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A comparative study between local injection of autologous platelet rich plasma and injection of corticosteroid in functional improvement of plantar fasciitis

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ABSTRACT

Background: Plantar fasciitis is a common cause of heel pain in adults. Although it is usually a self-limiting condition, the pain may become prolonged and severe enough to cause significant distress and disruption to the patient's daily activities and work. The primary objective of the study was to evaluate and compare the effectiveness of autologous platelet rich plasma (PRP) and steroid injections in chronic cases of plantar fasciitis (PF).

Methods: A prospective, randomized study was conducted from December 2013 to December 2015 amongst 60 patients with chronic PF were randomized prospectively in single tertiary care center in India. All the patients were enrolled according to inclusion criteria and divided into 2 groups i.e. group A (n=30) received PRP and group B (n=30) received corticosteroids injections. Roles and Maudsley score (RM Score) and Foot Function Index (FFI) was evaluated for all the included patients. The follow-up scheduled at 1 and 6 months after complete enrolment of patients.

Results: Between both the groups, the significant difference was observed at 1 and 6 months follow-up from the baseline. At 1-month follow-up, statistically significant improvement in mean RM scores were seen in both the groups from baseline and when RM scores were compared between two groups, group B had statistically better mean scores. At 1-month follow-up there was no statistically significant difference between the mean FFI score values between two groups. At 6-month follow-up, statistically significant improvement in mean FFI scores were seen in both the groups, however when both groups were compared to each other, improvement in mean FFI scores was statistically better in group A as compared to group B.

Conclusions: The present study concluded the use of PRP in chronic cases of plantar fasciitis seems more safe and effective in long term than the traditional treatment of steroid injection at different time period.

Keywords: Foot function index, Plantar fasciitis, Platelet-rich plasma, Roles and Maudsley score

INTRODUCTION

Plantar fasciitis (PF) is the most commonly reported cause of inferior heel pain. The condition is characterized by pain at the calcaneal origin of the plantar

fascia, exacerbated by weight bearing after prolonged periods of rest.² The prevalence of heel pain in the general population is estimated to range from 3.6% to 7%, and the disorder has been reported to account for about 8% of all running related injuries.³ Reduced ankle

dorsiflexion, standing for long periods of time at work, obesity, female gender and advancing age are listed as risk factors.⁴ The histological features of PF are poorly understood, although studies report a predominance of degenerative changes at the plantar fascia enthesis, including deterioration of collagen fibers, increased secretion of ground substance proteins, focal areas of fibroblast proliferation, and increased vascularity.⁵

Although there are many treatment modalities for PF, there is little consensus on its clinical approach. To date, there is no single treatment supported by the highest level of evidence.⁶

While there are many treatment options available, none of these are commonly reliable or acceptable. Conservative therapies are usually the first line of treatment includes ice, rest and avoidance of potentially strenuous activities, physical therapies, orthotics, arch supports, tapping and splinting. Other modalities include use of NSAIDS, ultrasonic shockwave therapy, and, in the recalcitrant cases, surgery. Corticosteroid injection is mainstays of early treatment.7 Corticosteroid injections have been used to treat plantar heel pain since the 1950s.8 The advantages of corticosteroid injections include low cost, low complexity and rapid pain relief. Many studies have been done to evaluate the efficacy of corticosteroid injections for the treatment of plantar fasciitis. Nevertheless, the effects of corticosteroids seems to be limited and short-lived and only to a small degree. 9 There are drawback in injecting the heel with steroids; mainly the rupture of plantar fascia and atrophy of the fat pad. 10 Moreover, many factors associated with PF, which includes; heel spurs have commonly been implicated as a factor for PF, decreased ankle dorsiflexion.¹¹

Platelet rich plasma (PRP) therapy is a revolutionary novel modality that relieves pain by stimulating long lasting healing of musculoskeletal conditions. PRP applied to the wound area accelerates the physiological healing process, provides support for the connection of cells, reduces pain and has anti-inflammatory and anti-bacterial effects. PRP is a part of whole blood that is centrifuged to a determined state, injected into the affected area and treated with an activating agent. 14

The objective of this study was to study the effect of local PRP injection in PF patients. Another objective was to study the effect of local corticosteroid injection in PF patients. For pain reduction and we used 'Roles and Maudsley score 'and 'Foot function index' was used to evaluate the changes in functional state at the time of injection and after 6 months.

METHODS

This was a prospective, randomized study, single-center conducted in tertiary care center of India from December 2013 to December 2015. A total 60 patients with chronic PF were included in this study. The male and female

patient age between 18 to 60 years of PF who did not respond to conservative treatment was included in the study. The patients with systemic diseases like rheumatoid arthritis, gout, degenerative arthritis, or neural injury were excluded in the study. Patients with calcaneodynia secondary to neural injury or fracture, neural entrapment or earlier surgery including endoscopic PF release or open plantar fascial release, received local steroid injection and /or PRP injection within 6 months and received NSAIDS within 1 week and patients with diabetes mellitus were excluded from the study.

Preparation of platelet rich plasma (PRP)

For the preparation of PRP, 15 ml of patients own blood is collected in 20 ml BD syringe. It is then transfer to sterile plastic tube which is pre filled with 1.5 ml anticoagulant (sodium citrate) at operation theatre of tertiary care center in India under sterile condition. Whole blood then centrifuge at the rate of 1800 revolutions per minute for duration of 15 to 20 minutes. This allowed the blood components to separate into three main layers as follows: plasma, buffy coat (leukocytes and platelets), red blood cells. Red blood cells along with buffy coat is then separated, remaining part is plasma with platelets. We got a 4 to 5 times concentrated platelets with plasma of approximately 1 to 2 ml above the buffy coat.

The chronic PF patients were assigning randomly using a simple method of randomization (odd for PRP and even for corticosteroid) into two equal groups (30 patients each) by one of the researchers who introduce the patients with either steroids or PRP injection (not guided by ultrasound) and did not share in clinical nor in ultrasonographic assessments: Group A PRP was injected 1-2 ml PRP in supine position with 22 gauge needle. In group B (corticosteroid) was injected 2 ml. The roles and Maudsley (RM) score for pain was used to evaluate the clinical results. RM score calculated at the time of baseline, 1-month and 6-month follow-up visit.

Statistical analysis

The data was entered in Microsoft excel sheet for analysis and tested statistically on SPSS for windows version 17 software. Quantitative variable were described in descriptive statistical analysis was done for continuous variables, frequency distribution, mean±SD and their percentages for categorical variables were calculated. Test was used for normal distributed data. Unpaired t test was used to see results in intergroup (between PRP and steroid group). P<0.05 is considered significant.

RESULTS

In this study, the aged of patients with PF between 29-56 years were enrolled. A total 65 patients were enrolled in this study; out of this 5 patients were excluded from the study due to screen failure. Selected patients allocated into group A and group B by randomization. All sixty

patients successfully completed at 6-month follow-up. Distributions of patients according to sex were shown in Table 1. In group A 18 (60%) was male and 12 (40%)

female patients. In group B 15 (50%) was male and 15 (50%) female patients. The calculated p value was 0.436 (p>0.05). It shows that gender does not affect the result.

Table 1: Gender wise distribution of study patients in Group A and Group B.

Gender	PRP (Group A) N (%)	Corticosteroid (Group B) N (%)	Total N (%)	X²-value p value
Male	18 (60)	15 (50)	33 (55)	$X^2=0.606$
Female	12 (40)	15 (50)	27 (45)	d.f.=1
Total	30 (100)	30 (100)	60 (100)	p=0.436

Table 2: RM score between two study groups.

Study navamatan	Group A: PRP		Group B: Steroid		Unpaired	P value
Study parameter	Mean	Std. Dev.	Mean	Std. Dev.	T-test	P value
Pre injection RM	3.93	0.254	3.87	0.346	0.851	0.398
Post injection RM	3.93	0.254	3.87	0.346	0.851	0.398
After 1 month RM	2.87	0.434	1.27	0.450	14.018	< 0.001
After six month RM	1.57	0.504	2.17	0.531	-4.490	< 0.001

(Std. Dev. = Standard Deviation).

Table 3: FFI score, percentage and mean pre and six month after injection in two study groups.

Ctudy novemetor	Group A: PRP		Group B	Group B: Steroid		P value
Study parameter	Mean	Std. Dev.	Mean	Std. Dev.	T-test	r value
Pre FFI score	159.90	18.598	155.73	19.984	0.838	0.405
Pre FFI%	69.53	8.212	68.17	N.296	0.603	0.549
Pre FFI mean	7.00	0.947	6.87	0.937	0.548	0.586
After 6 month FFI Score	30.80	20.271	71.43	23.382	-7.192	< 0.001
After 6 month FFI%	13.37	8.195	30.97	10.193	-7.119	< 0.001
After 6 month FFI Mean	1.30	0.952	3.20	1.031	-7.416	< 0.001

(Std. Dev. = Standard Deviation)

Improvement in pain

Roles and Maudsley score (RM Score)

At the baseline, there was no statistically significant difference (p>0.05) in the mean RM scores between two groups. At 1-month follow-up, statistically significant improvement (p<0.001) in mean RM scores were seen in both the groups from baseline and when RM scores were compared between two groups, group B had statistically (p<0.001) better mean scores. At 6-month follow-up, statistically significant improvement (p<0.05) was noticed in mean RM scores in both the groups, however group A had statistically better improvement (p<0.001) in mean RM scores than group B. The RM score analogue depicted in Table 2. The RM score prior to infiltration was similar (p>0.05) in both group A (3.9) and group B (3.9). The RM score became significantly (p<0.001) lower among the patients of group A and B at 1-month and 6-month of follow up (group A 2.9; 1.6 and group B 1.3; 2.2).

Improvement in function

Foot function index (FFI)

At baseline, there was no statistically significant difference (p>0.05) between the mean FFI Score values between the two groups. At 6-month follow-up, statistically significant improvement (p<0.001) in mean FFI scores were seen in both the groups, however when both groups were compared to each other, improvement in mean FFI scores were statistically (p<0.001) better in group A as compared to group B (As shown in Table 3).

At baseline, there was no statistically significant difference (p>0.05) between the mean FFI percentage values between the two groups. At 6 month follow up, statistically significant improvement (p<0.001) in mean FFI percentage were seen in both the groups, however when both groups were compared to each other, improvement in mean FFI scores was statistically (p<0.001) better in group A as compared to group B (Table 3).

At baseline, there was no statistically significant difference (p>0.05) between the mean FFI mean values between the two groups. At 6-month follow-up, statistically significant improvement (p<0.001) in mean FFI mean were seen in both the groups, however when both groups were compared to each other, improvement in mean FFI scores was statistically (p<0.001) better in group A as compared to group B (Table 3).

The FFI score prior to infiltration was similar (p>0.05) in both group A (159.9) and group B (155.73). The FFI score became significantly (p<0.001) lower among the patients of group A and B after 6-month follow-up (group A 30.8 and group B 71.43).

DISCUSSION

This study was design to compare the effect of RM score and FFI between two groups PRP injection and corticosteroid injection at 1-month and 6-month followup. According to the commonly accepted view in the literature, it is an inflammatory response to micro tears which form as an effect of mechanical loading. Conversely, Lemont et al reported no findings of histological inflammation in histological samples of plantar fasciitis.⁵ These paradoxical findings on the etiology of plantar fasciitis have not vet been explained. The use of steroid injections for plantar fasciitis has been reported to be useful in the short-term. 15 In our study, we found a positive effect on pain and functional scores in the steroid group which can be explained by the antiinflammatory effect. Nevertheless, steroid injections have been reported to be related to plantar fascia tear, fat pad atrophy, abscess, and osteomyelitis. 16-18

Platelet-rich plasma stimulates the proliferation of various cell types in cells and tissue and activates repair cells in the blood circulation. 19,20 More than 30 bioactive proteins are found within the alpha granules of platelets.²¹ Growth factors, such as platelet-derived growth factor, transforming growth factor, vascular endothelial growth factor and insulin-like growth factor, and proteins such as fibrin, fibronectin, vitronectin, and thrombospondin, found in PRP, play a role in many stages of tissue healing. These growth factors activate some of the cells that play a function in tissue healing and thus provide soft tissue healing and bone regeneration.²² Several nonsurgical treatment methods are available for the treatment of plantar fasciitis with various success rates. Ideal treatment for plantar fasciitis has not been determined.

Subjective evaluation of the treatment of plantar fasciitis, done by the modified Roles and Maudsley score, has shown contrasting results in the literature. Akşahin et al have shown that treatment with PRP and corticosteroids is similar at a 6-month follow-up, whereas Vahdatpour B et al have demonstrated superior results with PRP treatment over corticosteroids at the 6-month follow-up. ^{22,23} Results of subjective assessment of the present

study showed that there was significant difference in patient at 1-month and 6-month follow-up. Functional evaluations done by using the American Orthopaedic Foot & Ankle Society ankle hind foot score by 2 studies have shown opposing results.²⁴ Another study by Acosta-Olivo et al have shown improved functional outcome in both groups over a period of 16 weeks, but no significance difference was observed between the groups, whereas Monto has observed significant improvement in functional outcome of the PRP group compared to the corticosteroid group throughout a follow-up of 2 years.^{25,26} In the present study, although the functional outcome scores significantly improved on subsequent follow-up in both groups, but there was significant difference in the score between the groups. Results of functional evaluation done by using the FFI were also consistent with the above observation at 1-month and 6month outcome scores between the groups. The use of PRP in foot and ankle pathologies has begun to increase.

This study was design to compare the effect of RM score between two groups PRP injection and corticosteroid injection at one month and six months follow-up. The result of this study shows good clinical results to PRP injections at the end of one and six months follow-up to support by several previous studies on PRP in chronic PF. For PRP obtained from autologous blood, there are neither studies in the literature warning of hyperplasia, carcinogenesis or tumor growth of PR nor risk of immune reaction or disease transfer. This study having some limitations included deficient of placebo control group and evaluation of results with functional and pain scores due to lack of radiological and biological results. In addition, the low number of patients and relatively short follow-up period can also be considered limitations.

CONCLUSION

In conclusion, the administration of PRP in plantar fasciitis treatment appears to be a more effective method than steroid injection for the reduction of pain and provide better functional results at 6-month follow-up. However, prospective and randomized studies are main strength for results and also, long-term follow-up are needed.

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Institutional Ethics Committee

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