An Open Label Single Arm Clinical Study on Dashamooladi Yamaka Pratimarsha Nasya and Ashtavargam Kashaya in Vishwachi (Cervical Radiculopathy)

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ABSTRACT

Background: Vishwachi is one among the 80 Vatavyadhi. Lakshana of Vishwachi are Bahu Cheshtapaharana, Bahu Karma Kshaya, Stambha, Ruja, Toda, Spandana, Tandra, Gourava and Arochaka. Cervical radiculopathy is a condition similar to Vishwachi, which results from compression of cervical nerve roots. This leads to neck pain radiating along the distribution of the affected nerve root, numbness, altered reflexes and weakness in the muscles of arm. Objectives: To evaluate the combined effectiveness of Dashamooladi Yamaka Pratimarsha Nasya and Ashtavargam Kashaya in Vishwachi (Cervical Radiculopathy). Materials and methods: 30 subjects fulfilling the inclusion criteria were administered with Dashamooladi Yamaka Pratimarsha Nasya in the dose of 2 Bindu twice daily after food and Ashtavargam Kashaya, 15ml thrice daily after food, for 14 days. Ruja, Toda, Spandana, Stambha, Tandra, Gourava, Arochaka, Bahukarmakshya, Bahucheshtapaharana and Spurling test were assessed on 1st day, 7th day and 15th day. Data were analyzed using appropriate statistical tests. Results and conclusion: Statistically significant (P < 0.05) improvement was observed in symptoms such as Bahu Karmakshya, Bahu Cheshtapaharana, Ruja, Toda, Spandana and range of cervical movement. Dashamooladi Yamaka Pratimarsha Nasya and Ashtavargam Kashaya were found to be effective in the management of Vishwachi.

Key words: Vishwachi, Cervical Radiculopathy, Dashamooladi Yamaka, Ashtavargam Kashaya

INTRODUCTION

Vishwachi is one among the 80 Vatavyadhi. Karma Kshaya and Cheshtapaharana of Bahu are the symptoms of Vishwachi. It resembles Gridhrasi and is of two types - Vataja and Vatakaphaja. Ruja, Stambha, Toda, Spandana, Tandra, Gourava and Arochaka are other symptoms of Vishwachi. There is similarity in the presentations of Vishwachi and Cervical radiculopathy. Cervical radiculopathy is the result of degenerative changes such as cervical disc herniation and bone hyperplasia.¹ It results from compression of cervical nerve roots leading to neck pain that may radiate to shoulder, arm, forearm and digits. Associated clinical features include numbness, altered reflexes and weakness in the muscles of arm. Prevalence of Cervical radiculopathy is around 3.5 per 1000 people.² Annual incidence varies from 83 cases² to 210 cases³ per 100,000 people. There is a recurrence rate of 32% over a period of 4.9 years.⁴ Peak incidence of Cervical radiculopathy is most frequently reported to occur in the fourth or fifth decade of life.⁴ Non surgical management comprises of acetaminophen, non-
steroidal anti-inflammatory drugs, corticosteroid injections and cervical traction.

Vishwachi is a condition affecting Bahu. Dhatukshaya and resultant Vata Prakopa can be considered as the main factor leading to Vishwachi. Sneha helps in Vata Shamana. Administration of sneha in the form of Nasya is indicated in Bahusheershagata Vata.[5] Brimhana Nasya with Dashamooladi Yamaka[6] is indicated in Vishwachi. Brimhana helps in Vata Shamana and Dhatu Poshana. Ashtavargam Kashaya is Vatahara[7] Hence Dashamooladi Yamaka Pratimarsha Nasya and Ashtavargam Kashaya were chosen for the study.

**OBJECTIVE OF THE STUDY**

To evaluate the combined effectiveness of Dashamooladi Yamaka Pratimarsha Nasya and Ashtavargam Kashaya in Vishwachi (Cervical Radiculopathy).

**MATERIALS AND METHODS**

**Source of data:**

Subjects of Vishwachi were selected from Out Patient and In Patient Department of Sri Dharmanathala Manjunatheshwara Hospital, Hassan.

**Diagnostic criteria:**

Clinical features of Vishwachi and Cervical radiculopathy namely, Bahu Cheshtapaharana, Bahu Karmakshaya and radiating pain from neck and shoulder down to the arm were the criteria for diagnosis.

**Inclusion criteria**

1. Subjects between 30 - 70 years of age.
2. Subjects fit for Nasya Karma.
3. Subjects irrespective of gender, caste, creed, occupation, religion and socio economic status
4. Subjects who are willing to participate and ready to sign the informed consent form.

**Exclusion criteria**

1. Cases of uncontrolled diabetes mellitus, hypertension, impaired cardiac, renal, hepatic function and stroke.
3. Subjects who are known cases of neoplasm and infective disorders.
4. Pregnant women and lactating mothers.

**Ethical clearance and CTRI registration**

Ethical clearance was obtained from Institutional Ethics Committee. IEC No: SDM/IEC/74/2021

Trial was registered on www.ctri.gov.in with Registration No: CTRI/2022/05/042517 dated 12/05/2022

**Study design:** An open label, single arm, clinical study on Vishwachi (Cervical Radiculopathy) was carried out on 30 subjects, selected by convenience (non-random) sampling technique.

**Intervention:**

- **Ashtavargam Kashaya Route of administration - Oral**
- **Dashamooladi Yamaka Route of administration - Nasal**

**Source and authentication of drug**

- **Ashtavargam Kashaya** purchased from a GMP certified pharmacy was packed in 1 litre bottles at Sri Dharmanathala Manjunatheshwara College of Ayurveda Teaching pharmacy.
- **Raw drugs for Dashamooladi Yamaka** and **Bala** were purchased from CKKM pharmacy. **Masha** was purchased from a local vendor and authenticated from the Department of Dravya Guna, SDM college of Ayurveda and Hospital, Hassan.

**Method of preparation of Dashamooladi Yamaka**

Dashamoola, Bala and Masha, in a quantity of 100grams each, were finely powdered for preparing Kalka. Dashamoola, Bala and Masha, in a quantity of 2 kilograms each were coarsely powdered and soaked in 48 litres of water. This was heated over mild fire and reduced to 12 litres. Ghrita and Tila Taila 1.5 litres each, were heated in mild fire. Kalka and Kashaya were...
added to this and heated until the Sneha Siddha Lakshanas were obtained. Dashamooladi Yamaka was packed in 30ml bottles at Sri Dharmasthala Manjunatheshwara College, Teaching Pharmacy. Bottles were properly labelled with the name of the drug, reference, details of the manufacturer, batch number.

**Treatment plan:**

Ashtavargam Kashaya 15ml thrice daily after food and Pratimarsha Nasya with Dashamooladi Yamaka- 2 Bindu in each nostril, twice daily after food

**Duration:** 14 days.

**Assessment criteria**

Assessments were made based on the symptoms of Vishwachi, such as Ruja, Stambha, Toda, Spandana, Gourva, Arochaka, Tandra, Bahu Cheshtapaharana, Bahu Karma Kshaya.

**Table 1: Assessment parameters**

<table>
<thead>
<tr>
<th>SN</th>
<th>Parameter</th>
<th>Grade</th>
<th>Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Ruja</td>
<td>1</td>
<td>VAS 0 - No pain</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2</td>
<td>VAS 1-3 - Mild Pain</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3</td>
<td>VAS 4-7 - Moderate pain</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4</td>
<td>VAS 8-10 - Unbearable pain</td>
</tr>
<tr>
<td>2</td>
<td>Toda</td>
<td>1</td>
<td>No pricking sensation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2</td>
<td>Occasional mild pricking sensation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3</td>
<td>Frequent pricking sensation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4</td>
<td>Persistent pricking sensation</td>
</tr>
<tr>
<td>3</td>
<td>Spandana</td>
<td>1</td>
<td>Absent</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2</td>
<td>Present</td>
</tr>
<tr>
<td>4</td>
<td>Gourava</td>
<td>1</td>
<td>Absent</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2</td>
<td>Occasionally</td>
</tr>
</tbody>
</table>

**OBSERVATION**

57 subjects were screened, 36 were enrolled and 30 subjects completed the study. 6 were drop outs. Majority among 36 subjects - 17 belonged to the age group of 30-40 years, 21 were females; 13 had schooling up to Secondary school education; 36 were married; 12 were homemakers; 16 each belonged to Upper Middle Class and Lower Middle Class category; 30 were from rural locality; 24 had gradual onset of symptoms; 28 followed mixed diet; 22 were observed to follow Vishamashana; Chinta was observed as a manasika nidana in 20; 22 were observed to have Vishamagni; 17 had disturbed sleep.

Statistical analysis was done using SPSS VER. 23

**RESULTS**

30 subjects were administered with Dashamooladi Yamaka Pratimarsha Nasya (2 Bindu each nostril twice
daily after food) and Ashtavargam Kashaya (15ml thrice daily after food) for 14 days.

Table 2: Results of Friedman test on Ruja, Toda, Gourava and Arochaka.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>N</th>
<th>BT Mean</th>
<th>D 7 Mean</th>
<th>AT Mean</th>
<th>SD BT</th>
<th>D 7</th>
<th>AT</th>
<th>X²</th>
<th>Df</th>
<th>P Value</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ruja</td>
<td>30</td>
<td>3.3</td>
<td>2.9</td>
<td>2.3</td>
<td>2.6</td>
<td>2.1</td>
<td>1.3</td>
<td>0.5</td>
<td>0.8</td>
<td>0.7</td>
<td>37.5</td>
</tr>
<tr>
<td>Toda</td>
<td>2.0</td>
<td>1.6</td>
<td>1.3</td>
<td>2.5</td>
<td>1.9</td>
<td>1.6</td>
<td>0.9</td>
<td>0.6</td>
<td>0.5</td>
<td>28.8</td>
<td>2</td>
</tr>
<tr>
<td>Gourava</td>
<td>2.3</td>
<td>1.9</td>
<td>1.6</td>
<td>2.5</td>
<td>1.9</td>
<td>1.6</td>
<td>1.3</td>
<td>0.9</td>
<td>0.8</td>
<td>24.3</td>
<td>2</td>
</tr>
<tr>
<td>Arochaka</td>
<td>1.1</td>
<td>1.1</td>
<td>1.1</td>
<td>2.0</td>
<td>1.9</td>
<td>1.9</td>
<td>0.6</td>
<td>0.4</td>
<td>0.4</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

Table 3: Results of Mc Nemar test on Spandana, Bahu Cheshtapaharana, Bahu Karmakshaya and Spurling test.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>N</th>
<th>BT Present</th>
<th>D 7 Present</th>
<th>AT Present</th>
<th>Absent Present</th>
<th>Absent BT</th>
<th>Absent D 7</th>
<th>Absent AT</th>
<th>P Value</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spandana</td>
<td>30</td>
<td>14</td>
<td>9</td>
<td>5</td>
<td>21</td>
<td>25</td>
<td>25</td>
<td>0.004</td>
<td>S</td>
<td></td>
</tr>
<tr>
<td>Bahu Cheshtapaharana</td>
<td>30</td>
<td>0</td>
<td>25</td>
<td>5</td>
<td>5</td>
<td>25</td>
<td>25</td>
<td>0.001</td>
<td>S</td>
<td></td>
</tr>
<tr>
<td>Bahu Karmakshaya</td>
<td>30</td>
<td>0</td>
<td>23</td>
<td>7</td>
<td>17</td>
<td>13</td>
<td>13</td>
<td>0.001</td>
<td>S</td>
<td></td>
</tr>
<tr>
<td>Spurling Test</td>
<td>15</td>
<td>15</td>
<td>15</td>
<td>15</td>
<td>9</td>
<td>21</td>
<td>0.031</td>
<td>S</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 4: Results of Cochran’s Q on Tandra.

<table>
<thead>
<tr>
<th>Tandra</th>
<th>Mean Rank</th>
<th>N</th>
<th>Cochran’s Q</th>
<th>Df</th>
<th>P Value</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>BT</td>
<td>28</td>
<td>30</td>
<td>4.0</td>
<td>2</td>
<td>0.14</td>
<td>NS</td>
</tr>
<tr>
<td>D 7</td>
<td>28</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AT</td>
<td>30</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 5: Results of Repeated Measure ANOVA test on Neck - Flexion, Extension, Right and left rotation, Right and left lateral flexion.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>N</th>
<th>Mean</th>
<th>Greenhouse-Geisser</th>
<th>Greenhouse-Geisser error df</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neck flexion</td>
<td>30</td>
<td>65.2</td>
<td>72.3</td>
<td>0.001</td>
<td>56.2</td>
</tr>
<tr>
<td>Neck extension</td>
<td>40.8</td>
<td>42.5</td>
<td>45</td>
<td>0.001</td>
<td>53.2</td>
</tr>
</tbody>
</table>
Friedman test on Ruja, Toda and Gourava; McNemar test on Spandana, Bahu cheshtapaharana, Bahu karmakshaya and Spurling test and Repeated Measure ANOVA test on Neck- Flexion, Extension, Right and left rotation, Right and left lateral flexion showed statistically significant improvement at P < 0.05.

**DISCUSSION**

**Effect on Ruja and Toda**

Statistically significant reduction was noticed in Ruja and Toda with P < 0.05. Ruja and Toda are Lakshana of Prakupita Vata. Shoolahara property of Eranda, Shunthi, Nirgundi, Bilwa, Gambhari, Brihati, Gokshura, Masha and Lashuna helps in reducing Ruja and Toda.

**Effect on Spandana**

Statistically significant reduction was observed in Spandana with P < 0.05. Spandana is Kampa or Sphurana caused by Chala Guna of Vata. Dashamooladi Yamaka and Ashtavargam Kashaya are Vata Shamaka and can help in relieving Spandana.

**Effect on Gourava**

Statistically significant reduction was observed in Gourava with p < 0.05. Gourava is a Kapha Vridhi Lakshana. Majority of drugs in the intervention are Vatakaphahara & possess Ushna Veerya. This helps in pacification of Kapha and thereby reduction of Gourava.

**Effect on Stambha, Bahu Cheshtapaharana and Bahu Karmakshaya**

Stambha interpreted as stiffness of neck was assessed by measuring cervical range of movement using Goniometer. Statistically significant improvement was observed in Cervical range of movement, Bahu cheshta and Bahu Karma with p < 0.05.

Stambha is a Saama Vata Lakshana. Bilwa, Shyonaka, Gambhari, Kantakari and Lashuna possess Pachana Karma. Ama Pachana helps in relieving stambha.

Vyana Vata is responsible for body movements. Aushadha Kala for Vyana Vata is after food. Interventions were administered after food. This acts on Vyana Vata and helps in reducing Stambha, Bahucheshtapaharana and Bahu Karmakshaya.

**Discussion on mode of action of Pratimarsha Nasya**

Medicine administered through nostril, reaches Sringataka marma, spreads in Murdha and expels Doshas from Uttamanga. According to Acharya Vagbhata, Nasya pacifies Urdbhajatrubgata Vikara. Jatru is Greeva Moola. Hence the terminology Urdbhajatru includes Greeva. Pathology of Cervical radiculopathy lies in cervical vertebrae and intervertebral disc. Hence Pratimarsha nasya was helpful in pacifying symptoms of Cervical radiculopathy.

Snehaprayyoga after food is indicated in Urdbhajatrubgata Roga and Auttarrabhaktika Nasya is indicated in Bahu-Sheersha Gata Vata. Hence Snehaprayyoga in the form of Auttarrabhaktika Pratimarsha Nasya with Dashamooladi Yamaka gets justified in Vishwachi where Bahu is affected. Dashamooladi Yamaka Nasya is indicated in the evening, after food. Bhuktabhakta being a contraindication for Nasya in general, Pratimarsha Nasya was chosen. Pratimarsha Nasya is free from Yantrana (restrictions with respect to time or regimen) or Vyapat (complications). It alleviates Urdbhajatru Vikara and is capable of strengthening Greeva and Bahu. Nasya done in the morning is capable of pacifying Kapha and that done in the evening is capable
of pacifying Vata and Udhwajatu Vikara. Hence, two Nasya Kala chosen for the study can help in pacifying Vata and Kapha involved in Vishwachi.

Mode of action of Yamaka

Lipid form of medicine facilitates drug absorption. Ghrita is the best among Sneha. It does Vatapitta Shamana. Ghrita is Yogavahi and does Agni Deepana. Tila Taila is the best among Taila. It is Vatakaphahara. Vyavayi and Sookshma, Teekshna Gun of Tilataila help Yamaka to spread faster into sookshma Srotas. Tarpana Karma of Tilataila can correct Asthidhatu which is in Kshaya Avastha. It can pacify Kevala Vata as well as Kapha anubandha Vata. It is Mamsa-Bala Sthairyakara. Ghrita and Taila having Brimhana & Balya Karma help in relieving symptoms of Cervical radiculopathy which is caused by degenerative pathology.

Mode of action of drugs

Devadaru and Nirgundi are capable of doing Koshtthagata Ama Pachana. Eranda does Srotoshodhana. Bilwa, Agnimantha, Shyonaka, Gambhari and Kantakari are capable of doing Sthanika Ama Pachana. These can relieve Stambha caused by Saama Vata. Sookshma and Teekshna Gun of Eranda and Kantakari help in transport of medicinal properties to minute channels of circulation. Shunthi in Ashtavarga Kashaya is capable of enhancing bioavailability of the intervention. Balya Karma of Bala, Bilwa, Gokshura and Shalaparni and Mamsabalanapradha action of Masha are helpful in strengthening muscles of cervical region and relieving the symptoms. Rasayana Karma of Gambhari, Gokshura, Shalaparni, Lashuna, Shunthi and Ghrita helps in Dhatupushana. This can help in slowing down the degenerative pathology in Cervical radiculopathy and correcting Asthi Dhatu Kshaya caused by Vata Vridhi.

The root extract of Eranda, ethanolic extract of Shunthi, Stem bark extract of Devadaru, ethyl extract of Nirgundi, Premanazole in Agnimantha, aqueous extract & Gangetin isolated from hexane extract of Shalaparni root have proved anti-inflammatory activity. Anti-inflammatory actions of drugs helps in relieving inflammation caused by acute disc herniation and thereby relieving subsequent impingement on nerve root. Vata and Asthi have Asraya-Asrayi Bhava. In Vishwachi, Vata Prakopaka Nidana leads to Asthi Dhatu Kshaya. This is comparable to degenerative pathology in Cervical radiculopathy. Dashamooladi Yamaka and Ashtavargam Kashaya through Vata Shamana action helps in correcting Asthi Dhatu Kshaya and thereby relieves symptoms of Vishwachi.

CONCLUSION

Administration of Dashamooladi Yamaka Pratimarsha Nasya and Ashtavargam Kashaya showed statistically significant results in Ruja, Toda, Stambha, Spandana, Gourava, Bahucheshtrapaharana and Bahukarma Kshaya. Hence Dashamooladi Yamaka Pratimarsha Nasya-2 Bindu twice daily after food and Ashtavargam Kashaya - 15ml thrice daily after food for 14 days is effective in the management of Vishwachi (Cervical Radiculopathy).

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