WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 6.805
Volume 5, Issue 6, 1552-1561. Research Article ISSN 2277– 7105

EFFICACY OF PLANTAR IONTOPHORESIS WITH AQUEOUS SOLUTION OF GUGGULU RESIN IN THE MANAGEMENT OF PADA-KANTAKA (PLANTAR FASCIITIS): A PILOT STUDY

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Article Received on
14 April 2016,
Revised on 05 May 2016,
Accepted on 26 May 2016
DOI: 10.20959/wjpr20166-6358

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ABSTRACT

Pada-kantaka is a pathological condition caused by the vitiated vata and kapha. Aggravated vata takes ashraya in gulfa sandhi & padatala leading to the development of Pada-kantaka. As per the textual references available in Ayurveda, the clinical features of Plantar fasciitis can be accurately related with Pada-kantaka. Plantar fasciitis is the most common cause of chronic pain beneath the heel in adults. It is estimated that 1 in 10 people develop Plantar Fasciitis during their lifetime. Though frequent association with calcaneal spur in radiological findings is noted, still the degenerative process of plantar fascia is to be considered the main underlying pathology of Plantar Fasciitis. Rest, NSAIDs with physiotherapy is the first line of management followed by local injection of steroid are administered in most of cases for immediate relief. So an effort has been made to evaluate the efficacy of plantar Iontophoresis with aqueous solution of Guggulu resin in the management of Pada-kantaka (plantar fasciitis). Plantar Iontophoresis with aqueous solution of Guggulu resin yielded overall relief of 83.81%.

KEYWORDS: Aqueous solution of Guggulu Resin, Iontophoresis, Plantar fasciitis.

INTRODUCTION

Plantar fasciitis (PF), also known as Plantar fasciopathy or Jogger's heel, tennis heel, policeman heel is a common painful enthesopathy of the heel and plantar surface of the foot characterized by inflammation, fibrosis, or structural deterioration of the plantar fascia of the foot. This is commonly encountered condition in middle aged, overweight persons, whose work involves prolonged standing. As the pain in the heel is aggravated on weight bearing, it affects adversely daily activities and is often responsible for loss of many man hours of work.[1] The aetiology and treatment of the condition are poorly understood. Chronic cases of plantar fasciitis often demonstrate more degenerative changes than inflammatory changes and such cases are termed as plantar fasciosis.[2] Calcaneal spur is a common associated finding, but could not be related to the disease process. Though it is a self-limiting disease, due to it's sharpness of pain and long duration of course most of the patients bound to seek medical intervention.

Snehan, Bandhan, Raktamokshana and Agni-karma are the treatment for the Pada-kantaka.[3] Cold and heat application, splints, stretching and orthosis and non-steroidal anti-inflammatory drugs are the first line of treatment for this condition. Local infiltration of steroids is the commonest choice of treatment for resistance cases, but steroids are having a long list of side effect.[4] So, nowadays lots of alternative treatment are suggested with some merit and demerits. Extra-corporeal shock wave therapy, Autologous platelet rich plasma (PRP), and at last surgery are the recommended treatment. Recently Plantar Iontophoresis gaining popularity due to its simplicity of procedure and effectiveness.

Plantar Iontophoresis

Plantar Iontophoresis is a technique which involves applying anti-inflammatory substances topically to the plantar fascia and facilitating the permeation of the agent through the skin. Iontophoresis a physical process in which ions flow diffusively in a medium driven by an applied electric field.[5]

Plantar Iontophoresis drives a charged substance, usually a medication or bioactive agent, transdermally by repulsive electromotive force, through the skin. Plantar Iontophoresis with Aqueous solution of Guggulu resin may be an effective alternate for the management of plantar fasciitis.

INTERVENTION

Plantar Iontophoresis with Aqueous solution of Guggulu Resin.

Method to constitution of Aqueous solution of Guggulu resin

This is done following the method suitable for extracting water-soluble, heat stable constituents.

Step I

200 gm. of Guggulu resin is boiled in 800ml of distilled water till it get completely dissolved. After cooling it is filtered with filter paper.

Step II

Liquid extract is than kept in hot air oven at 1100 degree centigrade temperature for removal of water from the solution constituted in first step via evaporation. Liquid extract is placed in hot air oven till it dry up completely leaving behind dry powder.

Step III

20 gms of dry extract obtained via step II is mixed with 200ml of distilled water and heated up to temperature around 60 degree centigrade till it get completely dissolved. After cooling up-to body temperature it is used for Plantar Iontophoresis.

Methodology

First clean the skin with spirit and dry it to remove all traces of dirt and sebum, for skin resistance. Aqueous solution of Guggulu resin is taken in the plastic container for Iontophoresis and electrode is keep inside the containers. The affected part of the sole is kept in contact firmly with the electrode within the Guggulu solution. The other electrode is kept on firm contact with other sole. The device is turned on and the current start flowing from zero till the patient get a comfort tolerance level. The level of tolerance is normally 3 mA for the face and about 12 mA for other area.[6] The time of application may be increased on subsequent visits if required for check for about 2-3 min. and taking 15-20 min for the whole face when the procedure is complete on the affected area the current is gradually reduced just above zero[7] and a quick repetition of procedure done over the same area to allow chemicals effect to to be complete and not leave chemical residue on skin. In case of painful and burning sensation during the treatment it should be terminated and the current reverse should be done immediately to neutralize the irritation.. As Iontophoresis apparatus has two plates,

one of these is positively charged & other being negatively charged plate. On the contrary Aqueous solution of Guggulu resin when used for Iontophoresis through positively charged plate resulted in to much better outcome in comparison to the instance in which Iontophoresis with Aqueous solution of Guggulu resin is done through negatively charged plate. These outcomes have been noticed during the pilot study done in the pre clinical trial period.

MATERIALS AND METHODS

Aims & objectives

To study the effectiveness of Plantar-Iontophoresis with Aqueous solution of Guggulu resin in case of Plantar Fasciitis (Pada-kantaka).

Clinical Study

The study has been planned as per following protocol.

Plantar Iontophoresis has been done using standard protocol with Aqueous solution of Guggulu resin on alternate days for two consecutive weeks followed by standard instructions to the patients.

Sample size

Total number of trial subjects = 10

Total 10 patients have been randomly selected for the study, irrespective of age, gender, religion etc.

Source of data

i) Patients visiting Shalya- Tantra OPD of National Institute of Ayurveda, Jaipur have been selected for the study.

ii) The study has been explained clearly to the subjects and their written informed consent has been taken before starting the trial.

Ethical clearance

The study was designed after clearance given by ethical committee. My ethical clearance no is F 10 (5/EC/2014/7217/Date 07-11-2014.

Inclusion criteria

Patients presenting with the clinical features of Plantar fasciitis (Pada-kantaka) will be taken for the study irrespective of their age, gender, caste creed etc.

Exclusion criteria

i) Patient not consenting to the trial.

ii) Patients having open surgical procedure of plantar fascia.

Criteria for withdrawal

During the course of trial if any serious condition or any serious adverse effects arise-

a) That requires specific treatment.

b) Patients who himself/ herself want to withdraw from the clinical trial.

Laboratory investigations

i) Routine Blood Investigations.

ii) X-ray Ankle joint – Lateral view

Study design

The study was an open study in which 10 patients were selected on the basis of clinical assessment.

Plan of Intervention

Patient has been intervened by Plantar Iontophoresis with Aqueous solution of Guggulu resin on the plantar aspect.

Intervention (Plantar Iontophoresis)

Total Sittings Planned	-	Six.
Regimen	-	Thrice a week on alternate days for two weeks.
Time duration	-	20 minute for each sitting.

Assessment Criteria

Concerning the main presenting feature i.e. pain in Plantar Fasciitis, it is of worth mention that owing to its different sort of character an effort has been made to assess the efficacy of intervention in more elaborated way on following criteria.

A. Subjective Criteria

Pain Spontaneous

Pain (Rujah) Spontaneous	Grade
No Pain	0
No pain on rest but slight pain occurs after exertion	1
Pain present at rest but mild pain	2
Pain present at rest but moderate pain	3
Severe Pain present even at rest	4
Worse pain	5

Pain on walking

Pain (Rujah) on walking	Grade
No pain	0
Pain on walking occurs immediately after getting from bed for 30 min	1
Pain on walking occurs after getting up from bed for 30 min. to 2 hrs.	2
Continuous pain	3

In the present study VDS has been used both as scale as well as the parameter to quantify the pain as per the criteria mentioned above as under

VDS Score	Pain Quantification
1 & 2	Slight Pain
3 & 4	Mild Pain
5 & 6	Moderate Pain
7 & 8	Severe Pain
9 & 10	Extremely Severe pain

Verbal Descriptive Scale (VDS) for pain

The pain scale (Numeric rating scale)

Severity of the pain	Grade
No Pain	0
Pain is very mild, barely noticeable, most of the time not think about	1
Minor pain, annoying, may have occasional strong twings	2
Pain is noticeable & distracting however you can get used to it & adapt	3
Moderate pain if you deeply involved in an activity, it can be ignored for a period of time,but is still distracting.	4
Moderately strong pain, it can be ignored for more than few minutes, but with efforts, you still can manage to	5
Moderately strong pain, that interfere with normal routiene,with difficulty in concentrating.	6
Severe pain that dominates your senses & significantly limit the ability to perform the daily activities.	7
Intense pain physical activity is severely limited.	8
Excruciating pain unable to conserve.	9
Un-speakablepain, bed ridden & possibly delirious	10

B. Objective Criteria

Tenderness	Grade
No pain on pressure also	0
Pain occurs on deep pressure	1
Pain occurs on moderate pressure	2
Pain occurs on touch	3

Criteria for Assessing the overall Effect

Considering the overall improvement shown by the patients in symptoms and signs, the total effect of the therapy assessed as below.

Criteria for overall assessment of results

1. Very Good response: Complete relief in presenting symptoms and signs of the disease.
2. Good response: 75% and above relief of symptoms and signs
3. Fair response: 50% to 74% relief of symptoms and signs
4. Poor response: Somehow relief to 49% relief of symptoms and signs
5. No response: No response in presenting symptoms and signs of the disease.

OBSERVATION AND RESULTS

Table 1: Table showing the on Assessment parameters of Plantar Fasciitis on 3rd, 7th, 14th day after Plantar Iontophoresis with Aqueous solution of Guggulu resin.

S. No.	Name of features	Number of the Patients	Mean score B.T.	Mean Score		
				3rd Day	7th Day	14th Day
1.	Pain Spontaneous	10	3.4	2.7	1.8	0.3
2.	Pain on walking	10	2.7	2.4	1.7	0.4
3.	VDS	10	6.7	5.2	2.9	0.5
4.	Tenderness	10	2.8	2.5	1.4	0.4

Table 2: Table showing the effect of Plantar Iontophoresis with Aqueous solution of Guggulu resin after completion of 6 sittings (on 14th day) in plantar Fasciitis

S.No	Name of features	No of patients	Mean		MD	SD	SE	"P"	% Relief
			B.T	A.T					
1	Spontaneous Pain	10	3.4	0.3	3.1	0.3162	0.1	<0.002	91.17%
2	Pain on walking	10	2.4	0.4	2.3	0.4830	0.1528	<0.002	85.18%
3	VDS	10	6.7	0.5	6.2	0.4216	0.1333	<0.002	92.53%
4	Tenderness	10	2.8	0.4	2.4	0.5164	0.1633	<0.002	85.71%

Table: 3 Overall relief in Plantar Iontophoresis with Aqueous solution of Guggulu resin

1	Spontaneous pain	0.3	91.17%	Good response
2	Pain on walking	0.4	85.18%	Good response
3	VDS	0.5	92.53%	Good response
4	Tenderness	0.4	85.71%	Good response

RESULT & DISCUSSION

1. Effect on spontaneous Pain

Mean score of spontaneous pain B.T. was 3.4 which was reduced to 2.7 with relief of 20.59%

on 3rd day (i.e. after 1 sitting); 1.8 with relief of 47.05% on 7th day (i.e. after 3 sitting) and 0.3 with relief of 91.17% on 14th day (i.e. after 6 sitting). This was statistically very significant ($P < 0.002$).

2. Effect on Pain on walking

Mean score of pain on walking was 2.7 B.T. which reduced to 2.4 with relief of 11.11% on 3rd day, (e.g. after 1 sitting); 1.7 with relief of 37.03% on 7th day (i.e. after 3 sitting) and 0.4 with relief of 85.18% on 14th day (i.e. after 6 sitting. This was again found Statistically very significant ($P < 0.002$).

3. Effect on Pain Score on Verbal Descriptive Scale (Numeric scale)

Mean score of pain was 6.7 B.T. it was reduced to 5.2 with relief of 22.38% on 3rd day, (i.e. after 1 sitting); 2.9with relief of 56.71% on 7th day (i.e. after 3 sitting) and 0.5 with relief of 92.53% on 14th day(i.e. after 6 sitting). This was again found Statistically very significant ($P < 0.002$).

4. Effect on Tenderness

Mean score of tenderness B.T. was 2.8 which was reduced 2.5 with relief of 17.86% on 3rd day, (i.e. after 1 sitting); 1.4 with relief of 50% on 7th day (i.e. after 3 sitting) and 0.4 with relief of 85.71% on 14th day (i.e. after 6 sitting). This was again found Statistically very significant ($P < 0.002$).

CONCLUSION

Plantar Fasciitis is one among the commonly encountered entities. In the present study Pada-kantaka has been correlated with Plantar Fasciitis. The disease is actually a degenerative condition that may occur with or without inflammatory changes along with fibroblastic proliferation. The addition under the heading of electrotherapy are considered to be inclusions under Agni karma as refined & more acceptable alternate measures for traditional Agni karma.

The Iontophoresis procedure is easy to operate, found totally safe, no hospitalization is required and providing quick relief to the patients. Aqueous solution of Guggulu resin when used for Iontophoresis through positively charged plate resulted in to much better outcome in comparison to the instance in which Iontophoresis with Aqueous solution of Guggulu resin is done through negatively charged plate. All 10 number of patients were intervened as per

study design using the Aqueous solution of Guggulu resin yielded overall relief of 83.81%. Overall study concluded that Aqueous solution of Guggulu resin is significantly effective in the management of Plantar Fasciitis (Pada-kantaka). Guggulu as a whole or its active principles particularly Guggulsterone could be held responsible for the effect found in current study. This effect could be attributed to its Vatahara properties and the suppression of DNA binding of NF-κB induced by TNF along with COX-2–inhibitory activity, in Plantar Fasciitis. No ADR (Adverse reaction) of intervention has been reported during the trial or Follow up period.

Mode of action of intervention

Plantar Iontophoresis with Aqueous solution of Guggulu resin

The active ingredients of Guggulu resin, permeate through intact skin of the sole and reach the plantar fascia. Plantar fascia being fibrous tissue with limited blood perfusion retain the drug for a relatively longer time. This might explain the anti-inflammatory, analgesic effect of Aqueous solution Guggulu resin in an efficient way in plantar fasciitis.

As Inflammation is mainly caused by activation of inflammatory signal pathways such as the NF-κB signal pathway and release of inflammatory mediators such as the pro-inflammatory cytokines (e.g. TNF and IL-1β) and pro-inflammatory enzymes that mediate production of prostaglandins (e.g. COX-2) and leukotrienes (e.g. lipo-oxygenase), together with expression of adhesion molecules and MMPs. Cyclo-oxygenase 2 (COX-2) converts arachidonic acid into prostaglandins and prostanoids. COX-2 induction is responsible for inflammation and pain. Guggulsterone And other active principles present in aqueous solution of guggulu resin, prevent cytokine induced cell damage. Guggulsterone suppresses the inflammation by inhibiting inducible nitric oxide synthetase (iNOS) expression induced by lipopolysaccharide in macrophages. Because the inflammations are mediated through the activation of NF-κB, a nuclear transcription factor and Guggulsterone suppresses DNA binding of NF-κB induced by TNF. The COX-2–inhibitory activity of guggulu may explain in part its anti-inflammatory activity in plantar fasciitis.

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