





ORIGINAL ARTICLE

Creation of a severity index for hidradenitis suppurativa that includes a validated quality-of-life measure: the HIDRAScore

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Abstract

Background Hidradenitis suppurativa (HS) is a chronic, debilitating disease with a considerable effect on patient quality of life. Its clinical severity can be measured using different scoring systems; however, few of them include patient-centred parameters.

Objective To create a new scoring system for HS that includes a quality-of-life instrument, the HIDRADisk.

Methods This post hoc analysis was carried out within the framework of a multicentre, longitudinal, epidemiologic study conducted over 9 months on quality-of-life aspects of HS. The new severity score was created using as reference a question from the Subject Satisfaction Questionnaire (SSQ) concerning the severity of HS as evaluated by the patient. Associated variables were selected using univariable and multivariable logistic regression models. The discriminant capabilities of the final model and of the final score were evaluated by the area under the receiver operating characteristic curve and the Hosmer–Lemeshow test.

Results The study population included 308 patients with HS of any severity grade. According to the results of the regression models, the variables associated with the reference SSQ measure were number of inflammatory nodules, abscesses and draining fistulas; the HIDRADisk score; and the number of subumbilical lesions. The HIDRAScore is obtained by the sum of the scores associated with the number of these parameters. Possible scores range from 0 to 10.

Conclusion The HIDRAScore is a new scoring system for HS severity which, in addition to the clinical evaluation by the physician, includes a validated patient-reported outcome measure, the HIDRADisk.

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Conflicts of interest

A. Chiricozzi has been scientific consultant, advisory board member and/or clinical study investigator for AbbVie, Biogen, Eli Lilly, Janssen, Leo-Pharma, Novartis, Sanofi Genzyme and UCB Pharma and speaker for Eli Lilly, Janssen, AbbVie, Leo-Pharma and Novartis. A. Offidani has served as a speaker, advisory board member and/or consultant for AbbVie,

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Pfizer, Novartis, Eli Lilly, Galderma and Celgene. V. Bettoli has served as speaker, advisory board member and consultant for Galderma, Biogen, AbbVie, Mylan and Difa Cooper. L. Bianchi has served as speaker and advisory board member for Biogen, AbbVie, Difa Cooper, Pfizer, Janssen, UCB Pharma, Novartis, Eli Lilly and Leo-Pharma. F. Prignano has been speaker, advisory board member and/or consultant for Abiogen-Pharma, Abbvie, Eli-Lilly, Novartis, Leo-Pharma and Janssen-Cilag. P. Dapavo declares conflicts of interests with Novartis, Lilly, Abbvie, Janssen and Celgene. G. Gualberti and V. Saragaglia are AbbVie employees and may own stocks/options. A.V. Marzano, G. Giovanardi, G. Fabbrocini, F. Rongioletti, C. Potenza, V. Dini G. Micali and G. Argenziano declare no conflicts of interests.

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Introduction

Hidradenitis suppurativa/acne inversa (HS) is a chronic, inflammatory, recurrent, debilitating skin disease of the hair follicle that usually presents after puberty with painful, deep-seated, inflamed lesions in the apocrine gland-bearing areas of the body, most commonly the axillae, inguinal and anogenital regions (Dessau definition).¹ Considerable efforts have been made to find a measure that can clinically describe HS severity in patients. The first two clinical severity measures were based on clinical features: the Hurley staging system² assessed the presence and severity of abscesses, sinus tracts and scarring; the Sartorius score³ assessed the region involved, number and score of lesions, and distance between lesions. The Hidradenitis Suppurativa Physician's Global Assessment scale (HS-PGA)⁴ categorized HS into six degrees of progressive severity (clear, minimal, mild, moderate, severe or very severe) based on number of nodules, abscesses and fistulae. Since it was observed that these clinical measures may not be optimal in assessing treatment effectiveness, the Hidradenitis Suppurativa Clinical Response (HiSCR)⁵ was developed to evaluate clinical response in patients with HS. This instrument is exclusively designed for assessing treatment response, based on reduction of inflammatory nodules and abscesses, but not to evaluate disease severity cross-sectionally. The attempt to introduce a novel tool that could be easily used in clinical practice led to the creation of the International HS Severity Score System (IHS4),⁶ the result of a simple algorithm that included number of nodules, abscesses and fistulae/sinuses. In order to add a patient-reported outcome to IHS4, the authors tested the inclusion of DLQI but it was found to limit the performance of the score; therefore, they limited it to only the clinical evaluation.⁶ All these scorings systems are useful, but not ideal, and possible combinations have been suggested: Porter and Kimball⁷ proposed using Hurley staging to assess severity at each visit, the validated HS-PGA scoring system to track improvement in inflammatory lesions and a 10-point pain scale to monitor disease activity and severity. However, both Hurley and HS-PGA are

static tools, poorly accurate in detecting subtle changes in disease severity and treatment effectiveness, particularly in severe–very severe HS patients.

Besides the complexity of such an approach, all these tools are based only on physician-assessed clinical parameters and lack a patient-centred measure able to evaluate the overall burden of HS on patient quality of life.^{8,9} A recent review on outcome measures in HS studies¹⁰ has identified 10 potential efficacy outcome measure domains: quality of life, pain, lesion count, physician global assessment, patient global self-assessment, recurrence rate, overall satisfaction with treatment, impairment of function, cosmesis and duration of recovery. A recently developed HS severity score, the Severity Assessment of Hidradenitis Suppurativa (SAHS) score,¹¹ includes two patient-reported outcomes: the number of new boils or number of existing boils that flared up during the past 4 weeks and the assessment of current severity of pain of the most symptomatic lesion in the course of the patient's daily activities (e.g. sitting, moving or working), which are ranked on a numerical rating scale. Recently, a clinical severity measure has been proposed, the Acne Inversa Severity Index (AISI),¹² which includes a subjective parameter [a 0–10 visual analog scale (VAS)] to assess a patient's pain, discomfort and disability due to HS. However, a wholesome patient-reported measure of quality of life would be an important outcome measure in the assessment of HS.

In line with this unmet need, we aimed to define a novel integrated tool, HIDRAscore. Along with the clinical variables considered critical to assess disease severity according to experts in HS research, this tool includes a specific quality-of-life instrument, the HIDRADisk,¹³ which covers several aspects of the effect of HS on patients in a comprehensive clinical severity and quality-of-life measure.

Patients and methods

Study design

This was a retrospective analysis of a database (HIDRADisk study 11081, AbbVie srl, Italy) from a multicentre, longitudinal,

observational study that was conducted over 9 months in three visits on the quality of life in patients with HS. The HIDRADisk study has been approved by local Ethics Committees according to Italian regulations. The first EC approval was on 19Apr2016, from the Ethical Committee of the district of Brescia (approval n. NP2367).

Study population

The study population included patients with a diagnosis of HS, according to S1 European Guidelines,¹ of any severity assessed with Hurley and HS-PGA scores. Before any study-related activity, each patient provided written informed consent for participation in the study and for personal data processing in accordance with local regulations. Inclusion criteria were age ≥ 18 years, a diagnosis of HS (according to S1 European guidelines¹) of any grade ≥ 6 months before study entry and the ability to understand and complete study-related questionnaires, according to the physician's judgement. Patients were excluded in case of concomitant malignancies or any other condition that, in the physician's opinion, could affect a patient's quality of life; any relevant psychiatric comorbidities (e.g. severe depression, bipolar disorder, schizophrenia, either treated or untreated); and current participation in interventional studies for HS.

Collected data

For each patient who met the inclusion criteria, the physician collected the following data: age, sex, race, educational level, marital status, weight, height, smoking status and alcohol consumption. For each patient, the clinicians collected data on HS history and affected body areas. Patients then completed different questionnaires; for the purpose of the present analysis, the HIDRADisk data were taken into account.¹³

HIDRADisk is a new questionnaire that evaluates quality of life in patients with HS. It is a visual instrument composed of a disc divided into 10 sections, each corresponding to one of the following items: skin, symptoms control, uneasiness/personality, sexuality, social life, work, daily activities, odour, general health and pain. Each item is scored from 0 (no impairment) to 10 (maximum impairment). The HIDRADisk has been recently validated in the Italian language for the use of the patient alone or along with the support of a dermatologist.¹⁴

Assessment of clinical severity

During the HIDRADisk study, disease severity was assessed through the Hurley stage and the HS-PGA score, while at 3- and 9-month visits disease improvement was defined by the HiSCR. The Hurley severity stage² is based on three clinical stages: solitary or multiple isolated abscess formation without scarring or sinus tracts (Stage 1); recurrent abscesses, single or multiple widely separated lesions, with sinus tract formation (Stage 2); and diffuse or broad involvement with multiple interconnected sinus tracts and abscesses (Stage 3). The HS-PGA⁴ score is

divided into the following six categories: clear (no abscesses, draining fistulas, inflammatory nodules or non-inflammatory nodules), minimal (no abscesses, draining fistulas or inflammatory nodules, but with the presence of non-inflammatory nodules), mild (no abscesses or draining fistulas, 1–4 inflammatory nodules or 1 abscess or draining fistulas, and no inflammatory nodules), moderate (no abscesses or draining fistulas, ≥ 5 inflammatory nodules or 1 abscess or draining fistulas, ≥ 1 inflammatory nodules or 2–5 abscesses or draining fistulas and < 10 inflammatory nodules), severe (2–5 abscesses or draining fistulas and ≥ 10 inflammatory nodules) and very severe (> 5 abscesses or draining fistulas).

The HiSCR^{4,13} was adopted to evaluate the changes over time in the status of abscesses, inflammatory nodules and draining fistulas to identify responders to treatment (i.e. patients with $\geq 50\%$ reduction in baseline abscess and inflammatory nodule count, with no increase in abscess count and no increase in draining fistula count relative to baseline).

Patient's severity assessment

The Subject Satisfaction Questionnaire is a self-administered, six-question survey created ad hoc for the HIDRADisk study to evaluate patient perception of the disease and use of the HIDRADisk instrument. One of the questions was used as an assessment of HS severity from the patient's point of view: 'When compared with your total experience with HS, how would you describe the severity of your condition today?' Possible answers ranged from very mild to very high.

Time points

Data were collected at baseline, after about 3 months and after about 9 months; the two latter time points were performed depending on the patient's planned visit as per clinical routine practice.

Statistical analysis visit

Categorical variables were recorded as counts and percentages, and continuous variables were recorded as mean and standard deviation or median and interquartile range. To create a new instrument able to measure clinical severity of HS, taking into account each patient's subjective aspects, it was decided to use as the gold standard (GS) the question 'When compared with your total experience with HS, how would you describe the severity of your condition today?' of the Subject Perception Questionnaire used in the HIDRADisk validation study. Based on the patients' response to the question at baseline, patients were grouped into two categories representing those with low versus high severity. Patients in group GS(0) responded 'very mild' and 'mild'; those in GS(1) responded 'fair,' 'high' and 'very high'.

The association of clinical variables (i.e. the number of inflammatory nodules, draining fistulas and abscesses and the presence or absence of lesions in subumbilical area) and of the HIDRADisk score of the patients with GS outcomes was

Table 1 Description of the study population at baseline

Variable	
Sex, <i>n</i> (%)	
Male	135 (43.8)
Female	173 (56.2)
Smoking habits, <i>n</i> (%)	
Smoker	204 (66.2)
Never smoked	79 (25.7)
Ex-smoker (since > 6 months)	25 (8.1)
Duration of HS, <i>n</i> (%)	
<5 years	235 (76.3)
5–<14 years	54 (17.5)
≥14 years	19 (6.2)
Body mass index, <i>n</i> (%)	
<23	67 (21.8)
23–<25	53 (17.2)
25–<30	99 (32.1)
≥30	89 (28.9)
Hurley stage, <i>n</i> (%)	
1	90 (29.5)
2	134 (43.9)
3	81 (26.6)
HS-PGA, <i>n</i> (%)	
Clear	7 (2.3)
Minimal	5 (1.6)
Mild	72 (23.4)
Moderate	176 (57.1)
Severe	21 (6.8)
Very severe	27 (8.8)
Localization of lesions, <i>n</i> (%)	
Face/neck	20 (6.5)
Left axillae	162 (52.6)
Right axillae	157 (51.0)
Left breast	55 (17.9)
Right breast	56 (18.2)
Trunk	73 (23.7)
Left groin	156 (50.6)
Right groin	153 (49.7)
Left gluteus	87 (28.2)
Right gluteus	84 (27.3)
Genital area	89 (28.9)
Perineal area	89 (28.9)
Comorbidities, <i>n</i> (%)	
Hypertension	17 (5.5)
Dyslipidaemia	10 (3.2)
Obesity	35 (11.4)
Diabetes	7 (2.3)
Crohn disease	5 (1.6)
Age, years, median (IQR)	32 (24–44)
Time from onset, years, median (IQR)	8.3 (4.2–15.9)
Time from diagnosis, years, median (IQR)	1.8 (0.9–4.7)
Number of flares in the last year, median (IQR)	5 (3–12)
Number of inflammatory nodules, median (IQR)	4 (2–6)
Number of abscesses, median (IQR)	1 (0–2)

Table 1 *Continued*

Variable	
Number of draining fistulas, median (IQR)	1 (0–2)
HIDRADisk QoL score at visit 1, median (IQR)	73 (54.0–85.5)

HS, hidradenitis suppurativa; HS-PGA, Hidradenitis Suppurativa Physician's Global Assessment scale; IQR, interquartile range; QoL, quality of life.

evaluated using a multivariable logistic regression model, with stepwise procedure and threshold $P = 0.20$, with GS as the dependent variable. This procedure allows the exclusion of variables that are not associated with the outcome measure at a given significance level. To have numerically homogeneous groups, the clinical variables and HIDRADisk values were initially categorized on the basis of the quintile values. Then, contiguous quintiles were grouped when the estimated log-odds parameters were similar (difference < 20%) and the goodness of fit was not significantly changing (i.e. log-likelihood ratio test was not significant between nested models). The discriminant capability of the final model was evaluated by the area under the receiver operating characteristic curve (AUC ROC) and the Hosmer–Lemeshow test for the goodness of fit. The regression coefficients obtained in the final model were then used to calculate the scores associated with each patient for each variable by dividing each coefficient by the lowest one.¹⁵ At this step, the highest possible total score, summing the highest contribution score for each variable, was equal to 11.3. Therefore, all contribution scores were repropportionated and rounded to the closest integer to provide a total score of ten as the highest possible.

The final score (thereafter named HIDRAscore) for each patient was calculated as the sum of the single scores of the characteristics of each variable, and its discriminant capability was tested again by the AUC ROC. For each score cut-off, the sensitivity and specificity of the new measure were analysed.

The HIDRAscore was then applied to data from visits 2 (3 months after visit 1) and 3 (9 months after visit 1) to verify sensibility to change and reliability: mean values were then compared at different time points and in relation to the other clinical severity indexes, Hurley and HS-PGA.

Results

The study population included 308 HS patients at baseline, 291 patients (94.5%) at 3 months and 253 patients (82.1%) at 9 months. Demographic and clinical characteristics are described in Table 1. The mean age was 35.2 years, and 56.2% were women. More than 70% of patients had a high school or university education, 60.4% were single, and 66.2% were smokers. Lesions were localized in the axillae and groin in >50% of patients. The most frequent comorbidity was obesity (11.4%). The mean time from onset was 11.4 years, and the mean time from diagnosis was 3.9 years. Most patients (70%) had a Hurley

stage of 2 or 3. The mean \pm SD HIDRADisk score was 65.7 ± 23.3 .

At visit 1, the category GS(0) (according to the selected response 'very mild' and 'mild') included 49 patients (15.9%) and the category GS(1) ('fair,' 'high' and 'very high') was composed by the responses of 259 patients (84.1%). The variables that were significantly associated with the GS variable were the number of inflammatory nodules, number of draining fistulas, number of abscesses, presence of lesions in subumbilical area and HIDRADisk score. The resulting variables were grouped by amount (inflammatory nodules: 0–2, 3–5, ≥ 6 ; abscesses: 0, >0 ; draining fistulas: 0, >0 ; HIDRADisk: 0–20, >20 –60; >60 ; lower lesions: 0–2, >2). A logistic model in which the previous variables were included as continuous variables was developed, and it provided very similar results with a nearly identical AUC ROC curve.

In order to identify associated coefficients, we used a stepwise logistic regression model with the characteristics described above applied as independent variables and GS as the dependent variable, as shown in Table 2. All variables were significantly associated with GS at a threshold of $P < 0.2$. The area under the curve (AUC ROC) of the model was 0.88 (95% CI, 0.83–0.93), and the Hosmer–Lemeshow test was 0.885. On the basis of the coefficients obtained in the model, different scores were assigned to each category (Table 2) for the calculation of the HIDRAscore. The scores ranged from 0 to 10, with higher scores associated to higher severity of the disease. Compared with the GS measure, the HIDRAscore mean (\pm SD) value was 4.33 (± 2.21) for GS(0) and 7.39 (± 1.70) for GS(1). The predictive capability of the score was very good: AUC ROC was 0.88 (95% CI, 0.82–0.93) and Hosmer–Lemeshow test $P = 0.303$.

Sensitivity, specificity, the proportion of patients correctly classified and negative and positive predictive values are reported in Table 3 for each score cut-off. This table shows that, for example, for patients with a HIDRAscore of ≥ 5 , 90% will be correctly classified as GS(1) and for those with HIDRAscore < 5 , 75% will be correctly classified as GS(0).

The score calculated at baseline was then applied to data from the other visits obtaining, respectively, an AUC ROC (95% CI) of 0.79 (0.72–0.86) and 0.87 (0.82–0.92). The HIDRAscore also showed a good correlation with the other clinical severity measures (Table 4).

Discussion

HIDRAscore is a new instrument aimed at measuring severity of HS. Its innovation, compared with existing instruments, is the inclusion of an HS-specific measure to evaluate patient quality of life, the HIDRADisk.¹³ It has been shown that in chronic conditions, such as psoriasis, clinical severity measurements do not correlate well with quality-of-life measures.¹⁶ A condition that is clinically not severe (because it involves a small body surface area, for example) may have a strong impact on a patient's quality of life if the lesions are in visible part of the body or if they are particularly symptomatic. In HS, this aspect has been taken into account in three recent severity measures: the SAHS,¹¹ the AISI¹² and the IHS4.⁶ In the SAHS, patients are asked about the number of boils that flared up during the past 4 weeks and to rate current severity of pain of the most symptomatic lesion in the course of their daily activities (e.g. sitting, moving or working) on a numerical scale. In the AISI, a VAS was included to assess the patient's pain, discomfort and disability due to HS.

Table 2 Frequencies and percentages, adjusted estimated odds ratios and estimated partial scores of having a perception of a more severe HS (GS[1]) for the clinical characteristics considered

	<i>n</i>	GS(1), %	Odds Ratio	<i>P</i> > <i>z</i>	95% CI	Coefficients	Scores
Inflammatory nodules							
0–2 (ref)	107	68.2	1	–	–	0	0
3–5	100	89.0	3.23	0.009	1.35–7.75	1.17	1
≥ 6	101	96.0	8.49	0.002	2.19–32.85	2.14	2
Abscesses							
0 (ref)	128	71.1	1	–	–	0	0
≥ 1	180	93.3	2.15	0.076	0.92–5.00	0.76	1
Draining fistulas							
0 (ref)	148	73.0	1	–	–	0	0
≥ 1	160	94.4	2.59	0.041	1.04–6.46	0.95	1
HIDRADisk							
≤ 20 (ref)	13	15.4	1	–	–	0	0
21–60	94	76.6	21.09	0.002	2.99–148.92	3.05	4
> 60	201	92.0	51.94	0.000	7.29–369.95	3.95	5
Subumbilical lesions							
0–2 (ref)	204	77.9	1	–	–	0	0
> 2	104	96.2	2.28	0.164	0.71–7.26	0.82	1

GS(1), gold standard severity rating of fair, high or very high; HS, hidradenitis suppurativa; and ref, reference.

The IHS4 is a simplified score for assessing HS severity with few clinical signs, but when combined to DLQI, it failed to maintain accuracy.

In the search of a combination that fits both quality of life measures and HS severity, we assessed the classical clinical parameters as the number of inflammatory nodules, abscesses and draining fistulas, which are included in most of the existing clinical severity measures, and the new parameters of the HIDRADisk, HS-specific and validated quality-of-life assessment, and the number of subumbilical lesions.

The use of the HIDRADisk in our instrument adds more complete information on the effect of HS on patient quality of life. In fact, the HIDRADisk includes 10 specific aspects and thus gives a thorough evaluation of the psychosocial condition of the patient with HS. The idea of including a quality-of-life

questionnaire in a clinical severity measure was mentioned by Hessam and colleagues¹¹ in the paper on the creation of the SAHS. However, they recognized the limitations of implementing an instrument, such the Dermatology Life Quality Index (DLQI), in a scoring system, especially because it was not designed specifically for HS.

Lesions in the subumbilical area (i.e. groin–genital and gluteal areas) are particularly severe, both for the high impact on quality of life and unsuccessful response to treatment.¹⁷ Our data confirm that the presence of more than two subumbilical lesions is associated to the patient perception of a more severe HS, sustaining the weight of localization of the lesions in the overall burden of this disease.

To create an instrument that was as patient-centred as possible, we chose as the GS a question from the Subject Perception

Table 3 Sensitivity, specificity, proportion of patients correctly classified, positive predictive value and negative predictive value for each cut-off of the HIDRADisk

Cut-off HIDRADisk	Sensitivity, %	Specificity, %	Correctly classified, %	Predictive value, %	
				Positive	Negative
≥1	99.61	10.20	85.39	85.43	83.33
≥2	99.61	16.33	86.36	86.29	88.89
≥4	99.23	20.41	86.69	86.82	83.33
≥5	97.30	44.90	88.96	90.32	75.86
≥6	84.94	73.47	83.12	94.42	48.00
≥7	70.66	89.80	73.70	97.34	36.67
≥8	49.42	95.92	56.82	98.46	26.40
≥9	26.25	97.96	37.66	98.55	20.08

A cut-off ≥3 was not examined because present in only 2 cases, included in the previous category.

Table 4 Mean (SD) HIDRADisk for different levels of clinical severity measures

	Visit 1 HIDRADisk			Visit 2 HIDRADisk			Visit 3 HIDRADisk		
	n	Mean	SD	n	Mean	SD	n	Mean	SD
GS(0)	49	4.33	2.21	59	4.39	2.27	57	3.00	2.28
GS(1)	259	7.39	1.70	226	6.64	1.98	185	6.29	1.92
Hurley staging									
1	90	5.27	1.93	101	4.77	1.73	84	3.75	2.14
2	134	7.07	1.71	117	6.42	1.82	109	5.98	1.93
3	81	8.53	1.48	60	8.48	1.32	42	7.9	1.79
HS-PGA									
Clear/minimal	12	4.25	1.48	31	3.52	1.93	43	2.93	2.05
Mild	72	4.69	1.80	89	4.74	1.56	85	4.36	1.90
Moderate	176	7.38	1.40	141	7.03	1.59	101	6.59	1.91
Severe/very severe	48	9.17	1.02	29	8.97	1.30	21	8.67	1.32
HiSCR†									
Not achieved	–	–	–	174	7.10	1.82	119	6.55	2.21
Achieved	–	–	–	97	4.85	2.04	116	4.35	2.38

GS(0), gold standard severity rating of very mild or mild; GS(1), gold standard severity rating of fair, high or very high; HiSCR, Hidradenitis Suppurativa Clinical Response; and HS-PGA, Hidradenitis Suppurativa Physician's Global Assessment scale.

†Patients who achieved response had a ≥50% reduction in baseline abscess and inflammatory nodule count, with no increase in abscess count and no increase in draining fistula count relative to baseline.

Questionnaire. The question asks about the 'severity' of the patient's HS, and we used it as a proxy for the evaluation of clinical severity by the patient.

It is imperative to take into account quality of life in the evaluation, management and care of patients with HS. In a recent review,¹⁸ it has been highlighted that the burden of disease of HS is often ranked as the highest among other common dermatoses.¹⁹ Specific aspects have been evaluated, such as difficulties in sex life, which was reported by 66.7% of patients with HS in a large study on the psychosocial effect of dermatological conditions.²⁰ This result was at least three times higher than the average for other dermatoses. In addition, the prevalence of depression in HS is estimated to be as high as 42.9%,²¹ and the risk of suicide 2.5 times higher among patients with HS compared with the general population.²²

The HIDRAScore, in addition to the objective clinical examination, requires the involvement of the patient, which is the basis of the HIDRADisk. Being part of the evaluation of one's own disease can improve the patient's communication with the physician, and good communication can increase patient compliance, a feeling of control over the disease, patient satisfaction and clinical treatment outcomes.^{23–25} In the next future, the authors wish to extend the use of this innovative score for HS severity with the support of a validation process in a large real-life cohort of patients.

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Author contribution

All authors participated in the score ideation, and in writing and approval of the publication.

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