

## RESEARCH PAPER

# Comparing the Efficacy of *Agnikarma* with Ultrasound in the Management of Pain in *Vatakantaka* W.S.R. to Calcaneal Spur- A Randomized Controlled Study

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### Abstract

Vatakantaka is a Vata predominant Nanatmaja Vyadhi. In this condition, there is pain in heel. Irregular foot position on ground causes Vata vitiation and it is localized in the Khuda Pradesha (Heel region), which produces pain. Agnikarma is one of the prime treatments of Vatakantaka. It is especially indicated for the diseases of Snayu and Sandhi Vikara. Ultrasound Therapy is one of the Physiotherapy, which can reduce pain and tenderness by its heat and sound wave radiation. In this study, an attempt is made to observe the difference between the effect of Agnikarma and Ultrasound Therapy on pain.

**Methods:** Thirty patients of Vatakantaka were randomly divided into two groups, Group A received Agnikarma with Panchaloha Shalaka (Agnikarma instrument made of five type of metal) on 1<sup>st</sup>, 4<sup>th</sup> and 7<sup>th</sup> day. Group B received Ultrasound Therapy for 7 days daily. With help of assessment tools and gradation of symptoms, the findings of research works were statistically analyzed.

**Results:** In Group A- The overall response of after follow-up, out of 15 patients, 7 patients show moderate response, 4 patients show marked response, 4 patients show complete response. In Group B- 7 patients show moderate response, 3 patients show marked response, 3 patients show complete response, 1 patient shows mild response, and 1 patient shows unchanged symptoms.

**Interpretation and Conclusion:** Agnikarma and Ultrasound Therapy both showed good results in relieving the symptoms. However, Agnikarma was found to be statistically more effective on pain management in Vatakantaka.

**Keywords:** Vata Vyadhi, Vatakantaka, Agnikarma, Panchaloha Shalaka, Ultrasound Therapy

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### Introduction

Changing the lifestyle of modern human-being has created several disharmonies in their biological system. As the advancement of busy professional and social life, improper walking, continuous and overexertion, jerking movements during traveling and sports create pressure over the ankle. According to Ayurveda, simple freedom from disease is not health; rather he should be mentally and spiritually happy [1]. Among Tridosha, Vata is responsible for all types of movement and disease [2]. More importance and attention are given to the Vata Dosha because of its properties of locomotors [3, 4] dynamic entity and majority of its specific disorders in number [5]. Vatakantaka comes under Vata-roga [6]. Abnormal pressures and improper placement on the ground, induces excessive stretching of foot muscles and ligaments beyond their normal limits that lead to chronic planter heel, which is a painful condition of heel [7]. A heel spur is a type of bone growth that develops on the outside of the heel bone, where the plantar fascia ligament attaches [8]. Spurs may form when the planter fascia becomes inflamed causing calcification or bone growth [8]. They are often described as having a small hook, which causes pain by irritating the surrounding

soft tissue. Middle aged (40-50 years), female, overweight and athletic individuals are more prone to planter problems, as non-athletic people who spend a lot of time on their feet or suddenly become active after a long time of lethargy. The incidence of heel pain in calcaneal spur in various countries; Australia-55.1%, Thailand-15.5%, Caucasian population-15.7% and in Indian population it is found to be 59% [16].

The treatment in medical science depends on the degree or grade of pain. Proper footwear, heel rest, Ultrasound therapy, Analgesic, Anti-inflammatory drugs, steroid injections and endoscopic planter fasciotomy surgery are the treatment modalities followed in allopathic medical science. These treatment protocols are not cure, cannot prevent the reoccurrence and the surgery is a costly procedure. Still patients now a day are searching for alternative Ayurvedic therapeutics to stay away from analgesic, steroids and surgery. In Ayurveda in this condition, the pain can be correlated to Asthi gata vata. Therefore, Agnikarma can be an effective treatment modality [9]. According to Samhita, Agnikarma is said to be the best therapy as it prevents recurrence and restores haemostasia during the procedure [10, 11]. Ultrasound therapy is also used on pain caused by

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calcaneal spur. Ultrasound with frequency of 1-3 MHz is used for medical therapeutic purpose [12]. Hence, the present study is made to compare *Agnikarma* and Ultrasound therapy in *Vatakantaka*.

#### Aims and Objective of the Study

- To assess the effect of *Agnikarma* in the pain management of *Vatakantaka* (Calcaneal Spur).
- To assess the effect of Ultrasound Therapy in the pain management of *Vatakantaka* (Calcaneal Spur).

#### Methodology

**Trial / Research design**-30 patients suffering from *Vatakantaka* were selected and randomly divided into two groups, each having 15 members and named as Group A and Group B. Group-A; 15 patients had received *Agnikarma* in the morning on Day 1<sup>st</sup>, 4<sup>th</sup> on 7<sup>th</sup> until their tolerance. Group-B; 15 patients had received Ultrasound Therapy for 10 -15 minutes regularly for 7 days. In the Randomization the participants were randomly assigned to the intervention groups by lottery method.

#### Participants

##### Eligibility criteria

##### Exclusion Criteria

- Patients suffering from fractures and dislocation of Ankle joint
- Post Traumatic Ankylosis
- Rheumatoid Arthritis
- Gouty Arthritis
- Osteoporosis.
- Other disorders causing pain in the Sole of the Foot.
- Patients suffering from Hypertension, Diabetic mellitus, Cardiac disorder and other systemic disorders.

##### Inclusion Criteria

- The patients presenting the classical features of *Vatakantaka*.
- Heel Pain
- Heel Tenderness.
- Age group between 25-65 years of either sex.
- Patients fit for *Agnikarma* and ultrasound Therapy.

##### Diagnostic Criteria

##### Investigations: (for Diagnostic & Exclusion criteria)

- X – Ray of heel, lateral view (presence of calcaneal spur/ Heel spur)
- RBS

**Pathyapathya**- The patients were advised to avoid *Vataprakopaka Ahara Vihara*.

**Study Population**-Patients suffering from *Vatakantaka* fulfilling the inclusion criteria were selected from the OPD and IPD. This study was approved by Institutional Ethical Committee and registered in CTRI; vide **SJGAMC & HK/ICEC/2018/55** and **CTRI/2019/10/021515** respectively.

#### Interventions

- **Agnikarma (Fig. No. 2a, 2b, 2c, 3)**
- **Purva karma**- The site was cleaned with cotton dipped in normal saline water.
- **Pradhana karma**- The highest tenderness site was marked and *Agnikarma* as *Bindu* was done on the point and around.
- **Paschat karma**-After *Agnikarma*, *Shatadhouta ghrita* was applied over that area and Patient was informed about *Pathyapathya*.
- **Ultra-sound Therapy- (Fig. 4a, 4b)**
- **Purva karma** Patient was advised to sit comfortably on examination table and Contact gel was applied
- **Pradhana karma**- The Ultrasound head slowly moved in circular manner. In acute conditions 0.25 to 0.5 watts / square cm for 5 to 6 min and in chronic conditions 0.8 to 1.5 watts/square cm for 10 to 15 min was applied. (Chronic—disease duration more than 3 months and Acute means disease duration - less than 3 months)
- **Paschat karma**- Gel was removed from the treatment area.

#### Outcomes / Assessment Criteria-

Assessment was made based on changes found in the clinical signs of the disease. For this purpose, the clinical signs were given suitable scores according to their severity and assessment was done before and after treatment. The patients were assessed based on the assessment criteria according to (Table No. 1)

- Before the Treatment on day zero.
- On the 8<sup>th</sup> day after the completion of the Procedure.
- After follow-up, on the 22<sup>nd</sup> day.

**Statistical Analysis**- The subjective and objective parameters, before treatment, after treatment and after follow-up, were compared. The Wilcoxon sign rank test and the Man Whitney U test are used to analyze the significance of the therapies within the group and between the groups respectively.

#### Observations and Results

Pain and tenderness were used as subjective and objective parameters to collect and to assess the data through grading (Fig. No.1, Table No. 2, 3, 4). The mean value of Pain in Group A, was reduced from 3.3333 to 2.1333 after treatment and 0.7333 at follow up by 36% and by 78% respectively, which is highly significant at  $p < 0.001$ . In Group B, the mean value of Pain was reduced from 3.9333 to 2.5333 after treatment and 1.4000 in follow up by 36% and 64% respectively, which is highly significant at  $p < 0.001$ . The statistical data between the Groups before and after treatment was insignificant at  $P > 0.05$  on treating pain. Thus, it showed that both the groups are highly significant within the groups and insignificant between the groups, while treating pain

(Table No. 5, 6 and Fig 5).

The mean value of tenderness in Group A, was reduced from 0.3000 to 0.0333 after treatment and 0.000 at follow up by 89% and by 100% respectively, which is moderately significant at  $p < 0.001$ . In Group B, the mean value of tenderness was reduced from 0.3667 to 0.2000 after to 0.1333 in follow up by 45% and 64% respectively, which is insignificant at  $p < 0.001$ . The statistical data between the Groups before and after treatment were insignificant at  $P > 0.005$ . Group A is moderately significant within the group whereas group B is insignificant within the group. Both groups are equally potent while treating tenderness (Table No. 7, 8 and Fig 6).

### Discussion

Vatakantaka is a disease explained in the context of Vatavyadhi as a painful condition of the heel caused by the improper placement of the foot on the ground. The incidence of the calcaneal spur in the Indian population with heel pain is 59% among them 60% are women. The most common age group affected is 30-60 years. Every time a foot is stepped, the heel bears the load equal to 20 times the body weight. This load is softened by a pillow of fat and a large tendon under the sole. Repeated strain on these causes' inflammation and even small cracks in the tendon which leads to pain. As a repair mechanism, the body wraps it up in bone resulting in a small bony projection on the heel bone called a Calcaneal Spur [12]. Heel pain typically occurs in the middle-aged, overweight, overpronated feet, and non-athletic individuals. Women are more likely to get the problem than men. In modern Analgesics, Anti-inflammatory, Steroid injections along with surgical interventions like endoscopic-plantar- fasciotomy are used but they have many adverse effects. In this condition, Ayurveda treatment modality is a better option than Agnikarma therapy. It is safe and there is seldom a chance of reoccurrence and bleeding [10, 11]. In this research paper, we have tried to revalidate the treatment through the statistical analysis.

### Discussion on Observations and Results Assessment of Parameters

**Pain:** There was 36 % reduction in group A and B during treatment period. On 22<sup>nd</sup> day, there were 78% and 64% reductions of Pain in the groups respectively. But in some patients in Group B, it increased during the follow-up period.

**Tenderness:** There was 89% reduction seen in group A and 45% reduction in group B during the treatment period. There was complete reduction seen in Group A but in Group B, 64% reduction was recorded, and some patients Tenderness reoccur.

### Interpretation of comparison between groups

The treatment is effective for both Agnikarma and Ultrasound Therapy. When comparing the efficacy, it

is found that the efficacy of Group A is moderately significant as compared to Group B. While comparing both the Groups Regarding Pain and Tenderness Group A is better than Group B.

### Discussion on individual parameters of assessment in both the groups

#### Discussion on Pain

In Group A (Agnikarma), the mean of pain before treatment was 3.3333, which was reduced to 2.1333 and to 0.7333 respectively after treatment (AT) and on 22<sup>nd</sup> day (follow-up), which is highly significant at  $p < 0.001$ .

While In Group B (Ultrasound Therapy), the mean of pain before treatment was 3.9333, which was reduced to 2.5333 and to 1.4000 respectively after treatment (AT) and on 22<sup>nd</sup> day (follow-up), which is highly significant at  $p < 0.001$ .

It was observed that Group B was not showing good results in after follow-up period as compared to Group A, it might be due to the less chance of reoccurrences and sudden relief of Agnikarma.

#### Discussion on Tenderness

In Group A (Agnikarma), the mean of tenderness before treatment was 0.3000, which was reduced to 0.0333 and to 0.0000 respectively after treatment (AT) and on 22<sup>nd</sup> day (follow-up), which is Moderately significant at  $p < 0.001$ .

While in Group B- Ultrasound Therapy, before treatment mean was reduced from 0.3667 to 0.2000 and 0.1333 respectively after treatment (AT) and on 22<sup>nd</sup> day (follow-up), which is Insignificant at  $p < 0.05$ .

It was observed that in Pain, statistically the group showed good results. But in case of Tenderness the group had not shown good result.

#### Discussion on Mode of Action

##### Mode of action of Agnikarma

Initially due to Ushna (hot/warm), Tikshna (s harp), Sukshma (Subtle), and Ashukari Guna (very fast/quick) of Agni; it removes the Srotavarodha, pacifies the vitiated Vata and Kapha Dosha and maintains their equilibrium. Secondly, it increases the Rasa and Rakta Samvahana (blood circulation) to affected site [13]. The physiological effect of temperature occurs at the site of application of Agnikarma. Locally there is an increased blood flow with associated capillary dilatation and increased capillary permeability. Initially tissue metabolism increases and there may be an increase in the pain threshold, reduction of muscle spasm, Pain and tenderness. In other way it can be explained as therapeutic heat increases the blood circulation at the ankle-joint, leading to the proper nutritional supplement to the tissue. This induced circulation helps to flush away the pain because of the promotion of active oxygen, nutrition and improvement in flexibility and range of motion of muscle, producing substances from the affected site, ultimately reducing the local inflammation and pain [13].

Therapeutic heat stimulates the lateral spinothalamic tract, leading to stimulation of descending pain inhibitory fibers causing release of endogenous opioid peptide, which blocks the transmission of Pain. [14] The increased temperature at the applied site reduces nerve reflexes resulting in relaxation of muscle thereby causing a reduction of stiffness. (Flow chart No. 1)

#### **Mode of action of Ultrasound Therapy**

Ultrasound waves induce mechanical vibrations, from high frequency soundwaves, on skin and soft tissue via an aqueous medium. The transducer head converts power from the generator into acoustic power that can cause thermal or non-thermal effects. The therapeutic Ultrasound raises tissue temperature and metabolism, softens the tissues, increases blood circulation, increases the chemical activity of the tissues, increases the permeability of the cell membranes and modulates the molecular structures and the rate of pulsation and protein production. All these are potentially affecting the speed of tissue recovery [15]. (Flow Chart No. 2)

#### **Conclusion**

In this study, *Agnikarma* and Ultrasound therapy, both show good results in relieving the symptoms. However, *Agnikarma* was found to be statistically more effective

than Ultrasound Therapy on the pain management of *Vatakantaka*.

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**Registration-** This study was approved by Institutional Ethical Committee and registered in CTRI; vide **SJGAMC & HK/ICEC/2018/55** and **CTRI/2019/10/021515** respectively.

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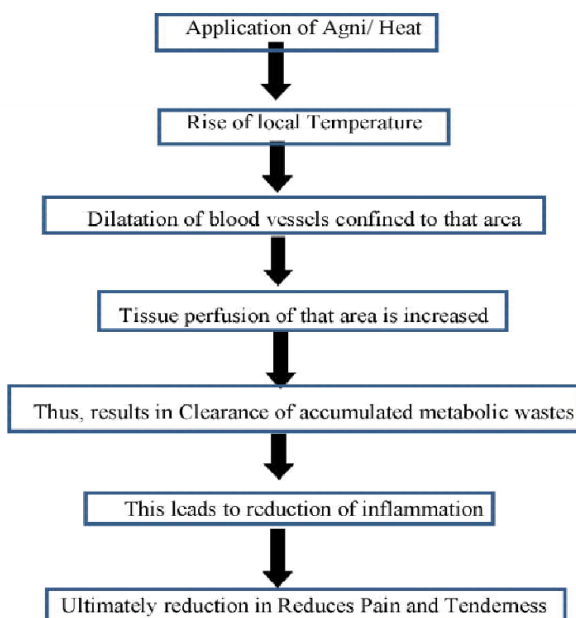
**Conflict of interest-** Nil

Conflict of interest- Nil

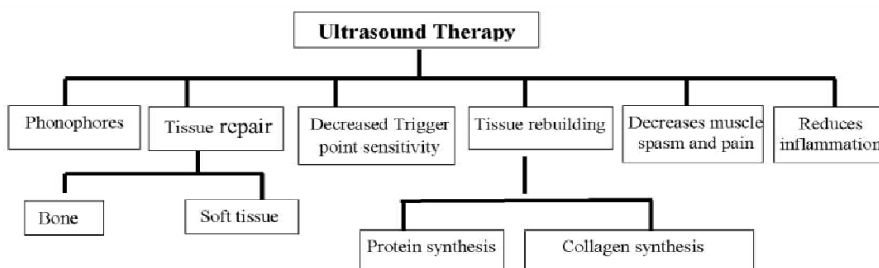
**Use of AI -** There is no use of AI or any of its tools during making this manuscript

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**Flow Chart No. 1: Flow chart showing Mode of Action of Agnikarma**



**Flow Chart No. 2: Flow chart showing Mode of Action of ultrasound therapy**



**Table No. 1 Study Duration of Procedures:**

Durations	Agnikarma	Ultra Sound Therapy
Study Duration	1 <sup>st</sup> , 4 <sup>th</sup> , 7 <sup>th</sup> day	7 days
Follow Up	14 days	14 days
Total Duration	21 days	21 days
Time Duration	Depending on the tolerance of the patients	10-15 minutes

**Table No.2 gradation of Pain**

VAS Points	Grade	Severity
0	0	No pain
1 to 3	1	Mild
4 to 7	2	Moderate
8 to 10	3	Severe

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**Table No. 3: Gradation of Tenderness**

Gradings	Characters
0	No tenderness
1	Tenderness to palpation without grimace or flinch
2	Tenderness with grimace and /or flinch to palpation
3	Tenderness with withdrawal
4	Withdrawal to non-noxious stimuli ( superficial palpation, pin prick, gentle percussion)

**Table No. 4 : Assessment of the Therapy**

Effect	Percentage
Good Response	Above 75%
Moderate Response	50% up to 75%
Mild Response	26% to 49%
Poor Response	Below 25%

**Table No. 5 : Showing the effect on Pain within the Groups**

Table : Effect of treatment on PAIN within the group											
GROUP	Descriptive Statistics				Wilcoxon Signed Ranks				Test Statistics		
	Paring	Mean	±SD	Reduction in %	R	N	Mean Rank	Sum of Ranks	Z	P	Remarks
GROUP-A (AGNIKARMA)	Group A: BT With AT				R+ (BT>AT)	15	8.50	136.00	3.82	<0.001	HS
	BT	3.3333	3.20918	36%	R- (BT<AT)	0	0.00	0.00			
	AT	2.1333	2.28539		RO (BT=AT)	5	-	-			
	Group A: BT With FU				R+ (BT>FU)	17	9.0	153.0	3.73	<0.001	HS
	BT	3.3333	3.20918	78%	R- (BT<FU)	0	0.0	0			
	FU	.7333	.98027		RO (BT=FU)	13	-	-			
GROUP-B (ULTRA SOUND THERAPY)	Group B: BT With AT				R+ (BT>AT)	18	9.5	171.0	4.00	<0.001	HS
	BT	3.9333	2.59885	36%	R- (BT<AT)	0	0.0	0			
	AT	2.5333	2.02967		RO (BT=AT)	12	-	-			
	Group B: BT With FU				R+ (BT>FU)	23	12.0	276.0	4.29	<0.001	HS
	BT	3.9333	2.59885	64%	R- (BT<FU)	0	0.0	0			
	FU	1.4000	1.83077		RO (BT=FU)	7	-	-			

SD- Standard Deviation; IS - Insignificant; MS - Moderately Significant; S - Significant; HS - Highly significant.

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**Table No. 6 : Showing Comparative difference of Pain between Group A and B:\*\***

Table : Comparisons Between Groups A and B in PAIN										
Assessment Observations Recorded on	Descriptive Statistics			Mann-Whitney U Test Ranks			Test Statistics			
	Comparing Groups	Mean	± S.D.	N	Mean Rank	Sum of Ranks	U	Z	P	Remarks
After Treatment	Group A	2.1333	2.28539	30	28.70	861.00	396.00	0.83	>0.05	IS
	Group B	2.5333	2.02967	30	32.30	969.00				
After Follow-Up	Group A	.7333	.98027	30	28.08	842.50	377.50	1.23	>0.05	IS
	Group B	1.4000	1.83077	30	32.92	987.50				

SD- Standard Deviation; IS - Insignificant; MS - Moderately Significant; S - Significant; HS - Highly significant.

**Table No. 7: Showing effect on Tenderness within the Groups**

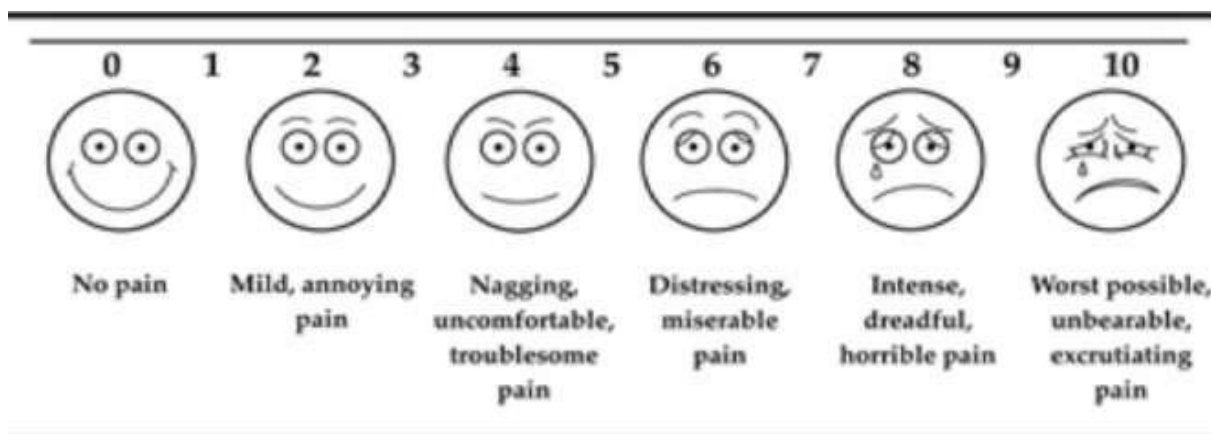
Table : Effect of treatment on TENDERNESS within the group											
GROUP	Descriptive Statistics				Wilcoxon Signed Ranks				Test Statistics		
	Paring	Mean	±SD	Reduction in %	R	N	Mean Rank	Sum of Ranks	Z	P	Remarks
GROUP-A (Agnikarma)	Group A: BT With AT				R+ (BT>AT)	7	4.0	28.0	2.53	<0.001	MS
	BT	.3000	.59596	89%	R- (BT<AT)	0	0.0	0			
	AT	.0333	.18257		RO (BT=AT)	23	-	-			
	Group A: BT With FU				R+ (BT>FU)	7	4.0	28.0	2.46	<0.001	MS
	BT	.3000	.59596	100%	R- (BT<FU)	0	0.0	0			
	FU	0.0000	0.00000		RO (BT=FU)	23	-	-			
GROUP-B (Ultrasound)	Group B: BT With AT				R+ (BT>AT)	4	2.5	10.0	1.89	<0.001	IS
	BT	.3667	.80872	45%	R- (BT<AT)	0	0.0	0			
	AT	.2000	.48423		RO (BT=AT)	26	-	-			
	Group B: BT With FU				R+ (BT>FU)	5	3.8	19.0	1.82	<0.001	IS
	BT	.3667	.80872	64%	R- (BT<FU)	1	2.0	2			
	FU	.1333	.50742		RO (BT=FU)	24	-	-			

SD- Standard Deviation; IS - Insignificant; MS - Moderately Significant; S - Significant; HS - Highly significant.

**Table No. 8 : Showing Comparative difference of Tenderness between Group A and Group B**

Table : Comparisons Between Groups A and B in TENDERNESS										
Assessment Observations Recorded on	Descriptive Statistics			Mann-Whitney U Test Ranks			Test Statistics			
	Comparing Groups	Mean	± S.D.	N	Mean Rank	Sum of Ranks	U	Z	P	Remarks
After Treatment	Group A	.0333	.18257	30	28.48	854.50	389.50	1.72	>0.05	IS
	Group B	.2000	.48423	30	32.52	975.50				
After Follow-Up	Group A	0.0000	0.00000	30	29.50	885.00	420.00	1.43	>0.05	IS
	Group B	.1333	.50742	30	31.50	945.00				

SD- Standard Deviation; IS - Insignificant; MS - Moderately Significant; S - Significant; HS - Highly significant.



**Fig. No. 1: VAS gradation of Pain**



**Fig 2a PANCHALOHA SHALAKA**



**Fig 2c : AGNIKARMA SPOTS**



**Fig 2b AGNIKARMA PROCEDURE**



**Fig 3 SATADHAUTA GHRITA**



**Fig 4a ULL TRASOUND APPARATUS**



**Fig. 4b ULTRASOUND PROCEDURE**

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### **सारांश**

**परिचय:** वातकंटक एक वात प्रधान नानात्मज व्याधि है। इस स्थिति में एड़ी में दर्द होता है। ज़मीन पर पैर की अनियमित स्थिति वात विकार का कारण बनती है और यह क्षुद्र प्रदेश (एड़ी क्षेत्र) में केंद्रित होती है, जिससे दर्द होता है। अग्निकर्म, वातकंटक के प्रमुख उपचारों में से एक है। यह विशेष रूप से स्नायु और संधि विकार के रोगों के लिए संकेतित है। अल्ट्रासाउंड थेरेपी, फिजियोथेरेपी में से एक है, जो अपनी ऊष्मा और ध्वनि तरंग विकिरण द्वारा दर्द और कोमलता को कम कर सकती है। इस अध्ययन में, अग्निकर्म और अल्ट्रासाउंड थेरेपी के दर्द पर प्रभाव के बीच अंतर का अवलोकन करने का प्रयास किया गया है। **विधियाँ:** वातकंटक के तीस रोगियों को यादृच्छिक रूप से दो समूहों में विभाजित किया गया। समूह 'A' को पहले, चौथे और सातवें दिन पंचलोह शलाका (पाँच प्रकार की धातुओं से बना अग्निकर्म यंत्र) के साथ अग्निकर्म दिया गया। समूह 'B' को प्रतिदिन सात दिनों तक अल्ट्रासाउंड थेरेपी दी गई। मूल्यांकन उपकरणों और लक्षणों के क्रम-निर्धारण की सहायता से, शोध कार्यों के निष्कर्षों का सांख्यिकीय विश्लेषण किया गया। **परिणाम:** समूह A में - अनुवर्ती कार्रवाई के बाद कुल प्रतिक्रिया, 15 रोगियों में से, 7 रोगियों में मध्यम प्रतिक्रिया, 4 रोगियों में उल्लेखनीय प्रतिक्रिया और 4 रोगियों में पूर्ण प्रतिक्रिया देखी गई। समूह B में - 7 रोगियों में मध्यम प्रतिक्रिया, 3 रोगियों में उल्लेखनीय प्रतिक्रिया, 3 रोगियों में पूर्ण प्रतिक्रिया, 1 रोगी में हल्की प्रतिक्रिया और 1 रोगी में अपरिवर्तित लक्षण देखे गए। **व्याख्या और निष्कर्ष:** अग्निकर्म और अल्ट्रासाउंड थेरेपी, दोनों ने लक्षणों से राहत दिलाने में अच्छे परिणाम दिखाए। हालाँकि, वातकण्टक में दर्द प्रबंधन के लिए अग्निकर्म सांख्यिकीय रूप से अधिक प्रभावी पाया गया।