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Original Research Article

A Comparative Study between the Fresh Frozen Plasma and Local Steroid Infiltration in the Treatment of Plantar Fasciitis

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Abstract: The treatment for plantar fasciitis was local steroid infiltration since many years, but recently there is a shift towards fresh frozen plasma infiltration. Hence a comparative study was done between the two methods of treatment. 58 patients suffering from plantar fasciitis were included in the study. None of them had received any form of treatment in the past. Patients involved in the study were between 25 to 50 years. Of these 27 were females and 31 were males. Patients were selected randomly for both the treatment methods. About 3ml of fresh frozen plasma with 2 ml 2% lignocaine was injected to and around the tender spots under aseptic precaution. The second group of the patient were injected with 80mg of methylprednisolone with 2ml of 2% lignocaine. Patients were evaluated according to the visual analog scale and foot and ankle disability index before infiltration and subsequently at 2, 4, and 6 months following infiltration. In patients who underwent steroid infiltration, the 't' value was 0.456 and the 'p' value was 0.651, which is stastically insignificant. In patients who underwent fresh frozen plasma infiltration, the 't' value was 1.847 and the 'p' value was 0.075, which again is statistically insignificant. The study showed even though steroid and fresh frozen plasma given symptomatic relief, fresh frozen plasma infiltration shows relatively superior results compared to steroid. Although both the modalities of treatment are effective in the treatment of plantar fasciitis, fresh frozen plasma was found to be relatively safer with less complication and less chance of recurrence. So, fresh frozen plasma infiltration is a viable alternative to steroid infiltration in the treatment of plantar fasciitis.
Keywords: Plantar Fascitis; Steroid; Fresh Frozen Plasma.

INTRODUCTION

Chronic plantar fasciitis is a common problem that affects sport participants as well as inactive middle-aged individuals [1, 2]. In general, the condition is self-limiting, and the majority of cases spontaneously resolve regardless of type of intervention received (including placebo) [3]. Increasing knowledge of the pathology has led to the widespread application of a large number of conservative treatments for recalcitrant plantar fasciitis [4], including physiotherapy, plantar-fascia-stretching exercises [5], icepacks, night splints, prefabricated and custom-made insert, shoe modification, nonsteroidal anti-inflammatory drugs (NSAIDs) and extracorporeal shock-wave therapy (ESWT) when conventional physical therapy is not effective [6]. Although the effect of ESWT remains controversial, reliable evidence supports the use of this approach for treating chronic plantar fasciitis [7, 8]. However, adverse effects such as pain during treatment, soft tissue damage (bleeding, hematoma, paresthesia), nausea, the need for peripheral nerve block and costs should be considered when proposing this procedure [9]. Recently, promising results were reported with the use of platelet-rich plasma (PRP) injections for treating muscle and tendon injuries and degeneration [10-13]. The rationale for using PRP is to increase tendon regenerative abilities with a high content of cytokines and cells, in hyperphysiologic doses, which should promote cellular chemotaxis, matrix synthesis, and proliferation [14]. Degranulation of the alpha granules in platelets releases many different growth factors that can play a role in tissue regeneration processes. PRP represents a treatment option for many foot and ankle pathologies, including tendinopathy (Achilles, peroneal, posterior tibial, flexor hallucis longus, anterior tibial) and chronic ligamentous injury, such as plantar fasciitis.

The purpose of this study was to assess the safety of PRP injections for treating chronic plantar fasciitis and provide initial clinical assessment of its effectiveness.

PATIENTS AND METHODS

Approval for this prospective clinical study was granted by the local ethics committee and informed consent was obtained from all patients participating in the study. Patients who had been diagnosed with plantar fasciitis and not treated were included in the study. Diagnosis of plantar fasciitis was made by clinical examination. Direct radiographs were examined to rule out other heel pathologies. Exclusion criteria were systemic disease, pregnancy, active tumor or haematological malignant disease, infection, a history of anticoagulant use, use of NSAIDs in the five days prior to the study, Hb values of less than 11 g/dL, thrombocyte count of less than 150,000/mm3, previous steroid injection to the heel area or ESWT therapy, a history of calcaneus fracture, or surgery in the heel area. A total of 58 patients were included in the study. Patients were separated into PRP and steroid groups of 29 subjects each. Patients informed about the treatment options and those who accepted were included in the PRP group (14 males, 15 females) and the others in the steroid group (17 males, 12 females). Platelet-rich plasma was prepared and applied under the same conditions using the method described by Anitua et al. A total of 30 cc peripheral blood was taken from the antecubital 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 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, a mixture of 40 mg/1 ml of methylprednisolone and 2 ml of lignocaine was injected. 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 the 2 month,4 month and 6th month follow-ups. The foot and ankle disability index and the Visual Analog Scale (VAS) were used in the clinical evaluation. Patients were questioned with regard to side effects and subjective satisfaction.

RESULTS

In patients who underwent steroid infiltration, the ‘t’ value was 0.456 and the ‘p’ value was 0.651, which is stastically insignificant. In patients who underwent fresh frozen plasma infiltration, the ‘t’ value was 1.847 and the ‘p’ value was 0.075, which again is stastically insignificant. The study showed even though steroid and fresh frozen plasma given symptomatic relief, fresh frozen plasma infiltration shows relatively superior results compared to steroid.

Table 1: Independent Students T Test to Compare the Fadi and the Vas Scores

	GROUP	N	Mean	Std. Deviation	T	df	P VALUE
AGE	FFP	29	41.69	8.346	-0.206	56	0.837
	STEROID	29	42.14	8.189			
FADI BEFORE	FFP	29	88.76	11.746	-1.741	56	0.087
	STEROID	29	94.07	11.476			
FADI AFTER 6 MONTHS	FFP	25	132.36	3.012	1.847	29.594	0.075
	STEROID	27	128	11.858			
FADI DIFFERENCE	FFP	25	44.04	9.172	3.374	50	**0.001**
	STEROID	27	35.11	9.858			
VAS SCORE BEFORE	FFP	29	5.17	2.172	0.973	56	0.335
	STEROID	29	4.62	2.145			
VAS SCORE AFTER 6 MONTHS	FFP	25	0.8	1.155	-0.456	50	0.651
	STEROID	27	0.96	1.4			
VAS DIFFERENCE	FFP	25	4.32	1.492	1.143	50	0.258
	STEROID	27	3.85	1.46			

Interpretation
Comparison of the AGE between the two groups shows that AGE is higher in STEROID group with a t value of -0.206 and is statistically non significant with a p value of 0.837
Comparison of the FADI BEFORE between the two groups shows that FADI BEFORE is higher in STEROID group with a t value of -1.741 and is statistically non significant with a p value of 0.087
Comparison of the FADI AFTER 6 MONTHS between the two groups shows that FADI AFTER 6 MONTHS is higher in FFP group with a t value of 1.847 and is statistically non significant with a p value of 0.075
Comparison of the FADI DIFFERENCE between the two groups shows that FADI DIFFERENCE is higher

in FFP group with a t value of 3.374 and is statistically significant with a p value of 0.001
Comparison of the VAS SCORE BEFORE between the two groups shows that VAS SCORE BEFORE is higher in FFP group with a t value of 0.973 and is statistically non significant with a p value of 0.335
Comparison of the VAS SCORE AFTER 6 MONTHS between the two groups shows that VAS SCORE AFTER 6 MONTHS is higher in STEROID group with a t value of -0.456 and is statistically non significant with a p value of 0.651
Comparison of the VAS DIFFERENCE between the two groups shows that VAS DIFFERENCE is higher in FFP group with a t value of 1.143 and is statistically non significant with a p value of 0.258

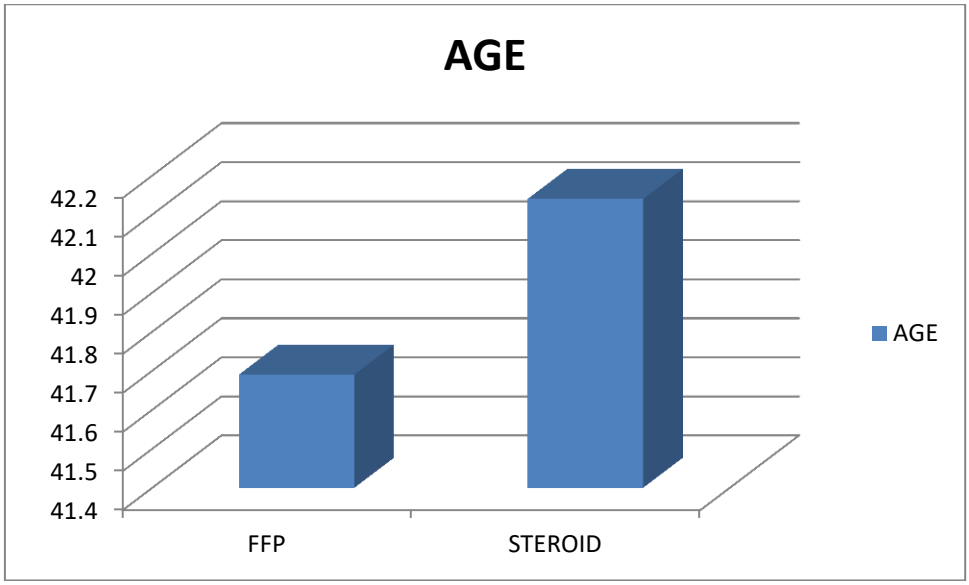


Fig-1: Comparison of the AGE between the two groups shows that AGE is higher in STEROID group with a t value of -0.206 and is statistically non significant with a p value of 0.837

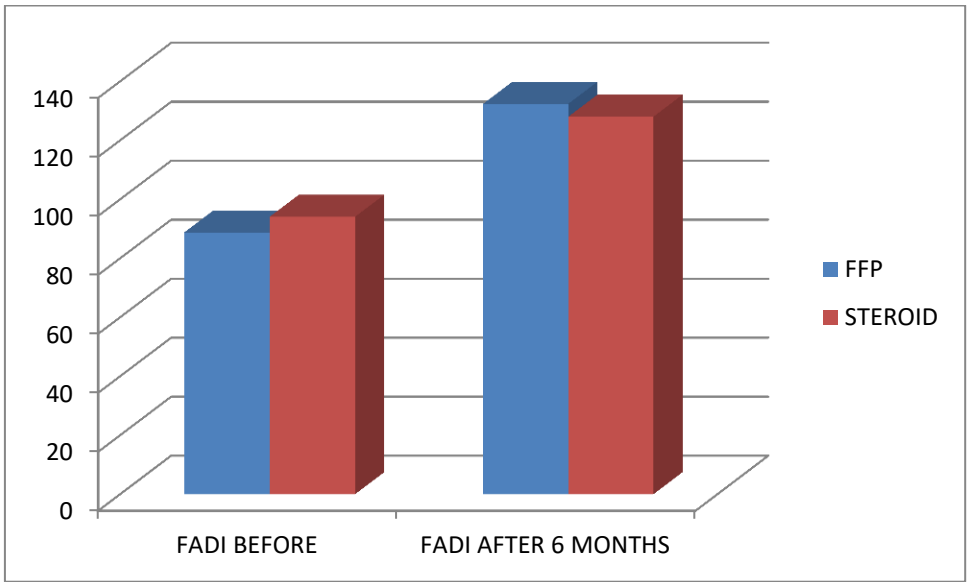


Fig-2: Comparison of the FADI BEFORE between the two groups shows that FADI BEFORE is higher in STEROID group with a t value of -1.741 and is statistically non significant with a p value of 0.087

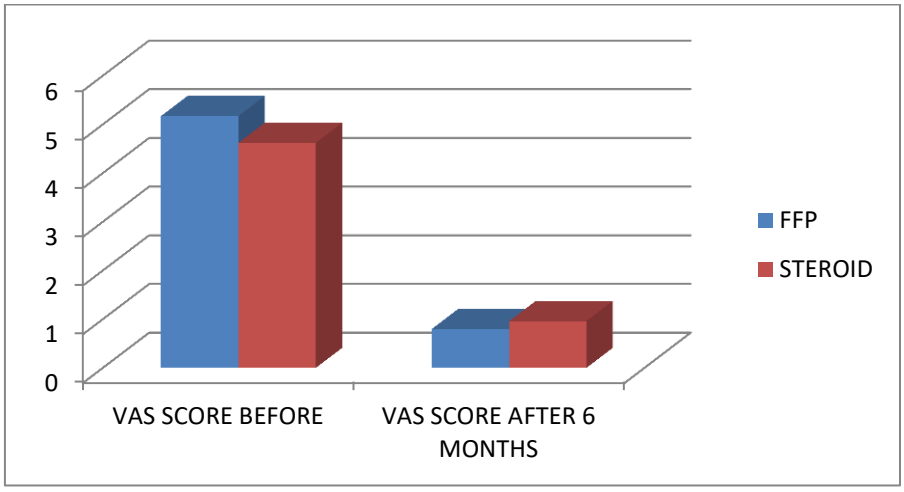


Fig-3: Comparison of the FADI AFTER 6 MONTHS between the two groups shows that FADI AFTER 6 MONTHS is higher in FFP group with a t value of 1.847 and is statistically non significant with a p value of 0.075

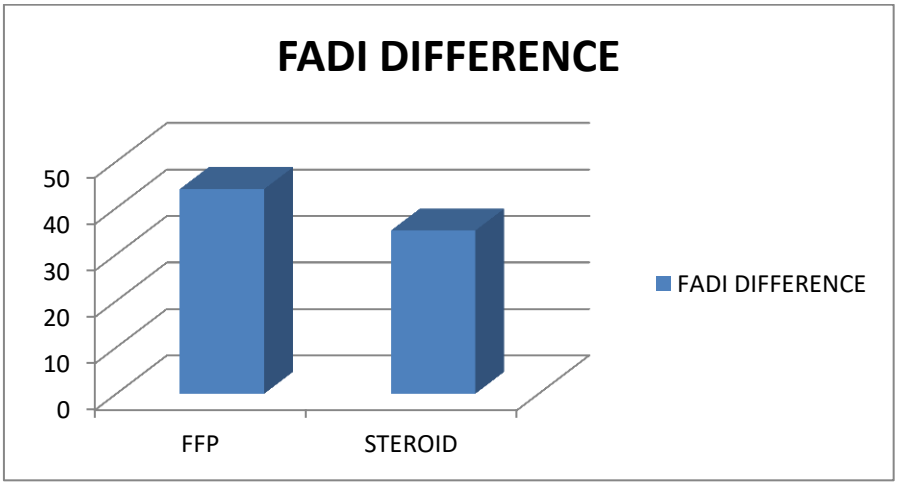


Fig-4: Comparison of the FADI DIFFERENCE between the two groups shows that FADI DIFFERENCE is higher in FFP group with a t value of 3.374 and is statistically significant with a p value of 0.001

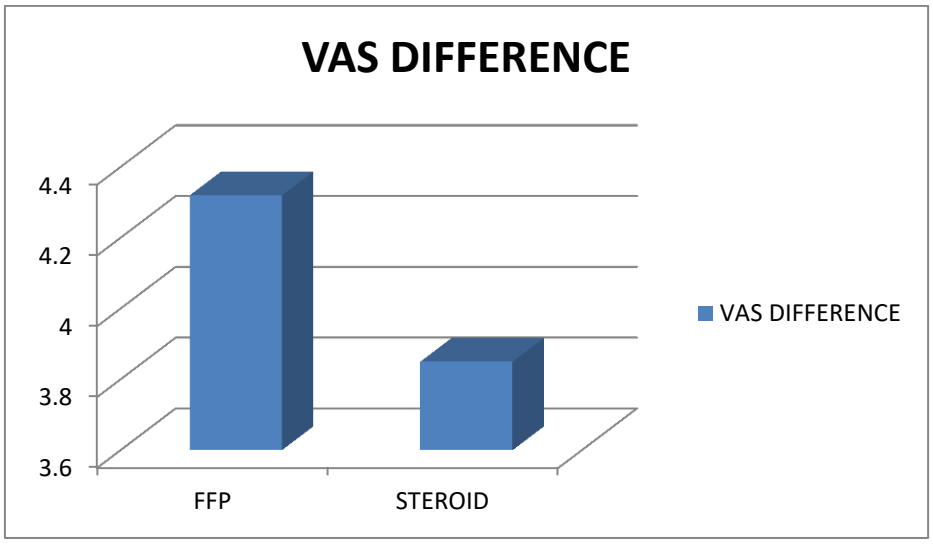


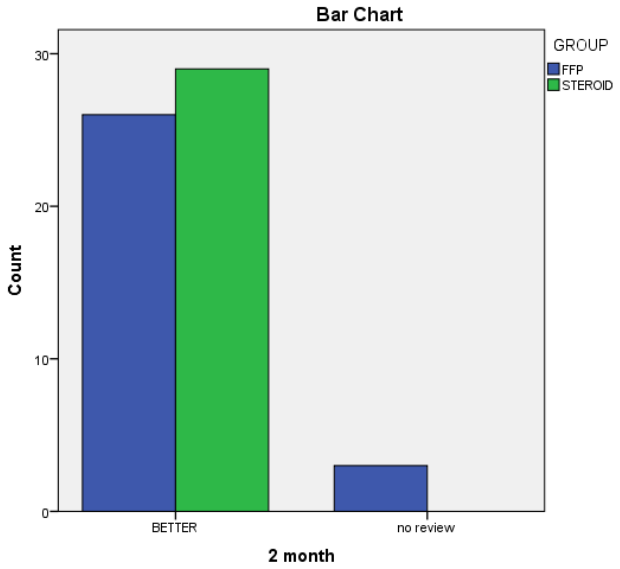
Fig-5: Comparison of the VAS SCORE BEFORE between the two groups shows that VAS SCORE BEFORE is higher in FFP group with a t value of 0.973 and is statistically non significant with a p value of 0.335

CHI SQUARE TESTS

2 month * GROUP

Crosstab					
			GROUP		Total
			FFP	STEROID	
2 month	BETTER	Count	26	29	55
		% within GROUP	89.7%	100.0%	94.8%
	no review	Count	3	0	3
		% within GROUP	10.3%	0.0%	5.2%
Total		Count	29	29	58
		% within GROUP	100.0%	100.0%	100.0%

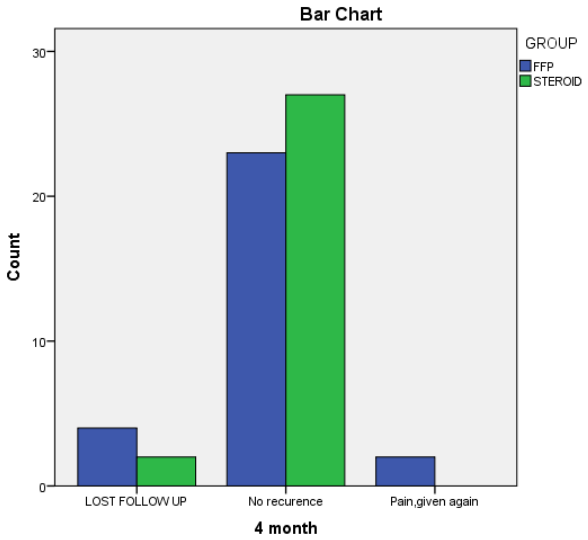
Chi-Square Tests		
	Value	P VALUE (SIGNIFICANT IF <0.05)
Pearson Chi-Square	3.164	.237
N of Valid Cases	58	



4 month * GROUP

Crosstab					
			GROUP		Total
			FFP	STEROID	
4 month	LOST FOLLOW UP	Count	4	2	6
		% within GROUP	13.8%	6.9%	10.3%
	No recurence	Count	23	27	50
		% within GROUP	79.3%	93.1%	86.2%
	Pain,given again	Count	2	0	2
		% within GROUP	6.9%	0.0%	3.4%
Total		Count	29	29	58
		% within GROUP	100.0%	100.0%	100.0%

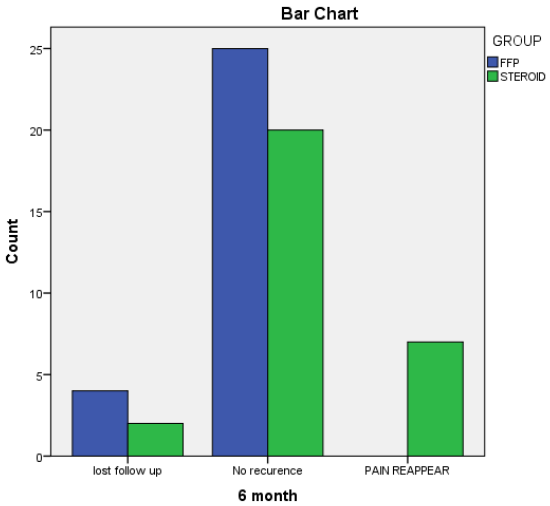
Chi-Square Tests		
	Value	P VALUE (SIGNIFICANT IF <0.05)
Fisher's Exact Test	2.602	.301
N of Valid Cases	58	



6 month * GROUP

Crosstab					
			GROUP		Total
			FFP	STEROID	
6 month	lost follow up	Count	4	2	6
		% within GROUP	13.8%	6.9%	10.3%
	No recurence	Count	25	20	45
		% within GROUP	86.2%	69.0%	77.6%
	PAIN REAPPEAR	Count	0	7	7
		% within GROUP	0.0%	24.1%	12.1%
Total		Count	29	29	58
		% within GROUP	100.0%	100.0%	100.0%

Chi-Square Tests		
	Value	P VALUE (SIGNIFICANT IF <0.05)
Fisher's Exact Test	8.512	.012
N of Valid Cases	58	

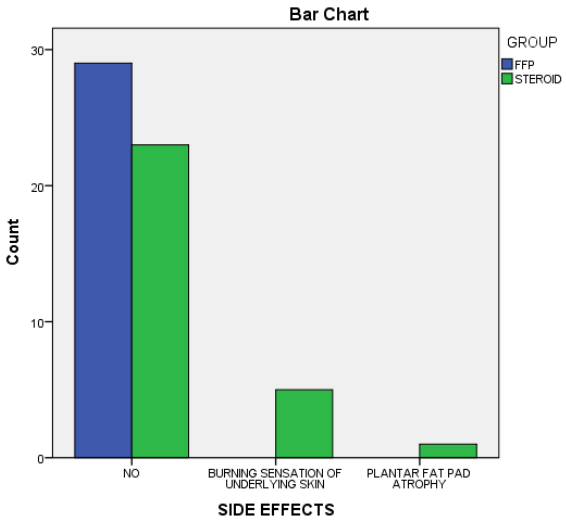


SIDE EFFECTS * GROUP

Crosstab					
			GROUP		Total
			FFP	STEROID	
SIDE EFFECTS	NO	Count	29	23	52
		% within GROUP	100.0%	79.3%	89.7%
	BURNING SENSATION OF UNDERLYING SKIN	Count	0	5	5
		% within GROUP	0.0%	17.2%	8.6%
	PLANTAR FAT PAD ATROPHY	Count	0	1	1
		% within GROUP	0.0%	3.4%	1.7%
Total		Count	29	29	58
		% within GROUP	100.0%	100.0%	100.0%

FFP HAS SIGNIFICANTLY LOWER NUMBER OF BURNING SENSATION OF UNDERLYING SKIN AND ATROPHY WITH P VALUE OF 0.023

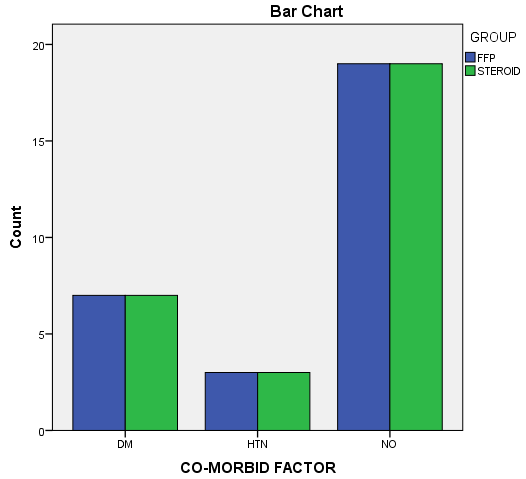
Chi-Square Tests		
	Value	P VALUE (SIGNIFICANT IF <0.05)
Fisher's Exact Test	6.487	.023
N of Valid Cases	58	



CO-MORBID FACTOR * GROUP

Crosstab					
			GROUP		Total
			FFP	STEROID	
CO-MORBID FACTOR	DM	Count	7	7	14
		% within GROUP	24.1%	24.1%	24.1%
	HTN	Count	3	3	6
		% within GROUP	10.3%	10.3%	10.3%
	NO	Count	19	19	38
		% within GROUP	65.5%	65.5%	65.5%
Total		Count	29	29	58
		% within GROUP	100.0%	100.0%	100.0%

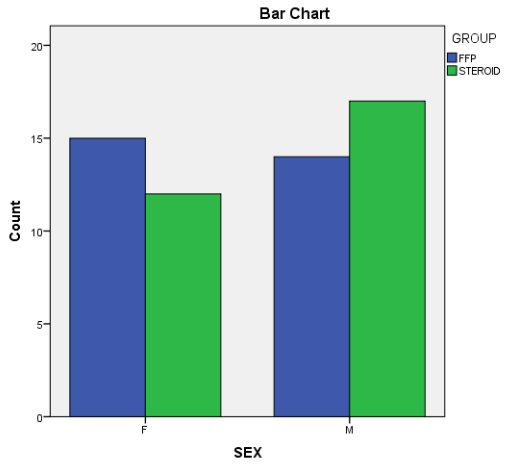
Chi-Square Tests		
	Value	P VALUE (SIGNIFICANT IF <0.05)
Fisher's Exact Test	.123	1.000
N of Valid Cases	58	



GENDER COMPARISON

SEX * GROUP					
			GROUP		Total
			FFP	STEROID	
SEX	F	Count	15	12	27
		% within GROUP	51.7%	41.4%	46.6%
	M	Count	14	17	31
		% within GROUP	48.3%	58.6%	53.4%
Total		Count	29	29	58
		% within GROUP	100.0%	100.0%	100.0%

Chi-Square Tests		
	Value	Exact Sig. (2-sided)
Pearson Chi-Square	.624	.599
N of Valid Cases	58	



DISCUSSION

The aim of the study was to evaluate this novel biological approach of treating chronic plantar fasciitis using PRP in order to assess safety and potential outcome measures that can be used in larger, randomised clinical trials to determine its effectiveness treating this pathology. We acknowledge that the limitations of this study, including lack of a randomised control group, small number of patients and short follow-up period, do not allow drawing final conclusions about the role of PRP injection for treating recalcitrant plantar fasciitis, and well-designed prospective randomised studies are warranted.

The reports by other authors suggest an improved healing process of tendons following local administration of growth factors through PRP injections [15, 16]. Although there are many studies in the literature that advocate PRP administration for treating chronic tendinopathy, evidence to date showing the benefit of PRP injections is controversial. De Vos et al. performed a randomised placebo-controlled trial of 54 patients with Achilles tendinopathy treated at a single centre with exercise (usual care) and injection of either PRP or saline solution (placebo group) [17]. The authors concluded that PRP injection did not provide greater pain relief or improvement of nonfunctional activities compared with placebo. In a prospective study of 15 patients with chronic elbow tendinosis, Mishra et al. found significant pain decrease two years after PRP injection [18]. An injection of autologous blood for managing chronic plantar fasciitis has been reported. A prospective randomised study by Lee et al. compared autologous blood injection with corticosteroid injection [19]. Although intralesional autologous blood significantly decreased pain levels and increased tenderness thresholds over the six month follow-up period, corticosteroid was considered superior in terms of speed and, probably, extent of improvement. The authors suggest that administration of intralesional autologous blood injection could be used for patients in whom first-line noninvasive treatment failed to decrease pain levels and when corticosteroid injection fails or is contraindicated. Barrett et al. applied a single injection of PRP in a pilot study of nine patients and reported 78 % symptom resolution at short-term follow-up of two months [20]. However, direct comparison with previous studies is difficult because of the different methodologies used to prepare PRP. Several systems are commercially available that allow efficient preparation for outpatient use. When selecting a preparation system, many factors must be taken into account, such as volume of autologous blood drawn, centrifuge rate/time, leukocyte concentration, delivery method, activating agent, final PRP volume and final platelet and growth-factor concentration. Due to differences in PRP characteristics, reported evidence for clinical effectiveness of PRP cannot be generalised to all of these systems. Furthermore, variation of haematologic parameters (e.g. leukocyte count, platelet count) between patients may also affect the final PRP preparation. Controversies regarding the optimal quantity of platelets and growth factors required for muscle and tendon healing still persist [21]. Although in previous studies clinically effective PRP is defined as having at least four times the normal platelet concentration [14], PRP's effectiveness is demonstrated with less concentrated preparations [20, 10].

CONCLUSION

Although both the modalities of treatment are effective in the treatment of plantar fasciitis, fresh frozen plasma was found to be relatively safer with less complication and less chance of recurrence. So, fresh frozen plasma infiltration is a viable alternative to steroid infiltration in the treatment of plantar fasciitis.

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