International Journal of Research in Medical Sciences
Upadhyay S et al. Int J Res Med Sci. 2018 May;6(5):1594-1599
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012
DOI: http://dx.doi.org/10.18203/2320-6012.ijrms20181430

Original Research Article

Autologous platelet rich plasma versus corticosteroid injection for chronic plantar fasciitis: a prospective controlled randomized comparative clinical study

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Received: 19 March 2018
Accepted: 23 March 2018

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ABSTRACT

Background: Primary objective was to evaluate and compare the effectiveness of autologous platelet rich plasma (PRP) and steroid injections in chronic cases of plantar fasciitis.
Methods: The present study was a prospective cohort study; 140 consecutive patients with chronic plantar fasciitis were enrolled and randomized in two groups: One receives the Platelet rich plasma (PRP) therapy (study group) and another receiving corticosteroid injection (control group). The outcomes in both groups are then evaluate and compared using visual analogue scale (VAS) and American Orthopaedic foot and Ankle Society (AOFAS) scale at 1month, 3month and 6 month post injection. The level of significance was set at $p < 0.05$.
Results: Prospective data was collected of 140 heels. The average follow up duration was about 6 months. The score on VAS scale and AOFAS improved from base line for both group but the patients received PRP therapy had a statistically significant ($p<0.05$) reduction in pain and improved AOFAS score at last follow up. No adverse complications were reported.
Conclusions: The result of present study showed that the PRP therapy has potential to reduce pain and improve the functional outcome in cases of chronic planter fasciitis. It was found to be more effective and significantly better than corticosteroid injection.

Keywords: AOFAS, Planter Fasciitis, Platelet rich plasma, Steroid, VAS scale

INTRODUCTION

Plantar fasciitis (PF) is an overuse injury that seriously affects the patient's daily activities and quality of life. Primarily it is a clinical diagnosis and a self-limited condition in majority of patients. It takes months and years to resolve; thus poses challenges to treating clinicians. Plantar fasciitis affects both sedentary and physically active individuals like athletic and military personnel's and are believed to arise from chronic overload, alignment or weakness issues either from lifestyle or exercise. The etiology is poorly understood and is unknown in nearly 85% of cases.[1] While there are a plethora of treatment options, none of these are universally reliable or acceptable. Conservative therapies are usually the first line of treatment includes ice, rest and avoidance of potentially strenuous activities, physical therapies, orthotics, arch supports, tapping and splinting. Other modalities include use of NSAIDS, ultrasonic Shockwave therapy, and, in the recalcitrant cases, surgery. Corticosteroid injection is a mainstay of early treatment. However, conflicting evidence exists to support the use of steroid injection. Platelet rich plasma (PRP) therapy is a revolutionary novel modality that

relieves pain by stimulating long lasting healing of musculoskeletal conditions.[2-4] This clinical study was thus undertaken in patients of chronic planter fasciitis, to evaluate and compare the effectiveness of single injection of autologous platelet rich plasma (PRP) and steroid injections.

METHODS

The study was designed as a single centre prospective controlled randomized research. The present research was approved by institutional review board, and informed consent was obtained from each subject. The current study recruited untreated patients of heel pain reporting to the Department of Orthopaedic, Traumatology and rehabilitation NSCB Medical College Jabalpur MP India from September 2013 to September 2014. A medical and demographic history was taken, and patients were examined.

Inclusion criteria

It included, all participants aged 40-70 years of either sex had to

- Have heel pain for more than 4month and/or have been diagnosed as having Chronic Planter Fasciitis (CPF)
- Ability to walk,
- Subject must understand the risk and benefit of the protocol and be able to give informed consent,
- Availability for the duration of entire study period.

Exclusion criteria

It includes following parameter

- Traumatic heel pain,
- Heel pain less than 4 month,
- Inflammatory disorder like gout, RA, Ankylosing spondylosis etc,
- Abnormal LFT and RFT,
- Hematological disorders or any history of coagulopathies,
- Diabetes,
- Cancer,
- Medically unfit patient,
- Hypersensitivity to NSAIDs,
- Compressive neuropathies,
- Skin disorders,
- Severe infection,
- Pregnant, breast feeding or planning to become pregnant.

Among two hundred subjects, 140 were satisfied the inclusion/eligibility criteria. The cohort included 41 men and 99 women. The mean age of the sample was 45.95 years (SD 7.446). Equally sized cohort were identified, each of sample group having 70 subjects of either sex, were randomized into two clinical groups based on their serial number (odd or even) assigned at their reporting time to the outpatient department. All patients with odd serial number were placed under group A (study group) (received PRP injection (single injection of 2ml of PRP)) and other patients with even serial number were gathered under group B (control group) (received corticosteroid injection (single injection of 40mg/mL of methylprednisolone), acted as control).

The patients treated received single injection either of PRP or corticosteroid during the course of study. The injection is combined with the peppering maneuver in both the group. Either group could request to shift to the NSAIDs therapy at any time during the course of the study. No attempt in either group was made to discourage the use of NSAIDS during the study course and they could request and receive the NSAIDS. Demographic variables, including age, sex, occupation and the use of NSAIDS drugs during the study period were recorded. Patients were advised to avoid strenuous activity for two-three days with other precautions following the injections. Follow-up was done at 1month, 3month, and 6month. All of the follow-up was done at the outpatient department, Department of Orthopaedics N.S.C.B Medical College. All data collection and critical evaluation using validated scoring instruments (VAS Score; AOFAS scale) was done by a senior author.

Device description

The present study utilized a REMI centrifuge C-854/6 System (Medico / Doctor Centrifuge); a dedicated Mini Centrifuge system, designed for routine centrifuging tests (Capacity: 6 x 15; Type of Head: Swing Out; Max. Speed: 3500 rpm; Max. RCF: 1600g; W x D x M (mm): 310 x 310 x 295; Supply: 220-240 Volts 50Hz Single Phase).

Methodology

The preparation (Platelet rich plasma (PRP)) can be performed in the operating theater during the actual procedure and takes about 20 minutes. Under aseptic precautions10 ml blood was withdrawn from antecubital vein in a 20ml sterile EDTA-coated disposable test tube. This sterile disposable test tube was centrifuged at 22-24degree room temperature at 1500rpm/min for 15 minutes in a REMI centrifuge C-854/6 System (Medico/Doctor Centrifuge).

Following centrifugation, the blood sample is separated in different blood fractions (from bottom to top of tube): lowest or red cell and granulocytes; middle or whitish opaque layer of buffy coat which contains osteoprogenitor cells, mononuclear cells and some platelets and the top one is yellowish transparent layer and contains plasma and platelets. This top layer is divided in two zones; upper platelet poor plasma (PPP) and lower platelet rich plasma (PRP) (Figure 1). PPP

layer was discarded with the help of a long bore sterile micropipette and around 2ml of PRP was collected and is ready to use (Figure 2).

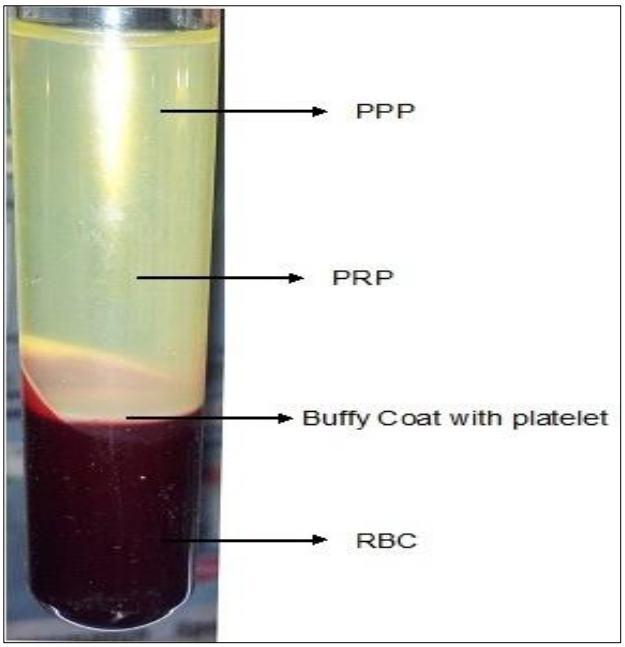

Figure 1: Centrifugation, the blood sample is separated in different blood fractions (from bottom to top of tube) RBC: Red Blood Cells; PRP: Platelet rich plasma; PPP: Platelet poor plasma.

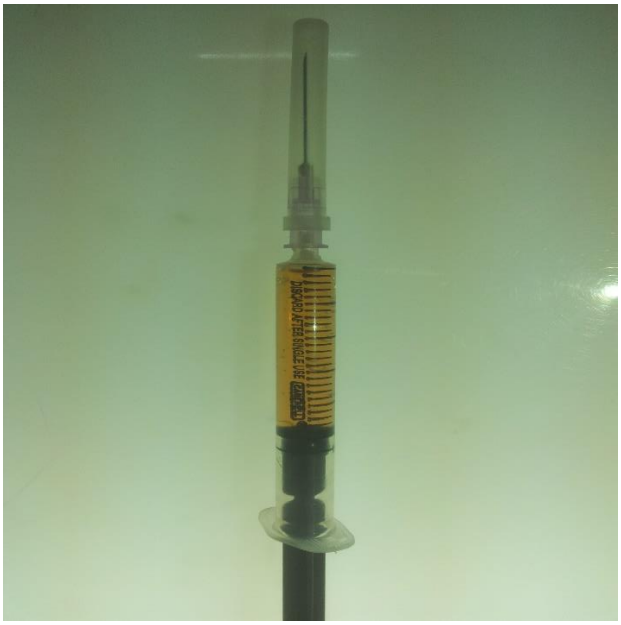

Figure 2: PPP layer was discarded with the help of a long bore sterile micropipette and around 2ml of PRP was collected and is ready to use.

Technique

Under aseptic precautions 1% lidocaine (Xylocaine) 2-3mL of local anesthesia (AST) was delivered to the point of maximum tenderness. Gentle massage was done. Dry needling, also called peppering, is used to locally ‘‘injure’’ the soft tissue to excite the inflammatory response. After contacting the hard bony end, the needle was gently partially withdrawn then advanced in a fan-like wheal, peppering the area 7 to 10 times; simultaneously injecting 0.2-0.3 ml of either steroid or PRP (Figure 3).

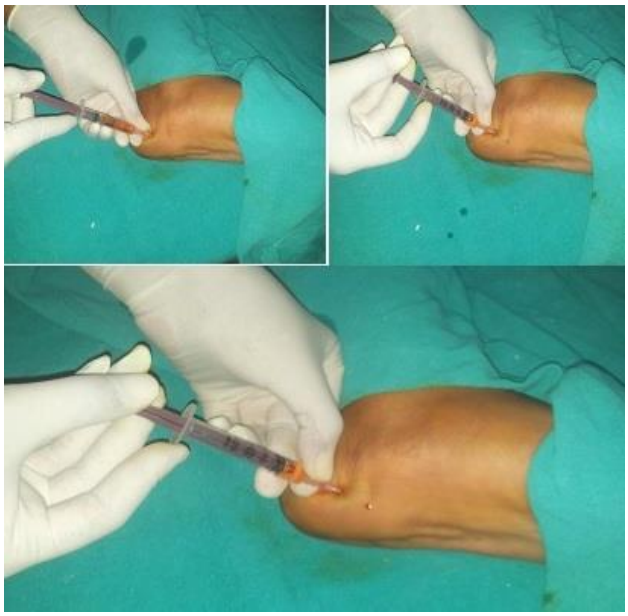

Figure 3: Peppering injecting technique.

Post-injection protocol

All patients were advised to refrain from Vigorous/sportive activities for at-least 3days post-procedure. Broad spectrum oral antibiotic and NSAIDS for three days were prescribed to patients. Icing and elevation are recommended if necessary. All the patients were encouraged for physiotherapy once the pain has subsided.

The outcomes in both groups are then evaluate and compared using visual analogue scale (VAS) and American Orthopaedic foot and Ankle Society (AOFAS) scale at 1month, 3month and 6month post injection.[5, 6]

Statistical analysis

The data are presented as means ±SD. All calculations and statistics were performed with Statistical package of social science (SPSS 20) software. A “p-value” of less than 0.05 (p-<0.05) was regarded as significant.

RESULTS

One forty individuals (29.3% men and 70.7% women) mostly middle-aged adults (40-50yr) (p<0.05) with chronic planter fasciitis (CPF) were evaluated at baseline, at 1, 3 and 6month (Table 1).

Table 1: Age wise distribution of plantar fasciitis in 140 patient most of patients are in age group of (40-50yr).

Age in years	Frequency	Percent
21-30	5	3.6
31-40	36	25.7
41-50	86	61.4
51-60	11	7.9
> 60	2	1.4
Total	140	100.0

Table 2: Sex wise distribution of plantar fasciitis.

Sex	Frequency	Percent
Female	99	70.7
Male	41	29.3
Total	140	100.0

Table 3: Case distribution according to occupation, table show most patient (51.4%) are house wife.

Occupation	No of cases	Percent
Driver	1	0.7
Farmer	12	8.6
Field worker	1	0.7
Guard	4	2.9
Government employ	5	3.6
House wife	72	51.4
Labour	16	11.4
Police	10	7.1
Private job	2	1.4
Shopkeeper	1	0.7
Student	6	4.3
Teacher	10	7.1
Total	140	100.0

Table 4: VAS score in group A and group B.

PRP/Steroid	PRP		Steroid			
	Mean	± SD	Mean	± SD	p value	Significance
VAS pre injection	7.10	0.750	7.03	0.572	>0.05	not significant
VAS 1month	4.52	0.779	2.46	0.742	<0.05	Significant
VAS 3month	3.06	0.856	6.46	0.905	<0.05	Significant
VAS 6month	1.41	0.495	6.88	0.681	<0.05	Significant

All patients completed the follow-ups. The average follow up duration was about 6 months. There was a pronounced female preponderance (70.7%) ($p<0.05$) (Table 2) mostly house wives (51.4%) (Table 3); among males incidence of signs of CPF in groups of heavy workers was significantly higher and had greater disease severity than sedentary groups ($p<0.05$) (Table 3). Both the cohort treated with PRP and with Corticosteroid injections showed improvements in pain scores from the base line parameters at the end of one month follow up ($p<0.05$); the corticosteroid group had significant improvement at end of one month follow up ($p<0.05$). However, at 6month PRP group showed a significant (7.10±0.750 to 1.41±0.495) ($p<0.05$) benefit compared with the corticosteroid group (6.88±.681) for the pain component (Table 4). The AOFAS scores-although better than baseline for both treatment groups-the patient treated with PRP injection showed statistically significant improvement (54±8.7 to 95±0) ($p<0.05$) at six month of follow up (Table 5). NSAIDS consumption was significantly lower in study group than it was in the control group ($p<0.05$). No complications were noted. Pain at the injection site was described by 90% (126) of the one forty patients, with no significant difference noted between the groups. This pain was attributed to the peppering maneuver before injection. The pain typically lasted no more than two days.

Table 5: Mean AOFAS score in both group at 1month, 3month and 6month.

PRP/Steroid		Pre injection	1 month	3 month	6 month
PRP	Mean	54.8	79.7	85.0	95.0
	± SD	8.7	6.4	0.0	0.0
Steroid	Mean	55.6	88.4	85.5	56.8
	± SD	8.7	4.9	3.6	10.0
Total	Mean	55.2	84.0	75.7	57.1
	± SD	8.7	7.2	2.6	7.8
	p value	>0.05	<0.05	<0.05	<0.05
	Significance	Not significant	significant	significant	Significant

DISCUSSION

Plantar fasciitis is commonly diagnosed inferior heel pain in adults and have a dramatic impact on physical mobility.[7] It continues to baffle doctors, since there are no definite combinations of clinical, biomechanical, or training variables, or causative factors in the development of CPF have been found.[8] Hence, optimal or preferred treatment is inadequate or even conflicting especially when conservative measures had been exhausted, and surgical intervention was not warranted. Though steroid injections are considered as one of the treatment modality but unfortunately it has short term results and is associated with complications.[9]

Recently, regenerative medicine therapies (platelet-rich plasma (PRP)) have been used as an alternative therapy for CPF and were associated with improved pain and function scores. Primary objective of present study was to evaluate and compare the effectiveness of autologous platelet rich plasma (PRP) and steroid injections in chronic cases of plantar fasciitis. Injection is the preferred method to administer PRP into the lesion and the authors had indicated that peppering technique is adequate for administration of PRP or steroid. They speculate that the multiple penetrations without withdrawing the needle allow dispersal of growth factors or corticosteroid to a larger area. Furthermore, peppering induce injury which may consequently stimulate bleeding and generate openings in the degenerative hypo-vascular tissue, allowing an improved healing response.[10]

The present study found that although both group showed improvement at the end of 1month and 3month, patients received PRP injections were found to have significantly improved pain scores at 6month compared with the control group ($p<.05$). The present study showed that at the end of the third month, pain score gradually increased after decreasing initially in control (Table 4). At this point the score was not statistically different with the baseline parameters. It could be concluded that the duration of pain relief effectiveness is less than 3months in patients received corticosteroid injections. Our result confirm the findings of Crawford F et al, who reported Statistically significant reduction in pain at 1month, but thereafter no differences could be detected.[11] Hence, it is concluded that steroid injections can provide short-term relief. On the contrary, the pain score remained significantly low at 3months and even at the end of 6month in group A.

This is attributed to the fact that the PRP containing concentrated growth factors which initiates and accelerate the body's healing mechanisms into growing new connective tissue.[12] PRP contains several different growth factors (cytokines) that encourage healing of bone and soft tissue.[12] PRP serves as a growth factor agonist and has both mitogenic and chemotactic properties. These growth factors in combination with anti-inflammatory components initiate the healing cascade and help in reversal of degenerative process.[13] In other words, the durability of efficacy of PRP is gradually improving and significantly longer compared to corticosteroid.

Also, authors do not recommend routine use of corticosteroid in cases of CPF owing to detrimental long-term effects.[11,14] In the present study, there was a clear trend for increased NSAIDS doses in the control group when compared with the study group. This could be attributed to weaning effect of corticosteroid injection.[11]

AOFAS hind foot score suggested that symptoms improved at end of 1month and 3months in both corticosteroid and PRP groups. The corticosteroid group had a pre-intervention average AOFAS score of 55.6±8.7, which initially improved to 88.4±4.9 at 1month; 85.5±3.6 at 3month post-treatment but declines and dropped to near baseline levels of to 56.8±10 at 6months.

In contrast, the PRP group started with an average pretreatment AOFAS score of 54.8±8.7, which increased to 79.7±6.4 at 1month; remained elevated to 85.5±1.0 at 3month and had a final score of 95.0±0.0 at 6month. PRP induces repair of the plantar fascia which contributes to improved functional outcome.[14] PRP is as effective as corticosteroid injection at achieving symptom relief initially, for the treatment of plantar fasciitis, but unlike Steroid, its effect does not wear off with time. At 6months follow up, PRP is significantly associated with improved pain and function scores when compared with corticosteroid injections. The present study supports previous findings.[7,8,10,15,16] Adverse effects were minimal, with both groups reporting self limited post injection pain.

The critical analysis of current research showed that PRP injection appears to have slower onset of action than steroid but it is much safer and longer acting as also supported by literature. The present study clearly demonstrate PRP injection to be an effective and well tolerated alternative to corticosteroid injection in management of patient with chronic plantar fasciitis with an added advantage of its biological nature and better patient compliance. Furthermore, PRP also possesses antimicrobial property which contributes to prevention of infection.[17]

Preliminary evidence supports the use of PRP therapy, although more clinical and basic science research is needed. Aside from the limited clinical data on functional outcome and the lack of a concrete understanding of molecular and cellular action mechanism, PRP therapy is lacking in the reported protocols for standardization and preparation of PRP extract and post-therapy management. It is advisable to standardize cost-effective individual preparation protocols, which can be reproduced in any

clinical setting. Despite PRP therapy becoming an increasingly popular treatment modality, authors recommend further research and development with large sample size. Whilst the findings of the current study could be applied in most instances, there were some important limitations.

- Small sample size and short follow up period further limits the generalization of findings of present study.
- In current study, no attempt has made to measure the PRP concentration in the prepared samples before the injection.
- The present study is purely subjective as no attempts have made to analysis the repair neither through imaging (MRI) nor through any histopathological analysis.
- The injections were given blindly without ultrasound guidance.

Further studies are required to optimize the number and spacing of injections for obtaining maximum desired functional outcome.

CONCLUSION

Preliminary results of present comparative clinical study of PRP therapy for the treatment of chronic Planter fasciitis showed that autologous PRP therapy can often lead to a more rapid and sustained reduction in symptom complaints when compared to corticosteroid injections. PRP injection holds promise as a potential therapy to hasten the healing of chronic plantar fasciitis.

ACKNOWLEDGEMENTS

Authors would like to thank the doctors and senior colleagues for providing fruitful and critical comments on the draft of this paper.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Upadhyay S, Damor V. Autologous platelet rich plasma versus corticosteroid injection for chronic plantar fasciitis: a prospective controlled randomized comparative clinical study. Int J Res Med Sci 2018;6:1594-9.