



Research Article

A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFECT OF *VATARI GUGGULU* AND *SHATPUSHPADI CHURNA* WITH *SIMHANADA GUGGULU* IN THE MANAGEMENT OF *AMAVATA* W.S.R. TO RHEUMATOID ARTHRITIS

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ABSTRACT

The disease *Amavata* described in classical Ayurvedic literature is closely resembles with Rheumatoid Arthritis (RA). *Amavata* is a crippling condition where simultaneously aggravated *Vata* and *Ama* associated with each other settles in *Sandhis* and produce *Sandhishoola*, *Sandhishotha*, *Sparshaasahitwa*, which is similar to Rheumatoid Arthritis. *Amavata* is the challenging problem for medical science with different treatment protocol. The objectives of this randomized parallel group Comparative study were to evaluate the effect of *Vatari Guggulu* and *Shatpushpadi Churna* with *Simhanada Guggulu* in the management of *Amavata* w.s.r. to Rheumatoid Arthritis This Study was conducted on 32 patients selected randomly from OPD and IPD of R.G.G.P.G. Ayurvedic College and Hospital, Paprola, Dist. Kangra (H.P.) and divided into 2 groups. Group I and Group II having 16 patients in each group. Group A were managed with *Vatari Guggulu* 500mg BD with lukewarm water and *Shatpushpadi Churna* 3gm BD with lukewarm water while Group B were managed with *Simhanada Guggulu* 500mg BD with lukewarm water for 6 weeks. Results showed statistically significant difference in effect of Group I and Group II on subjective parameters – *Angamarda*, *Trishna*, *Apaka*, *Jadya*, *Sparsh Ashyata*, *Vidvibandha*, *Nidravipraya*, ESR, walking time and grip strength. Percent wise *Vatari Guggulu* and *Shatpushpadi Churna* are found to be more effective than *Simhanada Guggulu* for all assessment criteria in the management of *Amavata*.

INTRODUCTION

Amavata is a disease of *Asthivaha* and *Rasavaha Strotas*. It is mainly produced due to *Ama* and vitiation of *Vata Dosha*. The *Ama* is carried by the aggravated *Vata* and deposited in *Sleshmasthanas* (seats of *Kapha* like joints etc.) producing features like *Angamarda* (body ache), *Aruchi* (loss of appetite), *Alasya* (weakness), *Sandhiruk* (joint pain), *Sandhishotha* (joint swelling).^[1] *Madhavakara* (700AD) was the first who described the features of *Amavata* in *Madhava Nidana* whereas the treatment of *Amavata*

was first explained by *Acharya Chakradatta*. *Amavata* is a disease of *Madhyama Rogamarga* hence it is said to be *Krichrasadhya* or *Yapya*. According to the clinical features *Amavata* very closely resembles with the rheumatoid arthritis. Rheumatoid arthritis is a chronic, progressive autoimmune arthropathy and characterized by bilateral symmetrical involvement of joints with some systemic clinical features^[2]. This disease affects mainly young population and the patients are gradually crippled physically as well as mentally due to bad prognosis of the disease. Hence it is a most burning problem in the society. Treatment in modern medicine has limitations due to their side effects. The prevalence of RA is 0.8% of the population (range 0.3–2.1%), women are affected approximately three times more often than men. The prevalence increases with age and sex differences diminish in the older age group. The onset is most frequent during the fourth and fifth decades of life, with 80% of all patients

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developing the disease between the ages of 35 and 50.3 Ayurveda advocates a range of promotive, preventive and curative measures and describes the *Sadvritta*, *Swasthavritta*, *Ahara-Vihara* and the unique therapeutics i.e., *Samshodhana* and *Samshamana*. Medicines are administered in different forms through different routes to obtain either *Shodhana* or *Shamana* effect. *Samshodhana* essentially refers to the bio-purification of the body aiming to cleanse the macro and micro channels of the biological system (*Srotas*).

The disorders treated by *Shodhana Chikitsa* do not reoccur whereas the disorders treated by *Shaman* therapy may reoccur in due course of time.

In *Amavata*, *Vata* is dominant *Dosha* and *Ama* is the chief pathogenic factor. Ancient *Acharyas* of Ayurveda have described sequential employment of *Deepana*, *Pachana*, *Shodhana* and *Shamana* therapies in the management of *Amavata*.

In present study research has been done to evaluate the effect of *Vatari Guggulu* and *Shatpushpadi Churna* with *Simhanada Guggulu* in the management of *Amavata* w.s.r. to rheumatoid arthritis

AIMS AND OBJECTIVE

Primary Objective

To determine the clinical efficacy of *Vatari Guggulu* and *Shatpushpadi Churna* in the management of *Amavata* w.s.r. to Rheumatoid Arthritis.

Secondary Objective

To determine the clinical safety of *Vatari Guggulu* and *Shatpushpadi Churna* in the management of *Amavata* w.s.r. to rheumatoid arthritis.

MATERIALS AND METHODS

Selection of the Patient: The patients are selected from the OPD/IPD of R.G.G.P.G. Ayurvedic College and Hospital, Paprola, Dist. Kangra (H.P.). A sample of 34 patients-17 patients in each group was assessed in the clinical study.

Study Design

Study type – Randomized clinical trial

Masking – Single blind

Timing – Prospective

Number of patients – 32 (16 in each group)

No of Groups – 2

Duration of trial – 6 weeks

Follow up visit – After every 14 days till the completion of trial

Diagnostic Criteria: The patients were diagnosed based on clinical features of *Amavata* as well as Rheumatoid Arthritis. For diagnosis of Rheumatoid Arthritis criteria given By American College of Rheumatology (ACR) was followed which is as follows:

- Morning stiffness
- Arthritis of three or more joint areas
- Arthritis of hand joints
- Symmetrical Arthritis
- Rheumatoid nodules
- Serum Rheumatoid factor
- Radiographic changes

Out of 7 criteria at least 4 should be present in patient for more than or equal to 6 weeks to meet the diagnosis.

Inclusion Criteria

- Patients willing to study.
- Patients in the age group between 30 - 70 years irrespective of gender and socio-economic status.
- Patient with signs and symptoms of *Amavata* w.s.r. to Rheumatoid Arthritis as described in texts and fulfil the diagnostic criteria.

Exclusion Criteria

- Patients are not willing for the trial.
- Patients with age group below 30 and above 70 years.
- Allergy to the trial drug.
- Patients having any type of arthropathy such as neoplasm of spine, ankylosing spondylosis, osteoarthritis, traumatic arthritis and pyogenic osteomyelitis etc.
- Patients suffering from chronic renal, respiratory, cardiac and hepatic disorders.
- Pregnant and lactating.

Investigations

- TLC, DLC, ESR, Hb gm%
- Serum uric acid, RA Factor
- FBS, Blood Urea, Serum Creatinine, SGOT, SGPT
- Urine- Routine and microscopic examination

Grouping of Patients: Study was conducted randomly on 32 patients in two groups (16 patients in each group). Group I was managed with *Vatari Guggulu* and *Shatpushpadi Churna* while Group II was management with *Simhanada Guggulu*. 1 patient dropped out from Group I and Group II. These 2 patients were excluded from the present clinical study. Hence the effect of therapy was studied on 30 enrolled patients.

Anupana: Lukewarm water

Shatpushpadi Churna

Drug dosage: 3gm twice a day

Route of administration: Oral

Anupana: Lukewarm water

Simhanada Guggulu

Drug dosage: 500mg twice a day

Route of administration: Oral

Anupana: Lukewarm water**Drug dosage:** 500mg twice a day**Trial Drugs****Route of administration:** Oral**Vatari Guggulu****Trial Drug Composition****Table 1: Vatari Guggulu Composition**

S.No.	Name of the Drug	Latin name	Family	Part used	Proportions
1	<i>Erand Tail</i>	<i>Ricinus communis</i> (Linn.)	Euphorbiaceae	Seed oil	1 Part
2	<i>Shudh guggulu</i>	<i>Commiphora wightii</i> (Hook ex. Stocks)	Burseraceae	Oleo - Gum Resin	1 Part
3	<i>Amalaki</i>	<i>Emblica officinalis</i> (Gaertn.)	Euphorbiaceae	Pericarp	1 Part
4	<i>Haritaki</i>	<i>Terminila chebula</i> (Retz.)	Combretaceae	Pericarp	1 Part
5	<i>Vibhitaki</i>	<i>Terminila bellirica</i> (Roxb.)	Combretaceae	Pericarp	1 Part
6	<i>Shudh gandhaka</i>	<i>Sulphur</i>			1 Part

Table 2: Shatpushpadi Churna Composition:

S. No.	Name of the drug	Latin name	Family	Part used	Proportions
1.	<i>Saunf</i>	<i>Foeniculum vulgare</i> (Mill.)	Apiaceae	Fruit	1 Part
2.	<i>Vaividang</i>	<i>Embelia ribes</i> (Burm. f.)	Primulaceae	Fruit	1 Part
3.	<i>Krishan maricha</i>	<i>Piper nigrum</i> (L.)	Primulaceae	Fruit	1 Part
4.	<i>Sendha Lavana</i>	Rock salt			1 Part

Table 3: Contents of Simhanada Guggulu Composition

S.No.	Name of the Drug	Latin name	Family	Part used	Proportions
1	<i>Haritaki</i>	<i>Terminila chebula</i> (Retz.)	Combretaceae	Pericarp	1 Part
2	<i>Vibhitaki</i>	<i>Terminila bellirica</i> (Roxb.)	Combretaceae	Pericarp	1 Part
3	<i>Amalaki</i>	<i>Emblica officinalis</i> (Gaertn.)	Euphorbiaceae	Pericarp	1 Part
4	<i>Shudh guggulu</i>	<i>Commiphora wightii</i> (Hook ex. Stocks)	Burseraceae	Oleo - Gum Resin	1 Part
5	<i>Erand Tail</i>	<i>Ricinus communis</i> (Linn.)	Euphorbiaceae	Seed oil	1 Part
6	<i>Shudh gandhaka</i>	<i>Sulphur</i>			4Part

Assessment Criteria**Subjective Criteria:** These are the subjective criteria given in the classical texts.

- *Angamarda*
- *Aruchi*
- *Trishna*
- *Alsaya*
- *Gauravata*
- *Jwara*
- *Apaka*
- *Agnimandya*
- *Daha*
- *Jadya*
- *Sparshashtva*
- *Sandhishoola*
- *Sandhishotha*
- *Vidvibandha*
- *Nidraviparaya*

Table 3: The grading of subjective parameters as follow

Bodyache (<i>Angamarda</i>)	
0	No body ache
1	Mild pain which do not disturb daily work
2	Moderate pain which slightly disturb daily work
3	Severe pain which disturb daily work relieves by rest

4	Very severe body aches which disturb daily work and relieves only by medicine
Loss of taste (<i>Aruchi</i>)	
0	No loss of taste
1	Loss of taste in morning hours
2	Loss of taste in morning hours and afternoon
3	Loss of taste in morning hours, afternoon and evening
4	Loss of taste throughout the day
Loss of thirst (<i>Trishna</i>)	
0	No thirst
1	Feel thirsty 2 to 3 times in a day
2	Feel thirsty 4 to 5 times in a day
3	Feel thirsty 6 to 6 times in a day
4	More than 7 times in a day
Lack of enthusiasm (<i>Alsaya</i>)	
0	No lack of enthusiasm
1	Loss of enthusiasm which last for 1-2 hours in the morning
2	Loss of enthusiasm throughout the morning
3	Loss of enthusiasm which lasts from morning upto afternoon
4	Loss of enthusiasm which lasts throughout the day
Heaviness (<i>Gauravata</i>)	
0	No heaviness
1	Heaviness is present but do not disturb daily works and relieves Without rest.
2	Heaviness is present but do not disturb daily works and relieves Only by rest
3	Heaviness which partially disturbs daily works and relieves only By rest
4	Heaviness which totally disturbs daily works
Fever (<i>Jwara</i>)	
0	Normal <98.8
1	Fever between 99°F and 100°F
2	Fever between 101°F and 102°F
3	Fever between 103°F and 104°F
Indigestion (<i>Agnimandya</i>)	
0	Gets normal appetite and digests the food normally.
1	Eats normal quantity of food but feels discomfort during the Digestion
2	Eats less quantity of food and digests it normally
3	can't digest the food even if taken in less quantity
4	Avoids taking food
Swelling of the body (<i>Sandhishotha</i>)	
0	No swelling of the body
1	Swelling of Lower limbs

2	Swelling of Lower limbs and Upper limbs
3	Swelling of Lower limb, Upper limb and Face
4	Swelling of whole body
Pain (<i>Sandhishoola</i>)	
0	No pain
1	Complaints of tolerable pain which do not need rest
2	Complaints of pain which relieves by rest
3	Complaints of pain which is difficult to tolerate and takes analgesic once a day
4	Intolerable pain and takes one analgesic more than once a day
Tenderness (<i>Sparshashtva</i>)	
0	No tenderness
1	Mild tenderness
2	Moderate tenderness
3	Severe tenderness
4	Very severe tenderness
Morning stiffness (<i>Jadya</i>)	
0	No morning stiffness
1	Up to 25% limitation of normal range of mobility
2	upto 50% limitation of normal range of mobility
3	upto 75% limitation of normal range of mobility
4	> 75% limitations of normal range of mobility
Constipation (<i>Vidvibandha</i>)	
0	No <i>Vidvibandha</i>
1	Motion once a day but not at regular interval
2	Motion in alternate days
3	Interval for more than one day
Disturbed Sleep (<i>Nidra viparya</i>)	
0	Normal sleep
1	Disturbed sleep during night with short naps during day
2	One to two hour reduction in night sleep with mild increase in day sleep
3	Three to five hour reduction in night sleep with gross increase in day Sleep
4	Wakes during night and sleep during day

Objective Criteria

All the routine laboratory investigations were done along with diagnostic parameter.

Hematological Investigations: Complete Blood Cytogram (CBC): Hemoglobin, TLC, DLC. Erythrocyte Sedimentation Rate:

SGOT/SGPT, blood urea, serum creatinine and blood sugar estimation is done for the safety profile of the patient before treatment and after treatment.

C - reactive protein (CRP titer)

Rheumatoid factor (RA titer)

Objective Profile

Under this category apart from routine examination of locomotor system like stiffness, deformities etc. Some special test like walking time, grip power, pressing power and range of motion were observed and measured at each successive follow up:

Walking time: The walking time taken by the patients for a fixed distance was observed and recorded to know the time consumed to cross the fixed distance. This test provides functional status of hip, knee, ankle

and smaller joints of the lower limbs. In the present study 20 meters distance was fixed for the purpose and grading was given:

- 0=20-30 sec
- 1=30-40 sec
- 2=40-50 sec
- 3=50-60 sec
- 4=> 60 sec

Grip power and pressing power: The functional status of wrist joints, metacarpophalangeal joints and interphalangeal joints was assessed by measuring of pressing power and grip power. For this test (grip power) patients were asked to grip the inflated cuff of a sphygmomanometer by both palms and fingers separately and the rise of manometer readings was recorded in mmHg of mercury at the time of registration and follow ups of the patients of *Amavata*. For measuring the pressing power the cuff of sphygmomanometer was inflated at the basal value and was placed on the table. The patient sitting on front of the table on a chair was told to press the inflated cuff by both hands separately. While pressing the cuff pressure should be applied from all the involved joints of upper limbs and the extent to which the patient can press the cuff is observed in terms of the rise in mercury column in mm of Hg at the time of registration and follow ups. In both the test the cuff of the sphygmomanometer was inflated up to basal value of 30 mm of Hg.

- 0=200 mmHg
- 1=198-158mmHg
- 2=156-110mmHg
- 3=108-70mmHg
- 4=<70mmHg

Final assessment of Results

Statistical Analysis: Data obtained during the trial was tabulated and statistically analysed using Student Paired 't' Test. The result was categorized significant or insignificant depending upon the value of p.

- Highly significant -p value <0.001
- Significant -p value <0.05
- Insignificant- p value >0.05

OBSERVATIONS AND RESULTS

Age wise distribution of patients shows that 31.25% of the patients were in the age group of 41-50 years, 21.88% of the patients were in the age group of 30-40 and 60-70 years, 15.63% of the patients were in the age group of 51-60 years. In this study, 71.88% patients were females whereas males comprised of 28.12%. Most of the studies done suggest that females are more affected by this disease. This study also supports the evidence. All the patients were Hindu because the study was conducted in Hindu Community.

The majority of patients in the present study were housewives (53.13%) followed by farmers (21.88%), labour class (15.63%) service class (9.38%). Educational qualification wise distribution of 32 patients shows that 40.63% patients were illiterate, 25% patients were under matriculation, 18.75% were matriculate, 9.38% were senior secondary qualified, and 6.5% were graduate. All the patients were married. Most of the patients came from rural areas (93.75%) while 6.25% patients were from urban areas. The majority of the patients i.e., 40.3% were of poor socio-economic status which was followed by 37.50% belonging to lower middle class, 15.63% middle class and 6.25% from rich class. Addiction wise distribution of 32 patients shows that 75% patients i.e., 24 patients were addicted to tea/coffee, 9.38% patients was addicted to smoking and alcohol and only alcohol (3 patients), and 6.25% patients was addicted to smoking. Lifestyle distribution of 32 patients showed that 71.88% patients were having sedentary lifestyle, 28.13% of patients were leading an active lifestyle. Dietetic habits of 32 patients showed that 71.88% of patients were taking mixed diet and 28.13% patients were taking vegetarian diet. The incidence of family history was absent in most of the cases i.e., 75%. It was present only in 25% of total cases. Symmetry-wise distribution of joint involvement of 32 patients showed that 100% of patients had symmetrical involvement of joints. Incidence of the duration of illness in 32 patients of *Amavata* revealed that maximum patients 27.11% had disease for 2-4 years, 28.63% had disease for >8 years and < 2 years followed by 15.63% for 5-8 years. Assessment of *Abyavaharana Shakti* revealed maximum patients had *Avara Abyavaharana Shakti* (46.88%) followed by *Madhyam Abyavaharana Shakti* (40.62%) and *Pravara Abyavaharana Shakti* (12.50%). Assessment of *Jarana Shakti* revealed maximum patients had *Madhyam Jarana Shakti* (78.12%) followed by *Avara Jarana Shakti* (21.88%). Assessment of *Koshtha* revealed maximum patients had *Madhyam Koshth* (71.88%) followed by *Karura Koshth* (28.12%). In the present study, 53.12% of patients were of *Vata-Kaphaj Prakriti*, 25% patients were of *Kapha-Vataj Prakriti*, and 21.88% patients were of *Vata-Pittaj Prakriti*. In the present study, 75% of patients were of *Rajas Prakriti* and 21.88% of *Tamas Prakriti*, and 3.12% of patients were of *Saatvik Prakriti*. Most of the patients of the present study i.e., 81.25% were having disturbed sleeping pattern and 18.75% patients were having normal sleeping pattern. 75% of patients in the present study reported gradual onset of their disease. Only 25% of patients had a sudden onset. Distribution of 32 patients based on joints involved shows that there was no involvement of DIP. PIP and MCP joints were involved in 26 (81.25%) patients, wrist joint was

involved in 19 (59.38%) patients, Elbow and Knee joint were involved in 17 (53.12%), MT was involved in 15(46.88%) patients, Ankle joint was involved in 13 (40.63%) patients, and shoulder was involved in 12 (37.50%) patients. In the present study the maximum number of patients i.e., 75% experience worsening of symptoms during winters followed by 18.75% in summers, and 6.25% patients do not show aggravation of symptoms in particular season. Among 32 registered cases, maximum patients had normal bowel habit i.e 56.25%, 31.25% were having altered bowel habit whereas 12.50% were constipated. In the **Signs and symptoms Wise Distribution**

present study RA factor in most i.e., 81.25% patients were having reactive RA factor followed by 18.75% having non-reactive RA factor. Predominance of signs and symptoms of *Amavata* were studied in 32 patients. It was observed that, *Sandhishoola* was present in 32 (100%) patients followed by *Sparshashyata*, *Nidra vipraya*, *Sandhishotha*, and *Alasya* 31 (96.99%) while *Sandhishotha*, *Jadya*, and *Vidvibandha* was present in 30 (93.75%) followed by *Angmarda*, *Aruchi*, and *Daha* was presented in 26 (81.25%). *Apaka*, *Aganimandya*, and *Trishna* were observed in 23 (71.88%). Only 12 (12.50%) Patients were complaints of *Jawara*.

Table 4: The incidence of signs and symptoms of Amavata in 32 patients

Sign and symptoms	Groups		Total
	Group I (n=16)	Group II (n=16)	
<i>Sandhishoola</i>	16	16	32 (100%)
<i>Sparshashyata</i>	16	15	31 (96.99%)
<i>Sandhishotha</i>	15	16	31 (96.99%)
<i>Alasya</i>	16	15	31 (96.99%)
<i>Nidra vipraya</i>	16	15	31 (96.99%)
<i>Gauravata</i>	14	16	30 (93.75%)
<i>Jadya</i>	15	15	30 (93.75%)
<i>Vidvibandha</i>	14	16	26(81.25%)
<i>Angamarda</i>	13	13	26(81.25%)
<i>Daha</i>	13	13	26 (81.25%)
<i>Aruchi</i>	12	14	26 (81.25%)
<i>Apaka</i>	12	11	23 (71.88%)
<i>Agnimandya</i>	11	12	23 (71.88%)
<i>Trishna</i>	11	12	23 (71.88%)
<i>Jawara</i>	7	5	12 (12.50%)

Table 5: Effect of therapy on subjective criteria of Amavata

Parameters	No. of patients	Group	Mean		% Changes	SD±	SE±	T value	P Value	Sig
			BT	AT						
<i>Angamarda</i>	13	Group I	0.7	0.4	44%	0.4	0.1	2.64	0.01	S
	13	Group II	0.5	0.3	42%	0.45	0.14	2.98	0.02	S
<i>Aruchi</i>	12	Group I	1.8	0.6	66.9%	0.6	0.17	6.9	0.031	HS
	14	Group II	1.9	1.2	52%	0.34	0.19	7.2	0.04	S
<i>Trishna</i>	11	Group I	0.72	0.4	45.6%	0.4	0.12	2.7	0.01	S
	12	Group II	0.67	0.39	43.9%	0.42	0.14	2.9	0.02	S
<i>Alasya</i>	16	Group I	2.13	1	53%	0.65	0.18	6.8	0.032	HS
	15	Group II	2.15	1.56	40%	0.9	0.7	5.9	0.04	S
<i>Gauravata</i>	14	Group I	1.6	0.6	58%	0.57	0.154	6.089	0.033	HS
	16	Group II	1.87	0.5	61%	0.58	0.234	6.123	0.034	HS
<i>Jwara</i>	1	Group I	0.27	0.2	24%	0.4	0.1	0.5	0.58	IS

	3	Group II	0.24	0.19	23%	0.5	0.15	0.45	0.47	IS
Apaka	12	Group I	1.6	0.9	56%	0.54	0.12	5.781	0.021	HS
	11	Group II	1.2	0.67	44%	0.561	0.132	4	0.03	S
Agnimandya	11	Group I	1.47	0.33	76.87%	0.64	0.65	6.859	0.031	HS
	12	Group II	1.44	0.78	56%	0.53	0.34	5.98	0.03	S
Daha	13	Group I	1.45	0.56	27%	0.55	0.134	4.67	0.23	IS
	13	Group II	1.49	0.55	24%	0.51	0.124	3.89	0.43	IS
Jadya	15	Group I	1.7	1.52	40%	0.56	0.113	2.312	0.03	S
	15	Group II	1.9	1.76	39%	0.43	0.145	2.56	0.03	S
Sparsh Ashyata	16	Group I	1.53	0.79	45%	0.354	0.098	9.5	0.04	S
	15	Group II	1.54	0.89	44%	0.345	0.076	8.7	0.03	S
Sandhi Shoola	16	Group I	1.93	0.87	67%	0.46	0.12	9.45	0.041	HS
	16	Group II	1.87	0.89	64%	0.43	0.21	7.89	0.032	HS
Shandi Shotha	15	Group I	1.56	0.78	60%	0.45	0.08	8.98	0.04	S
	16	Group II	1.6	0.4	75%	0.414	0.07	11.225	0.051	HS
Vidvibandha	14	Group I	0.98	0.23	43%	0.45	0.12	6.2	0.03	S
	16	Group II	1.01	0.45	40%	0.35	0.13	9.34	0.04	S
Nidravipraya	16	Group I	1.33	0.78	46%	0.45	0.14	5.5	0.02	S
	15	Group II	1.35	0.80	44%	0.46	0.12	5.8	0.02	S

Table 6: Intergroup comparison of subjective criteria of Amavata

Symptoms	% of relief		Diff. In %	P value	Sig
	Group I	Group II			
Angamarda	44%	42%	2%	0.45	IS
Aruchi	52%	66.9%	15%	0.04	S
Trishna	45.6%	43.9%	2%	0.12	IS
Alasya	40%	53%	13%	0.04	S
Gauravata	61%	58%	3%	0.25	IS
Jawara	24%	23%	1%	0.21	IS
Apaka	56%	44%	12%	0.65	IS
Agnimandya	56%	76.86%	21%	0.04	S
Daha	27%	24%	3%	0.45	IS
Jadya	40%	39%	1%	0.35	IS
Sparshashyata	44%	45%	1%	0.12	IS
Sandhishoola	64%	67%	3%	0.19	IS
Sandhishotha	60%	75%	15%	0.04	S
Vidvibandha	43%	40%	3%	0.25	IS
Nidra vipraya	46%	44%	2%	0.45	IS

Table 7: Effect of therapy on functional assessment

Function assessment	Group	Mean		% of change	SD	SE	T value	P value	Sig
		BT	AT						
Walking time	Group 1	3.04	1.24	64.2%	1.03	0.32	0.75	<0.05	S
	Group 2	3.01	1.41	61.5%	1.07	0.40	1.2	<0.05	S
Grip power	Group 1	3.02	1.72	80.3%	0.24	0.65	8.53	<0.05	S
	Group 2	2.37	1.43	78.1%	0.17	0.03	11.52	<0.05	S
Foot pressing power	Group 1	3.12	1.12	62.2%	0.08	0.63	9.38	<0.05	S
	Group 2	2.26	0.75	57.3%	0.05	0.35	20.2	<0.05	S

Table 8: Effect of therapy on Hematological profile

Category	Group	Mean		% Changes	SD	SE	T value	P value	Sig
		BT	AT						
TLC	Group I	10,000	9,200	8%	4.5	478.66	1.4	>0.05	IS
	Group II	8,500	8,400	1.18%	2.43	560.19	0.8	>0.05	IS
Neutrophils	Group I	58	56	3.45%	9.7	2.04	0.7	>0.05	IS
	Group II	61.2	58	5.3%	11.1	2.034	0.25	>0.05	IS
Lymphocytes	Group I	33	31	6.07%	3.4	1.66	2.5	>0.05	IS
	Group II	30	29	3.3%	3.2	1.8	0.6	>0.05	IS
Mixed Cell	Group I	10.09	9	10%	3.4	2.7	0.6	>0.05	S
	Group II	8.0	7.0	12.5%	3.9	0.6	2.1	>0.05	IS
ESR	Group I	80	60	12.4%	9.21	3.4	3.43	<0.05	S
	Group II	70	50	24.92%	11.7	7.2	3.2	<0.05	S
RA factor	Group 1	5.5	5.5	0	1.2	0.02	0.1	<0.05	IS
	Group II	5	5	0	1.0	0.01	0.14	<0.05	IS
CRP	Group I	52.53	22.6	27.93	2.3	1.23	6.2	<0.05	S
	Group II	48	22.8	25.2	4.8	1.8	6.0	<0.05	S
SGOT	Group I	45	38	15.6	6.8	1.42	9.0	0.053	IS
	Group II	34	30	11.8	5.0	1.05	1.0	0.08	IS
SGPT	Group I	35	31	11.4	12	2.6	7.4	0.07	IS
	Group II	42	38	9.5	3.3	0.8	1.0	0.10	IS
TSB	Group I	0.5	0.5	0.0	0.1	0.04	2.8	0.43	IS
	Group II	0.6	0.4	33.3	0.1	0.01	0.3	0.45	IS
DSB	Group I	0.2	0.1	5.0	0.16	0.04	2.5	0.13	IS
	Group II	0.1	0.2	0.0	0.00	0.001	0.2	0.21	IS
FBS	Group I	115	115	0.0	15.5	3.2	3.2	0.098	IS
	Group II	99	111	0.0	18.4	3.8	0.2	0.099	IS
Cholesterols	Group I	180	166	7.8	60	10.3	6.7	0.088	IS
	Group II	150	140	6.7	58	12.3	2.5	0.324	IS
Triglycerides	Group I	160	150	6.3	27	5.7	6.1	0.089	IS
	Group II	170	164	3.5	14	4.8	1.2	0.079	IS
HDL	Group I	40	39	2.5	4.1	0.9	0.8	0.076	IS

	Group II	46	44	4.3	9	2.0	1.89	0.067	IS
LDL	Group I	70	60	14.3	16.0	3.0	4.4	0.056	IS
	Group II	50	50	0.0	10	2.0	1.8	0.058	IS
VLDL	Group I	51	45	11.	26.5	10	9.8	0.107	IS
	Group II	45	41	8.9	3.0	0.7	0.7	0.06	IS
B. Urea	Group I	26.8	35.3	0.0	4.3	0.9	0.9	0.07	IS
	Group II	22	21	4.5	7.4	1.7	1.7	0.054	IS
Serum Creatinine	Group I	0.6	0.4	33.3	0.1	0.03	1.6	0.53	IS
	Group II	0.5	0.5	0.0	0.16	0.01	1.7	0.051	IS

Table 9: Effect of therapy on hematological profile

Category	Group	Mean		% Changes	SD	SE	T value	P value	Sig
		BT	AT						
TLC	Group I	10,000	9,200	8%	4.5	478.66	1.4	>0.05	IS
	Group II	8,500	8,400	1.18%	2.43	560.19	0.8	>0.05	IS
Neutrophils	Group I	58	56	3.45%	9.7	2.04	0.7	>0.05	IS
	Group II	61.2	58	5.3%	11.1	2.034	0.25	>0.05	IS
Lymphocytes	Group I	33	31	6.07%	3.4	1.66	2.5	>0.05	IS
	Group II	30	29	3.3%	3.2	1.8	0.6	>0.05	IS
Mixed Cell	Group I	10.09	9	10%	3.4	2.7	0.6	>0.05	IS
	Group II	8.0	7.0	12.5%	3.9	0.6	2.1	>0.05	IS
ESR	Group I	80	60	24.92%	9.21	3.4	3.43	<0.05	S
	Group II	70	50	19.4%	11.72	7.2	3.2	<0.05	S

Table 10: Intergroup Comparison of hematological parameter

Category	% of relief		Diff. In %	P value	Sig
	Group I	Group II			
TLC	8%	1.18%	6.82%	0.089	IS
Neutrophils	3.45%	5.3%	1.85%	0.123	IS
Lymphocytes	6.07%	3.3%	2.77%	0.056	IS
Mixed Cell	10%	12.5%	2.50%	0.055	IS
ESR	8%	1.18%	6.82%	0.089	IS

Table 11: Effect of therapy on biochemistry profile

Category	Group	Mean		% Changes	SD	SE	T value	P value	Sig
		BT	AT						
SGOT	Group I	50	30	60%	6.8	1.42	9.0	0.003	S
	Group II	34	22	35.29%	5.0	1.05	1.0	0.002	S
SGPT	Group I	44	20	54.55%	12	2.6	7.4	0.004	S
	Group II	46	22	52.17%	3.3	0.8	1.0	0.001	S
TSB	Group I	0.6	0.5	16.37%	0.1	0.04	2.8	0.432	IS
	Group II	0.6	0.4	33.33%	0.1	0.01	0.3	0.453	IS
DSB	Group I	0.2	0.19	5%	0.16	0.04	2.5	0.134	IS
	Group II	0.12	0.22	17%	0.007	0.001	0.2	0.212	IS

FBS	Group I	110	110	0%	15.5	3.2	3.2	0.098	IS
	Group II	116	115	0.2%%	18.4	3.8	0.2	0.099	IS
Cholesterols	Group I	180	178	1.11%	60	10.3	6.7	0.088	IS
	Group II	175	160	9.57%	58	12.3	2.5	0.324	IS
Triglycerides	Group I	200	160	20%	27	5.7	6.1	0.089	IS
	Group II	180	174	4.33%	14	4.8	1.2	0.079	IS
HDL	Group I	50	50	0	4.1	0.9	0.8	0.076	IS
	Group II	56	52	8.14%	9	2.0	1.89	0.067	IS
LDL	Group I	80	78	2.50%	16.0	3.0	4.4	0.056	IS
	Group II	54	54	0	10	2.0	1.8	0.058	IS
VLDL	Group I	53	40	26.47%	26.5	10	9.8	0.007	S
	Group II	50	42	16%	3.0	0.7	0.7	0.06	IS
B. Urea	Group I	28.3	28.2	0.55%	4.3	0.9	0.9	0.07	IS
	Group II	22.0	21	4.55%	7.4	1.7	1.7	0.054	IS
Serum Creatinine	Group I	0.9	0.8	11.11%	0.1	0.03	1.6	0.53	IS
	Group II	0.6	0.5	16.67%	0.16	0.01	1.7	0.051	IS

Table 12: Intergroup Comparison of biochemical parameter

Category	% of relief		Diff. In %	P value	Sig
	Group I	Group II			
RA Factor	0.75%	0.29%	0.5%	>0.05	IS
CRP	50%	46%	4%	>0.05	IS
SGOT	60	35.29	24.71%	<0.05	S
SGPT	12%	15%	2.33%	>0.05	IS
TSB	33.33%	30%	16.96%	>0.05	IS
DSB	17%	5%	12.00%	>0.05	IS
FBS	0.2%	0%	0.20%	>0.05	IS
Cholesterol	9.57%	1.11%	8.46%	>0.05	IS
Triglycerides	20%	4.33%	15.67%	>0.05	IS
HDL	8.14%	0%	8.14%	>0.05	IS
LDL	2.5%	0%	2.50%	>0.05	IS
VLDL	26.47	16%	9.53%	>0.05	IS
B. urea	4.55%	0.55%	4%	>0.05	IS
S. Creatinine	16.67%	11.11%	5.56%	>0.05	IS

Ingredients of Shatpushpadi Churna



Saunf



Vaividang



Krishan Maricha



Sendha Namak

Ingredients of Vatari Guggulu and Simhanada Guggulu



Erand Tail



Shudh Guggulu



Amalaki



Haritaki



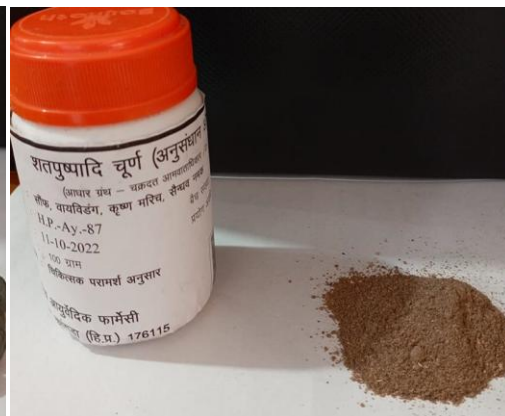
Vibhitaki



Shudh Gandhaka



Vatari Guggulu



Shatpushpadi Churna



Simhanada Guggulu

Effect of Therapy on Subjective Criteria Signs and symptoms (Table no- 4, 5, 6)

Predominance of signs and symptoms of *Amavata* were studied in 32 patients. It was observed that, *Sandhishoola* was present in 32 (100%) patients followed by *Sparshashyata*, *Nidra vipraya*, *Sandhishotha*, and *Alasya* 31 (96.99%) while *Sandhishotha*, *Jadya*, and *Vidvibandha* was present in 30 (93.75%) followed by *Angmarda*, *Aruchi*, and *Daha* was presented in 26 (81.25%). *Apaka*, *Aganimandya*, and *Trishna* were observed in 23 (71.88%). Only 12 (12.50%) patients were complaints of *Jawara*. There was a statistically significant decrease (p value= 0.031) in *Angamarda* by 78.71% in the group I. In group II only 56% decrease in *Angamarda* was observed after the therapy which was statistically significant (p-value= 0.03). In group I only a 66.9% decrease in *Aruchi* was observed after the therapy which was statistically significant (p-value= 0.031). There was a statistically highly significant decrease (p-value = 0.031) in *Aruchi* by 52% in group II. There was a statistically significant decrease (p value=0.018) in *Trishna* by 45.6% in group I. In group II only 43.9% decrease in *Trishna* was observed after the therapy which was statistically significant (p-value= 0.02). In group I only a 53% decrease in *Alasya* was observed after the therapy which was statistically highly significant (p-value=0.032). Whereas in group II 40% decrease was observed with p-value=0.04 which was statistically significant. There was a statistically highly significant decrease (p value<0.001) in *Gauravata* by 58% in group I. In group II only a 61% decrease in *Gauravata* was observed after the therapy which was statistically highly significant (p value <0.001). In group I only 24% decrease in *Jwara* was observed after the therapy which was statistically insignificant (p-value =0.58). In group II only 23% decrease in *Jwara* was observed after the therapy which was statistically insignificant (p-value=0.47). There was statistically highly significant decrease (p-value<0.001) in *Apaka* by 56% in group I. In group II only 44% decrease in *Apaka* was observed after the therapy which was statistically significant (p value=0.003). In group I only 76.87% decrease in *Agnimandya* was observed after the therapy which was statistically highly significant (p value=0.031). There was a statistically significant decrease p value=0.03 in *Agnimandya* by 56% in group II. In group I only 27% decrease in *Daha* was observed after the therapy which was statistically insignificant p-value=0.231. In group II only a 24% decrease in *Daha* was observed after the therapy which was statistically insignificant p-value=0.431. There was statistically significant decrease (p value=0.03) in *Jadya* by 40% in group I. In group II only 39% decrease in *Jadya* was observed after the therapy which was

statistically significant p value=0.02. There was a statistically significant decrease (p value=0.04) in *Sparsh Ashyata* by 45% in group I. In group II only 44% decrease in *Sparsh Ashyata* was observed after the therapy which was statistically significant p value = 0.03. There was statistically highly significant decrease (p value<0.001) in *Sandhi Shoola* by 67% in group I. In group II only 64% decrease in *Sandhi Shoola* was observed after the therapy which was statistically significant (p value=0.032). There was statistically significant decrease in *Sandhi Shotha* by 60% with p value = 0.04 in group I. In group II only 75% decrease in *Sandhi Shotha* was observed after the therapy which was statistically highly significant (p-value = 0.051).

There was a statistically significant decrease (p value=0.03) in *Vidvibandha* by 43% in group I. In group II only 40% decrease in *Vidvibandha* was observed after the therapy which was statistically significant (p value=0.04). There was a statistically significant decrease (p value=0.02) in *Nidravipraya* by 46% in group I. In group II only 44% decrease in *Nidravipraya* was observed after the therapy which was statistically significant (p value=0.02).

Effect of therapy on functional assessment (Table no.7)

Effect of therapy on Functional Assessment revealed that in group1 64.2% improvement in walking time while in group 2 there was 61.5%. In grip power there was 80.3% improvement in Group 1 while in group 2 it was 78.1%. In foot pressing power 62.2% improvement in group 1 while in group 2 there was 57.3% and all these parameters were have significant results with p-value <0.05.

Effect of Therapy on Haematological and Biochemical Parameters (Table no- 8, 9, 10, 11)

In the present study, no considerable change was noticed in Hb, TLC, DLC, FBS, blood urea and serum creatinine after treatment in both the groups, except ESR and CRP. In ESR there was 24.92% reduction in group I and 19.4% in group II. Both groups showed statistically significant result with (p value<0.05). In CRP Percentage of relief were 27.93% and 25.2% percentage respectively in Group I and Group II the result in both groups were statistically significant (p<0.05). Intergroup comparison revealed that result was statistically insignificant in both groups.

OBSERVATION

The main *Dosha* of *Amavata* is *Vata* and *Kapha*, all contents of the proposed drug have *Vatakapha shamaka* property, because of having- *Tikshna*, *Laghu Guna*, *Katu*, *Tikta*, *Rasa*, *Ushana Virya*. *Dushya* of

Amavata are Rasa and Majja. Due to Agnimandya at the Jatharagni level or Bhutagni level Rasadhatu and Anna were not digested properly and turn into Ama. The maximum contents of the drug are Katu- Tikta Rasa and Ushana Virya Pradhana which have Deepana-Pachana property. The basic Nidana of Amavata leads to Rasavaha and Majjavah- Stroto-Dushti, and Chikitsa of these: which is given in Charaka samhita as Agnideepana and Tikta and Madhura Rasa Pradhana Dravya are the indication in this stage.

In the first stage of disease pathogenesis, Amotpatti takes place At this stage, Simhanada Guggulu and Vatari Guggulu shows the Amapachana effect. All the general pharmacodynamic properties of drug i.e., Laghu, Tikshna, Ruksha Guna, Tikta Rasa and Ushana Virya are against the Guru Snigadha Picchila and Sheeta properties of Ama. Ama formation is stopped by the Deepneeya action. Associated symptoms like Vidvibandh and Anaha are reduced by Anulomana i.e., purgative properties of the drugs. Eranda oil and Triphala Guggulu relieves the symptoms of Sandhishoola and Shotha by analgesic and anti-inflammatory action. The type of Sangha Strotodushti occurs in Amavata. The proposed drug with Laghu, Ruksha, Ushana Virya helps to remove Strotokleda, Shodhana and Klednashakaguna.

Almost all these drugs have Ushana Virya, Laghu Ruksha Guna, Amahara, Deepana Vatakaphahara and Shotha, Shoolghana properties. By the Ushna Ruksha and Laghu Guna, it does the Pachana of Ama, which is seated in local Sandhis. Shandhi shotha in Amavata is brought about by the accumulation of Kapha Dosha and Ama, by Amapachana properties of all these drugs, it does liquefaction of Ama. At the same time, it also does Sroto Vikasa by its Ushana Guna resulting in increased circulation. Due to increased circulation Ama moves from Sandhi into circulation leading to Sthabdata nasha thereby joint movements come to normal.

As Amapachana take place, Margavarodha also reduces, so the movements of Vata come to normal. Vata Shamana in turn results in a reduction in pain.

CONCLUSION

The following conclusion may be drawn based on observations and analysis made in the clinical study

- The trial drugs Vatari Guggulu and Shatpushpadi Churna showed statistically significant results in subjective parameters- Angamarda, Trishna, Apaka, Jadya, Sparsh Ashyata, Vidvibandha and Nidravipraya.
- The objective parameter i.e., CRP, ESR showed statistically significant results in both groups but the maximum decrease was observed in Group II.
- In walking time, grip power and foot pressing power both groups showed significant statistical improvement. In addition to these parameters, the trial drugs Vatari Guggulu and Shatpushpadi churna also showed significant results in SGOT.
- In walking time, grip power and foot pressing power both groups showed significant statistical improvement.
- Hematological and other biochemical investigations i.e., TLC, DLC, blood urea, serum creatinine, SGPT and Serum lipid profile remained within normal range in both the groups after the completion of the trial.
- No adverse effects of Vatari Guggulu and Shatpushpadi churna were reported during the trial period.
- Thus on the basis of the present clinical study it was concluded that Vatari Guggulu and Shatpushpadi churna is efficient in improving signs and symptoms of Amavata.

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