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Safety and Efficacy of Intense Pulsed Light With Radiofrequency in United States Hidradenitis Suppurativa Patients

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ABSTRACT

Background: The combination of intense pulsed light and radiofrequency has been described in German populations to be a noninvasive therapy option for patients with hidradenitis suppurativa, demonstrating significant improvements in the quality of life and reduction in number of inflammatory lesions.

Objective: To evaluate the efficacy and safety of combination intense pulsed light and radiofrequency therapy in patients with hidradenitis suppurativa in the United States.

Methods: A prospective split body was conducted in the United States on patients with bilateral hidradenitis suppurativa. Subjects received 3 passes of intense pulsed light and radiofrequency per treatment session to a single involved body region on a randomized side of the body at least 2 weeks apart over 9 to 10 treatment sessions.

Results: When measured from baseline to final visit, the overall mean difference in Dermatology Life Quality Index was found to be statistically significant (-2.8, P=0.043, n = 9). Patients reported mild discomfort during therapy and no adverse events occurred during or after treatment sessions.

Conclusions: Although statistically significant, the mean difference in Dermatology Life Quality Index in treated patients found in this study did not reach the minimal clinically important difference for inflammatory skin disease.

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INTRODUCTION

Hidradenitis suppurativa (HS) is a chronic inflammatory skin disease characterized by painful inflammatory nodules, abscesses, sinus tracts, and scarring with a significant impact on patient quality of life. HS remains a very difficult dermatologic condition to treat with current management options including topical and oral antibiotics, intravenous antibiotics, lasers, biologic medications, and surgery. Intense pulsed light (IPL) and radiofrequency (RF) have previously been reported as potential noninvasive treatments for HS.[1,2] IPL may help HS by emitting various wavelengths of light that are absorbed by targets in the skin producing anti-inflammatory effects and inducing thermal damage to hair follicles.[3] RF is thought to work by decreasing the activity and volume of sebaceous glands and by stimulating the formation of collagen.[4]

A recent prospective study on 47 subjects in Germany using IPL, RF, or IPL+RF found that the IPL+RF group had a greater drop in active lesion count and a greater decrease in Dermatology Life Quality Index (DLQI) when compared to the IPL or RF groups alone.[5] The objective of this prospective, split body pilot study was to evaluate the safety and efficacy of the synergistic effects of IPL+RF in patients with HS in the United States.

MATERIALS AND METHODS

The study was approved by the Institutional Review Board at Henry Ford Hospital (IRB #11922). International Conference of Harmonization and Good Clinical Practice were followed in the conduct of this study. Prior to any study procedures, participants gave written informed consent to include material pertaining to themselves in this study and acknowledged they cannot be identified in study publications. We have fully anonymized all participants in this study. Subjects were included if they had bilateral HS and were on stable medication for the past 3 months. Patients were excluded if they were pregnant, breastfeeding, or on any biologic therapy. Subjects were randomized to receive 3 passes of IPL+RF treatment (IPL: 420-1200 nm, 4.4-6.0 J/cm^2, 4 sub-impulses: 8 ms/8 ms (duration/pause); RF: 1 MHz, 12.2 J/cm^2, 1 second) per session to a single HS area on a randomized side of the body at least 2 weeks apart for a total of 9 to 10 treatments. The contralateral side served as control.

TABLE 1.

Hidradenitis Suppurativa Outcome Measures from Baseline to Last Visit

HS Clinical Outcome Measure	Side Reference	N=9			N=8		
		Baseline Value (Mean, Median)	Last Visit Minus Baseline (Mean, Median)	*P*-Value[a]	Baseline Value (Mean, Median)	Last Visit Minus Baseline (Mean, Median)	*P*-Value[a]
DLQI	Overall	13.2, 14.0	- 2.8, - 3.0	0.043*	12.25, 11	-3.3, -3.0	0.031*
Pain VAS	Overall	2.7, 2.0	- 1.2, - 1.0	0.375	2.1, 1.5	-1.0, -0.5	0.656
HSPGA	Control	2.6, 2.0	- 0.1, 0.0	1.000	2.8, 2.5	-0.3, -0.5	0.688
	Treatment	2.8, 3.0	- 0.4, 0.0	0.313	2.9, 3.0	-0.5, -0.5	0.313
IHS4	Control	5.6, 4.0	0.7, 1.0	0.977	6.3, 5.5	0.6, 0.0	0.867
	Treatment	6.4, 6.0	- 0.3, -1.0	0.875	7.1, 6.5	-0.6, -1.0	0.695

DLQI, Dermatology Life Quality Index; HS, hidradenitis suppurativa; HS-PGA, Hidradenitis Suppurativa Physician Global Assessment; IHS4, International Hidradenitis Suppurativa Severity Score System; VAS, visual analog scale.
[a]Wilcoxon signed rank test
*Statistically significant, $P < 0.05$

Photographs, International Hidradenitis Suppurativa Severity Score System, and Hidradenitis Suppurativa Physician Global Assessment were obtained for both the treatment and control sides for the baseline and final visits. Overall (not side specific) DLQI and visual analog scale for pain were also obtained and compared between the baseline and final visit. Treatment and control sides were also examined at the final visit to determine if Hidradenitis Suppurativa Clinical Response was achieved.

Ten subjects (7 female and 3 male, ages 18–61 years, mean 42 years) were enrolled, and 9 subjects completed the trial. Of the subjects enrolled, 4 were Hurley stage I, 5 were Hurley stage II, and 1 was Hurley stage III. One male subject withdrew from the study after a single treatment due to concern for pubic hair loss that covered HS scarring. Of the 9 subjects who completed the trial, 2 subjects did not come for a final follow-up visit, which was 2 weeks after their final 10th treatment. Therefore, the final visit scores for these 2 subjects were calculated after a total of 9 treatments utilizing the assessments performed before the 10th treatment. The body regions treated were axillary (n = 2), inframammary (n = 2), and inguinal (n = 6). Apart from mild discomfort during therapy, there were no adverse events during or after treatment sessions.

RESULTS

A summary of score changes from baseline to last visit are displayed in Table 1. Statistical significance was not met on the treated side for improvement of Hidradenitis Suppurativa Physician Global Assessment, International Hidradenitis Suppurativa Severity Score System, and achievement of Hidradenitis Suppurativa Clinical Response compared to the control side from baseline to final visit. However, overall DLQI between baseline and final visits were observed to have a mean improvement of 2.8 points, which was found to be statistically significant (*P*=0.043, n=9). Although one of the 9 subjects did not meet the inclusion criterion of 3 inflammatory lesions at baseline, the above-mentioned results still hold true after excluding the data for this particular subject (n = 8 data in Table 1).

DISCUSSION

Despite the promising results of the recent IPL+RF study in German patients, no statistically significant clinical improvement with IPL+RF between the treatment and the control side from baseline to final visits were observed in this study.[5] Although the mean decrease of 2.8 points in overall DLQI was statistically significant from the beginning to end of the treatment period, the minimal clinically important difference of DLQI for inflammatory skin diseases has been determined to be ± 4.[6] Thus, the results found in this study did not reach the minimum threshold value for clinical importance.

The differing results from previous studies may be due to the clinical trial design. Patients had treatments performed at least 2 weeks apart with some up to several weeks in between treatments. The split-body design and smaller sample size of this study may explain the difference in results between this study and those of Wilden et al, which was a randomized controlled trial with a crossover option.[5] Alternatively, DLQI and pain visual analog scale are intended to assess the entire patient, rather than one half. A clinically important difference may have been achieved if both sides of the patient had been treated instead of split into treatment and control sides.

Despite some success in previous studies using IPL and RF described in some studies, there was no statistically significant clinical improvement in this study when comparing changes in scores from baseline to final visit between the treatment and control sides.[1,2,5] Moreover, the median change in DLQI is most likely not clinically significant, although 2 subjects did have a greater than 4-point improvement in DLQI. Nevertheless, the device was well-tolerated by patients with HS and this

technology may still hold promise, given other studies showing success.[1,2,5] As such, larger and randomized controlled trials are needed to draw further conclusions and identify optimal subgroups that may benefit significantly from this therapy.

DISCLOSURES

ABL, SN, IK, and RZ are sub-investigators for LENICURA and General Electric. APM is on AbbVie advisory board, has received AbbVie consulting fees, is Founding Director of Hope for HS (unpaid), HS Foundation Coordinator of Advocacy and Support (unpaid). IHH is the President of the HS Foundation, an investigator for LENICURA and General Electric, a consultant for Incyte, and is on AbbVie advisory board (unpaid). GJ and MC report no conflict of interest.

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