Aggravation of mild axillary hidradenitis suppurativa by microwave ablation: results of a randomised intrapatient-controlled trial

A.R.J.V. Vossen*
M.A.P.C. van Huijkelom*
T.E.C. Nijsten
E.W.P. Bakker
H.H. van der Zee
M.B.A. van Doorn
E.P. Prens
* shared first authorship

J Am Acad Dermatol – in press

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 hypothesised 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 randomised intrapatient-controlled trial. Ethical approval was given 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 anaesthesia. 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 numeric 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 randomised patients did not tolerate the miraDry treatment due to extreme pain during the procedure, despite the use of several local anaesthetics. 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 1). 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 (Figure 1). Patients suffered from active lesions for a median (IQR) of 43.0 (4.0-90.0) days in the miraDry-treated axilla versus a median of 5.5 (2.0-26.0) days in the contralateral axilla ($p = 0.14$). After 3 months, the median numeric rating scale score for pain in the miraDry-treated axilla was 7.0 (2.0-8.0) versus 0 (0-5.0) for the untreated axilla

(p = 0.07). 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 (3.0-5.0)/cm^2, a 50.9% decrease from baseline, compared with the untreated counterpart, median 8.5 (6.0-10.0)/cm^2, a 2.0% decline from baseline (p = 0.07). 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 (personal communication: Dr A. Roopram and Dr W. Venema - May 2018). Taken together, we question the utility of microwave ablative therapy in patients with HS in clinical practice.

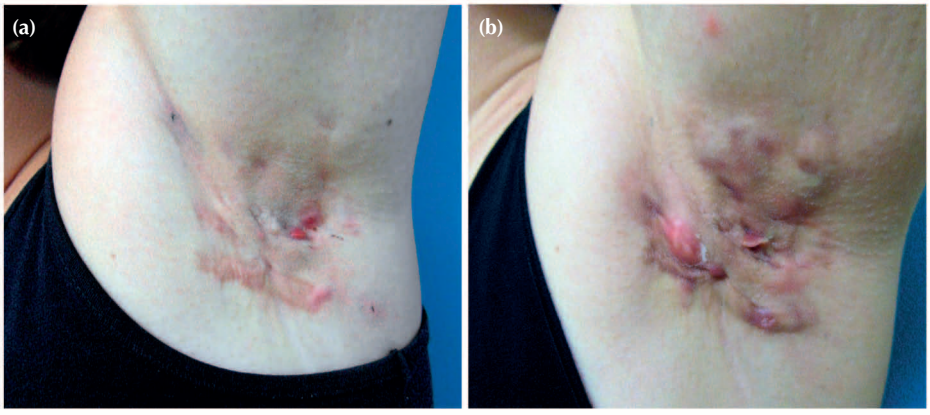

Figure 1. Baseline condition **(a)** and 3-month response **(b)** to miraDry treatment in the left axilla of patient 5 with hidradenitis suppurativa.

Table 1. Hidradenitis suppurativa patient demographics and clinical responses to miraDry treatment.

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

The control axilla was treated with topical clindamycin 10 mg/g BID, if necessary. miraDry (Miramar Labs Incorporated, Santa Clara, CA) axilla was treated by microwave ablation. Sinus count included draining sinus, fistula, and 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 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: numeric rating scale for HS-related local pain.

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