

# **A Comparative Clinical Study to Evaluate the Efficacy of Mustadi Yapana Basti and Ksheera Basti of Indigenous Drug in the Management of Janu Sandhigata Vata vis-à-vis Osteo Arthritis of Knee Joint**

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## **ABSTRACT**

*Janu Sandhigata Vata* is defined as *Vata Vyadhi* characterised by swelling in the knee joints, and pain which increases on extension and flexion of joints. The prevalence of osteoarthritis among elderly as per the recent study is 56.6%, making it a leading cause of disability. Considering all these the present study was undertaken.

**Objective:** To compare the efficacy of *mustadi yapana basti* and *ksheera basti* of indigenous drugs in *Janu Sandhigata Vata*.

**Materials & Methods:** It was a comparative clinical trial with pre and post-test design having *laksha guggulu* (internally) and *Ksheerabala taila* and *Mahavishagarba taila Janubasti* in the both groups, *mustadi yapana basti* in group A and in group B *ksheera basti* of indigenous drugs. The subjects fulfilling the diagnostic criteria of *Janu Sandhigata Vata* was assigned into two groups viz., Group A (*Mustadiyapana basti*) and Group B (*Ksheera basti* of indigenous drugs), each group consisting of 25 patients. *Sandhi Shoola*, *Sandhi Shotha*, *Sandhi iAtopa*, *Sandhi Stabdhatata* with grading and WOMAC- Index for Osteoarthritis were taken as parameters for assessment. The study consisted of two assessments i.e., 0 day and 9th day.

**Results:** The efficacy of *Mustadiyapana basti* has more clinically and statistically significant than the *Ksheera basti* of indigenous drugs in following parameters i.e., in reduction of pain, swelling, stiffness and WOMAC index for Osteoarthritis with high chi-square value.

## **INTRODUCTION**

- 1) *Sandhigata Vata* is one among *Shoola* and *Shotha Pradhana Vata Vyadhi* which is mentioned in the context of *Gata vata* in classical text. It is characterised by swelling in the joints, and pain which increases on extension and flexion of joints<sup>1</sup>. Osteoarthritis (OA) mentioned in western medicine has similarities with the signs and symptoms of *Sandhigata Vata*.
- 2) Osteoarthritis is an abnormality of the synovial joints characterised by softening, splitting and fragmentation of articular cartilage not attributable to direct contact with inflammatory tissue. This is usually accompanied by subchondral sclerosis and bony cysts, joint space narrowing and bony outgrowths at tissue joint margins<sup>2</sup>.
- 3) The prevalence of osteoarthritis among elderly as per the recent study is 56.6%, making it a leading cause of disability. The prevalence of OA rises strikingly with age. It is highly prevalent in those over age of 60. OA accounts for 55% of all arthritis related hospitalisation; 4,09,000 hospitalisation per year for OA as principal diagnosis<sup>3</sup>.
- 4) Management in western medicine includes NSAIDs, opioid analgesics and injection glucocorticoids. Full recovery can be expected only in 85% of adults and role of surgery

remains controversial because of poor outcome i.e., inability to recover complete range of motion post-surgery and instability of the joint. Long term usage of above medicines causes gastrointestinal toxicity in 50% of NSAID users, renal and hepatic metabolism impairment and economic burden in case of surgical intervention<sup>4</sup>.

In above situation, to explore time hold Ayurvedic therapy is an important area of research. An early effective intervention may not only provide symptomatic relief of pain but also may reduce need for surgical intervention. The treatment modalities described in Ayurveda for *JanuSandhigata Vata* include both the *Upakrama* mentioned in *Vata Vyadi* and specific modalities mentioned in *JanuSandhigata Vata*. *Basti chikitsa* is one among the most important treatment modality employed in *VataVyadi*, Indigenous drugs in the *Ksheera Basti* are *Yastimadhu*, *Shatavari*, *Ashwaganda*, *Guduchi*, *Eranda*, *Rasna*, *Saptaparna*, *Patola*, *Bhunimba* and *Nimba* and *mustadi yapana basti* were used in *basti chikitsa*. *Musthadi Yapana Basti* is mentioned in *Charaka Samhita* in *Uttara Basti Siddhi Adyaya* It is indicated in *Janu Shula*. It is *Sadhyobalakara* and *Rasayan*.

Indigenous drugs in the *Ksheera Basti* are *Yastimadhu*, *Shatavari*, *Ashwaganda*, *Guduchi*, *Eranda*, *Rasna*, *Saptaparna*, *Patola*, *Bhunimba* and *Nimba*.

*Yastimadu* has the properties of *Shotahara* and *Vedanastapana*, *Shatavari* has the properties of *Vedanastapana*, *rasayana* and *balya*; *Ashwaganda* has the properties of *Rasayana*, *Shophahara*, *Kshaya nashaka*; *Guduchi* has the properties of *Tridosha shamaka*, *Rasayana* and *Jarajanya Vyadi Nashaka*; *Eranda* is indicated in *Sandi shota*; *Rasna* is indicated in *Shotha* and is *Shoola hara* and *Vedanastapana*; *Saptaparna* has the properties of *Vedanastapana*; *Patola* is *Kapha Pitta Shamaka*; *Bunimba* is *Kapha Pitta Shamaka* and *Nimba* is *Kapha Pitta Shamaka*.and *Karpasasthyadi Taila* is indicated for *Sarva vata roga* hence this will be administered for *Anuvasana basti* in both the *basti* groups.

*Laksha Guggulu* is indicated in *Asti Ruja* and *Asti chyuthi*. So, it was selected for the study. *Ksheera Bala Taila* is indicated in all the *Vata vikara*. and *Mahavishagarbha Taila* is mentioned in *Bhaishajya Rathnavali Vata Vyadhiadhikara*. Therefore, *Janu Basti* with *Ksheera Bala Taila* and *Mahavishagarbha Taila* was selected for the study.

## OBJECTIVE OF THE STUDY

- 1) To evaluate and compare the added efficacy of *Mustadi Yapana Basti* and *Ksheera Basti* of indigenous drugs in the management of *Janu Sandhigata Vata vis-à-vis Osteoarthritis* of knee joint.
- 2) To evaluate the combined efficacy of *Laksha Guggulu*; *Janu Basti* with *Ksheerabala Taila* and *Mahavishagarbha Taila*; *Mustadi Yapana Basti* in the management of *Janu Sandhigata Vata vis-à-vis Osteoarthritis* of Knee joint.
- 3) To evaluate the combined efficacy of *Laksha Guggulu*; *Janu Basti* with *Ksheerabala Taila* and *Mahavishagarbha Taila*; *Ksheera Basti* of indigenous drugs in the management of *Janu Sandhigata Vata vis-à-vis Osteoarthritis* of knee joint

## MATERIALS & METHODS

**Source of Data:** Subjects were purposively selected and assigned into 2 groups from the O.P.D and I.P.D of Government Ayurveda Medical College and Hospital and Hi tech Panchakarma hospital, Mysore, India. A total of 55 Subjects between the age group of 30-60 years fulfilling the criteria for the diagnosis of the disease were registered for the study in

prescribed proforma. Out of these, 05 subjects dropped out during various stages of the intervention. The study was completed in 50 subjects.

**Study Design:** The study was a control with pre and post-test design.

### **Diagnostic Criteria**

- Presence of signs and symptoms of *JanuSandhigata Vata* such as *JanuSandhi Shoola*, *JanuSandhi Shotha*, *JanuSandhi Atopa*, *JanuSandhi Stabdhat* were considered as diagnostic criteria. Positive Appley's Grind Test, Anterior Drawer sign, Posterior Drawer Sign, Valgus Stress Test, Varus Stress test were taken as objective measures for the diagnosis. X ray antero-posterior view of knee joint was taken for the confirmation of diagnosis. Severity of the Osteoarthritis knee joint was assessed with the help of Kellgren– Lawrence Radiographic Grading Scale of Osteoarthritis.

### **Inclusion Criteria**

- Subjects of all gender belonging to the age group of 30 years to 60 years were selected for the study. Both fresh and treated cases were selected. Subjects with the symptoms of *JanuSandhigata Vata* for at least one month of duration were selected.

### **Exclusion Criteria**

- OA with co-morbidity of Rheumatoid Arthritis, Systemic Lupus Erythematosus, Psoriatic Arthritis, and Gouty Arthritis were excluded from the study. Complications of OA, like Pseudo gout, Spontaneous osteonecrosis of the knee, Ruptured Baker cyst, Bursitis, Anserine bursitis (knee), Charcot joint, post-surgical and prosthetic knee joints, Subjects with history of recent trauma (of less than 1 month duration) were excluded.
- Pregnant and lactating women were also excluded. Subjects suffering from other systemic disorders such as uncontrolled Diabetes mellitus (RBS >300 mg/dl), Renal disorders, Endocrine disorders, which interfere with the course of intervention were excluded.

### **Statistical Methods**

- The result was analysed statistically by using Descriptive statistics, t test- independent and paired samples, Repeated measure ANOVA and Chi -square test analysis using Service product for statistical solution (SPSS) for windows software.

### **Physiological, Biochemical and Radiological Investigations**

X-ray Antero-posterior view of knee joint was taken for diagnosis of Osteoarthritis. Haematological investigations namely Haemoglobin %, TC, DC, ESR, Random blood sugar, and Urine examinations namely Sugar, Albumin & Microscopic were carried out to rule out other systemic diseases in all the cases. Rheumatoid factor was done whenever necessary.

### **INTERVENTION**

#### **Group A**

- 1) Mustadi Yavana Basti<sup>5</sup> with Karpasasthyadi Taila Anuvāsana in Yoga Basti pattern.
- 2) Ksheerabala taila and Mahavishagarba taila for Janu Basti for about 45 minutes for consecutive 8 days.
- 3) Laksha Guggulu in the dosage of 500 mg per day in two equal divided doses of 250 mg, 2 tablets each of 125 mg in the afternoon and night twice daily with Ksheera as Anupana for 8 consecutive days.

### Group B

- 4) Ksheera Basti of indigenous drugs<sup>6</sup> with Karpasasthyadi Taila<sup>7</sup>, Anuvasana in Yoga Basti pattern.
- 5) Ksheerabala taila and Mahavishagarba Taila<sup>8</sup> for Janu basti for about 45 minutes for consecutive 8 days.
- 6) Laksha Guggulu<sup>9</sup> in the dosage of 500 mg per day in two equal divided doses of 250 mg, 2 tablets each of 125 mg in the afternoon and night twice daily with Ksheera as Anupana for 8 consecutive days.

**DURATION:** The duration of the study was 08 days.

### Assessment Criteria

#### Assessment Schedule

- Assessment was done on 0 day i.e., before starting the intervention. Post-test assessment was done on 9th day i.e., next day after the completion of Basti karma.
- **Parameters of Assessment:** Assessment parameters included the clinical grading of signs and symptoms of the disease *JanuSandhigata Vata* and WOMAC index for osteoarthritis.

Assessment was done based on following parameters:

- **Sandhi Shotha**  
No swelling:SO  
Mild swelling:S1  
Moderate swelling:S2  
Severe swelling:S3
- **Sandhi Shoola**  
No pain:PO  
Mild pain:P1  
Moderate pain:P2  
Severe pain:P3
- **Sandhi Atopa**  
No crepitus:A0  
Mild palpable crepitus:A1  
Moderate palpable crepitus:A2  
Audible crepitus:A3
- **Sandhi Stabdata**  
No stiffness:ST0  
Mild stiffness:ST1  
Moderate stiffness:ST2  
Severe stiffness:ST3
- WOMAC- Index for Osteoarthritis:
- The severity of the Osteoarthritis knee joint was assessed with the help WOMAC score grading given below:

**Table Showing Womac Score Grading**

	<b>SCORE</b>	<b>GRADE</b>
None	0	Grade 0
Mild	0-26	Grade 1
Moderate	26-52	Grade 2
Severe	52-78	Grade 3
Extreme	78-104	Grade 4

**Overall Assessment:** The assessment was graded with following manner:

- 1) Marked improvement: 76-100% improvement in signs and symptoms.
- 2) Moderate improvement: 51-75% improvement in signs and symptoms.
- 3) Mild improvement: 26-50% improvement in signs and symptoms
- 4) Insignificant improvement- less than 25% improvement.

## **OBSERVATION AND RESULTS**

### ➤ **Pre-test Observation:**

- 1) In this study among 50 subjects, 13 subjects (26.0 %) consulted the hospital for the first time to take treatment and 37 subjects (74%) had already taken different forms of treatment (Allopathic, Unani, Homeopathy and Physiotherapy) of varying duration. In *Mustadi yapana Basti* Group among 25 subjects pain was severe in 11 subjects (44.0%) and moderate in 14 subjects (56.0%) . Swelling was severe in 2 subjects (8.0%), moderate in 10 (40.0%), mild in 6 (24.0%) and absent in 7(28%). crepitus was severe in 3 subjects (12.0%), moderate in 11 (44.0%), mild in 7 (28.0%) and absent in 4 (16.0%). Stiffness was severe in 3 subjects (12.0%), moderate in 12 (48.0%), mild in 9 (36.0%) and absent in 1 (4.0%).
- 2) In *ksheera basti of indigenous drugs* among 25 subjects 11 subjects (44.0%) reported severe pain and 13 (52.0%) reported moderate pain, 1(4.0%) reported with mild pain. 15 subjects (60.0%) reported moderate swelling, 9 (36.0%) reported mild swelling and 1 (4.0%) reported no swelling. Crepitus was severe in 4 subjects (16.0%), moderate in 11 (44.0%), mild in 8 (32%), and absent in 2 (8%). 14 subjects (56.0%) reported moderate stiffness, 9 (36.0%) reported mild stiffness, and 2(8.0%) reported no stiffness. In fresh cases intervention was started from the next day after laboratory investigations and x-ray. In treated cases after complete withdrawal of earlier treatment flush out period of 7 days was given and then intervention was started.

### ➤ **Post-test Observation**

- 1) In *Mustadi yapana Basti* group 7 (28.0%) had moderate pain, 11 (44.0%) had mild pain and 7 (28.0%) had completely relieved from pain. 10 subjects (44.0%) had mild swelling and 15(60.0%) had no swelling. 7 (28.0%) had moderate crepitus, 11 (44.0%) had mild crepitus and 7 (28.0%) had completely relieved from crepitus.0 subject (0.0%) had severe stiffness, 2 (8.0%) had moderate stiffness, 13 (52.0%) had mild stiffness and 10 (40.0%) had completely relieved from stiffness.
- 2) In *Ksheera basti of indigenous drugs* group 4 (16.0%) had moderate pain, 15 (60.0%) had mild pain and 6 subjects (24.0%) had completely relieved from pain. 0 (0.0%) subjects had severe swelling, 0 (0.0%) had moderate swelling, 17 (68.0%) had mild swelling and 8 (32.0%) had no swelling. 2(8.0%) subjects had severe crepitus, 8 (32.0%) had moderate crepitus, 10 (40.0%) had mild crepitus and 5 (20.0%) had no crepitus. 0 (0.0%) had severe stiffness, 1 (4.0%) had moderate stiffness, 14 (56.0%) had mild stiffness and 10 (40.0%) had no stiffness.
- 3) In the clinical trial, the result obtained regarding the overall assessment showed better result in *Mustadi Yapana Basti* (Group A) than *Ksheera basti of indigenous drugs* (Group B) with high Chi -square value 0.575. Assessment of WOMAC score in between the Groups was statistically significant with p value 0.000 , with this *Mustadi Yapana Basti* indicating that showed better effect compared to *Ksheera basti of indigenous drugs*.

**Table No 1: Showing Result on Sandhi Shoola**

Groups		Sandhi Shula				Total
		No	Mild	Mod	Severe	
Group A	Day 0	0	0	14	11	25%
		0.0%	0.0%	56.0%	44.0%	100.0%
	Day 9	7	11	7	0	25
		28.0%	44.0%	28.0%	0.0%	100.0%
<b>Total</b>		7	11	21	11	50
		14.0%	22.0%	42.0%	22.7%	100.0%
Group B	Day 0	0	1	13	11	25
		0.0%	0.0%	52.0%	44.0%	100.0%
	Day 9	6	15	4	0	25
		24.0%	60.0%	16.0%	0.0%	100.0%
<b>Total</b>		6	16	17	11	50
		12.0%	32.0%	34.0%	22.0%	100.0%

**Table No 2: Showing Result on Sandhi Shotha**

Sandhi Shotha					TOTAL	
Groups		No	Mild	Mod		Severe
Group A	Day 0	7	6	10	2	25
		28.0%	24.0%	40.0%	8.0%	100.0%
	Day 9	15	10	0	0	25
		60.0%	40.0%	0.0%	0.0%	100.0%
<b>Total</b>		22	16	10	2	50
		44.0%	32.0 %	20.0 %	4.0 %	100.0%
Group B	Day 0	1	9	15	0	25
		4.0%	36.0%	60.0%	0.0%	100.0%
	Day 9	8	17	0	0	25
		32.0%	68.0%	8.0%	0.0%	100.0%
<b>Total</b>		9	26	15	0	50
		18.0%	52.0%	30.0%	0.0%	100.0%

**Table No 3: Showing Result on Sandhi Atopa**

Groups						
		No	Mild	Mod	Severe	
Group A	Day 0	4	7	11	3	25
		16.0%	28.0%	44.0%	12.0%	100.0%
	Day 09	7	11	7	0	25
		28.0%	44.0%	28.0%	0.0%	100.0%
<b>Total</b>		11	18	18	3	50
		22.0%	36.0%	36.0%	6.0%	100.0%
Group B	Day 0	2	8	11	4	25
		8.0%	32.0%	44.0%	16.0%	100.0%
	Day 09	5	10	8	2	25
		20.0%	40.0%	32.0%	8.0%	100.0%
<b>Total</b>		7	18	19	6	50
		14.0%	36.0%	38.0%	12.0%	100.0%

**Table No 4: Showing Result on Sandhi Stabdhatta**

Groups		Sandhi Stabdhatta				Total
		No	Mild	Mod	Severe	
Group A	Day 0	1	9	12	3	25
		4.0%	36.0%	48.0%	12.0%	100.0%
	Day 09	10	13	2	0	25
		40.0%	52.0%	8.0%	0.0%	100.0%
Total		11	22	14	3	50
		22.0%	44.0%	28.0%	6.0%	100.0%
Group B	Day 0	2	9	14	0	25
		8.0%	36.0%	56.0%	0.0%	100.0%
	Day 09	10	14	1	0	25
		40.0%	56.0%	4.0%	0.0%	100.0%
Total		12	23	15	0	50
		24.0%	46.0%	30.0%	0.0%	100.0%

## DISCUSSION

- 1) After observing the overall assessment of the study, it revealed that Group A (*Mustadi yapana basti*) shows better result than Group B (*Ksheera basti of indigenous drugs*) for overall assessment with high chi square value 0.575.
- 2) Also, the result obtained regarding the overall assessment showed clinically and statistically highly significant result in both the groups with p value 0.000.
- 3) This might be because of the it is indicated in *Janugraha Vata Doshahara, Brmhana, Asthi Poshaka* and in the management of *JanuSandhigata Vata vis-à-vis Osteoarthritis Knee joint*.
  - Mustadi Yapana Basti is Sadhyobalakara, Rasayana, Shukra mamsa bala janana and is indicated in conditions like Janugraha and Dhatukshaya.
  - Mamsa rasa used in this, possess qualities like Prinana, Hridya, Vayastapana and Mamsa vriddikara.
  - The ingredients of Mustadi yapana Basti mainly alleviates Vata and also strengthens the knee joint. Hence it was selected for the study, which helps in the Samprapti vighatana of Janu Sandhigata vata.
  - The ingredients of Ksheera Basti are predominant of Vayu and Prutvi Mahabhuta which helps in the preservation of normal health of Asthi dhatu.
  - Doshagnata of individual ingredients have Bruhmana, Rasayana, Vatadosha hara, Balakaraka, Shotaghna, Sandhaniya, Deepana, Vedanastapaka and Astiposhaka properties and the pharmacological activities includes anti-inflammatory, analgesic, anti-oxidant and immuno modulator effect.
  - Hence, it was selected for the study, which helps in the Samprapti vighatana of Janu Sandhigata vata.

## CONCLUSION

On the basis of concepts, analysis and clinical observations made in this study, the following conclusions were drawn:

- 1) *JanuSandhigata Vata* as a clinical condition is similar to Osteoarthritis -knee joint described in contemporary medical science.

- 2) *Mustadi yapana basti* explained in *uttara basti siddhi adyaya* in *charaka samhita* which is useful in *janu graha vata vikara mamsa kshaya* along with the *karpastyadi taila anuvasana basti* used in group A comparatively more effective than the group B
- 3) *Ksheerabasti* explained in *Charaka Samhita* is a formulation advised for *Vata Vikara* in general. *Ksheerapaka of indigenous drugs* for *Niruha Basti* and *karpasatydi taila* for *Anuvasana Basti* was used in the clinical trial. All the formulations were found to be effective in the management of Osteoarthritis knee joint.
- 4) In the study it was observed that *Mustadi yapana basti* (Group A) showed considerable clinical improvement and statistically highly significant results in reduction of the pain and stiffness and WOMAC- index for Osteoarthritis with p value 0.000 and swelling p value 0.001. It showed non-significant result in reduction of crepitus with p value 0.133
- 5) *Ksheera basti of indigenous drugs* (Group B) showed considerable clinical improvement and statistically highly significant result in reduction of pain, swelling, stiffness and WOMAC-index for Osteoarthritis with p value 0.000. It showed non-significant result in reduction of crepitus with p value 0.449.
- 6) On comparing the overall effect of the study, *Mustadi yapana basti* (Group A) showed considerable clinical improvement and statistically better results than *ksheera basti of indigenous drugs* (Group B) with high chi - square value 0.575. In *Mustadi Yapana basti* Group it was observed that among 25 subjects 7 subjects (28.0%) reported marked improvement, 12 (48.0%) reported moderate improvement, 5 (20.0%) subjects reported mild improvement and 1 (4.00%) reported insignificant improvement. Whereas in *Ksheera basti of indigenous drugs Group* among 25 subjects there was marked improvement in 5 subjects (20.0%), moderate improvement in 14 (56.0%), mild improvement in 3 (12.0%) and insignificant improvement in 3 subjects (12.0%). Hence, it can be concluded that *Mustadi yapan Basti* with *karpasatyadi Taila Anuvasana* has a considerable role in the management of *JanuSandhigataVata*.

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