ISSN 2456-3110 Vol 7 · Issue 10 November 2022



Journal of Ayurveda and Integrated Medical Sciences

www.jaims.in

Indexed

An International Journal for Researches in Ayurveda and Allied Sciences





Journal of Ayurveda and Integrated Medical Sciences

> ORIGINAL ARTICLE November 2022

A comparative clinical trial to evaluate the efficacy of Rasnadi Churna Basti with Ardha Matrika Basti in the management of Amavata vis-à-vis Rheumatoid Arthritis

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ABSTRACT

Background: Amavata is one among the pain predominant diseases. The disease Amavata has similarity with Rheumatoid arthritis in clinical presentation. In the present study an attempt was made to compare the efficacy of Rasnadi Churna Basti with Ardha Matrika Basti in the management of Amavata. Objective of the study: To compare the efficacy of Rasnadi Churna Basti with Ardha Matrika Basti in the management of Amavata vis-à-vis Rheumatoid Arthritis. Materials and Methods: A double arm open labeled clinical study with pre-post-test design was carried out at Government Ayurveda Medical College and Hospital, Mysuru. Data was collected as per the proforma prepared for the purpose of the study. Study was completed in 42 subjects with 21 subjects in both the groups. For Group A Rasnadi Churna Basti and for Group B Ardha Matrika Basti in Yoga Basti pattern for 8 consecutive days was administered. The data was analyzed using SPSS descriptive and inferential statistics. Results: The statistical values showed highly significant results in Sandhi Shoola, Sandhi Shotha, Sandhi Stabhdata, functional grading, ESR, and DAS parameters. In CRP parameter, result was statistically significant in Group-A and non significant in Group-B. Hb% parameter showed statistically non-significant results in both the groups. On overall assessment, there was no statistically significant difference in the results between the groups except CRP and DAS parameters. Conclusion: Both Rasnadi Churna Basti and Ardha Matrika Basti are useful in reducing the signs and symptoms of Amavata visà-vis Rheumatoid Arthritis.

Key words: Amavata, Rheumatoid Arthritis, Rasnadi Churna Basti, Ardha Matrika Basti

INTRODUCTION

Amavata is a Rasadushti Janya Vikara. It is mainly due to impairment of Jatharagni and Dhatwagni, resulting in production of Ama. Whenever Ama gets associated with Vikruta Vata and gets localized in Shleshma Sthana leading to manifestation of symptoms such as Body ache, Tastelessness, Excessive thirst, Weakness,

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Heaviness of the body and Fever.^[1] When the disease progresses, it causes Shoola and Shotha in the related joints. The disease Amavata simulates the signs and symptoms of Rheumatoid Arthritis.

Rheumatoid Arthritis (RA) is a chronic inflammatory disease of unknown etiology characterized by a symmetric, peripheral polyarthritis. Active RA often results in articular cartilage and bone destruction and functional disability, it is vital to diagnose and treat this disease early and aggressively before damage ensues^[2] The prevalence rate of RA is approximately 0.8% (0.3% to 2.1%) of the population, while in India the prevalence is 0.5% to 0.75%, with a female to male ratio 3:1. The peak age of onset is in the fourth and fifth decade of life.^[3]

Since the clinical course of Rheumatoid Arthritis is chronic with intermittent exacerbations and remissions there is need for safer and effective management. The line of management adopted in

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Amavata is Langhana, Swedana, Tikta Katu Deepana Dravya, Virechana, Snehapana and Basti.^[4] Among all Basti chikitsa is considered as Ardha Chikitsa in Ayurveda^[5] and it has lot to offer in this regard.

The present study was performed to evaluate the efficacy *Rasnadi Churna Basti* and *Ardha Matrika Basti* in the management of *Amavata* vis-à-vis Rheumatoid Arthritis. *Rasnadi Churna*^[6] consist of *Rasna, Vacha, Bilva, Ela, Pippali, Madanaphala, Devadaru Kusta, Putika* and *Shatapushpa* which are having *Vata-Kaphahara, Deepaniya, Shothahara* and *Amahara* properties. In *Ardha Matrika Basti*^[7] *Dashamoola Kwatha* was used for *Niruha Basti. Dashamoola possess Vata-Kaphahara, Shoolahara* and *Shothahara* properties. Hence the present study "A comprative clinical trial to evaluate the efficacy of *Rasnadi Churna Basti* with *Ardha Matrika Basti* in the management of *Amavata* vis-à-vis Rheumatoid arthritis" was carried out.

OBJECTIVE OF THE STUDY

To compare the efficacy of *Rasnadi Churna Basti* with *Ardha Matrika Basti* in the management of *Amavata* vis-à-vis Rheumatoid Arthritis.

MATERIALS AND METHODS

The materials used in the study were as follows:

In Group A: Rasnadi Churna Basti in Yoga Basti pattern.

Ingredients of Rasnadi Churna Basti are: Saindhava Lavana, Brihath Saindhavadya Taila, Rasnadi Churna, Ushna Jala and Dhanyamla.

In Group B: Ardha Matrika Basti in Yoga Basti pattern.

Ingredients of Ardha Matrika Basti are: Makshika, Saindhava Lavana, Brihat Saindhavadya Taila, Shatapushpa Kalka, Madanaphala Churna and Dashamoola Kashaya.

Methods

Method of collection of data

a) Study design

Double arm open labeled controlled clinical trial with pre - post test study design

b) Sample size

Study comprised of 44 registered subjects out of which 2 were dropouts. The study was completed on 42 subjects with 21 in each group.

c) Duration of intervention: 08 days

Inclusion criteria

Subjects of all gender, aged between 18 to 60 years with signs and symptoms of *Amavata* vis- à-vis Rheumatoid Arthritis were selected for the study.

Both fresh cases and treated cases were included.

Definition of fresh case includes; freshly detected and untreated cases of *Amavata* vis-à-vis Rheumatoid Arthritis.

Definition of treated cases includes; already diagnosed and treated cases of *Amavata* vis-à-vis Rheumatoid Arthritis, who voluntarily discontinued the treatment with flush out period of 7 days.

Exclusion criteria

- Subjects of Diabetes mellitus with RBS >200mg/dl were excluded.
- Subjects with a blood pressure>160/110mmHg and subjects with other systemic disorders which interfere with the intervention were excluded.
- Subjects suffering from rectal pathologies like hemorrhoids, fissure, and rectal prolapse were excluded
- 4. Subjects unfit for *Basti Karma* were excluded in the study.
- 5. Pregnant & Lactating women were excluded.

Diagnostic criteria

Diagnosis was based on the classical signs and symptoms of *Amavata vis a vis* Rheumatoid Arthritis and those who fit into 1987 Revised Criteria for the Classification of Rheumatoid Arthritis were included.

For the classification purpose a subject shall be said to have RA, If she / he has classified at least 4 of these 7 criteria.

Criteria 1 to 4 must have been present for at least 6 weeks.

Table 1: Showing 1987 Revised Criteria for theClassification of Rheumatoid Arthritis

SN	Criterion	Definition
1.	Morning stiffness	Lasting for at least 1 hour
2.	Arthritis of 3 or more Joint areas	At least 3 joint areas simultaneously have had soft tissue swelling or fluid.
3.	Arthritis of hand joints	At least 1 joint area swollen.
4.	Symmetric arthritis	Bilateral simultaneous involvement of same joint areas.
5.	Rheumatoid nodules	Subcutaneous nodules over bony prominence or extensor surface or in juxta articular regions.
6.	Serum Rheumatoid factor	Demonstration of abnormal amounts of serum Rheumatoid factor.
7.	Radiographic changes	Erosions or unequivocal bony prominence.

Assessment Criteria

1. Sandhi Shoola (Pain in the joints)

0 - No pain.

1 - Mild pain of bearable nature which occurs occasionally.

2 - Moderate pain but no difficulty in movement of joint, appears frequently.

3 - Slight difficulty in joint movements due to pain.

4 - More difficulty in moving joints, due to severe pain there will be disturbed sleep.

2. Sandhi Shotha (Swelling in the joints)

- 0 No swelling.
- 1 Slight swelling.
- 2 Moderate swelling.

- 3 Severe swelling.
- 3. Sandhi Stabdhata (Morning stiffness of the joints)

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- 0 No stiffness.
- 1 Stiffness lasting for 1 to 2 hours.

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- 2 Stiffness lasting for 2 to 8 hours.
- 3 Stiffness lasting for more than 8 hours.

4. Functional grading of Rheumatoid Arthritis

1 - Can carry all the daily activities without any difficulties.

2 - Moderate restriction of activities but independent.

3 - Marked restrictions of activities, mostly limited to self-care, Needs assistance.

4 - Bed or chair bound, Incapacitated and dependent.

Assessment schedule

Three assessments were done in the following schedule;

Pre test assessment was done on day 0, (before intervention)

Mid test assessment was done 2 days after completion of *Basti Karma* on 10th day

Follow-up assessment was done on 25th day

Investigations

Following investigations were done before intervention and after follow-up period; HB%, C-reactive protein and Rheumatoid Factor.

ESR was done before intervention, after intervention and after follow-up period.

Other relevant blood investigations and urine analysis were done where ever necessary to exclude other systemic disorders.

Statistical Methods

Results were analyzed statistically by using descriptive statistics, non-parametric tests like Chi Square, Wilcoxon sign rank test, Mann Whitney U test and

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Kruskal Wallis test using Service product for statistical solution (SPSS) for windows software.

Intervention

Group A:

a) Rasnadi Churna Basti in Yoga Basti pattern.
Ingredients of Rasnadi Churna Basti includes:
Saindhava Lavana - 12gms
Brihat Saindavadya Taila - 48ml
Rasnadi Churna - 24gms
Ushna Jala - 192ml
Dhanyamla - 48ml
Total quantity - 314ml
b) For Anuvasana Basti : Brihat Saindavadya Taila - 72ml

Group B

Ardha Matrika Basti in Yoga Basti pattern.

a) Ingredients of Ardha Matrika Basti includes:

Makshika - 96ml

- Saindhava Lavana 12gms
- Brihat Saindhavadya Taila 96ml

Shatapushpa Kalka - 12gms

Madanaphala Churna - 12gms

Dashamoola Kashaya - 200ml

Total quantity - 416ml

b) For Anuvasana Basti: Brihat Saindhavadya Taila -72ml

OBSERVATIONS

Age - 13 subjects were belonging to the age group of 31-40years and 41-50 years age group, 11 were in 51-60 years, 6 subjects were in 21-30 years and 1 subject was less than 20 years of age group.

Gender - 31 subjects were female and 13 were male.

Occupation - 8 were doing deskwork, 3 were doing fieldwork, 11 were doing fieldwork with physical labour and 22 subjects were homemakers.

Chronicity of disease - 11 subjects were suffering less than 1 year, 17 subjects were suffering for a period of

1-5 years, 11 subjects were suffering for a period of 6-10 years. 4 subjects were suffering for a period of 11-15 years. 1 subject was suffering from more than 16 years.

History of viral infection - 14 subjects had history of viral infection.

Rasa Pradhanyata - 31 subjects consume Madhura Rasa predominant food, 2 consume Amla Rasa predominant food and 11 subjects consume Katu Rasa predominant food.

Koshta - 5 subjects had *Mridu Koshta*, 20 had *Madhyama Koshta* and 19 subjects had *Krura Koshta*.

Exercise pattern - 3 subjects having habit of doing exercise regularly, 2 subjects were doing exercise occasionally and 39 subjects were doing only routine work.

RESULTS

A total of 44 subjects were registered for the study, there were 2 dropouts. The results were obtained by assessing 42 subjects who have completed the study.

Result on Sandhi Shoola

In Group A, before intervention the mean value was 3.52, after intervention mean value became 2.29 and the value came down to 1.14 after follow up. In Group B, before intervention the mean value was 3.62, after intervention mean value became 2.29 and the value came down to 1.19 after follow up. Between the groups statistically non significant result was obtained in *Sandhi Shoola* parameter with P value 0.871.

Results on Sandhi Shotha parameter

In Group A, before intervention the mean value was 2.29, after intervention mean value became 1.29 and the value came down to 0.62 after follow up. In Group B, before intervention the mean value was 2.14, after intervention mean value became 1.29 and the value came down to 0.48 after follow up. Statistically non-significant result was obtained between the groups with P value 0.488

Results on Sandhi Stabdhata parameter

In Group A, before intervention the mean value was 2.10, after intervention mean value became 1.14 and

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the value came down to 0.62 after follow up. In Group B, before intervention the mean value was 2.29, after intervention mean value became 1.14 and the value came down to 0.52 after follow up. Between the groups statistically non-significant result was obtained in RA Factor with P value 0.489.

Results on Functional Grading

In Group A, before intervention the mean value was 2.52, after intervention mean value became 1.81 and the value came down to 1.29 after follow up. In Group B, before intervention the mean value was 2.48, after intervention mean value became 1.71 and the value came down to 1.14 after follow up. Between the groups Functional-grading parameter shows statistically non-significant result with P value 0.294.

Results on ESR Parameter

In Group A, before intervention the mean value was 58.48, after intervention mean value became 59.62 and the value came down to 32.29 after follow up. In Group B, before intervention the mean value was 49.33, after intervention mean value became 48.33 and the value came down to 31.1 after follow up. Between the groups ESR parameter shows statistically insignificant result with P value 0.715.

Results on DAS

In Group A, 7.87 was the mean value before the intervention, mean value became 6.88 after intervention and it came down to 6.37 after the follow up. In Group B, 7.63 was the mean value before the intervention, mean value became 6.37 after intervention and it came down to 4.61 after the follow up. Statistically significant result was obtained between the groups with P value 0.021

Results on Hb% parameter

In Group A, before intervention the mean value was 10.53 and the value came down to 10.24 after follow up. In Group B, before intervention the mean value was 11.39 and the value increased to 11.55 after follow up. Statistically non-significant result was obtained between the groups with P value 0.82 in Hb parameter.

Results on RA Factor

In Group A, mean value was 12.91 before the intervention and it came down to 9.49 after the intervention. In Group B, before intervention the mean value was 19.10 and the value came down to 12.31 after follow up. Between the groups statistically non-significant result was obtained in RA Factor with P value 0.489.

Results on CRP parameter

In Group A, before intervention the mean value was 8.92 and the value came down to 3.94 after follow up. In Group B, before intervention the mean value was 10.86 and the value came down to 6.76 after follow up. Statistically significant result was obtained between the groups in CRP parameter with P value 0.036.

Table 2: Showing results on subjective parameters

Param eters	Shoola		Shotha		Stabdh ata		FG		DAS	
Group s	A	В	A	В	A	В	A	В	A	В
ВІ	3. 52	3. 62	2. 29	2. 14	2. 10	2. 29	2. 52	2. 48	7. 87	7. 63
AF	1. 14	1. 19	0. 62	0. 48	0. 62	0. 52	1. 29	1. 14	6. 37	4. 61
Mean Differe nce	2. 38	2. 43	1. 67	1. 66	1. 48	1. 77	1. 23	1. 34	1. 5	3. 02

Tab	le 3:	Showing	g results	on o	bjective	parameters
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Parame ters	ESR		RA		CRP		НВ	
Groups	А	В	A	в	А	В	A	В
BT	58. 48	49. 33	12. 91	19. 1	8.9 2	10. 86	10. 53	11. 39
AF	32. 29	31. 10	9.4 9	12. 3	3.9 4	6.7 6	10. 24	11. 55
Mean differen ce	26. 19	18. 23	3.4 2	6.8	4.9 8	4.1	0.2 9	- 0.1 6

Statistically highly significant results were observed within the groups in Sandhi Shoola, Sandhi Shotha,

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Sandhi Stabhdata, functional grading, ESR, and DAS parameters. In CRP parameter, result was statistically significant in Group A and non-significant in Group B. Hb% parameter showed statistically non-significant results within the groups. Between the groups statistically significant results observed in CRP and DAS parameters.

As both groups show significant results, both have positive effect on parameters such as *Sandhi Shoola*, *Sandhi Shotha*, *Sandhi Stabdhata*, functional grading, ESR and DAS on *Amavata* vis-a-vis Rheumatoid Arthritis. Hence, both *Rasnadi Churna Basti* and *Ardha Matrika Basti* are effective in the management of *Amavata* vis-à-vis Rheumatoid Arthritis.

DISCUSSION

The Chikitsa explained for Amavata includes Shodhana as well as Shamana which includes Langhana, Deepana, Swedana, Virechana, Snehapana and Basti. To remove deep routed Dosha, Basti has been selected in this study. In Churna Basti Ushna Jala has been mentioned in the place of Kwatha. Ushna Jala has Vata-Kaphahara, Deepana and Basti Shodhana properties. In Rasnadi Churna, among 10 drugs, 8 drugs were having Ushna Veerya, Vata-Kaphahara properties. Dhanyamla was used as Avapa, it possesses the properties like Agni Deepana, Sroto Shodhana, Bhedana, and is Vata-Kaphahara. In Ardhamatrika Basti, Dashamoola Kashaya was used. Dashamoola is having Vata-Kapha Shamaka, Vedana Stapaka and Shothaana properties. Shatapusha Kalka is Vata-Kaphahara, Laghu, Deepana in its properties and Madana Phala Kalka Kapha-Vatahara and Asthapanopaga. Asthapanopaga drugs due to their Ushna and Tikshna Guna helps to remove vitiated Dosha. Eranda Taila is used as a base for the preparation of Brihat Saindhavadya Taila. Eranda Taila pacifies the vitiated Vata Dosha. Brihat Saindhavadya Taila contains Sarii Kshara which is having Sukshma, Laghu and Tikshna properties which is Amahara and Kaphahara. It contains Triphala, which are Tridoshahara, Vata Anulomaka, Rasayana, Shothahara in action. Kanjika present in this Taila possess Bhedana, Rochaka, Pachaka properties, Shoola-AmaVibandhahara. Lavana present in Taila possess Deepana, Pachana, Shoolahara, Vibandhahara and Vatanulomaka properties. As Brihat Saindhavadya Taila contains drugs which possess Laghu, Ushna, Snigdha, Sukshma, Kshara, Tikshna, Vyavayi, Vata Anulomaka, Shoolahara, Shothahara properties along with Vata-Kaphahara. As Basti is considered as Sampoorna Chikitsa, combined effect of these drugs useful in reducing the Lakshana of Amavata.

CONCLUSION

Amavata is Kapha Vata Pradhana Vyadhi and is included under Rasavaha Srotovikara. It is mainly characterized by Sandhi Shoola, Sandhi Shotha and Sandhi Stabdhata along with symptoms such as Dourbalya, Angamarda, Aruchi, Trishna, Alasya, Gourava and Jwara. The disease Amavata has similarity with Rheumatoid arthritis in clinical presentation. The disease Amavata vis a vis Rheumatoid Arthritis is diagnosed based on classical signs and symptoms, specific laboratory tests like ESR, RA Factor and CRP and the individuals who comes under the 1987 Revised Criteria for the Classification of RA. A comparative clinical study was conducted on subjects of Amavata vis a vis Rheumatoid Arthritis with Rasnadi Churna Basti in one group and Ardha Matrika Basti in other group with 21 subjects in each group. In present study it is observed that within the groups showed statistically highly significant results in Sandhi Shoola, Sandhi Shotha, Sandhi Stabhdata, functional grading, ESR, and DAS parameters. There was no statistically significant difference in results between the groups. Both interventions help similarly in the management of Amavata.

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How to cite this article: Pratibha M Kodabal, V. Rajendra. A comparative clinical trial to evaluate the efficacy of Rasnadi Churna Basti with Ardha Matrika Basti in the management of Amavata vis-à-vis Rheumatoid Arthritis. J Ayurveda Integr Med Sci 2022;10:40-46.

http://dx.doi.org/10.21760/jaims.7.10.6

Source of Support: Nil, Conflict of Interest: None declared.

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