Original Article

Effectiveness of platelet rich plasma versus corticosteroid in the treatment of plantar fasciitis: a double-blind randomized controlled trial

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Abstract:

Background: *Plantar fasciitis is a common cause of heel pain. This condition is caused by degenerative changes resulting in repetitive microtears of the plantar fascia, which are in turn caused by biomechanical overuse from prolonged standing or running. Several nonoperative treatments have been employed, such as stretching, physical therapy, nonsteroidal anti-inflammatory drugs, extracorporeal shock wave therapy, needling and night splints, relative rest, etc. But clinical outcomes of these methods are controversial. Corticosteroid is also effective but provides only short-term pain relief with disappointing long-term results. This procedure is also associated with complications, including localized infection, fat pad atrophy, and plantar fascia rupture. In recent years, platelet-rich plasma (PRP) has been investigated as a treatment option for plantar fasciitis. PRP is a bioactive concentrate of various growth factors and cytokines that modulate cell proliferation and differentiation, angiogenesis, and chemotaxis.*

Objectives: *To evaluate the effectiveness of platelet rich plasma versus corticosteroid in the treatment of plantar fasciitis.*

Materials & method: *This Quasi-experimental study was carried out on adult patients with chronic Plantar Fasciitis attended in Dhaka Medical College Hospital, during the period of October 2021 to May 2022. The patients were randomly assigned to one of the two groups; group A (patients treated with PRP); group B (patients treated by with corticosteroid). After providing the allocated treatment, all patients were undergone follow-up examination at 1st week, 1st month, 3rd month and at 6th month for clinical improvement. Visual Analog Scale (VAS), Roles and Maudsley (RM), and Foot Function Index (FFI) scoring systems were used as outcome measures.*

Result: *Mean ± SD of age was calculated to be, 42.31 ± 7.6 for Group A and 42.29 ± 8.0 for Group B. Most of the participants in Group A [13 (72.1)] & in Group B [15 (65.2)] were females. Mean VAS score at different follow up time reveals, after 1 week of intervention, score was turn down or pain reduced in both groups, but comparatively better in group B. At 3rd month (Mean VAS 3.05 & 4.82 in group A & B respectively) and 6th month later (Mean VAS 1.67 & 4.12 in group A & B respectively) follow up period, significant improvement was found in group A. Use of corticosteroid (Group B) showed improvement in symptoms immediately at 1st week to one month (short duration), which did not last long. But PRP effective in prolong time. RM score shows that a significant difference among two groups at 1 and 3 months with P = 0.051 and P = 0.001, respectively. Mean FFI scores in Group A were significantly lower than Group B. No adverse events were noticed in any of the groups.*

Conclusion: *Platelet-rich plasma (PRP) injection is better than steroid injection in relieving the pain of planar fasciitis and improvement function of the patient foot.*

Key words: *Plantar Fasciitis, Platelet Rich Plasma, Corticosteroid.*

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Introduction:

Heel pain is a common presenting complaint in the foot and ankle practice. Plantar fasciitis (PF) is the most common cause of heel pain. It tends to occur more often in women and middle aged population[1, 2]. Pain is usually most severe with the first steps of the day or following a period of rest[3]. Pain is also frequently brought on by bending the foot and toes up towards the shin and may be worsened by a tight Achilles tendon. The condition typically progresses slowly. In about a third of people both legs are affected[4]. Typically there are no fevers or night sweats. Risk factors include overuse such as from long periods of standing, an increase in exercise, and obesity[4]. Many modalities are available to treat this condition, of which corticosteroid injection is, perhaps, the most popular. However, recent years have seen an increased interest in the use of plateletrich plasma (PRP) injections[5-7].

Pathophysiologically plantar fasciitis is a disorder of the insertion site of the ligament on the bone characterized by micro tears, breakdown of collagen, and scarring[4]. As inflammation plays a lesser role, many feel the condition should be renamed plantar fasciosis[8]. The diagnosis is typically based on signs and symptoms with ultrasound sometimes used to help. Other conditions with similar symptoms include osteoarthritis, ankylosing spondylitis, heel pad syndrome, and reactive arthritis. Most cases of plantar fasciitis resolve with time and conservative methods of treatment. Usually for the first few weeks people are advised to rest, change their activities, take pain medications, and stretch. If this is not sufficient physiotherapy, orthotics, splinting, or steroid injections may be options.

Typical signs and symptoms of plantar fascia rupture include a clicking or snapping sound, significant local swelling and acute pain in the sole of the foot[9]. Individuals with plantar fasciitis often report their symptoms are most intense during their first steps after getting out of bed or after prolonged periods of sitting[3]. Improvement of symptoms is usually seen with continued walking. Rare, but reported symptoms include numbness, tingling, swelling, or radiating pain[10]. Treatment options include non-surgical management, like non-steroidal anti-inflammatory drug (NSAID) prescription, physiotherapy, night splints and steroid injection, and surgical intervention[11]. There is no single treatment which has been proven as a gold standard for the treatment of chronic plantar fasciitis.

Corticosteroid injections are used for cases of PF refractory to conservative treatment and have been an effective modality for pain relief[12]. However, the effect seems to be limited and short-lived. Also, a number of complications may occur of which the most serious are plantar fascial rupture and plantar fat pad atrophy. Fascial rupture interrupts the intrinsic windlass mechanism of the foot and can promote further inflammation in the surrounding tissue. In addition, plantar fat pad atrophy diminishes subcalcaneal cushioning, availing the plantar fascia to further insult and, hence, more pain[13]. Platelet-rich plasma (PRP) has been gaining popularity as a treatment for PF recently. Previous study concluded that both PRP and corticosteroids injections both provide symptomatic relief in the treatment of plantar fasciitis both functionally and subjectively; but results at 6 months are suggestive that PRP injections provided better functional results[14].

Platelet-rich plasma (PRP) is a bioactive concentrate of various growth factors and cytokines that modulate cell proliferation and differentiation, angiogenesis, and chemotaxis. When it is injected into injured tissue, the presumed mode of PRP action is to promote collagen synthesis and enhance tendon and tissue healing[15, 16]. Not surprising, long-term pain relief has been reported by a few authors, suggesting that PRP treatment augments a natural healing response. In theory, this makes PRP an ideal treatment option, and in fact, several studies have demonstrated very positive treatment outcome effects[5, 6].

Soraganvi et al (2019) observed that in both PRP and steroid injection group, VAS and AOFAS score improved after one injection and improvement in pain and AOFAS score was more in the steroid group compared to PRP group at first follow-up visit[11]. Meta-analysis suggested that, PRP was associated with greater changes in visual analog scale (VAS) and American Orthopaedic Foot and Ankle Society Score (AOFAS) scores than other treatments. However, for Roles– Maudsley score (RMS), there was not significant different between the 2 groups. Subgroup analysis demonstrated that, the advantaged effect of PRP over other treatments was only observed at the 12 month, but not at the 1, 3, 6 months. Moreover, PRP was more effective than steroid and placebo in the change of AOFAS score. Results indicate that PRP has a long-term benefit in the management of plantar fasciitis and should be used as an alternative approach for patients with plantar fasciitis[7].

Methodology:

This quasi experimental study was conducted at a Dhaka Medical College Hospital, Bangladesh, from October 2021 to May 2022. 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 6month followup. VAS scores of patients were also recorded at 5 hours postinjection, just before leaving the hospital. 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. It was further classified as no pain (0), mild pain (1–3), moderate pain (4–6), and severe pain (7–10). Roles and Maudsley (RM) score was used to assess patient satisfaction and limitation of walking ability due to pain. 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. A doublecentrifugation 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. 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). All patients were undergone follow-up examination at 1st week, 3rd month and 6th month after the procedure. Follow up were carried out by personal visit of the patient in Pain Clinic at mentioned intervals or over the phone. All the information was recorded in data collection sheet. Statistical analysis of the data was done using the Statistical Package for the Social Sciences for Windows (SPSS Inc., Chicago) software version 22. Qualitative data was compared using Chi-square test. Quantitative data compared using independent t-test. $P < 0.05$ will be taken as statistically significant.

Result & Observation:

Total of 40 patients fulfilling inclusion/exclusion criteria were studied. Results and observations are given below:

Table I: Demographic profile of the patients

Variable	Frequency & Percentage		p-value
	Group-A (n=18)	Group-B (n=23)	
Age			
30-34	4 (22.2)	4 (17.3)	
35 - 39	6 (33.3)	10 (43.4)	
40 - 45	8 (44.5)	9 (39.1)	
Mean ± SD	42.31 ± 7.6	42.29 ± 8.0	0.914
Sex			
Female	13 (72.1)	15 (65.2)	
Male	5 (27.9)	8 (34.7)	0.525
BMI			
Non-obese	7 (38.9)	8 (34.7)	0.862
Obese	11 (61.1)	15 (65.2)	
Sides of pain			
Right	10 (55.5)	12 (52.1)	0.993
Left	8 (44.5)	11 (47.8)	

Table I shows the demographic profile of the patients. Mean ± SD of age was calculated to be, (42.31 ± 7.6) for Group A and (42.29 ± 8.0) for Group B. Accordingly, p-value = 0.914, which explains that there was no significant statistical difference among the groups. Most of the participants in Group A [13 (72.1)] & in Group B [15 (65.2)] were females. Body mass index (BMI) reveals, high BMI or obese was 11 (61.1) patients in group A & 15 (65.2) patients in group B. The difference was statistically non significant ($p>0.05$) between two groups.

Table II: Distribution of the study patients by VAS score

VAS score	Group-A (n=18)	Group-B (n=23)	P value
Pre-treatment	8.52	8.46	0.064
After 1 week	8.03	6.94	0.042
At 1st month	6.18	5.29	0.001
At 3rd month	3.05	4.82	0.001
At 6th month	1.67	4.12	0.001

Table II shows that mean VAS score at different follow up time. Mean VAS score at pretreatment was 8.52 in group A & 8.46 in group B. After 1 week of intervention, score was turn down or pain reduced in both groups, but comparatively better in group B. At 3rd month (Mean VAS 3.05 & 4.82 in group A & B respectively) and 6th month later (Mean VAS 1.67 & 4.12 in group A & B respectively) follow up period, significant improvement was found in group A.

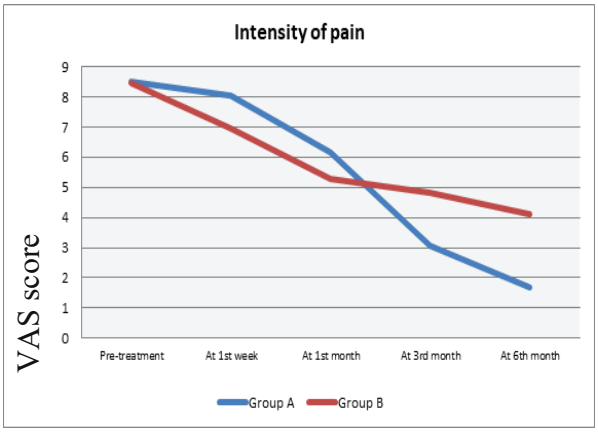

Figure 1: Comparison of mean visual analog scale score at different time intervals between the two treatment groups

Figure 1 shows that mean VAS score or alleviation of pain at different follow up time. Use of corticosteroid (Group B) showed improvement in symptoms immediately at 1st week to one month (short duration), which did not last long. But PRP effective in prolong time.

Table III: Evaluation of roles and maudsley score at different stages between the two treatment groups

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RM score	Group A (n=18)	Group B (n=23)	P value
Excellent			
Pre-treatment	0	0	
At 1st month	6 (33.3)	2 (8.69)	0.051
At 3rd month	13 (72.2)	0	0.001
Good			
Pre-treatment	0	0	
At 1st month	10 (55.5)	6 (26.0)	0.057
At 3rd month	4 (22.2)	3 (13.0)	0.442
Fair			
Pre-treatment	18 (100.0)	23 (100.0)	1.000
At 1st month	2 (11.1)	12 (52.1)	0.006
At 3rd month	1 (5.5)	7 (30.4)	0.048
Poor			
Pre-treatment	0	0	
At 1st month	0	3 (13.0)	0.116
At 3rd month	0	13 (56.5)	0.001

At pre-treatment, both groups had low or fair RM score without significant difference. After the intervention, a significant difference was observed in RM scores among two groups at 1 and 3 months with P = 0.051 and P = 0.001, respectively. Fair to good functional improvement was observed at 1 month in both groups. At 3 months, Group A showed significantly better function in terms of movement and patient satisfaction [Table III].

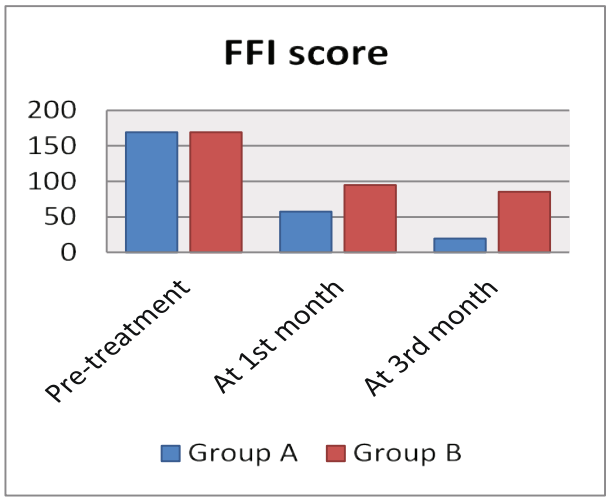

Figure 2: Comparison of mean foot function index score between the two treatment groups

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 1 and 3month followup. However, the mean FFI scores in Group A were significantly lower than Group B [Figure 2]. No adverse events were noticed in any of the groups.

Discussion:

This quasi experimental study is designed to test the use of concentrated autologous platelets in patients with plantar fasciitis. Plantar fasciitis is a degenerative soft tissue condition that occurs near the site of origin of the plantar fascia at the medial tuberosity of the calcaneus. In chronic cases normal fascia is replaced by angiofibroblastic tissue[17]. Historically plantar fasciitis was assumed to be an inflammatory process. Histological findings like chondroid metaplasia, calcification, and collagen necrosis suggest a degenerative mechanism. Hence, the term fasciosis was used by many authors rather than fasciitis. Plantar fasciitis is usually a selflimiting condition and non-operative method is usually successful. However, few patients develop chronic plantar fasciitis where pain persists and certainly affects the day-to day quality of life of the patients.

Many treatment modalities have been in practice, among which corticosteroid injections have been extensively used, but only seemed to be useful in the short term and only to a small degree[1, 11]. Potential complications associated with steroid injection raise concern about benefit against the risk involved in steroid injection. Histological studies have indicated plantar fasciitis as a degenerative disorder, hence prostaglandin mediated anti-inflammatory action of steroid is unclear. However, inhibition of fibroblast proliferation and expression of ground substance proteins by corticosteroids may be the possible explanation for the beneficial effect of steroid injection[18]. Various studies have shown that platelet-rich plasma injection as an effective treatment option for chronic plantar fasciitis.

Plantar fasciitis is considered a degenerative tissue condition due to micro-tear in fascia rather than inflammation. This results in denaturation of collagen and angiofibroblastic hyperplastic tissue is seen in histology[17]. PRP is rich in growth factors like transforming growth factor, vascular endothelial growth factor, and platelet-derived growth factor and inflammatory mediators like cytokines and interleukins, such as interleukin 4, 8, 13, interferon-α, and tumor necrosis factor-α. The concentration of these factors is low in the plantar fascia due to hypovascularity and hypocellularity. PRP delivers growth factors along with platelets directly to the site of the lesion, since all these factors affect healing stages necessary to reverse chronic plantar fasciitis[17]. Alpha particles of platelets release stored platelet-derived growth factors after stimulation. It increases fibroblast migration and proliferation and improves collagen deposition, which promotes angiogenesis and fiber repair.

Literature on treatment options show a variable outcome when PRP and steroid injection are used in the treatment of chronic plantar fasciitis. Some studies found PRP to be more effective whereas others did not find a significant difference in the outcome[19]. When steroid injection was compared with autologous blood injection in a study by Lee et al, they found that the corticosteroid group had significantly lower VAS than autologous blood group[20]. Monto et al comparing PRP and corticosteroid injection in the treatment of failed non-surgical treatment of plantar fasciitis, concluded that a single injection of PRP improved pain and function more than steroid injection and beneficial effects sustained for a longer time[21]. In our study, we compared the effectiveness of PRP and steroid injection in patients with plantar fasciitis where other conservative treatments had failed. In this technique, fascia is injected at multiple sites through a single skin portal. The injection was administered at the point of maximum tender points. All patients in our study received freshly prepared PRP. We have not used any agent to activate PRP.

Jain et al in their study comparing single injection of PRP and steroid injection in chronic plantar fasciitis, found no significant difference in functional outcome in both groups at six months follow-up[22]. Similar results were also observed in other studies[1, 11], whereas many studies have shown the longlasting beneficial effects of PRP when compared to steroid injection with improved roles and maudsley (RM) score and VAS score. In our study, we observed that in both PRP and steroid injection group, VAS and RM score improved after injection and improvement in pain and RM score was more in the steroid group compared to PRP group at first follow-up visit. On later follow-up both VAS and RM score in PRP group continued to improve and at the end of three months follow-up the PRP group showed better improvement compared to steroid group and improvement in score was statistically significant. The decline in pain and function scores of steroid group after three to six weeks suggest that steroid injection is more effective only for short-term relief.

The mechanism of reduction in pain and improvement in the function after PRP injection is not clear. PRP contains hepatocyte growth factor (HGF) along with other growth factors.

The anti-inflammatory action of HGF is mediated by disrupting the nuclear factor kappa B (NF-kB) transactivating activity, which results in decreased expression of COX-1 and COX-2 genes. By this action, HGF is known to protect tissues from inflammatory damages. Thus, the anti-inflammatory action of PRP is through HGF. This explains the initial improvement in VAS score and reduction in pain following PRP injection[23]. The results of this systematic review and meta-analysis suggest that PRP is superior to corticosteroid injections for pain control at 3 months and lasts up to 1 year. In the short term, there is no advantage of corticosteroid infiltration.

Conclusions:

Corticosteroid (CS) has an early effect, reducing pain to a moderate level in comparison to PRP. However, the effect is not sustainable over a long period. The PRP local injection is a new, readily available and well tolerated, with prolonged effect and safe choice of therapy for plantar fascitis. Comparing the long-term efficacy, we conclude that the use of PRP is an effective treatment method. However, the cost and the time for preparation the PRP are two of the disadvantages of this treatment. Steroid therapy effect appears in a short period, but PRP has a prolonged effect. There is a significant improvement in foot function and patient satisfaction as well at 6 months follow up. Therefore, PRP can be advised for a sustained and prolong impact on chronic PF.

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