WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.084
Volume 13, Issue 2, 692-719. Case Study ISSN 2277–7105

AN OPEN LABEL DOUBLE ARM CLINICAL STUDY TO COMPARE THE EFFECT OF AGNIKARMA WITH TAPTHA KSHOUDRA AND PANCHADHATU SHALAKA INLATERAL EPICONDYLITIS (TENNIS ELBOW) – CASE SERIES

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Article Received on
24 Nov. 2023,

Revised on 14 Dec. 2023,
Accepted on 04 Jan. 2024

DOI: 10.20959/wjpr20242-30972

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ABSTRACT

Tennis elbow is a painful disorder of the forearm; it may develop due to non-specific inflammation at the origin of extensor muscles of the forearm. It is clinically diagnosed by sensation of pain and tenderness at the lateral epicondyle of humerus which aggravates during the resisted dorsiflexion of wrist and fingers. On the basis of signs and symptoms, tennis elbow can be correlated with the condition of *Snayugata vata* described in *Ayurveda*. It is developed when *Vatadosha* aggravates due to *atichesta*, *ativyayama*. etc and gets localized in *snayu* of *Kurpara sandhi*. In *Ayurveda*, *Acharya Sushruta* has advocated various treatment modalities such as *snehana*, *upanaha*, *agnikarma* and *bandhana* for *snayugata vata.* Amongst these, *Agnikarma* seems to be more effective in providing distinct and instant relief. If it is done perfectly, disease does not reoccur. *Agnikarma* with *kshoudra* can be done in *snayugata vyadhi* according to *Acharya Susruta. Kshoudra* has *ushna, laghu, rooksha, sookshma guna* and it pacifies both *vata* and *kapha*. It aid the penetration of heat through *sookshma sira.* The study was conducted on 40 randomly assigned patients at Government Ayurveda and Unani Hospital, Bengaluru (SJGAUH) by dividing them into 2 groups -Group A and Group B. These groups were treated with *Agnikarma* using *Taptha kshoudra and Panchadhathu shalaka* respectively. Comparitive analysis of the overall effect of the treatments in both the groups showed that

they are equally effective in the management of Lateral epicondylitis.

KEYWORDS: Lateral epicondylitis, *Kurpara sandhi asrita snayu gata vata, Agnikarma, Tapthakshoudra, Panchadhathu shalaka*, Thermal property.

INTRODUCTION

Tennis elbow is a painful disorder of the forearm; it may develop due to non-specific inflammation at the origin of extensor muscles of the forearm. Clinically it is also called lateral epicondylitis or epicondylalgia or tendinopathy or tendinosis. The pathology behind the tennis elbow remains unknown but it seems to be the sum of tendon defect, change in pain perception, and motor impairment. It is clinically diagnosed by sensation of pain and tenderness at the lateral epicondyle of humerus which aggravates during the resisted dorsiflexion of wrist and fingers, while gripping and twisting movements of wrist and forearm. The disease is usually confirmed by its features like radiating pain from lateral epicondyle to the forearm and wrist, pain on resisted dorsiflexion of the wrist, tenderness on lateral epicondyle, weakness of forearm, weakened grip strength.[1]

The overall prevalence rate of tennis elbow is 1-3%. The highest incidence is found in the young age group and between the ages 40 and 60 years of life. For women, the incidence increases to 10% between the ages of 42 and 46 years.[2] But the general cause about manifestation of tennis elbow are the overuse of forearm/minor trauma/non-recognized trauma, weight lifting etc. Previously, the disease was found in athletes especially in tennis player. But in present day practice, it is known to affect painters, plumbers, carpenters, drivers, etc. Research studies have shown that automobile workers, cooks, and even butchers get tennis elbow more often than rest ofpopulation.[3] The dominant arm is significantly more often affected than the non-dominant arm.[4]

This is a self limiting problem and recovery is seen in about 90% of cases within 1-2 yearsof conservative management, whereas only in less than 10% of cases, surgery is indicated. In some cases, the problem may continue for longer period. A wide range of symptomatic treatment is available such as use of anti-inflammatory analgesic drugs, steroid injection, physiotherapy, exercise, etc. which have their own limitations and adverse effects.[5] Till date, no satisfactorytreatment is available for tennis elbow.

On the basis of signs and symptoms, tennis elbow can be correlated with the condition of

Snayugata vata described in Ayurveda. It is developed when *vata dosha* aggravates due to *atichesta, ativyayama.* etc and gets localized in *snayu* of *kurpara sandhi.*[6] In Ayurveda, *Acharya Sushruta* has advocated various treatment modalities such as *snehana, upanaha, agnikarma* and *bandhana* for *snayugata vata.*[7]

Amongst these, *Agnikarma* seems to be more effective in providing distinct and instant relief. If it is done perfectly, disease does not reoccur. *Agnikarma* with *Kshoudra* can be done in *snayugata vyadhi* according to *Acharya Susruta.*[8] *Agni karma* is indicated in *Vatakaphaja* diseases, also in *Atyugraruja* (Severe pain) of skin, muscles, veins, tendons, joints etc. *Agni* possess *Usna, Tiksna, Suksma, Asukariguṇ a* and has *Vatahara* and *Kaphahara* properties.[9] The things used for cauterization in *Snayugata vata* are *Snigdha dravya* such as *Kshoudra* (Honey), *Guda* (Jaggery), *Taila (*Oil*)* and *Vasa (*Fat) as they have deep heat penetration capacity with a greater latent period.[10] *Kshoudra* has *ushna,laghu, rooksha, sookshma guna* and it pacifies both *vata* and *kapha*. It aid the penetration of heat through *sookshma sira.*[11]

Considering these factors, an attempt is made in the current study, to evaluate the effectiveness of *Taptha Kshoudra* in the management of tennis elbow.

AIMS AND OBJECTIVES

1. To evaluate individual effectiveness of *Agnikarma* with *Taptha Khoudra* in the management of Lateral Epicondylitis (Tennis Elbow).
2. To evaluate individual effectiveness of *Agnikarma* with *Panchadhathu shalaka* in the management of Lateral Epicondylitis (Tennis Elbow).
3. To evaluate the comparative effectiveness of *Agnikarma* with *Taptha Khoudra* and *Agnikarma* with *Panchadhathu shalaka* in the management of Lateral Epicondylitis (Tennis Elbow).

Null hypothesis

- There is no significant effect of *Agnikarma* with *Taptha Khoudra* in the management of Lateral Epicondylitis (Tennis Elbow).
- There is no significant effect of *Agnikarma* with *Panchadhathu shalaka* in the management of Lateral Epicondylitis (Tennis Elbow).
- There is no significant difference between the effect of *Agnikarma* with *Taptha Khoudra* and *Agnikarma* with *Panchadhathu shalaka* in the management of Lateral Epicondylitis (Tennis Elbow).

Alternate hypothesis

- There is significant effect of *Agnikarma* with *Taptha Khoudra* in the management of Lateral Epicondylitis (Tennis Elbow).
- There is significant effect of *Agnikarma* with *Panchadhathu shalaka* in the management of Lateral Epicondylitis (Tennis Elbow).
- There is significant difference between the effect of *Agnikarma* with *Taptha Khoudra* and *Agnikarma* with *Panchadhathu shalaka* in the management of Lateral Epicondylitis (Tennis Elbow).

METHODOLOGY

Source of data

Patients with classical features of Lateral epicondylitis (Tennis elbow) were selected from the outpatient department of Shalya Tantra, Government Ayurveda and Unani Hospital, Bengaluru (SJGAUH).

This study was conducted between September 2022 and August 2023.

Method of data collection

A total of 40 patients presenting with the clinical features of Lateral epicondylitis (Tennis elbow) mentioned in the inclusion criteria were included for the current study.

A) Inclusion criteria

- Patients presenting with the clinical features of Tennis elbow such as pain and tenderness at the lateral epicondyle of humerus, which aggravates during the resisted dorsiflexion of wrist and fingers, weakened grip strength and with mild to moderate elbow pathology according to Oxford Elbow Score.
- Any individual above 20 and below 60 years of age will be selected irrespective of sex, occupation, religion and socioeconomic status.

B) Exclusion criteria

- Patients with history of systemic diseases such as Diabetes, TB, RA, Gouty arthritis, etc.
- Malignant tumours, senile osteoporosis etc around elbow joint
- Patients with fracture around elbow joint
- Vascular insufficiency to forearm and hand
- Patients with brachial plexus lesion

- Pregnant women

Materials required

Table No. 01: Materials required for the procedure.

Materials	Quantity
Dressing trolley	1
Streile gauze	QS
Sterile kidney tray	1
Stove	1
Lighter	1
Bowl	1
Borosilicate glass dropper	1
Kshoudra	QS
Panchadhatu shalaka	1
Skin marker	1
Kumari swarasa	QS
Madhu + ghrta	QS

Sampling design

A total of 40 patients of Lateral epicondylitis (Tennis elbow), those fulfilling the above criteria were included in the study and were randomly allotted into 2 groups namely Group A andGroup B with 20 patients each.

Study design

Group A

Patients of this group will be treated with *Agnikarma* with *Taptha Kshoudra*, in *binduakara*, with a gap of 0.5cm, 3 such sittings with an interval of 7 days. (*Agnikarma* willbe done over the most tender points).

Group B

Patients of this group will be treated with *Agnikarma* with *Panchadhatu shalaka*, in *bindu akara*, with a gap of 0.5cm,3 such sittings with an interval of 7 days. (*Agnikarma* will be done overthe most tender points).

Physical analysis of *kshoudra*

Kshoudra was experimented for its boiling point.A direct method was resorted for the purpose, which involved temperature measurement using a laboratory thermometer. The boiling point of the sample was determined to be 110^0C. On removing the heat source a gradual dissipationof temperature was noted at a rate of 2^0C per minute for a period of 3 - 4

minutes under normal atmospheric conditions. After this short initial duration there is a very fast dissipation of heat.

Length of borosilicate glass dropper - 5cm with 5cm jetDiameter of tip of dropper - 0.4cm.

Table no. 02: Details of *panchadhatu shalaka.*

Material used	Proportion
Tamra	40%
Loha	30%
Yashada	10%
Rajatha	10%
Vanga	10%

Total length of *Panchaloha Shalaka*: 8cm

Diameter of the tip of the *Bindu shalaka*: 1mm

Total length of the handle: 24.5cm

Weight of *shalaka*: 225gm

1. Methodology of Group A

Patients of group A were treated with *Agnikarma* with *Taptha kshoudra*

Procedure – *Agnikarma vidhi*

Purva karma

- The patients were explained about the management procedure
- Written consent was taken from every patient beforehand
- Advised to take *Snigdha* and *pichila Ahara* prior to the patient.
- The Minor O.T was well prepared
- Sponge holding forceps, cotton pieces, drape, *Kshoudra*, steel dish, Borosilicate glass dropper, *Kumari swarasa* and *Madhu Ghrta* mixture were kept ready.
- Patient were made to lie in prone position over the table.
- The elbow and surrounding area was cleaned with an antiseptic solution and allowed to dry.
- The elbow was bent to 90˚ with the pronated forearm so that there will be the prominence of the lateral epicondyle. The area of maximum tenderness was palpated, then marked with a skin marker (5-7 points in one sitting)

Pradhana karma

- 10 ml of *kshoudra was* taken in a sterile dish and heated over the stove.It was heated to 110° C. Care was taken to prevent it from charring.
- The tip of borosilicate glass dropper pipette was kept in this honey till the tip attained the temperature of honey. The *Tapta Kshoudra* was sucked using.

Borosilicate glass dropper (0.4 cm diameter), poured 0.5 cm above the pre - determined points (of maximum tenderness) and wiped off after a 1 minute. At least 0.5cm gaping is maintained between the *Dagdha Stana.*

- Total 3 sittings of treatment was given at 7 days interval each *Pashchat karma*
- Immediately after *Pradhana karma*, a swab soaked inpulp of the *kumari* was applied over the area of *Agnikarma* and wiped out after 1 minute using sterilized gauze pieces.
- *Madhu* and *ghrta* was applied over the *Dagdha Vrana*
- Patients were allowed to go home with the advice that not to cover the area of *agnikarma* with cloth or bandage. Patient was advised not to use water over that part for at least 24 hours. Patient was advised to avoid *Vatakara Ahara* and *Vihara*

Number of sittings

Three such sittings of *Agnikarma* was carried out on 1st day, 8th day, 15th day with a gap of 7 days each and obsevations were recorded in a proforma prepared before treatment(BT).

Follow up

After the completion of *Agnikarma*, the patients were examined in every 7 days upto 15 days to observe the status of the condition.

2. Methodology of Group B

Patients of group B were treated with *Agnikarma* with *Panchdhathu shalaka*

Procedure – *Agnikarma vidhi*

Purva karma

- The patients were explained about the management procedure
- Written consent was taken from every patient beforehand
- Advised to take *Snigdha* and *pichila Ahara* prior to the patient.
- The Minor O.T was well prepared. Cotton pieces, drape, *Panchdhathu shalaka*, *Kumariswarasa* and *Madhu Ghrta* mixture were kept ready.

- Patient were made to lie in prone position over the table.
- The elbow and surrounding area was cleaned with an antiseptic solution and allowed to dry.
- The elbow was bent to 90˚ with the pronated forearm so that there will be the prominence of the lateral epicondyle. The area of maximum tenderness was palpated, then marked with a skin marker.
- The gas stove was put on fire and *Panchadhathu shalaka* was heated to red hot

Pradhanakarma

- *Bindu type agnikarma* was made on each marked points in such a way that *samyak dagda lakshanas(Shabda pradurbhava, Durgandhata, Twaksankocha)*were seen, *Panchadhathu shalaka* was withdrawn immediatily after inflicting each burn
- Total 3 sittings of treatment was given at 7 days interval each

Pashchat karma

- Immediately after *Pradhana karma*, a swab soaked inpulp of the *kumari* was applied over the area of *agnikarma* and wiped out after 1 minute using sterilized gauze pieces.
- *Madhu* and *ghrta* was applied over the *Dagdha Vrana*
- Patients were allowed to go home with the advice that not to cover the area of *agnikarma* with cloth or bandage. Pateint was advised not to use water over that part for at least 24 hours. Patient was advised to avoid *Vatakara Ahara* and *Vihara*

Number of sittings

Three such sittings of *Agnikarma* was carried out on 1st day, 8th day, 15th day with a gap of 7 days each and obsevations were recorded in a proforma prepared beforetreatment(BT).

Follow up

After the completion of *Agnikarma*, the patients were examined in every 7 days upto 15days to observe the status of the condition.

Assessment criteria

Subjective parameters

1. Oxford elbow score

Interpretation

0 - 19 - Indicate severe elbow pathology

20-29 - Moderate to severe elbow pathology30- 39 - Mild to moderate elbow pathology 40-48 - Satisfactory elbow function

Objective parameters

1. **Tenderness:** Lateral epicondyle was gently palpated to assess the tenderness

0 - No tenderness

1 - Tenderness on deep palpation

2 - Tenderness on light palpation

3 - Patient does not allow touching the affected part

2. **Cozen's test:** Patient was asked to extend the clenched fist against resistance, considerable painexperienced by patient at lateral epicondyle was noted.

0 - No pain against any resistance

1 - Pain felt against hard resistance

2 - Pain felt against moderate resistance

3 - Pain felt against light resistance

3. **Mill's manoeuvre:** Patient wrist was passively flexed when his forearm pronated, pain experienced by patient on the attachment of common extensor tendon at lateral epicondyle was noted

0 - No pain felt

1 - Pain felt at full palmar flexion

2 - Pain felt in middle of palmar flexion

3 - Pain felt at the beginning of palmar flexion

4. **Maudsley's test:** Resists the extension of third digit of the hand, stressing the extensor digitorum muscle and tendon of patient, pain felt at lateral epicondyle was noted.

0 - No pain against any resistance

1 - Pain felt against hard resistance

2 - Pain felt against moderate resistance

3 - Pain felt against light resistance

5. **Grip with hand dynamometer:** Hand Grip was measured with hand dynamometer.

Table No. 03: Hand dyanamometer examination.

Score	Male	Female
Excellent	52+	31+
Good	47-51	28-31
Average	44-46	25-27
Below Average	39-43	20-24
Poor	<39	<20

6. **ROM with Goniometer:** Range of movements at elbow joint was measured with goniometerand noted in every sitting.

Table No. 04: Goniometer examination.

Movements	Grading	Range
Extension(0^0)	Grade-0	0
	Grade-1	0-20
	Grade-2	20-39
	Grade-3	40-59
	Grade-4	>60
Flexion(145^0)	Grade-0	145
	Grade-1	115-144
	Grade-2	85-114
	Grade-3	55-84
	Grade-4	<55
Supination(80^0)	Grade-0	80
	Grade-1	65-79
	Grade-2	50-64
	Grade-3	35-49
	Grade-4	<35
Pronation(75^0)	Grade-0	75
	Grade-1	60-74
	Grade-2	45-59
	Grade-3	30-44
	Grade-4	<30

Overall assessment

The net results obtained from various parameters of assessment by the treatment was takeninto consideration to assess the overall effect of the treatment

- **Marked response:** >75% to < 100% relief
- **Moderate response:** >50% to <75% relief
- **Mild response:** >25% to <50% relief
- **Minimal response:** <25% relief

RESULTS

The effect of therapy on different subjective and objective parameters were assessed after treatment and the values obtained were subjected to statistical tests to compare the mean values within the group and between the groups.

1. Oxford Elbow Score

Table 05: Effect of Group - A on Oxford Elbow Score of Lateral Epicondylitis.

Symptom	Mean score				%	S.D (±)	S.E (±)	t value	p value
	BT			BT-AT					
Oxford Elbow Score	33.65	1st	35.90	2.25	6.68	1.333	0.19	2.63	<0.05
		8th	38.95	5.30	15.75	2.250	0.32	6.44	<0.05
		15th	42.95	9.30	27.63	4.067	0.58	11.2	<0.05
		45th	41.80	8.15	24.22	3.990	0.57	9.09	<0.05

Table 06: Effect of Group-B on Oxford Elbow Score of Lateral Epicondylitis.

Symptom	Mean score				%	S.D (±)	S.E (±)	t value	p value
	BT			BT-AT					
Oxford Elbow Score	35.50	1st	37.85	2.35	6.62	0.988	0.14	2.81	<0.05
		8th	40.35	4.85	13.66	1.531	0.22	5.82	<0.05
		15th	43.35	7.85	22.11	2.540	0.36	10.9	<0.05
		45th	41.90	6.40	18.03	2.798	0.40	7.53	<0.05

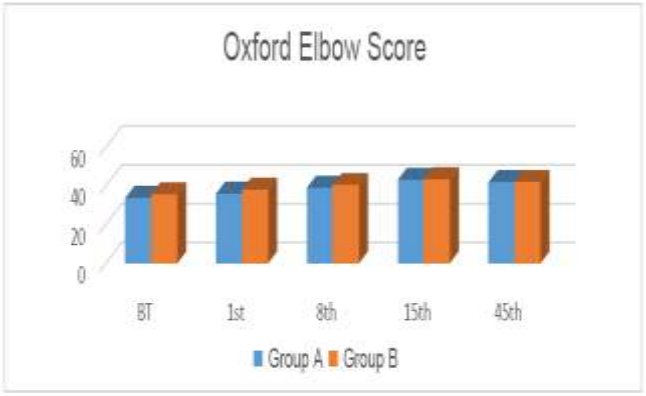

Chart No. 01: Comparative analysis of improvement in Oxford elbow score between GroupA and B.

2. Tenderness

Table 07: Effect of Group-A Tenderness of Lateral Epicondylitis (Tennis elbow).

Symptom	Mean score				%	S.D (±)	S.E (±)	t value	p value
	BT			BT-AT					
Tenderness	1.05	1st	0.90	0.15	14.29	0.366	0.05	1.76	<0.05
		8th	0.15	0.90	85.71	0.308	0.04	9.37	<0.05
		15th	0.00	1.05	100.0	0.224	0.03	21.00	<0.05
		45th	0.25	0.80	76.19	0.523	0.07	7.19	<0.05

Table 08: Effect of Group-B on Tenderness of Lateral Epicondylitis (Tennis elbow).

Symptom	Mean score				%	S.D (±)	S.E (±)	t value	p value
	BT			BT-AT					
Tenderness	1.05	1st	0.15	0.90	85.71	0.308	0.04	9.38	<0.05
		8th	0.10	0.95	90.48	0.224	0.03	11.17	<0.05
		15th	0.00	1.05	100.0	0.224	0.03	21.00	<0.05
		45th	0.35	0.70	66.67	0.571	0.08	5.82	<0.05

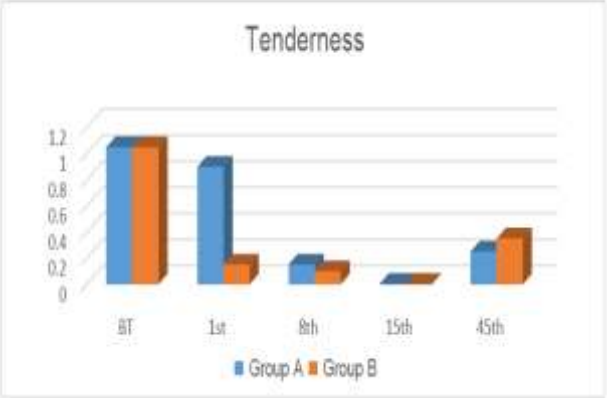

Chart No. 02: Comparative analysis of improvement in Tenderness between Group A and B.

3. Cozen's test

Table 09: Effect of Group-A Cozen's Test of Lateral Epicondylitis(Tennis elbow).

Symptom	Mean score				%	S.D (±)	S.E (±)	t value	p value
	BT			BT-AT					
Cozen's test	1.00	1st	0.85	0.15	15.00	0.366	0.05	1.83	<0.05
		8th	0.10	0.90	90.00	0.308	0.04	13.08	<0.05
		15th	0.00	1.00	100.0	0.000	0.00	0.00	0.00
		45th	0.10	0.90	90.00	0.308	0.04	13.08	<0.05

Table 10: Effect of Group-B on Cozen's Test of Lateral Epicondylitis (Tennis elbow).

Symptom	Mean score				%	S.D (±)	S.E (±)	t value	p value
	BT			BT-AT					
Cozen'sTest	1.00	1st	0.21	0.79	78.95	0.410	0.06	8.44	<0.05
		8th	0.05	0.95	95.00	0.224	0.03	19.00	<0.05
		15th	0.00	1.00	100.0	0.000	0.00	0.00	0.00
		45th	0.15	0.85	85.00	0.366	0.05	10.38	<0.05

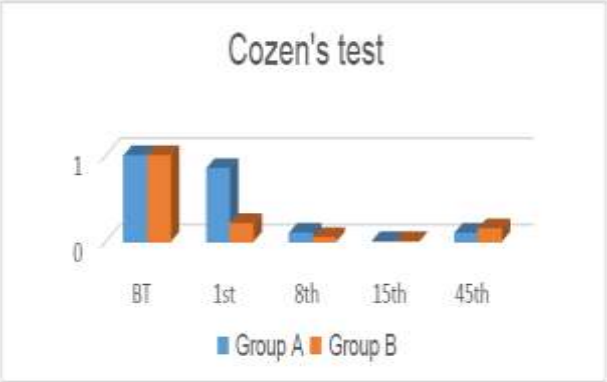

Chart No. 03: Comparative analysis of improvement in Cozen's test between Group A and B.

4. Mill's maneuver test

Table 11: Effect of Group-A Mill's Maneuver of Lateral Epicondylitis (Tennis elbow).

Symptom	Mean score				%	S.D (±)	S.E (±)	t value	p value
	BT			BT-AT					
Mill's Maneuver	1.00	1st	0.35	0.65	65.00	0.489	0.07	5.94	<0.05
		8th	0.05	0.95	95.0	0.224	0.03	19.00	<0.05
		15th	0.00	1.00	100.0	0.000	0.00	0.00	0.00
		45th	0.05	0.95	95.00	0.224	0.03	19.00	<0.05

Table 12: Effect of Group-B on Mill's Maneuver of Lateral Epicondylitis (Tennis elbow).

Symptom	Mean score				%	S.D (±)	S.E (±)	t value	p value
	BT			BT-AT					
Mill's Maneuver	1.15	1st	0.70	0.45	39.13	0.51	0.117	3.38	<0.05
		8th	0.60	0.55	47.83	0.51	0.117	3.95	<0.05
		15th	0.30	0.85	73.91	0.58	0.135	6.38	<0.05
		45th	0.15	1.00	86.96	0.56	0.129	8.63	<0.05

Chart No. 04: Comparative analysis of improvement in Mill's Maneuver between Group Aand B.

5. Maudsley's test

Table 13: Effect of Group-A Maudsley's Test of Lateral Epicondylitis(Tennis elbow).

Symptom	Mean score				%	S.D (±)	S.E (±)	t value	p value
	BT			BT-AT					
Maudsley's test	1.00	1st	0.55	0.45	45.00	0.510	0.07	3.94	<0.05
		8th	0.05	0.95	95.00	0.224	0.03	19.00	<0.05
		15th	0.00	1.00	100.0	0.000	0.00	0.00	0.00
		45th	0.05	0.95	95.00	0.224	0.03	19.00	<0.05

Table 14: Effect of Group-B on Maudsley's Test of Lateral Epicondylitis (Tennis elbow).

Symptom	Mean score				%	S.D (±)	S.E (±)	t value	p value
	BT			BT-AT					
Maudsley's test	1.00	1st	0.10	0.90	90.00	0.308	0.04	13.08	<0.05
		8th	0.05	0.95	95.00	0.224	0.03	19.00	<0.05
		15th	0.00	1.00	100.0	0.000	0.00	0.00	0.00
		45th	0.05	0.95	95.00	0.224	0.03	19.00	<0.05

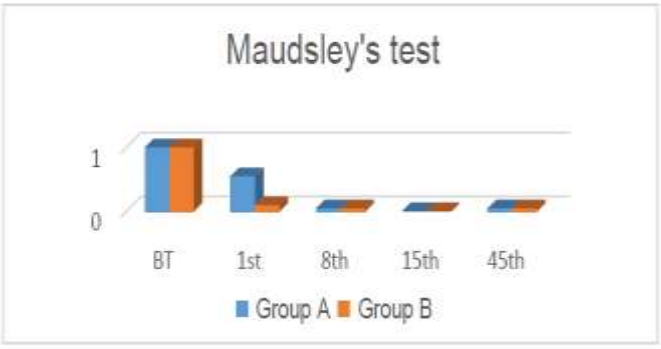

Chart No. 05: Comparative analysis of improvement in Maudsley's between Group A and B.

6. Grip

Table 15: Effect of Group-A Grip of Lateral Epicondylitis (Tennis elbow).

Symptom	Mean score				%	S.D (±)	S.E (±)	t value	p value
	BT			BT-AT					
Grip	35.25	1st	36.95	1.70	4.82	1.867	0.27	0.60	>0.05
		8th	38.95	3.70	10.50	3.570	0.51	1.36	>0.05
		15th	41.40	6.15	17.45	4.184	0.60	2.34	<0.05
		45th	40.55	5.30	15.04	4.054	0.58	1.93	<0.05

Table 16: Effect of Group-B on Grip of Lateral Epicondylitis (Tennis elbow).

Symptom	Mean score				%	S.D (±)	S.E(±)	t value	p value
	BT			BT-AT					
Grip	37.55	1st	38.90	1.35	3.60	1.785	0.26	0.35	>0.05
		8th	40.10	2.55	6.79	4.071	0.58	0.67	>0.05
		15th	41.00	3.45	9.19	4.872	0.70	0.91	>0.05
		45th	40.75	3.20	8.52	4.584	0.65	0.86	>0.05

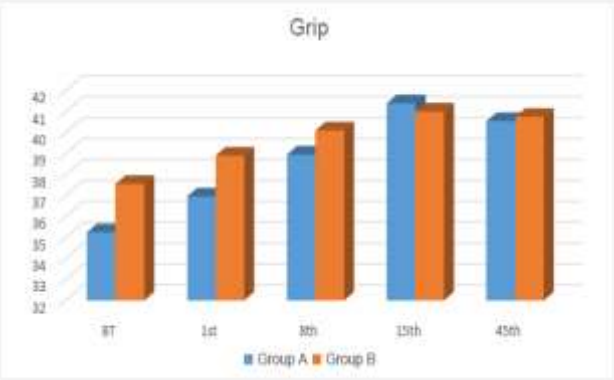

Chart No. 06: Comparative analysis of improvement in Grip between Group A and B.

7. Range of movement

Table 17: Effect of Group-A ROM of Lateral Epicondylitis (Tennis elbow).

Symptom	Mean score				%	S.D (±)	S.E (±)	t value	p value
	BT			BT-AT					
Rom	16.45	1st	15.20	1.25	7.60	3.193	0.46	0.39	<0.05
		8th	9.80	6.65	40.43	4.998	0.71	2.45	<0.05
		15th	5.10	11.35	69.00	9.287	1.33	4.80	<0.05
		45th	5.60	10.85	65.96	9.762	1.39	4.49	<0.05

Table 18: Effect of Group-B on ROM of Lateral Epicondylitis (Tennis elbow).

Symptom	Mean score				%	S.D (±)	S.E (±)	t value	p value
	BT			BT-AT					
Rom	17.30	1st	10.70	6.60	38.15	6.320	0.90	2.12	<0.05
		8th	7.80	9.50	54.91	7.937	1.13	3.39	<0.05
		15th	6.25	11.05	63.87	8.593	1.23	3.91	<0.05
		45th	7.50	9.80	56.65	7.777	1.11	3.32	<0.05

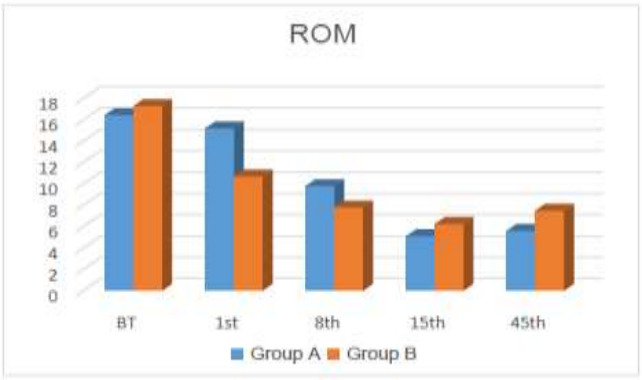

Chart No. 07: Comparative analysis of improvement in ROM between Group A and B.

Table No. 19: Comparative results of Group-A and Group-B.

Signs and Symptoms	GroupA (Mean Score)	GroupB (Mean Score)	SD	SE	T Value	P Value
Oxford Elbow Score	39.79	38.65	2.479	0.354	2.04	<0.05
Tenderness	0.33	0.47	0.206	0.029	2.97	<0.05
Cozen's Test	0.28	0.41	0.162	0.023	3.37	<0.05
Mill's Manoeure	0.20	0.28	0.101	0.014	3.56	<0.05
Moudsley's Test	0.24	0.33	0.137	0.020	2.56	<0.05
Grip	39.66	38.62	12.624	1.803	0.33	>0.05
ROM	9.91	10.43	7.463	1.066	0.26	>0.05

Assessment of total effect of therapy

Table No. 20: Overall effect of Agnikarma with Taptha Kshoudra (Group-A).

Effect of treatment in Group - A		
Class	Grading	No of patients
0-25%	Minimal	2
26%-50%	Mild	0
51% - 75%	Moderate	3
76% - 99%	Marked	10
100%	Complete Remission	5

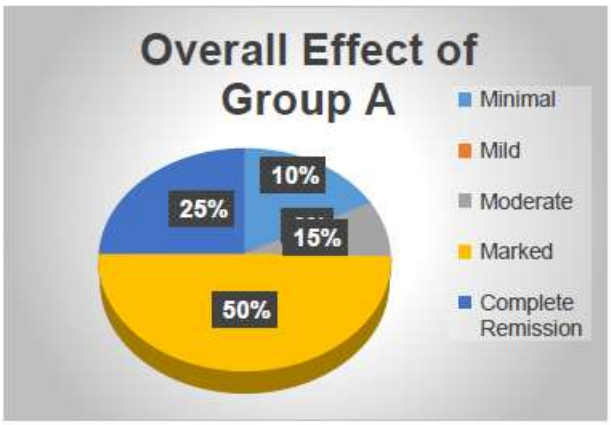

Chart no. 08: Overall Effect in Group A.

Table No. 21: Overall effect of Agnikarma with Panchadhathu shalaka (Group-B).

Effect of treatment in Group - B		
Class	**Grading**	**No of patients**
0-25%	Minimal	1
26%-50%	Mild	1
51% - 75%	Moderate	6
76% - 99%	Marked	10
100%	Complete Remission	2

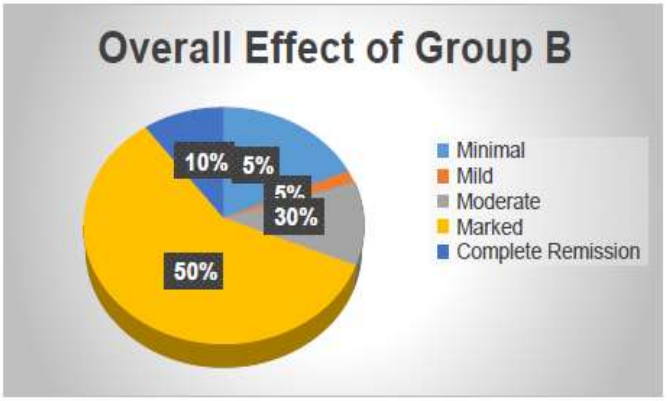

Chart no. 09: Overall Effect in Group B.

Comparative analysis of the overall effect of the treatments in both the groups was doneby statistically with unpaired t test. The test shows that the treatment is equally significant in Group B when compared to Group A. Group A overall result is 88.75% and Group B overall result is 86.25%.

DISCUSSION

Discussion on drug

Acharyas have mentioned *Agnikarma* as one of the treatment modality for the management of

Snayugata vata. Acharya susruta has explained *Dahanopakaranas* in the context of *Agnikarma*. The things used for cauterization in *snayugata vata* are *snigdha dravya* such as *kshoudra* (honey), *guda* (jaggery), *taila (*oil*)* and *vasa (*fat) as they have deep heat penetration capacity with a greater latent period. *Kshoudra* has *ushna, laghu, rooksha, sookshma guna* and it pacifies both *vata* and *kapha*. It aid the penetration of heat through *sookshma sira*. So under studygroup, *agnikarma* was done with *kshoudra*.

Panchadhatu shalaka is one which is already been standardized by Dr.P D Gupta. It is made out of tamra(40%), loha(30%), Yashada(10%), Rajata(10%), vanga(10%). It gives *bindu* type of *dahana akriti*, as it tapers and is made blunt at the end.

The thermal behaviour of *Kshoudra* and *Panchadhatu shalaka* were studied by direct methods employed in temperature measurement. The boiling point of Ksaudra was determined as 110°C with a dissipation of approximately 2°C per minute under normal atmospheric conditions. Above the boiling point the sample gets charred. When red hot the temperature of *Panchadhatu shalaka*, was found to be 235°C. An immediate decrease to 219°C is observed on removing the *Shalaka* from the heat source. This is followed by an approximate dissipation of 3-4°C per minute. All the experiments were carried out under normal atmospheric pressure and temperature.

On heating 10ml *kshoudra* in a bowl it took 1 minute to attaian 110^0C, which is the temperature needed for *Samyak dahana*. where as *panchadhatu shalaka* took 20 minutes to becomered hot(235^0 C), the temperature needed for *samyak dahana*. Burnt wound healed in 7 days in bothgroups.

Though *Pancadhathu shalaka* has a considerably higher temperature than that of the *Kshoudra* when employed for *Agnikarma, Kshoudra* owing to its higher Latent heat (heat retentioncapacity of sticky liquids is high) can effect a greater variation in the temperature of the tissue surface in contact with the molten honey and also that of the subsequent layers. Eventually the heat penetration will always be higher when such liquids are used for *Agnikarma*.

Discussion on probable mode of action

Agnikarma is an important therapeutic measure in Ayurvedic system of medicine, which has got worldwide popularity because of its simple administration and efficacy in variety of

disorders. It is unique form of therapy performed with the help of *agni* which has been described to be superior than *ksharakarma,* as the disease treated by it do not relapse and moreover those incurable by medicines (*bheshaja*), operations *(shastra*) and caustics (*kshara*) yield to it. This is subtype of *anushastra karma.*

Effect on *dosha*: *Agnikarma* is considered as best therapy for *vata* and *kapha dosha* because *Agni* possesses *ushna, sukshma, tikshna, ashukari guna* which are opposite to *vata* and *kapha*. It removes *srotovarodha* and increase the *rasa rakta samvahana* to the affected site.

Effect on *dhatu*: Therapeutic heat transferred by *Agni karma* increase the *dhatwagni,* so metabolism at *dhatu* level increases which helps to digest the *ama dosha*.

Here production of *ama* is expected from the *avarana* of *koshtagni* by aggravated vita as explained by charaka in nidanastana. Here *dushyas* are *snayu, sandhi, asthi* and *rogamarga* is *madhyama.*

Properties of *Agni* are-*Sookshma, Laghu, Tikshna* and *Ushna guna* it works both on *vata* and *kapha dosha*. It works on *vata* by *ushna tikshna guna* and on *kapha dosha by laghu sookshma teekshna* and *ushna guna.* It works deeper because of power of penetration in to the deeper tissue by virtue of *laghu sookshma* and *teekshna guna*. *Agni karma* is mainly indicated in disease having *vata prakopa* with pain as predominent symptom.

Another explanation is *ushna guna of agni* improves *dhatvagni* that pacifies *amadosha* and reduces the pain by these means as *vata prashamana* occurs, pain subsides spontaneously.

The justification for the superiority of *Agni karma* may be taken in the context of the non-recurrence of disease in *sadhya roga*. *Agnikarma* is indicated in all *vataja* and *kaphaja* diseases as the *usna guna* of *agni* is opposite to that of *sheeta guna* of *vata dosa* and *kapha dosa*.

According to an article by Petrofsky J S et al., the temperature of muscles, ligaments and tendons are below the core temperature of our body. The core temperature of our body is 37 degrees Celsius whereas on arms and legs the skin temperature is about 31 degrees Celsius. The temperature of the tissues like muscles and tendons which are situated below and deeper into the skin varies by the depth and the location. Usually deeper the tissue, the cooler the temperature they will be having. So on analyzing the concept of *dosa* there may be a

predominance of *vata* and*kapha dosa* in the tendon as *sheeta* is a *guna* of *vata* and *kapha*. Due to *nidana* factors there occurs a *vata prakopa* and an increase in *ruksa, khara* and *sheeta guna* of the tendon. So, by the processof *snigdha agnikarma* there occurs a transfer of *usna guna* of *agni* from *Kshoudra* to the *snayu* (tendon) which helps the tendon to overcome the *sita guna* of *vata* and *kapha*.

In an article by A.G. Ravisankar et al., it was also discussed that after *agnikarma* due to a rise in temperature the cell activity may also increase along with the rate of cellular interactions. The heat applied on the site may increase the blood flow to the region by vasodilation, an increase in blood flow may help to increase the rate of healing as lack of proper healing of the torn tendon is also a pathology behind tennis elbow. According to the article by A.G. Ravisankar et al., the thermal behaviour of *snigdha dravya* was studied and it showed that the *snigdha dravya* has higher latent heat (heat retention capacity) with the average heat dissipation of 2°C /min. Thearticle concluded that in *snayu gata vikara, snigdha agnikarma* may provide a better result than *ruksa agnikarma*. In an article by Petrofsky J et al., it is stated that moist heat warms up the tissuefaster than dry heat.

Agnikarma using *Kshoudra* was patient-friendly because the burning sensation felt duringthe procedure lasted only for 40 seconds to 50 seconds and so the participants showed no denial for the second sitting. Due to higher viscosity of *Kshoudra* the tendency to flow away from the site was reduced and this tendency was even further reduced because of the decrease in temperature of droplets due to the heat transfer from the surface and the droplet gets colder after application. The drops of *Kshoudra* did not flow away from the site and thus prevented the burning of the surrounding tissue and the temperature might have been transmitted to the specified area instead of spreading to the surroundings. Heat energy (*usna guna*) thus might have increased the tissue temperature, blood flow, metabolism and the extensibility of the connective tissue. Gate control mechanism.

Pain sensations are transferred by two types of fibers. "A" fibres (stimulated byheat, cold and touch) and "C" fibers (stimulated by pain). Here the gate mechanism is blocked by stimuli from A fiber, so the pain will not be felt.

Heat may stimulate lateral spinothalamic tract (SST), which leads to stimulation to descending pain inhibitory (DPI) fibers with release of endogenous opoid receptors at substantia gelatinous rolandi which inhibit the release of P substance (Presynaptic inhibition)

and blockade of transmission of pain.

Heat produced by the Agnikarma, helps to achieve muscle relaxation and relieve muscle spasm with inflammation. Agnikarma may stimulate the sensory receptor lying in the muscle, send message to the brain, which stimulates the pituitary gland to release endorphins which in turn binds with opiate receptors in the pain cells to block the pain stimuli. Endorphin is a naturally occurring neuro-peptide and like morphine and other opiates it has a marked propensity for bindingon the opiate receptors of the pain cell in the brain.

The low grade thermal acupuncture activates opioid receptors via the release of encephalin, B-endorphin and endomorphins in the supraspinal parts of the CNS and high grade stimulation activates opioids receptors via the release of dynorphin in the spinal cord.

Some of the recent study shows that endogenous opioids were released not only in the central nervous systems, but also into the peripheral blood.

These peripheral opioids actions might be triggered by release of corticotropin-releasing factors (CRF) or interleukin-ß elicited by low grade stimulation. This indicates that peripheral endogenous opioidergic mechanisms activated by thermal stimulation included the immune system in regulating included the immune system in regulating nociception in pathological conditions.

DISCUSSION ON RESULTS

Subjective parameters

1. Effect on oxford elbow score

Statistical analysis showed that, in Group A the mean score which was 33.65 before the treatment was increased to 42.95 after the treatment and after follow up it became 41.80 with 24.22% improvement and there is a statistical significance ($P<0.05$) and in Group B, the mean score which was 35.50 before the treatment was increased to 43.35 after the treatment and after follow up it became 41.90 with 22.11% improvement and there is a statistical significance ($P<0.05$). Final improvement in Oxford elbow score at the end in Group A was 24.22% and in Group B it was 22.11%.

It was noticed in the present study, the temperature plays a considerable role in pain management. And it gives instantaneous relief, may be due to stimulation of nerves, blood vessels and relaxation of muscular spasm. As a result patients became able to do their daily

activities thatinvolves the frequent usage of elbow with ease and without pain and restiction of movements thatshows a improvement in O xford elbow score

Objective parameters

1. Effect on tenderness

Magnitude of Tenderness in patients before and after the treatment analyzed statistically in patients registered in Group A showed the mean score which was 1.05 before treatment reducedto 0.25 after the treatment. Whereas in Group B showed the mean score which was 1.05 retreatmentreduced to 0.35 after the treatment. Final improvement in both groups is 76.19% and 66.67% respectively with statistical significance($P<0.05$).

An article by Nadler SF et al., states that on applying 40 degrees Celsius heat to the skin of the low back, the temperature of the muscle tissue at a depth of 38mm gets increased by 2 degrees Celsius. According to an article by Okabe et al., the forearm has a thinner epidermis and so the dermal conductivity is more. From the above, it may be inferred that during the procedure of *agnikarma* on the lateral epicondyle, the tendon may get heated up with minimal heat loss.

The heat generated in the tissue during *agnikarma* may stimulate the lateral spinothalamictract which further may lead to stimulation of descending pain inhibitory fibres which release endogenous opioid peptides. These peptides bind with opioid receptors at substantia gelatinosa ronaldi which inhibits the release of substance P (presynaptic inhibition) and blockage of transmission of pain sensation. Thus it may be inferred that, during the process of *agnikarma*, along with *usna guna* of *Agni*, the *tiksna guna* also helps for the deeper penetration of heat so thatit reaches *snayu* and together reduce the tenderness and pain through the process of *vata samana*.

2. Effect on cozen's test

Magnitude of Cozen's Test in patients of Lateral Epicondylitis (Tennis elbow) before and after the treatment was assessed and analyzed statistically. In patients registered in Group-A showed the mean score which was 1.00 before treatment reduced to 0.10 after the treatment. Whereas Group-B showed the mean score which was 1.00 before treatment reduced to 0.15 after the treatment. Final improvement in both groups is 90% and 85% respectively with statistical significance ($P<0.05$).

Due to *nidana* factors there occurs a *vata prakopa* and an increase in *ruksa*, *khara* and *sheeta guna* of the tendon. This may cause a decrease in the elasticity and strength of the tendon as well as the extensor muscles, resulting in tears and fibrotic changes. Also, the *sheeta guna* of *vata* and *kapha* causes *stambana* which may result in pain during movements. During the procedure of *agnikarma*, heat is transmitted in the form of conduction through the skin and tissues.So, by the process of *snigdha agnikarma* there occurs a transfer of *usna guna* of *agni* from *Kshoudra* to the *snayu* (tendon) which helps the tendon to overcome the *sheeta guna* of *vata* and*kapha*.

3. Effect on Mill's maneuver

Magnitude of Mill's Maneuver in patients of Lateral Epicondylitis (Tennis elbow) before and afterthe treatment was assessed and analyzed statistically. In patients registered in Group-A showed the mean score which was 1.00 before treatment reduced to 0.05 after the treatment. Whereas Group-B showed the mean score which was 1.15 before treatment reduced to 0.15 after the treatment. Final improvement in both groups is 95% and 91.3% respectively with statistical significance (P<0.05).

4. Effect on maudsley's test

Magnitude of Maudsley's Test in patients of Lateral Epicondylitis (Tennis elbow) before and afterthe treatment was assessed and analyzed statistically. In patients registered in Group-A showed the mean score which was 1.00 before treatment reduced to 0.05 after the treatment. Whereas Group-B showed the mean score which was 1.00 before treatment reduced to 0.05 after the treatment. Final improvement in both groups is 95% and 95% respectively with statisticalsignificance(P<0.05).

5. Effect on grip

Magnitude of Grip in patients of Lateral Epicondylitis(Tennis elbow) before and after the treatment was assessed and analyzed statistically. In patients registered in group-A showed significant improvement (P<0.05). The mean score which was 35.25 before treatment increasd to 40.55 after the treatment with 15.04% improvement. Group-B showed no significant improvement (P>0.05). The mean score which was 37.55 before treatment increased to 40.75 after the treatment with 8.52% improvement.

During the procedure of *agnikarma* on the lateral epicondyle, the tendon may get heated up with minimal heat loss in Group A when compared to Group B as Khoudra has deep heat

penetration capacity with a greater latent period than Panchadhatu shalaka.

According to Warren C G et al., at a higher temperature, there may be a relaxation of collagen in the connective tissue and thus it increases the flexibility of the tendon and enables it to sustain more force. This may be the reason for the significant improvement in grip in Group A where Agnikarma with Kshoudra was done.

6. Effect on range of movement

Magnitude of ROM in patients of Lateral Epicondylitis(Tennis elbow) before and after the treatment was assessed and analyzed statistically. In patients registered in group-A showed significant improvement (P<0.05). The mean score which was 16.45 before treatment increased to 5.60 after the treatment with 65.96% improvement. Group-B group showed significant improvement (P<0.05). The mean score which was 17.30 before treatment increased to 7.50 afterthe treatment with 56.65% improvement.

In an article by A.G. Ravisankar et al., a temperature range of 40°C to 45°C may increasethe extensibility of collagen tissue and thus reduce joint stiffness. The low melting temperature allows collagen molecules to melt and refold locally, which will provide elasticity and strength to the fibres. The heat also relaxes the muscles, relieving the stiffness and increasing the range of movements. The *usna guna* does *vata samana* and thus reduces the *kharaguṇ a* of the *snayu*. Thiswill result in increased elasticity of the tendon. In the present study it was found that there is increased grip strength and range of movements of wrist in participants after *agnikarma*. This may be attributed to the fact that the *usna guna* of *Agni* increases the elasticity of the tendon as evidenced by the above study.

Overall effect

Out of 20 patients of Group A 50% of patients got marked improvement, 25% of patients got complete improvement, 15% of patients got moderate improvement and 10% got minimal improvement.

Out of 20 patients of Group B 50% of patients got marked improvement, 30% of patients got moderate improvement, 10% of patients got complete improvement, 5% got mild improvement and 5% got minimal improvement.

CONCLUSION

Kurpara sandhi asrita Snayugata Vata is the disorder of *Snayu* and *Vata*. *Ativyayama,*

Atichesta (Excessive physical exercises/movements) and *Abhighata* (*Kurpara Marma Abhighata*) are the major contributory *Nidanas* which leads to the vitiation of *Sthanika Vata* which further leads to *Dhatuvaishamya (Meda* and *Snayu)* and complete the manifestation of the disease. The main component for the occurence of *Snayugata Vata* are *Vata Prakopaka Nidana, Prakupita Vyanavayu, Dhatuvaishamya* and *kapha avarana*. Thus, involvement of *Marma, Vata Dosha* and *Dhatuvaishamya*make disease more *Kashṭa Sadhya.*

Lateral epicondylitis is due to the mechanical overload occurring during sports with improper techniques and heavy machine work. Thus, repetitive activity and over use nowadaysare the most common factor for the trauma of the tendon. This condition is considered as degenerative tendinitis commonly known as tennis elbow.

The comparative results of both the groups assessed based on Oxford elbow score, tenderness, Cozen's test, Mill's maneuver, Maudsley's test, grip and range of movements is 24.22%, 76.19%, 90%, 95%, 95%, 15.04% and 65.96% in Group A and in Group B 22.11%, 66.67%, 85%, 95%, 95%, 8.52% and 56.65% of improvement in complaint respectively.

P value <0.05 in both groups shows significant statistical results. Hence, Group A and B showed stastistically significant results in Oxford elbow score, tenderness, Cozen's test, Mill's maneuver, Maudsley's test and range of movements. Grip has statistically significant result in Group A and but not in Group B.

Comparitive analysis of the overall effect of the treatments in both the groups was done by statistically with unpaired T test. The test shows that these treatments are equally significant in Group A when compared to Group B. Group A overall result is 88.75% and Group B overall resultis 86.25%. Hence, Agnikarma with Taptha Kshoudra is as effective as Agnikarma with Panchadhathu shalaka in Lateral epicondylitis (Tennis elbow).

In conclusion, the results of this series provided further evidence that Agnikarma is a very effective procedure and Agnikarma with Taptha kshoudra is as effective as Agnikarma with Panchadhatu shalaka in the management of Lateral epicondylitis (Tennis elbow).

Materials required for Agnikarma with Taptha Kshoudra.

Heating Kshoudra to boiling point.

Materials for Agnikarma with Panchadhatu shalaka.

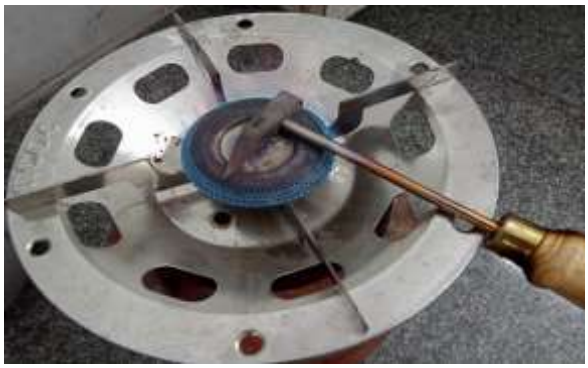

Figure no. 07: Heating Panchadhatu shalaka to red hot temperature.

Instruments used for clinical examination.

Agnikarma with Taptha Kshoudra(case-01) - 1st sitting.

Agnikarma with Taptha Kshoudra(case-01) – after 1st sitting.

Figure no. 10: Agnikarma with Taptha Kshoudra – on 7th day of treatment.

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