Application of Botox® for Pedal Hyperhydrosis

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Introduction

Pedal hyperhydrosis, or excessive sweating of the feet, is a medical condition caused by over-active sweat glands. Pedal hyperhydrosis, much like axillary hyperhydrosis, is often an embarrassing condition that carries social stigma and psychological discomfort. According to a recent report, 8 million Americans are suffering from hyperhydrosis, with 4 million of them experiencing it in their underarms and the other 4 million experiencing it in their palms and soles (1). For decades, if not centuries, healthcare professionals across the globe have tried different remedies to stop over-active sweat glands. Current treatment options for hyperhydrosis include application of topical drying agents, anti-cholinergic drugs, iontophoresis, and surgical denervation/ sympathectomy (2). The effects of botulinum toxin type A (Botox®) on sweat glands has opened a new door for treatment of hyperhydrosis.

Background

Botox® is manufactured by Allergan Inc.* Botulinum toxin type A is a neurotoxin protein complex produced by bacterium clostridium botulinum. When injected into living tissue, this compound blocks the release of acetylcholine from nerve endings. By blocking the release of acetylcholine, Botox® blocks the signal for muscle contraction (3). Botulinum toxin type A was licensed by the FDA on December 29, 1989 for treatment of muscle disorders, and abnormal muscle contractions in conditions such as adductor spasmodic dysphonia, oromandibular dystonia and torticollis (3, 4). Soon after its introduction, Botox® was utilized in cosmetics for minimizing prominent facial lines such as glabellar lines (5). Over the years, Botox® injections have proved to be extremely safe, with very few side-effects (5, 6).

A more recent application of Botox® involves its use in chemo-denervation of sweat glands. By blocking the innervations to the sweat glands, Botox® prevents their contraction, eliminating sweating. Dermatologists and plastic surgeons across the United States now have the FDA approval for underarm injection of Botox®, and the procedure is gaining increase popularity across the nation. With results that have lasted up to a year, many people are abandoning their nightly rituals of Drysol applications for a more permanent and more effective option of Botox® injection. Since the introduction of Botox®; repetitive, less-effective treatments, such as iontophoresis, are being abandoned, and more aggressive procedures such as surgical sympathectomy are even less utilized.

The advantage of Botox® injections over other treatments for hyperhydrosis is multifacet. Botox® has proven to be safe when administered properly (6). It is fairly easy to administer in an office setting. It is better tolerated than iontophoresis by patients, and carries fewer side-effects compared to anti-cholinergic drugs or surgical denervation. With Botox®, there are no reports of compensatory hyperhydrosis in other body sites, such as those encountered with sympathectomy. Each Botox® application usually lasts a few months; the results are very predictable and most important of all, there are very few complications (7).

The success of Botox® in axillary hyperhydrosis has opened the door for its application in other areas of the body. Even though the efficacy of Botox® injection for palmar and pedal hyperhydrosis is not as well-established as those for axillary hyperhydrosis, the initial findings are promising. In contrast to effects of the initial axillary injections which can last anywhere from six to 12 months (8), palmar and plantar injections appear to wear out quicker. The end result, however, appears to be the same: complete dryness of the injected site that starts within days of treatment and lasts for several weeks.

Case Presentation

The following is a case presentation and a 6-month follow-up of an individual who received Botox® injection in our office for treatment of bilateral pedal hyperhydrosis. This article will also describe the method we used for preparation and injection of Botox® in the plantar surface of the feet.

Case Report

A 45 year old female with chief complaint of excessive pedal sweating presented to our office in July 2004, requesting Botox® injections. The patient was referred to us by her plastic surgeon for treatment of pedal hyperhydrosis. According to the patient, her palmar hyperhydrosis was successfully treated by Botox® injections in 2003, and when she had requested injection of her feet, she was referred to our office.

HPI: The patient stated that she had been plagued by excessive sweating in her feet most of her life, and that this condition had negative effects on her self-confidence and limited her ability to participate in social activities and events. She was advised against anti-cholinergic medications by her primary physician due to the risk of possible interaction with her hypertension medications. Patient also reported that other conservative treatments had failed to provide adequate relief and she was worried about the risks and side effects associated with sympathectomy. The patient had received Botox® injection for palmar hyperhydrosis a year back and was very happy with the results. She was requesting the same procedure to be done on her feet. Past Medical History: Hypertension Medications: Beta-blockers

Social History: School teacher, dancer Allergies: No known drug allergies

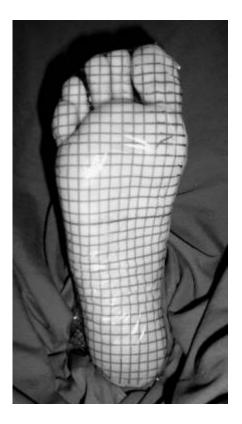
During our initial evaluation of the patient, conservative treatment options were reintroduced to the patient, including Domeboro foot soaks, topical anti-perspirant lotions and powders. The patient was also cast for custom-molded orthotics, with the aim of stabilizing pedal joints, reducing muscular activity and heat, and lowering the amount of stress and pressure on sweat glands. After three months of conservative therapy, the patient reported inadequate relief with the use of above mentioned modalities. Because of her previous success with palmar botulinum toxin injections, and at her request, we decided to try a course of Botox® injections in her right foot. The patient was reminded that currently there was no FDA approval for the injection of Botox® for treatment of plantar hyperhydrosis, and that she would be responsible for the cost of the treatment. Prior to the procedure, the planned operation was diagramed and explained in detail with the patient, and the appropriate informed consent was properly obtained and recorded in the patient's chart.

Materials and Methods

In formulating our Botox® injection treatment plan, we adopted the axillary injection method used by Dr. Dee Anna Glaser (8). A few modifications were made to her method to make it more geared toward the foot.

On the day of treatment (October 8, 2004), the patient was brought to one of the procedure rooms in our office and placed on a treatment chair with the feet elevated so that the plantar surface of the right foot was perpendicular to the ground for easy visualization and treatment. Utilizing a Betadine swab, the plantar surface of the right foot was painted and covered completely by Betadine and allowed to dry (a hair dryer can be used to expedite this step of the procedure). Next, a barber's brush was used to lightly cover the plantar surface of the foot with cornstarch. Ten minutes of time were allowed for the perspirations on the bottom of the foot to present themselves, marking the most active sites of hyperhydrosis. The areas with active sweat glands turned purple as the starch was soaked with sweat. As these areas appeared, they where circled with a water resistant marker/pen. After the hyperactive areas were marked, the plantar surface of the foot was cleansed with alcohol. Starch and excess Betadine were removed, taking care not to erase the marks made by the permanent marker. In our patient, the hyperactive sweat glands were located at the arch, distal to the met heads and between the web spaces of the right foot.

Each vile of Botox® contains 100 units of white powdery botulinum toxin type A. In order to dissolve the neurotoxin crystals, 2 cc. of sterile normal saline was instilled inside the vile of Botox® and mixed to a clear liquid solution. Next, a 30 gauge 1/2" needle with a 1 cc syringe was used to draw 1 cc. of the mixed solution aseptically, providing us with 50 units of Botox® in our 1 cc. syringe. Circled areas on the bottom of the right foot were injected, with the injections given approximately .5 cm. apart. To be more precise in equally distributing the injection sites, horizontal and vertical lines can be drawn on the plantar surface of the foot, with each line .5 cm. apart. Botox® injections can be done at the points where the vertical lines cross the horizontal lines (Figure 1).



This photo demonstrates the lines drawn in preparation for injections. Each box represents where an injection is given.

With each injection approximately .02 cc. of Botox solution was injected intraderamlly. This led to approximately 50 injection sites on the plantar surface of the right foot, divided half and half between the arch and the distal plantar aspect of the right foot.

The patient tolerated the injections with little discomfort, and no local or regional anesthesia was used. After the completion of the procedure, the patient was kept on the examination chair for an additional 10 minutes. Dry pinpoint bleeding that had occurred at some of the injection sites, along with the remaining Betadine and cornstarch, were wiped with alcohol-soaked gauze. No application of topical antibacterial creams or dressings was required. The patient was allowed to wear her socks and shoes, and she was discharged home approximately one hour after her arrival to our office. The patient was able to bear weight on the right foot without difficulty, but was instructed to limit activity for the following two days.

The patient returned to the office in one week on October 15, 2004 for application of Botox® on the contra-lateral foot. During her visit she reported dramatic reduction in right foot sweating that had started one day post injections. At this time the left foot was prepped and treated by the same exact technique. The patient was instructed to follow the same post-injection home care regiment and return to the office in 3 months. The patient was encouraged to call the office if there were any abnormal feelings or sensations, and call for an earlier appointment if excessive sweating resumes in the feet. On her 3- month follow-up visit, the patient reported some sweating had returned to both feet, with the majority of it being in the web spaces.

During that visit (January 14, 2005), with the request of the patient, repeat procedures were performed on both feet at the same time. This allowed for the usage of the whole vile of the Botox solution, 50 units per foot. During this visit the same method was utilized for injections, with the exception that both feet were treated, and the treatment sites were more concentrated in the web spaces. The patient was then scheduled for a 6 month follow-up, but she was instructed to call if any problems at the injection sites occurred, or if excessive sweating resumed.

The last follow-up of the patient was a telephone communication done on April 15, 2005 (3 months post her second pedal injections). During our conversation the patient reported that she had not yet encountered a relapse. She was extremely satisfied with the treatment results. She claimed that in case of a relapse, she would consider another round of injections. According to her, the results, even if they last only a few months, are well worth it, and she would recommend the procedure to a friend or a family member.

Conclusion

Currently, we are not aware of any published studies in the United States on the use of botulinum toxins for treatment of plantar hyperhydrosis. Short term results from two studies done in Belgium and Turkey are very promising and should spark further investigations (9, 10). Even though our one patient case report has been very limited in providing significant scientific findings, we are optimistic that a bigger, multi-patient study will soon follow and produce similar results in the United States.

Efficacy and safety of Botox ® injections for treatment of axillary hyperhydrosis is wellestablished and documented in the literature (1, 3, 4, 5, 6). The role of botulinum toxin type A for treatment of hyperhydrosis in other areas of the human body, including the plantar surface of the feet, has also been established overseas (9,10). Use of Botox® injections for plantar and palmar hyperhydrosis is on the rise and will soon gain the FDA approval. The role of the podiatric profession in accepting the responsibility to utilize this procedure lies with today's practitioners. As Botox finds its niche in other professions, we can only hope that our profession is not left behind.

References

1. Hampton, Angela: Botox ® Treatments for Hyperhydrosis, Eyewitness News 11. http://ewatch.prnewswire.com. August 2004.

3. Lewis, Carol. Botox Cosmetic: A Look at Looking Good. FDA Consumer Magazine. July-August 2002

4. Blitzer, Andrew, W. J. Binder, M. F. Brin: Botulinum Toxin Injections for Facial Lines and Wrinkles: Technique. Management of Facial Lines and Wrinkles. Lippincott, Philadelphia. 2000: 303-313.

5. Carruthers, J.A., et al.: "A multicenter, double-blind, randomized placebo-controlled study of the efficacy and safety of botulinum toxin type A in the treatment of glabellar lines". Journal of the American Academy of Dermatology. Volume 56. June 2002: 840-849.

^{2.} My Foot Shop: "Your Source for Healthy Feet", www.myfootshop.com. April 2005.

6. Material Safety Data Sheet for Botox® (Botulinum Toxin Type A): Allergan. October 31, 2003.

7. "Botox Treats Excessive Sweating": Botox Forum. www.botoxforum.com. March 17, 2002.8. Glaser, Dee Anna: Patient Management: Basics of Botox® for Excessive Sweating.

Practical Dermatology. October 2004: 26-35.

9. Sevim, Serhan, et al.: "Botulinum toxin-A therapy for palmar and plantar hyperhydrosis", Acta Neurol. Belg. December 2002. 102(4): 167-70

10. Vadoud-Seyedi, Javid: "Treatment of plantar hyperhydrosis with botulinum toxin type A", International Journal of Dermatology. December 2004. 43(12): 969-71

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