IAMJ

INTERNATIONAL AYURVEDIC MEDICAL JOURNAL

Research Article ISSN: 2320-5091 Impact Factor: 6.719

A RANDOMIZED CONTROLLED TRIAL TO COMPARE THE EFFECT OF AGNIKARMA WITH JAGGERY AND MUSTARD OIL IN TENNIS ELBOW

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https://doi.org/10.46607/iamj12052024

(Published Online: May 2024)

Open Access

Article Received: 11/04/2024 - **Peer Reviewed:** 29/04/2024 - **Accepted for Publication:** 13/05/2024.

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ABSTRACT

Tennis elbow or Lateral epicondylitis is a condition characterised by pain and tenderness at the lateral epicondyle of the humerus. It is associated with particular occupations and lifestyles. It often arises from the strain of the fibres of the common extensor tendon at its origin from the lateral epicondyle of the humerus. From an Ayurvedic point of view, Tennis elbow may be considered a *Snayugathavata Vikara*. *Acharya Susrutha* mentioned *Agnikarma* as a treatment of choice for *Snayugathavata Vikara*. *Salaka* has been used regularly for this process irrespective of the structure involved or the level of the pathology. The *Dahanopakarana* mentioned for *Snayugathavata Vikara* are *Guda*(jaggery*), Kshaudra*(honey*), Taila(*oil*), etc.*, as they have deep heat penetration capacity with a more significant latent heat period. Recently, many clinical research studies have been conducted to discover the most effective and straightforward process in *Snayugathavata Vikara,* especially in Tennis Elbow. So far, no clinical trial has been undertaken to evaluate the comparative effect of different *Snigdha Dahanopakarana* mentioned by *Acharyas* in *Snayugatavata Vikara*. The present study compares the impact of *Agnikarma* using Jaggery and Mustard oil in Tennis elbow. A randomised clinical study was conducted with 36 participants of the age group 20-60 years who had tennis elbows from the OP and IP departments of *Salyatantra*, satisfying inclusion and exclusion criteria. The participants were randomly selected and divided into two groups. *Agnikarma* with Jaggery in control group A and *Agnikarma* with Mustard oil in trial group B were done in a single sitting. Per subjective and

objective criteria, participants were assessed before and after treatment. The follow-up was done on the 7th and 30th day after treatment. Statistical analysis found a significant difference in the effect of *Agnikarma* using Mustard oil compared to that of Jaggery in the management of tennis elbow.

Keywords: *Agnikarma, Snayugathavata Vikara*, Tennis elbow, Jaggery, Mustard oil.

INTRODUCTION

Ayurveda is the supreme science of medicine because it advances health and cures diseases. *Bheshaja, Kshara, Agnikarma, and Shastrakarma* are curative treatments in Ayurveda; among these, *Agnikarma* is considered superior. The tennis elbow is the most common tendinopathy of the human body and is common in tennis players. That is why it is called the Tennis elbow. This condition is characterised by pain and tenderness at the lateral epicondyle of the humerus due to non-specific inflammation at the origin of the extensor muscles of the forearm[1]. Extensor carpi radialis brevis, Extensor digitorum, Extensor carpi ulnaris, and Extensor digit minimi are the four muscles which have a common tendinous origin at the lateral epicondyle, where the tendon of extensor carpi radialis brevis is most commonly involved in Tennis elbow. In tennis, specific movements of the elbow and wrist joints are painful. It may arise from minor pronation and supination strains in those whose work demands driving, painting and cooking. The patient finds it difficult to turn a doorknob, squeeze a cloth, or grasp any weight in a semi-pronated position of the upper limp. Patients also need help to do their daily routine work. The general population's prevalence is 1-3%, and men and women are equally affected[2]. The highest incidence is in the age group of 30 to 50 years. Based on signs and symptoms, Tennis elbow can be correlated with the condition of *Snayugathavata Vikara* in Ayurveda. *Snayugatavata* is characterised by *Stamba*(stiffness), *Soola*(pain), restricted movements, etc[3]., as mentioned by *Acharya Susrutha.* Tennis elbow can be referred to as *Kurparasandhi Snayugathavata Vikaara*. *Snehana, Upanaha, Agnikarma* and *Unmardana* are the specific management lines in *Snayugathavata Vikaras[4]*. *Sira-Snayu-Asthi-Sandhi Gata Roga Dahanopakarana, Guda* (jaggery*), Kshaudra*(honey*), and Sneha are mentioned.*[5] *Acharya Charaka* explains *Snayupradoshaja vikaras* as *Stamba* (stiffness), *Sankocha* (contraction*), Khalvi* (neuralgia of the upper & lower extremities), *Granthi* (tumours in ligament*), Spurana* (throbbing sensation), *Supthi* (numbness)[6]. The current management of Tennis elbow is steroid injection and NSAIDs, which have their side effects in the long term. The patients who do not respond to injections also have to go for surgical intervention. The complication and chance of recurrence are high in this management method and could be more cost-effective. So, in these circumstances, Ayurvedic management, like *Agnikarma*, is relevant. *Agnikarma*, a parasurgical treatment modality, has been used in clinical practice for a long time. It is best among *Anushatra Karma* and has been used in managing musculoskeletal disease as an effective, safe and cost-effective method. Moreover, it is simple, less invasive and can be done as an OPD procedure. *Acharya Susruta* mentioned *Snigdha Agnikarma* in the management of *Snayugatavata Vikara*. The *Dahanopakarana* mentioned for *Snayugathavata Vikara* are *Guda*(jaggery*), Kshaudra*(honey*), Taila(*oil*), etc.,* as they have deep heat penetration capacity with a more significant latent heat period.[7] In this scenario, an attempt was made to find out the comparative effect of *Agnikarma* using two different *Dahanopakarana* as mentioned by *Acharya Susruta* in Tennis Elbow (*Kurpara Sandhi Snayugatavata Vikara*). The present study was conducted on 36 participants diagnosed with Tennis elbow following inclusion criteria. The participants were randomly allocated to two groups, with 18 participants in each group. Assessment criteria were analysed statistically, and conclusions were drawn. This has been carried out using a strict clinical research methodology.

AIMS AND OBJECTIVES

- To assess the effect of *Agnikarma* with Jaggery and compare it with Mustard oil in Tennis elbow.
- To compare the effect of *Agnikarma* with Mustard oil and *Agnikarma* with Jaggery in the management of Tennis elbow.

MATERIALS AND METHODS

A randomised clinical study was conducted with 36 participants of the age group 20-60 years who had tennis elbows from my institution's OP and IP department of *Salyatantra*, satisfying inclusion and exclusion criteria. The participants were randomly selected and divided into two groups using the lottery method. Control group A is managed with *Agnikarma* with Jaggery, and Trial group B is managed with *Agnikarma* with Mustard oil in a single sitting. Per subjective and objective criteria, participants were assessed before and after treatment. The follow-up was done on the 7^{th} and 30^{th} day after treatment. After completing the study, all the data was analysed using the SPSS 23.0 software version.

DIAGNOSTIC CRITERIA

1. Pain on the lateral epicondyle of the humerus.
2. Tenderness over the lateral epicondyle.
3. Cozen's test: When the patient was asked to extend his clenched fist against resistance, considerable pain was experienced at the lateral epicondyle.
4. Pain occurs during certain activities, such as pouring a liquid container, lifting with the palm down, sweeping, and sports.

INCLUSION CRITERIA

1. Participants satisfying diagnostic criteria of Tennis elbow.
2. Age between 20 to 60 years.
3. Participants were selected irrespective of religion, caste and economic status.
4. Participants are willing to participate with written consent.

EXCLUSION CRITERIA

1. Participants contraindicated for *Agnikarma* as per classics.
2. Participants with a history of pathological fracture of the lateral epicondyle.
3. Known cases of Rheumatoid arthritis, Malignant tumours, and senile osteoporosis in and around the elbow region.
4. Participants with uncontrolled Diabetes Mellitus.
5. Participants with uncontrolled Hypertension.

PROCEDURE

Preoperative procedure

The procedure was explained in detail, and counselling was given regarding the post-operative precautions to take care of the burned part. Informed consent was taken. The participant was kept in a comfortable position (lying/sitting) with the elbow bent 90^0 with a pronated forearm so that the lateral epicondyle and the elbow were prominent. An eye bandage was given.

Procedure

The tender points were marked over the base of the affected elbow under aseptic precaution. A certain amount of Jaggery\ Mustard oil was taken in a sterile vessel and heated until it started boiling. The heated Jaggery \Mustard oil was applied over the most tender point in and around the lateral epicondyle with help of pipette as *Bindu visesha*. As it cools, immediately apply Aloe vera pulp to relieve burning pain.

Post-operative care: After wiping off the Aloe vera pulp, a mixture of Madhu and Ghrita was applied immediately after Agnikarma. The participants were observed for 30 minutes after the procedure. Burn spots were cleaned with an antiseptic solution, and they were advised to apply Madhu-Ghrita daily.

Heated Mustard oil

Agnikarma using Mustard oil

Heated jaggery

Agnikarma using Jaggery

CRITERIA FOR ASSESSMENT

Subjective parameters

- Pain by visual analogue scale
- Tenderness

Objective parameters

- Response to Cozen's test.

RESULTS AND ANALYSIS

The collected data were subjected to statistical analysis using appropriate statistical methods. Frequency and percentage were calculated for qualitative variables, while mean and SD were calculated for quantitative variables. Since the data distribution is nonnormal, non-parametric methods were employed to analyse the data. Wilcoxon signed-rank test was used to assess the significant effect before and after treatment within each group. Mann Whitney U test was used to compare two groups based on before and after treatment values. $p>0.05$ is considered to be statistically significant. All analyses were carried out with the help of software SPSS 23.0.

Most participants in this study were 30 to 55 years old, which is equal to the general prevalence of Tennis elbow. In Group A, male and female participants are equally distributed (50%), whereas the majority of the participants in Group B are females (55.6%). The rise in the incidence of the female gender in this disease may be due to the involvement of household chores. In the religion-wise distribution, Hindus were dominant, followed by Christians. This reflects the geographical preponderance of this particular region rather than any specific affinity of the disease with religion. The occupation-wise distribution shows the majority of the participants were Housewives and manual labourers, which suggests that the disease might have a significant relation with the activities of the Participants. Most of the cases belong to the middle-class group (72.2%%). This may be due to the nature of their occupation. In this study, most of the respondents in Group A and Group B are Right elbow affected, 66.7% and 83.3%, respectively. This may be because most participants are predominantly right-handed and exposed during daily activities requiring repeated or forceful movements.

Effect Of Treatment on Study Parameters

Pain - Group A and B participants did not differ significantly based on pain ($p>0.05$) before treatment. The initial conditions of Group A and Group B participants were similar. Thus, Group A and Group B can be compared after intervention. Mann-Whitney U test showed a significant difference in the pain level of Group B (3.333) compared to Group A (4.333). On the 30th day after treatment, Group A (0.389) and Group B (0.389) reported the same level of relief.

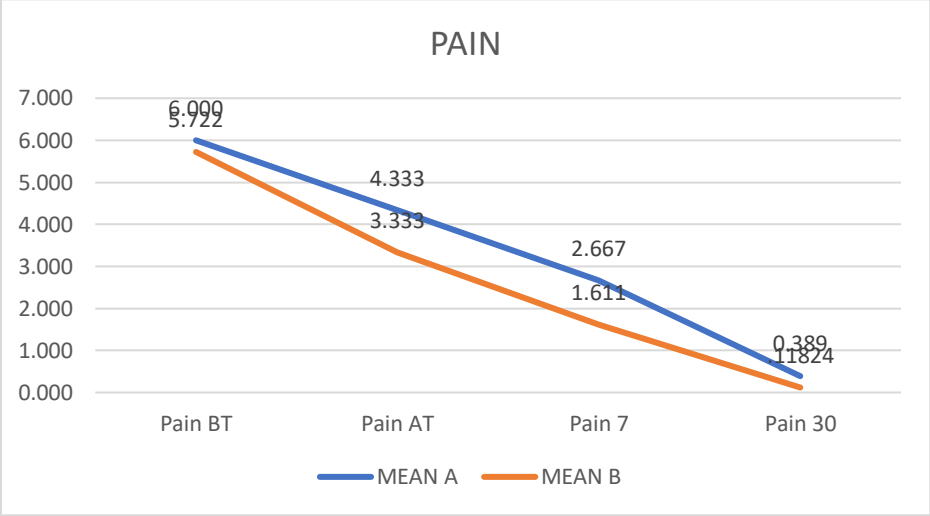

Figure 1: Line diagram on pain assessment

Tenderness - Group A and Group B participants do not differ significantly based on tenderness ($p>0.05$) before treatment. The initial conditions of Group A and Group B participants were similar. Thus, Group A and Group B can be compared after intervention**.** The Mann-Whitney U test showed no significant difference between Group A and Group B in Tenderness ($p>0.05$).

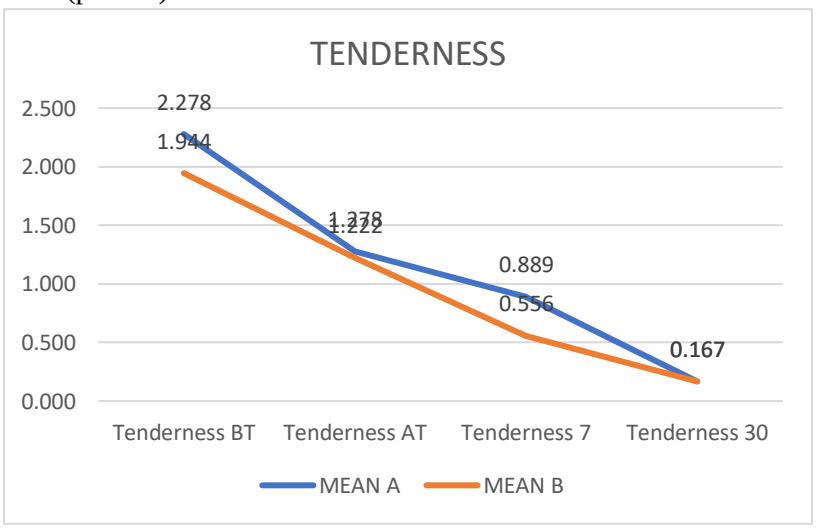

Figure 2: Line diagram on tenderness

Response to Cozen's test—Before treatment, Group A and Group B participants did not differ significantly in their response to Cozen's test ($p>0.05$). Group A and Group B participants were similar in their initial condition. Thus, Group A and Group B can be compared after intervention. The Mann-Whitney U test showed no significant difference between Group A and Group B in their level of response to Cozen's test($p> 0.05$).

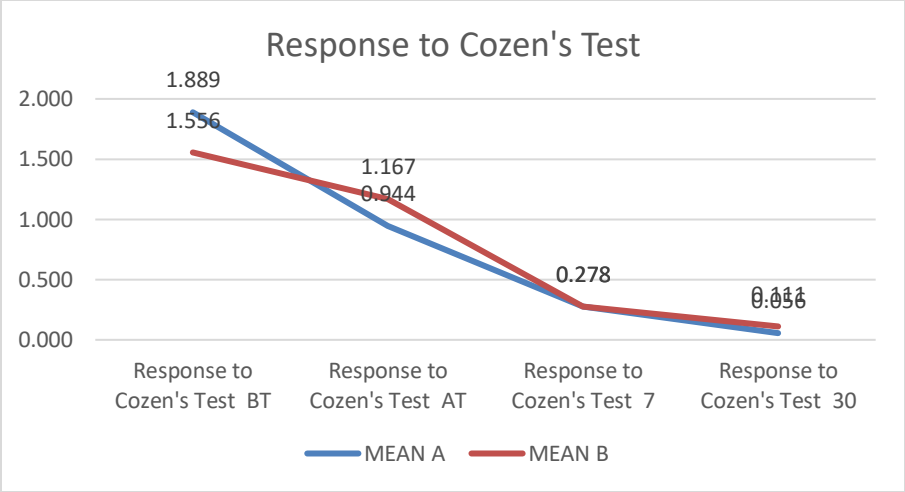

Figure 3: Line diagram in response to Cozen's test

DISCUSSION

In this study, the effect of *Agnikarma* using Mustard oil is compared with the standardised method *of Agnikarma* using Jaggery in Tennis elbow.

The p**robable mode of action of *Agnikarma***

Agnikarma is *kapha* and *Vata Shamana* due to its antagonistic properties like *Ushna, Tikshna, Sukshma, and Ashukari Guna*. In *Agnikarma, Ushna* (hot), *Tikshna* (sharp), and *Sukshma* (subtle) properties of *Agni* remove obstructions in *Srotas* and increase blood circulation to the affected site. Thus, *Agnikarma* helps flush the inflammation and pain, giving the patient instant relief. *Agnikarma* halts the progression of diseases by its *Ushna* property, stimulates the tissue metabolism (*Dhathvagni*) and aids in the *Amapachana* (combustion of the metabolic wastes), thereby removing the *Avarana. Agnikarma* increases *Pitta,* which in turn vitiates *Raktha* (blood). This suddenly leads to a burning sensation, blister formation, fever and thirst, which may be correlated to the acute immune response to burn.

Probable mode of action of *Agnikarma* using Mustard oil

Mustard oil is used as a medium for *Snigdha Agnikarma* in this study. *Agnikarma* is mainly done in painful conditions and *Vata Kaphaja* diseases. Mustard possesses *Guna* like *Tikshna and Ushna,* which is *Vata Kapha Hara*. *Agni* also possesses qualities similar to Mustard, *Sukshma,* and *Ashukari. The b*oiling point of *Singdha Dravya* ranges from 140^0-200^0, and it has higher latent heat. The heat dissipation rate of *Snigdha Dravyas* is about 2^0c. *Agnikarma* with mustard oil is observed to have a sheat retaining capacity for longer, resulting in deeper heat penetration through *Sukshma Siras* and high thermal conductivity.

Effect Of Treatment on Study Parameters

Pain: In both Group A and Group B, there was a noticeable decrease in pain levels after treatment, and this improvement continued during the follow-up period.

Both groups' Statistical and clinical data show that after the intervention, Group B showed better relief in pain. During the follow-up period, both groups show the same level of relief. This may be due to the *Vata Hara* property used by both *Dahanopakarana*. In Group B, there was immediate relief from pain noted on the very next day after treatment, and it was sustained up to the 7^{th} day. In contrast, in Group A, the reduction in pain occurred gradually. This difference could be attributed to the high thermal conductivity and *Vata Kapha Hara* properties of Mustard oil. The nerve stimulation theory explains the analgesic effect of *Agnikarma.* Heat or cold stimuli stimulate the skin's receptors, and the afferent nerve stimulated by heat may have an analgesic effect by acting on the gate control mechanism.

Tenderness: In both Group A and Group B, a significant reduction in tenderness was observed from be-

fore to after treatment, and these improvements continued during the follow-up period. However, when comparing both groups, there was no significant difference in tenderness. The present study shows that the pattern of reduction in the grade of tenderness is almost the same in both groups. This may be due to the body's basal metabolism increasing by a certain percentage for every ten rises in body temperature (Vant Hoff's principle). The temperature rise induces muscle relaxation. Thus, muscle spasms with inflammation and pain are reduced. **Response to Cozen's test:** In the criteria "Response to Cozen's test", when comparing within each group, both Group A and B show a significant change in grade. However, when comparing both groups, there is no significant change. This may be due to rising temperature lower the viscosity of the liquid. This change affects the fluids in narrow vessels and the fluid movement within and throughout the tissue space. This increases the rate of circulation and thereby acts as an anti-inflammatory. *Snigdha Agnikarma* helps get this effect in deeper tissue; it has more conduction, penetrating deeper tissue. Thus, the symptoms like pain and inflammation get reduced, and the range of movement increases.

CONCLUSION

The following conclusions can be drawn after analysing the data collected through the clinical study. Tennis elbow typically affects individuals aged 30 to 55 years, with a higher prevalence among females than males, as indicated by this study. Socioeconomically, it is more commonly found among individuals belonging to the middle-class stratum. The nature of one's occupation also plays a substantial role in developing this condition. According to the findings of this study, it is more prevalent among homemakers and manual labourers. This higher occurrence might be attributed to the repetitive wrist extension against resistance and twisting activities characteristic of their work profile. The thermal conductivity of Mustard oil is higher than that of Jaggery. Dahanopakarana *effectively reduces* pain, but Mustard oil shows quicker relief initially than Jaggery. However, during follow-up, both treatments have similar effects.

Both methods are equally effective regarding Cozen's test response and tenderness. When using Jaggery for *Agnikarma*, blisters commonly form and heal within two weeks, leaving a scar. In contrast, *Agnikarma* with Mustard oil rarely causes blisters but leaves a scar at the treatment site. Performing *Agnikarma* with Mustard oil is much easier than using Jaggery, as it is easier to handle during the procedure.

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Source of Support: Nil

Conflict of Interest: None Declared

How to cite this URL: Sreekutty K et al: A Randomized Controlled Trial to compare the effect of Agnikarma with Jaggery and Mustard oil in Tennis elbow. International Ayurvedic Medical Journal {online} 2024 {cited May 2024} Available from: http://www.iamj.in/posts/images/upload/862_868.pdf