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Research Article

COMPARATIVE CLINICAL EVALUATION OF RASNASAPTAK KWATH AND VAITARANA VASTI IN THE MANAGEMENT OF AMAVATA (RHEUMATOID ARTHRITIS)

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ABSTRACT

Amavata is one of the challenging diseases for the physicians due to its chronicity, incurability, complications and morbidity. It is decided to evaluate certain Ayurvedic management for a series of patients of rheumatoid arthritis which could be safe, effective, cheap, and easily available. **Methodology:** Total 56 patients of RA (*Amavata)* fulfilling the inclusion criteria and having symptoms of RA were enrolled for clinical trial from OPD & IPD of department of Kayachikitsa, SS Hospital, IMS, BHU, Varanasi. Patients were treated in four different groups- **Group A-** 18 clinically diagnosed and registered patients of *Amavata* were treated by- *Rasnasaptak Kwath*- 40ml BD with lukewarm water. **Group B:** 16 clinically diagnosed and registered patients of *Amavata* were treated by *Vaitarana Vasti* for 2 times at interval of 15 days in the format of *Yoga Vasti* with *Anuvasana* of *Saindhavadi Talia*. **Group C:** 5 clinically diagnosed and registered patients of *Amavata* were treated by- *Rasnasaptak Kwath and Vaitarana Vasti*. **Group D:** 17 clinically diagnosed and registered patients of *Amavata* were treated by- Leflunomide 10mg OD **Results:** After the trial, treatment given for the clinical study, we got *Vata-Kapha* trait appears to be more vulnerable for *Amavata* disease. Overall effect of trial suggests that group C provided better improvement in comparison to group A, B and D in maximum objective and subjective criteria. **Discussion:** The study concludes that, planned trial drugs and procedure are effective in terms of reduction of symptomatology of *Amavata* (RA) as compared to standard treatment group.

INTRODUCTION

Ayurveda being one of the most traditional system of medicine*. Amavata* is one of them. With the march of time, most of the dietary habits, social structure, life style and environment have been changing. Occurrence of *Amavata* on large-scale is one of the outcomes of this modification. It is commonest among chronic inflammatory joint disease in which joints become swollen, painful and stiff. *Amavata* is the disease affecting *Abhyantara* and *Madhyama Roga Marga*, as it involves *Marma*, *Asthi* and *Sandhis*.

Amavata is a product of vitiation of *Tridosha* though *Ama* and *Vata* are the initiating factors in its pathogenesis the exacerbation makes the disease more *Kashtasadhya* (Ma.Ni. 25). Reflects the equal role of both *Dosha (Vata*) and *Dushya (Ama)* in the causation of this disease. Moreover, the chief pathogenic factors, being contradictory in nature possess difficulty in planning the line of treatment. Drugs are available to ameliorate the symptoms due to inflammation in the form of NSAIDS and the long-term suppression is achieved by the DMARDs. But most of the NSAIDs have gastrointestinal side effects whereas DMARDs have marrow, renal and hepatic suppression.[1]

Presently, non-steroidal anti-inflammatory drugs (NSAIDs) are the mainstay of treatment in this condition, however they have serious adverse effects and have limitations for a long-term therapy.[2] The immunosuppressive drugs are reserved for selected cases, while the disease modifying drugs like got are costly and have low benefit to risk ratio. Therefore, required for drugs having good efficacy.

It is decided to evaluate certain Ayurvedic management for a series of patients of rheumatoid arthritis which could be safe, effective, cheap, and

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easily available. The formulations under trial in this study, *Rasna Saptak kwath* and *Vaitarana Vasti*, are described in the Ayurvedic Text in *Chakradatta Amavataadhikara* (25/52- 56) and in *Chakradatta Niruhadhikara* (72/32) respectively. The selected trial drug *Rasnasaptak kwath* is mentioned by Acharya Chakrapani in Chakradatta in reference to *Amavata Rogadhikara*, and *Vaitarana Vasti* is also mentioned by in text Chakradatta in *Niruhadhikara* in reference of *Amavata* with the emphasis that they destroy the disease from its *Kwath*. *Rasna Saptak kwath* is given by oral rout and *Vaitarana Vasti* in the format of *Yoga Vasti* with *Saindhavadi Taila* as *Anuvasana*. *Vaitarana Basti* comprises of following drugs i.e., *Saindhava*, *Guda* (jaggery), *Chincha* (Tamarindus), *Gomutra, Tila Taila.*

OBJECTIVES

1. To evaluate the efficacy of Ayurvedic trial drug *Rasna Saptak Kwath* in the management of *Amavata.*
2. To evaluate the efficacy of Ayurvedic trial drug *Vaitarana Vasti* - in the management of *Amavata*
3. To evaluate the comparative effect of *RasnaSaptak Kwath* along with *Vaitarana Vasti* with Leflunomide in the management of *Amavata.*

METHODOLOGY

Selection of Cases: Total 60 patients of *Amavata* were randomly selected for the present study, from the Kayachikitsa OPD and IPD of Sir Sunder Lal Hospital, Institute of Medical Sciences, Banaras Hindu University, Varanasi. The case selection was random regardless of age, sex, occupation and socio-economic conditions. Both acute and chronic phase of *Amavata* patients were taken for the study, following the criteria of the diagnosis of Rheumatoid Arthritis in Modern Medicine and the clinical features of *Amavata* described in Madhava Nidana.

Inclusion Criteria

1. The patients of rheumatoid arthritis with mild, moderate and severe degree of presentation were included in the present study.
2. Seropositive and Seronegative both cases were included in present study.
3. The patients included will be within age group of 15-65 yrs.

Exclusion Criteria

1. The patients having severe degree of deformities.
2. The patients having severe ankylosed joints.
3. The patients with major complications were also excluded.
4. The patients on corticosteroid therapy.

Diagnostic Criteria

The diagnosis of RA is based on clinical criteria, with laboratory and radiology findings helping to establish the diagnosis. The 2010 American College of Rheumatology/European League Against Rheumatism (ACR/EULAR) diagnostic criteria was applied for diagnosis as well as assessment of trial. [3, 4]

Categories Score

A. Joint involvement

1- Large joint 0

2-10 large joints 1

1-3 small joints (with or without involvements of large joints) 2

4-10 small joints (with or without the involvement of large joints) 3

Greater than 10 joints (at least 1 small joint) 5

B. Serology (at least one test result is needed for classification)

Negative RF and negative ACPA 0 low-positive RF or low-positive ACPA 2 high-positive RF or high-positive ACPA 3

C. Acute phase reactants (at least 1 test result is needed for classification)

Normal CRP and normal ESR 0

Abnormal CRP and abnormal ESR 1

D. Duration of symptoms

Less than 6 weeks 0

Greater than or equal to 6 weeks 1

Study Design and Treatment Schedule

The sample of 60 patients presenting with classical signs and symptoms of *Amavata* according to Ayurvedic classics, after subjection to modern parameters were sub divided randomly into four groups. The treatment schedule decided for each group was as under: Out of 60 patients only 56 patients completed the follow up study.

Group-A

No. of patients	Medicine	Dosage	Duration & follow up
(n=18)	*Rasnasaptak kwath* (orally)	40- ml BD (lukewarm water)	45 days with a follow up every 15 day

Group-B

No. of patients	Medicine	Dosage	Duration & follow up
(n=16)	*Vaitarana V*asti for 2 times at interval of 15 days in the format of *Yoga Vasti* with *Anuvasana* of *Saindhavadi Talia*	350ml *Vasti dravya*	Two times (for 8 DAYS) with a gap of 15 days, follow up every 15th day.

Group-C

No. of patients	Medicine	Dosage	Duration & follow up
(n=5)	*Vaitarana Vasti* for 2 times at interval of 15 days in the format of Yoga *Vasti* with *Anuvasana* of *Saindhavadi Taila* followed by *Rasnasaptak kwath* (orally)	350ml *Vasti dravya* 40- ml BD (Lukewarm water)	Two times (for 8 DAYS) with a gap of 15 days, follow up every 15th day. 45 days with a follow up every 15 day.

Group-D:

No. of patients	Medicine	Dosage	Duration & follow up
(n=17)	Leflunomide	10mg-OD	45 days with a follow up every 15 day

Nature of Study: Open randomized clinical trial.

Ethical approval: The clinical trial approval has been taken from Ethical committee of IMS, BHU, with reference no- 2018-23/EC/506

Investigations

1- Hematological Investigations

- TLC, DLC, Hemoglobin, platelets and ESR were evaluated.

2- Bio- Chemical Investigations

- Rheumatoid Factor (Normal value <20 IU/ml)
- C- Reactive Protein (Normal value <0.8mg/dl)
- Anti-cyclic citrullinated peptide Antibodies (Normal value <20 IU/ml)

Follow up Studies: On each follow up the patients were assessed for clinical symptoms, including physical examination. Laboratory investigations (HB, CRP, ESR, ACPA and RA factor) were obtained before and after trial treatment.

Statistical Analysis [5,6]

Continuous Variable

Intra-group (within the group) comparison: To test the significance of difference of mean of paired observations (BT and AT) Paired t test was applied. Wherever, the data did not satisfy the assumptions of parametric test viz., Wilcoxon Signed- Rank test was applied. In case of repeated measurements of same subject for various follow-ups, Repeated Measure ANOVA (Analysis of Variance) was applied whereas, a corresponding non-parametric test applicable here was Friedman Chi- square test.

Inter-group (within the group) comparison: To test the significance of difference of means of two independent groups Unpaired t test (Independent t test) was applied. Wherever, the data did not satisfy the assumptions of parametric test viz., Mann- Whitney test was applied. In case of more than two independent groups, One-way ANOVA (Analysis of Variance) was applied whereas, a corresponding non- parametric test applicable here was Kruskal- Wallis test.

Categorical Variable: For nominal and ordinal variables like signs and symptoms, cross tables showing number and percent before treatment and at different follows according to groups were shown.

Statistical Significance

p <0.05 considered as statistically significant

p <0.01 or p <0.001 as highly statistically significant

p >0.05 not statistically significant

OBSERVATION AND RESULTS

Along with literary and conceptual studies in the present study observation have been made on following aspects:

1. Demographic profile
2. Clinical and laboratory profile of *Amavata.*

A. Demographic profile

Table 1: Age and sex incidence in 60 patients of *Amavata*

Age group (in year)	Male		Female		Total	
	No.	%	No.	%	No.	%
15-25	6	10	15	25	21	35
26-35	3	5	3	5	6	10
36-45	2	3.33	9	15	11	18.33
46-55	4	6.66	8	13.33	12	20
56-65	3	5	7	11.66	10	16.66

Out of 60 patients taken for study 18 were male and 42 were female. Incidence of disease is found notably higher in females than in males. Though rheumatoid arthritis affects all age groups, the maximum number of patients registered were in between 15- 25 years of age group (35%).

Table 2: Incidence of occupational status in 60 patients of *Amavata*

Occupation	No. of Patient	Percentage
Housewife	28	46.66
Service	11	18.33
Student	9	15
Labour	6	10
Farmer	6	10

Majority of patient in the present study were housewives (46.66%) followed by serviceman (18.33%), labors (10%), student (15%), farmer (10%).

Table 3: Incidence of dietary habit of 60 patients of *Amavata*

Dietary habit	Male		Female		Total	
	No.	%	No.	%	No.	%
Vegetarian	13	21.66	22	36.66	35	58.33
Mixed Vegetarian	8	13.33	17	28.33	25	41.66

In the present study among 60 patient 35 (58.33%) were found vegetarian and 25 (41.66%) patient had mixed diet.

Table 4: Incidence of Habitat of 60 patients of *Amavata*

Habitat	Male		Female		Total	
	No.	%	No.	%	No.	%
Rural	8	13.33	12	20	20	33.33
Urban	13	21.66	27	45	40	66.66

In the present study among 60 patients 20 patients (33.33%) patients are rural origin and 40 (66.66%) patients are of urban origin.

Table 5: Incidence of bowel habit of 60 patients of *Amavata*

Bowel habit	Male		Female		Total	
	No.	%	No.	%	No.	%
Normal	7	11.66	8	13.33	15	25
Altered	9	15	23	38.33	32	53.33
Constipated	5	8.33	8	13.33	13	21.66

In the present study among 60 patients of *Amavata* were found constipated bowel habit in 13 (21.66%) patient. Altered bowel habit 32 (53.33%) and normal bowel habit in 15 (25%) patient.

Assessment of *Deha Prakriti* was done in all 60 patients. *Dwidoshaja Prakriti* with a relative incidence of 43.33% was found in *Vata Kapha*, 26.66% in *Vata-Pitta*, 16.66% in *Pitta Kapha Prakriti* and 13% in *Tridosaj Prakriti*. No case recorded in *Ekdoshaja Prakriti*. Thus, *Vata Kapha* trait appears to be more vulnerable for *Amavata* disease.

Table 6: Mean change in RA titre in 56 patients of *Amavata*

Group	BT	AT	BT~AT	Intra group comparison Paired t test	Inter group comparison on difference of mean AT
Group A (n=18)	43.06±57.39	17.77±20.43	25.28±48.11	3.32p<0.001 H. S	A vs D t=1.43 p=0.05 S
Group B (n=16)	87.95±78.14	21.65±15.62	66.30±76.20	3.89 p<0.001 H. S	B vs D t=2.39 p<0.01 Hs
Group C (n=5)	88.80±84.54	20.65±15.60	65.40±76.10	3.80p<0.001 H. S	C vs D t=2.89 p<0.01 Hs
Group D (n=17)	41.50±21.35	41.13±27.63	37.50±20.89	0.961 p>0.05 H. S	

In Group A, 't' value is 3.32 and p<0.01, so highly significant. In Group B 't' value is 3.89 and p<0.001, so highly significant. In Group C, 't' value is 0.05 and p>0.05, so not significant. In Group D, 't' value is 0.961 and p>0.05, so not significant. When the mean difference in Group A and B was compared with Group C the result is

statistically highly significant, therefore mean difference in Group A and B may be considered as more effective than Group C.

Table 7: Mean change in anti CCP Antibody in 56 patients of *Amavata*

Group	BT	AT	BT~AT	Intra group comparison Paired t test	Inter group comparison on difference of mean AT
Group A (n=18)	27.22±16.823	17.06±5.047	10.16±11.776	Z=2.83, P<0.001HS	A vs D, Z=1.62, p>0.05NS
Group B (n=16)	29.19±17.05	17.38±8.461	11.18±8.589	Z=3.01, P<0.001HS	B vs D, Z=1.61, p>0.05NS
Group C (n=5)	28.85±14.51	17.54±8.894	11.19±8.845	Z=2.99, P<0.001HS	C vs D, Z=1.61, p>0.05NS
Group D (n=17)	30.06±18.532	28.16±17.553	1.94±0.979	Z=2.80, P<0.01HS	

The result was highly significant in all the groups. In intergroup comparison, the difference of means was not statistically significant between A & D as well as B & D, but the difference in means BT & AT was greater in Group B so Group B shows better improvement.

Table 8: Mean change in CRP in 56 patients of *Amavata*

Group	BT	AT	BT~AT	Intra group comparison Paired t test	Inter group comparison on difference of mean AT
Group A (n=18)	6.32±4.89	2.50±3.15	3.820±5.115	4.72p<0.001HS	A vs C T=3.58 P<0.001HS
Group B (n=16)	6.65±6.67	1.73±1.29	4.915±4.84	4.54p<0.001HS	B vs C T=4.00 P<0.001HS
Group C (n=5)	6.70±6.78	7.95±8.35	4.818±3.84	4.55p<0. 001H.S	C vs D T=3.66 P<0.05S
Group D (n=17)	3.68±2.39	4.90±5.62	1.22±4.9	1.60p<0.05NS	

In Group A, 't' value is 4.72 and p<0.001, so highly significant. In Group B, 't' value 4.54 and p<0.001, so highly significant. In Group C, 't' value is 4.55 and p<0.001 so not significant. In Group D 't' value is 1.60 and p<0.05 so not significant. When the mean difference in Group A and B was compared with Group D the result is statistically highly significant, therefore mean difference in Group A and B may be considered as more effective than Group C.

Table 9: Mean change in Hb% in 56 patients of *Amavata*

Group	BT	AT	BT~AT	Intra group comparison Paired t test	Inter group comparison on difference of mean AT
Group A (n=18)	11.27±1.40	11.88±1.31	0.6075±0.756	5.08p<0.05S	A vs D T=3.34 P<0.05S
Group B (n=16)	11.99±1.33	12.29±1.17	0.305±0.383	3.56p<0.01HS	B v s D T=3.63 P<0.05S
Group C (n=5)	11.00±0.05	11.56±1.8	0.305±0.991	0.31p<0.01H.S	C vs D T=3.5 P<0.05S
Group D (n=17)	10.65±1.40	10.98±1.40	0.325±0.498	1.08p<0.05S	

In Group A, 't' value is 5.08 and p<0.05, so significant. In Group B, 't' value is 3.56 and p<0.01, so significant. In Group C, 't' value is 0.31 and p<0.01, so significant. In Group D, 't' value is 1.08 and p<0.05, so significant.

Table 10: Mean change in ESR in 56 patients of *Amavata*

Group	BT	AT	BT~AT	Intra group comparison Paired t test	Inter group comparison on difference of mean AT
Group A (n=18)	44.50±13.26	27.75±8.39	16.75±15.33	6.91p<0.001HS	A av D T=3.83 P<0.001HS
Group B (n=16)	48.55±10.20	29.40±7.40	19.15±10.97	7.80p<0.001HS	B vs D T=5.53 P<0.001HS
Group C (n=5)	11.99±1.33	12.29±1.17	0.305±0.383	3.56p<0.01HS	C vs D T=3.63 P<0.05S
Group D (n=17)	34.00±9.01	38.75±11.56	4.75±8.34	1.61p<0.151HS	

In Group A, 't' value is 6.91 and p<0.001, so significantly. In Group B, the 't' value is 7.80 and p<0.001, so highly significant. In Group C, 't' value is 3.56 and p<0.01, so not significant. In Group D, 't' value is 1.61 and p<0.151. When the mean difference in Group A and B was compared with Group C the result is statistically highly significantly, therefore mean difference in Group A and D may be considered as more effective than Group C.

DISCUSSION

The aim of this study was mainly to decide whether *Shamana (Rasnasaptak Kwath*) or *Shodhana* (in the form of *Vaitarana Vasti*) along with *Shamana (Rasnasaptak Kwath*) is the better way to acquire desired results.

Out of 60 patients registered for study 18 were male and 42 were female. Incidence of disease is found notably higher in females than in males. Though rheumatoid arthritis affects all age groups, the maximum number of patients registered were in between 36-45 years of age group (30%) followed by 26-35 years of age group (25%) In the present study of age and sex incidence in the patients of *Amavata* revealed maximum number of patients in third to fifth decade of their life, while there was a progressive decline of the incidence in the 6th and 7th decade. Higher incidence was found in accordance with the reported incidence in India and abroad. [7]

The disease was found more prevalent in housewives 50%. It may be because of higher incidence of females in general, and because of that most of the females of Indian population are engaged in household activities. The nature of household work, due to *Vega Dharana*, irregular delay habits, would have probably triggered the disorder more in females. Most of the patients enrolled for the study were of mixed dietary habit 60% & 40% patients had vegetarian diet.

All registered patients were examined to determine their *Deha Prakriti*. No case was recorded to have *Ekdoshaj Prakriti. Dwidoshaja Prakriti* with a relative incidence of 46.66% was found in *Vata kapha*, 23.33% in *Vata-Pitta*, 20% in *Pitta Kapha Prakrihi* and 10% in *Tridosaj Prakriti*. Thus, it was found that *Vata* predominant *Prakriti* is prone to develop *Amavata*. This seems rational because the natural predominance of *Vata* must be adding to the precipitation and exacerbation of the disease in the otherwise prone individuals. Patients with *Kapha* associated *Vata* suffered more which may be because *Kapha* shows similar nature like. Even though 23.33% of the patients were observed to be of *Vata Pitta* nature, the course of *Ama* the disease was of mild in those patients, as the *Pitta Guna* are opposite to those of *Ama*.

66.66% patients were resident in urban area and 33.33% patients were from the Rural area. This indicates the higher proportion of patients in urban area (Davidson). According to modern concept of RA, genetic predisposition is one, among the major cause of this disease. But the data shows that 70% patient gave negative family history of the disease. So, it can be said that *Nidana Sevana* plays important role in the manifestation of the disease compared to presence of family history.

Significant reductions were seen in the mean titre value of anti CCP antibody and mean ESR in all group A, B, and C. But the difference of means was greater in Group D. Mean reduction in CRP, RF, Hb was statistically significant in group A and B whereas it was non-significant in group C, with greater difference in group B.

The present study on the basis of observation and results shows that *Rasnasaptak Kwath* is significantly efficacious in patients of *Amavata* but the patients in whom it was given along with *Vaitarana Vasti*, the improvement was much better. This explained on the basis of difference in *Shamana* and *Shodhara Chikitsa. Gumana* therapy, though effective, is not able to completely remove *Doshas* out of body. When a bulk of *Doshas* is cleared after *Vaitarana Vasti*.

CONCLUSION

Rasnasaptak Kwath acts to pacify remaining *Doshas* and helps in *Apunarbhava Chikitsa* by virtue of *Shoolaprashman* action of *Rasnasaptak Kwath*. Thus, when administered in parallel, *Rasnasaptak Kwath* and *Vaitarana Vasti* produce action like "summation", i.e. additional action due to combination is also produced. The trial formulation *Rasnasaptak Kwath* is effective in the management or more precisely cure of *Amavata*. But it shows better result when given along with *Shodhana* in the form of *Vaitarana Vasti* in the format of *Yoga Vasti* with *Saindhavadi Taila* as *Anuvasana*. *Rasnasaptak Kwat*h acts due to *Deepana, Pachana, Sukshma Srotogamita, Vatakaphaghna* and *Shoola prashamana* properties. *Vaitarana Vasti* acts due to the action of *Vasti Karma* itself as well as *Deepana*, *Pachana*, *Srotoshodhana* and *Vatashamana* actions.

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