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ORIGINAL ARTICLE

Real-world effectiveness and safety of the LAight-therapy in patients with hidradenitis suppurativa

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Summary

Background and objectives: Hidradenitis suppurativa (HS)/Acne inversa (Ai) is a chronic debilitating disease with limited therapy options. The device-based LAight therapy was approved in Europe in 2017. The aim of this study was to evaluate the effect of real-world care with at least one treatment with LAight therapy on disease activity and burden in 3,437 patients.

Patients and Methods: Patients were included in the analysis if they had a diagnosis of HS and received at least one treatment. The endpoints *Hidradenitis Suppurativa Severity Score System* (IHS4), pain on the numeric rating scale (pain-NRS) and *Dermatology Life Quality Index* (DLQI) were analyzed using a linear mixed model for repeated measures (MMRM) over 26 weeks of care with LAight therapy. Furthermore, responder rates were calculated for all endpoints, and the therapy's safety profile and patient satisfaction were thoroughly examined.

Results: A significant decrease in IHS4, pain-NRS, and DLQI was achieved during 26 weeks of care with LAight. The BMI at baseline had a significant negative effect on therapy response for pain-NRS and DLQI.

Conclusions: This study confirms that LAight therapy leads to satisfactory disease control in all stages of severity and is a valuable addition to the therapeutic repertoire of HS.

KEYWORDS
acne inversa, hidradenitis suppurativa, laight-therapy, outpatient setting

INTRODUCTION

Hidradenitis suppurativa (HS)/Acne inversa (Ai) is a debilitating and chronic skin disease characterized by recurrent formations of abscesses and inflammatory nodules, which can turn into draining tunnels and scarring.[1,2]

First-line treatments for HS include topical and oral antibiotics that are limited in their long-term application.[3] For moderate to severe disease, biologic therapy with adalimumab or secukinumab is indicated after failure of systemic antibiotic treatment.[4–6] In all stages of HS, surgical procedures should be considered;[3] the importance of such interventions increases with disease severity.[7,8] However, around half of patients are dissatisfied or very dissatisfied with the current treatment options and procedures.[9,10] In a recent study, van der Zee et al.[11] highlighted that none of these treatment options can effectively fulfill the objectives of extending disease remission and preventing disease progression. In this context, there is a lack of effective treatments, especially for early or mild forms of HS. In 2017 the device-based LAight therapy (LENICURA, Germany) was approved for all disease severities of HS. It utilizes a combination of radiofrequency (RF) and intense pulsed light (IPL), for which technical details can be found in the online supplementary Table S1.[12] A randomized controlled trial involving patients with Hurley stage I and II demonstrated that a treatment combining LAight sessions every other week with topical clindamycin 1% solution over 16 weeks resulted in a significantly higher reduction in disease severity and improvement in quality of life compared to using clindamycin 1% solution alone.[13] Furthermore, the study revealed that a consecutive monotherapy with LAight every other week over an additional 16 weeks effectively maintained and even enhanced the positive outcomes.[14]

To supplement results from clinical trials with controlled settings and specific patient groups, it is crucial to collect real-world routine healthcare data. The LAight therapy is performed in outpatient centers in Germany and is accompanied by specific software from the manufacturer, which facilitates standardized collection of data following patient-informed consent. Therefore, we aimed to analyze the effect of LAight therapy on the longitudinal course of disease activity and burden in a real-world setting with 3,437 patients. Moreover, the safety profile of the therapy as well as patient satisfaction were examined.

PATIENTS AND METHODS

The data presented in this publication was evaluated within the EpiCAi-project (Epidemiology and Care in Acne inversa) which is a collaborative effort involving an international consortium of experts led by the Department of Dermatology at University Medical Center in Mainz, Germany. The study protocol was approved by the ethics committee of Rhineland-Palatinate and the trial was registered in the German Register for Clinical Trials (DRKS, # DRKS00025315).

The aim was to combine real-world data from the care of a large number of HS patients with additional prospective digital surveys. All HS-diagnosed patients who gave written consent to the documentation and evaluation of the data gathered in the manufacturer's software during the routine care with LAight therapy were part of EpiCAi. Invitations for the additional questionnaires were sent out either by mail to the address provided by patients, displayed by flyers at the treatment sites of the LAight therapy or made through central announcements on the project website (www.epicai.de). After logging into their own account, patients were shown questionnaires on different topics. It was not mandatory to fill out all questionnaires, but once a questionnaire was started, it had to be finished within seven days, otherwise the most recent status was saved.

Patients were included in the analysis if they were diagnosed with HS by a treating specialized physician and received at least one treatment with LAight. Hurley staging was documented and the disease severity was measured by the *Hidradenitis Suppurativa Severity Score System* (IHS4) as the sum of inflammatory nodules + 2 x abscesses + 4 x draining tunnels.[15] In addition, the patient reported outcomes *(PROs)* pain on the numeric rating scale from zero "no pain" to ten "worst pain imaginable" (pain-NRS),[16] and the *Dermatology Life Quality Index* (DLQI) were gathered.[17] While the collection of the two PROs was mandatory for every single treatment, the IHS4 was filled out regularly by the trained personal. Demographic variables, risk factors, and instruments describing the disease were evaluated using means and corresponding standard deviations or relative/absolute frequencies.

The endpoints IHS4, pain-NRS and DLQI were analyzed with a linear mixed model for repeated measures (MMRM) including 26 weeks of care with the LAight therapy, covering the so called "acute phase" of the treatment plan

as stated by the manufacturer, suggesting a treatment frequency of every 14 days during these 26 weeks. To fulfil the assumptions of linearity and normal distribution, each endpoint was logarithmically transformed. The model was adjusted for gender, Hurley stage and the two most common risk factors, body mass index (BMI) and smoking behavior. Besides the display of absolute changes in endpoints, a responder analysis was conducted at weeks 4, 8, 12, 16, 20, and 26 for each endpoint using the following definitions:

- *IHS4-55*: Patients achieving at least 55% reduction in IHS4.[18]
- *Pain-responder*: Patients starting with at least three points in pain-NRS and achieving at least 30% reduction of the value and a minimum of one point.
- *DLQI-responder*: Patients achieving the minimal clinically important difference of four points.[19]

Responder rates were based on observed values; however, missing values were imputed using the estimation obtained from the mixed model. For the MMRMs and responder analyses, only patients for whom improvement in endpoints had clinical relevance at baseline were included. Thus, only patients who started with a minimum of three inflammatory lesions, had a pain level of at least three or a minimum of four DLQI points at their initial visit were analyzed. These inclusion criteria align with those of most clinical trials in HS.[6,13] The occurrence of side effects was quantitatively assessed for all available data. In addition, a subgroup of patients answered the additional digital questionnaire about their experience with LAight therapy. The relative frequencies of self-reported therapy satisfaction were analyzed descriptively. Furthermore, the fractions of positive therapy effects were counted univariately.

RESULTS

Patient characteristics

In total 3,513 patients had a valid HS-diagnosis and thus were eligible for the analysis. Of those, 3,437 had at least one LAight treatment and 193 filled out the additional questionnaire on LAight therapy. The analyzed treatment period ranged from 4th of August 2017 to 18th of January 2023, also marking the end of the data collection for the EpiCAi project.

Table 1 shows the baseline characteristics of the 3,437 patients. Most patients were female (66.4%), but the gender divergence diminished with increasing severity and reached a rather equal distribution in Hurley stage III (58.0% vs. 42.0%). Overall disease severity and burden was high, with an average baseline IHS4 score of 13.02 ± 19.07 (severe HS), an average DLQI of 13.0 ± 7.99 (very large effect on patient's life) and an average pain-NRS of 3.89 ± 2.81, all associated with the Hurley stage. This confirms the disease impact on HS-patients' private and professional lives during disease progression.

Within the analyzed sample, the presence of the risk factors smoking and obesity was more prevalent among individuals with higher levels of disease activity. 52.1% with Hurley stage I smoked, this number increased to 64.0% in Hurley stage III. Similarly, 28.3% of patients classified as Hurley I were found to be obese, while the prevalence of obesity exceeded 50% in those classified as Hurley III.

Effects on inflammatory lesions (IHS4)

Table 2 depicts the model for the development of the IHS4 under LAight therapy. 1,568 patients had valid IHS4 scores, defined as at least three inflammatory lesions at baseline. The model-predicted values are shown in Figure 1. On average, patients in Hurley stage I showed an IHS4 of 5.6 at baseline (moderate disease). In comparison, IHS4 at baseline was 3.9 points (69.6%) higher among Hurley II patients and 12.8 points (228.6%) higher among Hurley III patients. The risk factors, smoking and BMI, also had a significant positive association with the IHS4 at baseline. Under treatment with LAight, the IHS4 significantly decreased over time with a comparable relative positive impact on all disease severities. The decrease was not influenced by the risk factors.

The results are resembled in the associated responder values. At week 26, 64.4% of Hurley I patients achieved IHS4-55, while the proportion of responders amounts to 50.7% for Hurley II and 47.6% for Hurley III (Figure 1). Reduction of the IHS4 was demonstrated gradually over time.

Effects on pain

Table 3 illustrates the model used for the evaluation of pain-NRS. 2,179 patients reported a minimum pain level of three or higher at the beginning of treatment.

On average, the level of pain was 3.2 points for Hurley stage I at baseline (Figure 1). In comparison, pain levels were 1.1 points (34.4%) higher in Hurley II and 1.9 points (59.4%) higher in Hurley III patients. Male patients reported a significantly lower pain level at baseline than female patients, and a higher BMI was associated with higher pain levels. Treatment with LAight significantly reduced pain scores over time, with comparable relative effects across all disease severities. The model showed that the pain reduction achieved was significantly lower in individuals with a higher BMI. This slightly affected the decrease in pain over 26 weeks in relation to baseline for higher severity stages, since higher proportions of obese patients were included.

The findings are reflected in the respective responder rates. By week 26, pain response was observed in 80.0% of

TABLE 1 Baseline characteristics of patients receiving at least one LAight treatment.

	All(n = 3,437)	Hurley I(n = 854)	Hurley II(n = 1997)	Hurley III(n = 586)
Demographics				
Sex, n (%)				
Female	2 282 (66.40)	592 (69.32)	1 350 (67.60)	340 (58.02)
Male	1 155 (33.60)	262 (30.68)	647 (32.40)	246 (41.98)
Age (M ± SD)[1]	38.60 (± 11.56)	37.24 (± 11.69)	38.43 (± 11.42)	41.14 (± 11.42)
Working status, n (%)				
Employed	1,584 (75.21)	417 (76.94)	909 (75.56)	258 (71.47)
Occupationally disabled	42 (1.99)	7 (1.29)	22 (1.83)	13 (3.60)
Not employed	55 (2.61)	10 (1.85)	39 (3.24)	6 (1.66)
Unable to work	33 (1.57)	7 (1.29)	16 (1.33)	10 (2.77)
Retired	80 (3.80)	16 (2.95)	41 (3.41)	23 (6.37)
Student	145 (7.93)	33 (6.09)	97 (8.06)	37 (10.25)
Other	145 (6.89)	52 (9.59)	79 (6.57)	14 (3.88)
NA	1,331	312	794	225
Risk factors				
BMI (M ± SD)[2]	28.99 (± 6.54)	27.33 (± 5.96)	29.14 (± 6.49)	30.94 (± 6.90)
BMI, n (%)				
BMI < 25	1052 (30.85)	347 (40.87)	584 (29.48)	121 (20.86)
Overweight	1068 (31.32)	262 (30.86)	639 (32.26)	167 (28.79)
Obesity	1291 (37.83)	240 (28.27)	758 (38.26)	292 (50.35)
Smoking behavior, n (%)				
Smoker (incl. E-Cig.)	1962 (64.69)	445 (59.65)	1142 (64.85)	375 (71.29)
Non-Smoker	862 (28.42)	254 (34.05)	499 (28.34)	109 (20.72)
Previous smoker	209 (6.89)	47 (6.30)	120 (6.81)	42 (7.98)
NA	404	108	236	60
Smoking behavior (M ± SD)[3]				
Cigarettes/day	14.14 (± 7.53)	13.46 (± 7.23)	14.30 (± 7.54)	14.47 (± 7.79)
Illness description				
DLQI (M ± SD)	13.04 (± 7.99)	10.36 (± 7.33)	13.28 (± 7.92)	16.11 (± 7.88)
NRS Pain (M ± SD)	3.89 (± 2.81)	2.90 (± 2.59)	3.96 (± 2.76)	5.08 (± 2.77)
IHS4 (M ± SD)[4]	13.02 (± 19.07)	6.15 (± 8.86)	12.04 (± 14.67)	29.38 (± 32.8)
Affected Regions (M ± SD)	3.30 (± 2.28)	2.45 (± 1.58)	3.27 (± 2.11)	4.64 (± 2.98)

Abbr.: SD, standard deviation; M, mean; NA, not applicable; BMI, Body Mass Index; DLQI, Dermatology Life Quality Index; NRS, numeric rating scale; IHS4, Hidradenitis Suppurativa Severity Score System

[1]Age between18 and 100 years, n = 3347

[2]BMI calculated by formula, n = 3410

[3]Only available for smoker, n = 1962

[4]First value within 5 treatments, n = 1695

Hurley I, 70.6% for Hurley II and 42.8% for Hurley III patients (Figure 1). In accordance with the IHS4 results, the response rates showed a gradual increase over time.

Effects on quality of life (DLQI)

Table 4 presents the model for the DLQI, including 2,973 individuals with a baseline score of four or higher. The final estimate of the model predicts a DLQI start level of 8.9 for Hurley stage I (Figure 1). In comparison, Hurley II patients had a 2.7 point (30.3%) higher DLQI at baseline and Hurley III patients had a 6.0 point (67.4%) higher DLQI at baseline. As in the results for pain, male patients reported a significantly lower DLQI level and a higher BMI was associated with higher DLQI levels. Under treatment with LAight, the DLQI significantly decreased over time with comparable relative magnitude for all disease severities. The model showed that the greater the individual's BMI, the smaller the reduction achieved. As with the pain score, the reduction in DLQI over 26 weeks from baseline was influenced by the greater number of obese individuals in

TABLE 2 Fixed and random effects for log-linear mixed model regarding IHS4, estimated by REML ($R^2_m = 0.158$/ $R^2_c = 0.619$). Overall, model contained 4,907 observations from n = 1,568 patients (full data of 1,423) of which Hurley I: 385 (24.55%), Hurley II: 914 (58.29%), Hurley III: 269 (17.16%).

Fixed effects on IHS4 (Log-Scale)		***β***	**SE**	**t**	**p**
Intercept		1.405	0.108	13.041	*< 0.001*
Sex (Ref: Female)					
Male		−0.050	0.046	−1.098	0.272
Hurley stage (Ref: Hurley I)					
Hurley stage II		0.457	0.051	8.918	*< 0.001*
Hurley stage III		1.102	0.067	16.430	*< 0.001*
BMI		0.014	0.003	4.104	*< 0.001*
Smoking behavior		0.006	0.003	2.546	*0.011*
Week		−0.029	0.008	−3.494	*< 0.001*
Week*BMI		$1.5 \cdot 10^{-4}$	$2.7 \cdot 10^{-4}$	0.543	0.588
Week*smoking behavior		$2.8 \cdot 10^{-5}$	$2.0 \cdot 10^{-4}$	0.139	0.889
Random effects	***Variance***	***SD***	***Correlation***		
Subject intercept	0.342	0.586			
Subject slope	0.001	0.022	0.31		
Residual	0.429	0.655			

Abbr.: SD, standard deviation; BMI, Body Mass Index; IHS4, Hidradenitis Suppurativa Severity Score System

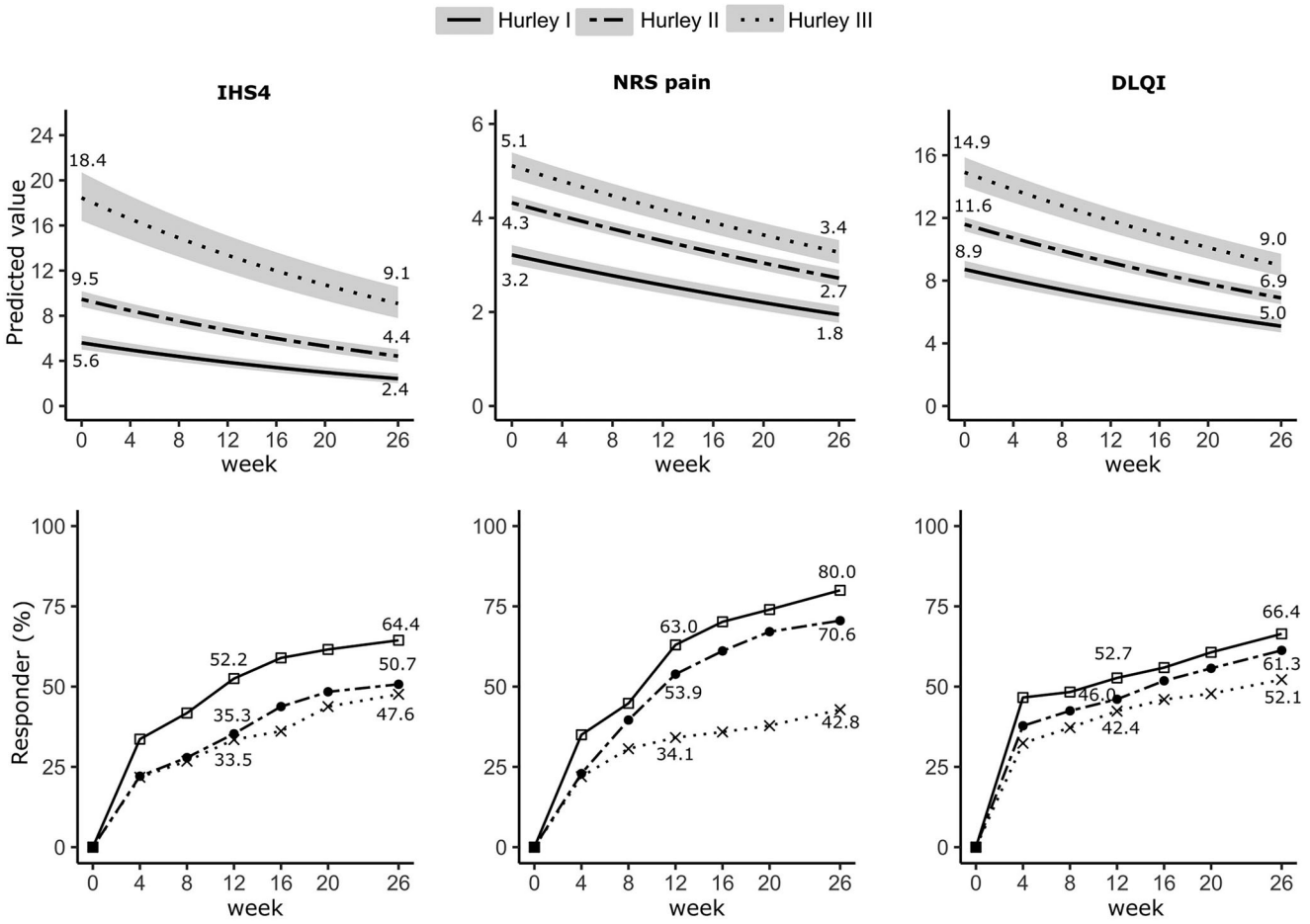

FIGURE 1 Predicted values from MMRM (baseline model) stratified by Hurley stage and proportion of responder for each endpoint. IHS4-55 responder: at least 55% reduction in IHS4. Pain responder: at least 30% reduction and a minimum of one point. DLQI-responder: reduction of at least four DLQI points.

TABLE 3 Fixed and random effects for log-linear mixed model regarding Pain-NRS, estimated by REML ($R^2_m = 0.07/R^2_c = 0.467$). Overall, model contained 14,890 observations from n = 2,179 patients (full data of 1,228) of which Hurley I: 419 (19.23%), Hurley II: 1,300 (59.66%), Hurley III: 460 (21.11%).

Fixed effects on Pain-NRS (Log-scale)	***β***	**SE**	**t**	**p**
Intercept	1.321	0.048	27.468	*< 0.001*
Sex (Ref: Female)				
Male	−0.081	0.021	−3.891	*< 0.001*
Hurley stage (Ref: Hurley I)				
Hurley stage II	0.209	0.025	8.341	*< 0.001*
Hurley stage III	0.349	0.030	11.545	*< 0.001*
BMI	0.005	0.001	3.362	*< 0.001*
Smoking behavior	0.001	0.001	1.159	0.247
Week	−0.024	0.003	−6.837	*< 0.001*
Week*BMI	$3.0 \cdot 10^{-4}$	$1.1 \cdot 10^{-4}$	2.657	*0.008*
Week*smoking behavior	$1.2 \cdot 10^{-4}$	$8.4 \cdot 10^{-5}$	1.446	0.148
Random effects	***Variance***	***SD***	***Correlation***	
Subject intercept	0.086	0.294		
Subject slope	0.001	0.016	0.45	
Residual	0.236	0.485		

Abbr.: SD, standard deviation; BMI, Body Mass Index; NRS, numeric rating scale

TABLE 4 Fixed and random effects for log-linear mixed model regarding DLQI, estimated by REML ($R^2_M = 0.158/ R^2_c = 0.619$). Overall, model contained 20,016 observations from n = 2,973 patients (full data of 1,866 patients) of which Hurley I: 670 (22.54%), Hurley II: 1754 (59.00%), Hurley III: 549 (18.46%).

Fixed effects on DLQI (Log-Scale)	***β***	**SE**	**t**	**p**
Intercept	2.073	0.057	36.174	*< 0.001*
Sex (Ref: Female)				
Male	−0.161	0.025	−6.366	*< 0.001*
Hurley stage (Ref: Hurley I)				
Hurley stage II	0.258	0.029	8.810	*< 0.001*
Hurley stage III	0.495	0.037	13.284	*< 0.001*
BMI	0.006	0.002	3.281	*0.002*
Smoking behavior	0.001	0.001	0.895	0.371
Week	−0.032	0.004	−8.585	*< 0.001*
Week*BMI	$4.6 \cdot 10^{-4}$	$1.2 \cdot 10^{-3}$	3.735	*< 0.001*
Week*smoking behavior	$5.9 \cdot 10^{-5}$	$8.9 \cdot 10^{-5}$	0.660	0.510
Random effects	***Variance***	***SD***	***Correlation***	
Subject intercept	0.241	0.491		
Subject slope	0.001	0.024	0.23	
Residual	0.284	0.533		

Abbr.: SD, standard deviation; BMI, Body Mass Index; DLQI, Dermatology Life Quality Index

higher severity levels. In line with these findings, we saw the following responder rates: By week 26, 66.4% of Hurley I patients demonstrated a reduction of at least four points in DLQI, compared to 61.3% for Hurley II and 52.1% for Hurley III. Notably, a significant response was already observed as early as week four for all levels of disease severity (Figure 1).

Safety profile and patient feedback

During the entire duration of the study, a total of 22,857 therapies were conducted, out of which 8,676 documented information on side effects of the treatment. The majority of these 8,676 therapies (91.1%) did not have any side effects. Of those with side effects, the most commonly

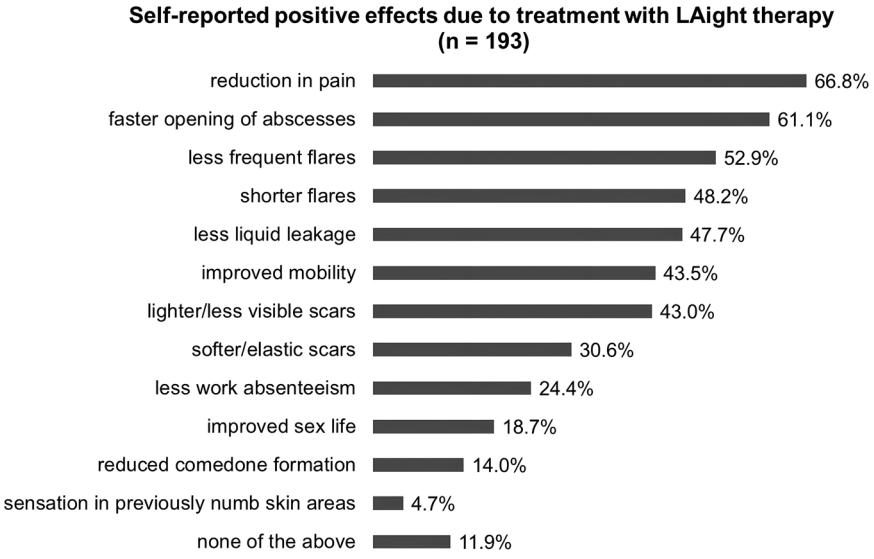

FIGURE 2 Positive effects due to LAight therapy (n = 193; multiple answers possible).

reported were erythema (5.7% of therapies) and oedema (2.9% of therapies). Other side effects, including pigmentation or wound infections, occurred in less than 1% of the performed therapies. All reported side effects were of a temporary nature.

From the analyzed cohort, a small subgroup of 193 patients filled out the additional questionnaire on LAight therapy. Patient characteristics can be found in online supplementary Table S2. Of these patients, 80.8% were under regular therapy at the time of the survey, while 19.2% did not receive regular treatments. When asked about the effects of LAight therapy (Figure 2), 66.8% of patients reported a reduction in pain, 61.1% stated that the treatment facilitates faster abscess drainage and influences flares both in frequency (52.9%) and duration (48.2%).

More than 93.6% of respondents were convinced that LAight therapy was able to control their HS in the long-term (45.2% very convinced, 31.2% quite convinced, 17.2% rather convinced, 4.3% not quite convinced and 2.1% not at all convinced). Moreover, 95.8% would recommend LAight therapy to other patients.

DISCUSSION

To our knowledge, this study, with 3,437 patients, is by far the largest evaluation of real-world data on the usage of device-based treatments in HS. There is a medical need for effective, cost-efficient, and well-tolerated treatment option with little contraindications which can be safely applied long-term and may prevent progression or relapses of the disease. Treatment with antibiotics is often unable to provide long-term remission of the disease,[10] and extensive research on the postulated anti-inflammatory role of antimicrobial substances is lacking.[20,21] In contrast, development of antimicrobial resistance under long-term antibiotic treatment, both with topical and systemic antibiotics, is an important issue that needs to be addressed.[22,23] With treatment options lacking, especially for mild and moderate HS, the interest in LAight therapy is considerable due to its demonstrated high effectiveness in this patient group.[13,14]

Our results confirm effectiveness of LAight therapy in the real-world setting. A significant decrease in IHS4, pain-NRS, and DLQI was achieved, independent of Hurley stage over 26 weeks of treatment. Although the effect of IPL + RF was primarily investigated for Hurley I and II patients, results at hand suggest that Hurley III patients may also benefit from LAight therapy.[6,9]

The newly established, dichotomous responder criterion IHS4-55 was preferred over HiSCR-50 as it dynamically factors in the number of draining tunnels, which have a high impact on the quality of life of HS patients. Interestingly, roughly 50% of both Hurley II and III patients achieved an IHS4-55 response over 26 weeks of treatment, suggesting a direct anti-inflammatory effect regulating the neutrophilic response in those patients. It was recently shown that utilization of radiofrequency microneedling leads to a reduction in the levels of IL-8, IL-17 and TNF-α directly in the skin as a result of neutrophil activation, which may provide a scientific explanation for our findings.[24]

In the analyzed sample, smoking was significantly associated with higher IHS4 levels at baseline, while a higher BMI had a significantly negative impact on all three analyzed endpoints (Tables 2–4). Indeed, obesity is one of the independent factors for the development of the disease.[25–28] Furthermore, our analysis underlines the influence of BMI on treatment results: Increased BMI was significantly associated with a lower pain and DLQI reduction in comparison to non-obese patients. Hidradenitis suppurativa prevalence in obese patients has been reported to be up to 18.1% ± 4.8%, while the probability of metabolic disease is 4.5-fold higher than in non-HS individuals.[26,29,30] Obesity leads to a proinflammatory state with an increase in IL-17R expression in HS smokers in comparison to HS non-obese non-smokers, although no differences in IL-17 levels were detected.[31] In

patients with a BMI > 30, the efficacy of adalimumab is also lower,[32] and dose intensification is recommended as an adjustment for both adalimumab at 80 mg weekly,[18,33] and secukinumab at 300 mg biweekly.[6,19]

A trusting, positive, and stable relationship with healthcare providers leads to better adherence to treatment and better control of disease symptoms.[34] This might be the reason for the observation that the DLQI response to treatment with LAight appeared to be more rapid than the scores for disease activity (IHS4 and pain). Moreover, this implies that patients achieve improvement in quality of life faster than the effects are manifested in disease symptoms. This phenomenon was also observed in the NICE trial.[12]

At this point, it should be emphasized that reducing pain is considered one of the most important target criteria for patients with HS. In this study we already saw a response rate of 25% in all patients at week 4, reaching up to 80% for Hurley stage I patients at week 26. The additional questionnaire also revealed that the pain reduction was the most cited beneficial effect of LAight therapy.

Socioeconomic aspects of the disease should not remain unmentioned, with direct costs for treatment having a central role. An American study named the inpatient treatment of HS as the largest cost factor, accounting for 37.4% of the total cost.[35–37] In contrast, a study from Hungary ranked biologic treatment first, accounting for 53.3% of the total cost of the disease.[38] The cost was estimated at EUR 6,791 per patient. Importantly, biologics only provide an average reduction of inflammatory lesions of 50%–55%, and appear to be not as effective as in other inflammatory skin diseases such as psoriasis. The regimen is usually continued after successful achievement of disease remission. LAight therapy achieves clinically meaningful response rates in IHS4-55 and represents a simple treatment method with minimal long-term side effects. It is a gentle, cost-effective (100–130 EUR/treatment) alternative to maintain remission and reduce relapses in HS.[12–14]

The main limitation of the study is that the data represents real-world care and, in contrast to RCTs, some of the patients may have received additional treatment options. Some patients did not follow the recommended schedule of undergoing sessions every 14 days for a duration of 26 weeks, as they were required to self-finance the LAight therapy. The lack of reimbursement may also have prompted individuals, especially those who experienced significant success with the treatment, to discontinue treatment prematurely to cut costs. Moreover, approximately one third of all patients did not undergo treatment for more than 13 weeks, which was often attributed to the efficacy of the treatment. The missing values were consequently imputed utilizing the estimated mixed model. Finally, only a small number of patients completed the additional LAight therapy questionnaires, which may lead to a high selection bias.

Studies show that most of the available treatment options do not lead to complete disease remission. LAight therapy resulted in satisfying disease control in all stages of severity. As patients with HS particularly favor therapies demonstrating a sustainable treatment effect,[39] LAight is a valuable addition to the therapy repertoire for HS.[40]

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CONFLICT OF INTEREST STATEMENT

Stephan Grabbe: Grants or contracts from any entity: Novartis, Pierre Fabre | Consulting fees: AbbVie, BMS, MSD, Genzyme, Klinge Pharma, Sun Pharma, Kyowa-Kirin, Novartis, Pierre Fabre | Participation on a Data Safety Monitoring Board or Advisory Board: Alcedis | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid unrelated to current work presented here: DeCOG, German dermatological cooperative oncology group - unrelated to current work presented here.

Michael Schultheis: Grants or contracts from any entity: LENICURA GmbH – auditor activity on the implementation of the contract "AOK-Priomed Akne inversa" | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events: AbbVie – honoraria for lectures | Support for attending meetings and/or travel: AbbVie, Pfizer – funding of travel, congress, and hotel fees.

Caroline Mann: Grants or contracts from any entity: Novartis; Allmirall | Consulting fees: Almirall-Hermal, Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events: PER, UNEV, AbbVie, Pfizer, Novartis, L'Oréal | Support for attending meetings and/or travel: AbbVie, Pfizer, Lilly, Almirall, L'Oréal, Takeda, Novartis– funding of travel, congress and hotel fees.

Petra Staubach: Grants or contracts from any entity: Novartis; Allmirall | Consulting fees: AbbVie, Allergika, Almirall-Hermal, Amgen, Beiersdorf, Biocryst, BMS, Boehringer-Ingelheim, Celgene, CSL-Behring, Eli-Lilly, Falk, Galderma, Hexal, Janssen, Klinge, Klosterfrau, LEO-Pharma, LETI-Pharma, L'Oréal, Novartis, Octapharma, Pfizer, Pflüger, Pharming, Regeneron, Shire, Takeda, Sanofi-Genzyme, UCB Pharma | Leadership or fiduciary role in other board, society,

committee or advocacy group, paid or unpaid unrelated to current work presented here: Society of dermopharmazie

Alexandra Strobel: Nothing to declare.

Marcus Heise: Nothing to declare.

Katharina Hennig: CEO and stakeholder of LENICURA GmbH

Georgios Nikolakis: Consulting fees – Dessau Medical Center received a consulting fee from Mölnlycke Health Care GmbH, for which I served as a consulting physician |Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events: Speaker for the EADV HS Course 28.–30.11.2022, Porto, Portugal | Support for attending meetings and/or travel: Elli Lilly Scholarship for attending EADV 2021 | Participation in a data protection monitoring board or advisory board – Dessau Medical Center received a consulting fee from Mölnlycke Health Care GmbH, for which I served as a consulting physician, travel grants from Abbvie

Uwe Kirschner: Consulting Fees: Novartis | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events: Novartis | Participation on a data protection monitoring board or advisory board: Novartis, EsmAiL, EpiCAi | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid: Deutsche Gesellschaft für Wundheilung und Wundbehandlung

Jacek C. Szepietowski: Advisory Board/Consultant for AbbVie, Leo Pharma, Novartis, Pfizer, Sanofi-Genzyme, Trevi, UCB and Vifor; Speaker for AbbVie, Almirall, Janssen-Cilag, Eli-Lilly, Leo Pharma, Novartis, Pfizer, Sanofi-Genzyme; Investigator for AbbVie, Almirall, Amgen, AnaptysBio, BMS, Boehringer Ingelheim, Celtrion, Galderma, Galapagos, Helm AG, Kliniksa, Incyte, InfraRX, Janssen-Cilag, Leo Pharma, Medimmune, Menlo Therapeutics, Merck, Novartis, Pfizer, Regeneron, UCB, Teva, Trevi

Lukasz Matusiak: Advisory Board/Consultant for AbbVie, Novartis; Speaker for AbbVie, Aristo, Leo Pharma, Medac; Investigator for AbbVie, Almirall, Amgen, AnaptysBio, BMS, Boehringer Ingelheim, Celtrion, Galderma, Galapagos, Helm AG, Kliniksa, Incyte, InfraRX, Janssen-Cilag, Leo Pharma, Medimmune, Menlo Therapeutics, Merck, Novartis, Pfizer, Regeneron, UCB, Teva, Trevi

Piotr Krajewski: Nothing to declare.

Esther von Stebut: Consulting fees: Janssen, Novartis | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events: Janssen, Novartis, Infectopharm, Leo | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid: Deutsche Dermatologische Gesellschaft, Deutsche Forschungsgemeinschaft, Mediziner Fakultätentag)

Hans Bayer: nothing to declare.

Simone Garcovich: nothing to declare.

Maurizio Poddda: Consulting fees: AbbVie, CSL, Galderma, Novartis, Janssen Cilag, UCB | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events: AbbVie, Beiersdorf, BMS, Eli Lilly, Galderma, Janssen Cilag, Leo Pharma, L'Oréal, Novartis, MSD, UCB | Support for attending meetings and/or travel: AbbVie, Beiersdorf, BMS, Eli Lilly, Galderma, Janssen-Cilag, Leo Pharma, L'Oréal, Novartis, MSD, UCB | Participation on a Data Safety Monitoring Board or Advisory Board: AbbVie, Boehringer Ingelheim, CSL, Galderma, Janssen-Cilag, MoonLake, Novartis, L'Oréal, UCB | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid: HiSNet Rhein Main e.V.,President.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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