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# Evaluation the Efficacy of Snehapana (Oral Route) and Matra Basti (Rectal Route) with Ksheera Bala Taila in the Management of Janu Sandhi Vata (Osteoarthritis of Knee) -A Pilot Study

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# ABSTRACT:

#### **KEYWORDS**

Snehapana, matra basti , janusandhigatavat a,knee osteoarthritis, ksheerbala tail Introduction: Knee osteoarthritis is age-related degenerative disorder that comes by age in men and women. The most common joint disease among human beings is knee osteoarthritis. It can be associated with *Janu Sandhigata vata* as its indications are like to classical symptoms of Janu *Sandhigata Vata*. Keeping in mind its higher prevalence because of numerous broken existences and Vatik Ahara Vihara, it is need of hour to intricate on the safe and actual organization of Janu Sandhigata Vata in Ayurveda sciences. Matra Basti is well well-established treatment of Knee osteoarthritis but it requires hospitalizations of patients and patients have to take leave from their work and it hamper their routine works. To avoid hospitalization and busy lifestyle of the current era, it is conceptualized to elaborate new treatment options like Snehapana (oral use of unctuous substance). It does not require hospitalisations, can be given without hampering of patient's routine work, and is easy to take Snehapana without taking much time. Ksheera Bala oil was indicated for the management of VataVyadhi by Acharya Charaka in VataVyadhi Prakarana. A pilot study was carried out in 10 patients to evaluate the effectiveness of Ksheera Bala oil Snehapana in comparison thru Ksheera Bala oil Matra Basti.

**Aim and objectives :** Aim: To conduct a new treatment protocol of Snehapana of Ksheera Bala oil for the administration of *Janu Sandhigata Vata*.

Objective: Evaluate Snehapana's effectiveness in managing Janu Sandhigata Vata.

**Material and methodology:** A total of 24 patients were registered for this experimental research which were aimlessly separated into 2 groups.

In collection one 12 patients were given 60 ml Matra Basti of Ksheera Bala oil and the rest of the 12 patients were given 20 ml Snehapana of Ksheera Bala oil

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**Results:** It exposed statistically extremely noteworthy relief in all signs and symptoms in the snehapana group.

**Conclusion:** The ayurvedic treatment procedure of snehapana is effective in the management of janusandhigatavata.

#### Introduction

According to the principles of *Ayurveda*, a good life can be achieved by maintaining the balance between body and mind. Only healthy people can build a healthy life and make the country prosperous and strong. Currently, the world is facing serious health problems, but modern medicine still cannot cure people.

Therefore, it is necessary to create knowledge about *Ayurveda* among people to have a better life.

Sandhis are a fragment of Madhyama Roga Marga and hence the combination of Madhyama Roga Marga, Vata Dosha & Dhatukshaya represents Kashta Sadhya disease. Therefore, Janu-Sandhigata Vata is Shoola and Shotha pradhana Vatavyadhi, which affects physical strength and makes one unable to perform daily activities. Stress occurs when a person faces problems in daily life due to physical damage. Therefore participation in Madhyama Roga Marga, and participation of Vata Dosha and Dhatukshaya can cause kashta sadhya disease.

The role of snehana is described by *Acharya Sushruta* in Chikitsa sthana, 'Sneha *sarovayam Purusha*, meaning the soul of the human body is Sneha. Therefore, by using the above literature, it would be wise to practice Snehapana as a form of treatment for Janu Sandhigata vata which will not only revive a technique of handling that is slowly fading off but also introduce a novel technique of treatment that will benefit society this will help conserve resources used in procuring equipment's for hospital, reducing the cost incurred by the hospital in admitting patient, reducing hospital bundled cost which will lead<sup>1</sup>

Janu-Sandhigata Vata disease can be described as Sandhi (Joint) disease having features like Sandhishoola (joint pain), Sandhishotha (bone pain), and Prasaranakuncananayoh Savedana (persistent pain during movement of joints, etc.) and Hanti Sandhigatah (joint movement restriction)<sup>2</sup>.

Charaka himself described this disease "SandhigattaaAnila" but did not contain it between the 80 kinds of Nanatmaja Vyadhi. 3 Vagabhatta also measured Vata Vyadhi as Maharoga. Sandhigata Vata is a complex disease that causes disability in industrialized countries even today. Sandhigata vata appears to have similar features, signs, and symptoms as Osteoarthritis. Osteoarthritis is the 2nd most common rheumatic disease & it is the utmost common joint disease in India by an occurrence of 22% to 39%. 4 It May appear asymptomatic at the age of 20-30. Symptoms such as pain and ache appear in middle age. Approximately 45% of women over the age of 65 years knowledge symptoms, and 70% of women concluded the age of 65years have radiological evidence 5.

#### Need of Study: -

Chronic pain from arthritis is common in medical practice. Commonly used analgesics and inflammatory drugs have short- and long-term limitations. Intra-articular steroids are extensively used for OA, especially in the knee. These medications can deliver symptomatic reprieve for weeks or months. Studies in animal models have shown glucocorticoids can damage cartilage, and high doses of steroids are generally associated with damage in humans, repeated injections into joints should be given no more than once every 4 to 6 months. Even surgical treatment does not provide permanent relief. Therefore, the world is looking to Ayurveda for the safe and effective treatment of Janu-Sandhigata Vata. Modern medicine has many antibiotics, physical therapy and finally surgery, but this is not the ultimate cure and it can happen again. However, Ayurvedic methods can help improve the quality of life of Sandhigata vata patients and surgical intervention can be avoided or postponed to some extent with Ayurvedic treatment.

Treatment of knee osteoarthritis is defined in modern medicine as prevention, analgesic (pain relief) and muscle relaxants, nonsteroidal anti-inflammatory drugs

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(NSAIDs), exercise, skin adhesion, complete bed rest, & Warlike treatments such as surgery.

Limitations of these therapies are:

- Some of the side effects of pain-relieving drugs such as NSAIDs include.
- Limiting the amount of work that the patients can do and their activities in the event of being placed on bed rest.
- Those who are not willing to take surgeries because of fear and so on.

Therefore, treatment for the same should be adopted through *Ayurveda*. Numerous researches have been conducted on dissimilar subjects for the treatment of *Janusandhigata Vata*(Knee Osteoarthritis) among *Vataghna* dealings with oral medicine as well as *Panchakarma* methods such as *Basti*, *Snehapana*, *swedana Upanaha*, *Agnikarma*. Noteworthy outcomes were achieved in all subjects & targets. These treatments have many limitations such as:

- For treatments like *Basti* and *Upanaha Sweda* and *Patra Pinda Swedana*, patients need to stay in the hospital or visit the OPD every day.
- Patients do not accept treatment like Basti due to fear.
- The patients suffer multiple burns in the affected area of the knee joint due to excessive heat resulting from the *Swedana* karma.
- Treatments like *Snehadhara* and *Patra Pinda Sweda* are expensive.
- Patra-Pinda Sweda / Upanaha Sweda / Snehadhara etc. needs a lot of help every day.

Keeping all this in mind, *Snehapana* (an oral oil medicine) was used in this research. *Snehapana* can be completed at the OPD level or home deprived of any medical supervision. *Snehapana* or *Snehana* karma is stated in *Ayurvedic* literature and *Ayurvedic Acharyas* had elucidated it in different forms of *Vatavyadhi*. *Acharya Sushruta* explains the reputation of *Snehana* in *Chikitsa sthana* stating "*Sneha Saroayam Purusha*" meaning that the spirit of the human body is *Sneha*.

Considering the above information, the use of *Snehapana* in the treatment of *Janu Sandhigata vata* not only facilitates regular treatment but also emerges as a

new treatment process that benefits people and helps reduce hospitalizations. Since the treatment can be done at home, it avoids the waste being generated at the hospital.

As there is a high occurrence and disability rate in creative life span & taking into account the effectiveness of *Snehana karma* in *Janu Sandhigata vata* and classical data, a randomized clinical trial was shown to assess the effectiveness of *snehana karma* in *Janu Sandhigata vata*.

#### **Material & Methods**

**Study Type:** Interventional study

Trial design: Pilot study, open label

**Type of randomization -**computerized random sampling

Total sample size =24(12 in each group)

**Case definition**- Diagnosed cases of Janu Sandhigata Vata (Knee Osteoarthritis).

#### Diagnostic Criteria<sup>6</sup>

- 1. Janu Sandhisool (knee joint pain)
- 2. Janu sandhi jaddyata ( stiffness of knee joint)
- 3. Walking difficulty

#### 1) Inclusion criteria:

- Knee pain and crepitus
- Continuous pain at least three mnth before enrollment
- Madhayam Kostha of patients<sup>7</sup>
- Patients Aged 40 to 70 years<sup>8</sup>
- · Both genders are included
- Moderate-to-severe pain while walking
- Patients who were fit for Snehana<sup>9</sup> and Matra Basti<sup>10</sup>
   & were eager to sign the written knowledgeable agreement were only encompassed in the research.

#### 2) Exclusion criteria:-

- Patients having systemic disorders like hypertension, heart diseases or respiratory disorders
- Patients contraindicated for Matra Basti<sup>11</sup>
- BMI index of more than 41 kg/m<sup>2</sup>
- Dyslipidemia

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- Recognized cases of foremost diseases such as TB, AIDS, Anorectal malignancy
- 2ndary osteoarthritis because of rheumatoid arthritis, TB, hemophilia gout, and trauma.
- Patient who was not giving knowledgeable agreement
- Knee osteoarthritis because of trauma

#### **Treatment Protocol & Posology**

Two groups each consisting of 12 patients (Total sample size 24) were taken for the study after considering inclusion criteria and simple randomization. In group A, after initial assessment, snehapana with ksheerbala tail was given for 21 days in a dose of 2 karsha (20 ml) daily after sunrise empty stomach. Then follow-up was taken after 42 days.

In group B, after initial assessment, matra basti was given for 21 days in the amount of 60ml daily after local abhyanga and nadi swedan. Then follow-up was taken after 42 days.

Preparation and Procedure( Group A-snehapana)

#### Step 1-

The patient was advised to perform a everyday routine previously enchanting Sneha Dravya

Step 2: *Snehapana* with *Ksheera Bala Taila* was given in *Hrusva* Matra after sunrise. Once one gets the *Jeernahara* Lakshana.

Step 3: It was recommended that *Snehapana Acharika* Vidhi should be followed during this period. During this trial and up to the follow-up period, Ahara and Vihara were followed by the patients *Satmya* and *Satvika*.

Preparation and Procedure (Group B-Matra Basti):

Step 1- The *Ksheera Bala* Oil was massaged on the abdomen and buttocks in a circular motion through the process of Abhyanga. Subsequently, the Nadi kind of *Bashpa Swedana* was administered on the central part of the body.

Subsequently, the patient were instructed to assume a left lateral location with the left lower limb straight and

right lower limb bent at the knee and hip joint respectively after performing appropriate *Purvakarma*. The patient were requested to put his left hand underneath the head.

Step 2: *Ksheera Bala Taila* was used in small quantities by applying to the anus. About 60 ML of lukewarm *Ksheera Bala Taila* was occupied in the enema syringe. The rubber tube pleated with *Ksheera Bala Taila* was connected to an enema syringe, the rubber tube was then inserted in the anus of the patient up to 4 cm. 5 inches. The total Taila was not given for not allowing the ingress of the air bubble in the *Pakvashaya*.

Step 3. Later management of Basti patient was advised to take proper Rest.

#### Ksheerbala Taila<sup>12</sup>

#### I. Formulation Composition:

**Table1**: Composition of Ksheerbala Taila

Contents	English/Bota nical Name	Quantity
Bala Kashaya	Sida cordifolia	16 Parts
Bala Kalka	Sida cordifolia	1 Part
Tila Taila	Sesamum indicum	4 Parts
Ksheera (Godugdha)	Cow's Milk	4 Parts
Jala	Water	16 Parts

#### **Assessment criteria:**

The upgrading was measured in the respite of signs and indications of knee osteoarthritis. All the signs & indications were allocated a notch liable on their strictness to measure the outcome of treatment, the particulars of which are given below:

#### Womac index<sup>13</sup>:

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 Table no.21 - The Western Ontario and McMaster Universities Osteoarthritis
 Index (WOMAC)

Scale of difficulty: 0 = none, 1 = Slight, 2 = Moderate, 3 = severe, 4 = extremely severe

Pain	Walking	0	1	2	3	4
	Stair climbing	0	1	2	3	4
	Nocturnal	0	1	2	3	4
	Rest	0	1	2	3	4
	Weight bearing	0	1	2	3	4
Stiffness	1.Morning stiffness	0	1	2	3	4
	2. Stiffness occurring later in the day	0	1	2	3	4
Physical	Descending stairs	0	1	2	3	4
Function	Ascending stairs	0	1	2	3	4
	Rising from sitting	0	1	2	3	4
	Standing	0	1	2	3	4
	Bending to floor	0	1	2	3	4
	Walking on the flat surface	0	1	2	3	4
	Getting in /out of the car	0	1	2	3	4
	Going shopping	0	1	2	3	4
	Putting on socks	0	1	2	3	4
	Lying in bed	0	1	2	3	4
	Talking off socks	0	1	2	3	4
	Rising from bed	0	1	2	3	4
	Getting in/ out of bath	0	1	2	3	4
	Sitting	0	1	2	3	4
	Getting on /off toilet	0	1	2	3	4
	Heavy domestic duties	0	1	2	3	4
	Light domestic duties	0	1	2	3	4

**WOMAC OA Grading** 

Extreme

None WOMAC OA Scoring

Mild Pain: 0- 20

Moderate Stiffness: 0-8

Severe Physical function: 0-68

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Total scoring: 0-96

WOMAC OA INDEX

None: 0

Mild: 1-24

Moderate: 24-48

Severe: 48-72

Extreme: 72-96

Total score from above reading is ............/96 = ......... Percent

**Statistical methods**: The data that were obtained remained evaluated with the help of both the scholar's 't' test and the Association. In the case of continuous variables, parametric tests were used for the analysis of the collected data. Data on discrete variables were

summarized using n (%). The continuous data were summarized using mean (SD) or median (minimum-maximum). Statistical analysis were completed by the Statistical Package for the Social Sciences (SPSS) version 20, where a p value of less than 0. 05 was used as the standard for significance.

#### **Statistical Analysis:**

The data collected through observation regarding various parameters were analyzed statistically with the help of Mean, SD and SE.

The results were calculated.

Not Significant – P value is greater than 0. 05

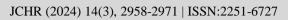
Moderate to - P < 0.1

Very Significant -P > 0.05, P > 0.01, P > 0.001, P > 0.0001.

#### **Observations:**

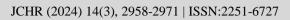
In the current research, total 24 patients were taken. Group-wise distribution of different parameters are as follows:

			GROUPING		Total		
			Matrabasti	Snehapana		Chisq	P-value
SEX	Female	Frequency	12	9	21	3.429	0.064
		%	100.0%	75.0%	87.5%		
	Male	Frequency	0	3	3		
		%	0.0%	25.0%	12.5%		
Total		Frequency	12	12	24		
		%	100.0%	100.0%	100.0%		
			GROUPING	j	Total		
			Matrabasti	Snehapana		Chisq	P-value
RELIGION	Hindu	Frequency	12	12	24	NA	NA
		%	100.0%	100.0%	100.0%		
Total		Frequency	12	12	24		
		%	100.0%	100.0%	100.0%		



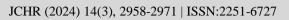


			GROUPING		Total		
			Matrabasti	Snehapana		Chisq	P-value
OCCUPATION	House wife	Frequency	12	10	22	2.182	0.14
		%	100.0%	83.3%	91.7%	-	
	Field Job	Frequency	0	2	2		
		%	0.0%	16.7%	8.3%		
Total		Frequency	12	12	24		
		%	100.0%	100.0%	100.0%		
			GROUPING	3	Total		
			Matrabasti	Snehapana		Chisq	P-value
MARITAL STATUS	Married	Frequency	12	12	24	NA	NA
		%	100.0%	100.0%	100.0%		
Total		Frequency	12	12	24	-	
		%	100.0%	100.0%	100.0%	-	
			GROUPING	<u> </u>	Total		
			Matrabasti	Snehapana		Chisq	P-value
APPETITE	Satiesfactory	Frequency	7	12	19	6.316	0.012**
		%	58.3%	100.0%	79.2%	_	
	Unsatiesfactory	Frequency	5	0	5		
		%	41.7%	0.0%	20.8%	_	
Total		Frequency	12	12	24	-	
		%	100.0%	100.0%	100.0%		
			GROUPING	<u> </u>	Total		
			Matrabasti	Snehapana		Chisq	P-value
BOWEL	Satiesfactory	Frequency	8	9	17	0.202	0.653



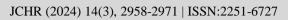


		%	66.7%	75.0%	70.8%		
	Unsatiesfactory	Frequency	4	3	7	=	
		%	33.3%	25.0%	29.2%	_	
Total		Frequency	12	12	24	=	
		%	100.0%	100.0%	100.0%		
			GROUPING	<u> </u>	Total		
			Matrabasti	Snehapana		Chisq	P-value
BLADDER	Satiesfactory	Frequency	12	12	24	NA	NA
		%	100.0%	100.0%	100.0%		
Total		Frequency	12	12	24	_	
		%	100.0%	100.0%	100.0%		
			GROUPING	J.	Total		
			Matrabasti	Snehapana			
SLEEP	Satiesfactory	Frequency	8	8	16	0	1
		%	66.7%	66.7%	66.7%	_	
	Unsatiesfactory	Frequency	4	4	8	-	
		%	33.3%	33.3%	33.3%	=	
Total		Frequency	12	12	24		
		%	100.0%	100.0%	100.0%		
			GROUPING	j J	Total		
			Matrabasti	Snehapana		Chisq	P-value
ADDICTION	None	Frequency	7	0	7	12.233	0.006
		%	58.3%	0.0%	29.2%	-	
	Tea	Frequency	5	7	12	1	
		%	41.7%	58.3%	50.0%	-	
	Coffee	Frequency	0	2	2		



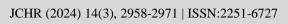


		%	0.0%	16.7%	8.3%		
	Alcohol	Frequency	0	3	3	_	
		%	0.0%	25.0%	12.5%	=	
Total		Frequency	12	12	24	_	
		%	100.0%	100.0%	100.0%		
			GROUPING	<u> </u> G	Total		
			Matrabasti	Snehapana		Chisq	P-value
BODY BUILT	Medium	Frequency	8	10	18	0.889	0.346
		%	66.7%	83.3%	75.0%	=	
	Heavy	Frequency	4	2	6	=	
		%	33.3%	16.7%	25.0%	_	
Total		Frequency	12	12	24	=	
		%	100.0%	100.0%	100.0%		
			GROUPING	<u> </u> 3	Total		
			Matrabasti	Snehapana			
BMI	Pk	Frequency	8	6	14	0.686	0.408
		%	66.7%	50.0%	58.3%	-	
	Vk	Frequency	4	6	10	-	
		%	33.3%	50.0%	41.7%		
Total		Frequency	12	12	24		
		%	100.0%	100.0%	100.0%	-	
1			GROUPING	<u> </u>	Total		
			Matrabasti	Snehapana		Chisq	P-value
PRAKRITI	Prakrati	Frequency	3	1	4	1.25	0.535
		%	25.0%	8.3%	16.7%	-	
	Sam Samveta	Frequency	2	2	4	=	





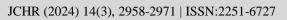
		%	16.7%	16.7%	16.7%		
	Vikrit Vishan	Frequency	7	9	16		
		%	58.3%	75.0%	66.7%	_	
Total		Frequency	12	12	24	-	
		%	100.0%	100.0%	100.0%	-	
			GROUPING	G	Total		
			Matrabasti	Snehapana		Chisq	P-value
VIKRITI	Avar	Frequency	8	11	19	2.274	0.132
		%	66.7%	91.7%	79.2%		
	Madhyam	Frequency	4	1	5		
		%	33.3%	8.3%	20.8%		
Total		Frequency	12	12	24		
		%	100.0%	100.0%	100.0%		
			GROUPING	<u> </u>	Total		
			Matrabasti	Snehapana		Chisq	P-value
SAAR	Avar	Frequency	2	0	2	2.182	0.14
		%	16.7%	0.0%	8.3%		
	Madhyam	Frequency	10	12	22		
	, , , , , , , , , , , , , , , , , , ,	%	83.3%	100.0%	91.7%	_	
Total		Frequency	12	12	24	=	
		%	100.0%	100.0%	100.0%	_	
			GROUPING	J	Total		
			Matrabasti	Snehapana		Chisq	P-value
SAMHANANA	Madhyam	Frequency	12	12	24	NA	NA
		%	100.0%	100.0%	100.0%	-	
Total		Frequency	12	12	24	=	
		%	100.0%	100.0%	100.0%	-	





			GROUPING	Ĵ		Chisq	P-value
SATVA	Avar	Frequency	4	0	4	4.8	0.028*
		%	33.3%	0.0%	16.7%	-	
	Madhyam	Frequency	8	12	20	<del>-</del>	
		%	66.7%	100.0%	83.3%	-	
Total		Frequency	12	12	24	-	
		%	100.0%	100.0%	100.0%		
			GROUPING		Total		
			Matrabasti	Snehapana		Chisq	P-value
PRAMANA	Madhyam	Frequency	8	12	20	4.8	0.028*
		%	66.7%	100.0%	83.3%	-	
	Pravar	Frequency	4	0	4	-	
		%	33.3%	0.0%	16.7%	-	
Total		Frequency	12	12	24	-	
		%	100.0%	100.0%	100.0%		
			GROUPING	<u> </u>	Total		
			Matrabasti	Snehapana		Chisq	P-value
AHAAR	Madhyam	Frequency	8	12	20	4.8	0.028*
SHAKTI							
		%	66.7%	100.0%	83.3%	-	
	Pravar	Frequency	4	0	4	-	
		%	33.3%	0.0%	16.7%	-	
Total		Frequency	12	12	24	-	
		%	100.0%	100.0%	100.0%		
			GROUPING	<u> </u> 	Total		

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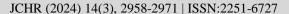
			Matrabasti	Snehapana		Chisq	P-value
VYAYAM	Avar	Frequency	9	1	10	10.971	<0.001*
SHAKTI							*
		%	75.0%	8.3%	41.7%		
	Madhyam	Frequency	3	11	14		
		%	25.0%	91.7%	58.3%		
Total		Frequency	12	12	24		
		%	100.0%	100.0%	100.0%		

			GROUPING		Total		
			Matrabasti	Snehapana		Chi Sq	P-value
Age_Group	40-55 Years	Frequency	0	9	9	14.4	<0.01
		%	0.0%	75.0%	37.5%		
	56 -70 Years	Frequency	12	3	15		
		%	100.0%	25.0%	62.5%		
Total		Frequency	12	12	24		
		%	100.0%	100.0%	100.0%		

## **Results:**

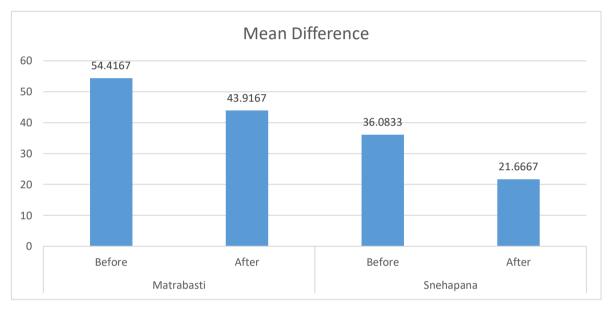
Paired Samples	Statistics						
GROUPING		Mean	N	Std. Deviation	Std. Error Mean	t-test	P-value
Matrabasti	Before	54.4167	12	5.58339	1.61179	8.426	<0.01
	After	43.9167	12	8.78489	2.53598		
Snehapana	Before	36.0833	12	9.70902	2.80275	9.275	<0.01
	After	21.6667	12	4.73542	1.36700		

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Independent t-te	Independent t-test						
GROUPING	N	Mean	Std. Deviation	Std. Error Mean	Diff.	Effect size	,P-value
Matrabasti	12	10.5000	4.31699	1.24621	3.9167	0.8074	0.062 NS
Snehapana	12	14.4167	5.38446	1.55436			



Paired t-test is used to find the significance difference amongst the means of WOMAC score , matrabasti (before& after) & snehabasti (before & after) Before giving the intervention WOMAC pre score recorded with mean 54.4167 & post with 43.9167 std. dev. With 5.58339 at pre & 8.78489 at post found resulted with significant p-value < 0.01. Thus, significantly improved (lowered down) on their score after giving the treatment of matrabasti. Similarly in snehabasti pre score recorded with mean 30.0833 & post with mean 21.6667 std. dev. With 9.709 at pre & 4.735 at post resulted with significant p-value < 0.01.

Difference between two of the treatment tested for finding the significant difference in comparative results matrabasti lowered the WOMAC score by 10.50 & std.dev.4.31 while Snehabasti decresed by 14.4167 & std.dev. 1.55 moderate effect size of 0.8074 encoutered

for the basic mean difference of 3.9167(37.88%) which can be considered as clinically significant between the two treatment .However this found to be statistically insignificant as Pvalue =0.062 > P-value=0.5.

#### **Conclusion:**

The present study also indicates that the Ayurvedic treatment protocol of Snehapana helps in the restoration of the working of knee joints. It is very useful in the handling of janusandhigatavata (Knee OA) deprived of somewhat side effects and also has long-term relief on follow-up. Thus, it can be considered a better option than the modern treatment modality and other conventional Ayurvedic treatment modalities in the management of Janusandhigatavata.

Conflict of interest: None

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