

A COMPARATIVE CLINICAL STUDY TO EVALUATE THE ADDED EFFICACY OF *SHUNTHYADI GHRITHA* AND *AJAMODA NIRGUNDYADI YOGA* IN THE MANAGEMENT OF *AMAVATA VIS-À-VIS RHEUMATOID ARTHRITIS*

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ABSTRACT

Introduction: *Amavata* is a *vata-kapha pradhana tridoshaja vyadhi* and *rasavaha strotajanya vikara* which is originating due to *ama*. It is mainly characterized by *shoola*(pain), *shotha*(swelling), and *sthabhdata* (morning stiffness) in *sandhi* due to *vikruta vata* associated with *ama*. The disease *amavata* has similarity with Rheumatoid arthritis in clinical presentation. **Methodology:** To compare and evaluate the added efficacy of *Shuntyadi ghritha* and *Ajamoda nirgundyadi yoga* (an indigenous formulation) in the management of *Amavata vis-a-vis Rheumatoid Arthritis*. It was a comparative clinical study with pre and post-test design, with sample size of 60 subjects, 30 subjects in each group. Assessment parameters used in the present

study were *sandhishoola*, *sandhi shotha*, *sandhi sthabhdata* and functional gradings. The data was collected on 0th day, 9th day (after *bastikarma*) and 30th day (after *shamanoushadhi*).

Result: The overall assessment revealed that both the groups are equally effective. The comparison of results between the group is statistically insignificant, hence the hypothesis of difference in added efficacy between the group is disproved. **Conclusion:** In the present study, on comparing the overall effect, it was observed that both the groups are equally effective. Hence, *Dwipanchamooladi basti* followed by oral administration of *Shuntyadi*

ghrita and *Dwipanchamooladi basti* followed by oral administration of *Ajamoda nirgundyadi yoga* has a better role to play in the management of *Amavata*.

KEYWORDS: *Amavata*, Rheumatoid Arthritis, *Shuntyadi ghrita*, *Ajamoda nirgundyadi yoga*.

INTRODUCTION

Amavata is a pain predominating and movement restricting disease, it hampers the normal activities of the patient. *Amavata* poses a challenge to the physician owing to its chronicity, incurability, complications and morbidity. *Amavata* is a *rasadushita vikara* and is mainly due to the impairment of *jataragni* and *dhatwagni*, resulting in the production of *ama*. Such *ama* when gets associated with *vikruta vata* and gets located in sandhi produces *shoola*(pain), *shotha*(swelling) and *Sthabhdhata* (stiffness) of *sandhi* (joints).^[1]

Amavata is having similarities with disease Rheumatoid arthritis.

Rheumatoid arthritis (RA) is a chronic systemic inflammatory polyarthritis that primarily affects small diarthrodial joints of the hands and feet in a symmetrical pattern. It is a heterogenous disease with variable severity, unpredictable course and a variable response to drug treatment.^[2]

Ayurveda explains two important treatment modalities i.e *Shodhana* and *Shamana* in the management of *Amavata*.

The line of treatment described in *Chakradatta*^[4] is as follows: *Agnideepana*, *Amapachana* and *Shodhana*. In the present study, *Dwipanchamooladi niruha basti*^[3] was administered to both the groups. It possess *amadoshahara*, *vata-kaphahara*, *rasayana*, *balya*, *vedanasthapaka*, *shothahara* properties.

OBJECTIVE

Primary objective

- To evaluate and compare the added efficacy of *Shuntyadi ghrita* and *Ajamoda nirgundyadi yoga* in the management of *Amavata* vis-à-vis Rheumatoid Arthritis.

Secondary Objective

- To evaluate the combined effect of *Dwipanchamooladi niruha basti* followed by *Shuntyadi ghrita* in the management of *Amavata* vis-à-vis Rheumatoid Arthritis.
- To evaluate the combined effect of *Dwipanchamooladi niruha basti* followed by *Ajamoda nirgundyadi yoga* in the management of *Amavata* vis-à-vis Rheumatoid Arthritis.

MATERIALS AND METHODS

Source of Data: Subjects were selected from OPD and IPD of Government Ayurvedic Medical College and Hospital, Hi-Tech panchakarma Hospital, Mysuru.

Sample size and Sampling methods

- The study was completed in 60 patients, irrespective of gender, socio-economic status and religion, having the signs and symptoms of *Amavata* vis-à-vis Rheumatoid Arthritis were registered for the study with the help of a proforma prepared for the purpose of study after taking informed consent.
- Incidental selection and purposive sampling technique was employed.
- Out of 67 subjects registered, total number of drop outs are 7, 3 dropouts in Group A and 4 dropouts in Group B and the study was completed in 60 subjects with 30 subjects in each Group.

DIAGNOSTIC CRITERIA

- The diagnosis was done based on the classical signs and symptoms of *Amavata* such as *ruja*(pain), *shotha*(swelling) and *sthambha*(morning stiffness) in the *sandhi*(multiple joints).

The new 2010 ACR-EULAR Classification Criteria for Rheumatoid Arthritis

- Target population (Who should be tested?): Subjects who: Have at least 1 joint with definite clinical synovitis (swelling) With the synovitis not better explained by another disease.
- Classification criteria for RA (score-based algorithm: add score of categories A–D; A Score of >6/10 is needed for classification of a subject as having definite RA)

INCLUSION CRITERIA

- Subjects irrespective of gender, aged between 18-60 years were included in the study.

- Subjects fit for *Basti karma* were included in the study.
- Both fresh cases and who have underwent treatment were included in the study.
- Individuals fulfilling the 2010 ACR EULAR classification criteria of Rheumatoid arthritis were included in the study irrespective of sero-positive or sero-negative Rheumatoid Factor.

EXCLUSION CRITERIA

- Subjects with co-morbidity of uncontrolled diabetes mellitus, uncontrolled hypertension and other systemic disorders which interferes with the intervention were excluded from the study.
- If subjects suffer with any rectal pathologies like hemorrhoids, fissure, rectal prolapse were excluded from the study.
- Pregnant & Lactating women were excluded from the study.

INTERVENTION

- This was a comparative clinical trial consisting of two groups. The interventions were as follows.

Group A

- *Dwipanchamooladi niruha basti* was administered in *yogabasti* pattern for first 8 consecutive days of intervention. *Shuntyadi ghrita* was administered orally in the dose of 12 ml once daily in the early morning before food, followed by luke warm water from 9th to 30th day.

Group B

- *Dwipanchamooladi niruha basti* was administered in *yogabasti* pattern for first 8 consecutive days of intervention. *Ajamoda nirgundyadi yoga* was administered orally in the dose of 12gms in two equally divided doses twice daily after food with luke warm water from 9th to 30th day.

Period of Intervention is 30 days.

ASSESSMENT

In this study, total three assessments of the subjects were done. Pre-test assessment was done on 0th day, Mid assessment was done on 9th day (after *basti* therapy) and Post-test assessment i.e, after the completion of the intervention was done on 30th day.

STATISTICAL METHODS

The results were statistically analysed using statistical methods such as Descriptive statistics, Chi-square test, paired sample 't' test and Contingency co-efficient analysis.

INVESTIGATIONS

- For Assessment and Diagnostic purpose, following investigations were done before and after the completion of intervention:
- Rheumatoid Factor.
- C-reactive protein.
- ESR.
- Other blood investigations and urine analysis were done wherever necessary to exclude other systemic disorders.

OBSERVATIONS AND RESULTS

OBSERVATIONS

- In the present clinical study, total 67 subjects were registered. Among them 33 subjects were assigned into Group A and 34 subjects were assigned into Group B. There were totally 7 drop outs, 3 drop outs in Group A and 4 drop outs in Group B at the various stages of intervention. Clinical study was completed in 60 subjects with 30 subjects in each group.

OVERALL ASSESSMENT

- In the present study, in Group A, maximum number of subjects i.e 14(47%) got moderate improvement, 12(40%) subjects got marked improvement and 4(13%) subjects got mild improvement.
- In Group B, maximum number of subjects i.e 17(57%) subjects got moderate improvement, 10(33%) subjects got marked improvement, and 3(10%) subjects got mild improvement.
- Overall assessment out of 60 subjects it is revealed that maximum number of subjects i.e 31(52%) subjects got moderate improvement, 22(37%) subjects got marked improvement, and 7(11%) subjects got mild improvement.
- The overall assessment revealed that both the groups are equally effective P value 0.004. The comparison of results between the group is statistically insignificant, hence the hypothesis of difference in added efficacy between the group is disproved.

Table no 1: showing the incidence of RA factor in subjects of *Amavata*.

Group		RA Factor		Total
		Positive	Negative	
Group A	BT	25(83.0%)	5(17.0%)	30(100%)
	AT	22(73.0%)	8(27.0%)	30(100%)
	Total	47(78.0%)	13(22.0%)	60(100%)
Group B	BT	23(77.0%)	7(23.0%)	30(100%)
	AT	21(70.0%)	9(30%)	30(100%)
	Total	44(73.0%)	16(27.0%)	60(100%)

Table no 2: showing incidence of C-Reactive Protein in RA subjects.

Group		CRP		Total
		Positive	Negative	
Group A	BT	18(60.0%)	12(40.0%)	30(100%)
	AT	13(43.0)	17(57.0%)	30(100%)
	Total	31(52.0%)	29(48.0%)	60(100%)
Group B	BT	12(40.0%)	18(60.0%)	30(100%)
	AT	10(33.0%)	20(67.0%)	30(100%)
	Total	22(37.0%)	38(63.0%)	60(100%)

Table no 3: showing the incidence of ESR in RA subjects.

ESR	GROUP A		GROUP B	
	BT	AT	BT	AT
0-20mm/hr	3(10.0%)	12(40.0%)	2(7.0%)	10(33.0%)
21-40mm/hr	7(23.0%)	10(33.0%)	10(33.0%)	8(27.0%)
41-60mm/hr	5(17.0%)	6(20.0%)	6(20.0%)	5(17.0%)
61-80mm/hr	5(17.0%)	2(7.0%)	5(17.0%)	4(13.0%)
81-100mm/hr	7(23.0%)	0(0.0%)	6(20.0%)	3(10.0%)
>100mm/hr	3(10.0%)	0(0.0%)	1(3.0%)	0(0.0%)
Total	30(100%)	30(100%)	30(100%)	30(100%)

Table no 4: showing the results on reduction of *Sandhishoola*.

		Descriptive	Statistics		
	Sandhi shoola S1	Group	Mean	Standard Deviation	N
S1	0 th day- Pre test	Group A	26.6000	8.66506	30
		Group B	33.0800	10.76615	30
		Total	29.8400	10.21076	60
S1	9 th day – Mid test	Group A	8.9600	5.47327	30
		Group B	13.5200	7.28652	30
		Total	11.2400	6.78101	60
S1	30 th day – Post test	Group A	3.6800	3.70495	30
		Group B	9.8400	7.11618	30
		Total	6.7600	6.41923	60
Source	Type-III sum of squares	Df	Mean square	F	Significance
Change	14978.613	2	7489.307	387.740	0.000

Change *group	26.453	2	13.227	0.685	0.507
Error(change)	1854.267	96	19.315		

Table no 5: showing the results on reduction of *Sandhishotha*.

		Descriptive	Statistics		
	Sandhi shotha S2	Group	Mean	Standard Deviation	N
S2	0 th day- Pre test	Group A	18.2000	6.50641	30
		Group B	19.0400	5.45802	30
		Total	18.6200	5.95867	60
S2	9 th day – Mid test	Group A	6.1600	4.20000	30
		Group B	8.3600	4.21189	30
		Total	7.2600	4.30856	60
S2	30 th day – Post test	Group A	3.7600	7.51266	30
		Group B	4.6000	3.95811	30
		Total	4.1800	5.95798	60

Source	Type-III sum of squares	df	Mean square	F	Significance
Change	5784.160	2	2892.080	164.567	0.116
Change *group	15.413	2	7.707	0.439	0.646
Error(change)	1687.093	96	17.574		

Table no 6: showing the results on reduction of *Sandhisthabdata*.

		Descriptive statistics			
	Sandhi sthabdata S3	Group	Mean	Standard Deviation	N
S3	0 th day- Pre test	Group A	23.3600	9.31790	30
		Group B	27.4000	9.17424	30
		Total	25.3800	9.37624	60
S3	9 th day – Mid test	Group A	7.8800	5.51755	30
		Group B	12.2000	6.46142	30
		Total	10.0400	6.33410	60
S3	30 th day – Post test	Group A	3.2000	4.61880	30
		Group B	8.0000	6.35741	30
		Total	5.6000	6.01020	60

Source	Type-III sum of squares	df	Mean square	F	Significance
Change	10771.293	2	5385.647	325.510	0.000
Change *group	3.693	2	1.847	0.112	0.895
Error(change)	1588.347	96	16.545		

Table no 7: showing the results on improvement of Functional Gradings.

Groups							Total
			1	2	3	4	
Group A	Session	Day 0	5	14	7	4	30
			Grade	47.0%	23.0%	13.0%	100%
		Day 9	7	19	2	2	30
			23.0%	63.0%	7.0%	7.0%	100%
		Day 30	22	6	1	1	30
			74.0%	20.0%	3.0%	3.0%	100%
		Total	34	39	10	7	90
			38.0%	43.0%	2.0%	8.0%	100%
Group B	Session	Day 0	6	10	14	0.0%	30
			20.0%	33.0%	47.0%	0.0%	100%
		Day 9	9	18	3	0.0%	30
			30.0%	60.0%	10.0%	0.0%	100%
		Day 30	18	12	0	0.0%	30
			60.0%	40.0%	0	0.0%	100%
		Total	33	40	17	0.0%	90
			37.0%	44.0%	19.0%	0.0%	100%

Tableno 8: showing the results on overall assessment.

		Group Cross tabulation		
		Group		Total
		A	B	
Marked improvement	Count	12(40.0%)	10(33.0%)	22(37.0%)
Moderate improvement	Count	14(47.0%)	17(57.0%)	31(52.0%)
Mild improvement	Count	4(13.0%)	3(10.0%)	7(11.0%)
No improvement	Count	0(0.0%)	0(0.0%)	0(0.0%)
Total	Count	30(100%)	30(100%)	60(100%)

► DISCUSSION

The ingredients of Dwipanchamooladi basti possess vata-kapha hara properties, vedanasthapaka, shothahara, deepana, pachana, balya, rasayana, jwarahara, anulomaka properties. Bruhat saindhavaadi taila^[5] used for Anuvasana basti possess vatanulomaka, shoolahara, shothahara along with Vata-kaphahara and tridoshahara properties. Hence it has therapeutic action in Amavata. Gomutra^[6] used for basti possesses tridoshahara, agnideepana, amapachana, sroto vishodana and vata anulomana properties, and also it is immnomodulatory in action and exhibits antioxidant properties.

Shuntyadi ghrita^[7] is Shoolahara, shophahara, jwarahara, adhmana hara, amavata hara, ojas tejo-balakaram, agnidipaka and aanaha hara in action. Gingerols and diaryl heptanoids of

Shunti act as potent inhibitor of prostaglandin biosynthesis^[8] enzyme and acts as a potent GI stimulant. Hence, it is therapeutically effective in Amavata. Ghrita is ojas tejo-balakaram, agnidipaka, shula-jwara-aanaha hara. Shunti possesses Deepana and Pachana properties, which improve Jatharagni. When Jatharagni is improved, it leads to the formation of other Dhatus and checks the formation of Ama. By virtue of Ushna Veerya, it digests and absorbs the vitiated Ama by its Shoshana Karma. Scientifically, it has been proved that Shunti possesses active principles of gingerol, dehydrozingerone, and gingerdione, and they are potent inhibitors of prostaglandin synthesis, indicating the mechanism of an anti-arthritis effect. Hence, this formulation is effective in correcting the pathological condition of the disease Amavata.

Ajamoda nirgundyadi yoga^[9] contains drugs which are *tridosahara*, mainly *vatakaphahara* with properties such as *amahara*, *deepaka*, *shoolahara*, *deepaka* and *balya* properties, ingredients also possess anti-inflammatory, analgesic and anti-rheumatic actions by this it is therapeutically effective in Amavata.

CONCLUSION

The disease Amavata explained in Ayurvedic classical texts is having close similarities in clinical presentation with the disease Rheumatoid Arthritis as explained in modern texts. The observation made in this study with respect to incidence of age and gender matches with general prevalence of Rheumatoid arthritis. In the present study, on comparing the overall effect of the study, it was observed that both the groups are equally effective. Hence, *Dwipanchamooladi basti* followed by oral administration of *Shuntyadi ghrita* and *Dwipanchamooladi basti* followed by oral administration of *Ajamoda nirgundyadi yoga* has a better role to play in the management of Amavata. Both groups showed statistically highly significant results. Hence, both are very effective in the management of RA. The comparison of results between the group is statistically insignificant, hence the hypothesis of difference in added efficacy between the group is disproved.

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