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Comparative Analysis between Platelet Rich Plasma and Corticosteroid injection in Plantar Fasciitis

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Abstract: ***Introduction**: Plantar fasciitis is a disorder resulting in pain in the heel and bottom of the foot. Risk factors include overuse such as from long periods of standing, an increase in exercise, and obesity and heel spur. Non-operative approaches include rest, contrast bath, sole inserts, stretching exercises, non-steroidal and steroidal anti-inflammatory medications. Interventions include Steroid injections, autologous blood and open, endoscopic or percutaneous fascial surgical release of plantar fascia and PRP application. **Aims & Objectives**: The aim of this study was to determine the effects on pain and function of PRP obtained manually as a cheap and easy method in the treatment of plantar fasciitis and to compare this data with that of steroid injection which is often used in clinical practice. The hypothesis was that a single dose of manually prepared PRP would reduce pain in plantar fasciitis and this effect issuperior to the steroid injection. **Materials and Methods**: The present study was conducted at our institute between August 2016 to September 2017; 40 consecutive patients with chronic plantar fasciitis were enrolled and randomized in two groups: One receives the Platelet rich plasma (PRP) therapy and another receiving corticosteroid injection. The outcomes in both groups were then evaluated and compared using Visual Analogue Scale (VAS) and The Foot and Ankle Disability Index (FADI) at 1st week, 4th week and 12th week post injection. The level of significance was set at p<0.05. **Results**: Prospective data was collected of 40 patients. The average follow up duration was about 12 weeks. The score on VAS Scale and FADI improved from the baseline for both the groups but the patients who received PRP therapy had a statistically significant (p<0.05) reduction in pain and improved at last follow up. No adverse complications were reported. **Conclusion**: The application of PRP appears to be more effective than steroid injection in terms of pain and functional results in the treatment of chronic plantar fasciitis.*

Keywords: PRP, Steroid injection, Plantar Fasciitis, VAS Scale, FADI Score

1. Introduction

Plantar fasciitis is a disorder that results in pain in the heel and bottom of the foot. Heel pain is the most common reason for presentation[1]. Approximately 10% of the population will experience heel pain in their life[2]. The pain is generally localized in the medial calcaneal tubercle. In the acute phase, the pain is sharp and typically on the first step of the day or after a period of rest. In the chronic phase, pain is continuous and of a duller nature[3]. Risk factors include overuse such as from long periods of standing, an increase in exercise, and obesity and heel spur[4]. While heel spurs are frequently found it is unclear if they have a role in causing the disease. Plantar fasciitis is generally a self-limiting condition. Symptoms in 80 to 90% of cases recover within 10 months[5].Non-operative approaches include rest, contrast bath, sole inserts, stretching and strengthening exercises, braces, night splints, non-steroidal and steroidal anti-inflammatory medication, and physical therapy[6]. Interventions include applying Steroid injections, autologous blood and open, endoscopic or percutaneous fascial surgical release of plantar fascia which have shown variable success in literature[7,8,9].

Recently, PRP has shown promising outcomes in the treatment of tennis elbow, osteoarthritis of the knee and various other musculoskeletal disorders. PRP is a concentrate of platelets (7 to 10 times) from the whole blood prepared by ultracentrifugation of the blood sample from the patient[10]. PRP is a rich source of a number of cytokines and growth factors that attract reparative cells[11].

These agents include platelet derived growth factor (PDGF), transforming growth factor- beta 1 (TGFB-1), epidermal growth factor (EGF), insulin-like growth factor (IGF), fibroblast growth factor (FBGF) and vascular endothelial growth factor (VEGF) etc. which modulate neovascularization and angiogenesis, promote mitogenesis, improve local collagen production, and have anti-inflammatory effects by blocking cylco-oxygenase-2 (COX-2) enzyme production.

The aim of this study was to determine the effects on pain and function of PRP obtained manually as a cheap and easy method in the treatment of plantar fasciitis and to compare this data with that of steroid injection which is often used in clinical practice. The hypothesis was that a single dose of manually-prepared PRP would reduce pain associated with plantar fasciitis and increase function and that this effect would be superior to the frequently-used steroid injection.

2. Materials and Methods

A total of 40 patients were included in the study. Patients were separated into 2 Groups- Group A- PRP and Group B- corticosteroid of 20 subjects each. Patients informed about the treatment options and those who accepted were included in the PRP group (8 males, 12 females; mean age: 44) and

the others in the steroid group (7 males, 13 females; mean age: 46.6).

Inclusion Criteria

It included, all participants aged 35-62 years of either sex had to

- Have heel pain for more than 4 month and/or have been diagnosed as having Chronic Planter Fasciitis (CPF)
- Ability to walk,
- Subject must understand the risk and benefit of the protocol and be able to give informed consent,
- Availability for the duration of entire study period.

Exclusion Criteria

It includes following parameter

- Traumatic heel pain,
- Heel pain less than 4 month,
- Inflammatory disorder like gout, RA, Ankylosing spondylosis etc,
- Abnormal LFT and RFT,
- Hematological disorders or any history of coagulopathies,
- Diabetes,
- Cancer,
- Medically unfit patient,
- Hypersensitivity to NSAIDs,
- Compressive neuropathies,
- Skin disorders,
- Severe infection,
- Pregnant, breast feeding or planning to become pregnant.

3. Procedure

Platelet Rich Plasma was prepared and applied under the same conditions using the method described by Ani-tua et al. A total of 30 cc peripheral blood was taken from the ante-cubital region and mixed with 3.2% sodium citrate. Samples were centrifuged at 1800 rpm for 8 minutes at room temperature. From the 3.5 ml PRP obtained, 1 ml was sent to the laboratory for bacteriological testing and platelet count. After activation, 2.5 ml of PRP containing 5.5% calcium chloride (Cl $_2$Ca) (50 µl of Cl_2Ca in 1 ml of PRP) was administered to the foot from the medial side to maximal tenderness area with palpation under sterile conditions. The patient was kept in the supine position for 20 minutes following administration.In the steroid group 40mg Depomedrol solution was injected in a similar manner.The peppering injection technique was used in both groups and the fascia was injected in 4 to 5 different locations. Standard Achilles and plantar fascia stretching and strengthening exercises were applied to all patients. Patients were advised to rest and not stand for the first day after the injection. No NSAID, orthosis or splint was given to any patient. Clinical evaluation was performed before treatment and at 1st week, 4th week and 12th week follow-ups. The Foot and Ankle Disability Index (FADI) Score and the visual analog scale (VAS) were used in the clinical evaluation. The FADI evaluation covered pain, function, maximum walking distance, walking surfaces, gait abnormality, sagittal motion, hindfoot motion, alignment, and ankle-hindfoot stability. Patients were questioned with regard to side effects and subjective satisfaction.

Sample Size

The pilot study observed mean values of VAS at 1st and 12th week in PRP was 5.4 ± 0.55 and 1.8 ± 0.45 respectively and in steroid was 4.8 ± 0.45 and 3.2 ± 0.45 respectively. Taking these values as reference, the minimum required sample size with 95% power of study and 5% level of significance is 19 patients in each study group. So total sample size taken is 40 (20 patients per group).

Formula used is:-

For comparing mean of two groups

$$N>=2\frac{(\text{standard deviation})^2*(Z_\alpha + Z_\beta)^2}{(\text{mean difference})^2}$$

Where Z_α is value of Z at two sided alpha error of 5% and Z_β is value of Z at power of 95% and mean difference is difference in post intervention mean values of two groups.

Statistical Analysis

Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean ± SD and median. Normality of data was tested by Kolmogorov-Smirnov test. If the normality was rejected then non parametric test was used.

Statistical tests were applied as follows-

1) Quantitative variables were compared using Independent T test/Mann-Whitney Test (when the data sets were not normally distributed) between the two groups.
2) Qualitative variables were correlated using Chi-Square test. p value of <0.05 was considered statistically significant. The data was entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0.

4. Results

At the initial visit before injection therapy, Group A (PRP) patients and Group B (Corticosteroid) patients had a mean VAS Score of 7.9 and 8 respectively and the mean FADI Score was 25 for Group A (PRP) and 20.6 for Group B (Corticosteroid) patients as shown in figure 1 and 2 respectively.

At 1st week, the mean VAS and FADI Score showed better results in Group B (Corticosteroid) patients as compared to Group A (PRP) patients. The mean VAS Score showed better results in Corticosteroid group (4.45) as compared to PRP group (5.45) and the same was seen with FADI Score in Corticosteroid group (58.55) and PRP Group (48.55) as shown in figure 3 and 4 respectively.

At 4th week, the mean VAS and FADI Scores showed almost equal results in Group A (PRP) and Group B (Corticosteroid) patients. The mean VAS Score in Group A (PRP) was 4.2 and in Group B (Corticosteroid) was 4.1 and the mean FADI Score in Group A (PRP) was 62.6 and in Group B (Corticosteroid) was 62.8 respectively as shown in figure 5 and 6 respectively.

However at 12th week post injection therapy, the group A (PRP) showed significant improvement in mean VAS as well as FADI Scores scores than Group B (Corticosteroid).

The mean VAS Score at 12th week in Group A (PRP) and Group B (Corticosteroid) was 1.85 and 3.4 respectively as shown in figure 7. The mean FADI Score at 12th week in Group A (PRP) and Group B (Corticosteroid) was 84.05 and 68.9 respectively as shown in figure 8. Steroids failed to show long term decrease in VAS score and increase in FADI Score ($p<0.05$) as shown in figure 9 and 10 respectively.

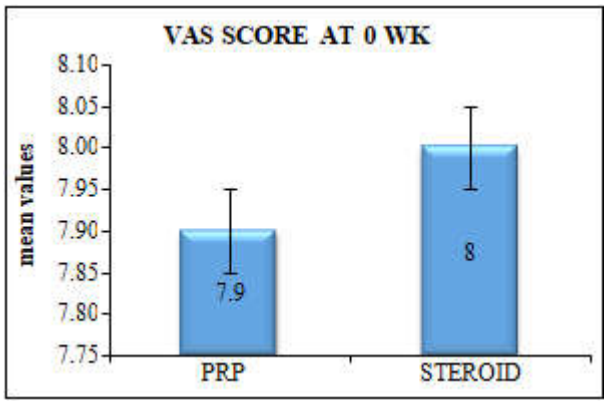

Figure 1: (Mean VAS Score in PRP and Steroid Group at 0 week)

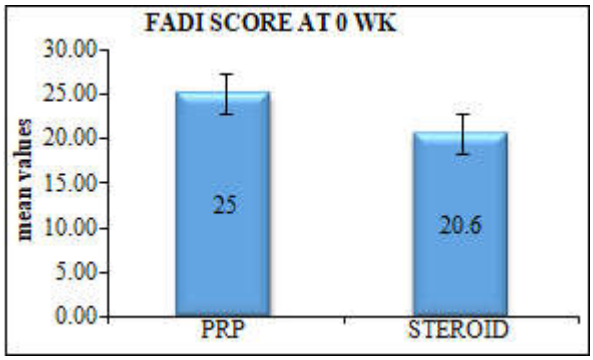

Figure 2: (Mean FADI Score in PRP and Steroid Group at 0 week)

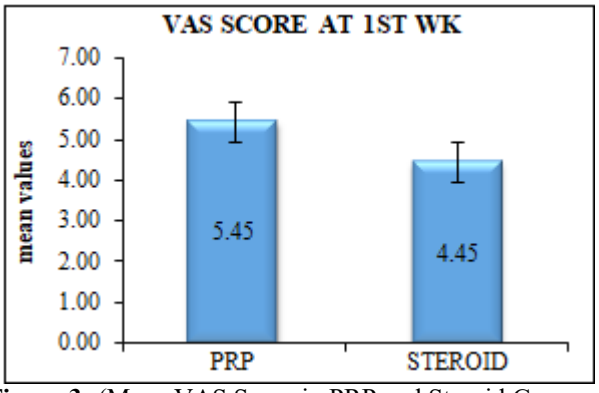

Figure 3: (Mean VAS Score in PRP and Steroid Group at 1st week)

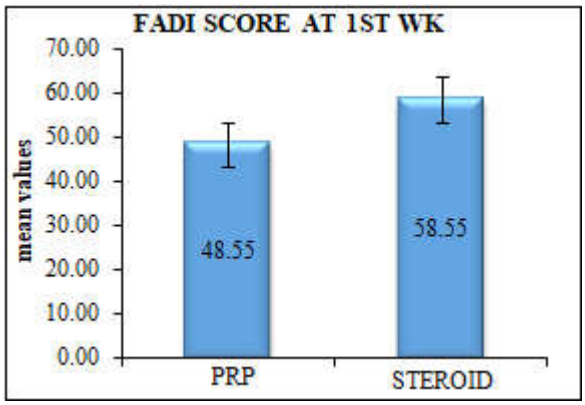

Figure 4: (Mean FADI Score in PRP and Steroid Group at 1st week)

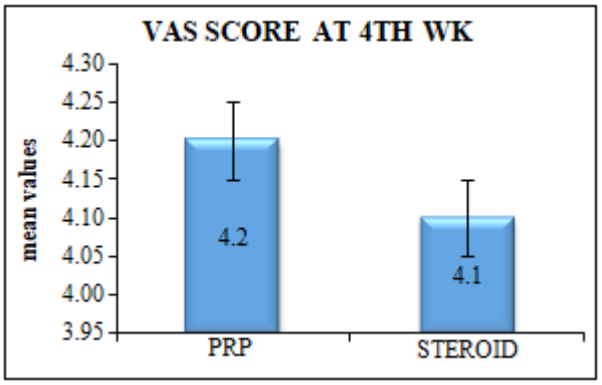

Figure 5: (Mean VAS Score in PRP and Steroid Group at 4th week)

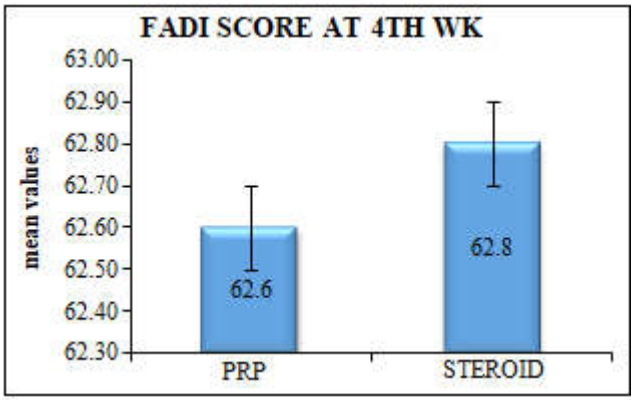

Figure 6: (Mean FADI Score in PRP and Steroid Group at 4th week)

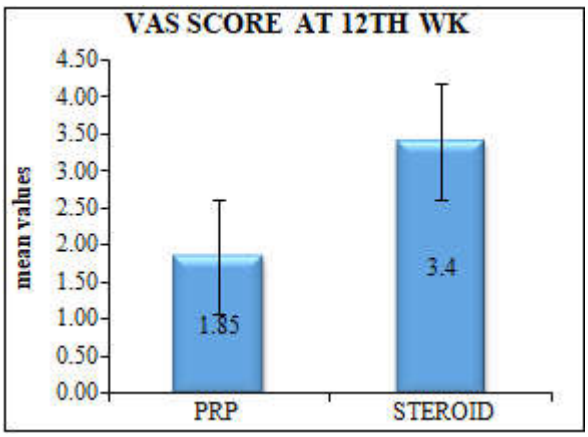

Figure 7: (Mean VAS Score in PRP and Steroid Group at 12th week)

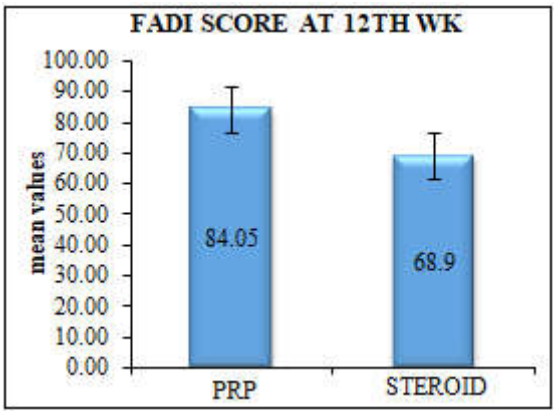

Figure 8: (Mean FADI Score in PRP and Steroid Group at 12th week)

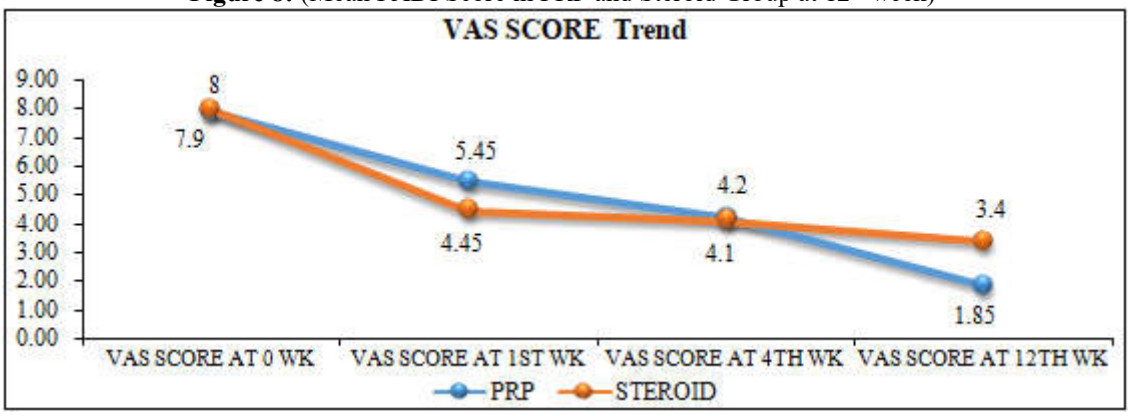

Figure 9: (VAS Score trend at 0,1,4,12 weeks)

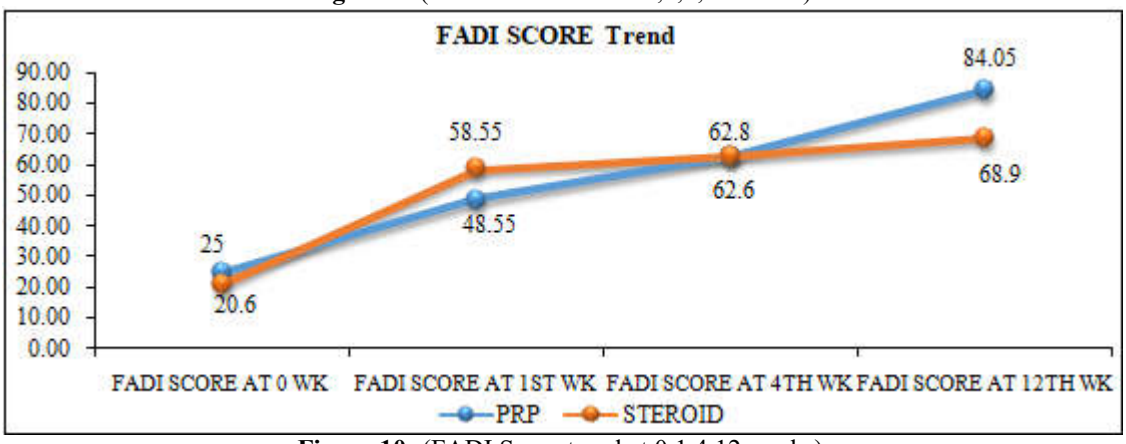

Figure 10: (FADI Score trend at 0,1,4,12 weeks)

Table 1: VAS and FADI Score at 0,1,4,12 weeks in PRP and Steroid

	PRP	STEROID
VAS SCORE AT 0 WK	7.9	8
	PRP	STEROID
VAS SCORE AT 1ST WK	5.45	4.45
	PRP	STEROID
VAS SCORE AT 4TH WK	4.2	4.1
	PRP	STEROID
VAS SCORE AT 12TH WK	1.85	3.4
	PRP	STEROID
FADI SCORE AT 0 WK	25	20.6
	PRP	STEROID
FADI SCORE AT 1ST WK	48.55	58.55
	PRP	STEROID
FADI SCORE AT 4TH WK	62.6	62.8
	PRP	STEROID
FADI SCORE AT 12TH WK	84.05	68.9

Table 2: P value of VAS and FADI Scores in PRP and Steroid at 0,1,4,12 weeks

	PRP	STEROID	P value
AGE			
Sample size	20	20	
Mean ± Stdev	47.45 ± 7.05	51.55 ± 6.77	0.068
Median	47	50.5	
Min-Max	39-60	40-62	
Inter quartile Range	40.500 – 52	47 – 58.500	
VAS score at 0 WK			
Sample size	20	20	
Mean ± Stdev	7.9 ± 0.72	8 ± 0.73	0.659
Median	8	8	
Min-Max	7-9	7-9	
Inter quartile Range	7 – 8	7.500 – 8.500	
VAS score at 1ST WK			
Sample size	20	20	
Mean ± Stdev	5.45 ± 0.6	4.45 ± 0.51	<.0001
Median	5.5	4	

Min-Max	4-6	4-5	
Inter quartile Range	5 – 6	4 – 5	
VAS score at 4TH WK			
Sample size	20	20	
Mean ± Stdev	4.2 ± 0.77	4.1 ± 0.31	0.441
Median	4	4	
Min-Max	3-5	4-5	
Inter quartile Range	4 – 5	4 – 4	
VAS score at 12TH WK			
Sample size	20	20	
Mean ± Stdev	1.85 ± 0.75	3.4 ± 0.5	<.0001
Median	2	3	
Min-Max	1-3	3-4	
Inter quartile Range	1 – 2	3 – 4	
FADI score at 0 WK			
Sample size	20	20	
Mean ± Stdev	25 ± 7.23	20.6 ± 6.7	0.053
Median	26.5	21	
Min-Max	10-33	11-32	
Inter quartile Range	21.500–31.500	14.500–22.500	
FADI score at 1ST WK			
Sample size	20	20	
Mean ± Stdev	48.55 ± 4.88	58.55 ± 5.14	<.0001
Median	48	61	
Min-Max	41-56	51-66	
Inter quartile Range	44.500–52.500	53.500– 62	
FADI score at 4TH WK			
Sample size	20	20	
Mean ± Stdev	62.6 ± 5.56	62.8 ± 3.53	0.713
Median	62	62	
Min-Max	56-72	54-69	
Inter quartile Range	58 – 66	61 – 65.500	
FADI score at 12TH WK			
Sample size	20	20	
Mean ± Stdev	84.05 ± 6.05	68.9 ± 4.33	<.0001
Median	84	71	
Min-Max	72-94	61-74	
Inter quartile Range	80.500–88.500	65 – 72	

5. Discussion

The most common cause of heel pain is plantar fasciitis, the diagnosis of plantar fasciitis is based on the patient's history and physical findings and xray's for at least 6 months. It is widely believed that plantar fasciitis results from repeated micro-trauma due to overuse, which results in micro-tears of the tissue substance until a macro injury occurs[12].

The present study was conducted during the period from August 2016 to September 2017 forty patients with chronic plantar fasciitis who failed to respond to conservative management were randomized prospectively into two groups and treated with PRP (Group A) and steroid injection (Group B). The minimum follow up period was 1 week and maximum follow up was till 12 weeks. We evaluated our results in terms of VAS Score and FADI scores and compared our results with the available literature.

In the present study we found that the improvement in VAS score at 1 week was statistically significant in the steroid group (4.45) as compared to PRP group (5.45). It was observed in the first week that the patients treated with corticosteroid injection (Group B) showed better results as compared to the patients injected with PRP (Group A). Patients treated by PRP can be mostly attributed to a possible anti-inflammatory effect due to the inhibition of cyclo-oxygenase-2 (COX-2) enzymes by the cytokines in PRP[13]. However, better early improvement in the steroid group implies that the anti-inflammatory effect of PRP due to COX 2 inhibition is less as compared to steroid.

In the present study, we observed that at 4th week follow up the VAS Scores were insignificant in both the groups (VAS Score 4.2 and 4.1 in PRP and steroid group respectively). Akashin et al[14], in a prospective study divided 60 patients in 2 non-randomized consecutive groups of 30 and treated them by either 40 mg methylprednisolone or 3 cc of PRP. They followed them for 6 months. The mean VAS scores decreased from 6.2 to 3.2 in the steroid group and from 7.33 to 3.93 in the PRP group at 6 months follow up. The results were found to be statistically insignificant. This is in tune with the observations in our study.

In the present study, the long term follow up results at 12th week were encouraging in the PRP (VAS score 1.85) group and it appeared to be more beneficial than steroid injection (VAS Score 3.4). The possible mechanism of long term clinical improvement is the release of growth factors and chemo-attractants from the highly concentrated platelets which improved collagen upregulation and neovascularization[15,16]. Ragab and Othman followed a group of 25 PRP treated patients with chronic plantar fasciitis for around 10.3 months and reported VAS score improvement from 9.1 to 1.6[17]. Ninety two percent of their patients had little or no noticeable limitations at the end of the study. Results similar to ours were also observed by Jain et al, Shetty et al and Say et al[18,19,20]. Martinelli et al used 3 weekly injections of PRP for chronic plantar fasciitis and observed that the average VAS scores decreased from 7.1 to 2.1 after 12 months[21]. This study advocates use of multiple injections of PRP instead of one with no potential complications and excellent long term pain. In the Indian sitting cost and compliance with multiple injections is a major concern, hence we resorted to single PRP injection.

Both methods were effective and successful in treating plantar fasciitis. Although there is no complication related to steroids are observed, when the potential risks of corticosteroid such as fat pad atrophy, osteomyelitis of the calcaneus, and iatrogenic rupture of the plantar fascia are taken into consideration, PRP injection seems to be safer while being just as effective in the treatment of plantar fasciitis. Taking the possible regenerative effect of PRP into consideration, the results of the PRP injection group were expected to be more satisfactory in cases of plantar fasciitis as shown in Table 1 and 2, since it is believed to be a degenerative process rather than an inflammatory reaction.

6. Conclusion

The use of PRP in chronic cases of plantar fasciitis seems more efficacious in long term than the traditional treatment of steroid injection. Although steroid possibly leads to a better short term outcome it fails to sustain its effect in the longer run. Also, despite the long-term benefit of PRP injection in chronic plantar fasciitis, it is advisable to stick to the fundamental treatment paradigm of conservative measures as they suffice in majority of the cases. The PRP

local injection is a new, readily available and well tolerated, with prolonged effect and safe choice of therapy for chronic pf.We can conclude that the use of PRP is an effective treatment method for patients with plantar fasciitis which do not respond to conservative treatment.The PRP injection is better than steroid injection in relieving the pain of planar fasciitis and in improvement of the function of the patient foot.

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