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A COMPARATIVE CLINICAL STUDY ON THE EFFECT OF *ERANDATAILA, VALUKA SWEDA & RASONAPINDA* IN THE TREATMENT OF *AMAVATA*

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ABSTRACT

Ayurveda contains a wealth of knowledge on health sciences since ancient times. It deals with good, bad, happy and unhappy life, its promoters and non-promoters, span and nature. And this science of life-Ayurveda deals with life as a whole which is conjunction of body, sense organs, mind and self. Now a day's modern science and allopath now believe in its principle and more and more research is being directed towards ancient herbs and natural therapies. All medical practitioners believe that prevention is better than cure and Ayurveda provides the path to a healthy lifestyle. Ayurveda sees health as a perfect balance between mind, body and consciousness. To achieve this it accepts a daily regimen of exercise, emotional balance and a healthy diet. This is a great way to prevent the onset of many life style diseases in itself. Ayurveda recommends a number of herbs for preventing cancer and there is a growing body of scientific studies that backs this ancient knowledge. Some common herbs are available which are proven to have anti-cancer properties.

Keywords: Ayurveda, Herbs, Diet, Body, Cancer

INTRODUCTION

Indulgence in specific etiological factors, cause simultaneous vitiation of *vata dosha* as well as *kapha dosha* which in turn initially afflicting the sacral region; later gradually stiffens the whole body manifesting as *amavata* and is paralleled to the rheumatoid arthritis of biomedicine. *Ama* is invariably involved in all stages of the pathogenesis hence the name *amavata.* Vitiated *vata dosha* in association with *ama* circulates in the whole body and then localizes in the different locations of *kapha dosha* with predilection of joints causing pain swelling as well as stiffness of the joints[1]related to extremities head and trunk. The patient may suffer from other systemic features like body ache, lack of taste in the mouth, excessive thirst, lack of enthusiasm, heaviness of the body and febrile illness. *Amavata* is categorized into three types based on the relative dominance of the *dosha* as *vatanuga, pittanuga* and *kaphanuga amavata*[2]. This crippling disease will make a person to depend on others for his daily

needs. Involving the *madhyama roga marga*, this illness poses difficulties in the curative approach. Clearing the *ama* and pacification of *vata dosha* is the sheet anchor of treating *amavata. Langhana shodhana shaman brimhana* and *rasayana* [3] form the complete treatment of *amavata*. Balanced approach that clears the *ama* and pacifies the *vata dosha* is effective in the management of *amavata*. In general, simultaneous administration of *antahparimarjana cikitsa*/internal medication as well as *bahiparimarjana cikitsa* / external medication is conveniently adapted in the management of *amavata*. Administration of *langhana, dipana, virechana, snehapana* and *basti* form *antahparimarjana cikitsa*. In conjunction with internal medication, the patient should be treated with external procedures like *ruksha sveda*, and *upanaha*[4]. *Langhana dipana pachana* and oral medication with bitter drugs are centred on the clearance of *koshta gata vata*. On the other hand *sneha virechana* and *kshara basti* are effective in the clearance of *sharira gata ama*. In addition to this *vyadhihara rasayana* is very effective in combating the disease. Among these *lashuna* being a *rasayana,* the formulation of *rasona pinda* proved to be effective in a pilot study is opted in this clinical study. *Rasona pinda* contains *Rasona* (Allium sativum Linn), *Hingu* (Ferula foetida Regel), *Jeeraka* (Cuminum cyminum), *Saindhava Lavana* (Sodii chloridum impura), *Sauvarchala Lavana* (Unaqua sodium chloride), *Shunthi* (Zingiber officinale Rosc), *Maricha* (Piper nigrum Linn), *Pippali* (Piper longum Linn)[5]. *Eranda* (Ricinus communis) is the drug of choice in the treatment of *amavata*[6]. Also it is effective as *sneha virechana* hence is taken for the study. Among the external treatment the *ruksha sveda*[7] stands number one in relieving the joint pain and swelling hence is opted in the study. The present study is about the therapeutic effect of *Eranda taila*, *valuka sveda* and *Rasona pinda* in patients suffering from *amavata* and is carried out in 100 patients allocated randomly into four groups.

Objectives of study

To evaluate the individual and collective therapeutic effect of *Eranda taila virechana*, *Valuka potalai sveda* and *rasona pinda prayoga* in *Amavata*

Materials and Methods

DESIGN: Study type – Interventional; Actual enrolment : 100 participants; Allocation –randomized; Endpoint classification - Efficacy study; Intervention Model - Parallel Assignment; Masking - Open Label; Primary Purpose - Treatment

Patients and randomization

Participants were selected for the study from I.P.D & O.P.D. of Alvas Ayurveda Medical College and Hospital,Moodbidri. *Rasona pinda, eranda mula quatha* and *eranda taila* were procured from Shri Dharmasthala Manjunatheshwara Ayurveda Pharmacy, Udupi.

Patients suffering from *Amavata* / rheumatoid arthritis with minimum 6 months history having Score ≥ 6 points as per ACR/EULAR (2010) Classification Criteria for RA, Erythrocyte Sedimentation Rate (ESR) of ≥ 28 mm/hr, Serum C-reactive protein (CRP) >= 0.80 mg/dL at screening, Disease Activity Score 28 (DAS28) ≥ 3.2 of both sex of age between 16 to 70 years with the history of more than five years of illness were screened under strict diagnostic, inclusion and exclusion criteria. Pregnant Females, subjects with history of inflammatory joint disease, subjects suffering from systemic disorders like Diabetes Mellitus, subjects with history of juvenile idiopathic arthritis and subjects with contraindication for *virechana* or *svedana* were excluded from the study. The eligible subjects were invited to participate in this clinical study, after signing a detailed informed consent and were then registered study. The registered participants were randomly allocated into four groups by adapting the permuted block randomization method with the block size of eight. Registered participants were treated with *eranda taila, valuka pottala sveda, rasona pinda* or combination of these as per the study protocol details are

provided in the table 01. The outcome measures are assessed at baseline and by the completion of the interventions.

Table 1: Arms and Interventions

Arm	Intervention / treatment
Experimental:1 **VR group** (*Virechana group)*	**Medicine** : *Eranda taila* Seed oil, 20 ml early morning around 6 am with 150 ml of warm water every day for 15 days
Experimental:2 **VPS group** (*Valuka pottala sveda* group)	**Procedure** : *Valuka pottala sveda* *svedana* procedure, *Valuka pottala sveda* is carried out on all painful joints for half an hour every day for 15 days
Experimental:3 **RP Group** (*Rasona pinda* group)	**Herbal formulation** : *Rasona pinda* Powder, 10grms was orally administered half an hour before breakfast with 150ml of *eranda mula quatha* for 30 days
Experimental:4 **CG group** (Combined group)	**Medicine** :*Eranda taila,* **Herbal formulation** - *Rasona pinda* **Procedure** : *Valuka pottala sveda* During initial 15 days internally *eranda taila* was given in a dose 20 ml early morning around 6 am with 150 ml of warm water and external treatment with *Valuka pottala sveda* is carried out on all painful joints for half an hour. during the next 30 days 10grms of *Rasona pinda* was orally administered half an hour before breakfast with 150ml of *eranda mula quatha*

Procedures and outcomes

Primary Outcome Measures were change in the symptom score of joint pain, joint swelling, joint stiffness and joint tenderness from the base line at completion of intervention. The severity of symptom was evaluated by four point categorical scale - 0=absent, 1=mild, 2=moderate, 3=severe; Change from baseline in Erythrocyte Sedimentation Rate (ESR) at completion of intervention expressed as mm at fist hour.

Secondary outcome measures included Change from baseline in Disease Activity Score 28 (DAS28) at completion of intervention and the expressed values are 0=best to 10=worst. Change from Baseline in Health Assessment Questionnaire-Disability Index (HAQ-DI) Score at completion of intervention and the total possible score ranges from zero to three. Zero means no difficulty and three mean worst possible difficulties. Change from baseline in the disability index at completion of treatment. The day of randomization and the first dose of intervention are defined as day 0 and the day of completion of intervention is the time point of primary outcome of the clinical trial.

Statistical analysis

125 Patients suffering from Amavata / rheumatoid arthritis were screened under strict diagnostic, inclusion and exclusion criteria. 110 Eligible participants were invited to participate in this clinical study and after signing a detailed informed consent, they were registered study. Among 110 patients 10 patients were dropped from the study for various reasons. Descriptive statistical analysis of these patients was analysed and presented by using the software Sigma Stat version 3.5. The parametric and nonparametric data obtained by assessing the pain swelling tenderness and stiffness were analysed by paired t test to note the significance of treatment with in the individual group. ANOVA test was used to compare the results between the groups

Patient involvement

None of the participants were involved in preparing the research question or selecting the regimen, primary and secondary outcome measures, nor were they involved in establishing the plans for recruitment, design, or implementation of the study. No participants were asked to suggest the interpretation or writing up of results.

Results

Demographic profile: Among the 100 patients 36 % belonged to the age group of 46 to 50 years, 68% were females, 68 % were Hindu, 80 % had middle socioeconomic status, 34% had primary education, 58% were housewives, and 44% of patients were from rural area.

Table 2: Demographic profile

Profile	Category	VR group		VPS group		RP Group		CG group		Total	
		No	%	No	%	No	%	No	%	No	%
Age group	25-30	00	00	00	00	08	08	04	04	03	03
	31-35	00	00	00	00	04	04	08	08	03	03
	36-40	00	00	00	00	04	04	08	08	03	03
	41-45	24	24	12	12	12	12	20	20	17	17
	46-50	36	36	40	40	36	36	32	32	36	36
	51-55	16	16	16	16	04	04	12	12	12	12
	56-60	24	24	24	24	24	24	16	16	22	22
	61-65	00	00	08	08	08	08	00	00	04	04
Gender	Male	56	56	20	20	16	16	36	36	32	32
	Female	44	44	80	80	84	84	64	64	68	68
Religion	Hindu	64	64	72	72	72	72	64	64	68	68
	Muslim	24	24	24	24	24	24	24	24	24	24
	Christian	12	12	04	04	04	04	12	12	08	08
Socio-Economic Status	Poor	08	08	20	20	24	24	28	28	20	20
	Middle	92	92	80	80	76	76	72	72	80	80
	Rich	00	00	00	00	00	00	00	00	00	00
Educational Status	Illiterate	28	28	68	68	72	72	68	68	59	59
	Primary	44	44	32	32	28	28	32	32	34	34
	Secondary	20	20	00	00	00	00	00	00	05	05
	PUC	08	08	00	00	00	00	00	00	02	02
Occupation	Student	00	00	00	00	00	00	00	00	00	00
	Business	00	00	00	00	00	00	00	00	00	00
	House wife	10	40	19	76	14	56	15	60	58	58
	Employee	15	60	06	24	11	44	10	40	42	42
Habitat	Urban	16	16	04	04	20	20	24	24	16	16
	Semi urban	40	40	52	52	44	44	24	24	40	40
	Rural	44	44	44	44	36	36	52	52	44	44

Observations of personal history: In all the groups 55 % of participants were married, 75 % recorded mixed diet, 41 % had the addiction of tobacco chewing, 47 % of patients had disturbance of sleep due to pain occasionally, 56 % of patients had impaired appetite and 46% patients had *madhyama koshtha*.

Table 3: Observations of personal history

Profile	Category	VR group		VPS group		RP Group		CG group		Total	
		No	%	No	%	No	%	No	%	No	%
Marital status	Single	00	00	00	00	72	72	64	64	34	34
	Married	84	84	88	88	24	24	24	24	55	55
	Widow	16	16	12	12	04	04	12	12	11	11
Diet	Vegetarian	16	16	24	24	28	28	32	32	25	25
	Mixed	84	84	76	76	72	72	68	68	75	75
Addictions	Tobacco	36	36	44	44	32	32	52	52	41	41
	Alcohol	16	16	00	00	04	04	04	04	06	06
	Tea / coffee	48	48	56	56	36	36	44	44	46	46
	None	00	00	00	00	28	28	00	00	07	07
Sleep	Sound	0	0	0	0	0	0	0	0	0	0
	Pain Disturbing occasion-ally	44	44	52	52	44	44	48	48	47	47
	Pain disturbing always	52	52	52	40	36	36	52	52	45	45
	Other cause Disturbing	04	04	04	08	20	20	00	00	08	08
Agni	Vishama	08	32	9	36	4	16	8	32	29	29
	Tikshna	00	00	0	00	0	00	0	00	0	00
	Manda	16	64	16	64	14	56	10	40	56	56
	Sama	01	04	0	00	7	28	7	28	15	15
Koshta	Krura	04	16	1	4	04	16	03	12	12	12
	Madhyama	12	48	11	44	12	48	11	44	46	46
	Mridu	09	36	13	52	09	36	11	44	42	42

Effect of treatments within group and comparison between the groups:

In all the four groups the mean joint pain score recorded statistically significant reduction. The mean joint pain score was 2.840 (±0.0748) in VR group that reduced to 1.00 (±0.115) following *virechana.* In the VPS group the initial joint pain score of 2.600 (±0.1000) was reduced to 1.720 (±0.108). The baseline score of 2.520 (±0.117) in joint pain came down to 0.680 (±0.125) following oral medication with *rasona pinda*. In the combined fourth group the joint pain score before treatment was 2.600 (±0.10) that reduced to 0.400 (±0.115). Thus maximum reduction was recorded in the combined group and is also proved to be statistically significant.

The mean joint swelling score was 2.360 (±0.0980) before treatment in VR group that reduced by 1.680 following the medication with *eranda taila*. The improvement recorded in VPS group was 1.280 from the initial mean score of in joint swelling2.520 (±0.102). The initial joint swelling score of 2.640 (±0.0980) in the RP group reduced to 0.440 (±0.101) following medication with *rasona pinda*. In the CG group the initial mean score of joint swelling of 2.520 (±0.102) was reduced to 0.440 (±0.117). The statistical analysis of this improvement by the paired t test proved the highly significant result with the p value of < 0.001 (Table 00) in all the groups. When compared the best response obtained in RP group is statistically significant as indicated by the Kruskal-Wallis One Way Analysis of Variance on Ranks with the $p < 0.001$ (Table 00).

The mean joint stiffness score before treatment was 1.480 (±0.102) in VR group, 2.520 (±0.102) in VPS group; 2.640 (±0.0980) in the RP group; 2.640 (±0.0980) in the CG group that came down to0.400 (±0.1000), 1.640 (±0.114), 0.640 (±0.0980) and 0.440 (±0.101) respectively. The best improvement

revealed in CG group is statistically significant when compared between the groups.

The mean joint tenderness score before treatment was 1.800 (±0.0816) in VR group, 2.280 (±0.0917) in VPS group; 2.760 (±0.0872) in the RP group; 2.520 (±0.131) in the CG group that came down to 0.560 (±0.101), 1.240 (±0.119), 0.440 (±0.101) and 0.400 (±0.115) respectively. The maximum reduction in RP group is statistically significant when compared between the groups.

The mean ESR before treatment was 78.480 (±4.799) in VR group, 59.120 (±3.638) in VPS group; 51.800 (±2.802) in the RP group; 64.360 (±3.583) in the CG group that came down to 43.640 (±3.347), 59.120 (±3.638), 36.080 (±1.948) and 35.120 (±2.009) respectively. The maximum reduction in ESR in VR group is statistically significant when compared between the groups.

The mean DAS 28 before treatment was 6.520 (±0.0777) in VR group, 6.212 (±0.0745) in VPS group; 5.744 (±0.0671) in the RP group; 6.116 (±0.0559) in the CG group that came down to 5.032 (±0.103), 5.481 (±0.0873), 5.024 (±0.0644) and 4.948 (±0.0691) respectively. The maximum reduction in DAS28 in CG group is statistically significant when compared between the groups by the method of One Way Analysis of Variance.

The mean disability index before treatment was 1.847 (±0.0562) in VR group, 1.990 (±0.0626) in VPS group; 2.086 (±0.0629) in the RP group; 2.196 (±0.0684) in the CG group that came down to 1.323 (±0.0634), 1.644 (±0.0721), 1.562 (±0.0537) and 1.572 (±0.0657) respectively. The maximum reduction in disability index in CG group is statistically significant when compared between the groups by the method of One Way Analysis of Variance.

Table 4: Therapeutic effect of treatments

Outcome	Group	Mean score		BT-AT	Within group t test				Between group
		BT (±SE)	AT (±SE)		±SD	±SE	T	P	P
Joint pain	VR	2.840 (0.0748)	1.000 (0.115)	1.840	0.688	0.138	13.372	<0.001	<0.001*
	VPS	2.600 (0.1000)	1.720 (0.108)	0.880	0.726	0.145	6.063	<0.001	
	RP	2.520 (0.117)	0.680 (0.125)	1.840	0.554	0.111	16.613	<0.001	
	CG	2.600 (0.1000)	0.400 (0.115)	2.200	0.707	0.141	15.556	<0.001	
Joint swelling	VR	2.360 (0.0980)	0.680 (0.150)	1.680	0.852	0.170	9.854	<0.001	<0.001*
	VPS	2.520 (0.102)	1.240 (0.119)	1.280	0.737	0.147	8.683	<0.001	
	RP	2.640 (0.0980)	0.440 (0.101)	2.200	0.500	0.1000	22.000	<0.001	
	CG	2.520 (0.102)	0.440 (0.117)	2.080	0.702	0.140	14.807	<0.001	
Joint stiffness	VR	1.480 (0.102)	0.400 (0.101)	1.080	0.493	0.0987	10.947	<0.001	<0.001*
	VPS	2.520 (0.102)	1.640 (0.114)	0.880	0.526	0.105	8.365	<0.001	
	RP	2.640 (0.098)	0.640 (0.098)	2.000	0.408	0.0816	24.495	<0.001	

	CG	2.640 (0.098)	0.400 (0.1000)	2.200	0.577	0.115	19.053	<0.001	
Joint tender-ness	VR	1.800 (0.0816)	0.560 (0.101)	1.240	0.436	0.0872	14.224	<0.001	<0.001*
	VPS	2.280 (0.0917)	1.240 (0.119)	1.040	0.539	0.108	9.656	<0.001	
	RP	2.760 (0.0872)	0.440 (0.101)	2.320	0.476	0.0952	24.365	<0.001	
	CG	2.520 (0.131)	0.400 (0.115)	2.120	0.666	0.133	15.920	<0.001	
ESR	VR	78.480 (4.799)	43.640 (3.347)	34.840	14.761	2.952	11.801	<0.001	0.002**
	VPS	59.120 (3.638)	49.280 (3.157)	9.840	3.923	0.785	12.541	<0.001	
	RP	51.800 (2.802)	36.080 (1.948)	15.720	6.755	1.351	11.636	<0.001	
	CG	64.360 (3.583)	35.120 (2.009)	29.240	12.972	2.594	11.270	<0.001	
DAS 28	VR	6.520 (0.0777)	5.032 (0.103)	1.488	0.367	0.0733	20.292	<0.001	<0.001*
	VPS	6.212 (0.0745)	5.481 (0.0873)	0.731	0.255	0.0511	14.321	<0.001	
	RP	5.744 (0.0671)	5.024 (0.0644)	0.720	0.290	0.0580	12.409	<0.001	
	CG	6.116 (0.0559)	4.948 (0.0691)	1.168	0.340	0.0680	17.176	<0.001	
Disability index	VR	1.847 (0.0562)	1.323 (0.0634)	0.524	0.179	0.0359	14.599	<0.001	<0.001*
	VPS	1.990 (0.0626)	1.644 (0.0721)	0.346	0.154	0.0308	11.240	<0.001	
	RP	2.086 (0.0629)	1.562 (0.0537)	0.524	0.191	0.0381	13.763	<0.001	
	CG	2.196 (0.0684)	1.572 (0.0657)	0.624	0.212	0.0425	14.693	<0.001	

* Kruskal-Wallis One Way Analysis of Variance on Ranks
**One Way Analysis of Variance

DISCUSSION

The etiological factors lead to the vitiation of *vata dosha* and generation of *ama.* Thus generated *ama* is circulated into the whole body by the vitiated *vata-dosha* and the same gets lodged in different parts of the body with predilection for sites of *kaphadosha* and more particularly the joints. This is the unique clinical status of *sharira gata ama* and is best treated by *virechana karma*. As shown by this study, the *nitya virechana* has reduced the severity of the joint pain, tenderness, swelling and stiffness and other primary and secondary outcome measures. Also the eranda being the drug of choice in amavata synergises the therapeutic effect. The *valuka pinda sveda* is said to instantly reduce pain swelling and stiffness and the same is true in this study showed reducing in the symptom severity of amavata. *Rasona pinda* is effective in reducing the severity of *amavata* as re-

vealed in the study with improvement in primary and secondary outcome measures. Definitely the individual approach of *virechana, valuka pinda sveda* and oral administration of *rasona pinda* have efficacy in bringing about the remission of the illness. The combined approach has synergistic effect with maximum benefit as shown by the study with statistically significant results. During the course of the study as there was no adverse reactions and it can be said as safe in the above said dosages. Since these interventions have not resulted in complete remission of the illness judicial planning of these procedures for a longer period may prove more effective.

CONCLUSION

Individually the *nitya virechana* with *eranda taila*, *valuka pinda sveda* on affected joints and oral medication with *rasona pinda* is effective in reducing the severity of *amavata.* Also the combined treatment is most effective in combating the illness *amavata.*

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