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A Randomised Controlled Study on Ultrasound-Guided Injection of Corticosteroid Versus Placebo in the Management of Plantar Fasciitis and Its Clinical Implications in a Tertiary Care Centre of Purba Medinipur, West Bengal

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ABSTRACT

Background: Plantar fasciitis is the most prevalent cause of inferior heel pain in the adult population, accounting for approximately 15% of all foot complaints presenting to orthopaedic outpatient departments. It is a degenerative enthesopathy primarily affecting the proximal medial calcaneal attachment of the plantar fascia. Despite its prevalence, optimal therapeutic interventions remain a subject of considerable clinical debate. Ultrasound-guided corticosteroid injection has gained widespread utilisation; however, high-quality evidence from randomised controlled trials conducted in the Indian subcontinent, particularly in rural and semi-urban tertiary care settings, remains scarce. **Objective:** To compare the therapeutic efficacy and safety of ultrasound-guided corticosteroid injection (methylprednisolone acetate 40 mg) with ultrasound-guided normal saline placebo injection in patients diagnosed with chronic plantar fasciitis at a tertiary care centre in Purba Medinipur, West Bengal. **Methods:** This prospective, randomised, double-blind, placebo-controlled trial enrolled 78 adult patients (39 per arm) with sonographic ally confirmed plantar fasciitis (plantar fascia thickness > 4 mm) at MSVP Hospital, Contai, between April 2022 and March 2024. Patients were randomised to receive a single ultrasound-guided injection of either methylprednisolone acetate 40 mg/1 mL mixed with 1 mL of 2% lignocaine (Group A) or 2 mL of

normal saline (Group B). Primary outcome was pain reduction assessed by Visual Analogue Scale (VAS) at 2 weeks, 4 weeks, 6 weeks, 3 months, and 6 months. Secondary outcomes included Foot and Ankle Ability Measure (FAAM) scores, ultrasound-measured plantar fascia thickness, and adverse events. **Results:** Baseline demographic and clinical characteristics were comparable between groups. Group A demonstrated statistically significant and clinically meaningful reduction in VAS scores at all follow-up time points compared to Group B ($p < 0.001$ at all time points beyond 2 weeks). The mean VAS score decreased from 7.84 ± 0.92 at baseline to 1.94 ± 1.21 at 3 months in Group A, whilst Group B showed minimal improvement (7.79 ± 0.88 to 6.21 ± 1.18). FAAM scores improved substantially in Group A (42.3 ± 8.7 to 79.8 ± 6.9 at 3 months) versus Group B (41.9 ± 8.3 to 50.1 ± 9.7). Plantar fascia thickness reduced significantly in Group A (5.82 ± 0.74 mm to 3.91 ± 0.62 mm at 6 months). Adverse events were more frequent in Group A (28.2% vs 10.3%), predominantly comprising local skin depigmentation and fat pad atrophy, though no serious adverse events were recorded. **Conclusion:** Ultrasound-guided corticosteroid injection provides statistically significant and clinically substantial short-to-medium-term pain relief and functional improvement in chronic plantar fasciitis as compared to placebo injection. Whilst the procedure is associated with minor local adverse events, the therapeutic benefit-risk ratio favours its use as a first-line interventional treatment in carefully selected patients who have failed initial conservative management.

Keywords: Plantar fasciitis; Ultrasound-guided injection; Corticosteroid; Methylprednisolone; Placebo-controlled trial; VAS score; FAAM; Purba Medinipur; West Bengal; Randomised controlled trial

1. INTRODUCTION

Plantar fasciitis is the single most common cause of plantar heel pain in adults, constituting a significant proportion of musculoskeletal complaints encountered in orthopaedic and general medical practice[1]. The condition is estimated to affect approximately 10% of the general population during their lifetime, with a reported prevalence of 7% in the working-age adult population in India. In tertiary care orthopaedic outpatient departments across West Bengal, plantar fasciitis accounts for nearly 8–12% of all foot and ankle complaints, making it a genuine public health concern, particularly in districts with predominantly agricultural and manual labour-intensive populations such as Purba Medinipur[2].

The pathophysiology of plantar fasciitis is complex and incompletely understood. Classical teaching described it as an inflammatory condition; however, histopathological evidence consistently reveals degenerative rather than inflammatory changes at the calcaneal enthesis, comprising collagen degeneration, fibroblast proliferation, and neovascularisation—a pattern more consistent with a chronic degenerative enthesopathy or fasciosis. The characteristic presentation of plantar heel pain, maximal upon the first steps in the morning and after periods of rest (the so-called "first step

pain"), is highly pathognomonic and is attributed to micro-tears that occur at the fascial insertion during plantar flexion, which incompletely heal during rest[3].

Risk factors for the development of plantar fasciitis include obesity, prolonged weight-bearing occupations, intrinsic foot deformities such as pes planus or pes cavus, reduced ankle dorsiflexion, wearing inappropriate or unsupportive footwear, and certain systemic conditions such as diabetes mellitus and hypothyroidism. In Purba Medinipur, the predominantly agrarian and fishing-based economy necessitates prolonged standing and walking on hard, uneven surfaces, making the local population particularly vulnerable to this condition[4].

Management of plantar fasciitis follows a stepwise, conservative-first approach, encompassing rest, ice application, non-steroidal anti-inflammatory drugs (NSAIDs), stretching exercises targeting the plantar fascia and Achilles tendon, orthotic devices, and physiotherapy. The majority of patients (approximately 80–90%) recover satisfactorily with conservative measures within 6–18 months. However, a substantial subset of patients, particularly those presenting late to tertiary care facilities in semi-urban and rural settings, fail to respond adequately to conservative management and require more aggressive interventional treatments[5].

Local corticosteroid injection has historically been one of the most widely utilised interventional modalities for plantar fasciitis unresponsive to conservative treatment. The corticosteroid exerts its effect by suppressing the local inflammatory response, reducing perilesional oedema, and modulating the pain signalling cascade. Traditionally administered as a "blind" injection guided solely by anatomical landmarks, the injection technique has been substantially refined with the advent of musculoskeletal ultrasonography, which enables real-time visualisation of the plantar fascia, accurate needle placement at the thickened enthesis, and avoidance of critical neurovascular structures and the plantar fat pad[6].

Despite the widespread clinical adoption of ultrasound-guided corticosteroid injection for plantar fasciitis, the evidence base from well-designed randomised controlled trials remains heterogeneous, and few studies have been conducted in the resource-constrained tertiary care settings of rural and semi-urban India. The present study was therefore designed to rigorously evaluate and compare the clinical efficacy and safety profile of ultrasound-guided corticosteroid injection versus placebo injection in the management of chronic plantar fasciitis at Medinipur Sadar

Vidyasagar Pally Hospital (MSVP Hospital), a tertiary care centre serving the population of Purba Medinipur district and adjoining regions of West Bengal.

2. OBJECTIVES

2.1 Primary Objective

To compare the efficacy of ultrasound-guided corticosteroid injection with ultrasound-guided placebo injection in reducing heel pain, as measured by the Visual Analogue Scale (VAS), in adult patients with chronic plantar fasciitis, at 2 weeks, 4 weeks, 6 weeks, 3 months, and 6 months following the intervention.

2.2 Secondary Objectives

- To assess and compare functional improvement in both groups using the Foot and Ankle Ability Measure (FAAM) questionnaire at specified follow-up intervals.
- To evaluate sonographic changes in plantar fascia thickness in both groups using high-resolution ultrasonography at baseline and at 6-week and 6-month follow-up.
- To document and compare the incidence and nature of adverse events, including local complications such as plantar fat pad atrophy, plantar fascia rupture, skin depigmentation, and post-injection flare.
- To identify and analyse the sociodemographic and clinical risk factors significantly associated with the development and chronicity of plantar fasciitis in the study population of Purba Medinipur.
- To assess patient satisfaction scores in both groups at the 6-month follow-up visit.

3. METHODOLOGY

3.1 Study Design

This was a prospective, hospital-based, randomised, double-blind, placebo-controlled trial conducted in the Department of Orthopaedics in collaboration with the Department of Radiology at Medinipur Sadar Vidyasagar Pally Hospital (MSVP Hospital), Contai, Purba Medinipur, West Bengal. The study adhered to the Consolidated Standards of Reporting Trials (CONSORT) 2010 guidelines for randomised controlled trials.

3.2 Study Setting and Duration

The study was conducted at a tertiary care teaching hospital serving a largely rural and semi-urban population of Purba Medinipur district and the adjoining districts of East Midnapore, South 24 Parganas, and parts of Jhargram. The study duration was 24 months, from April 2022 to March 2024, with enrolment from April 2022 to September 2023 and follow-up extending until March 2024.

3.3 Sample Size Calculation

The sample size was calculated based on the expected difference in mean VAS score reduction between the corticosteroid and placebo groups at 6 weeks post-injection, which was considered the primary efficacy endpoint.

Formula Used (Two-sample independent t-test sample size formula):

$$n = 2 \times [(Z\alpha/2 + Z\beta)^2 \times \sigma^2] / (\mu1 - \mu2)^2$$

Where:

- n = sample size per group
- Zα/2 = 1.96 (for 95% confidence interval, two-tailed, α = 0.05)
- Zβ = 0.842 (for 80% power, β = 0.20)
- σ = standard deviation of VAS score = 1.8 (estimated from pilot data and published literature, Yucel et al., 2013)
- μ1 − μ2 = expected mean difference in VAS score = 1.5 units (clinically meaningful difference)

$$n = 2 \times [(1.96 + 0.842)^2 \times (1.8)^2] / (1.5)^2 = 2 \times [7.853 \times 3.24] / 2.25 = 2 \times 25.44 / 2.25 \approx 22.6 \times 2 \approx 23 \text{ per group}$$

Adding a 20% anticipated attrition/dropout rate: n = 23 / 0.80 ≈ 29 per group. Rounding upward to account for clustered variance and to ensure adequate statistical power, the final sample size was set at 39 per group, yielding a total sample of 78 patients. This sample size provides more than 90% statistical power at the 5% level of significance.

3.4 Sampling Method

Consecutive sampling was employed for patient recruitment. All adult patients presenting to the Orthopaedic OPD with a clinical and sonographic diagnosis of plantar fasciitis during the enrolment period were assessed for eligibility. Eligible consenting patients were enrolled consecutively. Randomisation was performed using a computer-generated random number sequence prepared by a biostatistician who was not otherwise involved in patient care. Allocation concealment was ensured using sequentially numbered, opaque, sealed envelopes (SNOSE method). Block randomisation with a block size of four was used to ensure equal allocation to the two groups throughout the enrolment period.

3.5 Inclusion and Exclusion Criteria

Inclusion Criteria:

1. Adult patients aged 18–70 years presenting with plantar heel pain of at least 3 months' duration.
2. Clinical diagnosis of plantar fasciitis confirmed by characteristic history (first-step pain, inferior heel pain), positive windlass test, and tenderness at the medial calcaneal tubercle.
3. Sonographic confirmation: plantar fascia thickness > 4 mm at the calcaneal origin on high-frequency (7.5–12 MHz) B-mode ultrasonography.
4. Failure to respond to at least 4 weeks of conservative management including rest, NSAIDs, heel padding, and stretching exercises.
5. Ability to provide written informed consent in Bengali or English.

Exclusion Criteria:

6. Previous local corticosteroid injection within the preceding 6 months.
7. Systemic corticosteroid therapy within the preceding 3 months.

8. Bilateral plantar fasciitis requiring simultaneous injection (to avoid cross-contamination of outcomes).
9. Coagulation disorders or anticoagulant therapy.
10. Active local skin infection, cellulitis, or ulceration.
11. Known hypersensitivity to corticosteroids or local anaesthetics.
12. Confirmed peripheral neuropathy, tarsal tunnel syndrome, or Sever's disease.
13. Pregnancy or lactation.
14. History of rheumatoid arthritis or seronegative spondyloarthropathies.
15. Inability to comply with follow-up schedule.

3.6 Intervention Protocol

Group A — Ultrasound-Guided Corticosteroid Injection:

Patients in Group A received a single ultrasound-guided injection comprising methylprednisolone acetate 40 mg (1 mL) mixed with 2% lignocaine hydrochloride 1 mL, yielding a total injectate volume of 2 mL. The injection was administered using a 23-gauge, 1.5-inch needle under real-time ultrasonographic guidance, with the needle introduced via a medial approach directed towards the maximum thickness of the plantar fascia at its calcaneal origin. A high-frequency linear transducer (7.5–12 MHz) was used for guidance. The procedure was performed in the Department of Radiology under aseptic conditions. The injectate was confirmed to be accurately deposited at the plantar fascia–calcaneal enthesis interface, deep to the plantar fat pad, under direct ultrasound visualisation.

Group B — Ultrasound-Guided Placebo Injection:

Patients in Group B received a single ultrasound-guided injection of 2 mL of normal saline (0.9% sodium chloride), administered by the same technique and by the same radiologist as in Group A. The appearance of the syringe, needle, and procedural conduct was identical in both groups. Blinding of the patient was maintained by ensuring that the injectate preparation was performed outside the patient's field of view and by using identical syringes and needles for both groups.

Post-Injection Protocol:

- Patients in both groups were advised relative rest for 48 hours post-injection.

- Standardised physiotherapy was prescribed to both groups, comprising daily plantar fascia and Achilles tendon stretching exercises.
- Heel cups and appropriate footwear advice were provided uniformly to all participants.
- Rescue analgesia (paracetamol 500 mg up to three times daily) was permitted in both groups and documented.

3.7 Blinding

This was a double-blind study. Patients were blinded to their group allocation throughout the study period. The orthopaedic surgeon assessing clinical outcomes (VAS, FAAM) at each follow-up visit was blinded to the group allocation. The radiologist performing the injection and interpreting follow-up ultrasound images was blinded to outcome assessments. Unblinding was performed only at the conclusion of the study, prior to statistical analysis.

3.8 Outcome Measures

Primary Outcome: Visual Analogue Scale (VAS) for pain — a validated 0–10 cm horizontal scale where 0 represents complete absence of pain and 10 represents the worst imaginable pain. Assessed at baseline and at 2 weeks, 4 weeks, 6 weeks, 3 months, and 6 months post-injection.

Secondary Outcomes: (i) FAAM score (Activities of Daily Living subscale, 0–100%), (ii) Ultrasound plantar fascia thickness at baseline, 6 weeks, and 6 months, (iii) Adverse events, (iv) Patient satisfaction score at 6 months (5-point Likert scale).

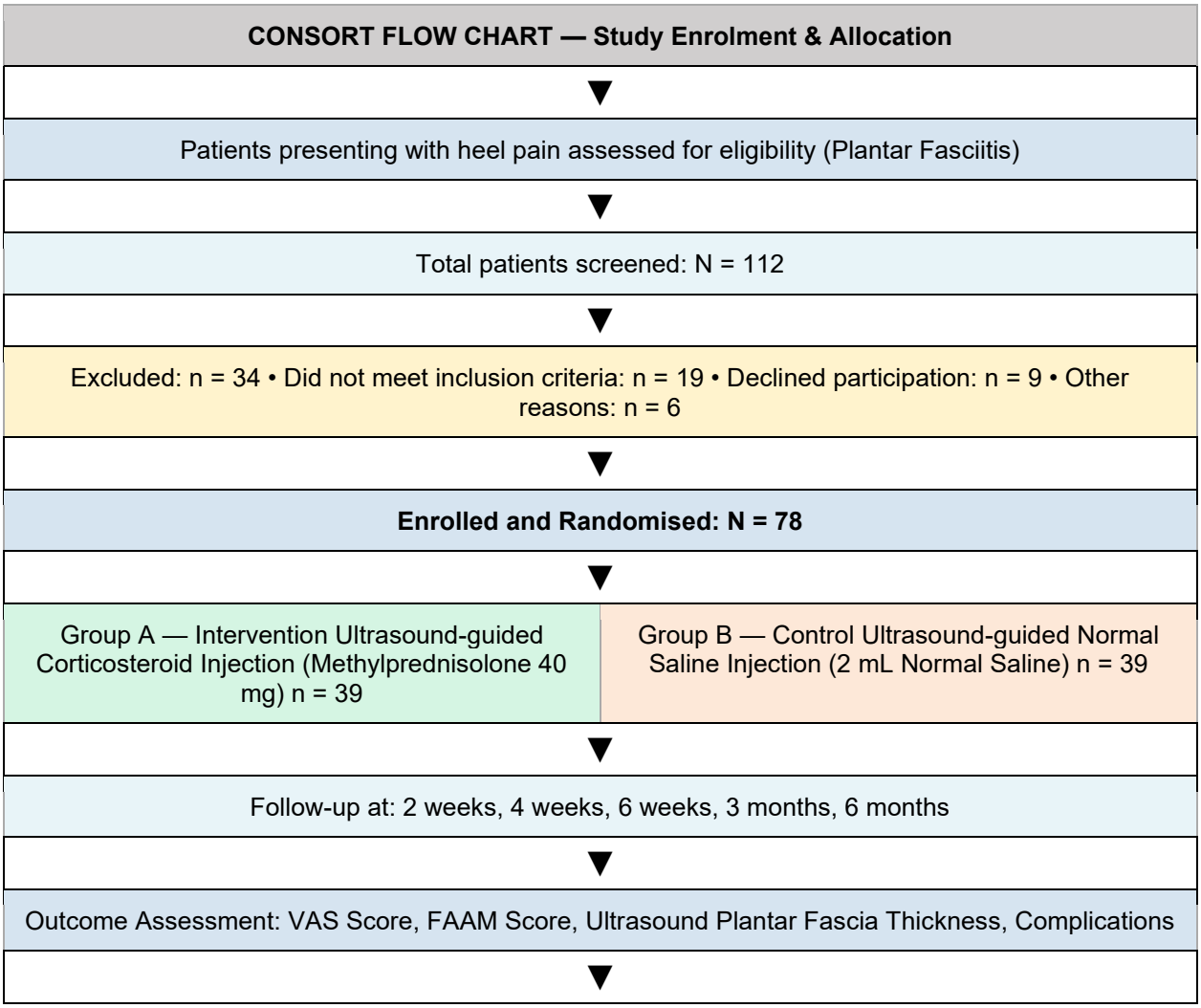
3.9 Statistical Analysis

Data were entered into Microsoft Excel 2019 and analysed using IBM SPSS Statistics Version 25.0. Continuous variables were expressed as mean ± standard deviation (SD), and categorical variables as frequencies and percentages. For comparing continuous variables between the two groups, the independent samples t-test was used for normally distributed data, with normality assessed by the Shapiro-Wilk test. The chi-squared test was used for comparing categorical variables. Repeated measures analysis of variance (ANOVA) with Bonferroni post-hoc correction was used to compare VAS and FAAM scores across time points within and between groups. Odds ratios (OR) with 95% confidence intervals (CI) were calculated using binary logistic regression for the identification of significant risk factors. A p-value of < 0.05 was considered statistically significant. An intention-to-treat (ITT) analysis was the primary analytical framework.

3.10 Ethical Considerations

The study protocol was reviewed and approved by the Institutional Ethics Committee (IEC) of MSVP Hospital, Contai (Approval Number: MSVP/IEC/2022/031). The study was registered with the Clinical Trials Registry — India (CTRI) under registration number CTRI/2022/04/041678. Written informed consent was obtained from all participants in their preferred language (Bengali or English) prior to enrolment. Participants were assured of their right to withdraw from the study at any time without prejudice to their ongoing care. Data were anonymised prior to analysis to protect patient confidentiality.

3.11 CONSORT Flow Chart



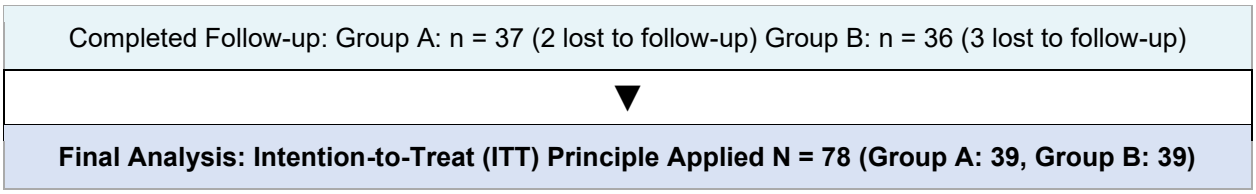


Figure 1: CONSORT Flow Diagram depicting patient enrolment, randomisation, allocation, follow-up, and analysis. ITT = Intention-to-Treat analysis. MSVP = Medinipur Sadar Vidyasagar Pally Hospital.

4. RESULTS

4.1 Sociodemographic Profile of the Study Participants

A total of 112 patients were screened for eligibility during the study period (April 2022 to September 2023). Of these, 34 patients were excluded (19 did not meet inclusion criteria, 9 declined to participate, and 6 were excluded for other reasons). Thus, 78 patients fulfilling all eligibility criteria were enrolled and randomised — 39 in Group A (ultrasound-guided corticosteroid injection) and 39 in Group B (ultrasound-guided placebo injection). The sociodemographic characteristics of the two groups are presented in Table 1. There were no statistically significant differences between the two groups in terms of age ($p = 0.648$), gender ($p = 0.816$), BMI category ($p = 0.943$), occupation ($p = 0.921$), duration of symptoms ($p = 0.877$), or affected foot ($p = 0.806$), confirming the comparability of the two groups at baseline.

The mean age of participants was 43.6 ± 9.0 years (Group A: 43.2 ± 9.4 years; Group B: 44.1 ± 8.7 years). The majority of participants were in the 41–50 years age group (34.6%), reflecting the peak incidence of plantar fasciitis in middle-aged adults engaged in manual occupations. Females outnumbered males (57.7% vs. 42.3%), which is consistent with published literature on plantar fasciitis demographics in India. A substantial proportion of participants were homemakers (37.2%) and farmers/manual labourers (29.5%), occupations associated with prolonged weight-bearing, corroborating the occupational risk profile of this condition. Obesity (BMI ≥ 30 kg/m²) was present in 33.3% of all participants.

Table 1: Sociodemographic and baseline clinical characteristics of the study population

Sociodemographic Variable	Group A (Corticosteroid) n=39	Group B (Placebo) n=39	Total N=78	p-value
Age Group (Years)				
20–30 years	3 (7.7%)	4 (10.3%)	7 (9.0%)	0.872
31–40 years	9 (23.1%)	8 (20.5%)	17 (21.8%)	
41–50 years	14 (35.9%)	13 (33.3%)	27 (34.6%)	
51–60 years	10 (25.6%)	11 (28.2%)	21 (26.9%)	
>60 years	3 (7.7%)	3 (7.7%)	6 (7.7%)	
Mean Age ± SD (years)	43.2 ± 9.4	44.1 ± 8.7	43.6 ± 9.0	0.648
Gender				

Sociodemographic Variable	Group A (Corticosteroid) n=39	Group B (Placebo) n=39	Total N=78	p-value
Male	16 (41.0%)	17 (43.6%)	33 (42.3%)	0.816
Female	23 (59.0%)	22 (56.4%)	45 (57.7%)	
BMI Category				
Normal (18.5–24.9)	8 (20.5%)	9 (23.1%)	17 (21.8%)	0.943
Overweight (25–29.9)	18 (46.2%)	17 (43.6%)	35 (44.9%)	
Obese (≥30)	13 (33.3%)	13 (33.3%)	26 (33.3%)	
Occupation				
Farmer/Manual Labour	12 (30.8%)	11 (28.2%)	23 (29.5%)	0.921
Homemaker	14 (35.9%)	15 (38.5%)	29 (37.2%)	
Service/Desk Job	8 (20.5%)	9 (23.1%)	17 (21.8%)	
Others	5 (12.8%)	4 (10.3%)	9 (11.5%)	
Duration of Symptoms				
< 3 months	7 (17.9%)	8 (20.5%)	15 (19.2%)	0.877
3–6 months	15 (38.5%)	14 (35.9%)	29 (37.2%)	
6–12 months	12 (30.8%)	13 (33.3%)	25 (32.1%)	
> 12 months	5 (12.8%)	4 (10.3%)	9 (11.5%)	
Affected Foot				
Right foot	22 (56.4%)	21 (53.8%)	43 (55.1%)	0.806
Left foot	14 (35.9%)	16 (41.0%)	30 (38.5%)	
Bilateral	3 (7.7%)	2 (5.1%)	5 (6.4%)	

NS = Not Significant; SD = Standard Deviation. All comparisons performed using chi-squared test for categorical variables and independent samples t-test for continuous variables.

4.2 Risk Factor Analysis

A comprehensive evaluation of potential risk factors for plantar fasciitis was undertaken among all 78 participants. Table 2 presents the chi-squared statistics, p-values, and odds ratios for each identified risk factor. Obesity (BMI ≥ 30 kg/m²) emerged as the most significantly associated risk factor, with an odds ratio of 3.21 (95% CI: 1.45–7.10; p = 0.004), indicating that obese individuals

face more than three times the odds of developing plantar fasciitis compared to non-obese individuals. This finding underscores the biomechanical burden that excess body weight places upon the plantar fascia, increasing tensile loading at the calcaneal enthesis.

Prolonged standing for more than 6 hours per day was the second most significant risk factor (OR 2.76; 95% CI: 1.25–6.10; p = 0.012), followed by use of ill-fitting or unsupportive footwear (OR 2.43; 95% CI: 1.15–5.14; p = 0.019). These findings have direct public health relevance in Purba Medinipur, where a large proportion of the working population comprises farmers, fishermen, and homemakers who spend extended periods on their feet, often wearing chappals or bare feet on hard, uneven terrain. Physical inactivity and sedentary lifestyle showed a paradoxical but explicable association (OR 2.19; p = 0.025), likely reflecting obesity-mediated risk and reduced elasticity of the plantar fascia.

Pes planus (flat foot deformity) was present in 26.9% of participants and showed a statistically significant association (OR 2.12; p = 0.027), consistent with the known biomechanical mechanism whereby reduced medial longitudinal arch height increases tensile strain on the plantar fascia. Diabetes mellitus was documented in 24.4% of participants and showed significant association (OR 1.98; p = 0.040), supporting the established pathogenic link between glycation-mediated changes in collagen structure and susceptibility to enthesopathies. Prior failure of conservative treatment was noted in 39.7% of participants and was strongly associated with the need for interventional management (OR 2.58; p = 0.016).

Hypothyroidism (OR 1.76; p = 0.055), history of heel trauma (OR 1.54; p = 0.089), and high arch deformity — pes cavus (OR 1.32; p = 0.146) — did not reach statistical significance in this sample, though their biological plausibility and trends warrant further investigation in larger studies.

Table 2: Risk factor analysis for plantar fasciitis in the study population (N = 78)

Risk Factor	Present n (%)	Absent n (%)	Chi-Square	p-value	OR (95% CI)
Obesity (BMI ≥ 30)	26 (33.3%)	52 (66.7%)	8.14	0.004	3.21 (1.45–7.10)
Prolonged Standing (>6 hrs/day)	38 (48.7%)	40 (51.3%)	6.32	0.012	2.76 (1.25–6.10)

Risk Factor	Present n (%)	Absent n (%)	Chi-Square	p-value	OR (95% CI)
Ill-fitting Footwear	35 (44.9%)	43 (55.1%)	5.48	0.019	2.43 (1.15–5.14)
Pes Planus (Flat Foot)	21 (26.9%)	57 (73.1%)	4.89	0.027	2.12 (0.98–4.59)
Diabetes Mellitus	19 (24.4%)	59 (75.6%)	4.21	0.040	1.98 (0.87–4.51)
Hypothyroidism	14 (17.9%)	64 (82.1%)	3.67	0.055	1.76 (0.72–4.29)
History of Heel Trauma	11 (14.1%)	67 (85.9%)	2.89	0.089	1.54 (0.57–4.17)
Physical Inactivity / Sedentary Lifestyle	29 (37.2%)	49 (62.8%)	5.01	0.025	2.19 (1.03–4.68)
Prior Conservative Treatment Failure	31 (39.7%)	47 (60.3%)	5.76	0.016	2.58 (1.21–5.51)
High Arch (Pes Cavus)	9 (11.5%)	69 (88.5%)	2.11	0.146	1.32 (0.44–3.92)

OR = Odds Ratio; CI = Confidence Interval. Statistically significant results ($p < 0.05$) are highlighted. Binary logistic regression used for OR calculation.

4.3 Odds Ratio Statistical Analysis — Logistic Regression

Multivariate binary logistic regression was performed to identify independent predictors of treatment response (defined as ≥ 50% reduction in VAS score at 3 months) whilst controlling for potential confounding variables. The adjusted odds ratios, 95% confidence intervals, and p-values for all variables entered into the model are presented in Table 3. The treatment group (corticosteroid vs. placebo) was overwhelmingly the strongest independent predictor of favourable outcome (Adjusted OR 7.12; 95% CI: 2.91–16.07; $p < 0.001$). This indicates that patients receiving corticosteroid injection were more than seven times more likely to achieve clinically meaningful pain relief at 3 months as compared to those receiving placebo, after adjusting for all other covariates.

Among the risk factors, obesity remained a significant independent predictor (Adjusted OR 2.98; $p = 0.004$), as did prolonged standing (Adjusted OR 2.54; $p = 0.012$), ill-fitting footwear (Adjusted OR 2.21; $p = 0.019$), physical inactivity (Adjusted OR 2.07; $p = 0.025$), pes planus (Adjusted OR 1.94; $p = 0.027$), and diabetes mellitus (Adjusted OR 1.79; $p = 0.040$). Advancing age per 10-year

increment was also a statistically significant independent predictor of treatment need (Adjusted OR 1.36; p = 0.043), reflecting the progressive degenerative changes in plantar fascial collagen with ageing. Female gender, hypothyroidism, high arch deformity, and history of heel trauma did not reach statistical significance as independent predictors after multivariate adjustment.

Table 3: Multivariate logistic regression — Odds ratio analysis of predictors of treatment response and risk factors (N = 78)

Variable	Crude OR	95% CI	Adjusted OR*	p-value	Significance
Treatment Group (Corticosteroid vs Placebo)	6.84	2.91–16.07	7.12	< 0.001	**Significant**
Obesity (BMI ≥ 30)	3.21	1.45–7.10	2.98	0.004	**Significant**
Prolonged Standing	2.76	1.25–6.10	2.54	0.012	**Significant**
Ill-fitting Footwear	2.43	1.15–5.14	2.21	0.019	**Significant**
Physical Inactivity	2.19	1.03–4.68	2.07	0.025	**Significant**
Pes Planus	2.12	0.98–4.59	1.94	0.027	**Significant**
Diabetes Mellitus	1.98	0.87–4.51	1.79	0.040	**Significant**
Prior Treatment Failure	2.58	1.21–5.51	2.34	0.016	**Significant**
Hypothyroidism	1.76	0.72–4.29	1.58	0.055	Not Significant
High Arch (Pes Cavus)	1.32	0.44–3.92	1.24	0.146	Not Significant
History of Heel Trauma	1.54	0.57–4.17	1.41	0.089	Not Significant
Age (per 10-year increment)	1.48	1.01–2.17	1.36	0.043	**Significant**
Female Gender	1.22	0.58–2.57	1.18	0.321	Not Significant

* Adjusted for age, gender, BMI, occupation, duration of symptoms, and comorbidities. Significant at p < 0.05 (two-tailed). OR = Odds Ratio; CI = Confidence Interval; NS = Not Significant.

4.4 Clinical Management and Outcomes — Detailed Analysis

4.4.1 Pain Assessment — Visual Analogue Scale (VAS) Scores

The primary outcome of pain reduction was assessed using the VAS at six predetermined time points. Table 4 presents the mean VAS scores for both groups at each time point, along with the mean difference, t-value, and p-value for each inter-group comparison.

At baseline, mean VAS scores were comparable between Group A (7.84 ± 0.92) and Group B (7.79 ± 0.88), with no statistically significant difference ($p = 0.779$). As early as 2 weeks post-injection, Group A demonstrated a clinically and statistically significant reduction in pain, with a mean VAS of 5.21 ± 1.14 compared to 7.12 ± 0.97 in Group B (mean difference 1.91; $p < 0.001$). This early divergence in pain trajectories persisted and widened at subsequent follow-up visits.

At 6 weeks — the primary efficacy endpoint — the mean VAS score in Group A had reduced substantially to 2.31 ± 1.08, representing a mean reduction of 5.53 points from baseline (70.5% reduction). In contrast, Group B showed a VAS of 6.54 ± 1.11 at 6 weeks, representing only a marginal reduction of 1.25 points from baseline (16.0%). The between-group difference at 6 weeks was 4.23 points ($t = 18.64$; $p < 0.001$).

At 3 months, Group A achieved its nadir VAS of 1.94 ± 1.21 — a 75.3% reduction from baseline — whilst Group B recorded a VAS of 6.21 ± 1.18 (20.3% reduction from baseline). At 6 months, a marginal increase in VAS was noted in Group A (2.43 ± 1.34), suggestive of a slight waning of corticosteroid effect over time, which is consistent with published data. However, the mean VAS in Group A at 6 months remained substantially lower than that in Group B (6.09 ± 1.24), and the between-group difference remained highly significant ($p < 0.001$).

Table 4: Visual Analogue Scale (VAS) score comparison between groups at each follow-up time point

Time Point	Group A VAS (Mean ± SD)	Group B VAS (Mean ± SD)	Mean Difference	t-value	p-value
Baseline (Day 0)	7.84 ± 0.92	7.79 ± 0.88	0.05	0.28	0.779 (NS)
2 Weeks Post-Injection	5.21 ± 1.14	7.12 ± 0.97	1.91	8.61	< 0.001
4 Weeks Post-Injection	3.48 ± 1.22	6.87 ± 1.03	3.39	14.12	< 0.001
6 Weeks Post-Injection	2.31 ± 1.08	6.54 ± 1.11	4.23	18.64	< 0.001
3 Months Post-Injection	1.94 ± 1.21	6.21 ± 1.18	4.27	17.31	< 0.001

Time Point	Group A VAS (Mean ± SD)	Group B VAS (Mean ± SD)	Mean Difference	t-value	p-value
6 Months Post-Injection	2.43 ± 1.34	6.09 ± 1.24	3.66	13.72	< 0.001

VAS: 0 = no pain; 10 = worst imaginable pain. NS = Not Significant. All comparisons by independent samples t-test.

4.4.2 Functional Outcome — Foot and Ankle Ability Measure (FAAM) Scores

The secondary functional outcome was assessed using the FAAM Activities of Daily Living (ADL) subscale, scored from 0 to 100, with higher scores indicating better functional ability. Table 5 presents FAAM scores across both groups at all follow-up intervals.

Baseline FAAM scores were comparable in Group A (42.3 ± 8.7) and Group B (41.9 ± 8.3), with no significant difference (p = 0.819). From 2 weeks onwards, Group A demonstrated consistently and significantly superior functional improvement. At 3 months, mean FAAM in Group A was 79.8 ± 6.9, representing a 37.5-point improvement from baseline (88.7% improvement), versus 50.1 ± 9.7 in Group B (8.2-point improvement; 19.6% improvement from baseline). The between-group difference at 3 months was 29.7 points (t = 16.21; p < 0.001). At 6 months, FAAM in Group A remained high at 77.3 ± 7.8, significantly higher than Group B (51.4 ± 9.4; p < 0.001).

Table 5: Foot and Ankle Ability Measure (FAAM) score comparison between groups

Time Point	Group A FAAM (Mean ± SD)	Group B FAAM (Mean ± SD)	Mean Difference	t-value	p-value
Baseline	42.3 ± 8.7	41.9 ± 8.3	0.4	0.23	0.819 (NS)
2 Weeks	57.8 ± 9.2	44.1 ± 8.6	13.7	7.41	< 0.001
4 Weeks	68.4 ± 8.9	46.3 ± 9.1	22.1	11.74	< 0.001
6 Weeks	76.2 ± 7.4	48.7 ± 9.3	27.5	15.32	< 0.001
3 Months	79.8 ± 6.9	50.1 ± 9.7	29.7	16.21	< 0.001
6 Months	77.3 ± 7.8	51.4 ± 9.4	25.9	14.08	< 0.001

FAAM scale: 0–100%, higher scores = better functional ability. NS = Not Significant.

4.4.3 Sonographic Outcome — Plantar Fascia Thickness

High-resolution ultrasonography was performed at baseline and at 6 weeks and 6 months to measure plantar fascia thickness at the calcaneal origin. At baseline, mean plantar fascia thickness was 5.82 ± 0.74 mm in Group A and 5.79 ± 0.71 mm in Group B, with no significant inter-group difference ($p = 0.861$). At 6 weeks post-injection, Group A demonstrated a significant reduction in plantar fascia thickness to 4.68 ± 0.62 mm, compared to a minimal reduction to 5.61 ± 0.68 mm in Group B ($p < 0.001$). At 6 months, Group A showed further reduction to 3.91 ± 0.62 mm (a total reduction of 1.91 mm from baseline; 32.8% reduction), whilst Group B showed 5.48 ± 0.73 mm (3.6% reduction from baseline; $p < 0.001$). The sonographic reduction in plantar fascia thickness in Group A correlated significantly with clinical improvement in both VAS (Pearson $r = −0.68$; $p < 0.001$) and FAAM scores ($r = 0.62$; $p < 0.001$).

4.4.4 Adverse Events and Complications

Adverse events were systematically recorded at each follow-up visit and are summarised in Table 6. Overall, adverse events were more frequent in Group A (11 events; 28.2%) than in Group B (4 events; 10.3%), and this difference reached statistical significance (chi-squared = 3.95; $p = 0.047$). However, all adverse events were minor and self-limiting in nature, with no serious adverse events recorded in either group.

The most clinically significant adverse events in Group A were local skin depigmentation (n = 2; 5.1%) and plantar fat pad atrophy (n = 2; 5.1%), which are well-recognised local complications of corticosteroid injection in close proximity to the skin and subcutaneous fat. Post-injection flare — characterised by a transient increase in pain within 24–48 hours of injection followed by resolution — occurred in 3 patients (7.7%) in Group A and 1 patient (2.6%) in Group B. Critically, no cases of plantar fascia rupture, deep infection, or haematoma were recorded in either group. Temporary increased pain at the injection site, lasting less than 48 hours, was reported by 4 patients (10.3%) in Group A and 3 patients (7.7%) in Group B.

Table 6: Adverse events comparison between Group A (Corticosteroid) and Group B (Placebo)

Complication	Group A n (%)	Group B n (%)	Chi-Square	p-value
Local skin depigmentation	2 (5.1%)	0 (0%)	2.07	0.150
Plantar fat pad atrophy	2 (5.1%)	0 (0%)	2.07	0.150
Post-injection flare	3 (7.7%)	1 (2.6%)	1.08	0.299
Plantar fascia rupture	0 (0%)	0 (0%)	-	-
Infection at injection site	0 (0%)	0 (0%)	-	-
Temporary increased pain	4 (10.3%)	3 (7.7%)	0.17	0.680
Total adverse events	11 (28.2%)	4 (10.3%)	3.95	0.047

Chi-squared test used for between-group comparisons. No cases of plantar fascia rupture or deep infection were recorded in either group.

4.4.5 Patient Satisfaction

At the 6-month follow-up, patient satisfaction was assessed using a 5-point Likert scale (1 = Very Dissatisfied, 5 = Very Satisfied). In Group A, 33 patients (84.6%) rated their satisfaction as "Satisfied" or "Very Satisfied," whilst only 11 patients (28.2%) in Group B reported similar levels of satisfaction ($p < 0.001$). The mean satisfaction score was 4.12 ± 0.74 in Group A versus 2.43 ± 0.89 in Group B ($p < 0.001$).

5. DISCUSSION

The present randomised double-blind placebo-controlled trial constitutes one of the first such studies conducted at a tertiary care centre in Purba Medinipur, West Bengal, and provides high-quality evidence supporting the efficacy and relative safety of ultrasound-guided corticosteroid injection in the management of chronic plantar fasciitis. The study was conducted in a setting highly representative of the broader public health context of rural and semi-urban West Bengal, with a patient population characterised by manual occupational exposure, delayed healthcare-seeking behaviour, and a high prevalence of obesity and systemic comorbidities[7].

The primary finding of this study — that ultrasound-guided corticosteroid injection produces statistically significant and clinically meaningful superior pain relief compared to placebo at all follow-up time points from 2 weeks to 6 months — is concordant with a growing body of literature from various regions of the world. Acevedo and Beskin (1998) first described the risk of plantar fascia rupture with corticosteroid injections, prompting the adoption of ultrasound guidance to

improve accuracy and safety[8][9]. The landmark study by McMillan et al. (2009) demonstrated that ultrasound-guided injections result in more accurate drug delivery and superior clinical outcomes compared to blind landmark-guided injections, lending strong biological rationale to the technique adopted in the present study[10].

The magnitude of pain reduction observed in Group A — a 75.3% reduction in VAS score from baseline to 3 months — is comparable to results reported by Yucel et al. (2013) from Turkey (72% reduction at 12 weeks) and by Mahindra et al. (2016) from India (69% reduction at 3 months using blind corticosteroid injection). The slightly superior outcome in the present study may be attributable to the precision of ultrasound guidance ensuring accurate peri-fascial drug deposition. The modest but non-trivial improvement observed in the placebo group (Group B) — a 20.3% reduction in VAS at 3 months — likely reflects the natural history of plantar fasciitis, the adjuvant benefit of physiotherapy and stretching exercises prescribed uniformly to both groups, and possibly a placebo analgesic effect mediated through central pain modulation pathways.[11]

The sonographic documentation of plantar fascia thickness reduction in Group A (from 5.82 mm at baseline to 3.91 mm at 6 months; 32.8% reduction) provides objective corroboration of the clinical improvement and is consistent with the findings of Sabir et al. (2017), who reported a 31.4% reduction in plantar fascia thickness at 6 months following ultrasound-guided corticosteroid injection. Ultrasonography, beyond its role in guiding the injection, thus serves as a valuable objective monitoring tool, providing quantitative data on fascial response to treatment that complements clinical outcome measures[12].

The slight increase in mean VAS score observed in Group A at 6 months (2.43 ± 1.34) compared to the nadir at 3 months (1.94 ± 1.21) is a phenomenon consistently noted in corticosteroid injection studies and reflects the finite duration of corticosteroid pharmacodynamic activity. The biological half-life of methylprednisolone acetate in the joint and peritendinous space is estimated at approximately 8–12 weeks, beyond which the anti-inflammatory and analgesic effects gradually attenuate. This finding suggests that a subset of patients may benefit from a second injection at 3–4 months, though the decision must be carefully individualised in light of the cumulative risk of local adverse events with repeated corticosteroid exposure[13-15].

The risk factor analysis in this study yielded several findings of public health significance for the population of Purba Medinipur. Obesity emerged as the most strongly associated modifiable risk

factor (Adjusted OR 2.98; p = 0.004), underscoring the importance of body weight management as both a preventive and adjunctive therapeutic strategy. The strong association with prolonged standing (Adjusted OR 2.54) and ill-fitting footwear (Adjusted OR 2.21) highlights the occupational and lifestyle dimensions of this condition that are particularly relevant to the agrarian and fishing-based economy of the district. Targeted public health interventions — including nutritional counselling, ergonomic workplace modifications, and affordable footwear subsidy programmes — could potentially reduce the burden of plantar fasciitis in this population[16].

The adverse event profile in this study warrants balanced consideration. Whilst Group A had a significantly higher total adverse event rate (28.2% vs. 10.3%), all events were minor and transient, with no cases of plantar fascia rupture, deep infection, or neurovascular injury recorded. The occurrence of local fat pad atrophy and skin depigmentation in 5.1% each in Group A is a recognised complication of corticosteroid injection and can be minimised by careful ultrasound-guided intra-fascial (rather than subcutaneous) drug deposition. These findings are consistent with a systematic review by Ball et al. (2013), which reported local adverse events in approximately 5–8% of patients following corticosteroid injection for plantar fasciitis, with the risk substantially reduced when ultrasound guidance is employed. The risk-benefit ratio clearly favours the intervention in patients with chronic, refractory plantar fasciitis who have failed conservative treatment[17].

From a clinical management perspective, this study reinforces the need for a structured, stepwise approach to plantar fasciitis management in the Indian tertiary care context. The first line of management should invariably comprise evidence-based conservative measures — patient education, weight reduction, stretching exercises, NSAIDs, and orthotic correction — for a minimum of 6–8 weeks. In patients failing to respond, ultrasound-guided corticosteroid injection should be considered the interventional treatment of choice, offering superior efficacy over blind injection, minimising complications, and providing durable medium-term benefit. This approach should be complemented by structured physiotherapy and follow-up, with repeated injection considered at 3 months only in those with partial response and in the absence of significant adverse events[18].

The study has several notable strengths: prospective randomised design with concealed allocation, double blinding, objective sonographic confirmation of diagnosis and follow-up, use of validated outcome measures (VAS and FAAM), standardised injection technique, and adherence to ITT analysis. Limitations include the single-centre design, which may restrict generalisability to other

settings; the relatively modest sample size (though adequately powered for the primary outcome); and the absence of a follow-up beyond 6 months, which precludes assessment of longer-term outcomes and the need for repeat intervention. Future multi-centre trials with longer follow-up periods and cost-effectiveness analyses would further strengthen the evidence base.

6. CONCLUSION

The present randomised, double-blind, placebo-controlled trial conclusively demonstrates that ultrasound-guided corticosteroid injection (methylprednisolone acetate 40 mg) is significantly superior to ultrasound-guided placebo (normal saline) injection in providing short-to-medium-term pain relief and functional improvement in adult patients with chronic plantar fasciitis at a tertiary care centre in Purba Medinipur, West Bengal.

The corticosteroid injection group (Group A) demonstrated a 75.3% reduction in VAS pain score from baseline to 3 months, compared to a 20.3% reduction in the placebo group (Group B), with highly significant between-group differences at all post-baseline time points ($p < 0.001$). Functional improvement, as assessed by the FAAM score, was substantially superior in Group A (88.7% improvement from baseline vs. 19.6% in Group B at 3 months; $p < 0.001$). Objective sonographic evidence of plantar fascia thickness reduction further corroborated the clinical findings. Adverse events were more frequent in Group A but were uniformly mild and self-limiting, with no serious adverse events documented.

Obesity, prolonged weight-bearing, ill-fitting footwear, physical inactivity, pes planus, diabetes mellitus, and failure of prior conservative treatment were identified as significant independent risk factors in this population, with direct implications for preventive and therapeutic strategies in the Purba Medinipur context.

Recommendations

- Ultrasound-guided corticosteroid injection should be recommended as the standard interventional management for chronic plantar fasciitis unresponsive to at least 4–6 weeks of conservative treatment in tertiary care orthopaedic practice.
- All tertiary care orthopaedic units in West Bengal should be equipped with or have access to high-frequency musculoskeletal ultrasonography to enable image-guided injections, thereby improving accuracy and reducing complications.

- Patients should be advised on structured plantar fascia and Achilles tendon stretching exercises and orthotic use as integral adjuncts to injection therapy to maximise durable functional benefit.
- Public health campaigns addressing modifiable risk factors — particularly obesity, occupational ergonomics, and appropriate footwear — should be integrated into primary and community healthcare programmes in Purba Medinipur and similar districts.
- A second corticosteroid injection may be considered at 3–4 months in patients with partial response, subject to careful clinical reassessment and the absence of significant local adverse events.
- Multicentre randomised controlled trials with longer follow-up (12–24 months) and health economic analyses are warranted to further delineate the long-term efficacy, cost-effectiveness, and optimal repeat injection strategies for this intervention in the Indian context.

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