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ORIGINAL ARTILE

EFFECTS OF ULTRASOUND GUIDED PLATELET RICH PLASMA ON PAIN SEVERITY AND PHYSICAL DISABILITY IN CHRONIC PLANTAR FASCIITIS

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Abstract:

Background: *Plantar fasciitis (PF) is one of the most common causes of heel pain and is frequently associated with mild to severe activity limitation. Autologous platelet-rich plasma (PRP) injection has recently been proposed as a treatment option for PF. Several studies have shown promising results with PRP therapy; however, the therapeutic efficacy of this treatment modality has not been adequately studied in our population. The aim of the study was to evaluate the effect of platelet-rich plasma injection on pain severity and physical disability in patients with plantar fasciitis attending a tertiary level hospital in Bangladesh.* ***Methods:*** *This quasi-experimental study was conducted in the Department of Physical Medicine and Rehabilitation, Chittagong Medical College Hospital (CMCH), from October 2021 to April 2022. A total of 35 patients diagnosed with plantar fasciitis were included in the study. Socio-demographic, clinical, and treatment-related information were collected using a case record form. Pain severity was assessed using the Visual Analogue Scale (VAS), and the Roles and Maudsley score was used to evaluate pain and functional limitation. All patients received a single ultrasound-guided injection of 3 cc autologous PRP into the origin of the plantar fascia. Follow-up assessments using VAS and Roles and Maudsley scores were conducted at 4 weeks and 12 weeks after injection. Data were analyzed using SPSS version 28.0.* ***Results:*** *The mean age of the participants was 43.7 ± 8.7 years, and 60% of the patients were male. The mean duration of disease was 5.2 ± 1.6 months. The mean baseline VAS score was 7.86 ± 0.77. At 4 weeks after PRP injection, the mean VAS score decreased to 4.86 ± 0.73, and at 12 weeks it further decreased to 2.71 ± 0.71, showing a mean improvement of 5.14 ± 1.03 points from baseline ($p < 0.001$). The mean Roles and Maudsley score was 3.43 ± 0.56 at baseline, which improved to 2.43 ± 0.74 at 4 weeks and 1.63 ± 0.69 at 12 weeks. The improvement in Roles and Maudsley score over time was statistically significant ($p < 0.001$).* ***Conclusion:*** *A single-dose PRP injection demonstrated clinically and statistically significant improvement in pain severity and physical disability in patients with chronic plantar fasciitis. Therefore, local PRP injection may be considered an effective treatment option for chronic plantar fasciitis.*

Keywords: *Plantar fasciitis, Platelet rich plasma, visual analogue scale, Roles & Maudsley score.*

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Introduction:

Plantar fasciitis (PF) is frequently manifested by a long term, but self limited pain on the plantar region of the foot and inferiorly in the heel that is, commonly revealed in adults limiting their activities due to severe pain and leading to physical disability.[1] PF is a common musculoskeletal injury affecting individuals across ages and activity levels. PF is most common between 40 and 60 years of age and contributes to 15% of foot injuries in general population without gender difference. The conditions may affect both athletic and non-athletic populations, but the incidence is higher among runners.[2]

By definition, inflammation is characterized in its acute stage by the classic clinical signs of pain, heat, redness, swelling, and loss of function, and histologically by leukocyte accumulation. In its chronic stage, inflammation is characterized histologically by infiltration with macrophages, lymphocytes, and plasma cells; tissue destruction; and repair involving new vessel proliferation and fibrosis. Therefore, not only must the cardinal signs of inflammation be observed clinically, but the classic histologic signs of inflammation should also be present. Typically, however, a diagnosis of PF is established solely by history and elicitation of pain on the plantar aspect of the heel.[3] Among different imaging modalities such as ultrasonography, MRI, and plain radiography (i.e., X-ray), ultrasonography is most widely accepted and primary diagnostic criteria from imaging is evaluating plantar fascia thickness. Meta-analysis showed that patients with plantar fasciitis had 2.16 mm thicker plantar fascia than controls and tended to have absolute plantar fascia thickness values exceeding 4.0 mm.[4]

The known risk factors are obesity, poor foot and ankle biomechanics, fat feet, prolonged standing, jumping, running and ill-fitting footwear. Plantar fasciitis can be isolated or associated with other systemic diseases like seronegative spondylo-arthropathies.[5]

Various therapies have been reported, but the available evidence for a single modality of management is inadequate and conflicting. As of now there is no gold standard treatment for PF. Even though the corticosteroid injections have shown satisfactory short-term results.[1] However, other than the risk of systemic adverse effect, steroid injection may be associated with an increased risk of developing persistent pain, local tissue atrophy, or plantar fascia rupture.[7,8] These adversities have led to search for other options for the treatment of plantar fasciitis.

Injection of autologous platelet rich plasma (PRP) has been recently proposed as a treatment for PF.[9] PRP are harvested from a patient's own peripheral blood and contain storage pools of growth factors such as platelet-derived growth factor, transforming growth factor, vascular endothelial growth factor. These growth factors modulate neo- vascularization and angiogenesis, promote mitogenesis, boost local collagen production, and provide anti-inflammatory effects by blocking cylco-oxygenase-2 enzyme production. The rationale behind using such platelet-rich preparations is the idea that the additional platelets may increase the growth factors at the injury site and enhance the healing process.[10] The autologous PRP does not have side effects compared to steroid injections. Moreover, USG guidance ensures accurate placement of drug at the desired site of injection.

There is evidence to support the use of PRP compared to corticosteroid or placebo, especially at longer terms such as at 3, 6, and 12 months. One of the most recent reviews by Hurley et al.[11] who limited studies evaluating PRP found benefits in terms of VAS score reduction even at 1–1.5 months. While PRP and corticosteroid can both decrease inflammation, PRP has biological regenerative properties such as augmenting cellular migration, enhancing cellular proliferation, and promoting angiogenesis.[12]

Though PRP is emerging as a promising treatment modality for PF and other chronic pain, data regarding the efficacy of PRP therapy from Bangladesh is very limited.[13-15] Therefore, the aim of this study was to evaluate the efficacy of ultrasound guided autologous PRP injection in treatment of chronic PF.

Methods:

This quasi-experimental study was conducted in the Department of Physical Medicine and Rehabilitation, Chittagong Medical College Hospital, Chattogram, Bangladesh over a six-month period from 19 October 2021 to 18 April 2022. The study population consisted of patients aged 18–60 years attending the outpatient department (OPD) of Physical Medicine and Rehabilitation at Chittagong Medical College Hospital who were diagnosed with chronic plantar fasciitis during the study period. Consecutive sampling technique was used to select the study participants. The sample size was calculated using the formula for hypothesis testing of a single mean based on parameters from a previous study where the population standard deviation (Ã) was 2.65 and the effect size was 1.77. The standard normal deviation at 95% confidence level (Z±) was taken as 1.96 and the standard normal deviation corresponding to 95% power (Z^2) was 1.64. The calculated sample size was 29.07. Considering a 20% increase to account for possible dropouts and to improve study power, the final sample size was

estimated at 34.88. Therefore, a total of 35 patients fulfilling the inclusion and exclusion criteria were enrolled in the study.

Inclusion criteria were patients aged 18–60 years of either gender diagnosed with chronic plantar fasciitis with a duration of more than 3 months. Patients having a Visual Analogue Scale (VAS) pain score of more than 5 in the morning, who had failed conservative treatment, were willing to participate in the study, and were able to understand and provide informed consent were included.

Patients with rheumatologic diseases such as rheumatoid arthritis, spondyloarthropathies, or gout were excluded. Patients who had received corticosteroid injection within the previous 6 weeks or who had taken aspirin or non-steroidal anti-inflammatory drugs (NSAIDs) within the last week were also excluded. Other exclusion criteria included history of prolonged standing, pregnancy or breastfeeding, obesity (BMI >30 kg/m^2), severe anemia (Hb <5 gm/dl), uncontrolled diabetes mellitus, hypothyroidism, peripheral neuropathy, local infection or malignancy (skin or bone), acute infection or fever, coagulopathies, and those unwilling to participate in the study.

Patients attending the outpatient department (OPD) of the Physical Medicine and Rehabilitation Department were evaluated through detailed history taking, clinical examination, and relevant investigations. The investigations included complete blood count (CBC), fasting blood sugar (FBS), blood sugar two hours after breakfast (2HrABF), plain X-ray of the involved calcaneus in anteroposterior and lateral views, and musculoskeletal ultrasonography of the affected heel. Patients fulfilling the inclusion and exclusion criteria were finally selected for the study. Written informed consent was obtained from the patients and/or their guardians. Face-to-face interviews were conducted using a semi-structured questionnaire to collect socio-demographic information and other relevant data. Information regarding previous treatment modalities and investigation profiles was collected from patients' statements and document review. Baseline pain severity and functional limitation were assessed using the Visual Analogue Scale (VAS) and Roles and Maudsley Score (RMS).

The procedure was performed on an outpatient basis under strict aseptic precautions. The patient was placed in the supine position with the lower limb externally rotated, and the skin was disinfected with povidone iodine solution. Local anesthesia was administered using lignocaine in the skin and subcutaneous tissue. A Sonosite ultrasound machine (M-Turbo P16893) with a linear probe (6–15 MHz) was used for guidance. The intervention was performed by the investigator with the assistance of an experienced physiatrist in musculoskeletal ultrasonography. Under ultrasound guidance, the thickest portion of the plantar fascia or the hypoechoic areas within the thickened fascia were identified, and 3 ml of autologous PRP was injected using a 5 ml syringe with a 25-gauge needle using the peppering technique. This technique involved a single skin portal with multiple directional passes into the plantar fascia. After injection, the needle was removed and a sterile bandage was applied. The patient was kept in a supine position for 15 minutes before discharge and was advised to limit use of the affected foot for 48 hours.

Post-injection precautions included the use of acetaminophen (paracetamol) as the only analgesic if required. Patients were advised to apply ice packs, rest, and elevate the affected limb for 72 hours and avoid full weight bearing for 48 hours. Activities that provoke pain, such as running or vigorous physical activity, were restricted for two weeks, and other pain-relieving modalities or interventions were avoided for 12 weeks. All patients were followed up in the outpatient clinic and assessed clinically at 4 weeks and 12 weeks after injection. Outcome measures were evaluated using the Visual Analogue Scale (VAS) and Roles and Maudsley Score (RMS). All collected information was recorded in a pretested questionnaire and stored securely to maintain confidentiality.

Data were collected using an informed written consent form and a structured questionnaire designed to obtain socio-demographic information such as age, gender, residence, occupation, and educational status, along with relevant clinical information. Pain severity and functional limitation were assessed using the Visual Analogue Scale (VAS) and Roles and Maudsley Score (RMS).

After collection, data were compiled in a Microsoft Excel worksheet and subsequently entered into SPSS (Statistical Package for Social Sciences) version 28 for analysis. Categorical variables were expressed as frequencies and percentages, while continuous variables were presented as mean ± standard deviation (SD). Repeated measures ANOVA was used to compare the mean VAS and Roles and Maudsley scores at different follow-up periods. A p-value of <0.05 was considered statistically significant.

A work manual was prepared and a standard questionnaire was developed and pretested to ensure the quality of data collection. Data collection and report preparation were conducted under the supervision of the research supervisor to maintain accuracy and reliability.

Ethical approval was obtained from the Ethical Review Committee of Chittagong Medical College. Written informed consent was obtained from all participants, and confidentiality of patient information was strictly maintained. Participants were informed of their right to withdraw from the study at any time without affecting their treatment.

Results:

After screening 55 patients in the OPD of the Physical Medicine and Rehabilitation center 35 patients were eligible for the study and received allocated treatment and all of them were available for final outcome assessment. The findings of the study are summarized in the following Tables and Graphs:

Table-I

Distribution of the patients by their age and sex (n=35)

Variables		Frequency	Percentage
Age, years	Mean ±SD	43.7±8.7	
	Range	25-59	
Sex	Male	21	60.0
	Female	14	40.0

SD: Standard deviation; Data were expressed as frequency and percentage.

The mean age of the patients at enrollment was 43.7 (±8.7) years with ranged between 25-59 years. There was male (60%) preponderance in the study with a male to female ratio of 1.5:1 (Table I).

Table-II

Baseline clinical characteristics of the patients (n=35)

Variables		Frequency	Percentage
Body mass index	Normal (18.5-22.9kg/m^2)	16	45.7
	Overweight (23.0-24.9 kg/m^2)	19	54.3
Duration of disease in months, Mean±SD	5.2±1.6		
Side of involvement	Right	12	34.3
	Left	23	65.7
Treatment received	Rest	17	48.6
	Shoe ware modifications	13	37.1
	orthosis	4	11.4
	Ice	5	14.3
	Physical therapy	7	20.0
	Therapeutic exercise	11	31.4
	Anti-inflammatory medications	28	80.0
	Immobilization	6	17.1
X-Ray Calcaneus involved side	Normal	23	65.7
	Presence of Calcaneal Spur	12	34.3
Baseline pain VAS score, mean±SD		7.86±0.77	
Baseline RMS score, mean±SD		3.43±0.56	

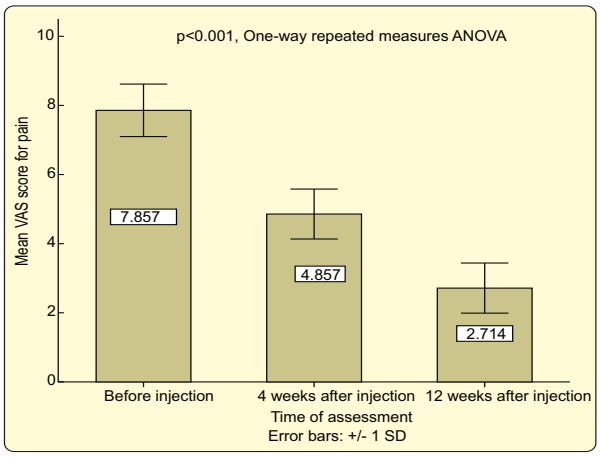

Figure 1: *Bar diagram with error bar showing mean (±SD) VAS score for pain over time*

The mean disease duration was 5.2±1.6 months and left sided involvement was more common (65.7%) in the current study. Twelve patients (34.3%) had calcaneal spur on X-ray examination. More than half (54.3%) were overweight in the study. Anti-inflammatory medication (80.0%) and foot ware modification were the two most common treatment modalities used for the patients (Table III).

The mean VAS value at the beginning of the study was 7.86 ± 0.77 points. Four weeks after the PRP injection, mean VAS score reduced to 4.86±0.73, and after 12 weeks injection mean VAS score was further reduced to 2.71±0.71, with a mean improvement at the end of treatment was 5.14 ± 1.03 points from the pretreatment value. The results observed were statistically significant (p< 0.001 by Repeated measure one way ANOVA test).

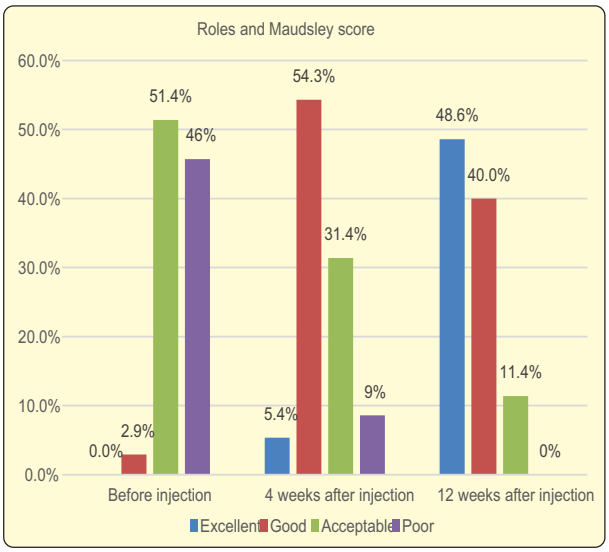

Figure 2: *Changes in Roles and Maudsley score over time in the patients*

The Roles and Maudsley score were measured before PRP injection, 4 weeks, and 12 weeks after PRP injection. Acceptable results were observed in 51.4% of patients and 46.0% were poor (pre injection). At the final follow up 48.6% were graded excellent and 40% were good, on the other hand, 11.4% of patients had acceptable results and none was graded poor as shown in Figure 3.

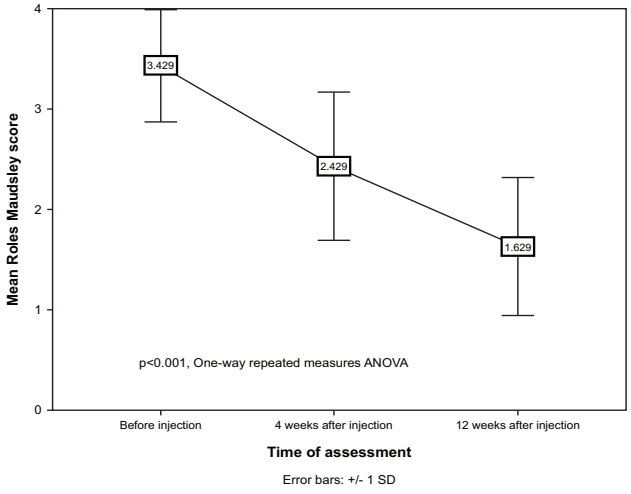

Figure 3: *Line diagram showing mean Roles and Maudsley for disability limitations over time*

The mean Roles and Maudsley score at the beginning of the study was 3.43 ± 0.56 points. The score was reduced to 2.43±0.74, and 1.63±0.69, respectively 4 weeks and 12 weeks after PRP injection. The Roles and Maudsley score showed statistically significant improvement overtime (5ØCÜ < 0.001 by Repeated measure one way ANOVA test (Figure 4).

Discussion:

The present study was done to determine the efficacy of ultrasound guided PRP injection in treating chronic PF with a quasi-experimental study design. Thirty-five patients of chronic PF were included from the OPD of the Physical Medicine and Rehabilitation department of CMCH. Single dose of three ml PRP was given in this study. Pain severity and physical disability were assessed at baseline, and thereafter 4-weeks and 12-weeks after PRP injection. PRP injection has been shown, in the present series, to be effective in both reducing pain and physical disability after failure of conservative treatment.

The mean age of the patients at enrollment was 43.7 (±8.7) years ranging between 25-59 years. The mean age of the patients was 45.85 (range 25-75) in the study of Kadam et al[16] and in the study of Baz et al.[17] the mean age was 46.5 years. Kalia et al.[18] found the mean age of 39.0±8.8 years (range 20–55 years) in their series of patients with chronic PF. The findings of the present study are similar to those of previous studies and existing evidence indicated that chronic PF is a disease of mid adult age and in more physically active persons.[1]

In the present study, male patients (60%) were more than female with a male to female ratio of 1.5:1. However, previous studies were not consistent regarding the sex distribution of the patients. Few studies[13,16,17] reported a male preponderance in patients with chronic PF similar to the present study, while others reported female preponderance.[18,19,20]

Most frequent occupational category in the study was manual laborer (28.6%), followed by homemaker (22.9%), farmer (14.3%), service (14.3%), athlete (8.6%), businessmen (5.7%), and retired (5.7%). Majority of the patients were literate with formal education and only 20.0% were either illiterate or only able to read and write (11.4%). Majority (62.9%) of the patients were from urban area in the study. As the study was conducted in a public tertiary level hospital, these sociodemographic characteristics might not represent the general chronic PF patients of Bangladesh.

Disease duration ranged from 3-9 months with the mean disease duration of 5.2±1.6 months and left sided involvement was more common (65.7%) in the current study. Twelve patients (34.3%) had calcaneal spur on X-ray examination. More than half (54.3%) were overweight in the study. Anti-inflammatory medication (80.0%) and foot ware modification were the two most common treatment modalities used for the patients. The mean VAS value was 7.86 ± 0.77 points for pain

severity at baseline. The Roles and Maudsley (RMS) score was measured to determine the physical function impairment. At baseline, the RMS was 3.43 ± 0.56 points, and most patients had a score of 3.

The effect of PRP was evaluated by the change in the severity of pain symptoms and improvement of physical function impairment. The mean VAS value at the beginning of the study was 7.86 ± 0.77 points. 4 weeks after the PRP injection, mean VAS score reduced to 4.86±0.73, and 12 weeks after PRP injection mean VAS score was further reduced to 2.71±0.71, with a mean improvement at the end of treatment of 5.14 ± 1.03 points from the pretreatment value. The present study findings were in line with the previous findings of the study by Baz et al.[17] where the VAS score showed improvement from an average of 8.14 (pre injection) to 2.59 at the 4th month post injection. In the study of Kalia et al.[18] the pre-injection VAS score for heel pain was 6.5±1.1 which improved to 2.7±0.5 and 1.8±0.8 at 6 and 12 week respectively which was statistically significant. Kadam et al.[16] observed that the mean pre injection VAS score was 7.15, at time of follow up after one week was 6.20, at time of follow up after 6 week was 5.62, and at the final follow up after 3 months was 3.20. The present study results are consistent with the results of previous studies and the systematic reviews, where it was consistently reported that PRP injection is effective in pain reduction which was evident by the reduction of VAS score.[1,6,11]

The cytokines and growth factors present in PRP may play an important role in the reduction of pain in chronic PF. PRP is rich in transforming growth factor, vascular endothelial growth factor and platelet-derived growth factor. In addition, PRP also has some anti-inflammatory and pro-inflammatory cytokines and interleukins, such as interleukin 4, 8, 13, interferon-±, and tumor necrosis factor-±.[21] The combination of these growth and anti-inflammatory components is necessary to initiate the healing stages and to reverse the degenerative process at the base of the plantar fascia.[22] Platelets contain dense and alpha granules; alpha particles can release stored platelet-derived growth factors after platelet stimulation, and platelet-derived growth factors can promote angiogenesis and fiber repair. Therefore, local injection of PRP promotes the repair of the plantar fascia.[21]

As the plantar fascia is inaccessible to high concentrations of platelets and growth factors because of hypovascularity and hypocellularity, Ultrasonographic guidance enable PRP injections to deliver directly into the lesion site.

For the above mechanism of PRP, functional ability of the patients with chronic PF was also improved over time. Roles and Maudsley scoring system were used for the assessment of patient reported pain and limitations of activity in the current study before PRP injection, 4 weeks and 12 weeks after PRP injection. This scoring system quantifies disability based on symptoms limiting daily and recreational activities, ranging from the excellent, which would be a score of 1 (no pain or limitations of daily and recreational activities), to the poor, which would be a score of 4 (constant pain with inability to undertake daily and recreational activities). Before injection majority of the patients had either acceptable (51.4%) or poor (46%) level of pain and activity limitation as assessed by Roles and Maudsley score. At the final follow up 48.6% were graded excellent and 40% were good, on the other hand, 11.4% of patients had acceptable results and none was graded poor. After 12 weeks of PRP injection mean Roles and Maudsley score decreased by 1.8 (±0.58) from the pretreatment value of 3.43 (±0.56). The present study results were in line with the other studies which assessed the efficacy of PRP injection in patients with chronic PF. Martinelli et al.[22] treated 14 consecutive patients with chronic PF with three injections of PRP into the plantar fascia. According to criteria of the Roles and Maudsley score, at 12 months of follow-up, results were rated as excellent, good, acceptable, and poor in, respectively 64.3 %, 14.3 %, 14.3 %, and 7.1 % of the patient. Kumar et al.[23] collect prospective data of 44 patients with chronic PF, who received PRP injection. At six-month review, Roles and Maudsley score improved from mean 4 to 2 ($p < 0.001$).

Conclusion:

The present study showed significant pain reduction and improvement in activity level with the single dose Ultrasonographic guided autologous PRP injection at least three months after treatment in patients with chronic Plantar Fasciitis. The results of the present study indicated that PRP injection appears to be an effective means for the treatment of chronic Platar Fasciitis.

Limitations:

It was a single-center study. The study population was relatively small. Long-term follow-up was not included.

Conflict of Interest:

The authors stated that there is no conflict of interest in this study

Funding:

This research received no external funding.

Ethical consideration: The study was approved by the Ethical Review Committee, Chittagong Medical College Hospital, Chattogram, Bangladesh. Informed consent was obtained from each participant or the caregiver of the patient.

Author Contributions:

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis, and interpretation, or all these areas; took part in drafting, revising, or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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