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A Protocol on Efficacy of Jalaukavacharan in Comparision to Agnikarma in Themangement of Vatakantaka (Planter Fasciatis)

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ABSTRACT:

The word Vata mainly denotes movement and which is the main cause for action and Kantaka means point of a needle which is like a thorn, which becomes troublesome; which produces a sharp stinging pain. So Vatakantaka refers to a condition caused by vata characterized by a sharp stinging pain at the heel. Planter Fasciitis is occurring as result of inflammation of plantar apo neurosis at its attachment on the tuberosity of the calcaneus. It is characterized by pain, swelling in the foot. The pain is usually severe with the first step of the day or following a period of rest. Vatakantaka can be correlate with Planter fasciitis. Based on the wide use of either Jalaukavcharan or Agnikarma by Ayurveda practitioners in treating vatakantaka, Jalaukavcharan and Agnikarma can be considered as one treatment in Ayurveda. Here to find out the efficacy of Jalaukavacharan in comparison to Agnikarma in management of vatakantaka (Plantar Fasciitis) will be done. For this topic assessment will be done by clinical trial.

Aim and Objectives: To Evaluate of effectiveness of Jalaukavacharan in Vatakantak in comparison with Agnikarma. Objectives: 1) To study the efficacy of Jalaukavcharan in Vatakantak. 2) To study the efficacy of Agnikarma in vatakantak. 3) To compare the efficacy of Jalaukavcharan with Agnikarma in Vatakantak. **Methodology:** This is a Randomized clinical trial. Approval of the study will be taken after presentation from institute's ethics committee.

Results: Observation will be noted & presented in the form of tables. Discussion will be drawn from the observations and results of individual groups and comparative statistical Analysis. A number of articles related to agnikarma, jaloukavacharan and vatakantaka ,plantar fasciitis conditions available in this region will be reviewed **Conclusion:** By this comparative clinical trial , prevention of progression of the vatakantaka(plantar fasciitis) can be achieved. This study helps to establish the covalent bond between the disease and its ideal treatment based on the relative predominance of dosha among them.

Keywords: Vatakantaka, Plantar Fasciatis, Agnikarma, Jaloukavacharan.

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1. Introduction

The word Vata mainly denotes movement and which is the main cause for action and Kantaka means point of a needle which is like a thorn, which becomes troublesome; which produces a sharp stinging pain. So Vata Kantaka refers to a condition caused by Vatacharacterized by a sharp stinging pain at the heel. The earliest reference regarding Vatakantakais available in Sushruth Samhita (1500 B C). Sushrutha explains this disease in the context of Vatavyadhi as a painful condition of heel caused by improper landing of foot (“Vishama”) during walking or running.^[1]

Vatakantaka is not a vital condition as it do not cause any harm to life, however It lead to difficulty in walking or standing for participant which affects his/her daily routine work, which alters quality of life. Therefore it is important to look after this condition. Planter fasciitis is a common cause of heal pain affecting 10% of the general population, men usually between 40-70 are affected more than women.^[2] Also in sports field, Athletics (e.g. runners) are more prone to affect with planter fasciitis. Planter Fasciitis is occurring as result of inflammation of plantar aponeurosis at its attachment on the tubrosity of the calcaneum. It is characterized by pain, swelling in the foot. The pain is usually severe with the first step of the day or following a period of rest.^[3]Vatakantaka can be correlate with Planter fasciitis. Ancient seers of Ayurveda were well aware of Vatakantaka and have mentioned its pathophysiology along with principle of its management. Line of management of Vatakantakais briefly mentioned by Govind Das in his treatise Bhaishajya Ratnavali. (Bhai. Ratnavali 26/49) In Ayurveda there are few management criteria's available for Vatakantaka (plantar fasciitis); for e.g. Raktavsechan, Agnikarma and Eranda Tailpaan.^[4] Use of NSAID's and corticosteroids such as Dexamethasone is the common line of treatment of plantar fasciitisin modern medicine ^[5]. However the effect of Ayurveda interventions is not much established with scientific database and thus its need to establish. On the other hand, the modern line of treatment is having some adverse effects and requires more time to cure the pain of Vatakantaka (Planter fasciitis).

Keeping in view of the lacunas of different medical treatments, there is a need for an effective, safe, economical, simple and short term therapy. Based on the wide use of either Jalaukavcharan or Agnikarma by Ayurveda practitioners in treatingVatakantaka, Jalaukavcharan and Agnikarma can be considered as one treatment in Ayurveda which can overcome the above said lacunas. Hence this study is taken up to explore the comparative effectiveness of Jalaukavcharan and Agnikarma as an effective and economical treatment for Vatakantaka.

Rationale of the study

In Ayurveda, Agnikarma is mostly utilized intervention for management of Vatakantak and the same has been elaborated by few published researches. However, the narration of Bhaishajya Ratnavali, Gadanigraha and Chakradatta clearly emphasizes significance of Raktavasechanin management of Vatakantaka. Jalaukavacharan is considered as best way for Raktavasechan. Various researches have evaluated efficacy of Agnikarma and found it extensively useful in treatment of Vatakantaka. On the other hand, there is lack of research evidences in context of efficacy of Jalaukavacharan in treating Vatakantaka, however it is found that Jalaukavacharan has been successfully utilized in management of diseases which have bit similar pathology to that of Vatakantaka for e.g. Tennis Elbow. Hence there is need to study the role of Jalaukavacharan in comparison to Agnikarma. Such research will help to know why the ancient seers of Ayurveda have narrated Raktavasechanfirst and foremost than Agnikarma. This study will elaborate the significance level of both the interventions and also an explanation of classical claim.

Research Question

Is Jalaukavacharan more effective than Agnikarma in the management of Vatakantaka?

Hypothesis

Alternative Hypothesis

Jalaukaavacharan may be more effective than Agnikarma in the management of Vatakantak

Null Hypothesis

Jalaukaavacharan may not be effective than Agnikarma in the management of Vatakantak.

Aim:

Evaluation of effectiveness of Jalaukavacharan in Vatakantak in comparison with Agnikarma.

Objectives

- 1) To study the efficacy of Jalaukavcharan in Vatakantak.
- 2) To study the efficacy of Agnikarma in vatakantak.
- 3) To compare the efficacy of Jalaukavcharan with Agnikarma in Vatakantak.

2. Materials Methods

Source of Data

Data will be collected in OPD and IPD of study Centre DMIMSU, Recognized study Centre.

Type of Study: Open Randomized clinical comparative trial.

Study Duration – 3 years

Sampling procedure:

Participants were selected using purposive sampling method and then divided into two groups randomly using simple random sampling.

Grouping

Study Group: Group A - Jalaukavacharan therapy

Control Group: Group B - Agnikarma Therapy

Sample size: 100 patients in each group.

Sample size calculation by using following formula

$$n = \frac{Z_{\alpha/2}^2 \times P(1-P)}{d^2}$$

Where, $Z_{\alpha/2}$ is the level of significance at 5 % i.e 95% confidence interval = 1.96

P =plantar fasciitis affection 10% of the general population

d =Desired error of margin =6%=0.06

$$n = \frac{1.96^2 \times 0.10 \times (1-0.10)}{0.06^2}$$

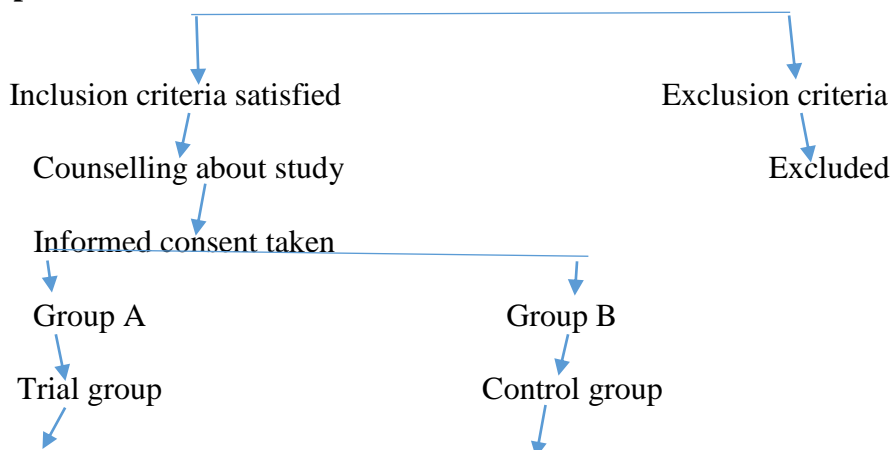
$$= \frac{0.3457}{0.0036}$$

$$= 96.04$$

$$= 96.04$$

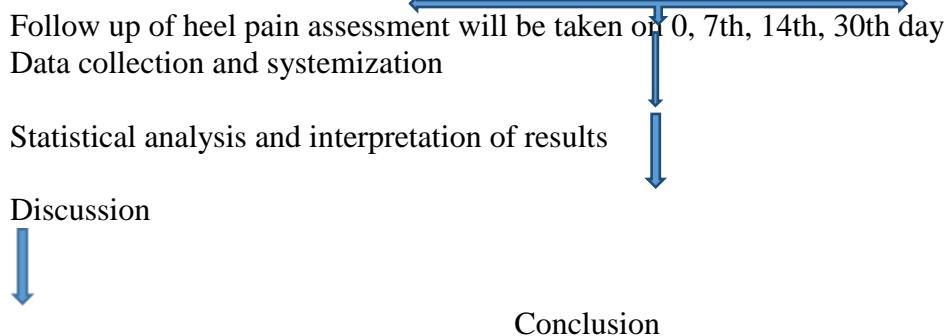
Study plan:(Chart No 1)

Screening of participants



Jalaukavacharan Therapy

Agnikarma Therapy

**Data collection tools and process:**

Participants fulfilling inclusion criteria and willing to give written consent will be enrolled for study. The selected participant will be informed about possible outcome and side effect

Inclusion criteria

1. Participant with age group of 18-60 years.
2. Extreme pain with the first step of the day.
3. Participant irrespective of gender, occupation, economic status.

Exclusion criteria

1. Wounds & Ulcer over foot.
2. Trauma of lower extremity
3. Fractures of bones of leg.
4. Rheumatoid disease of foot and ankle
5. Bleeding disorders
6. Those who are on antiplatelet drugs

Screening Parameters

- USG foot
- X ray foot
- HIV
- HBsAg
- B.T &C.T

Assessment parameters**Subjective parameter**

1) Visual Analogue Scale for Vedana (pain) Assessment

All above Clinical signs and symptoms is note before the treatment. Afterthat corresponding allotted therapy will give. The assessment as follows:

1) Vedana (Pain) by Visual Analogue Scale- theVedana (Pain) is assessed by Visual Analogue Scale. - A 10cm visual analogue scale of pain was used for measurement. - A line of 10cm length was drawn with 0 marking on left side and 10 marking on Right side. - 0=No pain; 5= Moderate pain; 10 = Worst possible pain

No Pain Worst Pain 0 1 2 3 4 5 6 7 8 9 10

~~Mild~~ Moderate Sever

Direction- Ask the patient to indicate on the 10cm line where the pain is in the relation to the two extremes. Ask the patient to indicate on the scale the severity of pain, with 10 being considered the worst pain imaginable.^[18]

Table No.1-

0	No Pain
1	Hardly Notice Pain
2	Notice Pain does not interfere with activities
3	Sometime Distract me
4	Distracts me, can do usual activities
5	Interrupts some activities
6	Hard to ignore, avoid usual activities
7	Focus of attention, prevents doing daily activities
8	Awful, hard to anything
9	Can't bear the pain, unable to do anything.
10	As bad as, it could be, nothing else matters

Quality of Life Score

Quality of life scale created originally by an American Psychologist John Flanagan in 1970s. For use in chronic illness groups. The QLS has low to moderate correlations with physical health status and disease measures for population with chronic disease, measurement of QLS provides a meaningful way to determine the impact of health care when cure is not possible. Revicki and colleagues define QLS as “A broad range of human experiences related to one’s overall well being.. It implies value based on participative functioning.”^[19]

Table No-2

Quality of Life Score Scale				
Responses	0 th day	7 th day	14 th day	30 th day
1) Terrible				
2) Unhappy				
3) Mostly Dissatisfied				
4) Mixed				
5) Mostly satisfied				
6) Pleased				
7) Delighted				

Objective parameter

USG (Ultra sonography) – Before and After Treatment

Details of method and experimental design:

Procedure of Jalaukavcharan:

Poorva Karma

Leeches will be collected from authentic supplier in a container. The cap of that container pierced to make pores. Jalaukas store in fresh water. Water in the container is change every alternate day. Jalauka is taken out of pot and placed in a pot or kidney tray which is filled with a mixture of water and turmeric powder. Jalauka kept in that pot till it regains active movements. Then the Jalauka is ready to apply on affected part of participant. Participants will be explaining about the whole procedure of Jalaukavcharan and how the procedure will be carried out. Written informed consent of Participant will be taken. Affected area will be cleaned with Normal Saline before starting of procedure.

Pradhana karma

Jalauka will be hold with a small gauze piece which covers its body. As the Jalauka taken over affected area, the skin of affected area is catch by Jalauka and it was stick there. In case if Jalauka is unable to bite or catch the desired area, then 1-2 drops of milk will be dropped on the desired part. If the Jalauka will not getting attached by doing so, then the skin at affected area will pricked with sterile needle to take out some blood drops outside as to catch the wound by leech. After the Leech gets attached, its body is covered with a wet gauze piece and drops of normal cool water are continuously dropped on the covering Gauze piece to providing cooling effect. When the leech is properly attached to the affected area and started sucking, the anterior sucker assumes like shape of "Horse shoe". Continuous pulsations and peristaltic wave movements are seen at the time of sucking. As the leech is sucking impure blood, when it is get full up to its capacity of sucking, it detach itself from the catch site. After some time when the participants having sensation of itching and pain at the applied site, it indicated that leech had sucked all the impure blood in the surrounding of applied area now started to suck the pure fresh blood, then the leech is removed from the site. If the leech is not detaching from the catch site even after the proper symptoms of "Raktavasechan" or still sticks to the affected site due to fondness of smell of blood, then it is remove by sprinkling turmeric powder on the attached site.

Paschat karma:

After leech is detached. Affected part is clean with cotton. Sterile dressing is applied. Tight pressure bandage was applied to stop bleeding. After leech is detached from catch site, the vomiting is induced to leech by sprinkling turmeric powder on Jalaukas mouth to expel all sucked impure blood. - This procedure is continued up to the complete vomiting of leech. - The Leech is then place in fresh water; if it is lying dull then vomiting should be repeated. Dull movements of Jalauka indicate that vomiting is not completed. - If leech moves rapidly in water, indicates that vomiting is completed. Leech is put in fresh water after completing the procedure. - Used leech is again applied after 7 days

Procedure of Agnikarma

Poorva Karma:-

Following obtaining informed written consent, a comprehensive clinical examination will be conducted, encompassing the assessment of vital signs. Participants will be counseled to adhere to a diet comprising Guru (heavy), Snigdha (unctuous), Sheeta (cooling), and Pichhila (slimy) components prior to the procedure. Subsequently, participants will be positioned supine on the operation table in the Agnikarma room.

Pradhan Karma:-

The affected part is cleaned with Triphala Kashaya. Then wiped with dry sterilized cotton gauze and draped with sterile sheet. Then Panchadhatu Shalaka heated on gas stove up to red hot. 15-20 Samyak Dagdha Vrana made by Red hot Panch Dhatu Shalaka with Bindu Dahan

Vishesh which penetrate up to Mansa Dhatu. Proper space between two Samyaka Dagdha near about 0.5 cm.

Paschata Karma:-

After making Samyaka Dagdha Vrana, Kumari swaras is applied on that to get relief from burning sensation. Then dusting of Yashtimadhu Churna done on that place. Above procedure will repeat 3 times at an interval of 7 days. Participant is advice to apply Jatyadi Ghrita twice a day up to normal appearance of skin

Procedure used for data collection:

Participants will be selected irrespective of their Age, Gender, Occupation, Religion, Marital status, Economical status etc. Detailed history of all participants will be obtained at the time of primary assessment. Participants will be divided into two groups for this comparative study. Total 200 participants will be selected and they will be divided in two equal groups by random sampling method. Assessment will be done on 0, 7th, 14th day and follow up after intervention will be taken on 30th day.

Data Analysis (statistical methods): -

Detailed history will be taken on specially prepared research proforma and fill record for statistical study. The statistical analysis will be done by using statistical tools.

Statistical Methods

With proper s Statistical analysis:Data will be analyzed by using suitable statistical methods (Z-test, X2-test) and software used in the analysis will be SPSS 22.0 version and Graph pad prism 6.0V and EPI-INFO 6.0 version

3. Assessment of Results

On the basis of both the tratments, in both groups (results) will be assessed regarding the clinical signs and symptoms of vatakantaka. All subjective-objectives parameters will be observed and recorded during observations then the comparison of the inter group relationship and intragroup relationship result of the group will be done.

Ethical consideration:

Study will be startedafter obtaining ethical clearance from IEC.

- Withdrawal Criteria: Patient will be withdrawn from the study if not willing to give proper information of his/her Vatakantaka (Planter Faciatis)
- Consent according to ICMR/WHO Format: Enclosed and will be taken.
- Information to the Patients: All information about study procedure will be given to the subject in his/ her language.

Expected Results

The Subjects with vatakantaka (plantar Fasciatis)sign and symptoms will be assessed and trated with jaloukavacharan and agnikarma and expected result will be withdrawn from observations.

By this comparative clinical trial, prevention of progression of the vatakantaka(plantar fasciitis) can be achieved. This study helps to establish the covalent bond between the disease and its ideal treatment based on the relative predominance of dosha among them.

Scope and Implications of the proposed study:

Agnikarma is frequently utilized method in management of Vatakantaka, however the growth and popularity of every science is depend on finding best interventions in a specific situation. Therefore attempts are expected to search for similar but more convenient, feasible and better options. Jaloukavacharana is an option at place of Agnikarma as it is nearly painless procedure, devoid of ADR and does not cause harms at the affected place. Finding the range of efficacy of Jaloukavacharana in comparison to Agnikarma will be helpful to open new gateway for management of Vatakantaka. Ancient seers of Ayurveda had a way to present most precise/applied aspects first followed by other secondary aspects. In context of Vatakantaka, ancient seers mentioned Raktavasechan (Jaloukavacharana) prior to all measures. Therefore this study will help to uncover the rationale behind way of narration by ancient seers and if this way found correct then many primary line of treatment can be decided to study based on sequence in Ayurveda references. Till date, no comparative data on efficacy of Jaloukavacharana and Agnikarma is available and this will be done by present research work. In modern era, the pain caused by Agnikarma while treating Vatakantaka can be considered as drawback as not all peoples are able to tolerate the severe pain during Agnikarma. However if Jaloukavacharana is found to possesses similar of better efficacy then it will be an option to all such patients. In other word it may be a parallel measure to the other indications where Agnikarma is advised. If the proposed study results in the positive outcome then it will give the best parallel modality for the management of vatakantak (plantar fasciitis).

4. Discussion

Discussion will be drawn from the observations and results of individual groups and comparative statistical Analysis. A number of articles related to agnikarma, jaloukavachatran and vatakantaka, plantar fasciitis conditions available in this region will be reviewed.

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