Reproducibility among dermatologists of outcome measure instruments used in hidradenitis suppurativa:

Protocol for an agreement and reliability study

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ABSTRACT

Introduction & objectives: Monitoring disease over time is a prerequisite for clinical studies. Without valid and reliable outcome measures, researchers and clinicians will likely lack important benchmarks for decision-making. Hidradenitis suppurativa (HS) is a chronic, inflammatory skin disease, characterised by recurrent outbreaks of painful inflamed lesions in the apocrine gland-bearing regions. In HS, there is little consensus on which instruments should be chosen, for what purpose, and the inter-observer reliability for the various scoring systems generally is not thoroughly investigated. The objective of the study is to investigate the inter-assessor reproducibility (incl. reliability and agreement) in outcome measure instruments currently used in HS, and in identifying typical HS lesions with HS-experienced dermatologists being the rater population of interest.

Material & Methods: 24 patients with HS severity from mild to severe will be picked at random according to a pre-specified sequence allocation to undergo a physical examination by 12 different raters and will be scored with seven different scoring systems on the same day. The raters will furthermore be asked to identify the number of typical HS lesions in each anatomic area. The patients will be re-examined by ultrasound one or two days after the rating process for identification of the number of specific HS lesions for comparison with the objective lesion count. The rating group will consist of dermatologists from different countries, who manage HS patients regularly, and are thus likely familiar with using the instruments in question. The raters will be selected from the International Dermatology Outcome Measures (IDEOM) initiative and from members of the European HS foundation. IDEOM is an international initiative that aims to develop evidence-based outcomes measures to evaluate the impact of treatments for dermatological patients. The study is designed and will be reported in in accordance with the 'Guidelines for Reporting Reliability and Agreement Studies' (GRRAS).

Results: Inter-rater reliability and agreement results on the various scoring systems and on identifying typical HS lesions will be provided. These estimates will enable competitive "head-to-head" comparisons, that will help guide which of the current measurement instruments that are superior (i.e. in terms of agreement and reliability).

Conclusions: The IDEOM initiative aims to create a tool considerate of patients and providers using the input of all relevant stakeholders in assessment of disease severity and response to treatment. The reliability and agreement results of the various instruments can be used to inform the consensus processes in the development of a core outcome measurement sets for the management of HS. The reliability and agreement results on identifying typical HS lesions could be used in a future development of a new, reliable HS severity score.

INTRODUCTION

Evidence-based and consensus-endorsed outcome measures are necessary to ensure that patients will receive the most effective and suitable treatments available. Monitoring disease over time is a prerequisite for clinical studies and without valid and reliable outcome measures, researchers and clinicians will likely lack consensus on the outcomes and critical benchmarks for recommending treatment options and evaluating patient's progress.

Hidradenitis Suppurativa (HS) is a chronic, inflammatory and relapsing skin disease, characterised by repeated outbreaks of painful inflamed nodules or boils in the apocrine gland-bearing regions (armpits, genital area, groin, breasts and perianal region). These nodules can progress to abscesses, sinus tracts and scarring (1). The estimated prevalence is 1-4 % worldwide and HS is three times more common in women than men (2-4).

Clinical measure instruments for assessing of the severity of HS have generally been based on the Hurley staging system (5). Other available clinical measures include the modified Sartorius score (MSS) (6, 7), the HS Physician's Global Assessment (HS-PGA) (8), the Hidradenitis Suppurativa Severity Index (HSSI) (9) the Hidradenitis Suppurativa Clinical Response (HiSCR) (10), and the recently proposed Acne Inversa Severity Index (AISI) (11) and most recently the Hidradenitis Suppurativa Severity Score System (HS4).

Rationale

In HS there is little consensus on which instruments should be chosen for what purpose and the inter-observer reliability for the various scoring systems generally is not thoroughly investigated.

Objective

The objective of the study is to investigate the interassessor reproducibility (incl. reliability and agreement) in outcome measure instruments used in HS (Hurley score, MSS, HS-PGA, HSSI and HiSCR, AISI and HS4) and in identifying typical HS lesions with dermatologists being the rater population of interest. A second objective is to investigate the agreement between objective assessments from dermatologist and examination by ultrasound in identifying typical HS lesions.

METHODS

Design and sample size

Twenty-four patients with HS will undergo a physical examination by twelve different raters and will be scored with seven different scoring systems (Hurley, MSS, HS-PGA, HSSI, HiSCR, AISI and HS4) on the same day. The raters will furthermore be asked to identify the number of typical HS lesions in each anatomic area. One or two days after the main study the patients will be called back to the clinic for an ultrasound examination.

The study will be designed and reported in in accordance with the "Guidelines for Reporting Reliability and Agreement Studies (GRRAS)" (12)

Outcome measure instruments under scrutiny

Hurley staging classifies patients into three stages (appendix A), and was originally designed for selection of the appropriate treatment modality in a certain body location. It does not aim to give an accurate assessment of the extent of inflammation within each stage. (10) The inter-observer reliability in assessments of Hurley scores has not been investigated before.

In the MSS you count the number and type of inflammatory and non-inflammatory lesions within seven anatomical regions, measure the longest distance between two lesions of the same type within each anatomical region and apply predetermined weights to specific types of lesion characteristics. Finally, you identify involvement of Hurley stage III lesions for each region and a total MSS is generated (Appendix B). The inter-observer reliability of the MSS has been investigated once previously. (13) In this study, however, all clinical investigators came from the same department and went through a joint training session before assessing the scores individually. The inter-observer reliability of the MSS has never been in investigated with clinical investigators from different medical centers and without a preliminary joint training session.

The HS-PGA is a 6-point scale that was developed and used in a recent phase II clinical trial. (Appendix C) The inter-observer reliability for HS-PGA has not been investigated before.

The HSSI has been used in two publications studying the clinical efficacy of infliximab. (9, 14) This score

incorporated categorical objective parameters with categorical subjective parameters (Appendix D). The inter-observer reliability for the HSSI has not been investigated previously.

HiSCR is defined as a ≥ 50% reduction in inflammatory lesion count (sum of abscesses and inflammatory nodules, AN), and no increase in abscesses or draining fistulas in HS when compared with baseline as a meaningful clinical endpoint for HS treatment (10) It has recently been used in Phase II adalimumab trial for HS. The inter-observer reliability for HiSCR has not been investigated. (10)

AISI it a recent suggestion for a new HS severity score from an Italian group (11). It hat been designed to include a physician-rated assessment that considers the type of lesions occurring and the affected body sites. Additionally it includes a 0-10 visual analog scale (VAS), named Illness-VAS meant to assess patient's pain, discomfort, and disability due to HS (Appendix E). The interobserver reliability for AISI has not been investigated

HS4 (Appendix F) is the result of a very recent academic discussion and Delphi ballot. Is has not been published or validated yet.

Participants

Patients:

Patients will be recruited from the outpatient clinic at Department of Dermatology, Roskilde Hospital.

Inclusion criteria:

- Have HS as defined in the Modified Dessau criteria.
- The patients must be competent, 18 years or older
- Have read and understood the oral and written information (in either Danish or English).

Exclusion criteria:

- Persons who cannot provide informed consent.
- Incarcerated persons or those committed to a psychiatric institution for care and treatment.

Sampling method:

In the outpatient clinic at Department of Dermatology, Roskilde Hospital all patients fill out the "HISREG" questionnaire (15) as a matter of routine. The HISREG questionnaires from the patients how have attended the outpatient clinic within in the last tree months before the sampling will be collected. The questionnaire contains the question:

"How many boils did you have within the last four weeks?"

To ensure that our study will contain HS patients of all severities the patents will be picked in the following way:

First the patients will be dived into 3 groups:

- Group 1.: Patients with the answer "1-4 boils within the last four weeks"
- Group 2.: Patients with the answer "5-9 boils within the last four weeks"
- Group 3.: Patients with the answer "10 or more boils within the last four weeks"

Each HISREG questionnaire/patient will then be assigned with a number, numbers will be placed in drawing bawl and a blinded draw will take place:

- From group 1 four patients will be drawn
- From group 2 ten patients will be drawn
- From group 3 ten patients will be drawn

The patients will then contacted by one of the doctors in the study group, informed about the study and asked if they wish to participate. If the patient does not wish to participate, another patient from the same group will be drawn blinded, phoned and asked to participate and so on, until five patients from group one, ten patients from group two, and ten patients from group tree has accepted participation in the study. In addition two patients from each group will be drawn to participate as a substitute in case of illness or non-attendance of others reasons among the original participants.

Health Care Professional

The rating group will consist of twelve dermatologists from twelve different medical centers in twelve different countries. All raters will be dermatologists used to working with rating in HS and used to using some of the instruments in question. They will all be dermatologist with the following qualifications:

1. A clinical background with a least 10 years of experience with HS

2. Publications on HS
3. Members of the European Hidradenitis Suppurativa foundation (EHSF)

The raters will be selected from the International Dermatology Outcome Measures (IDEOM) initiative and from members of the European HS foundation. IDEOM is an international initiative that aims to develop evidence-based outcomes measures to evaluate the impact of treatments for dermatological patients.

The following dermatologist will be invited to participate:

1. Hessel van der Zee, MD, PhD, Erasmus University Rotterdam, Rotterdam, the Netherlands
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6. John Ingram, MD, PhD, FRCP, Cardiff University, UK
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10. José Carlos Pascual, MD, Department of Dermatology, Hospital General Universitario de Alicante, Alicante, Spain
11. Jean Revuz, MD, PhD, Professor, Department of Dermato-Venereology Henri Mondor Hospital, France
12. Veronique del Marmol, MD,PhD, Université Libre de Bruxelles, Department of Dermatology and Venereology, Brussels, Belgium

Rating process

The rating will take place at the outpatient clinic at Department of Dermatology, Roskilde Hospital.

Each patient will be placed in a separate room and the raters will walk from room to room on rotation in two rounds. All room will be equipped with sufficient lightning and at standard examination couch. The VAS score, information on number of changes of dressings and the DLQI needed for some scores will be registered by the patient before the remaining ratings and only this once (Thus will be the same for all raters).

The raters will receive information on the patients' age and gender but no further information on the patients' health status, identity or history. The raters will not be blinded in the sense that they will be aware that their judgments will be compared with those of other raters. The raters will not be allowed any communication with each other while the rating is ongoing to ensure that ratings will be conducted independently.

The rotation will initially be set to take place every 10 minute, but if any of the raters feel they need additional time for the ratings, this interval will prolonged, so that no raters will be pressed for time.

Patients and raters will be randomised based on a computer generated list of random numbers, randomised with a varying block size from 3 to 4. The order in which each rater will meet each patient will be based on a prespecified patient-by-rater visit algorithm (Appendix G).

The raters will be asked to write their scores on provided scoring sheets in paper (Appendix H). The sheets with the individual scores will be shuffled like a stack of cards before assembly, so that the sequence of the individual scoring systems will be random and will vary from round to round. The sheet where the raters are asked to identify specific individual lesions will be put at last, so that the raters will not reuse the information from this sheet for the individual scorings systems. The physician VAS will also be put at last, as it makes sense to do the global evaluation after all the other ratings.

Ultrasound examination

All patients will be called in for an ultrasound examination one or two days after the rating process. The number of specific typical HS lesions (draining fistulae, non-draining fistulae, inflamed nodules, non-inflamed nodules, abscesses) will be determined by ultrasound for comparison with the objective lesion count.

Statistical considerations

For the quantification of the interrater reliability of the clinical scores the intraclass correlation coefficient (ICC) will be applied (using Kappa statistics for categorical data). ICC provides information on the ability to differentiate between the variation between subjects and measurement variation. The ICC will be defined as the ratio of variance among patients (subject variability) over the total variance (subject variability, observer variability and measurement variability). ICC ranges between 0 (no reliability) and 1 (perfect reliability), and values of ICCs are excellent when >0.75 and poor when <0.40. Results between these ranges represent moderate-to-good reliability (16). According to another reference, ICC >0.7 is considered good (17).

For the quantification of the inter-rater agreement examination of modified Bland-Altman method for assessing agreement will be applied. The Bland-Altman method provides insight into the distribution of differences in relation to mean values (18). In the original Bland-Altman approach, agreement is quantified by calculating the mean difference between two sets of observations and the SD for this difference; we will apply a customized form that allow for the clustered measures introduced by the 6 different assessors (ie, unlike the typical 2 rater-assessments). The closer the mean difference is to 0 and the smaller the SD of this difference; the better is the agreement. The 95% limits of agreement will be defined as the mean difference between the raters $\pm 1.96 \times SD_{\text{of the difference.}}$

Handling of biological material

No biological material will be taken from the subjects.

Practical execution

The patient investigations will take place at the Dermatology Outpatient Clinic at Roskilde Hospital. The estimated duration of the study is 18 months.

Protection of personal data

Personally identifiable data will be stored in the department of dermatology Roskilde Hospital. A public data controller will run the project. Data will be entered into a database as non-person-identifiable information.

Economy

The initiators of study are the doctors in the project group. The study has received a grant from IDEOM. The patients will receive a minor gift for their participation. The Parker Institute is supported by grants from the Oak Foundation.

Insurance conditions

The subjects will be covered by hospital insurance in the unlikely event of injury or illness due to participation in the study.

Ethics and dissemination

The study will be performed according to the Helsinki declaration and only persons who have given informed consent will be included in the study. There are no known risks or side effects of the described studies. All subjects are involved on a voluntary basis and may at any time decide to withdraw from the trial, without it affecting the any current or future treatment.
All results from the study, including inconclusive or negative results, will be published, in peer-reviewed indexed journals, with LT as first author and GJ as senior (last) author. The regional research ethics committees has been consulted and has stated that ethical approval is not required for this study.

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Appendix A

Hurley staging

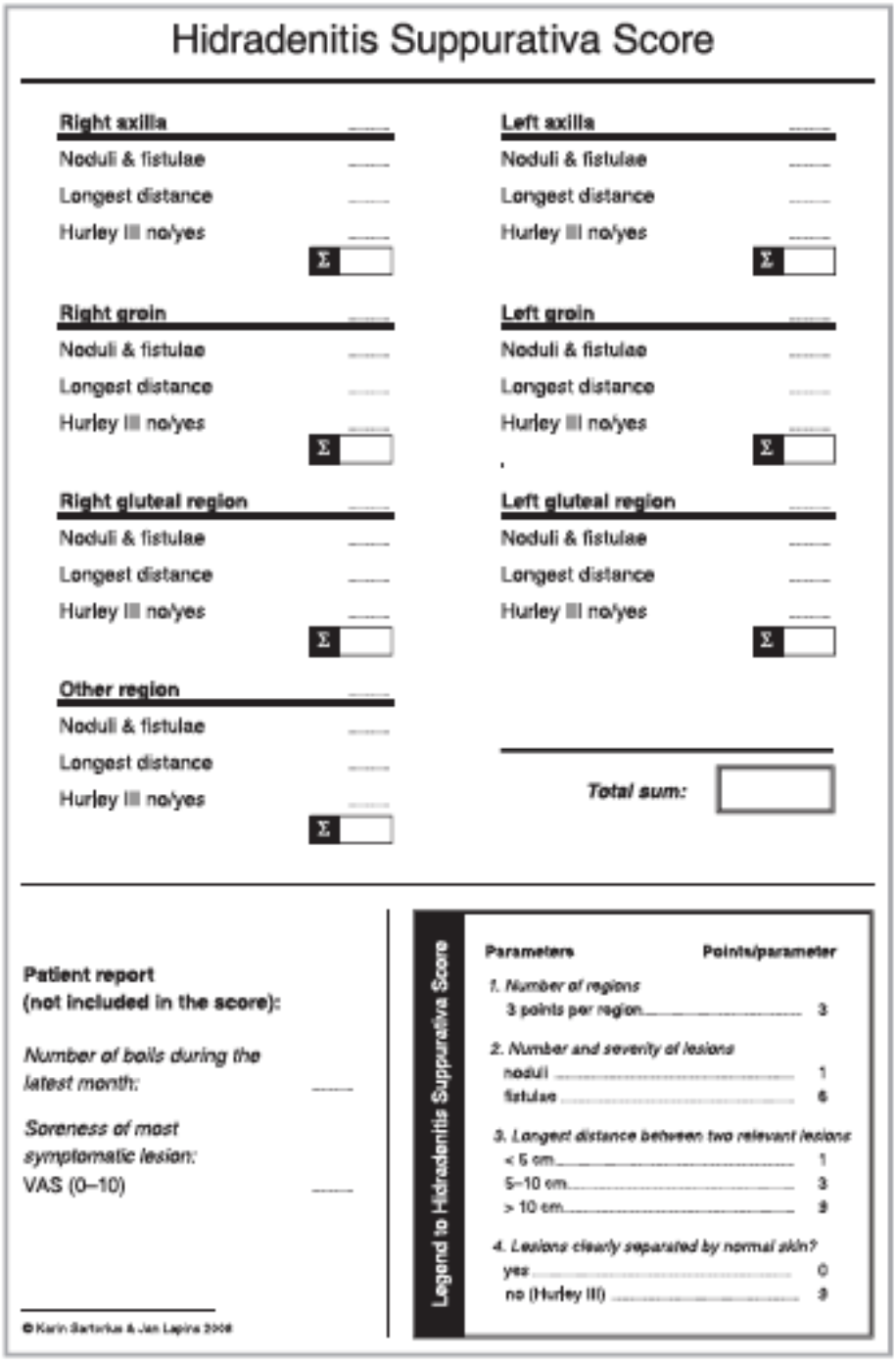
In 1989, a severity classification was first proposed by Hurley [4].

- Stage I: Abscess formation, single or multiple, without sinus tracts and cicatrisation.
- Stage II: Recurrent abscesses with tract formation and cicatrisation, single or multiple, widely separated lesions.
- Stage III: Diffuse or near-diffuse involvement, or multiple interconnected tracts and abscesses across the entire area.

(19)

Appendix B

The modified Sartorius score (MSS)



Hidradenitis Suppurativa Score

Right axilla ____
Nodules & fistulae ____
Longest distance ____
Hurley III no/yes ____
Σ ____

Left axilla ____
Nodules & fistulae ____
Longest distance ____
Hurley III no/yes ____
Σ ____

Right groin ____
Nodules & fistulae ____
Longest distance ____
Hurley III no/yes ____
Σ ____

Left groin ____
Nodules & fistulae ____
Longest distance ____
Hurley III no/yes ____
Σ ____

Right gluteal region ____
Nodules & fistulae ____
Longest distance ____
Hurley III no/yes ____
Σ ____

Left gluteal region ____
Nodules & fistulae ____
Longest distance ____
Hurley III no/yes ____
Σ ____

Other region ____
Nodules & fistulae ____
Longest distance ____
Hurley III no/yes ____
Σ ____

Total sum: ____

Patient report
(not included in the score):

Number of boils during the latest month: ____

Soreness of most symptomatic lesion:
VAS (0–10) ____

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Legend to Hidradenitis Suppurativa Score

Parameters	Points/parameter
1. Number of regions	
3 points per region	3
2. Number and severity of lesions	
noduli	1
fistulae	6
3. Longest distance between two relevant lesions	
< 5 cm	1
5–10 cm	3
> 10 cm	9
4. Lesions clearly separated by normal skin?	
yes	0
no (Hurley III)	9

(7)

Appendix C

Appendix Table 1. **Hidradenitis Suppurativa Physician's Global Assessment Scale**

Rating	Description
Clear	0 abscesses, 0 draining fistulas, 0 inflammatory nodules, and 0 noninflammatory nodules
Minimal	0 abscesses, 0 draining fistulas, 0 inflammatory nodules, and presence of noninflammatory nodules
Mild	0 abscesses, 0 draining fistulas, and 1–4 inflammatory nodules or 1 abscess or draining fistula and 0 inflammatory nodules
Moderate	0 abscesses, 0 draining fistulas, and ≥5 inflammatory nodules or 1 abscess or draining fistula and ≥1 inflammatory nodule or 2–5 abscesses or draining fistulas and <10 inflammatory nodules
Severe	2–5 abscesses or draining fistulas and ≥10 inflammatory nodules
Very severe	>5 abscesses or draining fistulas

(8)

Appendix D

Table I. Hidradenitis Suppurativa Severity Index

Score/category	No. of sites	Body surface area (%)*	No. of lesions (erythematous, painful)	Drainage (No. of dressing changes/working/leisure h)†	Pain (VAS)
0	0	0	0	0	0-1
1	1	1	1-2		
2	2	2-3	2-3	1	2-4
3	3	4-5	4-5	>1	5-7
4	≥4	>5	>5		8-10

VAS, Visual analog scale.
Sites: left armpit, right armpit, left side of chest, right side of chest, left side of groin, right side of groin, perianal area, sacral area, and perineal area.
Composite scoring (0-19): mild (0-7), moderate (8-12), and severe (>13).
Sample score: 3 sites (3) + 2% body surface area (2) + 4 lesions (3) + 1 dressing change (2) + VAS 10 (4) = 14.
*Palm of hand = 1% of body surface area.
†Interferes with daily activities.

(9)

Appendix E

AISI	If observed	Multiplied by the overall number of sites where the lesion occurs	Subtotal
Comedonic lesion	1 point		
Abscess / Inflammatory nodule	2 points		
Sinus tract	3 points		
Keloid, fibrotic adherence	4 points		
Fibrosclerotic inflammatory plaque	5 points		
Illness-VAS (pain-discomfort-disability)	0-10	////////////////////	
Total	////////////////////	////////////////////	

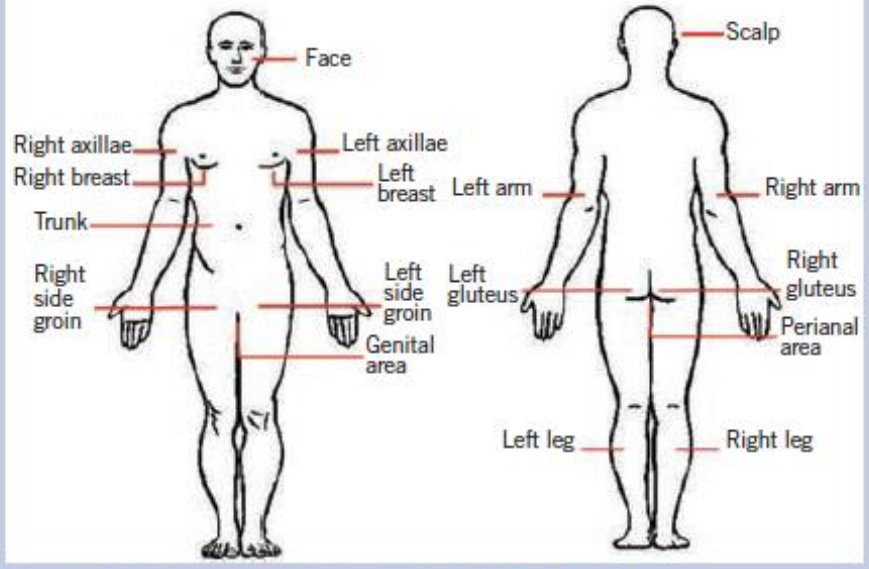

Figure 1. Acne Inversa Severity Index (AISI).

Appendix F

HS4

Mild HS: a) 1 anatomical localization involved OR up to 4 active inflammatory lesions (inflammatory nodules,
abscesses) OR
b) DLQI up to 10 points
Moderate HS: a) 2 or more anatomical localizations involved OR 5-9 active inflammatory lesions (inflammatory nodules,
abscesses or draining sinuses) OR
b) DLQI more than 10 und up to 20 points
Severe HS: a) 2 or more anatomical localizations involved AND 10 or more active inflammatory lesions (inflammatory
nodules, abscesses or draining sinuses) OR
b) DLQI more than 20 points

Appendix G

Round 1		**Round 2**		**Round 3**	
P1R1	P7R7	P1R12	P7R6	P1R11	P7R5
P2R2	P8R8	P2R1	P8R7	P2R12	P8R6
P3R3	P9R9	P3R2	P9R8	P3R1	P9R7
P4R4	P10R10	P4R3	P10R9	P4R2	P10R8
P5R6	P11R11	P5R4	P11R10	P5R3	P11R9
P6R6	P12R12	P6R5	P12R11	P6R4	P12R10

P=Patient
R=Rater

Round 4		**Round 5**		**Round 6**	
P1R10	P7R4	P1R9	P7R3	P1R8	P7R2
P2R11	P8R5	P2R10	P8R4	P2R9	P8R3
P3R12	P9R6	P3R11	P9R5	P3R10	P9R4
P4R1	P10R7	P4R12	P10R6	P4R11	P10R5
P5R2	P11R8	P5R1	P11R7	P5R12	P11R6
P6R3	P12R12	P6R2	P12R8	P6R1	P12R7

Round 7		**Round 8**		**Round 9**	
P1R7	P7R1	P1R6	P7R12	P1R5	P7R11
P2R8	P8R2	P2R7	P8R1	P2R6	P8R12
P3R9	P9R3	P3R8	P9R2	P3R7	P9R1
P4R10	P10R4	P4R9	P10R3	P4R8	P10R2
P5R11	P11R5	P5R10	P11R4	P5R9	P11R3
P6R12	P12R6	P6R11	P12R5	P6R10	P12R4

Round 10		**Round 11**		**Round 12**	
P1R4	P7R10	P1R3	P7R9	P1R2	P7R8
P2R5	P8R11	P2R4	P8R10	P2R3	P8R9
P3R6	P9R12	P3R5	P9R11	P3R4	P9R10
P4R7	P10R1	P4R6	P10R12	P4R5	P10R11
P5R8	P11R2	P5R7	P11R1	P5R6	P11R12
P6R9	P12R3	P6R8	P12R2	P6R7	P12R1

Round 13		**Round 14**		**Round 15**	
P13R1	P19R7	P13R12	P19R6	P13R11	P19R5
P14R2	P20R8	P14R1	P20R7	P14R12	P20R6
P15R3	P21R9	P15R2	P21R8	P15R1	P21R7
P16R4	P22R10	P16R3	P22R9	P16R2	P22R8
P17R6	P23R11	P17R4	P23R10	P17R3	P23R9
P18R6	P24R12	P18R5	P24R11	P18R4	P24R10

Round 16		**Round 17**		**Round 18**	
P13R10	P19R4	P13R9	P19R3	P13R8	P19R2
P14R11	P20R5	P14R10	P20R4	P14R9	P20R3
P15R12	P21R6	P15R11	P21R5	P15R10	P21R4
P16R1	P22R7	P16R12	P22R6	P16R11	P22R5
P17R2	P23R8	P17R1	P23R7	P17R12	P23R6
P18R3	P24R12	P18R2	P24R8	P18R1	P24R7

Round 19		**Round 20**		**Round 21**	
P13R7	P19R1	P13R6	P19R12	P13R5	P19R11
P14R8	P20R2	P14R7	P20R1	P14R6	P20R12
P15R9	P21R3	P15R8	P21R2	P15R7	P21R1
P16R10	P22R4	P16R9	P22R3	P16R8	P22R2
P17R11	P23R5	P17R10	P23R4	P17R9	P23R3
P18R12	P24R6	P18R11	P24R5	P18R10	P24R4

Round 22		**Round 23**		**Round 24**	
P13R4	P19R10	P13R3	P19R9	P13R2	P19R8
P14R5	P20R11	P14R4	P20R10	P14R3	P20R9
P15R6	P21R12	P15R5	P21R11	P15R4	P21R10
P16R7	P22R1	P16R6	P22R12	P16R5	P22R11
P17R8	P23R2	P17R7	P23R1	P17R6	P23R12
P18R9	P24R3	P18R8	P24R2	P18R7	P24R1

Appendix H

Handouts for raters

Patient: Rater:

Hurley staging

In 1989, a severity classification was first proposed by Hurley [4].

- Stage I: Abscess formation, single or multiple, without sinus tracts and cicatrisation.
- Stage II: Recurrent abscesses with tract formation and cicatrisation, single or multiple, widely separated lesions.
- Stage III: Diffuse or near-diffuse involvement, or multiple interconnected tracts and abscesses across the entire area.

(Zouboulis CC, Desai N, Emtestam L, Hunger RE, Ioannides D, Juhasz I, et al. European S1 guideline for the treatment of hidradenitis suppurativa/acne inversa. J Eur Acad Dermatol Venereol. 2015;29(4):619-44)

Right axilla: Left axilla:

Right groin: Left groin:

Right gluteal region: Left gluteal region:

Other region:

Patient:
Rater:

The modified Sartorius score (MSS)

Please calculate the total sum

Appendix 1

Hidradenitis Suppurativa Score

Right axilla .....
Noduli & fistulae .....
Longest distance .....
Hurley III no/yes .....
Σ

Left axilla .....
Noduli & fistulae .....
Longest distance .....
Hurley III no/yes .....
Σ

Right groin .....
Noduli & fistulae .....
Longest distance .....
Hurley III no/yes .....
Σ

Left groin .....
Noduli & fistulae .....
Longest distance .....
Hurley III no/yes .....
Σ

Right gluteal region .....
Noduli & fistulae .....
Longest distance .....
Hurley III no/yes .....
Σ

Left gluteal region .....
Noduli & fistulae .....
Longest distance .....
Hurley III no/yes .....
Σ

Other region .....
Noduli & fistulae .....
Longest distance .....
Hurley III no/yes .....
Σ

Total sum:

Patient report
(not included in the score):

Number of boils during the latest month: .....

Soreness of most symptomatic lesion:
VAS (0–10) .....

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Legend to Hidradenitis Suppurativa Score

Parameters	Points/parameter
1. Number of regions	
3 points per region	3
2. Number and severity of lesions	
noduli	1
fistulae	6
3. Longest distance between two relevant lesions	
< 5 cm	1
5–10 cm	3
> 10 cm	9
4. Lesions clearly separated by normal skin?	
yes	0
no (Hurley III)	9

(Sartorius K, Emtestam L, Jemec GB, Lapins J. Objective scoring of hidradenitis suppurativa reflecting the role of tobacco smoking and obesity. Br J Dermatol. 2009;161(4):831-9.

Patient: Rater:

Please **O** your answer.

Appendix Table 1. **Hidradenitis Suppurativa Physician's Global Assessment Scale**

Rating	Description
Clear	0 abscesses, 0 draining fistulas, 0 inflammatory nodules, and 0 noninflammatory nodules
Minimal	0 abscesses, 0 draining fistulas, 0 inflammatory nodules, and presence of noninflammatory nodules
Mild	0 abscesses, 0 draining fistulas, and 1–4 inflammatory nodules or 1 abscess or draining fistula and 0 inflammatory nodules
Moderate	0 abscesses, 0 draining fistulas, and ≥5 inflammatory nodules or 1 abscess or draining fistula and ≥1 inflammatory nodule or 2–5 abscesses or draining fistulas and <10 inflammatory nodules
Severe	2–5 abscesses or draining fistulas and ≥10 inflammatory nodules
Very severe	>5 abscesses or draining fistulas

(Kimball AB, Kerdel F, Adams D, Mrowietz U, Gelfand JM, Gniadecki R, et al. Adalimumab for the treatment of moderate to severe Hidradenitis suppurativa: a parallel randomized trial. Ann Intern Med. 2012;157(12):846-55.)

Patient: Rater:

HSSI

Table I. Hidradenitis Suppurativa Severity Index

Score/category	No. of sites	Body surface area (%)*	No. of lesions (erythematous, painful)	Drainage (No. of dressing changes/working/leisure h)†	Pain (VAS)
0	0	0	0	0	0-1
1	1	1	1-2		
2	2	2-3	2-3	1	2-4
3	3	4-5	4-5	>1	5-7
4	≥4	>5	>5		8-10

VAS, Visual analog scale.
Sites: left armpit, right armpit, left side of chest, right side of chest, left side of groin, right side of groin, perianal area, sacral area, and perineal area.
Composite scoring (0-19): mild (0-7), moderate (8-12), and severe (>13).
Sample score: 3 sites (3) + 2% body surface area (2) + 4 lesions (3) + 1 dressing change (2) + VAS 10 (4) = 14.
*Palm of hand = 1% of body surface area.
†Interferes with daily activities.

(Grant A, Gonzalez T, Montgomery MO, Cardenas V, Kerdel FA. Infliximab therapy for patients with moderate to severe hidradenitis suppurativa: a randomized, double-blind, placebo-controlled crossover trial. J Am Acad Dermatol. 2010;62(2):205-17)

Please O your answer. The patient will fill out drainage and Pain (VAS) on a separate paper. You do not have to calculate the sample score.

No. of sites

0 1 2 3 >4

Body suface area (%)

0 1 2-3 4-5 >5

No. of lesions (erythematous, painful)

0 1 2 3 >4

Patient: Rater:

AISI

AISI	If observed	Multiplied by the overall number of sites where the lesion occurs	Subtotal
Comedonic lesion	1 point		
Abscess / Inflammatory nodule	2 points		
Sinus tract	3 points		
Keloid, fibrotic adherence	4 points		
Fibrosclerotic inflammatory plaque	5 points		
Illness-VAS (pain-discomfort-disability)	0-10	////////////////////	
Total	////////////////////	////////////////////	

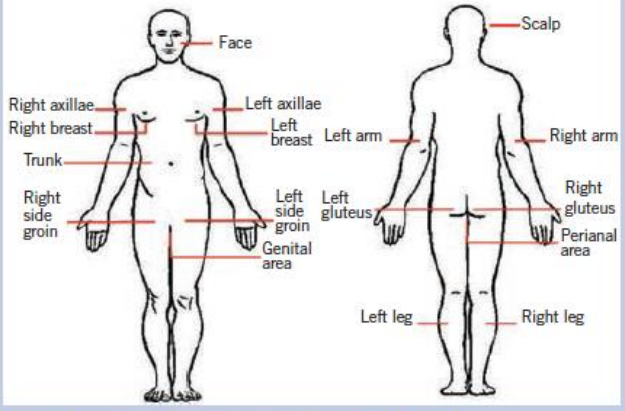

Figure 1. Acne Inversa Severity Index (AISI).

(Chiricozzi A, Faleri S, Franceschini C, Caro RD, Chimenti S, Bianchi L. AISI: A New Disease Severity Assessment Tool for Hidradenitis Suppurativa. Wounds : a compendium of clinical research and practice. 2015;27(10):258-64)

Patient: **Rater:**

Hidradenitis Suppurativa Clinical Response (HiSCR)

(Kimball AB, Jemec GB, Yang M, Kageleiry A, Signorovitch JE, Okun MM, et al. Assessing the validity, responsiveness and meaningfulness of the Hidradenitis Suppurativa Clinical Response (HiSCR) as the clinical endpoint for hidradenitis suppurativa treatment. Br J Dermatol. 2014;171(6):1434-42)

`Baseline` assessment
Inflammatory lesion count (sum of abscesses and inflammatory nodules, AN)

=

Patient: Rater:

HS4

Please **O** your **a)** answer

Mild HS: a) 1 anatomical localization involved OR up to 4 active inflammatory lesions (inflammatory nodules, abscesses) OR
b) DLQI up to 10 points
Moderate HS: a) 2 or more anatomical localizations involved OR 5-9 active inflammatory lesions (inflammatory nodules, abscesses or draining sinuses) OR
b) DLQI more than 10 und up to 20 points
Severe HS: a) 2 or more anatomical localizations involved AND 10 or more active inflammatory lesions (inflammatory nodules, abscesses or draining sinuses) OR
b) DLQI more than 20 points

Patient: Rater:

Typical HS lesions count

Right Axilla Number of draining fistulae: Number of non-draining fistulae: Number of inflamed nodules: Number of non-inflamed nodules: Number of abscesses:	**Left Axilla** Number of draining fistulae: Number of non-draining fistulae: Number of inflamed nodules: Number of non-inflamed nodules: Number of abscesses:
Right Groin Number of draining fistulae: Number of non-draining fistulae: Number of inflamed nodules: Number of non-inflamed nodules: Number of abscesses:	**Left groin** Number of draining fistulae: Number of non-draining fistulae: Number of inflamed nodules: Number of non-inflamed nodules: Number of abscesses:
Right gluteal region Number of draining fistulae: Number of non-draining fistulae: Number of inflamed nodules: Number of non-inflamed nodules: Number of abscesses:	**Left gluteal region** Number of draining fistulae: Number of non-draining fistulae: Number of inflamed nodules: Number of non-inflamed nodules: Number of abscesses:
Other region: Number of draining fistulae: Number of non-draining fistulae: Number of inflamed nodules: Number of non-inflamed nodules: Number of abscesses: No. abscesses:	

Patient: **Rater:**

Physician VAS disease severity