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ORIGINAL ARTICLE

A prospective clinical and histologic study of axillary osmidrosis treated with the microwave-based device

Yao-Yu Chang [1, 2], Chien-Hsun Chen [1, 2], Rosaline Chung-Yee Hui [1, 2], Shih-Ming Jung [2, 3], Chih-Hsun Yang [1, 2, *]

[1] Department of Dermatology, Chang Gung Memorial Hospital, Taipei, Taiwan
[2] College of Medicine, Chang Gung University, Taipei, Taiwan
[3] Department of Pathology, Chang Gung Memorial Hospital, Taipei, Taiwan

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ABSTRACT

Background/Objective: Microwave-based devices target sweat glands through energy delivery at the dermal–subcutaneous interface. These devices have been approved by the Food and Drug Administration as a noninvasive treatment for axillary hyperhidrosis. Treatment for osmidrosis has only been reported in one preliminary study. This study aimed to investigate the efficacy, safety, and histological changes of the microwave-based devices in treating axillary osmidrosis.

Methods: We conducted a prospective study in a tertiary referral center in Taiwan. Patients with axillary osmidrosis were recruited and received two consecutive treatment sessions with a 3-month interval. Skin biopsy was obtained to evaluate histological changes. The efficacy was determined by odor reduction using a patient reported 10-point odor scale. Responders were defined as participants with a reduction of at least 3 points of the Odor-10 score at their 90-day follow-up visit.

Results: Seven patients were enrolled. Mean reduction of odor was 61.8%. Six patients met the primary endpoint of odor reduction. Skin biopsy specimens reveled 93% reduction of apocrine glands. Histopathological changes include dermal fibrosis, necrosis of sweat glands, and subcutaneous fat necrosis. Transient swelling, bruise, numbness, lumps, and hypotrichosis were possible side effects. No patient reported disabling side effects.

Conclusion: Microwave-based devices are noninvasive and a potential alternative therapeutic modality for axillary osmidrosis treatment.

Introduction

Axillary osmidrosis refers to an offensive and unpleasant body odor from the axillary area. It is a very distressing issue impairing an individual's psychosocial well-being. Secretions from the apocrine glands of the axillae are responsible for the malodor. Thus, several surgical techniques have been developed to remove the glands, but the results and complication rates vary.[1–3] Microwave-based devices, approved by the United States Food and Drug Administration, have been developed to treat axillary hyperhidrosis by selectively heating the interface between the skin and underlying fat of the axilla.[4] However, treatment of axillary osmidrosis using this technique has only been reported in one preliminary study.[5]

The objectives of this study were to investigate the efficacy, safety, and histological changes of microwave-based devices in treating axillary osmidrosis.

Materials and methods

Patients

Seven adults with axillary osmidrosis (aged 22–53 years, 2 men and 5 women) were enrolled in a single-group unblinded study in a tertiary referral medical center in Taiwan. All patients were rated 3 or 4 on the hyperhidrosis disease severity scale (HDSS) and at least

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* Corresponding author. Department of Dermatology, Chang Gung Memorial Hospital, 199, Dun-hua North Road, Taipei City, Taiwan.
E-mail address: dermadr@hotmail.com (C.-H. Yang).

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5 on the Odor-10 scale. No patient had been treated with endoscopic thoracic sympathectomy, liposuction, or other surgeries for axillary osmidrosis or hyperhidrosis. They had no botulinum toxin injection within 1 year, and had not used any topical treatment within 14 days prior to treatment.

The study was approved by Chang Gung Memorial Hospital's institutional review board (103-4012C4), and informed consent was obtained prior to any study procedures.

Odor and sweat assessments

All participants were asked to record their own perception of their underarm odor using a 10-point scale (Odor-10), where 1 stands for completely no odor and 10 for severe odor.

The method of assessing the level of axillary sweat was patient-reported HDSS score. Table 1 provides the definition of the four scores respectively.

Treatment

Baseline evaluation including past medical history, physical examination, and sweat and odor self-assessment (HDSS and Odor-10) were performed on each patient. An incisional skin biopsy was taken from the left central axilla. The incision was 1.5-cm in length and depth to the deep subcutis. Treatment sessions began 1 month after the skin biopsy to avoid wound dehiscence during microwave treatment.

After being marked with a treatment template, the axillary area was anesthetized with 1% lidocaine with 1:100,000 epinephrine. Both axillary areas were fully treated by miraDry system (Miramar Labs, Santa Clara, CA, USA), which is a microwave-based device with integrated vacuum and cooling included. It allows different energy settings within a small range. Energy level 3 (the middle energy setting), which is the most commonly used setting in previous reports,[4] was used for the first treatment session. The second session was carried out 3 months after the first session. Energy level was increased to level 5 because there were no apparent side effects after the first treatment. The second session also covered the entire bilateral axilla region.

After completion of all sessions, all patients attended follow-up visits 30 days and 90 days after their last session. An additional skin biopsy was taken from a location 1 cm away from the previous biopsy site in the ipsilateral axilla to avoid scar tissue at their 30-day follow-up visits.

Study efficacy and patient satisfaction measurement

Efficacy of odor reduction was measured using the Odor-10 score. For the study's primary endpoint, responders were defined as a reduction of at least 3 points on the Odor-10 score at their 90-day follow-up visit. In addition, the HDSS score was used as a measurement of sweat reduction. Responders were defined as participants reporting a HDSS score of 1 or 2 at their 90-day follow-up visits.

All participants were asked about their satisfaction regarding the whole procedure at the 90-day follow-up visit. Patient satisfaction score was ranked on a scale of 1 to 5 (1 = very dissatisfied, 2 = somewhat dissatisfied 3 = no comment, 4 = very satisfied, and 5 = absolutely satisfied).

Histological evaluation

The skin biopsy specimens were stained with hematoxylin and eosin. All slides were reviewed by a dermatopathologist. Histological changes after the treatments were evaluated in terms of the reduction of apocrine glands, changes in hair follicles, nerves, and subcutaneous fat. Immunohistochemistry staining with CAM5.2 (BD Biosciences, Franklin Lakes, New Jersey, USA), which reacts with low molecular weight cytokeratin, was used to highlight apocrine sweat glands. All the immunohistochemistry slides were photographed and stored digitally. The total area of the tissue (TAT) and the area of the tissue containing apocrine sweat glands (AAG) were measured using computerized image processing software (Adobe Photoshop, San Jose, CA, USA) and subjected to statistical analysis.[6] Probability of error < 0.05 was set as the cut-point for level of significance.

Safety assessments

Postoperative pain was recorded using numeric pain rating scale from D0 to D6 after each treatment session. If there was discrepancy in pain between two sides of axilla, the higher pain score was recorded.

During each visit, patients were asked about adverse events. The degree to which the events were associated with the procedure was judged by the investigators. All events were monitored until they were adequately resolved.

Results

Demography

Demographic information and baseline sweat assessment values for all participants are shown in Table 2. All patients completed study visits up to 90 days of follow-up. Every patient underwent two procedure sessions and was skin biopsied twice.

Efficacy and patient satisfaction

The efficacy of odor and sweat reduction is shown in Table 2 and Figure 1. Six out of seven (85.7%) patients met the primary endpoint of odor reduction. The mean percentage of reduction in odor-10 scale was 76.4% and 61.8%, at 30-day and 90-day visits respectively. As for sweat reduction, six of seven (85.7%) patients

Table 1 Hyperhidrosis disease severity scale definition.

Score	How would you rate the severity of your hyperhidrosis?
1	My underarm sweating is never noticeable and never interferes with my daily activities
2	My underarm sweating is tolerable but sometimes interferes with my daily activities
3	My underarm sweating is barely tolerable and frequently interferes with my daily activities
4	My underarm sweating is intolerable and always interferes with my daily activities

Table 2 Demographic characteristics and the results of sweat reduction.

Patient	Age/Sex	BMI (kg/m^2)	Baseline Odor-10	Baseline HDSS Score	HDSS Score Day 30	HDSS Score Day 90
1	27/M	23.0	10	3	2	1
2	31/F	17.0	8	4	2	3
3	25/F	22.4	8	4	3	2
4	22/F	21.2	6	3	1	1
5	35/M	21.5	5	3	1	1
6	53/F	24.4	9	3	1	1
7	32/F	18.0	9	3	3	1

BMI = body mass index; HDSS = hyperhidrosis disease severity scale.