A CLINICAL STUDY ON VYADHIHARANA RASA IN SANDHIGATA-VATA

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INTRODUCTION

Vata is the governing factor for the maintenance of equilibrium in the body, but its vitiation leads to degeneration. As age advances, the Vata gains an upper hand leading to initiation of the process of degeneration. It is more marked and evident in parts subjected to stress in the yester years of life and one of its outcome is Sandhigata Vata (Osteoarthritis), which is more common in the elderly and obese persons. Osteoarthritis is a degenerative joint disease, characterized by pain, stiffness, synovitis, effusion, disability and limitation of movements. It has been reported on the basis of radiological and autopsy surveys that there is a steady rise in degenerative changes in joints from the age of 30 years. By the age of 65 years, 80% of the people show some radiographic evidence of osteoarthritis. Vyadhiharana Rasa is a Kupipakwa Rasayana and has been found efficacious in many skin diseases, sexually transmitted diseases, Sandhigata-vata, Upadamsha, Phiranga, Dushtavrina, Nadivrina etc. Vyadhiharana Rasa is prepared out of Parada, Gandhaka, Haratala, Manashila, Somal and Rasakarpoo. Due to the augmenting effect of Parada, this preparation has got genuine Rogahara property; ingredients like Haratala, Manashila and somal are possessing Vatakaphahara, Kapha-Raktahara and Tridoshaghna properties. Clinical study of Vyadhiharana Rasa for therapeutic effect on Sandhigata-vata patients with sample size of 30 showed moderate improvement in 20% patients and mild improvement in 46.66 % patients. No as such improvement was observed in 33.33% patients. Hematologically significant decrease in raised values of ESR and WBC Count after completion of treatment was observed. Overall it can be stated that, Vyadhiharana Rasa administration brought considerable improvement in Signs and symptoms of Sandhigata Vata. No side effects or complications of the drug noticed during or after the treatment.

Key words: Vyadhiharana Rasa, Ayurveda, Sandhigata Vata, Osteoarthritis.
the elderly and obese persons. It has been reported on the basis of radiological and autopsy surveys that there is a steady rise in degenerative changes in joints from the age of 30 years. By the age of 65 years, 80% of the people show some radiographic evidence of osteoarthritis, although only 25% may have symptoms. Males and females are both affected but osteoarthritis is more generalized and more severe in older women. The medial and patello-femoral compartments are usually first involved and more advanced disease is associated with knee deformities.

Kupipakwa Rasayanas are the most popular and therapeutically highly effective mineral preparations as through this “Avyabhicharita Vyadhighatakata” can be induced in Paradeeya compounds or through this a least toxic and highly effective Paradiya compounds of high therapeutic importance could be prepared to treat the diseases and to maintain the healthy process of life.

Vyadhiharana Rasa is a Kupipakwa Rasayana and has been found efficacious in many skin diseases, sexually transmitted diseases like Sandhigata-vata, Upadamsha, Phiranga, Dushtavrina, Nadivrina etc. Vyadhiharana Rasa is prepared out of Parada, Gandhaka, Haratala, Manashila, Somal and Rasakarpoo. Due to the augmenting effect of Parada, this preparation has got genuine Rogahara property; ingredients like Haratala, Manashila and somal are poecessing Vatakaphahara, Kapha-Raktahara and Tridosaghna properties. No pharmacological agent has been shown to prevent or delay the progression off or reverse the pathologic changes of osteoarthritis. Today also, in modern science, drug therapy is palliative only. Non-steroidal anti-inflammatory drugs are popular remedies for osteoarthritis which often decrease joint pain and improve mobility but the magnitude of this improvement is modest. Hence to evaluate the effect of Vyadhiharana Rasa in Sandhiga Vata Vis-à-vis Osteo arthritis scientifically the present study was planned.

MATERIALS AND METHODS

Source of Data:
- 30 patients fulfilling the criteria were selected from BVVS Ayurved Medical College & Hospital, Bagalkot.

Objective of the Study:
- To assess changes in signs and symptoms of Sandhiga vata after treatment.

Inclusion criteria:
- The patients who attended OPD of BVVS Ayurved Medical College & Hospital, Bagalkot, Karnataka fulfilling the criteria of diagnosis of Sandhiga Vata were registered.

Exclusion criteria:
- Patients suffering from other systemic disease like DM, KOCHS, IHD, STD, AIDS etc. were excluded.

Study Design:
- Single Blind Clinical Study with Pre-Test and Post-Test Design with a sample size of 30 Patients, attending OPD of BVVS Ayurved Medical College & Hospital, Bagalkot, Karnataka fulfilling the criteria of diagnosis of Sandhiga Vata were registered, irrespective of Age, Sex, Religion etc. based on simple random sampling technique.
- Detailed history was taken and physical examinations were done on the basis of a
special proforma incorporating all signs
and symptoms of the disease.

Materials used for clinical study:
• Vyadhiharana Rasa: Vyadhiharana Rasa, Haritaki Churna and Pippali Churna.

Research Design:
• Patients were administered Vyadhiharana Rasa 62.5 mg with Haritaki, Pippali Churna 500mg twice a day along with madhu and ghrita as Anupana for 48 days.

Investigations:
1. Routine hematological, urine and stool examination was carried out in patients to exclude any other pathology as well as to assess the condition of the patients.
2. Wherever required the patients were subjected for biochemical investigations like RBS, S. Cholesterol, S. Uric acid etc.
3. The diagnosis was confirmed by X-ray examination of the involved joint, wherever possible.

Follow up study:
After completion of treatment also the patients were followed up for 3 months.

Ethical clearance:
Ethical clearance was obtained from the Ethical Committee of the Institution

Criteria for Assessment:
The effects of the treatment were assessed on the basis of changes in signs and symptoms of the disease. These parameters were graded and based on that the assessments were made.

1. Pain (Sandhishoola)
2. Prasarana Akunchanayo Vedana (pain on flexion and extension of joints).
3. Joint Stiffness (Sandhihata)
4. Shotha / Inflammation (sandhishotha)
5. Crepitus (Sandhisphutana)
6. Tenderness (Sparsha Asahyata)

7. Shrama Asahyata

Criteria for the assessment of total effect therapy: Overall improvement in signs and symptoms of the disease Sandhigata Vata was taken into consideration to assess the total effect of the therapy. Total effect of the treatment was assessed with following gradation -

1. Complete remission – 100 % relief in signs and symptoms.
2. Markedly improved – patients showing improvement more than 75% but less than 100%.
3. Moderately improved – patients showing improvement between 50-75%.
4. Improved – Patients showing improvement between 25-50%.

Statistical Analysis: To analyze the effect of the therapy statistically, mean, percentage, SD, SE, t and P values were calculated using paired 't' test.

OBSERVATIONS
Totally 31 patients (Male-14pts, Female-17pts) were registered in this clinical study, out of which 30 patients completed the study. Maximum number of patients registered were belonged to the age group of 50-59 yrs i.e. (35.48%). 25.80% patients belonged to 40-49 years age group, 16.13 % patients were from 30-39, whereas 12.90 % patients were from 60-69 years age group and only 6.45 % and 3.22% patients were of the age 20-29 and 10-19 years respectively. Among 31pts registered, maximum 45.16 % patients were House wives, 22.58
% patients were running a private business, 16.13% were farmers and 6.45% each were Retired persons and students. 3.22% patients were in Govt. service. Among 31pts registered, maximum 41.94% patients were belonged to Middle class, 61.29% patients were of mixed diet and remaining 38.71% patients were Vegetarians. Maximum patients (90.32%) were taking Vishama diet. 90.32% patients were taking Lavana Rasa diet. Maximum number (74.19%) patients were used to take Ruksha food and 67.74% were taking Laghu diet. 70.97% patients were taking Vishama diet. 90.32% patients were taking Lavana Rasa diet. Maximum number (74.19%) patients were used to take Ruksha food and 67.74% were taking Laghu diet. 70.97% patients were using Sita food stuffs. 45.16% patients were belonging to Vata-Kapha Prakruti, 29.03% patients were belonging to Vata-Pitta Prakruti and other 25.80% patients were Vata Prakruti. This study showed that maximum 41.94% patients were labours, 35.48% patients sedentary habits, 12.90% were having standing type of work, the patients having sitting type of work were 9.68%, 6.45% each were belonging to agricultural and Travelling type of work, Whereas patients having manual type of work were 3.22%. The study also revealed that 58.06% patients were having chronicity of 1 years, 32.26% patients were of 1-2 years chronicity, 6.45% each patients had chronicity of less than 2-4 year where as 3.22% patients were reported to be of chronicity more than 6 years. Among 31pts registered, all the patients (100.00%) were affected by knee joint involvement, ankle and wrist joints were involved in 19.35% patients each. 12.90% patients were reported to be of involvement of each of shoulder and elbow joint, hip joints were afflicted in 6.45% patients whereas carpel & metacarpal and tarsal & meta tarsal joints were involved in 3.22% patients each.

RESULTS

Effect of Vyadhiharana Rasa on various clinical Signs and Symptoms of Sandhigata Vata.

On administration of Vyadhiharana Rasa over 48 days in patients of Sandhigata Vata, brought considerably reduction in Sandhishoola, Sandhigraha, pain on standing, Prasarana Akunchanayo Sandhi Vedana, joint swelling, the joint tenderness, Sandhisphutana (Crepitations in joints) and decrease in Shrama Asahyata.

Table depicting effect of Vyadhiharana Rasa on Sandhi Shoola.

<table>
<thead>
<tr>
<th>S. N</th>
<th>Parameters</th>
<th>n</th>
<th>Mean</th>
<th>% of change</th>
<th>S.D (±)</th>
<th>S.E.M (±)</th>
<th>t</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Sandhi Shoola</td>
<td>30</td>
<td>2.63</td>
<td>1.57</td>
<td>40.51</td>
<td>0.25</td>
<td>0.05</td>
<td>23.03</td>
</tr>
<tr>
<td>2</td>
<td>Sandhigraha</td>
<td>30</td>
<td>1.70</td>
<td>1.13</td>
<td>33.33</td>
<td>0.50</td>
<td>0.09</td>
<td>6.16</td>
</tr>
<tr>
<td>3</td>
<td>Joint Pain on Standing</td>
<td>30</td>
<td>1.87</td>
<td>1.20</td>
<td>35.71</td>
<td>0.48</td>
<td>0.09</td>
<td>7.62</td>
</tr>
<tr>
<td>4</td>
<td>P A Vedana</td>
<td>30</td>
<td>1.33</td>
<td>0.80</td>
<td>40.00</td>
<td>0.51</td>
<td>0.09</td>
<td>5.76</td>
</tr>
<tr>
<td>5</td>
<td>Joint Swelling</td>
<td>30</td>
<td>1.17</td>
<td>0.70</td>
<td>40.00</td>
<td>0.51</td>
<td>0.09</td>
<td>5.04</td>
</tr>
<tr>
<td>6</td>
<td>Tenderness</td>
<td>30</td>
<td>1.30</td>
<td>0.70</td>
<td>46.15</td>
<td>0.50</td>
<td>0.09</td>
<td>6.60</td>
</tr>
<tr>
<td>7</td>
<td>Crepitations</td>
<td>30</td>
<td>1.13</td>
<td>0.43</td>
<td>61.76</td>
<td>0.47</td>
<td>0.09</td>
<td>8.23</td>
</tr>
<tr>
<td>8</td>
<td>Shrama Asahyata</td>
<td>30</td>
<td>1.27</td>
<td>0.80</td>
<td>36.84</td>
<td>0.51</td>
<td>0.09</td>
<td>5.04</td>
</tr>
</tbody>
</table>
Vyadhiharana Rasa on administration brought improvement in Hb% levels by 4.02%, elevated ESR levels were reduced by 43.18%, varied levels of Neutrophils, lymphocytes, Basophils, Eosinophils and Monocytes were normalized.

Table depicting effect of Vyadhiharana Rasa on various Laboratory Parameters:

<table>
<thead>
<tr>
<th>S.N</th>
<th>Parameters</th>
<th>n</th>
<th>Mean</th>
<th>% of change</th>
<th>S.D (±)</th>
<th>S.E.M (±)</th>
<th>t</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>BT</td>
<td>AT</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Hemoglobin</td>
<td>30</td>
<td>11.87</td>
<td>12.35</td>
<td>4.02</td>
<td>0.69</td>
<td>0.13</td>
<td>3.76</td>
</tr>
<tr>
<td>2</td>
<td>ESR</td>
<td>30</td>
<td>22.23</td>
<td>12.63</td>
<td>43.18</td>
<td>11.62</td>
<td>2.12</td>
<td>4.53</td>
</tr>
<tr>
<td>3</td>
<td>WBC Count</td>
<td>30</td>
<td>10458.33</td>
<td>10670.00</td>
<td>2.02</td>
<td>517.77</td>
<td>94.53</td>
<td>2.24</td>
</tr>
<tr>
<td>4</td>
<td>Neutrophils</td>
<td>30</td>
<td>62.88</td>
<td>67.87</td>
<td>7.93</td>
<td>7.05</td>
<td>1.29</td>
<td>3.88</td>
</tr>
<tr>
<td>5</td>
<td>Lymphocyte</td>
<td>30</td>
<td>30.06</td>
<td>26.60</td>
<td>11.56</td>
<td>7.17</td>
<td>1.31</td>
<td>2.66</td>
</tr>
<tr>
<td>6</td>
<td>Basophil</td>
<td>30</td>
<td>0.15</td>
<td>0.00</td>
<td>100</td>
<td>0.55</td>
<td>0.10</td>
<td>1.46</td>
</tr>
<tr>
<td>7</td>
<td>Eosinophil</td>
<td>30</td>
<td>3.11</td>
<td>1.30</td>
<td>58.20</td>
<td>1.68</td>
<td>0.31</td>
<td>5.89</td>
</tr>
<tr>
<td>8</td>
<td>Monocyte</td>
<td>30</td>
<td>3.13</td>
<td>4.39</td>
<td>40.30</td>
<td>2.42</td>
<td>0.44</td>
<td>2.85</td>
</tr>
</tbody>
</table>

Overall effect of treatment

None of the patients have shown complete remission and markedly improvement from the disease. But moderately improvement was observed in 20% patients and mild improvement in 46.66% patients. No as such improvements were observed in 33.33% of patients.

<table>
<thead>
<tr>
<th>S.N</th>
<th>Effect of treatment</th>
<th>Total no. of pts.</th>
<th>No. of pts.</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Complete remission</td>
<td>30</td>
<td>00</td>
<td>00 %</td>
</tr>
<tr>
<td>2</td>
<td>Markedly improved</td>
<td>30</td>
<td>00</td>
<td>00 %</td>
</tr>
<tr>
<td>3</td>
<td>Moderately improved</td>
<td>30</td>
<td>06</td>
<td>20 %</td>
</tr>
<tr>
<td>4</td>
<td>Mild Improved</td>
<td>30</td>
<td>14</td>
<td>46.66 %</td>
</tr>
<tr>
<td>5</td>
<td>Unchanged</td>
<td>30</td>
<td>10</td>
<td>33.33 %</td>
</tr>
</tbody>
</table>

DISCUSSION

All the patients i.e. 100% gave the history of pain while 80% of the patients gave the history of Morning Stiffness and Tenderness. Pain is characteristic feature of Vata as this disease is dominated by Vata dosha. Hence pain was seen as one of the cardinal feature of this entity. Pain usually increases by movements, because of Vata Prakopa as the patients tries to do some work involving joints. Then due to movements pain occurs. Stiffness (Sthambha/Graha) is a symptom of aggravated or vitiated Vata. As a natural course vata aggravates at last portions of night and the Sthambha occurs thereafter, when the patient wakes up in morning and tries to walk, he feels stiffness which lasts for 10-30 minutes.

On administration of Vyadhiharana Rasa over 48 days in patients of Sandhigata Vata, Sandhi Shoola was reduced by 40.51%. Sandhigraha was reduced by 33.33%, reduction in joint pain on standing with 35.71%, 40% of reduction of Prasarana Akunchanayo Sandhi Vedana, 40% of reduction in joint swelling, the joint tenderness was reduced by 46.15%, 61.76%
of relief from Sandhisphutana (Crepitations in joints) and decrease in Shrama Asahyata with a 36.84 % of relief. Vyadhiharana Rasa on administration brought improvement in Hb% levels by 4.02 %, elevated ESR levels were reduced by 43.18%, varied levels of Neutrophils, lymphocytes, Basophils, Eosinophils and Monocytes were normalized.

None of the patients have shown complete remission and markedly improvement from the disease. However, moderately improvement was observed in 20% patients and mild improvement in 46.66 % patients. No as such changes in signs and symptoms were observed in 33.33% of patients. Thus from this study it can be stated that, all above results show Mild to Moderate improvement in Signs and symptoms of Sandhigata Vata. No side effects or complications of the drug have been observed during or after the treatment.

**CONCLUSION**

Clinical study of Vyadhiharana Rasa in Sandhigata Vata with sample size of 30 revealed, Mild to Moderate improvement in Signs and symptoms of Sandhigata Vata. No side effects or complications of the drug have been observed during and after the treatment. Vyadhiharana Rasa has been extensively used for curing various ailments in states like Rajasthan, Maharashtra, Andrapradesh and some parts of Karnataka. This Vyadhiharana Rasa if administered by compounding with suitable Bhaishajya dravyas, definitely considerable improvement can be obtained.

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Source of support: Nil,
Conflict of interest: None Declared

**Cite this article as**

Prakash R Deshpande: A Clinical Study on Vyadhiharana Rasain Sandhigata-Vata.
ayurpub 2016;1 (3) 108-113