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Original Research Article

Effect of platelet rich plasma versus triamcinolone versus placebo-normal saline in chronic plantar fasciitis: regenerative medicine in orthopaedics

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ABSTRACT

Background: Heel pain is a common presenting condition in orthopaedic outpatient units. There are many causes of this condition, but one of the most common is plantar fasciitis. This study was conducted to find out the efficacy of a single injection of platelet-rich plasma versus steroids versus normal saline as a placebo in treating patients suffering from plantar fasciitis.
Methods: Randomized single-blinded placebo-controlled trial with 3 months and 6 months follow-up using visual analogue scale and FAOS (Foot and Ankle Outcome Score) was carried out at a tertiary care hospital for a total of 120 patients (40 patients in each group). First group injected with platelet rich plasma, second group with triamcinolone and third group with normal saline.
Results: Pain relief achieved in the platelet-rich plasma group and triamcinolone group was found to be statistically significant as compared to normal saline at both 3 months and 6 months follow-up. Steroid injection was associated with complications like depigmentation at the injection site and sub dermal atrophy. No complications were found with PRP or normal saline.
Conclusions: This study concludes that the efficacy of a single injection of platelet-rich plasma to relieve the pain of Plantar fasciitis is better than triamcinolone or placebo over a short-term follow-up period. However, more studies are required to evaluate the efficacy of PRP over the long term with multicentric study and comparison with the currently available treatment options.

Keywords: Heel pain, Plantar fasciitis, Platelet rich plasma, Triamcinolone

INTRODUCTION

Plantar fasciitis is reportedly the most common cause of pain in the inferior heel and accounts for about 11 to 15 percent of all foot symptoms requiring treatment. The incidence is reportedly high in young adults between the ages of 40 and 60 years in the general population and younger people among runners. Plantar Fasciitis, once viewed as an inflammatory condition caused by repetitive micro-tearing of the plantar fascia is now thought to be a degenerative condition. It is known that degenerative changes with increasing age are the most constant findings in the elastic adipose tissue of the heel pad. Risk factors for Plantar fasciitis include Pes Planus, Pes Cavus, Limb Length Discrepancies, Obesity, Prolonged Standing, excessive running and walking occupations, Sedentary

lifestyle, tightness of intrinsic foot muscles, etc.[1,2] Plantar fasciitis is diagnosed based on a history of pain on taking the first few steps in the morning, worsening pain with weight bearing and tenderness to palpation over the medial/anteromedial heel/ calcaneal tubercle. Plantar fasciitis is often associated with a heel spur (exostosis); however, many asymptomatic individuals have bony heel spurs, whereas many patients with plantar fasciitis do not have a spur.[3] Plantar fasciitis can be a difficult problem to treat, no evidence strongly supports the effectiveness of any treatment for plantar fasciitis. Fortunately, most patients with this condition eventually have satisfactory outcomes with nonsurgical treatment. For patients who do not improve after initial treatment, corticosteroid injection or dexamethasone (Decadron) iontophoresis may provide short-term benefits. However, these therapies do not improve long-term outcomes and may cause plantar fascia rupture.[3,4] Focused extracorporeal shock wave therapy may be superior compared to radial extracorporeal shock wave therapy in plantar fasciitis using the same low-intensity energy flux densities. It was found that although there is limited evidence for the effectiveness of local corticosteroid therapy, the effectiveness of other frequently employed treatments in altering the clinical course of plantar heel pain had not been established.[5,6] Platelet-rich plasma is a good source of many growth factors and cytokines like PDGF, TGF-beta, IGF-1, IGF-2, FGF, VEGF, and EGF. Keratinocyte growth factors and connective tissue growth factors are one of the new ways of treating this painful and disabling condition. It has shown promise in many studies as compared to steroid injection and other modes of conservative treatment.[7] Various studies have concluded that PRP is more effective and durable than Cortisone injection for the treatment of chronic recalcitrant cases of Plantar Fasciitis.[8,9] Surgical management of plantar fasciitis is generally agreed to be indicated only after nonsurgical management has failed. No time limit is placed on this decision, but surgery is typically considered if symptoms do not significantly decrease within 4-6 months. Surgical management involves either "open" or endoscopic partial plantar fasciotomy.[3] Hence the present study was undertaken to evaluate the efficacy and role of autologous platelet-rich plasma injection in plantar fasciitis by comparing it with the local injection of corticosteroid and Normal saline.

METHODS

A total number of 120 patients in the age group of 20-60 years of either sex who are clinically having symptoms suggestive of plantar fasciitis were included in the study. This study was done at a tertiary care centre. This was a randomised prospective comparative study done at Bangalore Medical College and Research Institute, Bangalore. This study was done from July 2014 to September 2015. Allocation of patients was done to the particular group after informed consent. The subjects were allocated into three groups namely A, B and C (40 participants in each group) by choosing an envelope out of 1/2/3 signifying a particular method of intervention not known by the person himself who is choosing. Institute ethical clearance was taken priorily. Patients who had received any previous treatment in the form of local injections of steroids and other interventions were excluded from the study. Patients who were suffering from symptoms of pain around the anteromedial heel due to other reasons like Calcaneal spur, calcaneal osteomyelitis, old calcaneal fracture, compression neuropathies such as tarsal tunnel syndrome, or impingement of the medial calcaneal nerve, Gout, and Rheumatoid arthritis were excluded from the study. Patients clinically diagnosed to have plantar fasciitis and after excluding all other causes of heel pain were subjected to the ultrasonographic examination of the foot under study to diagnose plantar fasciitis.

Ultrasonography findings in the case of plantar fasciitis involve a hypoechoic signal from the plantar fascia origin suggestive of degeneration of plantar fascia insertion. Consent for the procedure was obtained. The patients were divided into three groups using the computer-generated Alphabetic sequence randomization software. The site of the injection-anteromedial heel at the site of maximum tenderness. The skin was painted with 7.5% betadine solution and ethyl alcohol. 1 mL of 2% lignocaine was injected at the injection site after giving the test dose.

After 10 min the proposed injection was injected. The injection was given around the plantar fascia insertion by peppering technique. If any resistance was felt during the injection the needle is withdrawn a bit and again injected. Patients were advised regarding post-injection care. Patients were advised not to overuse their lower limbs for 24-48 hours. Complete resumption of activities was allowed after 4 weeks as tolerated. The first group of patients was given autologous platelet-rich plasma, the second group was given steroid- Triamcinolone and the third group of patients was given a normal saline injection as the placebo. The results were recorded by visual analogue score-VAS and FAOS. The scores were recorded in the prepared proforma on the day of injection before giving the injection, then after 12 weeks and after 24 weeks.

Around 15 ml of the patient's blood was obtained by using a scalp vein catheter to avoid turbulence while drawing the blood. The platelet-rich plasma is prepared by differential centrifugation technique with two spins. The blood is collected in four citrate tubes having 0.9% sodium citrate as an anticoagulant. The first spin was performed at 1500 rpm for 15 minutes using a laboratory centrifuge machine. This spin separated the RBCs from the rest of the components. The upper half of the supernatant was discarded. The lower halves of the supernatant from all four tubes were transferred into another plain tube for a second spin. The second spin was performed at 2500 rpm for 10 min. The upper half of the supernatant of the second spin sample was discarded. 1 ml of the lower half was taken into a syringe having 0.1 ml of calcium chloride.The second group was given 1 ml of triamcinolone and the

third group was given 1 mL of normal saline as a placebo. After giving injections patients were given Paracetamol and Tramadol combination for initial pain relief in all three groups. Patients were asked to report immediately in case of an increase in pain and were asked to follow up at 12-week and 6 months intervals after the intervention. The symptoms were recorded by VAS and FAOS score in appropriate proforma on the day before giving injection, at 12 weeks and at 24 weeks. Patients were advised for hot fomentation, plantar fascia stretching exercises, MCR footwear usage after the injection. Repeated measure analysis for multiple assessment was done using ANOVA test (SPSS software) to analyze the difference of means for parametric data, and a p value <0.05 was assumed to be statistically significant. The Wilcoxon signed-rank test was performed to statistically evaluate the significance of clinical outcome by VAS and FAOS for all groups. The resulting p<0.05 was accepted as a statistically significant difference in the median of paired observations.

RESULTS

Out of the 120 participants, 46(38.3%) were males and 74 (61.7%) were females. In the PRP group, 15 were males and 25 were females. In the corticosteroid injection group, 17 were males and 23 were females. In the normal saline group, 14 were males and 26 were females. With a p value of 0.104, which was not significant, all the groups were comparable in terms of the number of males and females in each group (Table 1).

Table 1: Demographic Table.

S. no.	Contents	Group A	Group B	Group C
1.	Mean age	43.60±8.02	41.48±9.14	43.75±9.03
2.	Left side	47.5%	40%	40%
3.	Right side	52.5%	60%	55.8%
4.	Duration (<6 months)	40%	35%	35%
5.	Duration (6-12 months)	65%	65%	63.3%
6.	Males	15	17	14
7.	Females	25	23	26

Most of the patients i.e, 93 (77.5%) in our study were aged between 30-50 years, with an average age 42.94±8.73 years. Thus, all the groups were comparable in terms of age distribution within each group. The mean age in group-A was 43.60±8.02 years, in group-B the mean age was 41.48±9.14 and in group-C the mean age was 43.75±9.03 years. P value of 0.431, which is not significant suggesting all the groups were comparable with respect to age. Out of the 120 participants, 67 (55.8%) participants had their right heel affected and 53 (44.2%) had their left heel affected. P=0.789, which is not significant. Thus, all three groups were comparable in terms of side of heel involved. The mean duration of the symptoms in all 120 patients suffering from plantar fasciitis was 6.86±2.86 weeks. The mean duration of the condition in the PRP injection group was 6.80±2.94 months. The mean duration of the condition in the corticosteroid injection group was 6.68±2.82 Months. The mean duration of the condition in the Normal saline injection group was 7.10±2.89 Months. P=0.795 which is not significant. Thus, all the groups were comparable in terms of duration of the condition. In this study, the mean VAS score at the presentation were comparable in all the three groups (8.25±0.63 vs 8.23±0.53 vs 8.08±0.57; p=0.347). At 12 weeks these scores reduced significantly in group B (4.03±1.21) and in group A (4.18±1.05) compared to group C (5.53±0.85) with p value <0.001. Further, at 24 weeks the mean VAS scores in group A significantly reduced to 0.36±0.58 compared to group B and group C with 2.70±1.90 and 5.20±1.77 respectively (p<0.001). There was a statistically significant reduction in the VAS score in Group A at 6months compared to Group B and Group C done by ANOVA test (Figure 1). At 12 weeks, the mean FAOS score of group A is 77.70±6.23, group B is 73.48±13.48 and group C is 67.83±7.18 with p value <0.001 which are statistically significant. Hence, the FAOS score improvement at 12 weeks is statistically significant in the PRP group and corticosteroid injection group compared to Normal saline injection group (Figure 2).

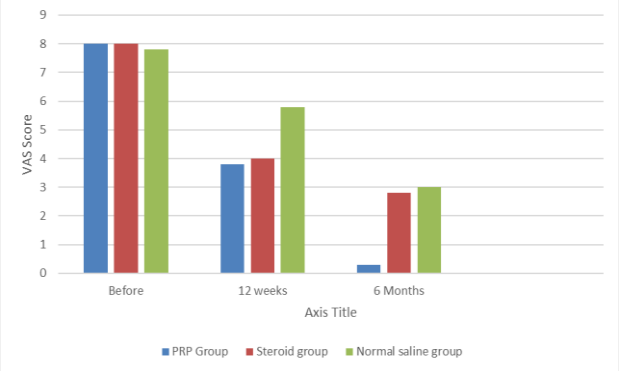

Figure 1: VAS score pre and post injection among PRP group, steroid group and normal saline group.

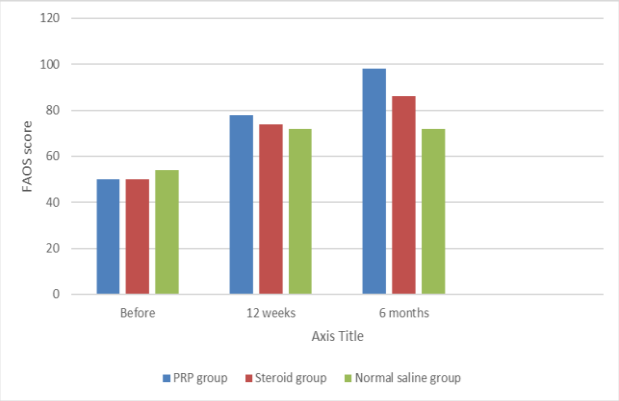

Figure 2: FAOS score (Foot and ankle outcome score) among PRP group, steroid group and normal saline group before and after injection.

Out of 120 participants four patients (10%) had skin hypopigmentation with local skin atrophy in corticosteroid injection group while no patient in PRP injection group had this problem. There was no statistical significance related to post intervention local skin atrophy (P value=0.125). When the potential complication of corticosteroid treatment was taken into consideration, PRP injection seems to be safer and having good effectivity in the treatment of plantar fasciitis. In the present study, recurrence was not observed in patients of group A, whereas 2.5% patients in group B reported recurrences at 24 weeks follow up suggesting significantly less recurrence rates.

DISCUSSION

Plantar fasciitis is the most common cause of heel pain for which professional care is sought. Although thought of as an inflammatory process, plantar fasciitis is a disorder of degenerative changes in the fascia originating at the medial calcaneal tuberosity of the heel. Plantar fasciitis is thought to be more common in middle aged women and athletically active younger males.[10] The present study also shows the predominance of this condition in females. Most of the patients in our study were involved in prolonged standing and weight bearing occupations which correlates to a study by Riddle et al, which infers that work-related weight bearing appear to be independent risk factor for plantar fasciitis.[11] The major component contributing to discomfort is the irritation occurring secondary to the disease process, rather than a spur or other mechanical factor. Traditional therapeutic efforts have been directed at decreasing the presumed inflammation. These treatments include icing, non-steroidal anti-inflammatory drugs (NSAIDs), rest and activity modification, corticosteroid injections, botulinum toxin type A, night splinting, shoe modifications, taping and orthoses. Other treatment techniques have been directed at resolving the degeneration caused by the disease process. In general, these techniques are designed to create an acute inflammatory reaction with the goal of restarting the healing process. These include autologous blood injection, platelet-rich plasma (PRP) injection, nitroglycerin patches, extracorporeal shock-wave therapy (ESWT), and surgical procedures. Formal physical therapy can include components that target both goals. Various studies showed that PRP was safe, effective in the treatment of plantar fasciitis.[12-14] Recently, research has focused on regenerative therapies with high expectations of success. The use of autologous growth factors is thought to heal through collagen regeneration and the stimulation of a well- ordered angiogenesis. These growth factors are administered in the form of autologous platelet-rich plasma (PRP). Platelets can be isolated using simple cell-separating systems/centrifuge machine. The degranulation of the α-granules in the platelets releases different growth factors that play a role in tissue regeneration processes. Platelet-derived growth factor. Transforming growth factor-β, Vascular-derived endothelial growth factor, Epithelial growth factor, Hepatocyte growth factor and Insulin-like growth factor are examples of such growth factors. Injections with autologous growth factors are becoming common in clinical practice. Hence, the present study was an attempt to evaluate the efficacy and role of autologous platelet rich plasma injection in plantar fasciitis by comparing with the local corticosteroid injection and normal saline-placebo injections.

The mean duration of symptoms and age in group A, group B and in Group C were comparable in terms of duration of symptoms and mean age of presentation. In this study slight female preponderance was seen in all the groups (62.5%,57.5 and 65%). The difference was statistically not significant (p=0.104). Riddle et al study also showed similar trend i.e., plantar fasciitis is more common in middle aged women and athletically active younger males.[9] At presentation the mean VAS scores were comparable in all the three groups. The demographic and clinical variables were comparable in all groups. Monto RR study also exhibited comparable VAS scores.[4] The current study outcomes were comparable to a similar study done by Mahindra et al concluded that local injection of platelet-rich plasma or corticosteroid was an effective treatment option for chronic plantar fasciitis. The authors believe that platelet-rich plasma injection was as effective as or more effective than corticosteroid injection at 3 months of follow-up.[15] Systemic review by Viglione V et al showed clinically significant results in the use of placebo effect in the conservative treatment of plantar fasciitis. [16] At 12 weeks these scores reduced significantly in group B (4.03±1.21) and group A (4.18±1.05) compared to group C (5.53±0.85) with P value <0.001. Further, at 24 weeks the mean VAS scores in group A significantly reduced to 0.36±0.58 compared to group B and group C with 2.70±1.90 and 5.20±1.77 respectively (p<0.001). At 12 weeks mean FAOS scores of group A and group B improved to 77.70±6.23 and 73.48±13.48 compared to group C is 67.83±7.18, which are statistically significant (p value <0.001). Hence the FAOS score improvement at 12 weeks is statistically significant in PRP group and corticosteroid injection group compared to Normal saline injection group. At 24 weeks FAOS scores in group A is 95.08±1.37, group B is 80.23±16.95 and group C is 67.15±12.54 with p value <0.001, hence the improvement is statistically significant in PRP injection group compared to corticosteroid injection group and Normal saline injection group. At six months of follow up, significantly more patients (92.50%) in group A were completely relieved of pain whereas more than half (77.5%) patients in group B and up to 92.5% in Group-C were not relieved of pain. In our study there is significant pain relief and improvement in FAOS at 24 weeks in platelet rich group (group A) compared to steroid group (group B) and normal saline group (group C).

There is limited data showing comparison between autologous PRP injection, corticosteroid injection and Normal Saline injection in the treatment of chronic plantar fasciitis.

CONCLUSION

The most prevalent cause of heel pain is plantar fasciitis, for which there is substantial uncertainty regarding the best course of treatment. There are numerous treatment options available, ranging from non-operative to operative interventions. With the current boom in stem cell and regenerative medicine, PRP is a safe, affordable, and potentially effective therapeutic option for a variety of musculoskeletal diseases, including plantar fasciitis. Our research has found that, during a brief follow-up time, a single injection of platelet-rich plasma is more effective than triamcinolone or normal saline at relieving the discomfort of persistent plantar fasciitis.

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