

To evaluate the role of platelet rich plasma in treatment of various enthesopathies: A prospective study

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Abstract

Background: Plantar fasciitis and epicondylitis are one of the most common enthesopathies affecting human body. Platelet rich plasma (PRP) is a bioactive component of whole blood that can enhance human stromal and mesenchymal stem cell proliferation. PRP is dependent on these growth factors for its regenerative properties. PRP has high amount of cytokines and growth factor which increases cellular movement, matrix synthesis, and increase in number leading to increase regenerative abilities of tendons. The aim of this study was to evaluate the role of platelet rich plasma in treatment of various enthesopathies. **Material and Method:** A total number of 52 patients, 26 each of plantar fasciitis and epicondylitis who presented to Orthopaedics OPD of Teerthanker Mahaveer Medical College and Research Centre, Moradabad and fulfilled the inclusion criteria, were included in this prospective study. Pre procedure investigations were done and patients were injected freshly prepared platelet rich plasma at effected site and followed immediately after giving PRP injection and then at an interval of 1, 2, 3 months and visual analogue scale was used to assess relief in pain symptom. **Result:** There was gradual decrease in pain severity and average VAS score in patients of plantar fasciitis and epicondylitis at monthly follow ups after giving PRP injection. No patient was lost to follow up. There was a statistically significant ($p < 0.001$) difference in the median scores of visual analogue scale among patients with Plantar fasciitis and Lateral epicondylitis between immediate follow-up and follow-up at subsequent months. The median was score was 7 at pre injection time which decreased to 2 at the end of 3rd month follow up. **Conclusion:** This prospective study indicates that PRP injection is safe and has potential to reduce pain in various enthesopathies.

Keywords: PRP, Lateral Epicondylitis, Plantar Fasciitis, VAS, Enthesopathies

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Introduction

Movement at joints result due to transmission of forces to bones which is done by connective tissue known as tendons. Injuries occur when joint is exposed to large physical stress which effect function of tendons.[1,2] Most common and easily to get injured are tendon of achilles, patellar tendon of patella and forearm extensor tendons due to over use. Usually tendons are less vascular. Tendinopathic tendons feature changes like accumulation of lipids, deposition of proteoglycans and calcification.[2]

Pain at bottom of the heel region is common characteristic of plantar fasciitis. It affects 10-20 percent of injured athletes.[3,4] Reoccurring injuries to plantar fascia at its genesis at the calcaneum results in plantar fasciitis.[5] Pain in plantar fasciitis occurs at bottom of the heel region and is most common in the morning which reduces with increase in time.[3] Plantar fasciitis conservative method includes nonsteroidal anti-inflammatory drugs (NSAIDs)

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physiotherapy, ice pack, night splint, plantar fascia stretching exercises, shoe modification. Shock-wave therapy is used when conventional physiotherapy fails in providing relief[6].

In about 2 percent of adult population major reason for pain is lateral epicondylitis. Major first coined the term tennis elbow in 1883.[8] Repetitive contraction of extensor muscles of wrist mainly the extensor carpi radialis brevis which causes microscopic tears in tendons progressing to epicondylitis.[9] Various methods for management of epicondylitis include topical and oral NSAID, laser, acupuncture, topical nitrates, botulinum toxin injection, ultrasonography, orthoses and surgery.[10]

PRP is a part of whole blood which is rich in platelets. It has higher concentration of platelets about 4 to 5 times of baseline. There are usually more than 1 million platelets per microlitre in PRP.[11] Growth factors, fibrin, WBC, platelets present in PRP bring about cellular changes in diseased tissue. Alpha granules and various other growth factor are present in platelets. [12,13]

PRP is dependent on these growth factors for its regenerative properties. PRP has high amount of cytokines and growth factor which increases cellular movement, matrix synthesis, and increase in number leading to increase regenerative abilities of tendons.[14]

Table 1: Roles of growth factors in PRP[15]

Role	Pro-	Anti-
Angiogenesis	Angiopoietin-1, TGF-B1, PDGF, VEGF, CD40L	Endostatin, thrombospondin-1, B-thromboglobulin, platelet factor-4
Matrix deposition	TGF-B	Matrix metalloproteinase 9 (MMP-9)
Inflammation	IL-1B, EGF, PDGF, VEGF	HGF
Cellular proliferation migration	FGF, EGF, IGF-1, HGH, TGF-B, PDGF	

Platelet poor plasma is produced during PRP preparation. It is blood plasma having less number of platelets. PRP gel is made up of platelet-rich fibrin membrane matrix. Its main use is in plastic surgery operations where it is used as a filling material in aesthetic use. PPP Gel is also known as glue and fibrin sealant. It includes plasma gel poor in platelets

Aim: Evaluation of role of platelet rich plasma in treatment of various enthesopathies.

Objectives

1. To identify cases of various enthesopathies.
2. To identify the cases that can be managed with Platelet Rich plasma (PRP)
3. To evaluate the results of Platelet Rich Plasma (PRP) Injection in patients of various enthesopathies.

Materials and Methods

Study Design

This prospective study was conducted from June 2019 to March 2020. After getting approval from the institutional ethics and research committee and a written informed consent, patients were recruited from Orthopaedics OPD of Teerthanker Mahaveer Medical College and Research Centre, TMU, India who were diagnosed with various enthesopathies after Clinical evaluation. The last patient was recruited in March 2020. The following inclusion and exclusion criteria was observed in patients selected for the study:

Inclusion Criteria

Patients between 18-75 year of age irrespective of gender with various enthesopathies and willing to participate in the study.

Exclusion criteria

Patients having any wound or skin lesion at the injection site, pregnancy, severe infection, known malignancy, bleeding disorder and previous surgery were excluded from the study.

Sample Size: Minimum of 50 patients were recruited.

Pre-Procedure Protocol: All patients filled an informed consent form as per guidelines of Institutional Ethics Committee (IEC). Following investigation were done:

- o Complete blood profile
- o CRP
- o Random blood sugar (RBS)

Under every aseptic precautionary measure, we acquired 34-42.5 ml of entire blood in 8.5 ml of citrate dextrose corrosive (ACD) tubes from the antecubital vein of the patient. PRP method

was used to make platelet rich plasma. Smooth spin @3000rpm/min was used for 3mins to centrifuge the blood. The patient was positioned on an operating table. Under full aseptic conditions PRP was injected using 20G needle at various enthesopathic sites i.e. 1 ml PRP given in case of epicondylitis and 1.5 ml in case of plantar fasciitis.

Post procedure protocol

Patient was sent back after 20 minutes of rest and was told to give rest and apply cold packs locally. Patient was prescribed analgesic orally and appropriate physical therapy including stretching exercises was started after 48 hours and patients were advised to take case specific precautions for 4 to 6 weeks.

Patient was followed up immediately after PRP injection and then at monthly interval upto 3 months using visual analogue scale. Patients were assessed by using Visual Analogue Scale. The visual analogue scale is a subjective psychometric response scale marked on a 10 centimetre line with numbers from "0" to "10" where:

- VAS assessment was done with numbers from "0" to "10", marked on a 100 mm line.
- The patients were explained that "0" means, they are experiencing no pain, "5" moderate pain and "10" unbearable pain and then they were asked to mark the appropriate score on the line describing their own pain.

Statistical analysis

The results are presented in frequencies, percentages and mean±SD. Friedman test was used for comparisons. The p-value<0.05 was considered significant. All the analysis was carried out on SPSS 24.0 version (Chicago, Inc., USA).

Results

We conducted this study in department of orthopaedics, TMMRC, Moradabad. A total of 52 patients, 26 each of plantar fasciitis and epicondylitis who fulfilled the inclusion criteria comprised this study. All the patients were given freshly made PRP injection at enthesopathic sites and then followed monthly till 3 months. Improvement in pain at each follow up was measured by VAS score. 61.5% of patients were male as compared to 38.5 % female patients. Most of the patients had their right side affected that is 65.4 percent of patients. majority of patients were above 40 years of age (table 2).

Table 2: Characteristics of the study population

Background characteristics	Frequency (n)	Percentage (%)
Age in years		
< 40 years	23	44.2
≥ 40 years	29	55.8
SEX		
Male	28	53.8
Female	24	46.2
Diagnosis		
Plantar fasciitis	26	50.0
Lateral epicondylitis	26	50.0
Side involved		
Right	32	61.5
Left	20	38.5

Table 3 shows median and interquartile ranges of visual analogue scale scores among participants with Plantar fasciitis and Lateral epicondylitis underwent PRP injection, followed up immediately after PRP injection and then follow-up at 1st month, at 2nd month and at 3rd month. Median and Interquartile ranges of visual analogue scale scores among participants with Plantar fasciitis and Lateral epicondylitis who were given PRP injection, followed up immediately after PRP injection and then at each month till 3rd month. It showed that there was gradual decrease in the average (median) visual analogue scale scores from immediate follow-up to follow-up at 1st month and then at subsequent follow ups. In order to find out whether there is a statistically significant difference in visual analogue scale

scores Friedman test was computed. There was a statistically significant difference ($\chi^2=132.07$, $p<0.001$) in median visual analogue scale scores between immediate follow-up, follow-up at 1st month, at 2nd month and at 3rd month. The findings indicating that visual analogue scale scores among participants were decreased after the intervention. This shows that platelet rich plasma injection is an effective intervention on reducing the tendinopathy (pain) among patients with Plantar fasciitis and Lateral epicondylitis. This shows that PRP injection is an effective intervention on reducing the tendinopathy (pain) among patients with Plantar fasciitis and Lateral epicondylitis.

Table 3: Visual analogue scale scores among participants with Plantar fasciitis and Lateral epicondylitis

Visual analogue scale score	N	Median	IQR (Q3, Q1)	Friedman (χ^2)-value	p-value
Immediate follow-up	52	7.00	2.00 (8.00, 6.00)	132.07	0.001*
Follow-up at 1 st months	52	5.00	3.00 (7.00, 3.00)		
Follow-up at 2 nd month	52	4.00	2.75 (4.75, 2.00)		
Follow-up at 3 rd month	52	2.00	2.00 (2.00, 0.00)		

($P<0.001$ ***-significant level)

Pairwise Comparison of Median and Interquartile ranges of visual analogue scale scores at different time points among patients with Plantar fasciitis and Lateral epicondylitis underwent platelet rich plasma injection is shown in table 4. There is a statistically

significant ($p<0.001$) difference in the median scores of visual analogue scale among patients with Plantar fasciitis and Lateral epicondylitis between immediate follow-up and follow-up at 1st month and then at subsequent follow ups.

Table 4: Pairwise Comparison of Median and Interquartile ranges of visual analogue scale scores at different time points

Visual analogue scale Score	n	Median	IQR (Q3, Q1)	Wilcoxon signed rank test (Z)	p-value
Immediate follow-up	52	7.00	2.00 (8.00, 6.00)	-5.96	0.001***
Follow-up at 1 st month		5.00	3.00 (7.00, 3.00)		
Immediate follow-up	52	7.00	2.00 (8.00, 6.00)	-6.06	0.001***
Follow-up at 2 nd month		4.00	2.75 (4.75, 2.00)		
Immediate follow-up	52	7.00	2.00 (8.00, 6.00)	-5.98	0.001***
Follow-up at 3 rd month		2.00	2.00 (2.00, 0.00)		
Follow-up at 1 st months	52	5.00	3.00 (7.00, 3.00)	-5.51	0.001***
Follow-up at 2 nd month		4.00	2.75 (4.75, 2.00)		
Follow-up at 1 st months	52	5.00	3.00 (7.00, 3.00)	-5.93	0.001***
Follow-up at 3 rd month		2.00	2.00 (2.00, 0.00)		
Follow-up at 2 nd month	52	4.00	2.75 (4.75, 2.00)	-5.07	0.001***
Follow-up at 3 rd month		2.00	2.00 (2.00, 0.00)		

($P<0.001$ ***-significant level)

Discussion

Plantar fasciitis typically involves pain involving the bottom of the heel.[3] Repetitive micro-rupture of the plantar fascia leading to inability of body to repair itself, results in degeneration. Heel spur syndrome is other name commonly used for this enthesopathy. (NSAIDs), physiotherapy, ice pack, night splint, plantar fascia stretching exercises are various conservative method for treatment of plantar fasciitis.[6]Tennis elbow can be caused by minor trauma to extensor muscles of the forearm during overload injury. The annual incidence in the general population is about 1 to 3 percent. Topical and oral NSAID, laser, acupuncture, topical nitrate, ultrasonography, use of orthoses and are common methods used in the treatment of epicondylitis.[10]PRP has higher concentration of platelets about 4 to 5 times of baseline. PRP usually contains more than 10 lack platelets per microliter.[11] Various growth factor present are (PDGF), (VEGF), (HGF), insulin-like growth factor-1,2(ILGF-1, 2), (TGF) . [12,13] are responsible for its regenerative properties. The present study was conducted in orthopaedics department, (TMMC&RC), Moradabad with the objective to identify cases of various enthesopathies and to assess the results of PRP Injection in patients of various enthesopathies. A total number of 52 patients were taken in this study. 26 patients were having plantar fasciitis and an equal

number of patients diagnosed as epicondylitis were included in this study.

They were given PRP injection at affected site and followed immediately after giving PRP injection and then at an interval of 1st, 2nd and 3rd month and VAS was used to assess relief in pain symptom. In relevant to our study, a case control study was conducted by Pingel J et al [16] which recruited a total of thirty patients. Another study done by Ertufrul Akoahin et al[17] included a total of 60 patients in a study comparing PRP and steroid in the management of plantar fasciitis whereas Peerbooms JC [18] study comparing effectiveness of steroid injections vs PRP in patients with chronic epicondylitis included 100 patients.

According to the age-wise distribution of the study subjects, most patients (55.8%) were observed in age group ≥ 40 years (29 patients) followed by the number of patients (23 patients) in the age group < 40 years. This coincides with study of Ahmed Mohamed Ahmed Othman and Ehab Mohamed Selem Ragab [19] in which average mean age for patients was 44 years and Ertufrul Akoahin et al[17] in which mean age of patients was 46.36+8.49. However, Albers et al[20] reported the study subjects with various age groups. Most of the patients were observed in age group between 18-44 years (42.1%), 45-64 years (35.7%), >65 years (18.3%) and 0-17 years (4%).

Of the total 52 patients included in our study, 28 patients were male (53.8%) and 24 patients were female (46.2%). Another study revealed by Daniel Florit et al [21] showed that the incidence of tendinopathy was most common in male cases as compared to female cases where as another study done by Miller LE et al. [22] showed the prevalence of enthesopathies in 54% of the female cases.

Of the total 52 cases in our study, 26 patients each were of Plantar fasciitis and Lateral epicondylitis. Study done by peerbooms et al [18] had suggested that PRP provides relief of symptoms for longer duration and increases function for lateral epicondylitis than corticosteroids. Another study done by Gosens T et al [23] also showed that treatment by PRP therapy is more sustainable.

PRP has short-term and long-term efficacy in treatment of epicondylitis as stated by Arirachakaran A et al and Krogh T P et al in their studies showed similar finding. [24,25]. Fat pad atrophy or plantar fascia rupture are common side effects of corticosteroid injection which are not present on PRP injection application [26]. Two studies done by Mahindra P et al and Monto R assessed PRP injections against corticosteroid injections, concluded PRP to be better option with respect to efficacy against corticosteroids. [27,28]

The present study showed that the Median and Interquartile ranges of visual analogue scale scores among participants with Plantar fasciitis underwent PRP injection, followed up immediately after PRP injection and then at each month till 3 months.

It revealed that there was gradual decrease in the average (median) visual analogue scale scores from immediate follow-up to follow-up at 1st month and then at subsequent follow ups till 3 months. Similar study was done by Martinelli N et al [29] in which they included 14 patients of plantar fasciitis who were given 3 injections of PRP and were assessed after 12 months.

VAS score decreased from 7.1 ± 1.1 to 1.9 ± 1.5 at the last follow up ($P < .001$). Another study done by Yadav R et al [30] studied PRP and corticosteroid effect on epicondylitis.

The mean pain score of all the patients at the time of injection was 9.9 ± 0.275 . The average pain score at 1st month, 2nd month and 4th month was 8.2 ± 0.66 , 5.96 ± 0.66 and 3.53 ± 0.68 respectively. In a similar study by Ragab EM, Othman AM et al. [19] average pain score decreased from 9.1 to 1.6 post injection as measured by VAS score. However, the present findings revealed that there was statistically significant difference ($r^2=67.71$, $p<0.001$) in median visual analogue scale scores between immediate follow-up and then subsequent follow ups till 3rd month, indicating that visual analogue scale scores among participants were decreased after the intervention.

This shows that PRP injection is an effective intervention on reducing the tendinopathy (pain) among patients with Plantar fasciitis. PRP injections deliver high concentrations of platelets and growth factors directly to the lesion site which is generally not accessible due to hypovascularity of plantar fascia. Platelets contain dense and alpha granules which release PDGF after platelet stimulation, which can promote angiogenesis and fiber repair. Therefore PRP promotes the repair of the plantar fascia.

Strength of Our Study: The strengths of the study were

- 1) Adequate sample size.
- 2) Visual analogue scale was used.
- 3) Freshly prepared PRP injection was used which was cost effective as well.

Limitations

- 1) Single centre study.
- 2) Lack of control or comparison group.
- 3) A short follow up time, so long term effect of PRP injection cannot be determined.

Conclusion

This prospective study concludes that PRP injection has potential to reduce pain in various enthesopathies. There was gradual decrease in the average (median) visual analogue scale scores from immediate

follow-up to follow-up at subsequent month till 3rd month after giving PRP injection at effected sites. There were no side effects reported on giving PRP injection. Thus PRP is a safe and cost effective therapy for treatment of various enthesopathies.

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