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ORIGINAL RESEARCH

Short-Term Effectiveness, Safety, and Potential Predictors of Response of Secukinumab in Patients with Severe Hidradenitis Suppurativa Refractory to Biologic Therapy: A Multicenter Observational Retrospective Study

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ABSTRACT

Introduction: Hidradenitis suppurativa (HS) is a chronic inflammatory skin disease. Biologic drugs have a key role in the long-term anti-inflammatory treatment of moderate to severe patients due to their immunomodulatory properties. The aim of this study is to evaluate the effectiveness and safety of secukinumab in patients with moderate to severe HS after 16 weeks of treatment, and to explore potential predictors of clinical response to the drug.

Methods: Multicenter observational retrospective study. Patients treated with secukinumab

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300 mg every 2 or 4 weeks who had completed at least 16 weeks of follow-up from nine hospitals based in southern Spain (Andalusia) were included in this study. Treatment effectiveness was assessed using the Hidradenitis Suppurativa Clinical Response (HiSCR). Information about adverse events was collected, the therapeutic burden of the patients was calculated as the summation of systemic medical treatments and surgical interventions (excluding incision and drainage) experienced until the start of secukinumab treatment.

Results: Forty-seven patients with severe HS were included for analysis. At week 16, 48.9% (23/47) of patients achieved HiSCR. Adverse events were present in 6.4% (3/47) of the patients. The multivariate analysis showed that female sex and, to a lesser extent, lower body mass index (BMI) and a lower therapeutic burden were potentially associated with a higher probability of HiSCR achievement.

Conclusions: Favorable short-term effectiveness and safety of secukinumab in the treatment of severe HS patients were observed. Female sex, lower BMI and a lower therapeutic burden may be associated with a higher probability of achieving HiSCR.

Keywords: Hidradenitis suppurativa; Secukinumab; Anti-IL-17; Hidradenitis suppurativa clinical response; HiSCR; Therapeutic burden

Key Summary Points

Why carry out this study?
There remain patients in whom proper control of hidradenitis suppurativa (HS) is not achieved. Given the role of IL-17 in HS pathogenesis, secukinumab, an anti-Il-17 drug, could be a potential treatment for this disease.
Is secukinumab effective and safe for the treatment of severe patients with hidradenitis suppurativa, and are there any factors that could predict the effectiveness of this drug?
What was learned from the study?
48.9% (23/47) of patients achieved Hidradenitis Suppurativa Clinical Response (HiSCR) at week 16, while 6.4% (3/47) of patients presented adverse effects. Female sex, lower body mass index and a lower therapeutic burden were independently associated with a higher probability of achieving HiSCR.
Secukinumab could be effective for the treatment of patients with severe hidradenitis suppurativa. There may be clinical factors that predict a greater likelihood of disease improvement.

INTRODUCTION

Hidradenitis suppurativa (HS) is a chronic inflammatory disease that affects the pilosebaceous follicle. It manifests as painful nodules, abscesses and draining fistulas, mainly in flexural areas, and causes a significant deterioration of quality of life in patients with this condition [1–3].

Although there are many medical and surgical options currently available for HS treatment, there remain patients in whom proper control of the disease is not achieved [4, 5].

It has been demonstrated that underlying HS pathogenesis is an immune system dysregulation dominated by an increased Th17 lymphocyte response. These lymphocytes typically produce interleukin (IL) 17, a proinflammatory mediator that promotes neutrophil recruitment and is increased in blood and skin lesions of HS patients [6].

Anti-IL-17 biologic drugs (secukinumab, ixekizumab, brodalumab) are approved for use in moderate to severe plaque psoriasis. Demonstration of the role of IL-17 in HS pathogenesis has encouraged the use of these drugs in HS patients in whom other lines of treatment have failed [7].

Recently, the data from two double-blind randomized phase III clinical trials have shown

the efficacy and safety of secukinumab for the treatment of moderate to severe cases of hidradenitis suppurativa compared to placebo, with between 42 and 48% of the patients achieving Hidradenitis Suppurativa Clinical Response (HiSCR) [8]. Previously, other clinical studies have indicated that this drug may be effective in the treatment of HS. In these studies, the proportion of patients who responded to the drug was variable [8–13].

The fact that secukinumab is only effective in a certain proportion of patients implies that there are characteristics of the patient or the disease that have an influence on the response to the drug.

Considering the high cost of biologic drugs and the quality-of-life impairment caused by the disease while it is active and progressing, it is clearly important to know which patients will have a better response to the treatment. This way, it would be possible to select the most appropriate drug for each patient at each moment, minimizing the time it takes to control the disease and optimizing the use of resources.

The aim of this study is to evaluate the effectiveness and safety of secukinumab in patients with moderate or severe HS after 16 weeks of treatment, and to identify those factors that may predict a positive clinical response to the drug.

MATERIAL AND METHODS

Design and Patients

A multicenter retrospective observational study was conducted, involving nine hospitals in southern Spain (Andalusia). Adults with moderate or severe hidradenitis suppurativa who initiated treatment with secukinumab between January 2018 and October 2022 were selected. These patients were followed for at least 16 weeks after initiation of the treatment to assess the effectiveness and safety of secukinumab and to explore potential predictors of clinical response to the drug.

Inclusion Criteria

Inclusion criteria were (a) patients with a clinical diagnosis of moderate HS (defined as Hurley stage II or International HS Severity Scoring System (IHS4) 4–10) or severe HS (defined as Hurley stage III or IHS4 > 11) [1, 14], (b) treatment with secukinumab 300 mg due to a lack of response or contraindication to adalimumab treatment, and (c) informed consent of the patient prior to inclusion in the study.

Exclusion Criteria

The exclusion criteria were (a) the patient's refusal to participate in the study and (b) age under 18 years.

Ethics

The study was conducted in accordance with the Declaration of Helsinki and was approved by the Hospìtal Universitario Virgen de las Nieves (HUVN) ethics committee. All participants signed an informed consent allowing access to their personal data and its use for the conduct of this study.

Variables of Interest

Patients were assessed prior to the initiation of secukinumab and at week 16 of the treatment. Data were collected by accessing electronic medical records. These data had been previously obtained from the history and physical examination of the patient.

Main variables:

(A) Effectiveness:

- Proportion of participants who achieved HiSCR at week 16 of treatment. HiSCR was defined as at least a 50% reduction in nodule and abscess count, no increase in the number of abscesses, and no increase in the number of draining fistulas compared to baseline [15].

(B) Safety:

- Adverse effects occurred during treatment with secukinumab were recorded.

Other variables of interest:

- The Hurley stage of HS was used to assess the structural severity of the disease [1].
- Number of areas affected by the disease.
- IHS4 was used to assess inflammatory severity. It was calculated according to the following formula: (number of nodules × 1) + (number of abscesses × 2) + (number of fistulas × 4). The IHS4 prior to the initiation of secukinumab treatment and the proportion of patients who achieved a 55% reduction in IHS4 by week 16 of treatment were collected [14].
- Pain according to the Numerical Rating Scale (NRS) [16].
- Therapeutic burden prior to the start of secukinumab, defined as the summatory of all cycles of systemic treatment (biologic or not) and all surgeries (excluding incision and drainage) that the patient had received as treatment for HS [17].

The following data were also collected: age, sex, body mass index (BMI), previous comorbidities, family history of HS, disease duration, HS phenotype (inflammatory, follicular or mixed), and other HS treatments received in combination with secukinumab.

Statistics

Descriptive statistics were used to evaluate the characteristics of the sample. The Shapiro–Wilk test was used to assess the normality of the variables. Continuous variables are expressed as mean and standard deviation (SD). Qualitative variables are expressed as relative and absolute frequency distributions. The $\chi 2$ test or Fisher's exact test, as appropriate, was used to compare nominal variables, and the Student's t test or Wilcoxon-Mann–Whitney test was used to compare nominal with continuous data. To explore possible associated factors, simple linear regression was used for continuous variables. The β coefficient and SD were used to predict the log odds of the dependent variable. Significantly associated variables ($p < 0.05$) or those showing trends towards statistical significance ($p < 0.20$) were included in multivariate analysis. Statistical significance was considered if p values were less than 0.05. Statistical analyses were performed using JMP version 9.0.1 (SAS institute, North Carolina, USA).

RESULTS

Sociodemographic Data and Baseline Characteristics of the Sample

Seventy patients with severe HS treated with secukinumab for at least 16 weeks were identified; 23 of those patients were excluded from the analysis because of missing data regarding variables of interest. Thus, 47 patients were included in this study. Sociodemographic data and baseline characteristics of the sample are shown in Table 1. There was a slight female predominance in the sample, with 51.1% (24/47) of patients being female. Mean age of the sample was 40.9 (SD 10.9) years and mean BMI was 29.6 (SD 6.6) kg/m^2. There was a family history of HS in 48.9% (23/47) of patients. The predominant HS phenotype was inflammatory, present in 55.3% (26/47) of patients. Mean disease duration was 18.8 (± 8.6) years. Regarding HS severity, there were 46.8% (22/47) patients with Hurley stage II disease and 53.2% (25/47) with Hurley stage III disease. All patients presented an IHS4 value higher than 10, which defined severe disease. Mean IHS4 was 21.1 (SD 11.9). Mean therapeutic burden prior to secukinumab initiation was 6.9 (SD 3.6) medical or surgical interventions. 97.9% (46/47) of the patients presented prior failure, 2.1% (1/47) presented a contraindication for adalimumab, and all had at least experienced another biologic drug prior to secukinumab initiation (mean number of biologic drugs used was 1.3; SD 0.7). Patients received secukinumab 300 mg subcutaneously at weeks 0, 1, 2, 3 and 4. Subsequently, 12 patients followed a regimen of secukinumab 300 mg subcutaneously every 2 weeks, and 35 patients were treated with secukinumab 300 mg subcutaneously every

Table 1 Baseline features of the patients

	N = 47
Age (years)	40.9 (SD 10.9)
Gender (female)	51.1% (24/47)
BMI (kg/m^2)	29.6 (SD 6.6)
Family history of HS (yes)	48.9% (23/47)
Disease duration (years)	18.8 (SD 8.6)
Hurley stage	
I	0%
II	46.8% (22/47)
III	53.2% (25/47)
Phenotype	
Follicular	21.3% (10/47)
Inflammatory	55.3% (26/47)
Mixed	23.4% (11/47)
Number of areas involved	5.2 (SD 2.0)
Number of previous systemic treatments	
Nonbiologic drugs	3.2 (SD 2.2)
Biologic drugs	1.3 (SD 0.7)
Number of previous surgical procedures, excluding incision and drainage	2.3 (SD 2.7)
Therapeutic burden	6.9 (SD 3.6)
Inflammatory nodules	4.0 (SD 3.4)
Abscesses	2.9 (SD 2.5)
Inflamed or draining tunnels	2.9 (SD 2.6)
HIS4	21.1 (SD 11.9)
Pain NRS	7.2 (SD 2.3)
Combined treatment	
No	72.3% (34/47)
Systemic antibiotic	12.8% (6/47)
Systemic corticosteroids	14.9% (7/47)
Combined surgery	
Yes	4.3% (2/47)
No	95.7% (45/47)
Dosage	
300 mg every 2 weeks	25.53% (12/47)
300 mg every 4 weeks	74,046% (35/47)

Data are expressed as relative (absolute) frequency and mean (standard deviation, SD)
HS hidradenitis suppurativa, *BMI* body mass index, *NRS* Numeric Rating Scale, *IHS4* International Hidradenitis Suppurativa Severity Scoring System

4 weeks. 27.7% (13/47) of patients received combination treatment at the beginning of secukinumab therapy. Treatment consisted of systemic antibiotics in 12.8% (6/47) of patients and systemic corticosteroids in 14.9% (7/47) of patients. Only 4.3% (2/47) of patients underwent surgery during secukinumab treatment.

Response to Secukinumab After 16 Weeks of Treatment

After 16 weeks of secukinumab treatment, 48.9% (23/47) of patients achieved HiSCR. The mean IHS4 decreased from 21.1 (SD 1.9) to 12.7 (SD 11.6) ($p < 0.0001$). A 55% reduction in IHS4 was observed in 40.4% (19/47) of patients. Pain rating according to the NRS decreased from 7.2 (SD 2.3) points prior to treatment initiation to 5 (SD 2.7) points at 16 weeks of follow-up ($p < 0.0001$). There were no statistically significant differences in effectiveness regarding dosages of 300 mg every 2 weeks vs. every 4 weeks: HiSCR was achieved in 33.3% (4/12) vs. 54.3% (19/35). Detailed data are shown in Table 2.

Adverse Effects and Treatment Discontinuation

Data on adverse effects and treatment discontinuation are summarized in Table 3. Adverse events were recorded in 6.8% of patients (3/47).

One patient developed oral candidiasis. Another patient suffered worsening of his psoriasis. Finally, one patient experienced joint pain and inflammation. Secukinumab treatment was discontinued in 19.1% (9/47) of patients after the week 16 visit. Secukinumab was discontinued In two patients due to adverse effects (worsening of psoriasis and joint pain and inflammation). In one patient, treatment was discontinued because his HS worsened despite secukinumab administration. Finally, in 12.8% (6/47) of patients the drug was discontinued due to a lack of response to the drug.

Predictors of Response to Secukinumab Treatment

Table 4 compares the characteristics of the population that achieved HiSCR at week 16 of secukinumab treatment versus those who did not. We observed that patients in the first group were predominantly female ($p = 0.012$), had a lower mean BMI ($p = 0.14$) and had a lower prior therapeutic burden ($p = 0.0062$), in addition to presenting a lower mean baseline IHS4 compared to those patients who did not achieve HiSCR ($p = 0.082$). There were no significant differences between the two groups in terms of mean age, family history of HS, HS phenotype, Hurley stage, disease duration, secukinumab regimen, or use of combination therapy with the biologic drug. Multivariate analysis (Table 4) showed that female sex ($p = 0.022$), lower therapeutic burden ($p = 0.0497$) and a trend towards lower body mass index ($p = 0.056$) were potentially associated with a higher probability of achieving HiSCR at 16 weeks of secukinumab treatment. The presence of a therapeutic burden equal to or less than five therapeutic interventions was associated with a HiSCR response rate of 70% (14/20), while only 33.3% (9/27) of patients with more than five therapeutic interventions achieved HiSCR.

Table 2 Clinical response at week 16

	Baseline	Week 16	*p* value
Inflammatory nodules	4.0 (SD 3.4)	2.5 (SD 3.0)	0.004
Abscesses	2.9 (SD 2.5)	1.6 (SD 2.2)	< 0.0001
Inflamed or draining tunnels	2.9 (SD 2.6)	1.7 (SD 2.0)	0.0006
IHS4	21.1 (SD 11.9)	12.7 (SD 11.6)	< 0.0001
Pain NRS	7.2 (SD 2.3)	5 (SD 2.7)	< 0.0001
HiSCR	–	48.9% (23/47)	–
IHS4-55	–	40.4% (19/47)	–

Data are expressed as relative (absolute) frequency and mean (standard deviation, SD)
IHS4 International HS Severity Scoring System, *NRS* Numeric Rating Scale, *HiSCR* Hidradenitis Suppurativa Clinical Response

Table 3 Adverse events and treatment discontinuation at week 16

	N = 47
Adverse events (all)	6.82% (3/47)
Oral candidiasis	2.1% (1/47)
Psoriasis worsening	2.1% (1/47)
Articular pain and inflammation	2.1% (1/47)
Treatment discontinuation (all)	19.1% (9/47)
Adverse event	4.3% (2/47)
Disease worsening	2.1% (1/47)
Lack of response	12.8% (6/47)

Data are expressed as the relative (absolute) frequency

DISCUSSION

The results of our study show that treatment with secukinumab in patients with severe hidradenitis suppurativa may be safe and effective. In addition, we have identified potential

Table 4 Univariate and multivariate analysis of clinical predictors of HiSCR

	Univariate analysis			Multivariate analysis	
	HISCR yes ***n*** **= 23**	**HISCR no** ***n*** **= 24**	***P*** **value**	**Beta**	***P*** **value**
Age (years)	38.9 (SD 2.2)	42.8 (SD 2.2)	0.21	− 0.03	0.44
Gender (female)	69.6% (16/23)	33.3% (8/24)	**0.012**	0.9	**0.022**
BMI (kg/m^2)	28.2 (SD 1.4)	31 (SD 1.3)	0.14	− 0.12	0.056
Familiar history (yes)	47.8% (11/23)	50% (12/24)	0.88	–	–
Phenotype (inflammatory)	52.2% (12/23)	58.3% (14/24)	0.89	–	–
Disease duration	17.7 (SD 1.8)	19.9 (SD 1.8)	0.39	–	–
Hurley stage (III)	43.5% (10/23)	62.5% (15/24)	0.19	–	–
IHS4 baseline	18 (SD 2.4)	24.1 (SD 2.4)	**0.082**	0.002	0.96
Dosage					
300 mg/2 weeks	17.39% (4/23)	33.34% (8/24)	0.3 1	–	–
300 mg/4 weeks	82.6% (19/23)	66.7% (16/24)			
Combined treatment with secukinumab nNo)	78.3% (18/23)	91.7% (22/24)	0.32	–	–
Therapeutic burden: surgical + systemic	5.5 (SD 0.7)	8.3 (SD 0.7)	**0.0062**	− 0.26	**0.0497**

Data are expressed as relative (absolute) frequency and mean (standard deviation, SD)
p-values < 0.005 are marked in bold
BMI body mass index, *IHS4* International Hidradenitis Suppurativa Severity Scoring System, *HiSCR* Hidradenitis Suppurativa Clinical Response

clinical characteristics that could be independently associated with a higher probability of achieving HiSCR: female sex, lower BMI, and lower therapeutic burden.

Adalimumab is currently the only biologic drug approved for the treatment of HS. If the disease is not controlled with this drug, there is no other approved therapeutic alternative [16]. In the context of severe refractory disease, off-label uses of biological drugs with potential benefit in HS, such as secukinumab, guselkumab, brodalumab and ustekinumab, among others, have been used [18–20].

The effectiveness of secukinumab for the treatment of HS has been previously studied in a clinical setting. Prussick et al. reported that 55.5% of a series of nine patients (5/9) achieved HiSCR at week 16 of treatment and 67% (6/9) at week 24 [9]. Casseres et al. found that 65% (13/20) of patients achieved HiSCR at week 12 [10]. In the study by Reguiai et al., 75% of patients (15/20) achieved HiSCR at week 16 [11]. Ribero et al. concluded that 26% (8/24) of patients achieved HiSCR at week 16 and 41% (7/17) at week 28 [12]. Finally, Melgosa et al. followed 23 patients, of whom 73.9% (17/23) achieved HiSCR at week 16, 71.4% (15/21) at week 24, 71.4% (10/14) at week 36, and 83.3% (10/12) at week 52 of secukinumab treatment [13].

Recently, the results have been published for two phase 3 randomized controlled trials (SUNSHINE and SUNRISE) which compared the use of secukinumab every 2 weeks versus secukinumab every 4 weeks and versus a placebo group in patients with moderate to severe HS. In the SUNNY trials, the HiSCR rates ranged from 42 to 46% under different regimens [8]. The HiSCR rate in our study is in the upper range of these clinical trials, considering that our patient population presents more severe

disease features compared to the population in clinical trials. Our population presented a higher proportion of patients at the Hurley III stage, a longer disease duration, and all patients presented previous exposure to biologic drugs and severe disease according to the IHS4 score compared to the SUNNY trials population. Under these circumstances, the effectiveness observed in our sample is notable.

Regarding potential predictors of response, we did not observe significant statistical differences between the two dosage regimen groups. A trend towards a worse response with every 2-week dosage was observed. This is probably explained by a higher disease severity among patients on this dosage compared to patients that received secukinumab every 4 weeks. However, we identified three potential clinical predictors of response. On the one hand, 66.7% (16/24) of the women in the study achieved HiSCR at week 16 of treatment, whereas only 30.4% (7/23) of the men achieved this outcome. In our geographic area, female sex represents a marker of milder disease, while men present more severe forms of the disease. In our sample, female sex was statistically significantly associated with Hurley II versus III and with a lower value of IHS4. This would be a possible explanation for these findings. Future studies focusing on gender differences and patients from different geographical areas are of great interest to clarify this finding.

On the other hand, there are data showing that a higher BMI is potentially associated with a poorer response to biologic therapy in immune-mediated diseases. It has been hypothesized that the usual dose of the drug could be insufficient in obese patients, since obesity implies a greater volume of distribution of the drug and therefore a lower drug concentration. Also, as the biologic drug is administered subcutaneously, a greater amount of subcutaneous adipose tissue could limit its absorption [21–24]. These hypotheses could be extrapolated to secukinumab treatment in HS, which could explain why a higher BMI is associated with a lower effectiveness of the drug. Further research is needed to assess whether obese patients would benefit from an increase in secukinumab dose or a decrease in the period between each administration.

Sex is a non-modifiable patient characteristic. Weight loss is one of the general measures recommended for patients with HS in different clinical guidelines, but weight is difficult to modify in clinical practice [16]. However, the therapeutic burden prior to initiation of biologic therapy is a factor that depends mainly on the medical care received and indirectly assesses the delay in the use of biologic therapy, how badly the window of opportunity for HS treatment is missed, and disease burden. In our study, a higher therapeutic burden was associated with a lower effectiveness of secukinumab treatment. These data suggest, in line with other published results, that earlier use of biologic therapy may reflect a better therapeutic response [25, 26].

Limitations of our study include the small sample size, the retrospective nature, the open-label design with no control group, and the short follow-up period.

CONCLUSIONS

To conclude, secukinumab can be considered a safe and effective treatment option in patients with severe hidradenitis suppurativa. There are clinical characteristics that potentially predict a better response to this drug, with the therapeutic burden being of special interest, since it is a factor that depends mainly on the medical care received by the patient and is potentially modifiable. Further studies are needed to fully determine the profile of patients that will benefit most from this treatment, with the aim of practicing personalized and precision medicine.

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Disclosures. The authors report they have nothing to disclose.

Compliance with Ethics Guidelines. This study was approved by the Research Ethics Committee of the Virgen de las Nieves Hospital. The patients in this manuscript have given written informed consent for the publication of their case details. This study is in accordance with the Declaration of Helsinki.

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

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