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Original Research Article

Functional and radiological outcome of autologous platelet rich plasma in chronic plantar fasciitis: A prospective study

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ABSTRACT

Background & Aim: Plantar fasciitis is one of the most common causes of foot pain. It results from sustained stress of weight bearing - hopping, jumping, running -which results in micro trauma to plantar fascia which further leads to plantar fasciitis. It constitutes 11% to 15% of all foot symptoms. Its prevalence is 8% to 10% in general population. It commonly affects at the age of 40 to 60 years. Recently platelet rich plasma was used in treating in degeneration, muscle and tendon injuries. Hence, the present study aimed to assess the treatment outcome of autologous platelet rich plasma injection in treatment of plantar fasciitis.
Materials and Methods: In this prospective study, we enrolled 35 patients with plantar fasciitis coming to OPD or casualty. Patients satisfying inclusion criteria were selected based on consecutive sampling. 11 patients responded well to conservative management and 3 patients had loss of follow up. The different scoring systems were adopted such as VAS and AOFAS for pain assessment. The thickness of plantar fascia was determined by ultrasound technique. Autologous platelet rich plasma was prepared and the same was injected. The outcome analysis was done at 2 weeks, 3 months, and 6 months; and compared with pre injection values.
Results: From pre-injection to up to post-6 months period, the VAS reduction was statistically significant (P<0.0001). All the time interval, the AOFAS was increased which was statistically significant (P<0.001). The injection was effective in reducing the thickness of plantar fascia, which was found to be statistically significant at all the time intervals (P<0.001).
Conclusion: Autologous PRP injection for chronic plantar fasciitis was found to be an effective treatment modality for chronic plantar fasciitis.

1. Introduction

Plantar fasciitis (PF) is a self-limiting illness that is a prevalent cause of adult heel discomfort.[1] It is a frequent and devastating degenerative disorder of the plantar fascia arising from repetitive micro trauma and excessive strain on the plantar area of the foot.[2] The 40–70 year old middle-aged female and elderly are high incidence groupsand its prevalence is estimated up to 7 percentage in the overall population.[3,4]

The underlying disease that causes plantar fasciopathy is a degenerative tissue condition that arises around the point of origin of the plantar fascia at the medial tuberosity of the calcaneum.[5] In acute situations, plantar fasciitis is marked by traditional signs of inflammation, including pain, oedema, and loss of function. However, inflammation is not the underlying tissue disturbance in more chronic disorders. Indeed, chronic cases' histology revealed no evidence of inflammatory cell infiltration into the afflicted area.[6] The normal fascia tissue is replaced by angio-fibroblastic

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hyperplastic tissue that spreads throughout the surrounding tissue, prolonging the degenerative process.

Plantar fasciitis is diagnosed based on the patient's medical history and physical examination. On the first step out of bed, the patient experiences initial pain, which is reduced with gradually increased activity and is provoked by probing of the medial plantar calcaneal region.[7] Although it is a self-limiting illness, total cure can take three to eighteen months or longer, affecting quality of life.[8] Orthoses, shockwave therapy, medication, stretching exercise, laser therapy, taping, and percutaneous injection have all been used to treat plantar fasciopathy.[8–18] However, PF is notoriously difficult to entirely cure. Increased understanding of the pathology has resulted in the widespread use of a variety of conservative treatments for recalcitrant plantar fasciitis, including physiotherapy, plantar fascia stretching exercises, icepacks, night splints, prefabricated and custom-made inserts, shoe modification, non-steroidal anti-inflammatory drugs (NSAIDs), and extracorporeal shock-wave therapy (ESWT) in cases where conventional physical therapy is ineffective.[19–21] Although the efficacy of ESWT is still debated, convincing evidence supports its usage in the treatment of chronic plantar fasciitis.[22,23] While considering this option, undesirable effects such as discomfort during treatment, soft tissue damage (bleeding, hematoma, paraesthesia), nausea, the requirement for peripheral nerve block, and associated expenditures should be considered.[24]

There are various conservative treatment options, among which platelet-rich plasma (PRP) is a relatively new and promising method.[25] PRP is a platelet-rich concentration with a platelet count several times that of the baseline.[26,27] It inhibits collagen formation, reduces inflammation, enhances tissue repair, and stimulates fibroblast activity.[28,29] PRP contains a high concentration of platelets as well as a complete complement of clotting and growth factors.[30] The role of PRP in the treatment of PF has received widespread attention in recent years.[31–38] However, the benefits of PRP in modern PF treatment have not been thoroughly established, and several randomized controlled trials have reached contradictory conclusions when comparing PRP to Corticosteroids or placebo.[39]

The present study aimed to assess the treatment outcome of autologous platelet rich plasma injection in chronic plantar fasciitis. Our objectives were to analyze the functional outcome of chronic plantar fasciitis patients treated with autologous Platelet Rich Plasma using V.A.S. for Foot Function Index subscale and A.O.F.A.S. score; and to analyze the effect of PRP on plantar fasciae thickness using ultra-sonogram.

2. Materials and Methods

2.1. Study design and population

The present study was a prospective study conducted in a Tertiary care centre, Pondicherry from November 2019 to September 2021, where all patients with plantar fasciitis coming to OPD or casualty satisfying inclusion criteria were selected based on consecutive sampling. Totally 35 patients were enrolled in the present study.

2.2. Eligibility criteria Inclusion criteria

1. Age > 18 years.
2. Plantar fascia ultrasound thickness > 4 mm.
3. Patients not responding to conservative management for at least two weeks (including treatment received outside), which includes ultrasound therapy for plantar fascia and plantar fascia stretching exercise.

2.3. Exclusion criteria

1. Previous injection or surgery for heel pain.
2. Achilles tendonitis
3. Infection or ulcer at injection site.
4. Peripheral vascular disease.
5. Coagulopathies. (Hemophilia, von willebrand disease, disseminated intravascular coagulation etc.)
6. Rheumatoid arthritis.
7. PES planus (flat foot).
8. Pregnancy.
9. Spondyloarthropathy.
10. Avascular necrosis of talus.
11. Sub-talar arthritis.
12. Calcaneal stress fractures.

All the patients satisfying the inclusion and exclusion criteria were included in the study using consecutive sampling method.

2.4. Scoring Systems to be used

1. Visual Analog Score of Foot function index - pre-injection, 2 weeks, 3 months, and 6 months.
2. AOFAS score - pre-injection, 2 weeks, 3 months, and 6 months.
3. Ultrasound thickness of Plantar Fasciae. (pre-injection, 2 weeks, 3 months, 6 months).

2.5. Autologous platelet rich plasma preparation

About 10 ml of whole blood was collected in vacutainer tube with sodium citrate. The blood was centrifuged for 10 minutes at 2100 rpm using a table top centrifuge. Blood was separated into three layers- lower red colored layer containing RBC, middle white colored buffy coat, top straw colored plasma. In the straw colored plasma layer the lower

third contains more platelets which are lifted in the syringe. Approximately 2 ml of platelet rich plasma was obtained for each patient. 8.4% of sodium bicarbonate added at the ratio of 0.05cc sodium bicarbonate to 1 cc of platelet concentrate to increase pH which was reduced due to addition of sodium citrate during withdrawal. The resulting platelet rich plasma has 6-8 times concentration of platelets compared to baseline whole blood. Each sample of PRP was analyzed to confirm the increased concentration of platelets. The resultant platelet rich plasma was activated with 0.05cc of 10% calcium chloride per ml of platelet rich plasma. This was done as an out-patient procedure. The quality of the centrifuge machine used to prepare Platelet Rich Plasma was checked weekly.

2.6. *Injection technique*

After preparing the foot with betadine solution. 2 ml of activated autologous platelet rich plasma was injected using a 22 gauge needle at the origin of plantar fascia in medial calcaneal region using a peppering technique.

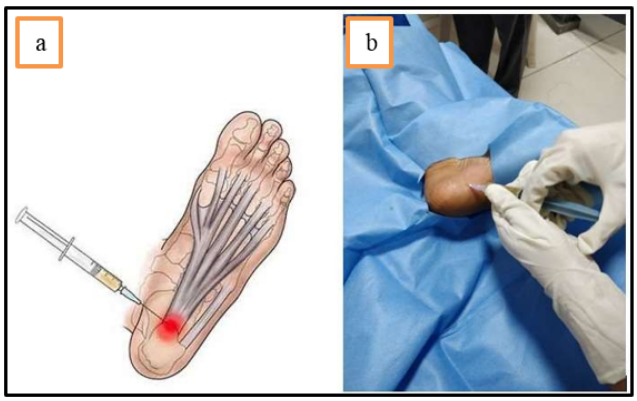

Fig. 1: a and **b:** Injection technique

2.7. *Post- injection protocol*

After injection of autologous platelet rich plasma the patient was advised to sit for 15 minutes without moving the foot. Patients were advised to minimize the use of feet for next 48 hours. Patients were given standardized stretching exercise protocol for 2 weeks and a formal strengthening exercise program was initiated after the stretching exercise. Patient was not allowed to take NSAIDS and was allowed for routine activities after four weeks of injection.

A visual analogue score of foot function index, AOFAS score, ultra-sonogram thickness of plantar fascia was used for outcome analysis at 2 weeks, 3 months, and 6 months and compared with pre injection values. Statistical analysis was done using SPSS 2.0 software. The one-way ANOVA test was used in the present study to find the statistical significance.

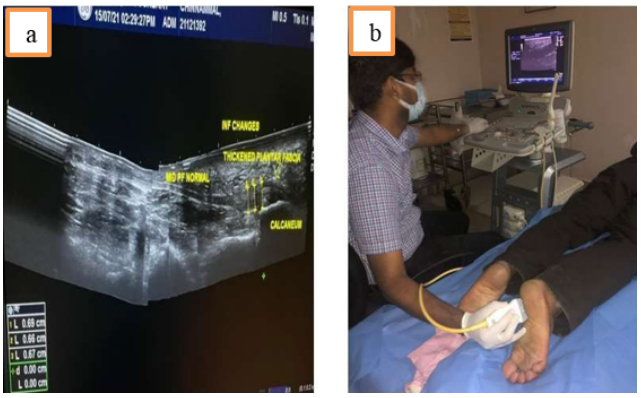

Fig. 2: a and **b:** Measurement of Plantar fascia thickness using USG

3. Results

Totally 35 patients were enrolled in the study. 11 patients responded well to conservative management and 3 patients had a loss of follow up. (n=21).

The mean age of the study patients was 45.1±10.92 years and ranged from 30 to 64 years. The majority of study patients were female (85.71%) and male was only 14.3 %. Diabetes mellitus was the predominant co-morbidity observed in the present study. (Table 1)

3.1. *Baseline demographics*

Table 1: Baseline characteristics of study participants

Variables	**Mean ±SD/N**	**%**
Age in years	45.1±10.92	
Gender (M:F)	3:18	14.3:85.7
Co-morbidities		
Diabetes Mellitus	3	15
Hypertension	1	5
Diabetes Mellitus with Hypertension	1	5

Among the study patients more than half patients were housewife (57.14%) and 19.05% of each was teacher and labourer in the present study.(Table 2)

Table 2: Occupational profile

Occupation	**Frequency**	**%**
Housewife	12	57.14
Teacher	4	19.05
Labourer	4	19.05
Retired from service	1	4.8

61.9% of patients had plantar fasciitis in their right-side leg, whereas 38.1% had left-side (Table 3).

Table 3: Profile of occurrence of plantar fasciitis

Condition	Right side	Left side
Plantar fasciitis	13 (61.9%)	8 (38.1%)

3.1.1. Body mass index

The mean body mass index was 25.20 kg/m2 and the same was displayed in Figure 3. Among the patients, 38.1% were overweight and remaining patients were normal weight.

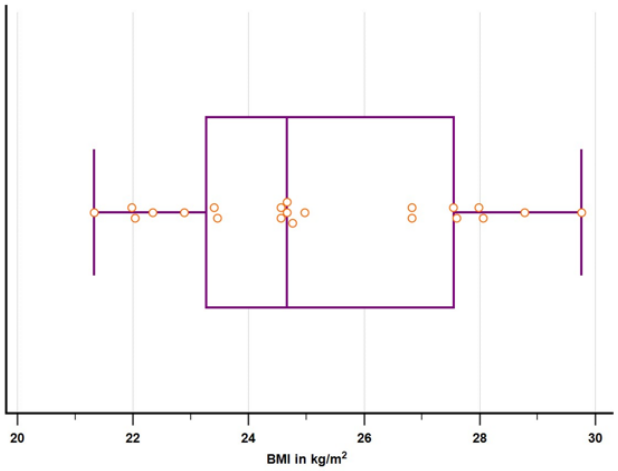

Fig. 3: BMI distribution

3.2. Assessment of the treatment outcome

3.2.1. Visual Analogue Scale

The platelet rich plasma injection was given to the 21 plantar fasciitis patients and their outcome was assessed at different intervals (Table 4). VAS for foot function index pain subscale was 66 ±3.13 at pre-injection stage. After injection, 2 weeks later the VAS score was reduced to 52 ± 6.56. Again the follow-up was continued and observed at 3 months post-injection, the VAS score was 33 ± 8.41 and at 6 months period it was reduced to 21.24 ± 8.51. The VAS score significantly reduced at all the time intervals towards no pain stage. From pre-injection to up to post-6 months period, the VAS score reduction was statistically significant (P<0.0001) (Figure 4)

3.3. American Orthopaedic Foot and Ankle Society (AOFAS) Score

The AOFAS score was determined at different time interval. At pre-injection stage, the score was 51.71 ± 10.43. After platelet rich plasma injection, at 2 weeks the score was assessed and found that significantly improved to 75.81 ± 7.53. The follow-up of the patients was continued and at 3 months post injection, the score was further increased to 87.67 ± 7.62. At 6 months post-injection period, the score was increased significantly to 92.09 ± 6.17. All the

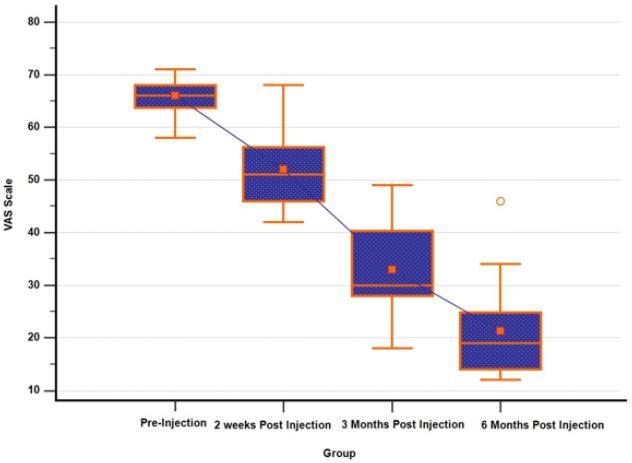

Fig. 4: Comparison of VAS at different time intervals

time interval, the score was increased which has statistically significant (P<0.001) (Figure 5)

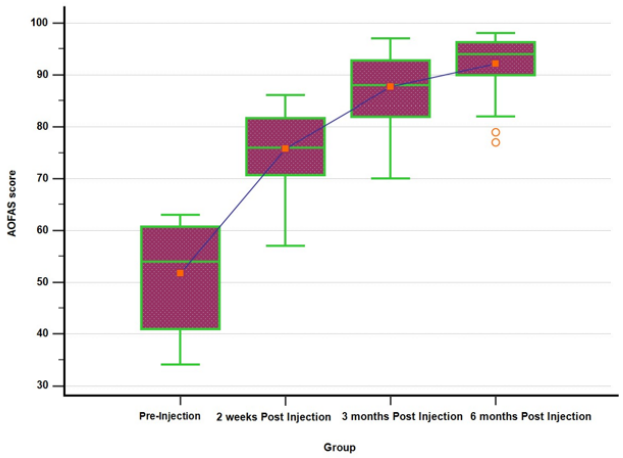

Fig. 5: Comparison of AOFAS Score at different time intervals

3.4. USG thickness of plantar fascia

The effect of Platelet Rich Plasma on planter fasciae thickness using ultra sonogram was done. The pre-injection stage it was 5.59 ± 0.82 mm. After platelet rich plasma injection, the thickness was reduced to 4.62 ± 0.67 mm at 2nd week of post injection. Further, the thickness was reduced at 3 months of post injection as 4.12 ± 0.63mm. At 6 months of the post injection, the thickness was almost maintained as previous thickness. The injection has the effect on reducing the thickness of plantar fascia was statistically significant at all the time intervals (P<0.001) (Figure 6).

Table 4: Comparison of treatment outcome at different time interval

Parameters	Pre- injection	Post 2 weeks	Post 3 months	Post 6 months	F Ratio	P value
VAS for foot function index pain subscale	66 ± 3.13	52 ± 6.56	33 ± 8.41	21.24 ± 8.51	169.175	<0.0001
AOFAS Score	51.71±10.43	75.81±7.53	87.67±7.62	92.09 ± 6.17	105.179	<0.001
USG Thickness of plantar fascia in mm	5.59 ± 0.82	4.62 ± 0.67	4.12 ± 0.63	4.11 ±0.56	22.083	<0.001

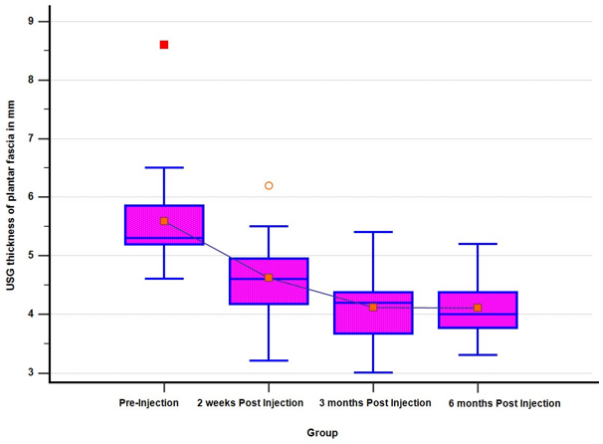

Fig. 6: Comparison of ultrasound thickness of plantar fascia at different time intervals

4. Discussion

PF is prevalent in the entire population, but is more prevalent in overweight individuals and those who spend a lot of time standing, and can have a significant impact on an individual's life and career. The cause of PF is unknown and may be complex.[40] Numerous therapies have been reported, however the data supporting any one of them is insufficient or perhaps contradictory. Steroid injections are considered since they have been shown to improve local edema, swelling, discomfort, and foot function in the short term by inhibiting the inflammatory response. Unfortunately, it has been documented those steroid injections are associated with abscesses, osteomyelitis, fat pad atrophy, and plantar fascia tears.[41] PF is frequently referred to be a degenerative tissue disorder rather than an inflammation of the plantar fascia at the calcaneus tuberosity. Because the normal fascia and surrounding tissue are replaced by angio- fibroblastic hyperplastic tissue, the lesion sites lack inflammatory cell infiltration, which are characteristic of chronic PF.[42]

PRP's cytokines and growth factors may have a significant function in the treatment of PF. PRP is rich in platelet-derived growth factor (PDGF), transforming growth factor (TGF-beta), and vascular endothelial growth factor (VEGF). Additionally, PRP contains a variety of pro- and anti-inflammatory cytokines and interleukins, including interleukin 4, 8, 13, interferon-a, and tumor necrosis factor-a.[43] The combination of these growth and anti-inflammatory factors is required to commence the healing process and reverse the degenerative process at the plantar fascia's base.[44] Due to the plantar fascia's hypo vascularity and hypo cellularity, high concentrations of platelets and growth factors are inaccessible; nevertheless, PRP injections permit delivery directly to the lesion site.[45] Platelets include dense and alpha granules; after platelet stimulation, alpha particles can release stored platelet- derived growth factors, and platelet-derived growth factors can stimulate angiogenesis and fiber repair.[46] As a result, local injection of PRP improves plantar fascia recovery.

Magnetic resonance imaging (MRI) and ultrasound are both capable of imaging the plantar fascia directly.[47] These tests demonstrated that patients with PF have a thicker plantar fascia than those without PF.[48] Thus, changes in the thickness of the plantar fascia following therapies in patients with PF are quantifiable using imaging techniques. The advantages of ultrasonography over MRI include that it is cost-effective, patient-friendly, and suitable for serial follow-up.[49] The present study used ultrasound to determine the thickness of PF.

Identifying factors associated with PF will help identifying at risk individuals and development of new and improved preventative and treatment strategies. According to the literature, there is a strong association between increased body mass index (BMI) and PF in a non-athletic population.[50] However, in the present study, there was no obese patients observed but we had 38.1% overweight patients. The evidence suggests that unlike weight, height has no association with PF as like our study findings.

Our study's findings indicated that PRP injections improved the VAS for pain. This finding corroborates previous reports indicating an enhanced healing process for tendons following local administration of growth factors via PRP injections.[51,52] All trials found that PRP significantly improved the VAS score at all-time points up to 6 months. This finding shows that PRP may be an effective pain reliever in the setting of plantar fasciitis; however the particular mechanism by which it acts on the plantar fascia is unknown.

According to Gonnade et al, prior observational studies and a few randomized clinical trials on plantar fasciitis have found that PRP is a good treatment for chronic cases, although there is still disagreement due to a lack of level

1 evidence.[52] Monto concluded that PRP injection is more efficacious and long-lasting than cortisone injection in the long-term management of severe chronic plantar fasciitis in a single-blinded prospective randomized longitudinal case series of 40 patients.[53]

Over the course of the 6-month follow-up, the potential regenerative benefits of PRP may have facilitated healing, which may account for the increased AOFAS score with the longer follow-up. Monto corroborated this by reporting a better AOFAS with PRP-treated plantar fasciitis at a 24-month follow-up compared to a 12- month follow-up.[54] However, there are no long-term data on the use of PRP in the treatment of plantar fasciitis, and it is unknown whether these improved functional outcomes are sustained over time.

Several case series and RCT's were published in the literature reporting the effectiveness of PRP injection in plantar fasciitis. Martinelli et al. reported a case series of 14 patients of plantar fasciitis treated with three doses of PRP injection, in their study the VAS scores had reduced from 7.1 pre-treatment to 1.9 at the 12-month follow-up.[54] Another case series by Ragab and Othman reported a complete alleviation of pain with a single dose PRP injection in 88% of their patients (n = 25) at 12 month follow-up.[55] Kumar et al. in their cases series of 44 patients (50 heels) treated with single PRP injection reported that at 6 month post-injection, baseline RM score, VAS score and AOFAS improved from mean 4 to 2 ($p < 0.001$), 7.7 to 4.2 ($p < 0.001$) and 60.6 to 81.9 ($p < 0.001$) respectively.[56] All the three studies concluded that PRP injection is very much effective in the treatment of plantar fasciitis. The present study results highly in accordance with the previously mentioned studies.

RCT by Jain et al., comparing PRP with steroid injections reported that the mean VAS, AOFAS, and RM scores in the PRP group was 3.3, 88.5, and 1.9 respectively and in the steroid group was 5.3, 75, and 2.6 respectively at the 12 month follow-up and the difference was significant.[57] He concluded that PRP is as effective as Steroid injection at achieving symptom relief at 3 and 6 months after injection, for the treatment of plantar fasciitis, but unlike Steroid, its effect does not wear off with time. At 12 months, PRP is significantly more effective than Steroid, making it better and more durable than cortisone injection. The present study had a minimum follow up period of 6 months. However, on further follow up of the patients, 20% of the total study population had shown recurrence of symptoms at 11 months period.

In general, Ultrasound could demonstrate a reduction of plantar fascia thickness with the PRP injection in patients with chronic plantar fasciitis. There is agreement among authors that US is a valuable non-invasive imaging modality for diagnosis of plantar fasciitis and in the follow-up assessment as it is free of the hazardous ionizing radiation. It doesn't affect the biomechanical function of the foot, it is inexpensive and portable, and it allows real-time imaging.[58,59]

It is arguable that ultrasound guidance may promise a more accurate placement of PRP and injection without ultrasound guidance may be considered as a shortcoming of a study. Nevertheless, no advantage of ultrasound guidance over direct palpation guidance was reported by Kane et al. during steroid injection for PF. In his study, the mean thickness (+/-standard error of the mean) of the plantar fascia, measured by ultrasonography, was 5.7+/-0.3 mm in symptomatic heels as compared with 3.8+/-0.2 mm in asymptomatic heels ($P<0.001$). Further, he concluded that ultrasonography may be used as an objective measure of response to treatment in plantar fasciitis.[60]

Kalaci et al. reported a superior effect in his study when peppering technique was used as compared to single direct. In peppering technique, the needle was placed into the target tissue and withdrawn slowly while maintaining the tip of the needle within the tissue. The needle was then angulated and reinserted to make another puncture onto the fascia at different sites. Peppering on the plantar fascia could possibly stimulate the release of endogenous growth factors that help in regeneration. In the present study, peppering technique was used for autologous PRP injection.[61]

5. Conclusion

A single autologous platelet rich plasma injection has shown significant improvement in patient satisfaction and symptomatic relief with good foot function. Radio-logically, we have found significant reduction in thickness of plantar fascia following an autologous platelet rich plasma injection. No complications were encountered in this study except for pain at the injection site for 2 days – which was managed with rest and ice pack application. No patient in our study had shown recurrence of symptoms within 6 months follow up period. However, on follow up, 20% of the patients had recurrence of symptoms after 11 months. Hence, autologous platelet rich plasma injection is a good option in treating chronic plantar fasciitis.

6. Limitations

The present study had some limitations- single centered study with small sample size and a short follow up period.

7. Conflict of Interest

The authors declare no relevant conflicts of interest.

8. Source of Funding

None.

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