CLINICAL EVALUATION OF THE EFFECT OF AJAMODADI CHURNA AND VAITARAN BASTI IN THE MANAGEMENT OF AMAVATA (RHEUMATOID ARTHRITIS)

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ABSTRACT:
Amavata is a disease mentioned in Ayurveda in which vitiation of vata dosha and accumulation of ‘Ama’ takes place in the joints and it simulates rheumatoid arthritis (RA) at modern parlance. The allopathic medicines have inconsistent clinical efficacy and unfavourable toxicity profile. However Ayurvedic medicines have lesser side effects and aim at treating the root cause of the disease. In the present study 68 patients of Amavata were registered from OPD and IPD department of Kayachikitsa, Govt. Ayurvedic College & Hospital, Guwahati and were considered under a single group for study. The patients were given Ajamodadi churna 3gm per day orally in two divided doses for 2 months. Along with that the patients were administered Vaitaran Basti for 8 days. Both the oral drug and the Vaitaran Basti shows very good result in pain, swelling, morning stiffness, tenderness, total count (TC), ESR, Rheumatoid factor (RF) and on the health assessment questionnaire for RA in the management of Amavata.

Keywords: Amavata, Rheumatoid Arthritis, Vaitaran Basti, Ajamodadi churna.

INTRODUCTION
Amavata is a disease mentioned in Ayurveda in which vitiation of vata and accumulation of Ama takes place in the joints and it simulates rheumatoid arthritis (RA) at modern parlance.

The disease is not found to be mentioned in the Brihat trayees of Ayurveda. Only in 7th century AD Acharya Madhavakar in his text Madhav Nidan described it as a separate disease entity. Later, many authors such as Vrinda Madhava (9th century), Cakradutta (11th century), Vangasena (12th century), Sarangadhar (13th century), Bhavaprakash (16th century) mentioned Amavata as a separate disease in their texts.
Amavata as mentioned in Ayurveda is a disease of GIT origin, manifested due to derangement of metabolism and resulting into both local clinical features like sandhisula, sotha, stabdhata etc. as well as systemic features like jvara, angamarda, utshahhani, bahumutrata, hridgraha etc.

Rheumatoid arthritis mentioned in modern medicine is a chronic inflammatory disease marked by symmetric, peripheral polyarthritis resulting in joint damage, physical disability and systemic involvements in the form of hematological, neurological, cardiac, renal abnormalities.

Both the disease entities bear similarities in term of clinical features while pathogenesis of amavata has remained a constant in Ayurveda through ages but pathogenesis of RA is changing after every decade owing to newer advances in genetic studies and immunology.

In Ayurveda treatment of amavata is described in the text Chakradutta. A treatment principle is mentioned that includes langhana, swedana, dipana, virecan, snehapan and basti with the help of appropriate drugs that aims to detoxify the body internally and pacify the vitiated vata dosha and ama.

However in modern system of medicine, NSAIDs and glucocorticoids were used formerly and till today alone or in combination to combat joint inflammation. Owing to the side effects due to chronic administration studies were conducted to evolve new drugs. A new group of drugs called DMARDS were developed in 1986 which showed ability to prevent structural progression of RA and is used till today. Due to their inconsistent clinical efficacy or unfavourable toxicity profile, search for new drug took place and developed the biologic DMARDS which revolutionised the treatment of RA over the past decade. Its use is limited by high cost and risk for opportunistic infections.

Developing countries are finding an increased number of RA in the face of ongoing poverty, rampant infectious disease and poor access to modern health care causing delay in diagnosis. In the present study a research has been done to evaluate the effect of a herbal compound named Ajamodadi churna and a panchakarma procedure named Vaitaran Basti mentioned in Ayurveda in the management of Amavata.

**Aim and objective:**

To evaluate clinically the combined effect of AJAMODADI CHURNA and VAITARAN BASTI in the management of Amavata (Rheumatoid arthritis).

**Methods:**

**Selection of cases:**

A total number of 68 patients were randomly selected for the study from OPD and IPD, department of Kayachikitsa, Govt. Ayurvedic College and Hospital, Guwahati- 14, Assam.
Method of collection of data:

- **Inclusion criteria:** Patients with age group of 18-60 years, fulfilling the diagnostic criteria of Amavata (Rheumatoid arthritis) have been selected.

- **Diagnostic criteria:**
  - Clinical features of Amavata like Sandhisula, sandhisotha, angamarda, aruchi, trishna, alasya, gaurava, jvara etc. have been taken into consideration.
  - The diagnostic criteria for Rheumatoid arthritis laid down by EULAR (2010) has also been taken into consideration.

Laboratory investigations:

The patients taken under the study were already diagnosed as RA by different physicians of Modern Medicine. However, during the study, the following investigations were conducted:

1. Total count (TC).
2. Erythrocyte sedimentation rate (ESR).
3. Rheumatoid factor (RF).

Exclusion criteria:

1. Complicated diabetes mellitus.
2. Hypertension.
3. Psychiatric disorders.
4. Severe metabolic disorders.
5. Epilepsy.
7. Rheumatoid arthritis with chronicity of more than 10 years.
8. Having severe deformities.
9. All are conditions which need regular medication are excluded.

Intervention with duration:

- Triphala swaras (50ml) giloy satva (3g) and eranda taila (10ml) had been given on 3 consecutive nights for mala sodhana before starting medication to the patients.

- Ajamodadi churna had been given orally to the patients at a dose of 3 gram per day after meal into two divided doses for 2 months along with Vaitaran Basti for 8 days from the beginning of the therapy uninterruptedly.
The patients were strictly advised to follow pathya- apathy of Amavata during the course of the treatment.

Total duration of treatment: 60 days:

Criteria for assessment:

In the present study, efforts were taken to follow the guidelines laid down by the classical texts of Ayurveda as well as European League for Rheumatism (2010) in respect of patient selection, their classification and final analysis of the result. The results were assessed in regard to the clinical signs and symptoms, functional capacity of the patients and laboratory investigation (especially ESR value).

A. Subjective parameters:

- Join pain
  0- No pain.
  1- Pain occasional and bearable.
  2- Pain frequent, can be managed with analgesics.
  3- Pain persistent, unmanageable even with analgesics.

- Morning stiffness:
  0- No stiffness.
  1- Early morning stiffness upto 30 minutes.
  2- Every morning stiffness more than 30 minutes but less than 45 minutes.
  3- Morning stiffness > 45 minutes.

- Swelling:
  0- No swelling.
  1- Just covering bony prominences.
  2- Severe swelling.

- Health Assessment Questionnaire (HAQ) for Rheumatoid arthritis.

  The health assessment questionnaire disability index (HAQ-DI) is a questionnaire for the assessment of Rheumatoid arthritis. The questionnaire is a patient reported outcome which is usually self-administered by the patient- The following categories are assessed by the HAQ- DI

  1. Dressing and grooming.
2. Arising.
3. Eating.
5. Hygiene.
6. Reach.
7. Grip.
8. Common daily activities.

The patients report the amount of difficulty they have in performing some of these activities. Each question grades on a scale ranging from 0 to 3. If the mentioned activities can be performed without any difficulty (scale 0) upto cannot be done at all (scale- 3).

B. Objective parameters:
   - Tenderness.
     0- No tenderness.
     1- Tender but bearable.
     2- Tender and winced.
     3- Tender, winced and withdraw.
   - Total count (TC).
   - Erythrocyte sedimentation rate (ESR).
   - Rheumatoid factor (RF).

**OBSERVATION AND RESULTS OF THE THERAPEUTIC TRIAL:**

The cases included in this study were classified into four different age groups i.e. 18- 30 years, 31-40 years, 41- 50 years and 51- 60 years. Among the 68 cases, 8 patients (11.76%) belonged to age group 18- 30 years, 16 patients (23.53%) belonged to age group 31- 40 years, 30 patients (44.12%) belonged to age group 41- 50 years, 14 patients (20.59%) belonged to age group 51- 60 years.

From the above data it can be inferred that maximum patients belonged to group 41- 50 years i.e. 30 (44.12%) followed by 16 patients (23.53%) belonged to (31- 40 years). This shows that Amavata is predominant in the middle age group.

Among the 68 patients included in the study 48 patients (70.59%) were female and only 20 patients (29.41%) were male.
This shows the predominance of this disease in females. The predominance of females may be due to possible role of estrogen in the disease pathogenesis. Estrogen may have a role in the stimulation of production of TNF- alpha.

Of the 68 patients studied, 54 patients (79.41%) were Hindus, followed by 12 patients (17.65%) were Muslims and only 2 patients (2.94%) were Christians.

In signifies the predominance of Hindu community in this area, as religion has no significant relationship with the disease.

Among the 68 patients studied, maximum number of patients belonged to high school category i.e. 26 patients (38.24%) followed by 18 patients (26.47%) were graduates, 16 patients (23.53%) belonged to primary school category and 8 patients (11.76%) were illiterate).

As the study included most of the people coming to this hospital from urban area, so it had more number of literate. The prevalence of this disease had showed no direct relation with educational status.

Among the 68 patients included in the study maximum patients i.e. 42 patients (61.8%) were housewives. It was followed by 8 patients (11.8%) who were servicemen and 8 patients (11.8%) were farmers. 6 patients (8.8%) belonged to ‘other’ category and 4 patients (5.8%) were businessmen.

This reveals that housewives are more in number and percentage owing to improper lifestyle, nature of house hold work and familial stress, which lead to occurrence of amavata more in them.

Among the 68 cases studied, maximum patients i.e. 42 patients (61.77%) belonged to middle class, followed by 20 patients (29.41%) belonged to higher class and only 6 patients (8.82%) belonged to lower class.

Majority of people included in this study belonged to middle economic status as the study was conducted in a government hospital where treatment facilities are available free of cost. This also reflects lack of awareness about health in the middle economic status category. However the disease has no direct relation with economic status.

Among the 68 patients, 54 patients (79.41%) were married and 8 patients (11.77%) were unmarried and only 6 patients (8.82%) were widow.

As most of the patients belonged to middle age group, maximum of them were married. However, the disease has no relation with marital status.

Among the 68 patients, maximum patients i.e. 38 patients (55.88%) belonged to urban area and 30 patients (44.12%) belonged to rural area.

The hospital where study was conducted belongs to urban area, so patients belonging to urban area category was more in number. Also cases are more in urban area due to sedentary living and faulty diet habits of the people in this area.
The 68 patients were categorized into four groups. Of them 6 patients (8.8%) had a duration of illness 0-1 year, 20 patients (29.4%) had a duration of 1-3 years, 18 patients (26.5%) had a duration of 3-5 years and 24 patients (35.3%) had a duration of more than 5 years.

Among 68 patients included in the study 2 patients (29.41%) felt more pain in the morning, 18 patients (26.47%) felt continuous pain, 16 patients (23.53%) felt more pain at evening and 14 patients (20.59%) felt more pain at night.

Among 68 patients including in the study, 27 patients (39.71%) felt more pain during rest, 22 patients (32.35%) felt more pain during work and 19 patients (27.94%) had no relation of pain with work.

Among the 68 patients studied all 68 of them (100%) had a history of taking NSAIDs, DMARDs and steroids before coming to take Ayurvedic treatment.

Among the 68 patients studied, maximum patients i.e. 65 patients (95.59%) were non-vegetarian and only 3 patients (4.41%) were vegetarian. As non-vegetarian diet is heavy, spicy and fatty it may lead to formation of ama due to difficulty in digestion.

Among the 68 patients studied, 26 patients (38.24%) had irregular bowel habit, 22 patients (32.35%) had constipation and 20 patients (29.41%) had normal bowel habit. Derangement of jatharagni may be the cause for irregular bowel habit and may be responsible for the disease process.

Among the 68 patients studied, 38 patients (55.88%) had normal sleep habit and 30 patients (44.12%) had disturbed sleep.

Among the 68 patients situated maximum patients i.e. 64 patients (94.12%) had negative family history while only 4 patients (5.88%) had a positive family history of the disease.

Among 68 patients studied, 53 patients (77.94%) were positive for RF and 15 patients (22.06%) were negative for RF. The presence of RF doesn’t establish the diagnosis of RA but it can be of prognostic significance because patients with high titres tend to have more severe and progressive disease.

RESULTS:

The effect of therapies was studied in a single group of 60 patients as 8 out of total 68 patients left the study due to various reasons. The effect of the drugs were statistically assessed with Z-test on the basis of changes observed in prefixed subjective and objective parameters. The group studied showed highly significant result and all the cases were followed up to 60 days.

SUBJECTIVE PARAMETERS:
Table-19: Effect of the drug on 60 patients (n=60) for criteria of pain after 60 days (i.e. after completion of trial).

<table>
<thead>
<tr>
<th>Mean BT</th>
<th>Mean AT</th>
<th>Mean BT-AT</th>
<th>SD&lt;sub&gt;BT&lt;/sub&gt;</th>
<th>SD&lt;sub&gt;AT&lt;/sub&gt;</th>
<th>SE</th>
<th>Z</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.06</td>
<td>1</td>
<td>1.06</td>
<td>0.78</td>
<td>1.01</td>
<td>0.16</td>
<td>6.6</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

Interpretation: The above data depicts the effect of Ajamodadi churna and vaitarana basti on criteria of pain. Mean score before treatment was 2.06 and SD ± 0.78 which came down to mean score 1 with SD ± 1.01, giving Z value 6.6 which shows highly significant result at P< .001.

Table-20: Effect of the drugs on group of 60 patients, (n=60) for criteria of swelling after 60 days (i.e. after completion of trial)

<table>
<thead>
<tr>
<th>Mean BT</th>
<th>Mean AT</th>
<th>Mean BT-AT</th>
<th>SD&lt;sub&gt;BT&lt;/sub&gt;</th>
<th>SD&lt;sub&gt;AT&lt;/sub&gt;</th>
<th>SE</th>
<th>Z</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.43</td>
<td>0.57</td>
<td>0.86</td>
<td>0.49</td>
<td>0.72</td>
<td>0.11</td>
<td>7.6</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

Interpretation: The above data depicts the effect of Ajamodadi churna and Vaitaran Basti on criteria of swelling. Mean score before treatment was 1.43 and SD ± 0.49 which came down to mean score 0.57 after treatment with SD ± .72 giving Z value 7.6 which shows highly significant result at P< .001.

Table-21: Effect of the drugs on group of 60 patients (n-60) for criteria of morning stiffness after 60 days (i.e. after completion of trial).

<table>
<thead>
<tr>
<th>Mean BT</th>
<th>Mean AT</th>
<th>Mean BT-AT</th>
<th>SD&lt;sub&gt;BT&lt;/sub&gt;</th>
<th>SD&lt;sub&gt;AT&lt;/sub&gt;</th>
<th>SE</th>
<th>Z</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.03</td>
<td>1.13</td>
<td>0.9</td>
<td>0.84</td>
<td>1.03</td>
<td>0.17</td>
<td>5.2</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

Interpretation: The above data depicts the effect of Ajamodadi churna and Vaitaran basti on criteria of morning stiffness. Mean score before treatment was 2.03 and SD ± 0.84 which came down to mean score 1.13 after treatment with SD ± 1.03 giving Z value 5.2 which shows highly significant result at P< .001.

Table 22: Effect of the drugs on group of 60 patients (n=60) for HAQ after 60 days (i.e. after completion of trial)
Interpretation: The above data depicts the effect of Ajamodadi Churna and vaitaran basti on the HAQ. Mean score before treatment was 1.87 and SD ± 0.92 which came down to mean score 1.09 after treatment with SD ± 0.79 giving Z value 5.2 which shows highly significant result at P<0.001.

**OBJECTIVE PARAMETERS:**

Table-23: Effect of the drugs on group of 60 patients (n=60) for criteria of tenderness after 60 days (i.e. after completion of trial).

<table>
<thead>
<tr>
<th>Mean BT</th>
<th>Mean AT</th>
<th>Mean BT-AT</th>
<th>SD_BT</th>
<th>SD_AT</th>
<th>SE</th>
<th>Z</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>0.87</td>
<td>1.13</td>
<td>0.73</td>
<td>0.99</td>
<td>0.16</td>
<td>7.1</td>
<td>&lt; .001</td>
</tr>
</tbody>
</table>

Interpretation: The above data depicts the effect of Ajamodadi churna and vaitaran basti on criteria of tenderness. Mean score before treatment was 2 and SD ± 0.73 which came down to mean score 0.87 after treatment with SD ± 0.99 giving Z value 7.1 which shows highly significant result at P< .001.

Table- 24: Effect of the drugs on group of 60 patients (n=60) on Total Count (TC) after 60 days of treatment (i.e. after completion of trial).

<table>
<thead>
<tr>
<th>Mean BT</th>
<th>Mean AT</th>
<th>Mean BT-AT</th>
<th>SD_BT</th>
<th>SD_AT</th>
<th>SE</th>
<th>Z</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>12500</td>
<td>10700</td>
<td>1800</td>
<td>596.60</td>
<td>1337.84</td>
<td>189.11</td>
<td>9.5</td>
<td>&lt; .001</td>
</tr>
</tbody>
</table>

Interpretation: The above data depicts the effect of Ajamodadi churna and vaitaran basti on Total Count (TC). Means score before treatment was 12500 and SD ± 596.60 which came down to mean score 10700 after treatment with SD ± 1337.84 giving Z value 9.5 which shows highly significant result at P < .001.

Table-25: Effect of the drugs on group of 60 patients (n=60) on ESR after 60 days (i.e. after completion of trial).

<table>
<thead>
<tr>
<th>Mean BT</th>
<th>Mean AT</th>
<th>Mean BT-AT</th>
<th>SD_BT</th>
<th>SD_AT</th>
<th>SE</th>
<th>Z</th>
<th>P</th>
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<tbody>
<tr>
<td></td>
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</tbody>
</table>
Interpretation: The above data depicts the effect of Ajamodadi churna and vaitaran basti on ESR. Mean score before treatment was 76.3 and SD ± 29.5 which came down to mean score 49.6 after treatment with SD ± 29.7 giving Z value 4.9 which showed highly significant result at P< .001.

Table- 26: Effect of the drugs on 60 patients (n=60) on Rheumatoid Factor (RF) after 60 days (i.e. after completion of trial).

<table>
<thead>
<tr>
<th></th>
<th>Mean BT</th>
<th>Mean AT</th>
<th>Mean BT-AT</th>
<th>SD_BT</th>
<th>SD_AT</th>
<th>SE</th>
<th>Z</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>63.6</td>
<td>47.4</td>
<td>16.2</td>
<td>23.7</td>
<td>26.7</td>
<td>4.6</td>
<td>3.5</td>
<td>&lt; .001</td>
<td></td>
</tr>
</tbody>
</table>

Interpretation: The above data depicts the effect of Ajamodadi churna and vaitaran basti on Rheumatoid Factor (RF). Means score before treatment was 63.6 and SD ± 23.7 which came down to mean score 47.4 after treatment with SD ± 26.7 giving Z value 3.5 which shows highly significant result at P < .001.

**DISCUSSION:**

In the present study Ajmodadi Churna was taken as samshaman yoga while Vaitaran basti was selected as samsodhana procedure for the management of Amavata.

Ajmodadi churna contains- ajamoda, vidanga, saindhava, devadaru, citraka, pippalimula, shatapuspa, pippali, maricha, pathya, vriddhadaru and nagara. Vaitaran basti contains- tila taila, gomutra, chinca kalka, saindhava and guda. All the drugs possess ushna virya, kapha-vathara, deepaniya and ama pachak quality.

The cases included in this study were classified into four different age groups i.e. 18- 30 years, 31- 40 years, 41- 50 years and 51- 60 years. Among the 68 cases, 8 patients (11.76%) belonged to age group 18- 30 years, 16 patients (23.53%) belonged to age group 31- 40 years, 30 patients (44.12%) belonged to age group 41- 50 years, 14 patients (20.59%) belonged to age group 51- 60 years.

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Mean score for pain before treatment was 2.06 ± 0.78 which came down to mean score of 1 ± 1.01 after 60 days of treatment. Z value was 6.6 which showed highly significant result at P<0.001.
Mean score for swelling before treatment was 1.43 ± 0.49 which came down 0.57 ± 0.72 after 60 days of treatment. Z value attained was 7.6 which showed highly significant result at p<0.001.

Mean score for morning stiffness before treatment was 2.03 ± 0.84 which came down to 1.13 ± 1.03 after 60 days of treatment Z value attained was 5.2 which showed highly significant result at P<0.001.

Mean score for Disability Index (DI) of the HAQ was 1.87 ± 0.92 before treatment which came down to 1.09 ± 0.79 after treatment. Z value attained was 5.2 which showed highly significant result at P<0.001.

Mean score for tenderness before treatment was 2.0 ± 0.73 which came down to mean score of 0.87 ± 0.99 after treatment for 60 days. Z value was 7.1 which showed highly significant result at P<0.001.

Mean score for TC before treatment was 12500 ± 596.60 which came down to 10700 ± 1337.84 after 60 days of treatment. Z value attained was 9.5 which shows highly significant result at P < .001.

Mean score for ESR before treatment was 76.3 ± 29.5 which came down to 49.6 ± 29.7 after 60 days of treatment. Z value attained was 4.9 which showed highly significant result at P<0.001.

Mean score before treatment was 63.6 ± 23.7 which came down to 47.4 ± 26.7 after 60 days of treatment. Z value attained was 3.5 which showed highly significant result at P< .001.

CONCLUSION:

The results were analyzed statistically which shows both Ajamodadi churna and vaitaran vasti are effective for the management of Amavata.

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