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 vatavyadhī. Osteoarthritis is the most common degenerative joint disease that begins asymptptomatically 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, raktta, ama, etc and gets located in the joint to produce the disease. Being a disease related to madhyamarogamarga, Sandhigata vata is either Kastasudhya or Asadhyya. 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
(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 85.33% 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).

Sandhisheetha (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 vatavriddi**

Among the symptoms of vata-vidrihi, 77.27% and 66.67% relief was reported in gatrasphurana (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 gatrasphurana 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 apraharsha (unhappiness) improved by 38.89% and 16.67%, respectively, in group B, which were statistically significant (P<0.01). Symptoms of pittavriddi, i.e. glani (fatigue) and balahani (loss of strength), improved by 6.25% and 16.67% respectively in group A, which was statistically in 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 kaphavriddi symptoms, 16.66% improvement was found in sandhivishlesha (looseness
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 sandhisathithiha (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 sandhisathithiha (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 a non-significant 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<0.001) in group A, while 16.67% improvement in karapadayahuntpata daha and 25.08% improvement in suptatashaangeshu (numbness of body parts) was observed in group B, which was significant (P<0.01).

Effect of therapy on asthivasaharasotras
Asthishula (pain in bones) and asthibheda (cutting type of pain) improved by 58.6% 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 parpevidika (P<0.025), while in Group B, asthiparvapida (59.09%) and parpevidika (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 (asthishula), and on movement results in crepitus (parvepidika) and later swelling (sandhishotha). The degenerative changes later result in manifestation of crepitus (prasarana akunchanya vedana), which becomes unbearable even on mild touch in the form of tenderness (sparsha asahyata). The degenerative changes later result in manifestation of crepitus (prasarana akunchanya vedana), which becomes unbearable even on mild touch in the form of tenderness (sparsha asahyata).

Shallaki possesses tika (bitter), madhura (sweet) and kashaya (astringent) rasas (taste); guna (quality) of Shallaki is raksha (dry), laghu (light) and tikshna; vipaka (post-digestive effect) is katu (pungent); whereas virya (strength or effect) is ushna. The doshakarma is kapha-pitta shodhaka. According to classics, Shallaki has potent vata-kaphahara properties.[39] 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

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

<table>
<thead>
<tr>
<th>Knee joint</th>
<th>Group A</th>
<th>Group B</th>
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<tbody>
<tr>
<td></td>
<td>BT</td>
<td>AT</td>
</tr>
<tr>
<td>Sadhishula</td>
<td></td>
<td></td>
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<tr>
<td>Left</td>
<td>2.47</td>
<td>0.56</td>
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<tr>
<td>Right</td>
<td>2.48</td>
<td>0.68</td>
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<tr>
<td>Sandhishotha</td>
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<td></td>
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<tr>
<td>Left</td>
<td>1.25</td>
<td>0.50</td>
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<tr>
<td>Right</td>
<td>1.58</td>
<td>0.50</td>
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<tr>
<td>Akunchana</td>
<td></td>
<td></td>
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<tr>
<td>prasarana vedana</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left</td>
<td>2.04</td>
<td>0.50</td>
</tr>
<tr>
<td>Right</td>
<td>2.13</td>
<td>0.50</td>
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<tr>
<td>Stambha</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left</td>
<td>1.37</td>
<td>0.47</td>
</tr>
<tr>
<td>Right</td>
<td>1.72</td>
<td>0.50</td>
</tr>
<tr>
<td>Sandhisphutana</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left</td>
<td>1.78</td>
<td>1.50</td>
</tr>
<tr>
<td>Right</td>
<td>1.95</td>
<td>0.85</td>
</tr>
<tr>
<td>Sparsha asahyata</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left</td>
<td>1.37</td>
<td>0.31</td>
</tr>
<tr>
<td>Right</td>
<td>1.72</td>
<td>0.33</td>
</tr>
</tbody>
</table>
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, 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.

In the present study, improvement was seen in the chief complaints, sandhishula, sandhishotha, akunchana prasaranyah vedana, stambha, sandhishputana 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 tiktkara, katuvipaka and ushnavirya, Shallaki pacifies vata 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.\[11\]

The symptoms of vata vridhi improved due to Shallaki as it has ushna virya, and according to some classics, to tikshna guna it acts as vata shamak. Shallaki also increases dhavagni by its tikta rasa, leading to proper nutrition of dhatu, whereas improvement of the symptoms of vata kshaya is due to rasayanam (immunomodulator) and bribhamiya prabhava of Shallaki.\[12\]

The symptoms of pitta vridhi improved due to tikta, kashaya, madhura rasa and snigdha guna, and pitta shamak nature, while improvement in the symptoms of pitta kshaya was reported due to ushna virya and katvipaka. The kapha vridhi symptoms improved by its tikta rasa, raksha and laghu gana, 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 rasavah srotas such as gaurava and angamardha improved due to its tikta rasa and ushna virya, whereas the symptoms of medovaha srotas, i.e. karapadayoh sipitata daaha, alaya and sipitataachangesha (numbness of body parts) improved due to its raksha, laghu gana and ushna virya; it also reduces medas. The symptoms of asthiavaha srotas and majavaha srotas improved due to tikta rasa and katvipaka, 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.

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.

**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 sparshaasahyata 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.

**References**

शनिधिवाल कह चिकित्सा में शालकी निर्यास के प्रभाव का अध्ययन