

# Effectiveness of Herbal Poultice (*Punarnavadi Upanaha Sweda*) in Relieving Pain and Stiffness in Osteoarthritis Patients: A Single-arm Clinical Trial

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## ABSTRACT

**Introduction:** In today's world, pharmacological, biochemical, and surgical treatments often fall short in effectively managing Osteoarthritis (OA). However, Ayurveda has suggested various therapies for its long-term efficacy, and Herbal Poultice is one among them. It is seen to provide analgesic and anti-inflammatory effects. The goal of the study was to evaluate the effectiveness of herbal poultice as a natural and supportive treatment option for knee OA.

**Aim:** The study's main aim was to evaluate *Punarnavadi Upanaha Sweda*'s efficacy in managing *Janusandhigatavata*, using daily poultice bandaging on the affected knee for upto seven days.

**Materials and Methods:** The present single arm clinical trial was conducted at Dr. DY Patil College of Ayurved Hospital and Research Centre Pimpri, Pune, Maharashtra, India, from April 2023 to October 2024. A total of 32 patients diagnosed with knee OA were included, and patients who had other joint disorders or permanent joint damage were excluded. Patients were also excluded if the patient had other joint disorders or permanent joint damage. The intervention consisted of *Punarnavadi Upanaha Sweda*, a poultice applied externally to the affected knee joint for six hours daily over seven consecutive days, preceded by a five-minute massage. Follow-

up assessments were conducted on the 14<sup>th</sup> day after the last treatment. Demographic parameters, including age, gender, and baseline pain levels, were recorded for all participants. To assess the effects of the treatment, joint pain was measured using the Visual Analog Scale (VAS), and joint restrictions were evaluated through goniometric measurements of the knee's range of motion. Statistical analysis was performed using the Friedman test for follow-up and the Wilcoxon signed rank test for before and after assessment, and a p-value of less than 0.05 was considered statistically significant.

**Results:** The subjective parameter viz., *Janusandhishool* (Pain), *Janusandhishotha* (swelling), *Akunchana Prasara Kashtata* (joint restriction) related to the knee joint and objective parameter viz., VAS for the pain of the knee joint and goniometric measurement for the restricted knee joint movements were statistically significant ( $p < 0.05$ ), indicating a significant improvement from baseline assessment to the end of treatment.

**Conclusion:** The study provides strong evidence for the effectiveness of *Punarnavadi Upanaha Sweda* in managing knee OA, demonstrating significant improvements in both joint pain and range of motion. These findings suggest that this Ayurvedic treatment can be a valuable option for alleviating symptoms and improving the quality of life in patients with knee OA.

**Keywords:** Healthcare, *Janusandhigatavata*, Knee osteoarthritis, Range of motion

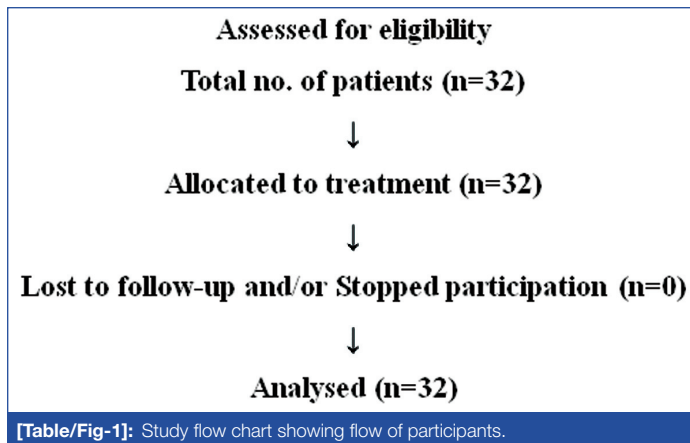
## INTRODUCTION

Osteoarthritis is a chronic degenerative condition. It primarily impacts major weight-bearing joints, such as the hips and knees. Most instances of OA are classified as primary OA, primarily associated with aging. In contrast, secondary OA arises due to another underlying disease or condition [1]. Osteoarthritis ranks as the second most common rheumatic condition and is the most prevalent Arthritis, affecting 22 to 39% of people in India [1]. In Pune specifically, the prevalence rate is 5.6% [2]. The treatment guidelines for knee OA from The National Institute for Health and Care Excellence (NICE), The American College of Rheumatology, and the European League against Rheumatism promote non-pharmacological methods. These include educating patients, providing social assistance, encouraging physical activity, and fostering weight loss [3-6]. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) are often the first treatment choice for their pain-relieving and anti-inflammatory effects, but they carry risks like gastrointestinal bleeding and kidney issues [7,8], as well as a higher chance of heart attack and stroke, particularly with COX-2 inhibitors [9]. Intra-articular injections of corticosteroids and sodium hyaluronate have limited effectiveness, leading many patients with advanced OA to consider knee replacement surgery,

which, while effective for pain relief, involves risks and costs [10,11]. Consequently, there is a growing interest in alternative therapies such as acupuncture and herbal remedies, with 60-90% of dissatisfied arthritis patients exploring Complementary and Alternative Medicine (CAM), particularly glucosamine and chondroitin sulfate [12].

In Ayurvedic texts, *Sandhigatavata* is a term used to describe a condition akin to OA. It is believed to result from improper diet, lifestyle, and aging, leading to a degeneration of bodily elements (*Dhatukshaya*), increased *Vata* (which governs bodily movements), and a decrease in *Shleshaka Kapha* which provides lubrication to the Sandhi. This increased *Vata* leads to [13] *Rukshata*, *laghavata*, and *Kharata* in the joints, contributing to degeneration. The primary symptom of *Janusandhigatavata* is knee joint pain (*Sandhi Shoola*), accompanied by swelling (*Shotha*), stiffness (*Stabdata*), crepitus (*Atopa*), and difficulty in joint function (*Akunchana Prasara Kashtata*).

*Upanaha* is classified as a form of *Swedana* in the condition of OA by *Aacharya Sushruta* and *Charaka* which pacifies *Vata* and *Kapha Dosha*. The treatment involves applying a hot, thick paste prepared with selected drugs to the area of joint pain [Table/ Fig-1], which is then wrapped in leaves and then bandaged. This



viscous paste generates sustained heat, relaxing tendons and muscles while enhancing blood circulation. The ancient text has mentioned Punarnavdi *Upanaha Sweda* in treating *Vata Vyadhi* and as *Janusandhigatavata* is categorised under *Vata Vyadhi* [14]. Therefore, *Punarnavadi Upanaha Sweda* was selected for the treatment of *Janusandhigatavata* (Knee OA).

The study aimed to evaluate the efficacy of *Punarnavadi Upanaha Sweda* in the management of *Janusandhigatavata*. The primary objective of the study was to assess the efficacy of *Punarnavadi Upanaha Sweda* in the pain reduction of *Janusandhigatavata* using the VAS scale. The secondary objective was to assess the efficacy of *Punarnavadi Upanaha Sweda* in the management of joint restriction of *Janusandhigatavata* using Goniometric measurement. The null hypothesis was *Punarnavadi Upanaha Sweda* was not effective in *Janusandhigatavata*. An alternate hypothesis was that *Punarnavadi Upanaha Sweda* was effective in *Janusandhigatavata*.

## MATERIALS AND METHODS

The present open-label, single-arm clinical trial was conducted to evaluate the efficacy of *Punarnavadi Upanaha Sweda* in patients with *Janusandhigatavata* at Dr DY Patil College of Ayurved Hospital and Research Centre, Pimpri, Pune, Maharashtra, India. The study was carried out over 18 months, from April 2023 to October 2024, involving selected patients from the Inpatient Department (IPD) and Outpatient Department (OPD). Ethical clearance was obtained from the Institutional Ethics Committee (IEC) of DY Patil Vidyapeeth (Approval No. DYPCARE/IEC/513, dated 05/08/2022), and the trial was registered with the Clinical Trials Registry of India (CTRI/2023/02/049879).

**Sample size calculation:** Based on the 5.6% prevalence of *Janusandhigatavata* in Pune [15] and an allowable error of 8%, the sample size was calculated using the formula  $n = Z^2 \times p \times (1-p) / d^2$ , resulting in a total of 32 participants.

Sample size (n) =  $Z^2 \times P \times (1-P) / d^2$

Where,

$Z = 1.96$

$p = \text{Prevalence of disease} = 5.6\%$

$d = \text{Allowable error} = 8\%$

$n = (1.96)^2 \times 0.056 \times (1 - 0.056) / (0.08)^2$

$n = 32$

So, the sample size is 32.

The total number of patients was 32. A purposive sampling technique was utilised. [Table/Fig-1] shows a flowchart depicting the flow of participants in the present randomised controlled trial.

### Inclusion criteria:

- Patients in the age group of 18 to 80 years of both genders.
- Patients of *Janusandhigatavata* have classical signs and symptoms like joint pain (*Shool*), joint swelling (*Shotha*), and

pain during movements (*Akunchan Prasaran Vedana*) (*ch. chi.28/37*) [16].

### Exclusion criteria:

- Patient with other joint disorders such as known cases of *Amavata* and *Vatarakta*;
- Known case of autoimmune diseases- diseases-ankylosing spondylitis;
- Known case of neoplasm;
- Permanent joint damage.

### Withdrawal criteria:

- The investigator felt that the protocol has been violated.
- The patient was not willing to continue the trial.

## Study Procedure

*Punarnavadi Upanaha Sweda* ingredients of *Punarnavadi Upanaha Sweda* and the quantity of each ingredient used in [Table/Fig-2], *Punarnavadi Upanaha* was prepared as mentioned in the Chapter. 1 of *Chikitsa Sthana* of *Sushrut Samhita* [17]. Treatment Protocol is explained in [Table/Fig-3].

S. No.	Ingredients	Quantity
1.	<i>Punarnava</i> ( <i>Boerhavia Diffusa</i> ) coarse powder	20 gm
2.	<i>Erand</i> ( <i>Ricinus Communis</i> Linn) coarse powder	20 gm
3.	<i>Yava</i> ( <i>Hordeum vulgare</i> ) coarse powder	20 gm
4.	<i>Atasi</i> ( <i>Linum usitatissimum</i> ) coarse powder	20 gm
5.	<i>Karpasasthi</i> ( <i>Gossypium Herbaceum</i> ) coarse powder	20 gm
6.	<i>Maasha</i> ( <i>Vigna mungo</i> ) coarse powder	20 gm
	Total 120 gm	
7.	<i>Kanji</i>	250 mL/Q.S.
8.	<i>Arkapatra</i>	Q.S.
9.	Cotton bandage	Q.S.

**[Table/Fig-2]:** Ingredients and quantity of drugs used in *Upanaha*.

Particular	Group
No. of patients	32
Treatment	<i>Upanaha Sweda</i>
Location/Area	<i>Janusandhi</i>
Duration	6 hr/day for 7 days
Assessment days	1 <sup>st</sup> and 7 <sup>th</sup> day
Follow-up	14 <sup>th</sup> day

**[Table/Fig-3]:** Treatment details of *Punarnavadi Upanaha Sweda* procedures.

**Preparation of medicine:** A course powder of *Punarnava*, *Erand*, *Yav*, *Atsi*, *Karpasasthi*, and *Masha* flour (20 gm each) was mixed and roasted until light brown, then a *Kalka* was made by adding *Kanji* (25 mL/QS).

**Preparation of patient:** A room devoid of air (*Nivatgrah*) was selected to avoid wind and discomfort. The patient, calm and following daily regimen (*Dinchariya*), was instructed to sit in a chair with the knee joint exposed, and Poultice (*Upanaha*) was applied.

**Main treatment (Pradhan Karma):** The prepared paste was applied uniformly over the affected area, about 5 mm thick, covered with *Arka* leaves and a cotton bandage for six hours, as leaves of *Calotropis procera* (*Arka Patra*) are a poor conductor of heat.

**Post-treatment (Pashat Karma):** After six hours, the Poultice (*Upanaha*) was gently removed, and a massage was done, followed by cleaning the area with lukewarm water.

**Criteria for assessment:** Patient improvement was primarily evaluated based on the relief of signs and symptoms associated with the condition. To measure the impact of the therapy both subjectively and objectively, each sign and symptom was assigned a score according to its severity. The following periodic functional

tests were conducted to subjectively and objectively assess the progress of patients with *Janusandhigatavata*. The subjective and objective parameters are mentioned in [Table/Fig-4] [18-20].

Subjective parameters	Grades	Features
<i>Sandhishool</i> (Joint pain)	0	No pain
	1	Mild pain
	2	Moderate pain
	3	Severe pain
<i>Sandhishotha</i> (Joint swelling)	0	No swelling
	1	Mild swelling
	2	Moderate swelling
	3	Severe swelling
<i>Akunchana Prasarana Kashatata</i> (joint restriction)	0	No restriction
	1	Partially restricted without painful movement
	2	Partially restricted with painful movement
	3	Fully restricted
Objective parameter using goniometer	Observation (in degree)	Scale
Flexion	135	0
	<135, >100	1
	<100, >75	2
	<75	3
Extension	0	0
	10	1
	20	2
	45	3
<b>VAS scale</b>		
Observed on 1 <sup>st</sup> Day 7 <sup>th</sup> Day 14 <sup>th</sup> Day		

[Table/Fig-4]: Subjective and objective parameters [18-20].

### The overall effect of therapy [21]:

Less than 25% relief=No change;

25-49% relief=Slight improvement;

50-74% relief=Moderate improvement;

75-99% relief=Significant improvement;

100% relief=Complete remission.

## STATISTICAL ANALYSIS

The result of before and after treatment by Wilcoxon signed rank test was p-value <0.05, there was a significant difference in grades of 'Goniometer Flexion,' 'Goniometer Extension,' and VAS scores after treatment. A negative rank indicated it reduced after treatment. Ties indicate it remains the same. As in most of the patients it gets reduced, and treatment is effective in reducing grades of Goniometer Flexion,' 'Goniometer Extension,' and VAS scores. Friedman test was applied too.

## RESULTS

The most affected age group was 51-60 years, with 11 patients (34%) in this category 10 patient (31%) from 61-70 years, six patients

(19%) from 41-50 years, three patients (9%) from 71-80 years, and only two patients (6%) from age group 31-40 years. Additionally, the majority of the patients were female (59%),19 patients, and 30 patients (94%) identified as Hindu. Half of the participants, 16 patients (50%), were housewives, while 18 patients (56%) followed a vegetarian diet. Furthermore, 14 patients (44%) had *Vata Prakruti*, 14 patients (44%) experienced *Vishama Agni*, and 27 patients (84%) were classified as having *Madhyama Koshtha*.

**Effect of therapy on outcome measures:** The results demonstrate a significant difference in the grades of '*Sandhi Shoola*,' '*Sandhishotha*,' and '*Akunchana Prasarana Kashtata*' after treatment, with a p-value <0.05. Most patients experienced reductions in symptoms, indicating the treatment's effectiveness [Table/Fig-5]. Similarly, showed significant improvements post-treatment, also with a p-value <0.05. Most patients reported decreased grades, further confirming the treatment's efficacy [Table/Fig-5]. Overall, these findings underscore the positive impact of the treatment on joint pain and mobility. 'Goniometer Flexion,' 'Goniometer Extension,' and VAS scores. The test statistics for all parameters are large (ranging from 38.079 to 94.182), and the p-values for all parameters are less than 0.001, indicating highly significant differences between the measurements at Day 1, Day 7, and Day 14.

The p-value being less than 0.05 for all tests confirms that there are significant changes in joint pain, swelling, restriction, goniometer measurements, and VAS scale over the course of the study. The analysis shows significant differences in the grades of '*Sandhi Shoola*,' '*Sandhishotha*,' and '*Akunchana Prasarana Kashtata*' at each follow-up, with a p-value below 0.05, indicating substantial reductions after treatment. Similarly, 'Goniometer Flexion,' 'Goniometer Extension,' and VAS scores also showed significant decreases during follow-ups, supported by a p-value below 0.05 [Table/Fig-6]. These results are further illustrated in Graphs 1, 2, and 3, confirming the treatment effectiveness.

**The overall effect of the treatment:** [Table/Fig-7] illustrate that 56% of patients i.e., 18 patients experienced moderate improvement after treatment, while 44% means 14 patients showed mild improvement. Notably, no patients exhibited marked improvement or reported no change and complete remission, indicating that the treatment was effective for all patients involved. This highlights the overall positive impact of the treatment on patient outcomes. Based on these outcomes, where all participants demonstrated some degree of clinical improvement, the null hypothesis was rejected, indicating that *Punarnavadi Upanaha Sweda* had a significant therapeutic effect in the management of *Janusandhigatavata* (knee OA).

The most affected age group was 51-60 years, with 11 patients (34%) in this category 10 patients (31%) from 61-70 years, six patients (19%) from 41-50 years, three patients (9%) from 71-80 years, and only 2 patients (6%) from age group 31-40 years. Additionally, the majority of the patients were female (59%),19 patients, and 30 patients (94%) identified as Hindu. Half of the participants, 16 patients (50%), were housewives, while 18 patients (56%) followed a vegetarian diet. Furthermore, 14 patients (44%) had *Vata Prakruti*, 14 patients (44%) experienced *Vishama Agni*, and 27 patients (84%) were classified as having *Madhyama Koshtha*. Based on

Parameters	Test	W value	p-value	Negative ranks	Positive ranks	Ties	Total
Subjective parameters	Joint pain ( <i>Sandhi shool</i> )	-5.000	<0.001	25	0	7	32
	Joint Swelling ( <i>Sandhi shotha</i> )	-4.359	<0.001	19	0	13	32
	Joint restriction ( <i>Akunchana prasarana kashtata</i> )	-5.099	<0.001	26	0	6	32
Objective parameters	Goniometer flexion	-4.472	<0.001	20	0	12	32
	Goniometer extension	-5.000	<0.001	25	0	7	32
	Vas scale	-5.016	<0.001	32	0	0	32

[Table/Fig-5]: Before and after treatment results for subjective and objective parameters.

Test applied - Wilcoxon signed rank test, (Negative Ranks indicate a decrease in the measured parameter (e.g., joint pain, swelling, restriction). Positive Ranks indicate an increase in the measured parameter. Ties occur when the paired measurements are the same (no change))



Parameters	Parameters	Mean Rank Day 1	Mean Rank Day 7	Mean Rank Day 14	Test statistics	p-value
Subjective parameters	Joint pain ( <i>Sandhi shool</i> )	2.88	1.78	1.34	52.000	<0.001
	Joint swelling ( <i>Sandhi shotha</i> )	2.61	1.97	1.42	38.079	<0.001
	Joint restriction ( <i>Akunchan prasaran kashata</i> )	2.89	1.72	1.39	51.455	<0.001
Objective parameters	Goniometer flexion	2.80	1.89	1.31	48.274	<0.001
	Goniometer extension	2.86	1.77	1.38	51.053	<0.001
	VAS scale	3.00	1.95	1.05	94.182	<0.001

**[Table/Fig-6]:** Follow-up-wise result for subjective and objective parameters.  
Test applied -Friedman test, p<0.001 considered significant

Overall effect	Number of patients	n (%)
Complete remission	0	0 (0%)
Significant improvement	0	0 (0%)
Moderate improvement	18	18 (56%)
Mild improvement	14	14 (44%)
No improvement	0	0 (0%)

**[Table/Fig-7]:** Overall effect of the treatment.

these outcomes, where all participants demonstrated some degree of clinical improvement, the null hypothesis was rejected, indicating that *Punarnavadi Upanaha Sweda* had a significant therapeutic effect in the management of *Janusandhigatavata* (knee OA).

**Adverse drug reaction:** It is significant to mention that no adverse drug reactions were noted during the trial, underscoring the safety of the treatment method.

## DISCUSSION

The findings from the present study align with previous research suggesting that age is a significant contributing factor to knee OA. The majority of patients in this study were in the 51-60 age groups, supporting the well-established trend that OA prevalence increases with age [22]. This is consistent with studies from the World Health Organisation (WHO), which also identified age as a significant factor in the development of OA.

Additionally, the study highlighted the higher prevalence of knee joint pain in women, with 59% of participants being female. This finding is consistent with research indicating that women are more susceptible to knee pain due to factors such as hormonal fluctuations, differences in bone density, and post-pregnancy changes [23]. These factors likely increase the risk of developing knee OA, particularly in the context of hormonal changes during menopause.

The demographic data also reflected the cultural and dietary influences of the study population. As Pune has a high population of Hindus, it is not surprising that a significant number of Hindu patients were enrolled, with no bias in selection [24]. Moreover, Pune's predominance of vegetarians was evident, as a large proportion of participants followed a vegetarian diet, which aligns with findings from other studies indicating the impact of diet on health outcomes [25]. In Ayurveda, dietary choices play a significant role in maintaining balance, and it is essential to consider these factors in the context of treatment efficacy.

From an Ayurvedic perspective, individuals with a *Vata-dominant Prakriti* are particularly susceptible to conditions like *Janusandhigatavata* (knee OA). This study corroborates the understanding that an imbalance in *Vata* is a primary cause of OA. The *Ruksha* (dry), *Ushna* (hot) and *Tikshna* (sharp) qualities of the ingredients in *Punarnavadi Upanaha Sweda* are well-suited to balance *Vata*, as they help to liquefy the *Doshas* and cleanse the channels, thereby addressing *Margavarana* (blockages) caused by *Vata* Dosha [26]. The *Snigdha* (unctuous) properties of the treatment further support the pacification of *Vata* Dosha, aiding in the relief of pain and stiffness. These effects are consistent with Ayurvedic principles, which emphasise the role of herbal treatments in correcting dosha imbalances.

In terms of pharmacological action, the ingredients in *Punarnavadi Upanaha Sweda* also play a significant role. *Punarnava* (*Boerhavia diffusa*), which contains saponins, has well-documented diuretic and anti-inflammatory properties [27]. *Erand* (Castor oil) is known for its analgesic and anti-inflammatory effects, thanks to its high concentration of ricinoleic acid [28]. The anti-inflammatory action of *Yava* (barley) saponins, which inhibit prostaglandin production, also contributes to the reduction of inflammation [29]. The inclusion of Alpha-linolenic acid (ALA) from *Atasi* (flaxseed) further enhances the anti-inflammatory potential of the treatment, as omega-3 fatty acids are known to support heart health and alleviate inflammation [30]. *Karpasasthi* and *Masha* contain antioxidants that help mitigate oxidative stress, which is a factor in the development and progression of OA. The bioactive peptides found in fermented foods like *Kanji* also possess antihypertensive and anti-inflammatory effects, further complementing the therapeutic properties of the herbal poultice.

The statistical findings from the study indicate that *Punarnavadi Upanaha Sweda* therapy effectively reduces pain, stiffness, and joint restriction, leading to significant improvements in knee joint function. The reduction in both VAS scores and goniometric measurements demonstrates the efficacy of this treatment in improving the quality of life. This supports the growing body of evidence on the therapeutic potential of Ayurvedic treatment in managing musculoskeletal disorders.

The findings of this study are consistent with those of previous clinical trials that have assessed the efficacy of Ayurvedic treatments for knee OA. Several studies have demonstrated that Ayurvedic therapies, such as herbal poultices, oils, and massages, can significantly reduce pain and improve joint function in OA patients. A study by (A comparative clinical study of the effect of *Upanaha Sweda* by using *Kottamchukkadi Churna* and *Grihadhumadi Churna* in *Janusandhigata Vata* w.s.r. to OA of Knee Joint by Dr. Reshmi PK, Dr. Sudarshan A, Dr. Jeejo Chandra found that Ayurvedic treatments provided relief from joint pain and stiffness, similar to the results observed in the present study [30]. However, our study adds value by highlighting the specific role of *Punarnavadi Upanaha Sweda* in managing *Janusandhigatavata* and supporting the broader body of evidence regarding Ayurvedic therapies for knee OA.

The results of this study highlight the potential of *Punarnavadi Upanaha Sweda* as an effective complementary therapy for knee OA. Its ability to reduce pain, stiffness, and joint restriction provides a promising treatment option for patients seeking non-invasive therapies. Future studies should focus on larger sample sizes, long-term follow-up, and comparisons with other standard treatments to better understand its full clinical potential. Additionally, exploring the underlying mechanisms of action and integrating modern pharmacological and Ayurvedic perspectives could further enhance the therapeutic efficacy of this treatment.

## Limitation(s)

However, the study does have some limitations. The study was limited to a short-term observation period of 14 days, and long-term effects were not assessed. Finally, being a single-arm study, the lack of a control group might introduce bias and limit comparisons with other treatments.

## CONCLUSION(S)

The study aimed to evaluate the efficacy of *Punarnavadi upanaha Sweda* in the management of *Janusandhigatavata*. Statistical analysis showed that *Punarnavadi Upanaha Sweda* significantly alleviates joint pain on the VAS and increases the range of motion, evidenced by improvement in goniometric measurements. Therefore, it is concluded that *Punarnavadi Upanaha Sweda* effectively manages *Janusandhigatavata* (knee OA), demonstrating its potential as a therapeutic approach in relieving symptoms of knee OA.

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