

**A CLINICAL STUDY ON THE COMBINED EFFECTIVENESS
OF SHATYADI KALKA WITH VARSHABHU
KASHAYA AS ANUPANA AND VAITARANA
BASTI IN AMAVATA (RHEUMATOID ARTHRITIS)**

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ABSTRACT

Background: *Amavata* is an autoimmune disorder caused by *Ama* and *Vata* resulting in *Lakshanas* like *Agnimandhya*, *Angamarda*, *Aruchi*, *Trishna*, *Alasya*, *Gaurava*, *Jwara*, *Nidraviparyaya*, *Utsahahani*, *Sandhiruja*, *Sandhishotha*, *Sandhisparshasahatva* and *Sandhistabdhatva*.^[1] *Amavata* is correlated to Rheumatoid Arthritis (RA) in modern dialect and characterized by pain, swelling, and stiffness of synovial joints, systemic features and extra-articular involvement. The prevalence of RA is 0.5-1% between the age group of 25-55 years after which it levels up until the age of 75 years.^[2] To break the chain of pathogenesis, *Amavata Chikitsa* like *Langhana*, *Swedana*, *Dipana*, *Pachana* with *Tikta-Katu dravyas* and *Shodhana* are intended.^[3] *Shatyadi Kalka* with *Varshabhu Kashaya*^[4] as *Anupana* and *Vaitarana Basti*^[5] were cited beneficial. *Shatyadi Kalka* contains

Shati, *Shunti* and *Varshabhu* which are easily available and exhibits *Vata-Kaphahara* and *Amapachana* actions whereas *Vaitarana Basti* exhibit *Amahara* and *Shulahara* effect and administered after food to understand the response of therapy. The study combination was selected with a view that it may reverse the sequence of pathogenesis. **Methods:** Among 46 registered subjects, 30 completed the course of treatment. They were administered *Shatyadi Kalka* (12gms) with *Varshabhu Kashaya* (~50ml) as *Anupana* for 24 days in combination with *Vaitarana Basti* in form of *Yoga Basti* after food. For statistical analysis, parameters were assessed with Friedman's test; Wilcoxon sign rank test, Repeated Measures ANOVA

and Paired t-Test. **Results:** There was a statistically significant improvement in the Primary and Secondary outcome measures of *Amavata*. **Conclusion:** *Shatyadi Kalka* with *Varshabhu Kashaya* as *Anupana* and *Vaitarana Basti* were found effective in the management of *Amavata*.

KEYWORDS: *Ayurveda*, *Amavata*, Rheumatoid Arthritis, *Shatyadi Kalka*, *Varshabhu Kashaya*, *Vaitarana Basti*.

INTRODUCTION

Ayurveda, the native medicine has given great emphasis on the promotion of health and prevention of disease. Several *Ayurveda* medications have been used for the management of various diseases in human beings. The prospective of *Ayurveda* medicine needs to be explored with modern scientific validation approaches for better restorative leads. To craft an accurate diagnosis of a disease, it's very important to know the contributing factors. "Ama" is one of such entities responsible for many diseases. *Ama* is an undigested form derived from food that gets absorbed into the system without proper assimilation. Such partly digested substances cannot be utilized and it clogs the system, thus eliciting an immune reaction. In *Ayurveda*, *Amavata* was the term mentioned for the first time by *Madhavakara* as a disease entity caused by 'Ama' and 'Vata' due to the faulty dietary habits and lifestyle irregularities producing the symptoms like joint pain-swelling and stiffness, etc. *Amavata* is correlated with Rheumatoid Arthritis and is characterized by its indefinite course, uncertain progression, unpredictable exacerbations and remissions. In many patients, the pain, disability, deformity, and reduced quality of life develop despite meticulous treatment plans. Rheumatoid Arthritis prevalence is approximately 0.5-1% between the age group of 25-55 years after which it levels up until the age of 75 years. Females are affected three times more often than males noted during the fourth and fifth decades of life.^[2] A diverse set of the causative and pathological interface has been explained in *Ayurveda* that can influence the effect of *Ama* on *Tridosha* and *Dhatus*. Many research modalities have been experimented to unravel this complex maze. There is still an invariable need for safe and effective treatment through process of research advances on *Amavata*. Here we intended to assess the combined effect of *Shatyadi Kalka* with *Varshabhu Kashaya* as *Anupana* and *Vaitarana Basti* in *Amavata* (Rheumatoid Arthritis).

METHODOLOGY

Screening: A screening form was prepared with all aspects of history, signs and symptoms of

Amavata (Rheumatoid arthritis) and laboratory investigations were conducted to arrive at proper diagnosis.

Diagnostic criteria: Among screened patients, Amavata (Rheumatoid Arthritis) was diagnosed on the basis of *lakshanas* of Amavata such as *Sandhiruja*, *Sandhishotha*, *Sandhi sthabdhata*, *sandhi sparshaasahayata* and 2010 ACR EULAR Criteria

Inclusion criteria: Rheumatoid arthritis diagnosed on the basis of 2010 ACR EULAR Criteria with Subjects aged between 18-70 years, of either gender, who are fit for *Basti Karma* and willing to participate in study and ready to sign the informed consent.

Exclusion criteria: Subjects with known case of uncontrolled diabetes mellitus and essential hypertension, with known case of impaired renal, hepatic and cardiac function, Pregnant and lactating woman.

Ethical Clearance and CTRI registration: Ethics clearance certificate obtained from Institutional Ethics Committee. Trial was registered on www.ctri.gov.in (CTRI NO: CTRI/2019/04/ 025473 dated 25th April 2019).

Study design

The study was an open label, single arm, prospective clinical trial in Amavata (rheumatoid arthritis) (n=30) selected using the convenience (non-random) sampling technique with pre and post design conducted in tertiary Ayurveda hospital attached to Ayurveda medical college located in district headquarters in southern India.

Intervention

1. Oral administration

Shatyadi kalka

Dosage - 1 Karsha (6 grams twice daily) before food (total 12 gms per day).

Anupana- Varshabhu Kashaya 1 Pala (25ml twice daily)

Duration- 24 days (1st day to 24th day)

2. Anal administration

Yoga basti (5+3=8 days)

Anuvasana basti- Brihat Saindhavadi Taila 70ml, post lunch

Vaitarana basti- Prepared kashaya 260ml, post lunch

Duration-8days (1st day to 8th day)

Total study duration – 24 days

Assessments: 1st day, 8th day and 24th day.

Method of preparation

Required packed quantity of raw material, *Shati*, *Shunti* and *Varshabhu* were purchased and authenticated from GMP certified pharmacy.

Brihat Saindhavadi Taila bottles (BATCH NO: 181180) and Purified *Gomutra* (*Amritasara* bottles- BATCH NO: 924) were purchased from *Sri Dharmasthala Manjunatheshwara College of Ayurveda* and Hospital, Hassan, Karnataka.

Varshabhu kashaya- One part of *Varshabhu* was boiled with eight parts of the water in a mild flame till it reduces to 1/4th of the quantity. Once the decoction was prepared, cooled and then it will be filtered. Prepared *Varshabhu Kashaya* was filled in bottle container each of 1000ml and 200 ml.

Vaitarana basti- Initially 1 *shukti* (25gms) of *Guda* (jaggery) was mixed with water and boiled until *gudapaka lakshanas* attained. To this one *karsha* (15grams) of *Saindhava lavana* was mixed. To the above mixture, one *pala* (~48ml) of *chinchā (amlīka) Kalka* was added. One *kudava* of *Gomutra* (~200ml) was added slowly and mixed continuously so as to have uniform *Basti dravyas*. *Basti dravyas* was filtered before administration and given post lunch.

Procedure

Poorva karma: After consuming *Laghu Bhojana*, *Stanika Abhyanga* and *Swedana* was done on the lower abdomen, waist and thighs of the subject. They were positioned to sleep on the left lateral position by keeping left leg straight and right leg flexed at the knee joint.

Pradhana karma: *Guda* and *vasti yantra* were anointed by oiled cotton swab. *Anuvasana Basti* /*Vaitarana Basti* were administered as per scheduled days using *Basti yantra*.

Paschat karma: After *Basti* administration, the subjects were advised to relax in supine position. They were advised to pass the bowel after getting the urge. The assessment was done before and after treatment.

Post basti therapy advice- Subjects were informed to follow the *Shatyadi Kalka* with *Varshabhu Kashaya* as per recommended dose, *Pathya Ahara* and *Vihara* and observe *parihara Kala* for double the period as undertaken in the entire course of *Basti* therapy.

Reporting of adverse drug reaction (ADR): Adverse drug reaction (ADR) was recorded as per the National Ayurveda protocol for ADR.

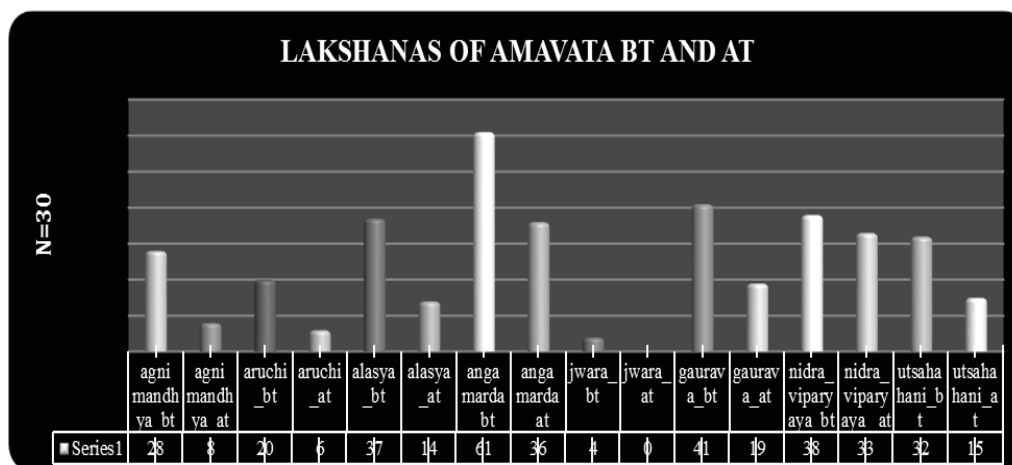
Assessment criteria: Early morning stiffness in minutes, Disease Activity Score of 28 joints' Erythrocyte Sedimentation Rate

Primary outcome measures: *Sandhi Ruja, Sandhi Shotha, Sandhi-sparshaasahyata, Sandhi Stabdhata, Agnimandhya, Angamarda, Aruchi, Alasya, Gaurava, Trishna, Jwara, Nidra viparyaya and Utsaaha haani.*

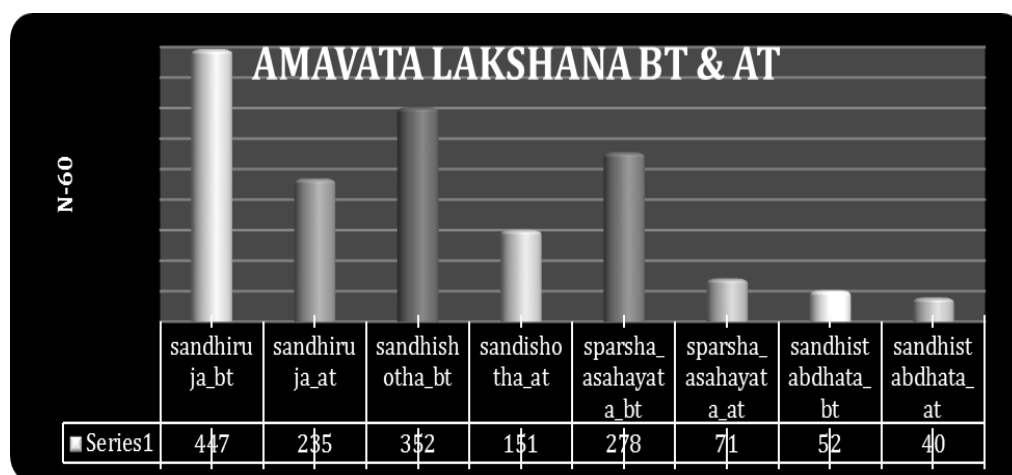
Secondary outcome measures: DAS 28 score, ACR EULAR score.

Laboratory parameters: RA factor (IU/ml) and CRP (IU/ml).

OBSERVATIONS AND RESULTS

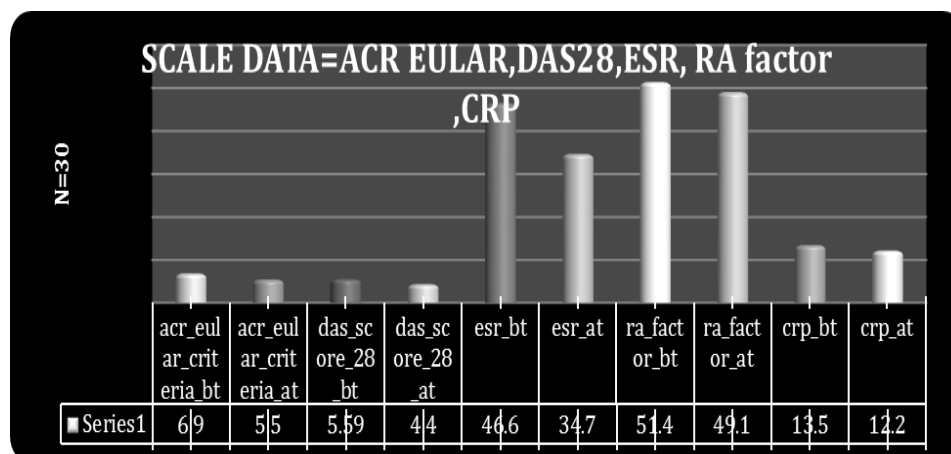


Picture 1: Lakshanas of Amavata BT and AT- Agnimandhya, Aruchi, Gaurava, Alasya, Trishna, Gaurava, Angamarda, Nidraviparyaya and Utsahahani.



Picture 2: Lakshanas of Amavata BT and AT- Sandhiruja, Sandhishotha, Sandhi-sparshaasahayata, Sandhistabdhata.

Therapy showed improvement in primary outcome measures. Initially there was reduction in *Shula, Shotha, Aruchi, Alasya, and Utsahahani*. Post basti therapy (i.e. after 8 days), there was further decrease in *Angamarda, Gaurava and Sandhistabdhata* which would have contributed to improved sleep.



Picture 3: Results of Assessment Parameters-ACR Eular Score, DAS 28 Score, RA factor (IU/ml), CRP (IU/ml).

In secondary outcomes, there was statistical significant reduction in ACR-EULAR and DAS28 score and ESR (mm/1st hour) but no statistical significant difference was noted in RA factor (IU/ml) and CRP (IU/ml).

DISCUSSION

1. There was statistically significant difference in *Agnimandhya*, *Aruchi*, *Gaurava*, *Alasya*, *Trishna*, *Gaurava*, *Angamarda*, *Nidraviparyaya* and *Utsahahani* with Friedman's test at $p < 0.05$. Post hoc with Wilcoxon signed rank test showed that there was statistically significant difference in *Agnimandhya*, *Aruchi*, *Alasya*, *Trishna* and *Utsahahani* between the mean at three intervals and statistically significant difference in *Gaurava*, *Angamarda*, *Nidraviparyaya* between the means at two intervals i.e. between BT and AT. But there was no statistically significant difference in *Jwara* with Friedman's test at $p > 0.05$ as there were only 4 subjects.
2. There was statistically significant difference in *Sandhiruja*, *Sandhishotha*, *Sandhi-sparshaasahyata*, *Sandhistabdhatta* with Friedman's test at $p < 0.05$. Post hoc with Wilcoxon signed rank test showed that there was statistically significant difference in means between three intervals in *Sandhiruja*, *Sandhishotha* and *Sandhi-sparshaasahyata* but there was statistically significant difference in means between two intervals i.e. from 8th to 24th Day and 24th Day to AT.
3. Repeated measure ANOVA with Greenhouse –Geisser correction showed statistically significant reduction in ACR EULAR Score and DAS-28 Score with $P < 0.05$ indicate the reduction of overall tenderness and swelling in total joint and showed statistically significant difference in ESR (mm/1st hour) between the means over three intervals at

$P < 0.05$ indicating the reduction of inflammation in joints

4. Repeated measure ANOVA with Greenhouse –Geisser correction showed no statistically significant difference in RA Factor (IU/ml) and CRP (IU/ml) with $P > .016$. Most of the subjects reported to hospital had clinical features of Amavata but not elevated levels of RA and CRP, hence didn't show much statistical significant difference.

5. Discussion regarding therapy

- a. **Shatyadi Kalka and Varshabhu kashaya:** Shunti has *Katu rasa, Guru, Ruksha, Tikshna guna, Ushna virya, and Madhura vipaka*; it is *Vata-kaphahara, Rochana, Dipana, Pachana, Hridaya, Anulomaka, Shula-prashamaka and Shothahara*. Shati has *Katu, Tikta, Kashaya Rasa, Laghu, Tikshna Guna, Ushna virya, Katu vipaka* and has *Vatakaphahara, Sandhishotha-Shulahara, Grahi and Mukhashodhaka*. Punarnavahas *Madhura, Tikta, Kashaya Rasa, Laghu, Ruksha Guna Ushna virya, Madhura vipaka* and has *Kapha-vatahara, Anulomaka, Shothahara and Mutrala*. Shunti and Shati in form of *kalka* and *Varshabhu* in form of *Kashaya* as *Anupana* was administered. They were shown to exert *Dipana Pachana* and were found to reduce *Sandhi ruja* and *Shotha*.^[3]

- b. **Anuvasana basti:** In *Amavata*, *Anuvasana basti* with *Brihat Saindhavadi taila* does *Pachana* as its base is *Eranda taila*. It may exert *Vatalomana* action and stimulates the action of *Jatarangni*.^[4]

c. Vaitarana basti

Saindhava lavana has *Laghu, Snigdha, Sukshma Tikshna guna, Sheeta virya, deepaka pachaka, Tila Taila* has *Katu, Tikta, Madhura rasa, Guru, Snigdha guna,*

Guda due to *Laghu, Anabhishtyandi, Agnivardhaka and Vatapittashamaka* can reach upto the micro-cellular level.

Amlika posses *Ruksha, Ushna, Amla, Vatakaphashamaka* property.

Gomutra has *Katu rasa, Katu vipaka, Ushnavirya, Laghu, Ruksha and Tikshna Guna*, pacify the *Kapha Dosha, Agnidipana, Pachana, Srotovishodhana and Vatanulomana*. **Vaitarana basti** may be given after food as its effect is said to be *uttama* (supreme). Since *Amavata* subjects are *Durbala* and have *Shula* and *Shotha*, they are unable to perform day today activities. In such condition, administration of *Vaitarana Basti* after food would be suitable as it was well tolerated by them and were able to retain the *Basti* for longer duration.^[5]

- d. Combined therapy of *Shatyadi Kalka* with *Varshabhu Kashaya* and *Vaitarana basti yoga* has exerted *Agnidipana, Pachana, and Srotovishodhana and Vatanulomana* properties. Hence may have reduced the symptoms of *Aruchi, Alasya, Trisna, Utsahahani and Sandhi ruja-shotha*. As the sample of subjects having *Jwara* was very small in this study,

the improvement shown by them was not statistically significant. Initially there were no changes in *Nidraviparyaya* between the 1st to 8th day as there was persisting *Angamarda*, *Gaurava* and *Sandhistabdhata*. From 8th to 24th day there was significant reduction in symptoms of *Angamarda*, *Gaurava* and *Sandhistabdhata* (early morning stiffness) probably due to *Amapachana* and *vatanulomana* action.

- e. After the completion of *basti* therapy, *Amapachana* and *laghavata* effect over the body and the continuation of *Shatyadi kalka* with *Anupana Varshabhu Kashaya* may have helped in reduction of *Angamarda*, *Gaurava* and *Sandhistabdhata* and thus improvement in sleep quality. Administration of *Basti* post food was found suitable because they had strength to undergo the process of *Basti* soon after food and were able to retain the *basti* for longer duration.

CONCLUSION

Shatyadi kalka with *Anupana Varshabhu Kashaya* and *Vaitarana basti* is beneficial in the management of *Amavata* (rheumatoid arthritis). No ADR was recorded during the study; both the formulations seem to be clinically safe.

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