

## ORIGINAL ARTICLE

# Age and gender influence on HIDRADisk outcomes in adalimumab-treated hidradenitis suppurativa patients

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## Abstract

**Background** Hidradenitis suppurativa (HS) is a chronic relapsing inflammatory skin disease characterized by a significant impairment of patients' quality of life (QoL). It has been recently found that clinical severity of HS does not correlate well with QoL. Therefore, it is important to enhance the evaluation of severity considering the disease burden on QoL. Recently, a new graphical tool able to better describe HS burden, the so-called HIDRADisk, has been introduced.

**Objective** To investigate the utility of HIDRADisk in clinical practice before and after treatment and to analyse whether specific factors such as age and gender may influence the outcomes in patients with moderate-to-severe HS.

**Methods** A single-centre retrospective study on 24 patients (13F/11M, mean age  $38 \pm 15$  years) with moderate-to-severe HS was performed. Clinical data (disease severity and quality of life) were collected at baseline and after 12 weeks of adalimumab.

**Results** HIDRADisk showed significantly better improvements in males ( $69.8 \pm 6.2$ – $49.6 \pm 10.8$ ) compared to females ( $80.7 \pm 6.0$ – $72.3 \pm 6.7$ ),  $P < 0.001$ . A significant correlation was found in the total population between HS severity values measured through the modified Sartorius score (mSS) and QoL measured through HIDRADisk. As regards the relationship between disease outcomes and age, a trend for better HIDRADisk outcomes in younger patients (<40 years) compared to older ones was observed.

**Conclusions** HIDRADisk appears as a complete and informative tool which can easily measure the global burden of HS, guiding treatment choice and evaluating its efficacy.

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## Conflict of interest

None.

## Funding source

None.

## Introduction

Hidradenitis suppurativa (HS) is a chronic relapsing inflammatory skin disease with nodules, abscesses and sinus tracts being the main clinical manifestations.<sup>1</sup> In addition, several comorbidities have been described in patients affected by HS, which led to a significant impairment on patients' quality of life (QoL).<sup>2</sup> It has been recently found that clinical severity of HS does not correlate well with QoL.<sup>3</sup> Indeed, even when the disease is clinically not very severe but the lesions are painful or located on visible part of the body, HS may have a strong impact on patients' QoL. Therefore, it is necessary to evaluate the severity of patients' condition considering the disease burden on QoL. Disease tools commonly used to describe patient discomfort

such as Dermatology Life Quality Index (DLQI), Skindex-16, as well as Work Productivity and Activity Impairment (WPAI) are not specific for HS and not useful on large numbers of patients. Recently, a new graphical tool able to better describe HS burden, the so-called HIDRADisk, has been introduced.<sup>4,5</sup> HIDRADisk is designed to be filled out by the patient with the dermatologist, fostering their communication. Being a visual instrument, with the answers shown graphically through a polygon, HIDRADisk gives an immediate and global picture of the disease burden, also allowing patients and physicians to visualize the course of the disease over time. When the burden of HS decreases, the area of the polygon shrinks, providing an intuitive representation of the progress achieved. Chiricozzi *et al.*<sup>4</sup> firstly introduced this tool through a mixed methodology: patient-only (patients affected by HS for  $\geq 24$  months) and physician-only (with well-

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documented experience in the research field) focus groups created to capture the experience and perspective of the disease on both sides; a modified Delphi method was then applied to assess the level of convergence of both opinions about the items selected and their weight within the disease experience of HS. A rewording of the items was performed to further simplify the questionnaire. A multicenter, longitudinal, observational study on 140 patients was therefore conducted to validate the HIDRADisk compared with other validated questionnaires and to evaluate its correlation with disease severity in patients with different degree of HS severity.<sup>5</sup> HIDRADisk showed to have a strong correlation with Skindex-16 and DLQI, and a good one with WPAI. It also significantly correlated with disease severity.

We herein performed a retrospective study to investigate the utility of HIDRADisk in clinical practice before and after treatment and to analyse whether specific factors such as age and gender may influence the outcomes.

### Material and methods

A single-centre retrospective study was performed among patients with moderate-to-severe HS attending the outpatient clinic of the Department of Clinical Medicine and Surgery, Section of Dermatology of the University of Naples Federico II from October 2017 to June 2018. Eligibility criteria were (i) moderate-to-severe HS in patients aged  $\geq 18$  years; (ii) HS duration of at least 6 months; and (iii) subjects starting adalimumab treatment (160 mg on day 1, 80 mg on day 15 and 40 mg every week from week 4). Patients affected by other skin diseases were excluded. Written informed consent from all patients was provided. All subjects received a complete dermatologic examination: disease severity and quality of life were registered using the modified Sartorius score (mSS) and HIDRADisk, respectively. Data were collected at baseline (T0) and after 12 weeks of adalimumab (T12). Student's *t*-test was used to calculate statistical differences between baseline and week 12 (T12). *P*-values  $< 0.05$  were considered to be statistically significant. Spearman test was used to evaluate the correlation among the parameters under study.

### Results

A total of 24 patients (13 females, 11 males, mean age  $38 \pm 15$  years) were included. HS mean duration was of  $6.7 \pm 3.4$  years. As expected, the anatomical sites most commonly involved were axillary regions (67%), groins (63%), gluteal regions (43%) and inter-mammary region (21%). Involvement of gluteal area prevailed in males (66%) whereas inter-mammary area in females (54%). To note, four out of 24 patients (16.7%) received for the first 4 weeks topical antibiotics or topical antiseptics concomitantly to adalimumab therapy. At baseline, mean mSS was  $76.0 \pm 6.3$ , decreasing to  $37.4 \pm 6.5$  at T12,  $P < 0.001$ . A similar trend was observed for HIDRADisk with  $75.7 \pm 8.22$  decreasing to  $61.95 \pm 14.4$  at T12,  $P < 0.001$ , with pain, odour and daily activities showing the highest rate of reductions. Despite almost

comparable improvements in mSS between males and females (from  $73.7 \pm 6.4$  to  $37.3 \pm 5.3$  in males and from  $78 \pm 5.7$  to  $37.5 \pm 7.6$  in females), HIDRADisk showed significant better improvements in males ( $69.8 \pm 6.2$ – $49.6 \pm 10.8$ ) compared to females ( $80.7 \pm 6.0$ – $72.3 \pm 6.7$ ),  $P < 0.001$ . However, a significant correlation was found in the total population between severity HS values measured through the mSS and the quality of life measured through HIDRADisk (Spearman  $r = 0.796$ ). As regards the relationship between disease outcomes and age, we observed a trend (although not statistically significant) for better HIDRADisk outcomes in younger ( $< 40$  years) compared to older adults ( $\geq 40$  years) despite no significant differences for mSS.

### Discussion

Due to its chronic nature and frequently occurring relapses, HS has a great impact on patients' QoL.<sup>5</sup> Hence, clinical disease severity assessment is essential for the development of evidence-based treatments. Several scoring systems are currently available for the assessment of HS disease severity including Hurley staging, HS Physician's Global Assessment (PGA), mSS and HS Severity Index.<sup>6–9</sup> Application of each of these assessments in daily practice has both advantages and limitations, and to date, there is no gold standard.<sup>10,11</sup> As regards the QoL, despite the fact that HS shows an index greater than any other dermatologic conditions, there are so far no specific and validated QoL instruments. However, in order to analyse all HS aspects, it is crucial to define the precise burden of the disease and to objectively evaluate the rate of HS improvement at baseline and after therapy. In this context, HIDRADisk, a simple and innovative visual HS QoL instrument, has been recently psychometrically validated in Italy demonstrating to improve the management of HS once implemented in routine clinical practice.<sup>4,5</sup> We herein showed, although in a retrospective study from a single centre, that improvement in HS after adalimumab treatment measured with mSS significantly correlated with QoL evaluated by HIDRADisk. These results are in line with a recent Italian multicenter study conducted on 140 HS patients which showed significant correlation between HIDRADisk score and HS severity evaluated through Hurley stage and HS-PGA.<sup>5</sup> Moreover, similar to a previous study,<sup>5</sup> we demonstrated that treatment led to the highest rates of improvement in HIDRADisk items such as pain, smell and daily activities. We also highlighted how different gender and age may influence disease perception and impact of HS on QoL. Specifically, we observed that females are linked to a higher perceived negative impact on QoL and sexual functions as already shown in the literature,<sup>12,13</sup> while males rarely report how the disease may affect intimacy. Interestingly, our study showed a direct relationship between age and disease duration: older age and consequent longer HS duration correlated with a more elevated impact on QoL. It is not surprising that longer disease duration may lead to increased negative impact on QoL, discouraging the patient, in line with data previously

reported by von der Werth *et al.*<sup>14</sup> who observed an indirect correlation between age at HS onset and impact on QoL, showing that patients with later disease onset experienced a lower impact on daily life and well-being. Altogether, the data described so far strongly encourage the dermatologist to be mindful of all clinical, emotional and QoL characteristics of HS patients in order to achieve an individualized treatment and maximize treatment outcomes.

In conclusion, approach to HS patients must be personalized taking into account different factors such as gender,<sup>15</sup> age, disease onset, site of skin lesions, comorbidities, patient's general health, sexuality and impact on QoL. Accordingly, HIDRADisk appears as a complete and informative tool that can easily measure the global burden of HS, guiding treatment choices and evaluating their efficacy.

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## Appendix

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