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Aggravation of mild axillary hidradenitis suppurativa by microwave ablation: Results of a randomized intrapatient–controlled trial

To the Editor: Hidradenitis suppurativa (HS) is a common chronic, recurrent, autoinflammatory skin disease of the hair follicle with limited treatment options.[1] No definitive treatment exists for this debilitating entity. MiraDry (Miramar Labs Incorporated, Santa Clara, CA) is a microwave device targeting the eccrine and apocrine sweat glands as well as hair follicles through thermolysis in the dermal-hypodermal junction.[2,3] We hypothesized that this noninvasive ablative technique could potentially improve the clinical symptoms of HS by reducing the number of hair follicles (primary action) and the destruction of the inflammatory cell infiltrate (secondary action) in HS lesions. We, therefore, evaluated the efficacy and safety of miraDry treatment for mild axillary HS in a randomized intrapatient–controlled trial (ethical approval by the IRB of the Erasmus University Medical Center; MEC-2017-390).

We aimed to include 20 HS patients for random allocation to a single miraDry treatment (5.8 GHz, energy level 5, manufacturer-recommended settings) of 1 axilla under tumescent anesthesia. Patients were required to have a total of 3-5 abscesses or nodules per axilla with ≤1 abscess or draining sinus. Additional inclusion and exclusion criteria are available at https://www.clinicaltrials.gov (identifier NCT03238469). The primary outcome was a left-right comparison of the axillary areas using the Hidradenitis Suppurativa Clinical Response (HiSCR). Secondary outcomes included a numerical rating scale on pain per axilla, treatment satisfaction, and a hair follicle count. Two independent blinded observers performed lesion counts at baseline and 3 months after the procedure.

Only 9 of 20 HS patients were tested; negative clinical outcomes during the recruitment period made it pertinent for us to do an interim analysis, resulting in the decision to discontinue the study. One of the randomized patients did not tolerate the miraDry treatment due to extreme pain during the procedure, despite the use of several local anesthetics. Of the 8 patients who concluded the miraDry treatment (all women, median age 31.5, interquartile range [IQR] 28.0-39.0 years), 7 completed the 3-month follow-up; 1 patient dropped out because of worsening of HS symptoms in the axilla treated by miraDry. Two patients achieved the HiSCR in the miraDry-treated axilla, and 2 patients achieved the HiSCR in the comparator axilla ($P = 1.00$) (Table I). In total, 5 of 8 patients showed worsening of their disease after miraDry treatment, with an increase in the abscess and nodule and sinus count (Fig 1). Patients suffered from active lesions for a median of 43.0 (IQR 4.0-90.0) days in the miraDry-treated axilla versus a median of 5.5 (IQR 2.0-26.0) days in the contralateral axilla ($P = .14$). After 3 months, the median numerical rating scale score for pain in the miraDry-treated axilla was 7.0 (IQR 2.0-8.0) versus 0 (IQR 0-5.0) for the untreated axilla ($P = .07$). One patient developed cellulitis of the upper arm after miraDry treatment, requiring antibiotic treatment, which was classified as a severe adverse event.

We observed that the number of hair follicles after 3 months was numerically lower in the miraDry-treated axilla, median 4.0 (IQR 3.0-5.0)/cm^2, a 50.9% decrease from baseline, compared with the untreated counterpart, median 8.5 (IQR 6.0-10.0)/cm^2, a 2.0% decline from baseline ($P = .07$). Because the miraDry device targets the dermal zone rather than a particular structure, its nonselectivity might have resulted in the poor study outcomes. Accordingly, we argue that the microwave energy is able to rupture pre-existing and subclinical or microscopic HS precursor lesions (cysts), subsequently resulting in an intense inflammatory response beyond the initially visible lesions.

Although the intervention was completed in only 8 patients, our findings indicate that microwave ablation using the miraDry device has no apparent clinical benefit and could even be harmful in patients with mild HS. Commercial miraDry clinics in the Netherlands also observed a few cases of flaring of the disease in HS patients (A. Roopram and W. Venema, personal communication, May 2018). Taken together, we question the utility of microwave ablative therapy in patients with HS in clinical practice.

Table I. Hidradenitis suppurativa patient demographics and clinical responses to miraDry treatment

No.	Age, y	Sex	BMI, kg/m^2	Smoking status	Skin type, Fitzpatrick	HiSCR of control axilla, 3 mo	HiSCR of miraDry axilla, 3 mo	AN count miraDry		Sinus count miraDry		Hair follicle count miraDry		NRS pain miraDry		miraDry recommendation at 3 mo	Adverse events
								0 mo	3 mo	0 mo	3 mo	0 mo	3 mo	0 mo	3 mo		
1	41	F	30.1	Y	5	+	-	3	4	0	1	14	MI	6	7	No	Edema, erythema
2	28	F	28.1	Y	5	-	-	4	D	0	D	9	D	9	D	D	Edema
3	28	F	40.5	Y	2	-	+	3	0	0	0	12	3	6	2	Yes	Edema
4	53	F	31.3	Y	5	-	+	5	0	0	0	15	9	5	0	Yes	Edema
5	28	F	32.5	N	1	+	-	3	4	0	2	6	4	1	8	No	Edema, erythema, cellulitis
6	29	F	31.9	Y	4	-	-	4	3	0	1	8	2	6	7	Doubt	Edema, mobility impairment
7	37	F	40.9	Y	1	-	-	3	3	0	0	4	4	7	6	Doubt	Edema
8	34	F	32.4	Y	4	-	-	3	3	0	2	10	5	6	8	No	Edema, erythema

The control was comparator axilla treated with topical clindamycin 10 mg/g BID, if necessary. miraDry (Miramar Labs Incorporated, Santa Clara, CA) axilla were treated by microwave ablation. Sinus count included draining sinus, fistula, or tunnel. Hair follicle count was the average number of hair-containing follicles in 3 fields of 1 cm^{-2} assessed by dermoscopy. A miraDry recommendation was obtained by asking patient "Would you recommend the miraDry treatment to other HS patients? − yes, no, doubt." Adverse events were all self-limiting; cellulitis in the axilla treated by miraDry, which was treated by flucloxacalin 500 mg QID for 10 days.

AN, Abscess and nodule; *BMI*, body mass index; *D*, discontinued because of worsening disease activity in the miraDry-treated axilla; *HiSCR*, Hidradenitis Suppurativa Clinical Response; *MI*, missing information; *NRS*, numerical rating scale for HS-related local pain.

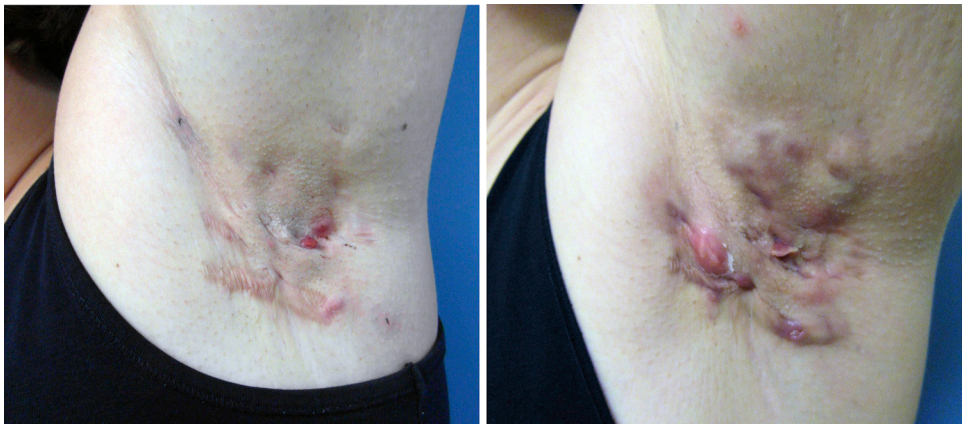

Fig 1. Baseline condition (*left*) and 3-month response (*right*) to miraDry treatment in the left axilla of patient 5 with hidradenitis suppurativa.

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Port-wine stains on the neck respond better to a pulsed dye laser than lesions on the face: An intrapatient comparison study with histopathology

To the Editor: Neck port-wine stains (PWSs) usually respond better than facial PWSs to treatment with a pulsed dye laser (PDL).[1] Until now, however, self-controlled studies with objective evaluation of efficacy and anatomic features have not been reported. In this study, we investigated the morphologic and anatomic features of both facial and neck PWS lesions and put forward a possible explanation for the difference in the therapeutic efficacy of PDL.

A total of 26 patients with untreated facial and neck PWSs received similar numbers (range, 2-3) of PDL treatments with a Vbeam laser (Candela Corporation, Boston, MA), with a radiant exposure of 12 J/cm^2, 1.5-ms pulse duration, 7-mm spot size, and cryogen spray cooling for 40 ms with a 20-ms delay on both sites. Clinical efficacy was evaluated by using a CR-400 chromameter (Minolta, Tokyo, Japan). Two months after the final treatment, the L*, a*, and b* color system of the International Commission on Illumination[2] were monitored, including the values of ΔE (color expressed change or improvement), Δa* (change in the vascular erythema), and blanching rate.[3] Additionally, pretreatment biopsies of both facial and neck PWS lesions were obtained from 9 patients. The PWS vascular diameter and depth and thickness of the epidermis were measured by using medical ImagePro Plus image analysis software (Media Cybernetics Inc, Rockville, MD).

After PDL treatments on both sides, the neck PWS lesions showed significantly better clearance than