Dermatology Practical & Conceptual

Secukinumab Efficacy Predictors in Korean Hidradenitis Suppurativa: A 48-Week Clinical Trial Analysis

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Key message: Faster initial responses to secukinumab in hidradenitis suppurativa patients are observed in those with milder disease, earlier treatment, and no previous biological therapy. Secukinumab also significantly reduced antibiotic usage.

Key words: Hidradenitis Suppurativa, Secukinumab, Korean Patients, Predictive Factors, IHS4-55

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ABSTRACT

Background: Hidradenitis suppurativa (HS) is a chronic inflammatory skin disease characterized by painful nodules, abscesses, and draining tunnels commonly occurring in body folds. The IL-17A inhibitor, secukinumab, has shown efficacy in reducing HS lesions in clinical studies, but data on epidemiologic and patient-specific factors influencing response remain limited.

Objectives: To assess how baseline disease severity, treatment initiation delay, and prior biologics exposure influence clinical response to secukinumab and patterns of antibiotic use.

Materials and Methods: This 48-week real-world prospective trial enrolled 10 Korean patients with moderate-to-severe HS. Patients received secukinumab 300 mg subcutaneously at weeks 0, 1, 2, 3, and 4, then every two weeks. Outcomes included Hidradenitis Suppurativa Clinical Response (HiSCR), a 55% reduction in the International HS Severity Score System (IHS4-55), mean change in abscesses and inflammatory nodules, a ≥ 30% reduction in pain score on a numeric rating scale (NRS30), and duration of concomitant antibiotic use.

Results: At week 48, 90% of patients achieved HiSCR, with 90% meeting the IHS4-55 threshold and 60% reaching the NRS30 criteria. Faster responses were recorded in subjects with Hurley stage II, treatment delays of <10 years, or no prior biologics use, although response rates equalized by week

48. All patients, particularly moderate cases, either discontinued or transitioned to monotherapy with systemic antibiotics.

Conclusions: Secukinumab demonstrated efficacy in alleviating HS symptoms in moderate-to-severe cases. Patients with less severe disease, shorter treatment delays, and/or no prior biologic therapy exhibited more rapid initial responses. Additionally, the majority of patients experienced a significant duration of antibiotic cessation, underscoring the importance of early intervention. Future studies with larger populations are required to substantiate these findings.

Introduction

Hidradenitis suppurativa (HS) is a chronic inflammatory skin disorder characterized by deep-seated abscesses and nodules that predominantly occur in intertriginous regions such as the axillae, groin, and perineal areas. Over time, the condition often progresses to draining sinus tracts and extensive scarring [1]. The disease significantly impacts patients' quality of life (QoL) owing to the debilitating pain, recurrent lesions, and social distress caused by disfigurement. Conventional treatments for HS primarily aim to control inflammation, secondary infections, and associated symptoms, including systemic antibiotics, triamcinolone acetonide intralesional injections (TA ILI), and surgical interventions such as incision and drainage (I&D) [2]. However, these therapies are often associated with limited efficacy, high recurrence rates, and suboptimal improvements in QoL [3].

The pathogenesis of HS remains incompletely understood, but it is believed to involve a combination of genetic predisposition, immune dysregulation, and pro-inflammatory cytokines, particularly tumor necrosis factor-alpha (TNF-α) and interleukin-17 (IL-17), at the pilosebaceous unit [4]. To better address this inflammatory nature, targeted biologic therapies have been explored. Adalimumab, a TNF-α inhibitor, received FDA approval for the management of HS in 2015 [5]. While it has provided meaningful clinical benefits, concerns regarding safety, diminishing efficacy over time, and variability in response have limited its utility in some cases [6-8].

Recently, the efficacy and safety of secukinumab, an IL-17A inhibitor, have been demonstrated in two large-scale, multicenter randomized controlled trials (RCTs): SUNSHINE and SUNRISE [9]. These trials reported response rates of 42–45% at 16 weeks, with continued improvement observed at 52 weeks, underscoring the drug's potential for long-term disease control [9]. Subsequent real-world studies have further corroborated the effectiveness of secukinumab [10-16], culminating in its FDA approval for moderate-to-severe HS on 31 October 2023.

Although data from RCTs and real-world studies have established the efficacy and safety profile of secukinumab, the influence of disease-related factors such as severity, treatment delay, and prior biologics use on therapeutic outcomes remains insufficiently explored. Severe HS often presents with extensive scarring and multiple interconnected sinus tracts, which may hinder treatment response compared to less advanced diseases. To address this gap, we conducted a 48-week real-world clinical trial on Korean patients with moderate-to-severe HS.

Objectives

This study aimed to evaluate how baseline disease severity (Hurley stage), treatment delay, and prior biologics exposure affect clinical response to secukinumab in Korean patients with moderate-to-severe HS over a 48-week treatment period in a real-world clinical setting. Additionally, this research sought to examine the impact of secukinumab on systemic antibiotic use.

Materials and Methods

Study Design and Participants

This prospective, non-controlled clinical trial recruited moderate-to-severe HS patients in a real-world setting at the Department of Dermatology, Severance Hospital, Seoul, Republic of Korea from May 2023 to November 2024. To facilitate easier access to adequate therapy, the global Managed Access Program (MAP) by Novartis was established, providing secukinumab treatment to moderate-to-severe HS patients. The requesting physician submitted a supply or resupply request for secukinumab through the Grants, External Requests, and Managed Access System (GEMS), and the request was evaluated based on the eligibility criteria. Our study recruited HS patients from MAP, specifically those over 18 years old, diagnosed with moderate-to-severe HS for over six months (defined as having a total of five inflammatory lesions, namely abscesses and nodules, in two different anatomical areas). Detailed descriptions of inclusion and exclusion criteria are provided in Table S1. Patients were administered 300 mg of secukinumab subcutaneously at weeks

0, 1, 2, 3, and 4, then every two weeks until 48 weeks. Other concurrent treatments, namely systemic antibiotics, TA ILI, and I&D, were permitted for continuation based on clinical guidelines and recommendations.

Baseline Characteristics

At baseline, demographic and clinical data were collected, specifically sex, age, age at onset, body mass index (BMI), smoking habit, family history of HS, treatment delay (defined as the duration from disease onset to the initiation of secukinumab, categorized as <10 years and ≥10 years), comorbidities, and prior treatments of HS.

Assessment of Clinical Endpoints of Secukinumab Treatment

At baseline, clinical symptoms, namely inflammatory nodules, abscesses, and draining tunnels, were assessed and quantified. Abscesses presented as a soft mass larger than 10 mm in diameter, surrounded by a red area, with central purulent material, often associated with inflammation, pain, and tenderness. Inflammatory nodules were raised, deep, three-dimensional round lesions that were tender, red, and infiltrated, potentially forming pyogenic granulomas and measuring over 10 mm in diameter. Draining fistulae were raised sinus tracts, tender with fluctuating tunnels of varying length and depth, connected to the skin surface, and exuding purulent fluid [9].

Subsequently, disease severity was categorized based on the Hurley staging system: stage I (mild), distinguished by single or multiple abscesses without the formation of sinus tracts or scarring; stage II (moderate), involving recurrent abscesses with one or more sinus tracts and scarring that are widely separated by areas of normal skin; stage III (severe), marked by widespread involvement with multiple sinus tracts and no areas of normal skin in between [17]. Moreover, skin pain was reported by the patients via the Patient's Global Assessment of Skin Pain numeric rating scale (NRS) at the worst level within the previous 24 hours, varying from 0 (no skin pain) to 10 (the worst skin pain conceivable). All patients were examined and evaluated for clinical symptoms and skin pain at baseline and at weeks 4, 8, 16, 32, and 48. Our main clinical endpoints include:

- Hidradenitis Suppurativa Clinical Response (HiSCR): a reduction of 50% or more from baseline in the count of abscesses and inflammatory nodules (AN), without any increase in the number of abscesses or draining tunnels [18].
- IHS4-55: a decrease of at least 55% from baseline in the International Hidradenitis Suppurativa Severity Score System (IHS4), calculated using the formula: number of nodules + (number of abscesses x 2) + (number of draining tunnels x 4) [19,20].
- Mean change in AN count from baseline: the average percentage change from baseline in the AN count.
- NRS30: A reduction of 30% or more, along with a decrease of at least two points, from baseline in skin pain assessed on a continuous NRS, applicable for those with a baseline NRS of three or higher [9].

The duration of single and multiple systemic antibiotic medications was quantified from the start to the end of the study, measured in week (s). All patients were asked to report any adverse event during secukinumab treatment.

Ethics

This study was approved by the Institutional Review Board of Yonsei University Hospital (IRB No. 4-2023-0201). All patients provided written informed consent before participation, in accordance with the Declaration of Helsinki.

Statistical Analysis

Means and standard deviation (SD) are used to describe continuous variables. Qualitative variables are displayed as a frequency distribution. Comparisons between continuous variables were conducted by an independent Student t-test or Mann-Whitney test based on normality results via the Shapiro-Wilk test. For nominal variables, the $\chi 2$ test or Fisher's exact test was utilized for comparison, as appropriate, and the relative risk (RR) was calculated with a 95% confidence interval (CI). Logistic regression analysis was conducted to assess any correlation between nominal endpoints (HiSCR, IHS4-55, NRS30) and patients' demographic characteristics. Simple linear regression was used to test possible related factors for the quantitative endpoint (Mean change in AN count from baseline). Statistical significance was set at $P<0.05$. Statistical analyses were performed using the R software (version 4.3.1). The graphing of results was done via the GraphPad Prism software (version 10.2.2).

Results

Ten patients with moderate-to-severe HS were enrolled and monitored over 48 weeks. Baseline demographic and clinical characteristics are summarized in Table 1, while baseline features categorized by Hurley stage, treatment delay, and prior biologics use are presented in Table 2. Notably, 70% of patients (N=7) were classified as Hurley stage II, while the remaining 30% (N=3) were Hurley stage III. All patients had prior treatments with antibiotics and TA ILI, and 40% (N=4) had previously received an anti-TNF-α biologic agent, specifically adalimumab. Patients with Hurley stage II or no

Table 1. Baseline Characteristics of Patients.

Patient number	Sex	Age	Age at onset	Secukinumab treatment delay	Family history	Body mass index (kg/m^2)	Smoking habit	Comorbidities	Prior treatment	Baseline Hurley stage	Baseline IHS4	Baseline NRS
1	M	20	15	5	Yes	24.97	Yes	Acne conglobata	Antibiotics TA ILI I&D	3	46	5
2	F	23	17	7	No	20.37	No	Acne conglobata	Adalimumab Antibiotics TA ILI	3	31	3
3	M	19	17	2	No	23.89	No	Acne conglobata	Antibiotics TA ILI I&D	3	31	4
4	M	31	18	13	No	25.51	Yes	Agent resistant to multiple antibiotics	Adalimumab Antibiotics I&D TA ILI	2	13	5
5	F	28	18	10	No	22.31	No	Acne vulgaris	Adalimumab Antibiotics TA ILI I&D	2	20	6.5
6	F	22	6	17	Yes	25.66	No	Female pattern alopecia	Adalimumab Antibiotics I&D TA ILI	2	8	8
7	M	22	20	2	Yes	25.08	No	Acne conglobata	Antibiotics TA ILI	2	16	1
8	M	23	9	15	No	27.17	Yes		Antibiotics TA ILI	2	11	3
9	F	54	52	3	Yes	32.37	No	Acne conglobata	Antibiotics TA ILI I&D	2	12	3
10	M	31	17	15	Yes	30.79	Yes		Antibiotics TA ILI I&D	2	9	0

Abbreviations: IHS4, International Hidradenitis Suppurativa Severity Score System; NRS, Patient's Global Assessment of Skin Pain on a continuous numeric rating scale; TA ILI, triamcinolone acetonide intralesional injection; I&D, incision & drainage.

Table 2. Summarized Characteristics of Patients, Stratified by Hurley Stage, Treatment Delay, and Prior Biologics Use.

	Overall	Hurley stage		Treatment delay		Prior biologics use	
		II (N=7)	III (N=3)	< 10 years (N=5)	≥ 10 years (N=5)	Biologics-experienced (N=4)	Biologics-naïve (N=6)
Sex, n (%)							
Male	6 (60)	5 (71.43)	1 (33.33)	3 (60)	3 (60)	1 (25)	5 (83.33)
Female	4 (40)	2 (28.57)	2 (66.67)	2 (40)	2 (40)	3 (75)	1 (16.67)
Age, years	27.3 ± 10.31	27.43 ± 12.34	27 ± 4.58	27.6 ± 14.84	27 ± 4.3	26 ± 4.24	28.17 ± 13.35
Age at onset, years	18.9 ± 12.42	21.67 ± 15.31	14.75 ± 5.85	24.2 ± 15.64	13.6 ± 5.68	14.75 ± 5.85	21.67 ± 15.31
Disease duration, years	8.9 ± 5.84	7.00 ± 6.29	11.75 ± 4.27	3.8 ± 2.17	14 ± 2.65	11.75 ± 4.27	7 ± 6.29
Family history, n (%)	5 (50)	4 (57.15)	1 (33.33)	3 (60)	2 (40)	1 (25)	4 (66.7)
Body mass index, kg/m^2	25.81 ± 3.6	26.38 ± 4.12	24.49 ± 1.89	25.33 ± 4.37	26.29 ± 3.08	23.46 ± 2.58	27.38 ± 3.46
Smoking habit, n (%)	4 (40)	3 (42.85)	1 (33.33)	1 (20)	3 (60)	1 (25)	3 (50)
Prior treatments, n (%)							
Adalimumab	4 (40)	1 (14.28)	3 (100)	1 (20)	3 (60)	4 (100)	0 (0)
Antibiotics	10 (100)	7 (100)	3 (100)	5 (100)	5 (100)	4 (100)	6 (100)
TA ILI	10 (100)	7 (100)	3 (100)	5 (100)	5 (100)	4 (100)	6 (100)
I&D	6 (60)	4 (57.14)	2 (66.67)	3 (60)	3 (60)	2 (50)	4 (66.7)

TA ILI, triamcinolone acetonide intralesional injection; I&D, incision & drainage

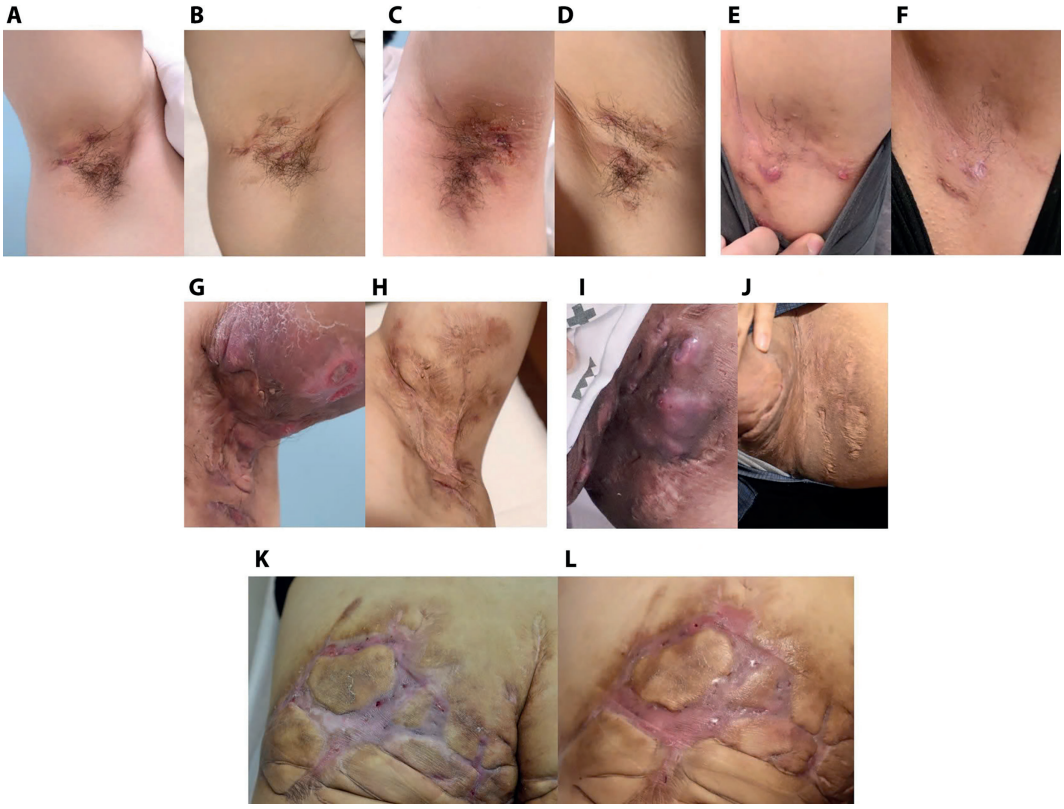

Figure 1. Visual improvements in lesions before and after the use of secukinumab in moderate and severe HS patients. Inflammatory nodules and abscesses before treatment in the right axillae (A) and left axillae (C, E) of Hurley stage II patients and after 48 weeks of secukinumab administration (B, D, F). Inflammatory nodules, abscesses, and draining fistula before treatment in the left axillae (G), inguinal (I), and gluteal area (K) of Hurley stage III patients and after 48 weeks of secukinumab administration (H, J, L).

prior biologics use had shorter disease duration than those with Hurley stage III or prior biologics exposure.

Reductions in inflammatory lesions following treatment are illustrated in Figure 1, with significant diminishment of abscesses and inflammatory nodules across all Hurley stages. However, sinus tract attenuation was less pronounced, particularly in patients with more severe disease.

The overall efficacy of secukinumab is presented in Figure 2. Rapid responses were evident across all endpoints by week 4, with 30% of patients achieving IHS4-55, 70% achieving HiSCR, and 40% achieving NRS30. Mean reductions included a -64.18 ± 27.89% decrease in AN count, IHS4 reduction from 19.4 ± 11.96 to 11.9 ± 12.38, and pain NRS improvement from 4.69 ± 1.83 to 2.59 ± 1.67. By week 16, 70% achieved IHS4-55, and 60% achieved NRS30. Improvements were reflected in a -84.46 ± 10.60% reduction in AN count, an IHS4 decrease to 7.6 ± 8.11, and a pain NRS decrease to 1.7 ± 1.54. However, HiSCR decreased from 100% to 90% from week 8 to week 16 due to the recurrence of an abscess in one male patient. Nonetheless, all endpoints maintained their improvement until week 48, with 90% of patients maintaining HiSCR, 90% achieving IHS4-55, and 60% sustaining NRS30. Moreover, AN count was reduced by -92.93 ± 11.42%, and IHS4 decreased further to 3.7 ± 5.48, but pain NRS increased slightly, to 1.99 ± 1.6, due to the aforementioned relapse.

Univariate analyses were conducted to evaluate the impact of participants' demographic characteristics on their responses to secukinumab administration. No statistically significant correlation was detected between sex, age, age at onset, BMI, smoking habit, and prior I&D and HiSCR, IHS4-55, mean change in AN count from baseline, and NRS30 (P>0.05) (Table S2).

Patients with Hurley stage II (moderate HS) achieved IHS4-55 responses more rapidly and to a greater extent than those with stage III (severe HS), with statistically significant differences at weeks 8 and 16 (RR: 0.00; 95% CI: 0.00–0.71; P=0.033; RR: 0.00; 95% CI: 0.00–0.56; P=0.0083; Figure 3A). Although moderate patients showed higher HiSCR rates at week 4, the difference was not significant (P>0.05; Figure 3B). A relapse in one male patient at week 16 lowered the HiSCR rate in moderate patients to 80%, but both groups maintained efficacy without further significant differences. This relapse also impacted the AN count and NRS30 outcomes. Moderate patients initially showed a greater reduction in AN count up to week 16, after which severe patients showed more improvement, though differences

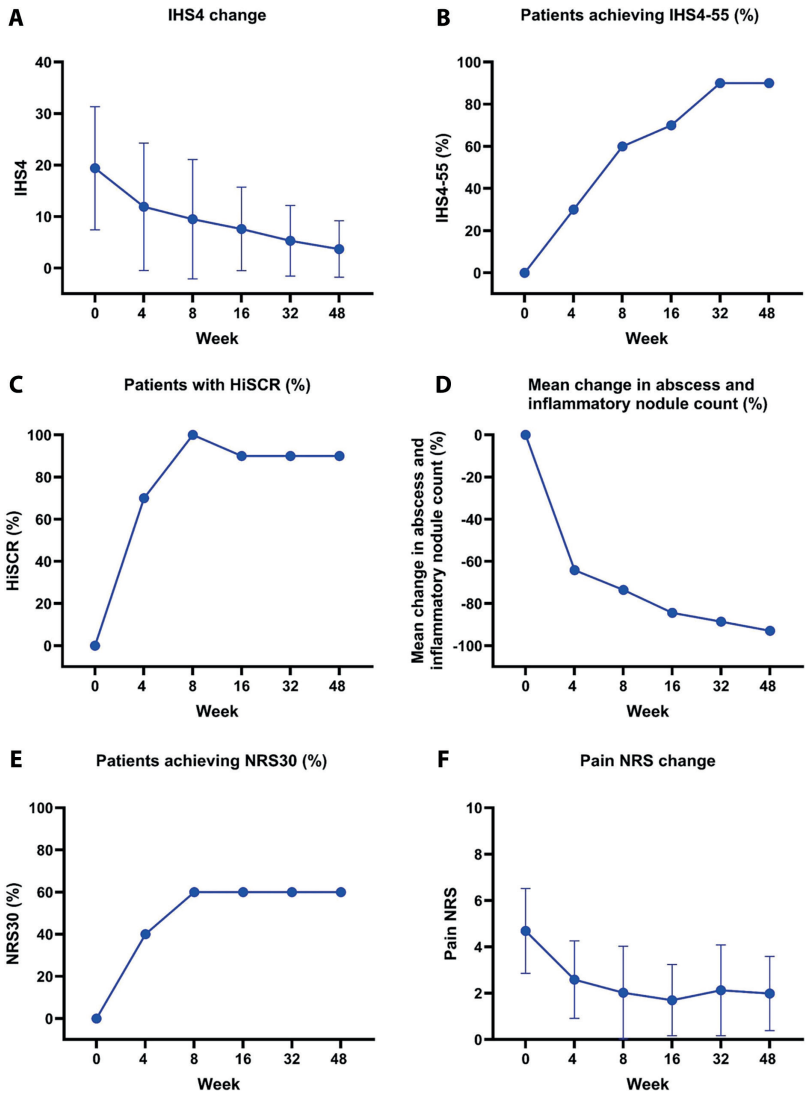

Figure 2. The effect of secukinumab on moderate-to-severe HS patients. Treatment responses are illustrated for HiSCR (A), mean change in abscess and nodule count from baseline (B), IHS4-55 (C), IHS-4 change (D), NRS30 (E), and Pain NRS change (F). HiSCR, Hidradenitis Suppurativa Clinical Response; IHS4-55, a 55% reduction in the International Hidradenitis Suppurativa Severity Score System; NRS30, a 30% or more reduction and reduction of two units or more from baseline in Patient's Global Assessment of Skin Pain on a continuous numeric rating scale.

were not significant (P>0.05; Figure 3C). NRS30 rates were consistently higher in moderate patients across all time points but dropped from 100% to 80% after the relapse, with no statistically significant difference observed (P>0.05; Figure 3D).

Patients with a treatment delay of less than 10 years showed higher IHS4-55 response rates at all time points, with a statistically significant difference at week 8 (RR: 0.2; 95% CI: 0.03622–0.6610; P=0.047; Figure 4A). HiSCR rates were initially higher in this group at week 4 but reversed after a relapse in one patient at week 16 (Figure 4B). AN count changes were comparable between groups throughout the study (P>0.05; Figure 4C). NRS30 rates were consistently higher in patients with shorter treatment delay, though not statistically significant (P>0.05; Figure 4D).

Biologics-naïve patients showed greater improvement in IHS4-55 compared to biologics-experienced ones, with a significant difference at week 16 (RR: 0.25; 95% CI: 0.046–0.70; P=0.033; Figure 5A). HiSCR rates were higher in biologics-naïve patients at week 4 but not significantly (P>0.05; Figure 5B). A relapse after week 16 reduced their HiSCR to 80% and impacted AN count and NRS30 rates, but the efficacy was maintained until the end of the study. AN count declined faster in biologics-naïve patients early on, but the difference was not significant (P>0.05; Figure 5C). NRS30 rates were higher in biologics-naïve patients at weeks 4–8, then equalized by week 16 (Figure 5D). At week 48, relapse lowered the NRS30 rate from 66.67% to 50%.

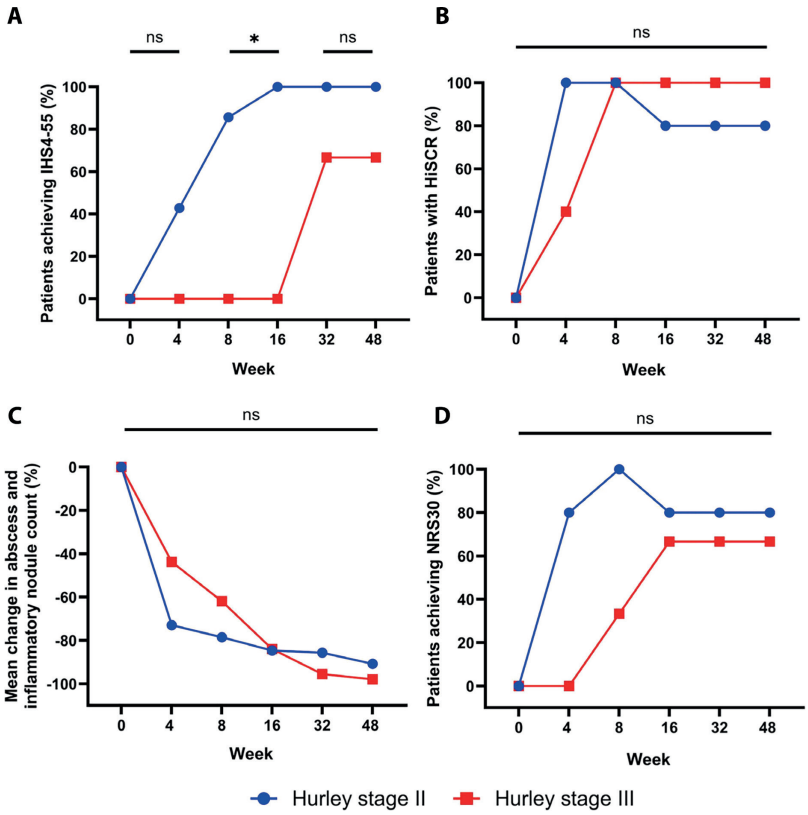

Figure 3. The effect of secukinumab, stratified by Hurley stage, on IHS4-55 (A), HiSCR (B), mean change in abscess and nodule count (C), and NRS30 (D). HiSCR, Hidradenitis Suppurativa Clinical Response; IHS4-55, a 55% reduction in the International Hidradenitis Suppurativa Severity Score System; NRS30, a 30% or more reduction and a reduction of two units or more from baseline in Patient's Global Assessment of Skin Pain on a continuous numeric rating scale; **P*<0.05; ns, no significance.

Moreover, we compared the antibiotic use duration between Hurley stage II and III patients (Figure 6). While the duration of antibiotic monotherapy was similar between the groups (*P*>0.05), patients with severe disease had significantly longer periods of combined antibiotic use than those with moderate disease (*P*<0.05). Notably, moderate patients had a significantly longer duration of antibiotic cessation than did severe cases (*P*<0.05).

Regarding adverse events, secukinumab was well tolerated, and no patient reported any non-serious or serious adverse event that could have led to the discontinuation of participation in the study (Table 3). Additionally, no new adverse event outside of the known safety profile of secukinumab was reported during the 48 weeks of treatment. Notably, the longest duration of treatment maintenance without any adverse event observed during our patient monitoring was 80 weeks.

Discussion

This 48-week prospective study demonstrates the robust efficacy of secukinumab in managing moderate-to-severe HS in a Korean cohort, providing clinically relevant insights into factors influencing treatment response. Our findings affirm the significant therapeutic potential of secukinumab while highlighting the role of disease severity, treatment timing, and prior biologics exposure in shaping patient outcomes.

Secukinumab elicited rapid and sustained clinical responses across key endpoints, including HiSCR, IHS4-55, and pain NRS30, with nearly all patients showing marked improvements by week 48. Patients with Hurley stage II disease, shorter treatment delays (<10 years), and biologics-naïve status exhibited faster initial responses, underscoring the importance of early intervention and patient-specific treatment planning. Notably, despite these early differences, long-term outcomes were favorable across all groups, reinforcing the broad applicability of secukinumab in HS management.

The variation in response based on disease severity emphasizes the inherent challenges in treating advanced HS. Patients with Hurley stage II disease achieved faster reductions in inflammatory nodules and abscesses, as evidenced by higher IHS4-55 rates at weeks 8 and 16, compared to

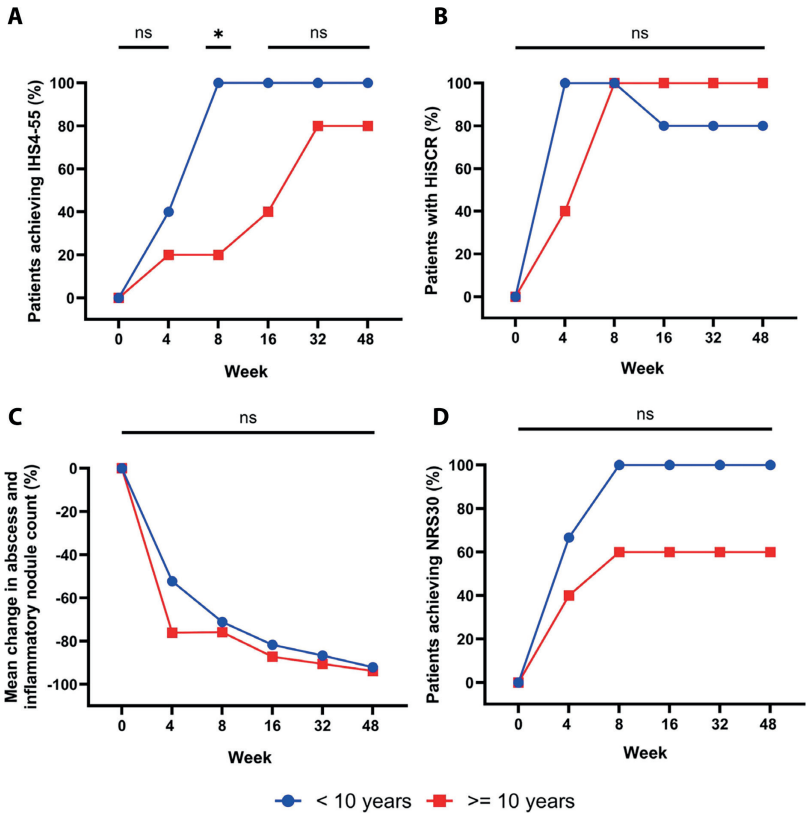

Figure 4. The effect of secukinumab, stratified by treatment delay, on IHS4-55 (A), HiSCR (B), AN count (C), and NRS30 (D). HiSCR, Hidradenitis Suppurativa Clinical Response; IHS4-55, a 55% reduction in the International Hidradenitis Suppurativa Severity Score System; NRS30, a 30% or more reduction and a reduction of two units or more from baseline in Patient's Global Assessment of Skin Pain on a continuous numeric rating scale; *P<0.05; ns, no significance.

those with Hurley stage III disease, who exhibited a slower but steady trajectory of improvement. The limited efficacy of secukinumab in addressing sinus tracts—chronic lesions predominantly observed in severe HS—suggests the involvement of alternative pathogenic pathways beyond IL-17A. These findings highlight the need for adjunctive or combination therapies targeting cytokines such as TNF-α or other profibrotic mediators, including hepatocyte growth factor, to address the complex pathophysiology of severe HS [21].

Treatment delay also emerged as a pivotal determinant of response; patients initiating secukinumab within 10 years of disease onset showed significantly faster and more pronounced improvements in IHS4-55 and pain NRS30 outcomes. These findings align with the concept of a "therapeutic window of opportunity," wherein early biologics intervention may prevent irreversible disease progression characterized by fistula formation and scarring. To illustrate, a retrospective Italian cohort found that longer delays in adalimumab initiation correlated with poorer response, and a recent multicenter study reported that high "therapeutic burden" (many prior treatments) was inversely related to secukinumab response [15,22]. These data support our emphasis that prompt recognition and therapy are crucial to optimizing long-term outcomes.

Prior biologics exposure further influenced treatment efficacy. Biologics-naïve patients achieved superior IHS4-55 rates at week 16 compared to those with prior biologics failure, although response rates between the two groups converged by week 48. This observation suggests that prior biologics failure may indicate more refractory disease phenotypes, potentially necessitating more prolonged or intensified therapeutic regimens. Nevertheless, the comparable long-term efficacy observed in both groups underscores secukinumab's therapeutic versatility in both treatment-naïve and biologics-experienced populations.

An additional strength of secukinumab therapy observed in this study was the significant reduction in systemic antibiotic usage. Nearly all patients discontinued or transitioned to antibiotic monotherapy, with the effect being particularly pronounced in those with moderate disease. This highlights secukinumab's immunomodulatory capabilities in mitigating the inflammatory drivers of HS and in reducing reliance on systemic antibiotics [4]. Given the increasing global concern over antimicrobial resistance, this finding is

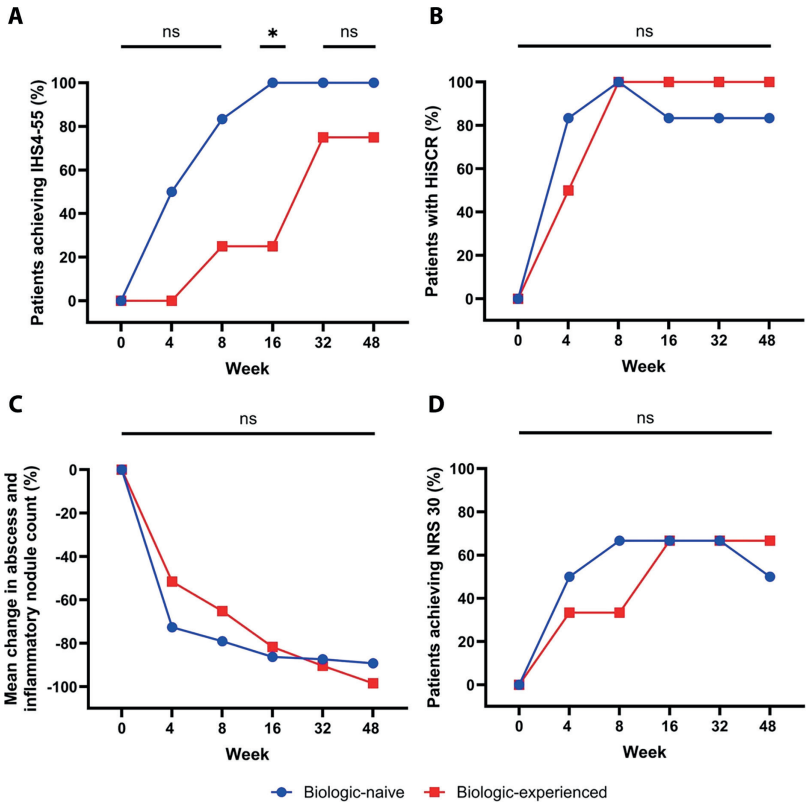

Figure 5. The effect of secukinumab, stratified by prior biologics use, on IHS4-55 (A), HiSCR (B), AN count (C), and NRS30 (D). HiSCR, Hidradenitis Suppurativa Clinical Response; IHS4-55, a 55% reduction in the International Hidradenitis Suppurativa Severity Score System, AN, abscess and nodule count; NRS30, a 30% or more reduction and a reduction of two units or more from baseline in Patient's Global Assessment of Skin Pain on a continuous numeric rating scale; *P<0.05; ns, no significance.

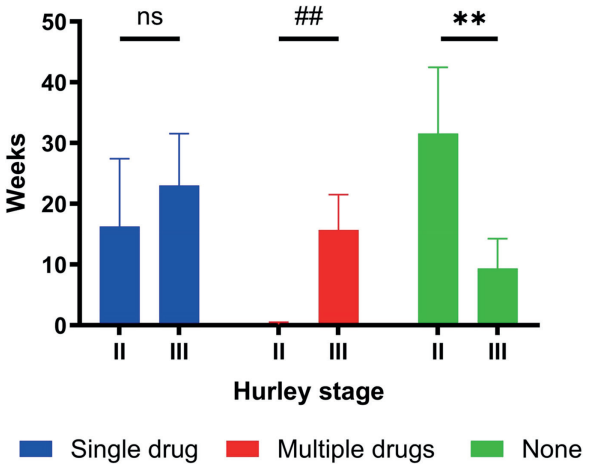

Figure 6. The duration of systemic antibiotic treatment stratified by Hurley stage after the administration of Secukinumab. ## P<0.01, Mann-Whitney test; ** P<0.01, independent t-test; ns, no significance.

clinically significant. However, further studies incorporating direct comparisons between antibiotic usage pre- and post-treatment are warranted to substantiate these observations.

Another novelty stemming from our study is the demonstration of secukinumab efficacy on Korean HS patients, a subgroup with various features distinct from those of the global population. Nationwide data showed that the incidence of HS in Korea rose six-fold between 2003 and 2019 (from 11.7 to 78.8 cases per million person-years), but overall prevalence remained low (0.06%), and the disease was male-predominant (female-to-male ratio of about 1:1.6) [23,24]. In contrast, most North American and European cohorts reported a prevalence of 0.1–1.0% and a female-to-male ratio of roughly 3:1 [25]. These demographic differences underline the importance of region-specific real-world data such as ours when evaluating treatment response.

From a safety perspective, secukinumab was well tolerated, with no serious adverse event or treatment discontinuation reported during the study period. These findings are consistent with data from pivotal RCTs, including the SUNSHINE and SUNRISE trials, which reported favorable safety profiles [9]. Although vigilance remains necessary, particularly in patients with coexisting inflammatory bowel disease [9,26], the safety and tolerability of secukinumab affirm its suitability for long-term management of HS.

In spite of promising results regarding biologic therapy, optimal HS management still requires a multidisciplinary approach. HS patients benefit from comprehensive care

Table 3. Adverse Events during 48 Weeks of Secukinumab Treatment in Moderate-to-Severe HS Patients.

Adverse event	Patients (N=10)
Patients with any adverse event, N (%)	0 (0.0)
Common adverse events, N (%)	
Headache	0 (0.0)
Nasopharyngitis	0 (0.0)
Patients with serious or other significant event, N (%)	
Death	0 (0.0)
Non-fatal serious adverse event	0 (0.0)
Discontinued study treatment due to any adverse event	0 (0.0)
Adverse events of special interest, N (%)	
Infections and infestations by system organ class	0 (0.0)
Upper respiratory tract infection	0 (0.0)
Fungal infectious disorders	0 (0.0)
Candida infection	0 (0.0)
Hypersensitivity	0 (0.0)
Malignant or unspecified tumor	0 (0.0)
Major adverse cardiovascular event	0 (0.0)
Inflammatory bowel disease	0 (0.0)

pathways, including smoking cessation, weight management, metabolic monitoring, and psychosocial support, in addition to targeted medical therapy [27]. Therefore, modern consensus statements emphasize that optimal HS care extends beyond dermatologic therapy and should integrate surgery, wound-care nursing, pain specialists, dieticians, psychologists, and primary care physicians [28]. In practice, a combined medical-surgical strategy may yield better outcomes: perioperative use of adalimumab has been shown to improve HiSCR rates after excisional surgery without increasing complications [29]. Hence, our findings support the paradigm that secukinumab can allow many patients to discontinue long-term antibiotics, facilitating coordination with surgeons for excisional procedures.

Additionally, differences in biologics availability across health systems may constitute an impact on secukinumab utilization. The European Academy of Dermatology and Venereology (EADV) has provided guidelines for biologic therapy as second-line treatment for HS, notably adalimumab and secukinumab [30]. The EADV additionally complemented bimekizumab, further expanding options [30]. The FDA in the United States also approved secukinumab as an authorized treatment for moderate-to-severe HS, along with the already authorized adalimumab [16]. In those settings, adalimumab or secukinumab could be administered first-line; inadequate responders may switch to the remaining option before relying on prolonged antibiotics or surgery. By contrast, Korean patients currently have routine access to mainly adalimumab for HS. Our data, therefore, provide early evidence to support policy discussions on widening biologics availability in Korea and in Asia in general, where the male-predominant, often deeply tunnelling phenotype may particularly benefit from timely escalation [23,24].

However, this study is limited by its small sample size, lack of a control group, and potential confounding factors such as demographic imbalances. These limitations underscore the need for larger multicenter studies with robust control measures to validate these findings and further delineate the optimal use of secukinumab in HS. Future investigations should also explore the integration of complementary therapeutic approaches to enhance outcomes, particularly in patients with advanced disease or refractory lesions. Despite these drawbacks, our small cohort yields useful real-world insights, partially from our extensive period of follow-up (48 weeks). In addition, the overall response rate and safety profile of secukinumab in our patients align with those reported in larger studies, supporting external consistency [14,15,31]. Notably, the phase 3 SUNSHINE/SUNRISE trials in North America and Europe showed that secukinumab achieved HiSCR in 42–45% of patients at 16 weeks, with effectiveness achieved in both TNF-naïve and TNF-experienced groups [9]. Similarly, real-world studies have reported good clinical responses and safety with IL-17–targeted therapy [10-16]. Observed trends in our data, namely higher response likelihood in patients with lower prior therapeutic burden, align with the "window of opportunity" concept and are similar to predictors identified in other analyses [15]. Finally, our study also noted a reduction in antibiotic dependence following secukinumab treatment, which is consistent with evidence that secukinumab is effective regardless of concomitant antibiotic use [32].

Conclusion

Secukinumab showed strong efficacy in Korean patients with moderate-to-severe hidradenitis suppurativa in real-world settings. Patients with Hurley stage III, longer treatment delays, or prior biologics use had slower and less pronounced responses than did those with stage II, shorter delays, or no biologics history. These findings highlight the benefits of early intervention. Continued treatment also significantly reduced the need for systemic antibiotics, suggesting secukinumab's potential to decrease antimicrobial dependence. Overall, secukinumab appears to be an effective option for HS, warranting further large-scale studies to validate these results and explore factors influencing treatment response for more personalized care.

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