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A clinical study on the combined effectiveness of *Pathyadi Churna* and *Kshara Basti* in *Amavata* (Rheumatoid Arthritis)

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ABSTRACT

Background & Objectives: *Amavata* (Rheumatoid Arthritis-RA) is a disease caused due to deranged *Agni* leading to *Ama* formation. The *Lakshanas* are very similar to Rheumatoid Arthritis (RA), an autoimmune disorder which causes chronic inflammation and symmetric, peripheral polyarthritis. *Pathyadi Churna* and *Kshara Basti* are mentioned in the classics for the treatment of *Amavata*. **Methods:** Among 33 registered patients, 30 of them completed the course of treatment. They were administered with *Pathyadi Churna* 1 *Karsha* (12g) thrice daily before food with *Ushnodaka* as *Anupana* (adjuvant) for a period of 15 days along with *Kshara Basti* in a modified *Yoga Basti* format for the first 5 days. Friedman's test with Wilcoxon sign rank test as post hoc was used to analyze the significance of change in Ordinal data and Repeated measure ANOVA after applying Bonferroni correction and Paired t test as post hoc was used to analyze the significance of change in Scale data. **Results:** There was statistically significant improvement in the primary and secondary outcome measures of *Amavata*. **Interpretation and Conclusion:** *Pathyadi Churna* and *Kshara Basti* are effective in the management of *Amavata*.

Key words: Ayurveda, *Amavata*, Rheumatoid Arthritis, *Pathyadi Churna*, *Kshara Basti*

INTRODUCTION

Ama is an important pathological factor in the body and is the cause for several diseases. *Amavata* is one such disease caused by *Ama*. In the disease *Amavata*, *Ama* combines with the *Prakupita Vata Dosha* and spreads all over the body producing symptoms like *Sandhi Shotha*, *Sandhi Shoola*, *Sandhi Stabdhatata* and *Sandhi Sparsha Asahyata* along with other *Lakshanas*

of *Ama*.

The general principles of treatment for this disease lays emphasis on stimulating and normalizing the impaired *Agni* by the use of both *Shodhana* and *Shamana Chikitsa*. *Langana*, *Swedana*, *Deepana*, *Katu* and *Tikta Rasa Dravyas*, *Virechana* and *Basti* are recommended. Specifically, *Kshara Basti* and *Anuvasana Basti* with *Brihat Saindavadi Taila* is advised.^[1]

Lakshanas of *Amavata* have a close resemblance with Rheumatoid arthritis (RA). RA is the most common type of Autoimmune Arthritis. It causes chronic inflammation and symmetric, peripheral polyarthritis. Persistent inflammation leads to erosive joint damage causing significant physical disability. As it is a systemic disease, it presents with a wide range of extra articular manifestations. Factors producing RA include infectious triggers, genetic predisposition and autoimmune response.

Worldwide the annual incidence of RA is approximately 3 cases per 10,000 populations and the prevalence rate

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is approximately 1%. Indian women are affected three times more than men. The prevalence increases with age peaking between the age 25 and 55 years after which it plateaus until the age of 75 years. Among these, around 40% are registered disabled within 3 years, while around 80% are moderately to severely disabled within 20 years. Family studies indicate a genetic predisposition. Patients with first degree relatives possessing the autoantibody are found to have a 2 to 10 times greater risk of developing severe RA than the general population. Monozygotic twins are four times more likely to develop RA than dizygotic twins.^[2]

Various research works have been conducted to solve this clinical enigma. As an effective treatment approach is still required for the management of *Amavata*, here we intended to assess the combined effectiveness of *Pathyadi Churna* and *Kshara Basti* in the management of *Amavata*.

METHODOLOGY

Method of collection of data

Screening

Subjects were screened and a form was prepared with all aspects of history, signs and symptoms of *Amavata* (Rheumatoid arthritis) and laboratory investigations for adequate diagnosis.

Diagnostic Criteria

Among screened patients, *Amavata* (Rheumatoid Arthritis) was diagnosed based on the *Lakshanas* of *Amavata* - *Angamarda* (myalgia), *Aruchi* (anorexia), *Trishna* (increased thirst), *Alasya* (laziness), *Gaurava* (heaviness), *Jwara* (fever), *Apaka* (indigestion), *Sandhi Shotha* (joint stiffness), *Sandhi Shoola* (joint pain), *Sandhi Sthabdata* (joint stiffness) and 2010 ACR-EULAR^[3] classification criteria for Rheumatoid Arthritis.

Inclusion Criteria

Amavata with features of Rheumatoid Arthritis as specified in 2010 ACR-EULAR classification criteria for Rheumatoid Arthritis with less than 10 years of chronicity, Subjects aged between 20-60 years of either gender, fit for *Basti* karma and willing to

participate in the study and ready to sign informed consent form.

Exclusion Criteria

Subjects with known case of essential hypertension and uncontrolled diabetes mellitus, with impaired renal, hepatic and cardiac function, known case of systemic arthritis, pregnant and lactating women.

Ethical clearance and CTRI registration

Ethics clearance certificate was attained from Institutional Ethics Committee. Trial was registered on Indian clinical trial registry (CTRI/2021/02/031002)

Study Design

The study was an open label, single arm, prospective clinical trial on *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

Pathyadi Churna^[4]

| | |
|-----------------|--|
| Dosage | 1 <i>Karsha</i> (12 grams) in divided doses thrice daily before food |
| Anupana | <i>Ushna Jala</i> |
| Duration | 15 days - Internal administration oral route |

Therapy: *Kshara Basti*^[5]

| | |
|------------------------|---|
| Anuvasana Basti | <i>Brihat Saindhavadi Taila</i> ^[6] 60ml post lunch anal route |
| Kshara Basti | <i>Basti Dravya</i> 450 ml morning on empty stomach anal route |
| Duration | 5 days as per modified <i>Yoga Basti</i> schedule (5 <i>Anuvasana Basti</i> + 3 <i>Kshara Basti</i>) |
| Assessment | Day - 0, 6 th day, 15 th day |

Basti was administered in a modified *Yoga Basti* schedule

| Day 1 | Day 2 | Day 3 | Day 4 | Day 5 |
|-------|-------|-------|-------|-------|
| | N | N | N | |
| A | A | A | A | A |

(A = Anuvasana Basti, N = Niruha Basti)

Assessment Criteria

Signs and symptoms of *Amavata* (Rheumatoid Arthritis) were assessed by giving suitable scoring at three intervals namely before treatment, 6th day and 15th day of treatment.

Primary Outcome Measures

Angamarda (myalgia), *Aruchi* (anorexia), *Trishna* (increased thirst), *Alasya* (laziness), *Gaurava* (heaviness), *Jwara* (fever), *Apaka* (indigestion), *Sandhi Shotha* (joint stiffness), *Sandhi Shoola* (joint pain) and *Sandhi Sthabdata* (joint stiffness).

Secondary Outcome Measures

DAS 28 score, RAPID 3 score, ACR EULAR score

OBSERVATIONS

Table 1: Demographic profile of 33 patients of Amavata

| Observation | Predominance | Percentage % |
|----------------|----------------|--------------|
| Age | 51-60 years | 14 (42.4%) |
| Gender | Female | 29 (87.9%) |
| Education | Primary school | 19 (57.6%) |
| Locality | Rural | 20 (60.6%) |
| Family History | Absent | 26(78.8%) |
| BMI | Normal weight | 29 (87.9%) |

Table 2: Baseline distribution of Lakshanas of Amavata

| Lakshana (Present) | Percentage % |
|--------------------|--------------|
| <i>Angamardha</i> | 33 (100%) |

| | |
|--------------------------------|------------|
| <i>Aruchi</i> | 27 (81.8%) |
| <i>Trishna</i> | 18 (54.5%) |
| <i>Alasya</i> | 32 (97%) |
| <i>Gourava</i> | 32 (97%) |
| <i>Jwara</i> | 25 (75.8%) |
| <i>Apaka</i> | 30 (90.9%) |
| <i>Sandhi Shoola</i> | 33 (100%) |
| <i>Sandhi Shotha</i> | 33 (100%) |
| <i>Sandhi Sthabdata</i> | 33 (100%) |
| <i>Sandhi Sparsha Asahyata</i> | 33 (100%) |

Table 3: Baseline distribution of Laboratory Parameters

| Parameter | Mean (+/-SD) |
|---------------|--------------|
| RA (IU/ml) | 63.36 |
| CRP (mg/dl) | 28.43 |
| ESR (mm/hour) | 62.39 |

RESULTS

Effect of therapy on Lakshanas of Amavata

Table 4: Effect of therapy on Lakshanas of Amavata (n=30)

| Lakshana | Mean Rank | | | Z | P | Remarks |
|-------------------|-----------|-----------------|------------------|--------|------|---------|
| | BT | 6 th | 15 th | | | |
| <i>Angamardha</i> | 2.82 | 2.02 | 1.17 | 49.515 | <.05 | S |
| <i>Aruchi</i> | 2.80 | 1.83 | 1.37 | 44.744 | <.05 | S |
| <i>Trishna</i> | 2.53 | 1.78 | 1.68 | 30.471 | <.05 | S |
| <i>Alasya</i> | 2.90 | 1.92 | 1.18 | 51.864 | <.05 | S |
| <i>Gourava</i> | 2.90 | 1.83 | 1.27 | 50.531 | <.05 | S |
| <i>Jwara</i> | 2.70 | 1.83 | 1.47 | 39.027 | <.05 | S |

| | | | | | | |
|--------------------------------|------|------|------|--------|------|---|
| <i>Apaka</i> | 2.85 | 1.92 | 1.23 | 48.887 | <.05 | S |
| <i>Sandhi Shoola</i> | 2.97 | 1.82 | 1.22 | 54.229 | <.05 | S |
| <i>Sandhi Shotha</i> | 2.77 | 1.90 | 1.33 | 43.628 | <.05 | S |
| <i>Sandhi Sthabdata</i> | 2.70 | 1.92 | 1.38 | 39.975 | <.05 | S |
| <i>Sandhi Sparsha Asahyata</i> | 2.88 | 1.92 | 1.20 | 50.871 | <.05 | S |

Freidman’s Test

Table 5: Effect of therapy on Lakshanas of Amavata (n=30)

| Parameters | N | | | Sum of ranks | Z | P | Remarks |
|---|-----|-----|---------|--------------|-------|-------|---------|
| | N R | P R | T Total | | | | |
| Angamardha | | | | | | | |
| BT-6 th Day | 22 | 0 | 8 | 253.00 | 4.600 | <.016 | S |
| 6 th day- 15 th day | 23 | 0 | 7 | 276.00 | 4.630 | <.016 | S |
| BT- 15 th day | 27 | 0 | 3 | 378.00 | 4.696 | <.016 | S |
| Aruchi | | | | | | | |
| BT-6 th Day | 23 | 0 | 7 | 276.00 | 4.630 | <.016 | S |
| 6 th day- 15 th day | 13 | 0 | 17 | 91.00 | 3.606 | <.016 | S |
| BT- 15 th day | 25 | 0 | 5 | 325.00 | 4.507 | <.016 | S |
| Trishna | | | | | | | |
| BT-6 th Day | 15 | 0 | 15 | 120.00 | 3.873 | <.016 | S |
| 6 th day- 15 th day | 28 | 0 | 2 | 3.00 | 1.414 | >.016 | NS |
| BT- 15 th day | 17 | 0 | 13 | 153.00 | 4.123 | <.016 | S |

| | | | | | | | | |
|---|----|---|----|----|--------|-------|-------|---|
| Alasya | | | | | | | | |
| BT-6 th Day | 25 | 0 | 5 | 30 | 325.00 | 4.914 | <.016 | S |
| 6 th day- 15 th day | 20 | 0 | 10 | 30 | 210.00 | 4.472 | <.016 | S |
| BT- 15 th day | 29 | 0 | 1 | 30 | 432.00 | 4.862 | <.016 | S |
| Gourava | | | | | | | | |
| BT-6 th Day | 26 | 0 | 4 | 30 | 351.00 | 5.014 | <.016 | S |
| 6 th day- 15 th day | 16 | 0 | 14 | 30 | 136.00 | 4.000 | <.016 | S |
| BT- 15 th day | 28 | 0 | 2 | 30 | 406.00 | 4.768 | <.016 | S |
| Jwara | | | | | | | | |
| BT-6 th Day | 18 | 0 | 12 | 30 | 171.00 | 4.243 | <.016 | S |
| 6 th day- 15 th day | 82 | 0 | 22 | 30 | 36.00 | 2.828 | <.016 | S |
| BT- 15 th day | 24 | 0 | 6 | 30 | 300.00 | 4.735 | <.016 | S |
| Apaka | | | | | | | | |
| BT-6 th Day | 24 | 0 | 6 | 30 | 300.00 | 4.811 | <.016 | S |
| 6 th day- 15 th day | 19 | 0 | 11 | 30 | 190.00 | 4.119 | <.016 | S |
| BT- 15 th day | 27 | 0 | 3 | 30 | 378.00 | 4.678 | <.016 | S |
| Sandhi Shoola | | | | | | | | |
| BT-6 th Day | 28 | 0 | 2 | 30 | 406.00 | 5.292 | <.016 | S |
| 6 th day- 15 th day | 17 | 0 | 13 | 30 | 153.00 | 4.123 | <.016 | S |
| BT- 15 th day | 30 | 0 | 0 | 30 | 465.00 | 4.930 | <.016 | S |
| Sandhi Shotha | | | | | | | | |
| BT-6 th Day | 18 | 0 | 12 | 30 | 171.00 | 4.243 | <.016 | S |

| | | | | | | | | |
|---|----|---|----|----|--------|-------|-------|---|
| 6 th day- 15 th day | 12 | 0 | 18 | 30 | 78.00 | 3.464 | <.016 | S |
| BT- 15 th day | 28 | 0 | 2 | 30 | 406.00 | 5.135 | <.016 | S |
| Sandhistha bdata | | | | | | | | |
| BT-6 th Day | 17 | 0 | 13 | 30 | 153.00 | 4.123 | <.016 | S |
| 6 th day- 15 th day | 12 | 0 | 18 | 30 | 78.00 | 3.464 | <.016 | S |
| BT- 15 th day | 25 | 0 | 5 | 30 | 325.00 | 4.716 | <.016 | S |
| Sandhi Sparsha Asahyata | | | | | | | | |
| BT-6 th Day | 23 | 0 | 7 | 30 | 276.00 | 4.796 | <.016 | S |
| 6 th day- 15 th day | 18 | 0 | 12 | 30 | 171.00 | 4.243 | <.016 | S |
| BT- 15 th day | 30 | 0 | 0 | 30 | 465.00 | 4.964 | <.016 | S |

Wilcoxon Signed rank test

Table 6: Effect of therapy on Number of Joints with Sandhi Shoola

| Number of joints with Sandhi Shoola | N | Mean | Greenhouse-geisser | | | Greenhouse-geisser error df | Remarks |
|-------------------------------------|----|-------|--------------------|---------|---------|-----------------------------|---------|
| | | | Df | F value | P value | | |
| BT | 30 | 18.0 | 2 | 116.024 | <.05 | 39.510 | S |
| 6 th day | | 11.93 | | | | | |
| 15 th day | | 6.00 | | | | | |

Repeated measure ANOVA test

Table 7: Pair wise comparison of Number of Joints with Sandhi Shoola

| Gross Score I | Gross Score J | Mean Difference (I-J) | Std. error | Sig. | 95% confidence interval for difference | | Remarks |
|---------------|---------------|-----------------------|------------|-------|--|--------|---------|
| | | | | | Lower | Upper | |
| 1 | 2 | 6.067 | 0.769 | <.016 | 4.114 | 8.019 | S |
| 3 | 1 | -12.000 | 1.001 | <.016 | -14.544 | -9.456 | S |
| | 2 | -5.933 | 0.518 | <.016 | -7.251 | -4.616 | S |

Table 8: Effect of therapy on Number of Joints with Sandhi Shotha

| Number of joints with Sandhi Shotha | N | Mean | Greenhouse-geisser | | | Greenhouse-geisser error df | Remarks |
|-------------------------------------|----|-------|--------------------|---------|---------|-----------------------------|---------|
| | | | Df | F value | P value | | |
| BT | 30 | 13.53 | 2 | 82.641 | <.05 | 39.336 | S |
| 6 th day | | 9.53 | | | | | |
| 15 th day | | 5.30 | | | | | |

Repeated measure ANOVA test

Table 9: Pair wise comparison of Number of Joints with Sandhi Shotha

| Gross Score I | Gross Score J | Mean Difference (I-J) | Std. error | Sig. | 95% confidence interval for difference | | Remarks |
|---------------|---------------|-----------------------|------------|-------|--|-------|---------|
| | | | | | Lower | Upper | |
| 1 | 2 | 4.000 | 0.597 | <.016 | 2.483 | 5.517 | S |

| | | | | | | | |
|---|---|--------|-------|-------|---------|--------|---|
| 3 | 1 | -8.233 | 0.823 | <.016 | -10.325 | -6.142 | S |
| | 2 | -4.233 | 0.444 | <.016 | -5.361 | -3.106 | S |

Table 10: Effect of therapy on Number of Joints with Sandhi Sthabdata

| Number of Joints with Sandhi Sthabdata | N | Mean | Greenhouse-geisser | | | Greenhouse-geisser error df | Remarks |
|--|----|-------|--------------------|---------|---------|-----------------------------|---------|
| | | | Df | F value | P value | | |
| BT | 30 | 17.13 | 2 | 101.556 | <.05 | 43.703 | S |
| 6 th day | | 12.20 | | | | | |
| 15 th day | | 7.33 | | | | | |

Repeated measure ANOVA test

Table 11: Pair wise comparison of Number of Joints with Sandhi Sthabdata

| Gross Score I | Gross Score J | Mean Difference (I-J) | Std. error | Sig. | 95% confidence interval for difference | | Remarks |
|---------------|---------------|-----------------------|------------|-------|--|--------|---------|
| | | | | | Lower | Upper | |
| 1 | 2 | 4.933 | 0.681 | <.016 | 3.202 | 6.665 | S |
| 3 | 1 | -9.800 | 0.843 | <.016 | -11.943 | -7.657 | S |
| | 2 | -4.867 | 0.493 | <.016 | -6.119 | -3.614 | S |

Table 12: Effect of therapy on Number of Joints with Sandhi Sparsha Asahyata

| Number of Joints with Sandhi Sparsha Asahyata | N | Mean | Greenhouse-geisser | | | Greenhouse-geisser error df | Remarks |
|---|----|-------|--------------------|---------|---------|-----------------------------|---------|
| | | | Df | F value | P value | | |
| BT | 30 | 17.00 | 2 | 128.222 | <.05 | 40.576 | S |
| 6 th day | | 11.80 | | | | | |
| 15 th day | | 6.03 | | | | | |

Repeated measure ANOVA test

Table 13: Pair wise comparison of Number of Joints with Sandhi Sparsha Asahyata

| Gross Score I | Gross Score J | Mean Difference (I-J) | Std. error | Sig. | 95% confidence interval for difference | | Remarks |
|---------------|---------------|-----------------------|------------|-------|--|--------|---------|
| | | | | | Lower | Upper | |
| 1 | 2 | 5.200 | 0.617 | <.016 | 3.633 | 6.767 | S |
| 3 | 1 | -10.967 | 0.877 | <.016 | -13.195 | -8.739 | S |
| | 2 | -5.767 | 0.509 | <.016 | -7.060 | -4.473 | S |

Table 14: Effect of therapy on Assessment Parameters

| Parameter | N | Mean | | | Greenhouse-geisser | | | Greenhouse-geisser error df | Remarks |
|-----------|----|--------|---------------------|----------------------|--------------------|---------|---------|-----------------------------|---------|
| | | BT | 6 th Day | 15 th Day | Df | F value | P value | | |
| DAS28 | 30 | 7.1523 | 6.0833 | 4.5507 | 2 | 247.807 | <.05 | 41.087 | S |

| | | | | | | | | |
|-----------|--------|--------|--------|---|---------|------|--------|---|
| RAPID 3 | 6.8033 | 4.5577 | 2.8567 | 2 | 411.531 | <.05 | 49.809 | S |
| ACR-EULAR | 8.333 | 7.8667 | 6.733 | 2 | 41.031 | <.05 | 48.706 | S |

Repeated measure ANOVA test

Table 15: Pair wise comparison of Assessment Parameters

| Gross Score I | Gross Score J | Mean Difference (I-J) | Std. error | Sig. | 95% confidence interval for difference | | Remarks |
|---------------|---------------|-----------------------|------------|-------|--|--------|---------|
| | | | | | Lower | Upper | |
| DAS 28 | | | | | | | |
| 1 | 2 | 1.069 | 0.071 | <.016 | 0.888 | 1.250 | S |
| 3 | 1 | -2.602 | 0.140 | <.016 | -2.957 | -2.246 | S |
| | 2 | -1.533 | 0.129 | <.016 | -1.861 | -1.204 | S |
| RAPID 3 | | | | | | | |
| 1 | 2 | 2.247 | 0.130 | <.016 | 1.917 | 2.576 | S |
| 3 | 1 | -3.974 | 0.163 | <.016 | -4.361 | -3.533 | S |
| | 2 | -1.700 | 0.117 | <.016 | -1.998 | -1.402 | S |
| ACR-EULAR | | | | | | | |
| 1 | 2 | 0.467 | 0.157 | <.016 | 0.068 | 0.866 | S |

| | | | | | | | |
|---|---|--------|-------|-------|--------|--------|---|
| 3 | 1 | -1.600 | 0.218 | <.016 | -2.153 | -1.047 | S |
| | 2 | -1.133 | 0.164 | <.016 | -1.551 | -0.716 | S |

Table 16: Effect of therapy on Laboratory Parameters

| Parameter | N | Mean | | | Greenhouse-geisser | | | Greenhouse-geisser error df | Remarks |
|-----------|----|---------|---------------------|----------------------|--------------------|---------|---------|-----------------------------|---------|
| | | BT | 6 th Day | 15 th Day | Df | F value | P value | | |
| RA Factor | 30 | 68.5600 | 59.303 | 55.5700 | 2 | 6.409 | <.05 | 42.837 | S |
| ESR | | 65.5667 | 54.1667 | 39.5000 | 2 | 19.761 | <.05 | 44.320 | S |
| CRP | | 30.3167 | 20.9900 | 16.2367 | 2 | 13.628 | <.05 | 36.108 | S |

Repeated measure ANOVA test

Table 17: Pair wise comparison of Laboratory Parameters

| Gross Score I | Gross Score J | Mean Difference (I-J) | Std. error | Sig. | 95% confidence interval for difference | | Remarks |
|---------------|---------------|-----------------------|------------|-------|--|--------|---------|
| | | | | | Lower | Upper | |
| RA Factor | | | | | | | |
| 1 | 2 | 9.257 | 3.969 | <.016 | -0.828 | 19.341 | NS |
| 3 | 1 | -12.990 | 4.482 | <.016 | -24.377 | -1.603 | S |
| | 2 | -3.733 | 2.458 | <.016 | -9.978 | 2.511 | NS |
| ESR | | | | | | | |

| | | | | | | | |
|------------|---|-----------------|-----------|-----------|---------|-----------------|---|
| 1 | 2 | 11.40 0 | 3.3 64 | <.0 16 | 2.852 | 19.94 8 | S |
| 3 | 1 | - 26.06 7 | 5.1 75 | <.0 16 | -39.216 | - 12.91 7 | S |
| | 2 | - 14.66 7 | 3.7 08 | <.0 16 | -24.088 | - 5.245 | S |
| CRP | | | | | | | |
| 1 | 2 | 9.327 | 2.8 57 | <.0 16 | 2.068 | 16.58 5 | S |
| 3 | 1 | - 14.08 0 | 3.5 02 | <.0 16 | -22.978 | - 5.182 | S |
| | 2 | -4.753 | 1.4 72 | <.0 16 | -8.493 | - 1.014 | S |

DISCUSSION

Effect of therapy on Ama Lakshanas

Angamardha, Aruchi, Trishna, Alasya, Gourava, Jwara and Apaka are the Lakshanas of Ama. Shunti, Ajamoda and Haritaki are the ingredients of Pathyadi Churna. Shunti is Katu Rasa, Ruksha, Tikshna and Laghu Guna, Ushna Virya and has Deepana Karma.^[7] Ajamoda is Tikta Katu Rasa, Laghu, Ruksha and Tikshna Guna, Ushna Virya, Katu Vipaka and has Deepana Karma.^[8] Haritaki is Kashaya Pradhana Pancharasa, Laghu, Ruksha, Ushna and Tikshna Guna, Katu Vipaka and has Amulomana, Lekhana, Deepana and Pachana Karmas.^[9] All these Gunas are responsible for destroying the Ama in the body thereby reducing the symptoms. Kshara Basti is specifically beneficial in Amavata as it tackles both Vata and Kapha which are responsible for the disease formation. Due to its Usha Virya, Tikshna, Sukshma, Lekhana and Deepana Gunas, it reduces Ama and its Lakshanas.^[10] Brihat Saindhavadi Taila has ingredients which are predominantly Vata Kaphahara and Deepana, hence reducing Ama and its Lakshanas.^[11] There was significant reduction in Ama Lakshanas after treatment.

Effect of therapy on Sandhi Lakshanas

Rheumatoid arthritis is an inflammatory arthritis and shows signs of inflammation in the joints. Pain and swelling is one among them. Shunti and Ajamoda present in Pathyadi Churna have Shoolahara and Shothahara properties. Their Ushna Virya and Katu Rasa works on pain caused due to aggravated Vata and Kapha. The Ruksha Guna works on swelling caused due to Ama.^{[7],[8]} In Kshara Basti, Gomutra is Anulomana and Shothahara,^[12] Amlika and Shatapushpa are Shoolahara.^{[13],[14]} Most of the ingredients in Brihat Saindhavadi Taila are Ushna Virya, Shoolahara and Shothahara.^[11] There was significant reduction in Sandhi Lakshanas after treatment.

Effect of therapy on functional ability (RAPID 3)

RAPID 3 is an assessment of the patients physical function and pain before and after treatment. As there was significant reduction in Sandhi Shoola, Sandhi Shotha and Sandhi Sthabdata, the overall physical function of the patient also improved.

Effect of therapy on disease activity (DAS 28, ACR EULAR)

DAS 28 Score is based on the number of swollen and painful joints, ESR and VAS Score. There was noticeable reduction in Sandhi Shotha, Sandhi Shoola, ESR value and pain in all 3 intervals, thus making it significant.

Parameters in ACR-EULAR criteria include duration of symptoms, joint distribution, serology and acute phase reactants. As there was considerable reduction in the number of joints affected with pain and swelling and as there was reduction in RA factor (serology), CRP and ESR (acute phase reactants) levels within 15 days, this score has been significant.

Discussion on probable mode of action of drug

Pathyadi Churna

Pathyadi Churna is a combination of Haritaki, Shunti and Ajamoda in equal proportions. All the drugs are predominantly Ushna Virya and have Agni Deepana and Ama Pachana properties which are required for the management of Amavata.

Haritaki is *Kashaya Rasa Pradhana Pancharasa* (except *Lavana*), *Laghu* and *Ruksha Guna*, *Ushna Virya*, *Madhura Vipaka* and is *Tridosahara*. It is also *Anulomana*, *Lekhana*, *Deepana*, *Pachana*, *Shothahara* and has *Rasayana* action.^[15] Its chemical constituents such as chebulagic acid acts as cox inhibitor which suppresses the inflammatory mediators like TNF-alpha, IL-1beta, IL-6. It also consists of flavonoids, alkaloids, tannins, saponins, glycosides and phenolic compounds which acts as immune modulators.^[16]

Shunti is *Katu Rasa*, *Ruksha*, *Tikshna* and *Laghu Guna*, *Ushna Virya*, *Madhura Vipaka* and is *Vata Kaphahara*. Other *Karmas* include *Deepana*, *Shophahara*, *Shoolahara* and *Ruchikara*.^[7] *Shunti* has a proven analgesic and antipyretic action. Its chemical constituents such as gingerols and gingerdiols are anti-inflammatory by suppressing the pro inflammatory cytokines. Paradols found in ginger have antioxidant effects.^[17]

Ajamoda has *Tikta* and *Katu Rasa*, *Laghu*, *Ruksha* and *Tikshna Guna*, *Ushna Virya*, *Katu Vipaka* and is *Kapha Vatahara*. Other *Karmas* include *Deepana*, *Shoolahara* and *Ruchikara*.^[8] Chemical constituents such as furanocoumarins and flavones present in *Ajamoda* have anti-oxidant and anti-inflammatory properties. It also contains trace elements such as sodium, potassium, calcium and iron.^[18]

Kshara Basti

Kshara Basti has *Kapha Vata Shamaka* properties. Due to its *Deepaniya* and *Lekhaniya* properties, it is specifically indicated in conditions like *Amavata*.

Kshara Basti comprises of *Gomutra* in maximum proportion which is *Katu*, *Tikta* and *Lavana Rasa*, *Laghu* and *Tikshna Guna*, *Ushna Virya*, *Katu Vipaka* and have *Karmas* such as *Agni Deepana*, *Lekhana*, *Ama Pachana*, *Anulomana* and *Malashodhaka*.^[12] It is proven to have antioxidant and immunostimulatory properties due to its free radical scavenging activity. It enhances the immunocompetence by facilitating the synthesis of interleukin-1 and 2, B and T lymphocytes blastogenesis and IgA, IgM and IgG antibody titers.^[19]

Amlika has *Amla* and *Madhura Rasa*, *Laghu*, *Ushna* and *Ruksha Guna*, *Ushna Virya*, *Amla Vipaka* and is *Vata*

Kapha Hara. It is also *Shophahara* and *Shoola Hara*. Its fruit contains tamarindienol which augments digestion. It is also a good source of antioxidants.^[13]

Guda has *Madhura* and *Lavana Rasa*, *Guru* and *Snigdha Guna*, *Ushna Virya*, *Madhura Vipaka* and is *Vata Pitta Hara*. It is also *Anabhishtyandi* and *Agni Vardhaka*. It is rich in sucrose, protein, minerals such as calcium and iron and contain traces of vitamins and amino acids therefore helps to maintain electrolyte balance.^[20]

Saindava Lavana has *Lavana* and *Madhura Rasa*, *Laghu*, *Snigdha* and *Ruksha Guna*, *Anushna Sheeta Virya* and *Madhura Vipaka*. It is *Tridoshagna* and have *Deepana* and *Rochana* properties. Due to its *Sukshma* and *Tikshna* properties, it helps to pass the drug molecule into the systemic circulation through mucosa. It helps the *Basti Dravya* to reach upto the molecular level.^[21,22]

Shatapushpa has *Katu* and *Tikta Rasa*, *Laghu*, *Tikshna* and *Ruksha Guna*, *Ushana Virya*, *Katu Vipaka* and is *Kapha Vata Hara*. It is also said to be *Deepana*, *Jwaragna*, *Shoola Hara* and *Rochaka*. It is rich in flavonoids thereby being a strong antioxidant. In *Basti*, it helps transfer the phyto chemicals of the enema into the system of the patient.^[14]

Brihat Saindhavadi Taila Anuvasana Basti

Brihat Saindhavadi Taila has a potent pharmacological action on *Amavata* due to its ingredients. Its ingredients include *Saindhava Lavana*, *Sauvarchala Lavana*, *Vida Lavana*, *Sarjikshara*, *Triphala*, *Rasna*, *Pippali*, *Gajapippali*, *Maricha*, *Kushta*, *Shunti*, *Yavani*, *Pushkaramoola*, *Jiraka* and *Ajamoda*. Majority of these drugs have *Lavana*, *Katu* and *Tikta Rasa*. *Lavana* and *Katu Rasa* are *Vata Shamaka* and *Tikta Rasa* is *Pitta Kapha Shamaka*. These have *Agni Deepana* and *Ama Pachana* qualities. Majority of the ingredients are of *Ushna Virya* thereby relieving the *Shotha*, *Shoola* and *Sthabdata* in the joints. *Eranda Taila* is the base used in this preparation. It has *Katu Rasa*, *Snigdha Guna*, *Ushna Virya* and *Kapha Vata Hara*. It has *Deepana*, *Bhedana*, *Krimigna*, *Amashodana* and *Srotovishodana* properties. Having anti-inflammatory and laxative properties, it is beneficial in RA. Overall *Brihat Saindhavadi Taila* is *Vata Kapha Shamaka*, *Agni*

Deepana, Bhedana, Amashodana, Srotovishodhana, Shothahara and Shoolahara thereby beneficial in Amavata.^{[6],[22]}

Probable mode of action of Basti

Basti is considered the best treatment in balancing Vata Dosha. Depending on the combinations in the Basti Dravya, it has Shodana, Shamana, Lekhana or Brimhana effects. Basti is considered to be Ayushya, Sukha, Balakrit, Agnikrit, Dhaardyakrit etc. Pakvashaya is the Sthana of Vata Dosha and administering Basti directly to the Sthana terminates the vitiated Vata from its root. There are various theories regarding its mode of action. A probable mode is based on its Virya. Though Basti is administered to the Pakvashaya, the Virya of the medicines in the Basti Dravya spread throughout the body by means of Srotas and brings about the desired action. According to modern pharmacokinetics, it is proven that rectal drug administration exceeds the oral value due to its partial avoidance of hepatic first pass metabolism.^[23]

CONCLUSION

Pathyadi Churna and Kshara 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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