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The Efficacy of Simhanada Guggulu & Local Application (Dusturadi Lepa) In The Management of Amavata Vis A Vis Rheumatoid Arthritis

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ABSTRACT

In the present clinical study 60 Amavata (Rheumatoid arthritis) patients were registered from the O.P.D. & I.P.D., Department of Kayachikitsa (General Medicine), Sir Sunderlal Hospital, Banaras Hindu University, Varanasi. 50 patients completed the treatment out of 60 and 10 patients left the treatment before completion of the therapy. The aim of the study was to evaluate the efficacy of selected Ayurvedic medicine and local application in the management of Amavata (Rheumatoid arthritis). The treatment schedule was that 1gm Simhanada guggulu (Ayurvedic pill medicine) orally twice a day with lukewarm water & Dusturadhi lepa (Ayurvedic paste medicine) applied locally over affected joints mixed with juice of datura leaves for 3 months. On the basis of observations and the results of this present study it can be concluded that effect of the trial drugs i.e.Simhanada Guggulu and Local Application are almost equally effective like Standard group of Diclofenac Sodium in majority of the symptoms of amavata.

Keywords: Amavata, Rheumatoid arthritis, Simhanada guggulu, local application

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INTRODUCTION

Ayurveda, the most ancient wisdom today is recognized worldwide as a system of medicine that provides sound mind in sound body¹ This traditional system of medicine of India has an un-enviable position in the field of providing remedies for the ailments and prevention of health² At present, man is climbing the step of success he is moving away from health. Unhealthy diet pattern, Physical inactivity, Stress, Endless desires and Anger have become a part of his life. All these factors have given birth to number of diseases.

Amavata was first described as an independent disease in Madhava Nidana³.It is the disease caused by Ama (undigested food material) and vitiated Vata and occupies in sleshma sthana (Asthi- Sandhi) and affecting Abhyantara and Madhyama Roga Marga⁴ The disease is a product of vitiation of Tridosha though Ama and vata are the initiating factors in its pathogenesis the exacerbation makes the disease more Kashtasadhya.

Amavata is one of the challenging disease for the physicians due to its chronicity, incurability, complications and morbidity. According to the modern medicine, this disease looks similar to Rheumatoid arthritis in its clinical appearance. It is a chronic inflammatory, destructive and deforming symmetrical polyarthritis in which joints become swollen, painful and stiff and associated with systemic involvement⁵. Allopathic system of medicine has a major role to comback this disease. But it has cleared that it created more side effects even after administration of drugs, and the disease has a tendency to persist progress and cripples the patient. Therefore, they consider it as a disease of remission and relapses.

In the present era, Amavata is the most common disease affecting a large number of population worldwide⁶The degenerative changes in bones and muscles arise from the age of 30 years to the age of 65 years. Male to Female ratio is 1:3⁷. The prevalence of this disease is such a great that it attracts the mind of almost all the physicians towards itself, that's why it becomes duty of the research scholar to work on the various aspects of this disease.

The Ayurvedic approach to the treatment of this disease is needed as no system is successful in providing the complete remission. So, Amavata is a challenging and a burning problem of medical science. Hence, the management of this disease is merely insufficient in other systems of medicine and patients are continuously looking with a hope towards Ayurveda to overcome this challenge.

In present study, Simhanada Guggulu mentioned in Bhaisjya Ratnavali (Vol.11 Cha. 29) and Local Application (Dusturadhi Lepa) mentioned in Ayurveda Pharmeacopeia (Vol 1– Part one published by Department of Ayurveda - Sri Lanka) were selected for the treatment of Amavata.

Aims and objectives

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- 1. To study the etiopathogenesis of Amavata as per ayurveda and modern.
- 2. To evaluate the therapeutic efficacy of selected formulae
- 3. To compare the efficacy of Simhanada Guggulu and local application with controlled group (Diclofenac sodium)⁸
- 4. To study the safety profile of the trial drug

MATERIALS AND METHOD:

A total number of 60 patients of Amavata were randomly selected for the present study, from the Kayachikitsa OPD and IPD of Sir Sunder Lal Hospital, Institute of Medical Sciences, Banaras Hindu University, Varanasi. The cases were selected randomly regardless of age, sex, occupation and socio-economic conditions. Both acute and chronic phase of Amavata patients were taken for the present study.

Inclusion Criteria:

- Diagnosed cases of Amavata based on symptoms and signs described in Madava Nidana and ACR 1987
- Sero positive & Sero negative both cases are included
- Patients willing to participate for this trial
- Age between 20- 60yrs both sexes

Exclusion criteria

- Patients having severe deformities
- Patients of Rheumatic arthritis, Gouty arthritis, Septic arthritis, Osteoarthritis & Ankylosing Spondylitis
- Immune suppressive patients like HIV, Tuberculosis, Hypertension, D.M. & other systemic problems
- Pregnant & lactating women
- Patients with major complications are also excluded
- Patients on corticosteroid therapy

Plan of Study

	Patients	treatment	Follow up
Group-1	30	Tab Simhanada Guggulu 500mg twice	Every month for
		daily with luke warm water	3 months period
		Local Application for apply over	
		affect joints twice daily.	
Group-11	30	Tab Diclofenac sodium 50mg twice	Every month for
		daily with luke warm water.	3 months period

Preparation of Simhanada Guggulu:

This is one of the well-known therapeutic preparation described in Baisajya Ratnawali – Amavata adhikara or the treatment of Amavata. It contains - Haritaki (Terminalia chebula), Bibhitaka (Terminalia belerica), Amalki (Emblica officinalis), Sudda Gandhaka (Purified Sulphur), Suddha Guggulu (Prified Commiphora mukul), Eranda Taila (Ricinus communis) Seed Oil. Prepared the drug according to guggulu paribasha.

Local Application: Contents:-

Cuttled bone fish, Hing powder, Alovera extraction, Domestic soot (Grihadhuma). Equal quantity of these drugs were taken and mix with juice of the Dhatura leaves and made the paste (Local application).

Clinical Assessment of the Disease:

Assessment on Clinical Features:

The relief of the clinical features was assessed on the basis of clinical features of Amavata (Rheumatoid arthritis) described in the Ayurvedic classics and criteria fixed by the American Rheumatology Association in 1988 and implemented after some modification. Sandhishula (Joint pain), Sandhishotha (Joint swelling), Sandhi-sthabdhata (Joint stiffness), Sandhi-sparsha-asahyatva (Joint tenderness), Angamarda (Body ache), Gaurava (Heaviness of the Body), Angmarda (Bodyache), Aruchi (Loss of taste), Trishna (Thirst), Alasya (Lack of enthusiasm), Gaurav (Heaviness), Jwara (Fever), Apaka (Indigestion) were selected for assessment of clinical features and the scoring pattern was adopted separately for assessment of those clinically.

Assessment on Functional Capacity: a) Walking time b) Grip Strength c)Foot pressure d) Rang of motion and Joint circumference ¹⁰III) Assessment on Overall Effect of the Therapy:

Effect of the rapy on cardinal symptoms

	Group-1	Group-11
Pain	56.9%	64%
Swelling	65.67%	64%
Stiffness	52.2%	55%
Tenderness	66.6%	62.06%

The relief observed in all the cardinal symptoms was statistically significant in both the groups. This proves trial drug Simhanada Guggulu and Local Application is highly effective in alleviating the cardinal symptoms of Amavata.

Table 1: Changes in Pain in total 50 patients of Amavata (Rhematoid Arthritis

Group	Grade	No.	and %	of c	Within the group					
		BT		$\mathbf{F_1}$		comparison				
		No.	%	No.	%	No.	%	No.	%	Friedman test
Group I	0	0	0	0	0	0	0	20	76.9	$\chi 2 = 57.60$
(n=26)	1	1	3.3	5	19.2	15	57.7	1	3.8	P<0.001
	2	17	56.7	16	61.5	10	38.5	4	15.4	

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	3	11	36.7	5	19.2	1	3.8	1	3.8	
	4	1	3.3	0	0	0	0	0	0	
Group II	0	0	0	0	0	0	0	0	0	$\chi 2 = 52.59$
(n=24)	1	1	3.3	4	16.7	19	79.2	19	82.6	P<0.001
	2	23	76.7	17	70.8	3	12.5	2	4.3	
	3	6	20	3	12.5	2	8.3	3	13	
	4	0	0	0	0	0	0	0	0	
Between the	group	χ2 =	=	χ2 =	=	χ2 =	=	χ2 =	=	
comparison		3.37	71	0.56	52	0.99	2	0.98	39	
χ2 - test		p=0	.338	p=0	.755	P=0	.319	P=0	0.804	

At the completion of the therapy 76.9% patients were found completely relieved from pain in Group I and 82.6% in Group II. (Table 01)

Table 2: Changes in Swelling in total 50 patients of Amavata(Rhematoid Arthritis)

Group	Grade	No.	and o	% of	cases					Within the group
		\mathbf{BT}		$\mathbf{F_1}$		$\mathbf{F_2}$		$\mathbf{F_3}$		comparison
		No.	%	No.	%	No.	%	No.	%	Friedman test
Group I (n=26)	0	0	0	0	0	1	3.8	17	65.4	$\chi 2 = 63.68$
	1	3	10	2	7.7	9	34.6	6	23.1	P<0.001
	2	18	60	20	76.9	16	61.5	3	11.5	
	3	8	26.7	4	15.4	0	0	0	0	
	4	1	3.3	0	0	0	0	0	0	
Group II (n=24)	0	0	0	0	0	3	12.5	13	54.2	$\chi 2 = 51.416$
	1	6	20	8	33.3	11	45.8	6	25	P<0.001
	2	14	46.7	1	45.8	9	37.5	5	20.8	
	3	10	33.3	5	20.8	1	4.2	0	0	
	4	0	0	0	0	0	0	0	0	
Between the group		χ2 =	=2.77	χ2		χ2 =	:	χ2		
comparison		p=0	.436	=6.2	54	4.08	7	=0.9	55	
χ2 - test				P=0.	.044	P=0.	252	P=0.	620	

At the completion of the therapy 65.4% patients were found completely relieved from swelling of body in Group I as compared to 54.2% in Group II. (Table 02)

Table 3: Changes in Morning stiffness in total 50 patients of Amavata

Group	Grade	No.	and %	of ca	ses					Within the group
		BT		$\mathbf{F_1}$		$\mathbf{F_2}$		$\mathbf{F_3}$		comparison
		No.	%	No.	%	No.	%	No.	%	Friedman test
Group I (n=26)	0	0	0	0	0	0	0	16	61.5	$\chi 2 = 46.98$
	1	1	3.3	7	28	10	38.5	2	7.7	P<0.001
	2	21	70	15	60	15	57.7	8	30.8	
	3	8	26.7	3	12	1	3.8	0	0	
	4	0	0	0	0	6.7	0	0	0	
Group II (n=24)	0	0	0	0	0	1	4.3	18	75	$\chi 2 = 41.84$
	1	8	26.7	10	41.7	15	65.2	2	8.3	P<0.001
	2	15	50	9	37.5	6	26.1	4	16.7	
	3	6	20	5	20.8	1	4.3	0	0	
	4	1	3.3	0	0	0	0	0	0	
Between the gro	up	$\chi 2 =$		χ2 =	:	$\chi 2 =$:	$\chi 2 =$		
comparison		0.77	39	2.51	0	5.69	5	1.37	3	
χ2 - test		p=0.	052	p=0.	285	p=0.	127	p=0.	503	

At the completion of the therapy 61.5% patients were found completely relieved from morning stiffness in Group I as compared to 75% in Group II. (Table 03)

Table 4: Changes in Tenderness in total 50 patients of Amavata

Group	Grade	No.	and %	6 of c	cases					Within the group
		\mathbf{BT}		$\mathbf{F_1}$		$\mathbf{F_2}$		\mathbf{F}_3		comparison
		No.	%	No.	%	No.	%	No.	%	Friedman test
Group I (n=22)	0	0	0	0	0	0	0	14	53.8	$\chi 2 = 44.98$
	1	7	23.3	9	34.6	14	46.7	10	38.5	P<0.001
	2	19	63.3	16	61.5	11	36.7	2	7.7	
	3	4	13.3	1	3.8	1	3.3	0	0	
	4	0	0	0	0	0	0	0	0	
Group II (n=26)	0	0	0	0	0	1	3.3	14	56	$\chi 2 = 40.36$
	1	9	30	9	36	14	46.7	7	28	P<0.001
	2	14	46.7	12	48	6	20	4	16	
	3	7	23.3	4	16	2	6.7	0	0	
	4	0	0	0	0	0	0	0	0	
Between the gro	up	$\chi 2$		χ2		$\chi 2 =$		$\chi 2 =$		
comparison		=1.8	326	=2.3	353	4.20		1.17	7	
χ2 - test		p=0.	401	P =(0.308	P=0.	520	P=0.	.555	

At the completion of the therapy 53.8% patients were found completely relieved from tenderness in Group I as compared to 53% in Group II.(Table 4)

The relief observed in all the cardinal symptoms was statistically significant in both the groups. This proves trial drug Simhanada Guggulu and Local Application is highly effective in alleviating the cardinal symptoms of Amavata.

Statistical significance was observed in Group I & II in forms of Grip Power on Intra Group comparison. Group I showed highest percentage of cured patients on symptom Grip Power. (Table 5) But on Pressing power mild improvement showed in Group I as compared to 0% in Group II. (Table 6)

Time taken to walk certain distance was reduced significantly in groups I & II after therapy. At the completion of therapy 19.2% patients was completely relieved in group I as compound to 20.8% in group II, on intergroup comparison was not significant. (Table 7)

Further, It reveals that the trial drug Simhanda Guggulu and Local Application have the equal effect of Diclofenac sodium in relieving the symptoms of Amavata. Table 06

Table 5 Changes in Grip power in total 50 patients of Amavata

Group	Grade	No.	and %	ofc	ases					Within the group
		BT		$\mathbf{F_1}$		\mathbf{F}_2		F ₃		comparison
		No.	%	No.	%	No.	%	No.	%	Friedman test
Group I (n=26)	0	20	69	8	30.8	5	19.2	8	30.8	$\chi 2 = 35.74$
	1	6	20.7	16	61.5	17	65.4	18	69.2	P<0.001
	2	3	10.3	2	7.7	4	15.4	0	0	
	3	0	0	0	0	0	0	0	0	
	4	0	0	0	0	0	0	0	0	

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Group II (n=24)	0	17	68	6	25	3	12.5	11	45.8	$\chi 2 = 47.67$
•	1	8	32	15	62.5	14	58.3	13		P<0.001
	2	0	0	3	12.5	7	29.2	0	0	
	3	0	0	0	0	0	0	0	0	
	4	0	0	0	0	0	0	0	0	
Between the grou	ıp	χ2 =	=	χ2 =	=	$\chi 2 = 1$.531	$\chi 2 =$.	
comparison		3.25	50	0.49	93	p=0.46	65	1.20	2	
γ2 - test		p=0	.197	p=0	.803			P=0	273	

p=0.197 p=0.803 P=0.273 **Table 6 Changes in Pressing power in total 50 patients of Amavata**

Group	Grade	No.	and %	6 of c	cases					Within the group
		BT		$\mathbf{F_1}$		\mathbf{F}_2		\mathbf{F}_3		comparison Friedman
		No.	%	No.	%	No.	%	No.	%	test
Group	Ι 0	0	0	0	0	0	0	1	3.8	
(n=26)	1	3	10	10	38.5	17	65.4	22	84.6	w2 - 42 94
	2	27	90	16	61.5	9	34.6	3	11.5	$\chi 2 = 43.84$ P<0.001
	3	0	0	0	0	0	0	0	0	P<0.001
	4	0	0	0	0	0	0	0	0	
Group	II 0	0	0	0	0	0	0	0	0	
(n=24)	1	1	3.3	7	29.2	16	66.7	24	95.8	~2 -49 91
	2	28	93.3	17	70.8	8	33.3	0	0	χ2 =48.81 P<0.001
	3	1	3.3	0	0	0	0	0	0	P<0.001
	4	0	0	0	0	0	0	0	0	
Between	the group	χ2	=	χ2	=	χ2	=	$\chi 2$		
compariso	on	2.01	8	0.48	0	0.00	9	=4.9	50	
$\chi 2$ - test		p=0	.365	p=0.	.488	p=0.	.924	p=0.	.175	

Table7: Changes in Walking time in 50 patients of Amavata

Group	Grade	No.	and %	of c	ases					Within the group
		\mathbf{BT}		$\mathbf{F_1}$		\mathbf{F}_2		\mathbf{F}_3		comparison Friedman
		No.	%	No.	%	No.	%	No.	%	test
8.3	0	0	0	0	0	1	3.8	5	19.2	$\chi 2 = 46.5$
	1	7	23.3	7	26.9	10	38.5	11	42,3	p<0.001
	2	14	46.74	12	46.2	13	50	10	38.5	
	3	9	30	7	26.9	2	7.7	0	0	
	4	0	0	0	0	0	0	0	0	
Group II	0	0	0	0	0	0	0	5	20.8	$\chi 2 = 45.24$
(n=26)	1	3	10.7	8	33.3	12	52.2	17	70.8	p<0.001
	2	19	67.9	14	58.3	9	39.1	1	4.2	
	3	6	21.4	2	8.3	2	8.7	1	4.2	
	4	0	0	0	0	0	0	0	0	
Between the	group	$\chi 2 =$	2.892	$\chi 2 =$:	χ2 =	=	χ2 =	=	
comparison				2.92		1.73		9.58		
χ2 - test				p=0.	232	p=0.	630	P=0	.022	

Among general symptoms which were considered here, more relief was observed in the symptoms of Bodyache, Thirst, Lack of enthusiasm, Heaviness and Fever in patients of giving trial drug Simhanada Guggulu and Local Application (Group-1) at significant level. (Table 8- Table 12)

Table 8: Changes in bodyache in total 50 patients of Amavata (Rheumatoid arthritis)

Group	Grade	No.	and %	6 of c	cases					Within the group
		\mathbf{BT}		\mathbf{F}_1		\mathbf{F}_2		\mathbf{F}_3		comparison Friedman
		No.	%	No.	%	No.	%	No.	%	test
Group I	0	0	0	0	0	0	0	3	11.5	$\chi 2 = 56.519$
(n=26)	1	3	10	3	11.5	10	38.5	16	61.5	P < 0.001
	2	15	50	17	65.4	13	50	5	19.2	
	3	10	33.3	4	15.4	2	7.7	2	7.7	
	4	2	6.7	2	7.7	1	3.8	0	0	
Group II	0	0	0	0	0	0	0	0	0	$\chi 2 = 49.63$
(n=24)	1	1	3.3	4	16.7	13	54.2	20	83.3	P < 0.001
	2	21	70	15	62.5	10	41.7	4	16.7	
	3	8	26.7	5	20.8	1	4.2	0	0	
	4	0	0	0	0	0	0	0	0	
Between the	e group	χ2=	4.222	χ2 =	:	χ2 =	=	χ2 =	=	
comparison	mparison p=0.238					2.039		5.484		
χ2 - test		-		p=0.512 p=0.564 p=0.140				140		

Table 9: Changes in thirst in total 50 patients of Amavata (Rheumatoid arthritis)

Group	Grade	No. and % of cases							Within the group	
		\mathbf{BT}		$\mathbf{F_1}$		$\mathbf{F_2}$		$\mathbf{F_3}$		comparison Friedman
		No.	%	No.	%	No.	%	No.	%	test
Group I	0	0	0	0	0	3	11.5	9	34.6	$\chi 2 = 29.931$
(n=26)	1	1	3.3	1	3.7	16	61.5	16	61.6	P < 0.001
	2	12	40	14	51.9	5	19.2	1	3.8	
	3	15	50	10	37	2	7.7	0	0	
	4	2	6.7	2	7.4	0	0	0	0	
Group II	0	0	0	0	0	1	2	4	9.5	$\chi 2 = 12.25$
(n=24)	1	1	3.3	2	9.5	15	9	14	66.7	P < 0.002
	2	7	23.3	6	28.6	10	10	6	23.8	
	3	18	60	13	61.9	0	0	0	0	
	4	0	0	0	0	0	0	0	0	
Between the group		χ2 =	=	χ2 =	=	$\chi 2 = \chi 2 = 6.8$		= 6.8		
comparison		7.58	9	5.25	7	5.35		p=0	.033	
χ2 - test		p=0.	180	p=0.	154	p=0	.148			

Table 10 Changes in lack of enthusiasm in total 50 patients of Amavata

Group	No.	and %	6 of c	ases	Within the group					
		\mathbf{BT}		$\mathbf{F_1}$		$\mathbf{F_2}$		\mathbf{F}_3		comparison Friedman
		No.	%	No.	%	No.	%	No.	%	test
Group I	0	0	0	2	7.7	4	15.4	6	23.1	$\chi 2 = 49.67$
(n=26)	1	2	6.7	4	15.4	9	34.6	12	46.2	P<0.001
	2	23	76.7	16	61.5	11	42.3	8	30.8	
	3	5	16.7	4	15.4	2	7.7	0	0	
	4	0	0	0	0	0	0	0	0	
Group II	0	0	0	0	0	0	0	2	8.3	$\chi 2 = 29.76$
(n=24)	1	8	26.7	10	41.7	13	54.2	18	75	$\tilde{P} < 0.001$
	2	19	63.3	14	58.3	11	45.8	4	16.7	
	3	3	10	0	8	0	0	0	0	
	4	0	0	0	0	0	0	0	0	
Between the	e group	$\chi 2 = \chi 2 =$		$\chi 2 = \chi 2 =$:			
comparison	- -	4.48		8.63	9	6.65	8	4.46		

 $\chi 2$ - test p=0.106 p=0.035 p=0.084 p=0.108

Table 11: Changes in heaviness in total 50 patients of Amavata (Rheumatoid arthritis)

Group	Grade	No.	and %	of c	ases					Within the group
_		\mathbf{BT}		$\mathbf{F_1}$		$\mathbf{F_2}$		$\mathbf{F_3}$		comparison
		No.	%	No.	%	No.	%	No.	%	Friedman test
Group I	0	0	0	1	3.8	1	3.8	3	11.5	$\chi 2 = 44.21$
(n=26)	1	2	6.7	7	26.9	10	38.5	13	50	P<0.001
	2	17	56.7	9	34.6	10	38.5	10	38.5	
	3	11	36.7	9	34.6	5	19.2	0	0	
	4	0	0	0	0	0	0	0	0	
Group II	0	0	0	1	4.2	1	4.2	2	8.3	$\chi 2 = 47.16$
(n=24)	1	3	10	4	16.7	11	45.8	18	75	P<0.001
	2	24	80	16	66.7	11	45.8	4	16.7	
	3	3	10	3	12.5.	1	4.2	0	0	
	4									
Between the	group	χ2 =	:	χ2		χ2 =	:	χ2 =	:	
comparison		5.96	7	=5.7	707	2.68	6	3.50	3	
χ2 - test		p=0.	051	p=0	.127	p=0.	443	p=0.	173	

Above table shows the improvement in symptom heaviness in subjects from initial level at subsequent follow ups in both the group

Table 12:Changes in fever in total 30 patients of Amavata (Rheumatoid arthritis)

Group	Grade	No.	and %	6 of c	ases					Within the group
		\mathbf{BT}		$\mathbf{F_1}$		$\mathbf{F_2}$		\mathbf{F}_3		comparison Friedman
		No.	%	No.	%	No.	%	No.	%	test
Group I	0	8	26.7	7	26.9	16	61.5	26	100	$\chi 2 = 44.77$
(n=26)	1	22	73.3	19	73.1	10	38.5	0	0	P<0.001
	2	0	0	0	0	0	0	0	0	
	3	0	0	0	0	0	0	0	0	
	4	0	0	0	0	0	0	0	0	
Group II	0	7	23.3	11	9.33	20	71.4	23	96.4	$\chi^2 = 43.41$
(n=24)	1	22	73.3	16	57.1	8	28.6	1	3.6	P<0.001
	2	1	3.3	1	3.6	0	0	0	0	
	3	0	0	0	0	0	0	0	0	
	4	0	0	0	0	0	0	0	0	
Between the group		$\chi 2 = \chi 2 =$		$\chi 2 = \chi 2 =$			=			
comparison	- l	1.06		2.07		0.59		0.94		
$\chi 2$ - test		p=0.	.587	p=0.		P=0		P=0	.331	

Significant reductions were seen in the mean titre value of RA factor, CRP and mean ESR in both the groups. Mean Hb in Group I & II was not statistically significant.

Group	RA Factor (Mean ± SD)	Within the group comparison paired			
	BT	AT	t test(BT-AT)			
Group I (n=26)	32.38+15.8	26.24+12.54	6.139+5.843 P<0.001	t=5.039		
Group II (n =24)	25.30+18.20	20.78+12.02	4.513+8.132 p<0.012	t=2.719		
Between the group comparison	t=0.656 p=0.514	t=1.522 p=0.135				

Unpaired t test

Group	CRP (Mean	n ± SD)	Within the group	
	BT	AT	comparisonPaired t-test	
Group I (n=26)	1.55+.76	0.59 ± 0.28	0.95+0.65	
			t=5.32	
			p<0.001	
Group II (n=24)	2.11 ± 1.36	1.04 ± 0.92	1.07+0.81	
-			t=6.79	
			p<0.001	
Between the group comparison	t = 1.73	t = 2.186	-	
Unpaired t-test	p=0.09	p=0.03		

Group	ESR (Mean±	(SD)	Within the group	
	BT	AT	comparison paired t test	
Group I (n=26)	42.68 ± 10.68	29.12 ± 8.82	1.356±7.87	
			t = 8.61	
			p<0.001	
Group II (n=24)	37.13 ± 13.02	26.69 ± 9.26	1.043±7.06	
			t = 7.08	
			p<0.001	
Between the group comparisor	t = 1.535	t = 1.080		
Unpaired t test	p=0.130	p=0.286		

Group	Hb changes	$\overline{(Mean \pm SD)}$	Within the group
	BT	AT	comparison Paired t-test
Group I (n=26)	11.58±	11.83 ±	0.096±10.450
	1.028	1.06	t=1.13
			p=0.267
Group II (n=24)	11.78 ± 1.72	11.98 ± 1.45	0.03 ± 0.86
			t=0.222
			p=0.826
Between the group	t = 0.354	t = 0.262	
comparison	p=0.724	p=0.795	
Unpaired t-test			

Analysis of Simhanada Guggulu and local application (Grihadhuma, Cuttle fish powder, Alovera extraction) was carried out by using analytical parameters. with the aim of Identification of Raw material & Analysis of the final product.

SAFETY PROFILE

The value of WBC (TC, DC), LFT/RFT (SGOT and SGPT, Serum Urea, Serum Creatinine), and Blood sugar were observed at before treatment and after treatment.

Probable mode of action of Simhanada Guggulu:

The majority of the ingredients of Simhanada Guggulu are katu tikta rasa. Ushna Laghu Tikshna Ruksha, guna, Ushna virya. ¹¹These properties of the drug are against the guru, Snigdha, Pichchila, Sheeta properties of Ama and these properties help to mitigate the

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Ama in to the body. The drug Simhanada Guggulu also increases the Agni bala i.e Pachakagni and Dhatvagni in to the body by its Agni deepaniya action and hence it prevents the further formation of Ama in the body.

It controls the prakopa of Vata and Ama by its Vata kapha shamaka property, because properties of Ama are more similar to kapha dosha. It reduces the Pratyatma Lakshan (Cardinal clinical features)¹²of Amavata, e.g Sandhi shula, Sandhi sotha, Sandhi sparshasahyata and Sandhi stabdhata by its Vedanasthapana Sothahara and Mutrakaraka action.

By antioxidant property it mitigates the Ama (i.e Free radical like substance) due to Rasayana effect of its some ingredients. It also replenishes and rejuvenates the impaired Dhatus by its Rasayana effect.On the basis of above information we can say that the drug Simhanada Guggulu is very suitable for the Samprapti Vighatana of the disease Amayata.

PROBABLE MODE OF ACTION OF LOCAL APPLICATION

DUSTURADI LEPHA is used to apply locally over the joints. The major ingredients of it are containing katu, tikta rasa, Ushna laghu, ruksha, tikshna guna, Ushna virya and katu vipaka ¹³ properties which are all against the properties of Ama. It helps to reduce the local Sandhi shula (Jointpain), Sandhi shoth (Joint swelling), Sandhi sparsha asahayata (Joint tenderness) and Sandhi stabdhata (Joint stiffness) by its Vedanasthapaka (Analgesic) and Shothahara (Anti inflammatory) action when it is used locally over affected joints. It helps to reduce the local prakopa of Vata and Ama of the affected joints by its Vata kapha shamaka property, when it is used locally.

So it can be said that local application is very much effective to break down the Samprapti locally of the diseases of the disease Amavata, when it is used locally over affected joints.

In the present clinical research work no side effects of the research drugs were observed during the clinical trial and follow up study.

CONCLUSION

On the basis of observations and the results of this present study it can be concluded that effect of the trial drugs i.e. ,Simhanada Guggulu and Local Application are almost equally effective like Standard group of Diclofenac Sodium in majority of the symptoms. The sign and symptoms e.g., Loss of appetite, Aruchi, Trishna, Aalasya, Jawara etc. were improved by the Trial drugs as compared to that in Diclofenac Sodium treated group. There was neither any side effect produced nor any unwanted effect observed during the trial drug. Though in standard group of Diclofenac sodium, some patients developed complaint of GI upset, acidity and burning sensation in epigastrium. The general digestion was found to be good with

the Trial drugs and simultaneously quality of life was also improved in comparison to Diclofenac Sodium Group.

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