

Anti-IL-17/23 Drugs for the Treatment of Moderate-to-Severe Hidradenitis Suppurativa in Patients With Concomitant Psoriasis: A Multicenter Retrospective Study

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ABSTRACT **Introduction:** Psoriasis and hidradenitis suppurativa (HS) are chronic inflammatory diseases with significant overlap in their immunologic pathways, which involve cytokines such as tumor necrosis factor- α , interleukin (IL)-17, and IL-23. Current treatment options for HS are limited, as only adalimumab and secukinumab are approved for severe cases. Given the overlapping pathogenetic features between HS and psoriasis, anti-IL-17 and anti-IL-23 drugs could represent valuable treatments for the management of HS.

Objectives: We sought to evaluate the effectiveness and safety of anti-IL-17 and anti-IL-23 drugs in patients with HS and concomitant moderate-to-severe plaque psoriasis.

Methods: We conducted a multicenter retrospective study in 11 Italian Dermatology Units. The effectiveness of the drugs was evaluated by assessing the percentage of patients achieving HS Clinical Response (HiSCR) each week.

Results: We enrolled 41 patients with at least 16 weeks of follow-up, with 17 of them completing 52 weeks of treatment. The most commonly prescribed anti-IL drug was secukinumab (27 patients), followed by ixekizumab (5) and guselkumab (5). The HiSCR was achieved by 39%, 74.3%, and 77.8% of patients after 16, 32, and 52 weeks, respectively. No severe adverse events (AEs) or AEs leading to discontinuation were observed during the study. The most common AE was nasopharyngitis (four patients).

Conclusion: In this real-world study, we highlight the effectiveness of anti-IL-23 and anti-IL-17 drugs in the treatment of concomitant plaque psoriasis and severe HS. Longer and larger studies are needed to further evaluate the long-term effectiveness and safety of these treatments in patients affected by HS.

Introduction

Hidradenitis Suppurativa (HS) is a chronic, debilitating, autoimmune-inflammatory skin disease affecting approximately 1% of the general population [1]. Clinically, it is characterized by recurrent painful nodules, abscesses, draining tunnels, and scarring, predominantly in intertriginous areas [1]. The pathophysiology of HS is complex and not fully understood, but it involves the dysregulation of the immune system. In particular, high levels of interleukin (IL)-1, IL-17, IL-23, and tumor necrosis factor (TNF)- α have been demonstrated [3].

Traditional therapies for HS have had limited success, and there is an urgent need for more effective treatment options, as currently only adalimumab (an anti-TNF- α drug) and secukinumab (an anti-IL-17 drug) are approved for the treatment of severe HS [4, 5]. In particular, secukinumab was recently approved for the treatment of severe HS by the US Food and Drug Administration (FDA) on 31 October 2023. In a large-scale population-based study, the prevalence of HS increased in patients affected by psoriasis compared with the control group (odds ratio 1.8; 95% Confidence Interval (CI):

1.5-2.3) [6]. The two diseases share immune pathogenetic pathways, including TNF- α , IL-12/23 and other cytokines produced by T-helper 17 cells [6, 7].

The overlapping pathogenesis of psoriasis and HS has led to the development of several clinical trials to investigate the role of anti-IL-17 and anti-IL-23 drugs for the treatment of HS. Among the anti-IL-23 (guselkumab, tildrakizumab and risankizumab) and anti-IL-17 (ixekizumab, bimekizumab, secukinumab and brodalumab) drugs, all approved for the treatment of moderate-to-severe psoriasis, only secukinumab has recently been approved for the treatment of severe HS after being evaluated in two Phase 3 clinical trials—SUNSHINE and SUNRISE [5, 8]. Data from Phase 3 clinical trials (BE HEARD I and BE HEARD II) have recently been published regarding the efficacy of bimekizumab in the treatment of moderate-to-severe HS [9]. Among the anti-IL-23 drugs, both risankizumab and guselkumab have failed to achieve the primary endpoints in Phase 2 clinical trials for HS [10, 11].

Our multicenter study aimed to assess the effectiveness and safety of anti-IL-17 and anti-IL-23 drugs in patients with HS and concomitant moderate-to-severe plaque psoriasis.

Objectives

We performed a retrospective multicenter study by analyzing the database records of 11 Italian Dermatology Units between January 2020 and December 2023 to evaluate the effectiveness and safety of anti-IL-17 and anti-IL-23 drugs in patients with HS and concomitant moderate-to-severe plaque psoriasis.

Methods

In our multicenter retrospective study, we enrolled 41 patients who had at least 16 weeks of follow-up. All patients had a diagnosis of moderate-to-severe hidradenitis suppurativa, defined as Hurley stage II/III or International HS Severity Scoring System 4 (IHS4) ≥ 4 . All patients had concomitant moderate-to-severe plaque psoriasis, and the eligibility for these treatments was assessed following the Italian adaptation of EuroGuiDerm guideline on the systemic treatment of chronic plaque psoriasis in patients with inadequate response or contraindications to systemic therapies [12]. Patients who developed paradoxical psoriasis during treatment with anti-TNF- α for HS were not included in this study.

Given the recent approval of secukinumab and the lack of approval of other anti-IL-17/23 biologics for the treatment of HS, these drugs have been administered to the Summary of Product Characteristics with the posology used for the treatment of psoriasis [5, 13-16]. Institutional review board approval was waived for this study, as the procedure did not deviate from good routine clinical practice.

All patients gave written informed consent for the retrospective retrieval of anonymized data. The study was conducted following the Helsinki Declaration of 1964 and its later amendments.

Demographic characteristics, comorbidities, disease characteristics, and clinical scores were retrieved from the electronic medical records at baseline, week 16, week 32, and week 52. Due to the retrospective nature of this study, not all patients completed all the follow-up visits. For patients who did not attend the scheduled dermatology visits and performed the injection of secukinumab at home or missed the dose, data were considered from the last observation carried forward.

At each time point, the effectiveness of each drug was assessed in terms of Hidradenitis Suppurativa Clinical Response (HiSCR), defined as the reduction of at least 50% in nodule and abscess count and no increase in the number of abscesses and draining fistulas compared to baseline [17]. A reduction of at least 55% in IHS4 from baseline (IHS4-55) [18] and a reduction in mean IHS4 and DLQI were also selected as effectiveness outcomes. We also recorded the

occurrence of any adverse events (AEs) at each visit, including serious AEs and AEs leading to discontinuation.

Continuous data are reported as mean and Standard Deviation (SD), while categorical parameters are reported as absolute numbers and percentages. Microsoft Excel was used for analysis and to generate tables and figures.

Results

This real-world study involved 41 patients, all of whom completed at least 16 weeks of treatment, with 17 of them reaching one year of follow-up. All patients had concomitant moderate-to-severe plaque psoriasis and previously failed systemic therapy or had a contraindication to them. The most commonly prescribed anti-IL agent was secukinumab (27 patients), followed by ixekizumab (5), guselkumab (5), bimekizumab (2), brodalumab (1), and risankizumab (1). Twenty-eight patients were female (68.3%), with a mean age of 40.59 years (SD 15). Thirteen patients (31.7%) were obese, with a mean BMI of 27.94 (SD 4.65). Twenty-three patients (56.1%) referred a medical history of concomitant cardiometabolic comorbidities (including arterial hypertension, type 2 diabetes mellitus, cardiovascular disease, hypercholesterolemia, and obesity). Slightly more than half of our patients were smokers (56.1%). Almost all patients (85.4%) had previously failed adalimumab. Before starting treatment with anti-IL-17/23 drugs, 17 patients (41.5%) had a Hurley score of II (moderate HS), while 24 (58.5%) had Hurley score III (severe HS). Complete baseline demographic and clinical characteristics of our population are shown in Table 1.

The mean IHS4 at baseline was 29.49 (SD 21.93), which decreased to 21.39 (17.64) after 16 weeks, to 15.29 (11.65) after 32 weeks, and to 10.83 (9.91) after one year of treatment (Figure 1A). Our cohort of patients also showed a significant impact on quality of life, as evidenced by a mean DLQI of 20.88 (SD 7.08) at baseline, which decreased consistently throughout the study period (Figure 1B). The mean DLQI (SD) at weeks 16, 32, and 52 was 15.05 (6.45), 10.8 (6.78), and 7 (5.71), respectively.

The HiSCR was achieved by 39%, 74.3%, and 77.8% of patients after 16, 32, and 52 weeks, respectively (Figure 2A). A reduction of at least 55% in IHS4 from baseline (IHS4-55) was observed in 14.6%, 45.7%, and 88.9% of patients at weeks 16, 32, and 52, respectively (Figure 2B).

Regarding the tolerability of these molecules, no new safety findings emerged during the study. Ten patients experienced at least one AE (24.4%). The most common AEs were nasopharyngitis (four patients) and injection-site reactions (three patients). No severe AEs or AEs leading to discontinuation were reported.

Table 1. Demographic Characteristics of Our Patients at Baseline.

Total Patients	41 N (%)
Female	28 (68.3)
At least one cardiometabolic comorbidity	23 (56.1)
Smokers	23 (56.1)
Previously treated with adalimumab	35 (85.4)
Hurley II	17 (41.5)
Hurley III	24 (58.5)
Obese	13 (31.7)
<i>Current biological drug</i>	
Secukinumab	27 (65.9)
Brodalumab	1 (2.4)
Ixekizumab	5 (12.2)
Bimekizumab	2 (4.9)
Risankizumab	1 (2.4)
Guselkumab	5 (12.2)
	Mean (SD)
Age, years	40.59 (15)
BMI	27.94 (4.65)
IHS4 at baseline	29.49 (21.93)
DLQI at baseline	20.88 (7.08)

Abbreviations: BMI: body mass index; IHS4: International Hidradenitis Suppurativa Severity Scoring System 4; DLQI: Dermatology Life Quality Index; SD: standard deviation.

Discussion

Our findings suggest that anti-IL-23 and anti-IL-17 drugs approved for moderate-to-severe plaque psoriasis could represent viable options also for treating HS. IL-17 inhibitors have been used for the treatment of HS in both clinical trials and real-life experiences. IL-17A, produced by neutrophils, mast cells, and T-helper 17 cells, plays a critical role by amplifying inflammation and promoting a cycle of keratinocyte activation and hyperkeratosis that drives HS progression [19]. Regarding secukinumab, in the Phase 3 SUNSHINE and SUNRISE trials, the primary endpoint of HiSCR at week 16 was met by secukinumab every two weeks in both trials, while secukinumab every four weeks reached the primary endpoint only in the SUNRISE trial [8]. In both trials, the HiSCR was maintained throughout 52 weeks of follow-up [8]. In a multicenter real-world study, HiSCR was obtained at week 28 from 41% of 31 enrolled patients, all treated with secukinumab for severe HS [20]. In a Spanish retrospective multicenter study, HiSCR was obtained in 48.9% of the 47 enrolled HS patients treated with secukinumab [21]. Recently, secukinumab has been approved as the first

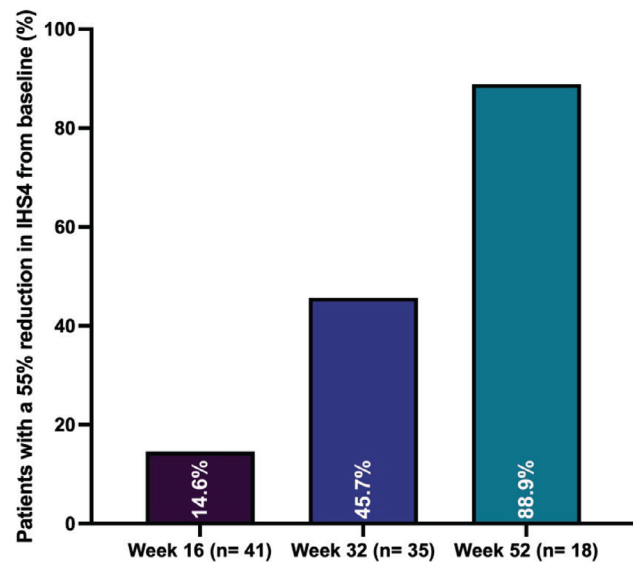
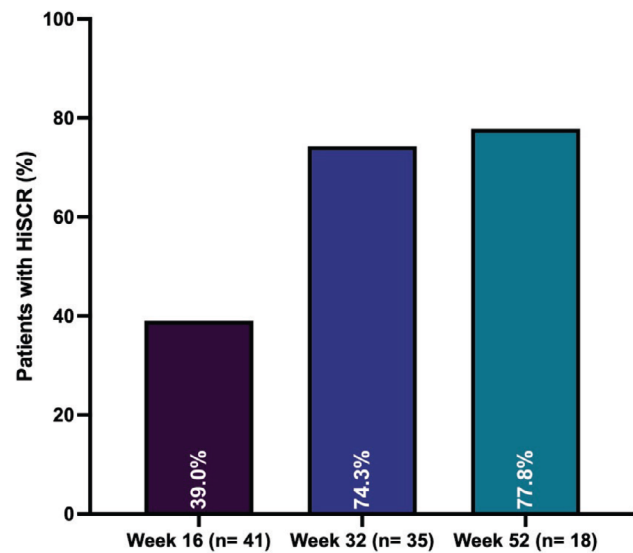


Figure 1. Effectiveness outcomes throughout 52 weeks of treatment. (IHS4 = International Hidradenitis Suppurativa Severity Scoring System 4; HiSCR = Hidradenitis Suppurativa Clinical Response.)

anti-IL17A inhibitor for moderate-to-severe hidradenitis suppurativa [22].

Data for ixekizumab in HS are limited to a case series and a few case reports. Esme et al. [23] described a case series of five patients treated with ixekizumab after failing adalimumab. In this study, four out of five patients achieved HiSCR at week 12 after being treated with ixekizumab according to the same posology for the treatment of moderate-to-severe plaque psoriasis [23].

Regarding brodalumab, data on its use in patients with HS are extremely limited. A recent case series reported a slight improvement in patient-reported outcomes after 16 weeks of treatment [24].

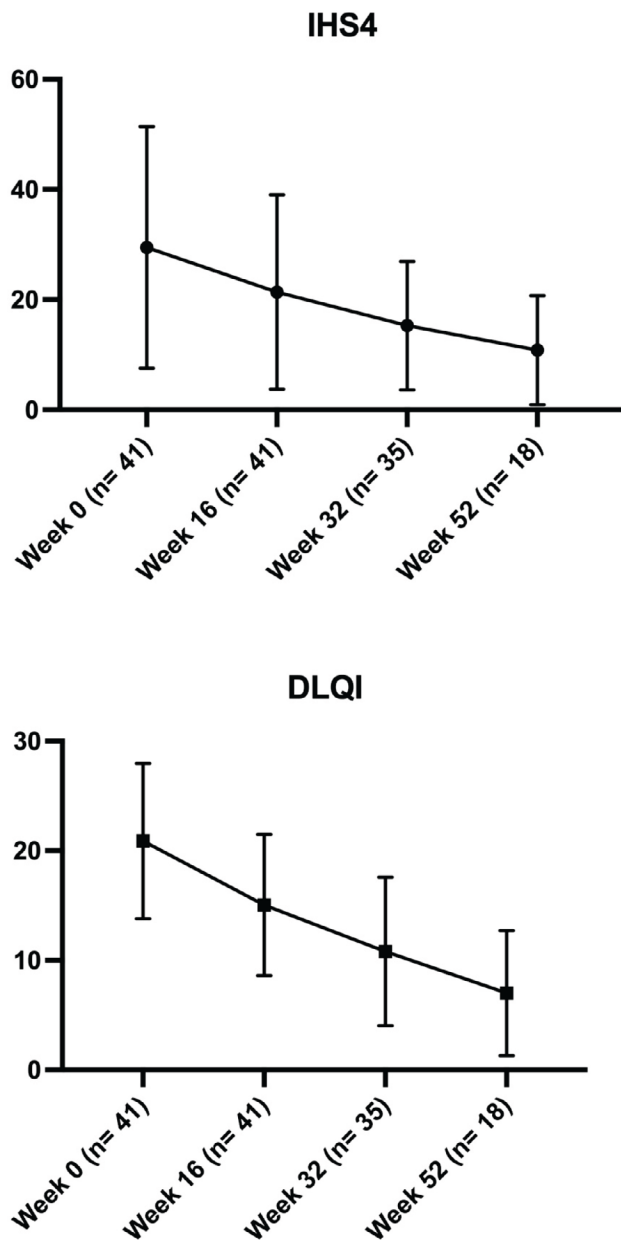


Figure 2. Reduction in the mean IHS4 and mean DLQI of our patients during the study. (IHS4 = International Hidradenitis Suppurativa Severity Scoring System 4; DLQI = Dermatology Life Quality Index.)

Navrazhina et al. conducted a study that demonstrates IL-17RA inhibition as a potential therapy for decreasing different pathogenic inflammatory axes in HS [25]. In particular, a significant reduction in neutrophil-associated lipocalin-2 (LCN-2) in skin biopsies and in IL-17A in serum was assessed in 10 HS patients treated with brodalumab [26].

Furthermore, another study assessed a good response to brodalumab in HS patients considering sonographic biomarkers (epidermal thickness and power-doppler) and correlating them with different clinical and patient-reported outcomes [26].

Bimekizumab administered every two weeks has recently been shown to be superior to placebo in both the BE

HEARD 1 and 2 Phase 3 clinical trials [9]. Data from the Phase 2 study showed a higher HiSCR rate at week 12 compared to placebo, meeting the primary endpoint of the trial [27]. The safety profile of bimekizumab for the treatment of HS was comparable to clinical trials for the treatment of moderate-to-severe psoriasis [9, 27].

Data on anti-IL-23 drugs for treating HS are still limited. Regarding tildrakizumab, Kok Y et al. [28] published a case series that included nine patients treated for 15 months. They reported a significant reduction in mean abscess and nodule count after 15 months in the absence of significant AEs [28]. In a recent case series including seven patients who had failed adalimumab, tildrakizumab 200 mg demonstrated an initial improvement in disease activity after 24 weeks of treatment [29].

Risankizumab failed to meet the primary endpoint in a Phase 2 clinical trial enrolling patients with severe HS [10]. Concerning real-world data, a retrospective study on six patients reported the achievement of HiSCR for all patients after six months [30].

Guselkumab did not achieve the primary endpoints in Phase 2 clinical trials [31,32]. In particular, the authors of one of these studies concluded that IL-23 does not appear to be a crucial cytokine in HS pathogenesis, while guselkumab showed efficacy only in a limited subpopulation of patients [32]. However, in a recent real-life multicenter study, a significant decrease in IHS4 and DLQI was observed after 48 weeks of treatment with guselkumab, while more than half of the patients achieved HiSCR at week 16 [4, 33, 34].

In our study, we observed good clinical responses among a cohort of 41 patients treated with inhibitors of IL-17 and IL-23. We can speculate that the effectiveness that we observed could be due to the concomitant presence of HS and plaque psoriasis with a supposed overexpression of IL-23 and IL-17-related cytokines.

Limitations

However, our experience has several limitations, the first being its retrospective nature. Moreover, due to the limited sample size, it was not possible to investigate the effectiveness profile of each molecule. Also, the heterogeneity of clinical evaluations from different clinicians could limit the generalization of our findings.

Conclusions

Our real-life study supports data from clinical trials and real-world experiences highlighting the effectiveness of anti-IL-17 and anti-IL-23 in the treatment of HS. Considering the recent and upcoming approval of anti-interleukin

drugs in HS, our preliminary report might be useful for our colleagues approaching these new treatment options.

Longer and larger studies are needed to further evaluate the effectiveness and safety profile of these molecules in the treatment of HS.

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