



ISSN 2456-3110

Vol 8 · Issue 9

September 2023

Journal of  
**Ayurveda and Integrated  
Medical Sciences**

*www.jaims.in*

**JAIMS**

An International Journal for Researches in Ayurveda and Allied Sciences



**Maharshi Charaka**  
Ayurveda

**Indexed**

# 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 *Sthaanavaishishtyatha* 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. Osteoarthritis principally targets the knee joint, hip joint and certain small joints. **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*. Thus,  $H_1$  is rejected and  $H_0$  is accepted.

**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,<sup>[1]</sup> 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.<sup>[2]</sup>

*Sandhigata Vata* is one of the *Vatavyadhi* named based on the *Sthaanavaishishtyatha* of vitiated *Vata*.<sup>[3]</sup> It mainly presents with *Sandhi Shoola* (Joint Pain) and *Shopha* (Swelling) further leading to difficulty in movements.<sup>[4]</sup>

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.<sup>[5]</sup> 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.

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Submission Date: 28/08/2023 Accepted Date: 21/09/2023

Access this article online

Quick Response Code



Website: [www.jaims.in](http://www.jaims.in)

DOI: 10.21760/jaims.8.9.4

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)<sup>[6]</sup> etc. are the *Bahya Chikitsa* and *Gokshuradi Guggulu*,<sup>[7]</sup> *Yogaraja Guggulu*,<sup>[8]</sup> *Maharasnadi Kwatha*<sup>[9]</sup> are some of the *Abhyanthara Chikitsa*. In *Sandhigata Vata*, along with morbid *Vata Dosha*, there can be morbid *Kapha Dosha* association also, which can be inferred from *Sandhi Stabdhatata*. So morbid *Kapha* also to be tackled during the course of treatment if there is morbidity of *Kapha Dosha*. In Modern science, weight loss, exercise and analgesic treatment has been advised for OA knee.<sup>[10]</sup>

*Shatavari Guggul*<sup>[11]</sup> 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*<sup>[12]</sup> 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 *Janusandhigata Vata* such as:

- *Shotha* - Oedema of the joints.
- *Shoola* - Pain in the joints.
- *Prasarana Akunchana 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* (Crepitus), *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.
4. Subjects who require surgical interventions.
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 16<sup>th</sup> day and on 31<sup>st</sup> day of clinical study.

Follow up was done after 15 days of the treatment i.e., on 46<sup>th</sup> day.

### Intervention

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

Group	Dose	Time of administration	Duration	Anupana
Group A - Shatavari Guggulu	500 mg, 2 Tablets	Thrice daily, After food	30 days	Ushnodaka (Warm water)
Group B - Trayodashanga Guggulu	500 mg, 2 Tablets	Thrice daily, After food	30 days	Ushnodaka

**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, Vriddhadaru, Shatavari, Shati, Rasna, Shatapushpa, Yavani, Nagara, Guggulu and Ghrita.

### OBSERVATIONS AND RESULTS

**Table 2: Observation of 60 patients**

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

### 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.

**Table 3: Effectiveness of the medicine before and after trial**

Assessment Criteria	Group	Mean Value		RM Anova On Ranks	
		BT	AT	Q Value	P<0.05
Janusandhi Shoola	Group A	2.233	1	8.839	Yes
	Group B	2.067	0.933	8.768	Yes
Janusandhi Stambha	Group A	0.0667	0.0333	0.283	No
	Group B	0.233	0.0333	1.697	No
Janusandhi Shotha	Group A	1	0.133	7.354	Yes
	Group B	1	0.333	5.657	Yes
Prasarana Akunchana Vedana	Group A	125	132.5	8.556	Yes
	Group B	125.833	131.833	8.273	Yes
Atopa	Group A	0.867	0.867	0	No
	Group B	0.933	0.933	0	No
Tenderness	Group A	0.1	0	0.849	No
	Group B	0.2	0.0333	1.414	No
VAS	Group A	4.933	2.267	10.253	Yes
	Group B	5	2.2	10.536	Yes
WOMAC	Group A	38.1	26.933	9.263	Yes
	Group B	37.267	26.167	9.758	Yes

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*, 86.7% 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**

Assessment criteria	Median Value (BT-AT)		Mann Whitney Test		Remark
	Group A	Group B	T Value	P Value	
Janusandhi Shoola	1	1	962	0.490	Non-Significant
Janusandhi Stambha	0	0	840	0.268	Non-Significant
Janusandhi Shotha	1	1	1005	0.184	Non-Significant
Prasarana Akunchana Vedana	5	5	852	0.355	Non-Significant
Atopa	0	0	915	0.994	Non-Significant
Tenderness	0	0	885	0.661	Non-Significant
VAS	3	3	862	0.437	Non-Significant
WOMAC	12	10	930.5	0.824	Non-Significant

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 *Vridhastha* 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 *Srotoavarodha*.

*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*.<sup>[13]</sup>

### 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 ( $H_0$ ) is accepted.

$H_0$  - There is no statistically significant difference in the effect of *Shatavari Guggulu* and *Trayodashanga Guggulu* in *Janusandhigata Vata*.

## ACKNOWLEDGEMENT

I would like to express my gratitude to my institution and hospital who gave me the possibility to complete this project. Also, I take this opportunity to express my gratitude to my Guide and Co-guide for their valuable guidance.

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**How to cite this article:** Swathilakshmi PS, Susheel Shetty, Babu Paul K. A randomized controlled clinical study to evaluate the efficacy of Shatavari Guggulu in Janusandhigata Vata. J Ayurveda Integr Med Sci 2023;09:22-27.

<http://dx.doi.org/10.21760/jaims.8.9.4>

**Source of Support:** Nil, **Conflict of Interest:** None declared.

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