CLINICAL EVALUATION ON MANAGEMENT OF AMAVATA (RHEUMATOID ARTHRITIS) WITH ALAMBUSHADI CHURNA TABLET, SIMHANADA GUGGULU AND SHATAPUSPADI LEPA

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ABSTRACT
In this clinical study 44 Amavata (Rheumatoid arthritis) patients were registered from the O.P.D. of Ayurveda Regional Research Institute, Tadong, Gangtok, Sikkim, India. 40 patients completed the treatment and 4 patients left the treatment before completion of the course. The aim of the study was to evaluate the role of selected drugs on Amavata or Rheumatoid arthritis. The treatment schedule was that 4 Alambushadi churna tablets orally thrice in a day with warm milk for 45 days (Each tablet containing 500 mg Alambusadi churna), 1 g Simhanada guggulu orally thrice in a day with warm water for 45 days and Shatpushapadi lepa applied locally over affected joints with warm water twice in a day for 45 days. In present clinical study maximum patient i.e. 65 % showed major improvement, 30 % showed minor improvement, 05 % showed no improvement and complete remission was nil. No complication was observed in the clinical study.

INTRODUCTION
Rheumatoid arthritis is a chronic, progressive autoimmune arthropathy and characterized by bilateral symmetrical involvement of joints with some systemic clinical manifestations. According to the clinical features, the disease Amavata very closely resembles with the Rheumatoid arthritis. In Ayurveda, Madhava kar (700AD) mentioned first the Amavata as a special disease entity and where Ama (bio-toxin) as well as Vata (biophysical force) plays a predominant role in the samprapti or pathogenesis of the disease Amavata1. Amavata or Rheumatoid arthritis is a most remarkable problem in the society in modern era. The suitable effective treatment of this disease is not available in the modern medicine till now. The national economy is badly affected due to this disease problem as the young aged people are mostly affected by this disease and the patients are gradually crippled both physically and mentally with regard to the worse prognosis of this disease. So it draws a major attention nowadays to different scholars for research purpose. Ayurveda is an ancient scientific medical knowledge in India2. It is one of the most important and oldest medical sciences in the world3. So many Ayurvedic medicines had been described in the Ayurvedic classical books for the treatment of Amavata (Rheumatoid arthritis)4. Hence, three important Ayurvedic medicines i.e. Simhanada guggulu, Alambushadi churna tablet and Shatpushapadi lepa had been selected for clinical evaluation on the management of Amavata (Rheumatoid arthritis).

MATERIALS AND METHODS
Total 44 patients were registered for the present clinical study as per the criteria for the diagnosis of the disease Amavata (Rheumatoid arthritis) and 4 patients were dropped out from the treatment before the completion of the therapy. The patients were selected from the O.P.D. and I.P.D. of Department of Kayachikitsa, Institute for Post Graduate Teaching and Research in Ayurveda, Gujarat Ayurved University, Jamnagar as per following criteria:-

Inclusion criteria
Patient between 18 to 60 years of both sexes, the patient who had the clinical features of Amavata according to Ayurvedic classics and the patient who had the American College of Rheumatology (ASIA), 1987-Reversed criteria for Rheumatoid arthritis.

Exclusion criteria
Osteoarthritis, Rheumatic arthritis, Septic arthritis, Gouty arthritis, Psoriatic arthritis, Traumatic arthritis, SLE (Systemic lupus erythematosus), Diabetes Mellitus, Hypertension, Tuberculosis, Thyroid disorders, Cardiac problems, Renal problems, Liver problems, HIV and any Malignancy, age below 18 years and above 60 years. The disease Amavata (Rheumatoid arthritis) was diagnosed on the basis of clinical features as described in Ayurvedic and Modern texts. R-A-factor and C-Reactice-Protein investigations had been done in all the patients for diagnosis and severity of the disease. Routine Blood, Urine and Stool examinations along with Serum uric acid, urea, creatinine, ASO titer, ANF, Lipid profile, Liver function test, ECG, Fasting Blood Sugar had been done to exclude other pathological conditions of the registered patients.

Aims and Objectives
To ameliorate the clinical features of Amavata and increase the work ability; to minimize the periodic fluctuation of the disease, to evaluate the role of selected drugs on Amavata or Rheumatoid arthritis.
Plan of Study
40 patients completed the treatment out of registered 44 patients and 4 patients left the treatment before completion of the course. The treatment schedule was that 4 Alambushadi Churna tablets (B.P. -26/69-70) were taken orally thrice in a day with warm milk for 45 days (Each tablet containing 500 mg Alambusadi Churna), 1 g Simhanada Guggulu (B.R.-29/185-190) was taken orally thrice in a day with warm water for 45 days, Shatapushpadi Lepa (B.R.-29/9-10) was applied locally over affected joints with warm water twice in a day for 45 days. All the above medicines were taken from Amavatargadhikara of Ayurvedic classics those are Bhaishajya Ratnavali (B.R.) and Bhava Prakash (B.P.).

Other Advice
Patients were given following advice during the therapy: – Don’t take cold drinks, ice cream, curd, banana, coconut, black gram, tobacco, smoking, alcohol, alcohol containing other beverages. Do not use cold water for bathing and use lukewarm water for bathing. Never sleep in day time.

Assessment Parameters
Following parameters had been taken for the assessment of this clinical study.

Assessment of Clinical Manifestations
The progress of the clinical manifestations was assessed on the basis of clinical features of the disease Amavata (Rheumatoid arthritis) which are mentioned in Ayurvedic classics as well as with the help of criteria fixed by American Rheumatology Association in 1988.

Assessment of Functional Capacity
Functional capacity of the treated patients was assessed with the help of three parameters those were Walking time, Grip Strength and Foot pressure.

Assessment of Overall Effect of the Therapy
The overall effect of the therapy or management was assessed with the help of the criteria collected from ARA (American Rheumatology Association 1988) and it was implemented after some modification. Results of that clinical study were evaluated in to four groups as follows: a) Complete Remission, b) Major Improvement, c) Minor Improvement and d) No improvement.

Observation, Results and Discussion
Maximum patients i.e. 66.36 % belonged to 30 – 50 years of age group. 83.46 % patients were female, 86.59 % patients were Hindu (As, Jamnagar is Hindu majority area), 95.87 % patients were Married, 72.16 % patients were Housewives (as, Maximum patients were middle aged female), 66.67 % were coming from Middle class, 74.46 % were in urban habitat, 85.96 % were educated from primary to graduate level. Majority of the patients i.e. 56.97 % were having negative family history, 82.46 % patients were having gradual onset, 92.33 % patients were having relapsing course and 44.45 % were having chronicity of less than 2 years. Cold and moist environment was aggravating factor for all the patients. Most of the patients i.e. 85.67 % were Vegetarian (as, the diet pattern of Jamnagar, India people is mainly Veg), 81.52 % patients were of poor appetite, 45.87 % were Kruha Kostha (Constipated), 51.26 % were Vata-kapha Prakriti and 56.76 % were Tamasik Manasik Prakriti. All the patients were more suffered in Varsha ritu (Rainy season) and Shita ritu (winter season). Maximum numbers of patients i.e. 70.42 % were found in history of Viruddhahara (maldiet habit), 61.54 % patients were found Viruddhachesta (malwork habit) history, 82.54 % were Divasawpna (Day sleep habit) history, 37.68 % were Nishchala (Sedentary habit) and 35.44 % were Chinta (Mental stress) history. In majority of patients (92.32 %) wrist joint was involved along with Metacarpophalangeal (83.32 %), Metatarsophalangeal (81.43 %), Ankle (78.24 %), Knee (75.57 %), Elbow (26.58 %), PIP (27.76 %), Shoulder (10.42 %), Hip (7.44 %), Jaw (5.54 %), DIP (7.45 %), Lumbo-sacral (5.33 %) and Cervical (3.33 %) joints were involved. C-Reactive-Protein positive was found in 68.55 % patients and R.A. factor positive was found in 25.30 % patients, rheumatoid nodule was present in 18.22 % patients and Deformity was observed in 3.10 % patients. According to Pratyatma Lakshana (Cardinal clinical features) all the patients were suffering from Sandhi-shula (Joint-pain), Sandhi-shotha (Joint-swelling), Sandhi-stabdhabta (Joint-stiffness) and Sandhi-sparsashasahyata (Joint-tenderness). According to Samanya Lakshana (General clinical features) Angamarda (body ache), Gaurava (heaviness of the body) and Agni-daurbalya (impaired digestive capacity) were observed in 68.55 %, 65.68 % and 84.86 % patients respectively.

<table>
<thead>
<tr>
<th>Clinical features</th>
<th>Mean Score</th>
<th>% of Relief</th>
<th>S.D.</th>
<th>S.E.</th>
<th>‘t’</th>
<th>P</th>
</tr>
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<tbody>
<tr>
<td>B.T.</td>
<td>A.T.</td>
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<tr>
<td>Sandhi-shula (Joint pain)</td>
<td>2.20</td>
<td>0.78</td>
<td>64.77</td>
<td>0.50</td>
<td>0.08</td>
<td>18</td>
</tr>
<tr>
<td>Sandhi-shotha (Joint swelling)</td>
<td>1.93</td>
<td>0.75</td>
<td>61.03</td>
<td>0.38</td>
<td>0.06</td>
<td>19.31</td>
</tr>
<tr>
<td>Sandhi-stabdhabta (Joint stiffness)</td>
<td>2.23</td>
<td>0.80</td>
<td>66.29</td>
<td>0.50</td>
<td>0.08</td>
<td>18.45</td>
</tr>
<tr>
<td>Sandhi-sparsha-asahyata (Joint tenderness)</td>
<td>2.03</td>
<td>0.75</td>
<td>62.96</td>
<td>0.45</td>
<td>0.07</td>
<td>17.83</td>
</tr>
<tr>
<td>Angamarda (Body ache)</td>
<td>2.0</td>
<td>0.69</td>
<td>65.38</td>
<td>0.47</td>
<td>0.07</td>
<td>17.47</td>
</tr>
<tr>
<td>Gaurava (Heaviness of the Body)</td>
<td>2.0</td>
<td>0.8</td>
<td>60.0</td>
<td>0.41</td>
<td>0.06</td>
<td>18.73</td>
</tr>
<tr>
<td>Agni-daurbalya (Impaired digestive capacity)</td>
<td>2.0</td>
<td>0.93</td>
<td>53.75</td>
<td>0.27</td>
<td>0.04</td>
<td>25.49</td>
</tr>
</tbody>
</table>

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<thead>
<tr>
<th>Criteria</th>
<th>Mean Score</th>
<th>% of Relief</th>
<th>S.D.</th>
<th>S.E.</th>
<th>‘t’</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walking time</td>
<td>12.65</td>
<td>10.65</td>
<td>15.81</td>
<td>0.23</td>
<td>0.04</td>
<td>55.89</td>
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<td>Grip strength</td>
<td>88.75</td>
<td>97.75</td>
<td>10.14</td>
<td>5.50</td>
<td>0.87</td>
<td>10.33</td>
</tr>
<tr>
<td>Foot pressure</td>
<td>19.78</td>
<td>22.60</td>
<td>14.29</td>
<td>0.87</td>
<td>0.14</td>
<td>20.45</td>
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In the present clinical study, all the results were statistically highly significant (P < 0.001) on afore said clinical manifestations and functional capacity parameters. Overall effect of the therapy evaluate that maximum patients i.e. 65 % showed major improvement, 30 % showed minor improvement, 05 % showed no improvement and complete remission was nil. Probable mode of action according to Ayurvedic view of the selected Ayurvedic medicines for the present study is that compositions of the Alambushadi Churna tablet and Simhanada Guggulu both were containing katu-tikta rasa, ushna-laghu-ruksha-tikshna guna, ushna virya, katu or madhur vipaka and vata-kapha-shamaka properties and had deepan (enzyme activating), ama-pachan (biotoxin neutralizing), shothaghna (oedema reducing), vedanasthapaka (analgesic), jwaraghna (antipyretic), valya (energy enhancing), and amavatahara (anti rheumatic) etc. actions which helped to enhance the agni-bala (digestive and metabolic capacity) and to mitigate the Ama (bio-toxins) as well as to hinder the Ama formation into the body, as a result both medicines helped to reduce the clinical manifestations of Amavata and also to break down the samprapti (pathogenesis) of Amavata. Compositions of the Shatapushpadi Lepa were containing ushna-laghu-ruksha-tiksha guna, ushna virya and vata-kapha-samaka property and had also shothahara (oedema reducing) and vedanasthapak (analgesic) actions. Hence, Shatapushpadi Lepa when used locally with warm water, it helped to reduce the local pain, swelling, tenderness and stiffness of the affected joints and to break down the Samprapti (pathogenesis) locally of the disease Amavata.

CONCLUSION

It can be concluded that Amavata looks similar to Rheumatoid arthritis in its clinical appearance and the Ayurvedic treatment was satisfactorily effective in the management of Amavata (Rheumatoid arthritis) in the present study and it could happened due to the combined effect of Alambushadi Churna tablet, Simhanada Guggulu and Shatapushpadi Lepa. No complications had been observed in this clinical study.

REFERENCES


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