



ORIGINAL ARTICLE

EFFECT OF SHALLAKI ON KNEE OSTEOARTHRITIS (JANU SANDHIGATA VATA)

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Abstract:

Background: As age advances vata dosha increases in an individual. This increasing vata triggers and accelerates dhatu kshaya (depletion of tissues) and bala kshaya (reduction of strength). Hence advancing age makes man prone to many diseases including degenerative disorders. Sandhigata vata manifests when the deranged vata lodges in joints. If the condition manifest in the janu sandhi (knee joint), it is called as janu sandhigata vata (knee osteoarthritis). Local pain and functional disability of the effected joint are the major manifestations of knee osteoarthritis. shallaki nirryasa, an oleoresin available from the plant *Boswellia serrata* is known for its anti inflammatory and analgesic property. In this study a clinical trial using oleoresin available from shallaki is done on participants suffering from knee osteoarthritis.

Objective: To evaluate the effect of shallaki in knee osteoarthritis.

Method: The clinical study was carried out for a period of 4 weeks where alcoholic extract of shallaki 400mg was given orally with water thrice daily after food. Concurrent analgesics/NSAIDs and steroids in any form were not permitted. Lifestyle and /or dietary restrictions were not imposed during the course of the study.

Results: The primary efficacy variables were pain in knee joints, modified WOMAC, joint crepitus and swelling in knees. Paired't' test was used for within group comparison. Pain and WOMAC showed significant improvement ($P < 0.001$) after treatment. Swelling in knees was absent after the treatment in 80% of volunteers who presented with the manifestation. Joint crepitus remained unchanged after completion of treatment in all individuals.

Conclusion: shallaki is effective and safe in the symptomatic treatment of knee osteoarthritis.

Keywords: knee osteoarthritis , knee, shallaki, *Boswellia serrata*, WOMAC

Introduction

With advancing age, man becomes a prey for different illness due to cellular and tissue changes in the body. Ayurveda explains this as the effect of increasing vata dosha on the body leading to the depletion of dhatus. The depletion reflects as deterioration in substance, qualities and function of the affected tissue. Sandhigata vata (osteoarthritis - OA) is the impact of aggravated vata on the sandhis. It is a pain predominant vata

disorder that occurs in the joints which affects man as age advances. This condition is clinically characterized by features such as pain; which is aggravated on movements, swelling in the affected joint, joint stiffness¹ and joint crepitus.² The clinical manifestations of osteoarthritis simulate the condition of degenerative joint disorder; which is described as a pain predominant disabling form of arthritis with a strong association with ageing. Pathologically it is the morbidity of synovial joints characterized

by focal loss of articular hyaline cartilage with proliferation of new bone & remodelling of joint contour and radiological by osteophytes and joint space narrowing³. There is a steady rise in the prevalence of osteoarthritis from age 30 such that by 65, 80% of the population have radiological evidence, though only 25-30% is symptomatic.⁴ The reported prevalence of osteoarthritis from a study in rural India is 5.78%. Indians are said to have increased knee osteoarthritis. The major risk factors associated with knee OA seen in a population study were: age, female sex, obesity, occupational knee bending, physical labour and chondrocalcinosis⁵. Potent analgesics and anti inflammatory drugs run the current market in the conventional system of medicine. But these drugs head the risk of producing side effects like gastric erosion, renal and hepatic toxicity. The gum resin of shallaki (*Boswellia serrata*) is vatahara and used in sandhi vata (arthritis) and asthi shotha⁶. In this view a clinical study was planned to evaluate the efficacy of shallaki in knee osteoarthritis.

Objective of the study:

To evaluate the effect of shallaki (*Boswellia serrata*) in knee osteoarthritis.

Materials and methods:

Before commencing the clinical trial, an approval from the institutional ethical committee for human experimentation was received with the Ethical clearance number: SDMCAU/ACA15/EC11/09-10. Informed consent was received from the research participants.

Investigational Drug:

Alcoholic extract of shallaki (*Boswellia serrata*) 400mg in capsule form.

Study Design:

Randomized open labelled, single arm, interventional clinical trial with pre-test and post test design.

Method of study:

Screening of patients suffering from knee osteoarthritis was done at arthritis camps conducted in and around Dakshina Kannada district. Finally 30 patients who fulfilled all

necessary criteria and gave a written consent for the clinical trial were enrolled for the trial as study volunteers. The selection was done at random using lottery method, irrespective of gender, occupation, educational status, social status, economical status considerations.

Inclusion criteria:

- Pain in knee joint with/without other features like stiffness, swelling and joint crepitus
- Evidence of radiological changes of knee osteoarthritis
- Patients of either sex with age 70 years and below
- Both fresh and already treated cases (with no treatment response to earlier treatment)
- Patients who agreed to sign the informed consent form and follow up the protocol

Exclusion criteria:

- Patients suffering from other forms of Arthritis
- Osteoarthritis of knee as a consequence of external injuries like fractures and dislocations
- Patients suffering from systemic illness which would decline the general condition of the patient and interfere with the clinical trial
- Vulnerable group like lactating mothers, pregnant women and mentally challenged persons

Investigations:

X-ray knee antero-posterior view and lateral view taken before treatment to know the extent of radiological changes before commencing the intervention.

Intervention:

One capsule of shallaki (*Boswellia serrata*) 400mg three times a day orally after food with water for a period of 4 weeks. Clinical assessment was done at baseline and 28th day of the treatment period.

Efficacy variables:

The efficacy variables pain (knee function assessment chart of the British Orthopaedic Association Research subcommittee) swelling and crepitus (criteria of Altman for the diagnosis of idiopathic osteoarthritis of knee using clinical and X-Ray data) were assessed. Patients completed the WOMAC⁷ assessment sheet before and after treatment.

Observations and results:

Demographic distribution:

Table 1: Demographic profile of 30 patients

<i>demographic characters</i>	<i>number of patients</i>	<i>percentage</i>
age in years		
41-50	08	26.67%
51-60	09	30%
61-70	13	43.33%
gender		
Male	02	6.67%
Female	28	93.33%
nature of work (present)		
Sedentary	12	40%
Physical	04	13.33%
Household activities	14	46.67%
occupational knee strain (past or present or both)		
Positive history	25	83.33%
Negative history	05	16.66%

Demographic distribution of influencing variables like age, sex and occupation of 30 participants is presented in Table 1. It was observed that 13 (43.33%) patients belonged to age group 61-70 years. Considering gender distribution, there were 28 females and 02 males in the study. Observing impact of nature of work in the study individuals, maximum participants were involved in household activities (46.67%). Occupation involving physical activities that have been exerting strain on the knee joints in the past years or present years or both was reported by 25(83.33%) out of 30 individuals.

Clinical observations: Among the 28 female participants, 18 (64.29%) females had reached menopause, 06 (21.43%) females were nearing menopause, and 04(14.29%) females had undergone hysterectomy for various gynaecological reasons. Patient's body weight was recorded along with other vital

examinations at baseline. The mean body weight of 30 participants was 65.60±14.95 kg.

Analysis of efficacy: The data obtained from 30 participants was analysed by using SPSS 16 software. Confidence interval was fixed at 95%. The scores of efficacy variables pain and WOMAC were tabulated and statistically analyzed by using paired 't' test. These efficacy variables showed statistically highly significant difference ($P < 0.001$) on 28th day from baseline measures. Table.2 shows the efficacy of the intervention drug shallaki on the outcome variables pain and WOMAC from baseline to 28th day of intervention.

Swelling was present in 15 participants out of 30 (50%), when examined before treatment. On assessment of swelling on the 28th day, 12 (80%) out of 15 study volunteers had absence of swelling. On [C] clinical examination of participants before treatment, knee joint crepitus was appreciated in all patients (100%). This clinical feature remained unchanged in all participants (100%) when assessed at the end of the study period.

Discussion

Demographic distribution and clinical observations: Maximum number of patients suffering from knee osteoarthritis was in the age group 61-70 years. All patients in the study were above the age of 40 years. Maximum participants were females in their menopausal ages and were moderately obese. Symptomatic and radiographic OA increases with age. The age related increase is more in females. The disease is more severe in them with more symptoms, more extensive involvement, and increased prevalence of knee.⁸ During and after menopause the falling levels of oestrogen and progesterone combined with the natural ageing process makes women more susceptible to osteoarthritis.⁹ Occupation influence was observed in the participants. Physical activities and house hold activities in females showed a relationship in the manifestation and aggravation of this condition. Occupational knee bending is strongly associated with OA. Prolonged squatting for day to day activities is associated with OA.¹⁰ Repetitive joint use is an important

risk factor for OA. The pattern of joint involvement in OA is influenced by prior vocational or avocational overload.¹¹ In the study it has been observed that, increase in body weight had an impact on the weight bearing

joints as most subjects in the study were moderately obese. Obesity and body mass index are particularly associated with knee OA. Obese people have a higher risk of developing OA that is progressive.¹²

Table.2 Comparison of efficacy measures (pain and WOMAC scores) at 28th day of treatment from baseline

<i>variable</i>	<i>BT</i>	<i>AT</i>	<i>MD</i>	<i>SEM</i>	<i>t value</i>	<i>P value</i>
Pain	2.40±0.114	1.57±0.133	0.833	.069	12.042	<0.001
WOMAC Pain	5.57± 0.483	3.43± 0.465	2.133	.243	8.771	<0.001
WOMAC Stiffness	2.03±0.089	1.07±0.166	0.967	.162	5.950	<0.001
WOMAC Difficulty	39.90± 1.548	32.97± 1.749	6.933	.625	11.093	<0.001
WOMAC Combined	47.50± 2.010	37.33± 2.213	10.167	.917	11.082	<0.001

BT = Mean score before treatment ± SE, AT = Mean score after treatment ± SE, MD = mean difference, n=30

Efficacy variables: Pain and WOMAC (scores for pain, stiffness, difficulty in functions and combined) showed clinical improvement when assessed on completion of treatment. Clinical results were supported by statistical methods. The above mentioned efficacy variables showed statistical significance at the level of $P < 0.001$ on 28th day of intervention. Swelling was not observed in all participants. 50% of participants presented with swelling before commencing the treatment. Out of the participants who presented with swelling, 80% participants had relief from the clinical manifestation at the end of fourth week. On clinical assessment, before treatment scores for knee joint crepitus remained without any change after 4 weeks of intervention. As there was no change in the grade of knee joint crepitus before and after intervention, the data was not subjected to further statistical test. There was no effect of the intervention drug on knee joint crepitus in the study.

Investigational drug: The effectiveness of the treatment on pain, swelling and WOMAC in the present study may be attributed to the analgesic and anti inflammatory activity of shallaki.¹³ For inflammatory conditions 300-400mg of a standardized extract (containing 60% boswellic acids) three times daily is suggested.¹⁴ Pharmacological studies of the gum resin of *Boswellia serrata* showed an analgesic effect in the nonphenolic fraction. The fraction produced analgesic effect in albino rats as seen by both the

hot wire and mechanical compression method.¹⁵ shallaki is active against pain and inflammation by inhibiting the activity of leukotriene synthesis. Specifically it inhibits the activity of the enzyme 5 lipoxygenase through a non redox reaction in osteoarthritis.¹⁶ The resinous part of shallaki (*Boswellia serrata*) possess monoterpenes, diterpenes, triterpenes, tetracyclic terpenic acids and four major pentacyclic triterpenic acids i.e β -boswellic acid, acetyl β -boswellic acid, 11-keto- β -boswellic acid and acetyl 11-keto- β -boswellic acid, responsible for inhibition of pro-inflammatory enzymes. Out of these acetyl 11-keto- β -boswellic acid is the most potent inhibitor of 5 lipoxygenase, an enzyme responsible for inflammation.¹⁷ Shallaki is vata kaphahara.¹⁸ Clinical research activities on shallaki in sandhivata have shown symptomatic improvement in sandhi sula, sandhi shotha, akunchana prasarana karma, stambha and sparsha asahyata.¹⁹ In the present study, no adverse event was observed in the intervention throughout the study.

Conclusion:

Shallaki was found to have highly significant improvement on pain, and WOMAC score in knee osteoarthritis. Knee joint swelling responded to the intervention drug in 80% of study volunteers who presented with the condition. There was no clinical change in knee joint crepitus after intervention in this study. The drug was found safe, well accepted and well

tolerated by patients. The overall compliance to the treatment was good. Thus it can be concluded that shallaki is effective and safe in the symptomatic treatment of osteoarthritis of knee.

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