AMERICAN ORTHOPAEDIC FOOT & ANKLE SOCIETY.

Foot & Ankle International
34(1) 8–14

DOI: 10.1177/1071100712460215
http://fai.sagepub.com

A Comparison of Botulinum Toxin A and Intralesional Steroids for the Treatment of Plantar Fasciitis: A Randomized, Double-Blinded Study

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Abstract

Background: The objective of this study was to compare intramuscularly applied botulinum toxin A (BTX-A) in the gastroc-soleus complex with intralesional steroids for the treatment of plantar fasciitis.

Methods: The patients were randomly divided into 2 groups according to the treatment received. The patients were evaluated over 6 months. The evaluation scores included the Visual Analog Scale (VAS), Maryland Foot and Ankle, Foot and Ankle Disability Index (FADI), and American Orthopaedic Foot and Ankle Society (AOFAS) score. Moreover, patients were instructed to perform plantar fascia stretching exercises over the course of the study. The final number of patients was 36, of whom 19 received BTX-A (10 men and 9 women) and 17 (6 men and 11 women) received steroids.

Results: When compared to patients who received steroids, the patients who received BTX-A exhibited more rapid and sustained improvement over the duration of the study.

Conclusion: A combination of BTX-A and plantar fascia stretching exercises yielded better results for the treatment of plantar fasciitis than intralesional steroids.

Level of Evidence: Level I, therapeutic studies.

Keywords: botulinum toxin A, intralesional steroids, plantar fasciitis, stretching exercise, randomized, double-blind study

Plantar fasciitis is the most frequent cause of chronic heel pain. This pathology generally presents in patients who are 40 years of age or older, overweight, sedentary, or engage in intense physical activity.[14,32] Because of its anatomic orientation and its tensile strength, the plantar fascia functions to prevent foot collapse. It is a piece of thick connective tissue that originates at the base of the calcaneus and extends distally to the phalanges. Stretching of the plantar fascia prevents the displacement of the calcaneus and the metatarsals and helps to maintain the medial longitudinal arch. The plantar fascia simulates a cable between the calcaneus and the metatarsophalangeal joints. The windlass mechanism described by Hicks[13] for the action of the plantar fascia explains that during dorsiflexion of the toes, the length of the plantar fascia is effectively shortened, causing an elevation of the arch. Extension of the toes increases the arc of tension with the metatarsophalangeal joints, similar to an axis or anchor point. Shortening of the plantar fascia that results from dorsiflexion of the hallux is the essence of the reel mechanism. When a complete fasciotomy is performed, this mechanism is lost, decreasing the stability of the arch and interfering with stability during the terminal stance phase.[4,10,13,16,20,29,33]

Historically, the development of plantar fasciitis was attributed to biomechanical defects, such as hyperpronation, contributing to excessive mobility of the foot, which in turn increases the stress applied to musculofascial structures and soft tissues via an elongation of the plantar fascia.[3,5,6,18] Other studies have demonstrated that one of the principal causes of plantar fasciitis is mechanical overload.[11,13,14,16,25]

A great variety of therapies have been reported for the treatment of this pathology: intralesional application of steroids, platelet-rich plasma, intralesional botulinum toxin A (BTX-A), extracorporeal shock waves, and all of these treatments in combination with stretching exercises of the gastrocnemius, soleus muscles, or the plantar fascia.[8,12,24,26,28,30,31,34]

BTX-A has been employed for the treatment of musculoskeletal pathology, and it has recently been used for the

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treatment of plantar fasciitis via intralesional application. The mechanism of action of this toxin involves blocking the release of acetylcholine at the neuromuscular junctions, but not the storage or flow of Ca^{++}, resulting in muscular paralysis. Moreover, this treatment causes proteolysis of the SNARE proteins, which are involved in the release of various neurotransmitters, including acetylcholine. Due to these autonomic and noncholinergic effects, introducing a toxin into noncholinergic nerve terminals permits its use for the treatment of both hypersecretory states and painful pathologies.[30]

Another very common form of treatment for plantar fasciitis is the application of intralesional steroids. However, there are reports of complications associated with these medications. One of the principal complications is the rupture of the plantar fascia, which occurs in 2.4% to 5.7% of patients. Despite relief of the pain resulting from the rupture, it has been associated with instability of the lateral column and calcaneocuboid joint pain.[1,15]

The purpose of this study was to compare the use of intramuscularly applied BTX-A in the gastroc-soleus muscle complex and the intralesional application of steroids. Both of these methods were combined with education regarding the disorder and a plantar fascia stretching program.

Methods

This study was a prospective, experimental, randomized, double-blinded, and controlled clinical trial. The patients who came to our clinic were recruited for the study and signed informed consent forms, which were previously approved by the ethics committee of the medical research department at our hospital.

The inclusion criteria were the following: skeletally mature, with heel pain at the insertion of the plantar fascia or in the anteromedial tuberosity of the calcaneus; failure of conservative treatment for 3 months, which consisted of pads in ordinary shoe and NSAID; and no previous injections. We excluded patients with associated pathologies, such as knee or ankle dysfunction, osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, Reiter's syndrome, neurological abnormalities, mental retardation or psychiatric abnormalities, cutaneous infection, or a history of infection in the previous 3 months, at the application site. We also excluded patients with adverse reactions to the applied components, those who voluntarily asked to leave the study, and those who did not complete the follow-up appointments.

The patients were divided into 2 groups: group A, who received BTX-A, and group B, who received injections with steroids (dexamethasone isonicotinate). Stretching exercises for the plantar fascia were demonstrated to both groups[7] and consisted of the patient crossing the affected leg over the contralateral leg, then the patient pulled the toes back toward the shin until a stretch was felt in the arch or in the plantar fascia; moreover, patients received information regarding their disorder. The patients were randomly assigned into either group using the Alea-T-7/33 program. All of the patients attended the 6 visits. During the initial evaluation, we completed a physical examination, the informed consent forms were signed, and initial clinical scale measurements were made using the Visual Analog Scale (VAS), the Maryland Foot and Ankle scale, the American Orthopaedic Foot and Ankle Society (AOFAS), and the Foot and Ankle Disability Index (FADI). The assigned medication was also applied at the initial evaluation. The patients were evaluated 15 days following the application of the medication and at 1, 2, 4, and 6 months. The clinical measures were assessed at all visits. The measurements were made by a blinded investigator who was unaware of the patient group assignments.

A total of 40 patients were enrolled in this study. Of these, 4 were eliminated due to loss to follow-up (1 in the toxin group and 3 in the steroid group). The final number of patients was 36, of whom 19 received BTX-A (10 men and 9 women) and 17 (6 men and 11 women) received steroids. The mean age of those who were administered the toxin was 41.6 years (29-53 years), and the mean age of the steroid group was 44.5 years (32-54 years). With the numbers available, no significant difference could be detected between the 2 groups with respect to age. The 4 patients who were lost did not come back for follow-up after treatment.

Scales Used for Evaluation

We decided to use several scales to evaluate foot and ankle pathology to obtain improved information and to perform a detailed analysis of the evolution of the patients who received either treatment. The VAS evaluated pain on a numerical scale from 0 to 10, where 0 signified no pain and 10 signified the worst pain experienced by the patient. This scale was complemented by a color scale, on which green signified no pain and bright red signified the most intense pain that the patient had experienced. We also used the Maryland Foot Score,[22] which was divided into several sections that evaluated pain (a score of 45 signified no pain, and 0 indicated an incapacity to work). Among the sections of this scale were function, which was divided into two additional sections (motion and functional activities), and a section that evaluated the shape of the foot. The best score possible was 100, indicating no problem with the foot, and the lowest score was 0. The AOFAS included a scale for the hindfoot, which evaluated the broad categories of foot pain, function, and alignment. Similar to the other scales, the highest score for the AOFAS was 100.[17] We decided to include the FADI score because plantar fasciitis presents in patients who actively participate in sports, and this pathology can cause them to become disabled. The FADI scale

evaluated several metrics, including activities such as standing up, walking on flat or irregular surfaces, walking on inclined planes, and the amount of time one could walk without difficulty. Moreover, this scale included a module for sports activities and foot and ankle pain. The highest score possible was 136 points.[21]

Application of Botulinum Toxin A

The patients were placed in the prone position with the feet raised off the examination table, relaxing the calf musculature. The sites of application were 2 points (medial and lateral) at the site of greatest thickness of each calf muscle, perpendicular to the muscular mass of each calf. One hundred units of toxin were applied to each muscle belly, and 1 application of 50 U was administered to the soleus, for a total of 250 U; all applications were guided by anatomical landmarks (postero-medial into the calf). Following the treatment, dorsiflexion and plantarflexion of the affected foot were performed. The stretching exercises were initiated up to 7 days following the application of the toxin, permitting the patient to perform activities of daily living with ease. The patients were not immobilized.

Application of Steroids

The patients in group B received the medication via injection into the medial plantar surface of the foot, placing the needle just superior to the plantar fascia. A combination of 2% lidocaine (2 mL) and 8 mg of dexamethasone (2 mL) was used. Similar to the other group, plantar fascia stretching exercises were initiated at 7 days following the injection, permitting easy performance of normal activities of daily living. The patients were not immobilized.

Data Analyses

For parametric distributions, we used the Student's t test; for nonparametric distributions, the Wilcoxon rank test was used. We used analysis of variance (ANOVA) tests to analyze intergroup variability and considered $P \leq .05$ to be statistically significant. Electronic data processing and descriptive and inferential statistics were performed using the STATA-IC-10-2008 program.

Results

No significant differences were identified in the initial evaluation between the 2 groups with respect to the results obtained for pain using the VAS (7.1 ± 1.75 toxin group vs 7.7 ± 1.32 steroid group). At the second patient visit, we observed a decrease in pain perception in both groups, but there was no difference between the VAS scores (3.0 ± 1.56 for the toxin group vs 4.0 ± 1.37 for the steroid group). Beginning with the third visit, the group receiving BTX-A exhibited a significant improvement compared to the steroid group; we found that the toxin group scored 1.9 ± 1.51 points on the VAS, whereas the steroid group scored 3.4 ± 1.24 points. At visits 4 and 5, the patients receiving BTX-A scored 1.6 ± 2.07 and 1.5 ± 2.17 points, respectively, whereas for the same visits, the steroid group scored 3.6 ± 1.94 and 3.7 ± 1.96, respectively. At the end of the study, the patients receiving BTX-A averaged 1.1 ± 1.5 points, whereas for the steroid group, the final average was 3.8 ± 1.15 points (Table 1). For group A (BTX-A), the Wilcoxon rank tests indicated statistically significant differences in pain scores at visit 1 compared to visits 2, 3, 4, 5, and 6. The scores for visit 2 differed significantly from those for visits 1, 3, 4, 5, and 6. The scores for visit 3 differed significantly from those for visits 1, 2, and 6. The scores for visit 4 differed statistically from those for visits 1, 2, and 6. For group B (steroids), the scores for visit 1 differed from those for visits 2, 3, 4, 5, and 6. The scores for visit 2 differed from those for visits 1 and 3 (Table 1).

At the initial evaluation, no differences were observed in the mean Maryland Foot and Ankle score between the patient groups; however, following the second visit and until the final evaluation, the BTX-A group exhibited significantly better results than those of the steroid group (Table 2). Using the ANOVA analyses, we observed that group A (BTX-A) exhibited statistically significant differences in the scores for visit 1 compared to visits 2, 3, 4, 5, and 6. The scores for visit 2 were significantly different from those for visits 1, 3, 4, 5, and 6. For group B (steroids), the scores for visit 1 were different from those for visits 2, 3, 4, 5, and 6. The scores for visit 2 were different from those for visits 1 and 3 (Table 2).

At the beginning of the study, the two groups did not exhibit differences between their AOFAS scores (46.0 ± 14.83 for the toxin group vs 46.8 ± 11.23 for the steroid group); however, at the second visit, a significant improvement was observed in the toxin group (85.2 ± 10.66 points) versus the steroid group (72.8 ± 8.01). Moreover, in the following visits, significant differences were observed in favor of the toxin group (Table 3). For group A, ANOVA tests indicated statistically significant differences in the scores for visit 1 compared to visits 2, 3, 4, 5, and 6. The scores for visit 2 were significantly different from those for visits 1, 3, 4, 5, and 6. The scores for visit 3 were different from those for visits 1, 2, 4, 5, and 6. The scores for visit 4, 5, and 6 were significantly different from those for visits 1, 2, and 3. For group B, the scores for visit 1 were different from those for visits 2, 3, 4, 5, and 6. The scores for visit 2 were different from those for visits 1 and 3 (Tables 1 and 2).

The initial FADI scores were similar for the 2 groups (75.4 ± 6.92 points for the toxin group and 77.0 ± 3.21

Table 1. Comparison Between Groups Evaluating Visual Analogue Scale (VAS), With $P \leq .05$

	Group A		Group B		
	Value	SD	Value	SD	*P*
Initial	7.1	±1.75	7.7	±1.32	*ns*
Visit 2	3.0	±1.56	4.0	±1.37	.02
Visit 3	1.9	±1.51	3.4	±1.24	.0004
Visit 4	1.6	±2.07	3.6	±1.94	.0009
Visit 5	1.5	±2.17	3.7	±1.96	.0005
Final	1.1	±1.50	3.8	±1.15	.0005

			ANOVA			
	Wilcoxon Rank Test (VAS)		FADI		AOFAS	
Visit	Group A	Group B	Group A	Group B	Group A	Group B
1 vs 2	$P \leq .0001$	$P \leq .0001$	$P \leq .0001$	$P \leq .0001$	$P \leq .0001$	$P \leq .0001$
1 vs 3	$P \leq .0001$	$P \leq .0001$	$P \leq .0001$	$P \leq .0001$	$P \leq .0001$	$P \leq .0001$
1 vs 4	$P \leq .0001$	$P \leq .0001$	$P \leq .0001$	$P \leq .0001$	$P \leq .0001$	$P \leq .0001$
1 vs 5	$P \leq .0001$	$P \leq .0001$	$P \leq .0001$	$P \leq .0001$	$P \leq .0001$	$P \leq .0001$
1 vs 6	$P \leq .0001$	$P \leq .0001$	$P \leq .0001$	$P \leq .0001$	$P \leq .0001$	$P \leq .0001$
2 vs 3	$P \leq .0001$	$P = .025$	$P \leq .0001$	$P = .005$	$P = .002$	$P = .017$
2 vs 4	$P \leq .0001$	*ns*	$P \leq .0001$	$P = .49$	$P = .001$	*ns*
2 vs 5	$P = .001$	*ns*	$P \leq .0001$	*ns*	$P \leq .0001$	*ns*
2 vs 6	$P = .001$	*ns*	$P \leq .0001$	*ns*	$P \leq .0001$	*ns*
3 vs 4	*ns*	*ns*	$P = .056$	*ns*	$P = .039$	*ns*
3 vs 5	*ns*	*ns*	$P = .032$	*ns*	$P = .20$	*ns*
3 vs 6	$P = .004$	*ns*	*ns*	*ns*	$P = .003$	*ns*
4 vs 5	*ns*	*ns*	*ns*	*ns*	*ns*	*ns*
4 vs 6	$P = .033$	*ns*	*ns*	*ns*	*ns*	*ns*
5 vs 6	*ns*	*ns*	*ns*	*ns*	*ns*	*ns*

FADI = Foot and Ankle Disability Index; AOFAS = American Orthopaedic Foot and Ankle Society.

points for the steroid group). We observed a significant improvement in the FADI scores beginning with the second visit, and this improvement was maintained through the end of the study, clearly indicating a significant improvement for the group treated with BTX-A (Table 4). For group A, the ANOVA test indicated statistically significant differences between the scores for visit 1 compared to those for visits 2, 3, 4, 5, and 6. The scores for visit 2 differed significantly from those for visits 1, 3, 4, 5, and 6. The scores for visit 3 differed significantly from those for visits 1, 2, and 5. The scores for visit 4 differed significantly from those for visits 1 and 2. The scores for visit 5 differed significantly from those for visits 1, 2, and 3. The scores for visit 6 differed significantly from those for visits 1, 2, and 3. For group B, the scores for visit 1 differed from those for visits 2, 3, 4, 5, and 6. The scores for visit 2 differed from those for visits 1 and 3 (Tables 1 and 2).

We did not have any adverse reaction with the treatments.

Discussion

Babcock et al[2] performed a double-blinded, randomized, placebo-controlled study with 27 patients with plantar fasciitis. The authors administered 70 U of BTX-A into 2 sites per foot (medially on the heel near the calcaneal tuberosity and in the plantar arch of the foot, 1 inch anterior and medial). The control group received saline solution. This study evaluated VAS scores, Maryland Foot scores, and pressure algometry measurements; these metrics were evaluated following the injection and at 3 and 8 weeks. The authors observed significant changes in all of these metrics in the group treated with BTX-A. In our study, we observed that VAS scores were improved in both groups of patients; however, this difference was statistically significant only

Table 2. Comparison Between Groups With Maryland Foot Ankle Score, With $P \leq .05$

	Group A		Group B		
	Value	SD	Value	SD	*P*
Initial	62.1	±9.84	60.0	±11.87	ns
Visit 2	87.8	±11.18	76.3	±15.41	.002
Visit 3	92.8	±8.40	84.6	±15.05	.02
Visit 4	94.3	±10.58	83.5	±16.05	.004
Visit 5	94.3	±10.62	79.2	±17.15	.0002
Final	94.4	±10.64	79.2	±14.96	.0001

	Maryland Foot Score	
Visit	Group A	Group B
1 vs 2	$P \leq .0001$	$P \leq .0001$
1 vs 3	$P \leq .0001$	$P \leq .0001$
1 vs 4	$P \leq .0001$	$P \leq .0001$
1 vs 5	$P \leq .0001$	$P \leq .0001$
1 vs 6	$P \leq .0001$	$P \leq .0001$
2 vs 3	$P = .002$	$P = .030$
2 vs 4	$P = .004$	*ns*
2 vs 5	$P = .004$	*ns*
2 vs 6	$P = .003$	*ns*
3 vs 4	*ns*	*ns*
3 vs 5	*ns*	$P = .042$
3 vs 6	*ns*	$P = .35$
4 vs 5	*ns*	*ns*
4 vs 6	*ns*	*ns*
5 vs 6	*ns*	*ns*

Table 3. Comparison Between Groups With American Orthopaedic Foot and Ankle Society (AOFAS) Score, With $P \leq .05$

	Group A		Group B		
	Value	SD	Value	SD	*P*
Initial	46.0	±14.83	46.8	±11.2	*ns*
Visit 2	85.2	±10.66	72.8	±8.01	.00006
Visit 3	89.4	±9.92	77.1	±9.85	.00008
Visit 4	92.3	±11.03	76.8	±13.73	.00006
Visit 5	92.8	±10.52	74.4	±13.34	.000006
Final	93.2	±9.31	74.8	±10.29	.00000006

Table 4. Comparison Between Groups With Foot and Ankle Disability Index (FADI) Score, With $P \leq .05$

	Group A		Group B		
	Value	SD	Value	SD	*P*
Initial	75.4	±6.92	77.0	±3.20	*ns*
Visit 2	90.6	±7.34	82.4	±5.51	.00007
Visit 3	94.0	±7.30	85.5	±5.22	.00007
Visit 4	94.9	±7.52	84.7	±6.53	.00003
Visit 5	95.2	±7.64	82.8	±6.67	.000004
Final	95.0	±7.27	83.0	±6.41	.000004

for patients treated with BTX-A. In the visit-by-visit analysis, we observed a rapid and sustained improvement in the patients treated with BTX-A compared to the steroid group.

In a randomized study, DiGiovanni et al[8] evaluated 82 patients using 1 of 2 types of stretching programs: one group performed a plantar fascia stretching program, and the other group performed an Achilles tendon stretching program. The different programs were evaluated using the Foot Function Index. All exhibited improvement with the exercises, but based on evaluation with the pain subscale, the patients performing the plantar fascia stretching program improved on item 1 (the highest degree of pain felt) and item 2 (the first steps in the morning). The principal goal of the plantar fascia stretching program is to recreate the windlass (reel) mechanism and to limit the repetitive microtrauma and chronic inflammation that occurs prior to the first steps in the morning or following prolonged periods of inactivity.

Placzek et al[24] examined 9 patients diagnosed with chronic plantar fasciitis for a mean duration of 14 months. The patients were treated with 200 U of BTX-A; at the evaluation conducted 6 months following the procedure, all patients exhibited a 50% reduction in pain when supporting their body weight. This effect was maintained over the 14 weeks of treatment. One study reported that changes occur in the elasticity of the plantar fascia during plantar fasciitis, decreasing the mobility of the foot, reducing contracture, and resulting in the development of heel pain.[27] Our study focused on recovering the windlass mechanism, as described by Hicks et al,[13] by relaxing the musculature of the gastroc-soleus complex via intramuscular application of BTX-A. We observed greater and more sustained improvement in patients who received BTX-A; the patients also reported significant improvement in their symptomatology and in their activities of daily living. The same results were obtained with respect to the scales used to measure pain and functionality (ie, AOFAS, FADI, and Maryland Foot and Ankle scores). Both groups exhibited improvement at the second visit; however, this improvement was greater and more sustained in the group receiving BTX-A.

In one study, it was reported that exercises stretching the plantar fascia result in a limited short-term benefit; however, it was also noted that this effect might have reflected a significant longer term improvement. Moreover, with respect to the use of BTX-A, this study reports both

short-term and long-term improvement. The use of steroids, however, appears to generally result in short-term patient improvement, along with the described complications.[31] Investigators have also reported that rigidity in the gastrocsoleus complex decreases the dorsiflexion movement of the foot, predisposing the individual to the development of chronic foot problems. Contracture of the gastrocnemius-soleus muscular complex, defined as a limitation in dorsiflexion of less than or equal to 10 degrees, is present in as many as 88% of patients.[9]

An increase in hamstring muscle tension can increase the chance of developing plantar fasciitis by up to 8.7-fold; moreover, a body mass index (BMI) greater than 35 increases the risk of plantar fasciitis by 2.4.[19] It has been reported that there is an association between plantar fasciitis and gastrocnemius contracture, which presents as limited dorsiflexion in the majority of patients.[23] We did not evaluate BMI in our study; however, it is a factor that needs to be z: considered when evaluating patients with this type of pathology.

In conclusion, we found that a combination of BTX-A applications into the gastroc-soleus complex and plantar fascia stretching exercises yielded better results for the treatment of plantar fasciitis than intralesional steroids. It is important to note that patients must perform plantar fascia stretching exercises to obtain a rapid and sustained improvement of plantar fasciitis.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

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