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# Assessment of comparative Efficacy of Nirgundipatra Upanaha and Trayodashang Guggulu with Diclofenac sodium Gel and Ibuprofen in the Management of Snayugata Vata Affecting Koorpara Sandhi (Tennis Elbow)

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## STUDY PROTOCOL

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## ABSTRACT

**Background**

Pain disturbs the routine and regular activities of each and every individual. Snayugata Vata affecting Koorpara Sandhi or Tennis elbow is one such condition, in which pain is the major feature. Though described as self-limiting, effective treatment can shorten the duration of symptoms and allow the patient to perform day to day activities without pain.

**Objectives**

To assess the comparative efficacy of Nirgundipatra Upanaha and Trayodashang Guggulu with Diclofenac sodium Gel and Ibuprofen in reducing pain and functional disability in the Management of Snayugata Vata affecting Koorpara Sandhi (Tennis Elbow).

**Methodology**

Procedure in this study, 100 patients will be separated haphazardly into 2 groups (50 in each). In Group A (Experimental Group) Nirgundipatra Upanaha (Local application) once daily and 2 Tablets of Trayodashang Guggulu 500 mg each twice a day will be given orally for 21 days and Group B (Control Group)– Diclofenac sodium gel for Local application once daily and 1 Tablet of Ibuprofen 500mg twice a day orally will be given for 21 days. Evaluation will be recorded on 0,7,14,21 and 28$^{th}$ day.

**Expected Result**

Reduction in pain will be observed with the help of objective and subjective parameters.

**Study Implications**

As the patients of Tennis Elbow are increasing, an easily available Ayurvedic treatment regimen which is non-invasive and easy to perform will be of great help to general public.

**Key Words**

Snayugata Vata, Nirgundipatra Upanaha, Trayodashang Guggulu, Tennis Elbow

## Introduction

Today, the most common reason for which the patients visit the Doctor is pain. It is defined as an unpleasant feeling that is transferred from the site of pain; to the brain by sensory neurons[1]. It disturbs the routine and regular activities of each and every individual. Snayugata Vata affecting Koorpara Sandhi or Tennis elbow is one such condition, in which Pain is the major feature.

Snayugata Vata is a type of Vata Vyadhi, which develops when Vata dosha aggravates or vitiates due to aticheshta, ativyayam and all other Vata Prakopaka Nidan[2]. Acharya Sushruta has described Snayugata Vata as, when provoked Vata lodge in Snayu causing stambha, Kampa, Shool and aakshep[3].

Snayugata Vata is a disease mentioned under Vata Vyadhi and hence the treatment given is Vatahara. The treatment of Snayugata Vata is described in detail by Acharya Charak, Sushruta, Vagbhaṭa and other Acharyas. Apart from oral medications, other therapeutic measures include Snehana (Oeleation), Upanaha (Poultice), Agnikarma (Cautry), Bandhana(Bandage) and Unmardana (massage)[4-5].

As per the symptoms of Tennis elbow or Lateral epicondylitis, it can be correlated with Snayugata Vata. Tennis elbow is the disorder of the forearm-painful forearm. The pain may develop due to non-specific inflammation at the origin of extensor muscles of the forearm[6] ora degenerative process associated with a microscopic or macroscopic tear of tendon, produced by mechanical overload due to repetitive action during sports or at work[7].

The main clinical features are pain, stiffness, restricted movement, tenderness and decreased grip strength. Besides Tennis players, surgery staff, secretaries, violin players, politicians shaking hands and house-wives, doing household work can also develop a Tennis-Elbow[8].

According to data 1-3 per cent of world population10 suffers from tennis elbow. Though it is prominently seen in the age group 30 and 50 years, it is associated with the people in the working age, from 20 to 60 years[9].

Tennis Elbow is described as self-limiting condition that could last for 6 months to 2 years. In spite of this self-limiting character, effective treatment can shorten the duration of symptoms and allow the patient to perform regular activities with comfort[10]. Local application as well as oral intake of the NSAID along with tennis elbow brace is used as standard treatment[11]. Local infiltration with corticosteroids and autologous blood, various types of manipulations under anaesthesia, Physiotherapy procedures, Para-surgical procedures and surgical treatments are also advised for its management. These symptomatic treatments have their own limitations and adverse effects[12]. Long-term use of anti-inflammatory and various analgesic drugs and steroid injections are also not free from adverse effects. Till date, no satisfactory treatment is available for tennis elbow[13].

Hence, in this study a genuine effort has been made, to look for such a modality of treatment, which will give not only relief from pain without complications but also which is within the reach of the patients in a developing country like India. Our study aims to compare the results of Diclofenac sodium Gel locally and standard anti-inflammatory medicine Tablet Ibuprofen orally with Nirgundipatra[14] Upanaha (poultice sudation)[15] locally and tablets of Trayodashang Guggulu[16] orally.

## Rationale of the Study

Tennis Elbow is associated not only with sports but also with particular occupations. Due to similarity of symptoms, it can be very well compared with Snayugata Vata of Koorpara Sandhi. Here a step has been put forward to study the co-relation between Snayugata Vata of Koorpara Sandhi and Tennis Elbow and to establish successful Ayurvedic regimen. Nirgundipatra Upanaha is applied locally and Trayodashang Guggulu is given orally. Nirgundipatra Upanaha is a type of Svedana (sudation therapy)[17]. Various Studies have revealed that lipid medium present in the medicine, is highly suitable for penetration of the drug molecule through stratum corneum[18]. On this basis, it can be assumed that the oil present in Nirgundipatra Upanaha serves as a lipoidal medium as it allows the penetration of the drug molecules of Nirgundi and exert an immediate anti-inflammatory effect. Nirgundi possesses Vedanasthapana (analgesic) and Shothahara (anti-inflammatory) actions[14]. Moreover heat applied with Nirgundipatra upanaha increases the local circulation and thus the rate of drug absorption.

Trayodashang Guggulu is a mixture of 13 herbs, which is processed in cow's ghee. It possesses essential properties like Vata Shamana, Sandhibalyakara and Vedanashamak along with other properties[19]. On undertaking an extensive study, it was found that various research projects are undertaken to study and compare Snayugata Vata with Tennis Elbow. But in most of the studies Agnikarma or Siravydha is performed for the treatment. They are invasive therapies and compliance and comfort of the patient remains an issue.

In the present study, the Ayurvedic treatment regimen of Nirgundipatra Upanaha along with Trayodashang Guggulu is considered as it is a non-invasive and easy to perform treatment with long-lasting effect. This treatment will enable better recovery and a rapid return to work.

## Aim and Objectives

### Aim of the Study

Assessment of comparative efficacy of Nirgundipatra Upanaha and Trayodashang Guggulu with Diclofenac sodium Gel and Ibuprofen in the Management of Snayugata Vata Affecting Koorpara Sandhi (Tennis Elbow).

### Objectives

1. To assess the effect of Nirgundipatra Upanaha and Tablet Trayodashang Guggulu in reducing pain and functional disability in the management of Snayugata Vata of Koorpara Sandhi (Tennis elbow).
2. To assess the effect of Diclofenac sodium gel locally and Ibuprofen orally in the management of Snayugata Vata of Koorpara Sandhi (Tennis elbow).

3. To compare the effect of Nirgundipatra Upanaha and Trayodashang Guggulu with Diclofenac sodium gel locally and Tab Ibuprofen orally in the management of Snayugata Vata of Koorpara Sandhi (Tennis elbow).

## Hypothesis

Nirgundipatra Upanaha and Tablet Trayodashang Guggulu are more effective in reducing pain and functional disability as compared to Diclofenac sodium gel locally and the NSAID Ibuprofen orally in Snayugata Vata affecting Koorpara Sandhi (Tennis elbow).

## Methodology

This is interventional single blind randomized controlled clinical trial. This parallel group, superiority study will be conducted at Mahatma Gandhi Ayurveda College Hospital & Research Centre, Salod, in Datta Meghe Institute of Medical Sciences, Wardha, Maharashtra, India. Interventions are shown in Table 1.

## Eligibility Criteria

**Inclusion Criteria**

- Patients of both genders between age-group 20-60 years[11].
- Pain on the lateral epicondyle of the elbow joint.
- Pain after Patient's wrist is passively flexed with forearm pronated (Mill's test)
- Pain after extending the clenched fist against resistance (Cozen's test)
- Pricking sensation or Tenderness.
- Inability to do daily routine work.
- Diagnosed cases of Tennis Elbow Acute as well as Chronic

**Exclusion Criteria**

- Patient not willing to participate in the present study
- Patients with Fractures and Arthritic changes as in Rheumatoid Arthritis, Osteoarthritis, Gouty Arthritis.
- Patients suffering from systemic diseases like Diabetes mellitus, Heart disease, Renal disease, Cancer, Tuberculosis and other major health problems
- Pregnant and Lactating women

## Investigations

Plain X-ray Elbow joint – to exclude Joint fractures and changes of Arthritis.

## Preparation of Drug

Dried powder of Nirgundipatra or crushed fresh Nirgundi leaves, Saindhavlavana and Tiltaila, all in equal quantity will be mixed and cooked over medium flame stirring well to form a uniform mixture and the consistency will be like thick paste (Table 2).

**Method of Application**

1. The composition once constituted will be applied warm, the temperature about 40 degrees centigrade, over the lateral epicondylar region of elbow securing well with the crepe bandage. It will be preferably applied in the evening hours (Vata kala).
2. The application will be held overnight.
3. The paste will be removed later by using lukewarm water.
4. The patient will be advised to use tennis elbow brace over the affected part or elbow while doing the routine works to avoid further strain on affected ligament.

To make the tablets Trayodashang Guggulu, following procedure will be followed. First step is shodhana of Guggulu. The common impurities like stone, glass bark etc. will be removed and then Guggulu will be crushed to small pieces. It will then be wrapped in a clean cloth and boiled in Dola-yantra having decoction of Triphala, till Guggulu becomes soft mass. It will be spread over wooden boards and smeared with ghee. Then, it will be dried in clean place and it will be ready for making Trayodashang Guggulu. Second step is cleaning and drying of above mentioned herbal drugs and making fine powders separately. Third step is mixing of these drugs with purified Guggulu in iron mortar to form a homogenous mixture. Ghee will be added to it for smoothening of the mixture. After the mixture is formed, pills of 500 mg each will be made. Pills would be dried in shade and then kept in air tight containers, without exposure to sunlight (Table 3).

**Outcomes**

Reduction in Pain, Functional disability, Pricking sensation, Radiation of pain, Tenderness, Cozen's test and Mill's maneuver's grades and improvement in Hand grip strength. Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg. change from baseline, final value, time to event), method of aggregation (eg. median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended.

**Participant timeline**

Data will be collected in Case record form for all the patients at baseline, 0,7$^{th}$ day, 14$^{th}$ day, 21$^{st}$ day and 28$^{th}$ day - compiled in the form of frequency tables and graphs.

**Sample size**

Sample Size is calculated by using the difference in the value in Group A and Group B. It is assumed that the test drug is superior to active control drug Strategies.

**Recruitment**

Allocation of interventions: Patients will be selected by computer generated random numbers.

**Criteria for discontinuing or modifying allocated interventions**

Subject will be withdrawn from the study if any untoward incidence, features of drug sensitivity or any other disease or problem arises, the subject will be offered free treatment till the problem subsides.

**Blinding**

The patients will be blinded before allocation

## Data Collection

**Procedure used for data collection**

Case registration form with detailed history and examination i.e.

- Consent form in English, Hindi and Marathi.
- Case Record Form
- Assessment of subjective and objective criteria
- Data of all patients will be collected and reported in Case sheet form.

## Analysis plan

Data will be collected in Case record form for all the patients at baseline, 7th day, 14th day, 21st day and 28th day - compiled in the form of frequency tables and graphs.

**Variables**

Quantitative variables: Improvement in Hand grip strength, in Kilograms.

Qualitative variables: Reduction in pain, Functional disability, Pricking sensation, Radiation of pain, Tenderness, Cozen's test and Mill's maneuver's grades.

**Assessment Criteria**

The overall improvement in the patients would be assessed based on relief they get in the symptoms and signs of the disease. The subjective and objective parameters will be as follows:

A. Objective parameter is Grip strength evaluation by Hand Grip Dynamometer.
B. Subjective parameters are Pain, Functional disability, Pricking sensation and Radiation of pain, Tenderness, Cozen's test and Mill's maneuver.

**Statistical methods**

Data will be analysed by the progressions utilizing Paired and Unpaired 't' Test.

Interpretations:

*p-value*<0.05-significant

*p-value*>0.05-not significant

## Discussion

**Snayugata**

Vata when provoked or vitiated by any internal or external factor, it roams in the body and if it resides in Snayu; it results in instantaneous manifestation of Snayugata Vata[22]. The vitiated Vata when gets ashritha in Snayu of one or more Sandhi, it produces features like stambha, Kampa, Shool and aakshep. When these features get manifested in Snayu of Koorpara Sandhi, it is termed as Snayugata Vata affecting Koorpara Sandhi. Snayugata Vata can be termed as Tennis Elbow. It is assumed that repetitive and overuse of a part, results in tendon disrepair and macroscopic abnormalities in the tendon collagen. Degenerative features are predominantly seen in tendinopathy, which include an abnormality in tendon structure and neovascularization[10].

The treatment is orientated towards management of pain, improvement in grip strength and endurance, preservation of movement, normal functioning of the joint and controlling further clinical deterioration[23]. Pain killers and local application of various creams and oil is used, but the results are not satisfactory. Till date, there is no fixed line of treatment, which is universally accepted. Hence Ayurvedic treatment regimen of Nirgundipatra Upanaha andTrayodashang Guggulu orally is considered.

Nirgundipatra Upanaha is a type of Swedana and Swedana give relief in Vatavyahis. Nirgundipatra or Nirgundi is Vatashamak andShothhara drug, which help in reducing pain and inflammation. Upanaha Sweda is Vatashamakdue to its Snigdhaand UshanaGuna. The application of Nirgundipatra Upanaha will promote local circulation and open pores of the skin due to heat and this will permit the medicines towards the affected site, as oil is present in it. Hence, Nirgundipatra Upanaha will have its effect for longer time as compared to Diclofenac gel application.

Trayodashang Guggulu is widely used for the management of Vata disorders or Vatavyadhi. It is a mixture of 13 herbs. The contents in Trayodashang Guggulu are Guru and Snigdhagunapradhan, Madhurrasatmak, Madhurvipakiand Ushnavirya which help in the Samprapti vighatan and play an important role in the treatment of Snayugata Vata[19]. Oral medicine Trayodashang Guggulu, due to the ingredients present in it - act as Vatahara, strengthen the Snayu and it has a role in regenerative process. It is given in all types of Vatavyadhis.

Drugs having Properties of Agnidiptikara, Balavardhaka, Vatanulomana are effective in Snayushoola[24]. Svedana, Seka, Pralepa treatment modalities should be preferred in Snayushoola and in all type of Snayu shoolavaatanaashakaghrita, taila and Rasayana should be used.

## Strengths

If the Ayurvedic treatment regimen of Nirgundipatra Upanaha and Trayodashang Guggulu works, it will give relief from pain without complications and will help people continue their routine and regular activities like work and sports, without pain.

## Limitations

This study will be conducted on patients with involvement of elbow joints only.

## Confidentiality

Strict confidentiality will be maintained before, during, and after the trial.

## Conclusion

The Ayurvedic treatment regimen of Nirgundipatra Upanaha and Trayodashang Guggulu is very effective in Vatavyadhi and many studies have been conducted in its support this. But this regimen for Tennis elbow or Snayugata Vata is not used in any study. Hence study is planned. It may be more beneficial and more effective than Diclofenac sodium Gel and Ibuprofen in pain reduction as well as other subjective and objective parameters.

## Study Implications

As the patients of Tennis Elbow are increasing, an easily available Ayurvedic treatment regimen which is non-invasive and easy to perform will be of great help to general public.

## Ethics and Dissemination

Research ethics approval; approval from research ethics committee has taken. No-Ref. No. MGACHRC/IEC/April2021/208.

**Consent or assent**

The made consent will be taken from the patients before starting the assessment. During the investigation the classification of every patient will be recorded.

**Dissemination policy**

The information will be dispersed by paper distribution. Creation qualification rules and any proposed utilization of expert scholars.

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## Tables

**Table 1: Interventions.**

| Groups | Sample size | Age (Years) | Sex | Intervention | Dose | Duration[20] |
|---|---|---|---|---|---|---|
| **Group A Experimental Group** | 50 | 20-60 | Male & Female | Nirgundipatra Upanaha<br>Tablet Trayodashang Gugguluorally | Local application once daily<br>2 Tablets of 500 mg each twice a day | 21 days |
| **Group B Control Group** | 50 | 20-60 | Male & Female | Diclofenac sodium gel<br>Tablet Ibuprofen orally | Local application once daily<br>1 Tablet of 500 mg each twice a day | 21 days |

**Table 2: Nirgundipatra Upanaha**

| Sr. No. | Contents | Botanical name | Part used | Proportion | Rasa | Guna | Veerya | Vipaka |
|---|---|---|---|---|---|---|---|---|
| 1 | Nirgundi[21] | Vitexnegundo | Leaves | 1 part | Katu Tikta | Laghu Ruksha | Ushna | Katu |
| 2 | Til Tailam | Sesamumindicum | Seed oil | 1 part | Katu Tikta Madhur Kashay | Guru Snigdha Ushna | Ushna | Katu |
| 3 | Saindhav Lavana | Sodium chloride | Salt | 1 part | Lavana Madhur | Laghu Snigdha | Sheeta | Madhur |

**Table 3: Trayodashang Guggulu**

| Sr. No. | Contents | Botanical name | Part used | Proportion | Rasa | Guna | Veerya | Vipaka |
|---|---|---|---|---|---|---|---|---|
| 1 | Aabha | Acacia Arabica | Fruit | 1 part | Kashay | Guru Ruksha | Sheeta | Katu |
| 2 | Ashwagandh | Withaniasomnifera | Root | 1 part | Tikta, Kashay | Laghu Snigdha | Ushna | Madhur |
| 3 | Hapusha | Juniperuscommunis | Fruit | 1 part | Tikta, Kashay | Laghu Ruksha | Ushna | Katu |
| 4 | Guduchi | Tinosporacordifolia | Stem | 1 part | Tikta, Kashay | Laghu Snigdha | Ushna | Madhur |
| 5 | Shatavari | Asparagus racemosus | Root | 1 part | MadhurTikta | Guru Snigdha | Sheeta | Madhur |
| 6 | Gokshura | Tribulusterrestris | Root | 1 part | Madhur | Guru | Sheeta | Madhur |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | Snigdha | | |
| 7 | Vriddhadaruk | Ipomoea Petaloidea/biloba | Root | 1 part | Kashay, Katu, Tikta | Laghu Snigdha | Ushna | Madhur |
| 8 | Rasna | Pluchealanceolata | Root | 1 part | Tikta | Guru | Ushna | Katu |
| 9 | Shatpushpa | Foeniculumvulgare | Fruit | 1 part | Katu Tikta | Laghu Tikshna | Ushna | Katu |
| 10 | Karchoora | Curcuma zedoria | Rhizome | 1 part | Katu Tikta | Laghu | Ushna | Katu |
| 11 | Yawani | Carumcopticum | Fruit | 1 part | Katu, Tikta | Laghu Tikshna | Ushna | Katu |
| 12 | Sunthi | Zingiberofficinale | Rhizome | 1 part | Katu | Snigdha | Ushna | Madhur |
| 13 | Ghrita (Clarified butter) | | | 6 part | Madhur | Snigdha Guru | Sheeta | Madhur |
| 14 | Guggulu | Commiphoramukul | Resins | 12 part | Tikta, Kashay Katu | Vishad Ruksha Laghu | Ushna | Katu |

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