA linked to this clinical target following the administration of guselkumab. Furthermore, as also observed in clinical trials [16–18], the administration of guselkumab was associated with an improvement of multiple domains of PsA in our cohort. In addition to an improvement of peripheral joints, we observed a reduction of LEI and of BASDAI, suggesting the effectiveness of the study drug on enthesis involvement and axial features [29–31]. Although conflicting findings are reported about these features, mostly axial involvement

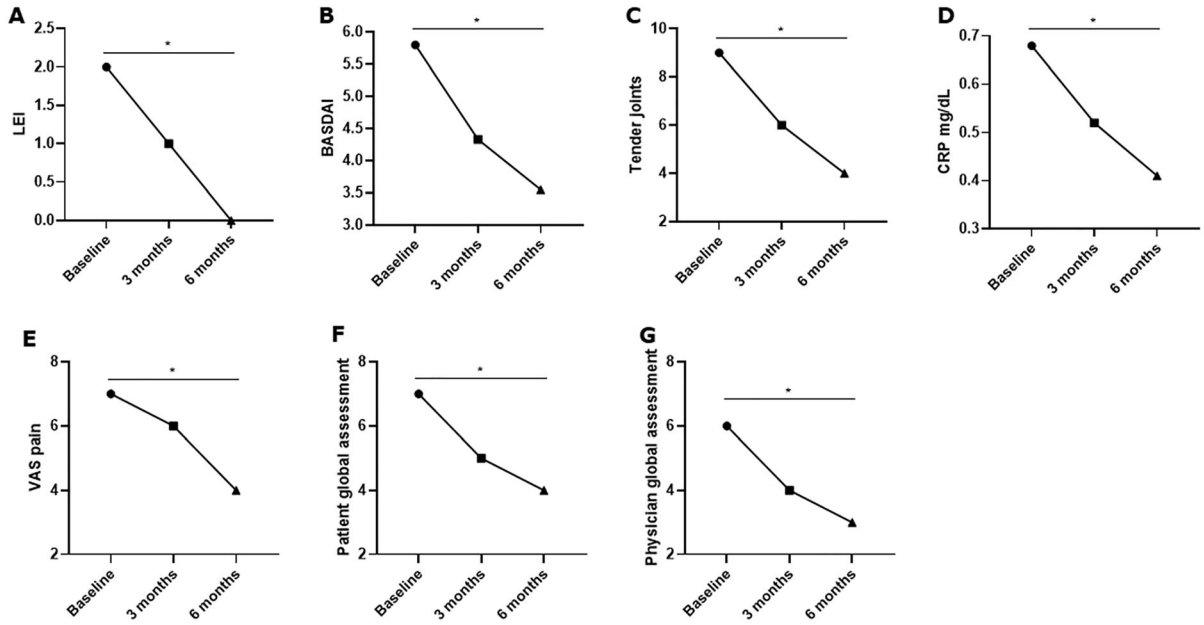

Fig. 2 6-month effectiveness on additional domains of psoriatic arthritis (PsA). The administration of guselkumab was associated with a significant reduction of **a** Leeds Enthesitis Index (LEI) ($p < 0.001$), **b** Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) ($p < 0.001$), **c** tender joints ($p < 0.001$), **d** C-reactive protein (CRP) ($p = 0.002$), **e** visual analogue scale (VAS) pain ($p < 0.001$), **f** patient global disease assessment ($p < 0.001$), and **g** physician global disease assessment ($p < 0.001$)

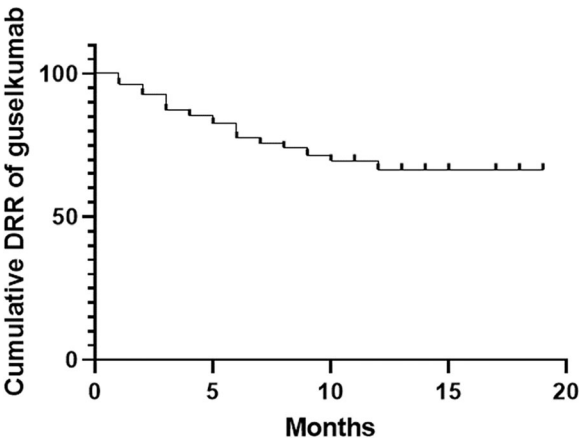

Fig. 3 Cumulative drug retention rate (DRR) of guselkumab. A cumulative 18-month DRR of guselkumab of 66.7% was estimated with a mean time of administration of 9.8 ± 4.1 months (median 9.0 [IQR 5.0] months)

[32], these data could further reinforce the idea of the efficacy of guselkumab in the heterogeneous clinical picture of patients with PsA. In parallel with the clinical response, we also reported a significant decrease of VAS pain and patient global assessment of the disease, suggesting drug effectiveness on such features.

In addition, we estimated a DRR of guselkumab of almost 67% in the cumulative 18 months of follow-up. Although further longer specifically designed studies are needed [33], a good drug persistence may be thus suggested in our "real-life" cohort similarly to data reported in the integrated assessment of IL-23 inhibitors in patients with PsA and/or psoriasis [34]. In addition, the DRR of guselkumab appeared to be not influenced by clinical features which may otherwise be associated with an impaired clinical response. Male sex did not influence the DRR of guselkumab, although possible sex-related differences in PsA are to be further assessed and clarified [35]. In addition, we stratified the results of the DRR of guselkumab according to the presence of comorbidities, considering any concomitant disorder. In our cohort, the presence of comorbidities did not influence the DRR of guselkumab. This may

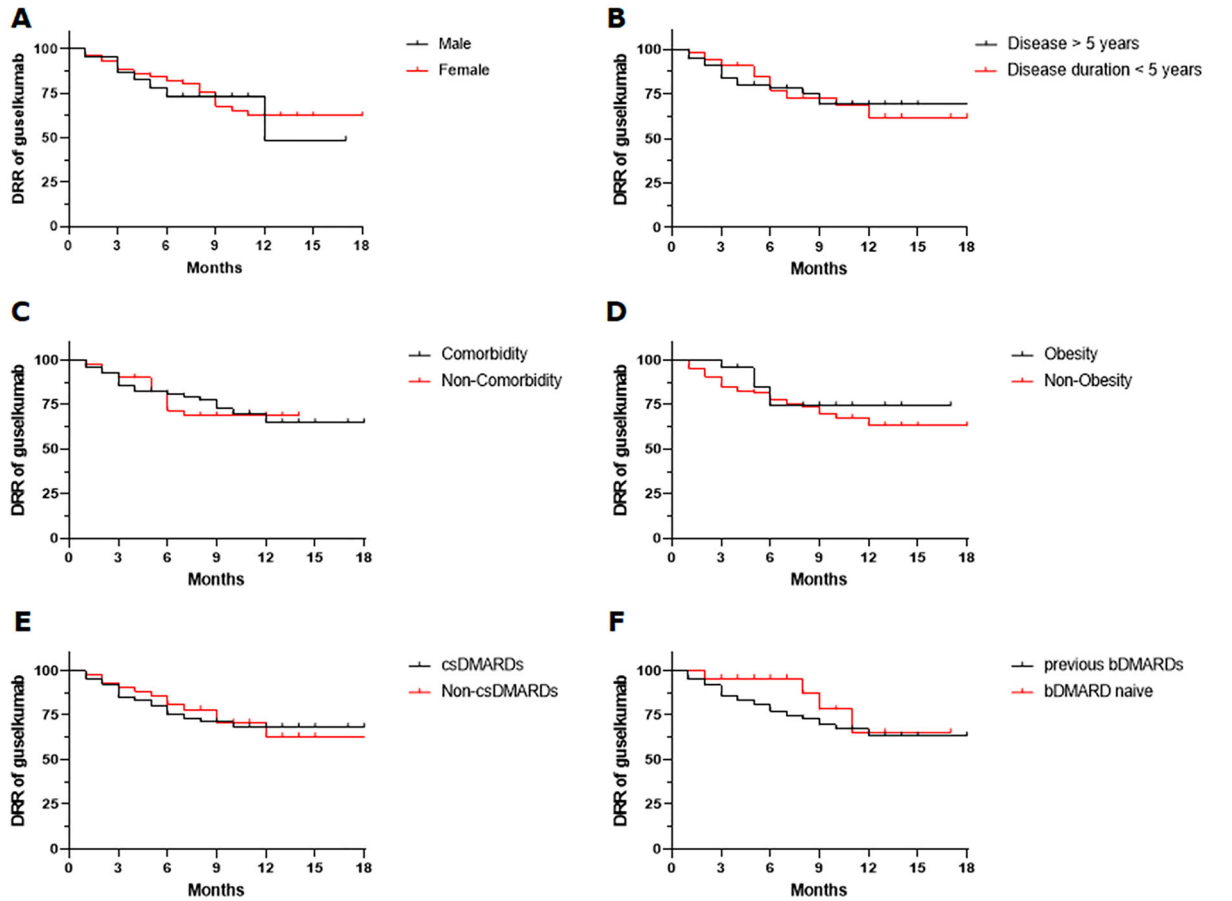

Fig. 4 Cumulative drug retention rate (DRR) of guselkumab according to patient characteristics. The DRR of guselkumab was not influenced by **a** male sex ($p = 0.941$), **b** disease duration $\geq$ 5 years ($p = 0.959$), **c** the presence of comorbidities, considering any concomitant disorder ($p = 0.824$), **d** obesity ($p = 0.444$), **e** concomitant conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) ($p = 0.854$), and **f** previous biologic DMARDs (bDMARDs) ($p = 0.293$)

be of importance since patients with PsA may have concomitant conditions making their management more difficult [36, 37]. In fact, patients with comorbidities may be at higher risk of complications and less responsive to therapy, in respect to those without comorbid conditions [38]. Moreover, we stratified the data about DRR of guselkumab on the basis of the presence of obesity. Patients with PsA characterised by a BMI higher than 30 did not show different results than others. The clinical relevance of this finding may be pointed out since patients with obesity may be less likely to achieve minimal disease activity, show a lower skin clearance rate, and be more likely to discontinue the administered therapies [39–41]. In our cohort, we also observed that previous bDMARDs and concomitant csDMARDs did not impact the DRR of guselkumab. These data may suggest the clinical usability independently of csDMARDs and different bDMARD lines as observed in randomised clinical trials [16–18]. Thus, these findings may support the effectiveness of guselkumab, which could be considered a suitable therapeutic option as monotherapy and in non-responders to previous bDMARDs. The latter could be also a feature of patients with a long disease, which did not appear to influence the DRR of guselkumab in our cohort of patients with PsA.

In regard to the safety, guselkumab was well tolerated by patients assessed in our cohort. We observed a low percentage of drug discontinuation due to adverse events which resolved without long-term consequences. No life-threatening side effects were observed. The assessment of safety did not reveal new signals other than those previously reported in an integrated analysis of randomised clinical studies [42].

Despite providing further insights into the "real-life" effectiveness of guselkumab in patients with PsA, our study has some limitations which could reduce the validity of the results. In fact, low internal validity, lack of quality control in data collection, and susceptibility to multiple sources of bias for collected variables may occur in these kinds of study, thereby impairing the generalizability of the derived results. All these confounding factors are not fully controlled in "real-life" studies. In addition, the relatively small sample size of assessed patients could suggest the need for larger cohorts to entirely confirm our findings. Taking together these observations, further reports are required to fully elucidate this topic according to a more tailored and personalised management of these patients with PsA [43, 44].

CONCLUSION

The 6-month effectiveness of guselkumab was shown in patients with PsA, mainly characterised by active long-standing disease, previously treated with bDMARDs, and with comorbidities, in a "real-life" cohort study. Furthermore, a good DRR of guselkumab was estimated in the cumulative 18 months of follow-up, which appeared to be not influenced by long disease duration, comorbidities, obesity, and previous bDMARDs. Although additional confirmatory studies with a long-follow-up are required, our findings may suggest the clinical usability of guselkumab in "real-life" patients with PsA.

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Declarations

Conflict of Interest. The authors (Piero Ruscitti, Giulia Cataldi, Martina Gentile, Alice Dionisi, Paola Volpe, Annacarla Finucci, Lucrezia Verardi, Claudia Di Muzio, Noemi Italiano,

Eleonora Celletti, Myriam Di Penta, Ilenia Di Cola, Alessandra Marrelli, Alessia Alfonsi, Francesco Delle Monache, Francesco Cipollone, Marco Gabini, Paola Cipriani) declare that they have no conflicts of interest for this work.

Ethical Approval. The local ethics committee (Comitato Etico Azienda Sanitaria Locale 1 Avezzano/Sulmona/L'Aquila, L'Aquila, Italy; protocol number 0204194/22) approved the study, which was performed according to the Good Clinical Practice guidelines and the Declaration of Helsinki. Informed consent was obtained from each patient for the use of clinical and laboratory data for study purposes. Consent for publication was not required as all patient data were de-identified.

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