

## The Efficacy of Botulinum Toxin-A versus Methyl Prednisolone Acetate Injection in Reducing Pain and Improving Functional Outcome in Plantar Fasciitis

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### Abstract

**Background:** Heel pain due to Plantar fasciitis is one of the most commonest complaints seen among foot disorders. Many conservative management and interventions like corticosteroid injection is the treatment commonly done in Plantar fasciitis, but there is level B evidence that Botulinum toxin can be probably effective and recommended for reducing pain in Plantar fasciitis.

**AIM:** The Efficacy Of Botulinum Toxin-A Versus Methyl Prednisolone Acetate Injection In Reducing Pain And Improving Functional Outcome In Plantar Fasciitis- A Randomized control study.

**Methodology:** Hundred Participants with plantar fasciitis was selected in PMR Outpatient Department in Government Institute of Rehabilitation Medicine Hospital, Chennai and divided into two groups by Simplified Randomized control study. Group 1 received Botulinum toxin-A injection and Group 2 received methylprednisolone acetate injection followed by scheduled exercise to both groups. Participants were assessed before and after intervention at 2months,4months,6months using Visual Analogue Scale, FAAM Score.

**Conclusion:** This study shows that in Botulinum toxin group1 there was significant reduction in VAS pain score and improvement in functional level after intervention and it was maintained after 6 months with no complications. In steroid group2 there was significant reduction in VAS pain score and FAAM score up to 3-4 months but that was not maintained after 4 months.

**Keywords:** Plantar fasciitis(PF),Botulinum Toxin-A (BTX A),Visual analogue pain scale (VAS), Foot ankle ability measure (FAAM).

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## Introduction

Plantar fasciitis is the most common cause of chronic heel pain in adults affecting 7 to 10% of population [1]. Every 1 in 10 people will develop Plantar fasciitis during their life period [2]. There is incidence of 8% of plantar fasciitis of all sports related injuries. Plantar fasciitis usually occurs between age group 45 to 64yrs. Rano et al in their study says that patient with Plantar fasciitis attending their clinic found to be 10 yrs more than those coming for other condition. Plantar fasciitis is more common in middle aged females, overweight and obese persons, young sports person, person with occupation requiring prolonged standing and doing sedentary work [3].

Nearly one-third of patients present with bilateral plantar fasciitis [4]. Plantar fasciitis also called as painful heel syndrome, calcaneal periostitis, heel spur syndrome, chronic plantar heel pain and runner's heel, jogger's heel, policeman's heel, tennis heel [5]. Also called Plantar fasciosis due to chronicity of the disease and because of degeneration than inflammation. There is no role of ethnicity and race in the incidence of plantar fasciitis. Usually the symptoms will last for 6 month-1 year in most patients. Previous two cohort study shows the mean duration of symptoms ranges from 13.3 to 14.1 months [6]. The American Podiatric Medical Association conducted a survey recently which shows that plantar fasciitis was the most common condition treated in podiatric clinics [7].

The predisposing factors for Plantar fasciitis are increased weight, foot deformity like pes cavus, pes planus, tight tendo Achilles, those involved in long standing works, runners, limited ankle dorsiflexion, hamstring tightness, lower limb length discrepancy [8]. Usually patient will present with early morning heel pain with difficulty in walking and aggravated by weight bearing activities. Heel pain occurs mostly over medial calcaneal tuberosity, but may also present in posterior

plantar heel, central arch, lateral heel. Mostly patient with Plantar fasciitis shows calcaneal spur in their x-ray but it is not concomitant with heel pain always.

The treatment approaches varies from medical management like NSAIDS, physical modalities like ultrasound therapy, iontophoresis, extracorporeal shock wave lithotripsy, icing, exercise therapy like stretching exercise to plantar fascia, stretching exercise to tendoachilles, hamstrings, intrinsic foot muscle exercise, orthotic modification like night splints, foot wear modifications, interventions like corticosteroids, platelet rich plasmatherapy, prolotherapy etc and if needed surgical management like resection of plantar fascia.

Corticosteroid injection is one of the treatment given most commonly in Plantar fasciitis but complications of steroid like plantar fascia rupture [9], heel pad atrophy, infections can occur. There is level B evidence that Botulinum toxin can be probably effective and recommended for plantar fasciitis. Botulinum toxin-A is found to act on synaptosomal associated protein with the molecular mass of 25KDn(SNAP 25) which is located in the cell membrane. This SNAP 25 present in sensory neurons acted upon by BTX producing anti-nociceptive effect [10]. Botulinum Toxin also inhibits neurotransmitters like substance P, CGRP, glutamate and also has anti inflammatory action [11]. Botulinum toxin- A also found to inhibits peripheral sensitization which leads to an indirect reduction in sensitization [12]. Nowadays many studies are conducted to find the action of Botulinum toxin on many pain disorders.

## Materials and Methodology

This study was done in Government Institute of Rehabilitation Medicine, K.K Nagar, Madras Medical College as a Prospective Assessor, participant and

physiotherapist blinded, simplified Randomized control study. 100 Participants were selected according to inclusion and exclusion criteria from individuals attending PMR-OPD and the study period was 10 months from January to October 2018. Patient with age 20-60 yrs, symptomatic heel pain of any side for 3 months, both sex, no improvement of heel pain after physical modalities were included in the study. Patients with any systemic disease with foot pain like rheumatoid arthritis, allergic to Botox, cellulitis foot, pregnancy, those who received steroids within 4 months were excluded from the study. 100 participants divided into two groups of each 50 participants by Simplified Randomized control method. Participants selected according to the protocol were briefed about the nature of the study and written informed consent was obtained from them in their own language Prior to the commencement of the study, the study was approved by the Institutional Ethics and Research Committee, Madras Medical College.

Under strict aseptic precautions, the injection site is anaesthetized with 2ml of 2% lignocaine, Group 1 received 50 units of Botulinum toxin-A mixed with 1ml of normal saline and Group 2 received 40 mg of Methyl prednisolone acetate injection into most tender spot on medial aspect of heel. Participants were assessed before and after intervention at 2months,4 months,6 months using Visual Analogue Scale and FAAM Score. Participants in each group followed exercise protocol like strengthening exercise to intrinsic foot muscle, stretching exercises to plantar fascia, tendoachilles, hamstrings after intervention.

### Statistical Analysis:

Analysis was done using standard software SSPS. Descriptive analysis for all the variables was expressed in frequency and proportions. Bivariate analysis using chi square test was done. The associations with the p value less than 0.05 was considered significant.

### Results

The mean age years affected by plantar fasciitis are 44.6 yrs in groups 1 and 44.8yrs in group 2. In our study female participants are more than male participants. In this study in group 1 there was 20(40%) overweight and 6(12%) obese participants. In group 2 there was 19(38%) overweight and 4(8%) obese participants. Body mass index results proves that overweight and obesity is one of the risk factor of plantar fasciitis. In group 1 the participant with heel pain in the right side is 21(42%), left side is 19(38%) and bilateral side 10(20%). In group 2 the participant with heel pain in the right side is 23(46%), left side is 18(36%) and bilateral involvement is 9(18%).The mean duration of symptom in group1 is about 6.8 months and in group 2 is about 7.3 months. In group1,49(98%) and in group2,48(96%) had history of early morning heel pain.

The outcome scale used in our study are visual analogue scale(VAS),Foot Ankle Ability Measure(FAAM).In group1 ,preintervention mean VAS score was 9.58 and in group 1 mean VAS was 9.4,post intervention VAS at 1month and 2month reduced significantly in both groups .After 4<sup>th</sup> month and 6<sup>th</sup> month there is significant reduction and maintenance of VAS score in group1 BTX-A compared to group 2 steroids. In group1, the preintervention mean FAAM score was 23 out of 100 and in group 2, the preintervention mean FAAM score was 24.22. Post intervention FAAM score in group 1 at 6 month was 74.18 and in group 2 it was 54.15.

**Table 1: Disease Demography**

Features		Treatment group				Chi-square test p-value
		Botulinum		Steroid		
		Freq	%	Freq	%	
H/O Early morning pain	Y	49	98	48	96	0.343
	N	1	2	2	4	
H/O Night pain	Y	4	8	6	12	0.444
	N	46	92	44	88	
Deformity	Y	12	24	11	22	0.812
	N	38	76	39	72	
OA knee	Y	8	16	6	12	0.564
	N	42	84	44	88	
Windlass test	Positive	47	94	46	92	0.695
	Negative	3	6	4	8	
Medial heel pain	Y	44	88	42	84	0.564
	N	6	12	8	16	

**Table 2: VAS Score**

Group	Statistics	PAIN-VAS SCORE				
		Pre inter	1 month	2 month	4 month	6 month
Botulinum toxin	Mean	9.58	4.8	3.14	3.18	2.74
	S.D	0.702	0.755	0.534	1.043	1.293
	Median	10	5	3	3	3
Steroid	Mean	9.4	6.3	3.9	4.9	5.4
	S.D	0.788	0.707	0.707	1.326	1.293
	Median	10	6	4	5	5

**Table 3: FAAM Score**

Group	Statistics	FAAM SCORE				
		Pre inter	1 month	2 month	4 month	6 month
Botulinum toxin	Mean	23	52.26	61.12	68.46	74.18
	S.D	4.261	5.783	5.762	6.581	4.148
	Median	22.5	46	60	69	74
Steroid	Mean	24.22	45.84	52.8	55.78	54.18
	S.D	4.925	6.931	6.931	5.334	4.493
	Median	23	54	54	57	55

**Table 4: Pre and Post intervention data analysis**

Measures	Statistics	Group 1		Group 2		P value
		Pre inter	Post inter	Pre inter	Post inter	
VAS	M	9.58	2.74	9.4	5.4	0.001
	SD	0.702	1.293	0.788	1.293	
FAAM	M	23	74.18	24.22	54.18	0.001
	SD	4.261	4.148	4.925	4.493	

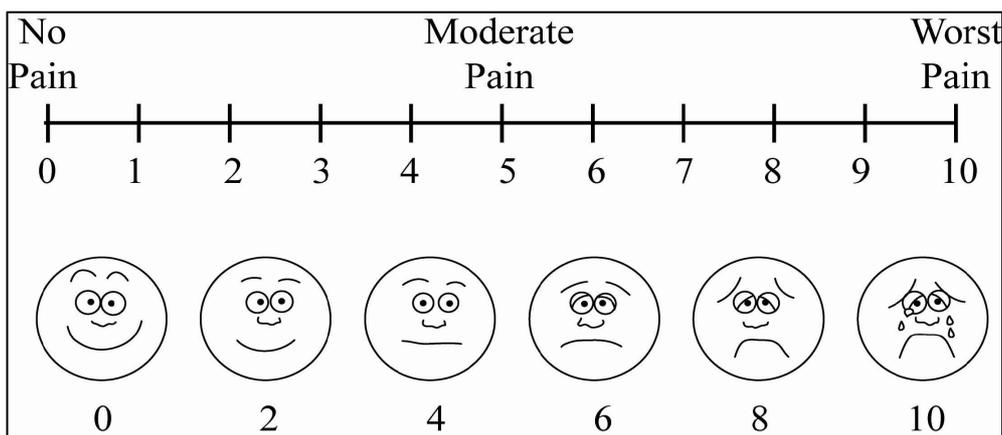


Figure 1: visual analog scale(VAS)

### Foot and Ankle Ability Measure (FAAM)

Please answer **every question** with the **one response** that most closely describes your condition within the past week. If the activity question is limited by something other than your foot or ankle mark N/A (not applicable).

	No Difficulty	Slight Difficulty	Moderate Difficulty	Extreme Difficult	Unable to do	N/A
1. Standing	<input type="checkbox"/>					
2. Walking on even ground	<input type="checkbox"/>					
3. Walking on even ground without shoes	<input type="checkbox"/>					
4. Walking up hills	<input type="checkbox"/>					
5. Walking Down Hills	<input type="checkbox"/>					
6. Going up stairs	<input type="checkbox"/>					
7. Going down stairs	<input type="checkbox"/>					
8. Walking on uneven ground	<input type="checkbox"/>					
9. Stepping up and down curbs	<input type="checkbox"/>					
10. Squatting	<input type="checkbox"/>					
11. Coming up on your toes	<input type="checkbox"/>					
12. Walking initially	<input type="checkbox"/>					
13. Walking 5 minutes or less	<input type="checkbox"/>					
14. Walking approximately 10 minutes	<input type="checkbox"/>					
15. Walking 15 minutes or greater	<input type="checkbox"/>					
Because of your foot and ankle how much difficulty do you have with:						
16. Home responsibilities	<input type="checkbox"/>					
17. Activities of daily living	<input type="checkbox"/>					
18. Personal care	<input type="checkbox"/>					
19. Light to moderate work (Standing or walking)	<input type="checkbox"/>					
20. Heavy work (pushing/pulling, Climbing, carrying)	<input type="checkbox"/>					
21. Recreational activities	<input type="checkbox"/>					
How would you rate your current level of function during your usual activities of daily living from 0 to 100 with 100 being your level of function prior to your foot or ankle problem and 0 being the inability to perform any of your usual daily activities? _____%						
Name (Please Print) _____				Date ___/___/___		
Foot and Ankle Ability Measure (FAAM)						

Figure 2: FAAM

## Discussion

In an average 3-5 cases per day of Plantar fasciitis attending PMR OPD in Government Institute Of Rehabilitation Medicine hospital. In this study 100 participants were included with 50 participants in each group (Group1: Group2) selected by randomized controlled trials. Mostly the participants belong to low and moderate socio-economic status and are doing semiskilled works including housewives which correlates with previous studies which says that those who continuously stand or walk, doing household works are more prone to develop Plantar fasciitis.

Most of the participants were between 31 to 40 yrs and between 41 to 50 yrs in our study. The mean age years affected by plantar fasciitis is 44.6yrs in group1 and 44.8yrs in group2 which is also correlated with previous studies which says plantar fasciitis is more common in middle aged persons. Females are involved more than males in both groups in our study as comparable with Raono et al whose studies also more prevalence of PF in females. [13] Body mass index results of this study proves that overweight and obesity is one of the risk factor of plantar fasciitis [14]. But only 10-20 percent had pes planus and pes cavus deformity [15]. Most of them had early morning heel pain and pain aggravation during prolonged standing and mainly antero medial heel pain over calcaneal tuberosity. Very few of them has arch pain also. [16]

Parameters and scales in both group were analysed by paired t test within group and unpaired t test between two groups. VAS score and FAAM score values was statistically significant with p value > 0.00001 in group 1 after 1 month of post intervention and with p value > 0.0001 maintained at 6 months after intervention. whereas in group 2 it was > 0.0001 at 1 month and > 0.001 at 6 months after intervention. Both groups shows significant reduction in pain and functional outcome

up to 12-14 weeks of intervention, but after 16 weeks group1 BTX-A shows reduction and maintenance of VAS score and improvement in function proved by increase in FAAM score which correlates with previous studies [17]. Complications like mild numbness of foot is noted in 2 participants in group2 and 1 participant in group 1. No allergic reactions were noted during intervention in both groups. Only 3 patients in group1 (Botulinum Toxin-A) has no significant improvement in VAS and FAAM score.

## Conclusion

Plantar fasciitis sometimes leads to unbearable pain and functional limitation in many cases even after conservative management failure. This study shows that in Botulinum toxin group there was significant reduction in VAS pain score after intervention and it was maintained after 6 months. There was also improvement in functional level in Botulinum toxin group measured by FAAM score which is maintained after 6 months. In steroid group there was significant reduction in VAS pain score and FAAM score up to 12-14 weeks but that was not maintained after 16 weeks. So BTX-A is cost-effective in reducing pain in chronic Plantar fasciitis. So in future Botulinum Toxin-A should be tried for all musculoskeletal pain-related conditions.

## Limitations:

Botulinum toxin injection is costly and no long term follow up done in this study. Both groups received exercise therapy in addition so effects of intervention alone not possible in this study.

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