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A randomized open label control clinical study to evaluate the efficacy of *Kshoudra* as *Dahanopakarana* for the pain management in *Snayuvikara* with special reference to Achilles Tendinitis

Anju DR[1], N Muralidhara[2], KM Sweta[3], Dhyan Surendranath[4]

[1]*Post Graduate Scholar, Department of PG Studies in Shalyatantra, Sri Sri College of Ayurvedic Science and Research Hospital, Bengaluru, Karnataka, India.*

[2]*Professor, Department of PG Studies in Shalyatantra, Sri Sri College of Ayurvedic Science and Research Hospital, Bengaluru, Karnataka, India.*

[3]*HOD and Professor, Department of PG Studies in Shalyatantra, Sri Sri College of Ayurvedic Science and Research Hospital, Bengaluru, Karnataka, India.*

[4]*Associate Professor, Department of PG Studies in Shalyatantra, Sri Sri College of Ayurvedic Science and Research Hospital, Bengaluru, Karnataka, India.*

ABSTRACT

Achilles Tendinitis is otherwise called as Achilles Tendinopathy which causes pain and stiffness, swelling, thickening and weakness of achilles tendon, which worsens with activity, commonly seen in sports person. As per Ayurvedic parameters this condition can be correlated to *Snayugata Vikara*, which usually presents with *Sthambha, Shula, Kriyavasakthi.* Treatment include *Snehana, Upanaha*, *Agnikarma*, *Bandhana* and *Mardana*. In the contemporary science the treatment modalities available are RICE technique, hydrocortisone injection, radiant heat or diathermy, release of plantar fascia from tuberosity of calcaneus through surgery. In *Susrutha Samhitha Agnikarma Chikitsa is* explained for the par excellence for these conditions considering its *Vatakapha Shamaka, Amapachaka* property and also this is easy to perform. *Agnikarma* with the help of *Panchadhathu Shalaka* was already established with 65% of success rate in the management of Achilles tendinitis. The therapeutic effects of *Agnikarma* with *Kshoudra* includes relief of pain and muscle spasm, acceleration of healing, promotion of resolution of inflammation and increase in the range of movement of joint. This study is done by considering *Vatakapha Shamaka, Amapachaka, Yogavahi* properties of *Kshoudra* and also this was easy to perform with better cosmetic value. Hence the stagnation of current knowledge demanded an effective method to tackle the painful heel condition.

Key words: *Agnikarma, Kshoudra, Achilles Tendinitis, Panchadhathu Shalaka, Snayuvikara, Dahanopakarana*

INTRODUCTION

Achilles Tendinitis is otherwise called as Achilles Tendinopathy which causes pain and stiffness, swelling, thickening and weakness of achilles tendon, which worsens with activity, commonly seen in sports person. Incidence is 7 per 1,00,000, having peak incidence at age group 20-60 years. Incidence is 35% in Indian population, having peak incidence at age group 20 - 60 years with predominance in females in India. This condition may affect 9% of recreational runners and causes up to 5% of professional athletes to end their careers.[1]

As per Ayurvedic parameters this condition can be correlated to *Snayugata Vikara*, which usually presents with *Sthambha, Shula, Kriyavasakthi. Snayugatavata* is described among the *Vatavyadhi* in *Brihatrayees* and *Laghutrayees.* According to Ayurveda, in *Snayugata Vata -Snehana, Upanaha, Agnikarma*, and *Bandhana* are the treatments advised.[2] *Agnikarma* with *'Ksoudragudasnehacha'* is mentioned in *Sandhi Asthi Sira Snayugata Vikara*. Treatment include *Snehana,*

Address for correspondence:
Dr. Anju DR
Post Graduate Scholar, Department of PG Studies in Shalyatantra, Sri Sri College of Ayurvedic Science and Research Hospital, Bengaluru, Karnataka, India.
E-mail: anju88506@gmail.com

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ISSN: 2456-3110 ORIGINAL ARTICLE July 2022

Upanaha, *Agnikarma*, *Bandhana* and *Mardana*. In *Brihatrayees*, it has mentioned *Agnikarma Chikitsa* in the management of *Sira, Snayu, Sandhi* or *Asthi Samprapthi.*[3]

Kshoudra is mentioned as *Dahanopakarana* for *Sira-Snayu-Asthi Sandhi* because of penetration to the deeper structures. The therapeutic effects of *Agnikarma* with *Kshoudra* includes relief of pain and muscle spasm, acceleration of healing, promotion of resolution of inflammation and increase in the range of movement of joint.[3]

Agnikarma with the help of *Panchadhathu Shalaka* was already established with 65% of success rate in the management of Achilles tendinitis. In *Susrutha Samhitha, Agnikarma Chikitsa is* explained for the par excellence for these conditions considering its *Vatakapha Shamaka, Amapachaka* property and also this is easy to perform.[4]

In the contemporary science the treatment modalities available are RICE technique, hydrocortisone injection, radiant heat or diathermy, release of plantar fascia from tuberosity of calcaneus through surgery.[5]

This study is done by considering *Vatakapha Shamaka, Amapachaka, Yogavahi* properties of *Kshoudra* and also this was easy to perform with better cosmetic value. Hence the stagnation of current knowledge demanded an effective method to tackle the painful heel condition.

Aim and Objectives

Aim

To evaluate the efficacy of *Kshoudra* as *Dahanopakarana* for the pain management in *Snayuvikara* with special reference to Achilles Tendinitis.

Objectives

1. To evaluate the efficacy of *Kshoudra* as *Dahanopakarana* for the pain management in Achilles Tendinitis.
2. To revalidate the efficacy of *Panchadhathu Shalaka* as *Dahanopkarana* for the pain management in *Achilles Tendinitis.*
3. To compare the efficacy of *Kshoudra* and *Panchadhathu Shalaka* as *Dahanopakarana* for the pain management in Achilles Tendinitis.

Materials and Methods

The study design was open, randomized prospective comparative clinical study. In this study 30 diagnosed cases of Achilles Tendinitis were selected from OP and IP of Department of *Shalyatantra*, SSCAS&RH, Bengaluru. The subjects were divided into two groups of 15 each in control and trial. Prior to the procedure educating the patient and informed consent was taken.

Duration of Study

Total Duration - 35 days

Duration of Intervention - 21 days (Day 0, Day 7, Day 14, Day 21)

Follow up - 2 weeks (Day 28, Day 35)

Diagnostic Criteria

1. Pain over Achilles tendon (1-4 weeks).
2. Pain 2-6 cm proximal to Achilles tendon.
3. Pain on tendon palpation.
4. Positive Arc test - Subject is asked to dorsiflex & plantar flex the ankle.

Positive if: Area of tendon swelling evidenced by palpation moves with ankle dorsiflexion and plantar flexion.

5. Positive Royal London Hospital Test (RLHT) - Once examiner has elicited local tenderness by palpating the tendon ankle in neutral position or slightly plantar flexed, subject is asked to actively dorsiflex & plantar flex the ankle. Tendon is again palpated with the ankle in end range dorsiflexion and plantar flexion.

Positive if: Tenderness present in ankle dorsiflexion.

Inclusion Criteria

1. Subjects aged 21-60 years
2. Subjects of both gender, religion, caste, race and socio-economic status.

ISSN: 2456-3110 ORIGINAL ARTICLE July 2022

3. Subjects fulfilled the diagnostic criteria of Achilles tendinitis (Grade 1 & Grade 2)

Exclusion Criteria

1. Subjects aged below 21 years and above 60 years.
2. Subject suffering from Diabetic neuropathy, Foot drop.
3. Subjects with fracture of calcaneum and Paget's disease affecting calcaneum.
4. Subjects having extensive rupture or tear of Achilles tendon falling in Grade 3.
5. Subjects associated with severe systemic diseases and auto immune disorders were excluded.

Grades of Achilles tendinitis

1. Grade 1 - Mild pain or discomfort especially in morning during activities over achilles tendon without evident swelling
2. Grade 2 - Moderate pain or strain increases with activity with or without swelling
3. Grade 3 - Complete tear or partial tear in which any type of activity increases pain and swelling with lump over achilles tendon.

Criteria of Assessment

The subjects were assessed on the basis of subjective and objective parameters before and after treatment.

Subjective Parameter

Pain Assessment done with Visual Analogue Scale (VAS)

Objective Parameter

1. Arc Test[5]
2. Royal London Hospital Test[5]

Assessed on Day 0 (Before Treatment), Day 7, Day 14, (During Treatment), Day 21 (After Treatment), Day 28th (Follow up-1), Day 35th (Follow up 2).

Intervention

Group A (Control Group)

Fifteen subjects of this group were subjected to *Agnikarma* with *Panchadhathu Shalaka* on the most tender points in four sittings. (Day 0, Day 7, Day 14, Day 21)

Group B (Trial Group)

Fifteen subjects of this group were subjected to *Agnikarma* with *Kshoudra* on the most tender points in four sittings. (Day 0, Day 7, Day 14, Day 21)

Procedure - In Control Group

Poorvakarma

1. Arrangement of materials (*Agropaharana*)
2. Subject taken to prone position and tender points were marked

Pradhanakarma

1. Heating of *Panchadhathu Shalaka*
2. *Agnikarma* performed over marked tender points with *Panchadhathu Shalaka*

Paschatkarma

1. Application of *Madhu Gritha* mixture.

Procedure - In Trial Group

Poorvakarma

1. Arrangement of materials (*Agropaharana*)
2. Subject taken to prone position and tender points were marked

Pradhanakarma

1. Heating of *Kshoudra*
2. Heated Kshoudra was sucked to glass pipette and dropped over tender points for 1-2 seconds

Paschatkarma

1. Application of *Madhu Gritha* mixture.

OBSERVATIONS

Observations during Intervention

- The temperature of *Dahana Upakarana* was observed using Digital Pyrometer.
- Time taken for heating *Panchadhathu Shalaka* is 3 min 21 sec and temperature was 323˚C when *Panchadhathu Shalaka* was red hot.

ISSN: 2456-3110 **ORIGINAL ARTICLE** July 2022

- On removing from the heat source and during transferring time the heat dissipation was 5˚C for one minute i.e., 318˚C. Gradual dissipation of temperature per minute was about 50˚ C -70˚C i.e., 242˚C.
- After performing *Agnikarma* with *Panchadhathu Shalaka* the temperature was 181°C.
- Time taken for heating *Kshoudra* is 24 sec and temperature was 130-140°C.
- On removing the heat source and during transferring time the heat dissipation was 0°C for one minute, gradual dissipation of temperature was noted at a rate of 4°C to 6°C per minute.
- After the short initial duration there was a gradual and almost constant dissipation of heat about 8°C to 10°C. After removing from heat source the *Kshoudra* caramelise within 5-6 minutes, so *Agnikarma* need to be performed within stipulated time (5-6 minutes).

Group A

Agnikarma with *Panchadhathu Shalaka* created small wounds which took almost 7-10 days to cure. After performing *Agnikarma* with *Panchadhathu Shalaka* subjects experienced burning sensation for 3-5 minutes.

Group B

The outcome of *Agnikarma* with *Kshoudra* was with no blisters and burning sensation

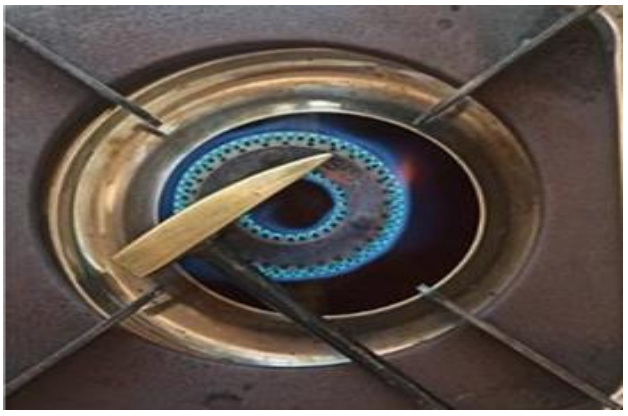
RESULT

Parameter	Group	Before Treatment	After Treatment		Follow up 1		Follow Up 2	
		Mean±SD	Mean±SD	P Value	Mean±SD	P Value	Mean±SD	P Value
Pain	Group A	8.13±0.64	4.53±0.99	0.001	4.07±1.10	0.002	3.53±1.85	0.030
	Group B	7.40±0.99	2.20±1.82		2.00±1.96		1.33±2.02	
Arc Test	Group A	1±0.000	1±0.000	0.061	1±0.000	0.040	1±0.000	0.011
	Group B	1±0.000	0.6±0507		0.4±0.507		0.33±0.488	
RLHT	Group A	1±0.000	1±0.000	0.061	1±0.000	0.040	0.87±0.352	0.011
	Group B	1±0.000	0.6±0.507		0.4±0.507		0.33±0.488	

By the end of the stipulated four sittings of *Agnikarma* using *Kshoudra*, it was seen that there was satisfactory improvement in the complaints of pain and restriction in the subjects. This result was assessed using VAS for Pain and Stiffness with Range of movements reduced from severe to mild. The therapeutic effect of *Agnikarma* with *Kshoudra* showed significant results during follow up with no recurrence.

Case - Control

Digital Pyrometer

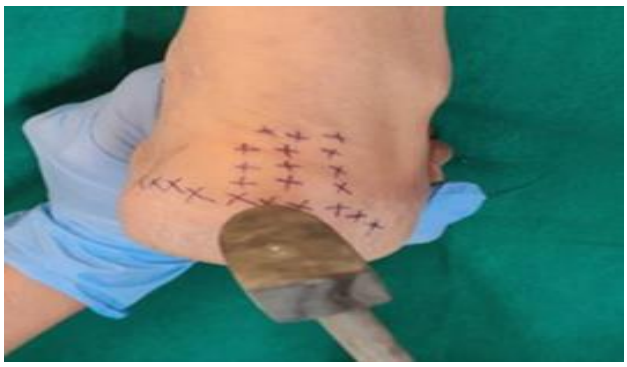


Heating of *Panchadhathu Shalaka*

Temperature checking

ISSN: 2456-3110 **ORIGINAL ARTICLE** July 2022

Tender points marked



Agnikarma **done with** ***Panchadhathu Shalaka*** **over tender points**

Application of ***Madhu Sarpi*** **mixture**

Case - Trial

Digital Pyrometer

Heating of ***Kshoudra***

Temperature checking

Tender points marked

Agnikarma **done with** ***Kshoudra*** **over tender points**

ISSN: 2456-3110 ORIGINAL ARTICLE July 2022

Application of *Madhu Sarpi* mixture

DISCUSSION

Discussion on Observation

Even though *Panchadhatu Shalaka* when heated has considerably higher heat capacity (J/g°c) than that of the *Kshoudra* it was observed that due to the less heat dissipation of *Kshoudra*, along with its *Yogavahi* and *Ashukari* properties, it was equally effective in clearing *Sroto Avarodha* by *Ama Pachana*.

Also *Kshoudra* possessing *Vata-Kapha Shamana, Ushna, Tikshana, Laghu*, *Ruksha*, *Sukshma Guna* when employed for *Agnikarma* reduces local inflammation; thus results in reduction of pain (*Shoola)* and improves the range of movements (*Kriyavasakthi).*

It was also noted that, outcome of *Agnikarma* was with no scar and the recurrence in the symptoms were not seen during the follow-up visits.

Discussion on Methodology

Agnikarma was performed in this study with four sittings on (0^{th}, 7th, 14^{th} and 21^{st}) days considering the minimum healing time for tendon repair i.e., 21 days.

Assessments were done using globally accepted scales like visual analogue scale for subjective parameters, ARC test and RLHT assessment tool for objective parameters.

These scales assisted in comprehensive evaluation of pain and range of movement, thereby detecting the changes observed during the course of intervention.

Discussion on Results

In Achilles tendinitis pain is the important feature and all the subjects presented with pain as the common symptom.

ARC Test and RLHT are clinical confirmatory test for diagnosing Achilles tendinitis.

The accuracy and sensitivity of ARC test is 78% & 85% and RLHT is 83% & 94% respectively.[5] The subjects enrolled for study reported positive ARC test and RLHT before treatment as per diagnostic criteria

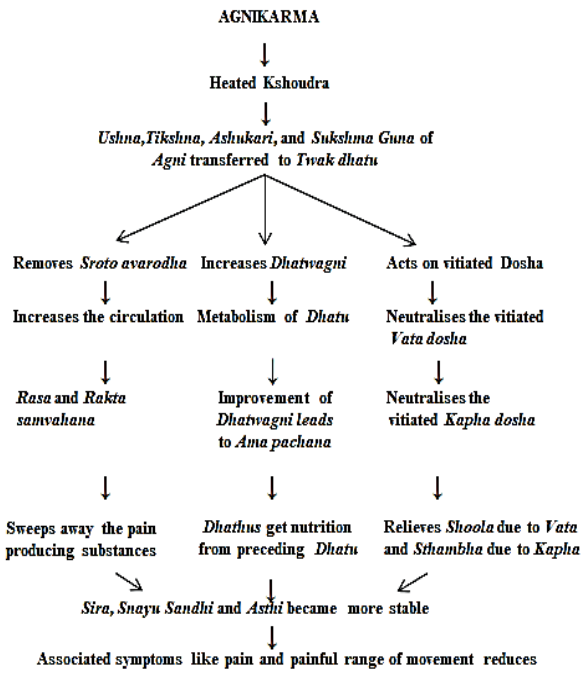
Pain, ARC test and RLHT reduced in both groups after *Agnikarma*, but Group B show better result than Group A with respect to mean rank.

Even though *Panchadhatu Shalaka* when heated has considerably higher heat capacity (J/g°c) than that of the *Kshoudra* it was observed that due to the less heat dissipation of *Kshoudra*, along with its *Yogavahi* and *Ashukari* properties, it was equally effective in clearing *Sroto Avarodha* by *Ama Pachana*.

Also *Kshoudra* possessing *Vata-Kapha Shamana, Ushna, Tikshana, Laghu*, *Ruksha*, *Sukshma Guna* when employed for *Agnikarma* reduces local inflammation; thus results in reduction of pain (*Shoola)* and improves the range of movements (*Kriyavasakthi).*

Heat in the *Kshoudra* produce *Dahana* (burn) whereas the same as such helps in healing the *Vaidyayuktha Dahana* too. Hence *Kshoudra* can be considered as superior over *Panchadhathu Shalaka.*

Discussion on probable mode of action



ISSN: 2456-3110 **ORIGINAL ARTICLE** July 2022

Theory of Pro-Inflammation[3]

Accordance with Van Hoff's

Due to the heat induced by *Kshoudra* the affected tissues accelerate the chemical changes.

↓

The increase in metabolism in the superficial tissues.

↓

Agnikarma stimulates vasomotor centre along with the heat regulating center in the hypothalamus

↓

Rise in temperature induces leads to vasodilatation of the superficial blood vessels.

↓

Relaxation of muscles & hence muscles spasm with inflammation and pain gets reduced.

LIMITATIONS

Kshoudra caramelise within 5-6 minutes after heating, so *Agnikarma* have to carried out within stipulated time (5-6 minutes).

CONCLUSION

Persistent tendon pain related to mechanical loading is the main signs of Achilles tendinopathy. This condition is one of the most common tendinopathies of the lower limb affecting mainly athletes involved in running and jumping sports. An accurate and timely diagnosis of Achilles Tendinitis is necessary to set up early treatments and to manage the problem conservatively. Diagnosis is primarily based on clinical assessment. Conservative treatment is effective in most cases, mainly using physical exercise based on eccentric training. In this clinical trial on 30 subjects, Group B (Trial group) showed significant results in most of the parameters (p value <0.05) and in Group A (Control Group) objective parameters showed not much significant results. All-inclusive, Group B (Trial group) rendered significantly better results over Group A (Control group) (p value <0.05). It can be concluded that *Kshoudra* as *Dahanopakarana* is a cost effective and an easy to perform *Anushastra* procedure with better aesthetic acceptance in the management of Achilles tendinitis.

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