Guselkumab Treatment Outcomes and Persistence in a Nationwide Real-world Cohort of Patients with Plaque Psoriasis

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Guselkumab treatment outcomes and persistence were assessed in a real-world cohort of Finnish patients with difficult-to-treat plaque psoriasis over a median follow-up of 1 year. Data on 181 patients who initiated guselkumab at the 15 study centres were collected retrospectively from the patient charts. Prior exposure to biologic therapies was common, with 56% and 35% having used at least 1 and 2 biologics, respectively. Median guselkumab treatment duration was 11 months with 21 patients (12%) discontinuing treatment during follow-up. Of 85 patients with a follow-up duration of at least 1 year, 73 (86%) were still on guselkumab at 1 year. Significant improvements during follow-up were seen in the absolute Psoriasis Area and Severity Index (PASI) scores with 32 patients (80%) having absolute PASI ≤2 after a 9–14-month treatment. Guselkumab treatment was effective and treatment persistence was high in the nationwide Finnish real-life setting.

Key words: psoriasis; guselkumab; treatment outcome; real-world; persistence.

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Guselkumab is a human monoclonal antibody that targets interleukin (IL)-23 and binds to its p19 subunit, thereby selectively inhibiting its intracellular and downstream signalling (1). Long-term data from the phase III, multicentre, randomized, double-blind, placebo-controlled clinical VOYAGE 1 trial (2) have confirmed sustained efficacy and safety of guselkumab in the treatment of moderate-to-severe plaque psoriasis (PsO) for up to 4 years. As more effective treatments for plaque psoriasis have become available, more stringent treatment goals, including the achievement of complete or nearly complete skin clearance, have been implemented in the treatment guidelines (3, 4).

SIGNIFICANCE

Only a limited number of real-world evidence studies analysing the efficacy and safety of selective anti-interleukin-23 therapy in patients with plaque psoriasis are available. This retrospective non-interventional chart review study of 181 patients shows that both naïve and bio-experienced Finnish patients benefitted from initiation of guselkumab treatment. After a median of 11 months treatment, the median absolute Psoriasis Area and Severity Index value was 1 and median body surface area value was 0. Guselkumab treatment was well tolerated and 86% of patients continued treatment over one year.

The generalizability of clinical trial findings to everyday clinical practice can sometimes be limited; the enforcement of strict patient eligibility criteria results in enrolment of patient populations that differ from those being treated in the real-world setting. Therefore, robust real-world effectiveness data are valuable for the overall assessment of the efficacy and use of new, often expensive, biologic therapies. For this purpose, a nationwide, multicentre, retrospective study was performed to evaluate the efficacy and persistence of guselkumab as a treatment for moderate-to-severe PsO in a Finnish real-word setting. Guselkumab has been available in Finland since November 2017 and reimbursed since June 2018 for the treatment of severe and difficult-to-treat PsO. Since November 2020 guselkumab has also been approved for the treatment of active psoriatic arthritis (PsA).

PATIENTS AND METHODS

Study design and outcomes

The FINGUS study was conducted in 15 Finnish treatment centres providing specialized care for patients with PsO. The retrospective chart review covered all the adult patients with a confirmed diagnosis of PsO who had initiated guselkumab therapy in the study centres at any time between 1 December 2017 and 1 December 2019.

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Table I. Patient and disease characteristics at guselkumab treatment initiation

Variable	All ($n = 181$)	Bio-experienced ($n = 102$)	Bio-naïve ($n = 79$)	p-value
Age, years, *n*, median interquartile range (IQR)	181, 52.2 (40.5–62.5)	102, 54.9 (42.4–62.7)	79, 50.6 (38.6–62.5)	0.258
Sex, *n* (%)				
Male	118 (64.8)	68 (66.7)	50 (63.3)	
Female	63 (35.2)	34 (33.3)	29 (36.7)	
Weight, kg, *n*, median (IQR)	126, 94 (80–116)	74, 94.5 (80–120)	52, 93.5 (78.5–112)	0.346
Body mass index, kg/m^2, *n*, median (IQR)	110, 30.3 (26–36.4)	62, 30.9 (26–37.9)	48, 29.3 (25.8–34)	0.177
Psoriatic arthritis, *n* (%)	39 (21.6)	28 (27.5)	11 (13.9)	0.028
Disease duration years, *n*, median (IQR)	181, 18.8 (11.9–29.8)	102, 22.8 (13.9–32.2)	79, 14.2 (7.3–25.5)	<0.001
Comorbidities, *n* (%)				
Psoriasis only	84 (46.4)	38 (37.3)	46 (58.2)	0.005
Metabolic syndrome	58 (32.0)	39 (38.2)	19 (24.1)	0.043
Diabetes	43 (23.8)	31 (30.4)	12 (15.2)	0.017
Depression	18 (9.9)	10 (9.8)	8 (10.1)	0.943
Disease activity, *n*, median (IQR)				
Body surface area	54, 7 (5–11)	27, 6 (3–10)	27, 9 (5–14)	0.038
Psoriasis Area and Severity Index	133, 7.0 (5.0–10.2)	73, 6.0 (4.7–9.0)	60, 8.0 (5.9–10.8)	0.004
Dermatology Life Quality Index	78, 14 (7–18)	25, 9 (3–16)	53, 15 (10–19)	0.018

The primary objectives of the study were to explore the persistence of guselkumab treatment and clinical outcomes at 9–14 months after treatment initiation in the Finnish real-world setting. The secondary objectives included the characterisation of patients who used guselkumab treatment for PsO during the study period, the assessment of guselkumab dosing patterns, and the reasons for treatment discontinuation, as well as the assessment of the clinical outcomes over short term, at 3–6 months, and longer term, at 15–18 months. Subgroup analyses for patients with and without prior biologic exposure were pre-planned.

The study did not seek to assess the safety of guselkumab. Due to the pharmacovigilance obligations of drug manufacturers, the investigators were nevertheless instructed to report directly to Janssen-Cilag Oy if they encountered notations related to adverse events that possibly, probably, or very likely were attributed to guselkumab while reviewing the patient charts within the scope of the information required by the protocol.

Study variables and data collection

Data were collected retrospectively from guselkumab treatment initiation until 31 March 2020. Collected baseline data could precede guselkumab treatment initiation and included age, sex, weight, height, smoking, psoriatic arthritis, comorbidities (diabetes, metabolic syndrome, mental health disorders), disease duration, and prior use of biologic and non-biologic systemic medications for the treatment of PsO.

The following information was collected at treatment initiation, and at 3–6, 9–14 and 15–18 months after initiation: concomitant systemic PsO medications, Psoriasis Area and Severity Index (PASI), body surface area (BSA) affected, Physician Global Assessment (PGA), and Dermatology Life Quality Index (DLQI). In addition, guselkumab treatment patterns (including dosage information and the reasons for treatment discontinuation) were collected from treatment initiation until the end of follow-up.

Ethical considerations

The study protocol was reviewed by the ethics committee of Tampere University Hospital (number R19132) and approved by the local register holders. The study was registered in the European Union electronic Register of Post-Authorisation Studies (EU PAS Register, EUPAS39376).

Statistical analysis

Data analyses were performed with Stata MP 14 statistical software (StataCorp 2015, Stata Statistical Software: Release 14. StataCorp LP, College Station, TX, USA). Descriptive outcomes were summarized as count data and percentage for categorical variables and as median and interquartile range (IQR) for continuous variables. Because only 19 patients (15 with continued guselkumab use) had follow-up data available at 15–18 months, results for that time-point are not presented.

Persistence of guselkumab treatment was assessed from the index date until guselkumab discontinuation or censoring. Censoring of patients occurred when the patient was either lost to follow-up or the study data collection period ended (i.e. 31 March 2020). Persistence of guselkumab treatment was depicted using the Kaplan–Meier estimator.

The significance of changes from baseline in outcome variables at each assessment time-point (3–6 months, 9–14 months) were tested with Pearson's χ^2 test for categorical variables and Wilcoxon matched-pairs signed-rank test for continuous variables. When comparing the outcomes in patients with and without prior biologic exposure, the significance of differences was tested with either Pearson's χ^2 test (categorical variables) or Wilcoxon rank-sum test (continuous variables). Differences in treatment persistence were tested using log-rank test for equality of survival functions. The results with a p-value below 0.05 were considered statistically significant.

Table II. Treatment history preceding guselkumab initiation ($n = 181$)

Treatment	*n* (%)
Phototherapy	158 (86.8)
Systemic therapies	
Methotrexate	173 (95.6)
Acitretin	127 (70.2)
Cyclosporine	58 (32.0)
Apremilast	18 (9.9)
Other	10 (5.5)
Biologic therapies	
Ustekinumab	59 (57.8)
Secukinumab	55 (53.9)
Adalimumab	50 (49.0)
Etanercept	34 (33.3)
Ixekizumab	19 (18.6)
Infliximab	10 (9.8)
Other	<5 (<4.9)
Number of prior biologics	
0	79 (43.7)
1	38 (21.0)
2	25 (13.8)
3	20 (11.1)
4	13 (7.2)
>5	6 (5.9)

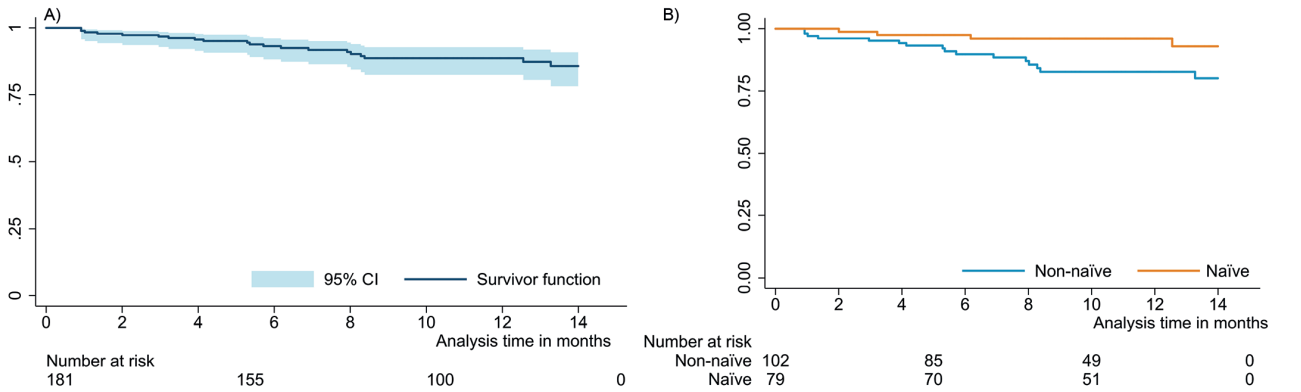

Fig. 1. Kaplan-Meier curve of guselkumab continuation in: (A) full patient population and (B) bio-naïve and bio-experienced patients (non-naïve), p=0.016. 95% CI: 95% confidence interval.

RESULTS

Baseline characteristics

Guselkumab treatment was initiated by 181 patients with PsO in the 15 study centres (**Table I**). At the time of initiation, the median age of patients was 52.2 years, and the median disease duration was 18.8 years. Approximately 65.2% of patients were male and 43.7% of patients had no prior exposure to biologic therapy (**Table II**). Patients, who have not previously used biologics (bio-naïve patients), had a significantly shorter disease duration (median 14 years vs 23 years, $p<0.001$), and lower prevalence of psoriatic arthritis (13.9% vs 27.5%; $p=0.028$) as well as comorbidities (i.e. diabetes and metabolic syndrome; $p<0.05$) than the patients who have previously used biologics (bio-exposed patients).

The psoriasis treatments preceding the start of guselkumab treatment are shown in Table II. Almost all patients (95.6%) had previously used methotrexate. The bio-exposed patients ($n=102$) had used 1–6 biologic therapies before guselkumab initiation with 62.7% of patients having used at least 2 prior therapies. The biologic agents most often preceding guselkumab treatment (with or without treatment break) were secukinumab (35.3%), ustekinumab (31.4%), ixekizumab (15.7%), and adalimumab (10.8%).

Follow-up times and persistence of guselkumab treatment

Guselkumab treatment was mostly initiated as monotherapy (85.1%) among the study patients, and the initiation was performed in line with the summary of product characteristics in 177 patients with 100 mg at weeks 0 and 4 followed by maintenance treatment. Guselkumab dose changes and short, temporary treatment breaks were infrequent during the maintenance treatment, both occurring in 4 patients.

The median follow-up time of the study population was 11.7 months (IQR 7.5–14.9). The median guselkumab treatment duration during the follow-up was 10.9 months (IQR 6.2–14.2) in the full study population, 9.6 months (IQR 5.7–14.2) in the bio-exposed group, and 11.7 months (IQR 7.5–13.7; $p=0.327$) in the bio-naïve group. Guselkumab treatment persistence over time is shown in **Fig. 1**. Significant differences in the survival curves of the bio-naïve and bio-exposed patients were observed ($p=0.016$).

Of 85 patients with a follow-up duration of at least 1 year, 73 (85.9%) were still on guselkumab at 1 year. The treatment was permanently discontinued in 21 patients (11.6%) either after induction ($n=5$) or during maintenance ($n=16$). Treatment discontinuations were more common among bio-exposed patients compared with bio-naïve patients (16.7% vs 5.1%; $p=0.016$). The most often reported reason for discontinuation was primary non-response (9 patients), followed by a patient's wish, tolerability, loss of response, non-adherence, or other reasons (fewer than 5 patients in each). Sixteen of 21 patients who discontinued guselkumab initiated either successive biologic therapy or apremilast.

Clinical outcomes

Clinical outcomes data were available for all 181 patients at baseline, 146 patients at 3–6 months, and 72 patients at 9–14 months, since not all patients had reached the

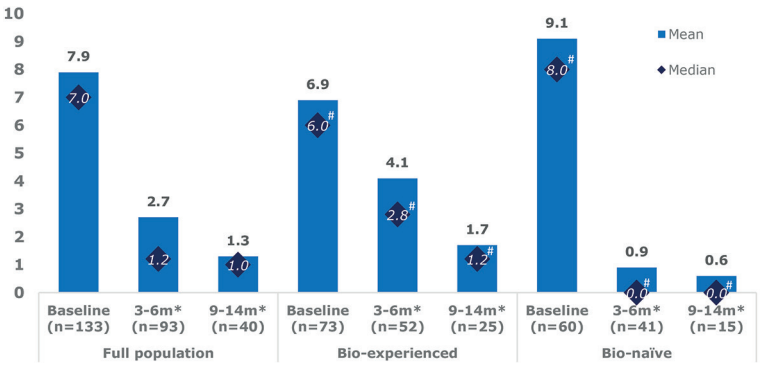

Fig. 2. Absolute Psoriasis Area and Severity Index (PASI) values during guselkumab treatment. *Statistically significant difference vs baseline; #Statistically significant difference between bio-experienced and bio-naïve subgroups.

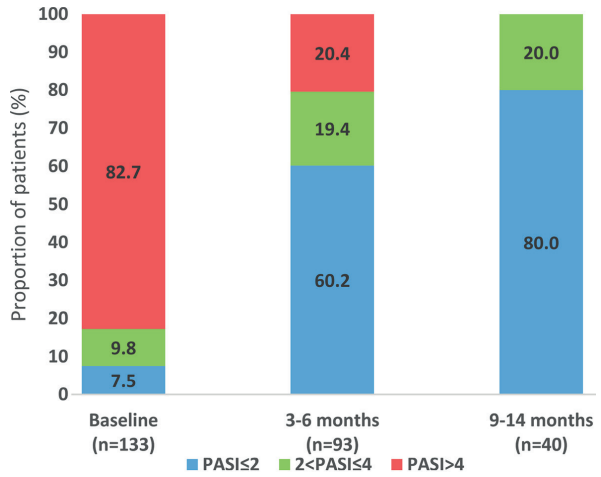

Fig. 3. Changes in Psoriatic Area and Severity Index (PASI) during guselkumab treatment over time.

subsequent time points. Mean of absolute PASI values at baseline and during follow-up are shown in **Fig. 2**. Since there was no wash-out period before the switch to guselkumab, the observed baseline PASI values (median; IQR) were quite low (7.0; 5.0–10.2; $n=133$). Nevertheless, significant reductions in absolute PASI values were observed at 3–6 months (1.2; 0.0–3.0; $p<0.001$; $n=93$) and at 9–14 months (1.0; 0.0–1.8; $p<0.001$; $n=40$). Likewise, the proportion of patients with PASI ≤2 increased from 7.5% at baseline to 80% at 9–14 months (**Fig. 3**). Significant improvements were also seen in BSA, DLQI and PGA (Fig. S1[1]). Psoriasis improvement was also remarkable among the bio-exposed patients, but slower than among the bio-naïve patients (Fig. S2[1]).

DISCUSSION

Guselkumab improved clinical patient outcomes of PsO patients in the Finnish real-world treatment setting, as assessed with PASI, BSA and DLQI scores. In addition, high persistence of guselkumab treatment was shown over the follow-up period.

Compared with patients enrolled in pivotal guselkumab clinical trials, the FINGUS study population was slightly older (median age 52.2 vs VOYAGE 1: mean 43.7 years) and had a more equal sex distribution (64.8% male vs 72.6%), a higher BMI (median 30.3 vs 28.4 kg/m^2), and a longer disease duration (median 18.8 vs 17.8 years mean). Prior use of phototherapy (86.8% vs 54.3%), conventional systemic therapies (99.4% vs 61.8%), and biologic therapies (56.4% vs 20.9%) were more common in the Finnish real-life patient population. Despite these differences in patient characteristics, similarities were nevertheless observed in clinical outcomes. For example, the proportion of patients achieving a DLQI score of 0/1 at 3–6 months in the current study was similar to that observed at 24 weeks in the combined analysis (5) of VOYAGE 1 and VOYAGE 2 trials (55.3% vs 58.9%). The findings observed for the proportion of patients achieving Investigator Global Assessment (IGA) scores of 0/1 at week 16 (VOYAGE 1 (6): 85.1%, VOYAGE 2 (7): 84.1%) and at week 48 (VOYAGE 1 (6): 80.5%) in VOYAGE trials were slightly higher, but in line with the PGA scores of 0/1 at 3–6 and 9–14 months (66.4% and 77.6%, respectively) in the current study.

In the current study population, the disease activity as measured with absolute PASI at baseline was low (median 7.0). This reflects the current Finnish treatment practices where patients switch treatment without any formal washout period for the preceding treatment(s). In this context, it was therefore not meaningful to assess the percentage improvement in PASI during guselkumab treatment. Instead, we assessed treatment effectiveness based on the absolute PASI values. Thus, the PASI outcome findings in the current study, with 80.0% of patients having PASI ≤2 at 9–14 months, were similar to those observed in the VOYAGE1 trial (6), where 76.3% of guselkumab-treated patients achieved a PASI 90 response after a 48-week treatment.

Only a few studies (8–11) on the effectiveness of guselkumab in real-life clinical practice have been published previously. All studies reported significant clinical improvements during guselkumab treatment in real-life treatment settings. Clinically significant clearance of psoriasis (BSA involvement of <1%) was observed in 73.3% of the patients treated in the Canadian community dermatology practice (8). Similarly, significant reductions in PASI score and high PASI response rates (PASI 75, PASI 90 and PASI 100 in 84.2–90.3%, 71.0–78.9%, and 51.6–63.2%) were observed during a 1-year follow-up among patients treated with guselkumab in Italy ($p<52$ (9)) and Spain ($n=87$ (10)).

Drug survival of guselkumab was 86% at 1 year in this study. A few other recent studies have also reported promising persistence data on guselkumab treatment in a real-world setting. In a German registry study, 88% of 303 patients continued guselkumab for at least 28 weeks (12), and in 2 other studies drug survival at 2 years was 90% ($n=398$) (13) and 92% ($n=43$) (14). Direct comparisons between these studies and the current study are not straightforward, due to different patient populations or outcomes of interest.

The current study had a nationwide coverage of municipal public healthcare treatment centres providing specialized care. The limitation of the study is a short follow-up time in some of the patients. Due to the high coverage of public health services in Finland, the majority of patients with PsO having received guselkumab treatment during the study period were included in this study. However, some Finnish patients also use the services of private service providers that complement the municipal, public services; these patients were not

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included in this study due to study permission-related challenges.

There are no tender mechanisms or binding guidelines that determine the order in which biologic therapies should be used. Instead, the Finnish dermatologists are free to choose the clinically most appropriate biologic therapy for their patients. Intravenous drugs are funded by the municipalities (from the hospital budget), whereas self-administered prescription drugs, including guselkumab, are funded by the Social Security Institution of Finland. Currently, biologic therapies for PsO are reimbursed for patients with severe and difficult-to-treat chronic PsO. Since guselkumab was the first IL-23-inhibitor on the market, it was most likely used in patients having failed other treatments. Despite this, the findings of this nationwide study support high treatment persistence and effectiveness of guselkumab for the treatment of PsO in the Finnish real-world setting.

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