Original Article

Effectiveness of Single Injection of Platelet-Rich Plasma over Corticosteroid in the Treatment of Plantar Fasciitis – A Randomized, Comparative Study

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Abstract

Objectives: Plantar fasciitis (PF) is not an uncommon cause of heel pain whose treatment is not yet standardized. Although platelet-rich plasma (PRP) and corticosteroid (CS) injections are the two commonly used modalities, yet not much importance has been given to the comparison of their roles in sustained functional improvement. We aimed to study the effect of PRP and CS injections in PF and compare their effectiveness with respect to pain relief and improvement of functional and patient satisfaction. **Methods:** Seventy-three cases were randomized into two groups: 39 patients (Group A) received a single injection of autologous PRP and 34 in Group B received a single injection of CS (40 mg of methylprednisolone) by the random selection. A structured home exercise program was demonstrated to both the groups, as baseline management. The effectiveness was assessed and compared in preinjection and postinjection at 3- and 6-months follow-up. Visual Analog Scale (VAS), Roles and Maudsley (RM), and Foot Function Index (FFI) scoring systems were used as outcome measures. **Results:** CSs had an early effect, reducing pain to a moderate level in 82.4% of patients compared to PRP ($P = 0.000$). However, the effect was not sustainable over a long period. On the other hand, PRP was found to have better pain relief over 3 months and 6 months follow-up with a mean VAS score of 2.0 ± 0.9 and 0.8 ± 0.8, respectively ($P = 0.000$). There was a significant improvement of FFI and RM score as well as at 6 months follow-up ($P = 0.000$). **Conclusion:** Injection of CS had an early effect, which is not sustainable, whereas PRP was found to have a prolonged impact on pain relief and better patient satisfaction with treatment outcomes. Therefore, PRP can be advised for sustained and prolonged improvement in PF.

Keywords: Corticosteroids, heel spur syndrome, Joggers' heel, plantar fasciitis, platelet-rich plasma, Visual Analog Scale

Introduction

Several terminologies were used to describe pain at the plantar surface of the heel, which includes policeman's heel, heel spur syndrome, joggers heel, sub-calcaneal pain, plantar heel pain, plantar fasciopathy, plantar fasciitis (PF), and plantar fasciosis.[1] The incidence of PF varies from 3.83 to 10.5/1000 population per year, with a higher incidence in females.[2,3] Increasing age and high body mass index are the factors associated with a higher incidence of heel pain.[4] Therapeutic modalities such as extracorporeal shock-wave therapy (ESWT), plantar fascia and Achilles tendon stretching exercises, night splints, shoe inserts and medical managements such as nonsteroidal anti-inflammatory drugs (NSAID), local corticosteroid (CS) injection, platelet-rich plasma (PRP) injection, and prolotherapy are used for the treatment of PF.[5]

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No consensus has been reached to make out the most effective modality. Moreover, the outcomes of different studies are inconsistent.[6] Although clinicians often use CS and PRP to treat chronic PF, the outcome of CS lacks high-level evidence for reliability.[7] Cochrane database of a systematic review comparing local steroid injection with placebo or no treatment in treating PF has shown a slightly reduced heel pain up

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to 1 month only.[8] A systematic review and meta-analysis also have shown no difference in pain or function score at long-term follow-up.[9] PF is considered a cumulative trauma disorder involving a degenerative process rather than inflammation. Therefore, PRP, having the potential for tissue regeneration, is theoretically superior to CS.[10] The anti-inflammatory and regenerative properties of PRP have been proved by several studies.[11,12] The literature on the efficacy of various treatment modalities for PF shows conflicting results. Although many studies have used PRP and CS in PF management, very few of them, have compared their role in terms of functional improvement and patient satisfaction.

The objective of the current study was to analyze the effectiveness of single PRP injection over CS injection in chronic PF combined with a structured home exercise program as baseline management and comparison of their efficacy in terms of pain relief and functional improvement. The study being conducted at a National Level Research Institute having divergent patient characteristics, the results will improve the level of evidence in evaluating the efficacy of the above two modalities.

Materials and Methods

This interventional study was conducted at a National Rehabilitation Training and Research Institute, India, from November 2017 to December 2019. Patients with heel pain at first steps in the morning or after a period of rest and sharp pain with the palpation of the medial plantar calcaneal region, aggravated with ankle and great toe dorsiflexion, were diagnosed to have PF. Those patients between 18 and 60 years of age who did not respond to a minimum of 3 months of conservative treatment, including analgesics, stretching exercises, and night splint, were included in the study. Those with a history of rheumatoid arthritis, gout, degenerative arthritis, neural entrapment syndromes, bleeding disorders, skin lesion on heel, pregnancy, malignancy, calcaneodynia secondary to injury or fracture, and cases with a prior history of local injection or any intervention within 6 months were excluded from the study. Patients with uncontrolled diabetic mellitus, anemia, low cognitive status, and those received NSAID 1 week before the study were also excluded.

Assuming that the patients presenting in the outpatient department randomly, every alternate patient was allotted to Group A, who were administered a single dose of autologous PRP Injection, and Group B, who received a single dose of CS (methylprednisolone) injection following simple randomization procedure, until the minimum sample size was met.

The outcome measures used were the Visual Analog Scale (VAS) score for pain, Roles and Maudsley (RM) score for pain on walking and patient satisfaction, and Foot Function Index (FFI) score for functional improvement. Scores were recorded before injection, at 3- and 6-month follow-up. VAS scores of patients were also recorded at 5 hours post-injection, just before leaving the hospital. The sample size determination has been done for the Chi-square test of independence using G*Power 3.1.9.2 statistical power analysis with a bio statistician's help. The minimum sample size came out as 69 to achieve the power of the test of 0.80 for 0.05 level of α. A total of 78 patients were enrolled for the study, out of which 5 patients were lost to follow-up. Therefore, the final sample size was 73.

The intensity of plantar heel pain was measured by VAS using a ruler with anchor points 0 as no pain 10 as the worst possible pain.[13,14] It was further classified as no pain (0), mild pain (1–3), moderate pain (4–6), and severe pain (7–10). Modified RM score was used to assess patient satisfaction and limitation of walking ability due to pain [Table 1].[15-17] The function in terms of pain, disability, and activity restriction was measured using FFI, which is a patient-related outcome questionnaire consisting of 23 items, divided into three subscales.[18]

A double-centrifugation technique was used for the preparation of PRP. Around 15 ml of autologous peripheral venous blood was collected atraumatically, avoiding platelet activation and anticoagulated with 1.5 ml sodium citrate. Initial platelet count was done for peripheral blood. Red blood cells were separated by the first centrifugation done at 2500 rpm for 15 min, followed by 3000 rpm for 5 min to obtain a plasma sample having a higher concentration of platelet, known as PRP. The total platelet count was compared with the initial platelet count. Around 3 ml pure PRP was obtained from the deeper layer and was injected immediately in the plantar fascia of group A patients. CS solution was prepared with 40 mg of methylprednisolone and 1 ml of 2% lignocaine and injected locally in Group B patients.

A standard injection technique was followed for injection into the plantar fascia.[19] The medial heel was exposed with external rotation of the affected limb. The PRP or CS was injected using a 25 G needle directing laterally on the plantar surface, just superior and anterior to calcaneus till it touches the periosteum. Care was taken to avoid injecting into the plantar fat pad. A home exercise program for plantar fascia and Achilles tendon stretching was demonstrated and explained to both groups (three sets of each exercise for 10 min duration with 10 repetitions in each set).[20]

Table 1: Roles and Maudsley Score

Rating	Interpretation
Excellent	No pain, patient satisfied with treatment outcome and unlimited walking without pain
Good	Symptoms substantially decrease, patient satisfied with the treatment outcome and the ability to walk without pain for >1 h
Acceptable	Symptoms somewhat decrease, pain at a more tolerable level than before treatment, patient slightly satisfied with the treatment outcome
Poor	Symptoms identical or worse, patient not satisfied with treatment outcomes

Statistical analysis

The data analysis was done using IBM SPSS Statistics, 24.0 software (IBM corp., Bio-statistician). The association of categorical variables such as VAS, RM, and FFI scores classified according to Group A and B and studied using the Chi-square test of independence. Computation of mean of VAS and FFI scores at different time intervals was done following descriptive statistics procedure and comparing their means between the two groups using the nonparametric Mann–Whitney U-test. For the statistical test of significance, a cut off "p" value was taken as <0.05.

Results

Out of 73 patients, 39 belonged to Group A and 34 to Group B. The age, gender, and laterality distribution are summarized in Table 2. The demographic criteria of patients in both the groups of the current study are comparable with other studies.[13,14,21-23] In patients with bilateral PF, the intervention was done in the most painful side. The Chi-square test of independence revealed no significant association between age distribution, gender distribution, and laterality between the two groups ($P = 0.233$, $P = 0.224$, and $P = 0.409$, respectively).

At 5 hours of postinjection, 97.4% of Group A and only 8.8% of Group B had preinjection pain ($P = 0.000$), with a mean VAS score of 8.0 ± 0.7 and 5.2 ± 1.2, respectively. At 3 months, the majority in Group A had mild pain (92.3%), whereas Group B had moderate pain (94.1%). Recurrence of severe pain (mean VAS 6.3) was observed in half of the Group B patients at 6 months, whereas all patients in Group A improved to either mild or moderate pain ($P = 0.000$) [Table 3].

Group A has shown a significantly lower mean VAS score than Group B, both at 3 and 6 months ($P = 0.000$) [Table 4]. Comparison of pain level and mean VAS score at different time intervals implied that Group A had no early pain relief, but there was substantial relief at 3 and 6 months. There was some pain relief at the early post-injection in Group B, which became remarkable at 3 months. However, the effect was not sustained, rather pain severity increased at 6 months, remaining below the preinjection level [Figure 1].

Comparison of Roles and Maudsley score

At preinjection, both groups had low or fair RM score without significant difference ($P = 0.442$). After the intervention, a significant difference was observed in RM scores among two groups at 3 and 6 months with $P = 0.026$ and $P = 0.000$, respectively. Fair to good functional improvement was observed at 3 months in both groups. At 6 months, Group A showed significantly better function in terms of movement and patient satisfaction [Table 5].

Table 2: Age, gender, and side distribution of study treatment groups

	Group A (PRP), *n* (%)	Group B (CS), *n* (%)	Total *n* (%)	*P*, Chi-square test *, *t*-test#
Age group (years)				
21-30	8 (20.5)	13.(38.2)	21.(28.8)	0.233*
31-40	14.(35.9)	9.(26.5)	23.(31.5)	
41-50	11.(28.2)	5.(14.7)	16.(21.9)	
51-60	6.(15.4)	7.(20.6)	13.(17.8)	
Mean±SD	39.4±10.2	37.0±11.9	38.3±11.0	0.365#
Gender				
Male	14 (35.9)	17 (50)	31 (42.5)	0.224*
Female	25 (64.1)	17 (50)	42 (57.5)	
Side				
Right	18 (46.2)	21 (61.8)	39 (53.4)	
Left	18 (46.2)	11 (32.4)	29 (39.7)	0.409*
Bilateral	3 (7.7)	2 (5.9)	5 (6.9)	
Total	39 (100)	34 (100)	73 (100)	

Symbol*: Indicates Chi- square test, Symbol # -Indicates t-test PRP: Platelet-rich plasma, SD: Standard deviation, CS: Corticosteroid

Table 3: Association of Visual Analog Scale score at different stages between the two treatment groups

Follow-Up	Group	No pain, *n* (%)	Mild pain, *n* (%)	Moderate pain, *n* (%)	Severe pain, *n* (%)	χ^2, *P*
Preinjection	A	0 (0)	0 (0)	0 (0)	39 (100)	*
	B	0 (0)	0 (0)	0 (0)	34 (100)	
Early postinjection	A	0 (0)	0 (0)	1 (2.6)	38 (97.4)	<0.001
	B	0 (0)	3 (8.8)	28 (82.4)	3 (8.8)	
3 months follow-up	A	3 (7.7)	36 (92.3)	0 (0)	0 (0)	<0.001
	B	0 (0)	1 (2.9)	32 (94.1)	1 (2.9)	
6 months follow-up	A	15 (38.5)	24 (61.5)	0 (0)	0 (0)	<0.001
	B	0 (0)	3 (8.8)	14 (41.2)	17 (50)	

Symbol*: Indicates *P* value for Chi- square test of early post injection, 3 months and 6 months follow up

Comparison of functional improvement with Foot Function Index score

The comparison of mean FFI score at the different time intervals between the two treatment groups has shown that the mean FFI score of both groups has reduced considerably at 3- and 6-month follow-up ($P = 000$). However, the mean FFI scores in Group A were significantly lower than Group B [Table 6]. No adverse events were noticed in any of the groups.

Discussion

The present study revealed that the pain relief of most of the CS (Group B) patients has come down from severe to moderate pain at the early postinjection stage, while at 3 months and 6 months follow-up, the effectiveness was significantly better with the injection of PRP. Most of these patients were satisfied with the treatment outcome having unlimited walking without pain. The early effect of both injections was measured after 5 hours of postinjection, just before the patient left the hospital. Lignocaine used with CS has a rapid onset of local anesthetic effect lasting for up to 30–60 min in its plain form.[24] Since the excretion half-life of Lignocaine is for 90–110 min,[24] the effect assessed after 5 hours postinjection was more of CS. The use of Lignocaine with PRP was avoided as it could directly interfere with platelet functionality, especially platelet aggregation.[25] Moreover, PRP injection combined with local anesthetic is less effective than PRP injection alone.[26] The PRP action on plantar fascia regeneration, pain relief, and functional improvement have been described by different authors in different ways. Some authors postulated PF to be a chronic degenerative condition due to repeated microtrauma associated with the formation of angiofibroblastic tissue.[13] In chronic cases, due to cumulative trauma, the micro-tears at its attachment cannot heal, leading to collagen denaturation. A degenerative mechanism in PF is established with histological findings such as collagen necrosis, chondroid metaplasia, and calcification.[27] Hypovascularity of plantar fascia prevents accessibility to a high concentration of platelet and other growth factors for natural repair. Injection of PRP directly delivers platelets into the lesion, which releases, platelet-derived growth factor, transforming growth factor beta, endothelial growth factors, that accelerate tissue healing. The anti-inflammatory and antinociceptive effects of PRP are well established in the literature.[28,29] Injection of PRP in Group A patients of the current study has shown an antinociceptive effect by relief of pain and functional improvement at 3- and 6-month follow-up. The meta-analysis by Chen *et al*.[30] has shown significant pain relief at 1.5 and 3 months in the CS group but sustained pain relief in the PRP group at 12 weeks, which is also reflected in the current study. Patient satisfaction and functional scores give a significantly better edge to patients in group A. A similar result was observed in a meta-analysis by Yang *et al*.[27] with better long-term pain relief after 24 weeks. However, no significant difference in the RM score and foot function score was observed among both groups. Our study results on the sustained effects of PRP over CS is supported by other studies.[13,17,21,22,31] The review article by Monto[32] suggested that PRP's effect can be considered an alternative to surgical care in case of severe chronic PF. A comparative study between PRP and CS by the same author[33] showed initial pain and function improvement scores at 3 months in the CS group, followed by a drop down to the baseline at 12 months. In contrast, the PRP group showed a sustained improvement beyond 24 months. A similar inference was drawn by Ling and Wang[34] in the meta-analysis of 10 randomized control trials

Table 4: Comparison of mean visual analog scale score between the two treatment groups

VAS score	Study groups, mean±SD		Mann-Whitney U, *P*
	Group A	Group B	
Preinjection	8.2±0.6	8.0±0.8	0.088
Early postinjection	8.0±0.7	5.2±1.2	0.000
3 months follow-up	2.0±0.9	4.9±0.9	0.000
6 months follow-up	0.8±0.8	6.3±1.5	0.000

VAS: Visual analog scale, SD: Standard deviation

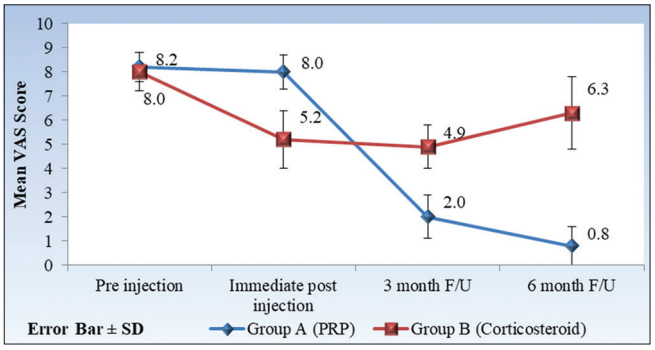

Figure 1: Comparison of mean visual analog scale score at different time intervals between the two treatment groups

Table 5: Comparison of roles and maudsley score at different stages between the two treatment groups

RM score	Preinjection score		3 months follow-up		6 months follow-up	
	Group A (*n*=39)	Group B (*n*=34)	Group A (*n*=39)	Group B (*n*=34)	Group A (*n*=39)	Group B (*n*=34)
Excellent	0	0	7	0	29	0
Good	0	0	20	17	10	03
Fair	23	17	12	15	0	16
Poor	16	17	0	02	0	15
χ^2, *P*	0.591, 0.442		9.278, 0.026		63.726, 0.000	

RM: Roles and maudsley

Table 6: Comparison of mean foot function index score between the two treatment groups

FFI score	Study groups, mean±SD		Mann-Whitney U,'*P*'
	Group A	Group B	
Preinjection	174.2±18.0	172.4±19.7	0.711
3 months follow-up	45.3±12.6	89.9±13.1	0.000
6 months follow-up	12.0±5.7	84.1±16.2	0.000

FFI: Foot Function Index, SD: Standard deviation

involving 445 patients except for the fact that the RM score on subgroup analysis with control regimen did not show any advantage of CS. The current study has shown a comprehensive outcome, including pain, disability, activity limitation, and overall patient satisfaction comparing two treatment groups at different follow-up intervals.

Martinelli *et al*. studied the safety and efficacy of PRP in PF[15] with three PRP injections at weekly intervals. The RM score at 12-month follow-up was excellent in 64% cases, and no adverse events were noted with repeated PRP injections. In the current study, excellent RM score has been observed at the end of 6 months follow-up in 74% of cases administered with a single PRP dose.

The systematic review and meta-analysis by Whittaker *et al.,*[7] which included 47 trials, supports CS injection as an effective treatment over other comparators for pain relief and functional improvement. Other systematic reviews and meta-analysis conducted by Singh *et al*.[9] and the study by Jain SK[35] reported no difference in pain or functional score at long-term follow-up between PRP and CS groups. A network meta-analysis by Babatunde *et al*.[5] for the comparative effectiveness of different treatment options, including CS injection, has shown an equivocal result. Cochrane database of systematic reviews on the treatment of plantar heel pain[8] found low-quality evidence that when local CS injection was compared with placebo or no treatment, heel pain was reduced slightly up to one month but not beyond that. A similar observation was made by Karls *et al*.[36]

Rupture of plantar fascia following repeated CS injections is rare but a known complication. In a retrospective study of 120 PF patients, 2.4% of cases reported plantar fascia rupture. following an average of 2.67 injections.[37] Suzue *et al*.[38] reported a case of plantar fascia rupture after 2nd CS injection in a young professional soccer player. Although a single dose of CS injection was given in Group B patients, clinical evaluation was done at each follow-up to rule out plantar fascia rupture Complications such as calcaneal osteomyelitis and heel abscess have been reported by Mohd Khalid and Bajuri following CS injection in an elderly lady with diabetes and rheumatoid arthritis.[39] PF patients with associated comorbidities such as uncontrolled diabetes and rheumatoid arthritis were excluded from the current study. Hence, we did not encounter any such complications in our study groups.

Besides PRP and CS, other treatment modalities for PF such as NSAID, physical therapy, ultrasound therapy, autologous whole blood, ESWT, dry needling, and Botulinum toxin cannot be ignored. The network meta-analysis by Haibo Li *et al*.[40] on comparing the efficacy of eight treatment modalities for PF revealed that ESWT ranked the first and was considered the most optimal treatment. In contrast, Botulinum toxin A and PRP remain suboptimal treatment. Currently, Raeissadat *et al*.[41] have used high-molecular-weight Hyaluronic acid and shown good results as CS. Despite extensive research on various modalities of treatment for PF, observations are continuing to be controversial. Further research with larger sample size is required on its basic pathophysiology to specify the ideal management methods.

Limitations

Blinding was not done during the allocation of samples; hence, the possibility of selection bias cannot be ruled out. The use of simple randomization in a sample size less than a hundred is a limitation to this study. The study duration was limited to 6 months, which may not be sufficient to study the long-term impacts. Compliance with the home rehabilitation program and its impact on results is not measured. Before administering PRP injection, whether the platelets should be activated or not, is not well established. Scherer *et al*.[42] observed in their animal model that nonactivated platelets stimulated wound healing more efficiently than activated platelets. Platelets, once activated with thrombin or calcium, release most of their growth factors and loses their ability, specifically to interact with the environment.

Conclusion

CS has an early effect, reducing pain to a moderate level (82.4%) in comparison to PRP (P = 0.000). However, the effect is not sustainable over a long period. On the other hand, PRP was found to have better pain relief over 3 months and 6 months follow-up with a mean VAS score of 2.0 ± 0.9 and 0.8 ± 0.8, respectively (P = 0.000). There is a significant improvement in foot function and patient satisfaction as well at 6 months follow up (P = 0.000). Therefore, PRP can be advised for a sustained and prolong impact on chronic PF.

Recommendations

Further studies are needed to find out the results of platelet activation before PRP injection. Whether single or multiple doses of PRP injection are required to achieve the desired result, needs to be established.

Ethical consideration

With the patient's informed consent, the study has been done in accordance with the Declaration of Helsinki. The institutional review board approved the study in December 2017. Ethical committee of Swami Vivekananda National Institute of Rehabilitation Training and Research held on 18/12/2017.

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Conflicts of interest

There are no conflicts of interest.

Author's contribution

PKS designed and supervised the study, interpreted the results of the study, revised the manuscript for critical intellectual content, and agrees to be accountable for all aspects of the work and to take the responsibility of the corresponding author. NAU collected the data, statistically analyzed the data, and prepared an initial draft of the manuscript. SPD revised the manuscript critically by providing important intellectual inputs. All authors have critically reviewed and approved the final version of the manuscript and are responsible for the manuscript's content and similarity index.

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