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Is botulinum toxin injection effective in reducing pain in patients diagnosed with plantar fasciitis?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies
Philadelphia College of Osteopathic Medicine
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ABSTRACT

OBJECTIVE: The objective of this selective EBM review is to determine whether or not botulinum toxin injection is effective in reducing pain in patients diagnosed with plantar fasciitis.

STUDY DESIGN: Review of three randomized controlled trials (RCTs) comparing the efficacy of botulinum toxin injections versus corticosteroid injections for improving pain and dysfunction in those diagnosed with plantar fasciitis.

DATA SOURCES: All articles were presented in English and were taken from peer reviewed sources using PubMed. All articles were published from 2012-2017.

OUTCOMES: Outcomes of investigation measured are pain score measured using the VAS-visual analog scale and Foot Health Status Questionnaire.

RESULTS: Ahmad et al. found significant improvement in subjective pain scores following the administration of botulinum toxin injected into the plantar fascia after a period of six months and one year when compared to a placebo of saline. Diaz-Llopis et al. found significant improvement in subjective pain scores following the administration of botulinum toxin injected into the plantar fascia after a period of six months when compared to a corticosteroid. Elizondo-Rodriguez et al. found significant improvement in subjective pain scores following the administration of botulinum toxin injected into the plantar fascia after a period of six months when compared to a corticosteroid.

CONCLUSIONS: These three studies showed a significant improvement in subjective pain scores after a minimum period of six months and formalized physical therapy program. The efficacy of botulinum toxin in the treatment of plantar fasciitis is apparent but more research is needed with larger sample sizes to solidify the hypothesis that botulinum toxin injection should be an accepted treatment option across the industry.

KEYWORDS: plantar fasciitis, botulinum, and injection

INTRODUCTION:

Plantar fasciitis is the most frequent cause of chronic heel pain which generally presents in patients who are 40 years of age or older, overweight, sedentary, or engage in intense physical activity. The plantar fascia functions to prevent foot collapse because of its tensile strength and anatomic orientation. The inflammation of this structure leads to the symptoms experienced by approximately 10% of the population.¹ Plantar fasciitis is a clinical condition that presents as sharp pain in the heel that spans from the medial border of the plantar fascia to its insertion at the medial tuberosity of the calcaneus. Pain is provoked with loading and with the initial few steps following periods of inactivity. These symptoms are elicited by actions such as rising from sleep in the morning and toward the end of day at rest. Development of plantar fasciitis is thought to be caused by biomechanical defects such as hyper-pronation. Hyper-pronation contributes to the excessive mobility of the foot which can increase stress on the plantar fascia.

Treatment options for plantar fasciitis include operative and non-operative. Operative options include plantar fascial debridement and release.² Non-operative options include physical therapy, injections, and insoles.¹ Injection options were initially restricted to corticosteroid injection which have only limited effectiveness but was the mainstay of treatment due to a lack of alternatives.³ An alternative has been proposed for the management of plantar fasciitis which is botulinum toxin injections.^{3,4,5} Botulinum toxin blocks presynaptic acetylcholine reuptake, produces weakness of the muscles related to the plantar fascia and reduces the tension which improves the pain.⁵ This is similar to botulinum toxin's action in the treatment of myofascial pain disorders.⁵ It also has an analgesic action due to the inhibition of the release of neurotransmitters involved in nociceptive neural pathways (glutamate, substance P and calcitonin-gene related peptide).⁴ Many practitioners have utilized this therapeutic measure after

all other options have been exhausted in the progression of the patient's case. Therefore, these patients may have responded favorably to this therapeutic injection without having to endure the other more drastic and painful measures if botulinum toxin was an accepted first line therapy.

OBJECTIVE:

The objective of this selective EBM review is to determine whether or not botulinum toxin injection is effective in reducing pain in patients diagnosed with plantar fasciitis.

METHODS:

Three randomized controlled trials were chosen for review. The patient population selected for review were ambulatory patients above the age of 18 years old with a diagnosis of plantar fasciitis. Interventions utilized included injecting botulinum toxin at 100 units into the inflamed plantar fascia. Depending on the study, subjects either received the botulinum toxin injection, a corticosteroid injection or a saline placebo. The outcomes were patient oriented and focused on subjective pain scores utilizing the VAS-visual analog scale or the foot health status questionnaire depending on the study.

The PubMed database was utilized to select the studies. Keywords to search were "plantar", "fasciitis", "botulinum", and "injection." The three studies selected were published in peer reviewed journals from 2012-2017 and all were written in English. The inclusion and exclusion criteria for all three studies were similar. The inclusion criteria was randomized, controlled, blinded study that evaluated subjects aged >18 years of age, ambulatory, and diagnosed with plantar fasciitis. The exclusion criteria was patients diagnosed with other pathology than plantar fasciitis for heel pain. Detailed inclusion, exclusion criteria, and other

individual study characteristics are provided in Table 1. The statistics reported in the studies and utilized for the review were mean changes from baseline and p-values.

Table 1: Demographics & Characteristics of Ahmad et al., Diaz-Llopis et al., & Elizondo-Rodriguez et al.

| Study | Type | # Pts | Age (yrs) | Inclusion Criteria | Exclusion Criteria | W/D | Interventions |
|------------------|------------------|-------|-------------|--|--|-----|---|
| Ahmad (2017) | RCT | 50 | 31-69 | Acute or chronic plantar fasciitis who had no improvement in symptoms after a minimum of 6 weeks of non-operative treatment | Prior botulinum toxin injections for plantar fasciitis | 0 | A 1 mL injection of 100U of IBTA vs. a saline placebo injection |
| Diaz (2012) | RCT | 56 | SD 51-56 | Clinical diagnosis of plantar fasciitis based on presence of heel pain during first steps after a period of rest or pain exacerbated by walking or by standing for many hours | Those with heel pain due to other causes or painful disorders of the foot that could coexist with plantar fasciitis. | 0 | 100U of botulinum toxin type A was diluted in 1 mL of normal saline and 70U were injected vs. 2 mL of betamethasone 6mg/mL plus 0.5 mL of 1% mepivacaine |
| Rodriguez (2013) | Double Blind RCT | 40 | 29-54 | Skeletally mature with heel pain at the insertion of the plantar fascia or anteromedial tuberosity of the calcaneus; failure of conservative treatment for 3 months, which consisted of pads in ordinary shoe and NSAIDs | Previous injections, associated pathologies or a history of infection at the injection site in the previous 3 months | 4 | 100U of BTX-A was injected into each muscle belly vs. a combination of 2% lidocaine and 8mg of dexamethasone injected into medial aspect of the plantar surface |

OUTCOMES MEASURED:

This review examined subjective pain scores after therapeutic injections were administered. Patients were evaluated over 6 month periods to assess response to the injections. To measure the subjective pain responses, two subjective scoring evaluators were utilized; the VAS-visual analog scale and the Foot Health Questionnaire. These subjective scoring systems evaluated the patients' response to the injections by their pain with various modalities following a designated time period.

RESULTS:

Ahmad et. al., conducted a randomized, double blinded, placebo controlled trial comparing 50 subjects who presented with a diagnosis of plantar fasciitis. The authors reported a mean age of 51.3 in the placebo group and 48.6 in the botulinum toxin group respectively.² This study included subjects with either acute or chronic plantar fasciitis who had no improvement in symptoms after a minimum of 6 weeks of non-operative treatment. This study excluded any subjects who had prior botulinum toxin for plantar fasciitis. This study examined the subjects' response to either a 1mL injection of 100U of IBTA vs. a saline placebo injection after 6 & 12 months.² The principal investigator, the neurologist giving the injections, and all study patients were blinded from what substance was injected.² Only the independent observer knew which study patients received IBTA and which patients received placebo.² There were 0% loss to follow up at the conclusion of the research. The researchers used continuous data, which is provided in Table 2. The results of this study show that IBTA provided significant relief of pain due to plantar fasciitis compared with normal saline injection. Using a mean change from

baseline, examiners found that there were significant changes from baseline when comparing IBTA injection to saline placebo using a $P < 0.05$ as being statistically significant.

Table 2: Post-injection Demographics between the Placebo and IBTA Groups.²

| Post injection Demographics | Placebo | IBTA | P-Value |
|-------------------------------|--------------|--------------|---------|
| VAS at 6 months, mean (range) | 7.9/10 (6-9) | 3.6/10 (0-8) | 0.01 |

Diaz-Llopis et. al., conducted a randomized, placebo controlled trial comparing 56 subjects who presented with a diagnosis of plantar fasciitis. The authors reported a mean age of 51.5 in the BTX-A group and 56.4 in the CS group respectively.⁵ This study included subjects with a clinical diagnosis of plantar fasciitis based on presence of heel pain during first steps after a period of rest or pain exacerbated by walking or by standing for many hours.⁵ This study excluded those with heel pain due to other causes or painful disorders of the foot that could coexist with plantar fasciitis.⁵ This study examined the subjects' response after 6 months following injection of either; 100U of botulinum toxin type A (BTX-A) which was diluted with 1mL of normal saline and 70U were injected or 2mL of betamethasone 6mg/mL plus 0.5 mL of 1% mepivacaine (CS).⁵ Patients did not know which treatment they were to receive and the medication was prepared out of sight of the specialist performing the injection.⁵ However, they could not describe this as a true double-blind study as the injection volumes of the two treatments were different and the specialist could therefore guess which one was being given.⁵ There were 0% loss to follow up at the conclusion of the research. The researchers used continuous data, which is provided in Table 3. The results of this study show that BTX-A provided significant relief of pain due to plantar fasciitis compared with the corticosteroid injection. Using a mean change from baseline, examiners found that there were significant

changes from baseline when comparing BTX-A injection to CS injection using a $P < 0.05$ as being statistically significant.

Table 3: Difference in foot health status questionnaire scores between baseline, 1 month and 6 months after treatment with BTX-A.³

| FHSQ-pain | At 1 month | Change (FHSQ 1 month-baseline) | At 6 month | Change (FHSQ 6 month- 1 month) | P-value |
|-----------|---------------|--------------------------------|---------------|--------------------------------|-------------|
| Mean (SD) | 63.30 (21.90) | 34.24 (21.10) | 75.71 (24.14) | 19.10 (24.76) | $P < 0.001$ |

Elizondo-Rodriguez et.al., conducted a randomized, double blinded, placebo controlled trial comparing 40 subjects who presented with a diagnosis of plantar fasciitis. The authors reported a mean age of 41.6 in the BTX-A group and 44.5 in the CS group respectively.⁶ This study included subjects who were skeletally mature with heel pain at the insertion of the plantar fascia or anteromedial tuberosity of the calcaneus; failure of conservative treatment for 3 months, which consisted of pads in ordinary shoe and NSAIDs.⁵ This study excluded those who received previous injections, associated pathologies or a history of infection at the injection site in the previous 3 months.⁵ This study examined the subjects' response to 100U of BTX-A which was injected into each muscle belly vs. a combination of 2% lidocaine and 8mg of dexamethasone (CS) injected into the medial aspect of the plantar surface after 6 months.⁵ The patients were randomly divided into 2 groups using a randomizing software program. The evaluation of the subjects' response to treatment were made by a blinded investigator who was unaware of the patient group assignments.⁵ There were 10% loss to follow up at the conclusion of the research. The researchers used continuous data, which is provided in Table 4. The results of this study show that BTX-A provided significant relief of pain due to plantar fasciitis compared with the corticosteroid injection. Using a mean change from baseline, examiners found that there were

significant changes from baseline when comparing BTX-A injection to CS injection using a $P < 0.05$ as being statistically significant.

Table 4: Comparison between Groups Evaluating Visual Analogue Scale (VAS).⁵

| | Group A (BTX-A): Value | Group A (BTX-A): SD | Group B (CS): Value | Group B (CS): SD | P-value |
|---------|------------------------|---------------------|---------------------|------------------|---------|
| Initial | 7.1 | 1.75 | 7.7 | 1.32 | Ns |
| Final | 1.1 | 1.50 | 3.8 | 1.15 | 0.0005 |

Infections and other risks are associated with the interventions employed in these studies. Cases of rupture of the plantar fascia have been reported after corticosteroid injection.^{3,7} However, none of the reviewed studies reported any drug related adverse effects or safety concerns.

DISCUSSION:

This evidence based systematic review focused on the use of botulinum toxin injections being utilized to treat the symptoms of plantar fasciitis in those over the age of 18 years old. The etiology and pathogenesis of plantar fasciitis are still not fully understood.⁶ Although some authors consider the disorder to be the result of excessive tension in the fascia, producing microscopic tears which lead to a subsequent inflammatory repair process, many others have demonstrated degenerative changes, though without finding signs of inflammation.⁶ Entrapment of the first branch of the lateral plantar nerve has also been cited as a possible cause of heel pain.⁶ Regardless if a consensus regarding the pathogenesis of this disorder has not been reached throughout the industry, the fact still remains that patients seek treatment for their symptoms and require a therapy that will alleviate their discomfort even if it may be temporary. This uncertainty

in having a widely accepted therapeutic intervention for plantar fasciitis mandates the need for further research into this topic.

Throughout researching this topic, there were a few study limitations that could have impacted this review. A limitation that was apparent early on was the fact that many plantar fasciitis studies focused on surgical management. This significantly narrowed the available studies to choose from. Another limitation was the fact that many of the studies had a small sample size. Therefore, finding studies that met the minimum requirements of statistical significance became challenging but was not overall impossible. If larger sample sizes could be utilized, the statistics would provide more evidence for the efficacy of the proposed treatment because the results could signify the true difference in efficacy and minimize the impact of confounding variables.

CONCLUSION:

The evidence presented in this systematic review shows that injections of botulinum toxin have a positive effect on subjective pain scores after a period of six months. Within this period of six months, patients were prescribed a formalized physical therapy program for a minimum of six weeks. Patients are encouraged to continue the modalities taught in these six week programs after the conclusion of the six weeks. The program involved active and passive stretching of the plantar fascia, great and lesser toe flexors, and Achilles tendons with and without resistance.² Other modalities that are regularly prescribed for physical therapy include ultrasound, massage, moist heat and cryotherapy.² The physical therapy programs were employed regardless of the intervention utilized in the study. Therefore, physical therapy should always be integrated into the treatment plan to maximize the recovery of the patient's symptoms.

Only a few studies exist showing the therapeutic benefit of botulinum toxin injections for plantar fasciitis exist. Therefore, the efficacy of botulinum toxin in the treatment of plantar fasciitis is apparent but more research is needed with larger sample sizes to solidify the hypothesis that botulinum toxin injection should be an accepted treatment option across the industry.

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