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ORIGINAL ARTICLE

Improvement in Hidradenitis Suppurativa and quality of life in patients treated with adalimumab: Real-world results from the HARMONY Study

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Abstract

Background Hidradenitis suppurativa (HS), a chronic, recurrent, debilitating skin disease, is characterized by painful, inflammatory, subcutaneous lesions of the axilla, inguinal and anogenital regions. Overall prevalence of HS is ~1%, and the impact of disease on patient quality of life (QoL) and healthcare resource utilization (HRU) is high.

Objectives To estimate the real-world effectiveness of adalimumab (Humira®) treatment in patients with moderate-to-severe HS on disease severity, pain, QoL, work productivity and HRU.

Methods HARMONY (Effectiveness of Adalimumab in Moderate to Severe HidrAdenitis SuppuRativa Patients – a Multi-cOuNtry studY in Real Life Setting) is a multicentre, postmarketing observational study in adult patients with moderate-to-severe HS. Disease severity and QoL parameters were evaluated using validated measures at 12-week intervals over 52 weeks of treatment. The primary endpoint was the proportion of patients achieving a Hidradenitis Suppurativa Clinical Response (HiSCR: ≥50% reduction in abscess and inflammatory nodule count, with no increase in abscess and draining fistula counts relative to baseline) at 12 weeks. Secondary endpoints were HiSCR at 24, 36 and 52 weeks and changes in QoL parameters and work productivity assessments. Analyses were conducted using as-observed data.

Results The proportion of patients reaching the primary HiSCR endpoint was 70.2% (n = 132/188 enrolled) and remained ≥70% until study completion. There were statistically significant ($P < 0.0001$) reductions in worst and average skin pain. All of the QoL measures evaluated improved significantly ($P < 0.0001$) by 12 weeks of adalimumab treatment, as did work productivity assessments ($P < 0.05$), and there was a ~50% decrease in HRU between baseline and week 52. Adalimumab was well tolerated.

Conclusions In this real-world setting, adalimumab treatment of moderate-to-severe HS resulted in decreased disease severity and improvements in QoL and productivity. Response to adalimumab was rapid (within 12 weeks) and sustained (52 weeks). No unexpected safety signals were reported.

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Conflict of interest

A Hafner has received funding/grant support, honorarium and fees for consulting or participating in a speakers bureaus from AbbVie Inc. PD Ghislain has received grants or fees for consultancy and/or participating in speakers' bureaus and serves as an investigator for AbbVie Inc., Almirall, Amgen, Bristol Myers Squibb, Eli Lilly, Flen Health, Galderma, Janssen, LEO Pharma, Maruho, Meda, Menarini Group, MSD, Novartis, PellePharm, Pfizer, Serono, UCB Pharma and Viatris. R Kovács has received honoraria for speaking at or participating in advisory boards from AbbVie Inc. and/or travel grants to attend conferences from AbbVie Inc., Janssen and Novartis. R Batchelor has received honoraria for speaking at or participating in advisory boards and/or sponsorship to attend conferences from AbbVie Inc., Almirall, Celgene, Dermal, Eli Lilly, Galderma, Janssen, LEO Pharma and Novartis. AC Katoulis has received payment from AbbVie Inc. for

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Introduction

Hidradenitis suppurativa (HS) is a chronic, recurrent, inflammatory, debilitating skin disease caused by obstruction of the hair follicles, secondary infection and inflammation of the apocrine glands, most commonly in the axillae, inguinal and anogenital regions, and with an onset after puberty.[1–3] The disease is characterized by painful, deep-seated, inflamed lesions that may, in severe disease, lead to scarring and the development of interconnected sinus tracts, unpleasant odour and recurrent discharge.[1,2,4]

Overall prevalence estimates for HS in the general population vary between 0.3% and 4% and according to sex and ethnicity.[5,6] Women are affected more frequently than men, and HS affects individuals during their most productive years, with a typical age of onset during the early 20s.[7–9]

Hidradenitis suppurativa has profound effects on both the physical and psychological aspects of a patient's quality of life (QoL), many of which correlate with severity of disease,[10–14] and impairment of QoL is higher than that associated with other chronic skin disease, such as psoriasis, alopecia areata and bullous pemphigoid.[15] This negative impact is influenced significantly not only by pain, but also by the clinically significant comorbidity associated with HS, including, among others, inflammatory bowel disease, metabolic syndrome, inflammatory arthritis, anxiety and depression.[2,8,10,11,16–18]

Hidradenitis suppurativa is difficult to treat, and clinical practice varies. Pharmacologic interventions to manage HS that have been reported in the literature include, but are not limited to, treatment with antiseptics, antibiotics, non-steroidal anti-inflammatory drugs, immunosuppressants, corticosteroids, anti-androgens, retinoids and tumour necrosis factor (TNF) inhibitors.[6]

Adalimumab (Humira®), a fully human monoclonal antibody against TNF-α, is currently the only approved treatment for HS in Europe, the United States, Canada and Japan.[19–22] Adalimumab showed efficacy and improvement in QoL in patients with moderate-to-severe HS in randomized controlled clinical trials.[23–25] Real-world effectiveness of adalimumab and its effect on QoL in patients with moderate-to-severe HS is not well characterized, with most recent real-world studies generally limited to small cohorts of patients.[26–29]

In this prospective study, we investigated the effect of adalimumab on disease severity, pain, QoL, work productivity and healthcare resource utilization (HRU) according to local label and clinical practice in a real-life setting.

Methods

Study design

The HARMONY (Effectiveness of Adalimumab in Moderate to Severe HidrAdenitis SuppuRativa Patients – a Multi-cOuNtry studY in Real Life Setting) study, a multicentre, postmarketing observational study (ClinicalTrials.gov identification: NCT02786576), evaluated adalimumab treatment according to routine clinical practice in patients with HS initiating adalimumab. The study was conducted at 59 sites in 11 countries in Europe and the Middle East: Austria, Belgium, Czech Republic, Great Britain, Greece, Hungary, Ireland, Israel, Lebanon, Slovenia and Switzerland.

Patient profile and selection

Eligible patients were aged ≥18 years and had a clinical diagnosis of moderate-to-severe HS; the decision to initiate treatment with adalimumab was made by a physician in accordance with the local label before any decision was made to approach the patient about participation in this study. Patients who had been treated with adalimumab before the baseline visit or were participating in a clinical interventional study were ineligible.

Disease severity was classified based on the Hurley 3-stage system: stage I – abscess formation, single or multiple, without sinus tracts and scarring; stage II – recurrent abscesses with tract formation and scarring with single or multiple, widely separated lesions; stage III – diffuse or near-diffuse involvement or multiple interconnected tracts and abscesses across the entire area.

Administration of adalimumab to patients with HS, follow-up visits, treatment, procedures and diagnostic methods were performed according to physicians' routine practice. Patients were observed for approximately 52 weeks, with clinic visits at 12, 24, 36 and 52 weeks. Written informed consent was obtained from patients before participation in the study.

Endpoints

Primary endpoint The primary effectiveness endpoint was the proportion of patients achieving a Hidradenitis Suppurativa Clinical Response (HiSCR) at week 12, defined as a ≥ 50% reduction in abscess and inflammatory nodule (AN) count from baseline, with no increase in abscesses and draining fistulas.

Secondary endpoints Secondary endpoints included the proportion of patients achieving HiSCR at 24, 36 and 52 weeks.

Patient-reported outcomes (PROs) from baseline to postbaseline time points for pain, QoL and work productivity; HRU; and adverse events (AEs) were monitored throughout the study. Patients' global assessment of skin pain was recorded on a numeric rating scale (NRS) from 0 (no skin pain) to 10 (worst skin pain imaginable). QoL was evaluated using 3 tools: (i) the Dermatology Life Quality Index (DLQI) with scores ranging from 0 (highest QoL) to 30 (lowest QoL); (ii) Patient Health 9-Item Questionnaire (PHQ-9), with each item scored from 0 (not bothered at all over the past 2 weeks) to 3 (bothered nearly every day during the past 2 weeks); and (iii) the Euro Quality of Life 5 Dimensions (EQ-5D) based on 5 weighted dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression). Scores ranged from –0.594 to 1.0 (higher numbers indicating better health status). The EQ-5D Global Health Status scores ranged from 0 (worst possible health state) to 100 (best possible health state).

Total work productivity impairment (percentage of overall work impairment due to HS) and total activity impairment (percentage of general [non-work] activity impairment due to HS) were scored from 0 (no impairment) to 100 (total impairment). Presenteeism was expressed as a percentage from 0 (no impairment while working due to HS) to 100 (total impairment while working due to HS), and absenteeism was expressed as a percentage from 0 (no work time missed due to HS) to 100 (all work time missed due to HS) using Work Productivity and Activity Impairment (WPAI)-HS.

Any changes from baseline in HRU associated with HS were reported. Serious AEs, any serious or non-serious malignancies in patients aged ≤30 years, and pregnancy were reported and documented per study protocol. Other AEs, adverse drug reactions and AEs leading to discontinuation were also documented if reported.

Statistical analyses

All statistical analyses were performed using SAS® v9.4 (SAS Institute Inc., Cary, NC, USA). The full analysis set (FAS) included all patients enrolled who fulfilled the selection criteria and who had data for ≥1 follow-up visit. All effectiveness outcomes (primary and secondary) were assessed in the FAS population. Analyses were conducted using as-observed data.

Quantitative data were analysed by statistical parameters: valid N; missing N; mean; SD; minimum, median, maximum and lower quartile (25%); and upper quartile (75%). Two-sided 95% CIs were calculated for the primary and, if applicable, secondary variables. Qualitative and categorical variables were presented by frequency (absolute and relative) distributions. Changes in quantitative variables assessed by PROs between baseline and follow-up visits were evaluated by one-sample Wilcoxon tests.

Reportable AEs were evaluated for the FAS population and coded using Medical Dictionary for Regulatory Activities v22.0 (the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use).

Results

Patient demographics and disease characteristics

A total of 231 patients at 59 sites were enrolled in this observational study, and 147 (64%) completed the study; 30 patients did not participate in the study after enrolment (i.e. provided no data) and were therefore not included in the FAS. All patients who fulfilled selection criteria and had ≥1 follow-up visit are included in the FAS (n = 201). Enrolled patients were examined an average of ≥4 times per year at most sites (81.4%), and the remaining patients were examined 3 (16.9%) and 2 (1.7%) times per year. Of the 59 sites, 54 (91.5%) followed standard treatment algorithms, including 40 sites (74%) that used international guidelines.

The study had similar proportions of men (51%) and women (49%), with a mean (range) age of 37 (18−74) years; most patients (90%) were White (Table 1), and most were current (64%) or past (16%) smokers (Table 1). Based on Hurley's staging system, 53% of patients were classified as having Hurley stage III severity, 45% as Hurley stage II and 2% as Hurley stage I (Table 1). At baseline, the duration of HS was ≤5 years in 24%, >5–10 years in 29%, >10–20 years in 31% and >20 years in 16% of the patients (Table 1). The majority of patients reported ≥1 comorbidity (74%); the most frequent comorbidities were obesity (28%), skin disease (27%), psychiatric disorders (18%) and sleep disorders (13%; Table 1).

At baseline, physician-reported mean number of abscesses, inflammatory nodules, draining fistulas and AN count were 3.5, 9.9, 4.1 and 13.4, respectively (Table 1); the regions most affected were axilla (73%) and the groin (70%), followed by buttock (43%), perineal (39%), perianal (30%) and intermammary area (23%).

At baseline, almost all patients (98%) had received ≥1 treatment for HS. Antibiotics (91%) and topical antiseptics (74%) were the most common treatments (Table S1).

A prior surgical procedure for the treatment of HS was reported for 70% of patients; incision and drainage was the most frequent procedure (53%) followed by local/limit excision (24%; Table 1).

Table 1 Baseline demographic and disease characteristics

Characteristic	Patients *n* = 201
Sex, n (%)	
Female	99 (49)
Male	102 (51)
Age, years	
Mean (SD)	37.0 (12.0)
Median (range)	36.0 (18–74)
Race/ethnic origin, n (%)	
White	181 (90)
Asian	8 (4)
Black	6 (3)
Other	6 (3)
BMI, kg/m^2	
Mean (SD)	30.1 (6.4)
Median (range)	29.6 (17.9–56.4)
Smoking status, n (%)†	
Current smoker	129 (64)
Past smoker	31 (16)
Non-smoker	40 (20)
Hurley stage, n (%)	
I	4 (2)
II	90 (45)
III	107 (53)
Number of lesions, mean (SD)	
Abscesses	3.5 (4.7)
Inflammatory nodules	9.9 (10.6)
Draining fistulas	4.1 (5.5)
AN count	13.4 (12.5)
Duration of HS, n (%), y†	
≤5	48 (24)
>5–10	58 (29)
>10–20	62 (31)
>20	32 (16)
Family history of HS, n (%)	51 (25)
Any comorbidity	149 (74)
Comorbidity, n (%)‡	
Obesity	56 (28)
Skin disease	54 (27)
Psychiatric disorder	37 (18)
Sleep disorder	27 (13)
Any surgical procedure	140 (70)
Incision and drainage	106 (53)
Local/limited excision	49 (24)
Wide excision	41 (20)
Local wound care	35 (17)
Other surgical procedure	11 (6)
Laser surgery	4 (2)

AN, abscess and inflammatory nodule (sum of abscesses plus nodules); BMI, body mass index; HS, hidradenitis suppurativa.
†Percentage based on *n* = 200.
‡Comorbidity reported in >12% of patients.

Effectiveness endpoints

A rapid and marked improvement in disease severity was observed with adalimumab treatment, with 70.2% of patients (132/188) achieving the primary endpoint of HiSCR at week 12. HiSCR rates remained at >70% at weeks 24 (75.7%; 131/173), 36 (71.3%; 102/143) and 52 (72.1%; 106/147; Fig. 1).

There were significant improvements from baseline for the PROs examined. Worst skin pain, assessed by NRS on a scale ranging from 0 (no pain) to 10 (worst pain), was significantly reduced from a baseline mean score of 5.87 to 3.20 at week 52 ($P < 0.0001$; Fig. 2a). Similarly, skin pain on average showed a significant reduction from baseline (5.08) at week 52 (2.69; $P < 0.001$; Fig. 2b).

All measures of patient-reported QoL evaluated showed a significant improvement from baseline to week 52 with adalimumab treatment ($P < 0.0001$; Fig. 3). DLQI and PHQ-9 scores decreased by approximately 50%, whereas both components of the EQ-5D (utility and global health status) showed a significant improvement from baseline to week 52. All 4 domains of the WPAI, presenteeism, absenteeism, total work productivity impairment and total activity impairment, improved significantly between baseline and week 52 of adalimumab treatment (Fig. 4).

Safety

At 52 weeks, 58 AEs had been reported among 41 patients (20.4%) in the FAS, 27 (46.6%) of which were considered mild in intensity (Table 2). The most frequent AEs were skin and subcutaneous disorders (15 patients [7.5%]), of which 10 (5%) were worsening of HS, followed by infections and infestations (10 patients [5%]). Eleven patients (5.5%) discontinued adalimumab treatment because of an AE, and 27 serious AEs were reported among 23 patients (11.4%), with 21 of these leading to new hospitalization or prolongation of hospital stay. One death was recorded in a 54-year-old man with a medical history of smoking (1 pack/d over ~30 years) and alcohol abuse.

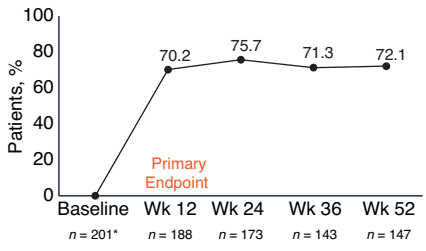

Figure 1 HiSCR Achievement. HiSCR, hidradenitis suppurativa clinical response; defined as ≥50% reduction in abscess and inflammatory nodule count with no increase in abscesses or draining fistulas. *Number of patients with abscess, inflammatory nodule and draining fistula count data at baseline.

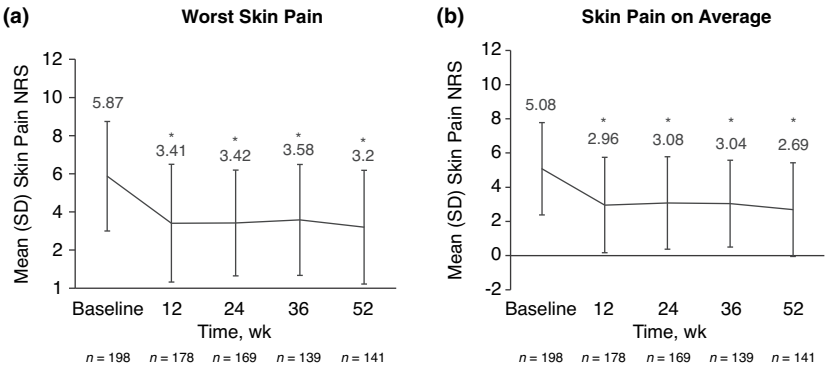

Figure 2 Skin Pain at Its Worst (a) and Skin Pain on Average (b) Over Time Assessed by NRS. Observed data are reported. NRS ranges from 0 (representing no skin pain) to 10 (representing worst skin pain imaginable). NRS, numeric rating scale. *$P < 0.0001$ compared with baseline using Wilcoxon rank sum test for patients with data at baseline and indicated time point. NRS ranges from 0 (representing no skin pain) to 10 (representing worst skin pain imaginable).

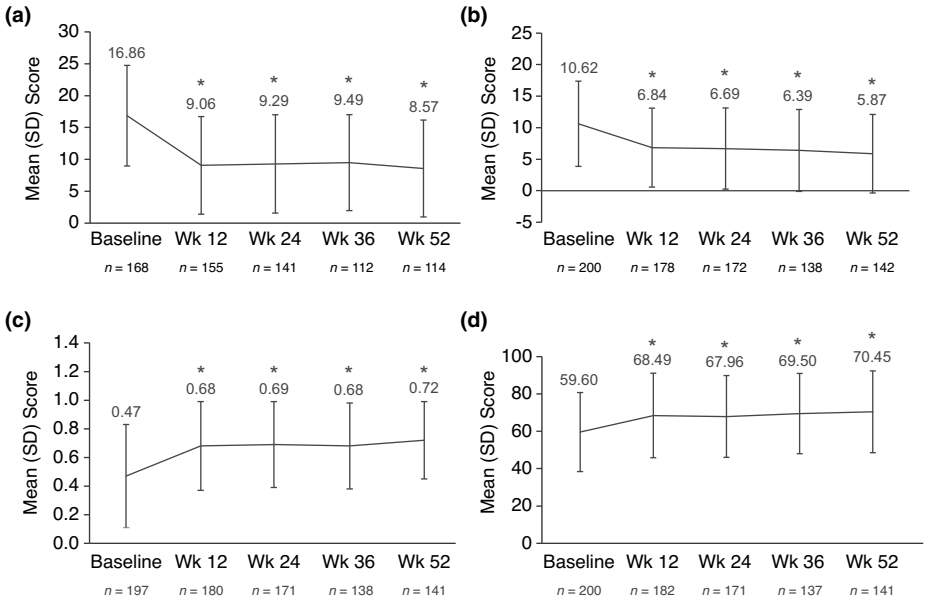

Figure 3 Patient-Reported QoL Assessed as DLQI (a), PHQ-9 (b), EQ-5D Utility Index (c) and EQ-5D Global Health Status (d). Observed data are reported. DLQI ranges from 0 (corresponding to highest QoL) to 30 (corresponding to lowest QoL). PHQ-9 is a 9-item questionnaire with each item scored from 0 (not bothered at all over the past 2 weeks) to 3 (bothered nearly every day during the past 2 weeks); the PHQ-9 score is calculated as a sum of the 9 items and ranges from 0 to 27. EQ-5D utility index is based on 5 weighted dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) and ranges from –0.594 to 1.0, with the higher number indicating better health status. EQ-5D Global Health Status ranges from 0 (worst possible health state) to 100 (best possible health state). DLQI, Dermatology Life Quality Index; EQ-5D, Euro Quality of Life 5 Dimensions; PHQ-9, Patient Health 9-Item Questionnaire; QoL, quality of life. *$P < 0.0001$ compared with baseline using the Wilcoxon rank sum test for patients with data at baseline and indicated time point.

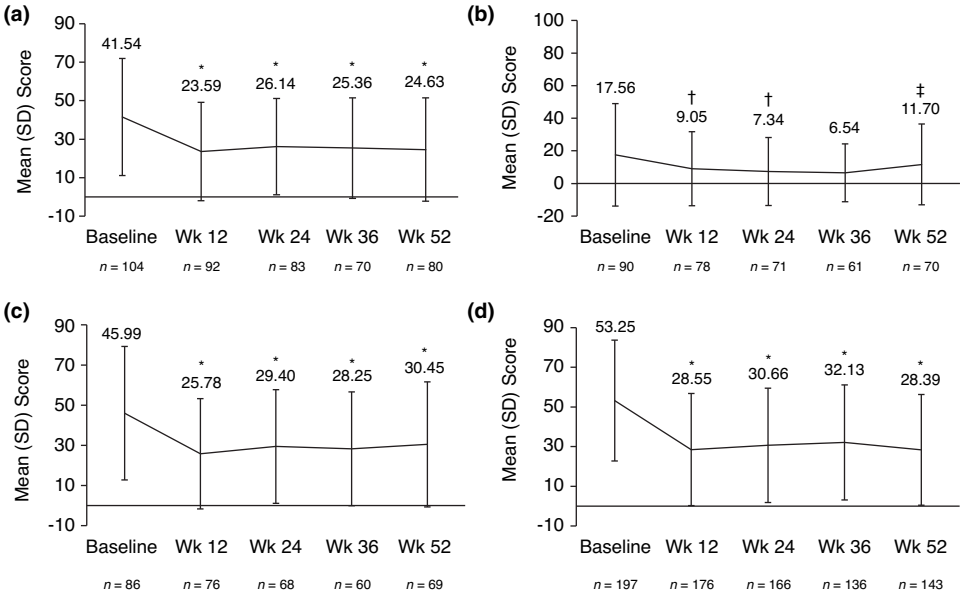

Figure 4 Mean WPAI-HS Presenteeism (a), Absenteeism (b), Total Work Productivity Impairment (c) and Total Activity Impairment (d). WPAI-HS: Presenteeism is expressed as a percentage ranging from 0 (no impairment due to HS while working) to 100 (total impairment due to HS while working). WPAI-HS: Absenteeism is expressed as a percentage ranging from 0 (no work time missed due to HS) to 100 (all work time missed due to HS). WPAI-HS: Total Work Productivity Impairment is expressed as a percentage of overall work impairment due to HS ranging from 0 (no impairment) to 100 (total impairment). WPAI-HS: Total Activity Impairment is expressed as a percentage of general (non-work) activity impairment due to HS ranging from 0 (no impairment) to 100 (total impairment). WPAI-HS, Work Productivity and Activity Impairment–Hidradenitis Suppurativa.*$P < 0.0001$, †$P < 0.01$ and ‡$P < 0.05$ compared with baseline using the Wilcoxon rank sum test for patients with data at baseline and indicated time point.

Ultrasound imaging results after 3 months of adalimumab showed multiplex hepatic metastases, whereas computed tomography and biopsy results confirmed primary bladder tumour and hepatic metastases. The investigator assessed the relationship to adalimumab treatment as reasonably possible.

Healthcare resource utilization

Overall, there was a 51% reduction in healthcare visits in the previous 6 months between baseline and week 52 (95%–46%), with the largest reduction during the first 24 weeks of adalimumab treatment. For all specialties with the exception of reconstructive surgery, there was a large reduction in HRU between baseline and week 24 that continued to week 52 (Table 3). Compared with visits to other healthcare specialists, visits to dermatologists were the most frequently reported at all 3 time points (91%, 45% and 37% at baseline, week 24 and week 52, respectively) followed by general practitioner/primary care visits (48%, 11% and 12%; Table 3).

Discussion

In this observational study conducted in patients with moderate-to-severe HS, real-world data on the use of adalimumab were collected over 52 weeks. The primary objective was to determine the effectiveness of adalimumab as a pharmacologic intervention for the treatment of HS and evaluate its effectiveness after 12 weeks of treatment.

The majority of enrolled patients had Hurley stage II (45%) or III (53%) disease. HiSCR was achieved in more than two-thirds of patients (70.2%) at 12 weeks, and improvement remained consistent until the end of the study at 52 weeks. All PROs improved throughout the study, and there were no new safety signals or unexpected trends.

Real-world effectiveness of adalimumab and its effect on QoL in patients with moderate-to-severe HS have not been well characterized to date, with most real-world studies being limited to small cohorts of patients (n = 19, 20, 34 and 41).[26–29]

The current postmarketing observational study, conducted across 11 countries in Europe and the Middle East, included data from the 201 patients who received adalimumab according to the local label and the treating physician's routine clinical practice and attended ≥1 follow-up visit. The 70.2% response rate (per HiSCR as-observed data) by 12 weeks, which was sustained to 52 weeks, was reflected in corresponding improvements in pain, QoL, work productivity and HRU, representing

Table 2 Adverse events and adverse reactions†

Patients, n (%)	Patients *n* = 201
Any AE	41 (20.4)
Serious AE	23 (11.4)
Adverse drug reaction‡	19 (9.5)
AE leading to study drug discontinuation	11 (5.5)
Most common AEs§	
Skin and subcutaneous disorders	15 (7.5)
Worsening HS	10 (5.0)
Psoriasis	2 (1.0)
Infections and infestations	10 (5.0)
Groin abscess	2 (1.0)
Nasopharyngitis	2 (1.0)
Nervous system disorders	4 (2.0)
General disorders and administration site concerns	3 (1.5)
Fatigue	3 (1.5)
Injury, poisoning and procedural complications	3 (1.5)
Neoplasms benign, malignant and unspecified (including cysts and polyps)	3 (1.5)
Surgical and medical procedures	3 (1.5)
Plastic surgery	2 (1.0)
AEs, *n* (%)	58
Mild	27 (46.6)
Moderate	22 (37.9)
Severe	9 (15.5)
Treatment related	29 (50.0)
Serious AEs, *n*	27
Requiring hospitalization/prolongation of hospitalization	21
Important medical event requiring medical or surgical intervention to prevent serious outcome	6
Death¶	1

AE, adverse event; HS, hidradenitis suppurativa.
†Serious AEs and any serious or non-serious malignancies in patients aged ≤30 years had to be reported and documented; other AEs, adverse drug reactions and AEs leading to discontinuation were documented if reported.
‡AEs with a reasonable possible relationship with study drug.
§By system order class for AEs that occurred in ≥3 patients and by preferred term for AEs that occurred in ≥2 patients.
¶Death in 54-year-old man with history of smoking 1 pack/d for 30 y and alcohol abuse due to primary urinary bladder tumour and hepatic metastases considered by the investigator to have a reasonable possible relationship to adalimumab.

Table 3 Healthcare resource utilization, FAS

HRU, *n* (%)	Baseline *n* = 201	24 Weeks *n* = 201	52 Weeks *n* = 201
Any	191 (95)	110 (55)	93 (46)
Dermatologist	183 (91)	90 (45)	75 (37)
General practitioner/primary care	96 (48)	23 (11)	24 (12)
Nurse	30 (15)	18 (9)	19 (9)
General surgeon	34 (17)	8 (4)	4 (2)
General surgery	33 (16)	4 (2)	7 (3)
Emergency department	17 (8)	8 (4)	5 (2)
Plastic surgeon	13 (6)	6 (3)	11 (5)
Plastic surgery	7 (3)	6 (3)	7 (3)
Other	10 (5)	6 (3)	1 (<1)
Gynaecologist	10 (5)	2 (1)	3 (1)
Psychiatrist/psychologist	3 (1)	3 (1)	3 (1)
Infectious diseases specialist	4 (2)	0	3 (1)
Pain clinic	2 (1)	2 (1)	2 (1)

FAS, full analysis set (multiple entries were possible); HRU, healthcare resource utilization.

one of the largest real-world studies of adalimumab in the treatment of HS.

Effectiveness in this postmarketing observational study was somewhat higher at week 12 (70.2%) than the response rates in the PIONEER I and PIONEER II phase 3 double-blind, placebo-controlled studies (41.8% and 58.9%, respectively), possibly reflecting the different methods of handling missing data (as-observed vs non-responder imputation) and the absence of a placebo control. The study populations in all 3 studies were broadly comparable, with similar proportions of patients having Hurley stage II or III disease. Adalimumab doses and frequency and discontinuation rates due to AEs were also comparable across the 3 studies. Other reasons for discontinuation of adalimumab in the HARMONY study were not collected.

A recently reported single-country study of 389 patients with HS treated in 21 centres in Italy corroborates our findings and has confirmed the importance of early treatment of HS, with those patients having delayed initiation of adalimumab and having received other immunomodulatory therapies responding less well in terms of both effectiveness and QoL.[30]

We acknowledge that our study has a number of limitations. In comparison with randomized controlled trials, the data from non-controlled studies inherently have a lower evidence level, and not all potential sources of bias can be ruled out (e.g. self-reported outcomes are subject to self-presentational and recall biases). In addition, as per the HARMONY study protocol, reporting was mandated only for serious AEs and serious and non-serious malignancies in patients aged <30 years, with other AEs being recorded only if reported spontaneously. The study is therefore limited in its ability to describe the full safety profile of adalimumab in HS in real-world clinical practice.

In conclusion, in the real-world setting, patients with moderate-to-severe HS treated with adalimumab for 12 weeks experience decreased disease severity (as assessed by HiSCR), decreased skin pain and improvements in both physical and psychological aspects of QoL and an improvement in work productivity. The marked reduction in severity of disease during the first 12 weeks of treatment indicates a rapid response to adalimumab, which was sustained through 52 weeks. Based on the safety data collected, there were no new safety signals or unexpected safety trends.

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Data availability statement

AbbVie Inc. is committed to responsible data sharing regarding the clinical trials we sponsor. This includes access to anonymized, individual and trial-level data (analysis data sets), as well as other information (e.g. protocols and clinical study reports), as long as the trials are not part of an ongoing or planned regulatory submission. This includes requests for clinical trial data for unlicensed products and indications. These clinical trial data can be requested by any qualified researchers who engage in rigorous, independent scientific research, and will be provided following review and approval of a research proposal and Statistical Analysis Plan (SAP) and execution of a Data Sharing Agreement (DSA). Data requests can be submitted at any time, and the data will be accessible for 12 months, with possible extensions considered. For more information on the process, or to submit a request, visit the following link: https://www.abbvie.com/our-science/clinical-trials/clinical-trials-data-and-information-sharing/data-and-information-sharing-with-qualified-researchers.html.

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Supporting information

Additional Supporting Information may be found in the online version of this article:

Table S1. Prior HS Treatment