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**Research Article** 

# EVALUATE THE EFFICACY OF *KSHARA BASTI* AND *SUNTHI-GUDUCHI CHURNA* IN *AMAVATA* (RHEUMATOID ARTHRITIS)- A CLINICAL STUDY

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# \_ ABSTRACT

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#### **KEYWORDS:**

Article info

Amavata, Rheumatoid Arthritis, Kshara Basti, Sunthi guduchi churna, CDAI score, gut brain. Amavata is a Rasa Pradosaja Vikara with two major pathogenic factors Ama and Vata, which mainly affect Sandhi followed by Asthi and Majja. The symptoms of Amavata are identical to Rheumatoid Arthritis, a chronic inflammatory polyarthritis affecting multiple systems. The symptoms of Amavata are identical to rheumatism, which include rheumatoid arthritis and rheumatic fever. It is observed that rheumatism is an autoimmune disorder, which is among the collagen disorders having strong and significant parlance with Amavata. Various drug trials were already carried out on Amavata, yet there is a lacuna in the management of Amavata. Hence, in the present clinical study, 100 patients were selected for Open Random trial and applied Kshara basti followed by oral Sunthi- Guduchi churna for 2 month for the management of Amavata. In disease active stage of Amavata synovial stromal-immune cell interactions lead to reciprocal metabolic changes that again potentiate the inflammatory response. Here we can understand the metabolic and cellular pathology during active stage of disease. Hence, metabolic reprogramming could represent a new therapeutic strategy for patients with RA, where our *Basti* therapy followed by *Rasavana* must have a great role. For the study collected data was distributed according to age, sex and *Prakruti*, and a paired t-test was applied for the clinical assessment of the subjective and objective parameters of Kshara basti followed by Sunthi guduchi churna in Amavata management and it has shown significant reduction in the Sandhi shool according to VAS scale (t >23.42 at the 0.001% level), Sandhi sotha (t >24.35, at the 0.001% level), Sandhi Stabdhata (t >20.58 at the 0.001% level), CDAI score (t >27.11 at the 0.001% level ) ANA score (t >53.23, at the 0.001% level), and for 1st 15 days ESR changes is not significant at t < 1.00 but after completion of treatment significant results was observed. By analysing statistical data with paired t test it reveals that 58% had major improvement followed by 37% had minor improvement and 5% of patients who had no improvement.

## **INTRODUCTION**

*Amavata* is one of the crippling diseases claiming the most common inflammatory arthritis. Manda *Agni* (metabolic abnormality) in both *Jatharagni* and *Dhatwagni* level is the main stimulator for *Amavata*. It was first mentioned as a separate disease in *Madhavakar*.<sup>[1]</sup>

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Symptoms of Amavata were closely similar Rheumatoid Arthritis. <sup>[2]</sup> RA is chronic with inflammatory disease characterized by inflammation of synovium of multiple joints. The synovitis of joints for long time leads to the damages of bones and cartilages. These damages can cause significant disability and even permanent loss of function due to erosion of bone surface, if left untreated. It is triggered when disease remains in active stage. So main aim of treatment is to achieve remission or reduces the disease activity to prevent further destruction. Thousands of research work done on Amavata and millions done on RA. But due to complex etiopathogenesis, immunological complexity, its root

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cause is still unknown, so specific treatment is yet to discover. Several researches had highlighted the interplay between metabolism, immunity and inflammation. In modern research it is said that metabolic reprogramming and cellular repairing could be a new hope for therapeutic strategy in RA. From here we see the importance of *Basti* therapy and *Rasayana Aushudhi* in RA. In Ayurveda, *Basti* therapy is considered as *Ardha chikitsa*, and supreme among all *Sothana* therapy.<sup>[3]</sup> After *Sodhan* when *Rasayan Ausadhi* with *Amapachak* property given, it act more effectively. By considering this fact my study was conducted.

# **AIM AND OBJECTIVE**

**Aim**: To evaluate the efficacy of *Kshara Basti* and *Sunthi-guduchi churna* in *Amavata* 

# Objective

- 1. Clinical Study to evaluate the efficacy of *Kshara Basti* and *Sunthi-guduchi churna* in *Amavata* for symptomatic relief.
- 2. To evaluate the efficacy of *Kshara Basti* and *Sunthiguduchi churna* in *Amavata* to find out serological evidences.

# **MATERIAL AND METHOD**

# **Reference of Trial Drug**

- *Kshara Basti* is mentioned in, *Chakradutta*, *Amavata chikitsa*, *sloka 1*.
- Sunthi Guduchi Churna for Amavata mentioned in Bhavaprakas, ch 26/44, Amavatadhikara.<sup>[4]</sup>

# Source of Drug Formulation

Drugs are collected locally and identify by the *Dravya* guna department, GACH.

*Sunthi- Guduch Churna* was prepared in the state Ayurvedic Pharmacy, Govt. Ayurvedic College & Hospital and mixed in the ratio of *Sunthi: Guduchi*= 1:3

# Materials to prepare Kshara Basti [5]

Imli (Amlika)- 2 Pala (approx. 100gm)

Guda - 2 Pala (approx. 100gm)

Saindhava Labvan - 1 Aksha (10gm)

Gomutra - 8 Pala (approx. 400gm)

Sauf (Satapuspa) - 1 Aksha (approx. 10gm)

\*\*Due to poor tolerance capacity of patient the dose of *Kshara basti* are reduces to half.

# Phase 1

# **Prior to Starting Trial**

- After approval of synopsis and clearance from ethical committee drug was prepared in State Ayurvedic Pharmacy, GACH.
- A sample was send in Drug Testing Laboratory-Physical evaluation of drug was done and no heavy metals or toxicity was observed.

- Before enrolling patient for my study, clinical trial registration was done for this study and my CTRI trial number was: CTRI/2021/09/036695.
- It is a single arm random open clinical study with sample size 100.
- Registration of 108 cases was done in the OPD/IPD of the department of *Kayachikitsa*, GACH, 8 of them are drop out so excluded for the study.
- The detailed research Performa was prepared incorporating all the clinical features of *Amavata* and assessment criteria from synopsis mentioned for statistical analysis of the study.
- Before administration of trial drug in patient, signature in consent form was taken.
- All patient taken after considering inclusion and exclusion criteria

# **Inclusion** Criteria

- 1. Patient with classical features of Amavata. [6].
- 2. The patients who were fulfilling 2020 ACR/EULAR classification for rheumatoid arthritis.<sup>[7]</sup>
- 3. Rheumatoid factor positive and negative both cases were included.
- 4. Age: from 16 years to 65 years.

# **Exclusion** Criteria

- 1. Chronicity of more than 10 years.
- 2. Having severe deformity.
- 3. Having cardiac disease, pulmonary tuberculosis & pregnancy.
- 4. Age less than 16 years and more than 65 years.
- 5. Complicated diabetic mellitus.
- 6. Malignancy, anorectal disease like bleeding haemorrhoid, fistula etc.
- 7. Ankylosing spondylitis
- 8. Arthritis due to other causes; e.g, rheumatic arthritis, septic arthritis, osteoarthritis, gouty arthritis etc.

# Phase 2

USHD

# **Clinical Study Design**

- Patients were selected for trial according to Inclusion and exclusion criteria.
- *Deepan- Pachan* with *Panchakola Churna* for 3 days prior to *Basti* therapy was given initially.
- *Nitya Virechana* given for 3 days for *Kostha suddhi* with *Triphala kasaya* 50ml+ *Guduchi kasayam* 50ml+ *Eranda taila* 10ml.
- From 5<sup>th</sup> day *Basti* therapy was started, *Sthanik abhyang*a with *Dasamool taila* and *Nadi swedan* with *Dasamool Kwatha* will be given before *Basti* therapy.
- *Kala basti* from 5<sup>th</sup> day with *Kshara basti* and *Saindhavadi Anuvasan Basti* given

• After *Samsarjana Karma* oral *Sunthi Guduchi churna* given as 4gm/day in two divided doses with lukewarm water as *Anupana* for 2 month and three follow up done according on 15<sup>th</sup>, 30<sup>th</sup> and 60<sup>th</sup> day.

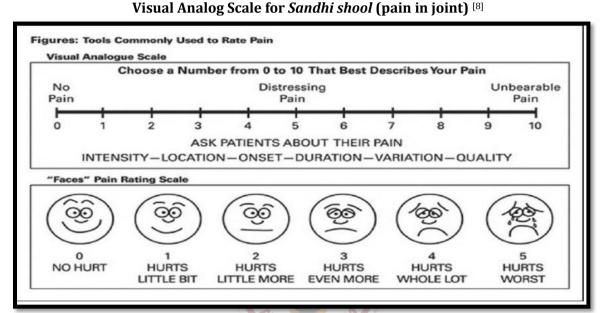
# Laboratory Investigation

- 1. Haematological Investigations: Blood RE
- 2. Biochemical Examinations
  - Blood Sugar Fasting & Postprandial
  - SGOT, SGPT (optional)

# **Assessment Criteria**

# **Subjective Criteria**

- Sr. Creatinine
- Sr. Uric Acid
- 3. RA factor
- 4. Anti CCP
- 5. C-Reactive Protein
- 6. ASO Titer
- 7. Stool for Routine Examination (optional)
- 8. Urine for Routine Examination (optional)



# Sandhi sotha (swelling of the joints) $\rightarrow$ score

No swelling - 00

Slight swelling + Heaviness - 01

Moderate swelling + Heaviness - 02

Severe swelling (Synovial effusion) - 03

# Sandhi Stabdhata (Stiffness of Joints) - >Score

No stiffness or stiffness lasting for 5, minutes - 00 Stiffness lasting for 5 minutes to 2 hours - 01 Stiffness lasting for 2 hours to 8 hours - 02 Stiffness lasting for more than 8 hours - 03

# Clinical Disease Activity Index for RA (CDAI) <sup>[9]</sup>

CDAI is calculated as follows: CDAI = SJC + TJC +PGA + EGA

Where:

SJC = Swollen Joint Count

TJC = Tender Joint Count

PGA = Patient Global Assessment of Disease Activity

EGA = Evaluator Global Assessment of Disease Activity.

# Interpretation

- ≤2.8: Remission
- >2.8 and ≤10: Low Disease Activity
- >10 and ≤22: Moderate Disease Activity
- >22: High Disease Activity

# **AHA Criteria**

Symptoms		BT	FU1	FU2	FU3
Annabhilasha					
Bhaktasya paripakam					
Vista	Mutra				
	Purisha				
Sharira laghavam					
Suprasana indriya					

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Sukha	Swapnam		
	Pravatanam		
Bala			
Varna			
Sumanasha			
Samagnitwam			
Total Score			

- Positive Symptoms=1
- Negative Symptoms=0

# **Objective Criteria**

# **Erythrocyte Sedimentation Rate (ESR)**

- ESR range 0-30: 0 score
- ESR range >30 : 1 score

# **Result and Statistical Analysis of the Study**

• From the demographic profile it is seen that *Amavata* is more prevalent Among women (68%) and in middle age group (30-50 years), 75%.

# Statistical Analysis of the Assessment Criteria

- 47% patient had irregular bowel habit and 71% had *Apakwa* (sticky, mucus mixed) stool consistency, it indicated poor GI condition in *Amavata* patient due to *Mandagni*.
- 37% patient felt pain and stiffness more at morning and 60% in rest condition.
- In clinical features *Sandhishola, sotha, Gaurava* and *Stabdhata* seen in all patient followed by *Angamarda, Apaka, Alasya, Jwara, Vid vibandha, Trishna, Vichika damsa vedana, Utsaha hani* and *Nidra Viparjaya* seen in more than 50% of people.
- 95% had a history of taking NSAIDs.

# Table 1: Pain Assessment According to Visual Analog Scale (VAS)

Symptoms	Ν	BT mean	Mean		lean Mean		Df	Paired t te	st		Significant
								SD SEM	Т	р	
Sandhi Shool	100	6.60	FU1	6.22	99	6.22±0.70	5.07	< 0.001	Highly significant		
(VAS)			FU2	4.69	99	4.69±1.00	15.61	< 0.001	Highly significant		
			FU3	3.38	9 <mark>9</mark>	3.38±1.17	23.42	< 0.001	Highly significant		

#### Table 2: Assessment of Sandhi sotha (swelling)

Symptoms	Ν	ВТ	Mean		df (N-1)	Paired t test			Signific ant
		mean				Mean±SD	Т	Р	
Sandhi sotha	100	2.14	FU1	1.78	99	1.78±0.50	6.43	< 0.001	Highly significant
(swelling)			FU2	1.10	99	1.10±0.41	19.61	< 0.001	Highly significant
			FU3	0.58	99	0.58±0.57	24.35	< 0.001	Highly significant

## Table 3: Assessment of Sandhi Stabdhata (stiffness)

Symptoms	Ν	BT mean	MEAN		df (N-1)	Paired t test			Remark
						SD SEM	Т	р	
Sandhi	100	1.95	FU1	1.62	99	1.62±0.56	6.98	< 0.001	Highly significant
stabdhata			FU2	1.08	99	1.08±0.58	17.21	< 0.001	Highly significant
			FU3	0.79	99	0.79±0.54	20.58	< 0.001	Highly significant

#### Table 4: Assessment of disease, Activity According to CDAI score

Symptoms	N	BT	Mean		df (N-1)	Paired t test			Remark
		mean				Mean± SD	Т	р	
CDAI	100	18.38	FU1	17.44	99	17.44±2.72	6.97	< 0.001	Highly significant
Score			FU2	14.22	99	14.22±2.59	18.83	< 0.001	Highly significant
			FU3	10.56	99	10.56±2.76	27.11	< 0.001	Highly significant

Symptoms	Ν	BT	Mean		df (N-1)	Paired t test			Significance				
		Mean				Mean±SD	Т	Р					
Ayurvedic	100	9.16	FU1	6.58	99	6.58±0.90	24.00	< 0.001	Highly significant				
Health			FU2	4.60	99	4.60±0.74	43.93	< 0.001	Extremely significant				
Asssesment Score			FU3	2.82	99	2.82±0.70	53.23	<0.001	Extremely significant				

# Table 5: Assessment of *Amavata* According to AHA criteria

#### Table 6: Assessment of disease activity According to inflammatory marker (ESR)

Symptoms	Ν	BT	Mean		df (N=1)	Paired t test			Remark
		Mean				Mean±SD	Т	Р	
ESR	100	0.90	FU1	0.89	99	0.89±0.31	1.00	>0.05	Not Significant
			FU2	0.25	99	0.25±0.34	13.56	< 0.001	Highly significant
			FU3	0.10	99	0.10±0.30	19.90	< 0.001	Highly significant

#### DISCUSSION

Amavata is a Rasa Pradosaja Vikara with two major pathogenic factors Ama and Vata, which mainly affect Sandhi followed by Asthi and Majja. The symptoms of Amavata are identical to rheumatoid arthritis, a chronic inflammatory polyarthritis effecting multiple system. Activation of endothelium and immune cells is fundamental for initiation of autoimmune diseases such as Rheumatoid Arthritis (RA), and it results in transendothelial cell migration and synovial fibroblast proliferation, leading to joint destruction. In inflamed joints, infiltrating immune and synovial resident cells have great cells requirements for energy and nutrients, so they adapt their metabolic profiles to generate sufficient energy to support their highly activated inflammatory states. Due to shift in this metabolic capacity of synovial cells enables them to produce the essential building blocks support their proliferation, activation to and invasiveness. Further it results in the accumulation of metabolic intermediates and alteration of redoxsensitive pathways, affecting signaling pathways that again potentiate the inflammatory response. In disease active stage synovial stromal-immune cell interactions lead to reciprocal metabolic changes that again potentiate the inflammatory response. Here we can understand the metabolic & cellular pathology during stage of disease. Hence metabolic active reprogramming could represent a new therapeutic strategy for patients with RA, where our *Basti* therapy followed by Rasayana must have a great role.

# **Probable Mode of Action**

# Kshara basti

It is a type of *Tikshna niruha basti* works on the basis of *Guna Vaisheshika Siddhanta* shows significant result in *Amavata*. All the ingredients of *Kshara Basti* have some specific role in the management of *Amavata*. Saindhava lavana via its Sukshma and *Tikshna guna* causes Srotoshodhana and it helps the *Basti Dravya* to reach up to the molecular level. Due to its irritant property, it helps in the elimination of waste material. It is capable of liquefying the viscous matter and break down them into tiny particles.

Purana Guda with Saidhava lavana forms homogeneous and nearly isotonic mixture and permeabilty through cellular level increases. Purana Guda is Laghu, Pathya, Anabhishyandi, Agnivardhaka and Vatapittashamaka so useful for Amavata chikitsha. Amlika has Ruksha, Ushna, Amla, Vatakaphashamaka properties which makes it useful for the Amavata. Gomutra due to its Katu rasa, Katu vipaka, Ushna virva, Laghu, Ruksha and Tikshna Guna pacify the Kapha Dosha. It also possesses Tridoshahara, Agnideepana, Srotovishodhana Pachana, and Vatanulomana properties. The drugs administered through the rectum can reached higher blood circulation due to partial avoidance of hepatic first pass metabolism because rectum has rich blood and lymph supply so the drugs can cross the rectal mucosa as they can cross other lipid membrane. So, unionized and lipid-soluble substances are readily absorbed from the rectum.

The portion absorbed from upper rectal mucosa is carried by superior hemorrhoidal vein into the portal circulation, whereas that absorbed from lower rectum enters directly into the systemic circulation via the middle and inferior hemorrhoidal veins and thus it provides quicker results. The rectal wall contains pressure receptors and neural receptors which are stimulated by various drugs present in *Kshara Basti Dravya* and results in increase in conduction of sodium ions. The inward rush of sodium ions is responsible for generating action potential. *Saindhava Lavana* present in *Kshara Basti Dravya*.

*Basti* therapy can be considered as a prime remedy for *Amavata*. It influences GIT, enteric nervous

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system also the autonomic nervous system thereby producing systemic effect.

The overall effect of *Kshara Basti* can be summarized as encolonic i.e., action on tissues of colon, endocolonic i.e., action inside colon and diacolonic (systemic action). Thus *Kshara basti* breaks the obstructions and expels out the morbid material from all over the body thus helps in breaking down the pathogenesis of diseases.

## Sunthi-Guduch Churna

Sunthi is having Laghu, Snigdha Guna, Katu Rasa, Madhura Vipaka and Ushna Virya. By Virtue of Ushna Virya it pacifies Kapha and Vata and also acts as Dipana, Pachana, Shulaprashamana, Shothahara. Sunthi help in modulation of metabolic health of disease person. It acts as anti inflammatory agent by producing inhibitory effect on prostaglandin synthesis and leukotriene biosynthesis.

*Guduchi* is having *Katu, Tikta, Kashaya rasa* and *Ushna virya*, it does *Ama pachana*. It also acts as *Agni deepak* and *Vatahara*. The anti-inflammatory effect *Guduchi* was mediated via reduction of the pro inflammatory cytokines such as: IL-16, TNF-alpha, IL-6, and IL-17 etc. Due to its *Rasayana* property it action was expected in micro level by cellular repairing, it may be the reason of its immnnomodulator effect.

# CONCLUSION

- By analysing statistical data with paired t test it reveals that 58% had major improvement followed by 37% had minor improvement and 5% of patients who had no improvement.
- According to CDAI score complete remission was not found in my 2 month study.
- In 1<sup>st</sup> follow up (after 15 day) symptomatic relieves is less compare with next two follow up and no significant serological changes was found.
- After completion of therapy patient get much Improvement in their general functional ability.
- From the statistical data of before and after treatment seen a positive result with highly significant p value and it indicate the efficacy of my trial drug in *Amavata*.
- As it a trial only for two month, its effect on serological evidence is not significant. As to follow

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remission criteria for RA many years of screening was needed. Nodoubt basti is very effective or may be a alternate way for management of RA. To evaluate it we need a continuous and micro level study.

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