

A Comparative Clinical Study on Vatariguggulu and Panchakarma Therapy with Special Reference to Kshara Basti and Virechana Karma in the Management of Amavata (Rheumatoid Arthritis)

Ashis KD1* and Tuhin KB2

¹Department of Panchakarma, Institute of Post Graduate Ayurvedic Education and Research, India

²Department of Kayachikitsa, J. B. Roy State Ayurvedic Medical College & Hospital, India

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*Corresponding author: Ashis Kumar Das, Department of Panchakarma, Institute of Post Graduate Ayurvedic Education and Research, Kolkata 700009, India, Tel: +919433063678; E-mail: ashisdas101080@gmail.com

Abstract

In the whole world, rheumatic diseases are the commonest cause of physical & mental crippling condition in the society with rheumatoid arthritis is sharing the lion portion [1]. Important role in the management of this crippling disease has been described in Ayurveda from ancient time. It appears from the point of view of modern medical sciences that *Amavata* can be simulated with rheumatoid arthritis in its clinical appearance. In spite of tremendous development of modern medical sciences, modern drugs for the management of rheumatoid arthritis shows serious side effects like gastritis, gastric ulcers, immune depression, decalcifications, hyperglycemia, etc. and ultimately no drug is found to be effective after a certain period of therapeutics. Panchakarma therapy is one of the important branches of Ayurveda, which deals mainly with purification of the aggravated *dosas* (pathological state of body humors) from the human system. *Amavata*, being a disease that develops due to involvement of '*Ama*' and '*Vata*' in particular. *Vasti* (enema) therapy is a special branch of *Panchakarma*, usually administered for elimination of *Vata*. *Virechana* or purgation is another important therapy under *Panchakarma* which is mainly administered mainly to eliminate *Ama dosa* in the present context. Beside, conventional panchakarma therapes like *Vasti* and *Virechana*, conservative conventional pacification therapies with Vatariguggulu was also added. Results were found significant (p<0.05) by combination with Panchakarma along with relevant pacification therapy.

Keywords: Amayata; Rheumatoid Arthritis; Kshara Basti; Virechana; Vatariguggulu

Abbreviations: SOP: Standard Operation Procedure; RA: Rheumatoid Arthritis

Introduction

Āmavāta is manifested due to dual inter action between "Āma" and 'Vāta'. Ama concept mimics with elevation of Kapha dosa due to indolence of Jatharagni or Pachaka Pitta. Vata itself represents motion. In the disease "Amavata" the dosa 'Vata' is encapsulated by kapha producing features of joint pain, swelling etc. Main principles of Amavata management includes Langhana (lightering therapy), Swedana (fomentration). Tikta Rasa (bitter substances), Dipana (stomachic) and Katu rasa (pungent taste), all of which helps to pacify Kapha dosha in the form of "Ama" so that encapsulated "Vata" becomes free [1]. This therapy is followed by Virechana Karma (purgation) to eleminate Pitta dosa situated within Rakta dhatu of sira that lies in Sandhi. Finally Snehapana as purvakarma and Vasti as pradhan karma (main purification therapeutic), may help to eliminate Vata so that the disease process will be under control.

According to Madhavkara, the disease 'Amavata' is characterized by manifestation of the symptoms like stiffness (Stabhdhatwa) and heaviness/ swelling (Gurutwa) of Sandhis (joints) [2]. Amavata is a disease under the category of Vata-Kaphaja disorders. The clinical presentation of Amavata closely mimics with the special variety of rheumatological disorders *viz.* rheumatoid arthritis, in accordance with their similarities on clinical features. These were selected on the basis of the criteria designed by American Rheumatological Society as mentioned in the inclusion criteria.

"Panchakarma therapy" is such a unique module of management described in Ayurveda, which can eliminate the causative pathogens (Dosa-Nir-Harana) from the system for complete eradication of disease process. In the present study, Virechana karma and Kshar Basti are selected for the Sanshodhana (purification) process while, Vatariguggulu was selected as Shamana (pacification) Yoga. Both of these procedures are mentioned in Chikitsa Sutra described by Chakradatta.

Vatariguggulu is applied as maintenance therapy in Amavata which is kricchasadhya (hardly curable) in nature because composition mainly dominated by ushna virya combating vata dosa so the chance of reversion is inhibited [3]. According to the modern concept of rheumatoid arthritis, IgG and IgM undergo for an anti-

immune reaction in a HLA- DR4 compatible patients⁵ leading to alteration of type II collagen synthesis [4]. Panchakarma therapy being a unique purification therapy that seems to have role in detoxification of body enzyme and reactions may arrest auto-immune reaction and thereby control disease process. Guggulu as one the important ingredient of vatariguggulu is reported to have anti – inflammatory effect.

Aims & Objectives

- To develop standard operation procedure (SOP) of certain panchakarma therapy in Amavata (Rheumatoid Arthritis)
- ii) To evaluate safety and efficacy of certain Panchakarma therapy in Amavata (R.A)
- iii) To establish "modus operandi" on the basis of comparative pharmacodynamics between Ayurveda and Modern medicine.

Materials and Methods

Selection of Patients

Complete 90 cases of 'Amavata' vis-à-vis 'rheumatoid arthritis were selected irrespective of sex, religion, habitat, income status, occupation etc. from the OPD and IPD of J. B. Roy State Ayurvedic Medical College and Hospital, Kolkata and other referred hospital as well as other clinics. All the patients were registered at J. B. Roy State Ayurvedic Medical College and Hospital, Kolkata for final evaluation. Patients fulfilling at least four out of seven criteria of Rheumatoid arthritis as per American Rheumatism Association 1988 revised guidelines, will be selected for the present research programme [5]. All the patients will be included according WHO-Helsinki protocol after taking their informed consent.

Study Variable

Variability of study extended in terms of age and duration of suffering with severity without having any serious connected associated diseases like cardiac problem, diabetes mellitus, pregnancy, hepatic disorders, renal diseases, malignancies, etc.

Sampling Design

The study was performed in three treatment groups as follows –

Treatment group	No. of Patients	Treatment Schedule
Group-I (Guggula 3	30	Kshara Vasti along
g/day for 15 days)	Patients	with Vatari
Group – II (3 g/day	30	Virechana karma with
for 15 days)	Patients	Vatari Guggula
Group – III (by Virechana for 15 days along with Vatari Guggula 3 g/day for 30 days	30 Patients	Kshara Vasti for 15 days followed

Objective Parameters

Following objective/ laboratory parameters were taken in present research programme –

- i) Routine blood examination including TEC, TLC, DLC, ESR, Hb%
- ii) Skiagraphy of joints involved
- iii) Rheumatoid factors

Statistical Analysis

All the data were statistically analysed using SPSS-Win package systems.

Drug Review

In Ayurveda, drvaya (medicament) has been emphasized as the second place amongst the four-fold factors i.e. Bhisaka (physician), Dravya (both drugs and food substance), Upasthata (attendant) and Rogi (patient) [6]. While treating a patient the selection of Ausadha comes after the proper diagnosis of the patient. It should be suitable to the patient and against the disease as well as dosa involved. The selection of drug was made accordingly for keeping the three dosas in balance state. The drugs in the present research work, is based on the above foundation.

Vatariguggulu has been selected due to its Katu (pungent) and Tikta (bitter) Rasa, Ushna Virya, Rasayana Prabhava, Ama Pachana and Vata-kaphashamana properties [3]. It helps to disrupt the pathogenesis (Samprapti Vighatana) of Amavata. Vatariguggulu is applied as maintenance therapy in Amavata which is kricchasadhya in nature because composition mainly dominated by ushna virya combating vata dosa so the chance of reversion is inhibited [7]. According to the modern concept of Rheumatoid arthritis IgG and IgM undergo for an anti-immune reaction in a HLA- DR4

compatible patients leading to alteration of type II collagen synthesis. Panchakarma therapy being a unique purification therapy that seems to have role in detoxification of body enzyme and reactions may arrest auto-immune reaction and thereby control disease process. Guggulu as one the important ingredient of vatariguggulu is reported to have anti– inflammatory effect.

Principal ingredients of Vatariguggulu are Eranda Taila (oil prepared from *Ricinus communis* Linn), Shuddha Gandhaka (sulphur), Shuddha Guggulu (*Commiphora mukul*), Haritaki (*Terminalia chebula*), Bibhitaka(*Terminalia bellerica*) and Amalaki (*Emblica officinalis*). The vatariguggulu was prepared in the pharmacy department of the host institute by conventional classical method.

The fruits of Amlaki are astringent, cooling, anodyne, carminative, digestive, stomachic, laxatives and tonic. Pharmacologically it is antioxidant, anti-inflammatory, antibacterial, antiulcer etc., [8]. The fruits of Bibhitaka is reported to have Shothahara, Deepana, Anulomana, Keshya, Svarya, Krimighna, Raktashodhaka etc in nature. Pharmacologically it is antifungal, antibacterial, purgative, antihistaminic, antistress in nature. Fruits of Haritaki (*Terminalia chebula* Linn) is used as Shotha-Vedanayukta Vikara (diseases associated with pain), Agnimandya, Shula, anaha,etc. Pharmacologically it has effect on oxidative stress [9].

Gandhaka is noted in Ayurveda widly for different formulation. Gandhaka is descrtibed to have kaphavatahara & pitta samak properties. Eranda taila is Kapha-vata Shamaka. It is Shothahara, Deepana, Bhedana, Amashodhana, Srotovishodhana, Vrishya, Kushthaghna, Angamardaprashamana, Shukrashodhana etc. Guggulu, the main ingredient of Vatariguggulu, is Lekhana, Ropana, Vedanasthapana, Nadibalya, Deepana, Saraka, Mutrala, Raktavardhaka, Rasayana, Bhagnasandhanaka, Jantughna and Pramehahara in properties.

Pharmacologycally gum resin showed different pharmacological properties like astringent, expectorant, aphrodisiac, demulcent, carminative, antispasmodic, emmenagogue, blood enhancer, anti-snake venom and anti-scorpion sting, anti-fertility, arthritis, leprosy, in impotence and sterility, in liver disorder and hemiplagia, hypocholesteremic, hypolipidaemic, atherosclerosis, thyroid stimulating, psoriasis and cardiac ischaemia.

Inclusion Criteria

- i) Patient having age between 20-50 years
- ii) Patients fulfill at least four out of seven criteria of American Rheumatism Association (1988) –
- Morning stiffness lasting for more than one hours
- Arthritis of three or more joints
- Arthritis of hand joints
- Symmetrical arthritis
- Rheumatic nodules
- Presence of rheumatoid factor
- Radiological changes (hand and wrist)

Rheumatoid arthritis is diagnosed if a patient carried out at least four of the above criteria for at least last 6 weeks.

- iii) Patients of both sexes, irrespective of religion, habitat, income status, occupation, etc.
- iv) Patients willing to include themselves in the study through informed consent form.

Exclusion Criteria

- i) Patients having age below 20 and above 50 years
- ii) Patients of rheumatoid arthritis with high titres<1:50 titre) rheumatoid factor, insidious onset of disease, early development of nodules, extra-articular manifestation, severe functional deformities, etc.
- iii) Patients suffering with diseases like cardiac problem, diabetes mellitus, hepatic disorders, renal diseases, malignancies, etc.
- iv) Pregnant mother
- v) Patients who does not fulfill at least four out of seven criteria of rheumatoid arthritis
- vi) Patients not willing to include themselves in the study through informed consent form

Recent Diagnostic Assessment

According to recent criteria for assessment of RA on the basis of arbitrary scoring is described in the 2010 American College of Rheumatology/European League Against Rheumatism classification criteria for rheumatoid arthritis, the diagnosis is done by following scoring system [10].

	Score
Target population (Who should be tested?): Patients who	
1) have at least 1 joint with definite clinical synovitis (swelling)	
2) with the synovitis not better explained by another disease†Classification criteria for RA	
(score-based algorithm: add score of categories A-D; a score of _6/10 is needed for	
classification of a patient as having definite RA)	
A. Joint involvement	
1 large joint	0
2-10 large joints	1
1-3 small joints (with or without involvement of large joints)	2
4-10 small joints (with or without involvement of large joints)	3
>10 joints (at least 1 small joint)	5
B. Serology (at least 1 test result is needed for classification)	
Negative RF <i>and</i> negative ACPA	0
Low-positive RF <i>or</i> low-positive ACPA	2
High-positive RF <i>or</i> high-positive ACPA	3
C. Acute-phase reactants (at least 1 test result is needed for classification)	
Normal CRP <i>and</i> normal ESR	0
Abnormal CRP <i>or</i> abnormal ESR	1
D. Duration of symptoms<6 weeks	0
≥6 weeks	1

Patients with a score of <6/10 are not classifiable as having RA, their status can be reassessed and the criteria might be fulfilled cumulatively over time.

Summary of the Previous Progress Reports

First year (2013-2014): An attempt was taken for inclusion of more numbers of patients suffering with Amavata (Rheumatoid Arthritis) in different treatment schedules. A total number of 17 patients were included in the year 2013-2014, who were divided into 3 groups with distribution of 10 patients in group A, 3 Patients in Group B and 4 Patient in Group C. No definite interpretation were drawn regarding the effect of drugs in the first year as the duration of therapy was very minimum.

Second year (2014-2015): A total number of 39 patients were enrolled including 17 patients of previous year. Distribution of 39 patients were done with 14 patient in group 'A', 12 patients in group 'B' and 13 patient in group 'C'. In accordance with this studies it was observed that remarkable iumprovementy were observed in the patient of group 'A' treated with Kshar Vasti along with Vatari Guggulu 3gms per day for 15 days.

Third year (2015-2016): Total 63 patients including 39 patients of previous year were enrolled in this year. They were distributed with 22 patients in group 'A', 21 patients in group 'B' and 20 patients in group 'C'. In accordance with this studies it was observe that remarkable improvement of different symptoms on the basis of arbritory scoring system in the patient of group 'A' treated with Kshar Vasti along with Vatari Guggulu 3gms per day for 15 days. However, moderate results were observed in groups 'B' & 'C'. The research work was continued with involvement of more number of patients to draw a consistent conclusion.

Final result: In response to above results, the study continued till September 2016 for inclusion of more number of patients including previous 39 patients. A total 90 patients were included up to the period of September 2016, who were distributed with 30 patient in group 'A', 30 patients in group 'B' and 30 patient in group 'C'. Result of the study is depicted from table 1 to table 14.

Criteria	G	roup 'A' (n=30)	(Group 'B'	(n=30)	Group 'C' (n = 30)			
Sandhishula	BT	AT	d±SE	ВТ	AT	d±SE	ВТ	AT	d±SE	
Left Wrist	2.20	1.10	1.10±0.09*	2.70	1.20	1.50±0.11*	2.50	0.40	3.10±0.90*	
Left Wilst	2.20	1.10	(n=26)	2.70	(n = 14)	(n = 14)	2.50	0.40	(n = 9)	
Left Shoulder	-	r -	_	_	0.54	0.18	0.36±0.24*	_	_	_
Left Siloulaei				0.54	0.10	(n = 04)				
Left Knee	1.05	0.40	0.64±0.35*	1.10	0.10	1.00±0.24*	1.00	0.09	0.90±0.17*	
Dere knice	1.05	0.10	(n = 18)	1.10	0.10	(n = 15)	1.00	0.00	(n = 11)	
Left Ankle	1.70	0.60	1.10±0.26*	1.45	0.09	1.36±0.21*	1.45	0.09	1.36±0.13*	
Left Ankle	1170	0.00	(n = 21)	1.10	0.07	(n = 11)	1.10	0.00	(n = 11)	

Legend: BT = Before Treatment, AT = After Treatment, d±SE = Mean differences ± Standard Error of Mean, * p<0.001

Table 1: Effect of different therapies on cardinal features of Sandhishula (pain in joints) of left side in Amavata (Rheumatoid arthritis) on group A, B & C (n=90).

Criteria	G	=30)	G	Group 'B' (n=30)			Group 'C' (n=30)		
Sandhishula	BT	AT	d±SE	BT	AT	d±SE	BT	AT	d±SE
			1.50 ±			1.50 ±			1.70 ±
Right Wrist	2.70	1.20	0.11*	2.70	1.20	0.21*	2.50	0.80	0.70*
			(n =26)			(n =14)			(n = 9)
						0.36 ±			
Right Shoulder				0.54	0.18	0.2*			
						(n = 4)			

Right Knee	1.10	0.10	1.00 ± 0.17* (n=18)	1.10	0.10	1.00 ± 0.24 * (n = 15)	1.00	0.27	$0.72 \pm 0.14*$
Right Ankle	1.45	0.09	1.36 ± 0.12*	1.45	0.36	1.09 ± 0.19*	1.45	0.45	1.00 ± 0.10*
Tugit Time	1110	0.03	(n =21)	1.10	0.00	(n =11)	2.10	0.10	(n =11)

BT = Before Treatment, AT = After Treatment, d±SE = Mean differences ± Standard Error of Mean,* p<0.001 Table 2: Effect of therapy on cardinal features in joints of right side in Amavata (Rheumatoid arthritis) in group A, B & C (n=90).

Criteria	G	roup 'A' (n=30)	G	roup 'B' (n=30)	Group 'C' (n=30)			
Sandhishoth	BT	AT	d±SE	BT	AT	d±SE	BT	AT	d±SE	
Left Wrist	2.70	1.20	1.50 ± 0.11*	2.70	1.20	1.50 ± 0.13*	2.50	0.80	1.70 ± 0.70*	
2.70	1.20	(n=21)	2.70	1.20	(n=14)	2.50	0.00	(n=09)		
Left Shoulder				0.54	0.36	0.18 ± 0.21*				
Left Shoulder				0.51		(n=4)				
Left Knee	0.90	0.10	0.60 ± 0.15*	1.10	0.30	0.80 ± 0.20*	1.00	0.27	0.72±0.14*	
Dere Milee	0.70	0.10	(n=16)	1.10	0.50	(n=15)	1.00	0.27	(n=6)	
Left Ankle	0.81	0.09	0.72±0.16*	1.40	0.64	0.82±0.09*	1.45	0.45	1.00±0.10*	
Left Ankle	0.81 0.09	0.07	(n=15)	1.10	0.01	(n =11)	1.10	0.15	(n=11)	

BT = Before Treatment, AT = After Treatment, d±SE = Mean differences ± Standard Error of Mean,* p<0.001 Table 3: Effect of therapy on cardinal features in joints of left side in Amavata (Rheumatoid arthritis) in group A, B & C (n=90).

Criteria	Gre	oup 'A' (n=	30)	Gre	oup 'B' (n=	:30)	Group 'C' (n=30)			
Sandhishoth	BT	AT	d±SE	BT	AT	d±SE	BT	AT	d±SE	
Right Wrist	2.70	1.20	1.50 ± 0.12*	2.70	1.20	1.50 ± 0.19*	2.27	0.81	1.45 ± 0.73*	
Right Whit	giit wiist 2.70 1.	1.20	(n=21)	2.70	1.20	(n=11)	2.27	0.01	(n=09)	
Right Shoulder				0.54	0.18	0.36 ± 0.24*				
Right Shoulder				0.34	0.10	(n=04)				
Right Knee	0.80	0.1	0.50 ± 0.15*	1.10	0.50	0.60 ± 0.18*	1.00	0.45	0.54 ± 0.27*	
Right Rifee	0.00	0.1	(n=16)	1.10	0.50	(n=15)	1.00	0.45	(n=06)	
Right Ankle	0.72	0.27	0.54 ± 0.12*	1.45	0.91	0.55 ± 0.16*	1.45	0.36	1.09 ± 1.00*	
Right Ankle	0.72	0.72 0.27	(n=15)	1.15	0.71	(n=11)	1.15	0.30	(n=11)	

BT = Before Treatment, AT = After Treatment, d±SE = Mean differences ± Standard Error of Mean,* p<0.001 Table 4: Effect of therapy on Sandhishotha in joints of right side in Amavata (Rheumatoid arthritis) in group A, B & C (n=90).

Criteria				G	roup 'B' (1	n=30)	Group 'C' (n=30)		
Sandhigrah	BT	AT	d±SE	BT	AT	d±SE	BT	AT	d±SE
Left wrist 2.7 1	1.2	1.50±0.09*	2.70	0 1.20	1.50±0.12*	2.27	1.18	1.09±0.45*	
	2.7	1.2	(n=21)	2.70	1.20	(n=14)	2.27	1.10	(n=09)
Left elbow	v 0.60 0.00	0.00	0.60±0.55*						
Left cibow		0.00	(n=06)						

Right shoulde	er			0.54	0.36	0.18±0.21*			
						(n=04)			
Knee	0.80	0.10	0.70±0.17*	1.10	0.30	0.78±0.21*	1.00	0.81	0.18±0.09*
Micc	0.00	0.10	(n=14)	1.10	0.50	(n=15)	1.00	0.01	(n=06)
Ankle	0.72	0.36	0.45±0.09*	1.45	1.1	0.36±0.16*	1.45	0.54	0.90±0.09*
Tilikie	0.72	0.50	(n=13)	1.43	1.1	(n=11)	1.45	0.54	(n=11)

BT = Before Treatment, AT = After Treatment, d±SE = Mean differences ± Standard Error of Mean,* p<0.001 Table 5: Effect of therapy on cardinal features in joints of left side in Amavata (Rheumatoid arthritis) in group A, B & C. (n=90).

Criteria	G	roup 'A' (n=30)	G	roup 'B' (n=30)	G	roup 'C' (Group 'C' (n=30)			
Sandhigraha	BT	AT	d±SE	BT	AT	d±SE	BT	AT	d±SE			
Right wrist	2.70	1.20	1.50±0.11*	2.70	1.20	1.50±0.19*	2.27	1.18	1.09±0.64*			
rugiit wrist	2.70	1.20	(n=21)	2.70	1.20	(n=14)	2.27	1.10	(n=09)			
Right elbow	0.50	0.20	0.20±0.07*	_	_	-			(n=00)			
Right elbow	0.50	0.20	(n=06)		_	(n=00)			(11-00)			
Right shoulder	-	_	_	0.54	0.18	0.36±0.24*			_			
ragiit silouluci				0.54	0.10	(n=04)						
Knee	0.80	0.40	0.40±0.09*	1.1	0.7	0.33±0.17*	1.00	0.45	0.54±0.27*			
Kilee	0.00	0.10	(n=14)	1.1	0.7	(n=15)	1.00	0.15	(n=06)			
Ankle	0.72	0.36	0.54±0.12*	1.45	0.73	0.73±0.13*	1.45	0.45	1.00±1.18*			
THIRIC	0.72	0.36	(n=13)	1.45	0.73	(n=11)	1.13	0.13	(n=11)			

BT = Before Treatment, AT = After Treatment, $d\pm SE$ = Mean differences \pm Standard Error of Mean,* p<0.001 Table 6: Effect of therapy on cardinal features in joints of right side in Amavata (Rheumatoid arthritis) in group A , B & C. (n=90).

Criteria	G	roup 'A'	(n=30)	G	roup 'B'	(n=30)	Group 'C' (n=30)		
Sparshasahyata	BT	AT	d±SE	BT	AT	d±SE	BT	AT	d±SE
Left wrist	2.70	1.20	1.50±0.09*	2.70	1.20	1.50±0.18*	2.27	0.90	1.36±0.54*
Here wrise	2.70	2.70	(n=11)	2.70	1.20	(n=14)	2.27	0.70	(n=09)
Right shoulder		_	0.72	0.45	0.27±0.21*			_	
rugiie silouidei				0.7 =	0.15	(n=04)			
Knee	0.60	0.30	0.30±0.08*	1.10	0.40	0.70±0.21*	1.00	0.27	0.72±0.45*
	0.00	0.00	(n=06)	1.10	0.10	(n=15)	2.00	0.27	(n=06)
Ankle	0.36	0.09	0.27±0.08*	1.45	0.82	0.64±0.14* (n=11)	1.45	0.36	1.09±0.81*
	3.30	3.07	(n=05)	1.73	0.02		1.10	0.00	(n=11)

BT = Before Treatment, AT = After Treatment, d±SE = Mean differences ± Standard Error of Mean,* p<0.001 Table 7: Effect of therapy on cardinal features in joints of left side in Amavata (Rheumatoid arthritis) in group A, B & C. (n=90).

Criteria	G	roup 'A' ((n=30)	G	roup 'B' ((n=30)	Group 'C' (n=30)		
Sparshasahyata	BT	AT	d±SE	BT	AT	d±SE	BT	AT	d±SE
Right wrist	2.20	1.20	1.50±0.09*	2.45	0.30	1.50±0.17*	2.27	1.36	0.90±0.45*
rught whot	2.20	1.20	(n=10)	2.10	0.50	(n=14)	2.27	1100	(n=09)
Right shoulder	_	_	_	0.72	0.45	0.27±0.33*			_
Right shoulder				0.72	0.10	(n=04)			
Knee	0.60	0.40	0.40±0.12*	1.18	0.45	0.72±0.13*	1.00	0.27	0.72±0.36*
Mice	0.00	0.10	(n=06)	1.10	0.15	(n=15)	1.00	0.27	(n=06)
Ankle	0.36	0.09	0.27±0.08*	1.45	1.09	0.36±0.15*	1.42	0.36	1.09±0.81*
Ankle	0.50	0.07	(n=05)	2.10	1.00	(n=11)	1.12	0.50	(n=11)

BT = Before Treatment, AT = After Treatment, $d\pm SE$ = Mean differences \pm Standard Error of Mean,* p<0.001 Table 8: Effect of therapy on cardinal features in joints of right side in Amavata (Rheumatoid arthritis) in group A , B & C. (n=90).

General	G	Group 'A' (n=30)			roup 'B' (n=30)	Group 'C' (n=30)		
Symptoms	BT	AT	d±SE	BT	AT	d±SE	BT	AT	d±SE
Angamarda	1.79	1.10	1.10±0.08*	2.00	1.14	0.86±0.50*	1.64	0.93	0.71±0.12*
migamarua	1.7)	1.10	(n=26)	2.00		(n=17)	1.04		(n=12)
Trishna	0.76	0.23	0.52±0.13*	0.71	0.29	0.43±0.16*	0.20	0.10	0.10±0.10*
TTISIIIIa	0.70	0.23	(n=12)	0.71	0.27	(n=16)	0.20		(n=01)
Aruchi	1.00	0.50	0.50±0.32*	2.00	1.28	1.28±1.50*	2.00	1.10	0.09±0.31*
Aluciii	1.00	0.30	(n=15)	2.00	1.20	(n=18)	2.00	1.10	(n=18)
Alacva	Alasya 0.93	93 0.50	0.43±0.52*	1.14	0.57	0.57±0.13*	0.80	0.40	0.40±0.13*
Alasya			(n=15)			(n=15)	0.00		(n=16)
Gaurava	2.00	1.00	1.00±1.00*	1.86	0.93	0.92±0.57*	0.92	0.38	0.38±0.32*
Gaurava	2.00	1.00	(n=13)	1.86	0.93	(n=13)	0.92	0.30	(n=22)
			0.30±0.09*			0.50±0.78*			0.28±0.31*
Jwara	0.60	0.30	(n=17)	1.00	0.50	(n=17)	0.57	0.28	(n=08)
			0.00.0.10.0			0.00.0.104			0.00 0.104
Apaka 1.80	1.80	0.90	0.90±0.10*	1.80	0.90	0.90±0.42*	1.80	0.90	0.90±0.10*
r.			(n=09)			(n=09)			(n=09)
Sunta-	1.20	0.60	0.60±0.09*	1.33	0.66	0.66±0.18*	1.20	0.60	0.60±0.13*
Anganama	1.20	0.00	(n=08)	1.00	0.00	(n=08)	1.20	0.00	(n=15)

BT = Before Treatment, AT = After Treatment, $d\pm SE$ = Mean differences \pm Standard Error of Mean Table 9: Effect of therapy on general symptoms in 30 patients each group in Amavata (Rheumatoid arthritis) in group A, B & C. (n=90).

Associated symptoms	Group 'A' (n=30)			G	Group 'C' (n=30)					
	BT	AT	d±SE	BT	AT	d±SE	BT		AT	d±SE
Daurbalya	1.80	0.90	0.90±0.06*		1.50	0.91±0.47*	1.90			1.10±0.06*
			(n=22)	1.58		(n=21)		1.10		(n=26)

Agnimandya	1.60	0.80	0.80±0.13*	2.00	1.33	0.66±0.33*	2.00	1.00	1.00±1.00*
rigiiiiiaiiaya	1.00		(n=20)	2.00	1.55	(n=17)	2.00	1.00	(n=24)
Kandu	0.80	0.40	0.40±0.09*	0.50	0.33	0.17±0.14*	0.02	0.10	0.10±0.31*
Kanau	0.00	0.10	(n=18)	0.50	0.55	(n=05)	0.02	0.10	(n=01)
Vibandha	1.40	0.70	0.70±0.09*	1.67	0.93	0.73±0.40*	1.85	0.77	1.08±0.32*
Vibalialia	1.10	0.70	(n=14)	1.07		(n=14)	1.05	0.77	(n=12)
Kukshishula	1.00	0.50	0.50±0.09*	1.36	0.64	0.73±0.48*	1.42	0.75	0.67±0.16*
Ruksilisilula	1.00	0.50	(n=05)	1.50	0.04	(n=19)	1.72	0.75	(n=09)
Antrakujana	0.50	0.20	0.30±0.09*	0.70	0.30	0.40±0.16*	1.10	0.50	0.60±0.17*
Tintiakujana	0.50		(n=03)			(n=04)	1.10	0.50	(n=09)
Anaha	0.20	0.10	0.10±0.06*	1.64	0.82	0.82±0.09*	1.80	0.90	0.90±0.10*
mana	0.20		(n=05)	1.01		(n=09)	1.00	0.70	(n=09)
Daha	0.50	0.50 0.20	0.20±0.08*	0.50	0.20	0.30±0.13*	0.50	0.20	0.20±0.13*
Bulla	0.50		(n=14)	0.50	0.20	(n=10)	0.50	0.20	(n=11)
Hridgraha (0.01	0.00	0.10±0.06*	_	_	-	_	-	_
Tittugrana (0.01	0.00	(n=01)						
Nidra Viparyaya	0.80	0.50	0.30±0.09*	ı	_		0.8	0.50	0.30±0.15*
itiaia vipaiyaya	0.00	0.50	(n=13)			-	0.0	0.50	(n=04)
Ushnata around	1.82	2 0.82	1.10±0.06*	_	_	_	2.00	0.90	1.10±0.06*
joints	1.02		(n=10)				2.00	0.70	(n=22)

BT = Before Treatment, AT = After Treatment, d±SE = Mean differences ± Standard Error of Mean Table 10: Effect of therapy on associated symptoms in 30 patients each group of Amavata (Rheumatoid arthritis) in group A, B & C. (n=90).

G	roup 'A' (n	n=30)	G	roup 'B' (r	n=30)	Group 'C' (n=30)			
ВТ	AT	d±SE	ВТ	AT	d±SE	ВТ	AT	d±SE	
22.80	21.80	1.00±*	20.70	19.10	1.60±0.32*	22.80	21.80	1.00±0.32*	
		(n=10)			(n=30)			(n=30)	
23.90	22.90	1.00±*	24.70	22.80	1.90±0.18*	23.90	22.90	1.00±0.32*	
		(n=10)			(n=30)			(n=30)	
	04.90	0.30±0.28*	10.20	09.20	1.00±0.47*	05.20	04.90	0.30±0.28*	
05.20		(n=03)			(n=15)			(n=13)	
	BT 22.80	BT AT 22.80 21.80 23.90 22.90	22.80 21.80 1.00±* (n=10) 23.90 22.90 1.00±* (n=10) 0.30±0.28*	BT AT $d\pm SE$ BT 22.80 21.80 $1.00\pm^*$ 20.70 $(n=10)$ $1.00\pm^*$ 24.70 $(n=10)$ $0.30\pm0.28*$ 10.20	BT AT d±SE BT AT 22.80 21.80 $1.00\pm^*$ 20.70 19.10 23.90 22.90 $1.00\pm^*$ 24.70 22.80 $(n=10)$ $0.30\pm0.28^*$ 10.20 0.920	BT AT d±SE BT AT d±SE 22.80 21.80 $1.00\pm^*$ 20.70 19.10 $1.60\pm0.32^*$ $(n=10)$ $(n=30)$ $(n=30)$ $(n=10)$ $(n=10)$ $(n=30)$ $(n=30)$ $(n=30)$ $(n=30)$ $(n=30)$ $(n=30)$ $(n=30)$ $(n=30)$ $(n=30)$	BT AT d±SE BT AT d±SE BT 22.80 21.80 $1.00\pm^*$ 20.70 19.10 $1.60\pm0.32^*$ 22.80 $(n=10)$ $(n=30)$ $(n=30)$ 23.90 $(n=30)$ $(n=30)$ $(n=10)$ $(n=10)$ $(n=30)$ $(n=30)$ $(n=30)$ $(n=30)$ $(n=30)$ $(n=30)$ $(n=30)$	BT AT d±SE BT AT d±SE BT AT 22.80 21.80 $1.00\pm^*$ 20.70 19.10 $1.60\pm0.32^*$ 22.80 21.80 23.90 22.90 $1.00\pm^*$ 24.70 22.80 $1.90\pm0.18^*$ 23.90 22.90 05.20 0.30±0.28* 10.20 09.20 1.00±0.47* 05.20 04.90	

BT = Before Treatment, AT = After Treatment, d±SE = Mean differences ± Standard Error of Mean Table 11: Effect of therapy on ring test in the 30 patients each group of Amavata (Rheumatoid arthritis) in group A., B & C. (n=90).

Hematological Parameters	Group 'A' (n=30)			Group 'B' (n=30)			Group 'C' (n=30)			
rai ailletei s	BT	AT	d±SE	BT	AT	d±SE	BT	AT	d±SE	
ESR	45.80	32.50	13.30±10.56*	62.80	52.00	10.80±7.86*	45.80	32.50	13.30±10.56*	
Hb gm%	12.03	11.97	0.06±0.18*	11.38	10.41	1.09±0.54*	12.03	11.97	0.06±0.18*	
TLC	7.24	7.34	0.10±0.26*	8.39	7.73	0.66±0.65*	7.24	7.34	0.10±0.26*	
Neutrophil	58.40	55.50	2.90±1.64*	63.60	64.50	0.90±1.68*	58.40	55.50	2.90±1.64*	
Lymphocyte	35	37.50	2.50±1.73*	30.00	29.20	0.80±1.40*	35.00	37.50	2.50±1.73*	
Eosinophil	3.70	3.70	0.00±0.33*	3.30	3.20	0.10±0.40*	3.70	3.70	0.00±0.33*	
Monocyte	2.9	3.30	0.40±0.27*	3.10	3.10	0.00±0.14*	2.90	3.30	0.40±0.27*	

BT = Before Treatment, AT = After Treatment, d±SE = Mean differences ± Standard Error of Mean Table 12: Effect of therapy on hematological parameters in 30 patients each group of Amavata (Rheumatoid arthritis) in group A, B & C. (n=90).

Biochemical	Group 'A' (n=30)			G	roup 'B' ((n=30)	Group 'C' (n=30)			
Parameters	BT	AT	d±SE	BT	AT	d±SE	BT	AT	d±SE	
Antinuclear antibodies	22.04	20.84	1.19±0.98*	19.37	18.50	0.87±0.11*	25.33	23.45	1.88±0.24*	
FBS	94.30	92.70	1.60±1.96*	94.30	92.70	1.60±3.40*	88.80	98.30	7.70±4.78*	

BT = Before Treatment, AT = After Treatment, $d\pm SE$ = Mean differences \pm Standard Error of Mean Table 13: Effect of therapy on biochemical parameters in 30 patients each group of Amavata (Rheumatoid arthritis) in group A, B & C. (n=90).

Effect of Vatari Guggulu, virechan karma & Kshara vasti	Group 'A' (n=30) Kshara Vasti along with Vatari Guggula					Virechana iri Guggula	Group 'C' (n=30) Kshara Vasti, Virechana karma along with Vatari Guggula			
Complete remission	No of Patients	Total	% of Remission	No of Patients	Total	% remission	No of Patients	Total	% Remission	
Marked improvement	0		0	0		0	0		0	
Moderate improvement	22	22	73.33%	12	12	40.00%	18	18	60.00%	
Mild Improvement	8	8	26.66%	18	18	60.00%	12	12	40.00%	
Unchanged	0	30	0	0	30	0	0	30	0	

Table 14: Overall Effect of Vatari Guggulu, virechan karma & Kshara vasti in group A, B & C. (n=90)

Discussion

Amavata is one of the important areas of diseases which is being described in various Ayurvedic texts emphasizing different aspects of therapies, covering both pacifying (Śamana) and purifaction (Śodhana) measures. The disease can be compared broadly with modern disease rheumatoid arthritis, to similarities in manifestation of clinical features. Rheumatoid arthritis

(RA), the most common form of chronic inflammatory polyarthritis, represents a significant health burden in the developed world. The damage and deformity of the synovial joints characteristic of RA most commonly develops in the sixth decade but can occur at any age and will usually require treatments and interventions for the rest of an individual's life [11]. Rheumatoid arthritis has a worldwide prevalence of approximately 1% (prevalence is the number of cases occurring in a population at a given

time) and is consistently observed to affect women 2-3 times more frequently than men. The occurrence of RA is not, however, the same throughout the world [12]. Prevalence rates are low in the less developed and rural parts of the world and it has been suggested that RA is a modern disease, its appearance seeming to coincide with industrialisation or urbanization [13]. Rheumatic diseases are a major cause of morbidity in India. Musculoskeletal pain is prevalent in 6.4%-23.6% of the Indian population. The most common causes of impaired quality of life due to musculoskeletal pain are the duration of symptoms, pain in shoulders and hand, and back pain. The most prevalent rheumatic problems are non-specific musculoskeletal complaints (4.25% - 6.25%),osteoarthritis (4.39%-6.25%, of which knee osteoarthritis comprised 3.34%-4.42%) and soft tissue rheumatism 1.31%-3.77%. Inflammatory rheumatic diseases had a prevalence of less than 1% each (rheumatoid arthritis 0.34%-0.67%, undifferentiated inflammatory arthritis 0.22%-0.76%, spondyloarthritis 0.23%- 0.3%, gout 0.04%-0.13% and lupus 0.02%) [14]. Inspite of many advancement of treatment has been developed by modern medical sciences but most of these can limit the disease process to a certain extent and is unable to re-establish the physiological activities. Moreover, most of these treatments may cause serious adverse effects like gastric irritations (e.g., NSAIDs), immune-suppression (e.g., corticosteroids), etc.

Treatment of *Amavata* is described classically in many texts of Ayurveda like Bhavaprakash Nighantu, Bangasen Samhita, Sharamgadhara Samhita, etc. However, most scientifically the principle of management has been described in Chakraduttam, written during 16th century AD [15]. The classical description of the principle of management of Amavata according to Ayurveda is as follows-

Lamghanam Swedanama Tiktam Dipanani Katuni Cha / Virechanam Snehapanam Vastyasha Amamarutaih // Saindhavadya Anuvasena Ksharavasti Prayojyate / Amavate Panchakola Siddha Pananabhisyate // Ruskhaseda Prakartobya Valuka Putakaisthata // -Chakradutta

i.e., in the treatment of Amavata, the principles of management are serial procedures like Lamghana (lightening therapy by means of fasting), Swedanama (fomentation), Dipana (application of appetizers), Tiktam – Katu (application of drug and diet that are bitter and pungent in taste), Virtechana (medicated purgation

therapy), Snehapanam (drinking of oily substances like ghee), Vasti (enema therapy), Anuvasana (Special type of enema administered with Saindhavadya oil) or some time alkaline enema (Ksarvasti), application of decoction of Panchakola (a preparation with medicinal plant parts like fruit and root of *Piper longum*, seed of *Piper nigrum*, fruit of *Piper chava* and *Zingiber officinalis*) and hot compress with sand bundles.

These series of therapeutics, covering both pacification and purification measures, were designed to eradicate the disease from its route so that the physiological condition of the body can be retained and the pathological condition can be deleted. Lamghana (lightening therapy) and Swedanam (fomentation measure) are rendered for dissolution of 'Ama' vis-à-vis auto-immunological changes; drugs and diets having Tikta (bitter taste) and Katu (pungent taste) are helpful for kindling power of digestion so that the progress of disease can be arrested by preventing initiation of further pathogenesis process and the symptoms as well as complications can be pacified by means of specific purification (*Panchakarma*) therapy like Virechana and Vasti. Kshara vasti is the specific variety of purification therapy mentioned in Ayurveda for Amavata only. Kshara Basti comprises of Saindhava, Guda, Chincha, Shatahva and Gomutra. In this Basti, maximum quantity is of Gomutra, which is having Kshara Guna. Kshara has the property of Lekhana and Vishoshana, which are antagonistic to Ama and is very much required in the conditions like Amavata [16,17]. Kshara vasti may have probability of aggravation of Vata and that can be combated by Vatashamaka drug guggulu, specifically Vatariguggulu.

The present research work of Amavata was designed on the basis of the above mentioned hypothesis for its scientific validation utilizing some modern parameters in comparison with fundamental Ayurvedic theories. In the present context of study it was observed that out of three groups, the first one comprising of 'Kshara Vasti' (medicated alkaline enema), and 'Vatariguggulu' (Ayurvedic drugs composed with Commiphera wightii Linn., Ricinus communis Linn., Terminalia chebula Linn., Phyllanthus emblica Linn., Terminalia bellerica Linn. and sulphur) was found to be best among other two groups comprises some fractions of the treatment. There were highly significant (p<0.001) improvement of subjective parameters like Sandhishula (pain in joints), Sandhigraha (stiffness of joints), Sparshasahyata (tenderness), Daurbalya (general weakness), Agnimandya (loss of appetite), Hridgraha (cardiac hypo-dynamicity), etc. All

these physical changes with first group of treatment within 30 days of therapy was well compensated (p<0.001) with objective findings like routine blood examination including ESR, RA-factors and antinuclear antibodies. It was observed by overall observation that in spite marked improvement were not observed with this treatment in selected 30 cases of rheumatoid arthritis but 73% moderate improvement (22 patients) and 27% mild improvement (08 patients) were observed with this classical regimen of Ayurvedic therapy described in Chakraduttam. The Ayurvedic justification behind this improvement were due to (i) pacification of Ama by Lamghana and Swedana, (ii) dissolution of pathological products i.e., Amavisa by means of Kshara Vasti and (iii) pacification of aggravated vata by means of Vatari Guggulu. On the other hand, the main pathology of rheumatoid arthritis is inflammation due to auto-immune reaction, which could be combated by anti-oxidant property of triphala (Terminalia chebula Linn., Phyllanthus emblica Linn., Terminalia bellerica Linn.) and anti-inflammatory activity by Commiphera wightii and Ricinus communis as reported in various modern research outcome. The Kshara Vasti and Virechana varieties of Panchakarma therapy are solely responsible for elimination of noxious pathological products of disease process deposited in many parts of the body so that the antigen-antibody reactions due to auto-immune mechanism could be mitigated. Inspite, Virechana is one of major procedure of therapeutics designed by Chakra Dutta for the management of 'Amavata' but by Ayurvedic pharmacodynamic nature of this therapy, it is responsible to eliminate 'pitta'dosa. The motto of virechan therapy as designed by Chakra Pani Dutta is probably to eliminate pitta, if it is superimposed with vata & kapha vis-a-via Ama. In the present contexts, the prakriti of patients were found to be vata-kapha predominant and therefore addition of Virechana in Group c was not found to be satisfactory. It is, therefore, may be concluded that the Ayurvedic module of combination therapy of pacification and purification can be considered as one of the best model of treatment for control and pacification of the incurable disease Amavata vis-à-vis rheumatoid Arthritis.

Conclusion

The present research work reveals that Amavata (Rheumatoid Arthritis) is a debilitating disease which is not only incurable but may also alter the life style. A best way of treatment is needed, preferably by natural way, to control the disease process so that the life style may be maintained. It has been observed from the current

research work that combination of Ayurvedic therapeutic module possessing Kshara Vasti and Vatari Guggula can be the suitable choice to satisfy the primary objects of the treatment for Amavata (Rheumatoid Arthritis).

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