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The efficacy of platelet rich plasma therapy versus corticosteroid injection in the treatment of plantar fasciitis in adults: A randomised controlled trial

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Abstract
Background: Plantar fasciitis is a common cause of heel pain. Prospective interventional study was done to compare the efficacy of PRP and corticosteroid injection for its treatment.
Methods: This study was conducted from August 2020 to July 2022. 50 patients were chosen with chronic Plantar Fasciitis which were divided in two groups, Group A (N=25) received PRP and Group B (N=25) received corticosteroid injections. They were evaluated at 1st, 2nd, 4th and 6th month after injection for pain relief and functional status on the basis of visual analogue scale (VAS), Roles-Maudsley subjective pain score (RMSPS) and Ankle-Hind Foot Scale (AHFS).
Results: While calculating baseline and mean VAS scores of the PRP group, the difference was maximum at 6th month (2.52) and in the steroid group, at the end of 2nd month (4.2). The difference between the baseline and mean RMPS scores in the PRP group was maximum at 6th month (1.56) and, in the steroid group, at the end of 2nd month (2.44). The baseline and mean AHFS scores in the PRP group, the difference was maximum at 6th month (83.68) and in the steroid group, at the end of 2nd month (66).
Conclusion: Significant differences were observed in both the groups at 1st & 6th month follow ups. The CCS group showed improvement at 1st & 2nd months which declined with time, while PRP showed initially slow improvement but the beneficial effect is safe, sustained and significant reduction at the end of 6th month.

Keywords: Corticosteroid injection, therapy versus, plantar fasciitis, beneficial effect

Introduction
Plantar fasciitis is a disorder of the connective tissue that supports the arch of the foot. This is one of the most common chronic tendinopathies affecting humans. It typically affects both men and women in the age group of 40-70 years, predominantly women. It occurs in around 10% of the general population and is bilateral in 33% of cases [1].
The cause of plantar fasciitis is not entirely clear. Risk factors include overuse, such as long periods of standing, exercise, and obesity [3]. It is also associated with inward rolling of the foot, a tight Achilles tendon, and a sedentary lifestyle [4]. Plantar fasciitis is a disorder of the insertion site of the ligament on the bone characterized by microtears, breakdown of collagen, and scarring. Since inflammation plays either a lesser or no role, there are views proposing that it be renamed plantar fasciosis [6].
Pain 1, 2 is typically sharp and usually unilateral. Bearing weight on the heel after long periods of rest worsens heel pain. Symptoms are most intense during their first steps after getting out of bed or after prolonged periods of sitting. Symptoms typically improve with continued walking [7].
Plantar fasciitis is diagnosed based on a detailed medical history. The location of pain can help determine its cause. Usually, no tests are required to diagnose plantar fasciitis but ruling out other significant causes of heel pain associated with other illnesses requires further investigation [8]. Sometimes an X-ray shows a bone spur from the heel bone. In the past, these bone spurs were often blamed for heel pain and removed surgically. However, many people who have bone spurs on their heels have no heel pain [9].

Most people recover in several months with conservative treatment, including resting, weight reduction, contrast bath, well cushioned footwear (silicon heel pad), stretching and physiotherapy exercises. Invasive treatment includes local steroid injection and platelet-rich plasma (PRP) injection [10].

Local injection of autologous PRP is an emerging concept in treating chronic plantar fasciitis. PRP obtained from the patient's own blood can be injected to promote tissue healing. It delivers platelets and growth factors 15 in high concentrations directly to the site of injury zones to induce and accelerate healing processes. Platelet Rich plasma helps in the healing of plantar fasciitis and the recurrence rates are low [11].

The clinical application of PRP and other regenerative therapies in sports, spine, and musculoskeletal medicine has soared in the last decade. Over this period, many factors converged to fuel this development. Today in musculoskeletal and sports medicine, PRP therapy has become highly attractive for its potential benefit and influence on repairing injured tissue, treating a wide range of degenerative disorders, and accelerating the return to sport [5].

The normal concentration of platelets in blood ranges from 150,000-350,000/μL [5]. A level of at least 1,000,000/μL is needed to promote healing [5]. Most PRP contains a 3-5-fold higher level than the baseline [5].

Current Theory behind PRP

Essentially PRP is used to increase the concentration of platelets at an injured site. In an acute injury, platelets are normally activated during the inflammatory phase to begin healing. The addition of PRP increases the concentration of platelets at the local tissue over the baseline. Chronic injuries that have failed conservative therapies presumably have ceased the inflammatory phase, and have a paucity of platelets and a decrease in healing potential [5].

PRP in these situations would provide 2 beneficial results. First, it stimulates the tissue and restarts the inflammatory process, thereby converting the chronic injury into a new acute injury. Second, the addition of autologous platelets theoretically augments the healing process. This new injury now has a known starting point and can be placed in a controlled post injection environment (e.g.; immobilization, bracing, or non-weight bearing) [12].

The proposed prospective study aimed to compare local injection of autologous PRP with local steroids in reducing pain and improving function in adult patients with chronic plantar fasciitis.

The objectives of the study were as follows

1. To assess and compare the clinical outcomes of local injections of autologous platelet rich plasma with local steroids in chronic plantar fasciitis in terms of pain.
2. To assess the merits and demerits of local steroid injection versus PRP injection.

Methods

After obtaining clearance from the ethics committee, a hospital based prospective randomized interventional study was conducted in the Department of Orthopedics from August 2020 until August 2022. A total of 60 patients in the age group of 18-60 years of either sex having symptoms suggestive of plantar fasciitis were included in the study. Out of 60 patients only 50 patients were reported for all defined follow-ups so the study and evaluation were performed only on 50 patients.

Inclusion criteria

1. Patients between the ages of 18 and 60 years presented with complaints of plantar heel pain, which was worse in the morning and/or after periods of sitting or lying for 3 months or more.
2. Patients with maximum tenderness at the attachment of plantar fascia on the medial tubercle of the calcaneus.
3. Both sexes-male and female

Exclusion criteria

1. Patients who had received any previous treatment in the form of local injections of steroids and PRP within 6 months.
2. Pain of less than 3 months duration
3. Patients without any trial of conservative treatment
4. Previous surgery for heel pain.
5. Infection or ulcer at the injection site
6. Rheumatoid arthritis
7. Seronegative spondyloarthritis
8. Pregnant/breastfeeding female patients.
9. Patients younger than 18 years

Randomization method: The patients were randomized into two groups using the simple random technique through the Chit box method.

Group A: These patients were treated with single injection of 2 ml autologous PRP injection locally.

Group B: These patients were treated with a single injection of 40 mg/ml methyl prednisolone acetate locally.

Informed written consent for the procedure was obtained from all the study participants. All patients were subjected to routine blood investigation including markers for inflammatory arthropathy.

Follow up

All selected patients were evaluated at definite intervals at the 1st, 2nd, 4th and 6th months after injection for pain relief and functional status on the basis of the visual analog scale (VAS), Roles-Maudsley subjective pain score (RMSPS) and ankle hind foot scale (AHFS).

At each follow-up, assessment was performed for local and systemic complications such as infection, unremitting pain, skin changes at or near the injection site (color and texture), ecchymosis etc.

Statistical analysis was performed by using Graphpad in Stat [Dataset 1.ISD] software. The comparison of means between two groups tested was done by using unpaired student's t test. For repeated measures, a paired test was also used. A p-value < 0.005 was considered significant.

Fig 1: Show the results depicted in the graph as discussed above, the autologous PRP

Preparation of PRP

In this study, an 18 cc venous blood sample was obtained from the cubital vein of the patient and mixed with 2 cc of anticoagulant [acid citrate dextrose solution (ACD)], to prevent clotting of the sample and to prevent platelet activation prior to its use. Here we used the double spin centrifugation method with soft and hard spin.

Steroid injection

Methylprednisolone acetate is the most commonly used steroid in the treatment of plantar fasciitis [13]. It has potent anti-inflammatory effects.

Post Injection Care

1. Patients were informed of the exaggeration of pain symptoms for 2-3 days.
2. Advised to avoid NSAIDS.
3. Rest and Ice Fomentation for 1-2 days.
4. The Physiotherapy exercises were performed twice a day.

Injection was given either with PRP obtained from preparation with said procedure or with methylprednisolone acetate obtained from pharmacy in filtered into the lesion.
Non-steroidal anti-inflammatory drug use was not permitted during the first 2 weeks after treatment and was discouraged throughout the entire study period.

Post op protocol

Table 1: Show Phase 1-3 the entire study period

Phase I Tissue protection	0-7 days	Consider non-weight bearing, especially if paining. Avoid NASAIDs Limited ice application	Relative rest, Assisted movement May have splint
Phase II Early tissue healing; collagen deposition	8-14 days	Progress to weight bearing without protective device. Avoid eccentric exercises, NSAIDs and Ice.	Aerobic exercises, avoid loading Gentle stretching of treated area, Begin kinetic exercises
	2-6 weeks	Avoid eccentric exercises, NSAIDS and Ice	Weight bearing activities, repetition isometrics with open kinetic exercises Soft tissue work up and dynamic stretching.
Phase-III Collagen strengthening	6-12 weeks	Avoid NSAIDs, Ice	Isometric exercises as long as pain scale < 3 Closed kinetic chain exercises. Polymetrics, proprioceptive training and other sport exercises
	After 3 months	Reassess improvement If pain not improved more than 75%,consider reinjection, begin from Phase I	Back to functional activities Max eccentric activities May return to sport if pain score less than 3

Results

Age: The mean age was 41.28 years for the PRP group and 41.92 years for the steroid group, and the total mean age was 41.6 years.

Gender: In our study groups 32 (64%) were females and 18 (36%) were males, suggesting that females are more prone to plantar fasciitis.

Body Weight: In our study groups, the mean weight was 63.36 kg for the PRP group and 63.12 kg for the steroid group. The overall mean weight was 63.24 kg.

Side Affected: In our study groups of 50 patients, 31 (62%) were left side, foot affected, and 19 (38%) were right side foot affected.

Mean VAS scores between the PRP and steroid groups at different follow-ups

When we calculated the difference between the mean VAS score in the pretreatment period, i.e., baseline and mean VAS scores at different intervals in the post injection period, it was found that in the PRP group, the difference was maximum at the 6th month, and in the steroid group, it was at the end of the 1st month. This shows that the maximum effect of PRP on VAS was at the 6th month, whereas in the steroid group, it was at the 1st month.
For the within-group comparison in the PRP group, the results were statistically significant (p<0.0001). The mean VAS score decreased from baseline continuously at the 1st, 2nd, and 4th months and up to the 6th month. The VAS score was found to be statistically significant in comparison with baseline at all durations.
In the steroid group, the results were also statistically significant. The mean VAS score decreased from baseline continuously at the 1st and 2nd months. However, at the end of the 4th and 6th months, there was a significant increase in the VAS score compared to the score at the 2nd month.

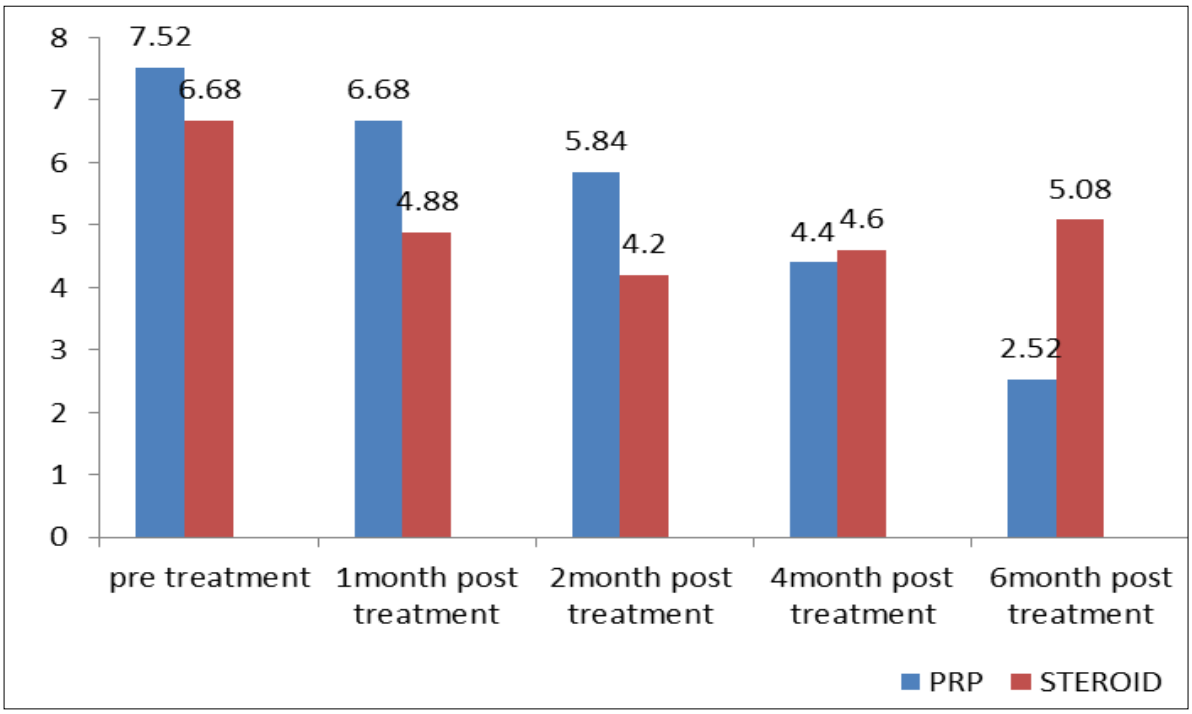

Fig 2: Show 1-6 month post treatment

Table 2: Show VAS score compared to the score at the 1-6th month

VAS	Intervention	N	Mean	SD	Mean Difference	P value
Pre treatment	PRP	25	7.52	1.19	0.84	0.683
	Steroid	25	6.68	1.90		
At 1st month post treatment	PRP	25	6.68	1.14	1.8	< 0.0001
	Steroid	25	4.88	1.83		
At 2nd month post treatment	PRP	25	5.84	1.40	1.64	< 0.0004
	Steroid	25	4.2	1.65		
At 4th month post treatment	PRP	25	4.4	1.58	-0.2	0.6395
	Steroid	25	4.6	1.41		
At 6th month post treatment	PRP	25	2.52	1.32	-2.56	< 0.0001 (SEG.)
	Steroid	25	5.08	1.77		

Mean RMSP Scores between PRP & STEROID groups at different follow ups

When we calculated the difference between the mean RMPS score in the pretreatment period, i.e., baseline and mean RMPS scores at different intervals in the post injection period, it was found that in the PRP group, the difference was maximum at the 6th month, and in the steroid group, it was at the end of the 1st month. This shows that the maximum effect of PRP on RMSPS was at the 6th month, whereas in the steroid group, it was at the 1st month.

For the within-group comparison in the PRP group, the results were statistically significant (p<0.0001). The mean RMSP score decreased from baseline continuously at the 1st, 2nd, and 4th months and up to the 6th month. The RMSP score was found to be statistically significant in comparison with baseline at all durations.

In the steroid group, the results were also statistically significant. The mean RMSP score decreased from baseline continuously at the 1st and 2nd months However, at the end of the 4th and 6th months, there was a significant increase in the RMSPS score compared to the score at the 2nd month. Mean ankle hind foot scores (AHFS) between the PRP and steroid groups at different follow-ups:

Table 3: Show significant increase in the RMSPS score compared to the score at the 1-6th month

RMSPS	Intervention	N	Mean	SD	Mean Difference	P-Value
Pre Treatment	PRP	25	3.44	0.65	0.04	0.8428
	Steroid	25	3.4	0.76		
At 1st month post treatment	PRP	25	3.12	0.72	0.2	0.3632
	Steroid	25	2.92	0.81		
At 2nd month post treatment	PRP	25	3	0.70	0.56	0.0075
	Steroid	25	2.44	0.71		
At 4th month post treatment	PRP	25	2.32	0.62	-0.36	0.0596
	Steroid	25	2.68	0.69		
At 6th month post treatment	PRP	25	1.56	0.58	-1.4	< 0.0001 (SEG.)
	Steroid	25	2.96	0.78		

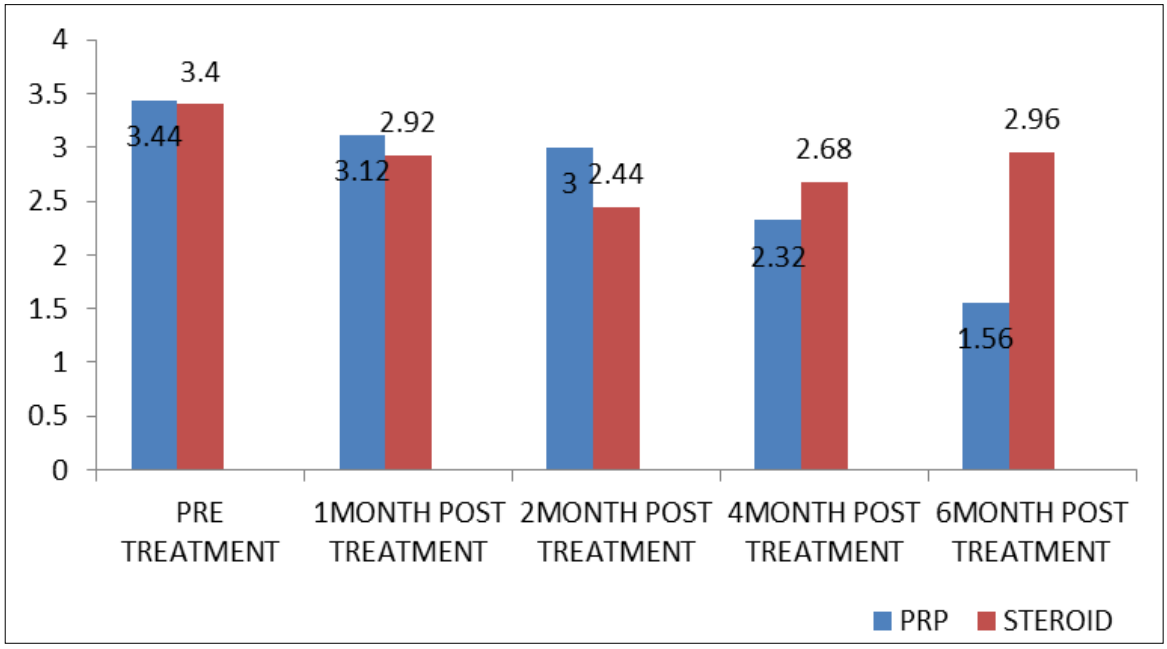

Fig 3: Show PRP and steroid groups 1-6th month post treatment

Ankle hind-foot score (AHFS): When we calculated the difference between the mean AHFS score in the pretreatment period, i.e., baseline and mean AHFS scores at different intervals in the post injection period, it was found that in the PRP group, the difference was maximum at the 6th month and in the steroid group, it was at the end of the 1st month. This

shows that the maximum effect of PRP on AHFS was at the 6th month, whereas in the steroid group, it was at the 1st month.

For the within-group comparison in the PRP group, the results were statistically significant (p<0.0001). The mean AHFS score increased from baseline continuously at the 1st, 2nd, and 4th months and up to the 6th month. The AHFS score was found to be statistically significant in comparison with baseline at all durations.

In the steroid group, the results were also statistically significant. The mean AHFS score increased from baseline continuously at the 1st and 2nd months. However, at the end of the 4th and 6th months, there was a significant decrease in the AHFS score compared to the score at the 2nd month.

Table 4: Show Ankle hind-foot score (AOFAS) and Intervention

Ankle hind-foot score (AOFAS)	Intervention	N	Mean	SD	Mean Difference	P-Value
Pre Treatment	PRP	25	37.52	11.30	-3.68	0.2995
	Steroid	25	41.2	13.14		
At 1st month post treatment	PRP	25	49.28	12.20	-8.88	0.0175
	Steroid	25	58.16	13.27		
At 2nd month post treatment	PRP	25	55.52	13.49	-10.48	0.0103
	Steroid	25	66	14.22		
At 4th month post treatment	PRP	25	67.4	14.09	3.32	0.3501
	Steroid	25	64.08	10.52		
At 6th month post treatment	PRP	25	83.68	14.52	25.52	< 0.0001 (SEG.)
	Steroid	25	58.16	14.98		

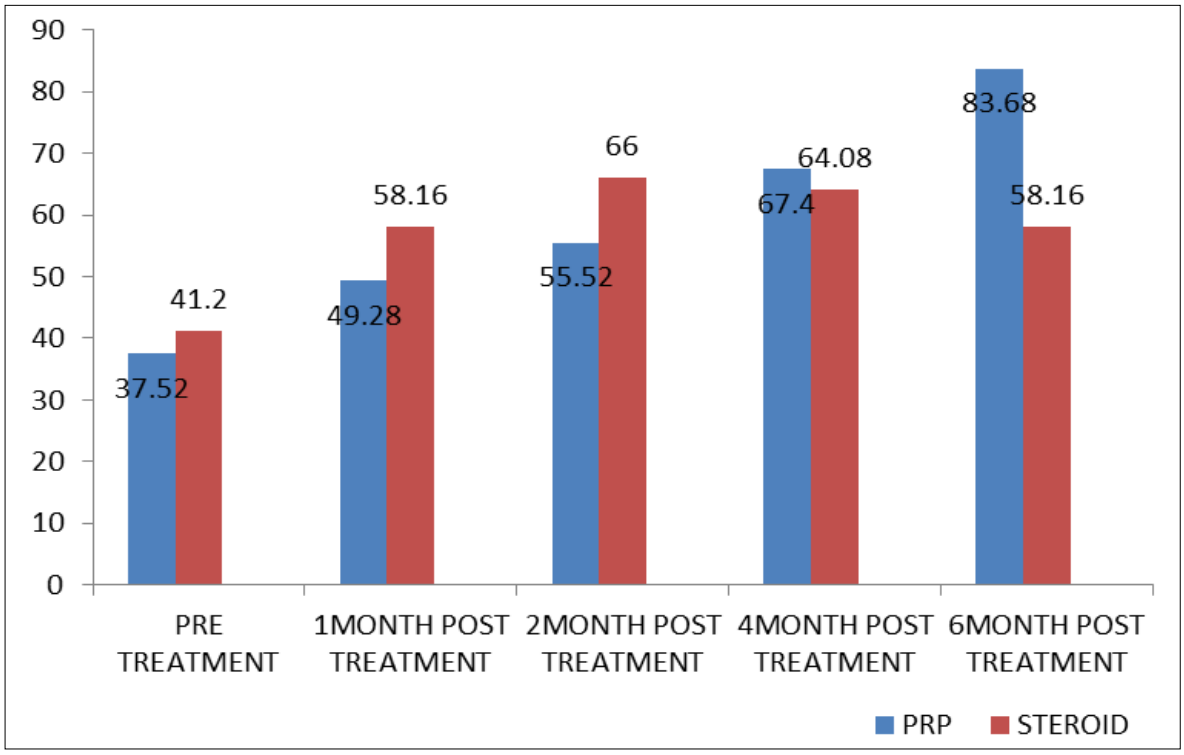

Fig 4: Show PRP & STEROID groups, no complications or allergies were noticed during or after the study

With these data and clinical outcome and from the results depicted in the graph as discussed above, the autologous PRP injection appears to have a slower onset of action than steroids but is long acting as all studied scores showed improvement from baseline throughout regular interval follow-ups, whereas the steroid group showed initial improvement at the 1st and 2nd month follow-up assessments. After that, the effect of steroids was weaned off, and at the 4th and 6th month follow-up, pain was aggravated, and a decrease in functional outcome was reported, suggesting that steroids have short-term action on pain and inflammation during the acute phase of disease and do not play any significant role in curing chronic plantar fasciitis.

In our study, a total of 50 patients were followed up for 24 weeks in both groups, with 25 in each group.

In the PRP & STEROID groups, no complications or allergies were noticed during or after the study.

Discussion

Chronic plantar fasciitis is one of the most common causes of foot complaints, accounting for up to 11-15% of foot symptoms requiring medical care among adults. 14 This study was designed to compare the efficacy of corticosteroid therapy to PRP therapy for chronic plantar fasciitis.

Females (64%) were affected more than males (36%) in our study. On the basis of laterality, the right side was more affected.

Most of the patients in our study were aged 18-60 years, with a mean age of 41.28 +/- 10.02 years in the PRP group and 41.92 +/- 10.96 years in the steroid group. This is similar to the observations in which the mean age was 42.76 +/- 9.38 years (steroid group) and 40.40 +/- 9.95 years in the PRP group[16] in 2019 and another study in which the mean age was 40.90 +/- 9.36 years in the PRP group and 37.82 +/- 11.04 years in the steroid group [17] in 2017.

In the present series, the VAS score among platelet rich plasma group A declined from a pre-injection score of 7.52 to 6.68 at the 1st month, 5.84 at the 2nd month, 4.4 at the end of the 4th month and 2.52 at the end of the 6th month.

A similar observation was also noted by Tank G *et al.* [17] in 2017, where the VAS pre injection score was 8.44, 7.747 at the 1st month, 6.26 at the 2nd month, 3.433 at the end of the 4th month and 1.46 at the 6th month.

In the present series, the RMSPS score among platelet rich plasma group A declined from a pre-injection score of 3.44 to 3.12 at the 1st month, 3 at the 2nd month, 2.32 at the end of the 4th month and 1.56 at the end of the 6th month.

Similar observation was also noted by Puri VP *et al.* [18] who noted RMSPS Pre injection score 3.93, at 1st month 3.58, at 2nd month 3.10, 2.87 at the end of 4th month and at the end of 6th month 1.57.

In the present series, the AHFS score among platelet rich plasma group A increased from a pre-injection score of 37.52 to 49.28 at the 1st month, 55.52 at the 2nd month, 67.4 at the end of the 4th month and 83.68 at the end of the 6th month.

Similar observation was also noted by Singh M *et al.*[16] 2019 study with AHFS Pre injection score 68.440, at 1st month 74.340, at 2nd month 89.840, and at the end of 6th month 89.920. In the present series, the VAS score among steroid group B declined from a pre-injection score of 6.68 to 4.88 at the 1st month, 4.2 at the 2nd month, 4.6 at the end of the 4th month and 5.08 at the end of the 6th month. A similar observation was also noted by Tank G *et al.* [17], where the VAS preinjection score was 8.38, 4.074 at the 1st month, 2.602 at the 2nd month, 1.188 at the end of the 4th month and 3.024 at the end of the 6th month.

In the present series the RMSPS score among steroid group B declined from a preinjection score of 3.4 to 2.92 at the 1st month, 2.44 at the 2nd month, 2.68 at the end of the 4th month and 2.96 at the end of the 6th month.

A similar observation was also noted by Puri VP *et al.* [18], where the RMSPS pre injection score was 3.87, 3.48 at the 1st month, 27 at the 2nd month, 2.07 at the end of the 4th month and 2.17 at the end of the 6th month. In the present series, the AHFS score among steroid group B increased from a pre-injection score of 41.2 to 58.16 at the 1st month, 66 at the 2nd month, 64.08 at the end of the 4th month and 58.16 at the end of the 6th month.

A similar observation was also noted by Singh M *et al.* [16], with AHFS scores of 67.440, pre injection, 85.760 at the 1st month, 84.160 at the 2nd month, and 83.920 at the end of the 6th month. Our PRP vs steroid comparison study matched the results of recent studies such as that of Omar *et al.* [19], who found a significant difference as regards to mean VAS between the two groups, favoring the PRP group at 1.5 months follow-up ($p<0.05$) and that of Monto *et al.* [20] who demonstrated that both PRP and steroid groups continued to improve up to 3 months and found that the improvement in the steroid group started to decline after 3 months and was sustained for longer periods in the PRP group.

Table 5: Show baseline score outcomes, last follow up scores outcome and complications

References	Score	Baseline score outcomes	Last follow up scores outcome	Complications
Monto *et al.*	AOFAS	PRP group:37 CCS group: 52	PRP:92 CCS:56	No
Kumar *et al.*	AOFAS R&M VAS	60.6±13.1 7.7±1.4 4(inter-quartile0.0)	81.9±16.6 4.2±3.2 2 (inter-quartile1.0)	No
Shetty *et al.*	VAS	PRP 8.1±1.32	PRP 1.8±1.12	No
		Steroid 7.8±1.12	4.27±1.41	
	AOFAS	PRP 33.9±8.15	PRP 83.1±10.11	
		Steroid 32.5±7.15	Steroid 70.5±9.18	
Omar *et al.*	VAS	PRP 8.2±1.3 CCS 8.8±0.9	PRP2.6±2.1 CCS 6.5±2.6	No
	FHSQ	PRP58.5±9.6 CCS57.5±9.4	PRP 25.1±12.4 CCS 49.0±19.1	
Our study	VAS RMSPS AHFS(AOFAS)	PRP 7.52±1.19 CCS 6.68±1.90 PRP 3.44±0.65 CCS 3.4±0.76 PRP37.52±11.30 CCS 41.2±13.41	PRP2.52±1.32 CCS 5.08±1.77 PRP1.56±0.58 CCS 2.96±0.78 PRP83.68±14.52 CCS 58.16±14.98	No

Conclusion

Chronic heel pain is a difficult condition to treat and takes a long time to resolve. This study has shown that PRP can provide successful long-term and safe treatment of severe chronic plantar fasciitis in patients who have failed to respond to traditional non-operative management techniques.

For short-term relief, both (steroids and PRP) are equally effective in the treatment of plantar fasciitis. Steroids showed better results than PRP during the 1st month post injection follow-up but their effect gradually declined with time. Steroid injections are easily available, cost effective and technically easy to use.

PRP showed long-term, safe and sustained beneficial effects in patients with plantar fasciitis, but it requires centrifugation machinery, which is not available at every center, and the patient's hesitancy for venous blood extraction also limits its usage.

Conflict of Interest

Not available

Financial Support

Not available

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