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Original article

Comparison of midterm results of Platelet Rich Plasma (PRP) versus Steroid for plantar fasciitis: A randomized control trial of 118 patients

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ABSTRACT

Background: Plantar fasciitis, which is a common cause of heel pain, often results in significant morbidity. In cases who are not responsive to initial conservative treatment, invasive procedures, often in the form of local infiltration of steroid are required. These procedures are associated with significant complications. Local Platelet Rich Plasma (PRP) infiltration is an emerging addition to these treatments. However, whether it is more effective in reducing pain and improving function than other treatments (such as steroid injections or whole blood) remains controversial.

Methods: Skeletally mature patients with plantar fasciitis who had failed conservative therapy were randomized using envelope method into 2 groups: PRP and Steroid group. The participants were assessed for pain using Visual Analog Scale on the day of presentation, and then after therapy at 2 weeks, 4 weeks, 3 months, and 6 months. They were additionally assessed on final follow-up using AOFAS hind-foot Score.

Results: 118 patients were randomized into 2 groups: 58 patients to the PRP group and 60 to the Steroid group. PRP was associated with greater improvement in VAS score and resulted in superior AOFAS score at 6 months as compared to steroid injection. The authors did not find any local or systemic complications in any of the groups. The result and difference were more pronounced as the time from injection increased and maximal benefit was observed at 6 months follow-up. None of the patients needed a repeat injection at 6 months.

Conclusion: Our study expands on the previous studies to provide a better evidence for superiority of PRP over local injection of steroid in plantar fasciitis, and the authors conclude that PRP provides better pain relief and function as compared to steroid injection.

Level of evidence: Level 1 Prospective Randomized Control Trial (RCT);

1. Introduction

Plantar fasciitis, which is a common cause of heel pain, often results in significant morbidity. The plantar fascia is a band of connective tissue connecting the calcaneus to the tendons of the forefoot, and goes onto proximal phalanges of all toes. Its purpose is to support the arch of the foot and to act as a shock absorber for pressure placed on the foot.[1,2] Plantar fasciitis is a degeneration of the plantar fascia as a result of repetitive microtears of the fascia leading to an inflammatory reaction and is not a primary inflammatory process as is customarily believed.[2] The cause of plantar fasciitis is unknown, but is believed to be multifactorial, with abnormal biomechanics and delayed healing as likely contributors.[3]

Various conservative treatment options include non-weight bearing, eccentric stretching, night splints, orthotics, and non-steroidal anti-inflammatory drugs. These treatment measures can resolve nearly 80% of the cases.[4] However, in cases who are not responsive to these treatments, invasive procedures in the form of local infiltration are required. Infiltration with intra-lesional steroids is commonly used in the treatment of chronic plantar fasciitis.[5] This procedure is effective, but only produces short-term relief. Moreover, it is also accompanied by complications, such as local infections, heel fat pad atrophy, and in some cases even plantar fascia rupture in case of multiple injections.[4,6]

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Local autologous Platelet Rich Plasma (PRP) infiltration is an emerging alternative for this condition. PRP is derived by centrifuging autologous whole blood and has a platelet concentration higher than that of blood.[7] The platelets release a variety of growth factors and cytokines, which can stimulate and accelerate the nature physiological tissue healing process.[7] Current evidence has shown promising results for PRP in the treatment of plantar fasciitis.[8–10] However, whether it is more effective in reducing pain and improving function than other treatments (such as steroid injection, or whole blood) remains controversial.[7] Aim of present study was thus to conduct a randomized control trial and to compare the effects of PRP and local depot preparation of methyl prednisone when injected locally in patients with plantar fasciitis who had failed conservative management.

2. Methods

The present study is a CTRI registered randomized control trial that took place in a tertiary level hospital over a period of one year from July 2018 to June 2019. The study was conducted on adults having heel pain for more than 4 weeks who were clinically diagnosed as plantar fasciitis, and were attending the outpatient department of the hospital. After taking due consent, participants were randomized using envelope method into 2 groups: Group A was given local injection of Platelet Rich Plasma and Group B was given local injection of Corticosteroid. All of the patients underwent conventional radiographs and magnetic resonance imaging (MRI) of the involved foot to rule out stress fractures, associated bone lesions or other causes of plantar heel pain. The inclusion criteria consisted of skeletally mature patients with heel pain at plantar fascia insertion, failure of conservative treatment for 4 weeks, and no previous injections. The exclusion criteria consisted of patients needing bilateral injections, patients with associated pathologies, inflammatory or degenerative osteoarthritis, uncontrolled diabetes, neurological conditions, skin infections, or a history of infection at the application site in the preceding 3 months. Approval was taken from the institute ethical and scientific committee. Informed written consent was taken from all of the included patients. Patients were assigned to one of the two groups in a randomized manner by selecting a sealed envelope (randomized using block randomization).

2.1. PRP preparation and injection

A bench-top centrifuge was used to concentrate platelets from autologous whole blood. 2 ml of PRP was obtained using a single step centrifugation procedure. 10 ml of blood was withdrawn from the Median Cubital Vein of the patient. The sample was collected in the EDTA Bulb and it was then centrifuged at 1800 rpm for 8 min in 2 centrifuge tubes. Bottom 1 ml of the plasma from each of the tubes, the platelet-rich plasma (PRP), was then harvested from each tube avoiding contamination by the buffy coat and red cell layers, for injection into the patient. The prepared PRP injection was given into the maximally tender point of the heel**.** Under aseptic precautions, patients in group A were given 1 ml of 2% Lignocaine at the medial side of the calcaneum which corresponded to the point of maximal tenderness which was infiltrated with an injection of 2 ml of autologous PRP.

Similarly, Group B patients were infiltrated with 2 ml of Depo-Medrol (40 mg methyl-prednisolone acetate) mixed with 1 ml of 2% Lignocaine into the point of maximal tenderness on the heel.

2.2. Post-procedure protocol

After the procedure, patients were instructed to apply ice, wear comfortable shoes. They were asked to avoid running, jumping and other high impact activities. Additional treatment permitted during the study included Analgesics like paracetamol only for one or two days to reduce the pain caused by the injection. NSAIDS were not advised after PRP injection.

2.3. Follow-up assessment

The participants were assessed for pain on the day of presentation and then after therapy at 2 weeks, 4 weeks, 3 months, and 6 months by Visual Analog Scale, and AOFAS hind-foot Score was taken at 6-month follow-up.

2.4. Sample size calculation

Power analysis for Unpaired *t*-test was conducted in G-POWER[11] to determine a sufficient sample size using an alpha of 0.05, a power of 0.80, an effect size of 0.5 (Medium effect size using Cohen's Convention), and two tails.[12] There was an equal allocation of participants into each group. Based on the aforementioned assumptions, the desired sample size was as follows:

t tests - Means: Difference between two independent means (two groups)

Analysis:A priori: Compute required sample size.
Input: Tail(s) = Two.
Effect size d = 0.5
α err prob = 0.05.
Power (1-β err prob) = 0.8.
Allocation ratio N2/N1 = 1.
Output: Noncentrality parameter δ = 2.8284271.
Critical t = 1.9789706.
Df = 126.
Sample size group 1 = 64.
Sample size group 2 = 64.
Total sample size = 128.

Thus a sample size of at least 64 in each arm was taken. Allowing for a 15% loss to follow-up 75 patients were included in each group.

2.5. Statistical analysis

Data was coded and recorded in MS Excel spreadsheet program (Microsoft Redmond, WA). SPSS v23 (IBM Corp, Chicago, IL) was used for data analysis. Descriptive statistics were elaborated in the form of means/standard deviations and medians/IQRs for continuous variables, and frequencies and percentages for categorical variables. Data was presented in a graphical manner wherever appropriate for visualization. Group comparisons for continuously distributed data were made using independent sample 't' test when comparing two groups. Chi-square test was used for group comparisons of categorical data. Continuously distributed paired variables were compared using Paired 't' test when comparing two variables, and Repeated Measures ANOVA when comparing more than two variables. Statistical significance was kept at $p < 0.05$.

3. Results

3.1. Comparison of baseline parameters

After obtaining institutional ethical and scientific committee clearance, 118 patients were recruited between July 2018 to June 2019 after necessary exclusions and loss to follow up. (CONSORT flow chart; Fig. 1). They were randomized into PRP group (n = 58) and Steroid group (n = 60). The two groups were comparable in terms of age, with the mean (SD) of age in PRP group being 32.57 (4.98) years while that in the steroid group being 34.70 (5.46) years

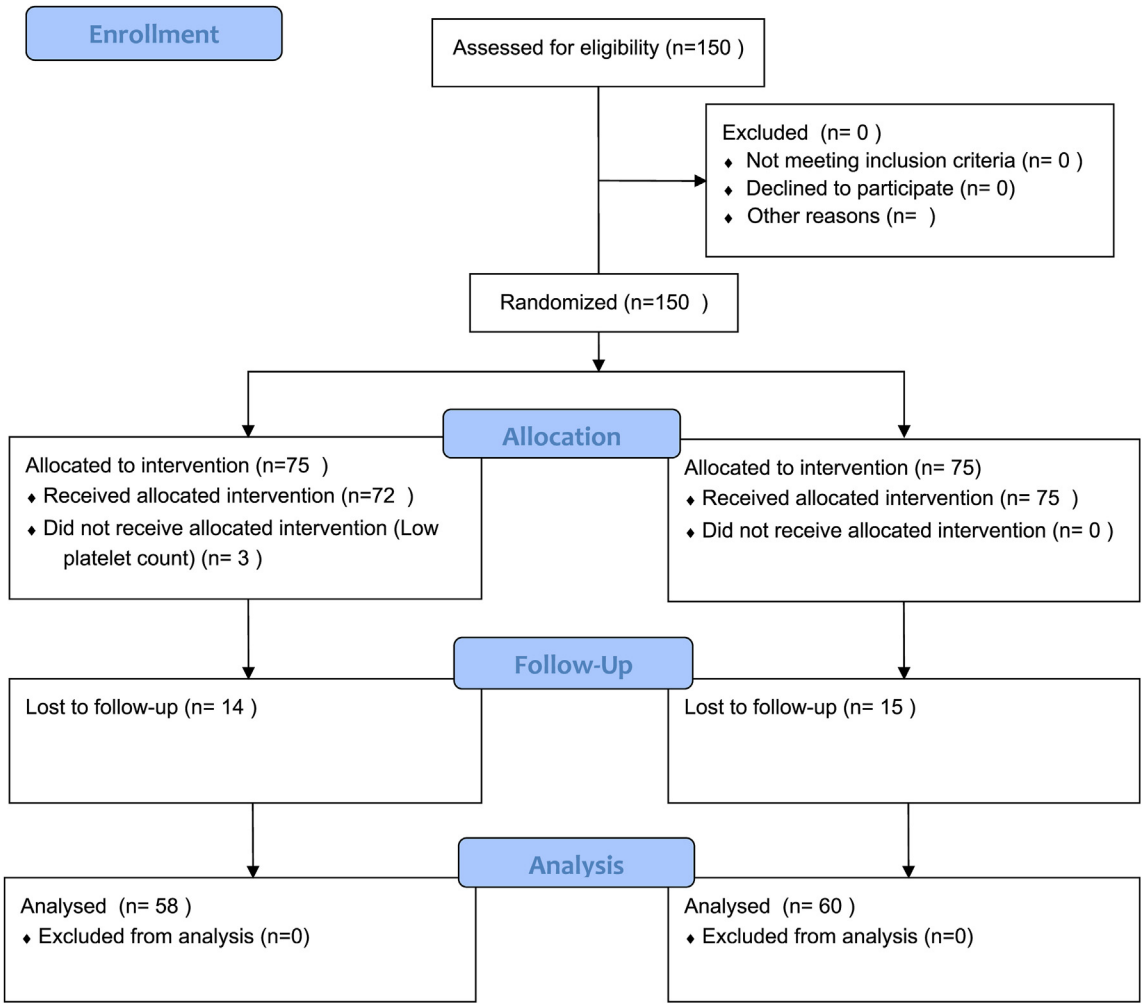

Fig. 1. CONSORT flow diagram.

(t = −2.215, p = 0.291). 86.2% of the participants in the PRP group had age less than 40 years, while 83.3% of the participants in the steroid group had age less than 40 years.

There was no significant difference between the various groups in terms of distribution of gender ($\chi^2 = 0.576$, p = 0.448). 58.6% of the participants in the PRP group were male while 51.7% of the participants in steroid group were male. There was no significant difference between the various groups in terms of distribution of side of disease ($\chi^2 = 0.025$, p = 0.875) (Table 1).

Table 1
Association between group and parameters.

Parameters	Group		p value
	PRP (n = 58)	Steroid (n = 60)	
Age (Years)* **	32.57 ± 4.98	34.70 ± 5.46	0.291[1]
Age			0.664[2]
<40 Years	50 (86.2%)	50 (83.3%)	
≥40 Years	8 (13.8%)	10 (16.7%)	
Gender			0.448[2]
Male	34 (58.6%)	31 (51.7%)	
Female	24 (41.4%)	29 (48.3%)	
Side			0.875[2]
Right	33 (56.9%)	35 (58.3%)	
Left	25 (43.1%)	25 (41.7%)	

***Significant at p < 0.05, 1: *t*-test, 2: Chi-Squared Test.

3.2. Comparison in terms of VAS score change

In PRP group, the mean VAS decreased from a maximum of 9.40 pre-injection to a minimum of 0.52 at 6 months (Repeated Measures ANOVA: F = 275.7, p = <0.001) (see Table 2). In steroid group, the mean VAS decreased from a maximum of 9.38 pre-injection to a minimum of 1.92 at 6 months (Repeated Measures ANOVA: F = 15.1, p = <0.001). The overall change in VAS over time was compared in the two groups using the generalized estimating equations (GEE) method. There was a significant difference in the trend of VAS over time in both the groups (p = <0.001) (Table 3). The maximum change from the pre-injection value was observed at the 6 months.

3.3. AOFAS score at 6 months

The mean (SD) of AOFAS Score (6 Months) in the PRP group was 95.09 (4.60) while in the steroid group was 85.96 (5.34).There was a significant difference between the 2 groups in terms of AOFAS Score (6 Months) (t = 9.527, p = <0.001), with the mean AOFAS Score (6 Months) being higher in the PRP group (Table 4).

3.4. Complications

No patient in any of the two groups suffered any complication (local or systemic) throughout their follow-up. There was no cross-

Table 2
Comparison of the Two Groups in Terms of change in VAS over time (n = 118).

VAS	Group				P value for comparison of the two groups at each of the time points (*t*-test)
	PRP		Steroid		
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	
Pre-Injection	9.40 (0.72)	10.00 (1.00)	9.38 (0.74)	10.00 (1.00)	0.922
2 Weeks	6.71 (0.99)	6.50 (1.00)	7.30 (1.09)	7.00 (2.00)	0.003
4 Weeks	3.98 (1.03)	4.00 (1.00)	4.93 (1.07)	5.00 (2.00)	<0.001
12 Weeks	1.45 (0.75)	1.00 (1.00)	2.72 (0.98)	3.00 (1.00)	<0.001
24 Weeks	0.52 (0.60)	0.00 (1.00)	1.92 (1.03)	2.00 (1.00)	<0.001
P Value for change in VAS over time within each group (Repeated Measures ANOVA)	<0.001		<0.001		
Overall P Value for comparison of change in VAS over time between the two groups (Generalized Estimating Equations Method)	<0.001				

Table 3
Change in VAS from Pre-Injection to the various follow-up time points.

Time point Comparison	Change in VAS from Pre-Injection to Follow-up Time points						Comparison of the Two Groups in Terms of Difference of VAS from Pre-Injection to Follow-up Timepoints	
	Group: PRP			Group: Steroid				
	Mean (SD) of Absolute Change	Mean (SD) of % Change	P Value of Change Within Group	Mean (SD) of Absolute Change	Mean (SD) of % Change	P Value of Change Within Group	P Value of Absolute Change	P Value of % Change
2 Weeks - Pre-Injection	−2.69 (0.82)	−28.7% (8.3)	<0.001	−2.08 (0.93)	−22.2% (9.7)	<0.001	<0.001	<0.001
4 Weeks - Pre-Injection	−5.41 (1.06)	−57.6% (10.2)	<0.001	−4.45 (0.89)	−47.6% (9.8)	<0.001	<0.001	<0.001
12 Weeks - Pre-Injection	−7.95 (0.98)	−84.6% (8.0)	<0.001	−6.67 (0.97)	−71.2% (9.6)	<0.001	<0.001	<0.001
24 Weeks - Pre-Injection	−8.88 (0.88)	−94.5% (6.3)	<0.001	−7.47 (1.07)	−79.7% (10.5)	<0.001	<0.001	<0.001

Post-Hoc pairwise tests for Repeated Measures ANOVA performed using Tukey method were used to explore the statistical significance of the change in VAS from the Pre-Injection time point to the various follow-up time points. Group comparisons for change in VAS performed using Student's t-test. Green background denotes statistically significant difference at $p < 0.05$.

Table 4
Comparison of the 2 subgroups of the variable group in terms of AOFAS score (6 Months) (n = 108).

AOFAS Score (6 Months)	Group		*t*-test	
	PRP	Steroid	t	p value
Mean (SD)	95.09 (4.60)	85.96 (5.34)	9.527	<0.001
Median (IQR)	95 (90–100)	86 (84–90)		
Range	85–100	73–97		

over allowed in our study. None of the patients required a repeat injection till 6 months follow-up.

4. Discussion

Plantar fasciitis is common among general population and can have serious implications on a patient's life and work. Successful and absolute treatment for plantar fasciitis remains an enigma till date. There have been several treatment options that have been used for plantar fasciitis, including orthoses, physical therapy, and steroid injections.[13–17] Injectable therapy has been considered second line treatment, after conservative methods fail to provide relief.[18] They are thought to reduce inflammation and pain, thereby improving functioning. The mainstay of such treatment, steroid injections, have been associated with infection, fat pad atrophy and in some cases even plantar fascia rupture.[19–21]

Plantar fasciitis is considered a degenerative condition of the plantar fascia with current evidence indicating the role of small tears of the plantar fascia. Normal plantar fascia has been observed to be replaced by angiofibroblastic hyperplastic tissue, with the lesion ironically not having any inflammatory cell invasion.[22,23] Cytokines and growth factors play a significant role in the treatment of plantar fasciitis. PRP is rich in such factors, including TGF-B (Transforming Growth factor), VEGF (Vascular Endothelial Growth Factor), PDGF (Platelet Derived Growth Factor), and several other anti-inflammatory cytokines and interleukins. The combination of these growth factors and anti-inflammatory cytokines are postulated to heal and reverse the degenerative process at the insertion of plantar fascia.[8,24] Recent evidence indicates that PRP increases collagen gene expression and production of vascular endothelial growth factor to promote healing.[25] Local PRP injection also enables delivery of growth factors because the hypo-vascular and hypo-cellular nature of the plantar fascia and high local concentration of PRP allows the regenerative process to begin shortly following infiltration.[26,27]

Our findings suggest that PRP was associated with greater improvement in VAS score and resulted in superior AOFAS score at 6 months as compared to steroid injection. We did not find any local or systemic complications in any of the groups. The result and

Table 5
Randomized control trials comparing PRP to local steroid injection for plantar fasciitis.

Study	Sample size		Steroid preparation	PRP volume (ml)	Maximal follow-up (months)	Outcome measure	Superior outcomes	Complications	
	PRP	steroid						PRP	Steroid
Omar et al., 2012	15	15	NS	NS	1	VAS, DASH, FHSQ	PRP	0	0
Tiwari and Bhargava 2013	30	30	40 methylprednisolone	5	6	VAS	PRP	NS	NS
Monto 2014	20	20	40 methylprednisolone	3	24	AOFAS	PRP	NS	NS
Sherpy et al., 2016	25	25	80 triamcinolone	3	3	VAS	Comparable	0	0
Jain et al., 2015	30	30	40 triamcinolone	2.5	12	VAS, AOFAS	PRP	NS	NS
Acosta-Olivo et al., 2017	14	14	8 mg Dexamethasone	3	4	VAS, AOFAS, FADI	Comparable	0	0
Mahindra et al., 2016	25	25	80 methylprednisolone	3	3	VAS, AOFAS	Comparable	NS	NS
Vahdatpour et al., 2016	16	16	40 methylprednisolone	3	6	VAS, RMS, Sonography	PRP	NS	NS
Ugurlar et al., 2018	39	40	40 betamethasone	5	36	VAS	Comparable	NS	NS
Jain et al., 2018	40	30	80 methylprednisolone	3	6	VAS, AOFAS, Sonography	Comparable	NS	NS
Shetty et al., 2019	30	30	80 methylprednisolone	2	18	VAS, RMS	PRP	NS	NS
PRESENT STUDY	**58**	**60**	**80 methylprednisolone**	**2**	**6**	**VAS, AOFAS**	**PRP**	**0**	**0**

NS=Not Specified.

difference were more pronounced as the time from injection increased, and maximal benefit was observed at 6 months follow-up. None of the patients needed a repeat injection at 6 months.

There have been a few published reviews and meta-analysis to compare the results of PRP and steroids. Ling et al. in their meta-analysis have found that PRP was associated with greater changes in VAS and AOFAS scores than other treatments.[28] The authors also found that the advantage of PRP over other treatments was only observed only at the 12 months, and not earlier. In contrast to these findings, our results show that the difference was significant at all time durations between 2 weeks and 6 months, but the difference was more marked at 6 months than at initial follow-up. Moreover, Ling et al. also found PRP to be more effective than steroid and placebo in the change of AOFAS score, which is similar to our results of AOFAS score at 6 months. Hsiao et al.[29] in their meta-analysis of autologous blood derived products (ABP) for plantar fasciitis have included studies using PRP as the ABP and 3 such studies have found that PRP showed a significantly greater reduction in VAS score as compared to corticosteroids at 3 months, but the reduction at 6 months was comparable between the two treatments, which is in contrast to our findings. We have found more significant improvement with PRP with the passage of time. Thus, whether PRP is superior to corticosteroids in long term remains uncertain based on inconstant results in available literature.

Our results were inconsistent with previous findings of Aksahin and Jain et al.[30,31] Aksahin et al. compared the effects of local injection of PRP with corticosteroids among sixty patients with plantar fasciitis who had failed conservative treatment.[31] At 3 weeks and 6 months after the treatment, the VAS score and RMS were significantly improved in both groups, however, the differences between them were not significant. Similarly, Jain et al.[30] compared the efficacy of PRP with steroid at 3, 6, and 12 months after injection and they found that, at 3 months, the VAS, AOFAS and RM scores were marginally better in steroid group than in the PRP group. At 6 months, these outcome scores were better in PRP group than in the steroid group. These differences in outcome scores, however, did not reach statistical significance at either 3 or 6 months.[24]

Contrary to the negative findings of Aksahin and Jain et al., some other studies observed entirely different results. In the study of Shetty et al., the authors compared the efficacy of corticosteroid injection (30 patients) with PRP injection (30 patients). At the 3-month of follow-up, the postoperative measure outcomes were significantly improved in both groups.[32] And these results were much better in the PRP group than that in the steroid group.[32] Similarly, Say et al. compared the effects of PRP and steroid in patients with plantar fasciitis.[33] The authors assessed 50 patients divided among each group.[22] PRP had a larger change in AOFAS and VAS scores than that in the steroid group, both at 6 weeks and 6 months.[22] With regards to the long-term effect of PRP, our results suggested that PRP was associated with greater changes in VAS and AOFAS scores compared to local steroid injections at 6 months.[30] Likewise, in the study of Monto et al., difference in AOFAS score between the PRP and steroid groups was clinically significant at the 12- and 24-month follow-up evaluations ($P = 0.001$).[34] Thus, available evidence indicates that PRP is more effective than steroid in the long term for the management of plantar fasciitis, a finding which is consistent with our own (Table 5).

In present study PRP was administered at the point of maximum tenderness of the heel. Previous studies have advocated the use of ultrasound guidance for the injection in plantar fasciitis,[35,36] since this could allow for more accurate placement of the injection. However, results from the trials conducted by Tsai

and Kane suggested that ultrasound-guided injection did not appear to more effective than palpation-guided injection in the treatment of idiopathic plantar fasciitis.[37,38]

VAS score is the more commonly used outcome score for evaluating effect of various treatment modalities for plantar fasciitis.[9,33,39,40] Primary concerns in treating plantar fasciitis is not just pain relief but also functional improvement and early return to day to day activities. So, to give a better idea of improvement with any therapy used for plantar fasciitis, methodologically superior recent literature uses functional scores like AOFAS score to report improvement with any therapy used.[22,24,25] Our study uses VAS as well as AOFAS to report outcomes of steroid and PRP injection for plantar fasciitis.

Large sample size in this study as compared to previous studies (Table 4) has enhanced the statistical power of our results, and the high quality in terms of level one evidence has ensured the reliability and credibility of the findings of present study. The credibility of our outcome is however limited by a follow-up of 6 months and that we were unable to determine if any patient had recurrence of symptoms with requirement of repeat injection later than that. Another limitation of our study was lack of blinding among treating physician and patients. Present study may additionally be underpowered as attrition was greater than the initial allowance of 15%. Despite some shortcomings, the current RCT suggests that Plantar fasciitis patients benefit from both PRP and steroid therapy. However, the benefit is more with PRP in terms of mid-term control of pain as well as functional improvement.

5. Conclusion

As shown in our RCT, significant differences were found in short-term and mid-term pain relief as well as mid-term functional benefit by use of PRP over steroid injection for plantar fasciitis. Considering the effectiveness of PRP, we recommend the use of PRP as the preferred treatment for Plantar fasciitis. Our study expands on the previous studies to provide a better characterization of evidence base for PRP over local steroid injection in plantar fasciitis.

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