

A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF ABHA GUGGULU AND YOGARAJA GUGGULU IN JANU SANDHIGATA VATA

[Archana B.H. Jadav](#)¹, [Susheel Shetty](#)²

¹Final Year PG Scholar, ²Professor, Guide and HOD;
Dept of Kayachikitsa, Alva's Ayurveda Medical College, Moodbidri, Karnataka, India

Corresponding Author: archanajadav18@gmail.com

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ABSTRACT

Mobility is the basic character of life that depends on the structural as well as the functional character of the body. As age advances, while proper nutrition is not available, the body loses its qualitative capacity for structure and function. *Janu Sandhigata Vata* has been explained classically by *Acharyas* and its *lakshanas* are *Vata Poorna-dhrithi Sparsha*, *Sandhi Shotha*, *Sandhi Shoola* and the presence of *Vedana* during *Prasarana* and *Aakunchana*. The *lakshanas* of *Janu Sandhigata Vata* is found to be congruent with Osteoarthritis of the Knee. Research statistics have shown that in India, 22% of the population shows Osteoarthritis and females slightly dominate in the incidence. *Abha Guggulu* and *Yogaraja Guggulu* are two formulations that contain the drugs of *Vatahara*, *Shothahara*, *Vedanasthapaka* property which will help in the management of *Janu Sandhigata Vata*. **Methods:** It was a single-blind randomized comparative clinical trial. The study was conducted on 40 subjects for 30 days. Observations were analyzed and findings were evaluated by using statistical methods. **Results:** The severity of symptoms markedly reduced in both the groups which is statistically significant and on comparing the effect between *Abha Guggulu* and *Yogaraja Guggulu*, there was no statistical difference obtained. **Conclusion:** The result suggests that both *Abha Guggulu* and *Yogaraja Guggulu* had a significant effect on *Janu Sandhigata Vata* There was no significant difference in the effect of *Abha Guggulu* and *Yogaraja Guggulu*.

Keywords: *Janu Sandhigata Vata*, *Abha Guggulu*, *Yogaraja Guggulu*

INTRODUCTION

Ayurveda is a holistic medicine that serves humans. Signs of well-being or independence are well represented in this ancient treatise in this fast-developing technological era, while people are motivated by new advanced medical science and technology, the oldest Ayurvedic science has retained its position in the science of life, which retains its principles of health. Mobility is the basic character of life that depends on the structural as well as the functional character of the body. As age advances, while proper nutrition is not available, the body loses its qualitative capacity for structure and function. *Janu Sandhigata Vata* has been explained classically by *Acharyas* and its *lakshanas* are *Vata Poornadhrithi Sparsha*, *Sandhi Shotha*, *Sandhi Shoola* and the presence of *Vedana* during *Prasarana* and *Aakunchana*¹.n According to *Ayurveda*, all the *dhatu*s are undergoing *Kshaya* in the 4th decade of life. This leads to *vata prakopaka* and the individual is susceptible to many illnesses. *Janu Sandhigata Vata* is having a higher incidence among them. It cripples the individual progressively without killing. *Janu Sandhigata Vata* is a *shoola* and *Shotha Pradhan Vataja Nanatmaja Vyadhi*; affecting the locomotor system; leaving the person disabled and making him unable to perform his daily routine activities. Being afflicted with *Pakalitha vata*; *sandhi's* are one of the forms of *marma* and forms a part of *Madhyama Roga Marga*. Thus, the presence of *Madyama Roga Marga*; *vata dosha* and *Dhatuksaya* causes the disease to be *Kastasadya* or *Krucchrasadya*. The *lakshanas* of *Janu Sandhigata Vata* is found to be congruent with Osteoarthritis of the Knee. Osteoarthritis is a degenerative disorder in which there is a biochemical breakdown in synovial joints, characterized by primary degenerative changes in the articular cartilage, further leading to joint stiffness, pain, and loss of mobility². Research statistics have shown that in India, 22% of the population shows Osteoarthritis and females slightly dominate in the incidence³. In Ayurveda classics, there is proven effects of *Shamanoushadi* for *Janu Sandhigata Vata* like *Kaishor Guggulu*⁴, *Gokshuradi Guggulu*⁵, *Shahada Guggulu*⁶ etc. *Guggulu* is said to be sroto Sho-

dhaka and has been shown to have anti-inflammatory and anti-arthritis properties by various research workers⁷. Various treatment modalities are present in modern science like usage of analgesics, corticosteroids, NSAID's etc. However, these medications are not as effective as they cause gastric degradation, hepatic and neurotoxicity with adverse effects⁸.

*Abha Guggulu*⁹ explained in *Cakradatta* was taken as the trial drug, for proving its efficacy in the management of *Janu Sandhigata Vata*. *Yogaraja Guggulu*¹⁰ explained in *Bhaishajya Ratnavali* has constituents like *Chitraka*, *pippalimula*, *Gokshura*, *Ajamoda* which are *shoolahar* and *Shothahara* and it was taken as a standard drug. This formulation works as *Vyadhi pratyaneeka chikitsa*; which is safe, economical, easily available and serves as fast-acting treatment in *Janu Sandhigata Vata* and meets the needs of today. Hence with the present clinical study, *Abha Guggulu* and *Yogaraja Guggulu* was taken, and results were compared for better efficacy in *Janu Sandhigata vata*.

AIM AND OBJECTIVES:-

1. To evaluate and ascertain the individual effect of *Abha Guggulu* and *Yogaraja Guggulu* in *Janu Sandhigata Vata*.
2. To compare the effect of *Abha Guggulu* and *Yogaraja Guggulu* in *Janu Sandhigata Vata*.

MATERIALS AND METHODS:-

SOURCE OF DATA:-

LITERARY SOURCE:-All the classical books like *Brihatrayees* and *Laghutrayis* and modern literature and contemporary text including the website about the disease, drug and procedure was reviewed and documented for the intended study.

DRUG SOURCE:-The raw drugs required were identified and collected from the source of availability and the medicines prepared according to the classical references at Alva's Pharmacy, Mijar.

SOURCE OF SAMPLE:- Patients of either sex attending OPD of Alva's Ayurveda Medical College & Hospital, Moodbidri and from other available sources who were diagnosed as *Janu Sandhigata Vata* was selected for the study.

ETHICAL CLEARANCE:- ICEC/KC/01

pling Method.

METHOD OF SAMPLING:- Simple Random Sam-

Table 1: INTERVENTION: -

GROUPS	DOSAGE	TIME OF ADMINISTRATION	DURATION OF TREATMENT	ANUPANA
GROUP A <i>Abha Guggulu</i>	500mg	Thrice daily after Food	30 days	<i>Ushnodaka</i>
GROUP B <i>Yogaraja Guggulu</i>	500mg	Thrice daily after Food	30 days	<i>Ushnodaka</i>

CRITERIA FOR SELECTION OF PATIENTS: -

DIAGNOSTIC CRITERIA:-

The diagnosis is mainly based upon the *lakshanas* of *Janu Sandhigata Vata* mentioned in Ayurvedic texts which will be correlated clinically.

Radiographs will be taken to confirm clinical findings.

INCLUSION CRITERIA

- ❖ Patients showing the classical *Lakshanas* of *Janu Sandhigata Vata* like *Sandhi Shotha*, *Sandhi Shoola* and *Prasarana Akunchana Vedana*; with or without *Atopa*, *Janu Sandhi Sparsha Akshamatva* and *Vata Poorna Dhrithisparsha*.
- ❖ Patients diagnosed with *Janu Sandhigata Vata*.
- ❖ Previously treated and untreated patients.

EXCLUSION CRITERIA: -

- ❖ Patients suffering from diseases like *Amavata* and other systemic disorders
- ❖ Secondary osteoarthritis.

INGREDIENTS OF FORMULATIONS: -

ABHA GUGGULU:- *Babbula*, *Triphala*, *Trikatu*, *Guggulu*

YOGARAJA GUGGULU: - *Chitraka*, *Yavani*, *Krishna Jeeraka*, *Vidanga*, *Ajamoda*, *Jeeraka*, *Pippali Moola*, *Devadaru*, *Chavya*, *Rasna*, *Gokshura*, *Dhanyaka*, *Triphala*, *Trikatu*, *Twak*, *Ushira*, *Yavakshara*, *Taleesapatra*, *Shuddha Guggulu*

Method Of Medicine Preparation:-

ABHA GUGGULU :-

Firstly 2 parts of *Shudda Guggulu* was taken in a vessel by adding enough water. Then the heating was continued until *Guggulu* got completely melted. Then 1 part of fine powders of *Babbula*, *Triphala* and *trikatu* was added and mixed well. Then the mixture

was allowed to cool down and *vatis* were prepared which were 500mg by weight. Finally, it was allowed to dry and was stored in a container.

YOGARAJA GUGGULU:-

Firstly 2 parts of *Shuddha Guggulu* was taken in a vessel by adding enough water. Then heating was continued until *Guggulu* got completely melted. Then 250g of fine powders of the rest of the ingredients were added and mixed well. Then the mixture was allowed to cool down and *vatis* were prepared which is 500mg by weight. Finally, it was allowed to dry and was stored in a container.

INTERVENTION:-

The interventions of the clinical study were carried according to the individual groups mentioned above. These groups assigned as Group A and B were treated with *Abha Guggulu* and *Yogaraja Guggulu* respectively. The patients fulfilling the criteria for inclusion were randomly assigned into 2 groups each comprising of 20 patients.

OBSERVATIONAL PERIOD:-

Patients were assessed clinically before treatment, on the 16th day and 31st day after treatment.

FOLLOW UP:- after 15 days of the treatment i.e., on the 46th day.

TOTAL STUDY DURATION:- 45 days.

INVESTIGATIONS:-

Haematological investigations:- Routine blood investigations and X-Ray of the affected Knee –AP and lateral views were done.

ASSESSMENT CRITERIA: -

Clinical assessments are made for the severity of the disease and the clinical improvement. Grading for the

severity of individual symptoms was framed for a point scale. The gradings of variables were given along with clinical Performa specially formatted for the study on *Janu Sandhigata Vata*.

STATISTICAL ANALYSIS:-

Pre-test and post-test data were compared by using the Wilcoxon sign rank test.

Comparison of Group A and Group B was done by using the Mann-Whitney u test by using IBM SPSS STATISTICS 2.0 software.

DISCUSSION

AGE:-In this study, the majority of the patients were belonging to the age group of 51-60yrs with 52.5%. This may be due to *Vrudavastha* is predominant of *Vata*, the process of degeneration is more seen.

GENDER:- Majority of patients were female about 73.5%. Female hormones affect cushioning cartilage to allow smooth joint movement.

OCCUPATION:- In this present study, the majority of patients were housewives about 72.5%. This may be due to prolonged standing, squatting, and cross-legged sitting.

PRAKRUTI:- *Vata Pitta Prakriti* patients were dominant which was 42.5%. The reason for this may be as *Vata* dominant people are prone to this disease.

SAMHANANA:- Among 40 patients in this study, the majority of patients were of *Madhyama Samshamana* about 60%.

WEIGHT:- Majority of patients present in this study

were overweight about 52.5%. Because of which there will be an increase in pressure over the knee joint.

VYAYAMA:- About 67.5% of patients in this study have *Avara Vyayama shakthi*. This is due to the disease and age factor. *Vata Prakopa*.

INCIDENCE OF PAIN:- Among all patients under this study, the incidence of pain was gradual. This is due to degenerative changes in the knee.

CHARACTER OF PAIN:- In this study, 67.5% of patients had dull aching pain. This is because of cartilage destruction.

COURSE OF PAIN:- Among 40 patients, 40% experienced progressive type course of pain. This is because of degenerative changes.

AGGRAVATING FACTORS:- In this study, about 72.5% of patients had evening time aggravation of pain as is said to *Vata Prakopa Kala*.

RELIEVING FACTORS:- Majority of patients that is 65% had relief of pain at rest. This may be due to reduced physical activity.

RESULTS

In the present clinical study, 40 patients of *Janu Sandhigata Vata* were treated in two groups. In Group A patients were treated with *Abha Guggulu* and Group B patients were treated with *Yogaraja Guggulu* respectively.

The signs and symptoms were assessed before treatment, during and after treatment and follow up based on the assessment criteria mentioned earlier.

Table 2: GRADINGS FOR SUBJECTIVE & OBJECTIVE PARAMETERS:-

Janu Sandhi Shoola:-	
Grade 0	No pain
Grade 1	Mild pain not interfering with activities and sleep
Grade 2	Moderate pain interfering with activities and sleep
Grade 3	Severe pain-reducing activities and sleep
Janu Sandhi Stambha:-	
Grade 0	Absent
Grade 1	Present
Janu Sandhi Shotha:-	
Grade 0	No swelling
Grade 1	Slight swelling
Grade 2	Covers well over a bony prominence
Grade 3	Much elevated

Janu Sandhi Prasarana and Aakunchana Vedana:-	
Grade 0	Full range of joint movement
Grade 1	>75% and < full range of joint movement
Grade 2	50 % – 75% of the full range of joint movement
Grade 3	Up to 50% of the full range of joint movement
Grade 4	No movement
Janu Sandhi Atopa:-	
Grade 0	Absent
Grade 1	Palpable
Grade 2	Audible
Janu Sandhi Sparshaakkshamatva:-	
Grade 0	No tenderness
Grade 1	Patients' complaints of joint tenderness
Grade 2	The patient winces on touch
Grade 3	The patient withdraws the affected joint
VAS (VISUAL ANALOG SCALE):-	
Grade 0	0 cm
Grade 1	1-3cms
Grade 2	4-6cms
Grade 3	7-10cms
WOMAC O.A INDEX:-	
Grade 0	None (0)
Grade 1	Mild(0-24)
Grade 2	Moderate (25-48)
Grade 3	Severe (49-72)
Grade 4	Extreme(73-96)

Pre-test and post-test data were compared by using the Wilcoxon sign rank test. Comparison of Group A and Group B was done by using the Mann-Whitney u test by using IBM SPSS STATISTICS 2.0 software.

TABLE 3: STATISTICAL RESULT OF INDIVIDUAL ASSESSMENT CRITERIA: -

Assessment criteria	Group	BT Mean	AT Mean	M.D	Effect of treatment (%)	S.D	Z-value	P-value	Rmks
<i>Shoola</i>	A	1.65	0.65	1	63.63%	0.81	3.31	0.001	HS
	B	1.55	0.70	0.85	58.06%	0.80	3.6	0.00	HS
<i>Stambha</i>	A	1.0	0.35	0.65	75%	0.48	3.60	0.00	HS
	B	1.00	0.40	0.6	70%	0.50	3.46	0.001	HS
<i>Shotha</i>	A	1.30	0.40	0.9	76.92%	0.59	3.81	0.00	HS
	B	1.50	0.55	0.95	80%	0.60	4.14	0.00	HS
<i>Prasarana Aakunchana Vedana</i>	A	2.00	0.85	1.3	65%	0.58	3.96	0.00	HS
	B	1.95	0.75	1.2	71.79%	0.78	4.02	0.00	HS
<i>Atopa</i>	A	1.25	1.25	20	0	0.0	0.0	1	IS
	B	1.15	1.15	0	0	0.36	0.00	1	IS
VAS	A	1.90	0.70	1.2	65.78%	0.80	3.87	0.00	HS
	B	1.80	0.60	1.25	69.44%	0.68	4.17	0.00	HS
WOMAC	A	3.0	2.30	0.7	30%	0.58	2.91	0.00	HS
	B	2.90	2.20	0.7	25.86%	0.41	3.07	0.001	HS

DISCUSSION ON RESULTS

EFFECT OF TREATMENT ON SHOOLA: -

The effect of treatment on *Shoola* within the group, before and after treatment also at follow up with p-value (<0.001) was statistically highly significant in both the groups.

On comparing the groups, the p-value (=0.86) revealed statistically no significant difference between the groups.

Percentage-wise relief on *Shoola* in Group A was 63.63% to that of Group B was 58.06%.

EFFECT OF TREATMENT ON STAMBHA: -

The effect of treatment on *Stambha* within the group, before and after treatment also after following up the p-value (<0.001) was statistically highly significant.

On comparing between the groups, the p-value (=1) revealed statistically no significant differences between the groups.

Percentage-wise relief on *Stambha* in Group A was 75% with that of Group B was 70%.

EFFECT OF TREATMENT ON SHOTHA: -

The effect of treatment on *Shotha* within the group, before and after treatment also at follow up the p-value (<0.001) was statistically highly significant in both the groups.

On comparing between the groups, the p-value (=1.500) revealed no significant differences between the groups.

Percentage-wise relief on *Shotha* in Group B was 80% whereas in Group A was about 76.92%.

EFFECT OF TREATMENT ON PRASARANA AAKUNCHANA VEDANA: -

The effect of treatment on *Prasarana Aakunchana Vedana* within the group, before and after treatment and at follow up with p-value (<0.001) was statistically highly signifi-

cant in both the groups.

On comparing between the groups, the p-value (=0.560) revealed statistically no significant differences between the groups.

Percentage-wise relief on *Prasarana Aakunchana* in Group B was 71.79% with that of Group A was 65%.

EFFECT OF TREATMENT ON ATOPA: -

The effect of treatment on *Atopa* within the group before and after treatment and at follow up was not significant with p-value (=1.000) of Group A and Group B.

On comparing between the groups, the p-value (=1.000) revealed statistically no significant differences between the groups.

There was 0% relief on *Atopa* in both groups.

EFFECT OF TREATMENT ON VAS: -

The effect of treatment on VAS within the group, before and after treatment also at follow up, the p-value (<0.001) was statistically highly significant in both the groups.

On comparing between the groups, the p-value (=1.000) revealed statistically no significant differences between the groups.

Percentage-wise relief in Group B was 69.44% to that 65.78% in Group A in VAS.

EFFECT OF TREATMENT ON WOMAC:-

The effect of treatment on WOMAC within the group, before and after treatment also at follow up with p-value (<0.001) was statistically highly significant in both the groups.

On comparing between the groups, the p-value (=1.000) revealed statistically no significant between the groups.

Percentage-wise relief in WOMAC in Group A was 30% to that of 25.86% in Group B.

TABLE 4: DISCUSSION ON COMPARATIVE EFFECT OF TREATMENT IN GROUP A & GROUP B:-

Symptoms	Mean Difference		SD	Z value	p-value	Rmks
	GROUP A	GROUP B				
<i>Shoola</i>	1.50	0.67	0.76	1.09	22.0	IS
<i>Stambha</i>	1.50	0.37	0.49	0.47	0.68	IS
<i>Shotha</i>	1.50	0.47	0.59	0.26	0.79	IS

Prasarana Aakunchana Vedana	1.50	0.80	0.68	1.35	0.177	IS
Atopa	1.50	1.20	0.40	781	0.435	IS
VAS	1.50	0.62	0.74	0.81	0.41	IS
WOMAC	1.55	2.27	0.50	0.53	1	IS

The result obtained after treatment in both groups was compared by MANN-WHITNEY U TEST. The result revealed that there is no significant difference between the effects of treatment in both groups.

DISCUSSION ON MODE OF ACTION: -

ABHA GUGGULU: -

- ❖ *Abha Guggulu* mainly acts on bones, joints, and parts of the musculoskeletal system. It mainly has *Agnideepana, Vatahara, Shothahara, Vedanasthapana* properties¹¹.
- ❖ The *Babbula* present in it enhances bone regeneration and supports increased biomineralization¹².
- ❖ The *Haritaki* and *Vibhitaki* reduce bone inflammation and prevents bone resorption¹³.
- ❖ The *Amalaki* exerts potent antioxidant action, improves calcium absorption and its utility in the body and prevents bone destruction¹⁴.
- ❖ The *Maricha, Pippali* and *shunti* enhance the bioavailability of nutrients, boosts bone mineralization, reduces bone inflammation, alleviates pain¹⁵.
- ❖ The *Shuddha Guggulu* reduces bone inflammation, alleviates pain, reduces swelling, pain and prevents bone resorption¹⁶.
- ❖ Guggulsterone is beneficial in the treatment of osteoarthritis and bone fractures, and it is a possible target for anti-inflammatory activity and reduces the activity of inflammatory responses¹⁷.
- ❖ Gallic acid and its derivatives are anti-inflammatory agents that are effective in the treatment of osteoarthritis¹⁸.
- ❖ Linolic acid prevents cartilage degradation and bone resorption, while galactose regulates articular chondrocyte proteoglycan synthesis¹⁹.
- ❖ Piperine has been shown to slow the progression of OA²⁰.

❖ Terpenoids have shown promise in modulating inflammatory mediators in the pathophysiology of arthritis²¹.

YOGARAJA GUGGULU:-

- ❖ It is an excellent medicine for the dry type of arthritis with degeneration of the joints due to excess Vata and deficiency of shlesaka kapha preventing the nourishment of the synovial fluid²².
- ❖ Plumbagin has been reported to exhibit analgesic and anti-inflammatory activity and prevents bone erosion directly inhibiting osteoclast formation²³.
- ❖ Hyoscyamine is used to relieve mild to moderate symptoms of osteoarthritis²⁴.
- ❖ Gallic acid and its derivatives are anti-inflammatory agents have been reported to have potent effects on osteoarthritis treatment.
- ❖ Thymol exhibits potent anti-inflammatory activity by diminishing the release of inflammatory mediators²⁵.
- ❖ Cuminaldehyde brings about wellness in OA patients by altering dysregulated inflammatory pathways²⁶.
- ❖ Vetiverol manages pain and muscular stiffness²⁷.
- ❖ Piperine regulates the progression of OA.
- ❖ Moretenol is useful in different forms of arthritis and their different anti-inflammatory, anti-arthritis properties have been evaluated for subjective improvement²⁸.
- ❖ Delta- linanol inhibits infiltration of synovial membranes by inflammatory cells like macrophages, t- cells²⁹.
- ❖ Linolic acid prevents cartilage degradation and bone resorption.
- ❖ Terpenoids are having promising effects in the modulation of inflammatory mediators in the pathophysiology of arthritis.

- ❖ Tannins suppress inflammation and joint damage in OA³⁰
- ❖ Cinnamate has been able to control OA pain by its anti-inflammatory activity.
- ❖ Cineol is effective in reducing pain, swelling, inflammation by inhibition of cytokine secretion by T lymphocytes.³¹
- ❖ Guggulsterone is useful in OA, bone fracture and has got a potential target for anti-inflammatory activity.

CONCLUSION

Vata is the controlling element in the body's preservation of balance. As age progresses, degeneration progresses with the influence of Vata, resulting in the process of progressive degeneration of the body. One of the consequences of this process, which is prevalent in elderly individuals is Sandhigata Vata. This is *Kastasadhya* and it is said that *Mahagada* takes place at *Marma Asthi Sandhi*. Janu is a *Marma-Sandhi*. In *Charaka Samhita*, it is clarified that *Vata Dosha* should be treated for the management of diseases at *Marma Sthana*. The analysis is intended to compare the effects of *Abha Guggulu* and *Yogaraja Guggulu* on *Janu Sandhigata Vata*. It can be concluded that both *Abha Guggulu* and *Yogaraja Guggulu* provided relief for most signs and symptoms other than *Atopa* after reviewing the research, observation, clinical trials, findings, and discussion. In both, groups signs and symptoms such as *Shoola*, *Stambha*, *Shotha*, *Prasarana Aakunchana Vedana* and parameters such as VAS, WOMAC decreased to a marked degree, which is highly significant statistically. Whereas no outcomes are seen in both categories, as in *Atopa*. There is no significant difference in the effect on signs and symptoms while comparing between the groups.

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