



Research Article

www.ijrap.net

(ISSN Online:2229-3566, ISSN Print:2277-4343)



A RANDOMIZED CONTROLLED CLINICAL STUDY ON TILA UPANAHA IN THE MANAGEMENT OF SANDHIGATA VATA

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Received on: 13/05/22 Accepted on: 01/07/22

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DOI: 10.7897/2277-4343.1305122

ABSTRACT

Introduction: Sandhigata vata is one of the vata vyadhi. Snehana and svedana are the commonly prescribed treatments for this. Upanaha sveda is a variety of svedana especially indicated in managing various vata vyadhi with pain and stiffness as presenting symptoms. A previous study on Atasi (*Linum usitatissimum*) upanaha in managing knee osteoarthritis showed an encouraging outcome. Tila (*Sesamum indicum* Linn) is a variety of svedopaga dravya, and tila taila (sesamum oil) is considered best in managing vata diseases. **Aim:** This clinical study will evaluate the efficacy of tila upanaha and atasi upanaha to ascertain the better. **Materials and methods:** 20 patients fulfilling the diagnostic and inclusion criteria of either sex was selected in each group. Upanaha was done for seven days. Findings were recorded in research performa on the 4th day and 7th day. Follow-up was done on the 15th, 30th, 45th and 60th days. **Results:** Tila upanaha sveda showed a highly significant ($p<0.001$) effect on tenderness, womac score, flexion (B/L knees), swelling, and crepitus (Rt knees). Significant ($P<0.05$) effect on swelling (Lt knee), extension (B/L knee), and insignificant ($p>0.05$) effect on crepitus (Lt knee). Atasi upanaha sveda showed a highly significant ($p<0.001$) effect on swelling, tenderness, crepitus, womac score, flexion (B/L knees) and extension (RT knee). Significant ($P<0.05$) effect on extension (Lt knee). In comparing, a significant difference was seen in swelling of the Rt knee ($P<0.05$) and Lt knee ($p<0.001$). **Conclusion:** Atasi upanaha sveda yielded better relief when compared with tila upanaha sveda in managing sandhigata vata (knee osteoarthritis).

Keywords: Svedana, Upanaha, Sandhigata Vata, Osteoarthritis, Tila, Atasi

INTRODUCTION

Sandhigata vata is a variety of vata vyadhi in which aggravated vata gets localized in joints, hampers its normal action, and causes shophya (swelling) and shoola (pain) over joints¹. The pathologic underpinnings of this disease are attributed to the aberration of vata and kapha dosha, affecting asthi (bones), sandhi (joints), mamsa (muscle) and snayu². It is characterized by vatapoorna driti sparsha shotha, prasarana akunjanayo pravruttscha vedana, and atopa³. Clinical features of sandhigata Vata nearly simulate the osteoarthritis of contemporary parlance. Osteoarthritis is a common variety of arthritis resulting in debility, especially in the elderly. It is characterized by pain in and around the joint, stiffness, swelling and crepitus⁴. Osteoarthritis has a prevalence of 22% to 39% in India⁵. If left untreated, it may reduce the quality of life and increase the risk of further morbidity. Svedana is a variety of shadvidopakrama, and it helps neutralize sthabdatha (stiffness), gouravatha (heaviness) and sheethatha (coldness)⁶. It is helpful to treat diseases caused by vata, kapha or both⁷. Abhyanga (massage), svedana, basti (enema), nasya (nasal inhalation), snehana (oleation) and virechana (purgation) are prescribed as common treatments in vata vyadhi⁸. Upanaha is one among the modality of svedana used widely in the management of sandhigata vata, which is found to be clinically beneficial⁹ by subsiding vata, which helps to conquer the rooksha (dryness) and sheeta guna (coldness) of vata by snigdha (unctuous) and ushna guna (hot potency)¹⁰. Reference of tila is available as svedopaga dravya¹¹. Hence the study is intended to compare the effect of

atasi upanaha sveda and tila upanaha sveda's management of sandhigata vata.

Objectives of the study

1. To evaluate the efficacy of tila upanaha sveda in sandhigata vata (Osteoarthritis of the knee).
2. To evaluate the efficacy of atasi upanaha sveda in sandhigata vata (Osteoarthritis of the knee).
3. To compare the efficacy of atasi upanaha sveda and tila upanaha sveda in sandhigata vata (Osteoarthritis of the knee).

MATERIALS AND METHODS

Study design – Randomized controlled single-blind clinical study.

The study was carried out after obtaining clearance from ICEC/AAMC/Date:29.02.2020

CTRI registered number for the study was-CTRI/2021/03/031912.

Sample source: Patients suffering from sandhigata vata (knee osteoarthritis) were selected from OPD and IPD of Panchakarma of Alvas Ayurveda Medical College Hospital, Moodbidri, Dakshina Kannada, Karnataka, India.

Sample size – A total of 40 patients, among which 20 patients each, were assigned randomly to AUS (Atasi Upanaha Sveda) and TUS (Tila Upanaha Sveda) groups for the study through the lottery method.

Trial drug details- Tila upnaha sveda contains tila (*Sesamum indicum* Linn) and dhanyamla as ingredients.

Control drug details- Atasi upanaha sveda contains Atasi (*Linum usitatissimum*) and dhanyamla as ingredients.

Criteria for selection of patients

Diagnostic criteria: The patients were diagnosed based on the following clinical features,

- Sandhi shoola-Pain in knee joints.
- Sandhi atopa - crepitus,

Associated with other symptoms, including

- Sandhi shotha- Swelling in knee joints.
- Prasarana akunchanayo vedana- Pain during flexion and extension of the knee

Inclusion criteria

- Patients fulfilling the diagnostic criteria
- Patients between 30 to 75 years were considered.
- Patients who were fit for upanaha sveda.

Exclusion criteria

- Patients having Rheumatoid Arthritis, Gouty Arthritis.
- Patient with acute traumatic injury to the knee.
- Congenital bony deformity of the knee joint.

Intervention

Purva karma- 150 g of either tila choorna or atasi choorna made to paste by adding 100 ml of dhanyamla. The prepared semi-solid paste is warmed and kept ready.

Pradhana Karma- Patients were asked to lie supine or sit comfortably with an exposed knee joint. Then warmed paste was applied over the janusandhi, covered with eranda patra, and firmly bandaged with khora cloth.

Paschat Karma- Upanaha is retained for 12 hours and then removed, and the part was cleaned with warm water.

Duration of treatment- The duration of treatment for both groups was seven days.

In this study, 44 patients were registered irrespective of their sex, religion etc. They were randomly divided into two groups-Tila, upanaha sveda (Group TUS) and Atasi upanaha sveda (Group AUS). Assessments of the patients were done before treatment, 4th day, after treatment and during follow-up time on the 15th day, 30th day, 45th day and 60th day.

Assessment criteria

Subjective criteria

The symptoms like pain, stiffness and physical function were evaluated based on a modified WOMAC SCORE (CRD- Pune Version).

Objective criteria

- Swelling
- Crepitus
- Tenderness
- Range of motion was assessed with a universal goniometer

Table 1: Scoring Pattern of Objective Criteria

Swelling	None (No swelling)	0
	Mild (Slightly obvious)	1
	Moderate (Covers well over bony prominence)	2
	Severe (Much elevated)	3
Tenderness	No tenderness	0
	Tenderness on palpation without a flinch	1
	Tenderness with flinch to palpation	2
	Tenderness with withdrawal	3
Crepitus	No complaints	0
	Mild sounds rarely	1
	Felt on examination	2
	Heard (Pt c/o sound from knee)	3
Range of movement	Angle of extension	
	180 degrees	0
	170-100 degree	1
	<100	2
	Angle of flexion	
	140 degrees	0
120-90 degree	1	
<90 degree	2	

OBSERVATION AND RESULT

Forty-four patients of janu sandhigata vata were selected and randomly grouped into two groups. A total of 24 patients were registered in group TUS, four dropouts were there, and 20 were registered in group AUS with no dropout. Out of 44 patients, 31(70.5%) were females. The maximum number of patients belonged to the age group of 30-45 years (45.6%), and most of them were housewives (31.8%) and did sedentary work (72.73%).

Most patients belonged to the vata- kaphaja prakruthi (45.45%). Vishamagni was noted in 45.45%. Patients showed the following symptoms of rasa kshaya lakshana - dryness (6.81%), tiredness on exertion (79.54%), emaciation (38.64%), intolerance of sound (52.27%) and weakness (68.18%). Patients showed the following symptoms: asthi kshaya lakshana- pricking type of pain (77.27%), falling of teeth, hair, and nail (31.81%). Patients showed the following symptoms of majja kshaya lakshana- osteoporosis (38.63%), giddiness (15.91%) and dimness of vision

(22.72%). Patients showed the following symptoms of medo vridhi lakshana- dyspnoea on minimal exertion (40.90%) and sagging of buttocks, breast, and abdomen (11.36%).

Complications of Procedure: Out of 44 patients, 11.36 % showed redness as a complication, and 9.1 % of patients showed itching as a complication. In group TUS, five patients have shown the symptoms of hypersensitivity reactions such as redness and itching. Among those 4 were dropouts. Hypersensitivity reactions like itching were shown within 3 hours of application of lepa.

The signs and symptoms were assessed before 4th day. After treatment, the assessment criteria are based on the 15th day, 30th day, 45th day and 60th day. The effect of the therapy was statistically analysed. Statistical analysis results within the group were done with the Wilcoxon signed rank test and between the groups with the Mann-Whitney rank sum test. In comparing both groups, atasi upanaha sveda was statistically significant on swelling.

Table 2: Effect of treatment in signs and symptoms on at, 15th day, 30th day, 45th day and 60th in group TUS and AUS (right)

		Swelling	Tenderness	Crepitus	Womac score	Flexion	Extension
Group Tila Upanaha Sveda	AT	p<0.001	p<0.001	p<0.001	p<0.001	p<0.001	p<0.05
	15 th day	p<0.001	p<0.001	p<0.001	p<0.001	p<0.001	p<0.05
	30 th day	p<0.001	p<0.001	p<0.001	p<0.001	p<0.001	p<0.05
	45 th day	p<0.001	p<0.001	p<0.001	p<0.05	p<0.001	p<0.05
	60 th day	p<0.001	p<0.001	p<0.05	p<0.05	p<0.05	p>0.05
Group Atasi Upanaha Sveda	AT	p<0.001	p<0.001	p<0.001	p<0.001	p<0.001	p<0.001
	15 th day	p<0.001	p<0.001	p<0.001	p<0.001	p<0.001	p>0.05
	30 th day	p<0.001	p<0.001	p<0.001	p<0.001	p<0.001	p>0.05
	45 th day	p<0.001	p<0.001	p<0.001	p<0.05	p<0.001	p>0.05
	60 th day	p<0.001	p<0.001	p<0.001	p<0.05	p>0.05	p>0.05

AT: After Treatment

Table 3: Effect of treatment in signs and symptoms on at, 15th day, 30th day, 45th day and 60th in group TUS and AUS (left)

		Swelling	Tenderness	Crepitus	Womac score	Flexion	Extension
Group Tila Upanaha Sveda	AT	p<0.05	p<0.001	p>0.05	p<0.001	p<0.001	p<0.05
	15 th day	p<0.05	p<0.001	p<0.001	p<0.001	p<0.001	p<0.05
	30 th day	p<0.05	p<0.001	p<0.001	p<0.001	p<0.001	p<0.05
	45 th day	p<0.05	p<0.001	p<0.001	p<0.05	p<0.001	p>0.05
	60 th day	p>0.05	p<0.05	p<0.05	p<0.05	p<0.05	p>0.05
Group Atasi Upanaha Sveda	AT	p<0.001	p<0.001	p<0.001	p<0.001	p<0.001	p<0.05
	15 th day	p<0.001	p<0.001	p<0.001	p<0.001	p<0.001	p<0.001
	30 th day	p<0.001	p<0.001	p<0.001	p<0.001	p<0.001	p>0.05
	45 th day	p<0.001	p<0.001	p<0.001	p<0.05	p<0.001	p>0.05
	60 th day	p<0.001	p<0.05	p<0.001	p<0.05	p>0.05	p>0.05

AT: After Treatment

Table 4: Overall assessment of relief in both the groups

Overall assessment	Group Tila Upanaha Sveda		Group Atasi Upanaha Sveda	
	Number of patients	% of patients	Number of patients	% of patients
Complete remission (100%)	0	0	0	0
Marked improvement (60-99%)	7	35%	5	25%
Moderate improvement (30-59%)	6	30%	9	45%
Mild improvement (1- 29%)	7	35%	5	25%
No improvement (0%)	0	0	1	5%

DISCUSSION

The disease incidence in the groups was 45.6% in the age group between 30-45 years; 27.2% belonged to the age groups 46-60 and 61-75 years. The prevalence of OA increases with age; there is a growing recognition that OA affects people at younger ages¹². Studies have proved Osteoarthritis (OA), or Degenerative Joint Disease (DJD), may first appear without symptoms between 20 and 30 years of age. The symptoms, such as pain and inflammation, appear in middle age¹³. Among 44 patients, 70.5% were female, and the females had a higher prevalence than males (11.4% vs 6.8%) in OA¹². In the menopausal and pre-menopausal periods, the deficiency of female hormone (oestrogen) leads to different bone and joints problem, and sandhigata vata is more common among them. Females, particularly those ≥55 years, tended to have more severe OA in the knee but not in other sites. Middle-aged women had a high prevalence of moderate-to-severe knee osteoarthritis. In patients with knee OA, serum vitamin D levels are significantly lower than in individuals without knee

OA, particularly at an early stage. Vitamin D deficiency increases the risk of knee OA. Studies have proven that higher than six pregnancies also increase the risk of knee OA by 1.95 times¹⁴. Joint injury increases the risk for knee OA; after a knee injury, women had a three-fold and men had a 5 to 6-fold risk for developing knee OA¹². 72.73 % of patients belong to sedentary work; abnormal mechanical loading in various sports activities or during heavy work may activate the biochemical cascade that leads to joint degeneration and pain¹². Most patients, 77.3%, followed the mixed diet; most of the patients in the study were in and around the coastal belt and consumed more katu, tikta, atiruksha, atisheetha aharas, which can cause sandhigata vata. A positive association has been shown between elevated serum cholesterol and OA. Highly processed and fried foods, including white flour, white rice, potatoes, whole milk, cheese etc., can worsen and increase AGE levels resulting in inflammation and aggravating OA¹⁵. The essential role of vitamin K in bone and cartilage health is incontrovertible. Vitamin K is involved in bone and cartilage mineralization¹⁶. Out of the 44 patients, 79.5 %

lacked exercise; lack of practice or exercise gradually leads to weight gain, ultimately leading to sandhigata vata. Quadriceps strength deficit in the joints is significant because it causes progressive loss of function. These symptoms significantly restrict the individual's ability to get up from a chair, walk, or climb stairs. Walking with a limp, poor limb alignment, and instabilities can also be observed in individuals with OA¹². 61.36% of the patients were addicted to tea, and the average tea consumption frequency in the study group was 3 per day; an important tea component is caffeine, which has an adverse effect on osteoporosis. Daily consumption of caffeine can accelerate bone loss¹⁷. Most patients had vata-kapha prakriti. As mentioned in the classics, vata-dominant prakriti persons are more prone to vata vikaras. Prakriti of an individual may be correlated to disease susceptibility. 36.36 % were in the group overweight (25-30 kg/m²). The effect of being overweight on OA has been thought to be mediated through the increased mechanical loading of the knee and hip. This would lead to cartilage damage in these weight-bearing joints¹⁸. Obese women with body mass index (BMI) of 30-35 kg/m² had a four times higher risk for knee OA than non-obese women. The corresponding was 4.8 for men¹². Out of the 44 patients, 27.27 % patients have waist circumference in the group of 101-110 cm; waist circumference is associated with the development of difficulty with walking at a speed of at least 1.2 m/s and distance of at least 400 meters over four years among adults with or at risk of knee OA¹⁸. Most patients suffer from Osteoarthritis in the cold season, and in this season, Vata usually aggravates and causes the disease. And due to prolonged standing and climbing stairs, decreased strength in the muscle groups involving the joints is significant because it causes progressive loss of function. These symptoms significantly restrict the individual's ability to get up from a chair, walk, or climb stairs; walking with a limp, poor limb alignment, and instabilities can also be observed in individuals with OA¹². Most patients showed rasa kshaya lakshana, 45.45% had vishamagni, and 6.82 % had mandagni. Rasa dhatu is the first dhatu formed out of ahara. If the ahara is not digested properly, then the rasa dhatu formation will be affected; mandagni and vishamagni will lead to improper digestion of ahara, thereby leading to rasa kshaya. Due to dhatukshaya (rasa dhatu), subsequent dhatus are not formed well; hence this may lead to the OA. 77.27 % were showing asthi kshaya lakshana, Vata dosha and asthi dhatu are related through ashraya ashrayi bhava; increase in vata dosha causes depletion of asthi dhatu. Hence presenting asthi kshaya lakshana¹⁹. Out of 44 patients, 40.90 % of patients were showing medo vridhi lakshana; studies have proven that weight loss alters pulmonary function. There was an increase in resting FVC, FRC and ERV after weight loss²⁰. Accumulating adipose tissue in the abdominal and gluteo-femoral regions is associated with developing overweight-related comorbidities²¹. In sandhigata vata, there is vridhi of vata dosha and kshaya of kapha dosha. The aggravated vata brings rukshatva, laghutva, saushirya and kharatva into the joints. It destroys the structure and function of the joint. Snehana and svedana come under the first line of treatment for vata-vyadhi, including sandhigatavata. Sushruta has typically mentioned upanaha sveda in sandhigata rogas. Upanaha is a type of svedana, and hence it induces hyperthermia which improves local blood and lymphatic circulation and thereby improving local tissue metabolism, reduces inflammation by modifying secretion of various inflammatory mediators, relaxes local musculature by the physical effect of heat and thereby reduces pain, increases the rate of transdermal drug delivery²². Tila upanaha contains only tila as an ingredient mixed with dhanyamla and applied over the affected knee. Tila possesses guru, snigdha, teekshna, sukshma guna, ushna veerya, vata kapha hara, and balya karma may have enabled better relief in sandhigata vata²³. Research showed the pharmacological properties of *Sesamum indicum* Linn related to osteoarthritis

include vaso relaxant activity and analgesic activity²⁴. Dhanyamla is having ushna veerya. The diseases of vatavaha srotas and asthivaha srotas can be effectively managed with shula prashamana and vedana sthapana actions of dhanyamla. The analgesic and anti-inflammatory actions of ingredients are beneficial in managing inflammatory condition²⁵. Atasi upanaha contains only atasi as an ingredient mixed with dhanyamla and applied over the affected knee. Atasi possesses guru, snigdha, pichila guna, ushna veerya, and vata hara properties²⁶. Research showed the pharmacological action of *Linum usitatissimum* as anti-inflammatory and analgesic properties²⁷.

CONCLUSION

Tila upanaha sveda showed a highly significant (p<0.001) effect on tenderness, womac score, and flexion (B/L knees). Swelling, crepitus (Rt knees). Significant (P<0.05) effect on swelling (Lt knee), extension (B/L knee), and insignificant (p>0.05) effect on crepitus (Lt knee).

Atasi upanaha sveda showed a highly significant (p<0.001) effect on swelling, tenderness, crepitus, womac score, flexion (B/L knees) and extension (Rt knee). Significant (P<0.05) effect on extension (Lt knee). In comparing, a significant difference was seen in swelling of the Rt knee (P<0.05) and Lt knee (p<0.001). In group TUS, out of 44 patients, 35 % have marked improvement, 30 % have moderate improvement, and 35 % have mild improvement. In group AUS, 25 % have observed improvement, 45 % have got moderate improvement, 25 % have mild improvement, and 5 % have got no improvement. Atasi upanaha sveda yielded better relief when compared with tila upanaha sveda in the management of sandhigata vata (knee osteoarthritis).

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Cite this article as:

Dharshana Krishnan O and Praveen BS. A randomized controlled clinical study on tila upanaha in the management of sandhigata vata. Int. J. Res. Ayurveda Pharm. 2022;13(5):53-57 <http://dx.doi.org/10.7897/2277-4343.1305122>

Source of support: Nil, Conflict of interest: None Declared

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