Received: 12 May 2021 | Revised: 5 July 2021 | Accepted: 22 July 2021

DOI: 10.1111/dth.15068

ORIGINAL ARTICLE

DERMATOLOGIC THERAPY WILEY

Ultrasound-guided injection of intralesional steroids in acute hidradenitis suppurativa lesions: A prospective study

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Funding information
Universita degli Studi di Pisa within the CRUI-CARE Agreement

Abstract

The management of hidradenitis suppurativa (HS) flares with intralesional steroids lacks strong scientific evidence but limited data suggest that it may be useful. The objective of this study is to assess the clinical and ultrasound responses of HS flares to ultrasound-guided injections of intralesional triamcinolone (40 mg/ml) with a dilution 1:4 versus 1:2 at 30-day (t1), 60-day (t2), and 90-day (t3) follow-up. We recruited patients with ≤3 acute lesions, unresponsive to topical therapy. At baseline we assessed lesions clinically and by ultra-high frequency ultrasound (48 or 70 MHz) and randomly performed an ultrasound-guided injection of triamcinolone. Assessments were repeated at t1, t2, and t3 follow-up, re-injecting the lesion in the case of no or partial response. We treated 49 lesions: 38.8% showed improvements at t1; 46.9% at t2; 6% at t3; and 8.3% showed no clinical and ultrasound improvements. Long-term follow-up data confirmed a statistically significant reduction in Visual Analogue Scale (VAS)-pain, Dermatology Life Quality Index (DLQI), and HS-Physician Global Assessment (HS-PGA), as well as edema and vascular signals. No adverse effects were reported. Our study suggests that ultrasound-injections with a 1:2 dilution are beneficial for HS flares that do not respond to topical treatment and should be included in the therapeutic algorithm.

KEYWORDS
acute flare management, hidradenitis suppurativa, HS flares, intralesional steroids, ultrasound guided injections

1 | INTRODUCTION

Hidradenitis suppurativa (HS) is a chronic relapsing inflammatory skin disease, characterized by recurrent and painful nodules, abscesses and sinus tracts involving the hair follicle.[1] The high impact on the individuals with a decreased quality of life and objective disease severity are

The preliminary results of this study were presented during the European Hidradenitis Suppurativa Foundation 2020 meeting in Athens and the abstract will be published in the supplements of Experimental Dermatology.

the main elements to be evaluated in terms of treatment choice.[2] Classical surgery or LASER techniques are the best options in locally recurring lesions, while medical therapy such as monotherapy or combined with surgery are preferable for widespread lesions. Medical therapy may be topical or systemic and includes antibiotics (clindamycin plus rifampicin, tetracycline), acitretin, short steroid therapy, and biologic immunomodulatory drugs (infliximab, adalimumab) according to a treatment algorithm based on an HS severity assessment.[2] The combination of clinical and high-frequency cutaneous ultrasound (HFUS) evaluations, performed using linear probes with a frequency from 7 to 18 MHz, is currently the best approach to a severity assessment.[3–5]

The clinical use of ultrasound scanners equipped with transducers above 20 MHz, conventionally referred to as "Ultra High-Frequency Ultrasound" (UHFUS), has introduced new diagnostic options in skin ultrasound. The advantages of this new ultrasound method in the diagnosis of HS have been recently described. UHFUS performed with transducers with a maximum frequency of up to 70 MHz, has been shown to detect lesions <0.1 mm, with better imaging resolution and details.[6]

The management of acute flares using intralesional steroids lacks strong scientific evidence and is not included in the current treatment guidelines.[2,7] The literature data on intralesional steroids in HS flares include best-practice guidelines based on clinical experience or expert consensus; case series; one double-blind, randomized, placebo-controlled trial; two retrospective clinical studies and one prospective trial.[8–14]

In literature only two studies investigate the efficacy and safety of ultrasound-assisted infiltrations to HS lesions. In the first study authors conclude that ultrasound-assisted injections of triamcinolone acetonide 40 mg/ml are useful for the treatment of abscesses and small to medium-size simple draining fistulas.[15] In the other study lincomycin was added to triamcinolone with a significant improvement of the HS lesions after the combined intralesional treatment.[16]

The aim of this study is to assess the clinical and ultrasound responses of HS acute lesions (inflammatory nodules, abscesses, draining-inflamed fistulae) to ultrasound-guided injections of intralesional triamcinolone (40 mg/ml) with dilutions of 1:4 versus 1:2 at 30-day (t1), 60-day (t2) and 90-day (t3) follow-up.

2 | MATERIALS AND METHODS

This was a prospective, single center, case–control study on UHFUS-guided intralesional injections of steroids. The study was performed in accordance with the Declaration of Helsinki for research on human subjects and approved by the Institutional Ethics Committee, who waived the requirement for informed consent. We recruited patients affected by HS with ≤3 acute lesions (inflammatory nodules, abscesses, draining-inflamed fistulae), which appeared in the previous 4 weeks prior to the baseline and did not respond to topical therapy. The study was conducted from April 2018 to October 2019.

The patients were assessed by a team of two dermatologists and one radiologist. UHFUS was performed using the device Vevo® MD (Fujifilm Visual Sonics, Toronto, Canada, Inc. 2016) for the baseline assessment and at t1/t2/t3-follow-up. UHFUS assessment was performed using a 70 MHz probe, bandwidth 29–71 MHz, axial resolution 30 μm, lateral resolution 65 μm, maximum depth 10 mm and image width max 9.7 mm) or 48 MHz probe (bandwidth xx-48 MHz, axial resolution 50 μm, lateral resolution 110 μm, maximum depth 23.5 mm, and image width max 9.7 mm) according to the depth of the lesion. For each lesion examined, we acquired at least two ultrasound clips by positioning the probe along the longitudinal and transverse axis. To assess the phlogistic increase in vascularization, at least two-color Doppler images (both along the longitudinal and transverse axes) were acquired; the velocimetric range of the color box was between ±1.9 cm/s. In order to obtain the most diagnostic ultrasound image, the ultrasonography parameters (such as gains, depth, time gain control, focus) were modified and optimized during examinations.

The second step consisted in disinfecting the skin, putting sterile gel over the entire probe head, covering the probe head with a cover, placing the probe perpendicular to the main axis of the lesion, maintaining low uniform pressure and injecting intralesional triamcinolone (diluted 1:4 or 1:2) with a lateral penetration technique in order to create a right angle between the 21G needle and the probe. The third step consisted in checking the correct placement of the needle inside the lesion with the probe and managing the infiltration phases on a screen monitor until the lesion has been completely filled, as shown in Figure 1. The total volume injected depended on the size of the lesion. The dilutions of 1:4 or 1:2 were randomly assigned.

At each follow-up visit, we evaluated the clinical and ultrasound responses. The clinical response was evaluated by two dermatologist experts in HS in terms of erythema, edema, and suppuration. An example of a complete clinical response is shown in Figure 2.

Ultrasound images were analyzed through the Radiant DICOM Viewer® software (Medixant, v.5.0.1.21910 of 06/29/2019). Two expert operators selected the most significant both longitudinal and transversal frames of each scan, and measured the edema grade (absent = 0, low = 1, moderate = 2, severe = 3) and vascularization grade (absent = 0, low = 1, moderate = 2, severe = 3) as shown in Figures 3 and 4. The final values were obtained from the average scores of the longitudinal and transversal scans.

If the lesion presented no clinical and/or ultrasound improvements, we performed another ultrasound guided injection. Any adverse events were registered at each follow-up visit.

Patient data were collected in an access database: patient initials, gender, age, past, and ongoing therapies, disease severity (Hurley, Sartorius, HS-Physician Global Assessment [PGA], Hidradenitis Suppurativa Severity Index [HSSI]), VAS-pain, Dermatology Life Quality Index (DLQI), number, type and location of lesions, clinical response, ultrasound edema grade (absent = 0, low = 1, moderate = 2, severe = 3), and ultrasound Color–Doppler signal (absent = 0, low = 1, moderate = 2, severe = 3) at baseline and at follow up visits.

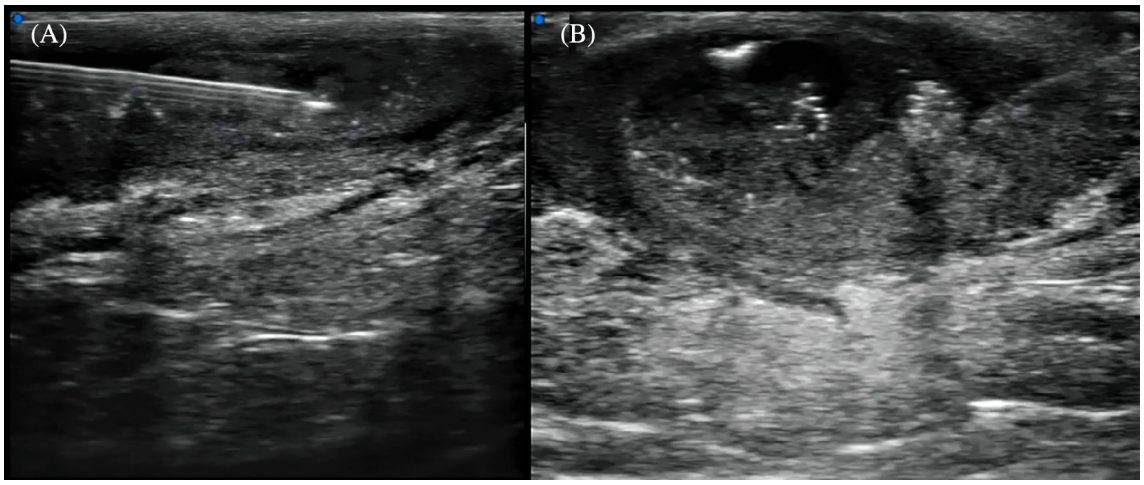

FIGURE 1 (A) Probe checks the correct placement of the needle inside the lesion; (B) Probe checks the complete filling of the lesion

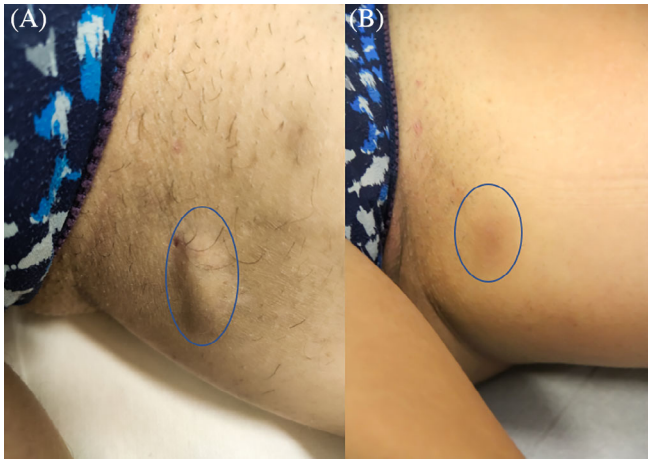

FIGURE 2 (A) Grade of edema 0 = absent; (B) Grade of edema 1 = low; (C) Grade of edema 2 = moderate; (D) Grade of edema 3 = severe

3 | STATISTICAL ANALYSIS

Categorical data were described by absolute and relative (%) frequencies, continuous data by mean and SD or range. To analyze long-term follow-up data (three measures), ANOVA for repeated measures was applied. To compare ultrasound and clinical variables between two measures, stratified for dilution, a *t*-test for pairs data (two-tailed) was performed. Significance was fixed at $p = 0.05$. All analyzes were carried out by SPSS v.26 technology.

4 | RESULTS

A total of 31 patients were included in the study, of which 11 were male (35.5%) and 20 were female (64.5%). All patients showed up for evaluation at the t1 follow-up. Four patients were lost at the t2 follow-up visit and five patients were lost at the t3 follow-up visit. The population characteristics are summarized in Table 1. A total of 49 lesions were treated and analyzed. No adverse effects were reported during the treatment procedure. Acute HS lesions were injected with a mean of 4 ml triamcinolone 40 mg/ml (range 1–8 ml). A total of 14 lesions (45.2%) were injected with a 1:4 dilution of; 17 lesions (54.8%) were injected with a 1:2 dilution. A total of 19 lesions (38.8%) showed a response at t1 follow up; 23 lesions (46.9%) at t2 follow up; three lesions (6%) at t3 follow-up; four lesions (8.3%) showed no response. Significant differences were found in relation to DLQI, HS-PGA, VAS-pain, HSSI, Sartorius, edema and Color–Doppler signal from the pre-injection baseline visit (t0) compared to the 30-day(t1) follow-up visit. Better results were found for the 1:2 dilution compared with 1:4 in terms of DLQI, HS-PGA, HSSI, mSartorius, edema, and Color–Doppler signals, as reported in Table 2.

Long term follow-up data (t2 and t3) confirmed a statistically significant reduction in the DLQI ($p = 0.030$), VAS-pain ($p = 0.013$), HS-PGA($p = 0.003$), edema ($p = 0.161$) and Color–Doppler signals ($p = 0.016$). For mSartorius and HSSI, a non-statistically significant variable increase was found (Figure 5 and 6).

5 | DISCUSSION

Conventional therapies for HS do not always provide control of inflammation. A better understanding of the HS pathogenetic mechanisms has enabled to improve disease management with new unconventional treatments.[17]

The lack of strong scientific evidence for the treatment of HS with intralesional steroids has led to its exclusion from the current treatment guidelines.[2,8] A Canadian group reported the useful management of acute HS flares in 29% of their patients with a reduction in the use of systemic antibiotics.[13] Riis et al. assessed the outcomes of intralesional triamcinolone acetonide 10 mg/mg in the management of acute HS lesions (inflammatory nodules and abscesses), and

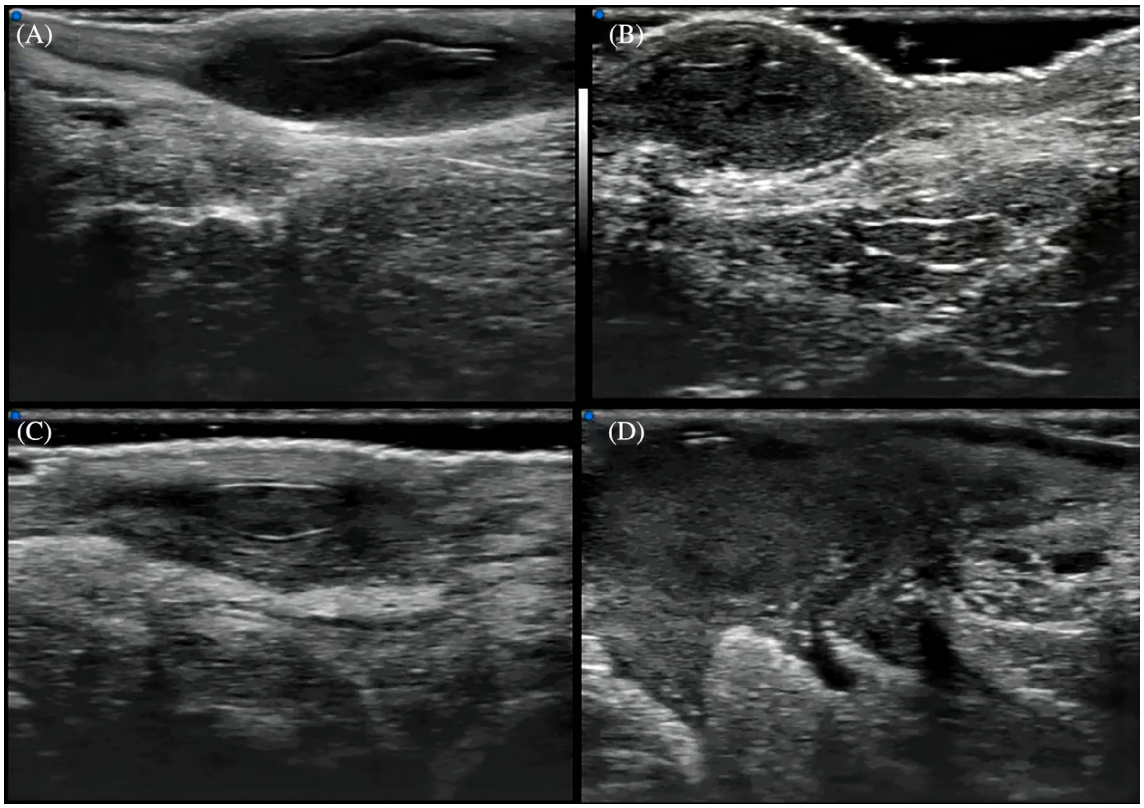

FIGURE 3 (A) Grade of vascularization 0 = absent; (B) Grade of vascularization 1 = low; (C) Grade of vascularization 2 = moderate; (D) Grade of vascularization 3 = severe

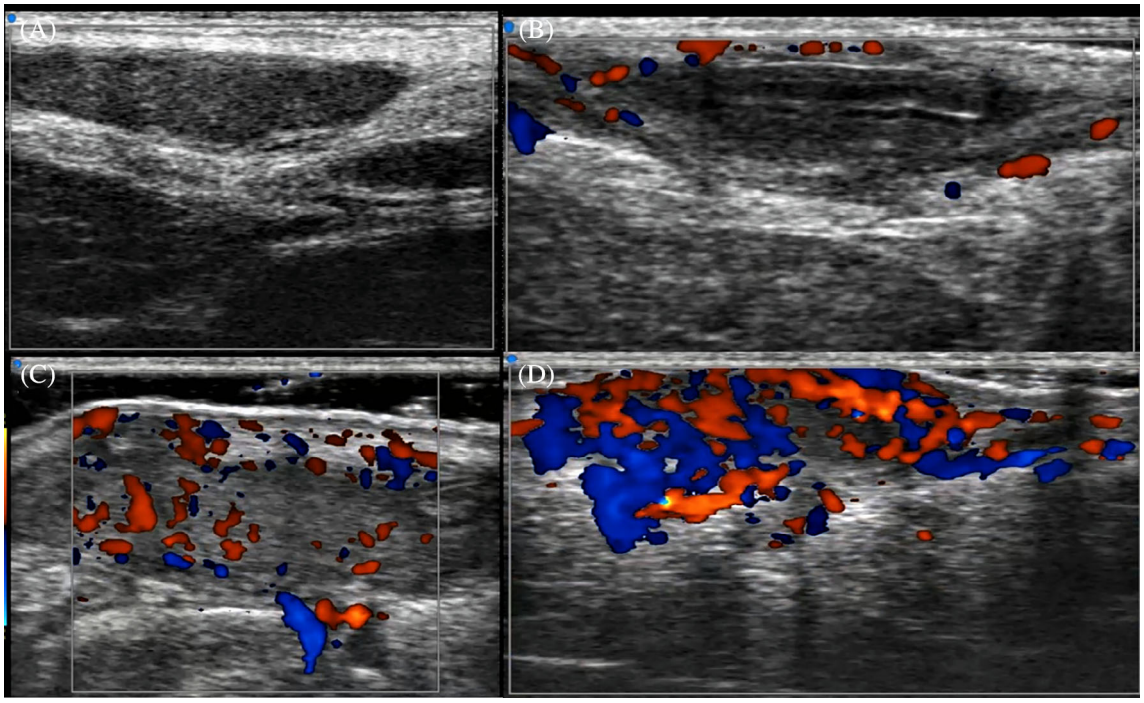

FIGURE 4 (A) HS draining fistula at baseline; (B) HS draining fistula at 90 day follow-up after 2 steroid injections

TABLE 1 Characteristics of population

	Statistics
Gender	
F	20 (64.5%)
M	11 (35.5%)
Systemic treatments	
Yes	7 (22.6%)
Not	24 (77.4%)
Biological treatments	
Yes	8 (25.8%)
Not	23 (74.2%)
Surgery	
Yes	13 (41.9%)
Not	18 (58.1%)
Lesion count	
1	17 (54.8%)
2	10 (32.3%)
3	4 (1%)
Steroid dilution	
1:4	14 (45.2%)
1:2	17 (54.8%)
Age (years)	33 (13)
Triamcinolone volume (ml)	4 (1–8)
Hurley stage	
I	9 (29.1%)
II	21 (67.8%)
III	1 (3.1%)

Note: Statistics: frequency (%) or mean (SD or range).

TABLE 2 Comparisons between pairs data (pre-injection baseline visit: t0, 30-day follow-up visit: t1) related to all ultrasound and clinical variables stratified by dilution

Dilution 1:4	Mean	SD	*p*-value
VAS_t0	4.1	3.2	0.035
VAS_t1	2.3	2.6	
DLQI_t0	8.9	9.0	0.043
DLQ_t1	7.4	8.2	
HS_PGA_t0	2.9	1.1	0.021
HS_PGA_t1	2.1	1.3	
HSSI_t0	2.1	1.0	0.014
HSSI_t1	1.5	1.0	
mSartorius_t0	29.8	17.6	0.038
mSartorius_t1	23.6	14.8	
EDEMA_t0	2.1	1.1	0.435
EDEMA_t1	1.9	1.1	
VASCULAR_SIGNAL_t0	2.5	0.8	0.999
VASCULAR_SIGNAL_t1	2.5	0.7	
Dilution 1:2	**Mean**	**SD**	***p*-value**
VAS_t0	4.5	2.9	0.114
VAS_t1	3.4	2.9	
DLQI_t0	9.8	7.8	0.007
DLQ_t1	6.9	7.2	
HS_PGA_t0	2.6	0.8	0.002
HS_PGA_t1	1.9	0.7	
HSSI_t0	2.1	1.0	0.001
HSSI_t1	1.4	0.7	
mSartorius_t0	26.6	20.8	0.031
mSartorius_t1	23.3	19.4	
EDEMA_t0	2.6	0.6	0.003
EDEMA_t1	1.8	1.0	
VASCULAR_SIGNAL_t0	2.6	0.7	0.003
VASCULAR_SIGNAL_t1	1.6	1.1	

Note: Statistics: mean (SD).

reported a significant reduction in VAS-pain after 1 day, and in physician-assessed edema, redness, and suppuration after 7 days with no adverse events.[10]

In a multicenter retrospective clinical study including both acute and chronic lesions, a Spanish group reported a complete response to intralesional triamcinolone in 70.37% of lesions, partial improvement in 25.19% and no improvement in only six out of 135 lesions (4.44%). Adverse events were reported in four cases: one atrophic scar, one local hypopigmentation and aggravation of two lesions.[11] In a prospective trial on 46 patients, another Spanish group reported clinical resolution in 28.3% of fistulous tracts, both clinical and ultrasound responses in 46.3% of fistulous tracts and no response in 28.3% of fistulous tracts after a single injection of triamcinolone 40 mg/ml at the 90-day follow up. Pigmentation changes were reported in 25 patients.[14]

A recent prospective cohort study investigates ultrasound guided injections of intralesional steroids: a total amount of 247 lesions were injected. A complete response of 81.1% (30/37)for nodules, 72% (108/150) for abscesses and 53.3%(32/60) for draining fistulas was reported at week 12. In the study was used a high potency corticoid such as triamcinolone acetonide, placed appropriately by ultrasounds. The maximum amount of triamcinolone acetonide administered per session was 40 mg. Two adverse events were reported: an alteration on glycemic imbalance in a patient with type I diabetes and a change in behavior in another patient.[15]

In line with the literature data available to date, our study shows that injection of triamcinolone into inflammatory nodules, abscesses and draining-inflamed fistulae of HS is beneficial in the management of acute disease flares and can stop the evolution of acute lesions into chronic lesions. Regarding the safety, no adverse events were registered. UHFUS guided injections with a lateral penetration technique enable the correct position of the needle inside the lesion to be checked with the probe and to monitor the entire infiltration phase until the lesion has been completely filled. Higher drug doses can thus be used, maximizing results with the minimal risk of adverse events such as atrophy.

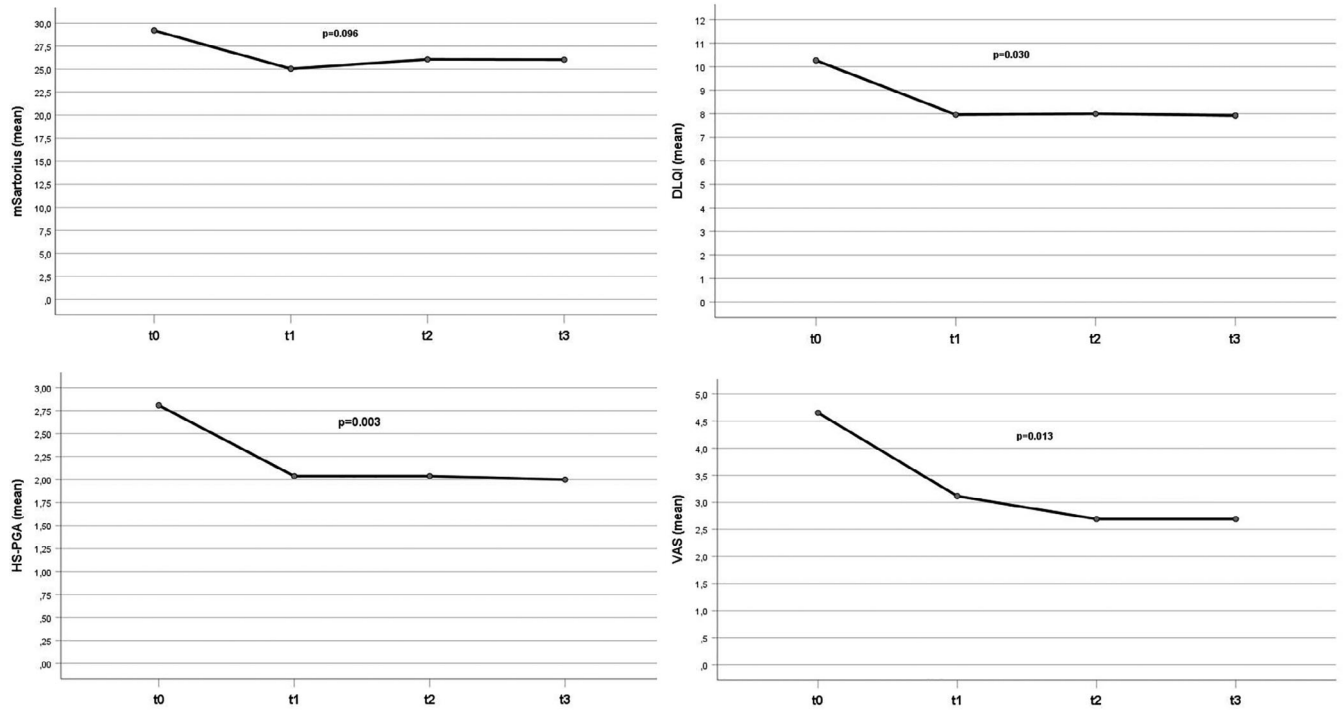

FIGURE 5 Mean mSartorius, HS-PGA, DLQI and VAS-pain at baseline, t1 (30 days), t2 (60 days) and t3 (90 days) follow-up

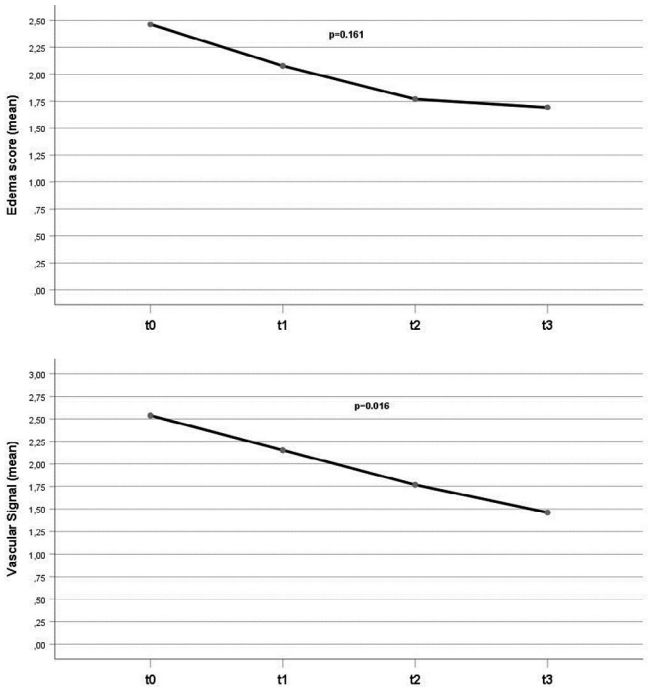

FIGURE 6 Mean edema score and vascular signal evaluated by UHFUS at baseline, t1 (30 days), t2 (60days) and t3 (90 days) follow-up

Only one study compared the average days to resolution after injecting 0.1 ml of normal saline or intralesional triamcinolone 10 mg/ml or intralesional triamcinolone 40 mg/ml (1:1:1), and detected a non-statistically significant difference between the interventions.[12] In our opinion this could be related to the fact that an insufficient volume was injected. In our study the mean volume injected was 4 ml. The literature reports a mean volume injected of 0.75 ml in a case series by Riis et al.[10]; 0.49 ml (range 0.2–1.0 ml) in a prospective study by Álvarez et al.[14] and between 0.5–1 ml in a multicenter retrospective study by García-Martínez et al.[11]

An accurate comparison of our results with the literature data is really difficult because of the lack of uniform outcomes and standard methodologies. In our experience triamcinolone 40 mg/ml with a 1:2 dilution gives the best clinical and ultrasound results, confirming the literature finding on effectiveness of high-dose intralesional triamcinolone for acute HS lesions.[18]

Another important finding of our study is that 19 lesions (38.8%) showed a response at t1 follow up; 23 lesions (46.9%) showed a response at t2 follow up and 3 lesions (6%) showed a response at T3 follow-up. This confirms that the best response to intralesional steroids is after the first 2 doses, and that the failure to achieve a complete response after 3 doses should lead to a change in therapeutic strategy. This is in line with the results reported by García-Martínez et al. confirming that the timing of steroid infiltrations and the creation of standardized therapeutic protocols are essential for the clinical improvement of treated patients.[11]

HFUS assessment of lesions before and after steroid infiltration has proven to improve the accuracy of skin lesion depth measurement, supporting diagnosis, staging, treatment plan and monitoring of treatment response.[14,19,20] UHFUS detects lesions <0.1 mm and small fluid collections with a better differentiation among HS lesions, thus improving patient monitoring.[6] Our data confirm that UHFUS is really useful in baseline assessment, in treatment planning, in managing the

infiltration phases and in monitoring of treatment response. The use of UHFUS enabled us also to select non fibrotic scarring fistulae, according to the Ultrasonographic Classification of Fistulous Structures, with a better chance of responding to medical therapy and reducing surgery, which is instead recommended when there is scarring tissue.[21,22] With UHFUS we were also able to assess edema and Color–Doppler vascularization, obtaining an important indication of the HS lesions' inflammation and treatment response.[23]

In addition, being able to detect small fluid collections even in clinically stable lesions (repeating the steroid infiltration monthly until the achievement of a clinical and ultrasound response) led to a complete clinical remission after 90 days in 70.4% of patients. This was shown by the long-term follow-up data confirming a statistically significant reduction in VAS-pain, DLQI, HS-PGA, edema and Color–Doppler signals. The variable non-statistically significant increase in mSartorius and HSSI scores could be because both scores are systemic and less focused on individual lesions, therefore they reflect the progression of the disease observed in five people who switched to systemic or biologic therapy.

The strengths of the study include the prospective design, the use of UHFUS in addition to a clinical assessment, the different types of inflammatory lesions included and the medium-term follow up period. The limitations of the study are the small sample size, open sample size and lack of a control group.

6 | CONCLUSIONS

Intralesional steroids are safe and effective in patients with ≤3 acute lesions that are not responsive to topical therapy, and can stop the evolution of acute lesions in chronic lesions, thus avoiding the use of systemic antibiotics. This treatment could be used as a therapeutic alternative to deroofing/laser/local excision in mild or moderate disease but also to manage acute flares in addition to systemic antibiotics or biological therapy in moderate or severe disease stages. In our experience, the 1:2 dilution gives better results than the 1:4 dilution with the same safety profile. Checking the correct position of the needle inside the lesion with the probe enables higher drug doses to be used, thus maximizing the results with a minimal risk of adverse events such as atrophy.

Long-term, multicenter, prospective, large cohort-based studies with control groups are needed in order to compare ultrasound guided injections with the standard procedure, to confirm the advantages of a more precise and controlled technique and to standardize the methodology.

ACKNOWLEDGMENTS

Open Access Funding provided by Universita degli Studi di Pisa within the CRUI-CARE Agreement. [Correction added on May 24, 2022, after first online publication: CRUI funding statement has been added.]

AUTHOR CONTRIBUTIONS

Michela Iannone, Teresa Oranges, Lorenzo Balderi, Bianca Benedetta Benincasa, Saverio Vitali, Giulia Tonini, Riccardo Morganti, and Giulia Davini contributed to the conception and design, acquisition of data, analysis and interpretation of data. Valentina Dini, Agata Janowska, and Marco Romanelli were involved in drafting the manuscript and revising it critically for important intellectual content.

ETHICS STATEMENT

Reviewed and approved by the Institutional Ethics Committee with protocol code SUS1-AD ASTRA.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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How to cite this article: Iannone M, Janowska A, Oranges T, et al. Ultrasound-guided injection of intralesional steroids in acute hidradenitis suppurativa lesions: A prospective study. *Dermatologic Therapy*. 2021;34(5):e15068. https://doi.org/10.1111/dth.15068