A Pilot Study, to Evaluate the Safety and Efficacy of Topically Applied Onabotulinum Toxin A Delivered through a Novel Iontophoresis Device in Subjects with Axillary Hyperhidrosis

Mark S. Nestor, M.D., Ph.D.[1,2], Haowei Han, D.O.[1], Anita Gade, D.O.[1], Francesca Ceci, M.D.[1], Alec Lawson, B.A.[1], Austin Dunn, D.O.[1,]
Faraz Yousefian, D.O., [1] Ciaran Smythe, D.O.[1]
[1]Center for Clinical and Cosmetic Research, [2] Department of Dermatology and Cutaneous Surgery, University of Miami Miller School of Medicine

Introduction

It is estimated that 4.8% of the United States population suffers from hyperhidrosis.[1] Onabotulinum toxin injections are FDA approved for the treatment of hyperhidrosis, but many patients do not want injections due to pain or fear of needles.[2] Iontophoresis is FDA approved for hyperhidrosis of the palms and works by sending electrical currents through the skin. In contrast with traditional iontophoresis, however, the novel iontophoresis device used in the present study uses low-intensity pulsed currents and has different electrode configurations developed to enhance the absorption of substances into the skin. Early studies have demonstrated its potential to deliver topical onabotulinum toxin to treat hyperhidrosis. This pilot study aims to evaluate the safety and efficacy of transdermal delivery of botulinum toxin delivered through the novel iontophoresis device for primary axillary hyperhidrosis.

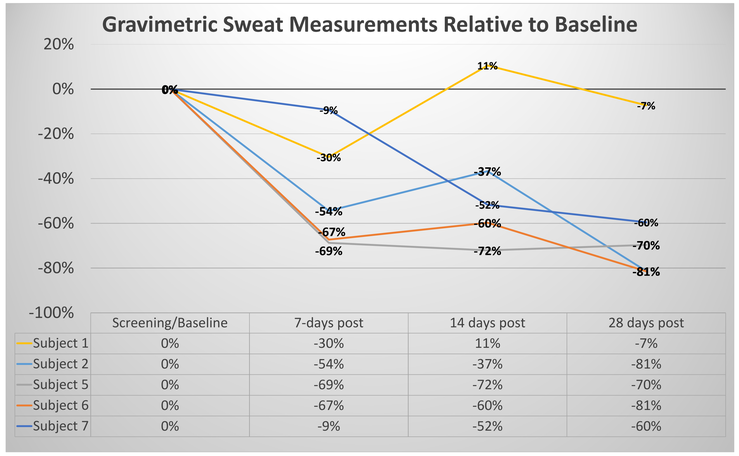
Methods

Subjects: 5 healthy subjects with documented hyperhidrosis (gravimetric >50 mg)

Study design: Baseline gravimetric sweat measurements and starch iodine tests, were assessed before study treatment. Topical onabotulinum (50 U per axilla) was delivered via the TransDermal Infusion™ novel iontophoresis device (Sensus Healthcare, Boca Raton FL). Follow-up measurements were taken 7, 14, and 28 days after treatment. For the first subject, the botulinum toxin was combined with double the amount of suspension used in the other subjects. It was noted that there was too much solution to be completely absorbed by the treatment area. Consequently, the methods were changed for the following subjects so that a fraction of the amount of suspension was used, creating a higher concentration of botulinum toxin.

Results

The subjects included 2 males and 3 females (age range: 19-47 years) with symptoms of hyperhidrosis for a mean of 9 years. Subject #1 acted as a control because of the excessive diluent. All other subjects demonstrated improved symptoms of hyperhidrosis, quantified by the gravimetric sweat tests (Figure 1). Figure 2 shows an example of the starch iodine test. Overall, the procedure was well tolerated by all patients. One patient reported muscle fasciculations of the left shoulder and chest for 2 days without pain or discomfort. No other adverse events were noted.



	Screening/Baseline	7-days post	14 days post	28 days post
Subject 1	0%	-30%	11%	-7%
Subject 2	0%	-54%	-37%	-81%
Subject 5	0%	-69%	-72%	-70%
Subject 6	0%	-67%	-60%	-81%
Subject 7	0%	-9%	-52%	-60%

Figure 1. Gravimetric sweat measurements relative to baseline

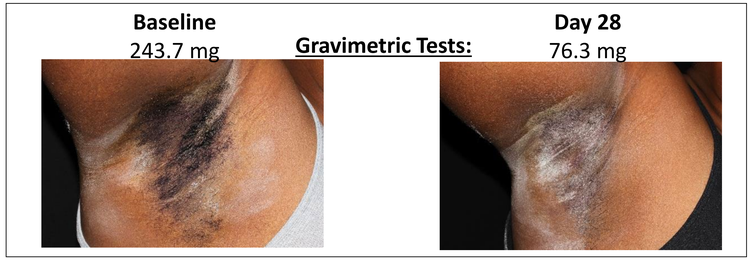


Figure 1. Starch iodine test at baseline (pre-treatment) and at day 28

Discussion

Previous clinical trials have demonstrated the efficacy of onabotulinum toxin injections for the treatment of hyperhidrosis. 91% (219/242) had at least a 50% reduction from baseline in axillary sweating 4 weeks post-injection of 50 units per axilla (mean reduction = 83.4% with a SD = 21.6). [3] The present study demonstrated similar results with the use of onabotulinum toxin delivered topically, without the use of needles. The lack of response to treatment in subject 1 who acted as control, was due to excessive gel which was not absorbed in the skin. For the subsequent subjects we utilized a fraction of the volume of normal saline which was completely absorbed in the skin. Subject 1 serves as a control to support the claim that the treatment success in the other subjects was due to the successful delivery of the topically applied botulinum toxin, and not due to the effects of iontophoresis alone.

Conclusion

This pilot study appears to demonstrate that after one treatment with the TransDermal Infusion™ novel iontophoresis device and topically applied onabotulinum toxin at injectable approved dose (50U per axilla), subjects had dramatically reduced axillary hyperhidrosis. The results suggest that this treatment is safe and efficacious for axillary hyperhidrosis. We anticipate a future, larger study, to determine this treatment's clinical significance.

References

1. Doolittle, J., Walker, P., Mills, T. & Thurston, J. Hyperhidrosis: an update on prevalence and severity in the United States. Arch. Dermatol. Res. 308, 743–749 (2016).
2. McLenon, J. & Rogers, M. A. M. The fear of needles: A systematic review and meta-analysis. J. Adv. Nurs. 75, 30–42 (2019).
3. Naumann, M. & Lowe, N. J. Botulinum toxin type A in treatment of bilateral primary axillary hyperhidrosis: randomised, parallel group, double blind, placebo controlled trial. BMJ 323, 596 (2001).