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TITLE

Efficacy of *Erand Sneha* (Castor Oil) in the management *of Amavata* (Rheumatoid arthritis) with respect to its *Sama* Stage

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ABSTRACT

BACKGROUND: *Amavata* (Rheumatoid arthritis) is a disease which is difficult to cure and one of the challenging disease for the clinicians due to its chronicity, incurability, complications and morbidity. *Eranda Sneha* (Castor oil) possess properties which causes increase in digestive fire, penetrate into micro-channel, remove obstruction from micro-channel, pacify *Vata-Kapha Doshas* and remove them *via* purgation. **AIM:** To assess the efficacy of Castor oil in the management of *Sama* condition (acute stage) of *Amavata*. **MATERIALS & METHODS:** In the present study 61 patients aged between 20 to 60 years, fulfilling the inclusion criteria and having symptoms of *Sama* stage were selected from the OPD and IPD of *Roga- Nidana Evam Vikriti Vijnana*, department, I.P.G.T. & R.A., Gujarat Ayurved University, Jamnagar. Patients were treated in two different groups with administration of *Eranda Sneha* (Castor oil) alone and with combination of *Shunti* (*Zingiber officinale)* once in morning on empty stomach. **RESULTS:** After the course of therapy for 15 days, similar symptomatic improvement was observed both the groups. Overall effect of therapy suggests that only group A provided moderate improvement in maximum objective and subjective criteria.**CONCLUSION:** The study concludes that both Castor oil alone and with combination of *Zingiber officinale* is effective to remove *Sama* stage of *Amavata* and thereby provide symptomatic relief.

Keywords: *Amavata*, Castor oil, Rheumatoid arthritis, *Zingiber officinale*

Introduction

Frequent indulgence in factors which leads to altered status of digestive fire at all level i.e. intestinal, sub-cellular and cellular leads to develop various kinds of diseases. [1] Ayurveda advocates that the causative factor for all disease is *Mandagni* (diminished digestive fire). [2] In 21st century Rheumatoid arthritis (RA) has been more common and distressing among all joints problem. About 0.8% of world population is affected by RA. Females are three times more affected than male. It is a chronic inflammatory joint disease with multi system involvement. The onset is usually during 4th & 5th decade of life; however people of any age group can be affected in any climate condition. Factor producing RA includes infectious triggers, genetic predisposition & autoimmune response.

The course of the disease include an insidious / acute onset with fatigue, anorexia, weakness and rapid development of polyarthritis accompanied with constitutional symptoms such as fever, lymphadenopathy & splenomegaly. Joint involvement is usually symmetrical. It is characterised by pain, swelling, tenderness & painful limitation of movements. Generalised stiffness may occur but morning stiffness lasting more than one hour is a characteristic feature. The metacarpophalangeal & proximal inter phalangeal joints of the hands, wrists, knees & metatarsophalangeal & proximal inter phalangeal joints of the feet are the most common joints involved. [3]

It is a challenging disease for the physicians and medical field as the uses disease modified anti-rheumatoid drug (DMARD), steroids and non-steroidal anti-inflammatory drug (NSAID) frequently have shown negative impact on immune system and gives only temporary relief. However, till date no satisfactory medical management has been developed for this problem. *Amavata* is the disease of *Madhyama Rogamarga*, bone and joints are the chief site for the manifestation of cardinal symptoms like pain, swelling and stiffness of joints, etc.

All the three *Doshas* (bodily humours) takes part in the pathogenesis of disease but *Ama* and vitiated *Vata* play the dominant role. *Amavata* is made up of two words, *Ama* and *Vata*. *Ama* means incomplete digestion of food which result in incomplete/improper formation of *Annarasa* (chyle), circulate in body & reach to target cell where it produces pathology like heaviness in body, loss of strength, drowsiness, aggravation of *Vata* & improper elimination of waste product. Body ache, undesirous to take food, thirst, fever, incomplete digestion of food, swelling in affected joints are the symptoms of *Amavata.*[4] The disease becomes difficult to cure when it grows in intensity. All symptoms mentioned are characteristic features of *Ama* & without treating *Ama* it is impossible to treat the disease so in this condition drug having *Ushna* (hot), *Tikshna* (strong), *Deepana* (stimulant), *Pachani* (digestive), *Vatashamaka* (pacifier of *Vata*),and *Shothhara* (anti-inflammatory) properties can be used.

In Bhavaprakash Samhita castor (*Ricinis Communis*) seed oil is mentioned as a best drug for *Amavata*. [5] Taking into above points of properties of drugs, Castor oil with *Zingiber officinale* was selected to assess their efficacy in the management of *Amavata* in *Sama* condition.

Ethical Clearance

Study was started after obtaining Ethical Clearance from the Institutional Ethics Committee, IPGT & RA, GAU, Jamnagar.

- **IEC - Ref. PGT/7/-A/Ethics/2015-16/1490 [Dated: 25/08/2015]**

Study was Registered in Clinical Trial Registry of India.

- **CTRI NO. - CTRI/2016/12/007569 [Dated: 14/12/2016]**

Materials & Method

Selection of Patients

- Patients suffering from *Amavata* in *Sama* stage were selected from the OPD and IPD of *Rog- Nidana Evam Vikriti Vijnana*, department, I.P.G.T. & R.A., Jamnagar.
- Before registering the patients informed consent were taken.

Criteria for Diagnosis

Diagnosis was confirmed on the basis of symptoms of *Sama* stage of disease with cardinal symptoms of *Amavata* like pain, swelling, stiffness and tenderness along with symptoms of rheumatoid arthritis (As mentioned according to revised criteria of American association of rheumatology 1987).

Inclusion Criteria

- Patients fulfilling the diagnostic criteria especially having symptoms of *Sama* stage of disease
- Age between 20 to 60 years.

Exclusion Criteria

- Patients having symptoms of rheumatoid arthritis but having absence of *Sama* symptoms
- Patients with complications of RA e.g. Pleuro-Pericardial disease, cardiac disease etc
- Patients with poorly controlled HTN, DM and other systemic diseases
- Patients on prolong medication especially corticosteroids, anticholinergics etc.

Registered patients were examined on the basis of specially prepared proforma containing detail assessment of disease encompassing Ayurveda and modern aspects.

Investigations

All the investigation were carried out before starting and after completion of therapy.

1. **Hematology:** Hb%, TLC, DLC, ESR (wintergreen method)
2. **Bio-Chemistry:** FBS, Blood urea, Sr. Uric acid, Sr. creatinine, LFT, RA factor (Quantitative), CRP, and ASO quantitative titer.
3. Urine analysis (Routine & Microscopic)
4. ECG (12 leads-if needed)
5. X- Rays of affected Joints.

Posology

Group A: *Eranda Sneha* & Decoction of *Shunti*

Dose: 30 ml (20 ml Decoction of *Shunti* & 10 ml *Eranda Sneha*)

Method of Preparation of decoction: 5 gm of coarse powder of *Shunti is* added with 80 ml of water is boiled until ¼ part (20 ml) is remaining, after preparing decoction, to which 10 ml of castor oil is added.

Group B: *Eranda Sneha*

Dose: 10 ml

Time of administration: In both the group at morning – empty stomach

Mode of administration: Oral

Duration: 15 days

***Anupana*:** Luke warm water

Criteria of Assessment

1) **Subjective:**
   - A. Local symptoms
   - B. Systemic symptoms
2) **Objective:**
   - A. Serological parameters
   - B. Hematological and others biochemical parameters.
   - C. Disability index (the Indian health assessment questionnaire)

Improvement in hand grip, foot pressure and walking time.

Clinical assessment: - Assessment of cardinal and associated symptoms were done and recorded on the zero day (i.e. one day before administering the trial drug), 5th, 10th and 15th day after starting the treatment. Changes in the signs and symptoms were assessed by adopting suitable scoring method.

Functional Assessment

Walking time: patients were advised to move 50 meters and time was recorded.

Hand Grip: To find out the functional capacity of the affected upper limb, Patients were asked to squeeze the inflated cuff of the sphygmomanometer and the grip strength has been recorded in mm of Hg.

Foot pressure: To have an objective view of the functional capacity of the legs, foot pressure was recorded by using a weighing machine.

Following statistical test has been applied in this work- Wilcoxon sign rank test (for comparison of two group in subjective criteria), Unpaired 't' test (for comparison of two group in objective criteria) and Paired't' test (for same group).

Software used: Sigma software was used for all statistical evaluation.

Observations & Results

Total 61 patients were registered, among them 53 completed the treatment and 08 dropped out. In group A, 31 were registered out of which 28 completed and 03 dropped out the course. In group B, 30 patients were registered out of which 25 completed and 05 dropped out.

31.14% of patients belonged to age group of 41-50 yrs. 59.01% were female among which 68.85% were Housewife. 26.22% were uneducated followed by primary education (24.59%). 34.42% belonged to lower middle class. 70.49% belonged to urban area. 78.68% were vegetarian. 57.37% had history of consuming sour diet. 81.96% each were taking oily and heavy diet followed by cold substances (70.49%). 27.86% of patients had disturbed sleep (27.86%) and 85.24% had a habit of day sleep. 50.81% had *Krura Koshtha* (hard and constipated stools). 72.13% had diminished function of digestive fire and Irregular function of digestive fire (11.47%). 68.85% had non satisfactory bowel habit and irregular bowel habit (44.26%). 54.09% had excessive micturition (polyuria). 66.66% of females patients enrolled had obstetric history of delivering baby by normal delivery followed by history of abortion (19.44%), and history of LSCS (13.88%). 63.93% had *Vata-Kaphaja Sharira Prakriti*. 80.32% had *Rajajasa-Tamasika Manasa Prakriti*. 14.75% had *Avara Sara*, 9.83% had *Avara Samahanana* and 57.37% had *Avara Satva*. 31.14% were over-weight and 18.03% were obese. 88.52% had *Madhyama Satmya*. 77.04% had *Avara Ahar Shakti*. 59.01% belonged to *Hani Awastha* (old age) followed by 37.70% of patients in *Sampurnata Avastha* (Adult) and 3.27% of *Yuva Awastha*. The *Dosha Avastha* in the patients are represented in table 1.

Table 1. *Dosha Avastha* in patients enrolled

Dosha	*Vriddhi*	*Kshaya*
Vata	*31.14%*	*4.91%*
Pitta	*22.95%*	*47.54%*
Kapha	*34.42%*	*1.63%*

60.65% had negative family history followed by positive family history in 39.34%. 42.62% had chronicity up to 1-5 yrs. 86.80% had gradual onset. 100% developed pain and stiffness, 95.08% had tenderness and swelling in 88.52%. 83.60% of patients showed laziness followed by 78.68%, 77.04%, 72.13%, 62.29%, 59.01%, 44.26% and 34.42% of patients with features of numbness, heaviness in body, body ache, disturb sleep, gargling sound in abdomen, giddiness and burning sensation respectively. 57.37% of patients showed thirst, polyuria and constipation and 55.73% showed loss of appetite. 98.36% had morning time as an aggravating factors followed by exertion (96.72%), day sleep (81.96%), cold wind and sour taste (90.16%). 95.08% had rest as a relieving factors followed by warm water (91.80%) and warm food (49.18%). 100% showed *Rasavaha Srotodushti lakshana* followed by 93.44%, 70.49%, 42.62%, 40.98%, 16.39% and 4.91% showed *Annavaha, Asthivaha, Purishvaha, Mutravaha*, *Majjavaha* and *Medavaha Shrotodushti* symptoms respectively. 18.03% developed joints crepitation followed by Boutonniere deformity, ulnar deviation and Swan neck deformity in 4.91%. 72.13% were suffering from diminished digestive fire followed by 62.29% consuming incompatible diet. 75.40% had done exercise after oily diet followed by suppression of natural urges (70.49%) and unwholesome activities (11.47%). 80.32% had stress as etiological factor followed by anger (34.42%), sadness(22.95%) and fear (4.91%).

Comparison of effect of therapy between group A and B

On comparing the effect of therapy on chief complaints with help of Wilcoxon sign ranked test both group showed statistically insignificant result which suggested that there was no major differences of effect of both group. However Group A showed comparatively significant efficacy clinically in *Sandhishotha* and *Sparshasahatva* based on the percentage of relief. Whereas Group B showed significant efficacy upon *Sandhishoola* and *Sandhigraha* (Table 2).

Table 2: Comparison of effect of therapy on chief complaints

Chief complaints	Group	n	Median	Relief %	Z	W	T+	T-	p
Sandhishoola	Group A	27	1.00	37%	0.382	23	138	-115	0.715 IS
	Group B	25	1.00	45.97%					
Sandhishotha	Group A	27	1.00	50.97%	-0.58	99.50	138	-131.50	0.569 IS
	Group B	23	1.00	48.79%					
Sandhigraha	Group A	27	1.00	60.03%	0.00	0.00	85.50	-85.50	1.000 IS
	Group B	25	1.00	66.66%					
Sparshasahatva	Group A	27	1.00	50.87%	-1.429	-48.00	36.0	-84.000	0.188 IS
	Group B	25	1.00	50%					

Table 3: Comparison of effect of therapy on associated symptoms

Associated symptoms	Group	n	Median	Relief %	Z	W	T+	T-	p
Angamarda	Group A	27	0.00	55.55%	0.000	0.000	52.5	-52.50	1.000 IS
	Group B	21	0.50	48.37%					
Aruchi	Group A	13	0.00	40.62%	0.688	24.00	80.0	-56.00	0.562 IS
	Group B	19	0.00	60.07%					
Trishna	Group A	22	0.50	44.43%	-0.595	-27.00	81.5	-108.50	0.595 IS
	Group B	23	0.00	40.02%					
Alasya	Group A	23	0.50	40.70%	-0.218	9.000	81.0	-90.00	0.865 IS
	Group B	25	0.10	44.73%					
Jwara	Group A	14	0.000	81.27%	0.721	22.00	63.5	-41.50	0.502 IS
	Group B	16	0.000	50.03%					
Apaka	Group A	16	0.000	87.5%	-1.147	-40.00	48.0	-88.00	0.323 IS
	Group B	20	0.000	53.33%					
Gaurav	Group A	17	0.000	57.16%	1.213	35.00	70.0	-35.00	0.296 IS
	Group B	24	1.000	55.21%					
Anga-Shunyata	Group A	19	1.000	77.14%	-0.790	-38.00	76.0	-114.00	0.465 IS
	Group B	23	1.000	48.79%					
Bahumutrata	Group A	21	0.000	46.12%	1.414	18.00	27.0	-9.00	0.250 IS
	Group B	20	0.500	53.57%					

On comparing the efficacy of therapy on associated complaints with help of Wilcoxon sign ranked test both group showed statistically insignificant result which suggested that there was no major differences of effect of both group. However based on the percentage of relief clinically Group A showed better relief in reliving symptoms like *Angamarda, Trishna, Jwara, Apaka, Gaurav, Anga-Shunyata* and Group B upon *Aruchi, Alasya, Bahumutrata* (Table 3).

On comparing the efficacy of therapy on functional parameters with the help of unpaired 't' test all the above functional parameter showed statistically insignificant result which suggested that there was not major differences of effect of both group, except foot pressure which showed significant result, Significant result means there was a measurable and better result in patients of group A than B (Table 4).

Table 4: Comparison of effect of therapy on functional parameters functional parameters

Functional parameters	Group	n	Mean	Relief %	Mean difference	SD ±	SE ±	t	p
Walking time	Group A	28	3.21	7.5%	-0.107	3.244	0.613	-0.094	0.925 **(IS)**
	Group B	25	3.32	9.35%					
Hand grip	Group A	56	-5.433	9.36%	-5.933	82.84	10.69	-0.464	0.643 **IS**
	Group B	50	0.500	10.80%					
Foot pressure	Group A	56	2.242	1.19%	-9.035	28.67	3.702	-2.055	0.042 **S**
	Group B	50	11.277	2.32%					
Disability index	Group A	27	0.607	40.46%	0.127	0.653	0.131	0.689	0.494 **IS**
	Group B	25	0.480	47.26%					

Table 5: Comparison of effect of therapy on serological parameter

Serological parameter	Group	n	Mean	Relief%	Mean difference	SD ±	SE ±	t	p
R.A. factor	Group A	28	10.618	3.70%	-14.566	122.21	24.44	-0.429	0.669 **IS**
	Group B	25	25.184	7.40%					
C.R.P	Group A	28	3.914	43.16%	0.858	19.403	3.881	0.214	0.832 **IS**
	Group B	25	3.056	12.44%					
A.S.O.	Group A	28	-16.218	12.97%	-141.13	213.93	42.78	-2.413	0.019 **S**
	Group B	25	124.920	25.91%					

On comparing the efficacy of therapy on serological parameters with help of unpaired 't' test both group showed statistically insignificant result which suggested that there was no major differences between both group, but ASO titre showed significant result in patients of group B than that in group A.

In the present study, the overall efficacy of both therapies suggested that Group A showed moderate improvement in 35.71% which corresponds to relief ranging between 50-74%, whereas in Group B it was only 20%. Which suggests that Group A was better than Group B in reducing the complaints in patients in a better way (Table 5).

Discussion

The present study revealed the onset of the disease condition in the patients was as early as 30-40 years and majority of the patients enrolled were females which justifies the various studies which claims the higher prevalence of RA in females. Majority of the population effected were from urban area and higher prevalence of people had a history of decreased physical activity, laziness and day sleep which acted as the triggering factor for the onset of the disease. In line with the reference mentioned in Charaka Samhita, Impaired appetite and metabolism was found significantly in most number of patients. Most of the patients were having chronicity for more than 2 years with history of consuming DMARD, steroids and NSAID frequently which have negative impact on immune system. Hence, such kind of patients need long time treatment along with *Pathyasevana* (strict diet and activities) following for better improvement.

The statistical analysis on chief complaints and associated symptoms did not show any changes between the two group of therapies, however individually they had showed significant results. On Serological parameters, it was noted that on applying paired 't' test, ESR and ASO titre was increased in group A while CRP decreased in both group, it was also seen during study that patients were responding better symptomatically where ASO and ESR were increasing but CRP values reduced significantly. There is no scientific reason for these type of response, which suggests that there is the need for further evaluation and analysis to understand the same.

Probable mode of action of *Eranda Sneha*

Eranda Sneha due to its *Sukshma Guma* [5] penetrate into micro channels and remove obstruction in them [6] also due to *Katu Rasa* and *Ushna Virya* it potentiate digestive fire, acts as *Vata Shamaka* due to its *Snigdha Guna*, finally it enters at *Dhatu* level (cellular level) where it acts as *Ama Pachaka* and *Kapha Shamaka* drug. [7]

Probable mode of action of *Shunti*

Shunti due to its *Katu Rasa* and *Ushna Virya* properties act as *Ama Pachaka* and *Kapha Shamaka* drug. It potentiates digestive fire and due to *Madhur Vipaka* [8] act as *Vata Shamaka*. *Shunti* due to its *Vata-Kapha Shamaka* [9] properties checks the formation of *Ama* and thereby help in reducing the symptoms of *Amavata* especially in *Sama* stage.

Almost all the chief complaints like pain, swelling, stiffness and tenderness with associated symptoms like loss of appetite, heaviness in body, laziness, polyuria, fever and over thirst etc. showed mild to moderate improvement in both groups. But group A showed more effective results than group B, it may be due to presence of *Shunti* in group A, which is having *Amapachaka* and *Vata-Kapha Shamaka* property which pacify *Dosha* to greater extend and bring them from *Shakha* to *Koshtha* and thereby provide better relief. On the basis of overall improvement group A showed better result than group B where all the complaints, associated symptoms, functional improvement and serological investigation are taken into consideration. This signifies that the efficacy may be attributed to the additional presence of *Shunti* in group A.

Conclusion

Even though statistical analysis revealed no significant difference between both the groups of treatment, the clinical efficacy of them cannot be ruled out. Hence the present study concludes that *Eranda Sneha* alone and or with combination with *Shunti* is effective in the *Sama* stage of *Amavata*, but clinically addition of *Shunti* has helped in improving the overall condition of the patient to a better level.

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