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TITLE

**Efficacy of *Nirgundi Taila* application in the
management of *Sandhigatavata* (Osteoarthritis)- An
open labelled single arm clinical trial**

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TITLE

Efficacy of *Nirgundi Taila* application in the management of *Sandhigataavata* (Osteoarthritis)- An open labelled single arm clinical trial

ABSTRACT

BACKGROUND: Proper functioning of locomotor system is essential for movement of body parts at different level in order to meet and sustain daily life activities. During *Jaravastha* (old age) due to wear and tear phenomenon of joint ligaments and muscles, the frequency of osteoarthritis is pronounced. Osteoarthritis may be regarded as a reward of longevity, which can be equated to *Sandhigataavata* described in Ayurveda which is a silent enemy of the physical ability of humanity. The disease is produced by morbid *Vatadosha*, which takes shelter in the *Sandhi* (joint) and the affected *Sandhi* resembles a bag filled with air resulting in *Shotha* (oedema) with difficult and painful flexion and extension. Ayurveda defines *Chikitsa* (treatment) as '*Samprapti Vighatana*' (breaking the pathogenesis), hence in the present instance the treatment is aimed at breaking the pathology which causes morbidity of *Vatadosha*. **AIMS:** To assess the efficacy of *Nirgundi Taila* in *Sandhigataavata*. **MATERIALS & METHODS:** In the present study 21 patients aged between 40 to 80 years, irrespective of their sex and socio-economical status fulfilling inclusion criteria of *Sandhigataavata* were selected from the OPD of dept. of Kayachikitsa, in I.P.G.T. & R.A., Gujarat Ayurved University, Jamnagar. Patients were treated with external application of *Nirgundi Taila* on affected joints for 20 minutes twice a day for 60 days. **RESULTS:** After the course of therapy for 2 months, symptomatic improvement was observed in Joint pain, Swelling, Range of joint movements, Walking and Climbing tests. **CONCLUSION:** *Sandhigataavata* is a multi-factorial chronic progressive degenerative disease that directly hampers individual's quality of life. Overall effect of therapy suggests that *Nirgundi Taila* locally provided mild improvement in maximum subjects.

KEYWORDS: *Jaravastha*, *Nirgundi taila*, *Osteoarthritis*, *Sandhigataavata*, *Vatavyadhi*

Introduction

Acharya Charaka the pioneer of *Kayachikitsa* was the first who described *Sandhigataavata* as *Sandhigata Anila*.^[1] Sushruta has described the disease under the broad umbrella of *Vatavyadhi*.^[2] In *Jaravastha* vitiation of *Vatadosha* is common. The vitiated *Vata* either combines with other *Dushyas* (body tissues), *Ama* (free radicals/wastes) etc. or separately locates in the joints which is *Madhyamarogamarga* (pathological sites), and generate *Sandhigataavata*.^[1] The disease is either *Kashtasadhya* (difficult to treat) or *Yapya* (palliative). Joint pain and swelling manifest as prime features of osteoarthritis (OA), due to swelling there is marked reduction in movements and patient gets extreme pain on even just simple movements. On the basis of these symptomatology and chronic/gradual progressive degenerative nature of the disease, *Sandhigataavata* is much similar to osteoarthritis, which is most common form of arthritis in old people. According to a survey, osteoarthritis tops all the ailments in the country and is the commonest joint problem among elders.^[3] In elderly female patients it is most common in menopausal age while radiologically the disease is more evident in people aged more than 65 years.^[4] OA is estimated to be the 10th leading cause of non-fatal burden.^[5]

OA occurs primarily in older persons, characterised 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), sub-chondral 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, focal disintegration of the articular cartilage and synovial inflammation.^[6] Clinical manifestations of OA ranges from mild to severe, and affects weight-bearing joints such as knees, hips, feet, spine and also hands and further leading to chronic disability.^[7] Aetiology of OA is multi factorial and depends on age, gender, body weight, B.M.I., trauma, repetitive stress on affected joints, genetic factors, etc which are the risk factors playing important role in its manifestation.^[8] For effective treatment of the conditions like *Sandhigataavata*, *Abhyanga* (massage) is mentioned as first treatment plan by Sushruta.^[9] As patient gets pain during movement of the joint local application of the oil helps in movement by soothing it. *Nirgundi Taila* is a classical preparation for *Vatavyadhi* as indicated by Charaka.^[10] Hence, the present study was carried out to assess the efficacy of *Nirgundi Taila* on *Sandhigataavata*.

Materials & Methods

Total 21 patients with signs and symptoms of *Sandhigatawata*, who fulfilled the inclusion criteria of the study and attended the OPD of dept. of *Kayachikitsa*, in I.P.G.T. & R.A., Gujrat Ayurved University, Jamnagar, were selected for the clinical trial.

Inclusion Criteria:

Patients irrespective of sex, occupation, socio-economic status, presenting with the classical signs and symptoms of *Sandhigatawata*, 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 Ayurveda and Modern parameters and the written consent was taken from the patients. The study was conducted as open labelled 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:

Nirgundi for the preparation of trial drug *Nirgundi Taila* were procured from the pharmacy, GAU, Jamnagar. While *Taila* was purchased from Khadi Bhandar, Jamnagar. The drugs were authenticated in the pharmacognosy dept. of I.P.G.T. & R.A. and the medicine were prepared by pharmacy, GAU. *Nirgundi Taila* was prepared as per the standard method mentioned in Shangadhara Samhita for *Tailapakavidhi* (procedure).^[11]

Posology:

The patients were treated with *Nirgundi Taila* locally on affected joints (8 ml twice a day) with 2 placebo cap (filled with starch-250 mg each) twice a day after meal with luke warm water. The duration of therapy was for 2 months with an follow up of 1 month.

Criteria for Assessment:

1) **Subjective criteria:** Signs and symptoms were given score depending upon the severity and assessed before and after treatment.

Total improvement was categorised as follows;

- no improvement: 0 - 25%,
- mild improvement: >25% -50%,
- moderate improvement: >50% -75%,
- marked Improvement: > 75% -<100% and
- Complete Remission 100%

2) **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 & climbing test.^[12]

4) **Investigation:** Routine haematological, 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

Sandhi Shotha (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 & 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

Nirgundi Taila showed significant improvement on cardinal symptoms like *Sandhi Shoola*, *Sandhi Shotha*, *Aakunchane-Prasarane Vedna*, *Sandhigraha*, *Sandhisphutana*, *Sparshasahyata*.

Nirgundi Taila also provided statistically highly significant result on walking-climbing test range of joint movement and synovial effusion whereas no significant results were found in other parameters like osteophytes, joint space and sub-articular sclerosis.

Highly significant relief was found in both the limbs in symptoms like joint pain, swelling and pain during flexion and extension of the joints. Significant relief was observed in synovial effusion of the joint. In all the patients, walking and climbing stairs tests were performed and was found highly significant. Highly significant improvement was also seen in knee joint flexion. (The results obtained have been shown in **Tables 1 to 5.**)

Overall effect of therapy suggests that treatment have provided mild improvement in maximum subjects (55%) and moderate improvement in 35% of the subjects. No any adverse drug effect was reported in any of the patient throughout the course and follow up period.

Discussion

OA is a degenerative, low inflammatory disorder, where joint inflammation initially causes pain and later swelling. Due to pain and swelling, the mobility of joints is restricted and on movement results in excruciating pain, which becomes unbearable even on mild touch in the form of tenderness. The degenerative changes later results in manifestation of crepitus. The current standard modern medical pharmacological management of osteoarthritis includes the administration of analgesics and non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs are associated with adverse effects. Due to which the use of alternative therapies is on the rise.

Sandhigatawata is a *Vata* dominant disease, in which, *Vataprokopa* (provocation) consequently produces *Agni-Vaiṣamyā* (disturbance of digestive fire) and *Asthivahastrotodusti* (bone nourishing channels). The term *Sandhigatawata* denotes a condition in which, *Vata* is pathologically seated in *Asthi-sandhi* (joints) and causing damage in its structures. Localisation of *Vata* in joints means increase of *Vata-Guna* i.e. *Laghu* (lightness), *Ruksha* (dryness) and *Khara* (roughness) in it. Increase of these properties antagonises the properties of *Kapha* resulting into *Shleshakakaphakshaya* (a variety of *Kapha Doshā* which nourishes the joints). The disease process of the *Sandhigatawata* is mainly produced by two major pathogenesis of *Vata* aggravation that is *Dhatukṣhaya* (depletion of body tissue) and *Margaavarāṇa* (obstruction to movement). *Dhatukṣhaya* which mainly happens due to *Kalaja* factor - *Jara* (age) and *Vatawardhakanidanasevana* (consumption of *Vata* aggravating factors). *Margaavarāṇa* mainly happens when there is *Duṣṭi* of *Kapha* as well as *Medasdhatu*, *Mamsa*, *Asthi* and *Majja*, but in both the ways *Agnidūṣṭi* is common. In *Margaavarāṇa* *Duṣṭi* of *Medadhatu* leads to *Sthaulya* and it creates a vicious cycle of repetitive stress on weight bearing joints with functional deterioration.

In female's sex steroids decreases up to a great extent immediately after menopause, which also contributes to development of osteoarthritis. Usually osteoarthritis takes time to develop but it becomes unbearable even on mild touch-tenderness (*Sparshasahyata*) later on it results in manifestation of crepitus (*Sandhisphutana*). *Sandhigatawata* and osteoarthritis can be co-related in that matter.

Clinical outcome of the patient depends on chronicity, severity, later age, obesity, multiple joint involvement, severe joint destruction and combination with other systemic diseases (*Vyadhisankarya*) does not yield good improvement in symptoms (taking more time).

Nirgundi possess *Katu* (pungent), *Tikta* (bitter) *Rasa* (taste), *Laghu* (light), *Ruksha* (dry), *Guna* (quality). It is a drug with *Ushna Virya* (hot potency), whereas its *Vipaka* (post digestive effect) is *Katu*. It pacifies *Vata-Kapha Doshā* and is quoted that *Nirgundi* has anti-inflammatory, antispasmodic, analgesic and anti-arthritis activity.^[1,13]

Tila Taila has *Snehana*, *Sandhaniya*, and *Shoola Prashamana* (analgesic) effect.^[14] Actions of *Tila Taila* is due to its principal chemical constituents like natural lipids, glycolipids & phospholipids (also in flower), 85% olielic & linoelic acid, myristic, palmitic, stearic acid etc. in traces. It also contains sesamin, sesamol and sterol salicylates.^[7] In the present study, the improvement was seen in chief complaints like *Sandhi Shoola*, *Sandhi Shotha*, *Aakunchaneprasaranevedna*,

Table 1: Effect of therapy on cardinal symptoms

Symptom	Side	n	Mean		d	%	SD(±)	SE(±)	t	P
			BT	AT						
<i>Sandhi Shoola</i>	Left	20	2.30	1.10	1.25	53.49	0.77	0.17	7.22	<0.001
	Right	17	2.41	1.29	1.12	46.29	0.64	0.20	5.75	<0.001
<i>Sandhi Shotha</i>	Left	20	1.45	0.85	0.60	41.38	0.60	0.13	4.49	<0.001
	Right	14	1.64	0.71	0.93	56.62	0.74	0.20	4.67	<0.001
<i>Aakunchane-Prasarane Vedna</i>	Left	20	2.20	1.10	1.10	50.00	0.74	0.17	6.65	<0.001
	Right	19	2.42	1.32	1.11	45.65	0.62	0.14	7.37	<0.001
<i>Sandhigraha</i>	Left	15	1.80	0.80	1.00	55.56	0.77	0.20	5.02	<0.001
	Right	15	1.60	0.73	0.87	54.17	0.75	0.19	4.48	<0.001
<i>Sandhisputana</i>	Left	15	2.00	1.27	0.73	36.67	0.79	0.20	3.58	<0.01
	Right	12	1.33	0.83	0.50	37.50	0.66	0.19	2.62	<0.01
<i>Sparshasahyata</i>	Left	8	1.50	0.63	0.87	58.33	0.67	0.24	3.71	<0.01
	Right	7	1.71	1.00	0.71	41.67	0.52	0.20	3.65	<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	n	Mean		d	%	SD(±)	SE(±)	t	P
		BT	AT						
Synovial Effusion	6	1.50	0.50	1.00	66.67	0.45	0.22	4.47	<0.01

Table 3: Effect of therapy on Walking and Climbing test

Test	n	Mean		d	%	SD(±)	SE(±)	t	P
		BT	AT						
Walking	20	3.77	3.61	0.16	4.18	0.28	0.06	2.51	<.001
Climbing	20	4.62	4.46	0.16	3.30	0.19	0.04	3.62	<.001

Table 4 : Effect of therapy on range of joint movement

Test	n	Mean		d	%	SD (±)	SE (±)	t	P
		BT	AT						
Knee joint flexion									
Left	20	114.65	117.55	-2.90	2.53	3.24	0.72	4.00	<.001
Right	20	113.00	115.60	-2.60	2.30	2.89	0.65	4.02	<.001

Table 5: Overall Effect of Therapy

Improvement	%
No improvement	5
Mild improvement	55
Moderate improvement	35
Maximum improvement	5

Stambha, *Sparshasahyata* and *Sandhisputana* due to *Shoolahara*, *Shothahara* effect of both *Nirgundi* and *Tila Taila*. In *Sandhigatawata* the *Vata* is mainly vitiated by *Shita*, *Ruksha* and *Chalaguna*, *Nirgundi* and *Tila Taila* both are *Ushnavirya* hence provide relief in *Shoola*. The *Rukshata* of *Vata* is hampered by *Tila Taila* as it is *Smigdha* and by preparation of *Taila Kalpana* it becomes more potent. *Sandhi Shoola* is mainly caused by impaired *Chalaguna* of *Vayu*, resulting in *Margavarana*. Due to *Katu Rasa*, *Katwipaka* and *Ushnaguna Taila* removes the obstruction, thus *Vata* can do its *Cheshta Karma* normally.^[15]

Nirgundi has inhibitory action on prostaglandin (PG) biosynthesis; latest research reveal that the anti-inflammatory and analgesic properties are mediated via PG synthesis inhibition. It acts as COX-2 inhibitors that might be responsible for its NSAID'S like activity.

The improvement in radiological findings, may be due to anti-inflammatory activity by external *Snehakalpana* as it reaches at the minute level of cell due to its *Sukshmaguna* (ability to pass through minute channels), *Anupravanabhava* (non-reoccurrence). The formulations is lipophilic and due to its action, it 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 improving the levels of synovial fluid, making the entire structure lubricated and easy to move. The improvement in walking and climbing and knee joint flexion can be attributed to increased blood flow and also due to *Sukshama* and *Smigdha-Guna* of *Taila*.

Conclusion

Sandhigatawata is a multi-factorial chronic progressive degenerative disease that directly hampers individual's quality of life. The improvement observed in the patients in concern to movements (*Cheshta*) of the affected joint was significant which indicates formulation's effectiveness on cardinal symptom. The therapy has also provided significant changes in walking test, climbing test and range of joint movements. Overall effect of therapy suggests that *Nirgundi Taila* locally provided mild improvement in maximum subjects.

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