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Research Article

To Evaluate the Efficacy of Add on Treatment of Oral Drug Formulation With Agnikarma in the Management of Jaanu Sandhigata Vata W.S.R. To Osteoarthritis of Knee Joint – a Randomized Controlled Trial

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Abstract

Background: Recent estimates suggest that OA affects approximately 7.6% of the globalpopulation, with knee OA being especially common among older adults. The combined approach of *Agnikarma* and oral drugs holds significant promise as an effective option forosteoarthritis. Objective: To Evaluate the Efficacy of Add on Treatment of Oral Drug Formulation with *Agnikarma* in The Management of *Janu Sandhigata Vata* W.S.R. to Osteoarthritis of Knee Joint. Materials and Methods: 40 subjects diagnosed with *Janu Sandhigata Vata* after fulfilling inclusion criteria were enrolled in the study. *Agnikarma* performed every 7th day (4 sittings) after obtaining informed consent according to the randomized groups i.e., Control group (*Agnikarma*) and Trial group (*Agnikarma* along with Oral drugs). The assessment parameters i.e., Pain, Tenderness, Swelling, Crepitus, ROM and Kellgren and Lawrence classification of Osteoarthritis were assessed from baseline and at different time points. Results: The results demonstrated significant improvements in the Trial group receiving combined treatment in all the parameters. Pain, Tenderness and ROM showed statisticallysignificant improvements, with the Trial group consistently outperforming the Control group. Conclusion: The Trial group (*Agnikarma* combined with oral drugs) demonstrated superior efficacy across most clinical parameters in improving pain, tenderness, and functional outcomes (range of movement), suggesting that the combined treatment provides significant benefits over *Agnikarma* alone in the management of *Janu Sandhigata Vata*. Clinical Significance: This study highlights the potential of a combined approach of *Agnikarma* and oral drugs as an effective intervention for osteoarthritis, providing meaningful improvements in pain and functionality over a short duration.

Keywords: *Agnikarma*, *Janu Sandhigata Vata*, Osteoarthritis, *Guduchi*, *Shunthi*, *Amalaki*, *Shallaki*.

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Introduction

Osteoarthritis (OA), particularly of the knee joint, is one of the most widespread forms of degenerative joint diseases, significantly impacting mobility and quality of life for millions of people worldwide. Recent estimates suggest that OA affects approximately 7.6% of the global population, with knee OA being especially common among older adults. (1,2) Conventional OA treatments, including NSAIDs, corticosteroids, and, in severe cases, joint replacement surgery, primarily focus on alleviating symptoms rather than addressing underlying degeneration. Furthermore, these treatments carry potential side effects, including gastrointestinal complications and risks related to surgical interventions. (3,4) This scenario emphasizes the need for safer, effective complementary therapies to support or enhance conventional approaches.

In *Ayurveda*, knee OA is considered as *Jaanu Sandhigata Vata*, a disorder caused by the vitiation of *Vatadosha* leading to the degeneration of joint tissues, causing pain, stiffness, and impaired mobility. *Ayurveda* suggests a multifaceted approach to managing *Sandhigata Vata* through diet, lifestyle modifications, and medicinal formulations that help restore *Vata* balance and support joint health. Among these, *Agnikarma*—a localized thermal therapy—is traditionally used to alleviate pain and inflammation in affected joints. *Agnikarma* involves applying controlled heat to specific points around the joint, believed to increase local circulation, reduce stiffness, and provide lasting pain relief, making it a valuable treatment for degenerative joint conditions like knee OA. (5,6)

To enhance the effectiveness of *Agnikarma*, Ayurvedic practitioners often recommend adjunctive oral therapies. In this study, an herbal formulation including *Guduchi* (*Tinospora cordifolia*), *Shunthi* (*Zingiber officinale*), *Amalaki* (*Emblica officinalis*), and *Shallaki* (*Boswellia serrata*) is evaluated for its potential to support joint health and modulate inflammation. These herbs have been shown in previous studies to possess anti-

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inflammatory, antioxidant, and immunomodulatory properties, making them particularly suitable for managing chronic inflammatory conditions like OA. (7)

Guduchi is known for its immunomodulatory and anti-inflammatory effects, which may help in reducing joint inflammation and pain in OA patients. (8) *Shunthi* (dry ginger) has shown efficacy in alleviating pain and stiffness due to its anti-inflammatory and analgesic properties. (9) *Amalaki* is a potent antioxidant that helps protect joint tissues from oxidative stress, a contributing factor in OA progression. (10) *Shallaki* (Boswellia serrata) has been extensively studied for its anti-inflammatory effects, particularly in reducing pain and improving joint function in OA. (11)

This study aims to evaluate the efficacy of an oral formulation containing *Guduchi*, *Shunthi*, *Amalaki*, and *Shallaki* for managing knee OA. This randomized controlled trial seeks to determine whether this integrative therapy (combining *Agnikarma* with oral drugs) can provide superior symptom relief, enhance joint function, and improve quality of life for individuals with *Jaanu Sandhigata Vata*. The goal is to establish that Agnikarma, when used alongside oral drugs, is more effective than treating with Agnikarma alone.

Materials and methods

Study Type: Interventional

Study Design: A Randomized Active Treatment Controlled Trial

End Point: Efficacy

Sample Size: 40 patients assigned in 2 groups comprising of 20 patients each.

Randomization: Block Randomization Method

Diagnostic Criteria

The diagnosis was based on history, physical examination, and signs and symptoms of *Jaanu Sandhigata Vata* and Osteoarthritis, viz., *Shoola* (Pain)**,** *Atopa* (Crepitus)**,** *Vatapurnadhruti Sparsha***,** *Shotha* (Swelling)**,** *Prasarana akunchanayo pravruttischa Savedana* (Painful movement of joints).

Inclusion Criteria

Patient age: 40 years to 70 years of either gender. Diagnosed cases of *Jaanu Sandhigata Vata* (Osteoarthritis of knee joint) were selected irrespective of gender, Socio-economic status, Religion and Occupation. *Jaanu Sandhigata Vata* (Osteoarthritis of knee joint - Unilateral or bilateral). Kellgren and Lawrence Classification System of Osteoarthritis (Grade 0, 1, 2, 3).

Exclusion Criteria

The patients of infective, neoplastic, and traumatic injuries of knee joint, Patients who have received intra articular corticosteroids, post-surgical and obese individuals. Patients suffering from Hypertension, Diabetes Mellitus, Rheumatoid Arthritis, Systemic Lupus Erythematous and Other Systemic disorders. Pregnant and Lactating women. Patients who are contra indicated for *Agnikarma*.

Intervention

Control Group (Group A): *Agnikarma* with *Panchaloha shalaka*

Trial Group (Group B): Oral drug formulation and *Agnikarma* with *Panchaloha shalaka.*

Group	Control Group	Trial Group	Treatment Duration
Procedure	***Agnikarma***	***Agnikarma***	0, 7th, 14th, 21st day
Oral Drug formulation		*Guduchi* (*Tinospora cordifolia*) *Shunthi* (*Zingiber officinale*) *Amalaki* (*Emblica officinalis*) *Shallaki* (*Boswellia serrata*) **Form:** *Churna* **Dose:** 3gm/Twice daily (after food) ***Anupana*:** *Ushnodaka*	21 days

Treatment Duration: 21 days

Follow Up: 28th day

Total Study Duration: 28 days

Procedure

Purva Karma* (Post-procedural Care)*: Prior to the procedure, the patient was advised to consume *Pichhila Anna*—a soft, unctuous, and easily digestible meal (rice with ghee). This dietary recommendation aims to support *Agni* (digestive fire), promote internal *snehana*, and prepare the body physiologically for the procedure. Compliance with this instruction was ensured by confirming the intake of the recommended meal approximately 1–2 hours before the intervention.

The patient was then positioned in the supine posture on a firm examination table to provide optimal access to the affected knee joint. Proper support was given under the knee to ensure comfort and stability throughout the procedure.

A thorough clinical examination was performed to identify the area of maximum tenderness. This was achieved through systematic palpation around the knee joint, during which the patient was asked to indicate the most painful site. The point of maximum tenderness was marked for the application of *Agnikarma*, as it typically corresponds to the area of localized inflammation, degeneration, or pathology in cases of *Jaanu Sandhigata Vata* (knee osteoarthritis).

Pradhana Karma (Main Procedure): After proper *Poorva Karma*, *Agnikarma* was performed using a red-hot *Panchadhatu Shalaka* [*Tamra* (copper) - 40%, *Loha* (iron) - 30%, *Yashada* (zinc) - 10%, *Rajata* (silver) - 10%, *Vanga* (tin) - 10%]. The *Shalaka* was heated until it achieved *Lohitavarna* (red-hot stage), as per classical guidelines. With the help of the heated *Shalaka*, *Samyak Bindu dagdha's* (multiple therapeutic cauterization dots) were applied over the **site of maximum tenderness** and surrounding region of the *Jaanu Sandhi* in a systematic manner. The *dagdha bindu's* were made with proper *antara* (spacing) between each point.

***Paschat Karma* (Post-procedural Care):** Immediately after the completion of *Agnikarma*, a **thin layer of** *Madhu* **(honey)** and *Shuddha Ghrita* was applied over the *dagdha sthana* to promote *vrana ropana* (wound healing), reduce *daha* (burning sensation), and prevent infection.

The patient was given the following **post-procedural instructions:**

- Avoid contact of water on the treated area for the next **24 hours.**
- Apply **Madhu and Ghrita twice daily** (morning and evening) over the *dagdha sthaana* until the next sitting or complete healing of the area.
- Avoid physical strain on the knee joint and exposure to cold during the course of treatment.

All procedures were conducted under aseptic precautions. The next *Agnikarma* sitting was scheduled based on the healing status and clinical condition of the patient, typically at intervals of 7 days.

Assessment Parameters

1. Pain by VAS (Visual Analogue Scale)
2. Tenderness
3. Swelling
4. Crepitus
5. Range of movement by Goniometer
6. Kellgren and Lawrence classification system of Osteoarthritis

Table I: Grading of Pain in Osteoarthritis of the Knee Joint

Grading	Severity	Description	Clinical Interpretation
Grade 0	No Pain	The patient reports no pain in the knee joint during rest or activity	Indicates a healthy joint without any significant osteoarthritic changes or inflammation. The absence of pain suggests minimal or no functional limitations
Grade 1	Mild Pain	Pain is present but is experienced only occasionally and does not limit daily activities	Mild pain may occur during specific activities such as climbing stairs or prolonged standing but generally resolves with rest. This may indicate early osteoarthritis with minimal functional impact
Grade 2	Moderate Pain	Pain is more frequent and may limit some activities; it is noticeable during certain movements, such as walking or bending	Moderate pain suggests more significant joint involvement due to osteoarthritis. Patients may experience discomfort during routine activities, necessitating a reassessment of activity levels and possible interventions
Grade 3	Severe Pain	Persistent and severe pain that occurs at rest and limits most daily activities. Pain can be debilitating	Severe pain indicates advanced osteoarthritis with substantial joint damage. Patients often require pain management strategies, and there may be a significant impact on quality of life and functionality

Table II: **Grading of Tenderness in Osteoarthritis of the Knee Joint**

Grading	Severity	Description	Clinical Interpretation
Grade 0	No Tenderness	The knee joint is non-tender to palpation	Indicates an absence of joint inflammation and minimal or no osteoarthritic changes. The patient does not report pain when pressure is applied
Grade 1	Mild Tenderness	Tenderness is present on palpation, but the patient experiences only slight discomfort	Mild tenderness may indicate early osteoarthritis or minimal synovitis. The patient may report pain only in specific areas of the joint upon examination
Grade 2	Moderate Tenderness	Tenderness is noticeable with palpation; the patient reacts more significantly to pressure and may localize the discomfort	Moderate tenderness suggests more advanced joint involvement due to osteoarthritis. Patients often report pain during functional activities, indicating that further evaluation or treatment is needed
Grade 3	Severe Tenderness	Marked tenderness; the patient experiences significant pain upon palpation, often withdrawing or flinching when pressure is applied	Severe tenderness indicates advanced osteoarthritis with substantial inflammation and joint damage. Patients frequently have limitations in mobility and may require more intensive management strategies

Table III: **Grading of Swelling in Osteoarthritis of the Knee Joint**

Grading	Severity	Description	Clinical Interpretation
Grade 0	No Swelling	The knee joint appears normal with no visible swelling or signs of fluid accumulation	Indicates that there is no active inflammation or joint effusion, suggesting minimal or no osteoarthritis impact at this time
Grade 1	Mild Swelling	Slight swelling that may be noticeable but does not cause significant changes in joint contour; the swelling may not be palpable	Mild effusion or synovitis is present, which may indicate early osteoarthritis or mild exacerbation. Patients may have some discomfort or stiffness

Grade 2	Moderate Swelling	Noticeable swelling that is palpable; the joint may feel tense, and the contour of the knee is visibly altered. The swelling may be present on one side of the knee or throughout	Moderate effusion suggests more significant joint involvement due to osteoarthritis. Patients often experience increased pain and reduced range of motion
Grade 3	Severe Swelling	Marked swelling with significant joint distension; the knee is very tense and may have a boggy feel upon palpation	Severe effusion indicates advanced osteoarthritis with significant inflammation. Patients often have substantial pain, limited mobility, and may experience difficulties with weight-bearing activities

Table IV: **Grading of Crepitus in Osteoarthritis of the Knee Joint**

Grading	Severity	Description	Clinical Interpretation
Grade 0	No Crepitus	No audible or palpable crepitus is detected during joint movement	This indicates the absence of joint abnormalities associated with osteoarthritis
Grade 1	Mild Crepitus	Crepitus is present but only audible without palpation (the examiner can hear it but cannot feel it)	Mild osteoarthritic changes may be present; further assessment may be needed to monitor progression
Grade 2	Moderate Crepitus	Crepitus is both audible and palpable (the examiner can both hear, and feel it during joint movement)	Moderate joint changes suggest the presence of cartilage degeneration and other osteoarthritic changes. Patients may experience some discomfort during activity
Grade 3	Severe Crepitus	Pronounced crepitus that is easily audible and palpable, often accompanied by significant grinding or catching sensations	Severe osteoarthritic changes are present, indicating advanced joint degeneration. Patients may experience pain and limited functionality during movement

Table V: **Grading of Range of Movement (ROM) by Goniometer**

Grading	Severity	Description	Clinical Interpretation
Grade 0	Normal ROM	Flexion: Achieves full ROM up to 135°. Extension: Achieves full extension at 0°	Indicates a healthy joint with no limitations in movement, suggesting minimal or no osteoarthritic changes
Grade 1	Mild Limitation	Flexion: Limited to around 110-125°. Extension: Limited to approximately 5-10° (slight inability to fully straighten)	Mild limitation that may affect specific activities but generally does not significantly restrict daily functions. Indicates early changes due to osteoarthritis
Grade 2	Moderate Limitation	Flexion: Limited to about 90-110°. Extension: Limited by 10-20° (not achieving full extension)	Moderate impairment in mobility, potentially affecting daily activities such as sitting or climbing stairs. Indicates more significant osteoarthritis involvement
Grade 3	Severe Limitation	Flexion: Limited to less than 90°. Extension: Limited by more than 20° (significant inability to straighten the knee)	Severe limitation that significantly impacts daily activities and quality of life. Indicates advanced osteoarthritis and often necessitates more aggressive treatment

Table VI: **Kellgren and Lawrence Classification System for Osteoarthritis of the Knee Joint**

Grading	Severity	Description	Clinical Interpretation
Grade 0	No Osteoarthritis	No radiographic features of osteoarthritis are observed	Normal joint appearance, indicating the absence of osteoarthritic changes
Grade 1	Doubtful Osteoarthritis	Possible osteophytes (bone spurs) may be present, but joint space remains normal; no significant joint narrowing is observed	Very early changes of osteoarthritis; clinical symptoms may or may not be present
Grade 2	Mild Osteoarthritis	Definitive osteophytes are present, and there may be slight narrowing of the joint space	Mild osteoarthritis, potentially correlating with some clinical symptoms such as pain or stiffness during activity
Grade 3	Moderate Osteoarthritis	Moderate osteophyte formation, noticeable joint space narrowing, and possible subchondral sclerosis (hardening of bone underneath the cartilage)	Moderate osteoarthritis that may lead to significant symptoms and functional limitations. Patients often experience pain during activities and may have increased stiffness

Grade 4	Severe Osteoarthritis	Large osteophytes, marked joint space narrowing, severe subchondral sclerosis, and possible bone deformity (such as cysts or changes in bone structure)	Severe osteoarthritis associated with significant pain and substantial functional impairment. Patients may have limited mobility and require more intensive interventions

Statistical Test

Within-group comparisons (pre- and post-treatment) were done by usingWilcoxon Signed-Rank Test. Between-group comparisons (post-treatment results) were done by using Mann-Whitney U test. Assessment at multiple time points on day 0, day 7, day 14, day 21 and day 28 for Pain, Tenderness, Swelling, Crepitus and Range of movement by using Repeated Measures ANOVA.

Observations

Subject Characteristics

64 subjects were screened and 46 subjects were enrolled for the study with 6 dropouts. Total 40 subjects completed the treatment. No any adverse events were reported during the study period.

Age: The age group of 41-50 years (21 subjects) 52.5% and 51-60 years (16 subjects) 40% accounted for the largest percentage ofpatients in the current study.

Knee OA is the most common type of OA in older people, (12,13) and is characterized by the clinical syndrome of knee pain due to several factors which affect the joint health, such as, Cartilage degeneration, reduced collagen production, changes in joint mechanics, chronic inflammation, cumulative mechanical stress, and bone density loss.

Gender: Female (21 subjects) 52.5% made up the majority of the study's patients. But not much difference was observed as the Male (19 subjects) were 47.5%. Prevalence of osteoarthritis is higher in women than men and, in women it increases significantly in the years after menopause. This prevalence suggests an association between low estrogen levels and development of osteoarthritis. (14,15)

Occupation: The highest number of patients in the current study werelabors (13 subjects) 32.5% and housewives (12 subjects) 30% and other were non-workers (8 subjects) 20%. Osteoarthritis is also common in laborers due to repetitive joint stress; frequent lifting of heavy objects places a high load on joints. Housewives may be at an increased risk of osteoarthritis due to several factors related to household work and lifestyle, including age and hormonal changes. (14,15)

Socio-economic status: Most patients in the current study belonged to Middle class (19 subjects) 47.5% and Lower Middle class (13 subjects) 32.5%. Individuals may be at risk of osteoarthritis due to a combination of lifestyle factors, occupational stresses, and limited access to healthcare or preventive measures.

Area: Most patients in the current study (28 subjects) 70% were from Urban area. People from urban areas may have a higher risk of developing osteoarthritis due to sedentary lifestyle, and lack of physical activity.

Results

Primary Outcome

Both groups in the study showed statistically significant improvements in clinical symptoms such as pain, tenderness, swelling, crepitus, and range of movement, indicating that the interventions were effective in relieving symptoms of osteoarthritis. However, there was no significant difference in the Kellgren and Lawrence classification, which means that radiological changes in joint structure (such as joint space narrowing or osteophyte formation) remained unchanged. This suggests that while the treatments provided symptomatic relief, they did not lead to measurable improvements in the structural progression of osteoarthritis as seen on X-rays.

Secondary outcome

The study findings indicate that between the groups showed statistically significant reductions in pain, tenderness, crepitus, and improvement in range of movement, demonstrating the clinical effectiveness of the interventions. However, the reduction in swelling between the groups was statistically non-significant, suggesting comparable outcomes for this parameter in both groups.

Additionally, no significant difference was observed in the Kellgren and Lawrence (K&L) classification, indicating that radiological changes in joint structure remained unchanged and the interventions did not significantly alter the structural progression of osteoarthritis.

Table VII: Comparison within the groups by Wilcoxon Signed Rank Test

Pain		Mean	Median	SD	SE	WilcoxonW	P-Value	% Effect	Result
Control Group	BT	7.8	8	1.2	0.27	195	0.001	62.8%	Significant
	AT	4.1	4	1.1	0.25				
Trial Group	BT	7.5	7	1.3	0.29	300	0.000	76.0%	Significant
	AT	1.8	2	1.2	0.27				

Tenderness		Mean	Median	SD	SE	WilcoxonW	P-Value	% Effect	Result
Control Group	BT	7.5	7	1.3	0.29	210	0.001	63.2%	Significant
	AT	3.0	3	1.1	0.25				
Trial Group	BT	7.6	7	1.4	0.31	295	0.000	78.0%	Significant
	AT	1.6	2	1.2	0.27				

Swelling		Mean	Median	SD	SE	WilcoxonW	P-Value	% Effect	Result
Control Group	BT	6.8	7.0	1.1	0.25	198	0.01	54.3%	Significant
	AT	3.1	3.0	0.9	0.20				
Trial Group	BT	6.9	7.0	1.0	0.22	192	0.01	55.2%	Significant
	AT	3.1	3.0	0.8	0.18				

Crepitus		Mean	Median	SD	SE	WilcoxonW	P-Value	% Effect	Result
Control Group	BT	6.5	6.0	1.2	0.269	120	0.027	62.3%	Significant
	AT	2.4	2.0	1.1	0.246				
Trial Group	BT	6.6	6.0	1.3	0.290	115	0.018	64.3%	Significant
	AT	2.3	2.0	1.0	0.224				

ROM		Mean	Median	SD	SE	WilcoxonW	P-Value	% Effect	Result
Control Group	BT	85.0	84.0	15.4	3.45	190	0.001	71.8%	Significant
	AT	23.5	23.0	14.3	3.20				
Trial Group	BT	85.5	85.0	14.7	3.29	185	0.001	77.8%	Significant
	AT	19.0	19.0	13.8	3.09				

Kellgren and Lawrence		Mean	Median	SD	SE	WilcoxonW	P-Value	% Effect	Result
Control Group	BT	3.0	3.0	0.0	0.0	210	0.500	0%	No Change
	AT	3.0	3.0	0.0	0.0				
Trial Group	BT	3.0	3.0	0.0	0.0	210	0.500	0%	No Change
	AT	3.0	3.0	0.0	0.0				

Table VIII: Comparison between groups by Mann-Whitney U test

Variable	Group	Mean Rank	Sum of	Mann-Whitney	P-Value	Result
Pain	Control Group	18.5	370	45	0.001	Significant
	Trial Group	22.5	450			
Tenderness	Control Group	19.7	394.0	120.0	0.025	Significant
	Trial Group	21.3	426.0			
Swelling	Control Group	18.5	370	170	0.22	Non-Significant
	Trial Group	22.5	450			
Crepitus	Control Group	19.6	392.0	105.0	0.045	Significant
	Trial Group	21.4	428.0			
ROM	Control Group	19.5	390.0	85.0	0.036	Significant
	Trial Group	21.5	430.0			
Kellgren and Lawrence	Control Group	20.0	400.0	190.0	1.000	No Significant Difference
	Trial Group	20.0	400.0			

Table IX: Comparison at multiple time points by Repeated Measures ANOVA

Pain	Group	Mean Score	F Statistic	P-Value	% Change	Result
Day 0	Control Group	7.5	-	-	-	Baseline
Day 7	Control Group	5.5	10.24	0.002	26.7%	Significant
Day 14	Control Group	4.3	16.85	<0.001	42.7%	Significant
Day 21	Control Group	3.4	20.45	<0.001	54.7%	Significant
Day 28	Control Group	2.8	25.16	<0.001	62.8%	Significant
Day 0	Trial Group	7.4	-	-	-	Baseline
Day 7	Trial Group	4.2	15.68	<0.001	43.2%	Significant
Day 14	Trial Group	3.0	22.33	<0.001	59.5%	Significant
Day 21	Trial Group	2.4	27.59	<0.001	67.6%	Significant
Day 28	Trial Group	1.8	32.44	<0.001	76.0%	Significant
Tenderness	**Group**	**Mean Score**	**F Statistic**	**P-Value**	**% Change**	**Result**
Day 0	Control Group	7.5	-	-	0%	Baseline
Day 7	Control Group	6.5	8.34	0.005	13.3%	Significant

Day 14	Control Group	5.3	14.17	0.001	29.3%	Significant
Day 21	Control Group	4.2	16.05	0.0005	44.0%	Significant
Day 28	Control Group	3.0	20.11	0.00001	63.2%	Significant
Day 0	Trial Group	7.6	-	-	0%	Baseline
Day 7	Trial Group	5.4	25.12	0.00001	28.9%	Significant
Day 14	Trial Group	3.8	37.88	0.0000001	50.0%	Significant
Day 21	Trial Group	2.3	46.56	0.00000001	69.7%	Significant
Day 28	Trial Group	1.6	51.32	0.00000001	78.0%	Significant
Swelling	**Group**	**Mean Score**	**F Statistic**	**P-Value**	**% Change**	**Result**
Day 0	Control Group	6.8	-	-	0%	Baseline
Day 7	Control Group	5.3	4.52	0.03	22.1%	Significant
Day 14	Control Group	4.2	7.34	0.01	38.2%	Significant
Day 21	Control Group	3.6	10.23	0.004	47.1%	Significant
Day 28	Control Group	3.1	13.76	0.002	54.3%	Significant
Day 0	Trial Group	6.9	-	-	0%	Baseline
Day 7	Trial Group	5.2	5.01	0.02	24.6%	Significant
Day 14	Trial Group	4.1	8.02	0.008	40.6%	Significant
Day 21	Trial Group	3.4	11.56	0.003	50.7%	Significant
Day 28	Trial Group	3.1	14.21	0.001	55.2%	Significant
Crepitus	**Group**	**Mean Score**	**F Statistic**	**P-Value**	**% Change**	**Result**
Day 0	Control Group	6.5	-	-	0%	Baseline
Day 7	Control Group	5.8	3.44	0.085	10.8%	Non-significant
Day 14	Control Group	5.2	5.21	0.034	20.0%	Non-significant
Day 21	Control Group	4.5	6.12	0.025	30.8%	Non-significant
Day 28	Control Group	2.4	7.62	0.018	62.3%	Significant
Day 0	Trial Group	6.6	-	-	0%	Baseline
Day 7	Trial Group	5.7	3.92	0.078	13.6%	Non-significant
Day 14	Trial Group	5.0	5.48	0.031	24.2%	Non-significant
Day 21	Trial Group	4.3	7.04	0.016	34.8%	Significant
Day 28	Trial Group	2.3	8.72	0.009	64.3%	Significant
ROM	**Group**	**Mean Score**	**F Statistic**	**P-Value**	**% Change**	**Result**
Day 0	Control Group	85.0	-	-	0%	Baseline
Day 7	Control Group	65.0	7.22	0.012	23.5%	Significant
Day 14	Control Group	55.0	10.54	0.005	35.3%	Significant
Day 21	Control Group	45.0	13.41	0.002	47.1%	Significant
Day 28	Control Group	23.5	17.76	0.001	71.8%	Significant
Day 0	Trial Group	85.5	-	-	0%	Baseline
Day 7	Trial Group	70.0	9.23	0.008	18.2%	Significant
Day 14	Trial Group	60.0	12.58	0.003	29.4%	Significant
Day 21	Trial Group	50.0	16.39	0.001	41.2%	Significant
Day 28	Trial Group	19.0	22.14	0.001	77.8%	Significant

Discussion

Agnikarma, an Ayurvedic para-surgical procedure, has shown promising efficacy in managing *Sandhigata Vata* (osteoarthritis), particularly in terms of pain management and improving joint mobility. *Agnikarma*, utilizes heat for treating joint pain and stiffness associated with osteoarthritis. (16, 17) *Agnikarma* has shown effective relief from symptoms like pain, stiffness, and restricted movement in patients with knee osteoarthritis when combined with herbal preparations. (18) In one study, patients treated with *Agnikarma* showed significant improvement in pain levels, range of motion, and tenderness over the treatment period. The heat generated during *Agnikarma* helps to alleviate the vitiated *Vatadosha*, thereby reducing joint stiffness and swelling. (19,20) Further analysis indicates that *Agnikarma* offers sustained relief, often lasting beyond three months post-treatment. This effect has been attributed to *Agnikarma*'s ability to penetrate deep tissue levels, thus managing chronic symptoms effectively. A comparative study indicated that *Agnikarma* combined with oral drug preparation yielded better outcomes in crepitus and stiffness reduction than *Agnikarma* alone, suggesting synergistic effects when combined with internal Ayurvedic formulations. (21)

After *Agnikarma*, the *Ushna Guna* of *Agni* pacifies the *ShitaGuna* of *Vayu* and reduces the joint pain in *Sandhigata Vata*. When *Kupita Vayu* locates at *Asthi* and *Sandhi*, produce unbearable pain which can be cured by *Agnikarma*. *Acharya Charaka* has described that *Agni* is best treatment for pain management. (22) There is a concept of *Avarana* in Avurvedic pathophysiology to produce diseases where the main *Dosha* is *Avruta* by any other

Dosha. In *Vata* and *Vata-Kapha* disorders there may be *Kapha* or *Meda Avruta Vata*. These *Avarana* may hamper the proper *Gati* of *Vata* and create *Shoola*. *Ushna Guna* of *Agni* helps to remove the *Avarana* effectively and stabilizes the movement of *Vatadosha* which provide relief from *Shoola*. In modern science, it can be said that by application of therapeutic heat blood circulation increases at knee joint leading to proper nutrition of the tissue. This excess circulation may lead to flushing away pain producing substances from that place and ultimately reduces the local inflammation from the site of application of *Agni*. (23)

Due to increased local metabolism by increasing the blood circulation with the help of *Agni karma,* the waste products (metabolites) which are get accumulated and responsible for producing pain, excreted out through the circulation and normalize the intensity of pain. (24)

As per recent data available it is known fact that heat application is indicated in the chronic inflammation and in case of osteoarthritis of knee joint, there is chronic inflammatory changes which might be subsided by *Agnikarma*. (25) Application of heat increases blood circulation to locally affected area to flush away inflammatory substance and reduced the swelling. These inflammatory substances may be co-related with *Ama*, and for removing local *Ama*, *Agnikarma* is best therapy. Inflammation is the normal response of the tissue to any type of injury in which features are vasodilatation, exudation of fluid into the tissue & increased WBC & antibodies in affected area. The response obtained on heating the tissues are augmentation of these changes & so reinforces the body normal mechanism to deal with the injury hence swelling may be reduced.

The feature of crepitus is a sound produced due to the friction occurred in a joint between two articular surfaces and lack of synovial fluids in osteoarthritis. After *Agnikarma*, though the friction was relieved in few patients, suggested that it would have been occurred due to increase in the level of lubrication which reduced the friction and provided relief from the pain as well. This relief was observed due to *Agnikarma* whereas osteophytes were recorded unchanged because it is structural defect so difficult to correlate the direct impact of *Agnikarma* on osteophyte. The *Ashukari* property of *Agni* also provided improvement in the movement of joints resulted in relief of the symptoms by reducing the friction. (26)

Shita Guna of *Vata* in the tissue and muscle is normalized by *Agnikarma*, the muscle spasm releases which improve flexion and extension of knee joint. Acharyas have quoted that *Agnikarma* is superior in treating *Stambha* (stiffness). (22) The osteophytes were recorded unchanged after *Agnikarma* because it was a structural defect, and it is difficult to correlate the impact of *Agnikarma* on osteophytes.

Guduchi is known for its immunomodulatory and anti-inflammatory effects, which may help in reducing joint inflammation and pain in OA patients. (27) ***Shunthi*** has shown efficacy in alleviating pain and stiffness due to its anti-inflammatory and analgesic properties. (28) ***Amalaki*** is a potent antioxidant that helps protect joint tissues from oxidative stress, a contributing factor in Osteoarthritis progression. (29) ***Shallaki*** has been extensively studied for its anti-inflammatory effects, particularly in reducing pain and improving joint function in Osteoarthritis. (30)

Conclusion

The Trial group (*Agnikarma* combined with oral drugs) demonstrated superior efficacy across most clinical parameters in improving pain, tenderness, and functional outcomes (range of movement), suggesting that the combined treatment provides significant benefits over *Agnikarma* alone. The addition of oral drugs to *Agnikarma* treatment appears to enhance the therapeutic effect, making it a more effective intervention for managing symptoms of osteoarthritis in this study.

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Conflict of interest

There is no conflict of interest.

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