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## **HIDRADisk: validation of an innovative visual tool to assess the burden of hidradenitis suppurativa**

HIDRADisk, the burden of hidradenitis suppurativa

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## Abstract

**Background:** Hidradenitis suppurativa (HS) is a chronic, relapsing, inflammatory skin disease characterized by painful inflamed nodules, recurrent abscesses, and fistulas located in apocrine gland-bearing body sites. The negative impact of HS on patient's quality of life (QoL) has been reported to be greater than other dermatologic conditions as psoriasis and atopic eczema, and its improvement is an important goal in disease management. Nowadays there are no specific validated QoL instruments available for HS and generic dermatologic questionnaires are used.

**Objective:** The objective of this study was to demonstrate the validity, reliability, and responsiveness of HIDRADisk, a new innovative tool designed for rapid assessment of HS burden and, at the same time, an intuitive graphic visualization of the measurement outcome.

**Methods:** A multicenter, longitudinal, observational study was conducted to validate the HIDRADisk compared with other validated questionnaires (Skindex-16, Dermatology Life Quality Index [DLQI], Work Productivity and Activity Impairment-General Health

[WPAI:GH]) and to evaluate its correlation with disease severity in Italian patients with any degree of HS severity, as measured by Hurley stage and HS Physician Global Assessment (HS-PGA).

**Results:** 140 patients (59% women; mean age 34.9±11.0 years) were enrolled in 27 dermatologic centers. HIDRADisk showed a strong correlation with Skindex-16 and DLQI, and a good one with WPAI:GH (correlation coefficient: 0.7568, 0.6651, and 0.5947, respectively) and a statistically significant correlation with both Hurley stage and HS-PGA. Very good internal consistency (Cronbach coefficient >0.80; intraclass correlation coefficient >0.6), with correlation between the 10 items, good test–retest reliability (Spearman correlation coefficient, 0.8331;  $p<0.0001$ ), and responsiveness to changes were demonstrated.

**Conclusion:** Our study shows that HIDRADisk, a short and innovative visual HS QoL instrument, has been psychometrically validated in Italian language and it may help improve the management of HS once implemented in routine clinical practice.

**Keywords:** Hidradenitis Suppurativa, Validation study, Quality of Life, Visual tool, HIDRADisk

## Introduction

Hidradenitis suppurativa (HS) is a chronic, relapsing, inflammatory skin disease clinically characterized by painful inflamed nodules, recurrent abscesses, and fistulas located in apocrine gland-bearing body sites<sup>1</sup>. The negative impact of HS on patients' quality of life (QoL) has been reported to be greater than other dermatologic conditions such as psoriasis, atopic eczema and chronic urticaria<sup>2</sup>. Indeed, involvement of an extensive surface area may interfere with daily activities, such as walking or hugging, due to pain in the groin and/or axillary area, and may cause social embarrassment due to purulent discharge odour<sup>3-4</sup>. HS is associated with high psychiatric morbidity and social impairment<sup>5</sup>, in particular with anxiety, depression, social withdrawal, and feelings of stigmatization. The effects of chronic skin diseases on the psychosocial, occupational, and interpersonal aspects of a patient's QoL are often underestimated by physicians and not taken into consideration by the healthcare system<sup>6-7</sup>. The improvement of QoL in HS patients is an important goal in disease management.

Nowadays there are no specific and validated QoL instruments available for HS and generic dermatologic questionnaires are used. In this setting, the HIDRADisk is the first Italian tool designed to assess HS burden<sup>8</sup>. Developed by a group of patients and dermatologists using the Delphi method, the questionnaire explores the impact of HS on 10 domains, such as the general state of health, pain, odour, symptom control, skin involvement, personality, social life, sexual life, work, and daily activities. The answers are graphically represented on a disk as a polygon, providing an immediate and intuitive representation of the impact of HS on patient's QoL at baseline and the achieved clinical benefit at following visits, since the area of the polygon shrinks when the burden of disease decreases. The HIDRADisk is designed to be completed by the patient but colored disk results are discussed with the dermatologist, fostering better patient–physician communication, which may positively influence treatment adherence<sup>7</sup>. Furthermore, the HIDRADisk is administered on electronic devices, offering dermatologists a fast and easy way to measure response in routine clinical practice or in clinical studies<sup>9</sup>. The aim of this study was to demonstrate the validity, reliability, and responsiveness of the HIDRADisk as a specific QoL instrument in patients with HS.

## **Materials and methods**

### **Study**

A multicenter, longitudinal, observational study was conducted on Italian HS patients enrolled between July and November 2016. The primary objective was to validate the HIDRADisk compared with other validated questionnaires (Skindex-16 and Dermatology Life Quality Index [DLQI]) in patients with HS and to evaluate its correlation with disease severity. Secondary objectives were to assess the influence of the new tool on the patient–physician relationship and to assess patient perception/satisfaction of the new instrument. Clinical HS severity was scored using Hurley stage<sup>10</sup> and HS Physician Global Assessment (HS-PGA)<sup>11</sup>. Clinical improvement was assessed using the HS Clinical Response<sup>12</sup> (HiSCR) and was defined as a reduction of  $\geq 50\%$  in total abscesses (A) and inflammatory nodules (N) count with no increase in abscesses and draining fistulas count compared to basal visit. For study purposes, we also assessed a partial HiSCR defined as a reduction of at least 25% of AN. According to the protocol, an interim analysis for the questionnaire validation was performed when the first 140 enrolled subjects completed the first 3 months of the study or prematurely discontinued from the study.

### **Centers and subjects**

The study was conducted in 27 Italian dermatologic centers selected on the basis of visiting  $\geq 1$  subject per month with moderate-to-severe HS (according to Hurley or HS-PGA staging) and availability of internet connection. The participation in the study was proposed consecutively to patients who had an outpatient visit during the study enrollment period. Inclusion criteria included male and female patients aged  $\geq 18$  years, affected by HS of any grade/severity, diagnosed  $\geq 6$  months before by a dermatology center, and able to understand and complete study-related questionnaires. Patients with current malignancies or any other important diseases (at the physician's discretion) that could impact significantly QoL, those with relevant psychiatric comorbidities, and those in a HS clinical trial were excluded from the study. Patients could be on any therapy for HS. The study protocol was approved by each local ethics committee. All patients provided informed consent for the use of their personal data. Each subject had 3 visits: visit 2 was performed between 2 to 7 days after visit 1, and visit 3 occurred 3 months after visit 1.

#### Questionnaires

The HIDRADisk, Skindex-16, DLQI, and WPAI-GH questionnaires were provided in an electronic format on a tablet device; the HIDRADisk App used in the study was developed in accordance to the Food and Drug Administration PRO Guidance for Industry<sup>13</sup>. The device did not permit unanswered questions. All questionnaires were administered at visit 1 and 3; the HIDRADisk was also administered at visit 2.

The HIDRADisk questionnaire is composed of 10 questions (refer to Supplementary Table 2). Patients answer each question by indicating their perception of HS burden on a visual analogue scale (VAS) ranging from 0 (absolutely not) to 10 (definitely yes). The total score is the sum of the single VAS (0=no impact of the disease on QoL; 100=maximum impact of disease on QoL; Fig 1)<sup>8</sup>.

The Skindex-16 is a QoL measure for patients with skin diseases. This 16-item questionnaire is subdivided into 3 domains: symptoms, emotions, and functioning. All scores vary from 0 (no effect) to 100 (effect experienced all the time)<sup>14-15</sup>.

The DLQI is a 10-item questionnaire that measures how much the skin disease affected QoL over the past week. The score has a maximum of 30 and a minimum of 0 (the higher the score, the greater the QoL impairment)<sup>16</sup>.

The WPAI-GH is a 6-item questionnaire on general health status and health problems' related fatigue on working activities<sup>17</sup>. WPAI outcomes are expressed as impairment percentages due to health, with higher numbers indicating greater impairment and less productivity, as

follows: missed work-time, impairment while working, overall work impairment, and activity impairment. The Italian translation was used in this study (Italian for Italy, WPAI:GH V2.3, 3/FEB/2015)<sup>18</sup>.

The Subject Satisfaction Questionnaire was created by the study team in order to evaluate patient perception of the disease and satisfaction with the HIDRADisk instrument. The first question queries the severity of disease (choices: “very mild,” “mild,” “fair,” “high,” “very high”); the second question explores whether the HIDRADisk questionnaire helped the physician understand how each patient experiences the disease; and the third question examines how much – from patient’s perception - the HIDRADisk usefulness in providing the physician with a satisfactory overall understanding of their problems due to the disease (both with 5 responses ranging from “not at all” to “very much so”).

#### Sample size

The sample size was determined according to validation criteria<sup>19</sup>: a total of 10 subjects per each item of the questionnaire were needed. The HIDRADisk questionnaire consists of 10 items; hence, the study would require a minimum sample size of 100 subjects. Due to the expected rate (20%) of patients lost to follow-up (based on previous experience from PSODisk questionnaire validation<sup>20</sup>), the sample size was increased to 140 subjects. The evaluable population for the validation study was defined as the first 140 patients diagnosed with HS who performed the first visit and met the inclusion criteria.

#### Psychometric evaluation

The evaluation was performed using the data collected at three different time periods (visits 1, 2, and 3). The **face and content validity** have already been assessed through focus groups using the Delphi method involving 10 Italian HS treating physicians and 9 patients<sup>8</sup>.

The **construct validity** was evaluated clinically and psychometrically at visit 1. First, differences in HIDRADisk total scores were analyzed using correlations between HIDRADisk total score and QoL scores at visit 1 in terms of Spearman’s rank correlation, as data were not normally distributed. Correlations between HIDRADisk total score and severity of HS (Hurley stage and HS-PGA) at visit 1 were provided using analysis of variance models on ranks, because of non-normality of residuals. Second, an exploratory factor analysis was performed to identify the factor structure underlying the HIDRADisk items. Under the hypothesis that the underlying factors are correlated (mainly in a clinical, psychological and a social subdomain), principal axes factor analysis, followed by an oblique rotation, was

applied. The number of factors was determined by retaining only those factors with an eigenvalue  $>1$  after factor rotation.

The **internal consistency reliability** was evaluated at visit 1 using Cronbach's alpha coefficient, a parameter calculated from the pairwise correlations between the 10 items of the HIDRADisk questionnaire. Internal consistency ranges between 0 and 1: 0.6 to 0.7 indicates acceptable reliability and  $\geq 0.8$  good reliability. Both raw and standardized Cronbach's alpha coefficients were calculated.

The **test-retest reliability** was determined by administering the same questionnaire to the same respondents in a short term interval (between visit 1 and visit 2). The correlation between the 2 sets of responses was provided in terms of Spearman's rank correlation and Intraclass Correlation Coefficient (ICC). The ICC was calculated for each item as the ratio between variability due to differences in the visits (intercept covariance parameter estimates) and total variability (intercept covariance parameter estimates + residual covariance parameter estimates). The less scattered the results, the greater the test-retest reliability of the study instrument.

The **responsiveness to change** was tested using a Wilcoxon signed rank test to compare the change in scores from visit 1 to visit 3 in 2 groups: patients who did and did not achieve partial HiSCR.

## Results

One hundred forty patients (59% women; mean age  $34.9 \pm 11.0$  years) were enrolled in 27 dermatologic centers. Baseline demographics of the study population are described in Table 1. One hundred thirty-six patients attended visit 2 (97.1%) patients, and 134 attended visit 3 (95.7%). Five patients were lost to follow-up and 1 withdrew consent.

Patients had varying HS severities at baseline (Table 2): Hurley stage 3, 24.6%; Hurley stage 2, 43.5%; Hurley stage 1, 31.9%; HS-PGA scores were very severe, 9.3%; severe, 11.4%; moderate, 47.1%; mild, 23.6%; minimal, 5.7%; clear, 2.9%. Patients' perception of HS severity, measured using the Subject Satisfaction Questionnaire, was very high (15.7%), high (41.4%), fair (30.7%), mild (7.1%), and very mild (5%).

At visit 3, 42/134 patients (31.3%) achieved HiSCR and 61/134 (45.5%) patients achieved a partial HiSCR. Patients' (n=132) perception of HS severity was very high (13.1%), high (27.7%), fair (36.2%), mild (17.7%), and very mild (5.4%). The most frequent locations at visit 3 were the same reported at visit 1: right and left axilla (reported by 48.5% and 47.0% of



patients, respectively), groin region (reported by 46.3% of patients for both), genital (31.3%), and perineal (21.6%) area. A reduction in the number of lesions (“improved”) was observed in almost 40% (38.8%) of patients, while 34.3% had the same number of lesions at both visits (“stable”), and 26.9% had an increase in the number of lesions at both visits (“worsened”). The other HS characteristics at visit 3 are described in Table 2. All questionnaires total scores decreased from visit 1 to visit 3 (Table 3) and varied in accordance with disease severity (Fig 2A according to Hurley and Fig 2B according to HS-PGA).

Psychometric evaluation

### **Construct validity**

All the correlations between HIDRADisk total score and QoL scores at visit 1 (DLQI total score, Skindex-16 total score, and WPAI:GH total activity impairment) were statistically significant ( $p < 0.0001$ ) and correlations coefficients were good (0.6651, 0.7568, and 0.5947, respectively). Correlations between HIDRADisk total score and the severity of HS (Hurley stage and HS-PGA) at visit 1 were both statistically significant ( $p = 0.0002$  and  $p = 0.0041$ , respectively). The factor analysis showed only 1 factor with an eigenvalue  $> 1$ , therefore, not allowing the grouping of items into domains and a factor rotation.

### **Internal consistency reliability**

Both raw and standardized Cronbach coefficient values were  $> 0.80$  (0.894 and 0.898, respectively). Correlation between the 10 items ranged between 0.308 and 0.673.

### **Test–retest reliability**

The correlation between visit 1 and 2 was statistically significant ( $p < 0.0001$ ) and correlations coefficients were good ( $> 0.70$  for 6 of 10 items). The Spearman correlation coefficient for the total HIDRADisk score was 0.8331 ( $p < 0.0001$ ). All ICC results were  $> 0.6$ , with the “sexuality” score  $> 0.80$ .

### **Responsiveness to change**

Among patients who achieved at least the partial HiSCR at visit 3 (45.5%), improvements from visit 1 to visit 3 were statistically significant for most parameters: total HIDRADisk score ( $p < 0.0001$ ), odour ( $p < 0.0001$ ), pain ( $p < 0.0001$ ), daily activities ( $p = 0.0020$ ), general health ( $p = 0.0018$ ), skin ( $p = 0.0012$ ), work ( $p = 0.0049$ ), and uneasiness/personality ( $p = 0.0039$ ).

In patients who did not achieve partial HiSCR, change from baseline was statistically significant only for the following parameters: pain ( $p=0.0011$ ), uneasiness/personality ( $p=0.0194$ ), and daily activities ( $p=0.0308$ ).

#### Secondary analysis

The Subject Satisfaction Questionnaire was completed by 140 patients at visit 1 and 132 out of 134 at visit 3. More than 80% of patients chose the 2 highest scores at both visits for question 2 and 3 (Figs 3A and 3B).

### Discussion

In this multicentric study, the HIDRADisk was validated psychometrically in a large sample of Italian patients with HS, with varying degrees of disease severity and independently from the medical treatment used.

This new questionnaire showed strong correlation with the dermatologic questionnaires, DLQI and Skindex-16, and a good one with WPAI:GH (total activity impairment). HIDRADisk correlation with the severity of HS was statistically significant for both Hurley stage and HS-PGA, confirming that higher scores on the HIDRADisk correspond to more severe disease. This evidence and the strong appreciation of HIDRADisk, as shown by patients through the satisfaction questionnaire, support the use of this HS-specific tool in clinical practice, together with any current validated severity index, to provide a “360-degree” assessment of patients burden of disease. The factor analysis showed that HIDRADisk is composed of a single dimension, as opposed to our hypothesis of three domains (clinical, psychological and social). Its unidimensionality allows the calculation of the total score as the sum of the scores of each question. The HIDRADisk also demonstrated very good internal consistency reliability and good correlation between the 10 items, showing a high consistency of the results delivered as a unique score and strengthening the unidimensionality of the questionnaire, where questions all address the same underlying construct. The test-retest reliability results highlighted the good HIDRADisk reproducibility in a short time interval, when the clinical conditions are assumed to be stable and therefore the QoL is expected to be almost the same. Furthermore, HIDRADisk proved to be responsive to disease changes as assessed over 3 months: the total score changed significantly among patients achieving at least a partial HiSCR. Despite being the most used instrument for HS treatment outcome the HiSCR may not be able to detect HS severity changes in normal clinical practice; it is plausible that HiSCR is not sensitive for revealing a minimal

improvement in HS severity, despite QoL changes from baseline. For this reason we addressed a medical need for a comprehensive QoL PRO specific for HS.

To date, several QoL questionnaires are in development to study the impact of HS burden on QoL; however, thus far, no patient-reported outcome measures have demonstrated to be easy to use, quick to score, and supporting dermatologists in the management of HS patients. Recently two QoL HS-specific tools have been developed: the composite HS Impact Assessment and HS Symptom Assessment tool (HSIA&HSSA)<sup>21</sup> (tested in 40 patients) and HS Burden of Disease<sup>22</sup> (tested in 29 patients). HSIA&HSSA are currently under validation in a population of 150 subjects. Furthermore, PRO measures are under investigation to be integrated in patients' clinical evaluation in order to provide a better description of HS burden, as in the recently developed SAHS score<sup>23</sup>.

From our perspective, a limitation of this validation model could be the use of comparison questionnaires there were not disease-specific; further analysis comparing HIDRADisk scores versus other HS-specific QoL tools might better support its usefulness. In addition, the effect of the various pharmacologic treatments and surgeries on QoL, as measured by HIDRADisk, still remains to be evaluated. Data from additional 160 patients with a follow-up of 9 months will be available shortly, as well as an evaluation of possible cut-off for patients classification based on disease impact on patient QoL. We also acknowledge a possible selection bias at enrollment due to the fact that routinely HS patients do not come back for a second visit in one week interval and therefore some patients might not have accepted to participate in the study. Furthermore, a limitation of this validation study could be its implementation only on the Italian population. For international use, the questionnaire must be translated and its psychometric properties need to be tested in different populations.

In conclusion, the HIDRADisk is a validated visual instrument administered on electronic devices, completed by patient and dermatologist together, making it an easy-to-use QoL tool that, in our wishes, should be implemented soon in routine clinical practice to improve the management of HS, as well as strengthen the patient–physician relationship.

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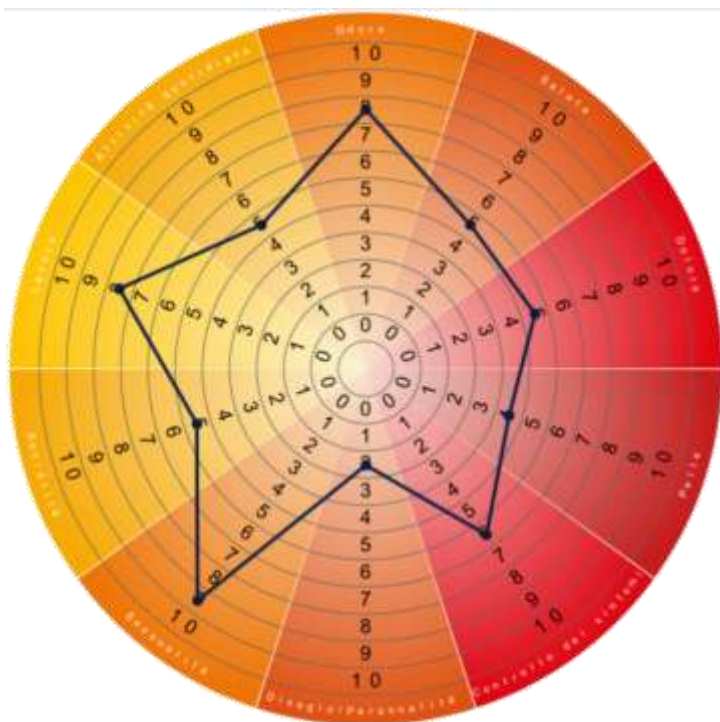
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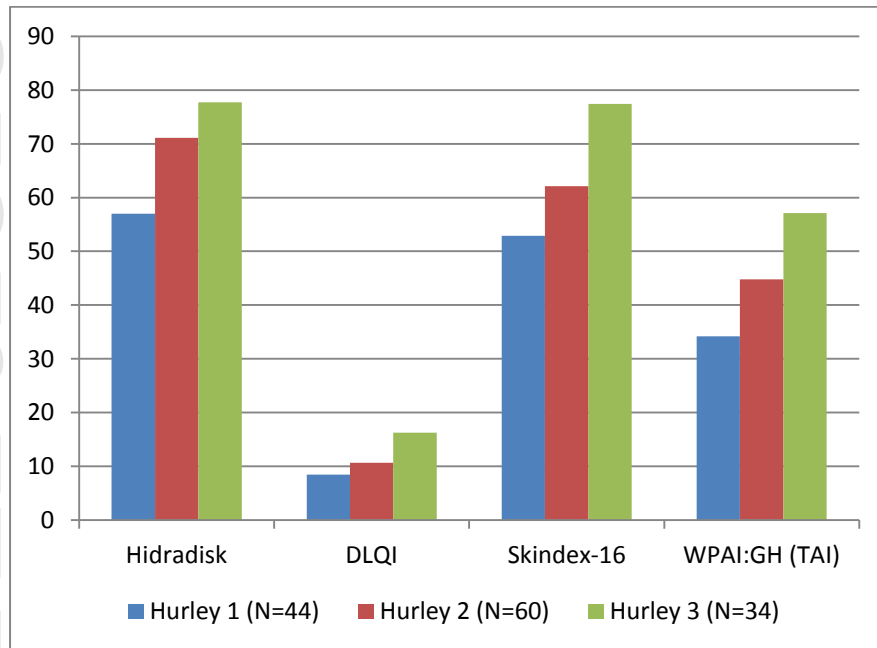
Figure 1. Example of a theoretic HIDRA disk score .



Single scores are summed to give the total score and visually linked together to draw a polygon reflecting the extension of the burden of the disease. In this example the final score is 57

**Figure 2. questionnaires scores stratified by Hurley (A) and HS-PGA (B)**

**A)**



**B)**

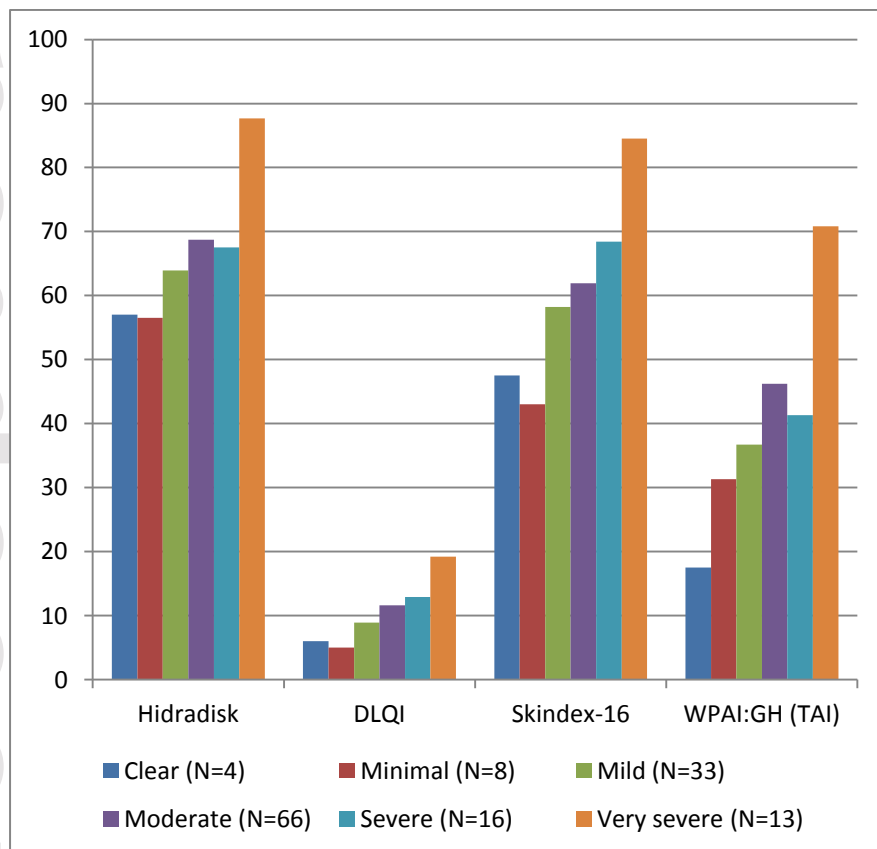
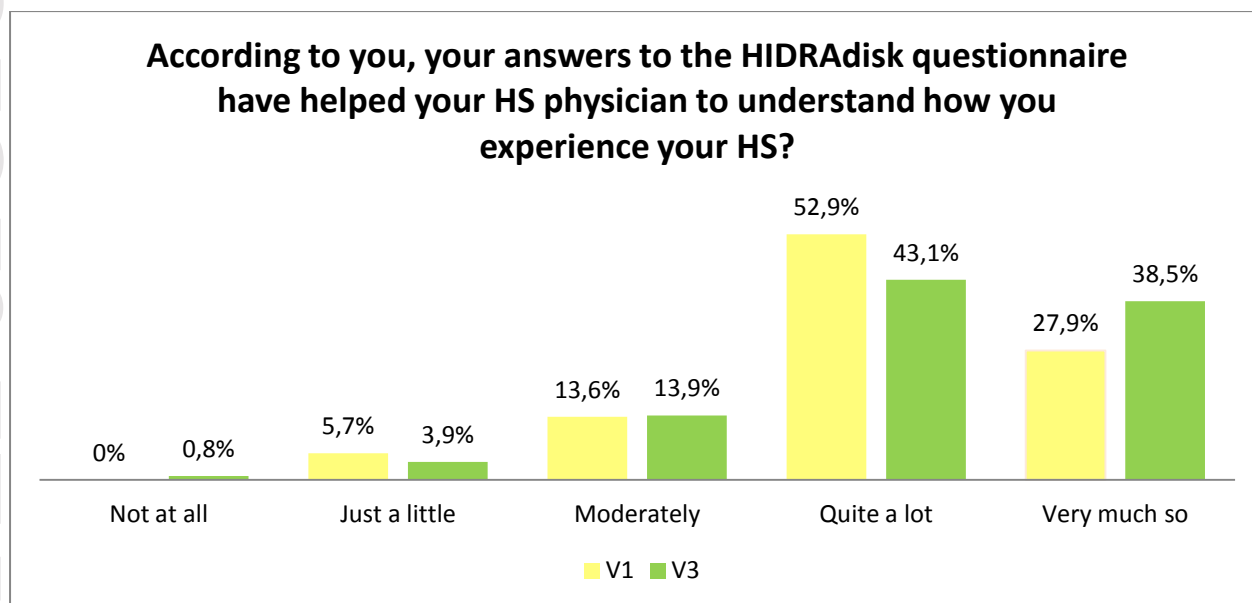
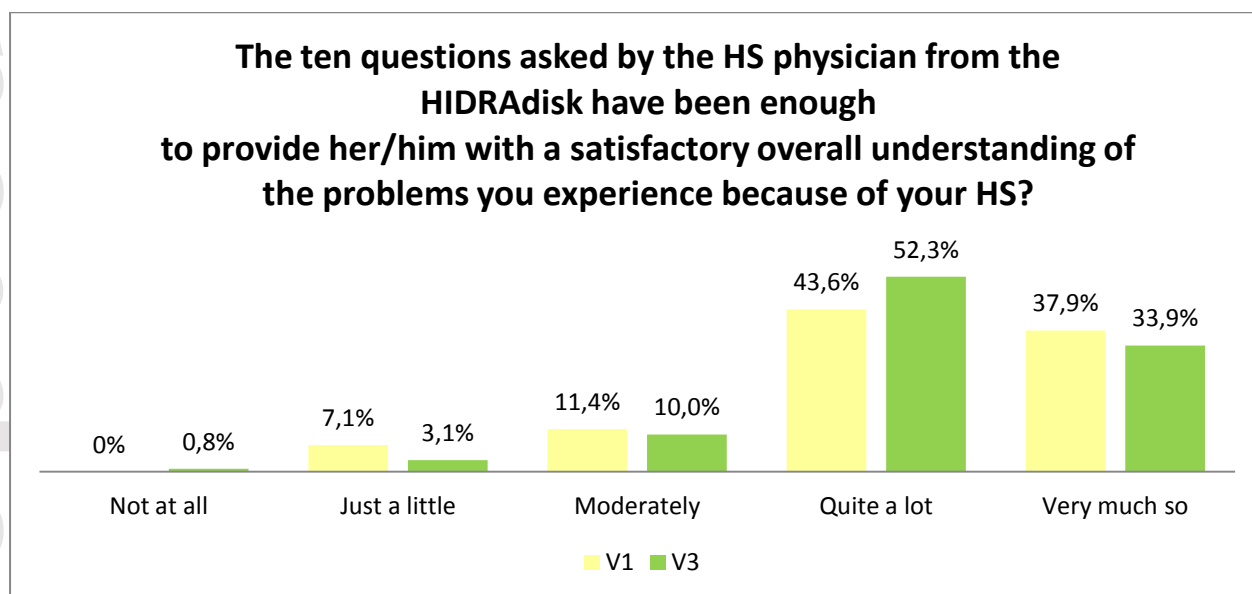


Figure 3. Subject's Satisfaction questionnaire responses

A)



B)



HS, hidradenitis suppurativa.



**Table 1. Patient demographics at baseline**

		n	%
Sex	Male	57	40.7
	Female	83	59.3
Age (years)	Mean $\pm$ SD	34.9 $\pm$ 11.0	
Race	White	138	98.6
	Asian	1	0.7
	Other	1	0.7
Civil status	Single	86	61.4
	Married	48	34.3
	Divorced	5	3.6
	Widower	1	0.7
Education level	Primary school	3	2.1
	Secondary school	42	30.0
	High school	78	55.7
	University	17	12.1
Smoking habits	Smoker	96	68.6
	Never smoked	33	23.6
	Ex-smoker (>6 months)	11	7.9
Alcohol consumption	Yes	28	20.0
	No	108	77.1
	Ex-drinker (>1 month)	4	2.9
BMI, kg/m <sup>2</sup>	Mean $\pm$ SD	28.0 $\pm$ 5.8	
	BMI <23		19.3%
	23 $\leq$ BMI <25		17.9%
	25 $\leq$ BMI < 30		30.7%
	BMI $\geq$ 30		32.1%
Time from	Mean $\pm$ SD	4.2 $\pm$ 5.0	

HS diagnosis to visit 1 (years)*			
Duration of illness†	<5 years	101	72.1
	5–14 years	28	20.0
	≥14 years	11	7.9
Patients with ≥1 major concomitant pathology	Yes§	39	28.3
	Missing	2	-
Major concomitant pathology	Obesity	17	12.1
	<b>5.1.1</b> Hypertension	<b>5.1.2</b> 7	<b>5.1.3</b> 5.0
	Dyslipidemia	5	3.6
	Diabetes	5	3.6
	Crohn disease	2	1.4
	Spondyloarthropathy	2	1.4
	Metabolic syndrome	2	1.4
	Depression	2	1.4
	Anxiety	2	1.4
	Arthritis	1	0.7
Other	10	7.1	

BMI, body mass index; HS, hidradenitis suppurativa; IC, informed consent; SD, standard deviation.

\*Time from HS initial diagnosis to IC signature was calculated in years as the difference between date of IC signature and the date of HS diagnosis + 1 day.

†Duration of illness was calculated, in years, as the difference between date of IC signature and the date of HS diagnosis + 1 day.

§ Patients could report >1 major other pathology.

**Table 2. HS characteristics and management at visits 1 and 3**

		Visit 1		Visit 3	
		N=140		n=134	
		N	%	N	%
Hurley stage	1	44	31.9	54	41.5
	2	60	43.5	49	37.7
	3	34	24.6	27	20.8
	Missing	2	-	4	-
Number of inflammatory nodules	Mean ± SD	5.2±6.6		3.7±4.7	
Number of abscesses	Mean ± SD	2.0±3.4		1.7±3.1	
Number of fistulas	Mean ± SD	2.0±4.6		1.5±3.8	
Hidradenitis Suppurativa Physician Global Assessment	Clear	4	2.9	4	3.0
	Minimal	8	5.7	19	14.2
	Mild	33	23.6	40	29.9
	Moderate	66	47.1	46	34.3
	Severe	16	11.4	11	8.2
	Very severe	13	9.3	14	10.5
Patients with ≥1 current pharmacologic treatment for HS at enrollment		86 <sup>#</sup>	62.3		
Surgical treatment for HS		73 <sup>**</sup>	52.1	7 <sup>††</sup>	5.2
Number of flares <sup>‡‡‡</sup>	Mean ± SD	8.8±8.9 <sup>‡‡</sup>		3.4±7.6 <sup>§§</sup>	
Need of a professional caregiver (nurse)		22	15.7	26	18.7
Number of medications	Mean ± SD	38.0±76.5		21.4±47.0	
Number of general practitioners + other specialists visits	Mean ± SD	3.6±4.0		1.5±2.1	

HS, hidradenitis suppurativa; SD, standard deviation.

<sup>#</sup>Patients could report >1 treatment: 22.9% reported anti-acne preparations, 20.7% reported antibacterials for systemic use, 16.4% reported immunosuppressants, and 12.9% reported antimycobacterials.

<sup>\*\*</sup>Patients with ≥1 surgical treatment since HS onset.

<sup>††</sup>Patients with ≥1 surgical treatment for HS in the past 3 months.

<sup>‡‡‡</sup> According to physicians' opinion.

<sup>‡‡</sup>Flares occurred in the past 12 months.

<sup>§§</sup>Flares occurred in the past 3 months.

<sup>†††</sup>Summarized considering the past 6 months before the study start. Reported by 133 out of the 140 patients.

<sup>##</sup>Summarized considering the past 3 months. Reported by all 134 patients who attended visit 3.

**Table 3. Questionnaire total scores**

Questionnaire Total Score Mean ± SD (range)		Visit 1 N=140	Visit 2 n=136	Visit 3 n=134
HIDRAdisk*		68.2±22.6 (1–100)	65.0±24.0 (1–100)	62.2±25.3 (0–100)
DLQI†		11.3±8.5 (0–30)	/	9.6±7.8 (0–30)
Skindex-16‡		62.5±25.6 (0–100)	/	53.4±29.7 (0–100)
WPAI-GH§	Overall work impairment	21.4±32.3% (0%–100%)	/	16.6±28.1% (0%–100%)
	Total Activity impairment	44.0±32.8% (0%–100%)	/	39.5±32.7% (0%–100%)

DLQI, Dermatology Life Quality Index; SD, standard deviation; WPAI-GH, Work Productivity and Activity Impairment–General Impairment.

\*Completed by 140 patients at visit 1, 136 patients at visit 2, and by 132/134 at visit 3.

†Completed by 140 patients at visit 1 and 132 patients at visit 3.

‡Completed by 140 patients at visit 1 and 128 patients at visit 3.

§Completed by 140 patients at visit 1 and 132 patients at visit 3.