Clinical evaluation of *Nirgundi Taila* and *Dashmoola Ghrita* in the management of *Sandhigata Vata* (Osteoarthritis)

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**INTRODUCTION**

Charaka the pioneer of Kayachikitsa was the first who described *Sandhigata Vata* as *Sandhigata Anila.*[1] Sushruta has described the disease under the broad umbrella of *Vatavyadhi.*[2] In Jaravastha (old age) vitiation of *Vata Dosha* is common. The vitiated *Vata* either combines with other *Dushyas, Ama* etc. or separately locates in the joints which is *Madhyam Roga Marga* and produce *Sandhigata Vata.*[3] The disease is either *Kashtasadhya* or *Asadhya.* On the basis of symptomatology and nature of the disease, *Sandhigata Vata* is much similar to Osteoarthritis, which is most common form of arthritis in old people.

Worldwide, musculoskeletal disorders are the most common causes of severe long term pain and physical disability. Joint diseases account for half of all the chronic conditions in aged people. Osteoarthritis (OA) is a common form of degenerative joint disease, occurring primarily in older persons, characterized 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), subchondral 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 and focal disintegration of the articular cartilage; synovial inflammation also can occur.[4] Clinical manifestations of OA range from mild to severe and affects weight-bearing joints such as...
knees, hips, feet, spine and also hands and later leading to chronic disability. According to epidemiology, Osteoarthritis accounts for 22% to 40% prevalence in India. Radiographic evidence of OA is present in majority of people over the age of 65. In India 5.3% male and 4.8% female are aged more than 65 years. It is projected that arthritis will be biggest epidemic in India by 2013, affecting around 650 million people. Osteoarthritis strikes women more often than men and it increase in prevalence, incidence and severity after menopause. Aetiology of OA is multifactorial. Various morphological as well as biochemical changes result in a softened, ulcerated and malfunctioning articular cartilage. Age, gender, body weight, B.M.I., trauma, repetitive stress on affected joints, genetic factors are the risk factors which plat an important role in the manifestation of Osteoarthritis.

AIMS AND OBJECTIVES

To evaluate the efficacy of Nirgundi Taila locally combined with Dashmoola Ghrita orally on Sandhigata Vata (OA).

MATERIALS AND METHODS

Total 21 patients with sign and symptoms of Sandhigata Vata (OA), irrespective of sex, occupation etc, who attended OPD of Dept. of Kayachikitsa, in I.P.G.T. and R.A., Gujarat Ayurved University, Jamnagar, were selected for the clinical trial. Out of that 1 patient dropped out and 20 patients completed the treatment.

Inclusion Criteria

Patients presenting with the classical signs and symptoms of Sandhigata Vata (OA), like Sandhi Shoola (Joint pain), Shotha (Swelling), Stambha (Stiffness), Sphutana (Crepitus), Sparshasahyata (Tenderness), Akunchana Prasarane Vedana (Pain during flexion and extention) 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 Ayurvedic and Modern parameters and the written consent was taken from the patients. The study was conducted as open labeled 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

All the drugs of Dashmoola and Nirgundi for the preparation of trial drugs were procured from the pharmacy, GAU, Jamnagar. While Ghrita and Taila was purchased from Khadi Bhandar, Jamnagar. The drugs were authenticated in the Pharmacognosy Dept. of I.P.G.T. and R.A. and the medicine were prepared by Pharmacy, GAU. Both Dashmoola Ghrita and Nirgundi Taila were prepared as per the method mentioned in Shangadhara Samhita.

Posology

The patients were treated by Nirgundi Taila locally on affected joints with Dashmoola Ghrita 12 gms. twice a day internally with meal. The duration of therapy was of 2 months and 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 categorized 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 and climbing test.

4. **Investigation:** The routine hematological, 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

**Sandhishotha (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 and 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

**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**

The clinical study showed significant improvement on cardinal symptoms like **Sandhi Shoola (Joint pain)**, **Sandhi Shotha (Joint Swelling)**, **Aakunchane - Prasaranve Vedna (Pain during flexion and extention)**, **Sandhigraha (Joint Stiffness)**, **Sandhisputana (Crepitus)**, **Sparhasahyata (Tenderness)**.

Treatment have provided statistically highly significant result on walking - climbing test and range of joint movement.

Treatment modalities provided statistically significant change on synovial effusion whereas no significant results were found in other parameters like osteophytes, joint space and sub-articular scelerosis. The results obtained have been shown in Tables 1-7.

**Table 1: Effect of therapy on cardinal symptoms.**

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Side</th>
<th>Mean D</th>
<th>SD (±)</th>
<th>SE (±)</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sandhi Shoola (Joint pain)</strong></td>
<td>Left, n = 20</td>
<td>2.3 0</td>
<td>0.7 5</td>
<td>1.5 5</td>
<td>0.6 0</td>
<td>0.1 3</td>
</tr>
<tr>
<td></td>
<td>Right, n = 20</td>
<td>2.0 6</td>
<td>0.8 5</td>
<td>1.2 0</td>
<td>0.4 8</td>
<td>0.1 0</td>
</tr>
<tr>
<td><strong>Sandhi Shotha (Joint Swelling)</strong></td>
<td>Left, n = 20</td>
<td>1.6 5</td>
<td>0.5 6</td>
<td>1.1 2</td>
<td>0.5 4</td>
<td>0.1 3</td>
</tr>
<tr>
<td></td>
<td>Right, n = 20</td>
<td>1.4 0</td>
<td>0.5 8</td>
<td>0.5 0</td>
<td>0.1 6.7</td>
<td>&lt;0.0 01</td>
</tr>
</tbody>
</table>
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Table 2: Effect of therapy on X-ray

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Mean</th>
<th>D</th>
<th>SD(±)</th>
<th>SE(±)</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synovial Effusion, n=9</td>
<td>1.80</td>
<td>0.40</td>
<td>1.40</td>
<td>0.75</td>
<td>0.34</td>
<td>4.16</td>
</tr>
</tbody>
</table>

N = Number, BT = Before Treatment, AT = After Treatment, SD = Standard Deviation, SE = Standard Error

Table 3: Effect of therapy on walking and climbing test

<table>
<thead>
<tr>
<th>Test</th>
<th>Mean</th>
<th>D</th>
<th>SD(±)</th>
<th>SE(±)</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walking, n=20</td>
<td>3.64</td>
<td>3.50</td>
<td>0.14</td>
<td>0.21</td>
<td>0.05</td>
<td>2.88</td>
</tr>
</tbody>
</table>

N = Number, BT = Before Treatment, AT = After Treatment, SD = Standard Deviation, SE = Standard Error

Table 4: Effect of therapy on range of joint movement.

<table>
<thead>
<tr>
<th>Test</th>
<th>Mean</th>
<th>D</th>
<th>SD(±)</th>
<th>SE(±)</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knee joint flexion</td>
<td>BT</td>
<td>AT</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left, n=20</td>
<td>114.40</td>
<td>119.20</td>
<td>-4.80</td>
<td>3.11</td>
<td>0.69</td>
<td>6.91</td>
</tr>
<tr>
<td>Right, n=20</td>
<td>113.55</td>
<td>117.90</td>
<td>-4.35</td>
<td>3.14</td>
<td>0.70</td>
<td>6.21</td>
</tr>
</tbody>
</table>

N = Number, BT = Before Treatment, AT = After Treatment, SD = Standard Deviation, SE = Standard Error

Table 5: Effect of therapy on investigation.

<table>
<thead>
<tr>
<th>Investigations</th>
<th>Mean</th>
<th>D</th>
<th>SD(±)</th>
<th>SE(±)</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>S. Cholesterol, n=20</td>
<td>185.79</td>
<td>178.00</td>
<td>-7.79</td>
<td>20.33</td>
<td>4.67</td>
<td>1.67</td>
</tr>
<tr>
<td>HDL, n=20</td>
<td>47.63</td>
<td>48.84</td>
<td>-1.21</td>
<td>9.94</td>
<td>2.28</td>
<td>0.53</td>
</tr>
</tbody>
</table>

N = Number, BT = Before Treatment, AT = After Treatment, SD = Standard Deviation, SE = Standard Error

Table 6: Overall effect of therapy

<table>
<thead>
<tr>
<th>Improvement</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild improvement</td>
<td>20</td>
</tr>
<tr>
<td>Moderate improvement</td>
<td>55</td>
</tr>
<tr>
<td>Maximum improvement</td>
<td>25</td>
</tr>
</tbody>
</table>

DISCUSSION

Osteoarthritis is also known as degenerative arthritis or degenerative joint disease. It is a clinical syndrome in which low-grade inflammation (Sandhi Shotha), results in pain in the joints (Sandhi Shoola), caused by...
abnormal wearing of cartilage that covers and acts as a cushion inside joints and decrease of synovial fluid that lubricates those joints. As the bone is less protected by cartilage, the patient get pain in the weight bearing joints like knee, ankle, hip etc. Due to pain and swelling the joint can’t move properly as the movement is restricted (Stambha) and by movements extreme pain (Aakunchane Prasaranar Vedana) occurs. Usually Osteoarthritis takes time to develop but it becomes unbearable even on mild touch-tenderness (Aakunchane Prasarane Vedana). Usually Osteoarthritis is mainly vitiated by Shita, Ruksha and Chala Guna, Nirgundi is Virya Pradhan drug and Taila is also Ushna Virya so they provide relief in Shoola. The Rukshata of Vata is hampered by Taila because Taila is Snigdha and by preparation of Taila Kalpana it becomes more potent. Sandhishooahola is mainly occurred by Chala Guna of Vayu, when Chala Guna of Vayu is obstructed, it results in Margavarana (obstruction) process. Due to Katu Rasa, Katu Vipaka and Ushna Guna Taila removes the obstruction, thus Vata can do its Cheshta Karma normally. Nirgundi has inhibitory action on prostaglandin biosynthesis; latest research proved that anti-inflammatory and analgesic properties mediated via PG synthesis inhibition. It acts as COX-2 inhibitors that might be responsible for its NSAID’S like activity.

Dashmoola is Vata-Kapha Pradhan Dravya (It acts on Vata as well as Kapha Dosha both), so it could be work in both ways, in Avaranajanya Samprapti it works by Katu, Tikta - Rasa, Ushna - Virya and its Amapachana Karma. In Dhatukshayajanya Samprapti, it works by their Madhura Skandhi Dravya like Shaliparni, Prushniparni, Gokshura, Bruhati, Kantakari etc. and by making formulation with Ghrita, it is helpful in Samprapti Vighatana. Azulene, glycoside oroksonilom, aegelin, oxalic acid, steroid, new β phenlethyllamine, volatile oil, harmine, dionsgenin, nilogenin, sitosterol, some saponin, glycoctode, tannin - provide analgesic, anti arthritic and anti-inflammatory effect.

The improvement in radiological findings may be due to anti-inflammatory activity by external and internal Sneha Kalpana it reaches upto the minute level as Sneha has Sukshama Guna, Anupravanabhava. Both

In the present study, the improvement was seen in chief complaints like Sandhisputana (Joint pain), Sandhishotha (Joint Swelling), Aakunchane Prasaranar Vedana (Pain during flexion and extension), Stambha (Joint Stiffness), Sparshasahyata (Tenderness) and Sandhisputana (Crepitus) due to Shoolahara, Shothahara effect of Nirgundi and Tila Taila both. In Sandhigata Vata the Vata is mainly vitiated by Shita, Ruksha and Chala Guna, Nirgundi is Virya Pradhan drug and Taila is also Ushna Virya so they provide relief in Shoola. The Rukshata of Vata is hampered by Taila because Taila is Snigdha and by preparation of Taila Kalpana it becomes more potent. Sandhishooahola is mainly occurred by Chala Guna of Vayu, when Chala Guna of Vayu is obstructed, it results in Margavarana (obstruction) process. Due to Katu Rasa, Katu Vipaka and Ushna Guna Taila removes the obstruction, thus Vata can do its Cheshta Karma normally. Nirgundi has inhibitory action on prostaglandin biosynthesis; latest research proved that anti-inflammatory and analgesic properties mediated via PG synthesis inhibition. It acts as COX-2 inhibitors that might be responsible for its NSAID’S like activity.
formulations are lipophilic and this action of their, 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 treating levels of synovial fluid making the entire structure lubricated and easy to move. By inhibitory action on prostaglandin biosynthesis, anti-inflammatory, analgesic activities, it acts as COX-2 inhibitors that might be responsible for its NSAID’S like activity. It also enhances the blood flow.

Decreased in serum cholesterol level may be due to Sukshma, Lekhana Guna, Ushna Virya, Katu Vipaka and Lekhana and Amapachana Karma of Dashmoola drugs and Taila.

The improvement in walking and climbing and knee joint flexion was due to increased blood flow and it is due to Sukshma and Snigdha Guna of Taila and Ghruta.

CONCLUSION

The improvement of the patients in regard of movements (Cheshta) of affected joint was significant that indicates formulation’s effectiveness on cardinal symptom. Therapy also provided significant changes in walking test, climbing test and range of joint movement. The combined treatment of Dashmoola Ghrita and Nirgundi Taila provided better and significant effect in Sandhishoola, Aakunchane Prasarane Vedana and Sandhishotha. The above effect was found due to Vednasthapan Karma of Nirgundi and Amahara, Shothahara, Dipana and Rasayana effect of Dashmoola. As both formulations are Sneha Kulpana, they soothe the joints and make them easily mobile. Overall effect of therapy suggests that Nirgundi Taila with Dashmoola Ghrita provided moderate improvement in maximum subjects.

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