



## PROTOCOL STUDY OF AN OPEN LABELLED RANDOMISED CONTROLLED CLINICAL STUDY TO EVALUATE THE EFFICACY OF *KSHEERBALA TAIL NASYA* AND *ASHWAGANDHA TAIL NASYA* IN THE MANAGEMENT OF CERVICAL SPONDYLOSIS

<sup>1</sup>\*Dr. Surbhi, <sup>2</sup>Prof. (Dr.) Ashish Mehta and <sup>3</sup>Dr. Mamta Rana

<sup>1</sup>M. D Scholar, PG Department of Panchakarma, I.A.S.R. Kurukshetra, Haryana.

<sup>2</sup>Professor and Head, PG Department of Panchakarma, I.A.S.R, Kurukshetra, Haryana.

<sup>3</sup>Associate Professor, PG Department of Panchakarma, I.A.S.R, Kurukshetra, Haryana.



\*Corresponding Author: Dr. Surbhi

M. D Scholar, PG Department of Panchakarma, I.A.S.R. Kurukshetra, Haryana.

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### ABSTRACT

**Background:** Cervical pain is experienced by all most all individuals in their life span and disturbs the routine. Cervical spondylosis is due to a degeneration at the level of Cervical spine or an inflammatory reaction in association with an early degenerative change at that level. In Ayurvedic context, sign and symptoms of Cervical spondylosis is best correlates with *Asthi-majjagata vata*. As Cervical spondylosis is one of the conditions occurring at *Manya pradesh*, hence it is *Urdhwajatrugata vikara* so *Nasya* is the choice of treatment. As it is a degenerative disorder so *Brhimhana*, *Vatashamaka* and *Dhatuposhak Aushadhi* will be administered. As *Bala* and *Ashwagandha* possess *Madhur*, *Snigdha* and *Dhatuposhak* properties the efficacy of *Ksheerbala tail nasya* in Cervical spondylosis is proved in previous research work. No work is done yet on *Ashwagandha tail nasya* in Cervical spondylosis so this comparative study is selected for research. **Aim:** To evaluate the efficacy of *Ashwagandha tail nasya* in management of Cervical spondylosis. **Objective:** To evaluate efficacy of *Ashwagandha tail nasya* in comparison with *Ksheerbala tail nasya* in management of Cervical spondylosis. **Methodology:** Total 60 patients of Cervical spondylosis will be selected randomly and divided in to 2 groups i.e. Group A (*Ksheerbala tail nasya*) and group B (*Ashwagandha tail nasya*). *Nasya* will be given for 7 sittings between 7-21 days in dose of 8 *bindu* in each nostril. And observation will be done on basis of before and after subjective and objective parameters.

**KEYWORD:** Cervical Spondylosis, *Asthi-majjagata vata*, *Nasya*, *Ksheerbala tail*, *Ashwaganda tail*.

### INTRODUCTION

Pain is the most distressing experience; one may have to face in their entire life and is also very critical one from the part of a practitioner. Cervical pain is experienced by almost all the individuals in their life span and disturbs the daily routines. Cervical spondylosis is due to a degeneration at the level of the cervical spine or an inflammatory reaction in association with an early degenerative change at that level.<sup>[1]</sup> The prevalence is similar for both sexes although the degree of severity is greater for males. Repeated occupational trauma, carrying heavy loads on heads or shoulders, dancing & gymnastics, using forward posture for an extended time like in computer workers or even mobile use may contribute to the development of cervical spondylosis.<sup>[2]</sup> Symptoms of cervical spondylosis manifest as neck pain and neck stiffness and can be accompanied by radicular symptoms where there is compression of neural structures.

In Ayurvedic context, many diseases related to cervical region are described such as *Greeva Hundana*, *Manyastambha*, *Avabahuka*, *Manyagraha*, *Vishwachi*, *Greevastambha*, *Bahushirshagata vata* and *Asthi-majjagata vata*. But according to signs & symptoms of cervical spondylosis, it best correlates with *Asthi-majjagata vata*.

As Cervical spondylosis is one of the conditions occurring at *Manya pradesh*, hence it is an *Urdhwajatrugata vikara* so *Nasya* is the choice of treatment.<sup>[3]</sup> As it is a degenerative disorder (*dhatukshaya janya vata vyadhi*) so *brimhana*, *vatashamaka* & *dhatuposhaka aushadhi* will be administered. As *shira* is the place of *tarpak kapha* so *tail* is used for *Nasya karma*.

Neck pain is a widespread condition, and the second most common complaint after low back pain. This

condition is associated with a significant burden of disease with substantial disability and economic cost. Neck pain is prevalent in the middle-aging population and primary cause of consultation worldwide. It affects 30-50% of people. 25% of patients attend physiotherapy clinics due to complaint of neck pain. Amid so many causes of neck pain and its aftermaths, cervical spondylosis is the most common cause in the middle-aged population over 40-50 years, prevalent as 13.76%.<sup>[4]</sup>

### Modern Review

Cervical spondylosis is a degenerative disorder of the cervical spine. There is degeneration of cervical vertebrae, intervertebral disc, with its protrusion and bony outgrowth (osteophytosis) of adjacent vertebrae, causing narrowing of intervertebral foramina and cervical canal. It may be asymptomatic or may cause compression of roots, cords or both. Clinical features include-

- Axial joint pain includes neck pain, shoulder pain or both along with stiffness.
- Cervical spondylotic radiculopathy (due to compression of the roots) - rotation and lateral movements of head are reduced. Irritation of sensory roots causes radicular pain along their distribution. The motor symptoms include motor weakness, atrophy of muscles depending on the roots compressed.
- Cervical myelopathy (due to compression of cord) – in patients with congenitally narrowed cervical canal. It is less common and presents with a progressive spastic paraparesis, loss of biceps reflex & bowel & bladder disturbances.
- Tinnitus, vertigo & intermittent blurring of vision may be present.<sup>[5]</sup>

### AYURVEDIC LITERATURE REVIEW

The signs & symptoms of *Asthi-majja gata vata* as mentioned by *acharyas* are as *Bhedo-Asthiparvanam* (breaking type of pain in bones), *Sandhi shola* (joint pain), *Mamsa Kshaya* (muscular wasting), *Bala Kshaya* (weakness) and *Aswapna Santatruka* (sleeplessness due to continuous pain).<sup>[6]</sup>

In Ayurvedic literature, administration of Panchakarma is the main treatment principle. Various treatments like *Basti* with *tikta ksheer & sarpi*, use of *Bahya & abhyantara Sneha*, *Upanaha*, *Nasya*, *Bandhan*, etc.<sup>[7]</sup> are advised. Among these *Nasya* is best treatment for *urdhwajatrugat rogas*. *Acharya Charaka* explains that *Nasa* is the *dwara* to the *Shira*. Hence it may be said that the medication instilled through nostrils may reach the *Shira* and thus act upon the aggravated *doshas*.

### AIMS AND OBJECTIVE

#### Aim

To evaluate the efficacy of *Ashwagandha tail Nasya* in the management of Cervical spondylosis.

### Primary objective

To evaluate the efficacy of *Ashwagandha tail Nasya* in comparison with *Ksheerbala tail Nasya* in the management of cervical spondylosis.

### Secondary objectives

1. To improve the mental & physical wellbeing of patient.
2. To improve the quality of life of patient.
3. To give a specified treatment to the patient.

### Case Definition

Patient having symptoms of Cervical Spondylosis such as Pain and stiffness in neck, headache, tenderness, paraesthesia, vertigo, restricted movement of neck etc.

### Research Question

Does *Ashwagandha tail Nasya* is more effective in the management of Cervical spondylosis?

### HYPOTHESIS

#### Research Hypothesis(H<sub>1</sub>)

(H1)- *Ashwagandha tail Nasya* is more effective than *Ksheerbala tail Nasya* in the management of cervical spondylosis.

(H2)- *Ashwagandha tail Nasya* is equally effective as *Ksheerbala tail Nasya* in the management of cervical spondylosis

#### Null Hypothesis(H<sub>0</sub>)

*Ashwagandha tail Nasya* is not effective as *Ksheerbala tail Nasya* in the management of cervical spondylosis.

### Experimental Source

It will be a pure Human Clinical trial; no animal experiment will be done.

### MATERIALS AND METHODS

To fulfil the Aim and Objectives, the study plan is divided into 2 sections

- Literary review
- Clinical study.

### Study design

- Type of Trial – Interventional
- Design- randomized clinical trial
- Method of randomization- Computer Assisted Randomised Sampling
- Purpose – Treatment
- Masking- Open Label
- Timing- Prospective
- End Point- Efficacy
- Duration of trial- 18 months
- Phase of trial- phase 2
- Number Of Groups- 2
- Subjects- 30 in each group.
- Statistical tool- Appropriate tool will be apply

**Selection of patients:** The patients fulfilling the criteria

and attending *Panchkarma* OPD and IPD of *Panchkarma* department of the I.A.S.R Kurukshetra Haryana will be selected for research study.

#### Inclusion criteria

1. Patients willing to sign the consent form.
2. Patients aged between 25 and 55 yrs of either sex.
3. Patients having signs and symptoms of cervical spondylosis exceedingly not more than 3 years with or without radiological changes.
4. Patients fit for *Nasya Karma*.

#### Exclusion criteria

1. Patients having age below 25 and above 55 yrs of either sex.
2. Patients with chronicity of more than 3 years.
3. Patients unfit for *Nasya karma*.
4. Patients not willing for the *Nasya karma*.
5. Patients diagnosed with Myelopathy or stenosis of Spinal Canal, and other related conditions like Ankylosing spondylitis.
6. Patient diagnosed with Tuberculosis of spine, spinal tumors, Vascular lesions, Neoplasms, history of trauma, fractures and surgical history.
7. Patients having any other systemic disorders like cardiac disease, renal diseases and hypertension or endocrinal disorders.
8. Pregnant or lactating mothers.

#### Withdrawal criteria

- During clinical trial, if any serious condition or serious adverse effect develops which require urgent treatment.
- Irregular follow up.
- If patient wants to withdraw from the clinical trial.

#### Investigations

For assessing the general condition of patient and

#### Contents

	PLANT	BOTANICAL NAME	PART USED	QUANTITY
1	Bala	<i>Sida cordifolia</i>	Root	240 gms
2	Tila	<i>Sesamum indicum</i>	Seed oil	540 ml
3	Goksheer	-	-	2160 ml

#### ASHWAGANDHA TAIL<sup>[14]</sup>

(Reference: *Chakradatta/ Vaatvyadhi adbhikara /adhyaya22/ shloka 129-133 & Ayurvedic Formulary of India* page no.137).

शतं पक्त्वाश्वगन्धाया जलद्रोणेऽंशशेषितम् । विस्त्राव्य विपचेत्तैलं क्षीरं दत्त्वा चतुर्गुणम् ॥129॥

कल्कैर्मृणालशालूक बिसकिज्जल्कमालती । पुष्पैर्हीबेरमधुक शारिवापन्नकेशरैः ॥130॥

मेदापुनर्नवाद्राक्षा मज्जिष्ठा बृहतीद्वयैः । एलैलवालुत्रिफला मुस्तचन्दनपद्मकैः ॥131॥

exclusion of other pathogenesis the following investigation may be performed:

#### 1. Routine laboratory investigation:

- Hb,
- ESR,
- RBS,
- Sr. Uric Acid,
- RA factor,
- S. Calcium

#### 2. Radiological Investigation:

X-ray Cervical Spine with A-P and Lateral view.

#### MATERIAL AND METHODS

**Clinical study materials:** patients indicated and fit for trial were selected from outpatient & in patient department of panchakarma, I.A.S.R. Kurukshetra Haryana.

**Conceptual study materials:** Literary references are be collected from *Ayurvedic Samhitas* and their Commentaries, Modern literature, Research journals, online portal like PubMed, Ayush research portal, Google scholar are analyzed to frame the conceptual work.

#### Drug Review

##### GROUP A- Control drug

##### KSHEERBALA TAIL<sup>[13]</sup>

(Reference- *Sahasra Yoga* by R. Vidyanath, *tail prakarana* page no. ११०)

बलामूलात्पंचपलं क्षीरपिष्टं च योजयेत् । क्षीरे चतुर्गुणे तैलप्रस्थं मृदग्निना पचेत् ॥

पाने वस्तै तथाभ्यंगे नस्यकर्मणि शस्यते । एतत् क्षीरबलातैलं वाताशीतिविनाशनम् ॥

पक्वं रक्ताश्रयं वातं रक्तपित्तमसृग्दरम् । हन्यात्पुष्टिबलं कुर्यात्कृशनां मांसवर्धनम् ॥132॥

रेतोयोनिविकारघ्नं घ्राणशोषापकर्षणम् । षण्ढानपि वृषान्कुर्यात्पानाभ्यङ्गानुवासनैः ॥133॥

## Contents

	PLANT	BOTANICAL NAME	PART USED	DOSE
1	Ashwagandha	<i>Withania somnifera</i>	Root	4.8 kg
2	Jala	Water		12.28 litres
3	Tail (Tila)	<i>Sesamum indicum</i>	Seed oil	768 ml
4	Kshira (godugdha)	Milk		3.072 litres

**KALKA DRAVYAS** -192 grams of each drug should be taken.

	PLANT	BOTANICAL NAME	PART USED
1	<i>Mrinala</i>	<i>Nymphaea stellata</i>	Stalk
2	<i>Saluka</i>	<i>Nymphaea alba</i>	Roots
3	<i>Bisa</i>	<i>Nelumbo nucifera</i>	Rhizome
4	<i>Kinjalka</i>	<i>Mesua ferrea</i>	Stamen
5	<i>Maltipushpa</i>	<i>Jasminum grandiflorum</i>	Leaf
6	<i>Hriversa</i>	<i>Plectranthus vettiveroides</i>	Whole plant
7	<i>Madhuka</i>	<i>Glycyrrhiza glabra</i>	Root
8	<i>Sariva</i>	<i>Hemidesmus indicus</i>	Root
9	<i>Padma-kesara</i>	<i>Nelumbo nucifera</i>	Stolon & stamen
10	<i>Meda</i>	<i>Polygonatum verticillatum</i>	Rhizome
11	<i>Punarnava</i>	<i>Boerhavia diffusa</i>	Whole plant
12	<i>Draksha</i>	<i>Vitis vinifera</i>	Ripened fruit
13	<i>Manjishtha</i>	<i>Rubia cordifolia</i>	Root
14	<i>Brhati</i>	<i>Solanum indicum</i>	Fruit
15	<i>Kantakari</i>	<i>Solanum virginianum</i>	Root
16	<i>Ela</i>	<i>Elettaria cardamomum</i>	Dried seed
17	<i>Elavalu</i>	<i>Prunus avium</i>	Seed
18	<i>Haritaki</i>	<i>Terminalia chebula</i>	Fruit
19	<i>Bibhitaka</i>	<i>Terminalia bellirica</i>	Fruit
20	<i>Amalaki</i>	<i>Embolia officinalis</i>	Fruit
21	<i>Musta</i>	<i>Cyperus rotundus</i>	Dried rhizome
22	<i>Chandana</i>	<i>Santalum album</i>	Wood
23	<i>Padmaka</i>	<i>Prunus cerasoides</i>	Wood

## Methods

## Plan of study

To follow the above objective, the research work has been planned as follow: -

## 1. Review of literature

Literary references will be collected from Ayurvedic Samhitas and Commentaries, Modern literature, Research journals, online portal like PubMed, Ayush research portal, Google scholar and will be analyzed to

frame conceptual work.

## 2. Clinical study

Clinical study will be done in patients under direct supervision, considering the inclusion and exclusion criteria.

Sample size - 60 divided in two groups, 30 in group A and 30 in group B.

Group A- *Ksheerbala tail Nasya*

Group B- *Ashwagandha tail Nasya*

Group	Drugs	Dose <sup>[8]</sup>	Route of Administration	Sample size	Duration <sup>[9]</sup>
A	<i>Ksheerbala tail Nasya</i>	8 bindu (4ml in each nostril.)	Nasal	30	7 Sittings in between 7-21 days
B	<i>Ashwagandha tail Nasya</i>	8 bindu (4ml in each nostril.)	Nasal	30	7 Sittings in between 7-21 days

(As per AFI 1 bindu = 10 drops = 0.5ml)

## PROCEDURE

## 1. Poorva karma

- ❖ Food, drink and bath should be avoided for at least two hours before and after the administration of *Nasya*. The patient is directed to clear the natural urges.

- ❖ He is asked to sit on a stool and *Snehana* is given by applying *Tila tail* to the scalp, face, neck and shoulders for five minutes.
- ❖ Then, *Swedana* is done with towel soaked in boiling water and after squeezing the water, towel was waved, touched and pressed on this area for 5 minutes.

- ❖ Position: *uttana shayan* (supine position), *Pralambita shirah kinchita* bend head.<sup>[10]</sup>

## 2. Pradhan karma

- ❖ Pour the lukewarm oil slowly into the right nostril with the help of container keeping left nostril closed with left hand.
- ❖ It is repeated twice or thrice till the required dose is completed.<sup>[11]</sup>
- ❖ Patient is advised to keep in supine position for 100 *Matra Kala* or unless the administered Taila Came in mouth.

## 3. Pashchat Karma

- ❖ A gentle massage is given to palms, planter aspects of the foot, face and shoulders.
- ❖ If there is discharge from the nose to the mouth Patient should spit into the bucket on sides without raising much.
- ❖ *Vacha Churna* is *avachurnita* on hot pan. Patient is asked to inhale 3 times with open mouth for 3 strokes covering his head along with pan with towel.
- ❖ After that *Gandusha* with lukewarm water mixed with *saindhav lavana* for 3 times.<sup>[12]</sup>

## Follow up

Patients will be followed up to assess variation in symptomatology and to know any complication.

- ❖ 1<sup>st</sup> Follow up- on next day after last sitting.
- ❖ 2<sup>nd</sup> follow up- 7 days after 1<sup>st</sup> follow up.
- ❖ 3<sup>rd</sup> follow up- 7 days after 2<sup>nd</sup> follow up.

## Criteria for Assessment

Assessment is done based on improvement in the subjective parameters such as

- Neck Pain
- Stiffness in neck
- Tenderness
- Headache
- Vertigo
- Tingling sensation
- Loss of sensation

## And objective parameters

- Restricted neck movements
- Reflexes – Biceps, Triceps & Supinator
- Muscle power strength

The results will be evaluated on the basis of clinical parameters obtained before and after the completion and the assessment will be carried out on further findings in below mention criteria:

S. No.	Positive Result Findings	Assessment
1.	Less than 25%	Non-satisfactory
2.	25% to 50%	Good
3.	50% to 75%	Satisfactory
4.	75% to 100%	Excellent

## OUTCOMES

### Primary outcome

- Mild, Moderate or Complete relieve in the sign and symptoms of Cervical Spondylosis.

### Secondary outcome

- The lifestyle of patient improved after the treatment.
- Patient can perform daily routine activity without any trouble.

## Sample Size

$$N_1 = \left\{ z_{1-\alpha/2} * \sqrt{\bar{p} * \bar{q} * \left(1 + \frac{1}{k}\right)} + z_{1-\beta} * \sqrt{p_1 * q_1 + \left(\frac{p_2 * q_2}{k}\right)} \right\}^2 / \Delta^2$$

$$q_1 = 1 - p_1$$

$$q_2 = 1 - p_2$$

$$\bar{p} = \frac{p_1 + kp_2}{1 + K}$$

$$\bar{q} = 1 - \bar{p}$$

$$N_1 = \left\{ 1.96 * \sqrt{0.525 * 0.475 * \left(1 + \frac{1}{1}\right)} + 0.84 * \sqrt{0.45 * 0.55 + \left(\frac{0.6 * 0.4}{1}\right)} \right\}^2 / 0.15^2$$

$$N_1 = 173$$

$$N_2 = K * N_1 = 173$$

P0 = proportion (incidence) of population i.e, 45%  
P1 = proportion (incidence) of study group i.e, 55%  
N = sample size for study group

$\alpha$  = probability of type I error (usually 0.05)

$\beta$  = probability of type II error (usually 0.2)

z = critical Z value for a given  $\alpha$  or  $\beta$

- Sample size should be 173 in each group

- Due to limitation of time period and other resources during PG studies, I will take 30 patients in each group.

## Statistical Analysis

The observations and results will be analyzed and presented on the basis of respective and applicable statistical tests.



**Ethical Clearance & CTRI Registration**

Study was started after obtaining ethical clearance from the Institutional Ethics Committee, I.A.S.R. Kurukshetra.

**REF/2024/06/086263**

Study was registered in CTRI: -**CTRI/2024/06/069268**.

**OBSERVATION AND RESULT**

The observations and results will be analysed statistically with relevant tests and level of significance will be reported.

**DISCUSSION:** The obtain results will be discussed on the basis of ayurvedic concept and modern parameters.

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