A PILOT STUDY ON AMAVATA (RHEUMATOID ARTHRITIS)

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ABSTRACT

The disease *Amavata* is a most common crippling and disabling disorder which by its clinical appearance can be compared with Rheumatoid Arthritis. A pilot study was conducted for 30 days on 70 patients by randomly divided into three groups. First group was given *Vatari Guggulu* twice a day but at 7 days interval also administered *Simhanada Guggulu* for *Virechana* purpose whereas second group was given only *Vatari Guggulu* twice daily. The third group was given piroxicam tab as control drug. Highly Statistically significant improvement was found in cardinal features among all groups but maximum improvement was found in trial group -1.

KEYWORDS: *Amavata*, Rheumatoid Arthritis, *Vatari Guggulu*, *Simhanada Guggulu*.

INTRODUCTION

The detail knowledge on *Amavata* was first explained by *Madhavakar*, whereas *Chakrapani Dutta* first gave knowledge about principle and management of the disease. *Amavata* is a clinical entity very much similar to the chronic but active inflammatory arthropathy, the Rheumatoid arthritis.[1,2] Till now, the etio-pathogenesis of Rheumatoid arthritis is not known precisely but among the hypothesis, entero-pathy along with autoimmune have important role regarding this disease and this hypothesis finds support from Indian medicine also [3, 4, 5, 6]

In *amavata*, due to impaired functioning of *'kayagni'* the *anna-rasa* undergoes fermentation resulted formation of *ama* (biotoxin) which combines with vitiated vata (biophysical force for movement) to form *Amavata*. So two important entities one is toxic and other is movement, when comes together and attack on joints the disease formed which is worst one. That's why swelling, severe pain, and restricted movements are the main features of *Amavata*. Severe pain, difficulty in movements, and swelling on the joints along with fever etc makes the patient's life miserable. Although *Ama* and *Vata* are chiefly pathogenic factors, *Kapha* and *Pitta* are also invariably involved in its pathogenesis (*Samprapti*). [7-12]

The therapeutic approach should be on *Vata dosha, Kapha dosha* and correction of *Amadosha* and of *Agni* viz. *Pitta*. The line of treatment for *amavata* also includes *langhanam, swedanam, tiktam, deepana, katu* drugs and *sodhana* treatment like *virechana, basti* etc.[13,14]

Vatari Guggulu carries indication for *Amavata* according to *Bhaisajya Ratnavali*.[15] The compositions in it are approachable lieu of principles of treatment of *Amavata*. Also under principles of treatment a known *virechaka* drug (*Simhanada guggulu*[16]) is added along with *Vatari Guggulu* to one group. For control study, tablet Piroxicam[17], is taken which is a well known & proven procedure for Rheumatoid arthritis.

AIM AND OBJECTIVES

This study aims to evaluate the therapeutic efficacy of *Vatari Guggulu* in the management of *Amavata* with various scientific parameters. The Clinical trial carried out in the P.G. Dept. Of *Kayachikitsa*, G.A.M, Puri.

MATERIAL AND METHODS

Plan of Study

The study was carried out for a period of 30 days**.** Out of the resembling cases of *Amavata* 70 cases were selected according to the selection criteria. They were divided into three groups (TGI, TGII, & TG$_{III}$) keeping behind parity in the age, sex etc. **Trial group I** (TGI) were administered *vatari Guggulu* (BR) of one gram twice a day with lukewarm water for a period of 30 days without any interruption but at 7 days interval they were administered the *virechana* tab - *Simhanada Guggulu* (BR) of 250 mg at bed time with warm water in 4 sittings. **Trial group II** (TGII) were administered *vatari guggulu* 1gm twice a day with lukewarm water without any interruption. Third group i.e. **Control group** (TGIII) were

administered tab Piroxicam-20mg, one tab once a day after principal meal for a period of 30 days.

Study Design

☞ TG_I (BT) vs. TG_I (AT) - Effectiveness of treatment group - I will be assessed

☞ TG_{II} (BT) vs. TG_{II} (AT) - Effectiveness of treatment group - I will be assessed

☞ TG_{III} (BT) vs. TG_{III} (AT) - Effectiveness of treatment group - I will be assessed

Inclusion criteria: Both male and female patients aged above 16 yrs having classical features of *Amavata* like *Angamarda, Aruchi, Trishna, Hrillasa, Gaurava, Jwara, Shula, Shotha* etc. and who had fulfilled the revised criteria for Rheumatoid arthritis fixed by the American college of Rheumatology in 1987 were selected for study. The statistical data based on following subjective and objective parameters.

Subjective parameters

• Joint pain

• Swelling

• Tenderness

• Morning Stiffness

• General function capacity

Objective parameters

• E.S.R.

• RA Factor

• C.R.P.

The Exclusion Criteria

• Other connective tissue disorders like osteoarthritis, gouty arthritis etc

• Patients having diabetes

• Patients who are unfit for *virechana karma*

RESULTS AND DISCUSSION

The clinical assessment of results will be noted after treatment basing upon the cardinal Clinical features. The result in view of percentage of improvement will classify as follows.

Assessment grade for Subjective and Objective criteria

	G_0	→	**No pain**
	G_1	→	Mild pain of bearable nature, comes occasionally
Joint pain	G_2	→	Pain, but no difficulty in joint movement, appears frequently and requires some Upasaya measures for relief
	G_3	→	Difficulty in joint movements due to pain, requires medication and/or pain may remain throughout the day
	G_0	→	No swelling
	G_1	→	Feeling of swelling with heaviness
Swelling	G_2	→	Moderate swelling
	G_3	→	Severe swelling
	G_0	→	No tenderness
	G_1	→	Subjective experience of tenderness
Tenderness	G_2	→	Wincing of face on pressure
	G_3	→	Wincing of face with withdrawal of affected parts on pressure or Resists to touch
	G_0	→	Morning stiffness < 5mins
Morning	G_1	→	Morning stiffness 5mins - < 1hr
stiffness	G_2	→	Morning stiffness > 1hr – < 8hr
	G_3	→	Morning stiffness > 8 hrs
General	G_0	→	Complete ability to do routine works
function	G_1	→	Normal activity despite slight difficulty in joint movement
capacity	G_2	→	Few activities but can do himself
	G_3	→	Activities can do with help of others or total bed riden
	G_0	→	< 15 mm
	G_1	→	>15 – 30 mm
ESR	G_2	→	> 30 – 45mm
	G_3	→	>45 mm
RA factor	P	→	Positive
	A	→	Negative
	P	→	Positive
CRP	A	→	Negative

OBSERVATIONS
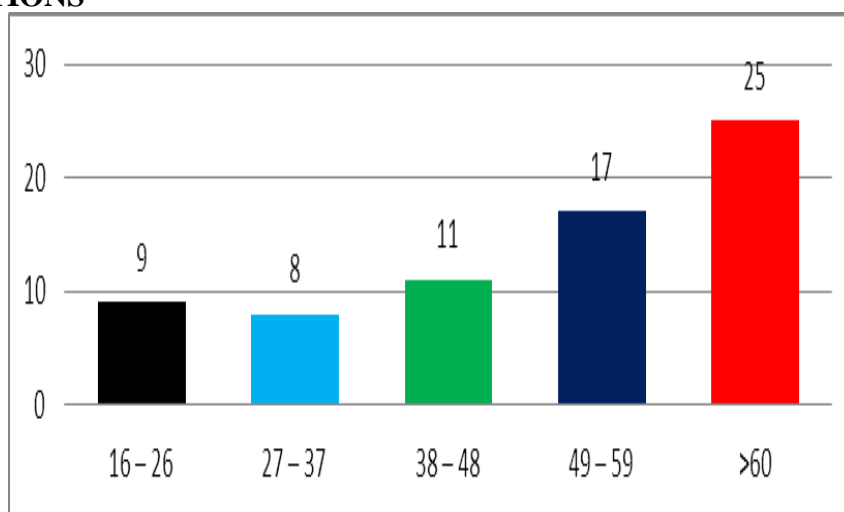
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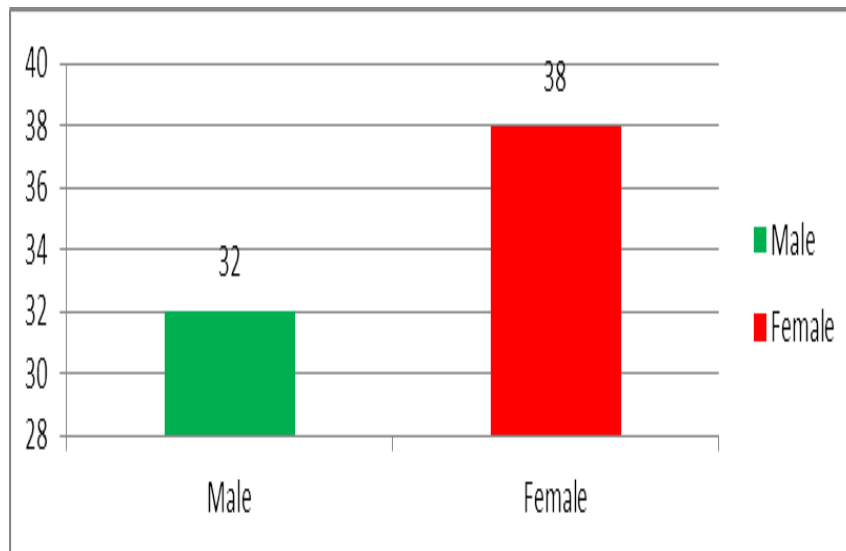
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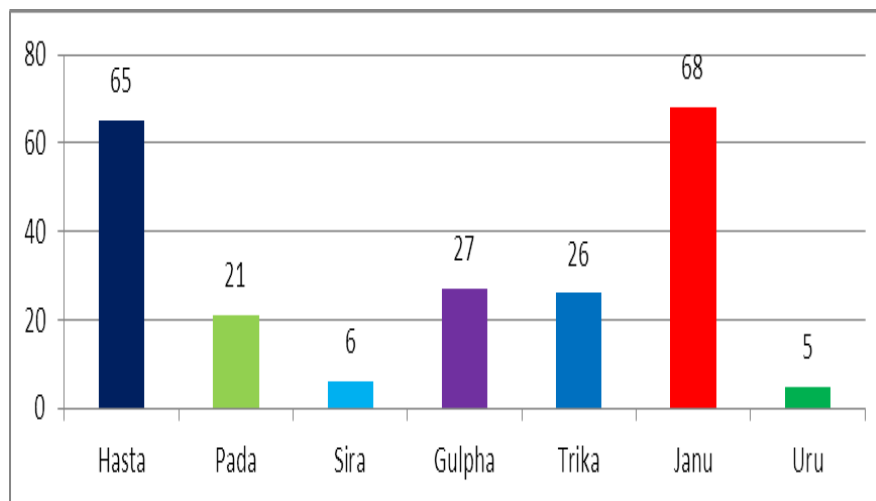
Fig 3 - S h o w i n g   t h e   i n c i d e n c e   o f   J o i n t   i n v o l v e m e n t

Table I - Showing the presence of Cardinal features, Degree of severity in TG$_I$

TG I	Presence of cardinal features		BT (Severity grad)								AT (Severity grade)							
			G$_3$		G$_2$		G$_1$		G$_0$		G$_3$		G$_2$		G$_1$		G$_0$	
	_f_	_%_	_f_	_%_	_f_	_%_	_f_	_%_	_f_	_%_	_f_	_%_	_f_	_%_	_f_	_%_	_f_	_%_
Joint pain	30	**100**	19	63.33	11	36.66	-	-	-	-	-	-	16	53.33	05	16.66	09	30
Swelling	30	**100**	8	26.66	13	43.33	9	30	-	-	-	-	04	13.33	16	53.33	10	33.33
Tenderness	30	**100**	3	10	24	80	3	10	-	-	-	-	2	6.66	14	46.66	14	46.66
Morning stiffness	30	**100**	1	3.33	9	30	20	66.66	-	-	-	-	1	3.33	6	20	23	76.66
General function capacity	30	**100**	-	-	14	46.66	16	53.33	-	-	-	-	-	-	9	30	21	70
ESR	30	**100**	24	80	5	16.66	1	3.33	-	-	-	-	6	20	12	40	12	40

			Positive			Negative			Positive			Negative		
			_f_		_%_	_f_		_%_	_f_		_%_	_f_		_%_
RA factor	30	**100**	24		80	6		20	4		13.33	26		86.66
CRP	30	**100**	18		60	12		40	21		13.33	26		86.66

BT – BEFORE TREATMENT	AT – AFTER TREATMENT	_f_ - FREQUENCY	% - PERCENTAGE	G$_0$, G$_1$, G$_2$, G$_3$ – RESPECTIVE GRADATIONS

Table II - Showing the presence of Cardinal features, Degree of severity in TG$_{II}$

TG II	Presence of cardinal features		BT (Severity grad)								AT (Severity grade)							
			G$_3$		G$_2$		G$_1$		G$_0$		G$_3$		G$_2$		G$_1$		G$_0$	
	_f_	_%_	_f_	_%_	_f_	_%_	_f_	_%_	_f_	_%_	_f_	_%_	_f_	_%_	_f_	_%_	_f_	_%_
Joint pain	30	**100**	25	83.33	5	16.66	-	-	-	-	-	-	17	56.66	05	16.66	08	26.66
Swelling	30	**100**	5	16.66	23	76.66	2	6.66	-	-	-	-	2	6.66	20	66.66	08	26.66
Tenderness	30	**100**	11	36.66	6	20	13	43.33	-	-	-	-	7	23.33	8	26.66	15	50
Morning stiffness	30	**100**	2	6.66	12	40	16	53.33	-	-	-	-	2	6.66	7	23.33	21	70
General function capacity	30	**100**	4	13.33	22	73.33	4	13.33	-	-	-	-	2	6.66	21	70	7	23.33

	Presence		BT G3		G2		G1		G0		AT G3		G2		G1		G0	
ESR	30	**100**	30	100	0	-	0	-	0	-	-	-	4	13.33	17	56.66	9	30

			Positive		Negative		Positive		Negative	
			f	**%**	*f*	**%**	*f*	**%**	*f*	**%**
RA factor	30	**100**	23	76.60	7	23.33	4	13.33	26	86.66
CRP	30	**100**	20	66.66	10	33.33	3	10	27	90

BT – BEFORE TREATMENT	**AT – AFTER TREATMENT**	***f* - FREQUENCY**	**% - PERCENTAGE**	**G₀, G₁, G₂, G₃ – RESPECTIVE GRADATIONS**

Table III - Showing the presence of Cardinal features, Degree of severity in CG

CG	Presence of cardinal features		BT (Severity grad)								AT (Severity grade)							
			G_3		G_2		G_1		G_0		G_3		G_2		G_1		G_0	
	f	**%**	*f*	*%*	*f*	*%*	*f*	*%*	*f*	*%*	*f*	*%*	*f*	*%*	*f*	*%*	*f*	*%*
Joint pain	10	**100**	7	70	3	30	-	-	-	-	1	10	1	10	1	10	7	70
Swelling	10	**100**	2	20	6	60	2	20	-	-	-	-	1	10	1	10	08	80
Tenderness	10	**100**	1	10	5	50	4	40	-	-	-	-	2	20	-	-	8	80
Morning stiffness	10	**100**	-	-	4	40	6	60	-	-	-	-	-	-	2	20	8	80
General function capacity	10	**100**	1	10	5	50	4	40	-	-	-	-	2	20	1	10	7	70
ESR	10	**100**	5	50	5	50	-	-	-	-	-	-	1	10	4	40	5	50

			Positive		Negative		Positive		Negative	
			f	*%*	*f*	*%*	*f*	*%*	*f*	*%*
RA factor	10	**100**	8	80	2	20	1	10	9	90
CRP	10	**100**	8	80	2	20	1	10	9	90

BT – BEFORE TREATMENT	**AT – AFTER TREATMENT**	***f* - FREQUENCY**	**% - PERCENTAGE**	**G₀, G₁, G₂, G₃ – RESPECTIVE GRADATIONS**

Table – IV- Showing the Average improvement (%) in TG_I, TG_{II}, CG

Sign & symptoms	Trial Group I %	Trial Group II %	Control Group %
Joint pain	53.16	54.11	77.77
Swelling	59.32	61.90	85
Tenderness	60	62.06	74.47
Morning stiffness	80.48	76.08	85.71
General function capacity	79.54	58.33	70.58
ESR	69.87	73.33	76
RA factor	86.66	86.66	90
CRP	86.66	90	90

Table – V - Showing the Clinical Results

Sl. No.	Clinical assessment	After treatment (30 Days)					
		TG_1 (n_1 = 30)		TG_2 (n_2 = 30)		CG (n_2 = 30)	
		f	%	*f*	%	*f*	%
1	Maximum improvement / Cured	18	60	11	36.67	8	80
2	Moderate improvement	10	33.33	14	46.67	1	10
3	Mild improvement	2	6.67	5	16.67	1	10
4	Unsatisfactory	-	-	-	-	-	-

Table – Vi - Statistical Analysis showing the effectiveness of Trial-I, Trial-II & Control drug With respect to Different Sign & Symptoms

Sign & Symptoms	Treatment Group	Duration Of treatment	Mean ± S.D.	d. f. (n-1)	t – Value	p - Value	Remarks
Joint pain	TG_I	B.T.	2.63±0.49	29	13.69	<0.001	***
		A.T.	1.23±0.89				
	TG_{II}	B.T.	2.83±0.37	29	11.46	<0.001	***
		A.T.	1.3±0.87				
	CG	B.T.	2.7±0.48	9	5.57	<0.001	***
		A.T.	0.6±1.07				
Swelling	TG_I	B.T.	1.96±0.76	29	23.89	<0.001	***
		A.T.	0.8±0.66				
	TG_{II}	B.T.	2.1±0.48	29	15.12	<0.001	***
		A.T.	0.8±0.55				
	CG	B.T.	2.0±0.66	9	5.65	<0.001	***
		A.T.	0.3±0.67				
Tenderness	TG_I	B.T.	2.0±0.45	29	3.20	<0.001	***
		A.T.	0.66±0.66				
	TG_{II}	B.T.	1.9±0.90	29	16.00	<0.001	***
		A.T.	0.73±0.83				
	CG	B.T.	1.7±0.67	9	4.32	<0.001	***
		A.T.	0.4±0.84				
Morning	TG_I	B.T.	1.37±0.56	29	19.40	<0.001	***

				n	t - Value	P-Value	
stiffness		A.T.	0.27±0.52				
	TG$_{II}$	B.T.	1.53±0.63	29	13.79	<0.001	***
		A.T.	0.37±0.61				
	CG	B.T.	1.04±0.52	9	6.01	<0.001	***
		A.T.	0.2±0.42				
General function capacity	**TGI**	B.T.	1.47±0.51	29	16.84	<0.001	***
		A.T.	0.3±0.66				
	TGII	B.T.	2.0±0.53	29	16.69	<0.001	***
		A.T.	0.83±0.53				
	CG	B.T.	1.7±0.5	9	6.01	<0.001	***
		A.T.	0.5±0.85				
ESR	**TG$_I$**	B.T.	2.77±0.50	29	12.13	<0.001	***
		A.T.	0.83±0.79				
	TG$_{II}$	B.T.	3.0±0	29	18.17	<0.001	***
		A.T.	0.83±0.65				
	CG	B.T.	2.5±0.53	9	6.90	<0.001	***
		A.T.	0.6±0.70				
RA factor	**TG$_I$**	B.T.	2.0±0.45	29	3.20	<0.001	***
		A.T.	0.66±0.66				
	TG$_{II}$	B.T.	1.9±0.90	29	16.00	<0.001	***
		A.T.	0.73±0.83				
	CG	B.T.	1.7±0.67	9	4.32	<0.001	***
		A.T.	0.4±0.84				
CRP	**TG$_I$**	B.T.	1.37±0.56	29	19.40	<0.001	***
		A.T.	0.27±0.52				
	TG$_{II}$	B.T.	1.53±0.63	29	13.79	<0.001	***
		A.T.	0.37±0.61				
	CG	B.T.	1.04±0.52	9	6.01	<0.001	***
		A.T.	0.2±0.42				
TG$_I$ – Trial Group-I		**t - Value – Test of Significance**					
TG$_{II}$ – Trial Group-II		**P-Value Probability at 0.1 % level**					
n = No. Of Patients		***** - Highly significance at 0.1 % level**					

Maximum improvement	-	> 75% improvement
Moderate improvement	-	> 50% to 75% improvement
Mild improvement	-	> 25% to 50% improvement
Unsatisfactory	-	Negligible (≤ 25%) improvement

DISCUSSION ON OBSERVATIONS

In the preset trial group 70 no. of patients registered their names of different age group. In this research study more cases were found in > 60 yeas age group which highlights the day by day progressiveness of *amavata* despite of several management procedures. Regarding sex it

is explained that the female and male suffering are in a ratio of 3: 1. But in this study 32 male and 38 female patient among 70 no. cases which indicates the female are more affected by this disease. Observation shows the multiple involvements of individual joints of the patients. *Hasta* 65 (92.85%), *Pada* 21 cases (30%), *Sira* 06 cases (8.57%), *Gulpha* 27 cases (38.57%), *Trika* 26 cases (37.14%), *Janu* 68 cases (97.14%), *Uru* 05 cases (7.14%). In this table *Hasta Pada, Janu, Pada* and *Gulpha* shows the involvement in sufferings more but all the joints are affected more or less by this disease.

As regards subjective parameters all patients belonging to TG_I, TG_{II} & CG were got relief, which has been critically assessed in the language of percentage. The statistical adjudication with suitable parameters shows that all drugs were highly significant at 0.1 % level on cardinal sign & symptoms and also in objective parameters. The Clinical assessment of results shows Maximum improvement got by TG_I group rather than TG_{II}.

Discussion on acceptability

The trial drug *Vatari Guggulu* was selected from ayurvedic text *Bhaisajya Ratnavali* having combination of *Erand taila, Shudha gandhak, Shudha Guggulu, Haritaki, Bibhitaki* and *Amalaki* in equal proportions. Maximum drugs of *Vatari gugguglu* have *ushna veerya* and *katu vipaka*. Also, it has dominantly *Tikta, Katu,* and *Kashaya Rasa*, but it also has a *Vatakapha Shamaka* property. *Amalaki, Haritaki* and *Gandhaka* has *Rasayana* effects and also antioxidant property.

Vatari Guggulu does *Amapachana* by the properties of *Laghu, Ruksha, Tikshna Guna, Katu, Tikta Rasa, Ushna Virya* and *Katu Vipaka*, all of which acts against the *Guru, Snigdha, Pichhila* etc. properties of *Ama*. Later, the imbalance of *Kapha* and *Vata* is checked by the *Vata-Kapha Shamaka* action of the drug. Further, *Ama* formation is stopped by the *Dipaniya* action. It relieves the symptoms of *Sandhishoola* (pain in joints), *Sotha* (swelling), *Aruchi* (dislike for food) etc., by its *Vednasthapana* (analgesic) and *Sothahara* (anti-inflammatory) action. Also the associated symptoms like *Vibandha* (constipation), *Anaha* etc., are reduced by *Anulomana* and *Virechan Karmas* of the drugs like *Haritaki* and *Erand taila*. Thus, due to its *Deepana-Paachana* and *Vata-Kapha Shamaka* properties, it is very suitable for interrupting the pathogenesis of the disease and to combat the main culprits, i.e. *Vata, Kapha (Ama)* and *Mandagni* that are the root cause of *Amavata*.

Virechana helps to normalize the *Pratiloma gati* of *vayu*. So, *snigdha virechna* is referable in this, therefore contents *Singhanada Guggulu* is recommended for *virechana karma* in 7 days interval to eliminate the *Amadosa* or *Amavisha* from the *koshtha* as well as *sakha* for *koshtha suddhi*.

CONCLUSION

Because of severe degree of pain and progressive crippling associated with *Amavata* (RA), it needs active and urgent care but the progressive crippling etc demanding the palliative treatment. *Vatari guggulu* with *simhanada guggulu* shows very effective in reducing symptoms of *amavata* which highlights in this present study.

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