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Original Article

Physical Medicine and Rehabilitation Section

Comparison between Ultrasound-guided Pulsed Radiofrequency Ablation of the Medial Calcaneal Nerve and Extracorporeal Shockwave Therapy in Managing Recalcitrant Plantar Fasciitis: A Randomised Controlled Trial

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ABSTRACT

Introduction: Plantar Fasciitis (PF) is one of the most common causes of heel pain, with a prevalence ranging from 3.6-7% in the general population. Approximately 90% of patients with PF respond well to conservative therapy, including rest, stretching, analgesics, physical therapy, shoe modifications, or steroid injections. However, around 10% of patients have recalcitrant cases that require invasive or surgical interventions. Pulsed Radiofrequency Ablation (PRFA) is a non neurodestructive method that provides non surgical pain relief in such cases.

Aim: To compare the effectiveness of ultrasound-guided PRFA of the Medial Calcaneal Nerve (MCN) and Extracorporeal Shockwave Therapy (ESWT) in managing recalcitrant PF.

Materials and Methods: This randomised controlled trial was conducted at the Department of Physical Medicine and Rehabilitation, Regional Institute of Medical Sciences, Imphal, Manipur, India over a two-year period from September 2018 to August 2020. A total of 78 patients with PF were included in the study, divided equally into two groups: a study group and a control group, each consisting of 39 participants. The study group received PRFA of the MCN, while the control group received ESWT of the plantar fascia. The Visual Analog Scale (VAS), Plantar Fascia Thickness (PFT), and American Orthopaedic Foot and Ankle Society (AOFAS) hindfoot score were measured at 1, 4, 12, and 24 weeks as outcome variables. Data analysis was performed using Statistical Package for the Social Sciences (SPSS) version 21.0, and statistical tests like Chi-square test, t-test, and repeated measures Analysis of Variance (ANOVA) were used. A p-value of <0.05 was considered significant.

Results: Of the 78 patients included in the study, 42 (53.8%) were females and 36 (46.2%) were males, with a mean age of 41.08±10.09 years. The VAS score in the study group improved from 5.51±0.82 at baseline to 1.92±0.80 at 24 weeks, while in the control group, the VAS score improved from 5.36±0.97 at baseline to 2.33±0.66 at 24 weeks. PFT in the study group improved from 4.45±0.374 at baseline to 2.26±0.231 at 24 weeks, while in the control group, PFT improved from 4.42±0.366 at baseline to 2.49±0.357 at 24 weeks. The AOFAS score also improved from 50.49±13.13 at baseline to 74.03±11.53 in the study group, and in the control group, the AOFAS score improved from 49.74±12.26 at baseline to 71.36±10.72 at 24 weeks (p-value <0.05).

Conclusion: Significant improvements were observed in all outcome measures in both the study and control groups, with a p-value <0.05. However, the improvements were more pronounced in the study group, with minimal to no side-effects. Hence, ultrasound-guided PRFA of the MCN can be considered an effective minimally invasive treatment modality for recalcitrant PF.

Keywords: Heel pain, Radiofrequency ablation, Visual analog scale

INTRODUCTION

Plantar fasciitis is one of the most common causes of primary heel pain, with a prevalence ranging from 3.6-7% in the general population and upto 8% in athletes. Patients typically present with pain on the medial surface of the plantar heel at the calcaneal tuberosity, which is usually worse with the first few initial steps out of bed and improves gradually with ambulation. The pain may worsen with prolonged standing or resting [1]. The aetiology of PF is varied and multifactorial. Identified risk factors include conditions that increase pressure on the plantar surfaces, such as prolonged standing on hard surfaces, flat feet, and reduced ankle dorsiflexion [2]. Obesity is an independent risk factor and is present in 70% of individuals with PF. Tightness of the Achilles tendon and improper footwear usage have also been identified as significant risk factors [3]. Previously believed to be an inflammatory condition, studies now suggest that PF is due to non inflammatory structural breakdown of the plantar fascia. The plantar fascia acts as a tension bridge in the foot, providing both static support and dynamic shock absorption. It is supplied by small plantar nerves and the MCN, which are invested in and around the fascia and play a role in pain sensation. The plantar fascia consists of three distinct structural components: the medial, central, and lateral bands. The central plantar fascia is the thickest and strongest section and is most commonly involved in PF [4,5]. The majority of patients (90%) respond to conservative treatment, including rest, stretching, analgesics, physical therapy, arch support, night splints, shoe modifications, or steroid injections. However, approximately 10% of patients do not respond to conservative treatment even after six months and are considered to have recalcitrant PF. Diagnostic imaging is necessary for recalcitrant cases to rule out other heel pathologies [3].

Extracorporeal Shockwave Therapy (ESWT) is an option for treating recalcitrant cases of PF, while radiofrequency ablation of the nerve is one of the latest minimally invasive modalities for managing such cases [6]. ESWT is a non invasive procedure used to treat tendinopathies, including PF. The shockwaves generated by ESWT release growth factors such as Insulin-like Growth Factor-1 (IGF-1),

Platelet-Derived Growth Factor and Vascular Endothelial Growth Factor (VEGF), and Transforming Growth Factor-β (TGF-β), which promote angiogenesis and vasodilation of blood vessels. It is also believed to hyperstimulate nerve fibers, blocking pain stimuli through the gate control theory of pain [7,8].

Pulsed Radiofrequency Ablation (PRFA) is a recent non neurodestructive method that provides pain relief by generating a small amount of heat to disrupt the myelin sheath on the sensory nerve. Radiofrequency Nerve Ablation (RFNA) can effectively control pain in PF by eliminating the sensory perception of inflammatory pain in the heel [9]. RFA can be considered as a presurgical treatment modality, as invasive surgical procedures like fasciotomy have varying success rates, risk of complications, and longer recovery durations [10,11].

Currently, there is limited literature available on RFA for the treatment of recalcitrant PF [1,9,10]. Therefore, this study aims to compare the effectiveness of ultrasound-guided PRFA of the MCN and ESWT in managing recalcitrant PF. This study is among the first prospective, randomised, controlled studies to investigate the effectiveness of pulsed RFA targeting the MCN under ultrasound-guidance for recalcitrant PF. Additionally, the comparison is made with another standard treatment modality, ESWT of the plantar fascia, making this study one of the first of its kind to compare radiofrequency ablation and ESWT.

MATERIALS AND METHODS

A randomised controlled trial was conducted at the Department of Physical Medicine and Rehabilitation (PMR), Regional Institute of Medical Sciences (RIMS), Imphal, India, involving 78 patients from Manipur who were diagnosed with recalcitrant PF between September 2018 and August 2020. Ethical clearance was obtained from the Research Ethics Board of RIMS, Imphal (A/206/REB-Comm(SP)/RIMS/2015/458/76/2018), and written informed consent was obtained from all participants. The study was also registered in the Clinical Trials Registry of India under the registration number CTRI/2019/09/021308.

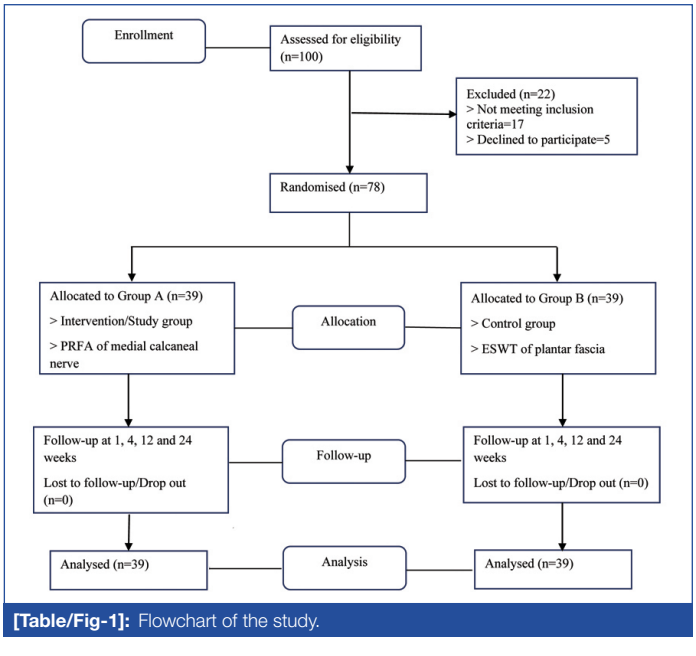
Inclusion criteria: Patients with PF for six months who did not respond to conservative management, aged between 20-60 years, and willing to comply with the treatment and follow-up assessments were included in the study.

Exclusion criteria: Patients with inflammatory arthritis of the foot, coagulopathy, neurologic conditions of the foot, infection, cancer, peripheral vascular disease, a history of prior steroid injection in the past three months, and patients with distorted anatomy of the foot were excluded from the study.

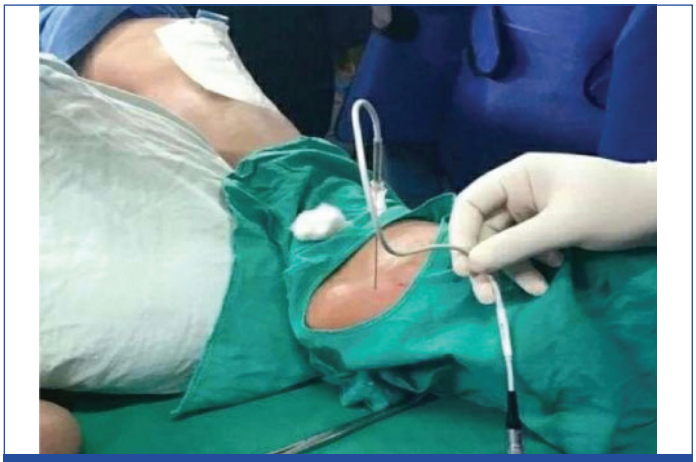
Sample size: A sample size of 78, with 39 patients in each group, was calculated based on a study conducted by Akinoglu B and Kose N [12]. The sample size calculation considered a type-I error of α=0.05, type-II error of β=0.2, a 95% confidence interval, and a dropout rate of 10%.

Study technique: Patients were assigned to two groups (Group A and B) using block randomisation. The study group (Group A) received PRFA of the MCN under ultrasound-guidance, while the control group (Group B) received ESWT of the plantar fascia [Table/Fig-1]. Patients were admitted to the PMR ward of RIMS, Imphal, and underwent a pre-enrollment evaluation, which included demographic data (age, gender), medical and surgical history, and assessment of co-existing diseases. Physical examination, including Body Mass Index (BMI) [13], local foot examination (inspection, palpation, range of motion, muscle strength, foot posture, and balance), gait analysis, and baseline investigations, were performed.

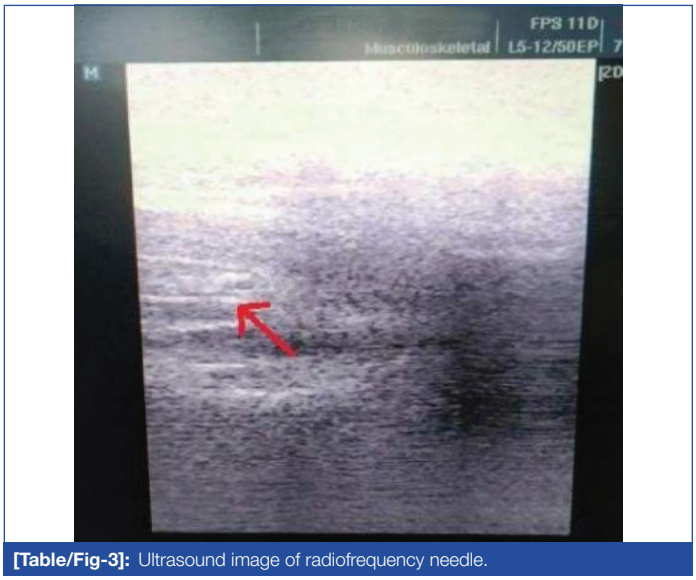
For PRFA of the MCN, the patient was positioned in a supine position. The area was cleaned with a 10% betadine and spirit solution, and an electrode was inserted into the area of maximum tenderness, which corresponds to the target nerve. After positioning, high-frequency sensory stimulation was performed to ensure the electrode was near the nerve, indicated by a tingling sensation. Low-frequency motor stimulation was then performed to check for muscle fasciculation, allowing repositioning of the needle if necessary to avoid damaging motor fibers. Once positioning was confirmed, 0.5 cc of 2% lidocaine was delivered through the probe cannula to anesthetise the skin and soft tissue before ablation. Two cycles of 90 seconds pulsed mode RF ablation were performed, maintaining a constant temperature of 42°C, frequency of 2 Hz, and pulse width of 20 milliseconds. Patients were observed for 30 minutes after the procedure [Table/Fig-2-4].



[Table/Fig-1]: Flowchart of the study.



[Table/Fig-2]: Radiofrequency ablation after inserting the electrode and confirmation of needle tip.



[Table/Fig-3]: Ultrasound image of radiofrequency needle.

[Table/Fig-4]: Radiofrequency generator machine during the procedure.

For patients undergoing ESWT of the plantar fascia, the patient was positioned prone with the foot supported on the edge of the bed. The area of maximum tenderness was marked, and ultrasound gel was applied. The ESWT probe was placed perpendicular to the area, and 2000 beats of shockwave were applied at a frequency of 6 Hz and pressure of three bars. The session was performed once per week for a total of three sessions.

Outcome measures: Pain, function, and improvement in plantar fascia thickness were measured at baseline before intervention, and follow-up assessments were conducted at 1, 4, 12, and 24 weeks. Decrease in pain was assessed using VAS. The AOFAS ankle hindfoot score was used to assess functional and alignment improvement, consisting of three categories: pain (40 points), function (50 points), and alignment (10 points), with a total of 100 points [14]. Plantar Fascia Thickness (PFT) was measured using ultrasonography, from the proximal origin of the plantar fascia to the calcaneal tubercle. Normal thickness ranges from 2-4 mm, and a thickness greater than 4 mm was interpreted as PF [1].

STATISTICAL ANALYSIS

An intention-to-treat analysis was conducted, and there was no loss to follow-up. The analysis was performed using SPSS version 21.0 (Armonk, New York). Descriptive statistics were reported as mean and Standard Deviation (SD). The Chi-square test was used for categorical data. Intra group analysis was conducted using repeated measures ANOVA, and inter group analysis was performed using a two-way ANOVA test. A p-value of <0.05 was considered significant.

RESULTS

There were no significant differences in the baseline characteristics of the two groups, indicating that they were comparable (p-value >0.05) [Table/Fig-5]. The mean age of patients in Group A (PRFA group) and Group B (ESWT group) were 50.01±5.75 and 49.08±5.60 years, respectively. Females constituted 42 (53.8%) of the total sample, and there were 46 (59%) obese patients [Table/Fig-5].

Characteristics		Study group: PRFA n=39 Mean±SD	Control group: ESWT n=39 Mean±SD	p-value
Age (years)	21-30	9 (69.2)	4 (30.8)	0.464
	31-40	11 (50)	11 (50)	
	41-50	12 (42.9)	16 (57.1)	
	51-60	7 (46.7)	8 (53.3)	
Gender	Male	17 (47.2)	19 (52.8)	0.821
	Female	22 (52.4)	20 (47.6)	
Body mass index	Normal	2 (40)	3 (60)	0.421
	Overweight	9 (37.5)	15 (62.5)	
	Obese	26 (56.5)	20 (43.5)	
	Extremely obese	2 (66.7)	1 (33.3)	
VAS		5.51±0.82	5.36±0.97	0.457
PFT		4.45±0.374	4.42±0.366	0.715
AOFAS score		50.49±13.13	49.74±12.26	0.797

[Table/Fig-5]: Baseline characteristics of the participants.
Chi-square test for categorical values; independent t-test for continuous variables; p-value <0.05 taken as significant; PRFA: Pulsed radiofrequency ablation; ESWT: Extracorporeal shockwave therapy; VAS: Visual analog scale; PFT: Plantar fascia thickness; AOFAS: American Orthopaedic foot and ankle society score

In the PRFA group, significant improvements were observed in all measured outcome variables at all follow-up periods (p-value <0.05) [Table/Fig-6]. Similarly, the ESWT group also showed improvements in all outcome variables (p-value <0.05) [Table/Fig-6]. However, when comparing the two groups, the PRFA group demonstrated significantly greater improvement at all follow-up periods, including VAS, AOFAS score, and PFT [Table/Fig-7].

Outcome measure		Study group PRFA n=39	p-value	Control group: ESWT n=39	p-value
VAS Mean±SD	Baseline	5.51±0.82	0.001	5.36±0.97	0.037
	1 week	4.38±1.02		4.13±1.03	
	4 weeks	3.59±0.85		3.49±1.02	
	12 weeks	3.03±0.71		2.87±0.89	
	24 weeks	1.92±0.80		2.33±0.66	
PFT Mean±SD	Baseline	4.45±0.374	0.006	4.42±0.366	0.018
	1 week	3.77±0.465		3.94±0.377	
	4 weeks	3. 32±0.408		3.42±0.404	
	12 weeks	2.80±0.355		2.95±0.539	
	24 weeks	2.26±0.231		2.49±0.357	
AOFAS score Mean±SD	Baseline	50.49±13.13	0.014	49.74±12.26	0.029
	1 week	55.87±12.59		54.87±12.34	
	4 weeks	61.51±12.21		60.31±11.85	
	12 weeks	67.28±12.11		65.59±11.48	
	24 weeks	74.03±11.53		71.36±10.72	

[Table/Fig-6]: Intragroup comparison of outcome measures at baseline, 1, 4, 12 and 24 week in the study group as well as control group.
*ANOVA; p-value <0.05 taken as significant; PRFA: Pulsed radiofrequency ablation; ESWT: Extracorporeal shockwave therapy; VAS: Visual analog scale; PFT: plantar fascia thickness; AOFAS: American Orthopaedic foot and ankle society score

Outcome measure		Study group (PRFA)	Control group (ESWT)	p-value
VAS	1 week	1.28±0.656	1.12±0.583	<0.001
	4 weeks	1.93±0.664	1.87±0.894	
	12 weeks	2.49±0.644	2.04±0.854	
	24 weeks	3.59±0.938	3.02±0.778	
PFT	1 week	0.679±0.524	0.474±0.359	<0.001
	4 weeks	1.129±0.485	0.998±0.319	
	12 weeks	1.648±0.489	1.46±0.512	
	24 weeks	2.184±0.491	1.926±0.451	
AOFAS score	1 week	5.385±1.161	5.128±1.056	<0.001
	4 weeks	11.026±2.631	10.564±1.744	
	12 weeks	16.795±3.928	15.846±1.829	
	24 weeks	23.538±5.236	21.615±2.862	

[Table/Fig-7]: Comparison of outcome measures between the two groups.
Two-way ANOVA; p-value <0.05 taken as significant; PRFA: Pulsed radio frequency ablation; VAS: Visual analog scale; PFT: Plantar fascia thickness; AOFAS: American Orthopaedic foot and ankle society score

DISCUSSION

Heel pain is a common complaint among patients requiring professional care, and PF is one of the most common causes of heel pain. The standard treatment is the standard approach, with approximately 90% of PF patients responding well to conservative therapy. However, a small percentage of cases, known as recalcitrant PF, do not respond to conservative treatment and may require invasive or surgical interventions [1].

This study aimed to explore the possibility of using disruption of nociceptive transmission for pain relief in the management of chronic pain. The MCN, which is a branch of the posterior tibial nerve, is considered as a target for intervention. The MCN provides sensory innervation to the heel and its anteromedial aspect, running between the medial surface of the anterior calcaneus and abductor hallucis. Based on this understanding, it was hypothesised that Radiofrequency Nerve Ablation (RFNA) of the MCN near its origin could provide pain relief in patients with recalcitrant PF [14,15].

PRF nerve lesioning was chosen as the intervention method due to its relative safety and minimal risks compared to other invasive procedures. Neuritis, de-afferentation pain, and neuroma formation are minimal, while clinical outcomes are generally much higher. Subsequent studies have supported the safety and non destructive nature of PRF nerve ablation, showing potential for long-lasting pain relief, reduced analgesic use, and high patient satisfaction [16].

The use of PRF ablation for PF treatment was first reported by Thapa D and Ahuja V, where they successfully performed diagnostic MCN blocks followed by PRF ablation in three PF patients [15]. Additionally, Chon JY et al., conducted ultrasound-guided PRF for posterior tibial nerve ablation in patients with recurrent tarsal tunnel syndrome, further demonstrating the feasibility and effectiveness of this approach [17]. Ultrasound-guidance during the procedure allows for real-time visualisation of the needle, minimising the risk of vessel injury and enabling dynamic monitoring of the procedure.

The study revealed that females (53.8%) were more commonly affected by PF compared to males (46.2%). This finding aligns with a study conducted by Kudo P et al., [18]. The higher prevalence among females can be attributed to differences in activities, with women often engaging in household tasks that involve prolonged standing and squatting. Additionally, the tendency of women to wear uncomfortable and high-heeled shoes, as well as performing daily activities barefoot, may contribute to their increased susceptibility. Obesity, which is present in 70% of PF cases according to a study by Goff JD and Crawford R [3], was observed in 59% of the patients in the present study. Although lower than the previous study, obesity still constituted the majority among the patients. This can be explained by the additional weight the feet have to bear during daily activities.

Significant improvements were observed in the mean scores of all outcome measures (VAS, PFT, and AOFAS scores) in both treatment groups at 1st, 4th, 12th, and 24th week follow-up (p-value <0.05). Similar findings of pain improvement upto 24 weeks were reported in a study by Osman AM et al., [10]. Wu YT et al., found that the maximum decrease in PFT occurred at 12 weeks of follow-up, whereas in the current study, it was observed at 24 weeks [1]. Yazar S also reported significant improvement in AOFAS scores, with maximum pain relief observed at 6-12 weeks in their study, while the current study showed maximum pain relief and improvement in function at 24 weeks [19].

Only a few patients experienced severe pain, while a small number reported pain at the injection site or site of ESWT application. These cases were managed with Tab. Paracetamol 500 mg as a rescue drug. No incidences of infection at the injection site or haematoma formation were reported. In summary, the study demonstrated that PRFA of MCN for the treatment of PF is more effective than ESWT.

Limitation(s)

The study had a small sample size, which may limit the generalisability of the findings to the broader population. Additionally, the study lacked long-term follow-up of the patients, which could have provided valuable information on the durability of the treatment effects. It is important to note that the study was conducted at a single hospital, which could be considered as another limitation.

CONCLUSION(S)

Both PRFA of MCN and ESWT of the foot resulted in improvements in pain and function lasting upto 24 weeks. However, the PRFA group exhibited greater pain relief and functional improvement compared to the ESWT group. It is worth noting that ESWT requires once-weekly therapy for three sessions, whereas PRFA is a one-time session. Taking all factors into consideration, ultrasound-guided PRFA of MCN appears to be a safe and effective treatment option for patients with recalcitrant PF. However, it is recommended to conduct further studies with larger sample sizes and longer follow-up periods to validate the findings of this present study.

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