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Clinical evaluation of *Nirgundi Taila* and *Dashmoola Ghrita* in the management of *Sandhigata Vata* (Osteoarthritis)

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ABSTRACT

Though *Sandhigata Vata* is described under the broad heading of *Vatavyadhi* in most of the *Samhita* and *Sangraha Granthas*, it is not included under 80 types of "Nanatmaja Vatavyadhi", Charaka was first, who described separately *Sandhigata Vata* as - "*Sandhigata Anila*" in *Vatavyadhi* chapter. The clinical presentation of *Sandhigata Vata* resembles to Osteoarthritis, which is the most common form of arthritis. It begins asymptotically in middle age with progressive symptoms in advancing age. It increases in prevalence with age especially in weight bearing joints. Female are prone with 25% prevalence were 16% in male. In present study 21 patients fulfilling diagnostic criteria of *Sandhigata Vata* were selected. Patients were treated with *Nirgundi Taila* locally 8ml on affected joints, with *Dashmoola Ghrita* 12g. with meal internally twice a day with luke warm water. After a course of therapy of 2 month symptomatic improvement was observed at various levels with better results in the patients treated with *Nirgundi Taila* and *Dashmoola Ghrita*.

Key words: *Sandhigata Vata*, Osteoarthritis, *Vata Vyadhi*, *Nirgundi Taila*, *Dashmoola Ghrita*.

INTRODUCTION

Charaka the pioneer of *Kayachikitsa* was the first who described *Sandhigata Vata* as *Sandhigata Anila*.^[1] *Sushruta* has described the disease under the broad umbrella of *Vatavyadhi*.^[2] In *Jaravastha* (old age) vitiation of *Vata Dosha* is common. The vitiated *Vata* either combines with other *Dushyas*, *Ama* etc. or separately locates in the joints which is *Madhyam Roga Marga* and produce *Sandhigata Vata*.^[3] The

disease is either *Kashtasadhya* or *Asadhya*. On the basis of symptomatology and nature of the disease, *Sandhigata Vata* is much similar to Osteoarthritis, which is most common form of arthritis in old people.

Worldwide, musculoskeletal disorders are the most common causes of severe long term pain and physical disability. Joint diseases account for half of all the chronic conditions in aged people. Osteoarthritis (OA) is a common form of degenerative joint disease, occurring primarily in older persons, characterized by joint pain, tenderness, crepitus, limitation of movements, occasional effusion and inflammation without systemic effects, erosion of the articular cartilage, hypertrophy of bone at the margins (i.e., osteophytes), subchondral sclerosis and a range of biochemical and morphologic alterations of the synovial membrane and joint capsule. Pathologic changes in the late stages of OA include softening, ulceration and focal disintegration of the articular cartilage; synovial inflammation also can occur.^[4] Clinical manifestations of OA range from mild to severe and affects weight-bearing joints such as

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knees, hips, feet, spine and also hands and later leading to chronic disability.^[5] According to epidemiology, Osteoarthritis accounts for 22% to 40% prevalence in India. Radiographic evidence of OA is present in majority of people over the age of 65. In India 5.3% male and 4.8% female are aged more than 65 years.^[6] It is projected that arthritis will be biggest epidemic in India by 2013, affecting around 650 million people.^[7] Osteoarthritis strikes women more often than men and it increase in prevalence, incidence and severity after menopause. Aetiology of OA is multifactorial. Various morphological as well as biochemical changes result in a softened, ulcerated and malfunctioning articular cartilage.^[8] Age, gender, body weight, B.M.I., trauma, repetitive stress on affected joints, genetic factors are the risk factors which play an important role in the manifestation of Osteoarthritis.^[9]

AIMS AND OBJECTIVES

To evaluate the efficacy of *Nirgundi Taila* locally combined with *Dashmoola Ghrita* orally on *Sandhigata Vata* (OA).

MATERIALS AND METHODS

Total 21 patients with sign and symptoms of *Sandhigata Vata* (OA), irrespective of sex, occupation etc, who attended OPD of Dept. of *Kayachikitsa*, in I.P.G.T. and R.A., Gujarat Ayurved University, Jamnagar, were selected for the clinical trial. Out of that 1 patient dropped out and 20 patients completed the treatment.

Inclusion Criteria

Patients presenting with the classical signs and symptoms of *Sandhigata Vata* (OA), like *Sandhi Shoola* (Joint pain), *Shotha* (Swelling), *Stambha* (Stiffness), *Sphutana* (Crepitus), *Sparshasahyata* (Tenderness), *Akunchana Prasarane Vedana* (Pain during flexion and extension) etc., aged between 40 - 80 years and patients without any major anatomical deformity were included.

Exclusion Criteria

Patients below 40 and above 80 years of age and suffering from uncontrolled diabetes, Psoriatic

arthritis, Gouty arthritis, Rheumatoid arthritis, Systemic Lupus Erythematosus (SLE), Bone TB and other major systemic disorders were excluded.

Before starting the treatment detailed clinical history was taken in the clinical research proforma based on Ayurvedic and Modern parameters and the written consent was taken from the patients. The study was conducted as open labeled interventional clinical trial. This project has been cleared by Institutional Ethics Committee vide its letter No PGT/7-A/Ethics/2010-11/1858, Date 1-9-2010.

Method of preparation of drugs

All the drugs of *Dashmoola* and *Nirgundi* for the preparation of trial drugs were procured from the pharmacy, GAU, Jamnagar. While *Ghrita* and *Taila* was purchased from Khadi Bhandar, Jamnagar. The drugs were authenticated in the Pharmacognosy Dept. of I.P.G.T. and R.A. and the medicine were prepared by Pharmacy, GAU. Both *Dashmoola Ghrita* and *Nirgundi Taila* were prepared as per the method mentioned in *Shangadhara Samhita*.

Posology

The patients were treated by *Nirgundi Taila* locally on affected joints with *Dashmoola Ghrita* 12 gms. twice a day internally with meal. The duration of therapy was of 2 months and follow up of 1 month.

Criteria for Assessment

- Subjective criteria:** Signs and symptoms were given score depending upon the severity and assessed before and after treatment. Total improvement was categorized as follows; no improvement 0 - 25%, mild improvement > 25% - 50%, moderate improvement > 50% - 75%, Marked Improvement > 75% < 100% and Complete Remission 100%.
- Radiological findings:** Improvement was assessed on the basis of changes in joint space, sub articular sclerosis, articular margin, articular erosion, any soft tissue abnormalities, ankylosis, synovial effusion, deformity, osteophytes and marginal erosion in comparison to initial findings.

3. Objective criteria: Range of joint movement, walking and climbing test.

4. Investigation: The routine hematological, biochemical investigations and urine analysis were carried out before and after treatment.

Scoring for different parameters was done as follows:

Sandhi Shoola (Pain)

- No pain - 0
- Mild pain - 1
- Moderate pain but no difficulty in walking - 2
- Slight difficulty in walking due to pain - 3
- Severe difficulty in walking - 4

Sandhishotha (Swelling)

- No swelling - 0
- Mild swelling - 1
- Moderate swelling - 2
- Severe swelling - 3

Sandhigraha (Stiffness)

- No stiffness - 0
- Mild stiffness - 1
- Moderate stiffness - 2
- Severe difficulty due to stiffness - 3
- Severe stiffness more than 10 minute - 4

Akunchanaprasaranjanya Vedana (Pain during flexion and extension)

- No pain - 0
- Pain without winching of face - 1
- Pain with winching of face - 2
- Prevent complete flexion - 3
- Does not allow passive movement - 4

Sparsha Asahyata (Tenderness)

- No tenderness - 0
- Patient feels tenderness - 1

- Winching of face on touch - 2

Sandhisphutana (Crepitus)

- Does not allow to touch the joint - 3
- Palpable crepitus - 1
- Audible crepitus - 2
- No crepitus - 0

Synovial Effusion

- Present - 2
- Regress - 1
- Absent - 0

RESULTS

The clinical study showed significant improvement on cardinal symptoms like *Sandhi Shoola* (Joint pain), *Sandhi Shotha* (Joint Swelling), *Aakunchane - Prasarane Vedna* (Pain during flexion and extention), *Sandhigraha* (Joint Stiffness), *Sandhisputana* (Crepitus), *Sparshasahyata* (Tenderness).

Treatment have provided statistically highly significant result on walking - climbing test and range of joint movement.

Treatment modalities provided statistically significant change on synovial effusion whereas no significant results were found in other parameters like osteophytes, joint space and sub-articular sclerosis. The results obtained have been shown in Tables 1-7.

Table 1: Effect of therapy on cardinal symptoms.

Symptom	Side	Mean		D	SD (±)	SE (±)	t	p
		BT	AT					
<i>Sandhi Shoola</i> (Joint pain)	Left, n = 20	2.3	0.7	1.5	0.6	0.1	11.52	<0.001
	Righ t, n = 20	2.0	0.8	1.2	0.4	0.1	11.22	<0.001
<i>Sandhi Shotha</i> (Joint Swelling)	Left, n = 20	1.6	0.5	1.1	0.5	0.1	8.09	<0.001
	Righ t	1.4	0.5	0.8	0.5	0.1	6.7	<0.001

	t, n = 20	3	0	3	1	4	4	01
Aakunchan e-Prasarane Vedana (Pain during flexion and extention)	Left, n = 20	2.3	0.8	1.4	0.5	0.1	11.00	<0.01
	Right, t, n = 20	2.1	0.8	1.2	0.5	0.1	10.52	<0.01
Sandhigraha (Joint Stiffness)	Left, n = 20	2.0	0.8	1.1	0.6	0.1	7.21	<0.01
	Right, t, n = 20	1.8	0.6	1.2	0.5	0.1	9.30	<0.01
Sandhisputana (Crepitus)	Left, n = 20	1.6	0.6	1.0	0.5	0.1	7.20	<0.01
	Right, t, n = 20	1.6	0.6	1.0	0.7	0.2	4.56	<0.01
Sparshasahyata (Tenderness)	Left, n = 20	1.9	0.7	1.2	0.5	0.1	7.04	<0.01
	Right, t, n = 20	2.0	0.6	1.3	0.6	0.2	5.83	<0.01

N = Number, BT = Before Treatment, AT = After Treatment, SD = Standard Deviation, SE = Standard Error

Table 2: Effect of therapy on X-ray

Symptom	Mean		D	SD(±)	SE(±)	t	p
	BT	AT					
Synovial Effusion, n=9	1.80	0.40	1.40	0.75	0.34	4.16	<0.01

N = Number, BT = Before Treatment, AT = After Treatment, SD = Standard Deviation, SE = Standard Error

Table 3: Effect of therapy on walking and climbing test

Test	Mean		D	SD(±)	SE(±)	t	P
	BT	AT					
Walking, n=20	3.64	3.50	0.14	0.21	0.05	2.88	<0.001

Climbing, n=20	4.52	4.22	0.30	0.28	0.06	4.61	<0.001
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N = Number, BT = Before Treatment, AT = After Treatment, SD = Standard Deviation, SE = Standard Error

Table 4: Effect of therapy on range of joint movement.

Test	Mean		D	SD (±)	SE (±)	t	P	
	BT	AT						
Knee joint flexion	Left, n=20	114.40	119.20	-4.80	3.11	0.69	6.91	<0.001
	Right, n=20	113.55	117.90	-4.35	3.14	0.70	6.21	<0.001

N = Number, BT = Before Treatment, AT = After Treatment, SD = Standard Deviation, SE = Standard Error

Table 5: Effect of therapy on investigation.

Investigation	Mean		D	SD (±)	SE (±)	t	P
	BT	AT					
S. Cholesterol, n=20	185.79	178.00	7.79	20.33	4.67	1.67	>.05
H D L, n=20	47.63	48.84	-1.21	9.94	2.28	0.53	>.05

N = Number, BT = Before Treatment, AT = After Treatment, SD = Standard Deviation, SE = Standard Error

Table 6: Overall effect of therapy

Improvement	%
Mild improvement	20
Moderate improvement	55
Maximum improvement	25

DISCUSSION

Osteoarthritis is also known as degenerative arthritis or degenerative joint disease. It is a clinical syndrome in which low-grade inflammation (*Sandhi Shotha*), results in pain in the joints (*Sandhi Shoola*), caused by

abnormal wearing of cartilage that covers and acts as a cushion inside joints and decrease of synovial fluid that lubricates those joints. As the bone is less protected by cartilage, the patient get pain in the weight bearing joints like knee, ankle, hip etc. Due to pain and swelling the joint can't move properly as the movement is restricted (*Stambha*) and by movements extreme pain (*Aakunchane Prasarane Vedana*) occurs. Usually Osteoarthritis takes time to develop but it becomes unbearable even on mild touch-tenderness (*Sparshasahyata*) later on it results in manifestation of crepitus (*Sandhisputana*). *Sandhigata Vata* and Osteoarthritis can be co-related in that matter.

Nirgundi have *Katu* (pungent), *Tikta* (bitter), *Rasa*, *Laghu* (light), *Ruksha* (dry) in *Guna* (quality), *Virya-Ushna* (hot) where as *Vipaka* (post digestive effect) is *Katu*. It pacifies is *Vata-Kapha*. It is quoted that *Nirgundi* has anti-inflammatory, antispasmodic, analgesic and anti arthritic activity.^{[10],[11]}

Tila Taila has *Snehana* (oelation), *Sandhaniya* and *Shoola Prashamana* (analgesic).^[12] Actions of *Tila Taila* are due to its principal chemical constituents like natural lipids, glycolipids and phospholipids (also in flower), 85% olielic and linoelic acid, Myristic, palmitic, stearic acid etc in traces. It also contains sesamin, sesamolin and sterol salicylates.^[13]

Dashmoola is *Vatakapha Pradhana*, *Tridoshahara Dravya* (though *Dashmoola* has action on *Tri-Dosha* but it acts mainly on *Vata* and *Kapha Dosha*). Overall *Dashmoola* has anti-inflammatory, analgesic, anti-arthritic action.^{[14],[15]}

Ghee is *Madhura* in *Rasa*, *Snigdha*, *Guru - Gunas*, *Virya - Shita*, *Madhura Vipaka* and *Medhya*, *Agni Vardhaka Karma*.^[16] Ghee contain 8% lower saturated fatty acids which makes it easily digestible. Due to having 4-5% lenoleic acid, an essential fatty acid, it promotes proper growth of human body. Ghee also contains vitamin A, B, E and K. vitamin A and E which are anti oxidant and are helpful in preventing oxidative injury to the body. Ghee is lipophilic and this action of ghee facilitates the transportation of ingredients of formulation to target organ and final

delivery inside the cell, because cell membrane is highly lipophilic.^{[16],[17]}

In the present study, the improvement was seen in chief complaints like *Sandhishoola* (Joint pain), *Sandhishotha* (Joint Swelling), *Aakunchane Prasarane Vedana* (Pain during flexion and extension), *Stambha* (Joint Stiffness), *Sparshasahyata* (Tenderness) and *Sandhisputana* (Crepitus) due to *Shoolahara*, *Shothahara* effect of *Nirgundi* and *Tila Taila* both. In *Sandhigata Vata* the *Vata* is mainly vitiated by *Shita*, *Ruksha* and *Chala Guna*, *Nirgundi* is *Virya Pradhana* drug and *Taila* is also *Ushna Virya* so they provide relief in *Shoola*. The *Rukshata* of *Vata* is hampered by *Taila* because *Taila* is *Snigdha* and by preparation of *Taila Kalpana* it becomes more potent. *Sandhishoola* is mainly occurred by *Chala Guna* of *Vayu*, when *Chala Guna* of *Vayu* is obstructed, it results in *Margavarana* (obstruction) process. Due to *Katu Rasa*, *Katu Vipaka* and *Ushna Guna Taila* removes the *obstruction*, thus *Vata* can do its *Cheshta Karma* normally. *Nirgundi* has inhibitory action on prostaglandin biosynthesis; latest research proved that anti-inflammatory and analgesic properties mediated via PG synthesis inhibition. It acts as COX-2 inhibitors that might be responsible for its NSAID'S like activity.^[18]

Dashmoola is *Vata-Kapha Pradhana Dravya* (It acts on *Vata* as well as *Kapha Dosha* both), so it could be work in both ways, in *Avaranajanya Samprapti* it works by *Katu*, *Tikta - Rasa*, *Ushna - Virya* and its *Amapachana Karma*. In *Dhatukshayajanya Samprapti*, it works by their *Madhura Skandhi Dravya* like *Shaliparni*, *Prushniparni*, *Gokshura*, *Bruhati*, *Kantakari* etc.,^[19] and by making formulation with *Ghrita*, it is helpful in *Samprapti Vighatana*. Azulene, glycoside oroksilonom, aegelin, oxalic acid, steroid, new β phenlethyllamine, volatile oil, harmine, diosgenin, gilogenin, sitosterol, some saponin, glycozyde, tannin - provide analgesic, anti arthritic and anti-inflammatory effect.^[20]

The improvement in radiological findings may be due to anti-inflammatory activity by external and internal *Sneha Kalpana* it reaches upto the minute level as *Sneha* has *Sukshama Guna*, *Anupravanabhava*. Both

formulations are lipophilic and this action of their, facilitates the transportation of ingredients of formulation to target organ and final delivery inside the cell, because cell membrane is highly lipophilic. It soothes the joints and also helps in treating levels of synovial fluid making the entire structure lubricated and easy to move. By inhibitory action on prostaglandin biosynthesis, anti-inflammatory, analgesic activities, it acts as COX-2 inhibitors that might be responsible for its NSAID'S like activity. It also enhances the blood flow.

Decreased in serum cholesterol level may be due to *Sukshma*, *Lekhana Guna*, *Ushna Virya*, *Katu Vipaka* and *Lekhana* and *Amapachana Karma* of *Dashmoola* drugs and *Taila*.

The improvement in walking and climbing and knee joint flexion was due to increased blood flow and it is due to *Sukshma* and *Snigdha Guna* of *Taila* and *Ghruta*.

CONCLUSION

The improvement of the patients in regard of movements (*Cheshta*) of affected joint was significant that indicates formulation's effectiveness on cardinal symptom. Therapy also provided significant changes in walking test, climbing test and range of joint movement. The combined treatment of *Dashmoola Ghrita* and *Nirgundi Taila* provided better and significant effect in *Sandhishoola*, *Aakunchane Prasarane Vedana* and *Sandhishotha*. The above effect was found due to *Vednasthapana Karma* of *Nirgundi* and *Amahara*, *Shothahara*, *Dipana* and *Rasayana* effect of *Dashmoola*. As both formulations are *Sneha Kalpana*, they soothe the joints and make them easily mobile. Overall effect of therapy suggests that *Nirgundi Taila* with *Dashmoola Ghrita* provided moderate improvement in maximum subjects.

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