



# A Comparative Study On Efficacy of Agnikarma And Yograja Guggulu In The Management Of Janu-Sandhigatavata W.S.R To Osteoarthritis of Knee Joint - A Study Protocol

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## ABSTRACT

As one of the most common musculoskeletal disorders encountered in Ayurvedic practice, *Janu-Sandhigatavata* has garnered significant attention due to its prevalence, especially among the aging population. This condition is often associated with degenerative changes in the knee joint, which can lead to chronic pain, stiffness, reduced mobility, and impaired quality of life. *Janu-Sandhigatavata* is correlated with Osteoarthritis of knee joint due to similar etiology and clinical features. It is a prevalent and debilitating condition characterized by the progressive degeneration of the knee joint's cartilage and surrounding structures. It is estimated that over 300 million people are affected by OA worldwide. Its treatment includes some medications, particularly long-term use of NSAIDs, can lead to side effects like gastrointestinal issues and an increased risk of cardiovascular problems. Surgical interventions, while often successful, come with risks, including infection, blood clots, and a potentially lengthy recovery period. Some treatments, especially surgical procedures and newer medications, can be costly and may not be accessible to all patients. Ayurvedic interventions for *Janu-Sandhigatavata* focus on restoring the balance of *Vata* dosha, strengthening the affected joint, and alleviating pain and inflammation through natural therapies, dietary modifications, and lifestyle recommendations. *Agnikarma* procedure will help in normalance of *Vata* dosha and *Yograja Guggulu* also has *deepana, pachana, stoto-vishodhana* property which works well in normalance of body metabolism. So, we desire to conduct research on the effectiveness of *Agnikarma* and *Yograja Guggulu* in the management of *Janu-Sandhigatavata*.

Key words : Kneejoint , *Janu-Sandhigatavata* , Osteoarthritis etc.

## INTRODUCTION

Ayurveda, the holistic life science aims at physical, social, and spiritual well-being of an individual. The modalities of preventive and curative healthcare have been well expounded in this science and may offer comprehensive solutions for the multifactorial diseases of the humanity. In *Vriddhavastha*, all *Dhatu*s undergo *Kshaya*, thus leading to *Vataprakopa* and making individual prone to many diseases. Among them *Sandhigatavata* stands top in the list. *Sandhigatavata* explained under *Vatavyadhi*. *Sandhigatavata* is first described by Acharya Charaka as *Sandhigata Anila* with symptoms of *Shotha* (swelling) which on palpation feels like a bag filled with air and *Shula* (pain) on *Prasarana* and *Akunchana* (pain on flexion and extension of the joints).<sup>[1]</sup> Acharya Sushruta also mentioned *Shula* and *Shotha* in this disease leading to the diminution (*Hanti*) of the movement of involved joint.<sup>[2]</sup> Madhavakara adds *Atopa* (crepitus in joint)<sup>[3]</sup> as additional feature of it. The pathologic underpinnings of this disease are attributing to the aberration of *Vata* and *Kapha Dosha*, affecting the *Asthi* (bone), *Sandhi* (joint), *Mamsa* (muscle), and *Snayu* (ligament). *Sandhigata Anila* predominantly affects major weight bearing joints of the body in which knee joint attains first priority. So in present study *Sandhigatavata* can be preferred as *Janu-Sandhigatavata*.

Comprehensive management of this condition in Ayurveda includes a judicious combination of external therapies (*Bahya Chikitsa*) and internal medication (*Abhyantara Chikitsa*). The *Bahya Chikitsa* include *Janu Basti*, *Abhyanga* (massage), *Raktamokshana*, *Agnikarma* (cautery), *Basti* (medicated enema), etc. *Abhyantara Chikitsa* include the internal medications in the form of *Churna* (powder of a single herb/combination of herbs), *Kashaya* (decoction), *Vati* (pills), etc.

Osteoarthritis is the most common arthritic condition affecting and increasing aging population. It is a slowly progressive joint disease. The primary complaints of patients with Osteoarthritis are pain and difficulty in joint mobility. The etiology of pain is multi-factorial, including inflammatory and non-inflammatory causes. Osteoarthritis most commonly affect the weight-bearing joints in particular the knee, hip and spine and the interphalangeal joints of the hand. The wrist, shoulder and ankle are less often involved. The disease is characterized by focal areas of destruction of articular cartilage, sclerosis of the bone and hypertrophy of the soft tissues.

On the basis of etiology and clinical features of osteo-arthritis of knee joint mentioned in modern texts, this disease can be co-related with *Janu-Sandhigatavata* as mentioned in classical ayurvedic texts.

## NEED OF STUDY

The incidence of osteoarthritis in India is as high as 12%. It is estimated that approximately four out of 100 people are affected by it. Osteoarthritis is the most common articular disorder begins asymptotically in the 2<sup>nd</sup> & 3<sup>rd</sup> decades and is extremely common by age 70. Almost all persons by age 40 have some pathologic change in weight bearing joint<sup>[4]</sup>, 25% females & 16% males have symptomatic osteoarthritis. Allopathic treatment has its own limitation in managing this disease. The disease is managed by NSAIDs, analgesic drugs, physiotherapy and corticosteroids etc. Above drugs are very costly and cause symptoms such as nausea, acidity, vomiting, diarrhea etc. These drugs also affects liver and kidneys vigorously. Even the surgical treatment does not provide complete relief & its quite expensive too which could not be affordable by common man. *Sandhigatavata* is predominantly occurs due to vitiated *Vata*. Manifestation of *Agnikarma* procedure will help

in normalance of *Vata* dosha by acting on the *Ushna* (hot) *Guna* of *Agni* pacifies the *Shita* (cold) *Guna* of *Vayu* and reduces the joint pain in the case of *Sandhigatavata*. Acharya Charaka described that *Agni* is the best treatment for *Shoola* (pain). *Guggulu kalpanas* are best in treating vitiated *Vata* dosha. Though herbal drugs mentioned in *Yograja Guggulu* also has *deepana*, *pachana*, *stroto-vishodhana* property which works well in normalance of body metabolism. So an effort will be done to assess the comparative efficacy of *Agnikarma* and *Yograja Guggulu* in the management of *Janu-Sandhigatavata*.

**AIM:** To evaluate the comparative efficacy of *Agnikarma* & *Yograja Guggulu*, also the combined efficacy of *Agnikarma* & *Yograja Guggulu* in the management of *Janu-Sandhigatavata* (Osteoarthritis).

### OBJECTIVE

- To study the effect of *Agnikarma* in the management of *Janu-Sandhigatavata* (Osteoarthritis).
- To study the effect of *Yograja Guggulu* in the management of *Janu-Sandhigatavata*. (Osteoarthritis).
- To compare the efficacy of *Agnikarma* and *Yograja Guggulu* in the management of *Janu-Sandhigatavata*. (Osteoarthritis).
- To study the combined efficacy of *Agnikarma* and *Yograja Guggulu* in the management of *Janu-Sandhigatavata*. (Osteoarthritis).

### RESEARCH QUESTION

Is there any significant difference in the efficacy of *Agnikarma* in the management of *Janu-Sandhigatavata* (Osteoarthritis) than *Yograja Guggulu*?

### HYPOTHESIS

- **Null hypothesis (H<sub>0</sub>):** - There is no significant difference between the efficacy of *Agnikarma* & oral intake of *Yograja Guggulu* in the management of *Janu-Sandhigatavata*.
- **Alternate hypothesis (H<sub>1</sub>):** - There is significant difference between the efficacy of *Agnikarma* & oral intake of *Yograja Guggulu* in the management of *Janu-Sandhigatavata*.

### CASE STUDY

This study included a selection of 90 patients from the outpatient and inpatient departments who had been diagnosed with *Janu-Sandhigatavatyadhi*. 90 Patients were divided into 3 groups and given specific treatment and observations were noted during its follow up.

**Study Design:** Comparative open Random, clinical Study

**Study type:** Interventional

**Method of Allocation Concealment:** Not Applicable

**Site of Study:** Institute for Ayurved Studies & Research Hospital, Kurukshetra

**Level of Study:** OPD level **Masking:** Not Applicable, open rial **Control:** Controlled Study **Sampling method:** Simple random

**Timing:** Prospective

**No. Of group:** three

**Sample Size:** 30

**Primary Purpose:** TREATMENT

**Study Duration:** 21 days

**End point:** Efficacy and Safety

Groups	Type of Treatment	Number of patients
Group A	Agnikarma	30
Group B	Oral intake of <i>Yograja Guggulu</i>	30
Group C	Agnikarma + <i>Yograja Guggulu</i>	30

## PROCEDURE GROUP A

Procedure of *Agnikarma*

The procedure performed in three stages as **Purva Karma**, **Pradhana Karma**, and **Paschata Karma** as mentioned by Acharya Sushruta.<sup>[6]</sup>

### Purva Karma

*Snigdha Picchila Annapana* (rice and curd) will be given prior to the procedure. The site of *Agnikarma* will be washed with distilled water and wiped with dry sterilized gauze. *Panchadhatu Shalaka* (Red Hot) *Ghritakumari* pulp, *Haridra Churna* kept ready for dressing.

### Pradhana Karma

In Osteoarthritis of the knee joint, supine position will be adopted as it is comfortable to the patient. Irrespective of a specific site, *Agnikarma* will be done at maximum tender site affected at the knee joint. The minimum space will be kept between two *Agnikarma* points to avoid overlapping of *Dagdha Vrana*. *Agnikarma* will be done in *Bindu Vishesha* Pattern using *Panchadhatu Shalaka*. Care will be taken to produce *Samyaka Dagdha Vrana*. After *Agnikarma*, fresh *Ghritakumari* pulp will be applied on *Dagdha* to relieve burning pain.

### Paschata Karma

After wiping of *Ghritakumari* pulp, honey and ghee will be applied on *Dagdha Vrana*, after that dusting of *Haridra Churna* will be done. Patient will be observed for 30 min after procedure and advised *Pathyapathya* as mentioned in Sushruta Samhita <sup>[7]</sup> until the healing of *Samyak Dagdha Vrana*. Patients will be strictly advised not to allow water contact at *Dagdha Vrana* site for 24 hours.

Total 4 sittings of Agnikarma procedure will be done in present study.

## Group B

**YOGRAJA GUGGULU<sup>8</sup>** (*Bhaishajya Ratnawali, shloka 90-95, page-502*)

*Yograja Guggulu* on the other side, we will use for oral medication on the patients. The *Yograja Guggulu* will be taken 500MG thrice a day with lukewarm water after meals for 21 days.

Drugs	Quantity
<i>Chitraka</i>	part
<i>Pippali mula</i>	part
<i>Yavani</i>	part
<i>Karavi</i>	part
<i>Vidanga</i>	part
<i>Ajamoda</i>	part
<i>Jeeraka</i>	part
<i>Devadaru</i>	part
<i>Chavya</i>	part
0. <i>Ela</i>	part
1. <i>Saindhava Lavana</i>	part
2. <i>Kushta</i>	part
3. <i>Rasna</i>	part
4. <i>Gokshura</i>	part
5. <i>Dhanyaka</i>	part
6. <i>Bibhitaki</i>	part
7. <i>Haritaki</i>	part
8. <i>Amalaki</i>	part
9. <i>Musta</i>	part
0. <i>Pippali</i>	part
1. <i>Maricha</i>	part
2. <i>Shunthi</i>	part
3. <i>Twak</i>	part
4. <i>Usheera</i>	part
5. <i>Yavagraja</i>	part
6. <i>Taleesapatra</i>	part
7. <i>Patra</i>	part
8. <i>Guggulu</i>	7 part
9. <i>Sarpi</i>	sufficient quantity

**Methods of Selection of Study Subject:****(i) Inclusion Criteria-**

- Patient suffering from classical sign and symptoms of *Sandhigatavata* are *Shula, Shotha, Stambha, Sparsha-asahyata, Sphutana, Akunchana Prasarana Vedana* etc. at the Osteoarthritis of knee joints.
- Patients between age group of 30 - 70 years.
- Patients with controlled Diabetes Mellitus.
- Patients willing to under go trial.

**(ii) Exclusion Criteria-**

- Age below 30 years and above 70 years.
- Patients of knee joint dislocation/fracture or has the history for the same.
- Patients having any previous surgical procedure of knee joint.
- Grade 4 (Severe)** <sup>5</sup>: large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of bone ends.
- Co-existence of lesions to knee joint.
- Patients suffering from disease like uncontrolled D.M., Carcinoma, Psoriatic arthritis, Gout, S.L.E., Polymyalgia Rheumatica & Tuberculosis will be excluded.
- Patients having pacemaker or angiography done.
- Malignant and Immuno-compromised patients (AIDS), HBsAg.
- Pregnant women and lactating mothers.

**(iii) Criteria for withdrawal-**

Patients reporting with any of the following-

1. Patients willing to quit in between will be allowed to quit and will be replaced.
2. If any acute illness or complications develops, patient will be treated accordingly and will be excluded from the study.

**SUPPORTIVE LAB INVESTIGATIONS:**

- Routine hematological, vit. D
- R.A. factor
- Serum uric acid
- Blood sugar, serum calcium, LFT, KFT. (if required)
- X-ray examination (AP & lateral) of the involved knee joint.

**Assessment Criteria:**

The improvement in the patient will be assessed mainly on the basis of relief in the signs and symptoms of the disease. To assess the effect of therapy objectively, all the signs and symptoms will be given scoring depending upon their severity.

**Subjective Criteria:** Pain

**Objective Criteria:** Tenderness, Swelling, Range of movement, crepitus

ASSESSMENT CRITERIA :	Grade	
<b>Shoola (Pain)</b>	0	No pain (0)
	1	Mild Pain (1-4)
	2	Moderate pain but no difficulty in walking (5-8)
	3	Severe difficulty in walking ( 9-10)
<i>Shotha</i> (Swelling) on joint	0	No Swelling
	1	Slight Swelling Pain
	2	Moderate Swelling (covers well over the bony prominence)
	3	Severe Swelling
<i>SparshaSahatva</i> (Tenderness) on joint	0	No Tenderness
	1	Patients Says tenderness
	2	Winching of face on touch
	3	Does not allow to touch the joint
Range of movement	0	Freely movable with no pain
	1	Movable with mild pain
	2	Movable with moderate pain
	3	Movable with severe pain
<i>Sandhisphutan</i> (Crepitus)	0	No crepitus
	1	Mild Audible Crepitus
	2	Moderate Audible and Palpable
	3	Crepitus

**MANAGEMENT OF THE DATA-** The principal investigators will be responsible for coding the data.

**ETHICS AND DISSEMINATION** - Research ethical approval has been given after the research topic has been subjected to critical review and presented to the ethical committee.

**CONSENT OR ASSENT** - Subjects will be given information in their native language regarding the specifics of their therapy in great detail. The patients will then be asked to provide their written consent before the beginning of the trial.

The DISSEMINATION POLICY will take the form of presentations as well as the publication of papers.

### **DISCUSSION –**

In Ayurveda, "*Vata*" refers to one of the three doshas, or bioenergetic principles, that govern the functioning of the body. *Vata* is associated with qualities such as dryness, coldness, lightness, mobility, and variability. When *Vata* becomes imbalanced, it can lead to various health issues, both physical and mental. "*Sandhigatavata*" is characterized by the vitiation (imbalance) of the *Vata* dosha specifically in the joints. When *Vata* becomes imbalanced in the joints, it can lead to a range of joint-related problems and pain. . *Dhatukshaya* is one of the things that can set it off. Due to the predominance of the *Vatadosha* in one's later years, the sickness known as *Janu-Sandhigatavata* will become apparent. Catabolism is something that happens naturally in old age, also known as *Vardhakya Avastha*. *Sandhigata Anila* with symptoms of *Shotha* (swelling) which on palpation feels like a bag filled with air and *Shula* (pain) on *Prasarana* and *Akunchana* (pain on flexion and extension of the joints).<sup>[1]</sup> Acharya Sushruta also mentioned *Shula* and *Shotha* in this disease leading to the diminution (*Hanti*)

of the movement of involved joint.<sup>[2]</sup> Madhavakara adds *Atopa* (crepitus in joint)<sup>[3]</sup> as additional feature of it.

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**çlkj.kkdq~-pu;ks% ço`fÜk'p losnuk AA (Ch. Chi. 28/37)**

The scientific and medical definition of Osteoarthritis is: - It is one of the most common form of arthritis, which runs chronic, slowly progressive course and usually affects almost all the weight-bearing and frequently used larger joints of the extremities with an exception to distal inter-phalangeal joints. It is a degenerative joint disease, which affect the smaller joint of the spine also. It is characterized clinically by pain, stiffness and at times swelling of the joints. A pathologically it shows degenerative changes in the articulating bones, together with irregular hypertrophy of the bone and cartilages, giving rise to osteophytes.

### **PROBABLE MODE OF ACTION OF AGNIKARMA**

After *Agnikarma*, the *Ushna* (hot) *Guna* of *Agni* pacifies the *Shita* (cold) *Guna* of *Vayu* and reduces the joint pain in the case of *Sandhigata Vata*. Acharya Charaka described that *Agni* is the best treatment for *Shoola* (pain).<sup>[9]</sup> *Ushna Guna* of *Agni* helps to removes the *Avarana* effectively and stabilizes the movement of *Vata*, which provide relief from *Shoola*. As per the modern medicine, therapeutic heat increases blood circulation at knee joint leads to the proper nutrition of the tissue. This induced circulation help to flush away pain producing substances from affected site and ultimately reduces the local inflammation.<sup>[10]</sup>

### **PROBABLE MODE OF ACTION OF YOGRAJA GUGGULU**

Mainly the drugs having property like *tikta*, *kashaya*, *katu rasa* and *ushna*, *ruksha guna*, *ushna virya* and acts as *kaphavatahara*. During pounding of *guggulu*, small amounts of *ghrita* are added to make *kuttitha guggulu*. The importance of repeated pounding could be to be presumably facilitate synergy among the various active constituents in *Yogaraja guggulu* and regulate their release inside the body, thereby enhancing absorption of the medicine.

### **STATISTICAL ANALYSIS**

For within the group analysis of assessment criteria **Student T test** will applied at 5% level of significance.

### **STRENGTHS -**

If the planned study yields a satisfactory result, it will be adopted as a new management method for the *Janu-Sandhigata vata*. We shall be given an effective and economical treatment for pain relief and discomfort in society.

### **LIMITATIONS -**

Sample size is small, for better results sample size can be increased.

Human error can be taken into consideration while mentioning the observations.

### **CONCLUSION -**

Conclusion will be mentioned after the analyzing data.

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