MICROWAVE ABLATION OF ECCRINE GLANDS AS A TREATMENT FOR RESIDUAL LIMB HYPERHIDROSIS

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FINAL REPORT

17 Sep 2019

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14. ABSTRACT-

Up to 66% of lower limb amputees report residual limb hyperhidrosis with a significant association between sweating and decreased prosthetic function. Microwave thermoablation is an effective permanent solution for axillary hyperhidrosis. The purpose of this study was to evaluate the use of microwave thermoablation for the treatment of residual limb hyperhidrosis. Dermatology Life Quality Index (DLQI) scores, Severity of Prosthesis Problem Scale (SPPS) scores, and gravimetric measurements of sweat after 10 minutes of exercise were taken at baseline and 3 months after treatment. Pre and post treatment measurements were compared using the Wilcoxon signed-rank test using SPSS (IBM, Armonk, NY). A total of 9 limbs in 8 patients (one double amputee) underwent treatment. There was a statistically significant decrease in DLQI (Z=-2.136, p=0.033) and SPPS (Z=-2.521, p=0.012) scores indicating improvement in quality of life and increased ease of prosthetic use, respectively. There was a statistically significant decrease in gravimetric amount of sweat produced (Z=-2.032, p=0.042). Microwave thermoablation significantly improves quality of life, increases ease of prosthetic use, and decreases amount of sweat produced in lower limb amputees. These effects are expected to be permanent.

15. SUBJECT TERMS-

Wounded warrior care, hyperhidrosis, amputee health

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1.0 EXECUTIVE SUMMARY

Up to 66% of lower limb amputees report residual limb hyperhidrosis with a significant association between sweating and decreased prosthetic function. Microwave thermoablation is an effective permanent solution for axillary hyperhidrosis. The purpose of this study was to evaluate the use of microwave thermoablation for the treatment of residual limb hyperhidrosis. Dermatology Life Quality Index (DLQI) scores, Severity of Prosthesis Problem Scale (SPPS) scores, and gravimetric measurements of sweat after 10 minutes of exercise were taken at baseline and 3 months after treatment. Pre- and post-treatment measurements were compared using the Wilcoxon signed-rank test using SPSS (IBM, Armonk, NY). A total of 9 limbs in 8 patients, of which one was a double amputee, underwent treatment. There was a statistically significant decrease in DLQI ($Z = -2.136$; $p = 0.033$) and SPPS ($Z = -2.521$; $p = 0.012$) scores, indicating improvement in quality of life and increased ease of prosthetic use, respectively. There was a statistically significant decrease in gravimetrically measured amounts of sweat produced ($Z = -2.032$; $p = 0.042$). Overall, these results show that microwave thermo-ablation of the target eccrine glands in the study subjects significantly improves quality of life, increases ease of prosthetic use, and decreases amount of sweat produced in lower limb amputees. Further, we think these effects may be permanent.

2.0 INTRODUCTION

This study was conducted to determine the utility of microwave-mediated thermal ablation of eccrine glands in improving the clinical outcomes for amputees. The microwave device we used was miraDry System, a 510 (K) device approved by the FDA (K103014) for such thermal ablation. The device functions by selective heating of the interface between the skin and underlying fat where the sweat glands reside to thermally destroy the eccrine coils of the sweat glands to permanently reduce sweating in the treated area. Current treatments for residual limb hyperhidrosis employ treatments routinely used for axillary hyperhidrosis in off-label locations, and most provide only temporary results. Our study employed this microwave treatment for hyperhidrosis in residual limbs to determine its viability as a successful treatment modality.

3.0 METHODS AND PROCEDURES

Procedures included evaluation by questionnaires and gravimetric sweat analysis, use of treadmill to exercise, and application of the miraDry machine. Originally the Hyperhidrosis Disease Severity Scale was going to be used as the primary outcome; however, it became apparent that this measurement tool did not well capture the problems specific to residual limb hyperhidrosis as it only assessed a single question on a scale from 1-4 without specific or in depth information related to the patients' prosthetic use. Instead, we chose to use the Dermatology Life Quality Index (DLQI) and the Severity of Prosthesis Problem Scale (SPPS) as primary outcomes which more extensively evaluated specific issues related to prosthetic use in the setting of residual limb hyperhidrosis. We also intended to use a vapometer to measure trans-

epidermal water loss as a proxy for sweat measurement; however, an adaptor to calibrate for temperature and humidity was not used when it should have been used. This data was therefore determined to be unreliable and was not used in our analysis. Patients were treated according to the initial protocol of one half of the residual limb followed by the other half after at least a 2-week period to avoid compartment syndrome. Surveys and gravimetric sweat analysis were performed prior to treatment and 3 months after treatment. Statistically significant results were achieved after only a single treatment. The determination was made that such results would allow justification for creating a new clinic policy for treatment of residual limb hyperhidrosis using microwave thermoablation. If such a policy were in place, it would allow for persistent efficacious treatment of amputee patients long after the investigator of this study undergoes PCS. The study was therefore closed, and a clinic policy for continued treatment was created.

4.0 MAJOR EVENTS/MILESTONES/SUCCESS

- IRB Approval – 30 April 2018
- Kick-Off Meeting – 16 May 2018
- Presentation of Project Outline at MHSRS – August 2018
- All experimental procedures completed – 16 May 2019
- Data Analysis – 01 August 2019
- The final study findings will be presented at a scientific conference
- A manuscript will be submitted for publication in a peer-reviewed journal

5.0 RISK ASSESSMENT

5.1 Risk Analysis

No unexpected side effects occurred in the treated patients.

5.2 Technical Challenges

A calibration device for the vapometer was not used when it should have been, and therefore the data generated by the instrument were excluded from this study.

6.0 TRANSITION PLAN

6.1 Military Relevance

The Dismounted Complex Blast Injuries (DCBI) Task Force aims to establish specialized centers where experience and subspecialists can come together to provide comprehensive care and to foster development of advanced skills in these locations. The Material section of the DCBI task force recommendations underscores the impact of this study, as one of the stated goals is to “improve prosthetic socket interfaces to prevent commonly occurring acute and chronic skin problems.” The need for these improvements is due to the physical, mental, social, and economic impacts of stump dermatoses on patients. This treatment has the

potential to allow wounded warrior amputees to better return to active duty service after injury.

6.2 Transition Strategy

We have established a new protocol within our clinic to continue to provide treatment for residual limb hyperhidrosis using this method. Patients will be referred for treatment by their providers at the Center for the Intrepid. They will then be evaluated in our clinic prior to being set up for treatment. On the day of treatment, patients will undergo nerve blocks performed by the anesthesia department followed by tumescent anesthesia and microwave thermoablation. The patients will undergo treatment of one half of their limb per treatment spaced 2 weeks apart to avoid compartment syndrome. The patients will be assessed for the need for retreatment 3 months after each full treatment.

7.0 RESULTS

A total of 9 limbs in 8 patients (one double amputee) underwent treatment. There was a statistically significant decrease in DLQI ($Z=-2.136$, $p=0.033$) and SPPS ($Z=-2.521$, $p=0.012$) scores. There was a statistically significant decrease gravimetric amount of sweat produced ($Z=-2.032$, $p=0.042$).

8.0 CONCLUSION/DISCUSSION

Microwave thermoablation significantly improves quality of life as indicated by the decrease in DLQI scores, increases ease of prosthetic use as indicated by the decrease in SPPS scores, and decreases amount of sweat produced in lower limb amputees as indicated by the decrease in gravimetric amount of sweat produced. These effects are expected to be permanent. For the vapometer data to have been usable, the calibrator for humidity and temperature should have been used. However, the other statistically significant results successfully demonstrate the utility of microwave thermoablation for residual limb hyperhidrosis. It is not uncommon for medical trials to close early if statistically significant results are achieved. In this study, statistically significant results were achieved after only a single treatment in a small number of patients. These results justified the creation of a new clinic policy for treatment of residual limb hyperhidrosis using microwave thermoablation. This policy will allow for persistent efficacious treatment of amputee patients long after the investigator of this study undergoes PCS.

9.0 DELIVERABLES

9.1 Publications

None currently

9.2 Presentations

2018 Military Health Science Research Symposium

10.0 COST

This work had no direct funding source and was performed using clinic resources.

11.0 REFERENCES

None

FIGURES AND TABLES

None

12.0 LIST OF SYMBOLS, ABBREVIATIONS AND ACRONYMS

Defined within the above text.