

ORIGINAL RESEARCH

A Randomized Control Study of Comparison of Standard Care versus Ultrasonography Guided Single Dose of Methylprednisolone Acetate Injection for Planar Fasciopathy

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ABSTRACT

Objectives: Plantar fasciitis is a painful condition but can be self-limiting condition. Among the different treatment which exist, physiotherapy and corticosteroid injection are effective and popular. In this study, the author evaluated the efficacy of standard care versus ultrasonography guided single dose of methylprednisolone acetate injection for planar fasciopathy.

Design: This randomized clinical trial conducted in Physical Medicine & Rehabilitation department of S M S medical college.

Method: Patients were allocated to standard care physiotherapy group (n=35) and ultrasonography guided steroid injection group (n=35) equally. Pain and functional ability on a visual analog scale (VAS), plantar fascia thickness and Foot Ankle Disability Index (FADI) were evaluated at baseline and at 6 weeks after treatment.

Results: The mean age was not different between both groups (40.60±10.64 years versus 41.43±9.66 years, p=0.734). There was a reduction in VAS from baseline to weeks 6 (after treatment) (65.315±7.182 vs 32.57±4.235, respectively) (P<0.001). PF thickness at 6 weeks significantly reduced to 3.895±0.18 compared to baseline (P<0.001). FADI had a considerable improved at week 6 (76.675±2.131) compared to baseline (62.915±1.823) (P<0.001).

Conclusion: Both interventions caused improvement in pain and functional ability 2 months after treatment. Although inter difference were not significant.

Key Words: Plantar Fasciitis, Corticosteroid Injection, Visual Analog Scale, Foot Ankle Disability Index, Ultrasonography.

INTRODUCTION

Plantar fasciitis is the result of collagen degeneration of the plantar fascia at the origin, the calcaneal tuberosity of the heel [1] and thickening and degenerative tissue findings are more common than inflammatory changes, so the term 'plantar fasciopathy' should better define the disorder known as 'plantar fasciitis'.

The plantar fascia plays an important role in the normal biomechanics of the foot. It acts as a static and dynamic stabilizer of the longitudinal arch of the foot and acts as a dynamic shock absorber during walking and running [2].

Chronic plantar fasciopathy is a painful degenerative condition typically with a focal point of tenderness at the medial plantar heel and medial longitudinal arch of the foot[3].It is characterized by progressive pain with weight bearing, especially in the morning when taking the first few steps after getting out of bed, after prolonged sitting, or at the beginning of workout. Once the patient starts walking, the pain tends to recede [4].

The etiologies of the plantar fasciitis remains unknown[2]and the risk factors include biomechanical factors (e.g. excessive pronation, reduced ankle dorsiflexion), improper footwear, obesity, and extensive standing, walking, and running.

Plantar fasciopathy (PF) is a critical public health problem issue; it is estimated to affect 15 % of all adults during their lifetime, 83% of whom are 25 to 65 year old, with the highest prevalence at age 40 to 60 years. Females present with the plantar heel slightly more commonly than males[5].

Plantar fasciitis is a clinical diagnosis; Patients have local point tenderness along the antero-medial of the calcaneum. Plantar fascia pain is especially evident upon the dorsiflexion of the patient's pedal phalanges, which further stretches the plantar fascia. Lateral radiograph of the ankle should be the first imaging study for assessment of heel spur, thickness of plantar fascia, and the quality of fat pad. Normal thickness of the plantar fascia when measured in ultrasound varies in range (mean 2–3 mm). People with chronic heel pain are likely to have a thickened plantar fascia with associated fluid collection, and that thickness values >4.0 mm are diagnostic of plantar fasciitis[6].The hypoechoic change in the fascia was another sonographic finding for plantar fasciitis[7].

Ultrasound-guided injection provides a well-tolerated, dynamic and precise location of injection. Thus, it is considered more effective than palpation guided injection [8].Many treatment options exist, including rest, electrotherapy agents, stretching, strengthening, manual therapy, proper footwear, arch supports orthotics, anti-inflammatory drugs, steroid injections, and surgery [9]. Advanced or invasive techniques may be tried e.g. extracorporeal shock wave therapy, botulinum toxin A, autologous platelet-rich plasma, dextrose-prolotherapy, or steroid injections.

A recent systematic review provided strong evidence for the use of manual therapy procedures, consisting of joint and soft tissue mobilization, to treat deficits in lower extremity joint mobility and calf flexibility to decrease pain and improve function in individuals with PF[10]. That review also found strong evidence to support calf stretching and plantar fascia-specific stretching. Other studies have specifically demonstrated that ankle dorsiflexion and stretching of the plantar fascia improves pain, activity, and patient satisfaction[11-13].

The purpose of this study is to evaluate a low cost treatment options in plantar fasciopathy to reduce the burden of morbidity in society due to plantar fasciopathy and improve the productivity in the society.

METHOD

STUDY DESIGN

In this randomized control study, patients with plantar fasciitis seeking evaluation in the out patients door (OPD) of department of physical medicine and rehabilitation of Sawai man Singh hospital were recruited between July 2019 and September 2020. Patients were evaluated at baseline and follow up at week 6.

Patients of both genders between 18-65 years of age diagnosed with plantar fasciitis for last 3 months were included.

Plantar fasciitis was diagnosed based on the following criteria by an experienced physiatrist:

- 1) tenderness on direct palpation of the medial calcaneal tubercle or proximal plantar fascia,
- 2) complaint of heel pain in the morning or after sitting for a long time,
- 3) plantar fascia

thickness >4 mm on Ultrasonography, 4) patient report a minimum heel pain of 20 mm on a 100 mm visual analog scale (VAS).

Patients were excluded if: 1) they had systemic inflammatory disease, diabetes mellitus and previous surgery of foot, 2) patients who had received a corticosteroid injection for plantar heel pain within the previous six months, 3) a known case of hypersensitivity to lignocaine hydrochloride, 4) patients have current skin or soft tissue infection near the injection site.

Sample size was calculated at .80 study power and $\alpha = 0.05$ assuming Standard Deviation (SD) of 4 in Foot Ankle Disability Index (FADI) at 6 weeks. For the minimal detectable difference in mean FADI of 3 points.

28 patients in each group were required as a sample size, which further enhanced to 35 patients in each group as final sample size assuming 20% drop out/lost follow up/attrition.

INTERVENTIONS

Each participant was randomly assigned to the Group-A (standard care physiotherapy) or the Group-B (steroid injection group) using the random number generation functions in a commercially available software program.

Group A: The standard care includes Foot Orthoses and 9 physiotherapy-lead exercises performed daily over a 6-week period.

The exercise program includes one physiatrist consultation with a therapist at the beginning of the study to review workplace conditions, discuss relevant clinical history, and overview the exercise program. Detailed instruction for each exercise was given and participants need to demonstrate mastery (confirmed by physiatrist) of at least the preliminary technique before involvement in the study. (Figures 1)

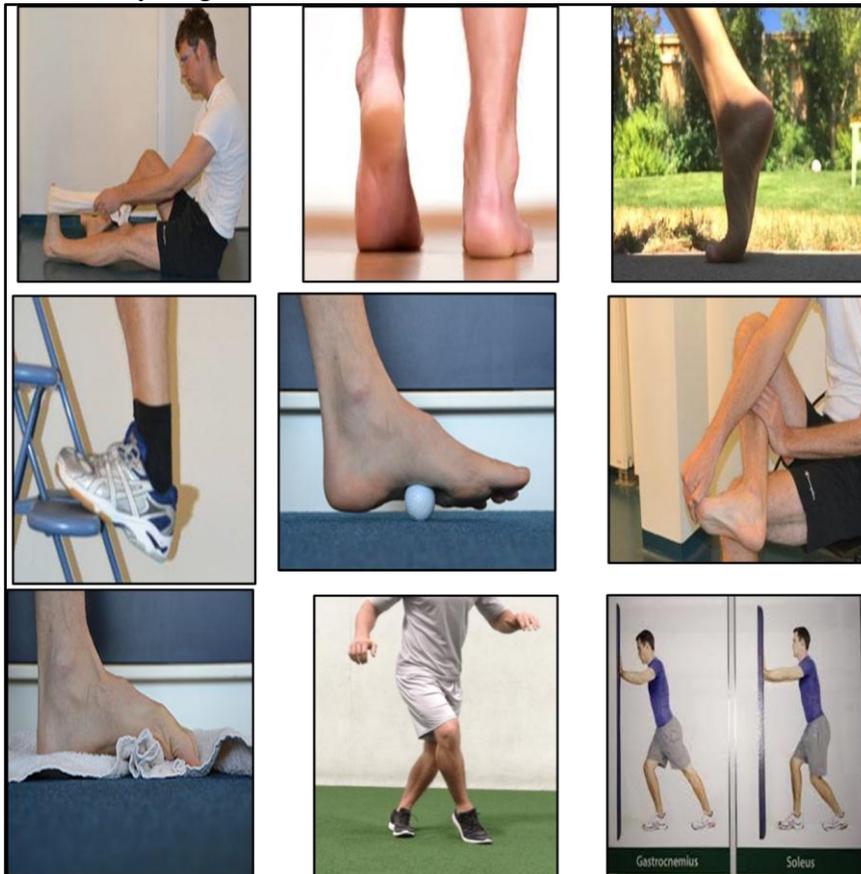


Figure 1: Illustration of the 9 exercise components included. 1. Achilles tendon and plantar fascia stretching. 2. Balance walking. 3. Forefoot extension exercise. 4. Calf

stretching on step. 5. Toe extension. 6. Plantar fascia stretching. 7. Towel pickup. 8. Gastrocnemius and soleus stretching. 9. Karaoke sidestepping.

1. Achilles tendon and plantar fascia stretching: Sit on a hard surface with your injured leg stretched out in front of you. Loop a towel around the ball of your foot and pull the towel toward your body, stretching the calf muscle, hold this position for 30 seconds and repeat 5 times.
2. Balance walking: walking along a straight line on the ground, for 5 sets of 30 strides.
3. Forefoot extension exercise: participant stands feet shoulder width apart with 1 foot ahead of the other and then contracting only calf muscles of the back leg, lifts the heel of the back leg until the metatarsophalangeal joint of that foot is maximally extended for 5 sets of 15 repetitions.
4. Calf Stretch on a Step: Stand with uninvolved foot flat on a step. Place involved ball of foot on the edge of the step. Gently let heel lower on involved leg to feel a stretch in your calf and hold 30 seconds, repeat 5 times.
5. Toe Extension: Sit with involved leg crossed over uninvolved leg. Grasp toes with one hand and bend the toes and ankle upwards as far as possible to stretch the arch and calf muscle. With the other hand, perform deep massage along the arch of your foot and hold 15 seconds, repeat for 15 times.
6. Plantar fascia stretch: Sit down and rest the arch of your foot on a round object (e.g. a tin of beans), roll the arch in all directions for a 2 to 3minutes.
7. Towel pickup: Sit down with a towel on the floor in front of you, keeping your heel on the ground, pick up the towel by scrunching it between your toes and repeat 10–20 times as you improve, add a small weight such as a tin of beans to the towel.
8. Gastrocnemius and soleus stretching: while standing in a neutral position and the knee extended, the foot is placed on top of a ramp elevating the forefoot on the rear foot (talocrural dorsiflexion) and held for 3 sets of 30 seconds each. Next the foot is again placed on top of a phone book with the knee flexed approximately 15 to 20 degrees and held for 3 sets of 30 seconds each.
9. Karaoke sidestepping: lateral side step movement involving crossing 1 foot over the next for 5 sets of 15 cross-overs in each direction.

The Orthoses were made from a negative cast of the patient's foot while the subtalar joint is in a neutral position. 3 mm polypropylene sheath will use for each orthosis. Orthosis was inserting in shoe and encourage patients not to change their regular shoe wear or activity level.

Group B: The injection group was received an ultrasound-guided Methylprednisolone Acetate injection followed by a daily routine of calf stretching. For the steroid injection procedure, using a 3-cm³ syringe with 22-gauge 1.5" needle, 1 ml of 40mg Methylprednisolone Acetate mixed with 1 ml of 2% lignocaine was prepared. Before injection, the skin was sterilized with povidone iodine. The needle was inserted 2–3 cm antero-medial to the focal point of pain in the inferior heel near the calcaneal tuberosity and moved towards the tender area under Ultrasonography-guidance. Both feet of participants with bilateral plantar fasciopathy were injected during one appointment. We advised participants to avoid running and other high impact activities for the 2 weeks after the injection. (Figures 2,3,4)

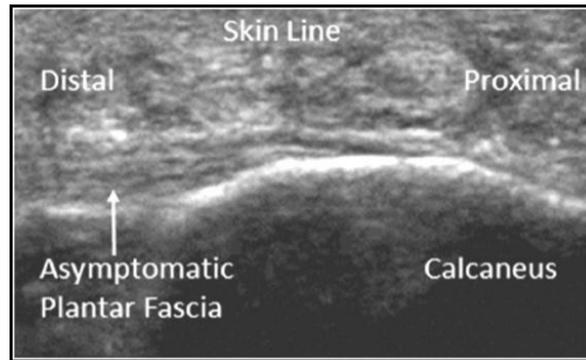


Fig 2: Asymptomatic Plantar Fascia



Fig 3: Symptomatic Plantar Fascia



Fig 4: USG Guided Injection in Planter Fasciopathy

OUTCOME MEASURES

The Foot and Ankle Disability Index (FADI) consist of 26 self-reported items divided into two sub-categories (pain and activity). The pain sub-categories consist of four items and measures foot pain in different situations. The activity sub-category consist of 22 items and measures limitation performing in various functional activities due to foot problems. Each item is scored from 0 (unable to do) to 4 (no difficulty at all). The FADI has a total point value of 104 points. The FADI scored separately as percentages, with 100% representing no dysfunction.

Pain intensity was quantified using a 100-mm Visual Analog Scale (VAS). The simplest VAS is a straight horizontal line of fixed 100-mm length. Pain intensity was referred as 0-100, in which no pain (0–4 mm), mild pain (5–44 mm), moderate pain (45–74 mm), and severe pain (75–100 mm).¹¹ patients were asked to mark the place on the VAS scale that corresponded to their level of pain.

Measurements of the plantar fascia thickness were taken using HIVISION Preirus ultrasound systems (Hitachi Ltd., Japan) with a linear 13 to 5 MHz transducer. The patient was asked to lie in a prone position with the bilateral lower limbs in full extension and both ankles at 90°. The probe of the ultrasound was placed on a line connecting the second toe and the midheel. The thickness of the plantar fascia was determined at its proximal end, close to the insertion point into the calcaneus, by longitudinal sonograms of the heel. Then, readings were also taken at the arch of the foot in the central metatarsal zone. Finally, the thickness of the plantar fascia was measured between the base of the first and second toes.

STATISTICAL ANALYSIS

The Qualitative data was expressed in percentage and proportion and Quantitative data was expressed in mean \pm SD. Significance of difference in proportion was calculated by chi-square test/Fisher exact test and Significance of difference in mean \pm SD was calculated by student t test/Mann Whitney U. Paired t test was used for dependent quantitative data.

Statistical analysis was performed with the SPSS, trial version 20 for windows statistical software package (SPSS inn, Chicago, il, USA) and PRIMER. P-value $<$ 0.05 was considered as statistically significant.

RESULTS

Thirty-five patients treated in standard care group and 35 patients were treated with USG guided local corticosteroids injections. The injection group was comprised of eleven male (31.4%) and 24 female (68.6%). The standard care physiotherapy group was comprised of 18 male (51.4%) and 17 female (48.6%), ($p=0.145$). The mean age was not different between both groups (40.60 ± 10.64 years versus 41.43 ± 9.66 years, $p=0.734$). In injection group, 37.14% patients were in the age group of 31-40 years while in standard care physiotherapy group 34.29% patients were in the age group of 41-50 years ($p=1.000$). The mean of body mass index in both groups were 27.20kg/m^2 ($p=0.325$). The mean of duration of symptoms in both groups were 7.76 months ($P=0.195$).

An anechoic area was seen in planter fascia USG of 20 patients in standard care group and 19 patients in injection group. There was no significance difference between groups regarding presence of anechoic area ($p=0.41$). In addition, significant correlation between pain reduction and functional improvement with presence or absence of anechoic area was not achieved among patients of both groups ($p=0.91$, $p=0.92$, respectively).

Baseline demographic and clinical characteristics of patients are shown in table 1.

Table 1: Baseline participants' demographic and clinical characteristics

Variable	SC Group (n=35)	Injection Group (n=35)	P Value
Sex			
Male	18 (51.4%)	11(31.4%)	0.145
Female	17(48.6%)	24(68.6%)	0.734
Age (Mean)	40 ± 10.64	41.43 ± 9.66	0.734
Age group			
20-30 yrs	7(20%)	5(14.29%)	1.000*
31-40 yrs	10(28.57%)	13(37.14%)	
41-50 yrs	12(34.29%)	11(31.43%)	
51-60 yrs	6(17.14%)	6(17.14%)	
BMI(kg/m²)	26.83 ± 3.16	27.57 ± 3.10	0.325
Duration (month)	8.37 ± 4.180	7.14 ± 3.647	0.195
Anechoic area in USG (no. of pt.)	20(57.10%)	19(54.30%)	0.410
* Chi square= 0.768 with 3 degree of freedom			

A student t test/Mann Whitney U. Paired t test revealed that there was no significant difference between treatment groups with respect to the VAS, PF thickness and FADI at baseline and 6 weeks after treatment (P=0.503, P=0.142, P=0.056, respectively). Although injection group had a higher reduction in the VAS, PF thickness as well as the FADI, these changes were not significant statistically. (figures 5, 6, 7)

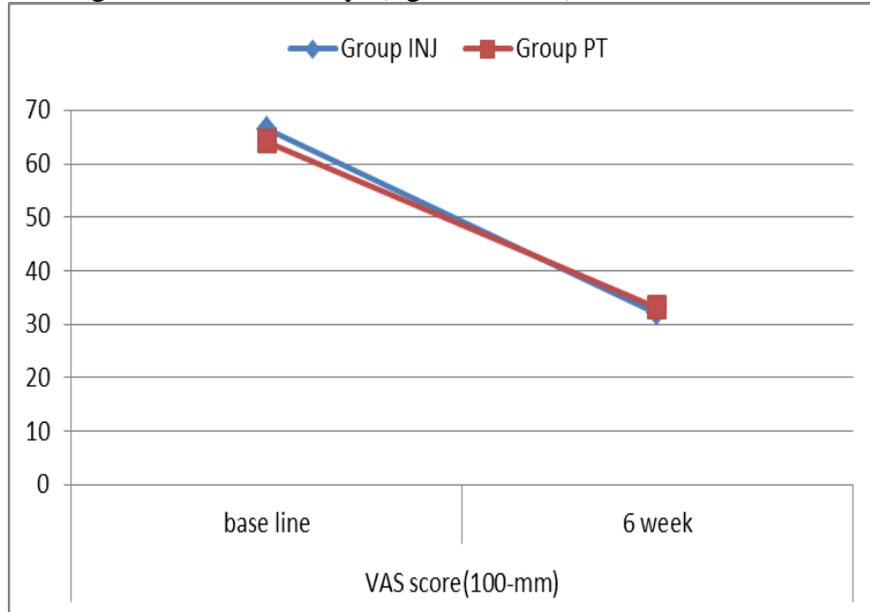


Fig 5: Changes in the VAS over the course of the study period in each group.

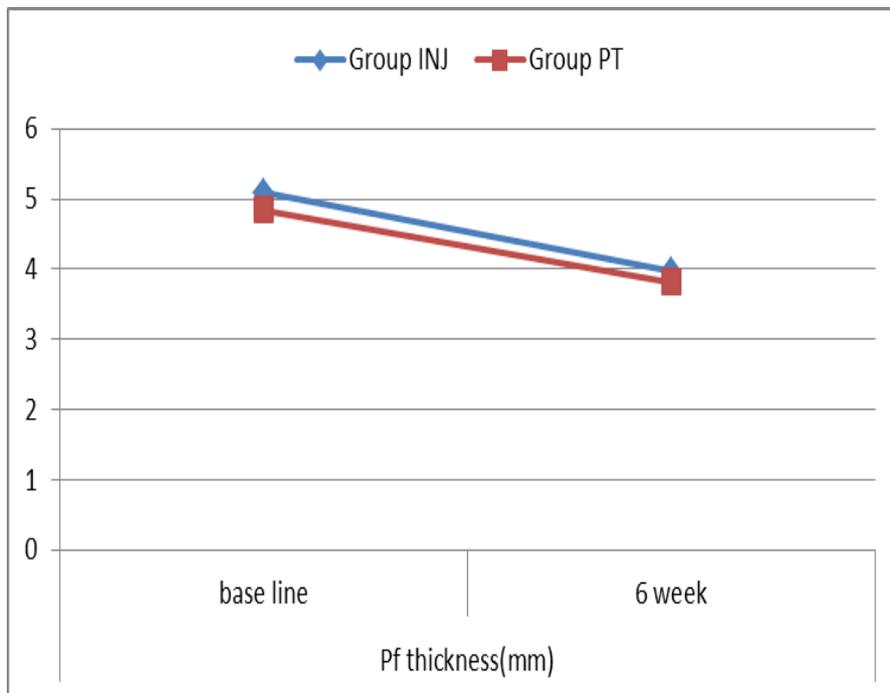


Fig 6: Changes in the PF thickness over the course of the study period in each group.

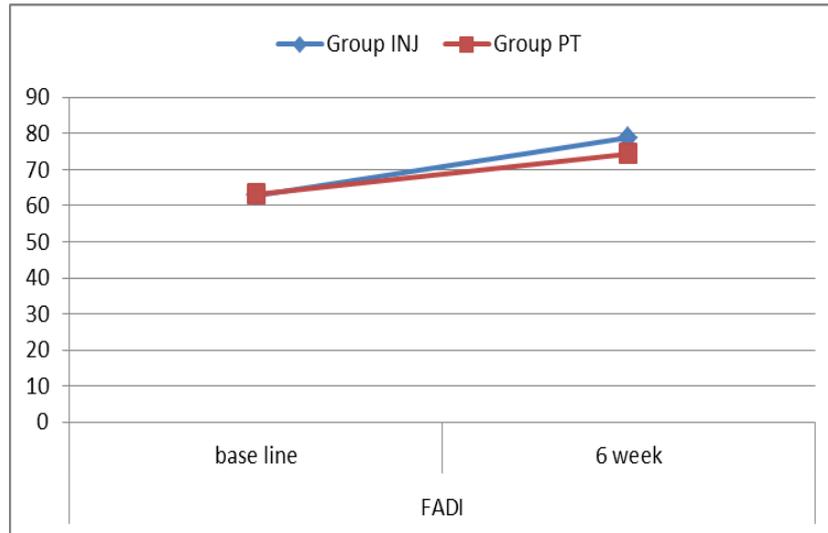


Fig 7: Changes in the FADI score over the course of the study period in each group.

Focusing on main effects determined that there was not a statistically significant difference within treatment groups with respect to the VAS, PF thickness and FADI ($P=0.355$, $P=0.096$, $P=0.775$, respectively) but all parameters had a continuous improvement in evaluation sessions ($P<0.001$, $P<0.001$, and $P<0.001$).

Post hoc tests using the bonferroni correction revealed that there was a reduction in VAS from baseline to weeks 6 (after treatment) (65.315 ± 7.182 vs 32.57 ± 4.235 , respectively) ($P<0.001$). PF thickness at weeks 6 significantly reduced to 3.895 ± 0.18 compared to baseline ($P<0.001$). FADI had a considerable improved at week 6 (76.675 ± 2.131) compared to baseline (62.915 ± 1.823) ($P<0.001$).

Changes in VAS, PF thickness and FADI at various study time points in standard care physiotherapy and injection groups are shown in Table 2.

Table 2: Changes of variables during the assessments points in standard care and injection groups

	Standard Care Group	Injection Group	Total	P Value
VAS (100mm)				
At baseline	64.14 ± 10.036	66.49 ± 10.985	65.315 ± 7.182	$P=0.355$
Week 6	33.11 ± 6.755	32.03 ± 6.741	32.57 ± 4.235	$P=0.503$
Pairwise comparison				
(Baseline * week 6)	$P <0.001$	$P <0.001$		
PF Thickness(mm)				
At baseline	4.85 ± 0.49	5.09 ± 0.68	4.97 ± 0.31	$P=0.096$
Week 6	3.82 ± 0.25	3.97 ± 0.35	3.895 ± 0.18	$P=0.142$
Pairwise comparison				
(Baseline * week 6)	$P <0.001$	$P <0.001$		
FADI				
At baseline	63.29 ± 3.847	62.54 ± 5.936	62.915 ± 1.823	$P=0.775$
Week 6	74.49 ± 3.737	78.86 ± 5.694	76.675 ± 2.131	$P=0.056$
Pairwise comparison				
(Baseline * week 6)	$P <0.001$	$P <0.001$		

Patient satisfaction with both treatments was also evaluated. Patients believed that treatment was good and excellent in 19 standard care physiotherapy cases (54%) and 23 corticosteroid

injection cases (65%) and poor to adequate in 16 standard care cases (46%) and 12 corticosteroid injection cases (35%), but the difference was not significant ($P>0.05$). Some patients reported transient pain in standard care physiotherapy group at initial sessions or during injection procedure, which were resolved after therapy continuation. Apart from that, no side effects related to physiotherapy or injections were seen during study.

DISCUSSION

In this hospital based comparative analysis, we evaluated and compared the effectiveness of standard care physiotherapy versus ultrasonography-guided single dose Methylprednisolone acetate injection for plantar fasciopathy.

In present study population, the mean age of patients was 41.01 ± 10.10 years, it is suggested that plantar fasciopathy predominantly affects middle age group as compared to young and older age groups. On comparing both groups they were found statistically comparable ($P=0.734$). Fariba Eslamian et al[14] were found, the age of patients varied from 18 to 65 years, with a mean of 41.45 ± 8.05 & 42.85 ± 8.62 in ESWT and steroid injection groups respectively. In our study female: male ratio was 1.41:1. So plantar fasciopathy predominantly affects females as compared to male. Ozdemir et al[15] in 2005 were also found that plantar fasciitis was more common in females as compared to males.

Both groups according to BMI (mean 27.20 kg/m^2), they were found statistically comparable ($P=0.325$). Riddle et al[16] performed a case control study to identify gender, high body mass index (BMI), age and weight as independent risk factor for the plantar fasciopathy and found those whose body-mass index is $>30 \text{ kg/m}^2$ are also at increased risk for the development of plantar fasciitis.

Pain at work and during ADL was measured using a 100-mm VAS. Values in parenthesis are standard error of the measure at selected time. VAS and FADI score at base line were 66.49 & 62.94 in steroid injection group and 64.14 & 63.29 in standard care physiotherapy group. When we compare both groups, no significant difference was observed for pain ($P=0.355$) as well as for the FADI score ($P=0.775$). Similar result at baseline found in study of Michael Ryan et al[17] in 2012.

On application of Student t test, the changes in difference in mean VAS score, FADI and PF thickness between base line and follow up was statistically significant (P value <0.001). So present study showed that steroid injection treatment and standard care physiotherapy treatment both were effective in improvement in VAS score, FADI and plantar fascia thickness.

Two previous studies have compared the efficacy of exercise and corticosteroid injection in patients with plantar fasciitis. Ryan et al [17] Observed VAS score, FADI and PF thickness showed significant improvement in physiotherapy group then steroid injection group. Stretching only has proven effect, but strength training has been shown to be superior to stretching at 3 months, although both exercise modalities had a similar positive long-term effect. Devrim Özer et al[18] in 2015 post-treatment VAS scores were statistically significantly lower than pre-treatment in patients with PF who did plantar fascia-specific stretching exercises ($p=0.0001$). Thus, plantar fascia-specific stretching exercise is an effective treatment option in PF.

Our results are in agreement with Crawford et al[19] that concluded corticosteroid injection had similar or somewhat higher efficacy than exercise.

Results from our study suggest that performing a multielement exercise program may be equally as effective as receiving a steroid injection for addressing symptoms of plantar fasciopathy in the short term. Positive structural improvements were also seen through ultrasound assessment from base line to the 6-week follow-up in both standard care physiotherapy group and steroid injection treatment group.

Steroids interfere at several steps in the inflammatory response, but the most important overall mechanism appears to be limitation of recruitment of inflammatory cells at the local site. So steroid actions are both local and direct.

The mechanism behind therapeutic success with exercise remain unknown but in present study the clinical outcome as result of a combination of the following therapeutic effects. First, the tissue specific stretching and forefoot extension exercise provide direct and systematic loading to the plantar fascia. Appropriate loading of soft tissue is an important element for mechano transduction-related maintenance of extra cellular tensile strength. The second effect comes from improve activation and strengthening of extrinsic foot muscle. Extrinsic foot musculature provides important dynamic support of the longitudinal arch, and direct activation of these extrinsic muscle groups could decrease stress passive stricture such as plantar fascia. Last effects of exercises were aimed at addressing overall posture and balance to minimise postural contribution to loading to the plantar fascia and increase calf tension.

CONCLUSION

Both USG- guided single dose of steroid injection and standard care physiotherapy improve pain and functional ability but local steroid injection is a better treatment modality as it causes early, rapid and sustained relief of pain and inflammation in plantar fasciitis. Although the exercises are relatively simple to perform, without side effects or adverse events but Plantar fascia-specific stretching exercises are not efficient in all PF patients. We suppose it depends on different factors (body mass index, thickness of the plantar fascia, etc.) which should be further investigated.

LIMITATIONS

There is large variation in the symptom duration reported in both groups in this study, suggesting that there may be different levels of pathology within this sample. Single and Short duration of follow-up limits definite conclusion on long term and multiple follow-up efficacy. Further studies are warranted to overcome these limitations.

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