2010 ASDS/ASCDAS Joint Annual Meeting

GD413: Accelerated Abstracts: Late Breaking Material Brought to you Fast!

Title: **A Randomized, Blinded Clinical Evaluation of a Novel Microwave Device for Treatment of Axillary Hyperhidrosis**

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Purpose: Current treatments for axillary hyperhidrosis are limited either by duration of effect and/or by effectiveness. Microwave devices, although not commonly used in dermatology, have the ability to focus heat at the interface between the skin and subcutaneous tissue and cause irreversible thermal necrosis of both apocrine and eccrine sweat glands. A new early generation microwave device for treatment of axillary hyperhidrosis has been developed and is available for research use.

Design: To demonstrate a durable, safe treatment for primary axillary hyperhidrosis using a microwave-based device. The primary endpoint of the study is a difference in subject-reported efficacy for sweat reduction 30 days after treatment compared to subjects who were treated with a sham device. Secondary endpoints include efficacy up to 12 months after treatment.

Summary: We report on a multi-center, randomized, sham-controlled study involving 120 adult subjects with primary axillary hyperhidrosis (PAH). Subjects were required to have a Hyperhidrosis Disease Severity Scale (HDSS) score of 3 or 4 (barely tolerable or intolerable sweating) and to have baseline gravimetric readings greater than 50 mg/ 5 minutes. Subjects were excluded if they had prior surgery for PAH or botulinum toxin A injections to treat PAH within the past 12 months.

At the time of the first treatment session, subjects were randomized in a 2-to-1 ratio to the treatment group (n=81) and sham group (n=39). Local anesthesia was used in both groups for comfort management and to protect the blinding. Treatments were provided using a microwave-based device with integrated vacuum and cooling. 83% of subjects had a “touch-up” session approximately 2 weeks after the first treatment session with the extent of treatment determined by the unblinded investigator. HDSS questionnaires and gravimetric assessments were administered by blinded data evaluators at follow-up visits. The timing for all follow-up visits was calculated relative to the last treatment session. Sham group subjects exited the study after the completion of a 6-month follow-up visit; treatment group subjects were followed for 12 months post-treatment.

For the primary endpoint, responders were defined as those subjects reporting an HDSS score of 1 or 2 at the 30-day follow-up visit. Secondary analyses included the same measure at other time points. Gravimetric efficacy success was defined as both a 50% reduction in weighed sweat compared to baseline data (sum of right and left values) and a 75% reduction in sweat. Safety information was collected for all enrolled subjects.

Results: Demographics for the enrolled subjects are shown in Table 1. There were no statistically significant demographic differences between the subjects in the treatment group compared to the sham group.

Table 1. Subject Demographics

		Treatment group (N=81)	Sham group (N=39)	Total (N=120)
Age	Median (years)	33	31	31
	≤ 30 years	17 (44%)	40 (49%)	57 (48%)
	> 30 – 45 years	15 (39%)	32 (40%)	47 (40%)
	≥ 45 years	7 (18%)	9 (11%)	16 (13%)
Gender	Male	13 (33%)	38 (47%)	51 (43%)
	Female	26 (67%)	43 (53%)	69 (58%)
Race	White	33 (85%)	68 (84%)	101 (84%)
	African American	4 (10%)	4 (4.9%)	8 (6.7%)
	Other	2 (5.1%)	8 (9.9%)	10 (8.3%)

Percentages across groups may not add up to 100% due to rounding.

Interim HDSS efficacy results are shown in Table 2. At the time of submission to late-breaking abstracts, the data for the six month follow-up visit was still being compiled. For all time points and both definitions of efficacy success, the efficacy for the treatment group was statistically significantly greater than the efficacy for the sham group. A ≥50% reduction in sweat as measured by a gravimetric assessment at the 30-day follow-up visit was seen in 80% of the treatment group and 67% of the sham group (p=0.097). Interestingly, there was a statistically significant difference when success was defined as a ≥75% reduction in sweat: the treatment group efficacy was 62% and the sham group efficacy was 39% (p=0.011).

Table 2. HDSS Efficacy results at the 30-day follow-up visit and the 3-month follow-up visit.

	30-day follow-up			3-month follow-up		
definition of success	TX Group (N=81)	Sham Group (N=39)	stat sig	TX Group (N=81)	Sham Group (N=39)	stat sig
HDSS = 1 or 2	89%	54%	p<0.001	74%	44%	p=0.001
HDSS reduces by ≥2	67%	13%	p<0.001	57%	13%	p<0.001

There were no serious adverse events reported in the study for any subject. Treatment-related adverse events were generally mild in nature and all resolved over time. The number of subjects with the listed adverse events were: numbness, tingling or sensitivity in the treatment limb (n=9, 7.5%); skin irritation/itching/rash (n=5, 4.2%); pain requiring prescription medication (n=5, 4.2%); edema in the treatment limb (n=4, 3.3%); blisters/ulcerations (n=4, 3.3%); axillary nodules/bumps (n=3, 2.5%); all others (n=6, 5%).

Conclusions: This study has demonstrated a statistically significant difference in sweat reduction for those subjects treated with the device compared to subjects who received a sham treatment through the 3 month follow-up visit. The safety profile of the treatment was good. Treatment group subjects will be followed for up to one year to determine the duration of the effect. The literature suggests that ontogenesis of sweat glands occurs only at the embryonic stage and no new sweat glands are formed; this suggests the therapy will provide a lasting reduction in sweat. Stabilization of efficacy is anticipated beyond 6 months. Further device and procedure improvements have been identified and may yield higher efficacy results along with further refinements in safety in future studies.

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Note: Typographic errors and table formatting in the published program have been corrected.