



## Comparing the efficacy of *Agnikarma* with therapeutic ultrasound in the management of tennis elbow - A randomised controlled preliminary study

R Sreelekshmi<sup>\*</sup>, Shaithya Raj, P N Rajeshwari, Rabinarayan Tripathy

Department of Shalya Tantra (Surgery), Amrita School of Ayurveda, Amritapuri, Amrita Vishwa Vidyapeetham, Vallikavu, Clappana P O, Kollam District, 690525, Kerala, India

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### ABSTRACT

**Background:** Tennis elbow is a common musculoskeletal disease of elbow and causes restricted movement of forearm. Various treatment modalities like NSAID, corticosteroid injection, counter bracing, physiotherapy, surgery etc are available but safety and efficacy of one treatment over another is under research. Ayurveda classifies this condition as *Snayugata vata*. According to Sushruta, *Agnikarma* (thermal cautery) is the one among the treatment modalities for *Snayugata vata*. Previously published randomised controlled trials have shown that therapeutic ultrasound is safe and effective for tennis elbow. However, the comparative efficacy of these two treatment modalities is unknown.

**Objective:** This study compares the effects of Agnikarma (AGK) with Therapeutic Ultrasound (TUS) in reducing pain, tenderness and restores the ability to do various tasks.

**Materials and methods:** A total of 30 patients were enrolled in the study as an open-label, double-armed, prospectively designed comparative clinical study, with 15 patients in each group. Group AGK received two sittings of Agnikarma and Group TUS received therapeutic ultrasound. To analyze the patients, three outcome measures were adopted: pain intensity, assessed with a Numerical Pain Rating Scale, tenderness – Grade 0 to Grade 4 (mentioned in Hutchinson's clinical methods) and pain and functional Disability assessed with the Patient Rated Tennis Elbow Evaluation (PRTEE) questionnaire. Assessment was done on 0<sup>th</sup>, 8<sup>th</sup>, 15<sup>th</sup>, 30<sup>th</sup> and 60<sup>th</sup> day.

**Result:** Tennis elbow can be effectively treated with AGK and TUS. ( $p < 0.001$  for pain, tenderness and PRTEE). While comparing between the groups, on 8<sup>th</sup> day and 15<sup>th</sup> day statistically significant difference in pain and PRTEE ( $p < 0.05$ ) was noted between AGK and TUS groups. Agnikarma showed better results than therapeutic ultrasound in pain management and showed an improved quality of life from 8<sup>th</sup> day onwards and for a period up to 2 months.

**Conclusion:** Both Agnikarma and therapeutic ultrasound have roles in the management of tennis elbow. However, starting on the 8<sup>th</sup> day and continuing for up to 2 months, Agnikarma showed a significant benefit in pain management and improved status for quality of life.

### 1. Introduction

Tennis elbow (TE) is a soft tissue injury characterized by pain and tenderness at the lateral epicondyle of the humerus due to degeneration at the extensor muscles of the forearm. It affects 1%–3% of the general population annually, making it a relatively common condition [1]. Although there are many distinct causes of TE, overuse and repeated microtrauma are particularly crucial in those who are genetically prone to this disease [2]. TE has a complicated and poorly understood

pathophysiology. Recent research claims, in addition to degenerative alterations, the tissue's histology reveals granulation tissue, micro-rupture, an abundance of fibroblasts, vascular hyperplasia, unstructured collagen, and most significantly, a lack of traditional inflammatory cells (macrophages, lymphocytes and neutrophils) [3,4]. Elevated levels of substance-P, calcitonin-generated peptide, and glutamate have been found within the ECRB tendon in patients of TE, may be considered as pain generators of this condition [2].

TE has no direct reference in Ayurveda. Based on the etiology and

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<sup>\*</sup> Corresponding author.

E-mail address: [sreelekshmisaray@gmail.com](mailto:sreelekshmisaray@gmail.com) (R. Sreelekshmi).

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symptoms, it can be classified as *Snayugata vata* [5]. Due to the activities that vitiate *vata* especially over exercise or excess movements of elbow joint, *vata* is vitiated, [6] and leads to the symptoms such as pain, stiffness and restricted movement.

Though the treatments of the disease TE are manifold, therapies with concurrent rapid pain reduction and amplification of tendon healing are not present. Therefore, a treatment that gives a sustained effect without giving rise to any adverse effects persists as a challenge in the management.

Evidence suggests TUS helps in reducing pain and stimulating the healing of the tendon. Treatment period and its effects are slightly longer than other treatments.

Acharya Sushruta explained the treatment modality for *Snayugata vata* are *Snehana* (oleation) *Upanaha* (bandage with hot medicated paste), *Agnikarma* (thermal cauterization) and *Bandhana* (bandaging) and *Unmardana* (massaging) [7]. *Agnikarma* appears to be more effective than the others and provides immediate relief. *Agnikarma* is a popular para-surgical procedure in Ayurveda in which thermal energy/heat is utilized. It offers total relief from certain disorders that cannot be treated with herbal medicine, surgery and alkaline cauterization [8]. We also hypothesize that *Agnikarma* action is related with inflammation reduction, theory of thermodynamics and the gate control theory of pain [9]. *Agnikarma* can be opted as safe and effective treatment for TE [10].

The objective of this study was to assess the efficacy of *Agnikarma* against therapeutic ultrasound in the treatment of TE.

## 2. Methods

### 2.1. Trial design

An open-label, double-armed, prospectively designed comparative clinical trial was carried out. The study was approved by the Institutional Ethical Committee (IEC) of Amrita School of Ayurveda, Amritapuri Amrita Vishwa Vidyapeetham, India via Certificate of Ethical Clearance (IEC-AIMS-2019-AYUR-164/26-08-2019) and registered with the Clinical Trial Registry of India with reference number: CTRI/2020/05/025109. For the study, the patients' prior, informed consent was obtained.

### 2.2. Eligibility criteria for participants

#### 2.2.1. Inclusion criteria

Patients were included if they experienced signs and symptoms of TE and were between the age group of 20–60. The disease can be diagnosed by tenderness on the lateral epicondyle and it is confirmed by simple clinical examination techniques, viz. Cozen's test and Mill's manoeuvre.

#### 2.2.2. Exclusion criteria

Patients diagnosed with joint disorders (viz. RA, OA, GA of elbow joint), Tuberculosis, Diabetes, Malignant tumors, senile osteoporosis in and around the elbow, patients who have received a corticosteroid injection during the past month, patients contraindicated for *Agnikarma* and patients contraindicated for therapeutic ultrasound were excluded.

### 2.3. Settings and locations where the data were collected

Patients were recruited from OP and IP Departments of Amrita School of Ayurveda.

### 2.4. Interventions

Patients of group AGK received two sittings of *Agnikarma* with an interval of 7 days and group TUS received continuous Therapeutic Ultrasound of intensity 1.5 W/sq.cm, Frequency 1 MHz for 5 min for 15 days.

### 2.4.1. Group AGK: *Agnikarma*

**2.4.1.1. *Purvakarma.*** All the patients are advised to take *pichila anna* (eg; Rice gruel) in previous night.

**2.4.1.2. *Pradhanakarma.*** Patient was positioned comfortably on a chair and elbow was supported by the attendant. The area of maximum tenderness was elicited and marked. The affected part is cleaned with normal saline and wiped with sterile gauze piece. *Agnikarma* was done till *samyak twak dagdha lakshana* (adequate therapeutic superficial burn) in bindhu form (making multiple dots) within 5 cm<sup>2</sup> marked area, sparing a gap of 0.5 cm between dots. Red hot *panchadhata shalaka* is used for this bindhu *Agnikarma*. Immediately after dahana (cauterization), *kumari* pulp was smeared over the area and then a paste of ghee and honey was applied. The procedure was done in two sittings. Fig. 2 shows the procedure of *Agnikarma*.

**2.4.1.3. *Paschatkarma.*** Scar is left open to heal. Patient was advised to apply little quantity mixture of ghee and honey once a day for 3 successive days to avoid infection.

### 2.4.2. Group B: *Therapeutic Ultrasound*

Patient was positioned comfortably on a chair and elbow was supported on the table. therapeutic ultrasound was administered using a HMS Indosonic 102 – ultrasound therapy equipment with a transducer which has 1 cm<sup>2</sup> application area, at 1.5 W/cm<sup>2</sup>, 1 MHz frequency, continuous mode in painful area, 5 min once a day for 15 days. In addition to the full contact techniques, rotational movements at a vertical angle to the skin were performed with aqua sonic gel. Fig. 3 shows the procedure of therapeutic ultrasound.

Patients in both groups are advised, not to carry out heavy work and to avoid straining of the elbow during the days of treatment.

## 2.5. Outcomes

To evaluate the patients, three outcomes measures were used: pain intensity, assessed by the Numerical Pain Rating Scale (NPRS), tenderness was assessed through the grading system mentioned in Hutchison's clinical methods (Grade 0 - Grade 4) [11], pain and functional disability, assessed by the Patient-Rated TE Evaluation (PRTEE) questionnaire [12].

Outcomes were recorded at 5 time points (1) 0<sup>th</sup> day (baseline), (2) 8<sup>th</sup> day, (3) 15<sup>th</sup> day, (4) 30<sup>th</sup> day and (5) 60<sup>th</sup> day by blinded assessor.

### 2.6. Sample size and randomisation

A minimum sample size of 30 was estimated for the research with an anticipated loss of 15% to follow-up. The final required sample size for the current study was adjusted to 36 participants by taking 5% level of significance and 90% power. Sample size was calculated using the formula  $n = \frac{(Z_{1-\alpha}/2 + Z_{1-\beta})^2 \cdot \sigma^2}{d^2}$  [13]. Mean of NPRS scores and standard deviation were taken from the pilot study. Simple random sampling (lottery method) was used to divide the patients into 2 groups. After all dropouts 30 patients were divided into two, each group consisting of 15 patients. A schematic representation of the patients' progression throughout the study is shown in Fig. 1.

### 2.7. Statistical methods

The statistical analysis was done with SPSS VER 26. The Shapiro-Wilk test was applied to check the normality of the variables. The Independent sample *t*-test was used to compare the Age between the group and the results are shown as mean  $\pm$  SD. The other baseline data of the groups were analyzed using Chi-square test for association. The Friedman Test was used to compare the results between each group's

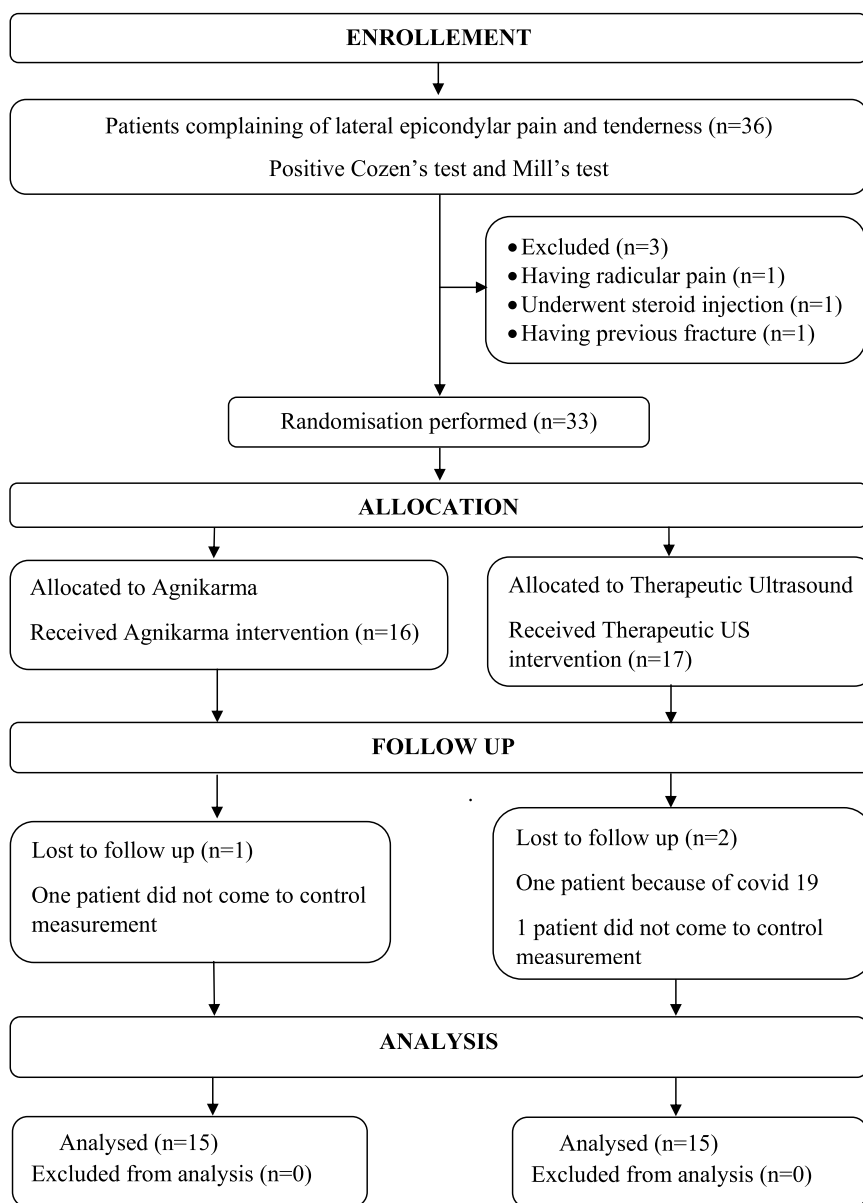


Fig. 1. Schematic representation of the patients' progression throughout the study.

treatment stages. Mann-Whitney *U* Test was employed to compare the results between groups in each treatment stage. The *p* value was set at 0.05.

### 2.8. Blinding

The evaluator-blinded data collection was carried out throughout the study. The outcome variables of interventions were documented and statistical analysis was also done in blinded manner.

## 3. Result

### 3.1. Demographic detail and baseline data

All patients' demographic and baseline data were evaluated, and the results indicated that there was no significant difference in the patients' age, gender, marital status, religion, education, socio-economic status, inhabitation, diet, prakurti, disease duration and history of other illness between AGK and TUS groups (Table 1). No patients were undergone any concomitant treatments during the study period.

### 3.2. Outcomes and estimation

Table 2 summarizes the outcome variables measured at baseline (Before treatment), 8<sup>th</sup> day, 15<sup>th</sup> day, 30<sup>th</sup> day and 60<sup>th</sup> day. Assessment is done separately for the AGK group and TUS group. There were no significant differences between the two groups in the baseline values for the NPRS, tenderness and PRTEE score ( $p > 0.05$ ).

The mean scores of NPRS, tenderness and PRTEE improved significantly ( $p < 0.001$ ) in both groups at 8<sup>th</sup>, 15<sup>th</sup>, 30<sup>th</sup> and 60<sup>th</sup> day assessment compared with baseline score. However, the best NPRS, tenderness and PRTEE scores were seen in AGK group from 8<sup>th</sup> day onwards and for a period up to 2 months.

Comparison between the two groups confirmed that statistically significant differences between the two groups in 8<sup>th</sup> day and 15<sup>th</sup> day for the NPRS and PRTEE score ( $p > 0.05$ ).

## 4. Discussion

In this study, which assessed lateral elbow pain, tenderness, and functional disability, both Agnikarma and Therapeutic Ultrasound are

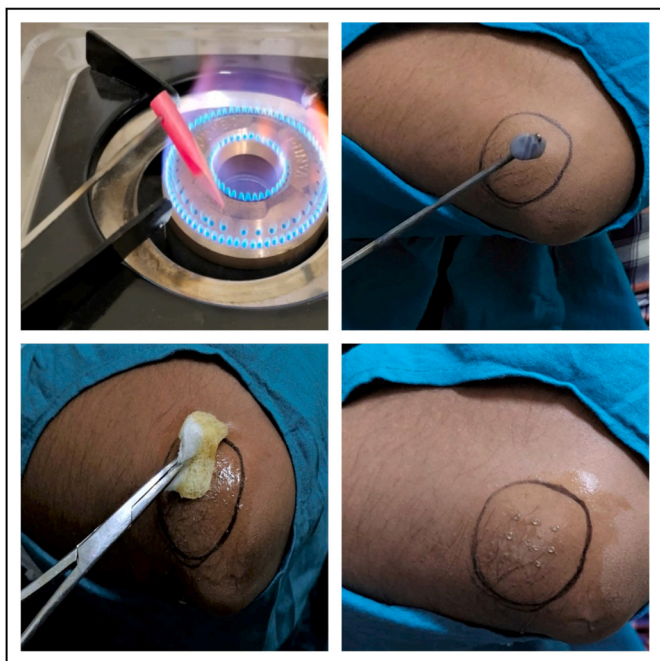


Fig. 2. Procedure of Agnikarma.



Fig. 3. Procedure of Therapeutic Ultrasound.

found to be efficient therapies for TE. However, the AGK group showed highly marked reduction in all the assessment parameters from 8<sup>th</sup> day onwards and showed better result in 15<sup>th</sup> day assessment and its effect sustained up to 2 months.

4.1. Possible action of Agnikarma

Pain is a characteristic sign of vitiated vata. When Agnikarma is performed using a cautery made up with five-metals, it releases obstruction of *vayu* and instantly relieves pain [9,10]. Every *dhatu* (tissue) has a unique *dhatvagni* (tissues’ digestive fire) for its nutrition, and

Table 1

Baseline data.

Clinical Profiles	Group AGK (n = 15)	Group TUS (n = 15)	p-value
<b>Socio-Demographic data</b>			
Age (yrs)	38.73 ± 9.80	37.00 ± 13.04	0.684
Gender - Male:Female	12:3	10:5	0.409
Marital Status - Married:Unmarried	12:3	7:8	0.058
Religion - Christian:Hindu:Muslim	1:14:0	1:12:2	0.341
Education - SSLC:Intermediate: Graduate	0:8:7	2:6:7	0.319
Socio Economic Status - BPL:Middle Class:APL:Rich Class	0:6:7:2	3:1:8:3	0.077
Inhabitance - Rural: Urban	13:2	11:4	0.361
Diet - Mixed: Vegetarian	11:4	13:2	0.361
<b>Diagnostic details</b>			
Prakruthi - KP: KV: PK: PV: VK: VP: KVP	2:3:1: 2:5:1:1	2:3:1: 2:4:3:0	0.909
Disease duration - <1Month: 1-6 Month: >1Year	4:7:4	5:7:3	0.881
History of other medical illness - No: Yes	12:3	13:2	0.624

KP – Kapha Pitta; KV – Kapha Vata, PK – Pitta Kapha, PV – Pitta Vata, VK – Vata Kapha, VP – Vata Pitta, KVP – Kapha Vata Pitta.

if there is a reduced digestive fire, it may affect muscle, fat, and bone. During Agnikarma, its hot property stimulates the tissue metabolism and may get relief of symptoms [14].

As per contemporary understanding, heat may stimulate the lateral spinothalamic tract, which stimulates the descending pain inhibitory fibres, that releases an endogenous opioid peptide which binds with the opioid receptors in the substantia gelatinosa Rolandi, inhibiting the release of P-substance and blocking the transmission of pain signals. *Agnikarma* (therapeutic burn) may produce acute inflammation and there by releasing certain cytokines (which are capable to produce macrophages), histamines, prostaglandins have important roles in tendon and ligament homeostasis. *Agnikarma* (therapeutic burn) may increase the temperature at the particular site of the body activate thermostatic centre and distribute this localised temperature throughout the body. As a result of vasodilation, blood flow increases, increased delivery of nutrients and efficient removal of waste products occurs. It will support the healing of tendon [15].

4.2. Action of Therapeutic Ultrasound

The thermal effect (when tissue temperature can be raised to 40–45 °C for at least 5 min) results in higher pain threshold, improved collagen extensibility, increased enzyme activity, increased tissue perfusion, and decreased nerve conduction velocity. Mechanical effects (which cause micro-massage of soft tissues and have a sclerolytic effect), cavitations (which speed up ion transmigration at the cellular level), and acoustic streaming (Free radicals and other waste products of cell metabolism are expelled and protein synthesis and repair process of the cell is activated) are all hallmarks of the non-thermal action of therapeutic ultrasound.

4.3. Limitations of the study

The sample size was not calculated for a superiority design. The 60 days are not enough to assess the long-term effects of the treatments.

5. Conclusion

Agnikarma and Therapeutic Ultrasound are effective treatment modalities for TE, but Agnikarma showed crucial role in pain management and improved status for the quality of life from 8<sup>th</sup> day onwards and for a period up to 2 months. Future researches are necessary to evaluate the



**Table: 2**

Baseline clinical assessment and effect of interventions on various clinical assessment scales. Expressed in mean and standard deviations (S.D.).

Variable		Baseline	8 <sup>th</sup> day	15 <sup>th</sup> day	30 <sup>th</sup> day	60 <sup>th</sup> day	p <sup>a</sup> & p <sup>c</sup>
<b>1.NPRS</b>							
AGK group	mean ± SD	2.20 ± 0.86	0.80 ± 0.56	0.0 ± 0.0	0.0 ± 0.0	0.07 ± 0.26	p <sup>a</sup> < 0.001
TUS group	mean ± SD	2.00 ± 0.76	1.73 ± 0.8	0.67 ± 0.72	0.13 ± 0.35	0.33 ± 0.62	p <sup>c</sup> < 0.001
	p <sup>ac</sup>	0.563	0.002	0.001	0.15	0.141	
<b>2.Tenderness</b>							
AGK group	mean ± SD	2.07 ± 0.8	0.60 ± 0.51	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	p <sup>a</sup> < 0.001
TUSgroup	mean ± SD	1.67 ± 0.72	0.93 ± 0.96	0.27 ± 0.6	0.13 ± 0.35	0.07 ± 0.26	p <sup>c</sup> < 0.001
	p <sup>ac</sup>	0.162	0.414	0.073	0.15	0.317	
<b>3.PRTEE Score</b>							
AGK group	mean ± SD	40.0 ± 11.05	9.90 ± 7.06	0.0 ± 0.0	0.0 ± 0.0	0.23 ± 0.90	p <sup>a</sup> < 0.001
TUS group	mean ± SD	37.03 ± 10.11	23.03 ± 12.18	6.87 ± 8.12	1.83 ± 3.94	2.47 ± 4.52	p <sup>c</sup> < 0.001
	p <sup>ac</sup>	0.34	0.002	0.001	0.073	0.118	

p<sup>a</sup>: p value within different stages of Agnikarma group.p<sup>c</sup>: p value within different stages of TUS group.p<sup>ac</sup>: p value between groups in each stage.

NPRS: Numeric Pain Rating Scale.

PRTEE: Patient-Rated TE Evaluation questionnaire.

long-term efficacy of Agnikarma with large number of patients and comparison with other treatment modalities for TE.

## 6. Informed consent

Informed consent was obtained from all patients included in this study.

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## Author contributions

**R Sreelekshmi:** Conceptualization, Methodology / Study design, Validation, Formal analysis, Investigation, Resources, Data curation, Writing – original draft, Writing – review and editing, Visualization. **Shaithya Raj:** Validation, Formal analysis, Writing – review and editing, Supervision. **P N Rajeshwari:** Validation, Formal analysis, Writing – review and editing, Supervision. **Rabinarayan Tripathy:** Validation, Formal analysis, Writing – review and editing, Supervision.

## Declaration of generative AI in scientific writing

During the preparation of this work the author(s) used no artificial intelligence tools.

## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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