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**“THE CLINICAL EVALUATION OF VATAGAJANKUSH RAS ALONG WITH ANUTAIL NASYA ON OESWESTREY NECK DISABILITY SCORE IN MANYAGHRAHA WITH SPECIAL REFERENCE TO CERVICAL SPONDYLOYSIS- A STUDY PROTOCOL”**

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**ABSTRACT:**

Cervical spondylosis is a progressive degenerative disorder of the cervical spine that primarily involves the intervertebral discs, facet joints, and surrounding ligaments. The increasing prevalence of sedentary lifestyles has contributed significantly to its occurrence, with the C5–C6, C6–C7, and C4–C5 vertebral segments being most commonly affected. Clinically, the condition presents either as cervical myelopathy due to spinal cord compression or cervical radiculopathy resulting from nerve root compression.

In Ayurveda, a comparable condition known as *Manyagraha* is described, characterized by pain and stiffness in the neck with restricted movements. Classical Ayurvedic texts such as the *Charaka Samhita* and *Sushruta Samhita* explain its etiology and management under the category of *Vatavyadhi*.

**Aims and Objectives-** The present study aimed to compare the therapeutic effects of two Ayurvedic formulations along with *Anu Taila Nasya* in one group, with *Vatagajankush Rasa* combined with *Anu Taila Nasya* in another group. The outcomes were assessed using the Oswestry Neck Disability Index, cervical range of motion, and overall symptomatic improvement.

**Materials and Methods-** A three-arm, open-label, randomized controlled clinical trial was conducted for a duration of 21 days. Eligible participants were randomly allocated into three groups, each receiving specific oral Ayurvedic medications along with nasal administration of *Anu Taila*.

**Results and Conclusion-** KI Statistical analysis was performed using descriptive statistics and inferential tests such as the *t-test* and *ANOVA*, with the level of significance fixed at  $p < 0.05$ .

**KEY WORDS:-** Cervical Spondylosis, Manyaghraha, Vatagajankush Ras, Vatavyadhi, Anutail

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**Key Message-**

This study protocol aims to evaluate the clinical effects of *Vatagajankush Rasa* combined with *Anu Taila Nasya* on the Oswestry Neck Disability Score in patients with *Manyagraha*, with particular emphasis on cervical spondylosis. The study seeks to generate evidence on the effectiveness of these Ayurvedic interventions in reducing neck-related disability and to contribute meaningful data to the field of complementary and integrative medicine.

## INTRODUCTION

According to Ayurveda, *Manyagraha* is a disorder caused by the vitiation of *Vata Dosha*, leading to pain and stiffness in the neck region. The aggravated *Vata* affects the *mamsa* (muscles), *snayu* (ligaments), nerves, and soft tissues of the posterior cervical region. McCormack et al. have reported that intermittent neck and shoulder pain is one of the most commonly encountered syndromes in clinical practice.(1)

Ayurvedic classics describe several etiological factors (*nidana*) for *Manyagraha*, including improper sleeping posture, use of high pillows, sleeping during daytime, and prolonged upward or downward gazing that strains the cervical spine.(2) Acharya Sushruta has elaborated specific causes (*hetu*) of *Manyasthambha/Manyagraha* in *Nidanasthana* and its management in *Chikitsasthana*.(3) Although *Manyagraha* is not explicitly mentioned in the *Vatavyadhi Prakarana* of *Chikitsasthana* by Acharya Charaka, the condition can be understood as a manifestation of *Vatavyadhi* localized in the *Manya* (neck region).(4)

Any disturbance of *Vata* arises either due to its aggravation (*Vata prakopa*) or due to *Avarana* (obstruction) caused by *Pitta* or *Kapha Dosha*. Obstructed *Vata*, in its attempt to regain normal movement, results in pain and restricted mobility.(5)

### Therapeutic Principle

According to Charaka, repeated administration of *Sneha* (oleation) and *Swedana* (sudation) is effective in conditions caused by vitiated *Vata*. In cases of *Kevala Vataprakopa*, treatments such as *Abhyanga* with medicated oils, *Patra Pinda Sweda*, *Griva Vasti*, *Shashtika Shali Pinda Sweda*, *Lepa*, and *Upanaha* using *Vata-shamaka* drugs are recommended. In *Kapha-Avaranajanya Vata Prakopa*, *Abhyanga* with *Kapha-hara* oils, *Churna Pinda Sweda*, *Lepa* or *Upanaha* with *Kapha-pacifying* drugs, and *Anu Taila Nasya* are advised. Various treatment modalities, including oral medications and *Nasya*, have been evaluated in *Manyasthambha* and documented in published research.

## DISCUSSION

### Materials and Methods

#### *Study Design*

An open-label, three-arm randomized controlled clinical trial was planned. Patients presenting with neck pain at the outpatient, inpatient, or casualty departments of the institute, irrespective of age, sex, religion, socioeconomic status, or educational background, were screened. Those fulfilling the diagnostic criteria of *Manyagraha* were selected for further evaluation.

#### *Diagnostic Criteria*

Diagnosis was based on the presence of the following signs and symptoms:

1. *Manya Shula* (neck pain)
2. *Ankunchana-Prasarana Shula* (pain during flexion and extension)
3. *Vivartana-yo Manya Shula* (pain during rotation and lateral movements)
4. *Shulasya Prasarana* (radiating pain)
5. *Graha* (restriction of movement)
6. *Pidana-asahatva* (tenderness)
7. *Shulasya Kala* (duration of pain)

Radiological evaluation of the cervical spine, including anteroposterior and lateral views, was performed before treatment to confirm the diagnosis.

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## Information Sheet and Consent

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All eligible patients were provided with detailed information regarding the study, and written informed consent was obtained prior to enrollment.

#### *Inclusion Criteria*

1. Patients presenting with classical signs and symptoms of *Manyagraha*
2. History of neck pain for more than three months
3. Oswestry Neck Disability Index score indicating disability
4. Willingness and ability to participate in the study
5. Radiological evidence of degenerative changes in the cervical spine

#### *Exclusion Criteria*

1. History of fracture, surgery, or invasive diagnostic procedures involving the cervical spine

2. Fixed joint deformity or established contractures
3. Uncontrolled hypertension ( $\geq 160/100$  mmHg) or uncontrolled diabetes mellitus (FBS  $>150$  mg/dL, PPBS  $>250$  mg/dL)
4. Patients unfit for *Nasya* therapy
5. Evidence of malignancy
6. Long-term use ( $\geq 6$  weeks) of corticosteroids, NSAIDs, antidepressants, anticholinergics, or other drugs influencing study outcomes
7. Presence of major systemic illnesses
8. Pregnant or lactating women
9. Participation in another clinical trial within the previous six months

#### *Laboratory Investigations*

1. Hemoglobin percentage and ESR
2. Fasting and postprandial blood sugar levels
3. Routine urine examination
4. Additional investigations were conducted in doubtful cases to rule out systemic disorders

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**Management** Patients meeting the diagnostic criteria were managed either on an outpatient basis or admitted for inpatient care as required. Detailed case histories were recorded using a standardized case record form. The day of admission or OPD visit was designated as Day 0, on which baseline clinical parameters and investigations were documented.

The Oswestry Neck Disability Index, cervical range of motion, and symptom scores were assessed before and after treatment. Patients were allocated to treatment groups using block randomization. Outcome measures recorded after the 21-day treatment period were considered post-treatment values. Follow-up assessments were conducted on the 7th, 14th, 21st, and 28th days.

**Table-1****Groups of Management**

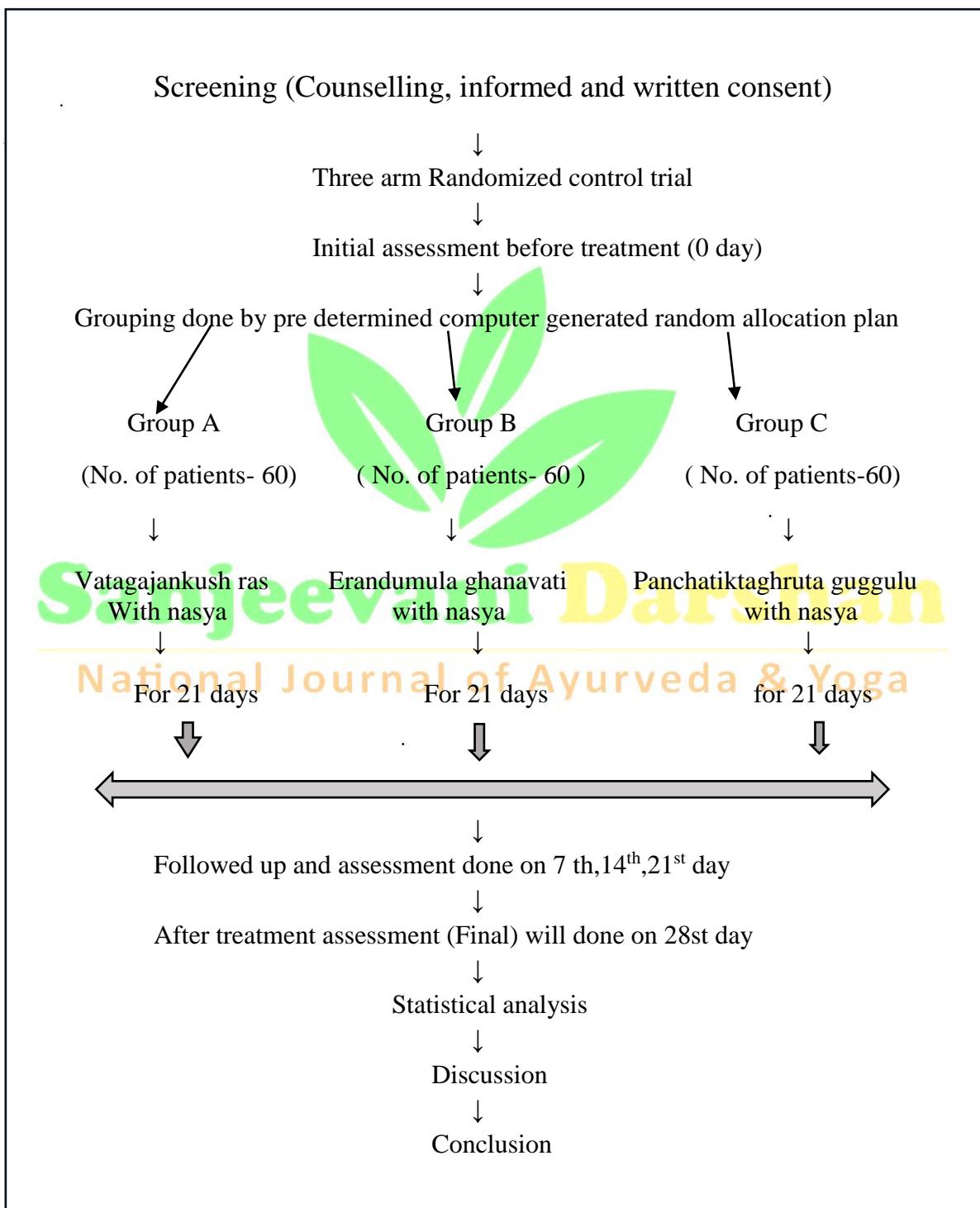
Groups of management	Treatment given	Duration	Dose	Anupana	Bheshaja Sevankala
Group A	Vatagajankush ras with Anutail nasya	21 days	250mg 8 drops	Koshna jal -----	After meal BID 2 times a day
Group B	Erandamula ghanavati with Anutail nasya	21 days	500 mg 8 drops	Koshna jal ----- _____	After meal BID 2 times in day
Group C	Panchtikta ghrut guggulu with Anutail nasya	21 days	500 mg 8 drops	Koshna jal -----	After meal BID 2 times in a day

The sample size was calculated based on the expected difference in mean values and the range of motion (in degrees) of cervical flexion, which was considered the primary outcome measure. The assumptions for the calculation were derived from a previously published study by Sunil Solanke and Prakash Kabra on the efficacy of *Eranda Mula Ghanavati* with *Nasya* in *Manyagraha*, with special reference to cervical spondylosis (*International Research Journal of Pharmacy*, 2021; 12(6)). (6)

**Table-2 National Journal of Ayurveda & Yoga**

Two Means - Hypothesis testing for two means	
Standard deviation in group I	7.66
Standard deviation in group II	7.74
Mean difference	4.81
Effect size	0.624675
Alpha error (%)	5
Power (1- beta) %	90
1 or 2 sided	2
Required sample size per group(n)	54

Assuming a 10% attrition rate over the 28-day study period, the effective sample size was adjusted to 60 participants per group. Accordingly, a total of 180 participants will be enrolled in the study and evenly allocated into three treatment groups. The adjusted sample size was calculated using the formula  $n' = n / (1 - d)$ , where  $d$  represents the anticipated dropout rate (10%).



## Figure 1: Flow Chart of Study Design

### Trial Drug and Its Standardization

*Bhaishajya Ratnavali* describes *Vatagajankusha Rasa* under the *Vatavyadhi Prakarana*. This formulation consists of equal proportions of *Parada*, *Loha*, *Suvarnamakshika*, *Shuddha Gandhaka*, and *Shuddha Hartala*, along with herbal ingredients such as *Haritaki*, *Karkatashringi*, *Shuddha Bachanaga*, *Shunthi*, *Maricha*, *Pippali*, *Agnimantha*, and *Tankana* in equal quantities.

All the ingredients are triturated together and subjected to *Bhavana* using *Nirgundi* and *Gorakhmundi Swarasa* continuously for one day. Following this process, tablets of one *Ratti* (125 mg) are prepared for oral administration. This formulation is traditionally indicated for various *Vata* disorders, particularly *Manyagraha*. (7)

Classical Ayurvedic texts such as *Rasendra Sara Sangraha*, *Rasa Chandamshu*, *Rasa Ratna Samucchaya*, *Brihat Nighantu Ratnakara*, *Dhanvantari Nighantu*, and *Bharat Bhaishajya Ratnakara* also describe *Vatagajankusha Rasa* with similar references. The trial medication was procured from a GMP-certified pharmaceutical manufacturer.

### Method of Assessment

Neck pain-related disability was assessed using the 10-item Neck Disability Index (NDI), a patient-reported outcome measure. The NDI was originally derived from the Oswestry Low Back Pain Disability Questionnaire and was first published in the *Journal of Manipulative and Physiological Therapeutics* in 1991, with a subsequent review by the same author in 2008. The instrument has demonstrated high test-retest reliability and established validity when compared with other pain and disability scales.

The questionnaire evaluates functional limitations in daily activities such as personal care, lifting, reading, occupational tasks, driving, sleeping, and recreation. Cervical range of motion was also assessed as an objective functional outcome measure.

### Data Analysis Methods

Collected data will be coded and entered into Microsoft Excel and subsequently analyzed using STATA statistical software, version 10.1 (2011). Descriptive statistics will be expressed as mean, standard deviation, and range for quantitative variables, while categorical variables will be presented as frequencies and percentages. Inferential statistics will include appropriate significance testing with corresponding *p*-values.

Paired *t*-tests will be employed to compare pre- and post-treatment values within each group.

Comparisons between groups will be performed using one-way ANOVA for more than two groups or an independent sample *t*-test for two-group comparisons. Post hoc pairwise comparisons will be conducted using the Bonferroni correction. Differences in proportions will be analyzed using the Z-test or Pearson's chi-square test, as appropriate. Statistical significance will be set at  $p < 0.05$ .

### **Mechanisms to Assure Study Quality**

A computer-generated random allocation sequence will be created using RALLOC software (2014) to assign 180 participants randomly into three treatment groups. Stratified block randomization with block sizes of six will be used to ensure allocation concealment during group assignment.

Quality assurance measures include the use of validated assessment tools and standardized outcome scales. Predesigned and structured proformas/case record forms (CRFs) will be utilized for secure and systematic data collection. Regular follow-up visits and continuous monitoring will be conducted to maintain the overall quality and integrity of the study.

### **CONCLUSION**

*Hetu, Dosha, Dushya, Srotas, Adhisthana, Marga, and Sadhyasadhyatva* constitute the *Vyadhi Ghataka Bhava*, which collectively participate in the *Samprapti* (pathogenesis) of a disease. The fundamental principle of management is to interrupt this *Samprapti* by pacifying the aggravated *Dosha* and restoring the normal equilibrium of *Dushya* (*Dhatu Samya Kriya*).

*Vatagajankusha Rasa*, characterized by *Katu* and *Tikta Rasa*, *Ushna Virya*, *Katu Vipaka*, and *Laghu*, *Yogavahi*, *Snigdha*, *Tikshna*, and *Sukshma Guna*, when administered along with *Anu Taila Nasya*, helps in pacifying *Vata* and *Kapha Dosha*. This therapeutic action results in a reduction of *Ruja* (pain), *Grahata* (stiffness), *Ankunchana-Prasarana Shula* (pain during flexion and extension), *Vivartana-yo Manya Shula* (pain during rotation and lateral movements), *Shulasya Prasarana* (radiating pain), and *Shulasya Kala* (duration of pain). Additionally, a decrease in the Neck Disability Index (NDI) score and an improvement in cervical range of motion (CROM) are observed.

*Acharya Charaka* emphasizes that a physician who possesses thorough knowledge of drug administration, considers *Desha* (place) and *Kala* (time), and prescribes treatment only after careful individual patient assessment is regarded as an ideal physician.(8)

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