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ORIGINAL RESEARCH

Guselkumab In A Subset Of Multifailure Patients With Hidradenitis Suppurativa: Real-Word Evidence from Federico II

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Introduction: Hidradenitis suppurativa (HS) is a chronic, debilitating inflammatory skin disorder characterized by painful nodules and abscesses, leading to substantial impairment in quality of life. Treatment remains challenging, particularly for patients with prior treatment failure or contraindications to anti-TNFα and anti-IL-17 therapies.

Methods: This prospective, real-life study assessed the efficacy and safety of guselkumab, an anti-IL-23 monoclonal antibody, in 10 adult patients with moderate-to-severe HS who had previously failed or were contraindicated for anti-TNFα and/or anti-IL-17 therapy. Guselkumab was administered using the psoriasis-approved dosing regimen. Patients were evaluated at baseline (week 0), week 16, week 32 and week 48 using the International Hidradenitis Suppurativa Severity Score System (IHS4), Dermatology Life Quality Index (DLQI), and visual analog scale (VAS) for pain. The primary endpoint was achievement of Hidradenitis Suppurativa Clinical Response (HiSCR) at week 16.

Results: At week 16, 40% of patients achieved HiSCR, increasing to 50% by week 48. Mean IHS4 scores decreased from 14.3 at baseline to 9.3 at week 16. This was accompanied by an average 10-point reduction in DLQI and a 4-point reduction in VAS pain scores. Despite these improvements, overall quality of life remained moderately impaired. One patient discontinued guselkumab due to loss of efficacy.

Discussion: The results support previous findings from smaller studies and case reports, indicating that guselkumab may offer clinical benefit in select HS populations, particularly those with comorbid psoriasis or Crohn's disease. Although limited by a small sample size, this study contributes to the growing real-world evidence supporting guselkumab as a potential treatment option in multi-refractory HS. Larger, placebo-controlled trials are needed to further define its role in treatment algorithms.

Keywords: hidradenitis suppurativa, guselkumab, secukinumab, adalimumab, treatments

Introduction

Hidradenitis suppurativa (HS) is a chronic inflammatory skin disorder characterized by painful lesions, including deep nodules, abscesses, skin tunnels, and fibrotic scars.[1] These lesions typically develop in intertriginous regions such as the axillae, groin, perianal, perineal, and inframammary areas.[1] Beyond physical discomfort, the condition significantly impacts patients' quality of life, as pain, drainage, malodor, and scarring can lead to severe psychosocial distress.[2] While the exact pathogenic mechanism of HS is not fully understood, it is believed that follicular hyperkeratosis within the skin-bearing terminal of hair folliclesserves as the primary initiating factor.[1,3] Recent studies have provided new insights into the role of pro-inflammatory cytokines in HS pathogenesis, particularly highlighting the involvement of tumor necrosis factor-α (TNF-α), interleukin (IL)-17 and −23 in disease progression.[4] The treatment of HS has always been challenging for dermatologists.[4] Adalimumab, an anti-TNF-α agent, was the first biologic drug approved by the FDA for

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HS in 2015, showing a clinical success rate of approximately 60% in real-life studies.[5] However, primary or secondary loss of response remains an important issue. Other biologics recently approved for HS include secukinumab (anti-IL17A) and bimekizumab (anti-IL17A and F). Guselkumab, a fully human monoclonal antibody targeting IL-23, is currently approved for moderate-to-severe plaque psoriasis and psoriatic arthritis.[6] Emerging evidences suggest that guselkumab may offer clinical benefit for HS, demonstrating improvements in disease signs and symptoms with a favorable safety profile.[7] Given the limited treatment options for HS and the variability in patient response, there is a growing need to identify novel therapeutic targets and establish a standardized treatment algorithm. Among emerging therapies, IL-23 inhibitors like guselkumab may represent a promising advancement in the management of a sub-group of HS subjects such as those with failure or contraindication to anti-TNF and/or anti-IL17.

Materials and Methods

This real-life, prospective observational study included adult patients with moderate-to-severe hidradenitis suppurativa (HS) who were treated with guselkumab. Inclusion criteria were: i) age ≥18 years; ii) Hurley stage II or III disease present for at least 6 months; iii) treatment with guselkumab; iv) previous treatment failure or contraindications to anti-TNFα and/or anti-IL-17 therapies. Exclusion criteria included: i) active or latent tuberculosis infection; ii) known immunodeficiency or ongoing immunosuppressive therapy (excluding permitted HS treatments); iii) current or recent malignancy; iv) pregnancy or breastfeeding; v) participation in another clinical trial; vi) inability to provide informed consent or comply with study procedures.

At baseline, the following data were collected: demographic characteristics (age, sex, BMI, smoking status), clinical and disease-specific features (disease duration, Hurley stage, number and location of affected areas), comorbidities (including psoriasis and Crohn's disease), and prior treatments with biologic agents (type, duration, and reason for discontinuation).

Guselkumab was administered according to the regimen approved for plaque psoriasis: 100 mg subcutaneously at weeks 0 and 4, followed by 100 mg every 8 weeks thereafter. Disease severity and treatment outcomes were assessed at baseline and at weeks 16, 32, and 48 using the International Hidradenitis Suppurativa Severity Score System (IHS4), the Dermatology Life Quality Index (DLQI), and the Visual Analog Scale (VAS) for pain. The primary endpoint was the achievement of Hidradenitis Suppurativa Clinical Response (HiSCR) at week 16. Secondary endpoints included changes in IHS4, DLQI, and VAS scores throughout the study period up to week 48.

All patients provided written informed consent prior to treatment initiation. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki.

Statistical Analysis

The collected data were processed using Graph-Pad Prism software (GraphPad Inc., La Jolla, CA, USA). Parameters were calculated for each variable (number of days of therapy performed, IHS4, VAS, DLQI) using mean ± standard deviation. Paired *t*-test was used to compare data collected before starting Guselkumab and after 48 weeks of therapy. In addition, paired *t*-test was used to compare the same variables (data collected at the beginning of Guselkumab treatment with data collected after week 48 within the original sample. P-value <0.05 with a 95% confidence interval was considered statistically significant in all analyses performed.

Results

The cohort analyzed consisted of 10 patients, including 6 males and 4 females with a mean age of 31 years. Particularly, in 50% of the patients, the average age was between 18 and 30 years, 3 patients (30%) were between 31 and 42 years old, and 2 patients (20%) belonged to the 42–65 age group. During the observation period only one patient (10%) discontinued therapy before the end of 48 weeks due to secondary ineffectiveness. One patient (10%) discontinued guselkumab treatment before the 48-week endpoint due to secondary inefficacy. Initially, this patient showed minimal clinical improvement during the first 12 weeks, failing to reach HiSCR at week 16. Despite continuing therapy, the patient reported persistent inflammatory nodules and abscesses with no significant reduction in lesion count or pain. Given the absence of objective or subjective clinical benefit and the progressive worsening of symptoms between weeks 16 and 24, treatment was discontinued in agreement with the patient. The mean duration of HS was 8 years, and all

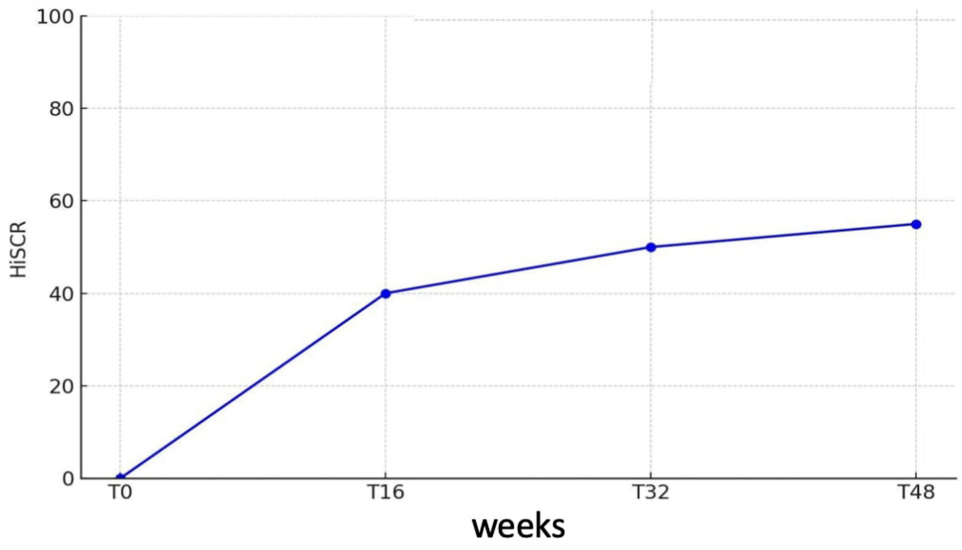

Figure 1 Mean HiSCR on 10 patients.

patients had been affected for at least 4 years. The entire cohort had previously been prescribed at least one line of antibiotic treatment for 12 weeks, such as rifampin and clindamycin or tetracyclines. Regarding biologics, 60% of patients had previously failed adalimumab, while only 1 patient (10%) had contraindication to adalimumab and failed secukinumab. Adalimumab paradoxical psoriasis had previously occurred in 2 of these patients. The remaining 30% of patients were bio-naïve but with contraindication to both adalimumab and secukinumab (heart failure, personal or family history of inflammatory bowel disease, concurrent atopic dermatitis). Eight out of ten patients (80%) had concomitant psoriasis, which was well-controlled at the time of observation. In these cases, guselkumab was prescribed according to its approved indications. All patients had moderate-to-severe HS with mean IHS4 at baseline of 14.3. As expected, the condition negatively affected their quality of life, as attested by the mean DLQI of 27.8. The disease burden is also evidenced by the average VAS score calculated at baseline of 9.1. At week 16, the primary endpoint HiSCR was achieved at week 16 by 40% (4/10) of patients, while at week 48 it was achieved by 50% (5/10) of the cohort (Figure 1). Regarding the other severity scores, the mean IHS4 at week 16 decreased to 9.3 ($p<0.0001$), and in all patients this score was reduced by at least 4 points. In one patient in particular, a reduction in IHS4 score of 7 points was observed (Figure 2). Similarly, a decrease in mean DLQI at week 16 of 10 points ($p<0.0001$) was found (Figure 3), while mean VAS was reduced by 4 points ($p<0.0001$), about 50% of the value at T0 (Figure 4). These values, however, remain quite high, testifying to the strongly negative impact of this pathology on patients' quality of life, despite a distinct clinical improvement. In conclusion, 60% of patients did not achieve HiSCR at week 16, the primary endpoint of the study. However, as evidence of clinical improvements with guselkumab, a 5-point reduction in mean IHS4 was observed over the same period, in addition to the DLQI and VAS scores described earlier. Moreover, these results continued to improve at week 48, with HiSCR being achieved in 50% of patients. (Figure 1). Table 1 summarizes the results described. No patients reported adverse events.

Discussion

Treatment of HS is challenging because of its chronic-recurrent nature and the high variability in outcomes of available therapies.[8] Currently, in addition to conventional treatments, three biologic drugs are approved against HS. The first is the anti-TNF adalimumab,[9] followed by the IL-17 inhibitors secukinumab and more recently bimekizumab.[10] As regards off-label treatments among the anti-IL-23 class, guselkumab presents the highest number of reports.[11] Kimball et al in a Phase 2 study observed achievement of HiSCR at week 16 in 50.8% of patients treated with guselkumab, greater than 38.7% in the placebo group, however without reaching statistically significance. No clear differences were reported at week 40.[12] Another phase 2 study by Dudink et al observed that of 20 patients with HS treated with guselkumab, at week 16, 65% of patients were

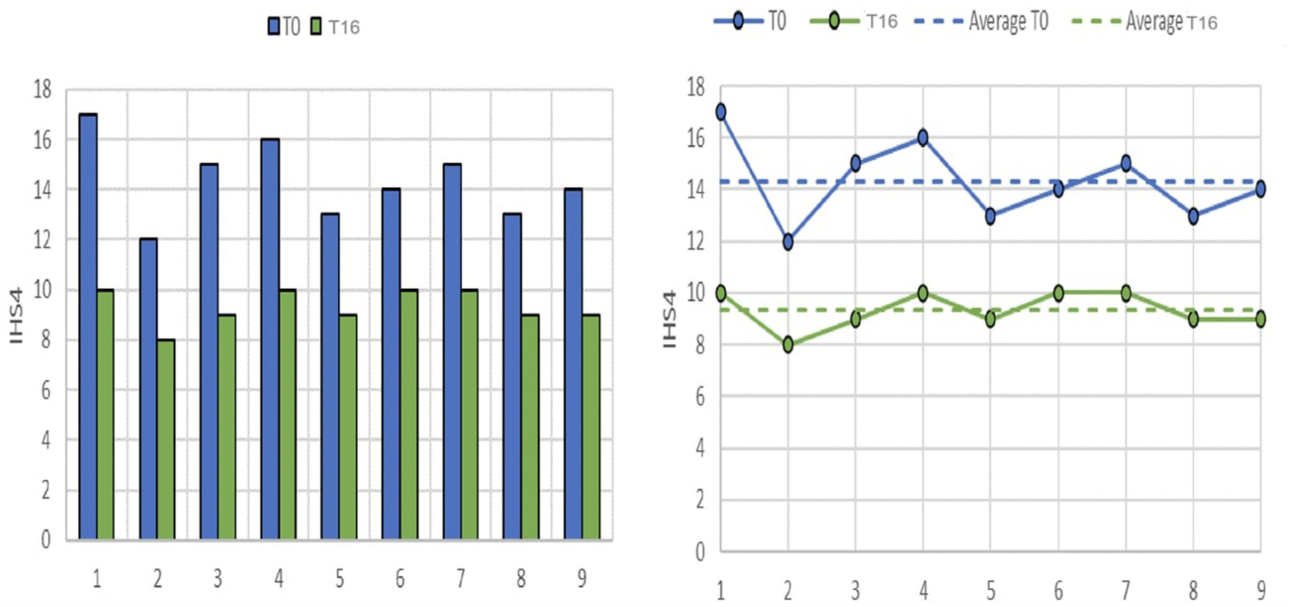

Figure 2 Data regarding IHS4 from week 0 to week 48.

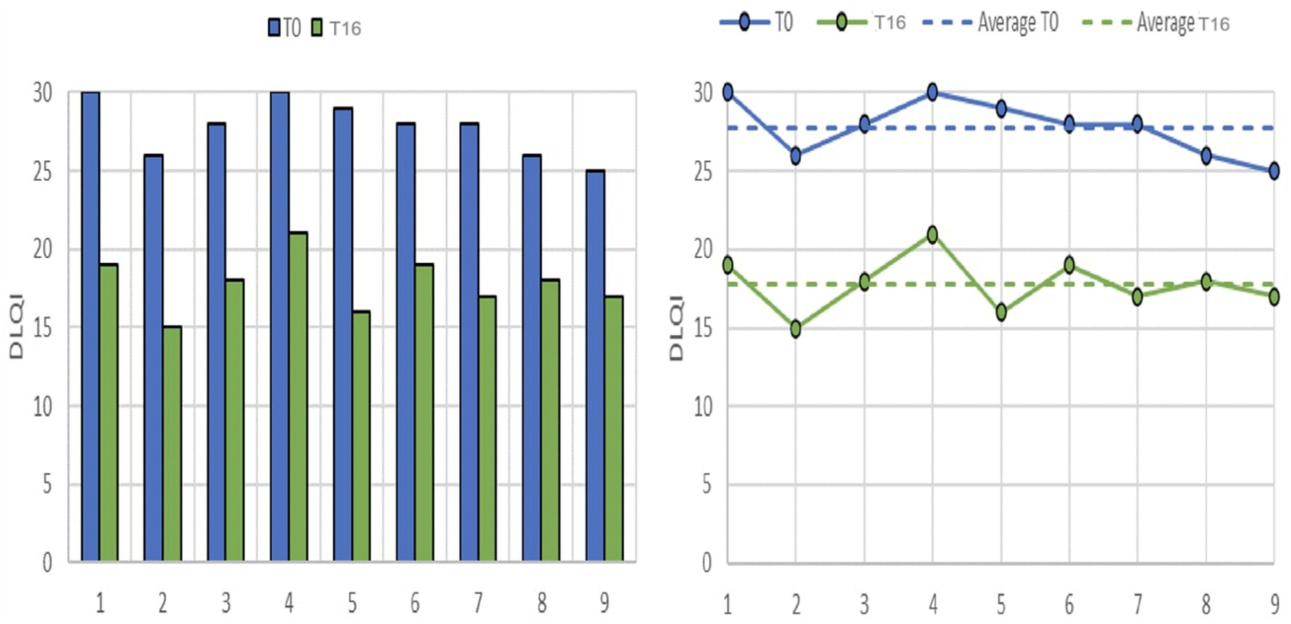

Figure 3 Data regarding DLQI from week 0 to week 48.

achieving HiSCR and there was a statistically significant reduction in mean IHS4 score and mean abscess and inflammatory nodule (AN) count. However, the study was limited by the small number of patients and the lack of a placebo group.[13] A multicenter retrospective Spanish study of 69 patients mostly with severe and long-standing HS showed that HiSCR was achieved in 58.3% of patients at week 16. In addition, a statistically significant reduction in various scores, including IHS4 and DLQI, also evaluated in the present study, was observed at week 48.[14] However, the authors also point out that 23.2% of patients discontinued guselkumab due to ineffectiveness or loss of efficacy.[14] Huang et al conducted a systematic review and meta-analysis of 16 randomized clinical trials (RCTs) with a total of 2076 patients with moderate-to-severe HS and 9 biologics. The meta-analysis revealed that only adalimumab and bimekizumab achieved statistically significant improvements on HiSCR and only adalimumab on DLQI.[15] For this aspect, guselkumab and bimekizumab also showed similar results superior to placebo.[15]

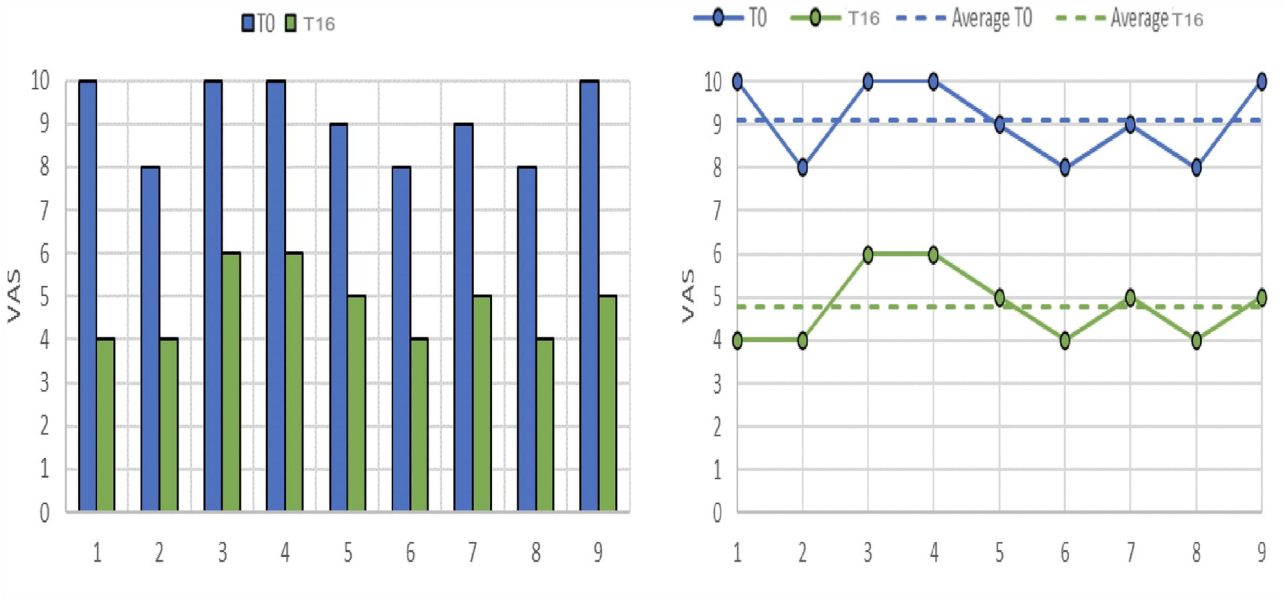

Figure 4 Data regarding VAS pain score from week 0 to week 48.

There are also several case series and case reports on the use of guselkumab for HS. Kovacs et al described 3 patients who had failed adalimumab or for whom it was contraindicated. Guselkumab reduced mean IHS4 from 21.3 to 9.3 at week 12 and improved VAS and DLQI scores, similarly to our study.[7,11] Montero-Vilchez et al treated 4 patients with guselkumab and observed a moderate reduction in IHS4, DLQI and VAS score in 2 cases. In no patient, however, HS-PGA improved, and in one patient HS severity worsened.[16] Casseres et al observed improvements in 5 of 8 patients (63%) after 4 months of guselkumab,[17] while Kearney et al reported the case of a 28-year-old girl who achieved resolution of active inflammatory lesions and significant improvement in pain in 12 months of therapy, with results maintained even at 24 months.[18,19] Some case reports have shown the efficacy of guselkumab for the treatment of conditions concomitant with HS.[20] Garcia-Melendo et al reported the case of a 26-year-old girl who developed a paradoxical psoriasiform reaction after 5 months of treatment with adalimumab for HS. The patient then switched to guselkumab with improvement in manifestations after the first injection. After 10 months, the patient had no inflammatory lesions of HS and the psoriasis had resolved.[21] Guselkumab has also been used in the treatment of concomitant HS and Crohn's disease (CD). Jørgensen et al described the case of a 25-year-old man with both conditions and multiple failures of conventional and biologic therapies. Therefore, he began therapy with guselkumab, with improvement in subjective symptoms of HS and CD, DLQI and VAS score after 7 months.[22] Other similar cases have been published for the efficacy achieved by guselkumab on both conditions.[23–25] Finally, Gargiulo et al published the results of a multicenter retrospective analysis on the use of anti-IL-17 and anti-IL-23 for the treatment of concomitant psoriasis and HS.[26] The authors highlighted the efficacy of these drugs on these conditions, although they pointed out the limited sample size that did not allow evaluation of the single-molecule efficacy profile. They conclude that one possible reason for the efficacy of these drugs on HS is the possible simultaneous overexpression of IL-17 and IL-23 typical of psoriasis.[26–29] IL-23 plays a key role in the pathogenesis of hidradenitis suppurativa by promoting the differentiation and maintenance of Th17 cells, which drive chronic inflammation through IL-17 and other downstream cytokines. Elevated IL-23 expression has been observed in lesional HS skin, suggesting its contribution to the inflammatory milieu and tissue damage in HS.[30,31]

Table 1 Clinical Outcomes at Week 16 and Week 48

Outcome Measure	Baseline	Week 16	Week 48
HiSCR achieved (n, %)	0	4 (40%)	5 (50%)
Mean IHS4	14.3	9.3 (−5)	—
Mean DLQI	27.8	17.8 (−10)	—
Mean VAS pain score	9.1	4.8 (−4.3)	—

https://doi.org/10.2147/CCID.S544180

Conclusion

In conclusion, although guselkumab has not passed phase 2 trials for the treatment of HS, several case series and reports describe the potential efficacy of this drug, particularly where concomitant conditions such as psoriasis and CD are present. Although the study was limited by the small number of patients and the lack of a placebo group, the results are comparable to those described by other reports in the literature, but with a larger sample size. Further studies are therefore needed to establish the efficacy and safety of guselkumab against peculiar subgroups of HS.

Data Sharing Statement

Data are reported in the current study and are on request by corresponding author.

Ethics and Consent Statements

The study was conducted in accordance with the protocol and applicable ethical guidelines and principles derived from the 1964 Declaration of Helsinki. The study protocol was reviewed and approved by Local Ethic Committee University of Naples Federico II. Patients provided written informed consent before undergoing the specific study procedures.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors report no conflicts of interest in this work.

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