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Effect of *Nadi Sweda* on symptoms of Pain, Swelling and Stiffness in Knee Osteoarthritis - An Open Labeled Single Arm Clinical Study

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ABSTRACT

Introduction: More than 100 million populations globally suffer from Osteoarthritis (OA) which is considered the leading cause of disability. The prevalence of OA knee in India is about 6% of total osteoarthritis. Therefore, there is a need for alternative and well-tolerable supplementary treatment which has no drug interaction with conventional drugs for OA. **Aim and objectives**: To evaluate the effect of traditional sudation therapy (*Nadi Swedana)* on pain, swelling and stiffness of patients with knee osteoarthritis. **Method:** The study was conducted after getting approval from Institutional Ethical Committee and was registered to the Clinical Trials Registry of India (CTRI/2018/03/012636 19/03/2018). A total of 20 patients with knee joint osteoarthritis were treated for 6 weeks. Pre-test and the post-test outcome measure was recorded on subjective parameters and statistically analyzed. **Results:** The applied score for pain, swelling and stiffness decreased significantly lower after the intervention ($p<0.05$). **Conclusions**: Traditional sudation therapy by *Nadi Swedana* was beneficial for patients with knee osteoarthritis.

Key words: *Ayurveda, Swedana, osteoarthritis, sudation therapy, CAM*

INTRODUCTION

Osteoarthritis is one of the leading causes of disability and is estimated that over 100 million people globally suffer from Osteoarthritis (OA).[1,2] It is reported that in India the prevalence of OA was found in between the range of 17 - 60 and 6% of this come under knee OA. The most common evident symptoms of knee OA are joint pain, stiffness and reduction in the function of the knee joint.[3] The main aim of OA treatment is to reduce joint pain and stiffness, improve mobility and quality of life, slow down the progress of disease and optimize the functions of patients.[4] To date, there are no disease-modifying treatments are available for OA in conventional medicine. Therefore, there is a need for alternative and well-tolerable supplementary treatment which has no drug interaction with conventional drugs for OA. As per the literature of Ayurveda *Vata, Pitta* and *Shleshma* are the primary and essential constitutional factors of the human organism. *Ayurveda* considers these three factors as the actual intrinsic factors whose imbalance causes or predisposes the various disease conditions. These factors are known as *Doshas* as they are susceptible to imbalance and vitiation. The imbalance of *Tridoshas* is the cause of diseases in the body.[5] *Vata Vyadhi* denotes a group of special disease entities caused by the disturbance of *Vayu* for all practical purposes. *Sandhigata Vata* (osteoarthritis) is an example of *Vata Vyadhi*.[6,7] The administration of *Vatahara Dravyas*(drugs or processes which have opposite properties of *Vata*) having properties like *Snigdha* (sliminess/unctuousness), *Guru* (heaviness), *Ushna*

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(hotness), *Manda* (mildness/slowness), *Shlakshna, Mridu, Pichchila and Sthira Gunayukta)* have seen advocated as specific treatment procedures for various for *Vata* disturbances. Among these procedures *Snehana* (therapeutic oleation), *Swedana* (sudation therapy) and *Basti* (therapeutic enema*)* are the prime importance.[8]

Nadi Swedana is one type of *Swedan Karma* (sudation therapy) and is a popular and easy method of traditional sudation therapy. *Nadi Swedana* is a specialized traditional method type of *Agnisvedaḥ* in which sudation is done by giving steam for relieving pain, swelling and stiffness.[9] A detailed description of *Swedana* is found in Ayurvedic literature and is used by *Ayurvedic* physicians in the management of *Sandhigata Vata.* However, we couldn't find any report in the literature of research investigating the effect of *Nadi Swedana* on pain, swelling and stiffness in a patient with knee osteoarthritis. Therefore, the purpose of this observational study was to evaluate the effect on pain, swelling and stiffness of traditional Sudation therapy for the patient with knee osteoarthritis.

Materials and Methods

A total of 20 patients suffering from osteoarthritis of the knee joint, attending the OPD and IPD of the department of *Kayachikitsa*, Radhakishan Tonshniwal Ayurved College and Hospital, Akola, Maharashtra University of Health Science, Nashik, were enrolled irrespective of age, sex, religion, caste. The study was conducted after getting approval from Institutional Ethics Committee (letter no.266/18) and was registered in CTRI (CTRI/2018/03/012636 on 19/03/2018).

Inclusion criteria

- Patients of the age group between 30 to 80 years.
- Clinically diagnosed with mild to moderate severity of symptoms of osteoarthritis (single or both knee joints) and confirmed by a radiologist or by an experienced Ayurvedic practitioner.

Exclusion criteria

- Pain in the knee is caused by congenital dysplasia of the affected knee, rheumatoid arthritis, autoimmune diseases, malignancies, knee surgery or knee-arthroscopy
- Co-morbid conditions such as a history of Cardiac Arrhythmia, Acute Coronary Syndrome, Myocardial Infarction, Stroke or Severe Arrhythmia in the last 6 months.

Study design: Single-arm study

Duration of treatment: 6 weeks

Intervention

Nadi Swedana is a unique form of *Swedana* procedure where sweating is induced by passing steam over the body part by using a special instrument known as *Nadi Swedana Yantra*. Application of oil (sesame oil) to the body part that is to be subjected to sudation (sweating) treatment, followed by passing the steam to the same part with help of a tubular pipe is the procedure of *Nadi Swedana*. The steam is passed through a rubber tube fitted to the instrument and it is an easy method of applying heat to a localized part of a body. *Dashmoola Kwath Choorna* (mixture of 10 raw drugs) in *Nadi Swedana Yantra* along with a sufficient quantity of water (Table 2).

During the study period all patients were given a placebo (capsule filled with starch powder) of 250 mg thrice daily. To compare the before and after effects of sudation therapy within the study group the paired t-test was done.

Table 1: Ingredients of *Dasamoola Kwath Choorna* with therapeutic actions[10,11]

SN	Drugs	Botanical Name	Therapeutic Actions
1.	*Shalaparni*	*Desmodium gangeticum*	Anti-inflammatory, carminative
2.	*Prishniparni*	*Uraria picta*	Anti-inflammatory, Antipyretic, carminative
3.	*Brihati*	*Solanum indicum*	Anti-pyretic, Digestive, Diuretic
4.	*Kantakari*	*Solanum surattense*	Anti-inflammatory, Digestive, Expectorant

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5.	*Gokshur*	*Tribulus terrestris*	Analgesic, Diuretic, Carminative
6.	*Bilva*	*Aegle marmelos*	Anti-diarrhoeal, Astringent, Digestive
7.	*Agnimanth*	*Premna integrifolia*	Anti-inflammatory, Antipyretic, Analgesic
8.	*Syonaka*	*Oroxylum indica*	Anti-inflammatory, Digestive, Anti-pyretic
9.	*Patala*	*Stereospermum suaveolens*	Anti-inflammatory, Antipyretic, Diuretic
10.	*Gambhari*	*Gmelina arborea*	Anti-inflammatory, Analgesic, Carminative

Assessment criteria

1. **Pain:** Subjective assessment was done as per the patient's severity of pain. This was recorded according to Visual Analog Scale for assessment of Pain (Table 2).

Table 2: Visual Analog Scale for assessment of Pain

Score	Grading of Pain
0	No Pain
1	Mild Pain that you are aware of but not bothered by.
2	Moderate Pain that you can tolerate without medication.
3	Moderate Pain that is discomforting and requires medication.
4-5	Severe Pain and the Patient began to feel anti-social.
6	Severe Pain
7-9	Intensely Severe Pain
10	Most Severe Pain. One may contemplate suicide over it.

2. **Swelling:** Assessment is done by measuring the circumference of the joint, before and after treatment at the fixed point over the joint in centimeters.

3. **Stiffness:** It was assessed as free movement against the normal range of movements (Table 3).

Table 3: Scale for assessment of stiffness

Complete free movement	No stiffness
¾ free movements against that of the normal range of movement	+ stiffness
½ free movements against that of the normal range of movement	++ stiffness
¼ free movements against that of the normal range of movement	+++ stiffness
Difficulty with the complete range of movements	++++ stiffness

Assessment of Clinical Parameters

Detailed clinical observations were done every week for assessment of results. For final assessments, the clinical data were divided into four groups.

1. Complete Improvement:

a) Complete or more than 75% relief or more.

b) 75% or more relief in swelling.

c) Decrease the angle of stiffness by 75% or more.

2. Marked Improvement:

a) 50 to 75% subjective improvement in pain. (Pain scale-1)

b) 50% or more relief in swelling.

c) Decrease the angle of stiffness by 50% or more.

3. Moderate Improvement:

a) 25 to 50% relief in pain. (Pain scale-2)

b) 25% or more relief in swelling.

c) Decrease the angle of stiffness by 25% or more.

4. Mild Improvement:

a) Pain not relieved or only less than 25% (Pain scale-3 & 4)

b) Less than 25% relief in swelling.

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c) Decrease in the angle of stiffness by less than 25%.

The purpose of the study was explained by physicians and oral informed consent was obtained from the study participants. Patient's data were recorded in a case Performa including information on demographic variables of the patients such as age, gender, education, occupation and family monthly income etc. The patient's symptoms of pain, swelling and stiffness were assessed clinically and documented.

RESULTS

70% of the patients in the study were from the age group of 41 - 60. Seventy percent of the patients enrolled in the study were married females, 75% with primary education, 50% were housewives and 85% of patients are from middle-class families (Table 4). 15% of the patients had a family history of OA and 85% had been diagnosed for OA more than one year. Among the study group, 50% of patients had left KOA (out of them 70% female) and 70% of the patients had taken conventional treatment. In the comparison of the "Pain, Swelling and Stiffness Score" of the patients in the group, the difference between pre-test and post-test score value was found to be statistically significant ($p<0.05$). Results after 6 weeks of given therapy 50% patient of the patients got moderate relief, 30% of the patient got marked relief and 20% of the patient got mild relief (Table 5).

Table 4: Distribution of the patients according to their descriptive features.

		Study Group (n)	%
Age Group	31 to 40	02	10
	41 to 50	08	40
	51 to 60	06	30
	61 to 70	01	05
	70 to 80	03	15
Gender	Female	14	70
	Male	06	30
Marital Status	Married	20	100
	Unmarried	0	
Occupation	Housewife	10	50
	Labour	08	40
	Employee/Teacher	01	05
	None/Retired	01	05
Income Status (Monthly Income)	Lower (below 6000)	3	15
	Middle (6001 to 15000)	17	85
	High (above 15000)	0	0
Education	Educated	15	75
	Uneducated	05	25
Family history of OA	Yes	05	25
	No	15	75
Duration of Diagnosis	< 1 Year	17	85
	> 1 Year	03	15
Joint affected by OA	Single	14 (Right KOA-4, Left KOA-10)	70
	Both	06	30
History of previous medication	Conventional only	14	70
	Conventional & CAM	06	30

Table 4: Outcome of treated Patients (Assessment at baseline and after 6 weeks)

Symptoms of OA		Study Group X±SD
Pain	Pre test	3.1±0.718
	Post test	1.9±0.641
	t	7.712
Swelling	Pre test	31.25±6.463
	Post test	30.35±5.752
	t	3.111

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Stiffness	Pre test	1.65±0.671	
	Post test	0.75±0.639	
	t	6.282	
Study Group		n %	%
Result of the treatment	Complete	00	
	Marked	06	30
	Moderate	10	50
	Mild	04	20

Discussion

Literature review revealed no studies investigating the effects of *Nadi Swedana* (sudation therapy) on pain, stiffness and swelling of patients with knee OA. *Nadi Swedana* is a traditional and popular method used in this research had a heat transfer effect on the applied area. It was reported that heat application decreased pain and disability of patients with Knee Osteoarthritis.[12] Blood flow, capillary permeability, nerve conduction and collagen extensibility increase through vasodilation as a result of heat treatment and it may reduce pain and stiffness.[13] The analgesic effect of *Dasamoola* drugs is already proven.[11]

Nadi Swedana (sudation) seems to be a traditional *Vata Shamaka* procedure. *Snehana* (oleation) and *Swedana* (sudation) are opposite properties of *Vata*, viz., *Sheeta* (coldness), *Ruksha* (dryness) etc. with this mechanism *Nadi Swedana* produces relief in all sorts of *Vata Vyadhi.*

Limitation

This study has a single arm and lacks a comparator arm with a small sample size. In this study, there is a lacuna regarding Standard Operating Process (SOP) for the intervention of *Nadi Swedana*, another limitation of the study is that pain and stiffness assessment was not evaluated as per WOMAC.

Conclusion

In fact, it is concluded that sudation therapy is the application of steam on the affected part has the potential to reduce the symptom of pain, stiffness and swelling due to the effect of heat. *Nadi Swedna* seems to be a traditional *Vata Shamaka* procedure. *Nadi Swedana* can be used as a supportive treatment in OA patients. Further clinical trials with a large sample size and longer follow up are warranted.

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