

## ORIGINAL ARTICLE

# A cross-sectional epidemiological study of hidradenitis suppurativa in an Irish population (SHIP)

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## Abstract

**Background** Hidradenitis suppurativa (HS), a chronic inflammatory disease that affects apocrine gland-bearing skin, has a significant impact on patients' quality of life. Estimates of the epidemiologic prevalence of HS are highly variable, and clinical data on disease characteristics and patient burden of disease remain limited.

**Objective** The primary objective of this study was to determine the number of patients with HS attending dermatology clinics in a hospital setting in Ireland (within a 6-month time period). Secondary objectives included the assessment of disease characteristics and the collection of patient responses on disease burden and work productivity.

**Methods** This was an epidemiologic, non-interventional, cross-sectional study across four dermatology clinics in Ireland over a 6-month time period. The disease prevalence was estimated by calculating the percentage of total patients with a diagnosis of HS (the primary population) across the selected sites. Secondary analyses were performed using the full analysis set, which consisted of eligible adults ( $\geq 18$  years of age) from the primary population who provided informed consent. Data from these analyses are presented as descriptive summary statistics, with the use of an analysis of covariance for continuous endpoints.

**Results** The prevalence of HS across the four selected sites was estimated at 1.4% (95% CI, 1.24–1.62). One hundred and fifty eligible patients comprised the full analysis set. The majority of participants were white (95.3%), female (70.0%), cigarette smokers (56.0%) and overweight or obese (body mass index  $\geq 25$  kg/m<sup>2</sup>, 81.8%). Most patients for whom data were available presented with Hurley stage II (50.4%), and more than a third of the full analysis set had a relative with HS (34.7%). Questionnaire responses revealed a profound impact on quality of life, including diminished work productivity and various psychological comorbidities.

**Conclusion** This study offers insight into the clinical features and disease burden of hidradenitis suppurativa in an Irish population.

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## Conflicts of interest

The design, study conduct, and financial support for the study were provided by AbbVie. AbbVie participated in the interpretation of data, review and approval of the manuscript. Emma Delany and Gemma Gormley are employees of AbbVie and may own AbbVie stock or options. Professor Brian Kirby has received research support from AbbVie, Janssen, MSD, Novartis and Pfizer, and has served as a consultant and/or received Honoraria from Abbott, AbbVie, Celgene, Eli Lilly, Janssen, MSD, Novartis and Pfizer. Dr Trevor Markham has received research support from AbbVie and Pfizer; has served as a consultant and/or received Honoraria from Abbott, AbbVie, Janssen, Novartis and Pfizer; and has served as a consultant to AbbVie in the conduct of the SHIP study. Dr Michelle Murphy has served as a consultant to AbbVie in the conduct of the SHIP study and has received research funding for the SHIP study from AbbVie. Dr Anne-Marie Tobin has served on advisory boards for AbbVie, Janssen, Leo Pharma, Novartis and Pfizer, and has received unrestricted grant funding from AbbVie, Merck Serono and Pfizer. Dr Rosalind Hughes, Dr Shivashini Kirthi and Dr Siobhan McCarthy have no conflict of interests to declare.

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## Introduction

Hidradenitis suppurativa (HS), also known as acne inversa, is a chronic inflammatory disease of apocrine gland-bearing skin that has a significant impact on patients' quality of life.<sup>1</sup> The disease is characterized by painful, inflammatory nodules or boils that may progress to abscesses, sinus tract formation and scarring.<sup>2,3</sup> Although the aetiology of HS is largely unknown, it is likely that multiple factors contribute to the development of the disease.<sup>4</sup>

The diagnosis of HS is often delayed, and both diagnosis and treatment are recognized as areas of unmet medical need.<sup>5</sup> A diagnosis is made based on a combination of patient history and physical examination. The most established method for classifying HS disease severity is the Hurley staging system,<sup>6</sup> which discriminates between patients based on the extent of tissue damage, and may be used as a guide for selecting the course of surgical treatment. Current treatment options include surgery and the use of pharmacologic agents, including local or systemic antibiotics; topical, intralesional, or less commonly, oral corticosteroids; and biologic agents (for moderate-to-severe disease).

Several endogenous factors have been postulated to contribute to the development and maintenance of HS. These include genetic predisposition, hormonal dysregulation and an aberrant immune response to commensal bacteria.<sup>7–10</sup> A number of exogenous influences have also been implicated in population-based studies of HS, particularly smoking and obesity,<sup>11</sup> although a causative relationship has not been established.

The prevalence of HS is reported to be approximately 1%–4% of the general population, with disease onset occurring typically in young adulthood.<sup>8,12–14</sup> The estimates of population-based prevalence are limited and are subject to considerable variation.<sup>11,15</sup> The majority of patients with HS present with Hurley stage I or II, with the incidence of stage III (severe disease) falling between 2.2% and 22.2%, according to recent reports.<sup>8,16,17</sup>

This was a cross-sectional, epidemiologic Study of HS in an Irish Population (SHIP). The primary objective of the study was to determine the number of patients with HS attending dermatology clinics in a hospital setting in Ireland within a 6-month time period. Secondary objectives included the assessment of current disease status, disease characteristics, referral and treatment patterns, patient disease burden, work productivity and total activity impairment (i.e. the impact on daily activities outside of work), evidence for all of which has been lacking to date.

## Materials and methods

### Study design

This was an epidemiologic, non-interventional, cross-sectional (single-visit), multicenter study in Ireland over a 6-month period in 2015. This time frame was chosen based on an estimate that patients with HS undergoing treatment in secondary care would attend one dermatology consultation every 3–6 months.

### Patients

Eligible patients were  $\geq 18$  years of age, diagnosed with HS by a consultant dermatologist in a hospital setting and attending a single routine dermatology clinic over a 6-month period. All patients who met the eligibility criteria were offered the opportunity to participate in the study. Any eligible patients attending the clinic who did not wish to participate in the study were recorded using the non-participating patient log, and the total number of patients who attended each clinic was tracked using the log from each site. All patients participating in the study provided signed and dated informed consent.

### Bias

Although it is estimated that all patients with HS currently undergoing treatment in secondary care will have a dermatology consultation every 3–6 months, it is not possible to completely eliminate bias within the framework of this study. It is possible that delays in diagnosis would result in a cohort of undiagnosed patients who do not attend a study visit for treatment, and were thus excluded from this study. Patients managed in primary care, as well as those who did not have active symptoms during the 6-month recruitment period, were omitted from this analysis. Detection bias may also be possible in the event that, for example, females were more proactive in seeking treatment than males.

### Study procedures and evaluations

The primary endpoint of this study was the number of patients with HS attending selected dermatology clinics in a hospital setting in Ireland. Secondary endpoints included assessment of disease characteristics and evaluation of patient burden of disease (including impacts on work productivity and other daily activities). Data were collected during a single, routine visit across four sites: St Vincent's University Hospital, Dublin; South Infirmary Victoria University Hospital, Cork; Adelaide and Meath Hospital, Tallaght; and Galway University Hospital, Galway.

A number of parameters were assessed in this study, some of which are reported in this manuscript. Demographic data were obtained for all of the participating patients, including race, age at study consent and employment status. In addition, a panel of disease-related parameters were measured, including smoking status, body mass index (BMI) and multiple markers of disease severity (Hurley stage, C-reactive protein [CRP] levels and HS-Physician Global Assessment [HS-PGA] score). Patient disease burden was assessed using a number of patient-reported outcomes. Quality of life was determined through the Dermatology Quality of Life Index (DLQI), as well as responses to the Euro Quality of Life Health Outcome Measure (EQ-5D-5L) questionnaire. Work productivity was assessed using a Work Productivity and Activity Impairment (WPAI) questionnaire, and depressive symptoms were assessed through the Patient Health Questionnaire-2 (PHQ-2). Both current and prior treatments

for HS were also recorded for all patients. No follow-up visits were planned or conducted in this study.

### Statistical analysis

This was an exploratory study without a predefined hypothesis. As such, formal power and sample size calculations were not necessary. The population for the primary analysis included all patients attending the clinics during the recruitment period with a diagnosis of HS. As a co-primary analysis, the prevalence was extrapolated as the percentage of total patients attending the four clinics during this period who presented with HS, regardless of whether or not they consented to participate in the study. A 95% confidence interval (CI), based on the exact binomial distribution, was provided around the prevalence estimate.

All patients providing consent were included in the secondary analyses and are referred to as the full analysis set. Data from these analyses are presented as descriptive summary statistics, with the use of an analysis of covariance for continuous endpoints. Patients with missing values were summarized in a 'Missing' category.

## Results

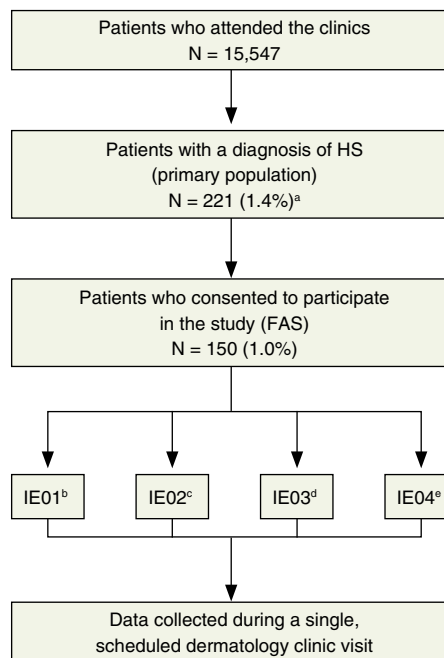
### Patient disposition, HS prevalence and baseline characteristics

A total of 15 547 patients attended dermatology clinics at the four sites during the recruitment period (Fig. 1), of which 221 had a diagnosis of HS and formed the primary population. This number was used to calculate an estimate of the prevalence of HS across the four clinics (1.4%; 95% CI, 1.24–1.62). Of the primary population, 150 eligible patients gave their consent to participate in the study and comprised the full analysis set (Fig. 1). The average age of participants was 37 years, and the majority were female (70.0%) and white (95.3%; Table 1).

### Clinical profile

The average duration of HS symptoms prior to diagnosis was 8.5 years (standard deviation [SD] = 7.9), with an average age at diagnosis of 31.3 years (SD = 10.1), and an average disease duration since diagnosis of 5.3 years (SD = 7.3). Male patients were older at diagnosis compared with female patients (34.8 vs. 29.9 years;  $P = 0.022$ ), and there was a statistically significant association between duration of symptoms until diagnosis and age ( $P < 0.001$ ; Fig. 2).

The majority of patients for whom data were available initially had Hurley stage I disease, as recalled by the patient ( $n = 41$ ; 55.4%). The majority had Hurley stage II at the study visit ( $n = 68$ ; 50.4%; Fig. 3a). The Hurley stage at diagnosis was not recorded for 50.3% of patients ( $n = 75$ ). The most common HS-PGA at diagnosis (as recalled by the patient) was mild ( $n = 27$ ; 40.9%), but this had progressed to moderate by the study visit ( $n = 59$ ; 43.7%; Fig. 3b).



**Figure 1** Patients attending clinics at the selected study sites. FAS, full analysis set; HS, hidradenitis suppurativa. <sup>a</sup>The prevalence of HS at the four study sites over the 6-month recruitment period was estimated to be 1.4% (95% confidence interval, 1.24–1.62). <sup>b</sup>IE01: St Vincent's University Hospital. <sup>c</sup>IE02: South Infirmary Victoria University Hospital. <sup>d</sup>IE03: Adelaide and Meath Hospital. <sup>e</sup>IE04: Galway University Hospital.

Average CRP levels correlated with both Hurley stage (stage I: 7.2; range, 0.6–49.7; stage III: 12.6; range, 0.5–85.0; Fig. 4a) and HS-PGA status (minimal: 6.5; range, 1.3–20.6; very severe: 33.3; range, 7.6–85.0; Fig. 4b). Most patients (81.8%) were overweight or obese (BMI  $\geq 25$  kg/m<sup>2</sup>; Fig. 5a), and 56.0% were current cigarette smokers (22.0% former; Fig. 5b).

### Family history

A total of 52 patients in the full analysis set (34.7%) had a relative with a diagnosis of HS, including 42 (28.0%) with a first-degree relative, 16 (10.7%) with a second-degree relative and 6 (4.0%; Fig. 3A) with a third-degree relative. The most common family members with HS were female first-degree relatives (23.4% mother; 21.9% sister).

### HS-related treatments

A total of 143 patients (95.3%) were either currently taking HS-related medications or had done so previously. Of the 319 medications taken previously, antibiotics were the most common. These included clindamycin/rifampicin (16.9%), flucloxacillin (15.7%) and tetracycline (14.4%). In comparison, of the 67

**Table 1** Socio-demographics of study population

Parameter	N (%)	Mean	SD
<b>Sex</b>			
Male	45 (30.0%)		
Female	105 (70.0%)		
<b>Age at study consent (years)</b>			
Male	45 (30.0%)	36.5	11.3
Female	105 (70.0%)		
<b>Height (cm)</b>			
Male	45 (30.0%)	167.8	10.4
Female	105 (70.0%)		
<b>Weight (kg)</b>			
Male	45 (30.0%)	91.2	24.5
Female	105 (70.0%)		
<b>BMI (kg/m<sup>2</sup>)</b>			
Male	45 (30.0%)	32.3	8.6
Female	105 (70.0%)	30.3	6.6
<b>Race</b>			
White	143 (95.3%)		
Black	1 (0.7%)		
Asian	1 (0.7%)		
Other	5 (3.5%)		
<b>Smoking status</b>			
Never smoked	33 (22.0%)		
Smoker	84 (56.0%)		
Former smoker	33 (22.0%)		
Number of smoking pack years <sup>†</sup>		17.0	12.7
<b>Alcohol consumption (units/week)</b>			
Male	45 (30.0%)	4.4	6.4
Female	105 (70.0%)		
<b>Employment status</b>			
Student	16 (10.7%)		
Employed	76 (50.7%)		
Unemployed	32 (21.3%)		
Temporary illness disability	4 (2.7%)		
Permanent illness disability	10 (6.7%)		
Other <sup>‡</sup>	12 (8.0%)		
Sick days in past 12 months	113	15.9	59.1

BMI, body mass index; SD, standard deviation.

<sup>†</sup>Data are presented for both current and former cigarette smokers.

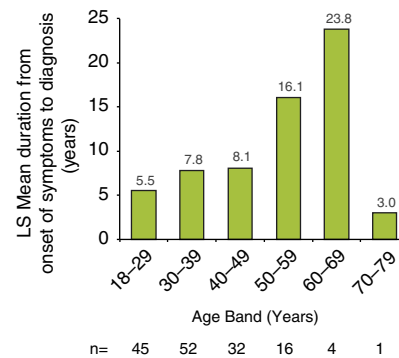
<sup>‡</sup>Includes caregivers; full-time and stay-at-home mothers; housewives; and patients who were retired, on maternity leave, doing voluntary work, or working full-time from home.

ongoing medications, the most common were clindamycin/ri-fampicin (35.8%), adalimumab (13.4%) and minocycline (10.4%).

### Employment and quality of life

The WPAI questionnaire was completed by 143 patients, almost half of whom were employed at the time of the study visit (49.7%). A substantial proportion of the full analysis set were unemployed (21.3%), while others were out of work due to temporary or permanent illness disability (9.4%).

Patient-reported outcomes concerning quality of life (reported by the DLQI) revealed that 91.7% of 145 responders were embarrassed/self-conscious about their skin, with 33.8% being very embarrassed/self-conscious and 93.8% reporting that the condition of their skin influenced the clothes that they wear. The

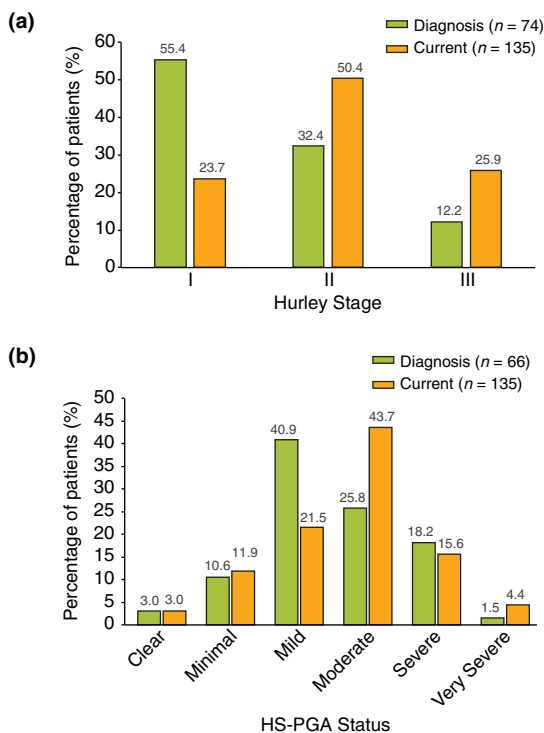


**Figure 2** Mean duration from onset of symptoms to diagnosis, by age band. HS, hidradenitis suppurativa; LS, least squares. The difference in LS means between the 18–29 age band and the remainder of the full analysis set was found to be statistically significant ( $P < 0.001$ ) based on an analysis of covariance. The duration of symptoms before diagnosis of HS was calculated in years (year + month/12). Where responses for years have been provided with only a lower limit (e.g. 25+ years), these are included in the calculation as 25. If the year was recorded but the month is unknown, then the month is taken as 0 for the calculation of the duration. If the year is unknown but the month was recorded, then the year is taken as 0 for the calculation of the duration. Partial dates are imputed as follows: if the day is missing, then the first day of the month (01) is taken; if the month is missing, then the first month of the year (January) is taken. Any patient who did not have a record of duration until diagnosis was removed from the analysis.

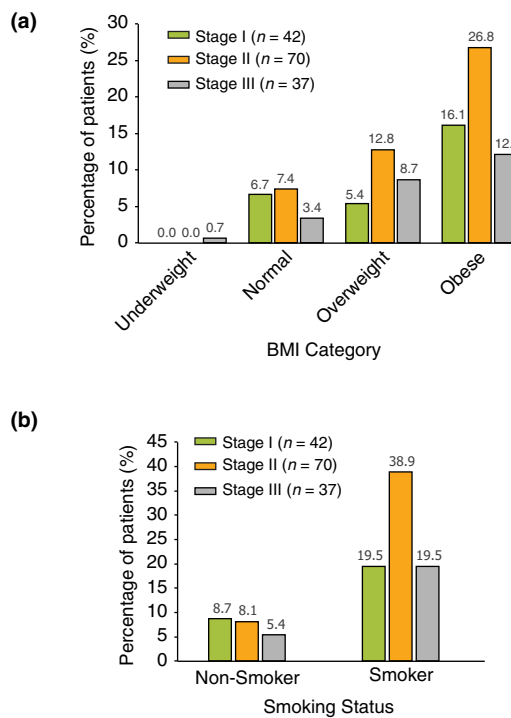
majority of responders indicated that their skin had an impact on social leisure activities ( $n = 120$ ; 82.8%); made it difficult to participate in sports ( $n = 110$ ; 76.4%); interfered with activities at home, in the garden, or while shopping ( $n = 102$ ; 70.3%); or that the treatment of their condition had been a problem ( $n = 78$ ; 55.3%). The responses to the EQ-5D-5L indicated that most patients had also felt anxious or depressed to some extent (Fig. 6a), which was consistent with responses from the PHQ-2 (Fig. 6b).

### Discussion

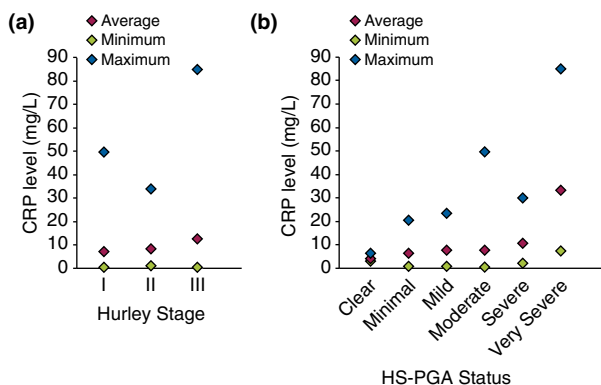
Hidradenitis suppurativa is a common condition in dermatology clinics in Ireland and has a considerable impact on patients' quality of life. The primary endpoint of this study was the number of patients with a diagnosis of HS attending selected dermatology clinics in Ireland within a 6-month time period. The study was performed across 4 clinics and identified 221 patients with HS, who formed the primary population. As a co-primary analysis, the primary population was used to estimate the prevalence of HS in these clinics (1.4%). It is thought that many patients with HS seek medical care from their general practitioner and equally, it is possible that patients with other dermatological diseases (e.g. acne) are less likely to attend dermatology



**Figure 3** (a) Hurley stage reported at diagnosis and at study visit and (b) HS-PGA status reported at diagnosis and at study visit. HS-PGA, hidradenitis suppurativa-Physician Global Assessment. Percentages are calculated from the number of patients who provided a response for each criterion.



**Figure 5** (a) Hurley stage at study visit correlated with BMI category and (b) Hurley stage at study visit correlated with smoking status. (a) BMI, body mass index; WHO, World Health Organization. BMI categories are based on WHO guidance, where values  $<18.50 \text{ kg/m}^2$  = underweight;  $\geq 18.50$  and  $<25.00 \text{ kg/m}^2$  = normal range;  $\geq 25.00$  and  $<30.00 \text{ kg/m}^2$  = overweight; and  $\geq 30.00 \text{ kg/m}^2$  = obese. Where current Hurley stage was not provided, the Hurley stage at diagnosis was substituted. Patients who did not have any record of a documented Hurley stage were removed from the analysis. (b) The smoker category combines both current and former cigarette smokers. Where current Hurley stage was not provided, the Hurley stage at diagnosis was substituted. Patients who did not have any record of a Hurley stage were removed from the analysis.

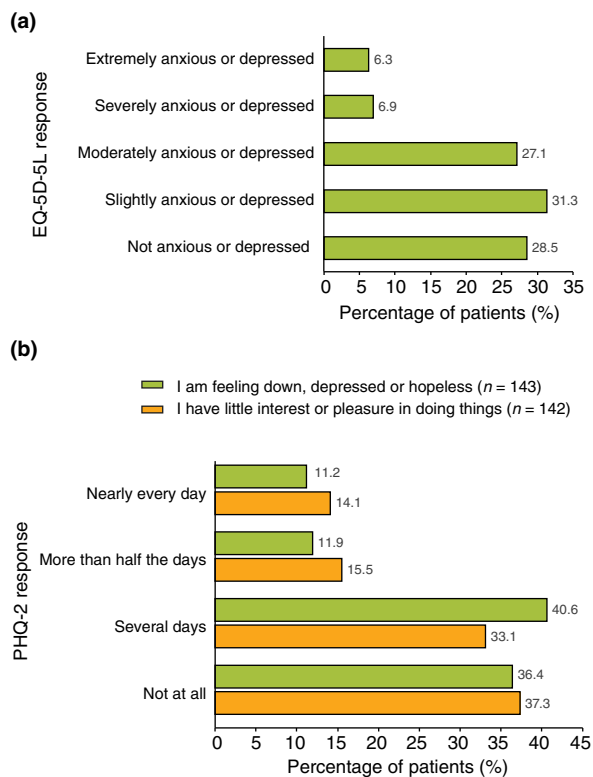


**Figure 4** (a) Hurley stage at study visit correlated with CRP and (b) HS-PGA status at study visit correlated with CRP. CRP, C-reactive protein; HS-PGA, hidradenitis suppurativa-Physician Global Assessment.

clinics, thereby artificially inflating the prevalence observed in this study. As such, this figure cannot be used to infer disease prevalence in the general Irish population.

The majority of patients participating in this study were female, which aligns with previous reports and validates the population chosen for observation.<sup>8,18</sup> In terms of disease severity, patients presented most commonly with Hurley stage II, followed by stage III, which is also in line with previous research.<sup>19</sup> CRP levels correlated with both Hurley stage and HS-PGA status, indicative of a systemic inflammatory response at more severe stages of the disease. This confirms the utility of CRP as a marker of disease severity.<sup>20</sup>

The mean duration between the onset of symptoms and diagnosis was 3 times shorter in patients aged 18–29 years than in those >50 years. We speculate that this difference could be explained by a multitude of factors, including increased



**Figure 6** (a) EQ-5D-5L quality of life questionnaire – anxious or depressed and (b) PHQ-2 responses. (a) EQ-5D-5L, Euro Quality of Life Health Outcome Measure. Percentages are calculated from the number of patients who provided a response for each question ( $n = 144$ ). (b) PHQ-2, Patient Health Questionnaire-2. Percentages are calculated from the number of patients who provided a response for each question.

awareness of HS and its treatment, and a more proactive approach to health care amongst younger patients.

More than a third of patients had a family member with HS, with the most frequently affected family members being mothers and sisters. This is consistent with previous reports of a hereditary predisposition in females, with mother–daughter transmission being the most common.<sup>21</sup>

The finding that 56% of the full analysis set were current cigarette smokers confirms previous reports of a relationship between smoking and HS.<sup>2,22</sup> This figure is striking when compared with the prevalence of smokers in the general Irish population, in which an estimated 19% of individuals aged  $\geq 15$  years smoke daily and a further 4% identify as occasional smokers.<sup>23</sup>

Disease severity (as measured by Hurley stage and HS-PGA) generally worsened from the time of diagnosis to the study visit, although it is worth noting that not all patients had their disease stage documented by a physician at diagnosis. Nevertheless, this trend implies that the disease is progressive in nature and

highlights the need for substantial improvements to existing treatment options. While there has already been a shift in the types of non-surgical treatments offered to patients, to align with the recently revised prescribing advice for HS,<sup>15</sup> antibiotics remained the most common course of treatment at the study visit, with anti-tumour necrosis factor therapy being the second most common treatment. This observation contrasts with a previous report, summarizing data from the 1990–2009 National Ambulatory Medical Care Survey, in which prescriptions of biologics for patients with HS were non-existent.<sup>24</sup> This study therefore offers insight into the evolving treatment paradigm for this disease.

Patients with HS may experience a negative impact on their quality of life and work productivity.<sup>25</sup> The EQ-5D-5L and PHQ-2 scores reported in this study reveal that the majority of patients were suffering from significant levels of self-reported anxiety and depression, with concurrent impacts on social activities and sexual relationships. In addition, about half of the participants in this study were not employed (49.3%), compared with just 7.3% of the general Irish population.<sup>26</sup> This is concordant with a previous report revealing a high rate of unemployment in patients with HS.<sup>27</sup>

This study is limited by the small number of centres and the homogeneous patient sample used for analysis. In particular, the cohort was predominantly white; as such, any interpretation of these data for other countries should be exercised with caution. The results obtained offer insight into the significant unmet need in this patient population and emphasize the need for improved management of the disease to improve patients' quality of life.

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