CLINICAL EVALUATION OF SHALLAKI NIRYAS (BOWELLIA SERRATA) IN THE MANAGEMENT OF GRIVAASTHI SANDHI GATA VATA (CERVICAL SPONDYLOSIS)

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ABSTRACT
Cervical spondylosis is a condition in which there is a progressive degeneration of the cervical inter-vertebral discs leading to change in the surrounding structures. The therapeutic value of Shallaki Niryas (kunduru) has been known. It possess anti-inflammatory, anti-arthritis and analgesic activity & it prevent the destruction of articular cartilage. To assess the efficacy of Shallaki Niryas in the management of cervical spondylosis, a study was conducted on 10 clinically, pathologically and radiologically diagnosed patients of cervical spondylosis selected from O.P.D /I.P.D wing of P.G. Dept. of Kaya Chikitsa, N.I.A., Jaipur, satisfying the inclusion criteria. Patients were treated with Cap. Shallaki - 2cap BD with luke warm water after meal (each cap had 500mg Shallaki Niryas). Assessments were done with regard to Shula (pain in cervical region), Prasaran Akunchana vedana (pain during flexion and extention), Shotha (swelling), headache, dizziness, numbness, weakness, tingling sensation in arm and neck disability index before and after treatment. Statistical analysis was done with help of Instat Graphpad 3 using Wilcoxon matched paired single ranked test. Statistically significant improvement was found. Results indicate that the Shallaki Niryas is effective in cervical spondylosis.

Keywords: Shallaki Niryas, Boswellia serrata, Cervical spondylosis, Shula

INTRODUCTION
Sandhigata Vata is mentioned under Vata Vyadhi. Acharya Charaka has mentioned that Nidana Sevana (etiological factors) aggravates Vata and this Prakupita (vitiating) Vata accumulates in Rikta Srotas to give rise to various generalized and localized diseases. In case, Vatadosha is vitiating in Griva Sandhi (cervical joints) it leads to Griva Asthi Sandhi Gata Vata. The symptomatology of Sandhi Gata Vata as described in Ayurvedic classics is as follows:

1. Shula (Pain in cervical region)
2. Prasaran Akunchana vedana (pain during flexion and extension)
3. Shotha (swelling in cervical region)
4. Vatapurnadriti sparsha³ (On palpation of the joints, the perception is similar to that of balloon inflated with air)
5. Hanti Sandhigatah (loss of function)
6. Aatopa (Crackling noise {Creptitus})

In contemporary medical science the similar condition of cervical joint is explained as cervical spondylosis. In cervical spondylosis the degenerative changes in the inter-vertebral discs lead to secondary change in the adjacent vertebrae. These changes in the cervical spine may affect one or more nerve roots, the cervical cord at one or more levels or may cause simultaneous damage to the nerve roots and cord.
The symptom and sign of cervical spondylosis fall into two main groups: those due to root compression—cervical radiculopathy, and those due to cord compression – cervical myelopathy. In radiculopathy, sensory symptoms are far more frequent than motor and the most common irritative root symptom is pain although various form of paraesthesia, hyperesthesia and hyperalgesia may occur. In cervical myelopathy the onset is usually insidious, the patient complaining of increasing disability over a period of month. The three common initial symptoms which may occur alone or in combination are dysaesthesiae in hand, weakness and clumsiness of hand and weakness in lower limbs. In addition there may be other related symptoms which include headache, pain in neck and symptom of vertebra-basilar insufficiency. All these may occur singly or in any combination.

In modern medical sciences the condition is managed by use of analgesic, corticosteroid, surgical decompression, traction which provides temporary relief and has a lot of side effects besides economic and physical burden. So it is an urgent need of time for a permanent, cost effective and safe treatment devoid of side effects.

**AIMS AND OBJECTIVES**

To assess the efficacy of **Shallaki Niryas** in the management of Cervical Spondylosis

**MATERIALS AND METHODS**

The study was conducted on 10 clinically, pathologically and radiologically diagnosed patients of **Griva Asthi Sandhi Gata Vata** (Cervical Spondylosis). The selection of patients was made from O.P.D. /I.P.D. wing of P.G. Dept. of **Kaya Chikitsa**, N.I.A, Jaipur.

**[a] Study Design:** Single centre, Open label

**[b] Inclusion Criteria:**

1. Patients of either sex with presenting symptoms of **Griva Asthi Sandhi Gata Vata** (Cervical Spondylosis) and X ray suggesting cervical spondylosis.
2. Patients above 18 years and less than 70 years.

**[c] Exclusion Criteria:**

1. Pregnancy and lactating mothers.
2. Contraindication and allergy to **Shallaki** or previously treated with **Shallaki** and on **Griva vasti**.
3. Recent cervical, spinal, or shoulder surgery or implanted instrumentation or previous surgery for cervical spondylotic myelopathy.
4. Stenosis of spinal canal
5. Patients suffering from any infectious disease (like tuberculosis etc), metabolic disease (like diabetes mellitus and hypothyroidism), and chronic disease (like rheumatoid arthritis, SLE, ankylosing spondylitis etc).

**Administration of Drugs:**

10 registered patients of Cervical Spondylosis were advised for Cap. **Shallaki** - 2cap BD (each cap had 500mg **Shallaki Niryas**) with lukewarm water after meal for a period of 1 month.

**Criteria for Assessment:**

**Subjective Parameters:**

a. Neck Disability Index
b. Clinical symptoms of **Griva Asthi Sandhi Gata Vata** (Cervical Spondylosis) before & after the course of therapy –
   1. **Shula** (pain)
   2. **Prasaran Akunchana vedana** (painful flexion and extension)
   3. **Shotha** (swelling)
4. Headache
5. Dizziness
6. Numbness in arm
7. Tingling sensation in arm
8. Weakness in arm

(a) Symptom 1-2, the severity of the symptoms pre and post trial was assessed on the basis of visual analogue scale (VAS).
(b) Symptom 3-9, the severity of the symptom pre and post trial was assessed according to the symptom rating scale developed by Prof. A. K. Sharma et al.

Statistical Methods Used:
Obtained observations were analyzed statistically with the help of Instat Graphpad 3 and Wilcoxon matched-pairs signed ranks test.

OBSERVATIONS
Maximum patients i.e. 31.42% were found in age group 41-50 yr. 62.85% patients were female. Cervical spondylosis was found maximum i.e. 31.43% in labours and nature of job was found maximum in lifting weight on head. Maximum patients (60%) had mixed type of dietary habit. Maximum patients (45.72%) had vata-pittaja prakriti. Maximum patients i.e. 34.28% had chronicity of 1-2 yr, followed by 28.59% patients had < 1 yr. Onset of disease was insidious in maximum patients i.e. 94.28%. All patients i.e. 100% had shula (pain in cervical region), 85.71% patients had prasaran akunchana vedana (painful flexion and extension), 71.42% patients had headache, numbness and tingling sensation in arm. 57.14% patients had dizziness/vertigo & weakness in arms and only 25.71% patients had shotha (swelling) in cervical region. [Table 1]

Table 1: Showing demographic and background characteristics at admission

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Observations</th>
<th>Percentage of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>Female</td>
<td>62.85</td>
</tr>
<tr>
<td>Age (years)</td>
<td>41-50</td>
<td>31.42</td>
</tr>
<tr>
<td>Occupation</td>
<td>Labour</td>
<td>31.43</td>
</tr>
<tr>
<td>Nature of job</td>
<td>Lifting weight on head</td>
<td>28.58</td>
</tr>
<tr>
<td>Education</td>
<td>Primary</td>
<td>40</td>
</tr>
<tr>
<td>Dietary habit</td>
<td>Mixed</td>
<td>60</td>
</tr>
<tr>
<td>Sharirika prakriti</td>
<td>Vata-pittaja</td>
<td>45.72</td>
</tr>
<tr>
<td>Chronicity</td>
<td>1-2 yr</td>
<td>34.28</td>
</tr>
<tr>
<td>Onset of disease</td>
<td>Insidious</td>
<td>94.28</td>
</tr>
<tr>
<td></td>
<td>Shool</td>
<td>100.00</td>
</tr>
<tr>
<td></td>
<td>Prasaran akunchana vedana</td>
<td>85.71</td>
</tr>
<tr>
<td></td>
<td>Shotha</td>
<td>25.71</td>
</tr>
<tr>
<td></td>
<td>Headache</td>
<td>71.42</td>
</tr>
<tr>
<td></td>
<td>Numbness in arms</td>
<td>71.42</td>
</tr>
<tr>
<td></td>
<td>Tingling sensation in arm</td>
<td>71.42</td>
</tr>
<tr>
<td></td>
<td>Weakness in arm</td>
<td>57.14</td>
</tr>
</tbody>
</table>
RESULTS

Neck Disability Index: Mean score of neck disability index, was 19.3 before treatment which lowered down to 6.3 after treatment with S.D± 5.7927 giving a relief of 67.35 % which is statistically very significant (P <0.01). [Table 2]

Table 2: Showing effect of therapy on Neck Disability Index

<table>
<thead>
<tr>
<th>Symptom</th>
<th>n</th>
<th>Mean score</th>
<th>Difference</th>
<th>% relief</th>
<th>S.D±</th>
<th>S.E±</th>
<th>p</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>BT</td>
<td>AT</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neck disability index</td>
<td>10</td>
<td>19.3</td>
<td>6.3</td>
<td>13</td>
<td>67.35</td>
<td>5.7927</td>
<td>1.8318</td>
<td>0.0020</td>
</tr>
</tbody>
</table>

*Shula (Pain in cervical region):* Mean of VAS scores for pain, before treatment was 3.3. It lowered down to 1.1 with S.D± 0.9189 giving a relief of 66.66% which is statistically highly significant (P <0.01).

*Pasaran Akunchana Vedana:* Mean of VAS score for *Pasaran Akunchana Vedana*, before treatment was 4.2. It lowered down to 1.8 with S.D± 1.578 giving a relief of 68.42% which is statistically highly significant (P <0.01).

*Shotha:* Mean score of *Shotha*, was 0.8 before treatment which lowered down to 0.3 after treatment with S.D± 0.8498 giving a relief of 62.50% which is statistically non significant (P >0.05).

*Headache:* Mean score of Headache was 1.4 before treatment which lowered down to 0.7 after treatment with S.D± 0.4830 giving a relief of 50% which is statistically significant (P <0.05).

Table 3: Showing effect of therapy on clinical features of the disease

<table>
<thead>
<tr>
<th>Symptom</th>
<th>n</th>
<th>Mean score</th>
<th>Difference</th>
<th>% relief</th>
<th>S.D±</th>
<th>S.E±</th>
<th>p</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>BT</td>
<td>AT</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Shula</strong></td>
<td>10</td>
<td>3.3</td>
<td>1.1</td>
<td>2.2</td>
<td>66.66</td>
<td>0.9189</td>
<td>0.2906</td>
<td>0.0020</td>
</tr>
<tr>
<td><em>Prasaran akunchana vedana</em></td>
<td>9</td>
<td>4.2</td>
<td>1.8</td>
<td>2.4</td>
<td>68.42</td>
<td>1.578</td>
<td>0.4989</td>
<td>0.0078</td>
</tr>
<tr>
<td><strong>Shotha</strong></td>
<td>3</td>
<td>0.8</td>
<td>0.3</td>
<td>0.5</td>
<td>62.50</td>
<td>0.8498</td>
<td>0.2687</td>
<td>0.2500</td>
</tr>
<tr>
<td><strong>Headache</strong></td>
<td>7</td>
<td>1.4</td>
<td>0.7</td>
<td>0.7</td>
<td>50.00</td>
<td>0.4830</td>
<td>0.1528</td>
<td>0.0156</td>
</tr>
<tr>
<td><strong>Dizziness</strong></td>
<td>5</td>
<td>1.0</td>
<td>0.3</td>
<td>0.7</td>
<td>70</td>
<td>0.9487</td>
<td>0.3</td>
<td>0.1250</td>
</tr>
<tr>
<td><strong>Numbness in arms</strong></td>
<td>6</td>
<td>1.2</td>
<td>0.4</td>
<td>0.8</td>
<td>66.66</td>
<td>0.7888</td>
<td>0.2494</td>
<td>0.0313</td>
</tr>
<tr>
<td><strong>Tingling sensation in arm</strong></td>
<td>8</td>
<td>1.9</td>
<td>0.6</td>
<td>1.3</td>
<td>68.42</td>
<td>0.9487</td>
<td>0.3</td>
<td>0.0078</td>
</tr>
<tr>
<td><strong>Weakness in arm</strong></td>
<td>3</td>
<td>0.6</td>
<td>0.3</td>
<td>0.3</td>
<td>50</td>
<td>0.4830</td>
<td>0.1528</td>
<td>0.2500</td>
</tr>
</tbody>
</table>

HS: highly significant; S: significant; NS: non significant
Dizziness: Mean score of dizziness, was 1.0 before treatment which lowered down to 0.3 after treatment with S.D± 0.9487 giving a relief of 70% which is statistically non significant (P>0.05).

Numbness in arms: Mean score of numbness in arms was 1.2 before treatment which lowered to 0.8 after treatment with S.D± 0.78 giving a relief of 66.66% which is statistically significant (P<0.05).

Tingling sensation in arms: Mean score of tingling sensation in arms was 1.9 before treatment which lowered down to 0.6 after treatment with S.D± 0.9487 giving a relief of 68.42% which is statistically very significant (P<0.01).

Weakness in arms: Mean score of weakness in arms was 0.6 before treatment which lowered down to 0.3 after treatment with S.D± 0.4850 giving a relief of 50% which is statistically non significant (P>0.05).

**DISCUSSION**

Today, the lifestyle which we lead is full of stress. The race of our world is taking us away from our natural habits and pushing us towards a life filled with disorders which is directly related to our way of living and cervical spondylosis is one of them. Traditionally, cervical spondylosis was considered a medical condition in which the degeneration of the inter-vertebral disks occurred due to oldage. However, this condition is commonly caused due to regularly ignoring the ergonomics of our bodies e.g., working for long hours with computers, wrong postures while performing day-to-day life functions, sports/repetitive injuries such as long hours of playing video games, texting etc.. In cervical spondylosis the degenerative changes in inter vertebral discs lead to secondary change in the adjacent vertebrae. These changes in the cervical spine may affect one or more nerve roots, the cervical cord at one or more levels or may cause simultaneous damage to the nerve roots and cord.

Any degenerative type of pathological conditions in the body can be considered under the broad umbrella of ‘vata vyadhi’. Sandhigata Vata is mentioned under vata vyadhi. The term gata is derived from the root “Gam” which means gone to, arrived at, situated in, directed to, so it can be revealed that the word gata is related with site (i.e. Griva asthi & sandhi) in which vitiated vata dosha get situated and develop the symptoms of asthi and sandhigata vata.

Shallaki Nirayas which is Madhura, Tikta, Katu in Rasa, Ushna and Snigdha in guna has been described as Vata shamak dravya. The experimental studies have proved that it has:

1. Anti inflammatory property[4].
2. Anti arthritic and analgesic activities[5].
3. Decreases pain, increases flexion and movements[6].
4. Property to prevent the destruction of articular cartilage[7].
5. Safe and well tolerated on oral administration[8].

**Probable Mode of Action of Shallaki Niryas (Kunduru):**

Shallaki Niryas (kunduru) possess madhura (sweet), katu (pungent) and tikta (bitter) rasa; guna of kunduru is tikshna and snigdha. Vipaka (post-digestive effect) is katu where as virya (strength or effect) is ushna. The dosha karma is vata kapha hara property.

Due to its tikta rasa, tikshna guna, katu vipaka, and ushna virya, kunduru
pacifies vitiated kapha and aama dosha. Madhura rasa and ushna virya pacifies vata dosha resulting in reduction of shotha, shula and other related symptoms. The pacified vata dosha in the sandhi helps to rearrange shleshmaka kapha and thereby relieves the symptoms of sandhivata. So, on the basis of its pharmacological properties, it can be concluded that it posses kapha vata hara action as mentioned in ayurvedic classics.

Since, sandhigata vata (vata dosha vitiation) may occur due to kshaya janya or avarana janya, the selected drug which has kapha vata hara action should be effective in the management of all form of vata vitiation i.e. sandhigata vata.

Kunduru also increases dhatvagni by its tikta rasa leading to proper nutrition of dhatus whereas improvement of the symptom of vata kshya is due to rasayan (immune modular [9]) and brimhaniya prabhava of kunduru.

The symptom of asthivaha and majja vaha srotas improved due to madhura, tikta rasa and katu vipaka, as they counteract the pathogenic process of sandhivata.

The main site of sandhivata is sandhis (joints) which is the site of shleshmaka kapha. By pacifying kapha dosha, tikta rasa leads to proper nutrition of other dhatus also.

The key constituents of kunduru are volatile oil (4-8%), acid resin (56-65%) and gum (20-36%). The triterpenoids are the active constituents and collectively called boswellic acid. The gum resin of B. serrata usually contain 43% boswellic acid which contain a combination of 6 major constituents mainly 3 acetyl, 11 keto boswellic acid which help to preserve the structural integrity of joint cartilage and maintain a healthy immune mediator cascade at cellular level, which is active against pain and inflammation by inhibiting the activity of the enzyme 5 lipoxygenase[10] through a non-redox reaction in O.A.

Shallaki Niryas possesses analgesic [11] and anti-arthritis properties, which are responsible for its analgesic and anti-inflammatory activities. It also acts as COX-2 inhibitor and reduces pain and inflammation without affecting the gastric mucosa. It soothes the joints and also help treat levels of synovial fluid, making the entire structure lubricated and easy to rotate and move.

It improves blood supply to joint and restores integrity of vessels obliterated by spasm of internal damage. [12]

In the present study improvement was seen in the chief complaints sandhishula, prasaran akunchana vedana, headache, tingling sensation and numbness in arms due to shotha hara and vedana sthapana property of shallaki.

CONCLUSION

Patients’ neck disability was improved significantly which indicates the efficacy of Shallaki over chief complaints. Remission in Shula, prasaran akunchana vedana and tingling sensation in arms was found very significant and significant result was found in headache and numbness in arms. All the patients tolerated cap. Shallaki very well and no side/toxic effects were reported in any of the patients registered for the trial. Therefore, it can be concluded that cap. Shallaki is safe and effective Ayurvedic treatment modality in the management of Grivasthi Sandhi Gata Vata (Cervical spondylosis).
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