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ORIGINAL RESEARCH

Effectiveness and Safety of Guselkumab for the Treatment of Psoriasis in Real-World Settings at 52 weeks: A Retrospective, Observational, Multicenter Study from China

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ABSTRACT

Background: Real-life studies evaluating the long-term efficacy of guselkumab in moderate-to-severe psoriasis in China are limited and not available.

Methods: In this real-life study, we retrospectively examined a total of 27 patients with moderate-to-severe psoriasis treated with guselkumab [100 mg, subcutaneous (s.c.)] with a follow-up period of at least 52 weeks in a real-life setting conducted at the Department of Dermatology, Xiangya Hospital, Central South University and Department of Psoriasis, Dalian Dermatosis Hospital. The primary endpoint of the study was long-term effectiveness [reduction of Psoriasis Area and Severity Index (PASI) score, improvement of Dermatology Life Quality Index (DLQI)], safety, and tolerability of guselkumab.

Results: Guselkumab treatment decreased the mean PASI score from 12.46 ± 6.34 at baseline to 4.03 ± 3.25 ($P < 0.001$) and 0.77 ± 1.25 ($P < 0.001$) at 12 and 52 weeks. At 12 weeks, PASI 75, 90, and 100 response was achieved in 44.4%, 18.5%, and 11.1% of patients, respectively. At 1 year, PASI 75, 90, and 100 response was achieved in 88%, 72%, and 48% of patients, respectively. At 52 weeks, 96% of patients achieved a PASI score of ≤ 3 and 80% of patients achieved DLQI (0/1). No patients withdrewed from the study due to primary or secondary ineffectiveness or failure to adhere to the medication. During the follow-up period, only two adverse events were reported (tinea capitis and diarrhea).

Conclusions: Our findings confirm that guselkumab is an appropriate therapeutic option in routine clinical practice, particularly when treating sophisticated patients with comorbidities or who failed to previous biologic therapy.

Keywords: Chinese; Guselkumab; Psoriasis; Real-life; Biologic treatment

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Key Summary Points

The evidence available to guide clinicians as to long-term efficacy of guselkumab in moderate-to-severe psoriasis in China is limited.

We make a considerable contribution to the evidence base as to the long-term effectiveness, safety, and tolerability of guselkumab in patients with moderate-to-severe psoriasis in China.

At 1 year, PASI 75, 90, and 100 response was achieved in 88%, 72%, and 48% of patients, respectively.

Guselkumab was a safe and well-tolerated treatment in a Chinese patient population, and also showed high efficacy in those patients in whom previous biologic agents failed.

INTRODUCTION

Psoriasis is an immune-mediated inflammatory disease leading to a substantial burden for individuals and society [1, 2]. In the past 15 years, breakthroughs in the knowledge of the pathogenesis of psoriasis have translated into many targeted and highly effective therapies, such as anti-TNF-α, anti-IL-23, and anti-IL-17 agents [3–6]. In spite of this, many patients still do not receive their treatment goals or experience treatment-related toxicities. Guselkumab is a fully human monoclonal antibody specifically targeting the p19 subunit of IL-23, which is a key driver of Th17 cell differentiation and survival and an upstream regulator of IL-17A and many pathogenic cells [7, 8]. Hence, guselkumab has a superiority of efficacy and brings convenient long intervals compared with both anti-TNF-a and anti-IL-17 agents.

Two phase-III trials (VOYAGE-1, VOYAGE-2) evaluated guselkumab superior efficacy and safety profiles compared with placebo and adalimumab [9, 10]. Furthermore, it was observed that difficult-to-treat areas, such as the palms and/or soles (VOYAGE-2) [10], and patients' inadequate response to ustekinumab also improved with guselkumab (NAVIGATE) [11]. Real-world studies were cited to demonstrate the actual efficacy of Gussekiu in the treatment of drug resistance and complications. [12, 13]. Even if there are many real studies on its efficacy and safety, long-term data are still limited, particularly in the Asian population [14].

This is the first study evaluating the use of guselkumab in a real-life setting with a follow-up period of 52 weeks to investigate the effectiveness, safety, and tolerability of guselkumab in adult patients with moderate-to-severe psoriasis in China.

METHODS

In this retrospective study, the patients included were adults (≥ 18 years) with a diagnosis of moderate-to-severe plaque psoriasis who had been treated with guselkumab between December 2019 and June 2022 in the Department of Dermatology, Xiangya Hospital, Central South University and Department of Psoriasis, Dalian Dermatosis Hospital. Patients included those with multiple comorbidities, hard-to-treat body parts, and ineffectiveness of previous biologics. Furthermore, we divided patients into two groups by whether they had received biology treatments; biology naïve and prior biology treatment (PBT).

All the patients were treated with the standard dose of guselkumab monotherapy (100 mg administered by subcutaneous injection at week 0 and week 4, followed by a maintenance dose every 8 weeks). Sex, height, weight, age, body mass index (BMI), psoriasis durations, comorbidities, and previous treatments of every patient were recorded at baseline using a dedicated database. Psoriasis severity was described using the Psoriasis Area and Severity Index (PASI) and patients' psychological suffering from psoriasis was described using the Dermatology Life Quality Index (DLQI). Each patient

came to the hospital for follow-up at the following time points: 4, 12, 20, 28, 36, 44, and 52 weeks. Written informed consent for participation in this study was obtained from all patients. The study followed the Declaration of Helsinki and was approved by the institutional research ethics boards of Xiangya Hospital.

Clinical effectiveness was primarily measured using PASI 75, PASI 90, and PASI 100 responses. Secondary effectiveness measurements included absolute PASI and DLQI change from baseline, in weeks. During our follow-up period, we assessed the safety and tolerability of guselkumab, including the presence of any adverse events (AEs).

Data were presented as mean ± standard deviation (continuous variables) or as number and proportion of patients (categorical variables). Statistical analysis using GraphPad Prism 4.0 (GraphPad Software Inc., La Jolla, CA, USA) was carried out in order to assess the statistical significance of clinical response. Paired samples student's *t*-test was used to evaluate the statistical significance of the differences in values obtained at the different timepoints of therapy for continuous ones. P values < 0.05 were considered to be statistically significant.

RESULTS

In this real-life retrospective analysis, 25 patients with moderate-to-severe plaque psoriasis were treated with guselkumab and followed over a period of 12 months, and 27 regularly followed up to 12 weeks. During the observation period, all patients were on regular medication and there was no discontinuation or combination of medications. Baseline characteristics of patients are presented in Table 1. The majority of patients were male (77.8%) with a mean age of 46.44 ± 12.68 and a long history of psoriasis (mean disease duration of 14.07 ± 11.97 years). Most patients were previously treated with traditional systemic medications ($n = 24$, 88.9%). A total of 17 patients (62.9%) were naïve to biologic therapies, and 10 (37.1%) had at least one biologic drug fail. Moreover, dyslipidemia was the most frequent comorbidity observed ($n = 13$, 48.1%).

Table 1 Demographic and baseline characteristics

Clinical characteristic	$N = 27$
Male, *n* (%)	21 (77.8%)
Age (years), Mean ± SD	46.44 ± 12.68
BMI, (kg/m^2)	25.23 ± 4.02
Current cigarette smoker, *n* (%)	14 (52%)
Disease duration (years)	14.07 ± 11.97
PASI at baseline	12.46 ± 6.34
DLQI at baseline	11.54 ± 5.97
Prior treatment	
Traditional systemic medications, *n* (%)	24 (88.9%)
Biologics agents	10 (37.1%)
TNF-α inhibitor exposure	7 (25.9%)
IL-17 inhibitor exposure	3 (11.1%)
Biologic naive	17 (62.9%)
Comorbidities, *n* (%)	
Hypertension	6 (22.2%)
Dyslipidemia	13 (48.1%)
Diabetes mellitus	4 (14.8%)
Coronary heart disease	2 (7.4%)

Data presented as mean ± standard deviation or number and %

PASI Psoriasis Area and Severity Index, *DLQI* Dermatology Life Quality Index, *BMI* body mass index

Guselkumab treatment decreased the mean PASI score from 12.46 ± 6.34 at baseline to 4.03 ± 3.25 at 12 weeks ($P < 0.001$) and 0.77 ± 1.25 at 52 weeks ($P < 0.001$) (Fig. 1A and Table 2). At 12 weeks, PASI 75, 90, and 100 response was achieved in 44.4%, 18.5%, and 11.1% of patients, respectively, whereas at 28 weeks, PASI 75, 90, and 100 response was achieved in 80%, 68%, and 52% of patients, respectively. At 52 weeks, PASI 75, 90, and 100 response was achieved in 88%, 72%, and 48% of patients, respectively (Fig. 1B). Furthermore, 80% of patients achieved a PASI score of ≤ 3 at 28 weeks and 96% of patients achieved a PASI score of ≤ 3 at 52 weeks (Fig. 1C). Additionally,

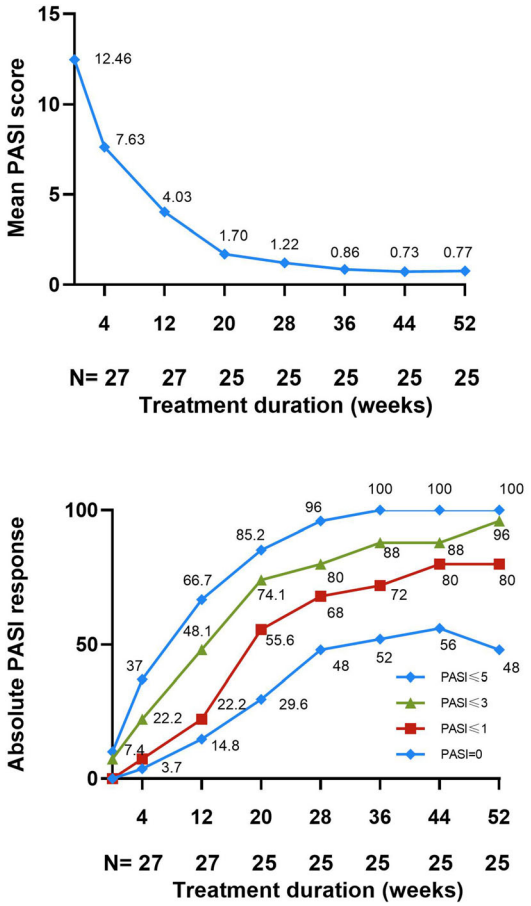
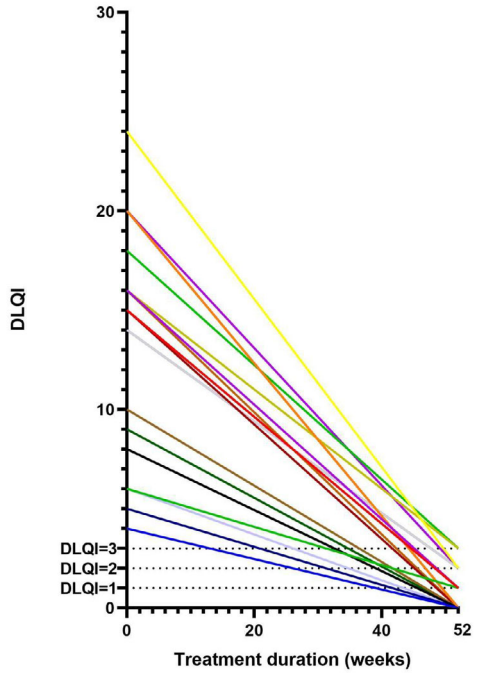


Fig. 1 Effect of guselkumab in patients with psoriasis for 52 weeks. **A** PASI is presented as mean values. **B** Percentage of patients who achieved PASI 75, PASI 90, and PASI 100. **C** Percentage of patients who achieved absolute PASI ≤ 5, ≤ 3, ≤ 1 was 0

Table 2 Outcomes at weeks 0, 12, 28, 52

Outcomes	Week 0	Week 12	Week 28	Week 52
PASI score, mean ± SD	12.46 ± 6.34	4.03 ± 3.25	1.22 ± 1.91	0.77 ± 1.26
PASI ≤ 1, *n* (%)	0	4 (14.8%)	12 (48%)	12 (48%)
DLQI score, mean ± SD	11.54 ± 5.97	–	–	0.72 ± 1.02
DLQI 0/1, *n* (%)	0	–	–	20 (80%)

PASI Psoriasis Area and Severity Index, *DLQI* Dermatology Life Quality Index



Each different colored line segment represents the DLQI change for different patients (n=25).

Fig. 2 The changes in DLQI of 25 patients treated with guselkumab at 52 weeks

80% of patients achieved a PASI score of ≤ 1. Regarding patients' psychological suffering from psoriasis, the mean DLQI score decreased from 11.54 ± 5.97 at baseline to 0.72 ± 1.02 at week 52 ($P < 0.001$), and 80% of patients achieved DLQI (0/1) (Fig. 2 and Table 2). No patients were lost due to primary or secondary inefficacy. Furthermore, six patients continued to take the medication and had stable lesion control (PASI 0) for the longest follow-up period of 2 years.

Over the 52 weeks of follow-up, we identified biologic naïve patients as having a relatively quicker onset of effect. Biologic naïve patients showed PASI 75, 90, and 100 response at week 12 to be 50%, 27.78%, and 11.1%, respectively (Fig. 3A–C). In groups of PBT, PASI 75, 90, and 100 response was achieved in 33.33%, 0%, and 0% of patients, respectively. However, the response rates of both groups were close at week 52.

Safety results are based on the evaluation of data from all patients at week 52. No patients withdrew from the study due to AEs. Between weeks 12 and 20, two slight adverse events occurred in two patients, respectively (tinea capitis in one patient and diarrhea in another patient) (Table 3).

DISCUSSION

Guselkumab is a novel biologic drug approved for moderate-to-severe psoriasis that binds to the p19 subunit of IL-23 with high affinity and specificity. However, there are limited data on the long-term efficacy of guselkumab in Chinese patients with psoriasis [14]. Our results showed that guselkumab had a progressive improvement in PASI 75, PASI 90, and PASI 100 responses over 52 weeks in Chinese patients with psoriasis. It was equally effective in patients with multiple comorbidities or failure of previous biologic agents or with hard-to-treat body parts (scalp, nails, and hands/feet).

Two phase III clinical trials (VOYAGE 1, VOYAGE 2) had already proven the superior efficacy of guselkumab in moderate-to-severe

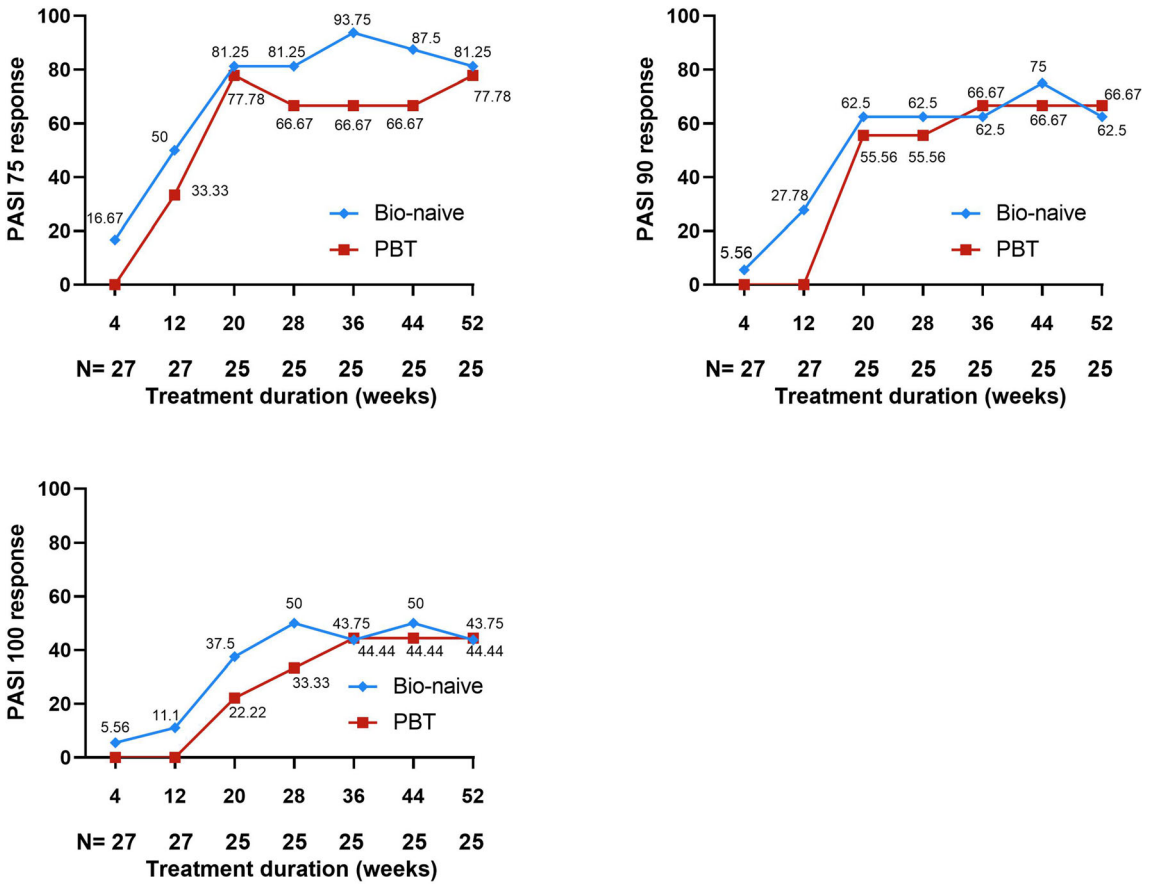


Fig. 3 Effect of guselkumab in subgroups of psoriatic patients on achievement of PASI 75, 90, and 100 response at 52 weeks (**A**–**C**)

Table 3 Reported adverse events during the treatment with risankizumab in our cohort

Adverse event (AE)	*N* (% on total population)
Tinea capitis	1 (3.7%)
Diarrhea	1 (3.7%)
Total	2 (7.4%)
Severe AEs	0 (0%)
AEs leading to discontinuation	0 (0%)

psoriasis compared with placebo and adalimumab [2, 4]. Our results confirm the positive findings of these clinical trials. Although we did not test the results at week 16, we can roughly compare them with the results at week 20. In VOYAGE-1, week 16 response rates for PASI 75, PASI 90, and PASI 100 were higher than our study (91.2% versus 76%, 73.3% versus 56%, 37.4% versus 36%). The deviation may be due to patients in our study with a lower mean PASI (12.46 ± 6.34 versus 22.1 ± 9.49). Moreover, at week 20, 74.1% of patients achieved PASI ≤ 3. Regarding PASI 100 response, 44.4% of patients in VOYAGE 1 achieved PASI 100 at week 24, remaining relatively unchanged up to 44 weeks (47.4%). PASI 100 response values at 44 weeks obtained from our real-life analysis were higher with respect to the VOYAGE results (56.0% versus 47.4%). Furthermore, in VOYAGE 1, PASI 75 and PASI 90 were 76.3% and 87.8%, respectively, at 48 weeks. Similar outcomes were obtained in our study, where 88% of patients

achieved PASI 75 and 80% of patients achieved PASI 90, at 44 weeks.

Our findings are also consistent with other real-life guselkumab studies [12, 15–19]. For example, an Italian study that had a mean ± SD baseline PASI score of 15.1 ± 6.1 showed that PASI 75, 90, and 100 were achieved by 95.6%, 73.9%, and 43.5% of patients at 44 weeks, respectively [15]. Likewise, our study achieved PASI 75, 90, and 100 in 88%, 72%, and 48% of patients at 52 weeks, respectively. Moreover, in another real-life study, 100% of patients had a PASI ≤ 3 at 48 weeks [16]. Our study showed that 96% of patients achieved a PASI ≤ 3 and 80% of patients achieved a PASI score of ≤ 1 at 52 weeks. What needs to be explained here is that residual dotted pattern lesions are mostly on the pretibial area, which is localization of treatment-resistant areas in patients with psoriasis on biologics [19]. In general, we observed that 80% of all patients achieved DLQI (0/1) at week 52, which usually indicates complete clearance of skin lesions.

Compared with the previous real-life study in China [14], the rates of PASI 90 achievement at week 12 was lower (86.4% versus 18.5%). These differences may be attributable to variations in baseline characteristics. In our study, patients were much older (46.44 ± 12.68 years versus 40.4 ± 14.71 years), and had a higher rate of exposure to biologic agents (37.0% versus 15.6%). Also, our patients have more comorbidities. Similarly, an Italian study revealed that number of comorbidities and PBTs were associated with an improved PASI 90 response at week 12 [20]. This may explain why we are slower in the rapid onset phase compared with the former study in China. In a subgroup analysis, PBTs showed a decreased trend of achieving a PASI 90 or greater response. However, it was also mentioned earlier that the long-term response rates were similar to clinical studies and real-event studies. Therefore, it is worth mentioning that our findings also showed that guselkumab was also effective in patients who had other biologics fail, especially in terms of long-term efficacy.

The last point is safety. Our results are similar to another study from China. The incidence of adverse events was low; mainly some common adverse reactions. In our study, registered AEs were tinea capitis in one patient and diarrhea in another patient. No patients dropped out of this study due to severe AEs, and we did not observe adverse events associated with clinical laboratory testing and vital signs.

The major limitation of this study was the relatively limited follow-up time (52 weeks) and a small number of participants, although the duration of our study was longer than existing real-life studies in China. Since guselkumab has been approved in China for a relatively short period of time, the possibility of a longer treatment period is limited. In addition, the incidence of adverse reactions is low and there may be a possibility of underreporting. It is also possible that rare adverse reactions were not observed at this time because of the limited number of people we observed. There is no doubt that there is a need to increase the number of patients and prospective studies to confirm the efficacy and safety of guselkumab in the field of psoriasis treatment with greater statistical validity.

CONCLUSIONS

In conclusion, our experience showed that guselkumab was a safe and well-tolerated treatment in a Chinese patient population. In addition to significantly improvement in PASI, a higher proportion of patients achieved improvement in lesion clearance and quality of life, and had higher drug retention rates. Furthermore, in a patient stratification analysis, guselkumab also showed high efficacy in those patients in whom previous biologic agents failed.

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Author Contributions. CL and YK conceptualized the study. JY and MT designed and acquired the data. JY wrote the manuscript. JC guided the design of study and revised the manuscript. KH and JY carried out the data analysis. MZ and JC provided help in collecting literature. All authors have read and agreed to the published version of the manuscript.

Disclosures. The authors have no conflict of interest to declare.

Compliance with Ethics Guidelines. This study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Ethics Committee of Xiangya Hospital, Central South University (Changsha, China)(Registration number:2018121106). All patients received guselkumab as in good clinical practice, in accordance with Chinese guidelines. All included patients had provided written consent for retrospective study of data collected during routine clinical practice (demographics, clinical scores). Written informed consent to participate in this study was provided by the participants.

Data availability. The datasets generated during and analyzed during the current study are available from the corresponding author on reasonable request.

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