



Clinical Research

Clinical evaluation of *Boswellia serrata* (Shallaki) resin in the management of *Sandhivata* (osteoarthritis)

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Abstract

Sandhigata vata is described under *Vatavyadhi* in all Ayurvedic texts. Charaka was the first to describe separately "*Sandhigata anila*", but it was not included under 80 types of *nanatmaja vatavyadhi*. Osteoarthritis is the most common degenerative joint disease that begins asymptotically in middle age with progressive symptoms in advancing age. Majority of people by the age 40 years may develop osteoarthritis, especially in weight bearing joints. Females are prone with 25% prevalence, whereas males have a prevalence of 16%. In the present study, 56 patients fulfilling the diagnostic criteria of *Sandhigata vata*, divided into two groups. Patients of first group were administered with 500 mg capsule of *Shallaki*, 6 g per day (in three divided doses) with lukewarm water ($n=29$) and the second group) capsule *Shallaki* as above along with local application of *Shallaki* ointment on the affected joints ($n=23$). After a course of therapy for 2 months, symptomatic improvement was observed in both the groups at various levels with promising results in the patients of first group.

Key words: *Boswellia serrata*, degenerative diseases, osteoarthritis, *Sandhigata vata*, *Shallaki*

Introduction

Osteoarthritis (OA) is the most common form of arthritis, which is degenerative in nature. It is characterized by progressive disintegration of articular cartilage, formation of new bone in the floor of the cartilage lesions (eburnation) and at the joint margins (osteophytes), and leads to chronic disability at older ages.^[1] Clinical manifestations of OA range from mild to severe, and affect the joints in hands and weight bearing joints such as knees, hips, feet and spine. OA is a clinical syndrome characterized by joint pain, tenderness, limitation of movements, crepitus, occasional effusion and variable degrees of inflammation without systemic effects.^[2] According to epidemiology, the prevalence of OA in India is 22-39%. Radiographic evidence of OA is present in majority of people over age 65; among them, 80% people are over 75 years. Approximately, 11% of those over 65 have symptomatic OA of the knee. In India, 5.3% males and 4.8% females are aged more than 65 years.^[3] OA strikes women more often than men and it increases in prevalence, incidence and severity after menopause. The etiology of OA is multifactorial. Various morphological

as well as biochemical changes result in a softened, ulcerated and malfunctioning articular cartilage.^[4] It has been postulated that age, gender, body weight, repetitive trauma and genetic factors are the risk factors which play an important role in the manifestation of OA.^[5]

Sushruta has described the disease in *Vatavyadhi* chapter under the heading of *Sandhigata vata*, while Charaka has described *Sandhigata vata* under the *Vatavyadhi* as *Sandhigata Anila*.^[6] The diseases produced by morbid *vatadosha* are more common in *Jaravastha* (old age). The vitiated *vata* combines with other vitiated *dosha*, *rakta*, *ama*, etc and gets located in the joint to produce the disease. Being a disease related to *madhyamarogamarga*, *Sandhigata vata* is either *Kastasadhya* or *Asadhya*. On the basis of symptomatology and nature of the disease, *Sandhigata vata* is much similar to OA, which is the most common degenerative joint disease in older people.

Aims and objectives

The present study was carried out to assess the efficacy of *Shallaki* (*Boswellia serrata* - Resin) on *Sandhigata vata* (OA) and to assess the comparative effect of *Shallaki* capsule given orally with combined therapy of *Shallaki* capsule given orally with *Shallaki* ointment applied externally.

Materials and Methods

A total of 56 patients with signs and symptoms of *Sandhivata*

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(OA), irrespective of age, sex, occupation etc who attended OPD of Department of Kayachikitsa in IPGT and RA Hospital, Gujarat Ayurved University, Jamnagar, were selected for the clinical trial. Out of these, 49 patients could complete the study and 07 patients discontinued the treatment.

Inclusion criteria

Patients between 40 to 70 years of age, presenting with clinical signs and symptoms of *Sandhivata*, viz. *Shula* (joint pain), *shotha* (joint-swelling), *stambha* (stiffness), *sparsha asahyata* (tenderness), *sphutana* (crepitus), *akunchana prasarana vedana* (pain during flexion and extension of the joint) etc and patients without any anatomical deformity were included.

Exclusion criteria

Patients below 40 years and above 70 years of age, suffering from uncontrolled diabetes, joint pathologies other than OA (psoriatic arthritis, gouty arthritis, systemic lupus erythematosus, bone TB), having other serious systemic disorders were excluded from the study.

Ethical issues

This study was cleared by the institutional ethics committee. Before starting the treatment, written consent was taken from the patients and detailed clinical history was taken in the clinical research proforma based on modern and Ayurvedic parameters. The study was conducted as a randomized, single-blind clinical trial.

Dose, duration and diet

The patients of group A were treated with *Shallaki* capsule 6 g in three divided doses with lukewarm water after meal, whereas patients of group B were treated with *Shallaki* capsule in the same dose, duration, frequency and *anupana* along with local application of *Shallaki* ointment.

Criteria for assessment

- i. *Subjective criteria*: Signs and symptoms were provided with scoring depending upon their 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%.
- ii. *Radiological findings*: Improvement was assessed on the basis of joint space, subarticular sclerosis, articular margin, articular erosion, any soft tissue abnormalities, ankylosis, synovial effusion, deformity, osteophytes and marginal erosion in comparison to initial finding.
- iii. *Mental state*: Patient's mental state was evaluated by 'Jung self-rating anxiety scale' and 'Jung self-rating depression scale'.
- iv. *Objective criteria*: The routine hematological and biochemical investigations, urine analysis and estimation of C reactive protein (CRP) were carried out before and after treatment. The results obtained were analyzed by student's test (paired and unpaired).

Observation and Results

Effect of therapy on chief complaints

In group A, *sandhishula* (joint pain) was relieved by 73.68%

and 70.96% in left and right knee joint, respectively, 100% in spine ($P<0.001$) and 83.33% each in both the shoulders ($P<0.01$), while in group B, pain was relieved 67.24% and 70.37% in left and right knee joint, respectively, 100% in spine ($P<0.001$) and 66.67% relief was reported in both left and right shoulders ($P<0.01$).

Sandhishotha (joint swelling) improved by 60% and 68.42% in left and right knee joint, respectively, and 100% in left ankle ($P<0.001$) in group A, while in group B, it improved by 87.50% and 82.14% in left and right knee joint, respectively, and the improvement was 100% in both the shoulders ($P<0.001$) in group A. *Akunchana prasarana vedana* (pain during movement) improved in group A to the extent of 73.33% and 74.46% in left and right knee joint, respectively, 100% in both hip joints and 87.50% in right ankle ($P<0.001$); this symptom was not found in left ankle of any patient. In group B, it improved by 71.11% and 69.56% in left and right knee joints, respectively, and 100% improvement was observed in spine ($P<0.001$). *Stambha* (stiffness) improved by 69.23% and 74.19% in left and right knee joint, respectively, in group A, while it was 74.07% and 77.78% in left and right knee joint, respectively, in group B. All the values were statistically highly significant ($P<0.001$). 56.62% and 56.41% improvement was reported in *sandhisphutana* (crepitations) in left and right knee joint, respectively, in group A, while in group B, crepitation improved to the extent of 44.83% and 46.67% in the same joints. Improvement of crepitation in the above joints was statistically highly significant ($P<0.001$). *Sparsha asahyata* (tenderness) of left and right knee joint improved by 73.07% and 77.42%, respectively, in group A, and by 77.78% and 76.00%, respectively, in group B. All the values were statistically highly significant ($P<0.001$) [Table 1].

Effect of therapy on vata-*vridhhi*

Among the symptoms of *vata-vridhhi*, 77.27% and 66.67% relief was reported in *gatrashpurana* (fasciculation) and *asthishula* (pain in bones), respectively, in group A ($P<0.001$), while the improvement in these symptoms was 50% and 63.89% respectively in group B. The relief in *gatrashpurana* was significant ($P<0.01$) and that of *asthishula* was highly significant ($P<0.001$). *Atopa* improved by 44.83% in group B, which was highly significant ($P<0.001$).

Among the symptoms of *vata-kshaya*, *alpa chesta* (reduced activity) improved by 36.67% and 30.76% in group A and group B respectively, which were statistically highly significant ($P<0.001$). *Angasada* (looseness of body parts) and *apraharsa* (unhappiness) improved by 38.89% and 16.67%, respectively, in group B, which were statistically significant ($P<0.01$). Symptoms of *pittavridhhi*, i.e. *glani* (fatigue) and *balahani* (loss of strength), improved by 6.25% and 16.67% respectively in group A, which was statistically significant. While in group B 25% improvement was found in each of *glani*, *balahani* and *angasada*, which was statistically significant ($P<0.01$).

Among the symptoms of *pittakshaya*, 57.14%, 66.67% and 22.22% improvement was reported in *stambha* (stiffness), *toda* (pricking pain) and *gaurava* (heaviness), respectively, in group A ($P<0.001$), while in group B, *stambha* (stiffness) and *gaurava* (heaviness) improved by 61.11% and 25%, respectively ($P<0.001$). Among *kaphavridhhi* symptoms, 16.66% improvement was found in *sandhivishlesha* (looseness

Table 1: Effect of therapy on cardinal symptoms on knee joints

	Knee joint	Group A				<i>t</i>	<i>P</i>	Group B			
		BT	AT	% Relief	BT			AT	% Relief	<i>t</i>	<i>P</i>
<i>Sadhishula</i>	Left	2.47	0.56	73.68	9.34	<0.001	2.64	0.77	67.24	10.23	<0.001
	Right	2.48	0.68	70.96	9.50	<0.001	2.24	0.68	70.37	9.79	<0.001
<i>Sandhishotha</i>	Left	1.25	0.50	60	4.58	<0.001	1.60	0.20	87.50	10.69	<0.001
	Right	1.58	0.50	68.42	7.29	<0.001	1.65	0.29	82.14	11.32	<0.001
<i>Akunchana prasarana vedana</i>	Left	2.04	0.50	73.33	9.50	<0.001	2.25	0.60	71.11	11.96	<0.001
	Right	2.13	0.50	74.46	10.16	<0.001	2.19	0.67	69.56	10.27	<0.001
<i>Stambha</i>	Left	1.37	0.47	69.23	18.00	<0.001	1.69	0.37	74.07	8.66	<0.001
	Right	1.72	0.50	74.19	11.76	<0.001	1.59	0.35	77.78	7.67	<0.001
<i>Sandhisphutana</i>	Left	1.78	1.50	56.62	5.78	<0.001	1.93	1.13	44.83	4.52	<0.001
	Right	1.95	0.85	56.41	5.77	<0.001	1.67	0.94	46.67	4.08	<0.001
<i>Sparsha asahyata</i>	Left	1.37	0.31	73.07	9.24	<0.001	1.42	0.26	77.78	6.53	<0.001
	Right	1.72	0.33	77.42	9.52	<0.001	1.47	0.35	76.00	7.68	<0.001

of joint) in group A ($P<0.01$), while 41.67% improvement was found in group B ($P<0.001$). Among the *kaphakshaya* symptoms, *udvestana* (calf muscles pain) improved by 55.56% ($P<0.001$); and 35.71% and 40% improvement was found in *angamarda* (bodyache) and *sandhishaitihilya* (looseness of joint), respectively, which was statistically significant ($P<0.01$), while in group B, *udvestana* (70.59%) and *angamarda* (56.25%) improved in a statistically highly significant manner ($P<0.001$) and *toda* (50%) and *sandhishaitihilya* (50%) improved in non-significant manner ($P<0.01$).

Effect of therapy on srotas

In *rasavahasrotas*, *gaurava* (heaviness) and *angamarda* (bodyache) improved by 19.23% and 16.66%, respectively, in group A ($P<0.01$), while *angamarda* (65.21%) improved in a statistically highly significant manner ($P<0.001$) and *angasada* (16.67%) in an insignificant manner ($P<0.01$) in group B. In *medovahasrotas*, *karapadayoh suptata daha* (burning or numbness of palms and soles) and *alasya* (laziness) improved by 17.64% and 13.63%, respectively which was statistically significant ($P<0.025$) in group A, while 16.67% improvement in *karapadayohosuptata daha* and 23.08% improvement in *suptatachaangesu* (numbness of body parts) was observed in group B, which was significant ($P<0.01$).

Effect on asthivahasrotas

Asthishula (pain in bones) and *asthibheda* (cutting type of pain) improved by 58.69% and 60.87% respectively in group A, while improvement of these was to the extent of 58.33% and 75% respectively in group B ($P<0.001$). Among the symptoms of *majjavahasrotas*, in group A, *asthiparvapida* and *sthulamulaparvas* improved by 54.76% and 60% respectively ($P<0.001$) and 41.67% improvement was found in *parvepidika* ($P<0.025$), while in Group B, *asthiparvapida* (59.09%) and *parvepidika* (58.33%) improved in a statistically highly significant manner ($P<0.001$) and *sthulamulaparvas* (50%) improved in an insignificant manner ($P<0.01$).

Being an age associated disease and due to its chronic nature, OA is undoubtedly linked with disturbed mental health. Assessment of mental status revealed that out of 56 patients, 5.36% patients ($n=3$) had mild to moderate anxiety and 12.5% patients ($n=7$) had mild to moderate depression.

Effect of therapy on X-ray examination

In group A, joint space, subarticular sclerosis and synovial effusion improved by 66.67%, 57.14% and 87.50%, respectively, which was statistically highly significant ($P<0.001$), and 50% improvement in each of articular erosion and osteophytes was found, which was statistically significant ($P<0.01$), while in group B, 46.67% and 100% improvement was found in joint space and synovial effusion, respectively, which was statistically highly significant ($P<0.001$) and osteophytes improved by 62.50%, which was statistically significant ($P<0.01$).

Effect of therapy on biochemical parameters

CRP and serum triglycerides reduced by 68.41% and 34.35%, respectively in group A, which was statistically highly significant ($P<0.001$), while serum triglycerides decreased by 23.90% which was statistically highly significant ($P<0.001$). The CRP increased by 57.19% ($P>0.05$) in group B, which was insignificant.

Discussion

OA is a degenerative inflammatory disorder, where joint inflammation initially causes pain (*sandhishula*) and later swelling (*sandhishotha*). Due to pain and swelling, the mobility of joints is restricted (*stambha*), and on movement results in excruciating pain (*prasarana akunchanayoho vedana*), which becomes unbearable even on mild touch in the form of tenderness (*sparsha asahyata*). The degenerative changes later result in manifestation of crepitus (*sandhisphutana*). *Sandhigata vata* and OA are quite similar diseases found in clinical practice in which the etiopathogenesis and symptoms overlaps.

Shallaki possesses *tikta* (bitter), *madhura* (sweet) and *kashaya* (astringent) *rasa* (taste); *guna* (quality) of *Shallaki* is *ruksha* (dry), *laghu* (light) and *tikshna*; *vipaka* (post-digestive effect) is *katu* (pungent); whereas *virya* (strength or effect) is *ushna*. The *doshakarma* is *kapha-pitta shamaka*. According to classics, *Shallaki* has potent *vata-kaphahara* properties.^[7,8] The key constituents of *Shallaki* are volatile oil (4-8%), acid resin (56-65%) and gum (20-36%). The triterpenoids are the active constituents and are collectively called boswellic acids. The

gum resin of *B. serrata* usually contains 43% boswellic acids, which contain a combination of six major constituents, mainly 3 acetyl, 11 keto, boswellic acids (AKBA), which help to preserve the structural integrity of joint cartilage and maintain a healthy immune mediator cascade at a cellular level,^[9] which is active against pain and inflammation by inhibiting leukotriene synthesis. Specifically, it inhibits the activity of the enzyme 5 lipoxygenase through a non-redox reaction in OA.^[10]

In the present study, improvement was seen in the chief complaints, *sandhishula*, *sandhishotha*, *akunchana prasaranayoh vedana*, *stambha*, *sandhisphutana* and *sparsha asahyata*, due to *shothahara* and *vedanasthapana* properties of *Shallaki*. The main site of *sandhivata* is *sandhi* which is the site of *shleshakakapha*. Due to its *tiktarasa*, *katuvipaka* and *ushnavirya*, *Shallaki* pacifies vitiated *kapha* and *vata dosha*, resulting in reduction of *shotha*, *shula* and other related symptoms. The pacified *vata* in the *sandhi* helps to rearrange *shleshaka kapha* and thereby improves the symptoms of *sandhivata*. *Shallaki* possesses analgesic and antiarthritic properties, which are responsible for its analgesic and anti-inflammatory activities. It also acts as COX-2 inhibitor and reduces the pain and inflammation without affecting the gastric mucosa. It soothes the joints and also helps treat levels of synovial fluid, making the entire structure lubricated and easy to rotate or to move.^[11]

Symptoms of *vata vriddhi* improved due to *Shallaki* as it has *ushna virya*, and according to some classics, due to *tikshna guna* it acts as *vata shamak*. *Shallaki* also increases *dhatvagni* by its *tikta rasa*, leading to proper nutrition of *dhatu*s, whereas improvement of the symptoms of *vata kshaya* is due to *rasayana* (immunomodulator) and *brihamniya prabhava* of *Shallaki*.^[12] The symptoms of *pitta vriddhi* improved due to *tikta*, *kashaya*, *madhura rasa* and *snigdha guna*, and *pitta shamaka* activity, while improvement in the symptoms of *pitta kshaya* was reported due to *ushna virya* and *katuvipaka*. The *kapha vriddhi* symptoms improved by its *tikta rasa*, *ruksha* and *laghu guna*, *ushna virya* and *katu vipaka*, consequently it pacifies *kapha*. *Shallaki* having *tikshna guna* and *katu vipaka*, acts against increased *kapha* and improves the symptoms of *kapha kshaya*.

The symptoms of *rasavaha srotas* such as *gaurava* and *angamarda* improved due to its *tikta rasa* and *ushna virya*, whereas the symptoms of *medovaha srotas*, i.e. *karapadayoh suptata daha*, *alasya* and *suptatachaangeshu* (numbness of body parts) improved due to its *ruksha*, *laghu guna* and *ushna virya*; it also reduces *medas*. The symptoms of *asthivaha srotas* and *majjavaha srotas* improved due to *tikta rasa* and *katuvipaka*, as they counteract the pathogenic process of *sandhivata*. The main site of *sandhivata* is *sandhis* which are the site of *shleshaka kapha*. By pacifying *kaphadosha*, *tikta rasa* leads to proper nutrition of the other *dhatu*s.

The improvement in radiological findings such as joint space, subarticular sclerosis, synovial effusion, articular erosion and osteophytes was due to the anti-inflammatory activity of *B. serrata* resin. It soothes the joints and also helps treat levels of synovial fluid, making the entire structure lubricated and easy to rotate or to move. AKBA helps preserve structural integrity of the joint cartilage and maintains a healthy immune mediator cascade at a cellular level. *Shallaki* is mediated through the vascular phenomenon; it improves blood supply to joints and

restores integrity of vessels obliterated by spasm of internal damage.^[13] Decrease in biochemical parameters, mainly, CRP, serum triglycerides and erythrocyte sedimentation rate (ESR), is due to anti-inflammatory activity.

Like other age related symptoms, excess free radical production and free radical induced damage may be a key cause of OA. Chronic pain, joint instability, gait difficulties and deformities disturb daily activities of the patient, and consequently the quality of life is impaired. This chronic pathological process in turn affects mental health resulting in stress, depression etc.

Overall effect of therapy

The patients reported complete remission (11.54%), marked improvement (15.38%), moderate improvement (57.69%), mild improvement (11.54%) in group A, while in group B none of the patients got complete remission. 8.69% patients showed marked improvement, 69.56% moderate improvement and 21.74% showed mild improvement. Overall assessment suggests that improvement was better in group A. Majority of the registered patients in this group were of less chronicity, younger age and with mild symptoms. This also may be cause for the significant results.

Conclusion

Patients' mobility was improved significantly in both the groups, which indicates the efficacy of *Shallaki* over chief complaints. Reduction in serum triglycerides was seen in both the groups, which confirms that *Shallaki* has hypolipidemic effect. Remission in *sandhishula*, *stambha* and radiological improvement was found to be better in oral *Shallaki* group. Remission in *sandhishotha* was maximum in group B patients treated with *Shallaki* both orally and locally, whereas equal improvement in *sparshasahyata* was observed in both the groups. Some patients in group A showed complete relief. Overall effect of therapy suggests that *Shallaki* provided moderate improvement in maximum subjects.

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हिन्दी सारांश

सन्धिवात कृह चिकित्सा में शल्लकी निर्यास के प्रभाव का अध्ययन

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सन्धिवात का वर्णन सभी आयुर्वेद ग्रंथों में वातव्याधि के अन्तर्गत किया गया है। आचार्य चरक ने सर्वप्रथम सन्धिगत-अनिल का पृथक रूप से वर्णन किया है, परन्तु वात के अस्सी नानात्मज विकारों में सम्मिलित नहीं किया है। ऑस्टियोआर्थराइटिस सन्धियों में होने वाली सर्वाधिक प्रचलित क्षयात्मक व्याधि है, जो मध्यम वय में लक्षणविहीन रूप में प्रारम्भ होती है और अवस्था के बढ़ने के साथ उत्तरोत्तर लक्षण व्यक्त होने लगते हैं। अधिकांश लोगों में यह रोग ४० वर्ष की आयु तक विशेषतः भारवाही सन्धियों को प्रभावित करने लगता है। पुरुषों (१६ प्रतिशत) की अपेक्षा यह व्याधि महिलाओं में (२५ प्रतिशत) अधिक पायी जाती है। इस अध्ययन में सन्धिवात के नैदानिक मानकों को पूर्ण करने वाले ५६ रोगियों को दो वर्गों में विभाजित कर निम्न औषधियां दी गयीं। १. कैप्सूल शल्लकी ६ ग्रा. प्रतिदिन (तीन विभाजित मात्रा में) कोष्ण जल के साथ, २. कैप्सूलशल्लकी उपरोक्त अनुसार के साथ – साथ प्रभावित सन्धि पर शल्लकी मलहम का स्थानिक प्रयोग। चिकित्सा की अवधि आठ सप्ताह थी। इस अध्ययन में व्याधि के प्रमुख लक्षणों के रूप में सन्धिशूल, सन्धिस्फुटन एवं आकुञ्चन प्रसारण वेदना पाये गये हैं। दोनोवर्गों के रोगियों की चलने-फिरने की क्षमता में महत्वपूर्ण सुधार पाया गया, जो रोग के लक्षणों में शल्लकी के प्रभावी होने की ओर इंगित करता है। दोनों वर्गों में पायी गयी सीरम ट्राईग्लिसराइड केन्द्र में गिरावट, शल्लकी के हाइपोलिपिडिमिक प्रभाव को निर्धारित करती है। सन्धिशूल तथा स्तम्भ में लाभ और एक्स-रे में होने वाले सुधार, शल्लकी के अन्तः प्रयोग वाले वर्ग में अधिक मिले, जबकि सन्धिशोथ में अधिकतम सुधार, शल्लकी के अन्तः तथा स्थानिक प्रयोग वाले वर्ग 'ब' में मिला। वर्ग 'अ' के कुछ रोगियों में पूर्ण स्वास्थ्य लाभ देखने को मिला है। चिकित्सा का कुल प्रभाव दर्शाता है कि शल्लकी अधिकांश रोगियों में मध्यम सुधार प्रदान करती है।