A COMPARATIVE CLINICAL TRIAL EVALUATING THE THERAPEUTIC EFFECT OF SVACCHANDA BHAIＲAVA RASA IN JANU SANDHIGATAVATA (OSTEO ARTHRITIS)

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INTRODUCTION

Disease is formed due to the vitiation of the dosha, and to be free from diseases the dosha has to be in its normal form. When there is a fluctuation in the normalcy of dosha, may it be any of the three dosha, it causes wide spread fluctuations in the body as the ripples across a waterbody created by an untoward anomaly. Similarly when the vata becomes morbid it leads to the formation of vatavyadhi. Sandhigatavata is described under the chapter of vatavyadhi where vata is following the principle of gatavata². The affliction of joints by morbid vata is mentioned in the pathogenesis expressing the specific symptoms related to it³. It is a disease that is difficult to cure and mainly occurs due to the etiological factors which

ABSTRACT

The objective of the study was to assess the effect of the formulation svacchanda-bhairava rasa, an oral medication in reducing the symptoms of janu sandhigata vata (Osteoarthritis knee). Among the various diseases mentioned in the classics, vatavyadhi is a disease that requires special focus. Vata is considered as the most vital among the tridosha and when there are alterations to the normal physiological functioning of vata, it leads to the formation of morbid vata dosha which in turn gives rise to vatavyadhi. Due to various etiological factors, vata attains the status of vitiation, thereby affecting the joints leading to the genesis of the disease sandhigata vata (Osteoarthritis). There is high prevalence of osteoarthritis worldwide and the incidence is high above the age group of 40 years. The symptoms of osteoarthritis are joint pain, stiffness, swelling, tenderness and restricted movements¹. Literature explains duo treatment modalities i.e the alleviating therapy and elimination therapies. Alleviation therapy mainly tackles vata dosha, provides rejuvenating effect and relieves pain and stiffness. On this basis the Svacchandabhairava rasa was taken for the study, as an oral medication in osteoarthritis. Objectives of the study were to evaluate the therapeutic effect of Svacchandabhairava rasa in patients suffering from Janusandhigatavata (OA). The study revealed that there was marked improvement in reducing the symptoms of pain, stiffness, swelling, tenderness and restricted movements. Thus the therapeutic usage of svacchanda-bhairava rasa as an oral medication in osteoarthritis was proved.

Keywords: Osteoarthritis; Janu Sandhigatavata; Svacchandabhairavarasa

are classified as dhatukshayajanya and margavaranajanya. The symptomatology includes pain, stiffness, swelling, crepitus, and restricted movement of the joints. The modalities of treatment mentioned in the contemporary science include non-pharmacological and pharmacological measures. Exercises, lifestyle changes and proper medication such as analgesics play an important role in reducing the symptoms. In circumstances where the conservative management is not able to tackle the situation at hand, surgery is an option. If not treated properly it will lead to further complications which may even make the patient restricted to bed.

In Ayurveda point of view, vatavyadhi is best treated by principles of treatment that includes alleviating and eliminative therapies. And further, alleviating therapies can be classified as internal and external methods of treatments. There are many alleviating therapies mentioned that are useful in the conditions like osteoarthritis. It includes decoctions, tablets, linctus, ghee preparations, bandaging, oil application et al. So to analyse the therapeutic effect of the alleviating therapy like the oral medication in the morbid condition of vatavyadhi, the present work was done.

MATERIALS AND METHODS

Source of data
15 patients suffering from sandhigata vata irrespective of sex and caste were selected from OPD and IPD of SDM Ayurveda Hospital, Udupi.

Study design
It was an open labelled clinical trial with pre-test and post-test design.

Method of collection
Patients were subjected to detailed clinical history, assessment and complete examination. The details were recorded in proforma.

Inclusion criteria
• Patients with prathyatma lakshana of janu sandhigata vata.
• Patient with signs & symptoms of osteoarthritis.
• Age groups between 30 years to 70 years were selected.

Exclusion criteria
• Age group below 30 years and above 70 years.
• Patient with Tuberculosis, Rheumatoid Arthritis, Systemic Lupus Erythematosus, Psoriatic Arthritis, Gouty Arthritis.

Assessment criteria
Assessed and graded based on the parameters of pain (Table no.1), stiffness (Table no.2), swelling (Table no.3), tenderness (Table no.4) and range of movement (Table no.5).

Subjective parameters
• Knee Joint pain
• Swelling
• Stiffness

Objective parameters
• Pain
• Swelling- Girth of joint was measured with measuring tape.
• Restricted movement of joints- Measured with Goniometer.
• WOMAC- Index for osteoarthritis.

Investigations
• Haematological investigations:
  Haemoglobin %
  TC, DC, Erythrocyte Sedimentation Rate, Random blood sugar
• Urological investigations:
  Sugar, Albumin & Microscopic
• Radiological investigations:
  X-ray: AP & Lateral view of knees.

Intervention
Svacchandabhairava rasa 250 mg was administered once a day in the morning with the anupana of Rasnadi kashaya 96 ml for 14 days.
Follow up

All the patients were assessed with follow up period of 14 days after treatment with weekly interval. Total duration of study was 28 days with 14 days of study and 14 days of follow up.

RESULTS

Out of the 15 patients who was diagnosed as osteoarthritis knee had undergone the study with the oral medication i.e swacchandabhairava rasa. Swacchanda-bhairava rasa in a dosage of 250mg OD was given to the patient. The effect of the medication on the symptoms was assessed before, during and after the treatment. The results thus obtained was further analysed statistically with paired t test.

Among the overall assessment of the parameters (Table no.6), the parameters like effect on pain of right knee joint(Figure no.1), effect on pain of left knee joint(Figure no.2), effect on morning stiffness of right knee joint(Figure no.3), effect on tenderness of right knee joint (Figure no.7) showed statistically significant changes with p<0.001.

Effect on morning stiffness of left knee joint (Figure no.4) had statistically significant value with (p=0.041). Effect on swelling right knee joint (Figure no.5) and left knee joint (Figure no.6) was statistically not significant (p=0.164). Effect on tenderness on 14th day of left knee joint (Figure no.8) was statistically significant (p=0.006). Effect on range of movement of right knee joint (Figure no.9) was statistically significant (p=0.011). Effect on range of movement of left knee (Figure no.10) was statistically not significant (p=0.092). Effect on WOMAC score (Figure no.11) was statistically significant with P=0.001.

Overall effect of improvement of symptoms

Considering the overall effect (Table no.7) in this treatment, percentage of improvement of the patients with respect to their symptoms showed that 46.66% each of the patients fell into mild and moderate improvement category respectively.

DISCUSSION

Mode of action

Maximum reduction in the symptoms was found during the 14 to 28 days of the study. This was during the after the treatment period and the follow-up period. From day 1 to day 14 there was significant reduction in the symptoms, while from 14th day to 28th day there was moderate reduction in symptoms. The results were statistically significant for pain, tenderness and morning stiffness. Significance of varying degrees was observed for other symptoms. There was gradual but identifiable reduction in the symptoms over the period of 28 days i.e. the whole duration of the study. This study shows that with the trial drug the symptoms have got reduced and the patients got relief.

Swacchandabhairava rasa is mentioned in the chapter of vatavyadhi treatment. In this hareetaki, visha and mundi are tridosha shamaka. They are having anti-spasmodic action. Visha showed its effect on chronic rheumatism. Hareetaki also has a rejuvenative action which acts on vatavyadhi caused due to depletion of dhatu. Pippali, maricha, agnimanta, and nirgundi have vatahara and kaphahara properties. Maricha has action of enhancing the digestive fire which aids in pathology related to margavarana. Agnimanta has anti-arthritic properties which also have helped in reducing the symptoms of osteoarthritis. The aqueous extract of agnimantha was found to be effective in reducing the edema of formalin induced arthritis. External application of alcoholic extract
was also found to be effective in reducing the edema. Rasoushadhi like parada, lohahasma, and tapya present in the formulation: svacchandabhairava rasa acts as tridoshahara. They are having rejuvenating power i.e. which helps in dhatukshayaja vatavyadhi. It also has action against oedema. Gandhaka, haratala and tankana are the trio that helps to reduce vata and kapha and help to enhance the agni. Lohahasma has its action on oedematous condition.

In Svachandabhairava rasa most of the drugs are vata kaphahara, so that it helps in alleviating the morbid vata as well as kapha dosha. The majority of the drugs in the formulation have hot potency so that the stiffness of joints occurring due to cold potency of vata gets neutralized. The anti-arthritic and anti-inflammatory effect of the drugs helps to pacify the symptoms of osteoarthritis. The presence of rasaoushadhi and also anupana kwatha aids in relieving the symptoms. The anupana kwatha contains the drugs like rasna, eranda and devadaru which have the property to relieve pain and swelling. The aqueous extract of rasna was found to be effective in reducing the edema of formalin induced arthritis. External application of alcoholic extract of eranda was also found to be effective in reducing the edema. The guggulu is having the anti-inflammatory action and vatahara and kaphahara property. This also helps for the remission of inflammation. In short svacchandabhairava rasa is a combination which acts on the pathology of vatavyadhi. Whether it be margavarana-janya or dhatukshayajanya vatavyadhi, svacchandabhairava rasa is a combination which gives promising results in reducing the symptoms.

CONCLUSION
The morbidity of vata by either of the aetiology like dhathukshaya or margavarana is the main cause for vatavyadhi. Pain, stiffness, swelling, tenderness and restricted movements of the knee are the cardinal features of osteoarthritis knee. Svachandabhairava rasa has proved to be effective drug in reducing the symptoms like pain, stiffness, restricted movements and functional abilities and WOMAC score with statistically significant values for which p<0.05 for all the parameters. The overall effect showed that 46.66% each of the patients fell into the category of mild and moderate improvement with the use of svachhandabhairava. Adverse drug reactions were not observed during the follow-up of the patients. Thus svachhandabhairava rasa is effective in reducing the symptoms of osteoarthritis.

REFERENCES
en.wikipedia.org/wiki/visual_analogue_scale.
18. Dr. Rajila T P Dr.Shrilatha Kamath. A comparative clinical trial evaluating the therapeutic effect of svacchanda bhairava rasa in janu sandhigata (osteo arthritis), Rajiv Gandhi University of Health sciences. 2015

ILLUSTRATIONS AND TABLES
Grading of Parameters
Table no.1: grading of pain

<table>
<thead>
<tr>
<th>Pain</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nil Pain</td>
<td>0</td>
</tr>
<tr>
<td>Not very severe</td>
<td>1</td>
</tr>
<tr>
<td>Quite severe</td>
<td>2</td>
</tr>
<tr>
<td>Severe</td>
<td>3</td>
</tr>
<tr>
<td>Very severe</td>
<td>4</td>
</tr>
</tbody>
</table>

Table no.2 Grading of stiffness

<table>
<thead>
<tr>
<th>Stiffness</th>
<th>Time(Hours)</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
Table no.3 Grading of swelling

<table>
<thead>
<tr>
<th>Swelling</th>
<th>Measurement (Cms)</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Mild</td>
<td>0-35cm</td>
<td>1</td>
</tr>
<tr>
<td>Moderate</td>
<td>35-40cm</td>
<td>2</td>
</tr>
<tr>
<td>Severe</td>
<td>40-45cm</td>
<td>3</td>
</tr>
<tr>
<td>Extreme</td>
<td>45-50cm</td>
<td>4</td>
</tr>
</tbody>
</table>

Table no.4 Grading of tenderness

<table>
<thead>
<tr>
<th>Tenderness</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>0</td>
</tr>
<tr>
<td>The patient says the joint is tender</td>
<td>1</td>
</tr>
<tr>
<td>The patient winces</td>
<td>2</td>
</tr>
<tr>
<td>The patient winces and withdraws the affected part</td>
<td>3</td>
</tr>
<tr>
<td>The patient will not allow the joint to be touched</td>
<td>4</td>
</tr>
</tbody>
</table>

Table no.5 Grading of range of movement

<table>
<thead>
<tr>
<th>Range of movement</th>
<th>Degree</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>&gt;130°</td>
<td>0</td>
</tr>
<tr>
<td>Mild</td>
<td>130°-120°</td>
<td>1</td>
</tr>
<tr>
<td>Moderate</td>
<td>120°-110°</td>
<td>2</td>
</tr>
<tr>
<td>Severe</td>
<td>110°-100°</td>
<td>3</td>
</tr>
<tr>
<td>Extreme</td>
<td>100°-90°</td>
<td>4</td>
</tr>
</tbody>
</table>

Table No.6 Overall assessment of the Symptoms

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Mean</th>
<th>Difference in Mean</th>
<th>Paired ‘t’ test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BT (±SE)</td>
<td>AT (±SE)</td>
<td>S.D</td>
</tr>
<tr>
<td>Pain (Right knee joint)</td>
<td>2.867 ± 0.307</td>
<td>2.067 ± 0.267</td>
<td>0.800</td>
</tr>
<tr>
<td>Pain (Left knee joint)</td>
<td>2.200 ± 0.312</td>
<td>1.467 ± 0.256</td>
<td>0.733</td>
</tr>
<tr>
<td>Stiffness (Right knee joint)</td>
<td>1.067 ± 0.153</td>
<td>0.600 ± 0.163</td>
<td>0.467</td>
</tr>
<tr>
<td>Stiffness (Left knee joint)</td>
<td>0.800 ± 0.145</td>
<td>0.533 ± 0.133</td>
<td>0.267</td>
</tr>
</tbody>
</table>
Table no.7 Percentage of improvement

<table>
<thead>
<tr>
<th>IMPROVEMENT</th>
<th>PERCENTAGE OF IMPROVEMENT (%)</th>
<th>NUMBER OF PERSONS</th>
<th>PERCENTAGE (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>&lt; 25</td>
<td>7</td>
<td>46.67</td>
</tr>
<tr>
<td>Moderate</td>
<td>25-50</td>
<td>7</td>
<td>46.67</td>
</tr>
<tr>
<td>Marked</td>
<td>50-75</td>
<td>1</td>
<td>6.67</td>
</tr>
<tr>
<td>Good</td>
<td>&gt;75</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Figure no.1 Effect on pain (Right knee joint)
Figure no.2 Effect on pain (Left knee joint)

Figure no.3 Effect on stiffness (Right knee joint)

Figure no.4 Effect on stiffness (Left knee joint)

Figure no.5 Effect on swelling (Right knee joint)
Figure no.6 Effect on swelling (Left knee joint)

Figure no.7 Effect on tenderness (Right knee joint)

Figure no.8 Effect on tenderness (Left knee joint)

Figure no.9 Effect on range of movement (Right knee joint)
Figure no.10 Effect on range of movement (Left knee joint)

Figure no.11 Effect on WOMAC

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