Hidradenitis Suppurativa Scoring Systems: Can We Choose Just One?

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Interest in hidradenitis suppurativa (HS) has exploded in the last few years. A PubMed search of articles indexed for MEDLINE using the MeSH term *hidradenitis suppurativa* yielded more than 900 articles on HS since 1947, with a sharp increase in publications over the last few years and 119 articles published in 2015 alone. In addition to publications, we recently saw adalimumab become the first and only US Food and Drug Administration–approved treatment of moderate to severe HS.

With new treatment options and enthusiasm for HS, further attention needs to be paid to the scoring systems or outcome measures that clinicians use to grade HS severity and disease. Utilization of validated outcome measures allows for comparability between treatment effects, which is essential for clinical trials, meta-analyses, and monitoring of treatment response in daily clinical practice. Designing a scoring scale for any dermatologic disease is challenging; however, as we move forward with value-based reimbursement models, we likely will encounter quality reporting guidelines that mandate providers demonstrate the positive impact of treatment. Thus, scoring systems for HS, particularly ones that accurately assess this impact of treatment, are essential. For psoriasis, the physician global assessment (PGA) and psoriasis area and severity index are standard outcome measures of disease severity in clinical trials. The PGA also can be used in a clinical setting to longitudinally track patient treatment outcomes.[1] Both the psoriasis area and severity index and PGA were cited as acceptable scoring tools for Medicare's Physician Quality Reporting System quality metrics reporting (Measure #410: Psoriasis: Clinical Response to Oral Systemic or Biologic Medications). Unfortunately, no such outcome measures consensus currently exists for scoring systems in HS.

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Many scoring systems have been proposed for HS. The most well known is the Hurley staging system. Developed in 1989 for surgical approaches, it is a straightforward tool to categorize disease severity but does not emphasize the inflammatory component of HS. Recently, a refined Hurley stage classification system was proposed. This 3-step algorithm expanded the Hurley stage classification to incorporate disease extensiveness, degree of inflammation, and presence of sinus tracts.[2] The modified Sartorius score (also known as the modified HS score) is a more detailed scoring system for assessing disease activity that requires measurements and precise counting of lesions.[3] The HS-PGA is an ordinal scale specific to HS that categorizes patients into clear, minimal, mild, moderate, severe, or very severe disease, and it was used successfully in a phase 2 interventional clinical trial.[4] The HS clinical response (HiSCR) score is an HS-specific, binary scoring system for patients with 3 or more abscesses or inflammatory nodules. It was engineered using raw data and outcomes from a large clinical trial, and subsequently was employed as the primary end point in 2 randomized controlled trials.[5,6] It is the only HS scoring system to undergo an extensive validation process of both physician- and patient-reported measures for assessment of therapeutic response in controlling the inflammatory manifestations of HS.

Designing a scoring system for clinical trials can be complicated. Sample sizes are dependent on the delta, or change, in efficacy or variation in response, and the design of the score will affect how easy it is to detect a statistically meaningful difference. These choices are a critical part of the design of small studies, particularly if obtaining enough statistical power can be challenging. Additionally, it is easier to detect change in more homogenous populations where we expect a more consistent response. Hidradenitis suppurativa is not a particularly homogenous disease, which furthers the risk of designing a trial that cannot detect important differences. The PGA often is required by the US Food and Drug Administration and has the major advantage that it is easy to understand, but the categories can sometimes be too broad

to detect change easily, and more granular data can provide the basis for more in-depth analyses. An ideal outcome measure is a simplified scoring system that assesses disease severity and responsiveness to treatment while accurately serving as a surrogate for patient-reported outcomes, such as the dermatology life quality index, visual analog scale for HS skin pain, the work productivity and activity impairment questionnaire (specific health problem), or the patient global assessment. Validation processes for outcome measures, such as the one that HiSCR underwent, are essential to ensure that the proposed scoring system has clinical meaningfulness to both the physician and patient.

A 2016 Cochrane review of interventions for HS included 12 randomized controlled trials that employed a total of 30 different outcome measures instruments. Because use of multiple scoring systems makes it difficult to compare analyses of treatment, the authors concluded that there was a need for improved validation of HS outcome measures for future clinical trials.[7] Schmitt et al[8] recognized that atopic dermatitis also was in a similar predicament; they noted that more than 20 outcome measures were employed to assess disease severity in clinical trials. The authors called this situation "a significant threat to evidence-based health care" and outlined the Harmonizing Outcome Measures for Eczema (HOME) research initiative's methodology for creation of core outcome sets for any dermatologic disease. Their consensus process involved first identifying what to measure, termed *outcome domains*, followed by developing how to measure these domains through outcome measures instruments, which would be assessed for validity, reliability, sensitivity to change, and feasibility.[8]

Using the framework set forth by the HOME initiative and data from the 2016 Cochrane review,[7] a recent review of all outcome measures instruments currently employed in HS found that 90% (27/30) were not validated.[9] Even those that were validated still could not be fully recommended by the authors. The authors identified 10 potential outcome domains for measurement, including quality of life, pain, lesion count, PGA, patient global self-assessment, recurrence rate, overall satisfaction with treatment, impairment of function, cosmesis, and duration of recovery. They recommended a further consensus process to better define these outcomes.[9]

Measuring all of these variables seems daunting, but as the speed of HS research rapidly progresses, we would greatly benefit from employing a standard validated scoring system that captures both disease severity and activity. Several groups are working to improve our current tools, but we will need to move quickly to a common approach so we can better compare treatment effects and build an evidence base for treatment decisions. For now, the HiSCR is the most validated clinical trials instrument, but it may not be ideal for the clinical setting. In our practice, we grade all patients each visit with Hurley staging, the validated HS-PGA scoring system to track improvement in inflammatory lesions, and a 10-point pain scale to monitor disease activity and severity. We have found these tools to be quick and effective for measuring treatment response and would recommend employment of these scoring systems as a standard measure in clinical practice until further consensus is reached.

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