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A randomized controlled clinical study to evaluate the efficacy of Shatavari Guggulu in Janusandhigata Vata

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ABSTRACT

Background: Sandhigata Vata is one of the Vatavyadhis named based on the Sthaanaavasishhtyatha of vitiated Vata. It mainly presents with Sandhishoola and Shopha further leading to difficulty in movements. Knee Osteoarthritis is the most common type of arthritis, which is a major cause of disability which reduces the quality of life.

Methodology: 60 patients fulfilling the diagnostic and inclusion criteria were selected for a single blind randomized controlled clinical study. They were randomly allocated into 2 equal groups Group A and Group B. Subjects of Group A received Shatavari Guggulu in a dosage of two tablets three times a day after food with Sukoshna Jala for 30 days and Group B subjects received Trayodashanga Guggulu with same dose and duration. Assessment was done before treatment, 16th day, 31st day (After treatment) and follow up on 46th day.

Result: When both groups were compared clinically, both showed effective changes in most of the parameters. The statistical analysis of within the group comparison showed statistically significant results in both groups for all parameters except in Atopa. When statistical comparison was done between the two groups, no significant difference was found.

Conclusion: Both Shatavari Guggulu and Trayodashanga Guggulu showed statistical significant effect in all parameters except in Atopa. On statistical comparison between the two groups there is no significant difference in the effect of both Shatavari Guggulu and Trayodashanga Guggulu.

Key words: Janusandhigata Vata, OA Knee, Shatavari Guggulu, Trayodashanga Guggulu, Vatavyadhi.

INTRODUCTION

Sandhigata Vata (Osteoarthritis) is a clinical condition that comes under the heading of Vatavyadhi. In normalcy Vata Dosha governs the remaining Doshas and the whole body, but in morbid state it can produce pathological conditions like Vatavyadhi. The presentation of Vatavyadhi varies depending upon factors like Sthana (Site) or structures involved.

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Sandhigata Vata is one of the Vatavyadhi named based on the Sthaanaavasishhtyatha of vitiated Vata. It mainly presents with Sandhi Shoola (Joint Pain) and Shopha (Swelling) further leading to difficulty in movements.

The signs and symptoms of osteoarthritis of knee joint resembles Lakshana of Janusandhigata Vata. Osteoarthritis is by far the most common form of arthritis. It shows a strong association with ageing and is a major cause of pain and disability in elderly.

Osteoarthritis principally targets the knee joint, hip joint and certain small joints. There is a steady rise in prevalence from age 30 such that by 65, 80% of people have radiographic evidence of OA, though only 25-30% are symptomatic. Due to the increased prevalence of this disorder and the disabilities produced, it has become a major problem and burden over the society, indirectly reducing the working potential which results into dependency.
Management of Sandhigata Vata includes a judicious combination of Bahya Chikitsa (External Medication) and Abhyantara Chikitsa (Internal Medication). Abhyanga (Massage), Upanaha (Type of fomentation), Agnikarma (Therapeutic heat burn), Bandhana (Bandage) etc. are the Bahya Chikitsa and Gokshuradi Guggulu, Yogaraja Guggulu, Maharasnadi Kwatha are some of the Abhyantara Chikitsa. In Sandhigata Vata, along with morbid Vata Dosha, there can be morbid Kapha Dosha association also, which can be inferred from Sandhi Stabdhata. So morbid Kapha also to be tackled during the course of treatment if there is morbidity of Kapha Dosh. In Modern science, weight loss, exercise and analgesic treatment has been advised for OA knee.

Shatavari Guggulu[11] mentioned in Rasaratna Samucchaya was taken as trial drug for proving its efficacy in the management of Janusandhigata Vata. It mainly contains drugs having Vatahara, Shoolahara, Agni Deepana properties. Trayodashanga Guggulu[12] was taken as standard drug.

Hence with the present clinical study Shatavari Guggulu and Trayodashanga Guggulu were taken, and results were compared for checking the better efficacy in Janusandhigata Vata.

**AIMS AND OBJECTIVES**

1. To evaluate the therapeutic effect of Shatavari Guggulu in the management of Janusandhigata Vata.

2. To compare the therapeutic effect of Shatavari Guggulu and Trayodashanga Guggulu in the management of Janusandhigata Vata.

**MATERIALS AND METHODS**

**Source of sample**

Patients of either sex attending OPD of Alva’s Ayurveda Medical College & Hospital, Moodubidire and from other available sources who were diagnosed with Janusandhigata Vata were selected for study. Details of the patients were documented in a case proforma.

**Study design**

Randomised controlled clinical study with single blinding.

**Methods of collection of data**

**Selection:** Incidental selection was done irrespective of gender, religion, occupation, marital status, educational status, socio-economic status, those fulfilling the diagnostic criteria and inclusion criteria were selected.

**Allocation:** Random allocation

**Method of sampling:** Lottery method

**Groups:** 2 groups

- **Group A - Shatavari Guggulu**
- **Group B - Trayodashanga Guggulu**

**Sample size:** 30 patients in each group

**Total sample size:** 60 patients minimum

**Diagnostic criteria**

Patients were diagnosed based on Lakshanas of Janusandhigatha Vata such as:

- **Shotha** - Oedema of the joints.
- **Shoola** - Pain in the joints.
- **Prasarana Aakunchana Vedana** - Presence of pain during flexion and extension of joint.

**Inclusion criteria**

1. Patients showing the classical Lakshana of Janusandhigata Vata like Sandhi Shotha, Sandhi Shoola and Prasarana Akunchana Vedana; with or without Atopa (Creptitus), Stambha (Stiffness).

2. Patients diagnosed with Janusandhigata Vata.

3. Patients of either sex between 30 to 70 years of age.

4. Subjects who are willing to participate and sign in the informed consent form.

**Exclusion criteria**

1. Subjects suffering from diseases like Amavata (Rheumatoid arthritis), Vatarakta (Gouty arthritis) or any other systemic disorders.
2. Secondary Osteoarthritis of Knee.
3. Subjects with deformities like Genu varum and Genu valgum.
5. Subjects who are under Intra-Articular injection of Corticosteroid 3 months preceding enrolment.
6. Pregnant women and Lactating mother.

**Subjective parameters**
- Janu Sandhi Shoola
- Janu Sandhi Stambha

**Objective parameters**
- Janu Sandhi Shotha
- Janu Sandhi Atopa
- Janu Sandhi Prasarana and Akunchana Vedana - measured using Goniometer and expressed in degrees.
  - Tenderness
  - Visual Analogue Scale (VAS)
  - WOMAC OA Index

**Observation period**
Patients were assessed clinically on day 0, on 16th day and on 31st day of clinical study.
Follow up was done after 15 days of the treatment i.e., on 46th day.

**Intervention**

**Table 1: Intervention given for both the groups**

<table>
<thead>
<tr>
<th>Group</th>
<th>Dose</th>
<th>Time of administration</th>
<th>Duration</th>
<th>Anupana</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group A - Shatavari Guggulu</strong></td>
<td>500 mg, 2 Tablets</td>
<td>Thrice daily, After food</td>
<td>30 days</td>
<td>Ushnodaka (Warm water)</td>
</tr>
<tr>
<td><strong>Group B - Trayodashanga Guggulu</strong></td>
<td>500 mg, 2 Tablets</td>
<td>Thrice daily, After food</td>
<td>30 days</td>
<td>Ushnodaka</td>
</tr>
</tbody>
</table>

**Ingredients of Shatavari Guggulu:** Shatavari, Guduchi, Gandhaprasarani, Gokshura, Pippali, Shatahva, Deepyaka, Rasna, Ashwagandha, Padmaka, Kachura, Nagara, Guggulu and Ghrita.

**Ingredients of Trayodashanga Guggulu:** Abha, Ashwagandha, Hapusha, Guduchi, Gokshura, Vridhdaradu, Shatavari, Shati, Rasna, Shatatpushpa, Yavani, Nagara, Guggulu and Ghrita.

**Observations and Results**

**Table 2: Observation of 60 patients**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Predominance</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>50-59 years</td>
<td>36.6%</td>
</tr>
<tr>
<td>Gender</td>
<td>Female</td>
<td>53.33%</td>
</tr>
<tr>
<td>Occupation</td>
<td>Housewives</td>
<td>35%</td>
</tr>
<tr>
<td>Family History</td>
<td>Negative</td>
<td>83.33%</td>
</tr>
<tr>
<td>Diet</td>
<td>Vegetarians</td>
<td>51.66%</td>
</tr>
<tr>
<td>Prakriti</td>
<td>Vata Kapha</td>
<td>48.33%</td>
</tr>
<tr>
<td>Satwa</td>
<td>Pravara</td>
<td>51.66%</td>
</tr>
<tr>
<td>Jarana Shakti</td>
<td>Pravara</td>
<td>68.33%</td>
</tr>
<tr>
<td>Vyayama Shakti</td>
<td>Madhyama</td>
<td>63.33%</td>
</tr>
<tr>
<td>BMI</td>
<td>Normal</td>
<td>61.66%</td>
</tr>
<tr>
<td>Onset of Pain</td>
<td>Gradual</td>
<td>100%</td>
</tr>
<tr>
<td>Character of Pain</td>
<td>Dull Aching</td>
<td>68.33%</td>
</tr>
<tr>
<td>Course of Pain</td>
<td>Intermittent</td>
<td>75%</td>
</tr>
</tbody>
</table>

**Statistical Analysis**

Statistical software used in the study was Sigma Stat version 3.1. RM Anova on Ranks and One way RM Anova was performed to prove the effectiveness of the medicine before and after trial. Mann-Whitney Rank Sum Test and Unpaired t-Test was performed for comparative analysis of the overall effect of the treatments in both the groups.
After the observations when results were statically analyzed by RM Anova on Ranks, in Group-A there was significant effect in all parameters except Stambha, Atopa and Tenderness. In terms of percentage relief, there was 55.21% relief in Janusandhi Shoola, 50% relief in Janusandhi Stambha, 6.7% relief in Shotha, 6% improvement in range of motion, no relief in Atopa, 54.04% reduction in VAS and 29.3% improvement in WOMAC OA index.

In Group B also there was significant effect in all parameters except Stambha, Atopa and Tenderness. In terms of percentage relief, there was 54.7% relief in Janusandhi Shoola, 85% relief in Janusandhi Stambha, 66.7% relief in Shotha, 4% improvement in range of motion, no relief in Atopa, 56% reduction in VAS and 29.7% improvement in WOMAC OA index.

Table 4: Comparative analysis of overall effect of the treatments in both the groups

<table>
<thead>
<tr>
<th>Assessment criteria</th>
<th>Median Value (BT-AT)</th>
<th>Mann Whitney Test</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group A</td>
<td>Group B</td>
<td>T Value</td>
</tr>
<tr>
<td>Janusandhi Shoola</td>
<td></td>
<td></td>
<td>962</td>
</tr>
<tr>
<td>Janusandhi Stambha</td>
<td></td>
<td></td>
<td>840</td>
</tr>
<tr>
<td>Janusandhi Shotha</td>
<td></td>
<td></td>
<td>1005</td>
</tr>
<tr>
<td>Prasarana Akunchana Vedana</td>
<td>5</td>
<td>5</td>
<td>852</td>
</tr>
<tr>
<td>Atopa</td>
<td></td>
<td></td>
<td>915</td>
</tr>
<tr>
<td>Tenderness</td>
<td></td>
<td></td>
<td>885</td>
</tr>
<tr>
<td>VAS</td>
<td></td>
<td></td>
<td>862</td>
</tr>
<tr>
<td>WOMAC</td>
<td></td>
<td></td>
<td>930.5</td>
</tr>
</tbody>
</table>
On comparing the effect of Shatavari Guggulu and Trayodashanga Guggulu in all the parameters suggest that there is no significant difference between both the groups on comparing the difference of treatment of all observation time points with reference to BT, D16 and AT which suggests that both the drugs are having equal effect in the management of Janusandhigata Vata.

DISCUSSION

As Janusandhigata Vata is a Vatavyadhi which usually occurs in Vriddhavastha we need a formulation which should contain Vatahara, Balya and Rasayana Guna.

Probable mode of action of Shatavari Guggulu

Shatavari and Gokshura are having Madhura Rasa, Guduchi, Gandhaprasarani, Padmaka, Rasna are having Tikta Kashaya Rasa, Guggulu, Ashwagandha, Deepyaka, Shatahva are having Katu Tikta Rasa and Naagara, Pippali has Katu Rasa. Most of the drugs are having Katu Tikta Kashaya Rasa which help to remove the Kapha which does the Avarana of Vata leading to Vataprakopa and Stambha in the Sandhi Pradesha. When the Avarana gets cleared, automatically Vata will come into normalcy thereby reducing the symptoms.

Prakupita Vata is the main culprit in Sandhigata Vata. As most of the drugs are having Vatahara effect it will help for the reduction of symptoms.

Majority of the drugs are having Ushnaveerya which helps to pacify the Vata dosha and to remove the Srotavarodha.

Shatavari, Guduchi, Gokshura, Pippali, Naagara are having Madhura Vipaka. Madhura Vipaka Dravyas will pacify the Prakupita Vata.

Due to Vataprakopa there will be Agnivaishamyata which leads to improper formation of Annarasa thereby forming Uttarottara Dhatukshaya. Deepaneeya Dravyas present in this formulation like Guduchi, Gokshura, Pippali, Shatahva, deepyaka, Shunti will correct the Agni in turn leading to the proper formation of Dhatu.[13]

Probable mode of action of Trayodashanga Guggulu

Vata and Kapha are the main culprit in Sandhigata Vata. Most of the drugs in the formulation are having Vata Kaphahara, Ushna Veerya, Madhura Vipaka, Deepana and Rasayana property which helps to the Samprapti Vighatana of the disease.

Guggulu Kalpana is a very important formulation where the drug augments the formulations with the other drugs in it without losing its potency and it acts effectively in treating the disease.

The Aushadha Sevana Kala (Time of administration of medicine) is Adhobhakta i.e., Bheshaja (Medicine) is administered after meals. As per the classics Adhobhakta Aushada Kala is indicated in Vyanavayu Vikriti and Udanavayu Vikriti. As in Janusandhigata Vata both the Shleshaka Kapha and Vyana Vayu are affected, this Aushadha Kala is opted.

CONCLUSION

When comparing both the drugs clinically, both the drugs showed effective changes. On statistical comparison within the groups, both the groups showed significant effect (P<0.05) Significant action of the drugs was not shown during the initial 15 days of treatment in all the parameters except VAS and WOMAC. After treatment there was significant effect on all the parameters except Atopa, where statistically insignificant effect was seen. The effect of the drugs was maintained even after the treatment till the period of follow up. On comparing between two groups, there was no statistically significant difference in the effect of treatment with P >0.05. Hence null hypothesis(H0) is accepted.

H0 - There is no statistically significant difference in the effect of Shatavari Guggulu and Trayodashanga Guggulu in Janusandhigata Vata.

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