Section: Orthopedics

Research

EFFECTIVENESS OF SINGLE DOSE INTRALESIONAL INJECTION OF PLATELET RICH PLASMA V/S CORTICOSTEROIDS IN CHRONIC PLANTAR FASCIITIS

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Abstract

Background: The plantar fascia contributes to the maintenance of the longitudinal arch of the foot. It undergoes tension when the foot normally bears weight, there by maintaining the arch. To study effectiveness of single dose intralesional injection of platelet rich plasma (PRP)v/s corticosteroidsin chronic plantar fasciitis. **Materials and Methods:** Study was done on plantar fasciitis patients admitted at Dept. of Orthopedics, KIMS, Hubballi – Karnataka. Study subjects were treated with single dose intralesional injection of PRP and steroid (50 cases each). Study period was August 2018 to September 2019.**Result:**Mean age group was 42.18yrs for PRP group and 49.08yrs for Steroid group, and the total mean age was 45.76 yrs.The VAS pre injection 7.53 later 6.16,5.21,4.37and 3.12 and F=130.279 ANNOVA measurement and mean VAS compared(BONFERRONI CORRECTION) was significant($p<0.005$).ROLES AND MAUDLEY score showing 3.26,2.84,2.28,1.98 and 1.47F=62.798($P<0.005$) ANNOVA, post hoc pair wise comparison significant 0.005.**Conclusion:**PRP is significantly more effective than steroid, making it better and more durable than cortisone injection as a treatment option.

INTRODUCTION

Plantar fasciitis literally means inflammation of the plantar fascia at the site of its attachment to the calcaneum. But recent studies indicate that it is acondition of degeneration of the plantar fascia rather than true inflammation.

According to a biomechanical study model, the plantar fascia bears 14% of the load of the foot.1 Its surgical release decreases dynamic load to ankle by 10%. In another cadaveric study, the plantar fascia failed only at loads as high as 1189newtons, below which it is bearing the load.[1] This failure most often occurred at the proximal attachment. This is consistent with the site involved in chronic plantar fasciitis, which is located at the calcaneum. Complete surgical release led to a decrease in the stiffness of the longitudinal arch of the foot. The plantar fascia plays a vital role in the dynamic function during normal gait. It elongates to an extent of 9-12% between mid-stance and toe off phase of gait, thereby to help in propulsive movement. During the propulsive phase, the toes are dorsiflexed, thereby resulting in tension of the fascia which results in elevation of the longitudinal arch of the foot. This is similar to the windlassmechanism.[1] Repetitive tensile overload of the plantar fascia at its attachment to the calcaneum leads to pathological changes similar to that seen in inflammation and degeneration. The pathology passes through a cascade of events including inflammation and degeneration.[2] There may be an association with heel cord contracture. But the real cause for the pain in chronic plantar fasciitis seems to be unclear till date.[2] According to some authors, the primary pathology in this condition is degeneration of the plantar fascia rather than true inflammation seen in acute conditions.[3]

The most common cause is the presence of very tight calf muscles which results in excessive over pronation of the foot. This leads to overstretching of

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the plantar fascia resulting in inflammation and degeneration of the fascia.
Similarly, over supination can also lead to altered foot biomechanics predisposing to its development. Other causes may be very high or very low arched feet and regular use of footwear with poor arch support.
Most of the patients get relieved of their pain with this treatment regime. Patients with pain not responsive to the above treatment protocol are subjected to more aggressive modalities.
Similar to that of autologous blood, but here the same effect is brought about by centrifuged platelet rich plasma rather than the administration of whole blood.
The local trauma and bleeding produced by the puncturing of the fascia may produce a physiological response similar to that seen with Platelet Rich Plasma injections. May mechanically breakdown the calcifications in the fascia.
PRP can be activated into a platelet gel using thrombin and calcium, which creates a product that can both distribute growth factors to stimulate wound healing while constricting blood vessels to reduce bleeding. In addition, the activation will increase the function of the platelets. The gel can improve tissue adhesion as a scaffold and protect from infection with its concentration of leukocytes. It has also been shown to reduce pain postoperatively. The platelet gel material is used mostly for intraoperative situations to promote bone healing and as a wound sealant.[4] Hence, this study was conducted to study effectiveness of single dose intralesional injection of platelet rich plasmav/s corticosteroids in chronic plantar fasciitis.

MATERIALS AND METHODS

This study was done on plantar fasciitis patients admitted at Dept. of Orthopedics, Karnataka Institute of Medical Sciences (KIMS), Hubballi – Karnataka. Study subjects were treated with single dose intralesional injection of PRP and steroid (50 cases each). Study period was August 2018 to September 2019. 100 cases of plantar fasciitis who met the inclusion and exclusion criteria entered the study.
Ethical clearance was obtained from the institutional ethical committee for the present study. Informed consent was taken from study subjects.

Sample Size: 100 Patients admitted during the specified period were included in the study.
Sample size Calculated as per this formula

Sample Size: $n \geq \frac{2(z1\text{-}\alpha/2 + z1\text{-}\beta)2\ \sigma2}{(\mu1-\mu2)2}$

μ1-Mean vas score AT 6 MONTHS IN PRP Group.
μ2- Mean vas Score AT 6 MONTHS IN steroid Group.
σ –Pooled standard deviation = z1-α/2- table values for alpha error of 0.01 (1%) is 2.58.
z1-β- table values for power of 0.99 (99%) is 2.32.
Considering the VAS score at 6 months as a primary outcome variable in two groups (PRP and steroid), the sample size was done for testing the hypotheses between two groups.
Data from previous studies indicate that mean VAS at 6 months for PRP group 2(SD 0.45) and for steroid 2.8(SD0.76).
to test the hypothesis of there is no difference in VAS score between 2 groups with alfa error 1% and power of 99%.
The minimum required sample size is 32 in each group total of 64.
Considering the lost follow up and non-response the final sample size was rounded off to 50 in each group total 100.
All patients with chronic plantar fasciitis were divided into 2 groups for prospective treatment and evaluation group 1 was treated with PRP, group 2 was injected 40 mg 1 ml of Methylprednisolone (Depomedrol, Pfizer).
All patients were screened with plain x ray of ankle joint lateral view and other investigation like Hb, RBS, Lipid profile and Renal Profile.
Following aseptic preparation of the skin, injection given either with PRP obtained from preparation with specific procedure or with Depo Medrol obtained from pharmacy infiltered into the lesion, later patients were placed into a Walker brace, CAM boot or MCR footwear for 2 weeks and allowed to return to activities as tolerated along with a daily home eccentric exercise and calf stretching regimen in both the groups.
Interval AOFAS hind foot scoring data, VAS and RM scoring done and physical examinations were conducted with clinical symptoms and pain status assessed and compared with pre-injection status. Pre and post injection status assessed periodically at 2^{nd} week, 4^{th} week, 12^{th} week, and24^{th}week after treatment with said scores.
With the patient in a prone position and the ankle in a neutral position at 90^0 the location of the swollen plantar fascia was confirmed by clinical examination and windlass sign. After preparing the skin with chlorhexidine and with local anesthetic drug and 18G intramuscular needle was introduced the most swollen fascia, peppering done and infiltered the adjacent tissues with 3 ml of PRP in group A, and with 40 mg methylprednisolone in group B.
The main outcomes measured were subjective based on the Visual analogue scale, Roles Maudsley score and American association of Orthopedics for Foot and Ankle Society Hind foot score done pre-injection, 2th, 4th, $12^{th}$and 24th weeks post injection. Final outcome was measured based on the pain and activity level at 6 months.
Statistical analysis: PRP and steroid groups are compared with the statistical scores. Pain and functional activities are assessed with pre injection

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and post injection status by using VAS, RMS and AOFAS.

RESULTS

Gender prevalence of Plantar fasciitis, in the study group 63% were females and 37% where males suggests that females are more prone to have the plantar fasciitis. In the study group of 100, 51 were left side, 38 were right foot and 11 were bilateral affections. In the study group 40 percent were associated with calcaneal spur. Mean age group was 42.18yrs for PRP group and 49.08yrs for Steroid group, and the total mean age was 45. 76yrs.In the study group, mean weight was 66.14 kg for PRP group and 61.41 kg for steroid group.

The VAS preinjection 7.53 later 6.16,5.21,4.37and 3.12 and F=130.279 ANNOVA measurement and mean VAS compared(BONFERRONI Correction) was significant(p<0.005). [Table 1].

Table 1: Comparison of mean VAS Scores between different follow up times in PRP group

PRP (VAS)	N	Mean	SD	Repeated measures ANOVA
PRE	50	7.53	1.83	F = 130.279 p<0.005 (Sig.)
2WKS	50	6.16	1.79	
4WKS	50	5.21	1.57	
3MNTS	50	4.37	1.50	
6MNTS	50	3.12	1.71	

Table 2: Post hoc pairwise comparison of mean VAS (Bonferroni correction.

Comparison (VAS)	Mean diff	P value
Pre Vs 2 wks	1.37	<0.005 (Sig.)
Pre Vs 4 wks	2.33	<0.005 (Sig.)
Pre Vs 3 mnts	3.16	<0.005 (Sig.)
Pre Vs 6 mnts	4.42	<0.005 (Sig.)
2 wks Vs 4 wks	0.95	<0.005 (Sig.)
2 wks Vs 3 mnts	1.79	<0.005 (Sig.)
2 wks Vs 6 mnts	3.05	<0.005 (Sig.)
4 wks Vs 3 mnts	0.84	<0.005 (Sig.)
4 wks Vs 6 mnts	2.09	<0.005 (Sig.)
3 mnts Vs 6 mnts	1.26	<0.005 (Sig.)

Roles and Maudley score showing 3.26,2.84,2.28,1.98 and 1.47F=62.798(P<0.005)ANNOVA,post hoc pairwise comparison significant 0.005.

Table 3: Comparison of mean RM Score between different follow up times in PRP group

PRP(RM Score)	N	Mean	SD	Repeated measures ANOVA
PRE	50	3.26	0.82	F= 62.798 <0.005 (Sig.)
2WKS	50	2.84	0.72	
4WKS	50	2.28	0.63	
3MNTS	50	1.98	0.67	
6MNTS	43	1.47	0.67	

Table 4: Post hoc pairwise comparison of mean RM Score (Bonferroni correction)

Comparison (RM Score)	Mean Difference	P value
Pre Vs 2 wks	0.42	0.018 (Sig.)
Pre Vs 4 wks	0.98	<0.005 (Sig.)
Pre Vs 3 mnts	1.28	<0.005 (Sig.)
Pre Vs 6 mnts	1.79	<0.005 (Sig.)
2 wks Vs 4 wks	0.56	<0.005 (Sig.)
2 wks Vs 3 mnts	0.86	<0.005 (Sig.)
2 wks Vs 6 mnts	1.37	<0.005 (Sig.)
4 wks Vs 3 mnts	0.30	0.01 (Sig.)
4 wks Vs 6 mnts	0.81	<0.005 (Sig.)
3 mnts Vs 6 mnts	0.51	<0.005 (Sig.)

AOFAS showing29.79 to 72.49 F= 147.871 (p<0.005),post hoc significant comparison between follow up.

Table 5: Comparison of mean AOFA Score between different follow up times in PRP group

PRP(AOFAS)	N	Mean	SD	Repeated measures ANOVA
PRE	50	29.79	12.80	F= 147.871 p<0.005 (Sig.)
2WKS	50	42.47	12.86	
4WKS	50	55.07	11.70	
3MNTS	50	61.21	12.92	
6MNTS	50	72.49	16.68	

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DISCUSSION

In our study the age range is 25-59 years(18-60 years inclusion criteria) the mean age for PRP 42.18years and for steroid is 49.08 years this is comparable to the above said study. Kawshik Jain et al.[5] reported the age range of patients in his study was 31-79 years The mean age was 55.6 years. In the same study among 60 patients categorized male female ratio to be 1:2. In our study female constitutes 63% and male to be 37%. So, relating the same sex ratio. Side affected in our study in both the groups 51% are left side involved. 38% are right side involvement and bilateral in 11% patients. According to R Kevin L et al. Indian population with heel pain found to be associated with calcaneal spur in 59%. In my study among 100 patients 40% had a calcaneal spur and 60% are without spur.[6,7]

Plantar fasciitis and heel spur are considered to be the same before much study, but in reality, this is not true.[7] Plantar fasciitis is a pathological diagnosis, whereas heel spur is a radiological finding. A heel spur may be present without any foot symptoms and fasciitis may not have a spur present always.[7]

The initial treatment of Plantar fasciitis is usually with conservative means including rest, icepacks, NSAID'S and footwear modifications.[8]

Most of the patients get relieved of their pain with this treatment regime. Patients with pain not responsive to the above treatment protocol are subjected to more aggressive modalities.

The literature seems to be mixed on the idea of activating the platelets before use. Some studies will not mention either way if the PRP was activated; whereas, others specifically delineate the product used to activate the PRP. A study was presented by de Vos and colleagues on the effects of PRP on Achilles tendinopathy without mentioning activation.[9] In their review article, Foster and colleaguessuggest activation with bovine thrombin.[10] Thomsand colleagues mention use of a combination of calcium and thrombin (bovine, human, or recombinant).[11] Fufa andcolleagues used type I collagen to activate PRP to create a collagen-PRP gel.[12] The brochure for the Magellan system calls for the activation of PRP by using adenosine diphosphate. The proper way to activate the platelets is determined by the intended use of the PRP.

Christos Thanasas et al used a "Gravitational platelet separator system 3 (GPS)" for PRP preparation. 27 to 55ml of blood was collected with 3-5ml of anticoagulant. They centrifuge the whole blood at 3200rpm for 15 minutes and finally give 3-6ml ofPRP.[13] T M Bielecki et al in an invitro study prepared PRP using a GPS 1 system where 54 ml of whole blood was collected in a tube containing 6 ml of citrate solution. The whole blood was centrifuged for 12 minutes at 3200 rpm and finally gives 6 ml of PRP.[14]

Samir Mehta in his article on platelet rich concentrate described about a non-centrifugation method of PRP preparation using assay device. 60 ml of anticoagulated whole blood is mixed with priming solution and allowed to flow through a filter device. After back flushing using sterile solution PRP was obtained. The PRP so obtained are similar to concentration which was obtained by centrifugation method and the process is 40 percent faster than the centrifugation method.[15]

The successful use of PRP formulations to treat chronic tendinopathies led to its application in treating severe cases of plantar fasciitis.[16]

In the only controlled study comparing PRP and cortisone treatment of chronic plantar fasciitis, Say et al.[17] (2014) compared PRP and Steroid in 50 patients (25 ineach arm) and found that both the VAS and AOFAS scores were significantly better at 6 weeks and 6 months in the PRP group compared to Steroid. Again this also comparable with our study, as we found both Steroid and PRP to be equally efficacious early on (up to 6 months). However, their study also is only short term, with no data available beyond 6 months. Monto et al.[18](2014) published the results of 40 patients, randomized to receive PRP and Steroid for chronic plantar fasciitis. All patients received ultrasound guided PRP and Steroid injection. The outcome measure in all patients was AOFAS. The Steroid group showed initial improvement, which tapered after 6 months. In the PRP group the benefit remained for 24 months. The limitation of this study is that only AOFAS score was used as the outcome measure. AOFAS may not be the best outcome measure to use in plantar fasciitis, as there is no limitation of function in this pathology and pain specific outcome measures such as RM and VAS are much better for this disorder. In contrast our study is limited to six months and AOFAS score is consistent with VAS and RMS.

In our prospective randomized, longitudinal case series, the use of local PRP injection proved more successfully than Cortisone injection in the long-term management of severe chronic plantar fasciitis in cases where prolonged traditional non-operative treatment had failed. The finding that the more improvement seen in our patients occurred in the first month following the PRP injection suggests an early anti-inflammatory effect possibly due to the inhibition of cyclo-oxygenase-2 (COX-2) enzymes by the cytokines in PRP.[19]The long-term excellent durability of clinical success in the PRP group in this 1-year study may be the result of improved collagen up regulation and neovascularization. In contrast to the encouraging results demonstrated in the PRP group in this study, the cortisone group long-term results were less satisfied. Although initial results initial days of post injection were encouraging, subsequent clinical scoring later not sustained. The strengths of this study are its randomized and prospective longitudinal nature, the long length of follow-up, and its high subject

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retention rate. The accelerated healing and recovery seen in the use of PRP in plantar fasciitis has also been seen in studies focusing on utilizing PRP to augment.[20] Future research will focus on optimization of the growth factor concentration in PRP, the effects of white blood cells, and the systemic results of PRP treatment.[21]

CONCLUSION

In this prospective study PRP is more efficient in 6 months period study and consistent compared to the steroid for chronic plantar fasciitis, hence we advocate autologous PRP injection as the first option in all chronic plantar fasciitis.

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