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CURRENT OPINION

Defining Moderate Disease and Progression in Hidradenitis Suppurativa: An Expert Framework to Unlock the Window of Opportunity for Prompt Treatment

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Abstract

The concept of a therapeutic window of opportunity, defined as the period from symptom onset during which treatment initiation yields the most favorable patient outcomes, is applied in routine clinical practice across a range of inflammatory conditions. It has become an increasingly important area of interest in hidradenitis suppurativa (HS), a disease in which recurrent inflammation and accumulating damage can lead to irreversible destruction of skin architecture. Biologic therapies, aiming to suppress the inflammatory burden and prevent disease progression, are currently only permitted in moderate to severe HS. However, as there is no consensus definition of moderate disease, physicians may face uncertainty about when to consider or switch biologic therapy. To identify the boundaries of the window of opportunity within HS, global HS experts have developed frameworks for defining moderate HS and disease progression. It is proposed that prompt medical treatment should be administered to patients with moderate HS, defined as patients with inadequate control of HS symptoms on conventional therapies, or one inflamed skin tunnel (draining/non-draining), or four or more inflammatory lesions (including inflammatory nodules and abscesses) involving two or more anatomic areas. Furthermore, the proposed definition for disease progression is the development of one or more new tunnel(s) and/or the extension of existing tunnels, or development of one or more persistent HS lesions in an anatomical region not previously affected, or any increase in the number of persistent HS lesions in an affected anatomical region. The proposed frameworks aim to provide practical advice to physicians and support targeting the window of opportunity during routine clinical practice.

1 Introduction

Hidradenitis suppurativa (HS) is a chronic, systemic, inflammatory disease characterized by painful skin lesions including deep-seated nodules, abscesses, and draining tunnels in the axillary, inguinal, genitoanal, or inframammary areas [1–6]. As HS is an inherently progressive disease, persistent inflammation and accumulating damage over time leads to irreversible destruction of the skin architecture, formation of dermal tunnels, and extensive scarring [3, 7]. This damage significantly contributes to the considerable negative impact HS has on all facets of a patient's life [3]. HS results in the impairment of workplace functioning for patients, leading to high rates of unemployment, and is therefore associated with a substantial financial burden for both patients and healthcare systems [8, 9].

Despite the relatively high prevalence of HS, affecting ~1% of the global population, it remains an underrecognized condition that is frequently misdiagnosed or overlooked [7, 10, 11]. Patients with HS experience substantial delays in diagnosis, that is, an average delay of 7–10 years, with fragmented care, suboptimal or inappropriate treatments, and disease progression during this time [9, 12, 13]. Due to the progressive nature of HS, delays in diagnosis and subsequent treatment are associated with a greater disease severity and overall disease burden. These observations are consistent with the increasingly important concept of the window of opportunity [12–15], whereby patients with a significant delay in treatment may be at a greater risk of experiencing irreversible sequelae [3, 16] and detrimental impacts to patient quality of life (QoL) and workplace functioning [3, 8, 9].

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Key Points

The concept of a therapeutic window of opportunity in hidradenitis suppurativa (HS) aims to prevent irreversible damage due to the condition's progressive nature. In order to support healthcare professionals targeting this therapeutic window, a group of global experts in HS management have developed framework definitions for moderate HS and disease progression.

It is proposed that the initiation of targeted medical treatment such as biologic therapy should be considered for patients with moderate HS, defined as inadequate control of HS symptoms on conventional therapies, or one inflamed skin tunnel (draining or non-draining), or at least four inflammatory lesions (including inflammatory nodules and abscesses) involving at least two anatomic areas.

The proposed definition for disease progression is the development of one or more new tunnel(s) and/or the extension of existing tunnels, or development of one or more persistent HS lesions in an anatomical area not previously affected, or any increase in the number of persistent HS lesions in an affected anatomical region.

In recent years, the HS disease paradigm has been radically altered by the emergence of targeted therapies with the potential to modulate immune mechanisms underlying the pathophysiology of HS.[17, 18]. Currently, there are three biologic therapies approved by the European Medicines Agency and United States Food and Drug Administration for the treatment of moderate to severe HS: adalimumab (anti-tumor necrosis factor alpha [anti-TNFα]), secukinumab (anti-interleukin-17 [anti-IL-17A]), and bimekizumab (anti-IL-17A and F) [17, 19, 20]. However, real-world data have shown the limited use of biologic therapy in the daily clinical management of HS [21–24].

While current treatment guidelines strongly recommend the use of biologics in moderate to severe HS [19], no clear direction is provided for physicians regarding when to initiate biologic therapy. This is partly due to the lack of a consensus definition for moderate disease, the earliest timepoint at which a biologic may be administered [19]. Furthermore, the current HS guidelines provide few instructions on identifying disease progression or on proactively managing progression with medical and surgical interventions [19].

Therefore, both patients with HS and their treating physicians may benefit from practical definitions of moderate disease and disease progression, which can inform partnered decision-making on appropriate and timely treatment with robust evidence for efficacy and safety. Herein, we provide expert-led frameworks to identify moderate disease and progression in patients with HS to support optimization of medical management and patient outcomes within the window of opportunity.

2 Window of Opportunity Concept

The window of opportunity is a concept that has been investigated and applied in clinical practice across a range of autoimmune and autoinflammatory diseases that cause tissue destruction (e.g., discoid lupus erythematosus, rheumatoid arthritis, axial spondyloarthritis, and Crohn's disease) [25–33]. The window of opportunity in these conditions is generally defined as beginning from the period of either symptom onset or diagnosis during which treatment initiation yields the most favorable results by altering long-term disease outcomes and preventing irreversible damage [14, 25–33]. When patients begin to progress beyond this window (at the onset of irreversible damage), physicians must refocus management to limit further damage for patients [34]. In recent years, the window of opportunity has become an increasingly significant area of interest in HS (Fig. 1) [14, 35].

3 Window of Opportunity and Hidradenitis Suppurativa

A key assumption of the window of opportunity in HS is that patients who do not receive timely and appropriate intervention will progress to more severe disease with irreversible damage [35]. In fact, while clinically validated biomarkers for HS are yet to be defined [7, 36, 37], diagnostic/therapeutic delays and patients' baseline disease severity demonstrate strong inverse correlations with clinical responses to biologic treatment [15].

These correlations were first observed in a real-world retrospective study of Italian dermatology centers where therapeutic delay (≥10 years) was demonstrated as a significant risk factor for nonresponse, as measured by an HS clinical response (HiSCR50; ≥50% reduction in the total count of abscesses and inflammatory nodules from baseline, without any increase in abscesses or draining tunnels) after both 16 and 52 weeks of adalimumab treatment [15]. Emerging data suggest that these observations are not exclusive to adalimumab.

A recent post hoc analysis of the BE-HEARD EXT-1 and BE-HEARD EXT-2 studies revealed that a greater proportion of patients with a shorter disease duration (< 2.38 years) at baseline achieved HiSCR50, including higher threshold responses (e.g., HiSCR75), after 2 years

of continuous treatment with bimekizumab compared to those with a longer disease duration (≥ 10.74 years) [38]. Similarly, data from a real-world evidence study showed that a shorter disease duration was associated with a greater International Hidradenitis Suppurativa Severity Scoring System (IHS4) response (IHS4-55; ≥55% improvement in patients' IHS4 total score from baseline) after 24 weeks of secukinumab treatment [39]. Furthermore, a pooled analysis of the SUNSHINE and SUNRISE studies showed greater clinical responses to secukinumab treatment at weeks 16 and 52 in patients without draining tunnels at baseline than in those with one or more draining tunnel [40]. In a similar post hoc analysis, lesser extent of disease at baseline, as measured by Hurley staging, was associated with improved clinical responses to secukinumab treatment at week 16 [41].

Notably, biologics provide significant benefits to patients through reduced lesion counts, improvements in QoL, and reduced requirement for acute episodic interventions and invasive surgeries, irrespective of baseline disease duration and treatment delay [42–44]. However, the window of opportunity indicates that the ceiling for these treatment outcomes is inherently dependent on baseline disease activity and accrued damage [41].

4 Framework Development Process

This framework was initiated based on the gap identified from the literature for expert guidance on how to target the window of opportunity or to identify disease progression in HS. The initiative was driven by a group of ten leading researchers investigating the clinical applicability of a window of opportunity within HS and was supported by two subject matter experts from Novartis Pharma AG. The expertise of this group spans multiple geographies including the European Union, the United Kingdom, North America, and Australia. Over a series of virtual meetings, the definitions were developed in an iterative manner until full agreement was met by all authors.

5 Prompt Treatment of Moderate HS

5.1 Framework

Despite the evidence supporting the benefits of timely biologic treatment in patients with HS, physicians lack guidance on how to target the window in which the benefits of biologic treatment may be optimized. To address this gap, a framework definition was developed for outlining the lower boundaries of moderate disease in HS and, as such, provide a threshold for initiating treatment with targeted therapies

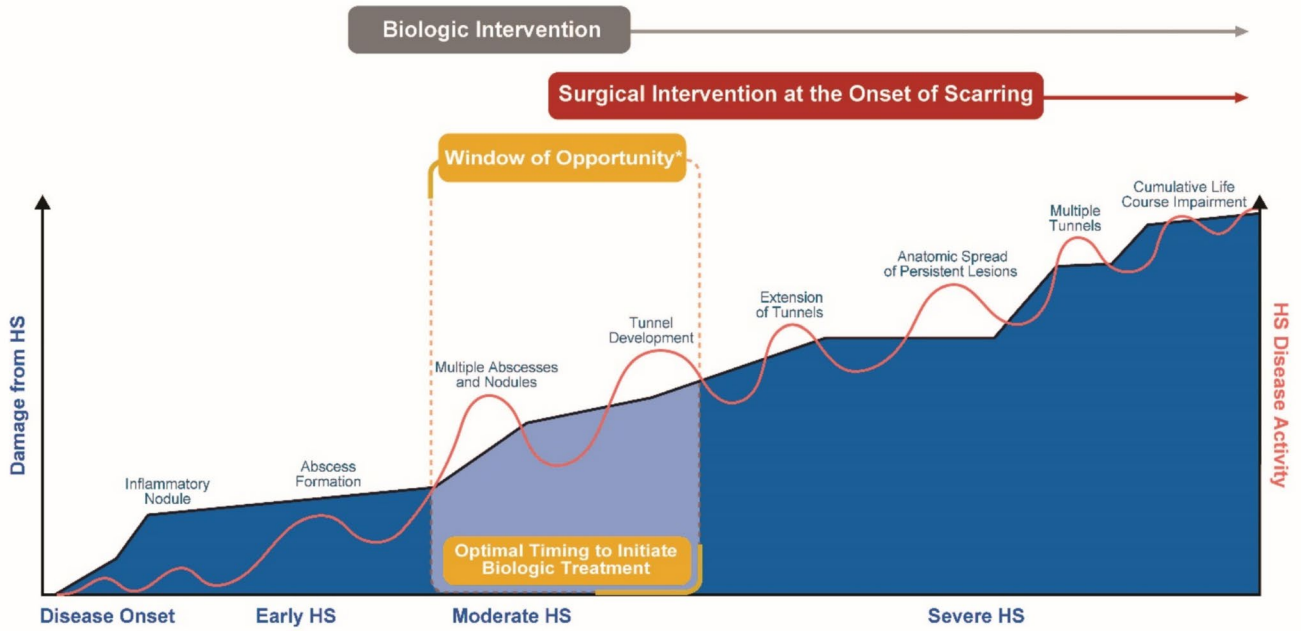

Fig. 1 Schematic of the window of opportunity in HS. This is adapted from a figure published in Actas Dermosifiliogr, 107, Martorell A, Caballero A, González Lama Y, Jiménez-Gallo D, Lázaro Serrano M, Miranda J, Pascual JC, Salgado-Boquete L, Marín-Jiménez I, Management of patients with hidradenitis suppurativa, 32–42, Copyright Elsevier (2016) [14, 35]. *HS* hidradenitis suppurativa

within the window of opportunity. The full definition and the rationale for each clause included are outlined in Table 1.

5.2 Considerations for the Use of the Framework

Physicians should refer to the framework definition when evaluating patients and should incorporate these considerations into their routine clinical practice. For example, Fig. 2 shows the clinical representation of a patient with HS who presented with an active tunnel, thus meeting clause 1 of the framework for moderate HS. Dermal tunnels are a unique feature of HS and are indicative of significant underlying inflammation and disease progression [51]. At the discretion of the treating physician, such patients require prompt disease control through the use of biologics or surgical interventions.

Figure 3 shows the clinical representation of a patient with more than four inflammatory lesions affecting the inguinal and axilla regions. This clinical presentation meets clause 3 of the framework for moderate HS. It should be noted that patients with bilateral lesions (e.g., a patient presenting with four inflammatory lesions across the left and right buttocks) would also meet the criteria for clause 3 of the framework.

The authors also advise physicians to consider the fluctuating and progressive nature of HS when applying this framework in clinical practice. Patients may not reach the threshold for moderate disease at an initial visit but may then rapidly progress in the subsequent weeks. Patient-reported histories should also be considered given the waxing and waning nature of the disease (e.g., a patient may present with few lesions at the time of an assessment but may report activity at most times that would clearly suggest moderate to severe disease severity). Physicians should aim to identify patients at risk of rapid progression and monitor patients accordingly. Follow-up appointments should be scheduled within 12−16 weeks for patients approaching the criteria for moderate disease or who are starting treatment with conventional therapies (e.g., antibiotics). Patients should be encouraged to contact their physicians in case of the emergence of any symptoms of progressive disease.

A limitation of the current framework is the lack of specific patient-reported components to the proposed definition. While no criterion in the definition is associated with specific patient-reported outcomes (e.g., Dermatology Life Quality Index, HS QoL [HiSQoL] score, and skin pain Numeric Rating Scale), physicians may utilize the

Table 1 Framework for defining moderate HS and supporting the rationale

Moderate HS	
Patients with inadequate control of HS symptoms on conventional therapies OR One active tunnel (draining or non-draining) OR At least four inflammatory lesions (inclusive of inflammatory nodules and abscesses) involving at least two anatomic areas	
Definition clause	Rationale
Inadequate control of HS symptoms	•Supported by findings from RWE studies examining the therapeutic burden of patients with HS. The therapeutic burden of HS relates to the overall impact of previous systemic treatments and surgical interventions on the lives of patients. Patients with a higher therapeutic burden are more likely to have experienced disease progression while receiving treatment(s), which afforded inadequate control of symptoms. Studies have indicated that biologic treatment outcomes are inversely associated with a patient's therapeutic burden [11, 45]
One active tunnel (draining or non-draining)	•Aligns with the IHS4 definition of moderate disease (presence of a draining tunnel is scored 4, indicative of moderate disease) [46, 47] •The inclusion of non-draining tunnels in this analysis allows for variation in tunnel inflammatory activity such that a tunnel can drain for a few days, followed by no drainage for a few days but with inflammatory activity still evident, reflected by the presence of pain or inflammatory signs [48, 49] •Among the recently described stages of the inflammatory tunnel identified through ultrasound, the dermal type A tunnel—which precedes the phase in which the tunnel begins to drain—shows the best response to medical treatment, due to the absence of epidermal damage at this stage [50]
Four inflammatory lesions	•Aligns with the IHS4 definition of moderate disease (presence of four inflammatory nodules gives a score of 4, indicative of moderate disease) [46, 47]
At least two anatomic areas	•Aligns with the inclusion criteria for the phase 3 clinical programs for biologics approved for use in moderate to severe HS [43, 44]

HS hidradenitis suppurativa, *IHS4* International Hidradenitis Suppurativa Severity Scoring System, *RWE* real-world evidence

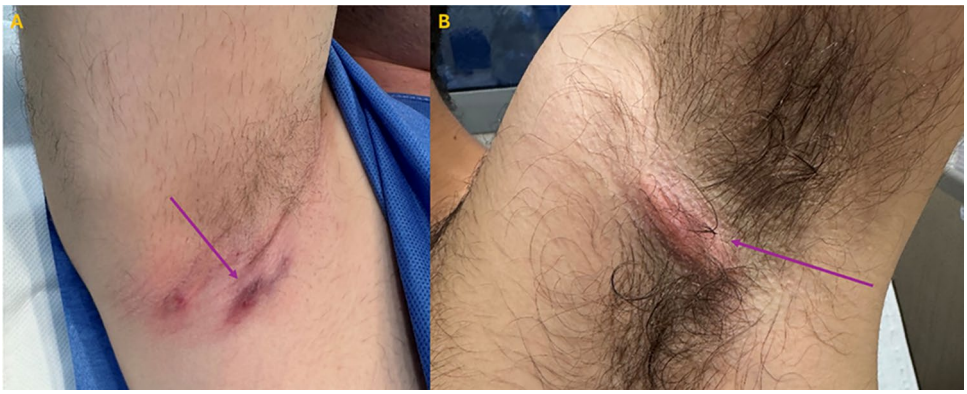

Fig. 2 Active draining tunnel (**a**) and non-draining tunnel (**b**). **a** Photograph of a draining tunnel in a 22-year-old male patient with disease onset 1 year earlier, considered as the inflammatory phenotype based on Martorell's phenotype model. Such draining tunnels are typified by openings within the skin that occasionally ooze fluid and may coalesce with numerous sub-dermal tunnels in the same body region [50, 52]. **b** Photograph of an active non-draining tunnel, defined by oblong shape with presence of erythema in absence of drainage (evidence of previous drainage), in a 29-year-old male patient who first developed HS 18 months earlier, considered as the inflammatory phenotype based on Martorell's phenotype model [52]. This form of dermal tunnel is generally nonscarring and represents the result of the coalescence of two or more abscesses that are located in the dermal layer with no connections with the epidermis and the subcutaneous fat tissue. *HS* hidradenitis suppurativa

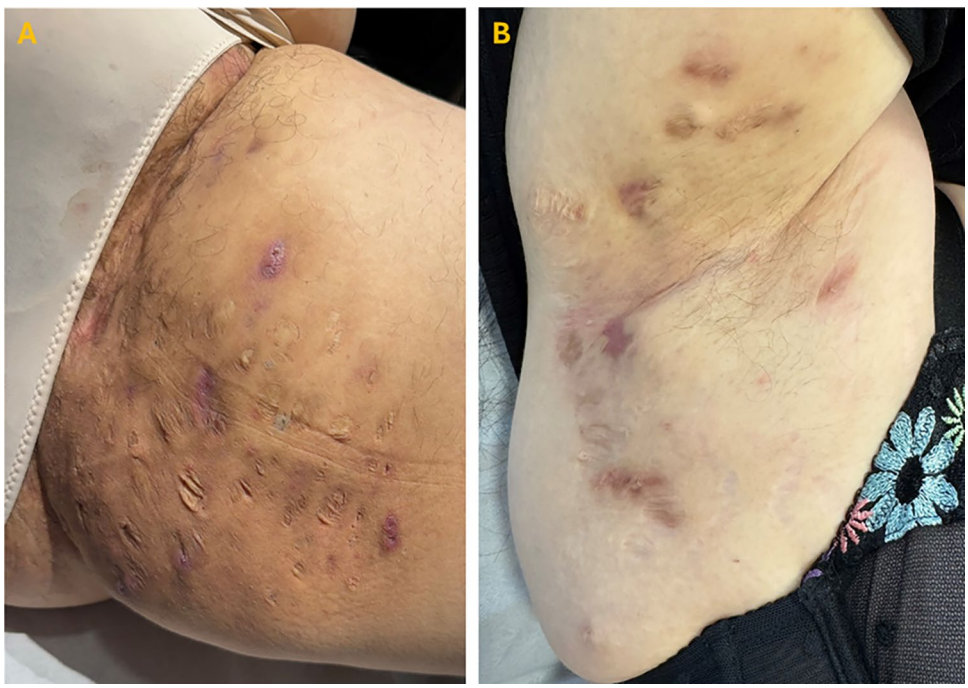

Fig. 3 Multiple inflammatory nodules in the inguinal (**a**) and axilla (**b**) regions. **a**, **b** The photographs show multiple inflammatory nodules in the inguinal and axilla regions of a 32-year-old female patient whose first onset of disease was 16 years ago, with a mixed phenotype based on Martorell's phenotype model [52]. The patient presents with residual scarring from persistent inflammatory lesions (inflammatory nodules and abscesses) despite the absence of tunnels (draining or non-draining).

"inadequate control of HS symptoms on conventional therapies" clause to justify the proactive management of patients whose QoL remains significantly impacted on their current treatment regimen despite not meeting the prescribed threshold based on lesion counts. In fact, thresholds for meaningful differences in the HiSQoL scoring system (e.g., mild, moderate, severe, and very severe) were recently described. Therefore, patients meeting moderate HiSQoL could be considered as fulfilling the criteria for clause 1 of the moderate disease framework [53].

6 Disease Progression in HS

6.1 Framework

A definition of disease progression in HS provides a framework for physicians to focus on limiting further irreversible damage to patients, with a possibility of reversing progression for some patients (Table 2) [34]. Additionally, while the window to prevent any irreversible damage may have

Table 2 Expert definition of disease progression in HS and supporting rationale

Disease progression in HS	
Disease progression in HS comprises:	
Development of one or more new tunnel(s) AND/OR extension of existing tunnels	
Development of one or more persistent HS lesions in an anatomical area not previously affected	
Any increase in the number of persistent HS lesions in an affected anatomical region	
Definition clause	Rationale
Development of new tunnel(s)	•Aligns with the IHS4 definition of moderate disease (presence of a draining tunnel is scored 4, indicative of moderate disease) [46, 47]
Extension of existing tunnels	•This worsening of existing draining tunnels represents an increasing burden of scarring that is likely to need more extensive surgical intervention [48]
New persistent HS lesions in a previously unaffected area	•Involvement of new skin regions demonstrates an increasing disease burden, for example, new functional impairment likely occurs when the disease previously localized to one axilla progresses to affect the groin [54, 55] •Persistence may be classified as the continuous presence of a lesion for 12−16 weeks aligning with the timelines proposed by the HiSTORIC group for persisting with biologic treatment [56]
Increase in persistent HS lesions in an affected area	•Aligns with the proposal from the HS UNITE registry in terms of Hurley stage progression in an affected body area and ensures that progressive disease, which remains localized to one body site, is still captured by the definition [55] •Persistence may be classified as the continuous presence of a lesion for 12−16 weeks aligning with the timelines proposed by the HiSTORIC group for persisting with biologic treatment [56]

HS hidradenitis suppurativa, *IHS4* International Hidradenitis Suppurativa Severity Scoring System

elapsed, patients may still urgently require proactive and aggressive management of their condition through targeted therapies and surgical interventions. More aggressive interventions may prevent damage to unaffected areas and mitigate further damage to areas with existing lesions, ensure effective symptom management, and improve patient QoL (e.g., reduced work impairment and improved work productivity).

6.2 Considerations for the Use of the Framework

Preventing and limiting permanent damage to the skin through scarring is a key aspect of HS management. To conserve the simplicity and clinical utility of the proposed framework, explicit guidance on hyperpigmentation and scarring as markers of disease progression has not been provided. However, it is important to note that the definition includes the development of new non-draining tunnels, or the extension of existing ones, to account for patients presenting with progressive scarring (indicating underlying uncontrolled inflammatory activity). The development of new lesions in the context of scarring between clinical visits, regardless of a flare or not, indicates inadequate disease control and the potential need for biologic and/or surgical intervention.

While treatment with biologics can provide rapid responses in patients with moderate to severe HS, some patients may experience a slower onset of response. As previously proposed by the HiSTORIC group [56], physicians should persist with biologic treatment for 12−16 weeks before assessing the treatment response and whether a change in the treatment approach is required (e.g., switch biologic therapy, surgery). However, it is also important to note that the full depth of treatment response with biologics may not occur until >16 weeks after biologic initiation.

7 Conclusions

The framework definitions presented herein aim to fulfil a current unmet need for physicians, providing practical advice to support targeting the window of opportunity for the prompt treatment of moderate HS and potentially optimize patient outcomes and improve patient QoL in the long-term. Of note, these definitions are proposed for use in routine clinical practice rather than as validated definitions for clinical trials. The proposed definitions will provide a useful starting point for future real-world studies investigating the potential impact of interventions with targeted therapies on patient outcomes earlier in the disease course.

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Declarations

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Code Availability Not applicable.

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