

Role of *Bhallataka Kshira Paka* in the Management of *Amavata* (Rheumatoid Arthritis) - A Clinical Study

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Abstract:

Amavata (Rheumatoid arthritis) is one of the chronic, painful, dangerous and crippling diseases affecting multiple joint and manifested mainly due to *Agnimandya* (lack of digestive power) and *Ama* (undigested harmful portion formed from incompletely digested food or bio toxin). *Madhava Nidana* (700AD) has first mentioned the *Amavata* as a special disease entity, where *Ama* as well as *Vata* (biophysical force) plays a predominant role in the *Samprapti* (pathogenesis) of the disease. In contemporary practices *Amavata* can be compared to rheumatoid arthritis based on its etio-pathogenesis and clinical manifestation. The present work, *Bhallataka* (*Semicarpous anacardium*) *Kshirapaka* was compared with known Ayurveda drug *Shuddha Guggulu* (*Commifera mukul*) as and Ibuprofen (contemporary drug) as controls. Total of 63 patients (21 in each group) were enrolled and completed the 4 weeks treatment schedule. On analyzing the statistical results and clinical findings it can be understood that treatment of *Amavata* with *Bhallataka Kshirapaka* differs significantly from the treatment *Shuddha Guggulu* and Ibuprofen. There was no significant difference between Ibuprofen and *Shuddha Guggulu* treated groups. Hence if the choice is to be made among the three treatments, *Bhallataka kshirapaka* might be considered as the best and most effective drug. The trial drug did not show any side effects and complications in *Amavata* patients.

Key words: *Amavata*, *Bhallataka kshirapaka*, Ibuprofen, Rheumatoid Arthritis, *Shuddha Guggulu*

Introduction:

Amavata is one of the diseases being capable of producing severe crippling deformities and functional disability. Elaborative description is available in Ayurveda texts regarding *Amavata* which can be correlated with rheumatoid arthritis. It is one of the rheumatic disorders of the connective tissues, joints and bones in which pain and stiffness, affecting some part of musculoskeletal system. This disease starts most commonly between the 3rd & 4th the decades of life. Rheumatic diseases affect people of both sexes and all ethnic groups but it has been observed that, the incidence of this disease is three times more in female patients than male. The prevalence of rheumatoid arthritis (RA) varies between 0.3% and 1% worldwide [1] and in developed countries.

The incidence of this disease is more common in temperate climate; however it is equally prevalent in our country. This disease is said to get exacerbated or precipitate during winter season. In Ayurvedic point of

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128

view Madhavakara [2] has described its pathology and etiology and later on Bhava Mishra [3] included its management. In *Amavata*, *Dosha* (three basic humor viz. *Vata*, *Pitta* and *Kapha*), *Dhatu* (body constitute) as well as *Malas* (excretory products) are vitiated by *Ama* which is manifested in *Amashaya* (stomach) due to *Agnimandhya*. In this stage food is not properly digested and metabolized because of insufficient digestive power [4] as a result the patient gets loss of appetite, severe pain in joints and stiffness in all small and big joints of body.

As there is no specific medicine to treat such condition, an attempt has been made to find out suitable, easy, economically cheap and easily available drugs for treatment of this painful disease. The drug *Bhallataka kshirapaka* was used in Ayurveda for a long period in treating *Amavata* and significant result were observed general practice. However no data has been found published to attract attention of researchers. Hence present was planned to assess the anti-rheumatoid action of *Bhallataka kshirapaka* and compare its effects, to confirm the effect of *Bhallataka kshirapaka* on hematological parameters and to assess the side effects, if any.

Material & Methods:

Bhallataka kshirapaka was freshly prepared before administration for each patient as per *Sharangdhara Samhita*. Good quality *Bhallataka* (*Semicarpus anacardium*) nuts were selected, 5gm of these fruits were broken into pieces, 250 ml milk and 1 liter water taken in a vessel and added the above pieces *Bhallataka* and prepare done fourth decoction till only added part of milk remained. The obtained mixture i.e. *Bhallataka kshirapaka* was filtered and given in two doses for period of one month [5].

Observation for toxic symptoms:

During the period of treatment patients were observed for manifestation of any toxic symptom such as high colored and scanty urine, urine sometimes tinged with blood, irritable and loose bowels with griping, erythematous skin eruption with itching and burning etc. As *Bhallataka* is corrosive in nature hence care was also taken by observing over dose related toxic symptoms which includes blisters in throat, feeling fear, dyspnea, tachycardia, hypertension, cyanosis, dilated pupils, delirium etc [6].

Criteria for selection of the patient:

Inclusion criteria:

Amavata patient were selected from the OPD of R.T Ayurved college Akola for study. Patients who were found fulfilling the criteria laid down by the American Rheumatism association [7] were selected and registered for detailed investigations and follow up. Patients of either sex between age group 10-60 years who gave written consent and does not have major systemic disorder were included in this study.

Criteria for exclusion of the patient:

Patients below 10 and above 60 years were not selected for this study. The patient who had the history of major diseases or suffering from major diseases such as Diabetes Mellitus, Pulmonary Tuberculosis, Extensive blood loss, Chronic alcohol, Hypertension, Hemophilia etc. diseases and those who are not willing to participate in clinical trial were excluded from the study.

Table-A: Treatment groups with posology:

| Group | No of patient | Drug | Dose (after meal) |
|-------|---------------|-----------------------------------|-------------------|
| A | 21 | <i>Bhallatakakshirapaka</i> [8,9] | 80 ml BD |
| B | 21 | <i>Shudhaguggula</i> [8,9] | 500 mg BD |
| C | 21 | Ibuprofen [10] | 400 mg BD |

Duration of treatment:

After final diagnosis patients and beginning of treatment, patients were advised for follow up after 1 week for a period of 4 weeks and advised to continue follow up after 2 weeks of stopping the treatment.

Clinical assessment:

The patient were examined and graded accordingly before starting the treatment and at the end of every week during the treatment period.

Mobility of joint (walking time):

Mobility of the Joint is assessed by the degree of passive movement of individual joints affected without causing pain and also time taken to walk 25 feet in number of seconds before and after the treatment.

Joint swelling:

The circumference of big joint sat selected points has been recorded in centimeters. As regards finger joints the change in size has been noted by using a set of jeweler's rings from 1 to 33 numbers.

Grip strength:

Grip strength is recorded by using a

sphygmo manometer. The patient was asked to squeeze the rubber bulb with full strength and the average of three reading is considered.

Joint Tenderness:

The joint tenderness has been recorded in four grades as under.

| Grade | Sign |
|-------|---|
| I | patient says the joint is tender |
| II | the patient winces |
| III | The patient winces and withdraws the affected part. |
| IV | The patient will not allow the joint to be touched. |

Table-B: Gradation of Symptoms

| A] Sandhishool (pain in joints) | Score |
|---|-------|
| No pain | 0 |
| Mild pain | 1 |
| Moderate pain, but no difficulty in moving | 2 |
| Slight difficulty in moving due to pain | 3 |
| Much difficulty in moving the bodily parts | 4 |
| B] Sandhishotha (swelling on joints) | |
| No swelling | 0 |
| Slight swelling | 1 |
| Moderate swelling | 2 |
| Severe swelling | 3 |
| C] Sparshasahyata (tenderness in joint) | |
| No tenderness | 0 |
| Subjective experience of tenderness | 1 |
| Wincing of face on pressure | 2 |
| Wincing of face and withdrawal of the affected part on pressure | 3 |
| Resist to touch | 4 |
| D] Sandhigraha (stiffness in joints) | |
| No stiffness or stiffness lasting for 5 mins. | 0 |
| 5 min to 2 hrs | 1 |
| 2 to 8 hrs | 2 |
| More than 8 hrs | 3 |

Spontaneous pain over the joints:

| Score | Percentage |
|-------|------------|
| 0 | Normal |
| 1 | 1-25% |
| 2 | 26-50% |
| 3 | 51-75% |
| 4 | 76-100% |

Laboratory assessment:

Laboratory investigations such as Routine Urine Examination, Routine Stool Examination were along with routine hematological tests. Erythrocyte sedimentation rate, RA tests [11] are under taken to assess the disease condition.

Assessment of clinical results:

Assessment of the Result is done by comparing the Baseline data to Final data in to four based on effects observed in parameters.

Table C: Overall assessment of therapy

| | |
|---------------------------------------|--------------------|
| 0 - 25 score in assessment criteria | Complete remission |
| 26 - 50 score in assessment criteria | Major improvement |
| 51 - 75 score in assessment criteria | Minor improvement |
| 76 - 100 score in assessment criteria | Unchanged |

Statistical analysis:

The statistical methodology adopted in the present study was Analysis of variance technique (anova) and chi-square test.

Observations and results:

In present clinical study 63 patients of Amavata were included and grouped into three treatment groups consisting 21 patients. From the present study, it has been seen that maximum number of patients 71.42% belonged to the age group of 11 to 40 yrs. Incidence of Amavata was maximum found in female 71.42%. Patient belonging to middle income group (53.96%) were found to be maximum. The patients especially females engaged in house hold activities were the more sufferers (42.85%).

It has been found that the Vat-Pittaj Prakruti patients were maximum (28.57%). Mandagni was seen in maximum number of patients (87.30%). Maximum numbers (49.20%) of patients were having Mrudu Kosta. Maximum involvement of knee joints (69.84%), ankle joints (53.96%) wrist joints (35%) as well as right first interphalangeal joint of index finger (9.52%) and right first joint of thumb was seen (7.90%). From present study it has been revealed that the patients who met with injury (23.80%) and extensive blood loss (9.52%) in the previous history had been associated with Amavata. The incidences of maximum involvement in upper limb joint of patients in three groups were RtKupara Sandhi in group 1 and 2 and Left Manibandh Sandhi

in group 3 (Table 1). The maximum involvement of lower limbs joints were Right *Janu* and Right *GulphaSandhi* in Group 1. Left *Janu Sandhi* in Group 2 and Right *Janu.Sandhi* in Group 3 (Table 2).

The percentage of relief from the symptoms in all the three groups has been presented in Table 3. The overall results suggested that 42.85% of patients in Group 1 had excellent results. And 47.61% had good results. In group 2 and 3, 23.8% and 33.33% patients felt good results respectively. Majority of patients in group 3 i.e. 52.38% had good relief in major symptoms. (Table 4) After treatment in group 1, the investigations done revealed that, except one patient all remaining had sero ve test. However there was no change in the patients of group 2 & 3 in above parameter. (Table 5) The Critical difference obtained after treatment in reduction of ESR level was 14.7 and it is significant (Table 6). The Critical difference after treatment in the reduction of weight was 0.75 (Table 7). The tabulated value of F for degrees of freedom (2.60) for *Jawra*, *Alasya* and *Apaka* was significant at $p < 0.05$ (Table 8). On the symptom *Gaurava* was highly significant at $p < 0.01$ and *Agnimandya*, *Aruchi*, *Sunata Anganam*, *Angamarda*, *Daha*, *Bahumutrata* and *Trushna* was also highly significant at $p < 0.001$.

Discussion:

It was noted statistically that the improvement was seen in almost all clinical symptoms of *Amavata*. From the clinical study it has been observed that G-I Group patient have got excellent relief in 9 (42.85%) patients, good relief in 10 (47.61%) patients where as fair relief is seen in 2 (9.52%) patients. In G-2 Group it has been observed that the *Amavata* patients have got good relief in 5 (23.80%) patients, fair relief in 9 (42.85%) patients and poor relief in 7 (33.33%) patients. In group G-3 the *Amavata* patients have got good relief in 7 (33.33%) patients, fair relief in 11 (52.38%) patients. Whereas poor relief in 3 (14.28%) patients. Pathological investigation like E.S.R. has shown significant reduction in *Ballataka kshirpaka* group patients than other group. The present study it has been revealed that the significant results of Seronegativity of R.A. test have been seen in *Ballataka kshirpaka* group (3.86). As the calculated value of F with respect to the symptoms was greater than the corresponding tabulated value of F the Null hypothesis that all the treatment (drugs) are equally effective was rejected and concluded that three drugs were not

equally effective on the symptoms of *Amavata*.

Bhallataka Possess *Ushna* and *teekshna Guna* due to which it acts as a *Kaphavata Shamaka*. As the main *Dosha* involved in *Amavata* is *Kapha* and *Vata*. The drug is ideally suited to bring about those *Dosha Shamaka* effects. By virtue of its pharmacological properties described by various Acharya the drugs possess the ability to improve the symptoms of *Amavata* patients.

Conclusion:

Amavata is one of the crippling disease by which millions of people are affected and become physically handicapped. In spite of advancement in the field of rheumatology the incidence and curability of the disease is still a concern. *Bhallataka* is an efficient drug indicated in *Amavata* by almost all *Acharyas* of Ayurveda. In the present study total of 63 patients (21 in 3 groups) were included. Among which all the patients completed full course of the study without any discontinuance. No patient treated with *Ballataka kshirpaka* complained any side effects or ill effect throughout the course of study or even in follow up period. On analyzing the statistical results and clinical findings it can be understood that treatment of *Amavata* with *Ballataka kshirpaka* differs significantly from the treatment *Shuddha guggul* and *Ibuprofen*. There was no significant difference between *Ibuprofen* and *Shuddha Guggul* treated groups. Hence if the choice is to be made among the three treatments, *Ballataka kshirpaka* might be considered as the best and most effective drug. The trial drug did not show any side effects and complications in *Amavata* patients.

Suggestion:

Repeated clinical trial with large number of subjects is needed to establish similar findings on effect of *Ballataka kshirpaka* in *Amavata*. Phytochemical studies and standardization of *Ballataka kshirpaka* is also needed to make this effective formulation available in market.

| Table no. 1:-Incidence of joint involvement of upper limb | | | | | |
|---|-----------------------------------|----|---------------|--------------|--------------|
| Sr.No. | Joint involvement | | % of patients | | |
| | | | G-1 | G-2 | G-3 |
| 1. | <i>Ansasandhi</i> | Rt | 14.28 | 4.76 | 23.80 |
| | | Lt | 14.28 | 14.28 | 23.80 |
| 2. | <i>Kurparsandhi</i> | Rt | 28.57 | 28.57 | 33.33 |
| | | Lt | 19.04 | 14.28 | 33.33 |
| 3. | <i>Manibandh Sandhi</i> | Rt | 23.80 | 23.80 | 57.14 |
| | | Lt | 23.80 | 23.80 | 61.90 |
| 4. | <i>Anguliparvasandhi angustha</i> | Rt | 19.04 | 00 | 4.76 |
| | | Lt | 4.76 | 00 | 4.76 |
| | <i>Tarjani</i> | Rt | 19.04 | 4.76 | 4.76 |
| | | Lt | 4.76 | 4.76 | 4.76 |
| | <i>Madhyama</i> | Rt | 00 | 4.76 | 4.76 |
| | | Lt | 00 | 4.76 | 4.76 |
| | <i>Anamika</i> | Rt | 4.76 | 4.76 | 00 |
| | | Lt | 00 | 4.76 | 00 |

| Table no. 2:-Incidence of joint involvement of lower limb | | | | | |
|---|---------------------------|----|---------------|--------------|--------------|
| Sr.No. | Joint (sandhi)involvement | | % of patients | | |
| | | | G-1 | G-2 | G-3 |
| 1. | <i>Vankshana</i> | Rt | 4.76 | 00 | 00 |
| | | Lt | 4.76 | 00 | 00 |
| 2. | <i>Janu</i> | Rt | 71.42 | 61.90 | 76.19 |
| | | Lt | 66.66 | 71.42 | 71.42 |
| 3. | <i>Gulpha</i> | Rt | 71.42 | 47.61 | 42.85 |
| | | Lt | 47.61 | 52.38 | 42.85 |
| | | Lt | 00 | 4.76 | 00 |

| Table no. 3:- The incidence of 63 Amavata patients according to history of present illness before and after the treatment. | | | | | | | |
|--|----------------------|---|-------|-------|-------|-------|-------|
| Sr.No. | Symptoms | Percentage of symptoms present in patients before and After treatment | | | | | |
| | | Group-1 | | G-2 | | G-3 | |
| | | BT | AT | BT | AT | BT | AT |
| 1. | <i>Agnimandya</i> | 85.71 | 42.85 | 100 | 42.85 | 100 | 61.90 |
| 2. | <i>Aruchi</i> | 95.23 | 28.57 | 100 | 42.85 | 100 | 47.61 |
| 3. | <i>Trushna</i> | 85.71 | 4.76 | 85.71 | 25.80 | 95.23 | 19.04 |
| 4. | <i>Alasyam</i> | 90.47 | 33.33 | 100 | 38.09 | 100 | 52.38 |
| 5. | <i>Gauravam</i> | 95.23 | 19.04 | 100 | 23.80 | 100 | 38.09 |
| 6. | <i>Jwar</i> | 47.61 | 00 | 52.38 | 00 | 61.90 | 00 |
| 7. | <i>Sunataanganam</i> | 100 | 66.66 | 100 | 80.95 | 100 | 85.71 |
| 8. | <i>Angamarda</i> | 95.23 | 00 | 100 | 00 | 100 | 00 |
| 9. | <i>Dah</i> | 52.38 | 00 | 66.66 | 00 | 80.95 | 9.52 |
| 10. | <i>Bahumutrata</i> | 76.19 | 00 | 57.14 | 00 | 90.47 | 00 |
| 11. | <i>Apak</i> | 90.47 | 4.76 | 100 | 19.04 | 95.23 | 33.33 |

| Table no.4:- Overall result obtained in three groups | | | | |
|--|-----------|----------------------------|-----------------------|--------------------|
| Sr. No. | Results | G-1 (Bhallatakkshirpak) | G-2 (Suddhaguggul) | G-3 (Ibuprofen) |
| 1 | Excellent | 42.85 % | 00 | 00 |
| 2. | Good | 47.61 % | 23.80 % | 33.33 % |
| 3. | Fair | 9.52 % | 42.85 % | 52.38 % |
| 4. | Poor | 00 | 33.33 % | 14.28 % |

| Tablono.5:- Total effect of three groups on RA test | | | | | | | |
|---|-----------|-------------------------|----|--------------------|----|-----------------|----|
| Sr. no | RA test | G-1 (Bhallatakkshirpak) | | G-2 (suddhaguggul) | | G-3 (Ibuprofen) | |
| | | BT | AT | BT | AT | BT | AT |
| 1 | Sero – ve | 14 | 20 | 10 | 09 | 13 | 13 |
| 2 | Sero + ve | 07 | 01 | 11 | 12 | 08 | 08 |

| Tablono.6:- Critical Difference in E.S.R. | | | |
|---|-------------------|-----------------|------------|
| Sr.no. | Treatment | Mean difference | difference |
| 1. | Bhallatakkshirpak | 41.47 | |
| 2. | Suddhaguggul | 23.45 | 18.02 |
| 3. | Ibuprofen | 23.04 | 0.42 |
| C.D.=14.708997 | | | |

| Table no.7:- Critical Difference in Weight reduction | | | |
|--|-------------------|-----------------|------------|
| Sr.no. | Treatment | Mean difference | Difference |
| 1. | Bhallatakkshirpak | 2.42 | |
| 2. | Suddhaguggul | 1.42 | 1.00 |
| 3. | Ibuprofen | 1.09 | 0.33 |
| C.D.=0.75808 | | | |

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Table no. 8:-Analysis of Variance of Response in Symptoms

| Sl.no | Symptoms | Source of Variance | Sum of Square | Degree of Freedom | Mean Sum of Squares | F Cal |
|-------|----------------------|--------------------|---------------|-------------------|---------------------|-------|
| 1 | <i>Agnimandya</i> | Treatment (Trss) | 23.23 | 2 | 11.61 | 28.18 |
| | | Error (Err) | 26.61 | 60 | 0.44 | |
| | | Total (Tss) | 49.85 | 62 | | |
| 2 | <i>Aruchi</i> | Treatment (Trss) | 8.9 | 2 | 4.45 | 10.88 |
| | | Error (Err) | 24.57 | 60 | 0.40 | |
| | | Total (Tss) | 33.48 | 62 | | |
| 3 | <i>Trushna</i> | Treatment (Trss) | 27.07 | 2 | 13.53 | 20.90 |
| | | Error (Err) | 38.85 | 60 | 0.65 | |
| | | Total (Tss) | 65.93 | 62 | | |
| 4 | <i>Alasya</i> | Treatment (Trss) | 6.88 | 2 | 3.44 | 4.86 |
| | | Error (Err) | 42.38 | 60 | 0.70 | |
| | | Total (Tss) | 49.26 | 62 | | |
| 5 | <i>Gauravam</i> | Treatment (Trss) | 5.16 | 2 | 2.58 | 5.07 |
| | | Error (Err) | 30.57 | 60 | 0.50 | |
| | | Total (Tss) | 35.74 | 62 | | |
| 6 | <i>Jwar</i> | Treatment (Trss) | 8.51 | 2 | 4.25 | 3.66 |
| | | Error (Err) | 69.71 | 60 | 1.16 | |
| | | Total (Tss) | 78.23 | 62 | | |
| 7 | <i>SunataAnganam</i> | Treatment (Trss) | 10.69 | 2 | 5.34 | 8.35 |
| | | Error (Err) | 38.38 | 60 | 0.63 | |
| | | Total (Tss) | 50.07 | 62 | | |
| 8 | <i>Angamarda</i> | Treatment (Trss) | 17.36 | 2 | 8.68 | 9.03 |
| | | Error (Err) | 57.62 | 60 | 0.96 | |
| | | Total (Tss) | 74.98 | 62 | | |
| 9 | <i>Daha</i> | Treatment (Trss) | 12.66 | 2 | 6.33 | 8.88 |
| | | Error (Err) | 42.76 | 60 | 0.71 | |
| | | Total (Tss) | 55.42 | 62 | | |
| 10 | <i>Bahumutrata</i> | Treatment (Trss) | 21.23 | 2 | 10.61 | 14.99 |
| | | Error (Err) | 42.47 | 60 | 0.70 | |
| | | Total (Tss) | 63.71 | 62 | | |
| 11 | <i>Apak</i> | Treatment (Trss) | 6.69 | 2 | 3.34 | 4.07 |
| | | Error (Err) | 49.28 | 60 | 0.82 | |
| | | Total (Tss) | 55.98 | 62 | | |

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