



Plantar Fasciitis- A Randomised Control Study between Physiotherapy and Corticosteroid Injection as Treatment

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KEYWORDS

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ABSTRACT:

Introduction: Plantar fasciitis is a common condition presenting to the Orthopaedic outpatient department, which is treated with analgesics, physiotherapy or intralesional injections. However, which of these treatment modalities provide quicker pain relief is still uncertain.

Objectives: This study aimed to assess the efficacy of physiotherapy versus intralesional injection in treating plantar fasciitis using Visual Analogue Score (VAS) and Foot and Ankle Ability Measure (FAAM) score over a period of 3 months.

Methods: Sixty patients diagnosed with plantar fasciitis, who presented to the Orthopaedic outpatient department, were included in this prospective single-blinded randomised control study. Institutional ethics approval and enrolment of the study in the National Clinical Trial registry were done before initiation of the study. Written and informed consent was obtained from all patients including permission to use clinical pictures for publication purposes. Newly diagnosed plantar fasciitis patients were included in the study. The 60 patients were allotted by computer randomisation into physiotherapy group (Group A) and intralesional injection group (Group B). VAS score and FAAM score were recorded at the start of treatment, at 1-month and 3-month follow-up. Analysis of Variance (ANOVA) and unpaired t-test were used for intragroup and intergroup analysis of outcomes respectively. P-value <0.05 was considered statistically significant.

Results: Both groups showed improvement of pain at 3-month follow up, however, intralesional corticosteroid injection provided significant pain relief (P value 0.005) compared to physiotherapy.

Conclusions: Intralesional corticosteroid injection can provide better short-term pain relief compared to physiotherapy.

Introduction:

Plantar fasciitis results from microtrauma from daily strenuous activities. It aggravates with initiation of standing from rest, especially when waking up in the mornings. Pain is typically at the entheses of plantar fascia- medial calcaneal tubercle, due to degeneration of collagen fibres from repetitive microtears [1,2]. Plantar fasciitis is a clinical diagnosis [2,3]. Various factors like

daily physical activities, body mass index (BMI) and comorbid conditions have been attributed to its development and progression [2]. The primary management options are analgesics, footwear modifications, physiotherapy and intralesional injections. Physiotherapy includes stretching exercises, extracorporeal shock wave diathermy (ESWD) and ultrasound therapy. Intralesional injection options are corticosteroids and platelet-rich plasma. This study aims



to assess the efficacy of stretching exercises and ultrasound therapy versus intralesional corticosteroid injection in relief of plantar fasciitis pain.

Subjects and Methods:

The study was designed as a prospective single-blinded single-centred randomised control trial conducted in the orthopaedic outpatient department after ethical approval from the institution's ethical committee board. The study was registered in the national clinical trial registry following which written and informed consent for the study as well as for publishing clinical pictures was obtained from all participants who were enrolled in the study.

The sample size was calculated using the formula:

$$n \geq \frac{[Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}]^2 [\sigma_1^2 + \sigma_2^2]}{(\mu_1 - \mu_2)^2}$$

Where $Z_{1-\frac{\alpha}{2}} = 1.96$ corresponded to a 95% confidence interval; $Z_{1-\beta} = 0.84$ corresponded to 80% power; $\sigma_1 = 1.6$ and $\sigma_2 = 3$ were taken as the standard deviation for both the groups respectively; $\mu_1 = 28.3$; $\mu_2 = 30$ were taken as the means of the two groups respectively and hence the required sample size was calculated to be 30 participants in each group and the sample size was calculated based on the study conducted by Celik et al [4]. A total of 73 patients were recruited to be included in the study.

Based on the exclusion criteria of previous surgery or trauma to the ipsilateral foot and/or ankle, already on treatment or had undergone treatment for plantar fasciitis of the same foot or those who had received intralesional injection to the heel pad or Achilles tendon, 13 patients were excluded from the study. Out of the 13 patients, four had previous surgery to the ipsilateral ankle joint, five of them had undergone treatment previously for plantar fasciitis and four had previous trauma to the foot. However, these patients still received appropriate treatment for plantar fasciitis. Hence, based on the inclusion criteria of patients' age more than 18 years diagnosed clinically with plantar fasciitis and those who consented to the study, 60 patients were finally enrolled into the study. None of the patients dropped out of the study or were lost to follow-up. These patients were divided into two groups of 30 each- those receiving

physiotherapy as group A and those receiving intralesional corticosteroid injection as group B, by computer randomisation using random number generator. The primary investigator was blinded in this study. The patients were not blinded. Before the start of treatment, visual analogue scale (VAS) pain score and foot and ankle ability measure (FAAM) score- activities of daily living subscale, were assessed for all 60 patients. Demographic data such as age and BMI were also taken into consideration. Table 1 shows the patient demographics.

Patients in group A received therapeutic ultrasound via continuous waves given at 1Mhz at 1.4W over the most tender site- medial process of calcaneal tuberosity for 8 minutes- 3 sessions per week for 4 weeks (figure 1a, 1b) (device from Technomed company manufactured by Sunshine Biomedical solutions); each of the following exercises done for 4 sets of 10 cycles each per day (1 set each in the morning, afternoon, evening and before going to bed at night) for 4 weeks- plantar fascia stretching exercise (figure 2a), ankle dorsiflexion exercise (figure 2b), gastrocnemius stretching exercise (figure 2c) and soleus stretching exercise (figure 2d). Group B patients received a single dose of 2ml of 40mg of Triamcinolone acetonide mixed with 2ml of 2% Lignocaine injected over the medial process of calcaneal tuberosity under sterile aseptic precautions at the start of the study (figure 3). Following the completion of 1 month since intervention, patients were called for review, wherein, their VAS score and FAAM score were assessed. They were further followed up for 3 months for reassessment of the scores. VAS scores and FAAM scores at pre-treatment, 1-month and 3-month follow-up were compared within the group and between the two groups. All patients in group A followed the exercise protocol as advised. None of the patients found it difficult to perform the exercises. No patient was lost to follow-up among both the groups.

All data were analysed by a single principal investigator from the Department of Orthopaedics. Statistical Package for the Social Sciences (SPSS) version 21.0 was used for descriptive analysis of the data. Analysis of Variance (ANOVA) and unpaired t-test were used for intragroup and intergroup comparison of outcomes among the two groups respectively. P-value <0.05 was



considered statistically significant with 95% confidence interval.

Results:

On analysing patient demographics, there were more males in group A while the number of male and female patients were equal in group B. The average age between both groups was found to be statistically significant (*P* value 0.0351) (49 years in group A; 56 years in group B). The average BMI among both the groups was also found to be statistically significant (*P* value 0.0032) (24.5 in group A; 26 in group B) (Table 1).

Over the course of 3 months, patients in both groups showed a significant reduction in pain as evidenced by improvement in VAS and FAAM scores from pre-treatment to the end of the study (*P* value <0.00001) (Tables 2,3 and 4). However, on comparing the individual VAS and FAAM scores at each assessment interval, there was statistical significance at 3 months for VAS score (*P* value 0.0043) and before the start of treatment for FAAM score (*P* value 0.0263) between both groups (Table 5). There was no statistical significance at 1 month follow-up for VAS or FAAM score among both groups. There was no statistical significance at 3-month follow-up for FAAM score.

Discussion:

Through this study, it was observed that increased age and a higher BMI contributed to increased severity of plantar fasciitis pain. The improvement of VAS and FAAM score in both groups throughout the follow-up period concludes that intervention with either physiotherapy or intralesional injection is needed for pain relief. The primary outcome analysis of pain relief in both groups measured by the improvement in VAS score was statistically significant at 3 months in the intralesional corticosteroid injection group which can be concluded as this mode of treatment gives better short-term pain relief. However, long-term pain relief will need to be assessed [5]. The FAAM score used to assess the secondary outcome of functional improvement did not show statistical significance among the groups suggesting that both groups have similar functional improvement at 3 months. In this study, 12 sessions of therapeutic ultrasound in continuous waves were given to the patients in addition to the stretching exercises which were simple to perform since there is no standardised dosage and number of sessions for the

application of therapeutic ultrasound, certain studies have concluded that an average of 9-15 sessions would provide good pain relief [6]. Since ESWD is contraindicated in pregnancy, patients with cardiac pacemakers and on anticoagulant therapy and due to complications, such as swelling and erythema during treatment, a safer option of therapeutic ultrasound was opted in this study [7]. Continuous ultrasound waves efficiently deliver heat to the body's tissues especially at the entheses and aid in the healing by restructuring collagen fibres and boosting cellular metabolism [8]. The specific muscle-targeted stretching exercises given in this study were based on a targeted and structured approach to engaging the plantar fascia directly thus playing a crucial role in maintaining its tensile strength [9]. A combined stretching protocol including plantar fascia as well as Achilles tendon has proven to be more effective in pain reduction [10,11]. Hence, this study included stretching exercises for plantar fascia, gastrocnemius and soleus.

Corticosteroids were injected along with a local anaesthetic agent for even distribution of the drug and to prevent post-injection flare at the injection site thus reducing the pain considerably [12]. The medial approach for administering the drug was chosen due to the ease of access to the plantar fascia compared to the plantar approach [12]. Repeated administration of corticosteroids may cause heel fat pad atrophy and is a risk factor for infections and plantar fascia rupture [4,13,14]. Hence, the patients in this study were given only a single dose of corticosteroid injection at the start of the study. Triamcinolone acetonide has been found to have deleterious effect on collagen synthesis which can be proposed to cause plantar fascia rupture [14,15]. However, no cases of plantar fascia rupture were encountered at the end of this study, inferring that a single dose of triamcinolone acetonide has a very low margin of risk for plantar fascia rupture. Canyilmaz E et al, [13] suggested that radiation therapy provides better pain relief compared to corticosteroid injection with smaller doses than that used for malignancies but considering the accessibility and cost of radiation therapy, this modality of treatment was not considered in this study as an interventional arm. Biswas et al observed the recurrence of heel pain after discontinuation of oral non-steroidal anti-inflammatory drugs (NSAIDs) and had an added complication of systemic side effects such



as gastritis, pruritic and esophagitis, which were not seen with giving a single dose of steroid injection mixed with a local anesthetic agent [16].

This study is bound by its limitations. The follow-up period was only 3 months thus the long-term effect of stretching exercises with therapeutic ultrasound versus intralesional corticosteroid injection was not explored. Like several other studies, this study did not consider the thickness of plantar fascia as an outcome parameter since plantar fasciitis is essentially a clinical diagnosis [3]. Several studies were done on using silicone insoles to reduce plantar fascia pain which was comparable to the effectiveness of steroid injections [17,18]. Yet, in this study, insoles were not taken into consideration for an intervention arm due to its cost factor.

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Tables:

Table 1- Patient demographics

	Physiotherapy (30)	Intralesional corticosteroid (30)	P value	95% confidence interval
Mean age	49.13 ± 15.08	56.4 ± 10.08	0.0351	-14.01 to -0.53
Sex distribution				
Female	17	15		
male	13	15		
Mean body mass index	24.56 ± 2.16	26.1 ± 1.67	0.0032	-2.54 to -0.54

Table 2- line diagram showing a decline in mean visual analogue score throughout the treatment course in group A and group B

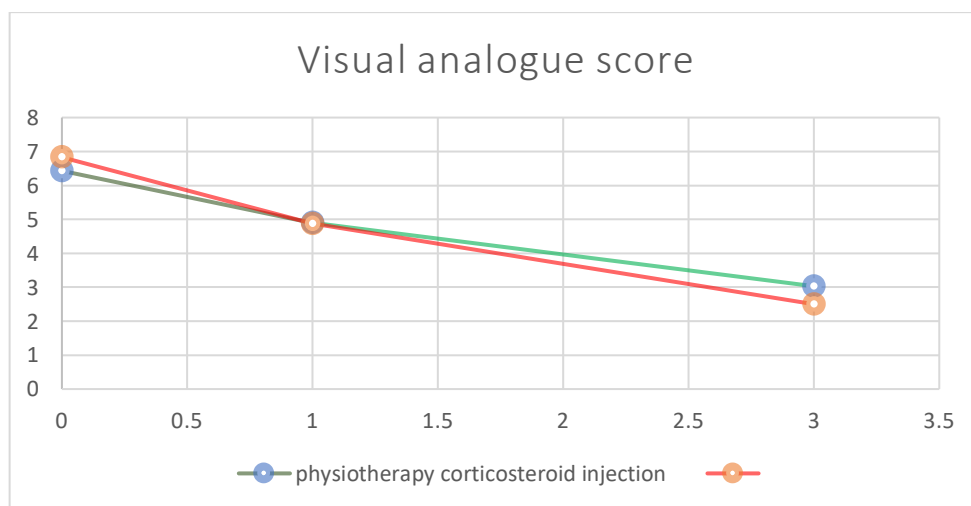




Table 3- line diagram showing an improvement in mean foot and ankle ability measure score throughout the treatment course in group A and group B

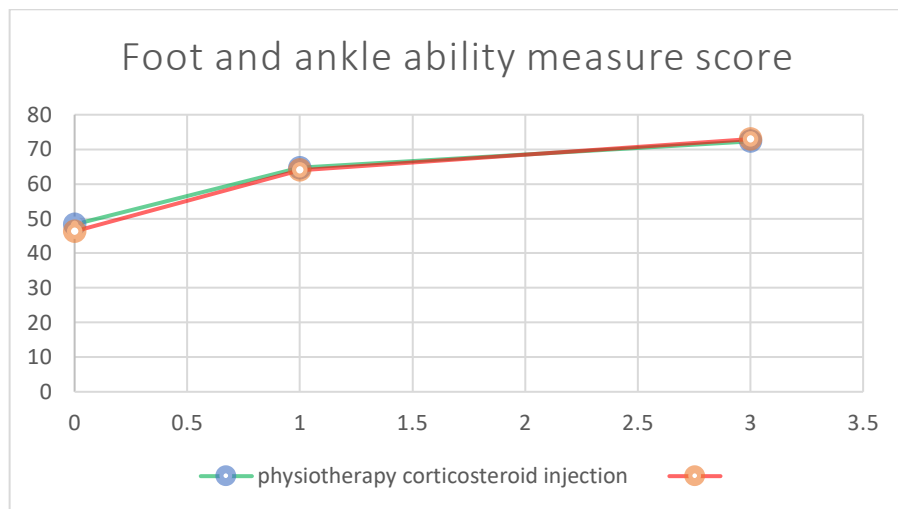


Table 4- Intragroup results

	Mean ± standard deviation	P value (ANOVA)	F ratio
Physiotherapy			
Visual analogue score			
Pre-treatment	6.43 ± 0.96	<0.00001	106.52839
At 1 month	4.90 ± 0.98		
At 3 months	3.03 ± 0.71		
Foot and ankle ability measure score			
Pre-treatment	48.33 ± 4.34	<0.00001	475.04063
At 1 month	64.67 ± 2.35		
At 3 months	72.30 ± 2.00		
Intralesional injection			
Visual analogue score			
Pre-treatment	6.83 ± 0.90	<0.00001	183.0283
At 1 month	4.87 ± 0.99		
At 3 months	2.50 ± 0.67		
Foot and ankle ability measure score			

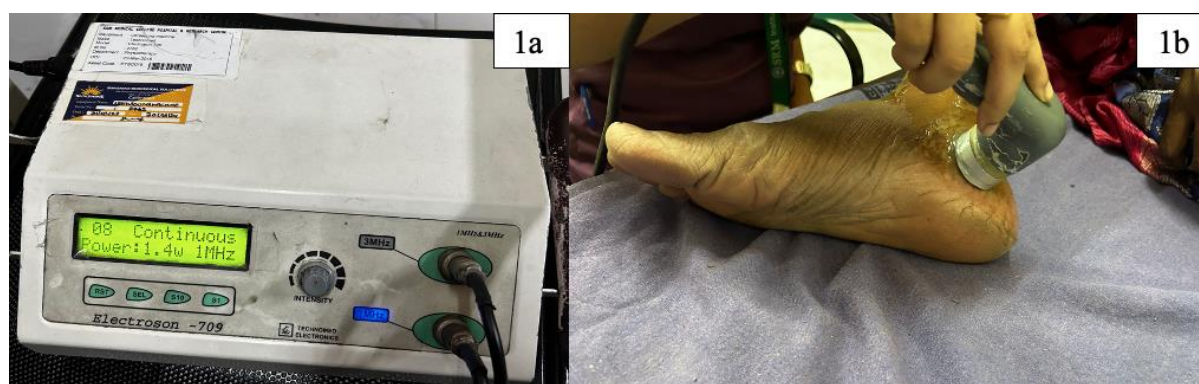


Pre-treatment	46.33 ± 2.06	<0.00001	1053.78787
At 1 month	63.97 ± 2.68		
At 3 months	72.96 ± 2.06		

Table 5- Intergroup results

	physiotherapy	Intralesional injection	P value	95% confidence interval
Mean Visual analogue score				
Pre-treatment	6.43 ± 0.96	6.83 ± 0.90	0.1013	-0.88009 to 0.0809
At 1 month	4.90 ± 0.98	4.87 ± 0.99	0.9065	-0.4791 to 0.5391
At 3 months	3.03 ± 0.71	2.50 ± 0.67	0.0043	0.1732 to 0.8868
Mean Foot and ankle ability measure score				
Pre-treatment	48.33 ± 4.34	46.33 ± 2.06	0.0263	0.2443 to 3.7557
At 1 month	64.67 ± 2.35	63.97 ± 2.68	0.2865	-0.6026 to 2.0026
At 3 months	72.30 ± 2.00	72.96 ± 2.06	0.2131	-1.7093 to 0.3893

Figures:



Figure

1- Group A, 1a- ultrasound therapy machine with settings at continuous waves at the power of 1.4W and 1MHz for 8 minutes; 1b- application of ultrasound therapy over the medial process of calcaneal tuberosity on patient “x” (property of the author)

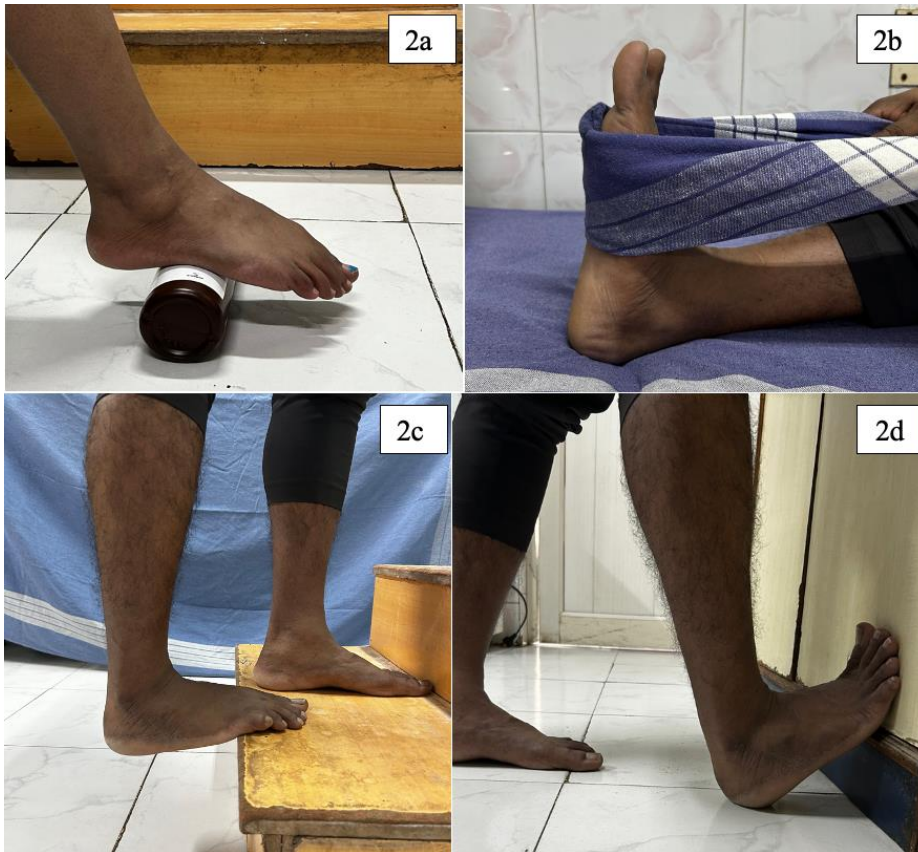


Figure 2- Group A, 2a- plantar fascia stretching exercise; 2b- ankle dorsiflexion exercise; 2c- stretching exercise for gastrocnemius; 2d- stretching exercise for soleus (property of the author)



Figure 3- intralesional injection of 2ml of 40mg of Triamcinolone acetonide mixed with 2ml of 2% Lignocaine over the medial process of calcaneal tuberosity on patient "a" (property of the author)