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A randomized controlled trial to evaluate the effect on pain by Agnikarma with Madhuchista (bee wax) and Panchaloha Shalaka in Vatakantaka

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ABSTRACT

Background: *Vatakantaka* explained in the context of *Vatavyadhi*, it has been said that when the foot is kept on the uneven ground or placing the foot improperly (while walking) or by over exertion of the foot, *Vata* localized in the *Khudaka* (heel region) gets aggravated and produces pain. Sharp stinging pain at the heel of foot which resembles the symptoms of calcaneus spur. All the Ayurvedic classics have given due importance to the *Vatavyadhi* and especially *Shoola Pradhana Vatavyadhi*. Among the *Anushastra Chikitsa*, *Agnikarma* is gaining acceptance and becoming more popular among Ayurvedic surgeons. The procedure of *Agnikarma* is very short and gives instant relief. In this study *Agnikarma* is performed with two different materials in the treatment of *Vatakantaka*. Hence here is an attempt is made to compare the efficacy of *Agnikarma* with *Panchalohashalaka* with *Madhuchista* in the management of pain in *Vatakantaka*.

Key words: *Vatakantaka*, *Calcaneal Spur*, *Agnikarma*, *Madhuchista*, *Panchalohashalaka*.

INTRODUCTION

Agnikarma is superior among all of them and has proved to be a boon where local involvement of *Vata* and *Kaphadoshas* are observed in the disease. It is quoted in many critical diseases like *Arbuda*, *Arsha*, *Apachi*, *Bhagandara*, *Antravidhi Gridhrasi*, etc.^[1] Sushruta highlights the importance of *Agnikarma* practice in case of highly painful conditions precipitated by *Vata* affected *Sira*, *Snayu*, *Asthi* components.^[2] The diseases treated with *Agnikarma*

do not reoccur,^[3] no fear of bleeding, putrefication and ultimately it produces balancing effect on vitiated *Vata Dasha*. For easy transfer of heat and to produce *Samyak Dagdha Vrana* (Therapeutic Burn), in ancient classics *Dahana Upkarana* (devices) like *Pippali*, *Ajashakruth*, *Godanta*, *Shara*, *Shalaka*, *Jambaustha*, *Madhu*, *Guda*, *Sneha* are mentioned for the particular *Dhatu* involved in the disease.^[4] The profound influence of *Agnikarma* becomes more clear from the wide description about Para-surgical procedure in various diseases.

A classical text supremacist the word *Vata*, which mainly denotes the one who has movement and which is the main cause for action and *Kantaka* means point of a needle which is similar like a thorn.^[5]

So, *Vatakantaka* denotes to a condition caused by *Vata* characterized by a sharp stinging pain at the heel of foot which can be which resembles the symptoms of calcaneus spur.

Calcaneal spur is seen most often in person over the age of 40 which causes pain in the heel. This is a projection or spike of bone at the anterior edge of the

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calcaneal tuberosity. The cause attributed goes to mainly repeated attacks of Plantar fasciitis, repeated trauma, ill fitting footwear. The occurrence of a spike of bone at the anterior edge of the calcaneal tuberosity's, usually the medial side is known as calcaneus spur. Modern system of medicine has treatments like local infiltration of steroids, NSAID's and Surgery for the management of Calcaneal spur,^[6] which are widely practiced but it goes with the limitations like risk of recurrence, surgical and post surgical complications, chances for infections, and post operative immobility period for healing.

The pain management modality which is easy to perform with lesser complications and better rate of success should be the criteria in choosing the management of this disease.

Agnikarma is mainly quoted in the pain management.^[7]

For *Agnikarma* procedure various *Dahanopakaranas* are quoted among them *Kshoudra*, *Guda* and *Sneha* are used in the management of pain *Gambhirdhatu* like *Sira*, *Snayu*, *Sandhi* and *Asthi*.^[8] *Acharya Vaghbata* quoted *Madhuchista* also as one of the *Dahanopakarana*.^[9] Moreover *Taptadrava* are considered to have more penetrating power than *Rooksha* instruments such as *Shalaka*.^[10]

Keeping in view of the lacunas of different modern medical treatments, there is a need for an effective, economical, simple therapy. *Agnikarma* may be considered as one such treatment in Ayurveda which may overcome the above said lacunas.

Hence, *Madhuchistha* is taken in the present study, to compare its efficacy with *Panchalohashalaka* and its feasibility in *Agnikarma*.

AIMS AND OBJECTIVES

1. To assess the effect on pain by *Agnikarma* with *Madhuchista* in *Vatakantaka*.
2. To evaluate the effect on pain by *Agnikarma* with *Madhuchista* comparatively with *Panchaloha Shalaka*.

MATERIALS AND METHODS

40 Patients suffering from *Vatakantaka* were selected by Diagnostic, Inclusive and Exclusive criteria taken for the study from SDM trust's ayurvedic hospital and divided into two groups each comprising of 20 by simple randomization technique. Group-A (control Group) were subjected for *Agnikarma* with *Panchaloha Shalaka* and Group-B (trial group) with *Madhuchista*. Irrespective of their sex, religion, socioeconomic status etc. Each patient was selected for the trial after voluntary consent. The effect of treatment was assessed based on subjective and objective criteria before and after treatment.

Study design - Randomized Controlled trial.

Diagnostic criteria

The diagnosis is mainly based on clinical presentation of the patient according to signs and symptoms of *Vatakantaka* like pain, Stiffness, Tenderness, Walking distance .

Inclusion Criteria

- Patients having *Pratyatma Lakshana* of *Vatakantaka*.
- Patients were selected irrespective of Gender and Religion.
- Patients were selected from Age group of 20 to 60 years.

Exclusion Criteria

- Deformity of the joint.
- History of previous surgery on Ankle joint.
- Patients with systemic diseases like Diabetes Mellitus, Tuberculosis.
- Patients on any Analgesic
- Patients with impaired circulation to lower extremities.
- Patients with referred pain due to Sciatica & other Neurological disorders.
- Acute Exacerbation of Osteoarthritis is excluded.
- Ankle sprain/soft tissue injury cases are excluded

Investigations

- X ray of affected foot - AP/Lateral view
- Blood sugar level
- CBC
- Serology

Procedure of Agnikarma**Poorva Karma**

All patients are advised to have *Picchilaahara*. After taking informed written consent from patient the procedure was explained in brief to the patient. *Madhuchista* 5-10gm taken into a vessel and heated over fire till it melts. *Panchalohashalaka* was heated till its tip becomes red hot.

Pradhana Karma

The patient was made to lie down on dressing table in comfortable position with affected foot area exposed properly. Most tender points were identified and marked with marker pen. Then area was cleaned with surgical Betadine using an sponge holding forcep under aseptic condition.

- **Group A** - *Agnikarma* was done with *Tapta Panchalhoashalaka* at most tender point in the form of bindu till *Samyagdagdha Lakshana* attains.
- **Group B** - *Agnikarma* was performed at most tender point with *Madhuchista*, using glass dropper.

Paaschat Karma

Samyak Dagdha Vrana was smeared immediately with *Ghritakumari* pulp.

Duration of the treatment

2 sittings of *Agnikarma* with interval of 7 days + 1 week of Follow-up after 2nd sitting.

Total duration of the study 14 days.

Observation and Follow-Up Period

Before the *Agnikarma* severity of *Vatakantaka* was assessed with assessment criteria and immediately after *Agnikarma* and 3rd day of treatment, effect was

assessed. After 7 days same procedure was repeated and 9th day of treatment and after 1 week of Follow-up i.e. after 14 days assessment was done and statistical analysis was done.

Assessment Criteria**Subjective parameters**

- Pain
- Stiffness

Objective criteria

- Tenderness
- Walking distance in feet/ 5 min

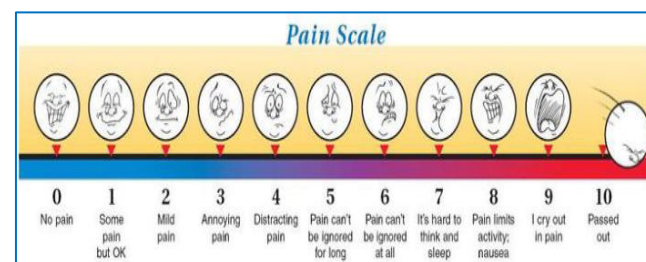
Grading and Grouping

Grading and grouping to the assessment criteria and measurement scale concerned to each item categorically differentiated the findings among the assessment in the clinical study.

1. Pain (Ruk)

Pain will be assessed on the basis of visual analogue scale.

Pain	Grade
No pain	0
Mild pain	1
Moderate pain	2
Severe pain	3



VAS scale (visual analogue scale) was used for pain gradation. Pain intensity 0 = no pain, 1-3 = mild pain (pain present but doesn't disturb the routine), 4-6 = moderate pain (pain present which disturbs the

routine), 7-10 = severe pain (patients rolls on the bed due to pain).

2. Stiffness (Stambha)^[11]

Stiffness	Grade
No stiffness	0
Sometimes for 5-10 minutes	1
Sometimes for 10-20minutes	2
Sometimes for 30-60 minutes	3

3. Tenderness (Sparshahishnutha)^[12]

Tenderness	Grade
No tenderness	0
Tenderness to palpation without flinch	1
Tenderness with flinch to palpation	2
Tenderness with Withdrawal	3

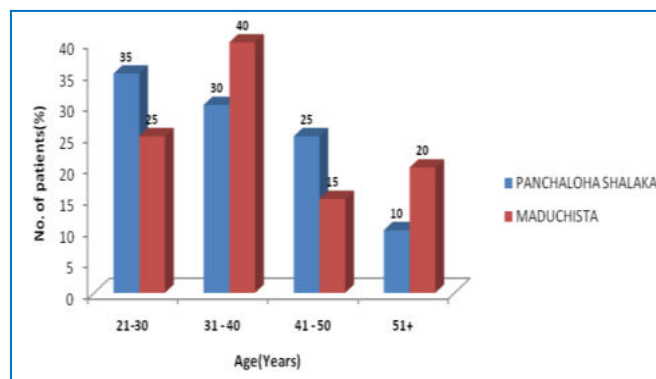
4. Distance walked by patient within 5 minutes.^[13]

Distance in feet	Grade
90 feet	0
60 feet	1
30 feet	2
Less than 30 feet	3

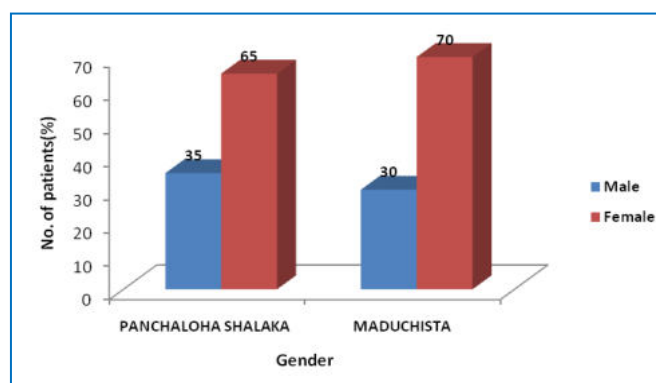
OBSERVATIONS AND RESULTS

The clinical observations from the different aspects approaching to the treatment for the patients of both the Group-A and B have been represented showing the incidence, statistic analysis of effectiveness along with clinical assessment of results etc., the data of each item are explained here under and have been represented in the tabular form with footnotes.

Graph 1: Distribution of patients according to age (years).



Graph 2: Distribution of patients according to gender



Graph 3: Distribution of patients according to socio economic status.

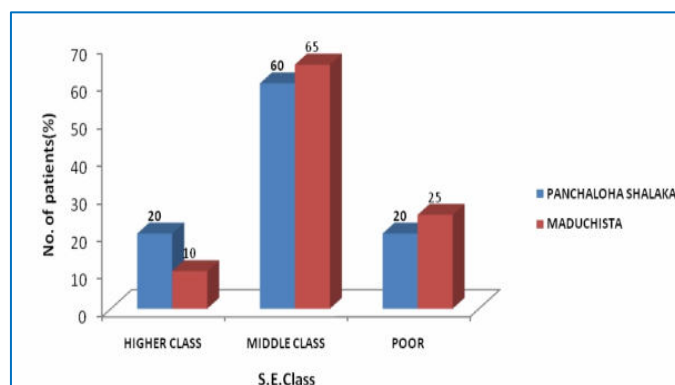


Table 1: Multiple comparisons in Pain.

Group	Comparison between	Sig.	Remarks
Panchaloha Shalaka	B T 1 st day soon after treatment	<0.05	Sign
	3 rd day	>0.05	NS
	2 nd sitting	>0.05	NS

		7 th day	<0.05	Sign
		9 th day	<0.001	HS
		14 th day	<0.001	HS
Madhuchista	B T	1 st day soon after treatment	<0.05	Sign
		3 rd day	<<0.05	HS
		2 nd sitting	>0.05	NS
		7 th day	<0.001	HS
		9 th day	<0.001	HS
		14 th day	<0.001	HS
NS: Not significant, HS: Highly significant				

75%-100%	Excellent Response	17	85	15	75	32	80
	Total	20		20		40	

The overall effects of *Panchalohashalaka* in Group-A, had excellent response in 17 (85%) patients, Good response in 03 (15%) patients and No response to Moderate and Poor.

The overall effects of *Madhuchista*, in Group-A, had excellent response in 15 (75%) patients, Good response in 05 (25%) patients and No response to Moderate and Poor.

The overall effect in Group-A & Group-B, Both the Groups shows Excellent response but when comparing all the parameters Group-A shows excellent response to all the parameters then in the Group-B.

Table 2: Comparative efficacy of Group-A with Group-B on sign and symptoms.

Overall Improvement in symptoms	Panchaloha Shalaka (Mean)		Madhuchista (Mean)	
	BT	AT	BT	AT
Pain	2.70	0.45	2.75	0.55
Stiffness	2.20	0.30	2.10	0.55
Tenderness	2.55	0.40	2.50	0.50
Walking Distance	2.30	0.40	2.35	0.60

Table 3: Overall Result

Class	Grading	(Group-A) - Panchaloha Shalaka		(Group-B) - Madhuchista		Total	
		No	%	No	%	No	%
<24%	Poor Response	0	0	0	0	0	0
25%-49%	Moderate Response	0	0	0	0	0	0
50%-74%	Good Response	3	15	5	25	8	20



Fig. 1: Materials used for Agnikarma

DISCUSSION

Agnikarma is indicated in diseases of *Vata* also. It reduces pain quickly by breaking down the obstruction (*Sanga*) to the normal movement of *Vata*, thus restoring the normal movement and function of *Vata*. In the present study *Agnikarma* was performed with *Panchalohashalaka* and *Madhuchista*. Doing *Agnikarma* with both the *Panchaloha Shalaka* was convenient. Scar marks were regular due to round tip of the *Shalaka*. Whereas with *Madhuchista* it was bit

difficult because of its solidification nature, so multiple glass droppers are used to overcome this practical problem. In both cases scar marks went after 15 days to one month.

As compared to *Panchalohashalaka*, *Maduchista* is economical and easily available as crude form and can be used directly.

As per *Acharya Sushruta*, *Agnikarma* has to be done at the site of *Ugraruja*, i.e., maximum tenderness point and it has been followed.

As in current study two sitting was considered, *Agnikarma* done on first day and seventh day.

Comparison of both *Dahanopakarana's*

- The *Panchaloha Shalaka* took more time to get red hot, but once heated the heat conduction (retaining heat capacity) of *Panchalohashalaka* is more than *Madhuchista*, which is convenient for doing *Agnikarma* for more spots after heating for one time and produces *Samyak Dagdha Lakshanas*.
- *Madhuchista* which is melted can get solidified if removed from fire so it is reheated again in between as per the requirement, to cover the entire area of tenderness, there required 2-3 times of re-heating. And the even though multiple glass droppers were used for convenience, glass droppers are tends to get blocked, so after the procedure used droppers were boiled and cleaned.

Overall effect

The overall effect of the therapy was drawn after the follow up of 14th day in relation to assessment parameters like pain, stiffness, tenderness, walking distance there is no statistically significant difference is seen.

When we compare individually;

- The effect of pain relief is more (83.33%) seen in control group (treated with *Panchalohashalaka*)

as compared to trial (*Madhuchista*) group (79.62%) on 14th day of follow up,

- The effect on stiffness is more (86.36%) in control group as compared to trial group (73.81%).
- The effect on Tenderness is more (84.31%) in control group as compared to trial group (80%).
- The walking distance is improved (82.61%) in control group as compared to trial group (74.47%).

So, this study confirms that *Agnikarma* with *Panchaloha Shalaka* is more effective in relieving symptoms in *Vatakanataka* than *Madhuchista* clinically, probable reason may be better conduction of heat and better transfer of heat to the tissues across the heel by *Panchaloha Shalaka* than over *Madhuchista*.

Probable mode of action^[14]

According to Ayurveda

1. **Effect on *Dosha*:** *Agnikarma* is considered as the best modality for *Vata* and *Kaphadosha* because *Agni* possesses *Ushna*, *Sukshma*, *Tikshna* and *Aashukari Guna* which are opposite to *Vata* and *Kapha*. It removes *Srotovarodha* and increase the *Rasa Raktasamvahana* to the affected site.
2. **Effect on *Dhatu*:** The therapeutic heat transferred by *Agnikarma* increases the *Dhatwagni*, so the metabolism at *Dhatu* level increases which helps to digest the *Amadosha*.

Possible scientific explanations

Gate control theory: Cutaneous sensations are transferred by two types of fibers. A fibers (stimulated by heat, cold and touch) C fibre (stimulated by pain) here the gate mechanism is blocked by stimuli from a fibre so the pain will not be felt.

The A delta fibers and the C fibres carry pain signals to the spinal cord. Delta fibers are faster and carry sharp pain signals while C fibers are slower and carry diffuse pain signals.

Heat acts on thermal receptors. They cause the Stimulation of Lateral Spinothalamic Tract.

This leads to stimulation of Descending Pain Inhibitory fibers which cause the release of endogenous Opioid receptors at Substantia Gelatinosa Rolandi, which inhibiting the release of P-substance (Presynaptic inhibition) resulting in the blockade of pain sensation.

Agnikarma is usually done at the most tender points only. Probably *Agnikarma* inactivates the A-delta fibers. That is why sharp pain gets relieved instantly and not the diffuse pain, which is carried by C-fibres.

Increased metabolic activity

According to scientist Dr. VenHanff : The place where heat burns the local tissue, metabolism is improved and it leads to increased demand of oxygen and nutrient of the tissues. This causes enhanced delivery of nutrients and more efficient removal of waste products, hence speeding up the natural process of repair.

Pathway for pain and thermal signals run parallelly and end in same area (in brain), but only stronger one can be felt. Therefore complete exclusion of pain impulse by heat occurs.

Blocking mechanism: *Agnikarma* probably blocks the pathway of pain, which makes the person not to feel the pain.

- **Increased blood supply:** Heat causes vasodilatation, so the increased blood flow to superficial tissue, prompts oxygen and nutrient supply and removal of waste products. Thus providing the instant relief from pain.
- **Counter irritation theory:** A counter irritant stimulates sensory nerve endings and relieves pain.
- **Effect on muscle tissue:** Heat induces muscle relaxation.

Trividha Karma are equally important in *Agnikarma Chikitsa*. If anyone *Karma* is not performed properly result is not satisfactory.

Group-A

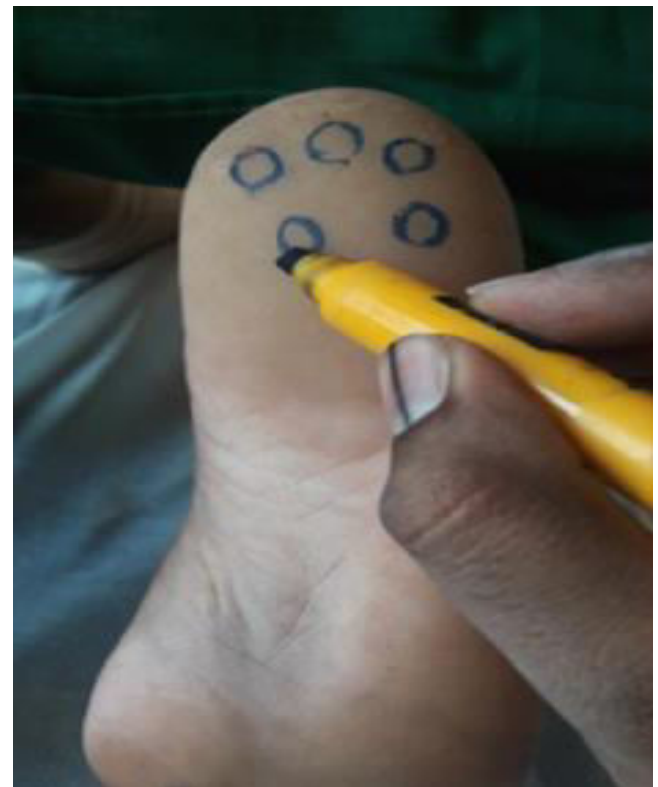


Fig. 2: Marking the maximum tender points



Fig. 3: After Painting & Draping



Fig. 4: Heating the *Panchalohashalaka*



Fig. 6: *Dagdha vrana* smeared with *Ghritakumari*



Fig. 5: *Agnikarma* with *Taptapanchalohashalaka*



Fig. 7: On 3rd day of follow-up.

Group-B



Fig. 8: Marked maximum tender points

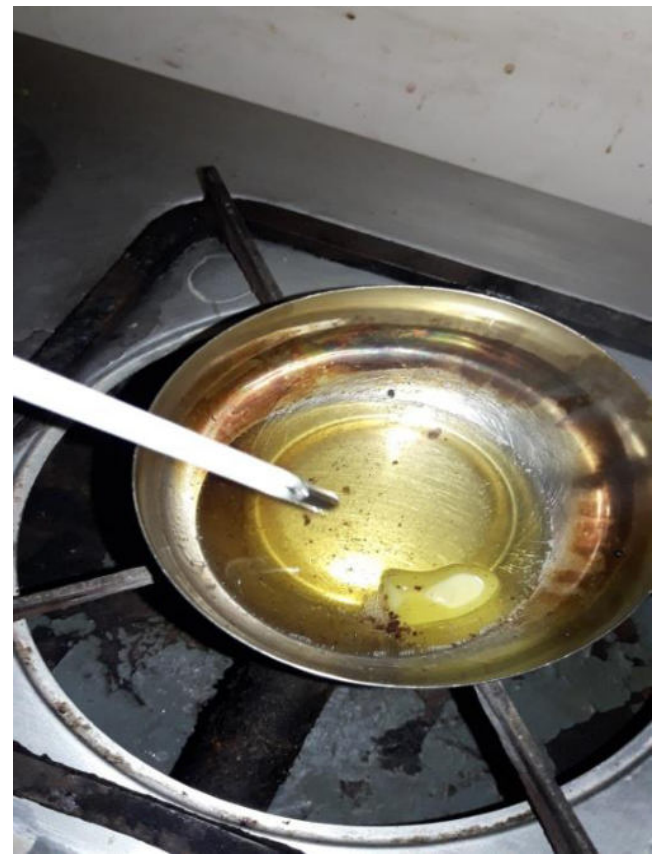


Fig. 10: Madhuchista kept on fire for melting



Fig. 9: After Painting & Draping



Fig. 11: Madhuchista Agnikarma



Fig. 12: *Dagdha Vrana* smeared with *Ghridakumari Pulp*



Fig. 13: On 3rd day of follow-up

CONCLUSION

Vatakantaka is the result of improper care given to foot. It is more common in age group of 31-50 years and most of case had chronicity between 3-7months. Clinically the effect of *Panchalohashalaka Agnikarma* over pain was more effective than *Madhuchista* but statically there was no difference found in between the groups. Achilles tendinitis, plantar fasciitis, tendoachillis bursitis, retrocalcaneum bursitid and calcaneal spur come under painful heel according to contemporary medical science. Calcaneal spur can be managed very effectively and we can save the patient from side effects of analgesics and steroid injections.

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