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Original Research Article

Ultrasound-guided injection of corticosteroid versus placebo in management of plantar fasciitis

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ABSTRACT

Background: Plantar Fasciitis (PF) is a prevalent musculoskeletal condition causing heel pain, with approximately 1 million annual U.S. physician visits. It is more common in women, aged 45-64, and obese individuals. Diagnosis relies on clinical history and examination, and various treatments target pain relief, though consensus on the most effective modality is lacking. Corticosteroid injections are commonly used but pose risks.

Materials and Methods: This six-month prospective randomized controlled trial with 50 individuals assessed the efficacy of corticosteroid versus placebo injections for resistant PF. Ultrasound-guided injections were administered, and outcomes were measured at 3 weeks and 3 months.

Results: Results indicated significant improvement in pain scores, Ankle and Hindfoot scores, and plantar fascia thickness with corticosteroid injections compared to placebo. No serious adverse events were observed.

Conclusion: Corticosteroids aim to reduce inflammation, and studies link decreased plantar fascia thickness to pain relief. Ultrasound guidance enhances precision in delivery. While some protocol limitations exist, this trial contributes valuable insights into the pharmacological effects of corticosteroids in PF treatment, aiding in evidence-based recommendations.

1. Introduction

Plantar Fasciitis (PF) is a common cause of adult heel pain, stemming from repetitive strain on the plantar fascia—a dense structure supporting the foot arch. This chronic musculoskeletal condition is frequently diagnosed and managed in rehabilitation settings. Prolonged running or standing can cause heightened tension, leading to acute or chronic changes in the plantar fascia.[1] Remarkably, around 1 million visits to physicians occur each year in the United States for the diagnosis and treatment of plantar fasciitis.[2] This condition exhibits a higher prevalence among women compared to men, particularly in the age group of 45-64 years as opposed to 18-44 years, as well as in individuals classified as obese rather than those with a body mass index (BMI) below 25 kg/m.[2–4]

Additional risk factors for its development include calcaneal spur, pes planus, pes cavus, limited ankle dorsiflexion, weak intrinsic foot muscles, excessive foot pronation, inappropriate footwear, and restricted extension of the first metatarsophalangeal joint.[5,6] Plantar fasciitis diagnosis relies mainly on clinical history and examination. While it typically affects one foot, around 30% of cases present bilaterally. Common physical exam findings include tenderness at the medial calcaneal tuberosity, tightness in plantar flexors, increased discomfort with passive dorsiflexion of the big toe, or standing on tiptoes.

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Managing plantar fasciitis aims to relieve pain with various approaches such as extracorporeal shock-wave therapy (ESWT), stretching exercises, night splints, shoe inserts, and medical interventions like NSAIDs, corticosteroid injections, platelet-rich plasma (PRP), and prolotherapy. However, there's no consensus on the most effective treatment, and study outcomes vary.[7,8]

The predominant pathological characteristics observed in plantar fasciitis include the degradation of collagen fibers, heightened secretion of ground substance proteins, focal regions of fibroblast proliferation, and increased vascularity. While exploring biochemical markers of inflammation, such as cytokines and prostaglandins, remains limited, several studies have reported nonspecific indications of localized inflammatory changes.[9,10]

Corticosteroids (CS) are the primary injection for PF, offering low cost, simplicity, and fast pain relief. Despite potent anti-inflammatory effects, they pose risks of plantar fascia rupture and fat pad atrophy[11] A randomized controlled trial compared the effects of a 25 mg hydrocortisone injection to a placebo (normal saline), revealing no significant difference in pain reduction between the groups two months after treatment. However, the trial's small sample size (19 participants) made it statistically underpowered to detect clinically meaningful distinctions.[12]

Ultrasound is increasingly popular in clinical settings due to affordable equipment and its capability for targeted invasive procedures. This imaging method provides high-resolution images without ionizing radiation exposure and allows real-time assessment of tissue dynamics.[13] Studies show that ultrasound-guided corticosteroid injections offer more prolonged pain relief for treating plantar fasciitis compared to palpation-guided injections.[14]

Numerous randomized controlled trials (RCTs) have examined corticosteroid injections versus placebos for treating plantar fasciitis. However, ongoing debate persists regarding the efficacy of corticosteroid injections in this context.

2. Aims

1. To determine the effectiveness of corticosteroid injections compared to placebo injections for treating heel pain associated with plantar fasciitis.
2. To examine how ultrasound-guided corticosteroid injections affect pain reduction, plantar fascia thickness, and functional outcomes.
3. To contrast the short-term (3 weeks) and medium-term (3 months) results between the corticosteroid injection group and the placebo injection group in terms of alleviating pain, reducing plantar fascia thickness, and improving functionality.

3. Materials and Methods

The research was conducted at the Department of Orthopaedics of Narayan Medical College and Hospital in Sasaram over a six-month period from January 2023 to July 2023. It involved a prospective randomized controlled trial with a total of 50 participants (25 in each treatment group).

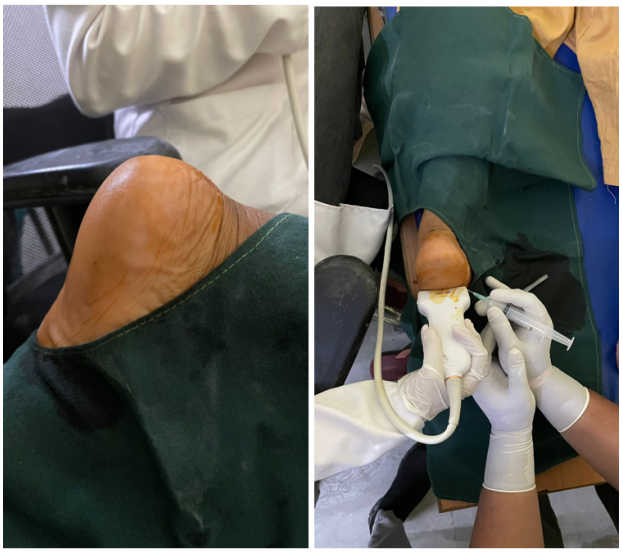
Inclusion criteria encompassed individuals aged 25 to 70 years diagnosed with resistant plantar fasciitis, experiencing no relief from medication for six weeks, and having a Morning Visual Analogue Scale (VAS) pain score exceeding 5. Exclusion criteria comprised individuals aged <25 or >70 years, those with a history of multiple corticosteroid injections in the past three months, NSAID use within one week before intervention, BMI > 40, foot deformity, previous foot surgery, peripheral neuropathy, known diabetes mellitus, hypertension, or those unwilling to provide consent.

Patients displaying clinical signs and symptoms of plantar fasciitis, diagnosed through clinical examination and ultrasound, underwent evaluation. Those meeting the criteria were included in the study, with routine blood investigations, clinical assessments, and radiographs of the involved feet conducted as part of the protocol.

The participants were randomly assigned into two groups (25 participants each): group A corticosteroid group (intervention) and group B placebo Normal Saline group (control). In group A, 2 ml of a 50/50 mixture of Triamcinolone Acetonide 40 mg/ml and Xylocaine 2% was administered under Ultrasound guidance using a 22 gauge needle while in group B, 2 ml of a 50/50 mixture of Normal Saline and Xylocaine 2% was administered under Ultrasound guidance using a 22 gauge needle. The needle insertion for both injections followed a standardized technique, where it was placed through the medial heel in a 30° angle to the long axis of the ultrasound transducer (Figure 1). The needle was then carefully advanced under continuous real time ultrasound guidance into the center of the hypoechoic, oedematous plantar fascia and injected (Figures 2 and 3). To minimize the risk of infection, all injections were performed using an aseptic technique, which included the use of sterile gloves, sterile transducer covers, and sterile transmission gel.

After the treatment, participants were instructed to refrain from engaging in running and other high impact activities for a minimum of 2 weeks. Pain assessment using the VAS Score, measurement of plantar fascia thickness, and evaluation of functional outcomes using the AOFAS Ankle and Hindfoot score was conducted before injection, at 3 weeks, and at the 3 month follow-up. Statistical analysis was performed to compare the outcomes between the corticosteroid and placebo groups at different time points.

Data entry and statistical analysis was carried out using Microsoft Excel 2010.



(A) (B)

Figure 1: (**A**): Injection site scrubbed painted and draped following aseptic precautions; **(B):** Under USG guidance needle passed through the medial heel in 45 degrees to the long axis of the ultrasound transducer

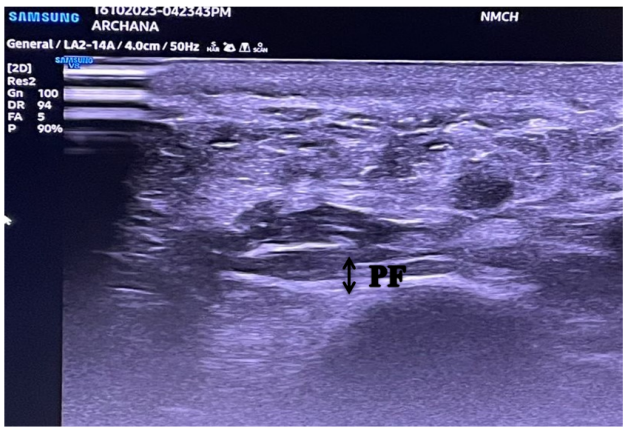


Figure 2: Plantar fascia visualised under USG guidance and it's thickness measured using digital ruler

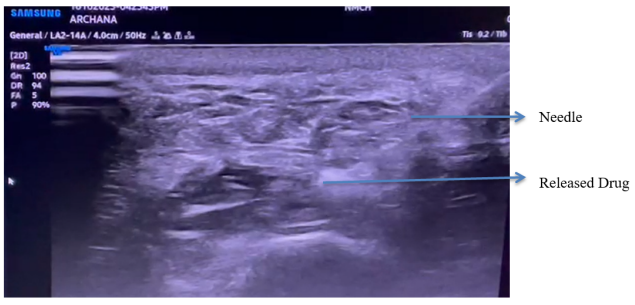


Figure 3: USG picture shows needle advanced into the plantar fascia and drug released

4. Result

The patient cohort comprised 37 (74%) females and 13 (26%) males, with a mean age of 49 years. Table 1 presents the baseline demographic characteristics of the participants. Table 2 details the comparison of corticosteroid and placebo groups concerning PF thickness, VAS, and AOFAS scores at various treatment time points using an independent test.

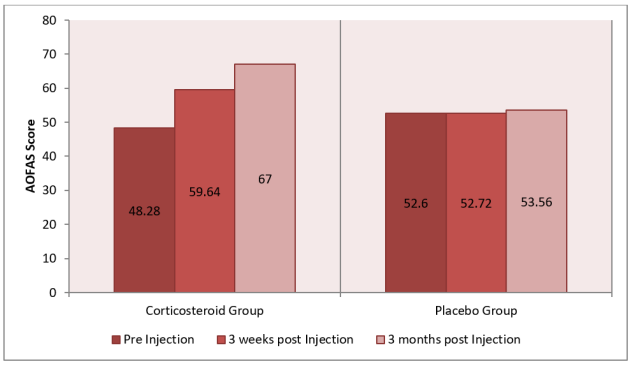
Tables 3 and 4 illustrate the effects of corticosteroid and placebo injections on plantar fascia thickness, AOFAS score, and VAS score before application, at 3 weeks, and 3 months post-treatment in each study group. Notably, a significant improvement in VAS scores for daily morning pain and AOFAS score values was observed in study group A at 3 weeks and 12 weeks after injection, while group B did not exhibit marked improvement.

Regarding ultrasonographic measurement of PF thickness at its insertion point, corticosteroid injection led to a significant improvement at 3 weeks and 3 months compared to placebo. Graph 1 depicts a comparison between the Corticosteroid and Placebo groups based on AOFAS Score, while Graph 2 illustrates the PF Thickness comparison, and Graph 3 shows the VAS Score comparison between the Corticosteroid and Placebo groups.

The interaction effects of time and group on VAS score, AOFAS score and PF thickness were statistically significant. All patients tolerated the intervention procedures well, and no serious adverse events were observed in any of the participants.

Table 1: Comparison of demographic indices in corticosteroids and Placebo groups

Group	Assessment	Number	Mean
Age	Corticosteroids	25	46.96
	Placebo	25	51.04
BMI	Corticosteroids	25	28.84
	Placebo	25	29.16



Graph 1: Comparison between corticosteroid group and placebo group on basis of AOFAS score

Table 2: Comparison of corticosteroid and placebo with PF thickness, VAS and AOFAS scores at different treatment time points by independent test

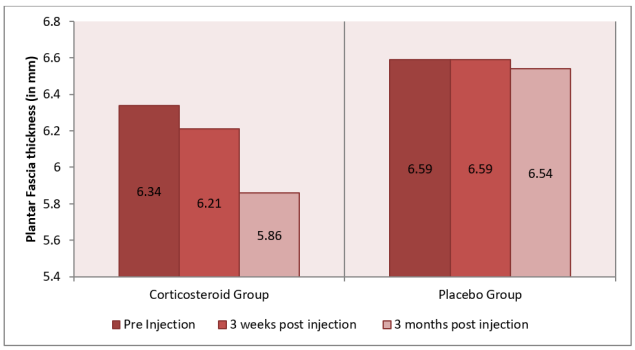
Parameters	Corticosteroid group		Placebo group		p-Value
	Mean	SD	Mean	SD	
Age	46.96	12.4146419	51.04	10.79151	0.043764919
BMI	28.84	1.51877143	29.16	1.344123	0.199662743
Pre Injection PF thickness	6.336	0.44740995	6.590	0.311455	0.005384885
3 weeks post injection PF thickness	6.21	0.42855377	6.587	0.322704	0.0000875672
3 months post injection PF thickness	5.860	0.38424688	6.540	0.329121	0.0000000048866
Pre Injection AOFAS score	48.28	11.3229855	52.6	8.722576	0.076120803
3 weeks post injection AOFAS score	59.64	10.1319626	52.72	9.744742	0.005401022
3 months post injection AOFAS score	67	9.05998528	53.56	9.069546	0.00000135877
Pre Injection VAS score	6.68	1.06926766	6.24	1.011599	0.058949046
3 weeks post injection VAS score	4.56	0.91651514	5.2	1.080123	0.013089496
3 months post injection VAS score	3.64	0.86023253	5.12	1.053565	0.0000016138

Table 3: Comparison between corticosteroid group and placebo group on basis of PF thickness and AOFAS score values

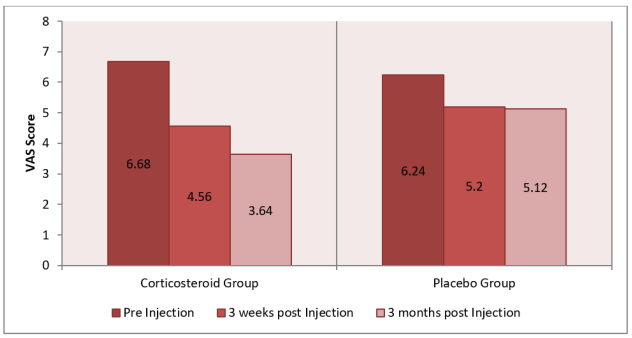
Assesment	Plantar Fascia Thickness			AOFAS Ankle and Hindfoot score		
	Pre Injection	3 weeks post Injection	3 months post Injection	Pre Injection	3 weeks post Injection	3 months post Injection
Corticosteroid Group	6.68 mm	6.37 mm	6.06 mm	48	60	78
Placebo Group	6.94 mm	6.88 mm	6.72 mm	52	56	60

Table 4: Comparison between corticosteroid group and placebo group on basis of VAS score

Assessment	VAS score		
	Pre Injection	3 weeks post Injection	3 months post Injection
Corticosteroid Group	7.2	6.6	5
Placebo Group	7	6.8	6.6



Graph 2: Comparison between corticosteroid group and Placebo group on basis of PF thickness



Graph 3: Comparison between corticosteroid group and placebo group on basis of VAS score

5. Discussion

The primary aim of administering corticosteroid injections is often to inhibit the synthesis of arachidonic acid from membrane phospholipids. This mechanism effectively diminishes prostaglandin-mediated inflammation and pain. Studies have shown that corticosteroids have the capacity to hinder fibroblast proliferation and the expression of

ground substance proteins.[15] Administering a combination of corticosteroid and local anesthetic solutions before soft tissue injection presents various reported benefits, including temporary pain relief, dispersing potentially harmful corticosteroid crystals, and ensuring precise solution deposition.[16]

The fusiform thickening of the plantar fascia is a well-acknowledged feature of plantar fasciitis. A meta-analysis of diagnostic imaging studies revealed that individuals with plantar heel pain exhibit a substantially higher likelihood of having an abnormally thickened plantar fascia (> 4.0 mm) compared to asymptomatic controls, with the odds being more than 100 times greater. Additionally, it has indicated a noteworthy decrease in plantar fascia thickness shortly after corticosteroid injection.[17]

In a study, a connection was identified between the decrease in plantar fascia thickness and pain relief (Pearson $r = 0.61$, $P < 0.001$).[18] Nevertheless, given the absence of a control group for comparison in this study, it's crucial to acknowledge that the observed results might have been influenced, at least partially, by the natural progression of the condition. The existing evidence suggests that assessing plantar fascia thickness can offer valuable objective data, contributing to the evaluation of overall improvement in the condition. Ultrasound guidance is commonly employed for procedures like fluid aspiration, tissue biopsy, and therapeutic injections. Here, we introduce a method for the ultrasound-guided injection of the heel in patients with persistent plantar fasciitis. This technique allows accurate delivery of corticosteroid directly to the thickened and swollen plantar fascia.

6. Conclusion

This randomized trial investigates the effects of corticosteroid injection in individuals diagnosed with plantar fasciitis. It's important to acknowledge certain protocol aspects that might limit the generalizability of the findings to routine clinical settings, including the use of ultrasound-guided injection and the administration of a mixed corticosteroid solution with local anesthetics.

Despite these limitations, the trial aims to provide high-quality evidence on the pharmacological effects of corticosteroids in treating plantar fasciitis. The results within the defined protocol will be utilized to establish evidence-based recommendations for the use of corticosteroid injections as a treatment approach for this condition.

7. Source of Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

8. Conflict of Interest

None.

9. Data Availability Statement

The datasets generated and analyzed during the current study are not publicly available due to patient confidentiality concerns but are available from the corresponding author on reasonable request.

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