

## EFFICACY STUDY OF CHITRAKA RASAYANA IN PATIENTS WITH AMAVATA

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### ABSTRACT

**Objective:** To evaluate the efficacy of *Chitraka Rasayana* on disease severity and measuring the Health Related Quality of Life of *Amavata*/Rheumatoid Arthritis patients under the treatment. **Methods: Design:** Open label Non randomised Single group Interventional Efficacy study. **Setting:** 30 patients selected from OPD & IPD of S.D.M Ayurveda Hospital, Udupi. **Intervention:** Day 1 to Day 7- *Nitya Virechana* with 20 ml *Eranda taila* and 20ml *Shunti Kashaya* as *Anupana*. Day 8 to Day 37 Capsule *Chitraka* 12 OD with lukewarm water in empty stomach every day morning. **Statistical Analysis:** Paired t test for nominal data & Wilcoxon signed rank test for ordinal data. **Results:** Almost all the outcome measures recorded statistically significant improvement. An overall improvement of 66.66% having moderate improvement, 3.33% with best improvement and 26.66 % with average improvement was seen in patients. **Conclusion:** *Chitraka Rasayana* is proved to be efficacious in reducing the cardinal symptoms of *Amavata* and hence improving the Quality of Life.

**Keywords:** Rheumatoid Arthritis; *Amavata*; *Chitraka*; *Rasayana*.

### INTRODUCTION

*Amavata* is a disease which has a direct impact on the freedom of mobilisation of an individual. It is a unique disease characterised by involvement of two distinct pathological entities of *Ama* and *Vata* having mutually opposite properties. Painful swelling of the different joints, stiffness, impaired ability of digestion and febrile illness are the common symptoms of *Amavata*.<sup>1</sup> All of these features can be understood under the heading of Rheumatoid Arthritis in modern parlance. Rheumatoid arthritis is a chronic inflammatory disease distinguished by symmetrical polyarthritis associated with systemic complications in its later stage.<sup>2</sup> The disease prevalence worldwide

is approximately 0.8% of the adult population. In India the prevalence being 0.5% to 0.75%.<sup>3</sup>

This crippling disease in its chronic stage afflicts the joint stability leaving an impact on the patient's ability for ambulation. The disease presents most commonly in the fourth and fifth decade of life<sup>4</sup>, which form the productive years of an individual. It afflicts the joints causing severe pain and swelling and there will be structural deformities observed when the disease attains chronicity. Hence it has a major impact on physical functioning furthermore affecting the mental wellness.

*Ama* and *Vata* being the main culprits in the causation of this disease and *Agnimandya* the main pathology, a balanced treatment approach that considers all these three in the forefront is necessary.

Lot many research studies have been taken up in the field of *Ayurveda* with regards to relieving the discomfort caused by this disease. Even though there are many studies done regarding *Shodhana* and *Shamana* line of management, very less has been done regarding the mode of treatment of *Vyadhihara Rasayana*.

*Amavata* being a chronic lingering disease, *Rasayana chikitsa* is paramount in controlling the disease process. *Agnimandya* is the main pathology of this disease, which if treated would help in providing complete and long term relief. *Chitraka* is one of the best drugs in treating *Agnimandya* and is also *Vata-kaphahara* at the same time, which can be given in the *Rasayana vidhi* had been selected for the study.

#### Objectives of the Study:

- Efficacy of *Chitraka Rasayana* on disease severity in patients suffering from *Amavata* / Rheumatoid Arthritis.
- Measuring the Health Related Quality of Life of Rheumatoid Arthritis patients under *Chitraka Rasayana* treatment.

#### MATERIALS AND METHODS:

##### Source of Data:

Minimum 30 patients diagnosed as *Amavata* / Rheumatoid Arthritis were taken for the study from O.P.D and I.P.D of Shri Dharmasthala Manjunatheshwara Ayurveda Hospital, Kuthpady The aqueous extract of *Chitraka* in capsule form and *Eranda taila* was obtained from SDM Ayurveda pharmacy, Kuthpady, Udupi.

##### Method of Collection of Data:

A special proforma was prepared with all points of history taking, physical signs, and symptoms as mentioned in the classics as well as in allied science.

Analysis of the signs and symptoms was supported by laboratory investigations.

#### Study Design:

- Study Type: Interventional
- Allocation: Non-Randomized
- Endpoint Classification: Efficacy Study
- Intervention Model: Single Group Assignment
- Primary Purpose: Treatment
- Masking: Open Label

#### Intervention:

- ◆ *Nitya Virechana* on Day 1 to day 7 – oral administration of *Eranda taila* in empty stomach, in a dose of 20 ml in the morning followed by the *Anupana* of *Shunti Kashaya*.
- ◆ *Chitraka Rasayana* on Day 8 to day 37–oral administration of *Chitraka Rasayana* in a dose of 6 Gms in empty stomach half an hour before breakfast with the *Anupana* of lukewarm water.

**Follow up duration-** 30 days

**Total duration of study** - 37 days of Intervention followed by 30 days of Follow up period.

#### Inclusion Criteria:

1. All patients fulfilling the Diagnostic criteria.
2. Patients must be from 16 to 70 years of age (both ages inclusive).
3. Having signed a written informed consent form.

#### Exclusion Criteria:

1. Subjects with contraindications for *Virechana*.
2. Women who are pregnant, attempting to conceive, or nursing an infant.
3. Subjects with history of excessive menstruation.
4. Patients suffering from connective tissue disorders other than Rheumatoid Arthritis.
5. Patients who develop secondary complication of Rheumatoid Arthritis e.g. Pleuro-pericardial disease, severely damaged joint with bed ridden patients.

6. Patients with uncontrolled Diabetes Mellitus & Hypertension.
7. Patients with unstable Cardio vascular disease.
8. History of hypersensitivity to the trial drug.

#### Diagnosics Criteria:

1. Cardinal manifestations of *Amavata*
2. The 2010 American College Of Rheumatology – European League Against Rheumatism (ACR-EULAR) classification criteria for Rheumatoid Arthritis

**Criteria for Assessment:** Assessment was done on the basis of Primary & Secondary outcome measures before and after the treatment.

#### Primary Outcome Measures:

- 1) Participants Assessment of Pain Over Time [Time Frame: Baseline and day 38 ]
- 2) Swollen Joint Count (SJC) Over Time [Time Frame: Baseline and day 38 ]
- 3) Tender Joint Count (TJC) Over Time [Time Frame: Baseline and day 38 ]
- 4) Assessment of Stiffness of Joints Over Time with Likert Scale [Time Frame: Baseline and day 38 ]
- 5) Change in Average Range Of Movement Of Affected Joints Over Time [Time Frame: Baseline and day 38 ]
- 6) Change From Baseline in Disease Activity Score (DAS) 28 [ Time Frame: Baseline and day 38 ]

#### Secondary Outcome Measures:

- 1) Erythrocyte Sedimentation Rate (ESR) Over Time [Time Frame: Baseline and day 38 ]
- 2) C-Reactive Protein (CRP) Levels Over Time [Time Frame: Baseline and day 38 ]
- 3) Change from baseline in Health Assessment Questionnaire Disability Index (HAQ DI) [ Time Frame: Baseline and day 38 ]
- 4) Percentage of Participants With Low, Moderate and High Disease Activity [Time Frame: Baseline and day 38 ]

#### Statistical Analysis:

For assessing the improvement of symptomatic relief and to analyse statistically the observations were recorded before and after the treatment. Paired t test was used for nominal data and Wilcoxon signed rank test was used for ordinal data. Sigma stat 3.5 version was used for the statistical analysis.

#### OBSERVATIONS:

The current clinical study revealed that maximum of 33.33% patients belonged to the age group of 41-50 years with a Female predominance of 76.66%. It is a well-established fact that RA is more prevalent in the fourth & fifth decade of life. As patients here were identified in their most productive age with a hectic work schedule and erratic eating habit, they contribute to the formation of *Ama* as well as vitiating *Vata*. Also various studies conducted reveal a possible role of estrogen for an enhanced immune response which might be the reason for the female predominance<sup>5</sup>.

Due to the geographical predominance 80% of patients were from Hindu religion, 70% belonged to middle Socio economic status and 86.66% patients were married. A majority of 56.66% of patients had finished their primary education with a maximum occupational incidence of Housewives amongst 63.33% of patients. It is a well-known fact that Housewives are involved in more hectic work schedule and follow an irregular pattern of food consumption which may be the cause in the manifestation of the illness

With regards to the Personal history, a majority of 90% of patients followed mixed diet pattern. 83.33% of the patients registered in this clinical study had regular bowels with 60% of patients complaining about disturbed sleep. Looking into the non-vegetarian diet pattern that is prevalent around the place of study (Udupi) which is a coastal area, Fish is the staple non vegetarian diet. Excessive consumption of Fish causes *Bahudoshavridhhi* in the body and this kind of diet directly may lead to *Mandagni* thus contributing in the causation of

*Amavata*.<sup>6</sup> As per the literature patients of *Amavata* may have *Vid Vibaddata* as one of the clinical presentation.<sup>7</sup> The same has been depicted in this study as we can find patients with both regular and constipated bowel habits. Pain is the cardinal feature of this disease and when the pain is severe it may even affect the sleep of the patient. This can be understood as the *Nidra Viparyaya* which is one of the clinical presentation of *Amavata*.<sup>8</sup>

The data regarding the assessment of *Dashavidha Pariksha* of this clinical trial revealed that 63.33% of patients had *Vata Kapha Prakriti*. Evaluation of *Sara* (96.66%), *Samhanana* (76.66%), *Pramana* (63.33%), *Satmya* (90%) and *Satva* (60%) all revealed a maximum incidence in *Madhyama Avastha*. On keen evaluation of the *Ahara Shakti*, it was found that 50% of the patients had *Madhyama Ahara Shakti* and 46.66% of patients had *Avara Ahara Shakti*. Ability of exercise revealed that there were 76.66% of the patients with *Avara Vyayama Shakti*.

In view of the Observations of disease history, 100% of the patients had Pain, Swelling, Joint Tenderness, Stiffness and Symmetrical Joint involvement. All these form the cardinal features of RA and hence the presence of them in all the patients is justified.

Regarding the mode of onset maximum of 70% had gradual mode of onset with Knee joint being the first joint of involvement having 30% incidence. In this clinical trial there were 80% of the patients with a positive finding of Deformity. Amongst all the patients, 96.66% had the history of intake of NSAIDs, 43.33% of the patients revealed of having used Steroids, remaining 23.33% and 6.66% had the history of using DMARDs and Immunosuppressants respectively. NSAIDs, DMARDs and Immunosuppressants which are considered very effective at the cost of their side effects are the standard prescriptions of RA.

There was presence *Angamarda* in 83.33% of patients, *Jadya* was present in 63.33% of total patients and 26.66% of them presented with *Jwara*.

## RESULTS:

In the present clinical study, the mean score of the symptom Pain reduced from 7.174 to 1.775 and is statistically significant. The mean score of Average Circumference Swelling which was 163.394 prior to treatment got reduced to 151.100 after the treatment with a p-value < 0.001 is a statistical significant result. With regards to Joint Tenderness, the mean score came down to 0.466 from 2.435 which is again a statistically significant result. Though there was a reduction in the mean score of Morning Stiffness from 3.133 to 2.833, it was not found to have significance after applying the statistical test. While assessing the effect of treatment on Range of Movement, the mean score dropped from 66.503 to 22.318 with a statistical significant result. The Disease Activity of the patients in this study had a statistical significant improvement as shown by the reduction of mean score of 6.396 to 5.501 after the treatment. The treatment was also found to be statistically significant in reducing the inflammatory markers of ESR & CRP with mean score difference of 21.367 and 8.333 respectively. The mean scoring of Disability Index of all the patients in this study showed a marked reduction from 2.058 to 1.260 and also is statistically significant. These results have been tabulated and graphically represented in Table No. 1 and Figure No. 1 respectively.

On calculating the Overall improvement in all the patients, a maximum of 66.66% had Moderate improvement with 26.66% gaining Average improvement. Best improvement was seen in 3.33% of patients and another 3.33% of patients had unchanged results. No one of the patients had worsening of the disease condition. Thus by assessing all these measures it is evident that *Chitraka Rasayana* has efficaciously reduced the symptoms of *Amavata* and also contributed in improving the Quality of Life.

## DISCUSSION

When an individual indulges in faulty food habits & faulty lifestyle, it is a definite cause leading to manifestation of many disorders. One such disease caused

by discrepancy in food habits added with erroneous lifestyle is *Amavata*. It is a disease that begins with a flaw in the digestive fire which will result in the formation of *Ama*, with a further progression there is association with *Vata* and which presents itself with Pain & Stiffness in all joints of the body.

*Eranda (Ricinus communis)* is the best drug of choice for the disease *Amavata*<sup>9</sup>. *Eranda* belongs to the *Bhedaniya Gana* and is mainly *Kapha Vatahara* by its *karma*<sup>10</sup>. As *Chitraka* is being given in the form of *Rasayana vidhi*, the best result can be expected by administering this after a short course of *Shodhana* in the form of *Nitya Virechana*, which is also a pre requisite for administering *Rasayana Dravya*. The *Anupana* selected here is *Shunti Kashaya*<sup>11</sup>. *Shunti (Zingiber officinale)* also being a *Kapha Vatahara* drug, helps prevent the griping that mostly occurs on administration of laxative drugs<sup>12</sup>. Both these drugs have the *guna* of *Deepana* and are *Kapha Vatahara*, hence acting directly on the pathology of disease *Amavata*. *Virechana* here is given in the form of *Nitya Virechana* as it is the safest method as elimination of the *Dosha* from the body is achieved in a milder form without causing discomfort to the patient. Thus one can expect the desirable results in a short duration of 7 days. The dose of both *Eranda taila* and its *Anupana Shunti Kashaya* was fixed to 20 ml, in order to attain only *Avara Pramana* of *Shodhana*.

*Rasayana chikitsa* is one amongst the eight branches of Ayurveda. *Rasa* is the best or finest nourishing part of all body elements and *Ayana* means course or circulation. Hence proper circulation of this *Rasa dhatu* itself is responsible for healthy state of the body. It is this very same *Rasa dhatu* that is involved in the pathogenesis of disease *Amavata*. This *Rasa dhatu* when corrected has a direct impact on the disease process of *Amavata* which is best achieved by administering *Rasayana chikitsa*.

The *Rasayana prayoga* of *Chitraka (Plumbago zeylanica)* has been explained by both *Acharya Sushruta*<sup>13</sup> and *Acharya Vagbhata*<sup>14</sup> in the form of *Kamya Rasayana & Vyadhihara Rasayana* respec-

tively. As per the literature, use of *Chitraka* is explained in *Vatavyadhi* as well as in the form of *Agni deepaka* with the *Anupana* of *taila*. It is advised to be given in the form of *Choorna* for a duration of one month. The ideal dosage of *Choorna* given in the text is one *Karsha*. In the present study, aqueous extract of this drug was used in the form of capsules for better palatability and cost effectiveness. Capsules will be in more concentrated form and hence can be inferred to render more potent action than *Choorna*. The maximum dosage of this drug as per classics is 12 grams and as it is a potent drug, moderate dosage of the same was taken for study i.e. 6 grams was administered. As each capsule weighed 500mg, a total of 12 capsules were administered in the empty stomach as *Rasayana*. *Abhakta* is the *Annakala* mentioned in literatures for bestowing best effects of *Rasayana Dravya*. As an after drink oil, buttermilk, lukewarm water and so on are prescribed by the text<sup>15</sup>. *Usnodaka* which is *Shleshmahara, Amavatahara & Agni Deepaka* by nature and keeping the palatability and comfort of the patient in consideration, Luke warm water was advised to the patients in this clinical study.<sup>16</sup>

## CONCLUSION

Emphasizing the concept of *Rasayana*, *Chitraka Rasayana* is opted for the study. The study revealed that *Chitraka Rasayana* is very effective in reducing the symptoms of *Amavata*. Reduction in the symptoms of Pain, increased range of joint movement proves the effect of treatment in ameliorating the vitiated *Vata dosha*. Morning stiffness, joint swelling and impaired digestion that is reduced by *Chitraka Rasayana* indicates its efficacy in counteracting the *Ama* by this medication. It also had a direct impact on improving the Quality of Life of patients suffering from *Amavata*. Also the treatment has not given complete relief from the symptoms. This indicates that the same treatment may be more effective in different dosage pattern and when continued for more duration of time. Thus this definitely paves way for newer clinical studies in revealing the

effect of *Chitraka Rasayana* in patients suffering from lingering disease *Amavata*.

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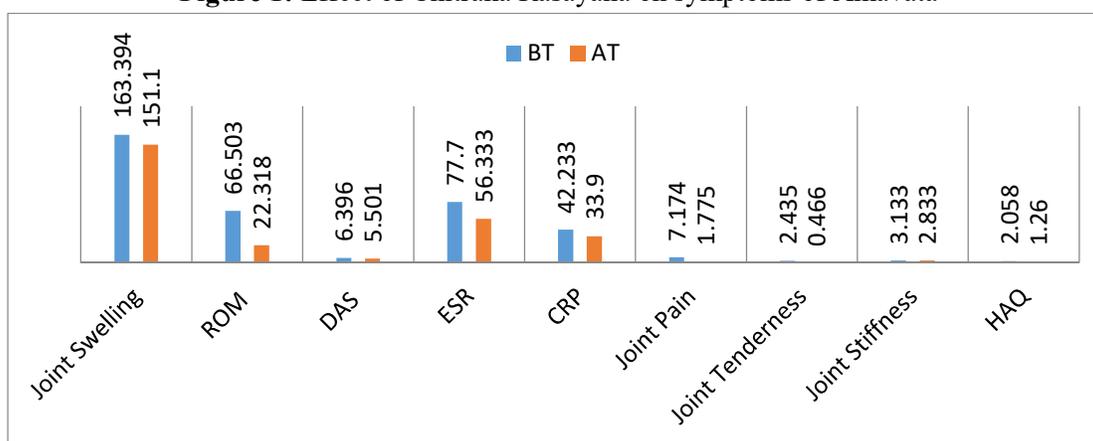
## TABLES AND FIGURES:

**Table 1:** Effect of *Chitraka Rasayana* on symptoms of Amavata

| Sl. No. | Symptom                              | Mean score          |                     | Difference in means | % improvement | Paired 't' test |        |         |         |
|---------|--------------------------------------|---------------------|---------------------|---------------------|---------------|-----------------|--------|---------|---------|
|         |                                      | BT ( $\pm$ SE)      | AT( $\pm$ SE)       |                     |               | S.D             | S.E.M  | t value | p value |
| 1.      | Joint Swelling                       | 163.394<br>(17.005) | 151.100<br>(15.781) | 12.294              | 7.5 %         | 6.953           | 1.269  | 9.685   | <0.001  |
| 2.      | Range of Movement of Affected Joints | 66.503<br>(4.418)   | 22.318<br>(2.170)   | 44.185              | 66.44 %       | 19.802          | 3.615  | 12.222  | <0.001  |
| 3.      | Disease Activ-                       | 6.396               | 5.501               | 0.895               | 13.99 %       | 0.500           | 0.0913 | 9.803   | <0.001  |

|  | ity Score (DAS28)   | (0.141)           | (0.145)           |        |         |         |       |       |        |
|--|---|-------------------|-------------------|--------|---------|---------|-------|-------|--------|
| 4.   | ESR   | 77.700<br>(4.809) | 56.333<br>(4.239) | 21.367 | 27.49 % | 13.034  | 2.380 | 8.979 | <0.001 |
| 5.   | CRP   | 42.233<br>(8.422) | 33.900<br>(6.964) | 8.333  | 19.73 % | 10.623  | 1.940 | 4.297 | <0.001 |
| <b>Wilcoxon Signed Rank Test (p value)</b> |   |                   |                   |        |         |         |       |       |        |
| 6.   | Joint Pain  | 7.174<br>(0.271)  | 1.775<br>(0.169)  | 5.399  | 75.25 % | < 0.001 |       |       |        |
| 7.   | Joint Tenderness  | 2.435<br>(0.0703) | 0.466<br>(0.0536) | 1.969  | 80.86 % | < 0.001 |       |       |        |
| 8.   | Joint Stiffness   | 3.133<br>(0.164)  | 2.833<br>(0.167)  | 0.3    | 9.57 %  | 0.004   |       |       |        |
| 9.   | Health Assessment Questionnaire Disability Index (HAQ DI) | 2.058<br>(0.0696) | 1.260<br>(0.0546) | 0.798  | 38.77 % | <0.001  |       |       |        |

**Figure 1: Effect of Chitraka Rasayana on symptoms of Amavata**



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