ISSN (P) : 2589-9120 / (O) : 2589-9139
PubMed-National Library of Medicine - ID: 101773527

International Journal of Medical Science and Applied Research (IJMSAR)

Available Online at: https://www.ijmsar.com

Volume – 4, Issue –2, April – 2021, Page No. : 37 – 48

Comparison Of Dextrose Prolotherapy And Triamcinolone Injection In Treatment Of Plantar Fasciitis

[1]Dr. Chand Mohamed Ikram Malik, Senior Resident, Department of Physical Medicine and Rehabilitation, National Institute for Locomotor Disabilities, Kolkata, India

[2]Dr. Mohammad Kaleem Ul Haque, Senior Resident Department of Physical Medicine and Rehabilitation, Sher-I-Kashmir Institute of Medical Sciences, Srinagar, India

[3]Dr. Junis Ali, Medical Officer, J & K Health Services, India

Citation of this Article: Dr. Chand Mohamed Ikram Malik, Dr. Mohammad Kaleem Ul Haque, [3]Dr. Junis Ali," Comparison Of Dextrose Prolotherapy And Triamcinolone Injection In Treatment Of Plantar Fasciitis", IJMSAR – March – 2021, Vol. – 4, Issue - 3, P. No.37-48.

Corresponding Author: Dr. Junis Ali, Medical Officer, J & K Health Services, India

Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

Background

Plantar fasciitis (PF) is one of the most common causes of heel pain in adults. The predisposing factors for PF are prolonged standing (athletes), tight foot muscles (Achilles tendon, intrinsic foot muscles)[1,2]. The prevalence of PF is described as between 3.6% and 7% in general population. Among runners, it is associated with 8% of sport injuries[3]. At present, there is no consensus in medical fraternity regarding the management of plantar fasciitis. Recent advancement in treatment, including Prolotherapy was one of the reasons for doing this study.

Objectives

To determine the effects of Dextrose Prolotherapy injection and local Triamcinolone injection in cases of plantar fasciitis.

Methods: Study site and populations

The patients with plantar fasciitis visiting the outpatient department NILD, Kolkata were listed out as per inclusion and exclusion criteria.

Study design and sampling strategy

It is a prospective, randomized and comparative study over duration of one year. After getting Institutional ethical committee clearance, in which 32 patients were selected by convenience sampling and randomized through chit box method into two groups. All patients were advised therapeutic lifestyle changes (TLC), customised footwear modification and home exercises. A total 12 weeks assessment was done through for pain relief and foot function.

Analysis was done with the help of SPSS (version 24.0; SPSS Inc., Chicago, IL, USA) and GraphPad Prism version 5

Results

At 12 weeks, Dextrose Prolotherapy group had improved foot function compared to local Triamcinolone injection group. Both Dextrose Prolotherapy and local Triamcinolone injections were effective mode of treatment in plantar fasciitis. But the overall improvement was better in Dextrose Prolotherapy group as compared to local Triamcinolone injection group in terms of pain relief and function as assessed by VAS and FFI respectively.

Conclusions

Dextrose Prolotherapy group had better pain relief compared to local Triamcinolone injection group at 4 and 8 weeks, but there was no significant difference in pain relief at 12 weeks. Hence improvement in pain and FFI in Dextrose Prolotherapy group in 4 and 8 weeks follow up should be taken with caution as long term follow up is desirable.

Keywords: Plantar Fasciitis, Dextrose Prolotherapy, Triamcinolone Injection, Visual Analog Scale, Foot Functional Index

Introduction

Plantar fasciitis (PF) is one of the most common causes of heel pain in adults.[4,5] It is self- limiting condition which usually subsides with lifestyle modification and use of appropriate footwear. It results in pain in the heel and bottom of the foot that is usually most severe with the first steps of the day or following a period of rest. Pain is also frequently brought on by bending the foot and toes up towards the shin. The pain typically appears gradually, and it affects both feet in about one third of cases. [6,7]It is characterized by micro tears, breakdown of collagen, and scarring at the insertion site.

Incidence of plantar fasciitis is about 10% of the general population as well. It may present bilaterally in a third of cases. [8]Women are affected by plantar fasciitis twice as often as men.

The predisposing factors for PF are prolonged standing as in athletes, tight foot muscles eg. tightness of achilles tendon and intrinsic foot muscles. Other intrinsic factors include pes planus, overpronation, pes cavus, leg-length discrepancy, excessive lateral tibial torsion, and excessive femoral anteversion [9,10,11]and obesity, occupations requiring prolonged standing and weight-bearing, and heel spurs.[4,12]Training errors and foot wear problems are usual extrinsic factors. 9,10

Histologically, the lesion shows degenerative changes along with increased vascularity, proliferation of fibroblast, and destruction of collagen fibers.[1,2]The prevalence of PF is described as between 3.6% and 7% in general population. Among runners, it is around 8% of the sport associated injuries. [3]

Imaging is not routinely done for the diagnosis of PF. The diagnosis is done based on a clinical history and at tenderness elicited at the heels. The ultrasound (US) of foot is an inexpensive method to rule out soft tissue pathologies of the heel. On US, proximal plantar fascial thickness greater than 4 mm along with areas of hypogenicity favours a diagnosis of PF. For recalcitrant heel pain, magnetic resonance imaging can be done to determine the severity of inflammation. [13]

Conservative management of PF includes foot and ankle stretches, eccentric stretches, [14]deep myofascial massage, and iontophoresis. The above mentioned modalities are used together with suggestions to avoid prolonged standing, to reduce weight, use of proper footwear[84], night time splints. [15]Therefore, the efficacy of any one of the conservative approach is difficult to establish. Pharmacological management involves use of acetaminophen and non- steroidal anti-

inflammatory drugs which can benefit in early stages of the disease.

Corticosteroid injection is required when the conservative and pharmacological methods of treatment fail. In a few surveys the American Podiatrists and Orthopedicians suggested Corticosteroid injection for chronic plantar pain. [16] The advantages of Corticosteroid injections are by reducing the edema and inflammation of the fascia. This injection along with physical therapy is usually sufficient for many of the patients. Other injections which are mentioned in literature are hyperosmolar dextrose prolotherapy, whole blood, platelet rich plasma, and Botulinum toxin. [17,18]Extracorporeal shock wave therapy and plantar fasciotomy [19] are reserved for patients with chronic recalcitrant PF. [20]For patients with chronic PF, corticosteroid has been used successfully and patients usually have significant pain relief up to 4 weeks after the injection. Corticosteroid injections have also shown to reduce the thickness of plantar fascia on subsequent follow-up visits.

About 80% of plantar fasciitis cases resolve spontaneously by 12 months; 5% of patients end up undergoing surgery for plantar fascia release because of failure of all conservative measures.

Education is the single most important means of preventing plantar fasciitis. It is important to instruct athletes with plantar fasciitis to warm up sufficiently before initiating activity, continue stretching programs, and ice down after activity. Patients may need to decrease their running temporarily; later, they may resume their earlier level of activity at the discretion of the physician and physical therapist.

In cases of plantar fasciitis arising becauseof one's occupation, evaluation of the worker's shoes and work environment is essential for preventing a recurrence of this condition. [15,19]

Prolotherapy

Prolotherapy is a practical and efficacious therapeutic strategy to treat ligamentous laxity and related musculoskeletal and arthritic conditions.[21,22]Prolotherapy is a nonsurgical regenerative injection technique that introduces small amounts of an irritant solution to the site of painful and degenerated tendon insertions (entheses), joints, ligaments, and in adjacent joint spaces during several treatment sessions to promote growth of normal cells and tissues. [23,24]A major goal of prolotherapy in chronic musculoskeletal conditions is the stimulation of regenerative processes in the joint that will facilitate the restoration of joint stability by augmenting the tensile strength of joint stabilising structures, such as ligaments, tendons, joint capsules, menisci, and labral tissue. [25]

The most common prolotherapy agent used in clinical practice is Dextrose, with concentrations ranging from 12.5% to 25%. [26]The mechanism of action behind prolotherapy is not clearly understood. However, current theory holds that the injected proliferant mimics the natural healing process of the body by initiating a local inflammatory cascade, which triggers the release of growth factors and collagen deposition. This is accomplished when induced cytokines mediate chemomodulation, which leads to proliferation and strengthening of new connective tissue, joint stability, and a reduction in pain and dysfunction.[24,27]

In this study Dextrose was selected as an agent of choice for Prolotherapy because it is easily available at low cost in comparison to other agents like monosodium morrhuate and phenol-glycerine-glucase. There are no side effects of dextrose injection except for local pain and erythema at the site of injection. There are

few literatures available on the effectiveness of Dextrose Prolotherapy injections as a treatment option for the plantar fasciitis. Also, among the medical fraternity, there is no consensus about which treatment modality is best and when to use. Very few studies have evaluated effectiveness of Dextrose Prolotherapy injections as a treatment modality of plantar fasciitis, therefore this research was undertaken.

Methodology

The study was conducted in outpatient Department in National Institute for Locomotor Disabilities, Kolkata with a sample size of 32 grouped into two groups of 16 each. It was prospective, randomised comparative study and was conducted for a period of one year from June 2018 to June 2019. Subjects were assigned to receive either Dextrose Prolotherapy or local Triamcinolone injections for plantar fasciitis.

Inclusion Criteria

1. Age group from 18 years to 60 years
2. Both newly diagnosed case of plantar fasciitis as well as those who have failed a course of conservative management (NSAIDs, exercise therapy) of any duration will be included in our study
3. Presence of calcaneal spur in X-ray
4. Either side (right or left heel) or both sides
5. Early morning heel pain on first steps or pain after prolonged rest.

Exclusion Criteria

1. Allergy to the drugs injected
2. Systemic disease with foot pain like rheumatoid arthritis, hyperuricemia etc.
3. Past history of bleeding disorders
4. Past history of treatment with prolotherapy for plantar fasciitis.
5. Local infection at the site of injection
6. Uncontrolled diabetes or other co-morbid conditions
7. Pregnant or lactating mothers
8. Psychiatric or cognitive problems which may hamper the outcome evaluation
9. Malignancy

Methodology

Institutional scientific and ethical committee clearance was taken for the study. Patients were selected according to inclusion and exclusion criteria. After obtaining consent for the study technique, subjects were assigned to receive either prolotherapy or Corticosteroid injections for plantar fasciitis.

The selected cases were screened first according to inclusion and exclusion criteria. The patients with volar heel pain presenting to outpatient department of National Institute for Locomotor Disabilities, Kolkata-700090, were examined and screened according to inclusion and exclusion criteria. Aim of the study and procedure was explained and a written consent was taken from patients, who agreed to participate. Thorough history and physical examination was done as per study proforma. Each subject was treated with injections over an 8week period, seen for in person follow-up over 12 weeks. 40 patients who met initial clinical inclusion criteria were approached for study proposal; 34 patients were found to be eligible and were offered participation. Of these, two declined participation. A total of 32 patients satisfying the above criteria were enrolled in the study after informed consent. They were randomised through chit box method to Dextrose Prolotherapy (group A) or local Corticosteroid injection (group B) groups. It is a simple method of generating random sequence. For random allocation of 32 cases into two groups in 1:1 ratio, 16 chits were prepared writing “A”

(for group A) on 16 chits & "B" (for group B) on 16 chits. After folding the chits & putting in a box & mixing well, a chit was drawn, letter written on it was noted, & then drew the second chit without replacing the first, noted it down & proceeded similarly until the last i.e. 32nd chit is drawn. After that assessment data was taken according to Study Proforma.

Nature of the procedures likely to be done was explained to each patient as per Study Proforma. Relevant history was recorded including history of medications taken for the same and history of any medical conditions like diabetes, hypertension and any infection.Complete physical examination including body mass index and relevant investigations including complete haemogram with erythrocyte sedimentation rate (ESR), fasting blood sugar (FBS), Serum uric acid and plain X-ray of calcaneum- axial and lateral view of involved foot was done. Baseline values of each parameter according to VAS, FFI score were recorded for each patient.

All the patients received standard physical and occupational interventions. Both the groups received footwear modifications and exercise therapy. Patients were instructed not to take any NSAIDs and local ultrasound therapy from 1 week before to 12 weeks after the 1st injection. If any analgesics were needed, acetaminophen was prescribed. All patients were advised therapeutic lifestyle changes (TLC).

Patients were divided in two groups—

Group A & Group B.

Group A received Dextrose Prolotherapy injection [12.5% Dextrose in 1% Lidocaine without epinephrine in total volume of 4ml].Which was prepared by adding 2 ml of 25% Dextrose to 2 ml of 2% Lidocaine.

Group B patients received local Corticosteroid injection [Triamcinolone acetonide 20 mg in Lidocaine 1% without Epinephrine in a total volume of 2ml] which was prepared by adding 1ml of 20mg/ml Triamcinolone acetonide to 1ml of 2% Lidocaine.

Site of injection: Skin preparation was done by using 1% povidone iodine and spirit. The injection was given over the site of maximum tenderness of the heel using a medial approach.

Palpation was done to identify the most anterior aspect of the medial plantar calcaneal tubercle and the needle was injected and advanced to reach the most anterior aspect of the medial calcaneal tuberosity.

We should avoid injecting within the superficial layers of the subcutaneous tissue, because Corticosteroid injection in to the superficial fat pad can cause fat necrosis and atrophy, which reduces the shock-absorbing capacity of the heel.

Before injection, skin hypersensitivity test was performed. Injections were given to each patient at 0, 4, and 8 weeks and follow-up at 4, 8 and 12 weeks. Patient was called back 48 hours after each injection to look for any side effects and adverse effects. Assessment data was recorded before treatment, after treatment and at 4, 8 and 12 weeks.

Data Collection/ Parameters/Study Tools

1. Visual analog scale [VAS] for pain.
2. Foot functional index score. [FFI]

Statistical Analysis

For statistical analysis data was entered into a Microsoft excel spreadsheet and then analysed by SPSS (version 24.0; SPSS Inc., Chicago, IL, USA) and GraphPad Prism version 5. Data was summarised as mean and standard deviation for numerical variables and count and percentages for categorical variables. Two-sample t-tests for a difference in mean involved

independent samples or unpaired samples. Paired t-tests were a form of blocking and had greater power than unpaired tests. A chi-squared test ($\chi 2$ test) was used in any statistical hypothesis test wherein the sampling distribution of the test statistic is a chi-squared distribution when the null hypothesis is true. Without other qualification, 'chi- squared test' often was used as short for Pearson's chi-squared test. Unpaired proportions were compared by Chi-square test or Fischer's exact test, as appropriate.

Explicit expressions that can be used to carry out various t-tests are given below. In each case, the formula for a test statistic that either exactly follows or closely approximates a t- distribution under the null hypothesis is given. Also, the appropriate degrees of freedom were given in each case. Each of these statistics can be used to carry out either a one- tailed test or a two-tailed test.

Once a t value is determined, a p-value was found using a table of values from Student's t-distribution. If the calculated p-value was below the threshold chosen for statistical significance (usually the 0.10, the 0.05, or 0.01 level) then the null hypothesis was rejected in favour of the alternative hypothesis.

p- value ≤ 0.05 was considered to be statistically significant.One-way analysis of variance (one-way ANOVA) was a technique used to compare mean of three or more samples for numerical data (using the F distribution).

Results and Observations

Forty subjects who met initial clinical inclusion criteria were approached for the study proposal; 34 patients were found to be eligible and were offered participation. Of these, two declined participation. A total of 32 patients satisfying the above criteria were enrolled in the study after informed consent. Patients in group A received Dextrose Prolotherapy injection and patients in group B received local Triamcinolone injection. Out of the total 32 patients enrolled in study, 30 completed full 12 weeks follow up, 15 each in group A and group B. A total of 2 patients, 1 in each group were lost to follow up and were excluded from the statistical analysis.

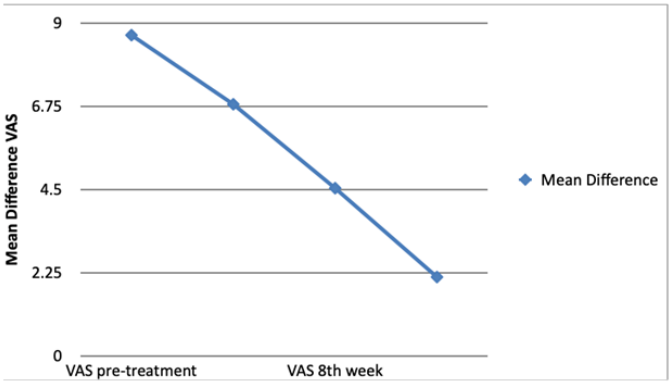
In group-A, the mean age (mean±s.d.) of patients was 42.0000 ± 9.9642 years. In group- B, the mean age (mean±s.d.) of patients was 38.5333 ± 10.1268 years. Difference of mean age between the two groups was not statistically significant (p=0.3527). In group-A, the mean VAS1 (mean±s.d.) of patients was 8.4000 ± .7368. In group-B, the mean VAS1 (mean±s.d.) of patients was 8.6667 ± .8997. Difference of mean VAS1 between the two groups was not statistically significant (p=0.3820). Difference of mean VAS2 between group A and group B was statistically significant (p=0.0022). Difference of mean VAS3 between both groups was statistically significant (p=0.0047). Difference of mean VAS4 between group A and group B was not statistically significant (p=0.0587). Difference of mean FFI 1 between the 2 groups was not statistically significant (p=0.2355). Difference of mean FFI 2 between group A and group B was not statistically significant (p=0.3581). Difference of mean FFI between the two groups was not statistically significant (p=0.1630). Difference of mean FFI 4 between group A and group B was statistically significant (p=0.0285). Difference of mean pain subscale 1 between the two groups was not statistically significant (p=0.9721). Difference of mean pain subscale 2 between the two groups was not statistically significant (p=0.9707). Difference of mean pain subscale 3 between the two groups was not statistically significant (p=0.3010). Difference of mean pain subscale 4 between both the groups was not statistically significant (p=0.1207). Difference of mean disability subscale 1

between both groups was not statistically significant (p=0.1718). Difference of mean disability subscale 2 between the two groups was not statistically significant (p=0.3499). Difference of mean disability subscale 3 between the two groups was not statistically significant (p=0.2989). Difference of mean disability subscale 4 between group A and group B was statistically significant (p=0.0223). Difference of mean activity limitation subscale 1 between the two groups was statistically significant (p=0.0191). Difference of mean activity limitation subscale 2 between group A and group B was statistically significant (p=0.0194). Difference of mean activity limitation subscale 3 between group A and group B was statistically significant (p=0.0082). Difference of mean activity limitation subscale 4 between group A and group B was statistically significant (p=0.0334).

Group A						
	Dextrose Prolotherapy Group					
	t	df	p-Value	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
VAS pre-treatment	44.155	14	<0.0001	8.400	7.99	8.81
VAS 4th week	26.879	14	<0.0001	5.667	5.21	6.12
VAS 8th week	18.924	14	<0.0001	3.600	3.19	4.01
VAS 12th week	6.487	14	<0.0001	1.533	1.03	2.04

Table/Fig 1. Difference of mean VAS pre-treatment, 4th week, 8th week and 12th week in Group A

Table/Fig 1. It was found that in case, mean difference of VAS pre-treatment was 8.400 with 95% confidence interval [7.99–8.81, P < 0.001]. Mean difference of VAS at 4th week was 5.667 with 95% confidence interval [5.21–6.12, P < 0.001]. Mean difference of VAS at 8th week was 3.600 with 95% confidence interval [3.19–4.01, P < 0.001]. Mean difference of VAS at 12th week was 1.533 with 95% confidence interval [1.03–2.04, P < 0.001].



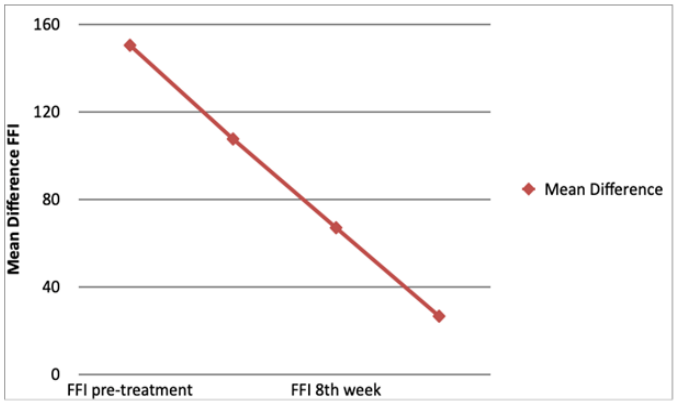
[Table/Fig 2] One-Way ANOVA difference of mean VAS in control during follow-up in Dextrose Prolotherapy group

Table/Fig 2. One-Way ANOVA showed that difference of mean VAS in case during follow-up was statistically significant in Dextrose Prolotherapy group.

Group A						
	Dextrose Prolotherapy Group					
	t	df	p-Value	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
FFI pre-treatment	39.259	14	<0.0001	150.333	142.12	158.55
FFI 4th week	27.227	14	<0.0001	107.533	99.06	116.00
FFI 8th week	18.969	14	<0.0001	67.000	59.42	74.58
FFI 12th week	9.908	14	<0.0001	26.600	20.84	32.36

Table/Fig 3. Difference of mean FFI pre-treatment, 4th week, 8th week and 12th week in Group A

Table/Fig 3. It was found that in case, mean difference of FFI pre-treatment was 150.333 with 95% confidence interval [142.12–158.55, P < 0.001]. Mean difference of FFI at 4th week was 107.533 with 95% confidence interval [99.06–116.00, P < 0.001]. Mean difference of FFI at 8th week was 67.000 with 95% confidence interval [59.42–74.58, P < 0.001]. Mean difference of FFI at 12th week was 26.600 with 95% confidence interval [20.84–32.36, P < 0.001].



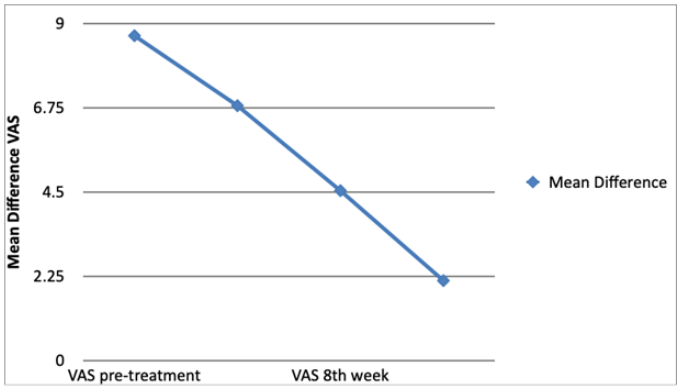
[Table/Fig 4] One-Way ANOVA difference of mean FFI in case during follow-up in Dextrose Prolotherapy group

Table/Fig 4. One-Way ANOVA showed that difference of mean FFI in case during follow-up was statistically significant in Dextrose Prolotherapy group.

Group B						
	Triamcinolone Injection Group					
	t	df	p-Value	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
VAS pre-treatment	37.306	14	<0.0001	8.667	8.17	9.16
VAS 4th week	25.968	14	<0.0001	6.800	6.24	7.36
VAS 8th week	19.179	14	<0.0001	4.533	4.03	5.04
VAS 12th week	11.117	14	<0.0001	2.133	1.72	2.54

Table/Fig 5. Difference of mean VAS pre-treatment, 4th week, 8th week and 12th week in Group B

Table/Fig 5. It was found that in control, mean difference of VAS pre-treatment was 8.667 with 95% confidence interval [8.17–9.16, P < 0.001]. Mean difference of VAS at 4th week was 6.800 with 95% confidence interval [6.24–7.36, P < 0.001]. Mean difference of VAS at 8th week was 4.533 with 95% confidence interval [4.03–5.04, P < 0.001]. Mean difference of VAS at 12th week was 2.133 with 95% confidence interval [1.72–2.54, P < 0.001].

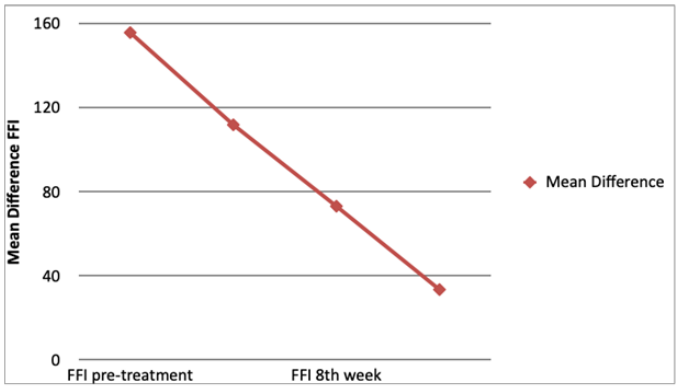


[Table/Fig 6]One-Way ANOVA difference of mean VAS in control during follow-up.

Table/Fig 6. One-Way ANOVA showed that difference of mean VAS in control during follow-up was statistically significant.

Table/Fig 7. Difference of mean FFI pre-treatment, 4th week, 8th week and 12th week in Group B

Table/Fig 7. It was found that in control, mean difference of FFI pre-treatment was 155.733 with 95% confidence interval [150.85–160.61, P < 0.001]. Mean difference of FFI at 4th week was 111.867 with 95% confidence interval [106.65–117.08, P < 0.001]. Mean difference of FFI at 8th week was 73.133 with 95% confidence interval [67.95–78.32, P < 0.001]. Mean difference of FFI at 12th week was 33.467 with 95% confidence interval [30.73–36.20, P < 0.001].



[Table/Fig 8]One-Way ANOVA difference of mean FFI in control during follow-up

Table/Fig 8. One-Way ANOVA showed that difference of mean FFI in control during follow-up was statistically significant.

Discussion

We found that mean VAS before injection in group-A (Dextrose Prolotherapy) and group- B (local Triamcinolone injection) was not statistically significant (p=0.3820). Difference of mean VAS at 4 weeks after injection in group-A was significantly lower than group-B (p=0.0022). Difference of mean VAS at 8 weeks in group-A was significantly lower than group-B (p=0.0047).The same finding was corroborated by Singh P et al [28] in 2017 who did a systematic review and meta-analysis of platelet-rich plasma versus corticosteroid injections for plantar fasciopathy and concluded that PRP injections are associated with improved pain and function scores at three month follow-up when compared with Corticosteroid injections and Kalaci A et al [29], Kushvaha RP et al [30]and Sen Mausumi et al. [31]However, Difference of mean VAS at 12 weeks in both groups was not statistically significant (p=0.0587). It was concluded that post 4 and 8 weeks after injection, Dextrose Prolotherapy group had better pain relief compared to local Triamcinolone injection group.

We found that difference of mean FFI at 4 and 8 weeks in both groups were not statistically significant. But difference of mean FFI at 12 weeks in group-A was significantly lower than group-B (p=0.0285). Hence Dextrose Prolotherapy group had improved foot function compared to local Corticosteroid injection group at 12 weeks. Group A had no early response changes as compared to group B. This finding was in synchronous with Jain K et al [32](2015) who found that PRP is better for the treatment of chronic plantar fasciitis as compared to steroid. In comparison of the two groups, change of VAS during follow-up was significantly higher in Triamcinolone injection group but change of FFI during follow-up was significantly higher in the Dextrose Prolotherapy group. Hence both Dextrose Prolotherapy and local corticosteroid injections were effective methods of treatment in plantar fasciitis and suggested by Kim E et al [28] who found that the mean Foot Functional Index total and subcategory score improvements were greater in the PRP group compared with the Dextrose Prolotherapy group.

This finding was also corroborated by Ersen Ö et al [33]who found that VAS and FFI scores were significantly improved in both groups (p<0.001). But overall improvement was better with Dextrose Prolotherapy as compared to local Triamcinolone injections in terms of pain relief and foot function as assessed by VAS and FFI respectively.

Conclusion

Hence both Dextrose Prolotherapy and local corticosteroid injections were effective methods of treatment in plantar fasciitis. But overall improvement was better with Dextrose Prolotherapy as compared to local Triamcinolone injections in terms of pain relief and foot function as assessed by VAS and FFI respectively. Improvement in pain and FFI in Dextrose Prolotherapy group should be taken with caution as a larger sample with longer follow-up duration is needed to observe the long term effects of these two different methods of treatment.

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