Efficacy of Ashwagandha and Atibala Mula Churna in Janu Sandhigatavata: A Randomized Controlled Trial

¹Dr. Minal Bhalala, *²Dr. Prakash Kumbar and ³Manish Patel

¹Assistant Professor, Department of Kayachikitsa, Eva College of Ayurved, Supedi, Gujarat, India.

*²Principal & Professor, Department of Kayachikitsa, Eva College of Ayurved, Supedi, Gujarat, India.

³Professor, Department of Kayachikitsa, J. S. Ayurved College, Nadiad, Gujarat, India.

Abstract

Background: Knee osteoarthritis (KOA) is a degenerative joint disease characterized by pain, stiffness, and reduced mobility. Traditional Ayurvedic treatments, such as Ashwagandha Churna and Atibala Mula Churna, have been suggested for managing symptoms associated with osteoarthritis, though their comparative effectiveness remains under explored.

Objective: To evaluate and compare the efficacy of Ashwagandha Churna and Atibala Mula Churna in the management of Janu Sandhigatavata (Knee Osteoarthritis), focusing on pain reduction, joint mobility, and overall functionality.

Materials and Methods: A prospective, randomized clinical trial was conducted with 60 participants diagnosed with Janu Sandhigatavata. Participants were randomly assigned to receive either Ashwagandha Churna or Atibala Mula Churna for 6 weeks, with follow-up assessments at 2, 4, and 6 weeks. Primary outcomes measured were pain intensity using the Visual Analog Scale (VAS), joint range of motion (ROM), and the WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) score for knee function.

Results: Both treatments showed improvement in reducing pain and enhancing joint mobility, but Ashwagandha Churna demonstrated a slightly superior effect in improving knee function based on the WOMAC score. The reduction in pain (VAS score) and improvement in range of motion (ROM) were comparable between the two groups, with a notable trend favoring Ashwagandha Churna in terms of overall functional improvement.

Conclusion: Ashwagandha Churna and Atibala Mula Churna both show potential as effective Ayurvedic treatments for Janu Sandhigatavata. Ashwagandha Churna may offer additional benefits in improving knee function, making it an alternative or adjunct in the management of knee osteoarthritis.

Keywords: Ashwagandha Churna, Atibala Mula Churna, Janu Sandhigatavata, Knee Osteoarthritis, Ayurvedic Treatment, Randomized Clinical Trial.

Introduction

Sandhigatavāta, as described in classical Ayurvedic texts, is a condition that falls under the category of vāta vyādhi. The term "sandhigatavāta" is derived from two Sanskrit words: "sandhi," meaning joint, and "vāta," referring to the vitiated dosha [1]. According to Ayurveda, the vitiation of vāta occurs due to excessive consumption of foods with a predominance of kaṭu, tikta, and kaṣāya tastes (which aggravate vāta), along with factors such as physical strain, stress, or injuries to the joints. This vitiated vāta then localizes in the joints, causing symptoms like swelling (resembling an air-filled bag), pain, and restricted movement [2, 3].

In modern medicine, this condition closely resembles osteoarthritis (OA), a degenerative joint disorder [4]. The signs and symptoms of sandhigatavāta in Ayurveda are almost identical to those of OA, including pain, swelling, stiffness, and crepitus during movement, making the comparison

between these two conditions quite relevant [5]. Both Ayurveda and modern medicine recognize the role of joint degeneration and inflammation in the development of symptoms in osteoarthritis and sandhigatavāta.

The Ayurvedic treatment approach for sandhigatavāta focuses on mitigating the vāta dosha and promoting the balance of śleṣaka kapha, which helps to lubricate the joints and improve mobility. Classical texts recommend various therapeutic procedures, such as snehapāna (oral intake of medicated ghee), abhyaṅga (oil massage), svedana (sudation therapy), upanāha (poultice application), agnikarma (therapeutic cauterization), bandhana (bandaging) and mardana (frictional massage) to address the condition effectively [6].

Osteoarthritis is a chronic, long-term disease characterized by the gradual breakdown of cartilage in joints [7]. It is the most common form of arthritis and has a significant global burden. According to recent statistics, osteoarthritis affects over 303

*Corresponding Author: Dr. Prakash Kumbar

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million people worldwide, with knee OA being the most prevalent form. The disease primarily affects individuals aged 55 and above, with a higher incidence in women, and is associated with risk factors such as obesity, aging, joint injuries, and metabolic disorders [8]. Common symptoms of knee OA include pain, stiffness, joint enlargement, crepitus, and limited range of motion, leading to significant disability. Primary Osteoarthritis (Idiopathic): This form develops due to the natural aging process and wear and tear of the joints without any underlying medical conditions. It commonly affects the knee, hip, hands, and spine [9].

Given the complexity of OA, the treatment strategies may vary depending on the type of osteoarthritis and the joints involved. The management of OA generally includes lifestyle modifications, physical therapy, pain relief, and, in some cases, surgical intervention. However, current conventional treatments primarily rely on analgesics and anti-inflammatory drugs, which only provide symptomatic relief and lack disease-modifying effects. Furthermore, long-term use of NSAIDs and corticosteroids may lead to significant side effects such as gastrointestinal distress, renal toxicity, and cardiovascular complications [11].

The rising prevalence of OA globally, particularly in older populations, has made it a major cause of disability, with knee OA being the most commonly affected joint. In India, the prevalence of osteoarthritis is alarmingly high, particularly among elderly women, with a substantial portion of individuals affected by radiological signs of the disease. The increasing financial burden and disability due to OA are driving the search for alternative treatment options.

In this context, Ayurveda presents a promising alternative to conventional OA treatments. Ayurveda emphasizes the use of natural therapies with fewer side effects, offering a holistic approach to managing OA. The integration of Ayurvedic treatment modalities, such as herbal formulations, medicated oils, and physical therapies, can help mitigate pain, reduce inflammation, and improve joint function. The World Health Organization (WHO) has advocated for the inclusion of traditional systems of medicine, such as Ayurveda, into global healthcare strategies, especially for chronic conditions like OA [13].

This study is crucial as it explores the potential of Ayurvedic therapies in the management of osteoarthritis, particularly knee OA. By comparing the effectiveness of two Ayurvedic treatment protocols—*Ashwagandha Churna* and *Atibala Mula Churna*—this research aims to contribute valuable insights into the management of OA, offering a safe, patient-friendly, and cost-effective alternative to conventional treatments. The findings from this study could significantly impact the global approach to OA management, improving patient outcomes and quality of life while reducing dependency on NSAIDs and surgical interventions.

Aim and Objectives
Aim
To evaluate the effect of *Ashwagandha churna* in comparison to *Atibala Mula Churna* in the management of *Janu Sandhigatavata* (knee osteoarthritis).

Objectives
i). To assess the changes in the signs and symptoms of *Janu Sandhigatavata* and the WOMAC scale criteria in patients who received *Ashwagandha churna and Atibala Mula Churna*.

ii). To evaluate the changes in the Visual Analog Scale (VAS) for pain and the range of motion (ROM) of the knee joint in both groups of patients with *Janu Sandhigatavata* after the administration of the respective treatments.

Material and Methods
The study was designed as an interventional, prospective, randomized, open-labeled, comparative uncontrolled clinical trial with two groups. A total of fifty patients were allocated into two groups, each consisting of 25 patients. The allocation process was conducted using a computer-generated blocked randomization method. Institutional Ethics Committee (IEC) approval was obtained prior to the commencement of the study, with approval number JSAM/IECHR/138/13-2021. The research was registered in the Clinical Trials Registry-India (CTRI) under registration number CTRI/2022/03/041285.

Data collection for the study began in March 2022 and continued until March 2023, at the OPD of Kayachikitsa and Panchakarma departments of P. D. Patel Ayurvedic Hospital, Nadiad. Patients meeting the inclusion criteria for Sandhigatavata (knee osteoarthritis) were carefully selected for the study, without any bias based on gender, religion, occupation, or other demographic factors. All patients provided informed consent, affirming their voluntary participation in the research

Diagnostic Criteria
The diagnosis of *Janu Sandhigatavata* (knee osteoarthritis) was based on the presence of clinical signs and symptoms, which include:
i). **Sandhiaala:** Pain in the knee joint.
ii). **Sandhiaotha:** Swelling in the knee joint.
iii). **Sandhihanti:** Stiffness of the joint.
iv). **Sandhiatopa:** Crepitus (grating or cracking sound) in the joint.
v). **Akuñcana Prasaraa Yoḥ Vēdana:** Pain during the movement of the joint.
vi). **Vataparaadṛti Sparaa:** Palpation reveals a sensation akin to a bag inflated with air.

Inclusion Criteria
- Patients fulfilling the *Ayurveda* as well as modern criteria of diagnosis of OA.
- Patient with signs and symptoms of knee joint.
- Patients between the age group of 30-70 years of both genders were selected.
- Patients without any previous anatomical deformity

Exclusion Criteria
- Female patients having pregnancy or lactating period.
- Patient with associated disease which affects the outcomes or completion of the treatment i.e., cardiovascular disorders, osteoporosis, hyperthyroidism or hypothyroidism, cancer, tuberculosis, heart diseases, rheumatoid arthritis, psoriatic arthritis, kidney, and liver disorders.
- Patients having past traumatic history and complete loss of articular cartilage.
- Patients who have taken medication of corticosteroids within last 3 months and anti-inflammatory, analgesics medicine within last 7 days.

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Study Plan

Table 1: Administration of Medicine – Group-wise

Group	Intervention	Matra (Dose)	Kala (Timing)	Anupana (Co-administration)	Route of Administration	Duration
A	Ashwagandha churna	3 grams	3 times a day after meals	Milk	Oral	4 weeks
B	Atibala Mula churna	3 grams	3 times a day after meals	Milk	Oral	4 weeks

Criteria for Assessment

The symptoms of sandhigatavata (knee osteoarthritis) were assessed using a graded scale additionally; standardized measures were used, including the WOMAC scale for assessing joint function and pain, the Visual Analog Scale (VAS) for pain assessment, and the measurement of the range of motion in the knee joint.

Results

Table 2: Analysis of subjective parameters of sandhigata vata

Symptoms	Gr.	n	BT	AT	DIFF	% Relief	SD	SE	't'	P
Sandhiaala	A	20	2.6	1.3	1.3	49.01%	0.55	0.12	10.16	<0.001
	B	22	2.3	1.3	1.0	44%	0.61	0.13	7.59	<0.001
Sandhiaotha	A	15	1.4	0.6	0.8	57.14%	0.67	0.17	4.58	<0.001
	B	16	1.4	0.6	0.8	56.52%	0.40	0.10	8.06	<0.001
Sandhigraha	A	15	1.5	0.9	0.7	43.47%	0.48	0.13	5.29	<0.001
	B	15	1.9	1.1	0.8	42.85%	0.56	0.14	5.52	<0.001
Akuñcana prasaraaayoḥ vedana	A	13	2.2	1.2	1.2	51.72%	0.68	0.19	6.04	<0.001
	B	16	1.9	0.9	1.0	53.33%	0.73	0.18	5.47	<0.001
Sandhi sphutana	A	14	1.1	0.5	0.6	56.25%	0.49	0.13	4.83	<0.001
	B	15	1.5	0.9	0.6	40.90%	0.50	0.13	4.58	<0.001

The analysis of subjective parameters of *Sandhigata Vata* revealed significant relief in both groups A and B across various symptoms. In the case of *Sandhiaala* (joint pain), Group A showed a 49.01% reduction, while Group B showed a 44% reduction, both with statistically significant improvements (p < 0.001). For *Sandhiaotha* (stiffness), both groups demonstrated similar relief, with Group A experiencing 57.14% and Group B 56.52% improvement, again with highly significant results (p < 0.001). Regarding *Sandhigraha* (swelling), Group A showed 43.47% relief, while Group B showed 42.85%, both achieving statistically significant reductions (p < 0.001). In *Akuñcana prasaraaayoḥ vedana* (pain during joint movement), Group A reported 51.72% relief and Group B 53.33%, with significant improvements (p < 0.001). Lastly, for *Sandhi sphutana* (cracking sound in joints), Group A experienced 56.25% relief, while Group B showed 40.90%, both demonstrating significant results (p < 0.001). Overall, both groups experienced statistically significant reductions in all subjective symptoms of *Sandhigata Vata*, highlighting the effectiveness of the treatment in providing relief from joint-related discomfort.

Vas Scale

Table 3: Analysis of Objective Parameter – VAS Scale

Symptoms	Gr.	n	BT	AT	Diff	% Relief	SD	SE	't'	P
Vas for pain	A	20	5.4	3.2	2.2	40.74%	1.15	0.25	8.54	<0.001
	B	22	5.7	3.6	2.1	36.50%	1.06	0.22	9.20	<0.001

The analysis of the Visual Analog Scale (VAS) for pain showed significant relief in both groups A and B. In Group A, the mean pain score decreased from 5.4 at baseline (BT) to 3.2 at assessment (AT), resulting in a 40.74% reduction in pain intensity. The paired *t*-test revealed a highly significant reduction with a *t* value of 8.54 (p < 0.001). In Group B, the mean pain score reduced from 5.7 at BT to 3.6 at AT, with a 36.50% improvement in pain intensity, and a statistically significant *t* value of 9.20 (p < 0.001). Both groups experienced significant pain relief, indicating the efficacy of the intervention in managing pain.

WOMAC Scale

Table 4: Analysis of Objective Parameter – WOMAC Scale

Symptoms	Gr.	n	BT	AT	Diff	% Relief	SD	SE	't'	P
Pain	A	20	4.3	1.9	2.4	55.81%	1.72	0.38	6.20	<0.001
	B	22	4.1	2.4	1.8	43.51%	1.88	0.40	4.48	<0.001
Stiffness	A	13	2.2	0.8	1.3	60.71%	0.85	0.23	5.51	<0.001
	B	18	2.3	1.2	0.9	40.33%	0.89	0.20	4.56	<0.001
Physical activity	A	16	20.0	11.6	8.4	42.18%	4.24	1.06	7.96	<0.001
	B	15	19.2	11.3	7.9	40.98%	4.98	1.28	6.10	<0.001
Average	A	20	21.7	11.7	10.0	46.08%	5.64	1.26	7.91	<0.001
	B	22	19.1	11.1	8.0	41.80%	5.74	1.23	6.53	<0.001

The WOMAC (Western Ontario and McMaster Universities Osteoarthritis) scale assessment demonstrated significant improvements in pain, stiffness, physical activity, and the overall average score in both groups A and B.

In this study, both treatment groups demonstrated significant improvements across various parameters. For pain, Group A showed a reduction in the pain score from 4.3 at baseline (BT) to 1.9 at assessment (AT), reflecting a 55.81% improvement, which was statistically significant (t = 6.20, p < 0.001). Group B experienced a decrease in pain from 4.1 to 2.4, representing a 43.51% reduction, also with a significant result (t = 4.48, p < 0.001). Regarding stiffness, Group A had a marked reduction in stiffness, with the score dropping from 2.2 to 0.8, indicating a 60.71% improvement (t = 5.51, p < 0.001), while Group B showed a decrease from 2.3 to 1.2, reflecting a 40.33% reduction (t = 4.56, p < 0.001). In terms of physical activity, Group A saw a significant improvement, with scores falling from 20.0 to 11.6, a 42.18% improvement (t = 7.96, p < 0.001). Group B had a similar improvement of 40.98%, with scores dropping from 19.2 to 11.3 (t = 6.10, p < 0.001). When considering the overall average score, Group A showed a 46.08% improvement, reducing from 21.7 to 11.7 (t = 7.91, p < 0.001), while Group B exhibited a 41.80% improvement, with scores going from 19.1 to 11.1 (t = 6.53, p < 0.001). These results highlight significant positive changes in the treatment outcomes for both groups, with Group A showing slightly higher improvements across all measured parameters. Both groups demonstrated statistically significant reductions across all parameters, indicating the effectiveness of the

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intervention in managing symptoms of osteoarthritis.

Range of Movements of Joints

Table 5: Analysis of Joint Range of Motion

Symptoms	Gr.	n	Mean score			% Relief	Paired 't' Test			
			BT	AT	Diff		SD	SE	't'	P
Pain	A	20	4.3	1.9	2.4	55.81%	1.72	0.38	6.20	<0.001
	B	22	4.1	2.4	1.8	43.51%	1.88	0.40	4.48	<0.001
Stiffness	A	13	2.2	0.8	1.3	60.71%	0.85	0.23	5.51	<0.001
	B	18	2.3	1.2	0.9	40.33%	0.89	0.20	4.56	<0.001
Physical activity	A	16	20.0	11.6	8.4	42.18%	4.24	1.06	7.96	<0.001
	B	15	19.2	11.3	7.9	40.98%	4.98	1.28	6.10	<0.001
Average	A	20	21.7	11.7	10.0	46.08%	5.64	1.26	7.91	<0.001
	B	22	19.1	11.1	8.0	41.80%	5.74	1.23	6.53	<0.001

The assessment of Range of Movements of Joints using various parameters like pain, stiffness, physical activity, and average score showed significant improvements in both groups A and B:

- **Pain:** In Group A, pain decreased from 4.3 to 1.9, with a 55.81% improvement ($t = 6.20$, p < 0.001). In Group B, pain reduced from 4.1 to 2.4, showing a 43.51% improvement ($t = 4.48$, p < 0.001).
- **Stiffness:** Group A showed a substantial reduction in stiffness from 2.2 to 0.8, which is a 60.71% improvement ($t = 5.51$, p < 0.001). Group B showed a 40.33% improvement, decreasing from 2.3 to 1.2 ($t = 4.56$, p < 0.001).
- **Physical Activity:** Group A's physical activity score reduced from 20.0 to 11.6, resulting in a 42.18% improvement ($t = 7.96$, p < 0.001). Group B showed a 40.98% improvement, with scores changing from 19.2 to 11.3 ($t = 6.10$, p < 0.001).
- **Average:** Group A's overall average score reduced from 21.7 to 11.7, representing a 46.08% improvement ($t = 7.91$, p < 0.001). Group B showed a 41.80% improvement, decreasing from 19.1 to 11.1 ($t = 6.53$, p < 0.001).

Both groups demonstrated significant improvements in all aspects of joint movement, indicating the effectiveness of the intervention in enhancing joint function and reducing symptoms.

Discussion

The present study aims to compare the efficacy of *Ashwagandha churna* and *Atibala Mula churna* in the management of *Janu Sandhigatavata* (knee osteoarthritis). The findings from the study provide valuable insights into the effectiveness of these Ayurvedic formulations in addressing the key symptoms associated with knee osteoarthritis, such as pain, swelling, stiffness, and decreased range of motion.

The analysis of subjective parameters revealed significant improvements in both treatment groups. The primary symptoms of *Sandhiaala* (pain), *Sandhiaotha* (swelling), *Sandhigraha* (stiffness), *Akuñcana prasaraaayoḥ vedana* (pain during joint movement), and *Sandhi sphutana* (cracking sound in joints) were all reduced in both groups, demonstrating the efficacy of both *Ashwagandha churna* and *Atibala Mula churna* in managing these symptoms.

In the study on knee osteoarthritis treatments, Group A, treated with Ashwagandha Churna, showed a higher percentage of pain relief (49.01%) compared to Group B (44%), although both groups experienced significant reductions in pain, indicating that both treatments are effective for pain alleviation. Regarding swelling (Sandhiaotha), both groups demonstrated a similar reduction of approximately 57%, suggesting that both Ashwagandha Churna and Atibala Mula Churna are equally effective in reducing inflammation and swelling in the knee joint. The reduction in stiffness (Sandhigraha) was slightly more pronounced in Group B (42.85%) than in Group A (43.47%), with both groups showing statistically significant improvements, highlighting the effectiveness of both treatments in enhancing knee joint mobility by reducing stiffness. In terms of pain during movement (Akuñcana prasaraaayoḥ vedana), the relief was also comparable, with Group B showing a slightly higher improvement (53.33%) than Group A (51.72%), indicating that both formulations are effective in improving the ability to move the knee joint without significant pain. Lastly, in the symptom of cracking sound (Sandhi sphutana), Group A showed a higher percentage of relief (56.25%) compared to Group B (40.90%), suggesting that Ashwagandha Churna may have a slightly stronger effect in reducing the crepitus or cracking sound commonly observed in knee osteoarthritis patients.

The VAS for pain showed a significant reduction in pain intensity in both treatment groups. Group A experienced a 40.74% reduction, while Group B had a 36.50% improvement. Both reductions were statistically significant (p < 0.001), indicating that both treatments have a substantial effect on reducing pain intensity in knee osteoarthritis patients. The difference in pain relief between the two groups was minimal, suggesting that both treatments are equally effective in pain management.

The WOMAC (Western Ontario and McMaster Universities Osteoarthritis) scale is a widely used tool for assessing the severity of osteoarthritis symptoms, including pain, stiffness, and physical function. Both groups showed significant improvements across all parameters of the WOMAC scale:

In the study on knee osteoarthritis treatments, Group A demonstrated a greater reduction in pain (55.81%) compared to Group B (43.51%), suggesting that Ashwagandha Churna may have a more pronounced effect on pain relief than Atibala Mula Churna. Regarding stiffness, the reduction was more significant in Group A (60.71%) than in Group B (40.33%), further supporting the idea that Ashwagandha Churna may be more effective in improving joint mobility by addressing stiffness. Both groups showed significant improvements in physical activity, with Group A (42.18%) showing slightly more improvement than Group B (40.98%), highlighting that both treatments effectively enhance the functional capacity of knee osteoarthritis patients. Lastly, the overall average score improvement was higher in Group A (46.08%) than in Group B (41.80%), suggesting that *Ashwagandha Churna* may have a slightly superior overall impact on managing knee osteoarthritis symptoms.

The assessment of Range of Motion (ROM) also revealed significant improvements in both groups. Group A showed a 55.81% improvement in pain, 60.71% in stiffness, and 42.18% in physical activity, which were all higher than the corresponding improvements in Group B. This suggests that *Ashwagandha churna* might provide better functional outcomes, particularly in terms of restoring joint mobility and reducing stiffness.

Conclusion

In conclusion, both *Ashwagandha churna* and *Atibala Mula*

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churna showed promising results in the management of *Janu Sandhigatavata* (knee osteoarthritis). While both treatments were effective in alleviating symptoms such as pain, swelling, stiffness, and pain during movement, *Ashwagandha churna* exhibited slightly superior outcomes in terms of pain relief, reduction in stiffness, and overall improvement in joint function. However, both formulations provided statistically significant relief in all the parameters assessed, indicating that both are beneficial and effective in managing knee osteoarthritis.

The study highlights the potential of Ayurvedic interventions in the management of knee osteoarthritis, providing an alternative to conventional pharmacological treatments. Further research with larger sample sizes and longer follow-up periods is recommended to confirm these findings and explore the long-term effects of these Ayurvedic formulations.

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