

Role of Platelet Rich Plasma in the Management of Plantar Fasciitis: A Prospective Interventional Study

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ABSTRACT

Introduction: Plantar Fasciitis (PF) is one of the most common chronic degenerative foot condition associated with pain in the bottom of the foot (enthesopathy), encountered by an orthopaedic practitioner. Various treatment options have been implicated and it has been frustrating problem for both patients and treating doctors. Very limited studies are available showing the variable effects of Platelet Rich Plasma (PRP), the autologous conditioned plasma, in human tissues.

Aim: To determine the role of PRP in the management of patients with PF.

Materials and Methods: This prospective interventional study was conducted in the Department of Orthopaedics in collaboration with blood bank in SRM Medical College and Hospital, Potheri, Chengalpet district, Tamil Nadu, India, between November 2017 to April 2019. In this study, 70 patients with PF were treated with single dose of local injection of 3 mL autologous PRP. These patients were assessed for pain relief using the Visual Analogue

Scale (VAS) and Foot and Ankle Ability Measure (FAAM). In addition ultrasonographic evaluation of thickness of plantar fascia was done six months after treatment. The statistical analysis of each clinical outcomes was analysed individually, using Statistical Package for the Social Sciences (SPSS) version 22.0. Statistical significance was done with student's t-test and p-value <0.05 was considered statistically significant.

Results: The mean age of the patients in this study was 38.8±4 years. There were 39 (55.7%) female and 31 (44.3%) male patients in the study. The mean symptom duration from the approximate onset of symptom to the study enrollment was 7±2.3 months. The statistically significant reduction in VAS score from the baseline and reduction in thickness of plantar fascia was observed in the study. FAAM score also gradually improved from mean 32.05±8.20 at baseline to 60.97±8.94 after 24 weeks with mean difference of 28.92.

Conclusion: The present study observed that PRP is potentially effective and safe treatment option for long term relief of PF.

Keywords: Autologous conditioned plasma, Chronic enthesiopathy, Conservative management, Heel pain

INTRODUCTION

The treatment and complete cure from the chronic enthesopathies has always been ranked the most difficult and frustrating problem for both patients and treating doctors. PF is a common foot condition encountered by orthopaedic practitioner. It accounts for 15% of all foot disorders with almost 10% of the population affected over their lifetime [1].

The aetiology and cause of pain is not well understood and is multifactorial. The risk factors which precipitate include intrinsic and extrinsic factors. The intrinsic factors include anatomical, functional and degenerative factors. Increased stress on plantar fascia occurs due to anatomical factors like pes planus, pes cavus, overpronation, leg length discrepancy, excessive lateral tibial torsion and femoral anteversion; functional risk factors like tightness or weakness in gastrocnemius, soleus muscles and Achilles tendon; and degenerative factors includes ageing and atrophy of heel pad of fat [2-4]. The extrinsic risk factors include excessive use, training error among athletes and improper footwear. The pain is sharp, insidious in onset, typically worst in the morning usually after first step and also appears after prolonged sitting or inactivity [3].

The PF occurs at the proximal attachment, the medial calcaneal tuberosity. Non Steroidal Anti Inflammatory Drugs (NSAID) night splints, foot orthosis, steroid injections, stretching protocols, deep X-ray therapy and Extra Corporeal Shock Wave Therapy (ESWT) are available [4]. However, associated with adverse effects such as pain, damage to soft tissues and nerve or ends up without any satisfactory long term outcome [5-7]. PRP is an autologous biological blood-derived product, on its application, the alpha granules of platelet are degranulated and releases various growth factors that enhance

the regenerative abilities of bone, tendon and ligament in natural way. In recent years, PRP therapy is being used for injuries and degenerative lesions of muscle and tendon such as tennis elbow, etc., [8,9]. Studies were conducted to evaluate the effect of PRP in PF, but many are either inconclusive or with contradictory results [8-10]. Therefore, this study was done to determine the role of PRP in the management of patients with PF.

MATERIALS AND METHODS

This prospective interventional study was conducted at Department of Orthopaedics in collaboration with Blood Bank in SRM Medical College and Hospital, Potheri, Chengalpet district, Tamil Nadu, India, during the period November 2017 and April 2019. Institutional Ethical Committee (IEC) approval (1284/IEC/2017) was obtained.

Inclusion criteria: The patients who were presenting with complaints of heel pain for four or more weeks, patients with pain worsening in morning and/or after prolonged period of sitting or lying down, patients with tenderness maximum at the medial tubercle of calcaneus, patients with plantar fascia thickness of >4 mm measured via Ultrasonogram (USG) and gave consent to participate for the investigational technique and follow-up were included in the study.

Exclusion criteria: Patients with any history of previous treatment with corticosteroid in the last six months or with NSAIDs treatment within the last seven days or have undergone surgery for heel pain, or patients with dysfunction of knee, ankle, foot or work related compensable injury or with neuropathic symptoms like radiculopathy, tarsal tunnel syndrome, tarsi sinus syndrome or with systemic diseases like inflammatory or degenerative polyarthritis, Diabetes mellitus, local or systemic infection, peripheral vascular diseases, gout, or clotting disorder, anticoagulation therapy and

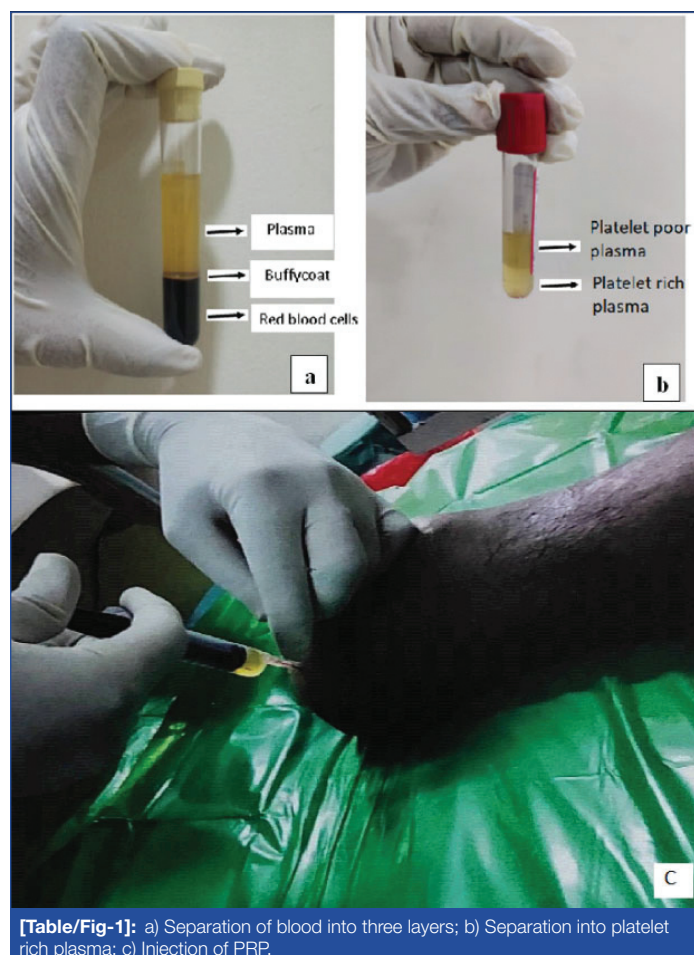
female patients who are pregnant, breastfeeding and those patients not consenting were excluded from the study.

Sample size calculation: A total of 70 patients were included in the present study. The sample size was calculated based on Jain K et al., study, using the formula $(z^2\sigma^2)/\text{Margin of error}$; where $z=1.96$, paired standard deviation (σ)=3.58, Margin of error is 0.9, at 95% confidence interval, the minimal sample size required to conduct the study was 61 [10].

The diagnosis of PF was made with triple assessment, first the clinical presentation of chronic heel pain unilateral/bilateral, for more than four weeks, which was worse in morning (first steps) and or after prolonged period of inactivity; second the physical examination finding of tenderness that is maximum at the medial tubercle of calcaneus, where the plantar fascia is attached and third the radiological assessment with ultrasound of both feet for evaluation of the thickness of plantar fascia. The USG is a diagnostic ultrasound machine with a 4 cm wide transducer head and 8 MHz probe was used. The plantar fascia was measured perpendicularly at the maximum thickest portion, from the base of the medial calcaneal tubercle taken to the inferior border of the plantar fascia. The plantar fascia of thickness more than 4 mm was considered as abnormal [11].

PRP Preparation Method [12]

A 20 mL of a patient's venous blood was withdrawn from antecubital vein. Under aseptic condition blood was collected into a tube containing anticoagulant acid citrate dextrose. This blood was then centrifuged at 1000 rpm for 10 minutes (soft spin), at temperature (22-24°C), which allows the blood to separate into three distinct layers of bottom most red blood cells (55%), middle layer buffycoat (5%) and top most (40%) Platelet Poor Plasma (PPP) [Table/Fig-1a,b]. The platelet poor plasma was discarded. Using a sterile syringe the buffy coat was transferred into another tube without an anticoagulant and was again centrifuged for 10 minutes at 3000 rpm (hard spin). The supernatant, the fluid above the sediment



was discarded and the sediment, platelet concentrate was the PRP. The platelet concentration, compared to baseline whole blood, had approximately 6-8 times of the platelets.

Under complete aseptic precautions, patients were administered PRP, as outpatient care procedure [Table/Fig-1c]. Lidocaine sensitivity was assessed and 2cc of 2% Lidocaine was infiltrated, into the skin and subcutaneous tissue as local field block, followed by 3cc of PRP was injected at the origin of the plantar fascia and site of maximum tenderness. A peppering technique i.e., spreading in clockwise manner was used to achieve a more expansive zone of delivery, with a single skin portal and 4-5 passes through the fascia itself. Patients were allowed to rest for 15 minutes and then advised to walk. The patients were monitored for 20 minutes for any reactions and then were sent home, advised to limit movement for period of 48 hours. The use of non steroidal medication was not advised. After 48 hours, patients were given a stretching protocol that was to be followed for two weeks. After this stretching protocol a strengthening program [13] was advised to patients. Post procedure (at four weeks), patients, if tolerated well, were allowed to proceed with normal or recreational activities.

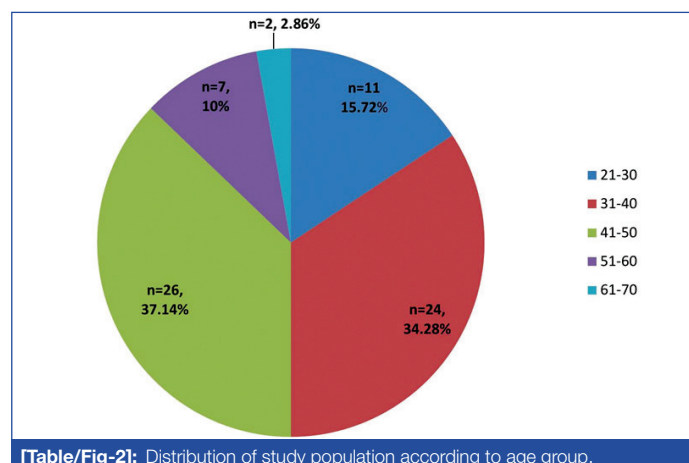
The patients were followed at four weeks, eight weeks, 12 weeks and after 24 weeks VAS and FAAM were used for assessment of pain relief. VAS is a psychometric response scale used to measure subjective characteristics or attitudes (such as pain) and the FAAM that possesses many of the clinimetric qualities, is a region-specific, non-disease-specific outcome measurement instrument [14,15]. The ultrasonographic evaluation of thickness of plantar fascia was done before PRP treatment and at 24 weeks post-treatment. The each of the individual clinical outcomes was analysed.

STATISTICAL ANALYSIS

The SPSS version 22.0 was used to analyse all data. Statistical significance was done with Analysis of Variance (ANOVA), student's t-test and was accepted, when p-value <0.05 was considered statistically significant.

RESULTS

In the present study, there were 70 patients diagnosed with PF, treated with PRP therapy. The mean age of the patients in this study was 38.8 ± 4 years. There were 26 (37.14%) in the age group of between 41-50 years and 24 (34.28%) in the age group of 31-40 years [Table/Fig-2]. Gender distribution is shown in [Table/Fig-3]. The mean symptom duration from the approximate onset of symptom to the study enrollment was 7 ± 2.3 months. Around 57 (81.4%) of the study population had pain for around 6-8 months [Table/Fig-4]. The side of involvement is shown in [Table/Fig-5]. In the present study, 23 (32.9%) of patients had taken analgesics and 7 (10%) had undergone physiotherapy prior to PRP treatment [Table/Fig-6]. The mean VAS score before the procedure was 6.34 and after procedure were 3.56. The mean difference of 2.78 was statistically significant. There was a significant raise of mean FAAM



score (28.92) after 24 weeks of treatment and the difference was statistically significant [Table/Fig-7]. The thickness of plantar fascia, before and after the PRP, assessed using USG showed a mean difference of 1.08, which was clinically significant [Table/Fig-8].

Gender	Number	Frequency
Male	31	44.3
Female	39	55.7
Total	70	100

[Table/Fig-3]: Distribution of study population according to gender.

Duration of pain (Months)	Number	Frequency
5	4	5.7
6	18	25.7
7	19	27.2
8	20	28.6
9	7	10
10	1	1.4
12	1	1.4
Total	70	100

[Table/Fig-4]: Distribution of study population according to duration of pain.

Side involved	Number	Frequency
Right heel	29	41.4
Left heel	36	51.4
Both heels	5	7.2
Total	70	100

[Table/Fig-5]: Distribution of study population according to the side involved.

Treatment taken	Number	Frequency
None	38	54.2
Analgesic	23	32.9
Physiotherapy	7	10
Analgesic And Physiotherapy	2	2.9
Total	70	100

[Table/Fig-6]: Distribution of study population according to treatment taken before the procedure.

Parameters	Duration	Mean±Standard deviation	p-value*	PRP responders	PRP non responders
VAS score (n=70)	Baseline	6.34±1.49	<0.001	94.2% (n=66)	5.8% (n=4)
	4 weeks	4.55±1.11			
	8 weeks	4.07±0.97			
	12 weeks	3.91±0.58			
	24 weeks	3.56±1.08			
FAAM score (n=70)	Baseline	32.05±8.20	<0.001	90% (n=63)	10% (n=7)
	4 weeks	37.79±6.22			
	8 weeks	49.80±8.93			
	12 weeks	52.50±5.89			
	24 weeks	60.97±8.94			

[Table/Fig-7]: VAS and FAAM Score at follow-up period.

*Repeated measures ANOVA test

Parameter	Mean±Standard deviation		Mean difference	t-value	Significance p-value
	Before the procedure	After the procedure			
Plantar fascia thickness	4.46±0.772	3.38±0.470	1.08	11.965	0.003

[Table/Fig-8]: Comparison of mean between the parameters taken before procedure and after 24 weeks.

*Student's t-test

There were about 66 (94.2%) patients who responded to the treatment except in 4 (5.8%) patients, who did not showed any improvement in VAS score. The mean FAAM score was observed to improve in 63 (90%) patients whereas 7 (10%) patients did not improve significantly and those were treated with another modality with anti-inflammatory drugs.

DISCUSSION

In the present study, 70 patients with PF were treated with autologous PRP therapy. PF is a common ailment, especially among individuals with increased Body Mass Index (BMI) and in those who stand for prolonged periods [4]. It can certainly interfere with the body kinetic chain and quality of life. Its aetiology is not well understood but studies suggest microtrauma as an initiating factor [16]. The histopathological changes include necrosis of collagen, proliferation of fibroblasts and blood vessels, chondroid metaplasia, dystrophic calcification [7]. Although there are many treatment modalities for PF, their clinical outcomes are not satisfactory. PRP injection is a recently emerging treatment alternative for many musculoskeletal conditions [17]. However, the studies [18,19] on the role of PRP in PF are inconclusive, therefore this study was conducted.

Mazzocca AD et al., Scioli MW, Peerbooms JC et al., studied the preparation of PRP, who concluded that platelet high spin method results in higher number of growth factors and platelets in the sample, which promotes regeneration of tissue and also observed that the technique of PRP injection (peppering) to be effective. Therefore this method was used in this study [20-22].

Although VAS is subjective, still widely used due to its simplicity, adaptability less time consuming and more sensitive [23]. Smith MV et al., have concluded that FAAM score is a sensitive and most extensively validated foot and ankle outcome instrument [24]. Fabrikant and Soon park T, Wu CH et al., had described the advantages of ultrasound over the MRI that it is non invasive, radiation free, cost-effective, well tolerated by patients and appropriate for serial follow-up [25,26]. In the present study, the clinical outcome was measured using the VAS and FAAM along with sonographic assessment of thickness of plantar fascia.

In the present study, the mean VAS score decreased from baseline continuously at four weeks, eight weeks, 12 weeks, and up to 24 weeks which was statistically significant. There were about 66 (94.2%) of the patients who responded to the treatment except in 4 (5.8%) patients, who did not showed any improvement in VAS score. The mean FAAM score was observed to improve in 63 (90%) patients whereas 7 (10%) patients did not improve significantly and those were treated with another modality with anti-inflammatory drugs.

Heel fat pad atrophy and plantar fascia rupture are the two most feared, intractable long term complications associated with corticosteroid injections [27]. No such complications were seen in any patients treated with PRP in this study. In a study by Jain SK et al., PRP was observed to be a better treatment of chronic PF as against steroid. They observed no statistical difference in effectiveness, between both the therapy at early stage of treatment and also remarked that the effectiveness of PRP does not decline with time, making it more durable [28]. Similarly, there was a steady decline in the VAS score at four weeks, eight weeks, 12 weeks and 24 weeks from the baseline score (pretreatment) over the course of this study.

In a Lee TG and Ahmad TS study, a group of 64 patients had been given PRP and steroid therapy for the management of PF. They were followed-up for a period of six months and found that there was significant improvement in both the groups in term of function

and pain, but they also said that at the end of six months there was no major difference between the two groups [29]. In contrast, in this study, a significant reduction was observed in VAS score at six months and significant increase in FAAM score at six months with PRP therapy, showing better clinical outcome.

The study by de Vos R et al., concluded that there was no greater improvement in chronic tendinopathy patients treated with PRP as against saline injection, instead it was attributed that the clinical improvement was due to the eccentric exercises. In addition, they had explained that the effect of PRP depends on the length of time, the platelets remained in the degenerated area, after injection. The greater and rapid the PRP diffusion, the lesser would be its effect [30]. Similarly, Sheth U et al., in their study on the efficacy of autologous PRP use for orthopaedic indications, had concluded that there was uncertainty of evidence, to support its clinical utility. This could be possibly explained by lack of standardised protocol [31].

In a study conducted by Rahim A and Tiwari M, the cortisone group had a pretreatment mean VAS score of 8.5, which initially improved to 1.1 at 12 weeks post-treatment to 4.9 at 26 weeks, and then continuously increased to near baseline levels of 8.4 at 52 weeks. In contrast, the PRP group started with an average pretreatment 8.6 score decreased to 3.4 at 12 weeks, remained declining to 1.2 at 26 weeks and 0.3 at 52 weeks [32]. Similarly in the present study the mean FAAM score increased from baseline continuously at 4,8,12 and up to 24 weeks and was statistically significant in comparison with baseline at all durations.

In the current study, the reduction of plantar fascia thickness measured by ultrasonography in patients who received PRP was statistically significant post-treatment after 24 weeks. Ragab EM and Othman AM; and Kianimehr L et al., also evaluated PRP therapy with plantar fascia thickness and found significant reduction in thickness post-therapy [33,34].

Few studies had reported conflicting results regarding the PRP procedure like, preparation technique of PRP, amount to be injected, injection technique, the number of sessions and the interval between them required for best therapeutic effect [35,36]. This study observed that injecting PRP is effective and a safe modality in treatment of PF. The strengths of the study include patients with illness or therapy interfering with platelet function was excluded, the patients were followed-up for maximum of 24 weeks and the outcome was measured on both patient perspective and objectively by radiology with measurement of plantar fascia thickness.

Limitation(s)

The present study was not without limitations, which includes small sample size and comparison with other conservative treatment modalities (local steroid injection) was not done. The platelet quantification was not done and the platelet count in PRP was dependent on the patient's platelet count.

CONCLUSION(S)

The present study observed by follow-up of PRP treated PF patients at intervals, revealed that this procedure is safe, efficient and effective for long term pain reduction along with reduction in thickness of plantar fascia. Further, large scale multicentre comparative study are recommended to optimise the procedure by unveiling the grey zones including patient selection, injection technique, dosage of PRP, effective platelet count.

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