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A clinical study to evaluate the *Upashayatmaka* effect of *Trikarshika Kwatha* in *Amavata* (Rheumatoid Arthritis)

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ABSTRACT

Background: *Amavata* is the disease which is caused due to the involvement of *Ama* and *Vata*. Rheumatoid Arthritis is having significant parlance with *Amavata* in terms of the symptoms produced in the body. The prevalence of Rheumatoid Arthritis is approximately 0.8% of the population. Women are affected approximately three times more often than men. **Objectives:** To carry out comprehensive literary work covering classical and modern aspect of *Amavata* and to evaluate the *Upashayatmaka* effect of *Trikarshika Kwatha* in *Amavata*. **Methodology:** A Single group open labelled clinical study with pre and post test design was carried out in 30 subjects of *Amavata* aged 16-70 years. Patients were analyzed and selected accordingly who fulfilled the diagnostic and inclusion criteria. *Trikarshika Kwatha* 48ml twice a day before food was given for 15 days. Detailed proforma was prepared to assess the observation. **Results:** All the parameters were highly statistically significant with $p < 0.001$ except RA Factor which was statistically insignificant throughout the study. **Conclusion:** *Trikarshika Kwatha* proved beneficial in reducing the symptoms of *Amavata*.

Key words: *Amavata*; *Rheumatoid Arthritis*; *Upashaya*; *Trikarshika Kwatha*.

INTRODUCTION

Ayurveda, the Holistic branch of science is welcomed globally for its rich heritage and everlasting principles and concepts. It stems from the ancient *Vedic* culture and is considered to be the oldest healing science. *Ayurveda* advocates the principle that "Prevention is better than cure". Accordingly, various theories have

been proposed to maintain a healthy life.

Human beings live in an era where there is rapid advancement in the field of Science and Technology. This advancement has made their lives much easier at the same time a bit complicated. The ultimate aim of life is to attain the *Dharma*, *Artha*, *Kama*, *Moksha*. In an attempt to lead a luxurious life, regardless of health, they started harming their body. Thus, knowingly, or unknowingly they are prone to various diseases.

Movement is a fundamental aspect of life. When the movement gets affected, life becomes miserable harming the daily activities. Sedentary lifestyles pose serious impact on the physical function giving birth to many diseases, most common among them being diseases affecting the joints.

Amavata is one of the crippling diseases claiming maximum loss of human power. It is caused due to

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Mandagni.^[1] The two principle causative factors *Ama* and *Vata* have equal importance in the pathogenesis of the disease. The improper digestion of the food that results in the *Apakva Anna Rasa* or *Ama* is considered to be the root cause of various diseases, important among them is *Amavata*.

When one indulges in *Viruddha Ahara*, *Ama* associated with vitiated *Vayu* moves to different *Sleshma Sthanas* and *Dhamanis* and blocks the channels. It simultaneously affects the joints and causes stiffness of the body. It also produces symptoms like *Angamarda*, *Aruchi*, *Trishna*, *Alasya*, *Gourava* and *Jwara*.

Acharya Charaka has used the term *Amavata* in various contexts, while *Acharya Vaghbhatta* has told the *Lakshanas* of *Sama Vata* while describing the *Sama Doshas*. The disease was described in detail as a separate chapter for the first time by *Acharya Madhava*. According to *Madhavakara*, *Amavata* falls under the category of *Vata Kaphaja Vyadhis*. It is observed that Rheumatoid Arthritis is an autoimmune disease having strong and significant parlance with *Amavata*.^[1]

Rheumatoid Arthritis is a chronic multisystem disease of unknown cause. The prevalence of Rheumatoid Arthritis is approximately 0.8% of the population. Women are affected approximately three times more often than men. The prevalence increases with age. The characteristic feature of Rheumatoid Arthritis is persistent inflammatory synovitis, usually involving peripheral joints in a symmetric distribution. The potential of synovial inflammation to cause cartilage damage and bone erosion and subsequent changes in joint integrity is the hallmark of the disease. Although the causes for Rheumatoid Arthritis remain unknown, Auto-immunity plays an important role in its chronicity and progression. Therefore, it has become the foremost among the joint disorders.^[2]

Though there are analgesics, anti inflammatory drugs, immunosuppressants and disease modifying antirheumatic drugs for the management of Rheumatoid Arthritis, their long-term use causes

adverse effects.^[3] Hence, there is a scope for safer treatment modalities.

In *Ayurvedic* classics, various treatment modalities for *Amavata* have been explained in detail. After much exploration, "*Trikarshika Kwatha*" was chosen to evaluate its efficacy in the disease *Amavata*. It is explained by *Chakradatta*.^[4] It comprises of *Amrutha*, *Nagara* and *Dhanyaka* 1 *Karsha* each. It has *Deepana*, *Pachana*, *Vatakapahara* properties.

Considering the increased incidence of *Amavata*, the present study is planned as "A Clinical study to evaluate the *Upashayatmaka* effect of *Trikarshika kwatha* in *Amavata* (Rheumatoid Arthritis).

Materials and Methods

Sample source

Minimum of 30 patients of either sex suffering from *Amavata* were selected for the study. Patients were analyzed and selected accordingly who fulfills the Diagnostic and Inclusion criteria.

Preparation of Drug: *Trikarshika Kwatha*

Ingredients

Guduchi, *Nagara*, *Dhanyakam* were taken in equal quantity and the *Kashaya* was prepared according to the classical method as mentioned in *Sharangadhara Samhitha*.^[5]

Inclusion criteria

- Age of patients between 16 to 70 years.
- Patients of either sex were included.
- Patients fulfilling the diagnostic criteria.

Exclusion criteria

- Patient suffering from other serious systemic, complicated diseases.
- Patient with other types of Arthritis like Gouty Arthritis, Psoriatic Arthritis.
- Lactating and pregnant women.

Diagnostic criteria

- Diagnosis is made on the basis of classical symptoms of *Amavata*.

- Based on 2010 American College Of Rheumatology or European League Criteria against Rheumatism classification criteria for Rheumatoid Arthritis.^[6]

Table 1: 2010 ACR/EULAR Criteria for RA

Domain	Category	Point score
A	Joint involvement (0-5 points)	
	1 large joint	0
	2-10 large joints	1
	1-3 small joints (large joints not counted)	2
	4-10 small joints (large joints not counted)	3
	>10 joints including at least one small joint	5
B	Serology (at least one test needed for classification: 0-3 points)	
	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 (atleast one test needed for classification:0-1 point)	
	Normal CRP and normal ESR	0
	Abnormal CRP or abnormal ESR	1
D	Duration of symptoms	
	<6 weeks	0
	≥6 weeks	1

Add scores of categories A-D; a score of ≥6/10 is needed for classification of a patient having definite RA.

Investigations

- Blood routine (Hb, TC, DC, ESR)

- RA Factor
- Radiological investigations (if required).

Study Design

Single group open labelled clinical study with pre and post test design.

Intervention

Sample size : 30 patients
 Drug : *Trikarshika Kwatha*
Anupana : *Ushna Jala*
 Duration : 15 days
 Dosage : 48ml bd before food
 Observation : 0th day, 7th day, 15th day

Assessment criteria

Response of the treatment was assessed on the basis of detailed case sheet proforma which was prepared along with gradings of subjective and objective parameters before and after treatment.

Subjective Parameters

- Sandhishoola*
- Sandhi Shotha*
- Stabdhata*
- Jwara*
- Aruchi*

Objective Parameters

- Local Temperature
- Range of joint movement
- Erythrocyte Sedimentation Rate
- RA Factor

Score Assessment Pattern

1) *Sandhi Shoola*

- No pain - 0
- Discomfort to mild pain - 1
- Moderate to intermittent pain - 2

Severe pain-Continuous - 3

2) Sandhi Shotha

No swelling - 0

Slight swelling; moves the joint without Pain - 1

Moderate swelling; moves the joint with Pain to full extent - 2

Severe swelling; Restricted/No movements - 3

3) Sandhi Stabdata

No stiffness - 0

Stiffness lasting for 5 minutes to 2 hours - 1

Stiffness lasting for 2-8 hours - 2

Stiffness lasting for more than 8 hours - 3

4) Jwara

Present (1) / Absent (0)

5) Aruchi

Present (1) / Absent (0)

6) Local Temperature

Present (1) / Absent (0)

7) Range of joint movement: Goniometric measurement

From 101° to 130° - 0

From 70° - 100° - 1

From 30° - 69° - 2

From 0° - 29° - 3

8) ESR at the end of hour

0-20 - 0

20-35 - 1

35-50 - 2

Above 50 - 3

9) RA Factor

Present (1) / Absent (0)

Statistical Analysis

The obtained data was analyzed statistically with Paired t test, Wilcoxon signed rank test and Kendall's coefficient test.

Overall Assessment

Relief	Percentage
Complete	75 - 100%
Marked	50 - 75%
Moderate	25 - 50%
Mild	0 - 25%
No relief	0%

OBSERVATIONS

Among 30 patients registered for the study, there were no dropouts. In the study, 66.7% of patients belong to the age group of 41-60 years. In this age group, because of stressful busy life, people doesn't follow *Dinacharya* & *Ritucharya*, follows *Mithyahara* & *Viruddhara Sevana*.^[7] Thus causes vitiation of *Doshas* & derangement of *Agni*. 73.3% were females. It may be due to the household works, responsibility and stress which then vitiates the *Vata*, *Agni* and then leads to the *Ama* formation. 53.3% belonged to Hindu religion. This may be because of the Hindu dominated population in the area where the study was conducted. 76.6% were married. It may be due to the inclusion criteria and majority of patients were in the age group of 41-60 yrs. 80% were of middle-class family. This shows that incidence is common where health awareness is poor. 46.7% were housewives. This may be because of their more physical activity and day sleep which might have contributed to the increased incidence of *Amavata*. 66.7% were having middle school education. This shows that incidence is common where health awareness is poor. 70% were not having any relevant family history. 60% were non-vegetarians this shows that Non vegetarians tend to have more saturated fats which can trigger inflammation. In the study, most of the patients indulges in regular intake of *Madhura Rasa* (86.7%). *Madhura rasa* have *Guru*, *Snigdha* and *Sheeta Virya*.^[8] So it will cause *Kapha Vriddhi*. So, regular intake of *Madhura rasa* causes *Agnimandya* and in turn lead to the production of *Ama*. A rise in blood sugar

promotes the body to produce pro inflammatory chemicals like cytokines that inturn causes inflammation in the joints. 53.3% of patients in the study have the habit of taking *Katu Rasa Pradhana Ahara*, but if consumed in excess, it will cause vitiation of *Vata Dosha*, impairs the *Agni* and leads to *Ama Utpatti*. 40% of patients indulges in taking *Lavana Rasa Pradhana Ahara*. *Lavana Rasa* is *Kledakara*. So, if it is consumed in excess, it will cause *Mandagni* and *Ama* formation. Salts, which contain Sodium, may cause the collection of extra fluid, resulting in inflammation. 70% were having poor appetite this is due to the presence of *Amatva* in the body. 86.7% were having regular bowel habit. This observation cannot be justified as the sample size is small. 56.7% was having disturbed sleep. This may be due to their severe pain. 63.3% were not doing exercise. Moderate physical activity helps to keep muscles and joints in motion. Sedentary lifestyle is the root cause of the disease. 76.7% were addicted to tea and the significance of observation is not clear. 83.3% were of *Vatakapha Prakriti*. This is because person belonging to this type of *Prakriti* are more prone to *Vata-Kaphaja* disease like *Amavata*. 60% were having *Madhyama Sara*. *Sara* denotes the immunity of the individual. *Madhyama* and *Avara Sara* persons are more prone to diseases. All the patients were of *Madhyama Samhanana*. *Samhanana* reflects the compactness of the body. *Madhyama* and *Avara Samhanana* persons are more prone to diseases. 70% were having *Madhyama Satva*. This is because in these categories of people, stress factors in their day to day life may aggravate the disease. All the patients were having *Madhyama Satmya*. This is because *those who indulges in taking only one Rasa will have relatively less strength, less resistance to drugs and treatment*. 60% were having *Madhyama Abhyavaharana Shakti*. This is because the power of ingestion is less because of *Agnimandya*. 56.7% were having *Avara Jarana Shakti*. In 70% of patients, the onset was acute. This may be because of the repeated exposure to the *Nidana*, the one who went to bed healthy one night woke up next morning with great deal of pain. The progression of disease was slow in 63.3% of patients. This may be because only acute conditions of the disease were taken for

the study. 76.7% were having raised ESR. It may be the *Guru Guna* of *Ama*, which is responsible for the raised ESR during the *Amavastha*. 56.7% were having raised Local temperature. This is probably because of the inflammatory reaction taking place in the affected joints and Color is the characteristic symptom of inflammation. 80% were seropositive for Rheumatoid factor. This may be because patients with high titre of RA Factor have more severe and progressive disease with extra articular manifestations.

Pradhana Lakshanas: In the study, almost 90% of the patients had *Sandhidhoola*, 70% had *Sandhishotha*, 80% had *Sandhistabdhatta*, 90% of patients in the study had *Jwara* and 90% had *Aruchi*.

Aggravating Factors: The study shows that for 80% of patients, the symptoms aggravated on taking *Snigdha Aharas*. For 50% of patients in the study, symptoms aggravated after *Sheeta Jala Snana* and 36.7% had their symptoms worse during rainy season.

Aharaja Nidana: In the present study, 80% had the habit of taking *Snigdha Ahara* and 40% had the habit of taking *Guru Ahara*. 60% indulges in *Viruddhahara Sevana*, 40% have *Vishamashana* and 20% have the habit of *Adhyashana*. 70% had the habit of taking *Kanda Shaka*.^[9]

Viharaja Nidana: 80% had the habit of *Diwaswapna*, 60% of participants in the study had *Nischeshta*, 50% had the habit of *Vegasandharana*, and 10% had *Ratrijagarana*.

Manasika Nidana: 60% had *Chinta*, 20% had *Shoka*, 13.3% had *Krodha* and 6.7% had *Bhaya*.

RESULTS

Effect of Trikarshika Kwatha in Sandhishoola

Sandhishoola	Mean BT	Mean AT	MD	% of relief	SD	SE	P
0-7	2.30	1.867	0.433	18.8%	0.504	0.092	0.002
7-15	1.867	1.300	0.566	30.3%	0.678	0.124	<0.001

0-15	2.30	1.300	1.000	43.4%	0.871	0.159	0.004
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Effect of Trikarshika Kwatha in Sandhi Shotha

Sandhi shot ha	Mean BT	Mean AT	MD	% of relief	SD	SE	P
0-7	1.33	1.100	0.233	17.2%	0.430	0.078	<0.05
7-15	1.10	0.566	0.533	48.4%	0.571	0.104	<0.001
0-15	1.33	0.566	0.766	57.5%	0.568	0.103	<0.001

Effect of Trikarshika Kwatha in Sandhistabd hata

Sandhistabd hata	Mean BT	Mean AT	MD	% of relief	SD	SE	P
0-7	1.533	1.233	0.300	19.6%%	0.466	0.085	0.003
7-15	1.233	0.800	0.433	35.1%	0.504	0.092	<0.001
0-15	1.533	0.800	0.733	47.6%	0.583	0.116	<0.001

Effect of Trikarshika Kwatha in Jwara

Symmetric Measures

Jwara (0-7 TH Day)	Value	Asymp. Std. Error	Approx. T	Approx. Sig.
Kendall's tau-b	-.735	.087	-8.396	.000

p<0.001

Jwara(7 TH -15 TH Day)	Value	Asymp. Std. Error	Approx. T	Approx. Sig.
Kendall's tau-b	-.76	-.083	-9.25	.000

p=.000

Jwara(0-15 TH Day)	Value	Asymp. Std. Error	Approx. T	Approx. Sig.
Kendall's tau-b	-.767	.083	-9.262	.000

p=0.000

Effect of Trikarshika Kwatha in Local Temperature

Local Temperature (0-7 TH Day)	Value	Asymp. Std. Error	Approx. T	Approx. Sig.
Kendall's tau-b	-.133	.128	-1.042	.297

p=0.297

Local Temperature (7-15 TH Day)	Value	Asymp. Std. Error	Approx. T	Approx. Sig.
Kendall's tau-b	-.251	.123	-2.007	.045

p= 0.045

Local Temperature (0-15 TH Day)	Value	Asymp. Std. Error	Approx. T	Approx. Sig.
Kendall's tau-b	-.377	.118	-3.154	.002

p<0.001

Effect of Trikarshika Kwatha in Aruchi

Aruchi (0-7 TH DAY)	Value	Asymp. Std. Error	Approx. T	Approx. Sig.
Kendall's tau-b	-.466	.107	-4.077	.000

p<0.001

Aruchi (7 TH -15 TH Day)	Value	Asymp. Std. Error	Approx. T	Approx. Sig.
Kendall's tau-b	-.364	.115	-3.024	.002

Aruchi (0-15 TH Day)	Value	Asymp. Std. Error	Approx. T	Approx. Sig.
Kendall's tau-b	-.767	.083	-9.262	.000

Effect of Trikarshika Kwatha in Range of Joint Movement

ROM	Mean BT	Mean AT	MD	% of relief	SD	SE	T	P
0-7	1.567	1.333	0.233	14.8%	0.733	0.141	1.651	=0.109

7-15	1.33 3	1.06 7	0.26 6	20%	0.52 0	0.09 5	2.80 4	<0.00 8
0-15	1.56 7	1.06 7	0.50 0	31.9 %	0.86 1	0.15 7	3.18 1	<0.00 1

Effect of Trikarshika Kwatha In ESR

RO M	Mea n BT	Mea n AT	MD	% of relief	SD	SE	T	P
0-7	2.03 3	1.86 7	0.16 6	8.19 %	0.59 2	0.10 8	1.54 2	=0.1 3
7-15	1.86 7	1.60 0	0.26 67	14.2 %	0.69 1	0.12 6	2.11 2	<0.0 5
0-15	2.03 3	1.60 0	0.43 3	21.29 %	0.77 3	0.14 1	3.06	<0.0 5

Effect of Trikarshika Kwatha in Ra Factor

RA Factor (0-7 TH Day)	Value	Asymp. Std. Error	Approx. T	Approx. Sig.
Kendall's tau-b	.000	.129	.000	1.000

p=1.000

RA Factor (7 TH -15 TH Day)	Value	Asymp. Std. Error	Approx. T	Approx. Sig.
Kendall's tau-b	.000	.129	.000	1.000

P=1.000

RA Factor (0-15 TH Day)	Value	Asymp. Std. Error	Approx. T	Approx. Sig.
Kendall's tau-b	.000	.129	.000	1.000

p=1.000

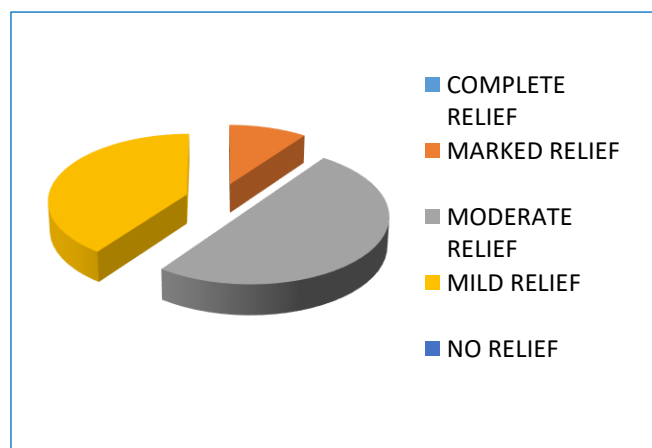
Showing significance of subjective and objective criteria

Criteria	% of Relief	P Value	Significance
Sandhishoola	43.4%	0.004	Highly significant

Sandhishotha	57.5%	<0.001	Highly significant
Sandhistabdatha	47.6%	<0.001	Highly significant
Jwara	76.7%	<0.001	Highly significant
Aruchi	76.7%	<0.001	Highly significant
Local temperature	36.7%	<0.001	Highly significant
Range of joint movement	31.9%	0.003	Highly significant
ESR	21.29%	<0.05	Significant
RA Factor	0%	1.000	Insignificant

Showing overall assessment of treatment.

Relief	Number	Percentage
Complete relief	0	0%
Marked relief	3	10%
Moderate relief	15	50%
Mild relief	12	40%
No relief	0	0%



Graph 1: Showing overall assessment of the treatment

DISCUSSION

The effect of treatment was assessed by Wilcoxon signed rank test, Paired t test and Kendall's coefficient test. The effect of *Trikarshika Kwatha* in main complaints like *Sandhishoola Sandhistabdhatta*, *Jwara* and *Aruchi* shows statistically significant change on 7th day itself. But the percentage of relief in these 7 days duration was insufficient for analyzing the results. So comparison of results on 7th day with 15th day became necessary and the results on comparison showed that except Local temperature, ESR and RA Factor, other criteria's were highly significant. RA Factor was found statistically insignificant throughout the study ($p=1.000$). Among the 9 criteria's, 7 criteria showed highly significant change with ($p<0.001$) on 15th day in comparison to 0th day.

Discussion on the *Upashayatmaka* effect of *Trikarshika Kwatha* in *Amavata*

Rasadi properties of *Trikarshika Kwatha* are discussed below.^[10] The *Upashayatmaka* effect of the drug on the disease can be analysed on the basis of it. So, the formulation is predominantly having *Tikta*, *Kashaya*, *Katu Rasa*. The *Katu* and *Tikta Rasa* helps in *Agni vardhaka*, *Ama Pachana* and *Kaphahara* property. Thus, it helps in cleansing the *Ama* and *Srotorodha* from the body. Thus, the formulation is *Guru* and *Snigdha guna* predominant. Thus, it helps in normalizing the *Vata dosha*. *Ruksha* and *Laghu guna* cleanses *Srotas* and mitigates *Kapha Dosha*. *Tikshna Guna* also helps in relieving the *Srotorodha* caused due to *Ama*. All the three drugs in the formulation is *Ushna Veerya Pradhana* which pacifies both *Vata* and *Kapha Dosha*. Thus, it shows that the formulation is effective in providing *Upashaya* to *Amavata lakshanas* as it is a *Kapha Vata Pradhana Vyadhi*. All the three drugs in the selected formulation have *Madhura Vipaka* which can pacify the *Prakupita Vata*. The formulation is having *Vata Kaphahara*, *Deepana pachana*, *Jwarahara*, *Tridosha shamaka* property. As the drug is having *Tridosha Shamaka*, *Vata Kaphahara* property, it will provide *Upashaya* to *Sandhishoola*, *Sandhishotha* and *Sandhi Stabdhatta*. As it is having *Jwarahara* property, it will relieve the *Santapa*

Lakshanas. As it is having *Deepana* and *Pachana* property, it helps to expel *Ama* from the body and provide *Upashaya* from *Aruchi*.

As *Ama* is an important factor in the production of *Amavata*, the *Dravyas* which are antagonistic to the nature of *Ama* is considered to provide *Upashaya*. *Trikarshika Kwatha* having *Katu*, *Ruksha*, and *Ushna* property act as *Hetu Vyadhi Vipareetha Oushadha*^[11] and provides relief from the disease. The previous pharmacological studies also shows that the drugs in the formulations have antirheumatic, anti-inflammatory, antioxidant and antipyretic properties. Overall, *Trikarshika Kwatha* provides *Upashaya* to *Amavata Lakshanas*.

CONCLUSION

Intake of *Viruddhahara* and *Vishamashana* have significant role in the causation of *Amavata*. The habit of *Diwaswapna* and *Nishchestha* also have inevitable role in the disease. The habit of *Vegasandharana* has triggered the *Doshas*, hampered the *Agni* and paved way for the disease. In majority of participants, *Manasika Nidanas* like *Chinta* and *Shoka* were the root cause of the disease. *Upashaya* is one of the effective tool mentioned in *Ayurveda* for the diagnosis and treatment of the diseases. *Trikarshika Kwatha* having *Katu*, *Ruksha* and *Ushna* property act as *Hetu Vyadhi Vipareeta Oushadha* and provides relief from the disease. *Trikarshika Kwatha* proved beneficial in reducing the symptoms of *Amavata* w.s.r. Rheumatoid Arthritis and are statistically significant with $p<0.00$ i.e., There is significant effect of *Trikarshika Kwatha* in *Amavata*.

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