CLINICAL EFFICACY OF SHIRISH (Albizia lebbeck (L.) Benth.) KWATH AS VISHAGHNA DRAVYA IN AMAVATA

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ABSTRACT
Symptomatic relief has become a popular mode in the management of any disease that shows up. Amavat has been a debilitating disease mentioned in our historical textbooks since laghutrai and is a crippling disorder leading to debility. Its 1st entire explanation came into lime light through a textbook named Madhav nidana[1]. Nonstandard dietary practice, community structures, changes in way of life and surroundings directs to Amavata. Rheumatoid arthritis is a very parallel to Amavata in modern science. Shirish has been chosen to have a high quality results with low cost and no adverse events in contest to R.A. In the present study, 30 patients were randomly selected and divided into 2 groups with 15 patients in each group. Group-A was treated with Shirish Kwath and Group-B was treated with placebo capsules. Study under taken was single-blind. On inter-group comparison it was seen that the trial conducted was statistically non-significant with significant result on sandhishoota and sundhishool. So it was concluded that drug has positive effect on the management of Amavata, but still Shirish has to be given in combination with the other drugs to manage all the complications of the disease.

Keywords: Amavat, Shirish, Adverse Drug Reaction, Rheumatoid Arthritis, Placebo.

INTRODUCTION
The history of use of medicinal plants is one of uninterrupted phenomenon since antiquity and hence oldest subject of research for human being. By innumerable experiments depending on need and necessity, ancient acharya of ayurveda made their own vegetable material media. This research work is a same kind of effort in which we have tried to evaluate the efficacy of Shirish as a vishaghna dravya[2] within modern parameters.

शिरीषो विषाणां च च. सु (25/40)
Many food products either of mineral origin or vegetable origin, if incompatible to our body, produces delayed toxic effect on our body are kept under the banner of “DUSHI VISHA”[3]. Amavisha also falls under its parameter.
Mangwal Ketan et al: Clinical Efficacy Of Shirish (Albizia Lebbeck (L.) Benth.) Kwath As Vishaghna Dravya In Amavata

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The prevalence of Amavata and other joint disorders have increased dramatically in the recent years owing to our changing lifestyle. As per CDC (CENTRE FOR DISEASE CONTROL) and collective facts from the National Health Interview Survey (2010-2012), 22.7 % (52.5 million) of adults were establish affirmative for Rheumatoid Arthritis, with elevated age-adjusted frequency in women (23.9%) than in men (18.6%). Nowadays, due to strenuous work schedule and increased pace of life, it has become a burning problem. Because of the crippling nature of disease in the advanced stages, it decreases the quality of life and reduces the life expectancy of the individual. Our counter pathies are also being proved fruitless in terms of full remedy for amavat.

HYPOTHESIS MODEL

- Ama can be compared to free radical which is supposed to enhance the process of joint destruction.
- Hyper-activity of immune system.
- Acute/chronic inflammation of joints.

In Allopathic system of medicine, the treatment of Rheumatoid arthritis involves mainly the use of NSAIDs (Non –steroidal anti-inflammatory drugs), DMARDs (Disease Modifying Anti-Rheumatic Drugs) and Corticosteroids. It is seen that they provide symptomatic relief and are beneficial in acute conditions but they have many side-effects to the misery of the patients. This type of treatment is against the principles of Ayurveda which focuses on Shuddha Chikitsa\(^5\).

Amavata is the most common weakening joint disorder that almost cripples the patient's life. It is most frequently seen in patients with changed dietary habits, social structure, environment, plus mental stress and strain. In this respect, Ayurveda has a lot to offer.

AIM AND OBJECTIVES

- To study amavat as per classical text.
- To study rheumatoid arthritis as per modern text, articles, search engines etc.
- To evaluate Vishaghana property of Shirish kwath.
- To assess the efficacy of Shirish kwath in Amavata

MATERIAL AND METHODS: The methodology is divided into 3 parts-
Collection of raw drug from natural habitat, its identification and finally its conversion from raw state into course powder form.

Clinical study.

Data collection and Statistical analysis.

**CLINICAL STUDY:** The third part, called a clinical study contains Aim and Objectives of the study, plan of the study, research design, inclusion and exclusion criteria, grouping pattern, data collection technique and criteria for assessment.

**Selection of Patients**

Total 30 Patients of *Amavata* were selected from the O.P.D / I.P.D at Uttarakhand Ayurved University, Rishikul Campus- Haridwar. The study was conducted on the patients randomly divided into 2 groups that means 15 patients were taken in each group on the basis of inclusion and exclusion criteria depending on the detailed clinical history, physical examination and other necessary / desired investigations.

**Selection of Drug**

- **Shirish kwath**–Bark was collected in the month of Feb and dried in sun. Bark was made into coarse powder and packed, and patient was directed to prepare *kwath* as per (classical method) *Sharangdhar*.

- **Authentication of the collected sample:**
  *Shirish* was collected from the natural sources and their identification was carried out by imminent person of Dravyaguna Dept. at Rishikul Campus-Haridwar (UAU). Further authentication was done from Botanical Survey of India, Dehradun (BSI/NRC Tech./Herb[Ident].2018-19/200).

**Dose of Drug**

- Dose of drug was calculated, keeping in mind an average person.
- *Shirish kwath* 40ml B.D[^6].

**Method of preparation:** 20gm of drug was taken and a decoction was prepared by putting 160 ml of water, in a ratio 1:8(Drug: water), and on remaining 40ml (¼) it’s ready to be consumed. (Sa.Sm)

- **Duration of study:** 45 days.
- **Type of Study:** Single blind
- **Follow up:** The follow up of the patients was done at an interval of 15 days.

**Drug Trial Schedule**

The selected patients for trial were divided into following 2 groups.

- **Group A**—15 clinically diagnosed & registered patients of *Amavata* were treated by Placebo capsules containing starch 1 capsule two times a day with Luke warm water after meal.

- **Group B**—15 clinically diagnosed & registered patients of *Amavata* were treated by *Shirish kwath*, 40ml twice a day (Before Meals).

Both the groups were kept under strict food regimen, with an advice to intake “*Ushana Odaka*”[^7] in place of normal water whenever required by the patient. Patients were advised to visit O.P.D later on to prevent pathogenesis of the disease.

**Criteria for Assessment**

The assessment of the trial was done on the basis of following parameters:

1. **Subjective, 2.Objective**

- **Subjective:** The subjective assessment was done on the basis of: Improvement in following signs and symptoms of *Amavata* as described in classics[^8].

<table>
<thead>
<tr>
<th>No.</th>
<th>Signs &amp; Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td><em>Sandhishoola</em> (Joint pain)</td>
</tr>
<tr>
<td>2.</td>
<td><em>Sandhishotha</em> (Joint swelling)</td>
</tr>
<tr>
<td>3.</td>
<td><em>Gaurav</em> (Heaviness in the body)</td>
</tr>
<tr>
<td>4.</td>
<td><em>Jwara</em> (Fever)</td>
</tr>
<tr>
<td>5.</td>
<td><em>Aruchi</em> (Loss of appetite)</td>
</tr>
<tr>
<td>6.</td>
<td><em>Jaadya</em> (Morning stiffness)</td>
</tr>
<tr>
<td>7.</td>
<td><em>Sparshasahyata</em> (Tenderness)</td>
</tr>
<tr>
<td>8.</td>
<td><em>Apaaka</em> (Indigestion)</td>
</tr>
<tr>
<td>9.</td>
<td><em>Bahumutrata</em> (Frequency of micturition)</td>
</tr>
<tr>
<td>10.</td>
<td><em>Utsahahani</em> (Loss of vigour)</td>
</tr>
</tbody>
</table>

[^6]: Dose of *Shirish kwath* 40ml B.D
[^7]: “Ushana Odaka” in place of normal water
[^8]: Improvement in following signs and symptoms of *Amavata* as described in classics.
Inclusion Criteria
- Patients having classical features of *Amavata*.
- Age group of 20-60 years.
- Patients fulfilling American College of Rheumatology (ACR) criteria, 1987:
  1. Morning stiffness
  2. Arthritis of 3 or more joints
  3. Arthritis of hand joints
  4. Symmetric arthritis
  5. Rheumatoid nodules
  6. Serum rheumatoid factor
  7. Radiographic changes

Exclusion Criteria
- If disease is severe and needs emergency treatment.
- Chronicity for more than 15 years.
- Having severe crippling deformity.
- Patients with other systemic diseases like Cardiac disease, Tuberculosis, Diabetes mellitus, Hypertension.
- Medically and surgically ill patients.
- Personal matters
- Aggravation of complaints
- Intercurrent illness
- Any other difficulties
- Leave against medical advice

Objective: The objective assessment was done on the basis of changes in clinical findings, relevant laboratory parameters, and Functional assessments.

Investigations
1. C.B.C
2. E.S.R
3. R.A factor

OBSERVATIONS AND RESULTS:

**Percentage of effect on the symptoms in Group-I**
- Sandhishool (53.8%), Sandhishotha (52.2%), Jwara (10%), Sparshashayata (50%), Bahumutrata (10%), Utsahhani (25%), Aruchi (72.7%), Apaka (77.8%), Jadyata (35%) and Gaurav (38.5%).

**Percentage of effect on the symptoms in Group-II**
- Sandhishool (8.3%), Sandhishotha (12.5%), Jwara (0%), Sparshashayata (0%), Bahumutrata (0%), Utsahhani (0%), Aruchi (55.6%), Apaka (71.4%), Jadyata (16.7%) and Gaurav (26.7%).

**Effect on biochemical & hematological Investigations:**
After treatment in both the groups, hematological investigations remained almost the same (C.B.C, E.S.R). And all parameters were found statistically insignificant R.A (14.3%).

**Overall Effect of Therapy:**
- In Group-I (14 patients) overall effect was assessed as moderate to mild improvement in 36.4% and 27.3% of symptoms respectively, with no improvement in 27.3% of symptoms.
- In Group-I (11 patients) overall effect was assessed with no improvement in 72.7% of symptoms, with moderate to mild improvement in 18.2% and 9.1% of symptoms respectively.

**RESULT:**
Statistically Non-significant improvement is found on intergroup comparison. But it is also seen that significant improvement is found in sandhishoth and sandhishool in Group-I as compared to Group-II.

**COMPARISON BETWEEN GROUP A AND GROUP B:**

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Group</th>
<th>N</th>
<th>Mean Rank</th>
<th>Sum of Ranks</th>
<th>Mann-Whitney U</th>
<th>P-Value</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sandhishool</td>
<td>Group A</td>
<td>14</td>
<td>19.50</td>
<td>273.00</td>
<td>14.000</td>
<td>0.000</td>
<td>Sig</td>
</tr>
<tr>
<td></td>
<td>Group B</td>
<td>11</td>
<td>8.08</td>
<td>105.00</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>25</td>
<td></td>
<td></td>
<td>14.000</td>
<td>0.000</td>
<td></td>
</tr>
<tr>
<td>Sandhishotha</td>
<td>Group A</td>
<td>14</td>
<td>17.79</td>
<td>249.00</td>
<td>38.000</td>
<td>0.004</td>
<td>Sig</td>
</tr>
<tr>
<td></td>
<td>Group B</td>
<td>11</td>
<td>9.92</td>
<td>129.00</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>25</td>
<td></td>
<td></td>
<td>38.000</td>
<td>0.004</td>
<td></td>
</tr>
<tr>
<td>Jwara</td>
<td>Group A</td>
<td>14</td>
<td>14.46</td>
<td>202.50</td>
<td>84.500</td>
<td>0.335</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>Group B</td>
<td>11</td>
<td>13.50</td>
<td>175.50</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>25</td>
<td></td>
<td></td>
<td>84.500</td>
<td>0.335</td>
<td>NS</td>
</tr>
</tbody>
</table>
For comparison between Group A and Group B, we have used Mann Whitney U test. From above table we can observe that P-Values for almost all parameters are greater than 0.05. Hence we conclude that, there is no significant difference in effect of Group A and Group B. But it was also observed that the trial drug depicted statistically significant effect on sandhishoola and sandhishotha.

**DISCUSSION**

*Amavata*, a rasavaha srotas’s vyadhi that ends up producing *Angvaikalyta*, is one of the most crippling vyadhi ever encountered. The *Nidana sevana*, which nowadays is most commonly referred to as an unpredictable lifestyle, deranges the *Vata Pradhan tridosha*. Due to which it is *sammurchita* with *Ama* (rasavaha srotas). Finally the *sandhi* (mainly *Triksandhi*) became the *adhishthana* of *dosh - dushya sammurchna*. In this present study, data shows that Maximum (52%) of the patients were R.A. negative and 48 % R.A. positive. The presence of Rheumatoid Factor does not establish the diagnosis for RA, but it can be of prognostic significance, because patients with high titres tend to have more severe and progressive disease with extra-articular manifestation. Statistically the decrease in R.A Factor was found non-significant in both Group-A and Group-B. Statistically the relief in *sandhisool* was found significant in group-A and non-significant in group-B with respective values (p=0.000) and (p=0.083) respectively. Percentage of relief found in Group-A and Group-B were found to be 53.8% and 8.3% respectively. Statistically intergroup comparison was observed significant (p<0.05) *Shoola* is the features of vitiated *Vata*. The *shoola* in *Amavata* is caused by *Ama's* involvement. *Shirish Kwath* has the properties of the *shoolhara* (Analgesic). Therefore, after using this *kwatha*, the *shoola* reduces. Statistically significant relief in sandhishool was found in group-A (p=0.001) and non-significant in group-B (p=.0180). Percentage of relief found in Group-A and Group-B are 52.2% and 12.5%
Shotha is caused in the joint space by the presence of Ama and Kapha. Shirish, anushana, teekshana guna help diminish the shotha\textsuperscript{[11]}. Statistically significant relief in jadyata (0.008) and gaurav in both group-A (p=0.008, 0.025) and in group-B (p=0.046, 0.025). The percentage of relief in Group-A and Group-B for Jadyata and Gaurav were found to be (35%, 38.5%) and (16.7%, 26.7%) respectively. But statistically intergroup comparison was observed to be non-significant (p>0.05). The joint's stiffness and heaviness is brought out by the Ama and kapha collection which does the vata Avarana. Shirish's katu and tikta rasa\textsuperscript{[12]}, are deepan and panchan and bring about the Ama pachna, kapha shaman, in so doing reducing the jadyata. Statistically significant relief in Apaka and Aruchi was found in both group-A and group-B, (p=0.008, 0.005) and (p=0.025, 0.025) respectively. Percentage of relief for Apaka and Aruchi were (77.8%, 72.7%) and (71.4%, 55.6%) respectively. Intergroup comparison was observed to be statistically non-significant (p>0.05). Aruchi and Apaka are present due to ama and kapha dosha. These entities are decreased due to Katu and tikta rasa of shirish. Statistically effect on Sparshasahyata, Jwara, Bahumutrata and Utsahhani were found to be non-significantly in group-A and in group-B, (P=0.317, 0.317, 0.317, 0.083) and (1.000, 1.000, 1.000, 1.000) respectively. Percentage of relief found in Group-A and Group-B for these symptoms were (50%, 10%, 10%, 25%) and (0%, 0%, 0%, 0%) respectively. Statistically intergroup comparison was also observed to be non-significant (p>0.05).

CONCLUSION

Conclusion is made on the basis of subjective and objective parameters:

The Shirish Kwatha is effective only in mild to moderate aggravated cases of Amavata. Shirish Kwath acted as an immunomodulator, antioxidant, analgesic and anti-inflammatory drug. Only Shaman Aushdi is not enough in chronic cases, shodhna would also be desirable.

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