ASIAN JOURNAL OF PHARMACEUTICAL AND CLINICAL RESEARCH



FUNCTIONAL OUTCOME OF PATIENTS WITH CHRONIC PLANTAR FASCIITIS TREATED BY LOCAL INJECTION OF AUTOLOGOUS PLATELET-RICH PLASMA

RAJESH KUMAR KANOJI*[®], PRADEEP KUMAR SUTHAR[®], HIMANSHU[®]

Department of Orthopedics, National Institute of Medical Sciences and Research Jaipur, Rajasthan, India. *Corresponding author: Rajesh Kumar Kanoji; Email: kanojirajesh70@gmail.com

Received: 24 May 2023, Revised and Accepted: 04 July 2023

ABSTRACT

Objectives: The objectives of the study are as follows: To assess functional outcome of patients with chronic plantar fasciitis (PF) treated by autologous injection of platelet-rich plasma (PRP). (1) To know the side effects, if any, in these patients.

Methods: This was a prospective study conducted in the Department of orthopedics of a tertiary care medical college. Forty patients having chronic PF were included in this study on the basis of a predefined inclusion and exclusion criteria. Autologous PRP was injected in plantar fascia at the point of maximum tenderness. Patients were followed up for 3 months. Intensity of pain and functional outcome was assessed using the visual analog score (VAS) score and American Orthopedic Foot and Ankle Score (AOFAS) score. For statistical purposes, p<0.05 was taken as significant.

Results: There were 14 (35.00%) males and 26 (65.00%) females with a M: F ratio of 1:1.85. The mean age of male and female patients was found to be 43.82±9.98 years and 41.68±10.12 years, respectively. Majority of the patients (65%) were overweight whereas 6 (15%) patients were obese and 8 (20%) patients were having a normal healthy body mass index. The mean duration of symptoms was found to be 10.67±3.89 months. The mean VAS score at the time of final follow-up was significantly less (0.96±0.46) as compared to pre-injection VAS score (7.20±1.38) whereas the AOFAS score at the time of final follow-up (91.9±6.68) significantly improved as compared to pre-injection AOFAS score (38.96±8.78). There were no major side effects in any of the studied cases.

Conclusion: Local injection of autologous PRP appears to be an effective treatment for chronic PF in terms of reduction of pain and functional improvement with no significant side effects.

Keywords: Plantar fasciitis, Platelet-rich plasma, Visual analog score, Functional outcome.

© 2023 The Authors. Published by Innovare Academic Sciences Pvt Ltd. This is an open access article under the CC BY license (http://creativecommons.org/ licenses/by/4.0/) DOI: http://dx.doi.org/10.22159/ajpcr.2023v16i8.49770. Journal homepage: https://innovareacademics.in/journals/index.php/ajpcr

INTRODUCTION

Plantar fasciitis (PF) is a common and debilitating condition which affects millions of individuals worldwide, particularly those engaged in activities that place excessive stress on the plantar fascia, such as athletes and individuals with prolonged weight-bearing occupations [1]. This condition, characterized by heel pain and inflammation of the plantar fascia, represents a significant burden on both patients and health-care systems. In recent years, the management of PF has seen a shift toward a more comprehensive understanding of its etiopathogenesis, clinical features, diagnosis, and treatment modalities, including the utilization of newer interventions such as corticosteroid injections and plateletrich plasma (PRP) therapy [2].

The etiopathogenesis of PF is multifactorial, involving a complex interplay of biomechanical, anatomical, and inflammatory factors. The primary cause of PF is considered to be overuse and microtrauma to the plantar fascia. Prolonged or excessive stress on the plantar fascia can lead to microscopic tears and inflammation, resulting in the characteristic heel pain [3]. Various factors can contribute to this overuse, including obesity, excessive running or walking, unsupportive footwear, and structural abnormalities of the foot. In addition to mechanical factors, genetics may also play a role in the development of PF. Some individuals may have a genetic predisposition to conditions that affect connective tissues, making them more susceptible to developing PF. Furthermore, systemic conditions like rheumatoid arthritis can increase the risk of PF by causing inflammation in the joints and surrounding tissues [4].

The hallmark symptom of PF is heel pain, typically characterized by sharp, stabbing discomfort that is most pronounced with the first steps

in the morning or after prolonged periods of inactivity. This pain often improves with activity but worsens as the day progresses, particularly after standing for extended periods. Patients commonly report tenderness at the insertion of the plantar fascia into the calcaneus. The clinical diagnosis is primarily based on the patient's history and physical examination findings, and imaging studies may be used to rule out other causes of heel pain or to assess the extent of tissue damage [5].

Diagnosing PF typically relies on clinical evaluation and the exclusion of other potential causes of heel pain. A thorough medical history is essential, with a particular focus on the onset, duration, and exacerbating factors related to the pain. Physical examination often reveals localized tenderness and pain at the plantar fascia's insertion on the heel. Radiological studies, such as X-rays, may be ordered to rule out other causes of heel pain, including calcaneal spurs or stress fractures. Radiological confirmation of the diagnosis of PF may be done by ultrasound which may show plantar thickness of more than 4 mm [6].

The management of PF is multifaceted and may involve conservative and invasive interventions, depending on the severity of the condition and the patient's response to treatment. Conservative measures include rest, ice, non-steroidal anti-inflammatory drugs, stretching exercises, and supportive footwear. In addition, orthotic devices or custommade shoe inserts may be recommended to improve foot alignment and reduce strain on the plantar fascia. In cases where conservative treatments fail to provide relief, more invasive options are considered. Corticosteroid injections have been widely used to alleviate pain and inflammation associated with PF [7]. Steroid injections aim to reduce inflammation and suppress pain, but their effectiveness can be limited, and there is a risk of tissue atrophy and weakening. Over the past decade, there has been growing interest in the utilization of regenerative therapies for PF. Corticosteroid injections have traditionally been employed to reduce inflammation and pain, but they may not address the underlying structural damage and, in some cases, can lead to complications such as plantar fascia rupture. One such emerging treatment modality is PRP therapy. The growth factors found in PRP are thought to stimulate the repair of damaged tissue, making it an attractive option for conditions like PF where tissue healing is paramount. In recent years, studies have explored the efficacy of PRP therapy in the treatment of PF, with promising results. PRP injections have been shown to reduce pain and improve function in some patients, with a lower risk of side effects compared to corticosteroid injections. This shift toward regenerative therapies raises intriguing possibilities for a more targeted and effective management of PF [8].

We undertook this study to find out the efficacy of PRP injection for the treatment of PF not responding to conservative means.

METHODS

This was a prospective and cohort study in which 40 patients having PF and who have not responded to conservative management for 6 months were included on the basis of a predefined inclusion and exclusion criteria. The study was conducted in the Department of orthopedics of a tertiary care medical college. The sample size was calculated on the basis of pilot studies done on the subject of PF assuming 90% power and 95% confidence interval, the sample size required was 36 patients. Based on the central limit theorem, the sample size was calculated to be sufficient if it was more than 36 thus, 40 patients were included in each group. An informed and written consent was obtained from all the patients before enrolling them in the study. Demographic details such as age, gender, occupation, socioeconomic status, weight, and body mass index (BMI) were noted in all the cases. The detailed history with respect to duration, severity, and diurnal variations were asked for and noted. The presence of any comorbid condition such as diabetes mellitus, hypertension, arthritis, or any other musculoskeletal disorders was asked for and noted. Hematological investigations such as complete blood count, C-reactive protein, and erythrocyte sedimentation rate were done in all the patients. X-ray of the foot in anteroposterior and lateral projections was done in all the cases to rule out fractures and any focal bony lesions. Confirmation of diagnosis was done on the basis of ultrasound thickness of more than 4 mm in selected cases magnetic resonance imaging was done.

The injection site was anesthetized using lidocaine injection after a skin sensitivity test has ruled out the possibility of hypersensitivity to a local anesthetic drug following which the patient received 3 ml of autologous PRP injection at the affected side by peppering technique in which skin was penetrated at the point of maximal tenderness and PRP was injected. After the injection, patients were discharges on the same day with an advice to restrict the activity to a minimum level and patients were prescribed oral analgesic to be taken if required. In all the patient's severity of pain at the time of the first presentation and subsequently, during follow-up visits was assessed by visual analog score (VAS) [9]. The functional outcome of patients was assessed on the basis of American Orthopedic Foot and Ankle Score (AOFAS) [10]. A VAS score within the range of 0-3 was considered indicative of pain relief, while a VAS score within the range of 4-10 was classified as indicating no pain relief. AOFAS scores falling within the ranges of 90-100, 80-89, 60-79, and <60 were categorized as excellent, good, fair, and poor outcomes, respectively. Follow-up was done at 4, 8, and 12 weeks.

The statistical analysis was conducted using SPSS version 21.0 software. To compare groups, independent sample t-tests were employed for continuous data, while Chi-square tests were utilized for categorical data. For repeated observations, paired t-tests or repeated measures ANOVA were applied, depending on the suitability of the method. A p-value below 0.05 was considered as indicative of statistical significance.

Inclusion criteria

- The following criteria were included in the study:
- Patients having PF who have not responded to conservative management for 6 months.
- 2. Age between 18 and 50 years.
- 3. Those who gave informed consent to be part of the study.

Exclusion criteria

The following criteria were excluded from the study:

- 1. Those who refused consent.
- 2. Patients having arthropathies likely to affect the outcome in patients.
- 3. Patients in whom any local surgical intervention was done for any reason.
- 4. Patients having progressive musculoskeletal disorders.
- 5. Any local infection of the same foot.
- 6. Recent anticoagulation therapy.

RESULTS

Out of 40 studied cases included in this study, there were 14 (35.00%) males and 26 (65.00%) females with a M: F ratio of 1:1.85 (Fig. 1).

The analysis of age group of the affected cases showed that the most common affected age group in our study was between 41-45 years (40.00%) followed by 46-50 (27.50%) years and 36-40 years (17.50%). Only 6 (15%) patients were below 35 years of age in our study (Table 1).

The mean age of male and female patients was found to be 43.82 ± 9.98 years and 41.68 ± 10.12 years, respectively. The mean age of female patients was less than males; however, the difference was not found to be statistically significant (p=0.5254) (Table 2).

The analysis of the duration of the pain in patients showed that in the majority of the patients, it was between 6-9 months (57.50%) followed

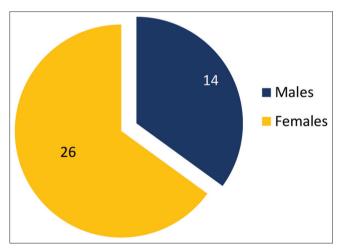


Fig. 1: Gender distribution of studied cases

Table 1: Gender-wise age distribution of studied cases

Age (in years)	Males		Females		
	No of patients	Percentage	No of patients	Percentage	
18-25	0	0.00	1	2.50	
26-30	1	2.50	1	2.50	
31-35	1	2.50	2	5.00	
36-40	3	7.50	4	10.00	
41-45	5	12.50	11	27.50	
46-50	4	10.00	7	17.50	
Total	14	35.00	26	65.00	

by 9–12 months (22.50%) and 12–18 months (12.50%). Only 3 (7.50%) patients reported pain of more than 18 months duration. The mean duration of symptoms was found to be 10.67 ± 3.89 months (Fig. 2).

The analysis of the patients on the basis of BMI showed that out of 40 cases, majority of the patients (65%) were overweight whereas 6 (15%) patients were obese and 8 (20%) patients were having a normal healthy BMI (Table 3)

The analysis of the patients on the basis of pain as assessed by VAS showed that at the time of presentation, almost all of the patients had severe pain. The mean VAS score at the time of presentation was 7.20 \pm 1.38. After treatment by injection of PRP at 4-, 8-, and 12-week follow-up, the mean VAS scores were found to be 3.34 \pm 1.12, 2.86 \pm 0.98, and 0.96 \pm 0.46, respectively. The pain reduced in almost all patients. The mean VAS score at the time of final follow-up was less as compared to at the time of presentation and the difference was statistically highly significant (p<0.0001) (Table 4).

All the patients were assessed for functional ability by American Orthopedic Foot and Ankle Society (AOFAS) scores. AOFAS scores of all the patients were determined at the time of presentation. All patients were found to have a poor (<60) AOFAS score at the time of presentation signifying significant functional impairment. The mean AOFAS score at presentation was found to be 38.96±8.78. After PRP injection at the time of the first follow-up at 4 weeks, the mean AOFAS score was 74.58±8.26. At the time of subsequent follow-up visits at 8 and 12 weeks, the mean AOFAS score at the final follow-up was found to have improved as compared to the AOFAS score at the time of presentation and the difference was found to be statistically highly significant (p<0.0001) (Fig. 3).

Finally, the analysis of patients on the basis of adverse effects showed that no patient had any major complication or adverse effect. Three patients developed pain at the injection site which was treated by oral analgesics. One patient developed skin discoloration at the injection site and one patient had minor allergic manifestations. All patients were managed conservatively (Fig. 4).

DISCUSSION

Out of 40 studied cases included in this study, there were 14 (35.00%) males and 26 (65.00%) females with a significant

Table 2: Mean age o	of studied	cases
---------------------	------------	-------

Gender	Mean age	Standard deviation	Test of significance
Males	43.82	9.98	p=0.5254 Not significant
Females	41.68	10.12	

Table 3: Body mass index of the studied	Table 3: Bod	/ mass index	of the	studied	cases
-----------------------------------------	--------------	--------------	--------	---------	-------

Body mass index	Number of patients	Percentage	
Healthy weight (18.5–24.9)	8	20.00	
Overweight (25–29.9)	26	65.00	
Obese (30 or above)	6	15.00	
Total	40	100.00	

Table 4: Comparison of VAS score at presentation and during follow-up

VAS score	Mean	Standard deviation
At presentation	7.20	1.38
4 weeks	3.34	1.12
8 weeks	2.86	0.98
12 weeks	0.96	0.46

95% CI: -6.6979--5.7821. P<0.0001* (highly significant)

female preponderance. Many studies have reported that it is more common in females as compared to males. Although the exact cause of PF being common in females is not known various studies have suggested role of wearing footwear with inadequate arch support and hormonal influence in females to be responsible for increased propensity for the development of PF [11]. Yi *et al.* conducted a study to investigate the causes of plantar heel pain and find differences in the clinical features of PF and fat pad atrophy, which are common causes of plantar heel pain, for use in differential diagnosis [12]. In this study, 250 patients with PF were enrolled. Out of 250 enrolled cases, there was a female preponderance as there were 114 men and 136 women patients with a mean age of 43.8 years and mean heel pain duration of 13.3 months. Similar findings were also reported by the authors such as Palomo-López *et al.* [13] and Granado *et al.* [14].

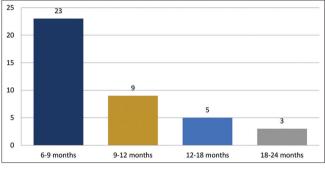


Fig. 2: Duration of pain in studied cases

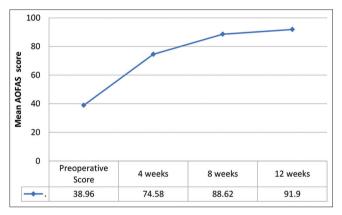


Fig. 3: Comparison of American Orthopedic Foot and Ankle Score at presentation and during follow-up

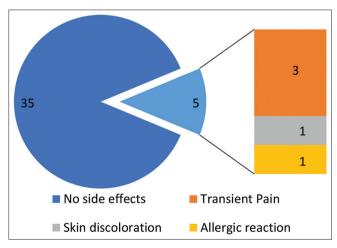


Fig. 4: Adverse effects in the studied cases

The mean age of male and female patients was found to be 43.82±9.98 years and 41.68±10.12 years, respectively. Out of 40 cases, majority of the patients (65%) were overweight whereas 6 (15%) patients were obese and 8 (20%) patients were having a normal healthy BMI. In this study, being overweight or obese is one of the risk factors for PF. Tas et al. conducted in a study in which 87 healthy sedentary individuals (52 female and 35 male) aged between 19 and 58 years (mean age 34±11 years) were investigated to examine the impact of BMI on plantar fascia and heel pad stiffness and thickness [15]. Participants were categorized as either normal weight (18.5 kg/m²<BMI<25 kg/m²) or overweight and obese (BMI \geq 25 kg/m²). The results revealed that overweight and obese individuals exhibited significantly higher values for heel pad thickness (p<0.001), plantar fascia thickness (p=0.001), heel pad microchamber layer (MIC) stiffness (p<0.001), and heel pad microchamber layer (MAC) stiffness (p<0.001). Similar propensity to develop thickened plantar fascia in overweight and obese individuals were also reported by authors such as van Leeuwen et al. [16] and Riddle et al. [17].

The study assessed patients based on pain VAS and found that initially, all patients experienced severe pain with a mean VAS score of 7.2±1.38. After receiving PRP injections at 4, 8, and 12 weeks, the mean VAS scores progressively decreased to 3.34±1.12, 2.86±0.98, and 0.96±0.46, respectively. The pain significantly reduced, with the final follow-up VAS score lower than the initial presentation (p<0.0001). Functional ability, as assessed by the AOFAS score, was initially poor (< 60) with a mean AOFAS score of 38.96±8.78. After PRP treatment, AOFAS scores improved to 74.58±8.26 at 4 weeks, and further to 88.62±9.68 at 8 weeks, and 91.9±6.68 at 12 weeks, demonstrating highly significant improvement (p<0.0001). Kalia RB et al conducted a prospective case series involving 30 patients with chronic unilateral PF lasting 6 months or more and assessed the effectiveness of a single autologous PRP injection [18]. The patients' mean age was 39 years (range 20-55). Before PRP injection, the mean VAS for heel pain was 6.5±1.1. At 6- and 12-weeks post-injection, the VAS scores significantly improved to 2.7±0.5 and 1.8±0.8, respectively (p<0.001). Baseline foot and ankle disability index and AOFAS hindfoot score component scores were 53.1±9.0 and 72.2±5.7, respectively, and they improved to 65.5±5.3 and 76.1±4.5 at 6 weeks and 77.9±4.4 and 85.7±4.6 at 12 weeks, all showing significant improvement (p<0.001). The initial mean plantar fascia thickness, 4.9±0.3 mm, significantly decreased to 3.9±0.3 mm at 12 weeks post-PRP injection (p<0.001). On the basis of these findings, the study concluded that single-dose PRP injection causes clinical and statistically significant improvements in VAS for heel pain, functional outcome scores, and plantar fascia thickness. Similar improvements in patients of PF treated by PRP injection were also reported by the authors such as Ragab et al. [19] and Yang et al. [20].

No serious side effect was reported in any of the cases of chronic PF treated by PRP. Minor side effects such as transient pain at injection site, itching, and discoloration was skin were reported in some cases; however, all these side effects could be managed conservatively.

CONCLUSION

Local injection of autologous PRP has shown encouraging outcomes in terms of reduction of pain and improved functional outcomes in patients of chronic PF. There were no major side effects of this therapy in any of the cases.

ACKNOWLEDGMENT

The authors would like to acknowledge the support extended by faculty and staff of Department of Orthopaedics, National Institute Of Medical Science Research and hospital, Jaipur, Rajasthan, India in undertaking this study.

FUNDING

None.

CONFLICTS OF INTEREST

None.

REFERENCESS

- Waclawski ER, Beach J, Milne A, Yacyshyn E, Dryden DM. Systematic review: Plantar fasciitis and prolonged weight bearing. Occup Med (Lond) 2015;65:97-106. doi:10.1093/occmed/kqu177
- Peng Y, Li F, Ding Y, Sun X, Wang G, Jia S, *et al.* Comparison of the effects of platelet-rich plasma and corticosteroid injection in rotator cuff disease treatment: A systematic review and meta-analysis. J Shoulder Elbow Surg 2023;32:1303-13. doi:10.1016/j.jse.2023.01.037
- Wearing SC, Smeathers JE, Urry SR, Hennig EM, Hills AP. The pathomechanics of plantar fasciitis. Sports Med 2006;36:585-611. doi:10.2165/00007256-200636070-00004
- Falsetti P, Frediani B, Acciai C, Baldi F, Filippou G, Marcolongo R. Heel fat pad involvement in rheumatoid arthritis and in spondyloarthropathies: An ultrasonographic study. Scand J Rheumatol 2004;33:327-31. doi:10.1080/03009740410005395
- McNally EG, Shetty S. Plantar fascia: Imaging diagnosis and guided treatment. Semin Musculoskelet Radiol 2010;14:334-43. doi:10.1055/s-0030-1254522
- Draghi F, Gitto S, Bortolotto C, Draghi AG, Ori Belometti G. Imaging of plantar fascia disorders: Findings on plain radiography, ultrasound and magnetic resonance imaging. Insights Imaging 2017;8:69-78. doi:10.1007/s13244-016-0533-2
- Ang TW. The effectiveness of corticosteroid injection in the treatment of plantar fasciitis. Singapore Med J 2015;56:423-32. doi:10.11622/ smedj.2015118
- Matthews M, Betrus CJ, Klein EE, Joshi A, Hamer SW, Sorensen MD, et al. Comparison of regenerative injection therapy and conventional therapy for proximal plantar fasciitis. J Foot Ankle Surg 2023;62:469-71. doi:10.1053/j.jfas.2022.11.010
- Langley GB, Sheppeard H. The visual analogue scale: Its use in pain measurement. Rheumatol Int 1985;5:145-8. doi:10.1007/BF00541514
- SooHoo NF, Shuler M, Fleming LL, American Orthopaedic Foot and Ankle Society. Evaluation of the validity of the AOFAS clinical rating systems by correlation to the SF-36. Foot Ankle Int 2003;24:50-5. doi:10.1177/107110070302400108
- Umar H, Idrees W, Umar W, Khalil A, Rizvi ZA. Impact of routine footwear on foot health: A study on plantar fasciitis. J Family Med Prim Care 2022;11:3851-5. doi:10.4103/jfmpc.jfmpc_637_21
- Yi TI, Lee GE, Seo IS, Huh WS, Yoon TH, Kim BR. Clinical characteristics of the causes of plantar heel pain. Ann Rehabil Med 2011;35:507-13. doi:10.5535/arm.2011.35.4.507
- Palomo-López P, Becerro-de-Bengoa-Vallejo R, Losa-Iglesias ME, Rodríguez-Sanz D, Calvo-Lobo C, López-López D. Impact of plantar fasciitis on the quality of life of male and female patients according to the foot health status questionnaire. J Pain Res 2018;11:875-80. doi:10.2147/JPR.S159918
- Granado MJ, Lohman EB 3rd, Daher NS, Gordon KE. Effect of gender, toe extension position, and plantar fasciitis on plantar fascia thickness. Foot Ankle Int 2019;40:439-46. doi:10.1177/1071100718811631
- Tas S, Bek N, Ruhi Onur M, Korkusuz F. Effects of body mass index on mechanical properties of the plantar fascia and heel pad in asymptomatic participants. Foot Ankle Int 2017;38:779-84. doi:10.1177/1071100717702463
- 16. Van Leeuwen KD, Rogers J, Winzenberg T, van Middelkoop M. Higher body mass index is associated with plantar fasciopathy/'plantar fasciitis': Systematic review and meta-analysis of various clinical and imaging risk factors. Br J Sports Med 2016;50:972-81. doi:10.1136/ bjsports-2015-094695
- Riddle DL, Pulisic M, Pidcoe P, Johnson RE. Risk factors for plantar fasciitis: A matched case-control study [published correction appears in J Bone Joint Surg Am 2003;85-A:1338]. J Bone Joint Surg Am 2003;85:872-7. doi:10.2106/00004623-200305000-00015
- Kalia RB, Singh V, Chowdhury N, Jain A, Singh SK, Das L. Role of platelet rich plasma in chronic plantar fasciitis: A prospective study. Indian J Orthop 2020;55:142-8. doi:10.1007/s43465-020-00261-w
- Ragab EM, Othman AM. Platelets rich plasma for treatment of chronic plantar fasciitis. Arch Orthop Trauma Surg 2012;132:1065-70. doi:10.1007/s00402-012-1505-8
- Yang WY, Han YH, Cao XW, Pan JK, Zeng LF, Lin JT, *et al.* Plateletrich plasma as a treatment for plantar fasciitis: A meta-analysis of randomized controlled trials. Medicine (Baltimore) 2017;96:e8475. doi:10.1097/MD.00000000008475