

Clinical Research

A randomized controlled clinical trial to assess the efficacy of *Nasya* in reducing the signs and symptoms of cervical spondylosis

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Abstract

This work was designed to assess the efficacy of *Nasya* in reducing the signs and symptoms of cervical spondylosis. The patients attending the O. P. D of Department of Kaya Chikitsa and Panchakarma, Government Ayurveda College Hospital, Thiruvananthapuram were enrolled and subjected to the treatment schedule. Total duration of treatment was 21 days. The schedule for the first 14 days was similar in both the groups. It included *Rooksha Sveda* for 7 days followed by *Patra Pottali Sveda* for 7 days. During this period, 90 ml *Gandharvahastadi Kashaya* twice and *Guggulu Tiktaka Kashaya* once were given internally. After this, in the *Nasya* group *Nasya* was done for 7 days with *Dhanwantaram Tailam* (21 times *Aavartita*), *Mridu Paka* in *Madhyama Matra* (8 Bindu). Along with this *Guggulu Tiktaka Kashaya* was given thrice. In the control group, *Guggulu Tiktaka Kashaya* alone was given thrice daily. Assessments were done with regard to pain, tenderness, radiation of pain, numbness, range of movements and hand grip strength. These were done before treatment, before *nasya*, after treatment and after 1 month follow-up. The statistical hypothesis was tested using paired 't' test and 'Z' test for proportion. The trial proved that conventional management along with *Nasya* was more efficacious than conventional management alone in reducing the signs and symptoms of cervical spondylosis.

Key words: Cervical spondylosis, *Gandharvahastadi Kashaya*, *Guggulu Tiktaka Kashaya*, *Nasya*

Introduction

The effects of aging become visible in all types of tissues in the body. Vertebral column which facilitates erect posture in man is no exception. Cervical spondylosis is a common health problem encountered in practice. People in the 4th and 5th decades of life suffer more from this degenerative condition.

Treatment is categorized under two main headings as *Brimhana* and *Langhana*. This division is broad and is purely based on the two-fold nature of diseases as *Santarpanajanya* and *Apatarpanajanya*.^[1]

Degeneration is an implication of *Apatarpana*. Hence conditions like spondylosis occurring as a sign of degenerative changes in intervertebral joints and vertebrae need obviously nourishing or *Brimhana* therapies.

Nasya (Nasal medication) has been explored from time immemorial and is widely employed in Ayurveda. It is the only one therapeutic measure among *Panchakarma* which is instilled in to nostrils, which has a direct access to head.

Although *Nasya* has been generally categorized under *Shodhana*, by altering the medicine used, *Brimhana* effect can be obtained.^[2] Here the attempt was to assess the efficacy of 21 times *Aavartita Dhanwantaram Tailam* when given as *Brimhana Nasya* along with conservative management compared to conservative management (*Rooksha Sveda*, *Patra Pottali Sveda* and internal use of *Gandharvahastadi Kashaya* and *Guggulu Tiktaka Kashaya*) alone in reducing the signs and symptoms of cervical spondylosis.

Materials and Methods

The study is randomized controlled clinical trial. Total 36 patients registered in the study. There was one dropout in study group and two dropouts in control group.

Population: The population comprises of patients diagnosed as Cervical Spondylosis coming under the inclusion criteria.

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Patients: The Patients were selected from the OPD of Department of Kaya Chikitsa and Panchakarma, Govt. Ayurveda College Hospital, Thruvananthapuram. Those diagnosed, based on clinical and radiological findings were selected for the study and admitted in the IP section. Patients in the study group were randomly distributed in *Nasya* group and control group by lottery method.

Inclusion criteria

Age : Between 20 and 60 yrs
Sex : Both sexes
Signs and Symptoms : Patients with signs and symptoms of cervical spondylosis with radiological changes suggestive of the disease.

Exclusion criteria

Age : Below 20 and above 60 yrs
Sex : No discrimination

The below conditions were also excluded from the study.

1. IVDP of cervical spine
2. Ankylosing spondylitis
3. Vascular lesions and Neoplasms
4. Nasal polyps
5. *Urdhvagata Raktapitta* (bleeding through upper orifices of body)
6. *Navapeenasa* (initial stage of rhinitis)
7. Unwilling patients

Duration of the study

Course of treatment : 21days and 1-month follow-up.

Treatment schedule

Patients both in the study and control group were subjected to conservative management mentioned above.

The conservative treatment schedule was applied in the following way.

Initially all the patients were subjected to *Rooksha sveda* for 7days. After *Rookshana*, *Patra Pottali Sveda* was done for 7days. During this period, internally *Gandharvahastadi Kashaya*^[3] was given twice daily and *Guggulu Tiktaka Kashaya*^[4] (90ml) once daily in empty stomach without any *Anupana*. After this, in the study group *Nasya* was performed with *Dhanvantaram Tailam*^[5] (21) *Avarti*. The dose was scheduled as *Madhyama Matra* (8 *Bindu*=4ml). Duration of *Nasya* was 7days. During the period of *Nasya*, *Guggulu Tiktaka Kashaya* was given thrice daily (empty stomach) in the study group. In the control group *Kashaya* alone was given.

Nasya-Preparatory measures

Abhyanga and *Ushma Sveda* of head and neck were performed. *Abhyanga* of *Urdhvanga* was done with *Dhanvantaram Tailam*.

Major procedure-Nasya

Nasya with 21times *avartita Dhanvantaram Tailam* was done for 7days in *Madhyama Matra*. The *Madhyama Matra* of *Taila* is 8 *Bindu*, which becomes approximately 4ml.

Dose fixation

Standardization of Bindu

Ten patients were randomly selected from the ward, they were asked to dip the distal 2 *Parvas* of index finger of right hand in

Gingelly oil and the number of drops fallen after dipping, were counted separately and average was calculated.

Average was found to be eight drops which measured 0.5ml

Madhyama Matra - 8 *Bindu*^[6]=4ml

Post-operative measures

Dhoomapana and *Kavala* were performed.^[7]

Assessment criteria

Both subjective and objective parameters were considered for assessing the response.

Pain

The method used for pain assessment was Visual Analogous Scale (VAS).

VAS

A scale of 10cm was drawn on a paper and the patient was instructed to mark against the reading relating to his or her pain severity before treatment, which was considered to be the initial pain scale reading.^[8]

Pain reading was graded as follows

0 : Nil
1-3 : Mild
4-6 : Moderate
7 and above : Severe

Tenderness

Tenderness was graded as follows

Grade 0 : No tenderness
Grade 1 : The patient says the joint is tender
Grade 2 : The patient winces with pain
Grade 3 : The patient winces and withdraws the affected part
Grade 4 : The patient does not allow the joint to be touched^[9]

Vertigo and radiation of pain were subjectively graded as yes, partial and nil. Presence and absence of numbness was also noted. Range of movements was assessed with the help of goniometer.

Hand grip strength

Grip strength was recorded with the help of an apparatus.

The gripper apparatus helps in measuring the compressive stiffness and tensile strength of the hand.

The difference in the readings before and after treatment will show the improvement in the patient's condition.

Collection of data

The patients were examined thoroughly and both subjective and objective parameters were recorded. Routine blood and urine examinations were done. The collected data were segregated under the following headings.

1. Data related to cervical spondylosis and its clinical findings.
2. Data related to response to treatment.

Assessments was done before treatment, after treatment and after 1month follow-up.

Data analysis

Data collected was rendered to Master sheet and tables were constructed. Statistical constants like Arithmetic mean, Standard deviation and percentage were computed. Necessary diagrams and charts were prepared, paired 't' and 'z' test for proportion were done to assess the effectiveness of treatment.

Results

Pain

In Control group, the mean decrease of pain was found to be 1.3 ($P < 0.01$). In Nasya group, mean decrease was 3.5. The difference was significant with P value < 0.001 . Before and after Nasya, a mean decrease of 2.8 was obtained. This was significant ($P < 0.001$).

Tenderness

In Control group, the mean difference was 0.5, which was statistically significant ($P < 0.01$). Nasya group, mean difference was 1.7, significant with $P < 0.001$. Before and after Nasya, mean decrease was 1.5 which was significant ($P < 0.001$).

In total the effectiveness of treatment in reducing tenderness was more significant in Nasya group.

Total four patients had vertigo, among them one patient (25%) had vertigo vividly and three patients (75%) had partial vertigo before treatment. After treatment also the same status was maintained, with no difference in mean value.

Radiation of pain

In Control group, the mean difference of was 0.2, which is insignificant. Nasya group, the mean values of pain radiation showed a difference of 0.9 which was significant ($P < 0.001$). Separate analysis of values before and after Nasya, also showed a mean difference of 0.8 with significance ($P < 0.001$).

Numbness

In Nasya group, 15 patients had numbness before treatment. After treatment only 9 of them (60%) had numbness and 6 patients (40%) were relieved of numbness. This result was significant with $P < 0.001$ by doing Z test for proportion. In the control group no significant result was observed.

Movements of cervical spine

Extension

In Nasya group, the mean increase was 7.2, which was found to be significant. ($P < 0.001$). In values before and after nasya, significant result was observed. In control group, there was a mean difference of 2.3 with P value < 0.05 .

Forward flexion

In control group, the mean increase was 2.1. This was insignificant ($P > 0.05$).

In study group, the mean increase was 5.5 which was significant. The mean value of forward flexion also had an increase of 5 after Nasya from the value before Nasya. This was significant.

Right lateral flexion

In Nasya group, the mean increase was 6.9, significance was shown at the level $P < 0.001$. In the control group there was a mean difference of 2.5 ($P < 0.05$).

Left lateral flexion

In Nasya group, a mean increase of 5 was observed by taking the values before and after treatment, the same difference was seen before and after Nasya, thus rendering the whole difference as the effect of Nasya. The result was significant. In control group, mean difference was 2 and $P < 0.01$.

Rotation to right

In Nasya group, there was a mean increase of 6.2 and statistical significance was noted. In the control group the difference was insignificant ($P > 0.05$). In separate analysis before and after Nasya the result was significant ($P < 0.001$).

Rotation to left

Mean increase in Nasya group was 5 and separate analysis before and after Nasya had a mean difference of 4.7. Both were significant ($P < 0.01$). In the control group there was a mean difference of 1.3, $P < 0.05$.

Hand grip strength

In study group, mean increase of right hand grip was found to be 15.7 before treatment to after treatment. This was significant ($P < 0.01$). The mean values before and after Nasya showed mean increase of 10.6 this was significant at $P < 0.05$.

In the control group also there was a mean difference of 4.3 and was significant at $P < 0.05$. In left hand grip strength, control group showed a mean increase of 6.9 which was found to be significant with paired t ($P < 0.05$). In Nasya group the results were insignificant ($P > 0.05$).

Discussion

The prevalence of cervical spondylosis is increasing day by day because of sedentary work, keeping neck stiff, degeneration due to aging, injuries to the cervical spine, weight bearing, various professions involving more neck movements and excess usage of artificial food which contain chemicals that are harmful to the body.

Interpretation of changes in signs and symptoms

The exact mechanism of action of Nasya in reducing the signs and symptoms is obscure. Still a humble attempt to analyse the possible modes of action is made. Considering pain relief, patients in the study group had considerable relief of pain compared to that of control group. Analysis of the values on pain scale before and after Nasya proved specific efficacy of Nasya in reducing pain. *Brimhana Nasya* is *Vatahara* so as to reduce pain. On the other hand, Nasya gives stimulation to the brain through the olfactory pathway thus inducing the production of Neuro peptides which act as pain relievers. The *Paka* of the *Taila* used for Nasya is *Mridu*, which retains the water-soluble principles along with lipid soluble particles at an optimum level. Moreover *Avartana* increases the concentration of fat soluble phytoconstituents. The peripheral processes of the olfactory cells respond to volatile, water soluble and lipid soluble odorless chemical substances. The drug used for Nasya is of *Mridu Paka* which maintains the water solubility for diffusing through the olfactory epithelium and lipid solubility for interacting with the lipids of the membranes of olfactory receptors. All these factors contribute well for the specific ability of *Sneha Nasya* in stimulating the brain through olfactory

pathway. In fact, structures of the Limbic system including Thalamus, Hypothalamus, Hippocampus, Amygdala and parts of the Basal ganglia are concentration areas for neuropeptides called nodal points. *Nasya* can stimulate areas like Amygdala in Limbic system, thus activating neuropeptide pathway.

In case of neck stiffness, *Nasya* relieved it considerably. The cause for neck stiffness is dehydration of intervertebral discs. *Nasya* with a nourishing drug can induce some nourishment to tissues by impregnating *Kapha Bhavas* and may reduce degeneration.

Most of the drugs in *Dhanvantaram Tailam* have *Vatahara* property and it contains groups of drugs like *Dashamoola* which have specific effect in *Shopha* and *Shoola*. This may be the reason for reduction in tenderness.

In cervical spondylosis, degenerative changes and osteophytosis occur which compress the nerve roots. This leads to radiculopathy and resultant radiation of pain. It is difficult to reverse these structural changes. So, complete relief cannot be expected in radiation of pain. Still, better results were obtained by *Nasya*. The exact mechanism is obscure but it is assumed that *Nasya* improves circulation and prevents degeneration up to some extent.

Brimhana Nasya alleviates vitiated *Vata* which is responsible for stiffness and movement restriction. This may be the reason for improvement of range of movements.

As far as vertigo is concerned, there was a mean decrease of 0.6, which was statistically insignificant but patients got satisfactory relief. In Ayurvedic terms *Brimhana* effect of the *Nasya* done may be responsible for reducing vertigo. *Brimhana* is *Vata-Pitta Shamaka*. Vitiation of *Vata-Pitta* with *Rajas* cause *Bhrama*. The nourishing and strengthening effect of *Nasya* is evident from the improvement of hand grip strength.

When the *Snigdha Bhavas* exhaust from the body as a part of natural wear and tear, the most vulnerable regions start showing symptoms, the cervical spine is one such.

Based on the theory of *Svaabhavoparama*, there is an inherent tendency for natural self cure. The body heals by itself and a natural cure is endowed after every injury and insult. The role of medicine is only to assist the nature.

Here the major processes in pathology are disc dehydration and bone degeneration – vividly showing a reduction in *Kapha Bhavas* and increase of *Vata*. At the level of *Mahabhootas* the *Prithvi* and *Jala Mahaabhootas* exhaust gradually with a subsequent increase of *Vayu* and *Aakaasha Bhootas*. Hence body needs to acquire more *Snigdha Bhavas* to resist the process of degeneration.

Here the facts to be considered are

1. Nostrils are the easiest routes to approach diseases above the clavicle.^[10]
2. Drugs with a certain quality increases similar principle in the body (*Samanya* theory).^[11]
3. The duty of medicine is to help the natural healing process.^[12]

By giving *Brimhana Nasya* with *Avartita Taila* which has increased amount of fat-soluble principles, we are giving a stimulus to the body with those *Gunas* which are necessary to induce natural *Kapha Bhaavas*.

The mode of action of *Nasya* is explained in Ayurveda as follows. The instilled medicine moves up the channels to the *Shringataka*, spreads all over the head, channels of eyes, ears, and throat there by removing *Doshas*. Thus cures the diseases affecting the *Urdhva Jatru*.^[13]

The position specifically advised for performing *Nasya* is such that the head is kept a little down and the feet a little high from the plane.^[14] This can increase the pressure of CSF due to gravitational back flow from the pressure of CSF due to gravitational back flow from the spinal cord. When the CSF pressure rises and equals the arterial pressure, it compresses the whole brain as well as arteries in the brain and cuts off the blood supply to the brain. This initiates a CNS ischemic response that causes the arterial pressure to rise as a part of natural homeostatic mechanism. When the arterial pressure rises to a level higher than the CSF pressure, blood flows once again into the vessels of the brain to relieve ischemia. This mechanism is known as cushioning reaction^[15] and potentially deserves mention in this context. Probably it plays a crucial role in spread of active principles of the medicine used for *Nasya* through circulatory channels at the earliest.

Conclusions

1. Conservative management including *Rooksha Sveda*, *Patra Pottali Sveda* and internal medicines like *Gandharvahastadi Kashaya* and *Guggulu Tiktaka Kashaya* along with *Nasya* relieves the clinical signs and symptoms of cervical spondylosis better than conservative management devoid of *Nasya*.
2. Conservative management along with *Nasya* reduces pain, neck stiffness, tenderness, radiation of pain and numbness and improves the range of movements of the cervical spine more effectively.
3. *Brimhana Nasya* can decrease the rate of degeneration. Analysis of various parameters before and after *Nasya* proved the specific efficacy of reducing the pain, stiffness, tenderness and radiation of pain. Also it could improve the range of movements.

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हिन्दी सारांश

सर्वायकल स्पोण्डिलोसिस में नस्य के प्रभाव का चिकित्सात्मक अध्ययन

राधिका सी., विनोद कुमार जी, मेहरजाँ के.

सर्वायकल स्पोण्डिलोसिस (ग्रीवाशूल) एक साधारण व्याधि है। इसके लक्षणों को कम करने में नस्य का प्रभाव समझने हेतु यह चिकित्सकीय अध्ययन किया गया। पंजीकृत आतुरों को दो वर्गों में बाँटा गया। प्रथम वर्ग में सर्व प्रथम रुक्ष स्वेद (७ दिन), पश्चात् पत्रपोटलस्वेद (७ दिन), गन्धर्वहस्तादि कषाय (दिन में २ बार ७ दिन तक) और गुग्गुलुतिक्तक कषाय (दिन में १ बार ७ दिन तक) साथ-साथ दिये गये। द्वितीय वर्ग में इन औषध उपक्रमों के अतिरिक्त धन्वन्तरं तेल (२१ आवर्तित) द्वारा नस्य (७ दिन) भी किया गया। चिकित्सा पश्चात् द्वितीय वर्ग में शूल, ग्रीवाग्रह, स्पर्शासह्यता, सुप्तता आदि लक्षणों में अधिक सार्थक लाभ पाया गया।

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