An Alternative Method of Pain Management for Microwave Treatment of Primary Axillary Hyperhidrosis

William P. Coleman III, MD, W. Patrick Coleman IV, MD
Coleman Center for Cosmetic Dermatologic Surgery

Objective

A novel microwave device has been utilized widely for over 2 years to treat primary axillary hyperhidrosis [1-3]. The device works by heating the subdermal layer of the skin where the sweat glands are primarily located. Clinical studies to date and commercial use have employed injected stock solutions of local anesthetic for analgesia. This study was undertaken to determine if the use of tumescent anesthesia would provide similar pain management without negative effects on sweat reduction efficacy. The potential advantages include increased comfort for the patient during anesthesia administration and less trauma to the dermis in the treatment site.

Study Design and Methods

This study is a randomized, split-patient, unblinded study. Each patient was required at baseline to have significant axillary hyperhidrosis, defined as gravimetric sweat levels of greater than 50mg/5min in each axilla, with relatively symmetric sweat levels (within a factor of two). At the time of the first treatment session, subject's axillae were randomly assigned to be anesthetized with either of two methods. See Table 1 for a comparison of the two techniques.

Table 1. Different anesthesia methods compared

	Method 1 – Injection	Method 2 - Tumescent
Anesthesia used	1% lidocaine with 1:100000 epinephrine	0.2% lidocaine in buffered saline with 1:500000 epinephrine
Range of volumes (cc)	15 - 32	200 - 500
Method of infiltration	Injection with 30g needles at approx 1cm spacing, using manufacturer supplied grid	Blunt cannula using peristaltic pump

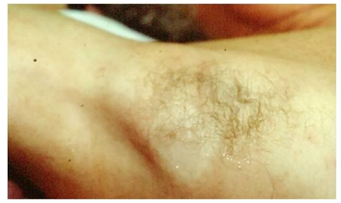
- The microwave device (miraDry System, Miramar Labs, Santa Clara, CA) allows the operator to choose between 5 different energy levels, where energy level 1 corresponds to 2.4sec of energy delivery per antenna and energy level 5 corresponds to 3.0sec of energy delivery.
- The energy levels selected for this clinical study were the same as used in clinical practice and were the same for both underarms.
- Subject pain scores (scale of 1 to 10, with 10 being the worst pain) were separately gathered for each underarm for the discomfort of anesthesia administration and the discomfort of treatment.
- Follow-up visits were scheduled at 1 month, 3 months, 6 months, 9 months and 12 months after the second treatment. Sweat levels were measured using the HDSS (Hyperhidrosis Disease Severity Scale) scores and gravimetric assessments.

Table 2. Subject demographics (n=17)

Characteristic	Distribution
Male	**9 (53%)**
Female	**8 (47%)**
Age (Average)	**32**
Baseline Gravimetric scores (ave) – Method 1 axilla	**204 mg**
Method 2 axilla	**191 mg**

Results

Figure 1.
Example of axilla after high volume anesthesia has been administered.



For the first treatment session, all patients were treated at energy level 3 with the first few superior rows kept at energy level 1 as is carried out in clinical practice. For the second treatment session, 60% of patients were treated at energy level 4 with the remaining 40% of patients treated at energy level 3.

Table 3. Average pain scores for each treatment session (n=17). 1 is no pain, 10 is severe pain.

	Treatment 1		Treatment 2	
	Score for anesthesia admin	Score for treatment	Score for anesthesia admin	Score for treatment
Injected Axilla	4.5	1.4	3.6	1.1
Tumescent Axilla	3.6	1.4	2.6	1.1

The efficacy results were similar for both methods, according to both gravimetric assessments and HDSS scores. See Tables 4 and 5 and Figure 2 for the results. The results for the 12 month visit are preliminary, there are still some patients scheduled.

Table 4. Efficacy results based on gravimetric measurements

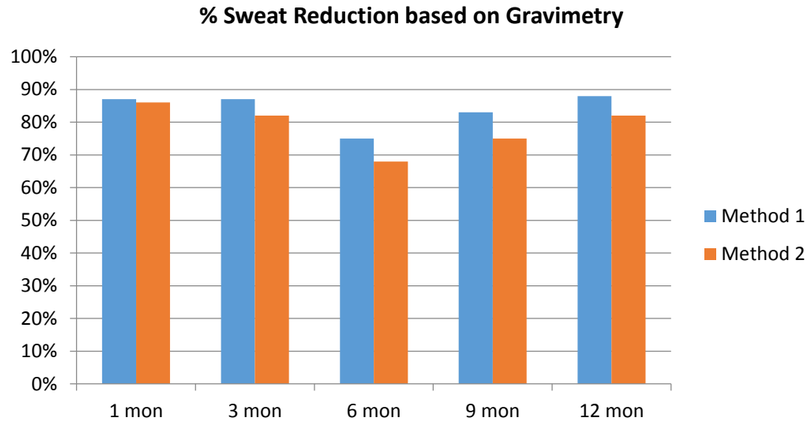
	% sweat reduction based on gravimetric measurements				
	1 month (n=14)	3 month (n=14)	6 month (n=13)	9 month (n=9)	12 month (n=7, partial)
Injected Axilla	**87%**	**87%**	**75%**	**83%**	**88%**
Tumescent Axilla	**86%**	**82%**	**68%**	**75%**	**82%**

Table 5. Efficacy results based on HDSS scores

	% with HDSS scores of 1 or 2*				
	1 month	3 month	6 month	9 month	12 month (Partial)
Injected Axilla	100% 13/13	100% 12/12	100% 10/10	89% 8/9	100% 7/7
Tumescent Axilla	100% 13/13	100% 12/12	100% 10/10	89% 8/9	100% 7/7

*Two patients self-rated as HDSS score of 2 at baseline, so they are not included. Not all patients completed the questionnaire.

Figure 2. Sweat reduction comparison between the two methods at each follow-up visit. The methods used to administer anesthesia gave equivalent results (within measurement error).



In addition to wetness reduction, patients self-reported odor assessments at baseline and follow-up visits. For patients who started with scores of 5 or more (on a 1 to 10 scale, with 10 being a severe odor problem), the average reduction in odor was 6.7 and 6.9 points for Method 1 and Method 2 respectively (at the 6 month follow-up visit, n=7 patients).

The general side effects reported were temporary swelling and some tenderness in the treated area which is consistent with previous commercial use of the device. In this series, 3 patients reported infection on the side that had injected anesthesia and were managed with short-term antibiotics. This is a higher rate than has been seen with commercial use of the device. The authors theorize that the tumescent approach decreases the risk of infection by eliminating multiple needle sticks throughout the treatment field. Tumescent anesthesia has also been shown to reduce infections in liposuction although the mechanism is debated

Conclusions

The results of this study demonstrate that the two methods of anesthesia provided similar comfort management and efficacy. This provides supportive evidence for physicians who want to use different anesthesia approaches. The results seem to be stable through a full year of follow-up. It is possible that there may be ways to optimize the microwave treatment by utilizing a higher volume of anesthesia with higher energy levels that may improve the results further.

References

1. Glaser DA, Coleman WP, Fan LK, et al. A Randomized, Blinded Clinical Evaluation of a Novel Microwave Device for treating Axillary Hyperhidrosis: the DRIUP Study (Dermatologic Reduction In Underarm Perspiration). Dermatol Surg 2012; 38: 185-191.

2. Hong HC-H, Lupin M, O'Shaughnessy KF. Clinical Evaluation of a Microwave Device for Treating Axillary Hyperhidrosis. Dermatol Surg 2012; 38: 728-735.

3. Lupin M, Hong HC-H, O'Shaughnessy KF. Long-term Efficacy and Quality of Life Assessment for Treatment of Axillary Hyperhidrosis With a Microwave Device. Dermatol Surg 2014; 40: 805-807.

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