EFFECTIVENESS OF DEXTROSE PROLOTHERAPY IN CHRONIC PLANTAR FASCIITIS: A CROSS-SECTIONAL STUDY

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ARTICLE INFO

Received: 18 January, 2023
Accepted: 12 March, 2023
Published: 19 August, 2023

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ORA 335

DOI: https://doi.org/10.3126/bjhs.v8i1.57281

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Citation

Effectiveness Of Dextrose Prolotherapy In Chronic Plantar Fasciitis: A Cross-sectional Study. Ajay Mahato, Mithlesh Kumar Gupta, Rajan Panthee, Manish Raj Pathak, Santosh Nepal. BJHS 2023;8(1)20.1927-1931.

ABSTRACT

Introduction

Plantar fasciitis is a very common musculoskeletal condition encountered in the outpatient department of orthopedics. It's the most common cause of heel pain. Patients have pain on weight-bearing, which limits their activities. Usually, plantar fasciitis is diagnosed on the basis of history and clinical examination; however, X-ray and USG can be helpful in atypical presentations. Mostly, plantar fasciitis is managed conservatively, which includes stretching exercises, footwear modification, ultrasonics, and injections. Prolotherapy is a very cost-effective, and OPD-based procedure that has shown promising results in many tendinopathies. There are no other risks involved in this procedure, and patients can start light activities immediately after the injection.

Objective

To evaluate the efficacy of dextrose prolotherapy in the treatment of chronic resistant plantar fasciitis (PF).

Methodology

This prospective, cross-sectional study, was conducted from July 2021 to December 2021 at Birat Medical College Teaching Hospital after taking permission from the Institutional Review Committee (IRC). Patient selection was done using inclusion and exclusion criteria. A total of 66 patients were included in the study, who received two prolotherapy injections in a gap of two weeks and were followed up after 12 weeks. Patient's clinical (Visual Analogue Score for pain at rest and activities), functional (Foot Function Index), and ultrasonograhic (plantar fascia thickness) findings were noted pre- and post-test and were evaluated.

Result

There were 66 adult patients included in the study, out of which 39 patients (59.1%) were female and 27 patients (40.1%) were male. Their age ranged from 26 to 68 years, with a mean age of 43.91 and a standard deviation (SD) of 10.225. The mean BMI was 25.758 with an SD 2.69 (range: 19.6-33.2). The clinical score (VAS-R and VAS-A), functional score (FFI), and ultrasonographic findings (PF thickness) yielded significant outcomes following prolotherapy.

Conclusion

Prolotherapy is a safe, economical, and effective treatment module for plantar fasciitis that has shown significant improvement in pain, functional outcomes, and patient satisfaction.

KEYWORDS

Prolotherapy injection; plantar fasciitis; heel pain



INTRODUCTION

Plantar fascia (PF) is an aponeurosis (thick connective tissue) extending from the calcaneal tuberosity to the heads of the metatarsals that support the arch of the foot. Due to the repetitive micro-trauma, there is tendinopathy over the calcaneal tuberosity, leading to heel pain, also known as Plantar Fasciitis (PF). The pain is usually worse while getting out of bed in the morning, fades gradually with activities, and starts up again on prolonged standing, thereby limiting the activities. In a recent systematic review and metaanalysis, excessive dorsiflexion, a high body mass index (BMI), and a high body mass were considered the most important risk factors for plantar fasciitis. Plantar fasciitis is usually diagnosed on a patient's history and clinical examinations. Other diagnostic modalities, such as X-rays, ultrasound (US), and Magnetic Resonance Imaging (MRI) do help in atypical cases. A calcaneal spur can be seen on x-rays, and thickening of plantar fascia >4mm is usually suggestive of PF. US is also helpful in monitoring disease activity during the rehabilitation period. 3-6

PF is usually managed conservatively by most clinicians. Conservative methods include stretching exercises, non-steroidal anti-inflammatory drugs, arch support, night splints, physical therapy, extracorporeal shockwave therapy (ESWT), and injections.^{7,8} Injections include corticosteroids, platelet-rich plasma (PRP) therapy, administration of botulinum toxin, acupuncture, dry needling, and prolotherapy.⁹ Although corticosteroids have shown short-term effectiveness in relieving the pain of PF, the long-term effect is still not clear.¹⁰

Prolotherapy (PrT) is an injection-based technique in which a small amount of irritant solution is injected at the degenerated site. Animal model studies suggest there is local inflammation at the injection site, which stimulates growth factors, thereby stimulating fibroblasts and repairing the degenerative musculoskeletal conditions. Hyperosmolar dextrose solution is commonly used, usually three times in short intervals, to stimulate healing. Prolotherapy is also associated with minimal to no complication risks and a high success rate with a short period of rehabilitation.¹¹

Despite the good results of prolotherapy, only a few studies have been done to support its efficiency. Hence, this study is done to establish the efficacy of dextrose prolotherapy using clinical, functional, and sonographic tools, so that this cost-effective, no-risk procedure can be brought into practice in patients who have failed other conservative measures.

METHODOLOGY

This prospective, cross-sectional study, was conducted from July 2021 to December 2021 at Birat Medical College Teaching Hospital after taking permission from the Institutional Review Committee (IRC). Patient selection was done using inclusion and exclusion criteria. Inclusion criteria included (i) 18 years of age or older (ii) having unilateral resistant heel pain for at least six months (iii) having

undergone non-steroidal anti-inflammatory therapy for at least one month, exercise therapy, and arch support among other conservative treatments but with no desired outcome (iv) morning pain measured by the visual analog scale (VAS) being above 5 (v) plantar fascia thickness measured by ultrasonography being >4 mm, and (vi) providing informed consent. Exclusion criteria included (i) bilateral PF (ii) presence of other diseases of the foot or ankle (arthritis, old or new fractures, tarsal tunnel syndrome, etc.) (iii) history of surgical treatment for PF (iv) having received steroid injections for PF within the last six months (v) having undergone oral non-steroidal anti-inflammatory therapy in the last week (vi) presence of chronic pain syndromes (vii) being diagnosed with diabetes mellitus, rheumatologic disease, central neurologic diseases (epilepsy, cerebro vascular disease, etc.) or mental disorders causing lack of insight and judgment (schizophrenia spectrum and other psychotic disorders, bipolar and related disorders, etc.) (viii) the presence of peripheral vascular disease or peripheral neuropathy related to the lower extremities (ix) having a disorder or using medication that impairs the bleeding profile (x) Presence of infection at the injection site. A total of 66 patients were included in the study, who received two prolotherapy injections in a gap of two weeks and were followed up after 12 weeks. The objective of the study was to evaluate the efficacy of prolotherapy injections in patients with chronic plantar fasciitis.

Ultrasound Examination

All the ultrasound (USG) examinations were done by a single radiologist using the Voluson S10 Expert (GE Healthcare) with a frequency of 5-17 MH. The first USG was done before prolotherapy, the thickness of the PF was noted, and patients with PF thickness >4 mm were included in the study (Fig 1). The second USG was done at 12 weeks following the second injection, and PF thickness was noted again.



Figure 1: Shows an ultrasound image of the plantar fascia at the calcaneal insertion, with an arrow pointing to a marked cursor indicating thickened (>4 mm) plantar fascia.

Hyperosmolar Dextrose Injection

Using a 27 gauge needle, 1 ml of 50% dextrose solution (25gm/50ml) mixed with 1 ml of 2% lidocaine; making the strength of dextrose <u>25%</u>, was injected by palpation technique at plantar fascia attachment sites by a single health professional expert in musculoskeletal prolotherapy.



The procedure was done following all aseptic guidelines. Following prolotherapy, no NSAIDs were given for 72 hours to avoid interaction with the action of dextrose prolotherapy. The patients were asked to follow up after two weeks for the second prolotherapy injection. They were asked to avoid heavy activity for at least 12 weeks.

Data Collection and Analysis

After informed written consent, clinical details and findings were noted as per the proforma and questionnaires. Visual Analogue Scale at Rest (VAS-R), Visual Analogue Scale at Activity (VAS-A), Foot Function Index (FFI), and PF thickness were noted before prolotherapy and 12 weeks after the second injection. The data were collected and analyzed using IBM SPSS version 23. MS Excel was used for data entry. A P-value of <0.05 was considered significant.

RESULTS

There were 66 adult patients included in the study, out of which 39 patients (59.1%) were female and 27 patients (40.1%) were male. Their age ranged from 26 to 68 years, with a mean age of 43.91 and a standard deviation (SD) of 10.225. The mean BMI was 25.758 with an SD 2.69 (range: 19.6-33.2). There were significant improvements (p<0.05) noted in VAS-R, VAS-A, FFI, and ultrasonographic findings (PF thickness). The clinical score (VAS-R and VAS-A), functional score (FFI), and ultrasonographic findings (PF thickness) details are depicted in the below-mentioned table 1.

Table 1: A summary of baseline and outcome scores for VAS-R (Visual Analogue Scale at Rest), VAS-A (Visual Analogue Scale at Activity), FFI (Foot Function Index), and Plantar Fascia (PF) thickness and their statistical significance

	Before Prolotherapy	After Prolotherapy	
	Mean (SD)	Mean (SD)	P Value
VAS-R	8.09 (0.74)	1.65 (0.54)	<0.05
VAS-A	7.91 (0.67)	1.95 (0.64)	<0.05
FFI score	76.72 (1.50)	18.95 (5.09)	<0.05
PF Thickness	4.60 (0.48)	3.02 (0.45)	<0.05

DISCUSSIONS

Plantar fasciitis is a chronic overuse injury leading to degenerative changes, that is, the breakdown of type I collagen and proteoglycans. This ultimately reduces the strength of the fascia and predisposes it to reinjury. The present study shows significant improvement in VAS-R, VAS-A, FFI, and plantar fascia thickness in patients who have received prolotherapy.

Prolotherapy is believed to be an effective therapeutic measure in cases of chronic tendinitis such as lateral epicondylitis, and plantar fasciitis. The mechanism works on the principle which helps in the adequate formation of fibroblasts and connective tissue. ^{15,16} Prolotherapy is the local infiltration of a hypertonic dextrose solution or an

irritant solution. One of the mechanisms suggests the initiation of an inflammatory cascade, ultimately leading to the sclerosis of the pathological tendons, fascia, etc. However, another theory suggests that the stimulation of growth factors ultimately helps in soft tissue healing. 17,18

Regenerative injection therapy, also known as prolotherapy, has shown effectiveness in treating painful ligament and tendon pathologies. The study also suggests the formation of collagen and fibroblast proliferation, which are associated with the strengthening of tendons and ligaments, improved joint function, and pain reduction. ^{19,20}

Nowadays, multiple injection-based procedures are in practice for chronic plantar fasciitis. The commonly practiced procedure is a local steroid injection, which has shown promising results in decreasing inflammation, and, ultimately, pain reduction. Although the use of local steroids has shown good short-term benefits, there are several side effects associated with its use such as localized infection, calcaneal osteomyelitis, lateral plantar nerve injury, plantar fascia rupture, and plantar fat pad atrophy. 21,22 Platelet-rich plasma (PRP) is another injection-based procedure that has shown good results in plantar fasciitis. PRP has shown good tissue healing, pain relief, and functional as well as clinical outcomes. However, PRP is an invasive procedure and also lacks a standardized preparation protocol. Prolotherapy, when compared to steroid injections and PRP, is simple to prepare, easy to use, non-invasive, less costly, and provides better and longer duration of tissue healing. 21,23

In a systemic review and meta-analysis on the effectiveness of dextrose prolotherapy in plantar fasciitis done by Wei-Fu Lai et al, six studies with 388 patients diagnosed with plantar fasciitis were included in the meta-analysis. The study revealed better pain scores improvement and functional outcomes in the long term for patients treated with dextrose prolotherapy compared to those treated with the corticosteroid injections, and the physiotherapy group. However, no significant differences were found between patients treated with dextrose prolotherapy and plateletrich plasma. The meta-analysis concluded dextrose prolotherapy as a safe and effective treatment option, and also emphasized further studies with a standardized protocol.²⁴

In a study conducted by Ersen et al, a randomized-controlled trial was done on 26 patients receiving prolotherapy and 24 patients in control groups. The study concluded significant improvements in VAS, FAOS (Foot and Ankle Orthopedic Society), and FFI scores at 42 and 90 days of follow-up, which is consistent with the present study.²⁵

In a pilot study conducted by Maxwell et al, sonographically guided intratendinous injections of hyperosmolar dextrose were given to patients with Achilles tendinosis. The study yielded a significant decrease in VAS pain scores at rest and during loading activities. ²⁶ Ryan et al conducted a pilot study in which they gave ultrasound-guided dextrose/lidocaine injections to 20 patients with chronic plantar fasciitis. The result showed significant improvement in pre-test and posttest VAS values, which is in correlation with our study. ²⁷



Yelland et al conducted a randomized trial for painful Achilles tendinosis. They formed 3 random groups: the first group received prolotherapy, the second group with eccentric loading exercises, and the third group received both treatments. They showed better results with groups receiving both treatments than with the other two groups ²⁰ Scarpone et al conducted a pilot study in which prolotherapy was used for treating lateral epicondylitis. The study showed improved long-term effects of prolotherapy in patients with refractory lateral epicondylitis. ²⁸ Yildiz et al in their study followed the protocol of three injections of Prolotherapy three weeks apart in recreational athletes suffering from patellofemoral pain syndrome and achieved significant clinical improvement. ²⁹

In a study conducted by Ang et al, steroid injections were given using an ultrasonography-guided technique and a palpation technique. Both techniques showed no significant difference between the groups at the end of the 25th month suggesting that palpation technique is equally effective compared to ultrasonographic-guided injection. ³⁰ Similarly, in a study conducted by Yucel et al, a comparison was done that included three techniques for steroid injections. The techniques were ultrasound-guided, palpation-guided, and scintigraphy-guided steroid injections. The study concluded that steroid injections can be given either by the ultrasoundguided technique or by the palpation method without any significant difference.³¹ Both the studies, Ang et al and Yucel et al, support our palpation technique method used for prolotherapy. AH Apaydin et al in their study followed the protocol of two injections of prolotherapy in recreational athletes with plantar fasciitis, given two weeks apart, and showed significant improvement in VAS and Foot and Ankle outcome scores.³² In our study as well, we gave two prolotherapy injections two weeks apart and yielded similar results.

CONCLUSION

There are multiple treatment modalities for chronic plantar fasciitis, which include both conservative and surgical management. However, dextrose prolotherapy can be considered a safe, economical, and effective treatment module for plantar fasciitis that has shown significant improvement in pain, functional outcomes, and patient satisfaction.

RECOMMENDATIONS

This study recommends the safe and effective application of dextrose prolotherapy injection as an alternative treatment module in cases of chronic plantar fasciitis.

LIMITATION OF THE STUDY

A few limitations of the study were: 1. No control group or randomization, 2. short-term follow-up 3. A small sample group 4. Lack of specific prolotherapy guidelines

ACKNOWLEDGEMENTS

We would like to acknowledge our head of department, our study participants, and the staffs of Birat Medical College Teaching Hospital and statisticians who helped constantly during this study.

CONFLICT OF INTEREST

The authors have no conflict of interest.

FINANCIAL DISCLOSURE

The authors received no financial support for the research.

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