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EFFICACY OF *JĀNUDHĀRA* (MEDICATED OIL POURING OVER THE KNEE) WITH *MAHABALA TAILA* IN COMPARISON TO *KETAKYĀDI TAILA* IN THE MANAGEMENT OF OSTEOARTHRITIS OF KNEE - A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT: **Introduction:** Osteoarthritis of the knee is a common degenerative joint disorder and a major cause of pain and disability, especially among the elderly. In Ayurveda, the condition closely resembles *Sandhigata Vāta* (degenerative joint disorder). *Jānudhāra* (continuous pouring of lukewarm medicated oil over the knee joint) is categorized under *Snehayukta Svedana* (unctuous fomentation therapy) due to its combined oleation and sudation effects. Previous studies on *Ketakyādi Taila* had established its effectiveness in osteoarthritis management. *Mahābala Taila* is commonly employed for osteoarthritis of the knee, though systematic research data regarding its clinical efficacy are limited. **Aim and Objectives:** This study aimed to evaluate and compare the efficacy of *Jānudhāra* using *Mahābala Taila* and *Ketakyādi Taila* in the management of osteoarthritis of the knee and to determine any significant difference in symptom relief and joint mobility. **Methods:** This randomized controlled clinical trial was conducted on 24 patients diagnosed according to the American College of Rheumatology clinical criteria. Participants were randomly allocated into two groups. The trial group received *Jānudhāra* with *Mahābala Taila*, while the control group received *Jānudhāra* with *Ketakyādi Taila*, once daily for seven consecutive days. Assessment was carried out using the WOMAC score and range of motion measured by goniometry at baseline, Day 8, and Day 15. **Results:** Both groups showed statistically significant improvement in WOMAC total scores and knee joint range of motion. Intergroup comparison revealed no statistically significant difference between the two groups. No adverse drug reactions were reported during the treatment or follow-up period. **Discussion:** Comparable outcomes observed in both groups suggest that the therapeutic benefit may be largely attributed to the combined oleation and sudation effects of *Jānudhāra* rather than the specific oil used. Both formulations reduce pain and functional limitation in knee osteoarthritis through similar mechanisms of action. **Conclusion**: *Jānudhāra* with *Mahābala Taila* is equally effective as *Ketakyādi Taila* in reducing pain, stiffness, and functional disability in knee osteoarthritis.
Key-words: *Jānudhāra*, *Sandhigata Vāta*, *Mahābala Taila*, *Ketakyādi Taila*, Osteoarthritis of knee, WOMAC score.

INTRODUCTION: In Ayurveda, osteoarthritis is conceptually understood under the broad spectrum of *Sandhigatavāta* (degenerative joint disease), a clinical condition characterized by the vitiation of *Vāta doṣa* (bio-regulatory principle governing movement) in the joints. Progressive ageing contributes to *dhātu kṣaya* (degeneration of body tissues), which in turn leads to the aggravation of *Vāta doṣa* (bio-regulatory principle governing movement).[1] The aggravated *Vāta* localizes in the *Sandhi* (joints), producing classical features such as *Sūla* (pain), *Stabdhata* (stiffness), and restricted joint movements, ultimately resulting in functional limitation. Classical management of *Sandhigatavāta* (osteoarthritis) emphasizes therapies such as *Snehana* (oleation therapy), *Svedana* (sudation therapy) and procedures like *Agnikarma* (therapeutic cauterization), among which *Jānudhāra* (therapeutic streaming of medicated oil over the knee joint) plays an important role due to its combined oleation and sudation effects.[2]

Osteoarthritis is a chronic degenerative joint disorder characterized by progressive degradation of articular cartilage, menisci and ligaments, along with minimal synovial inflammation and structural changes in the subchondral bone.[3]In India, around 23.46 million people were affected by Osteoarthritis in 1990, which has increased to over 62.35 million in 2019.[4] In Kerala, the age-standardized prevalence was reported to be as high as 5658 per 10,0000 population in 2019.[5] Clinically, osteoarthritis presents with persistent pain, swelling, morning stiffness and restricted movement, leading to impaired quality of life and significant socioeconomic burden.[6] Diagnosis is commonly based on clinical criteria such as the American College of Rheumatology guidelines. Despite advances in modern medical management, the treatment of osteoarthritis remains largely palliative.

Parisheka sveda[7] (therapeutic streaming sudation therapy) is one among the two varieties of *Drava sveda* (liquid sudation therapy) described in Ayurveda, wherein warm medicated liquids such as *Kvātha* (herbal decoction), *Taila* (medicated oil), *Ghṛta* (medicated ghee), *Dugdha* (medicated milk), *Kāñji* (fermented sour gruel) and *Gomūtra* (cow's urine) are poured continuously over the body from a specific height, a procedure commonly referred to as *Seka* (therapeutic pouring).[8] Depending on the extent of application, it may be performed as *Ekāṅga* (localized application to a single body part) or *Sarvāṅga Parisheka sveda* (whole-body streaming sudation therapy).[9] Classical texts describe its effectiveness in alleviating pain, stiffness and functional impairment associated with conditions such as trauma, burns and lacerated wounds.[10] When administered locally over the knee joint, it is termed *Jānudhāra* (therapeutic streaming of medicated oil over the knee joint), wherein lukewarm medicated oil is poured in a continuous stream for a stipulated duration. This procedure is categorized under *Snehayukta svedana* (oleation-based sudation therapy), as it combines the effects of *Snehana* and *Svedana*. *Jānudhāra* is predominantly indicated in painful conditions, which can be degenerative or post inflammatory

phases of joint diseases and other musculoskeletal pains.[11]

The classics of Ayurveda describe various *taila* (medicated oil) formulations for external therapeutic procedures. Among them, *Mahābala taila*,[12] a formulation from the medieval period and a variant of *Dhanwantaram Taila*[13] is indicated in repeated trauma, vital injuries and various *Vātavyādhi* (neuromuscular and degenerative disorders caused by *Vāta*). Clinically, it is widely used in the management of osteoarthritis of the knee, especially in procedures like *Jānudhāra*. *Ketakyādi taila*,[14] indicated for aggravated functional imbalance *affecting Asthi dhātu* (bone tissue), has been extensively studied and proven effective in osteoarthritis of the knee. Previous clinical studies[15] have demonstrated significant improvement in pain, stiffness and functional ability with *Ketakyādi taila* based *Jānudhāra* in *Sandhigatavāta*. However, comparative clinical evidence between *Mahābala taila* and *Ketakyādi taila in Jānudhāra* remains nil. *Mahābala taila* is popularly used for *Jānudhāra* in osteoarthritis of knee. therefore, a comparative evaluation is essential to generate evidence-based guidance for clinical practice.

AIM AND OBJECTIVES

- To evaluate and compare the efficacy of *Jānudhāra* using *Mahābala Taila* and *Ketakyādi Taila* in the management of osteoarthritis of the knee
- To determine any significant difference in symptom relief and joint mobility

Materials and Methods

Diagnostic criteria

The American College of Rheumatology clinical classification criteria of knee OA[16]

Major criteria

- Pain in knee

Minor criteria (Any three)

- Age > 50 years
- Morning stiffness < 30 minutes
- Crepitus on knee motion
- No palpable warmth
- Bony tenderness
- Bony enlargement

Inclusion criteria

- Participants fulfilling the diagnostic criteria
- Age – 40 -70 years
- Gender- No discrimination
- Radiological finding of knee of Grade 2-4 in Kellgren-Lawrence Grading scale[17]
- Fit for *Snigdhasweda*
- Participants willing to give informed consent

Table no 1 Assessment parameters

Item	End point	Frequency
Reduction of signs and symptoms	**Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) Score[18]**	**0^{th}, 8^{th} and 15^{th}**
Range of movement	**Goniometry**	**0^{th}, 8^{th}, and 15^{th}**

The study was a randomized, open labelled, parallel group, controlled trial. The study got approved by the Institutional Ethics Committee (approval number IRB/CL/21/23, dated 11/10/2023).

A total of 24 participants who met the inclusion criteria were enrolled in the study. The sample size of 24 participants (12 in

each group) was selected considering the exploratory nature of the study and feasibility constraints, to obtain preliminary evidence regarding the comparative efficacy of the two interventions.

A computer-generated randomization method was used to allocate participants into two groups. The trial group received *Jānudhāra* with *Mahābala Taila*, while the control group received *Jānudhāra* with *Ketakyādi Taila*.Both *Mahābala Taila* (Batch no: 222182) and *Ketakyādi Taila* (Batch no: 010288) used in the study were procured from Arya Vaidya Sala, Kottakkal, a GMP-certified pharmaceutical manufacturer.

Informed consent:

A structured informed consent proforma approved by the Institutional Ethics Committee was provided in the local language (Malayalam), explaining the study protocol, potential benefits, and possible complications. Written informed consent was obtained from all participants before enrolment. A pre-designed case record form (CRF) proforma was maintained for each participant to systematically document demographic data, clinical findings, intervention details, and outcome assessments.

The study was conducted in the In-Patient Department (IPD) of VPSV Ayurveda College Hospital, Kottakkal.

In both groups, *Jānudhāra* was performed with the participant positioned comfortably and the affected knee adequately exposed. The medicated oil was heated using a hot water bath and maintained at 39°C–42°C throughout the session. Lukewarm oil was then poured in a continuous, steady stream in a circular manner over the entire knee joint from a height of 12 *Aṅgula* (24 cm), along with gentle manual massage. Approximately 2.5 liters of oil was used per session for 45 minutes daily for seven consecutive days (8 AM–5 PM). The same oil was reused for up to three days, with fresh oil introduced on the fourth day. After completion, participants were advised to rest for one hour followed by a warm water bath.

Image 1 showed standardized *Janudhara* with controlled height and continuous stream

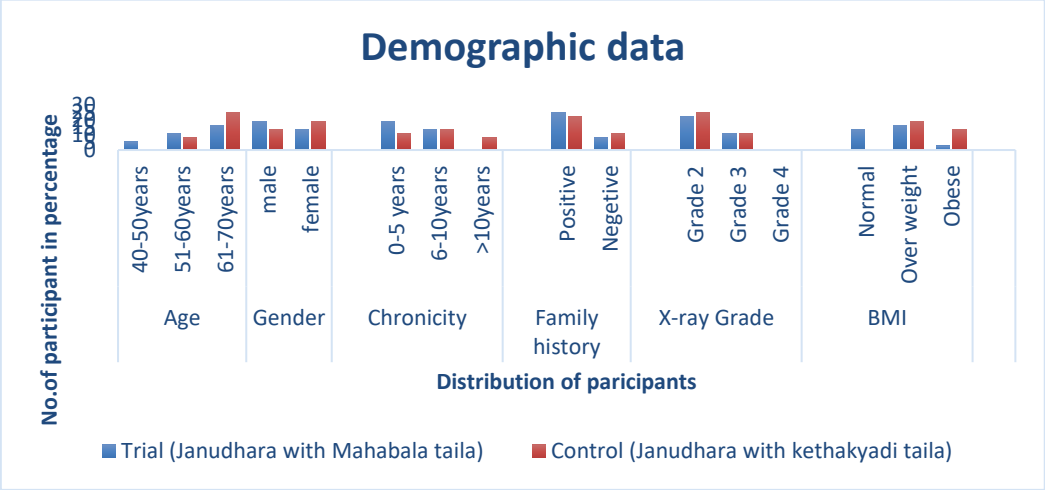
To keep the height accurate, a uniform flow and continuous *Dhāra*(pouring), *Dhāra* vessel and *Dhāra* unit conventionally used for head was taken for conducting the procedure. For standardization, one *Aṅgula* (classical Ayurvedic unit of linear measurement) was considered equivalent to 2 cm[19]. The temperature of the medicated

oil was maintained between 40°C and 42°C, which was intermittently monitored using a laboratory thermometer. Fresh oil was used on every fourth day, while the same oil was reused for a maximum of three consecutive days after reheating.

Intention-to-treat principle was followed and a significance level of $p < 0.05$ was fixed. As the data were not normally distributed, Friedman test was used for within-group comparison, Wilcoxon signed-rank test for pairwise comparison, and Mann–Whitney U test for between-group comparison.

OBSERVATION AND RESULT

The demographic distribution showed that the majority of participants in both groups belonged to the 61–70 years age group, with a slight male predominance in the trial group and female predominance in the control group. Most participants had a disease duration of 0–5 years and a positive family history of osteoarthritis. Radiological evaluation based on the Kellgren–Lawrence scale revealed Grade 2 osteoarthritis as the most common finding, followed by Grade 3, with no Grade 4 cases reported. A considerable proportion of participants in both groups were overweight.



Graph -1 Multiple bar diagram showing the distribution of participants according to demographic variables

Table No.2 Comparison of WOMAC TOTAL score between different period for each group using Friedmann's test

Treatment	Mean Rank			Chi square	P value
	Baseline	After treatment	Follow up		
Trial	3.00	1.88	1.13	22.80	.000
Control	2.92	1.71	1.38	20.48	.000

In Table No.2, there was a statistically significant reduction in WOMAC total scores across baseline, after treatment, and follow-up in both the trial and control groups ($p < 0.05$). The progressive decrease in mean rank values indicates continuous improvement over time in both groups.

Table No.3 Within group changes in WOMAC TOTAL scores using Wilcoxon signed – rank test

Group	BT-AT		AT-AF	
	Z	P value	Z	P value
Trial	-3.062	.002	-2.680	.007
Control	-2.941	.003	-1.841	.066

Table No.3 showed a statistically significant reduction in WOMAC total scores from baseline to after treatment in both trial and control groups. From after treatment to follow-up, the trial group showed significant improvement, while the control group did not show a statistically significant change.

Table No.4 Effect of treatment on WOMAC TOTAL score between groups using Mann-Whitney test

	Groups	Mann- whitney U	Z	P value
BT-AT	Trial	58.500	-.783	.443
	Control			
AT- AF	Trial	45.000	-1.65	.128
	Control			

Table No.4 shows the between-group (trial Vs Control) analysis of WOMAC total scores using the Mann–Whitney U test demonstrated no statistically significant difference between the *Mahābala taila* and *Ketakyādi taila* groups during both baseline to post-treatment ($p = 0.443$) and post-treatment to follow-up ($p = 0.128$) periods, indicating comparable therapeutic outcome.

Table No.5 Comparison of flexion between different period for each group using Friedman's test

Treatment	Mean Rank			Chi square	P value
	Baseline	After treatment	Follow up		
Trial	1.25	2.25	2.50	16.80	.000
Control	1.21	2.08	2.71	18.16	.000

Table No.5 shows a statistically significant improvement in knee flexion in both the trial and control groups across baseline, after treatment, and follow-up periods ($p < 0.05$).

Table No.6 Within group changes in Flexion using Wilcoxon signed – rank test

Group	BT-AT		AT-AF	
	Z	P value	Z	P value
Trial	2.59	.009	1.34	0.180
Control	2.53	.011	2.21	0.003

In Table No.6, Both groups showed significant improvement in knee flexion from baseline to after treatment ($p < 0.05$). However, from after treatment to follow-up, significant improvement was seen only in the control group.

Table No.7 Effect of treatment on range of motion between groups using Mann-Whitney test

Range Of Motion	Comparison	Mann-whitney U	Z	P value
Flexion	**BT – AT**	58.00	-.828	.443
	AT – AF	68.50	-.212	.843
Extension	**BT – AT**	66.00	-1.00	.755
	AT – AF	66.00	-1.00	.755

Table No.7, Mann–Whitney U test showed no statistically significant difference in flexion and extension between the trial and control groups at different assessment intervals ($p > 0.05$).

DISCUSSION: The present randomized controlled clinical trial was conducted to evaluate the efficacy of *Jānudhāra* with *Mahābala Taila* in comparison to *Ketakyādi Taila* in the management of osteoarthritis of the knee. A statistically significant reduction in WOMAC total score was observed within both trial and control groups, indicating effective reduction in pain, stiffness, and functional disability following *Jānudhāra.* Within-group analysis from after treatment (AT) to after follow-up (AF) also demonstrated sustained improvement in WOMAC scores, suggesting that the therapeutic effects of *Jānudhāra* persisted even after completion of the treatment period. This indicates that the procedure may provide prolonged symptomatic relief in patients with knee osteoarthritis. However, between-group comparison did not reveal a meaningful result, suggesting that *Jānudhāra* with *Mahābala Taila* is equally effective as *Jānudhāra* with *Ketakyādi Taila* in improving overall disease severity.

Mahābala Taila is rich in *Guru* (heavy), *Snigdha* (unctuous), and *Uṣṇa Guṇa* (hot potency attributes) and possesses *Balya (strength-promoting), Rasāyana* (rejuvenative)*, and Vāta-Kaphahara* (Relieves pain, stiffness, heaviness, and swelling), making it effective in conditions associated with *Dhātu kṣaya* (tissue depletion) and joint degeneration.[18] *Ketakyādi Taila*, indicated in *Asthigata Vāta*[20] (aggravated functional imbalance affecting bone tissue) , also exhibits strong *Vāta-hara* (Supports smooth movement and relieves discomfort), *Vedanāsthāpana* (analgesic), and *Śothahara* (anti-inflammatory) actions.[21]

The comparable efficacy observed in this study suggests that both formulations adequately address the underlying pathophysiology of osteoarthritis, supporting their interchangeable use in clinical practice when administered through *Jānudhāra*.

Pain is the most common symptom of osteoarthritis and arises from a combination of structural, inflammatory, and neurophysiological mechanisms rather than cartilage degeneration alone. [22]Exposure of the richly innervated subchondral bone, synovial inflammation mediated by prostaglandins and cytokines (IL-1β, TNF-α, IL-6), osteophyte formation, capsuloligamentous stretching, altered biomechanics, and central sensitization all contribute to pain perception, explaining the poor correlation between radiographic severity and symptoms.[23]

The continuous pouring of warm medicated

oil during *Jānudhāra* provides sustained thermal and mechanical stimulation, promotes vasodilatation, enhances tissue absorption, and produces hypoanalgesic effects.[24]

In the present study, both groups showed statistically significant improvement in WOMAC pain scores with comparable percentage relief. From an Ayurvedic perspective, pain is attributed to aggravated *Vāta doṣa*, and *Jānudhāra*, as a *Sneha-sveda* therapy, pacifies *Vāta* and alleviates pain. Similar pain relief with *Jānudhāra* at 12 *Aṅgula* (24cm; traditional unit of measurement) has been reported by Richa Parmar et al.[25] supporting the present finding.

A statistically significant reduction in stiffness scores was observed in both groups, with nearly equal percentage improvement. Stiffness in osteoarthritis is related to synovial inflammation, capsular fibrosis, osteophyte formation, and muscle weakness. The unctuous and warming effects of *Jānudhāra* may help soften periarticular tissues, improve lubrication, and reduce resistance to movement. In Ayurvedic terms, stiffness (*Stambha*) is a manifestation of *Sandhigata Vāta*, and the combined *Snehana* and *Svedana* effects of *Jānudhāra* counteract the *Rukṣa* (dry quality) and *Śīta Guṇa* (cold attribute) of aggravated *Vāta*.[26]

Assessment of knee range of motion revealed improvement in flexion in both groups, with no statistically significant difference between *Mahābala Taila* and *Ketakyādi Taila*. Knee extension remained normal throughout the study period in all participants, likely due to the predominance of mild to moderate radiographic changes. While *Jānudhāra* effectively reduces pain and stiffness, it does not provide the deep mechanical stretch required to reverse established capsular or ligamentous shortening, which may explain the absence of marked changes in extension. These observations are consistent with previous studies,[27] reporting improvement in flexion but minimal effect on extension in osteoarthritis.

The therapeutic benefits of *Jānudhāra* may be attributed to a combination of thermal, mechanical, pharmacological, and neurophysiological mechanisms. Sustained warmth enhances local circulation and tissue flexibility.[28] While gentle mechanical stimulation activates cutaneous mechanoreceptors and modulates pain perception through spinal gating mechanisms.[29] The medicated oils contribute anti-inflammatory and analgesic effects, and continuous external application may facilitate transdermal absorption and improved joint lubrication.[30] And also, the rhythmic and soothing nature of the procedure promotes relaxation and parasympathetic dominance, contributing to overall symptom relief.[31]

The absence of a statistically significant difference between the comparison groups has also been reported in several other procedural studies.[32,33] This observation warrants careful consideration by the Ayurvedic research community, as it may reflect methodological limitations in study design. Although no significant difference was observed in efficacy scores between the trial and control interventions, variations may exist in qualitative attributes described in Ayurveda, such as *Snigdhata* (degree of unctuousness) and *Gurutva* (degree of heaviness), etc. These properties are inherently difficult to quantify using conventional outcome measures. Therefore, future

research may incorporate objective assessment tools to evaluate parameters such as degree of oleation or tissue changes to better differentiate the effects of various formulations.

Limitations

As participants eligible for Snigdha Sveda were included in the study, a few participants received preparatory interventions such as *Lepa* (topical medicated paste application), *Dhanyamla Dhāra* (pouring of fermented herbal liquid), or *Upanaha* (medicated poultice application) prior to the initiation of *Jānudhāra* to alleviate inflammatory features or symptoms suggestive of *Āma* (metabolic toxins). Since these interventions possess independent anti-inflammatory and analgesic properties, their administration may have contributed to symptomatic improvement and potentially influenced the overall treatment outcomes. In addition, some participants had osteoarthritis in only one knee, while others had both knees affected. Even though the duration of *Dhāra* was given separately for each joint, this difference in joint involvement which might have influenced the treatment responses among participants.

CONCLUSION: The study revealed a significant improvement in the WOMAC total score within both the trial and control groups. However, the between-group analysis did not demonstrate statistical significance, indicating that both interventions *Jānudhāra* with *Mahābala Taila* and *Jānudhāra* with *Kethakyādi Taila*, were equally effective in reducing the WOMAC scores in osteoarthritis of the knee.

Self Declaration: hereby declare that I have not used Artificial Intelligence (AI) or AI-based tools for the preparation of this manuscript.

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