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AN AYURVEDIC CLINICAL RESEARCH ON AUTOIMMUNE DISORDER -RHEUMATOID ARTHRITIS

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ABSTRACT

Title - "An open label single arm study to evaluate the combined efficacy of Hinguvadi churnaand Erandamooladi niruha basti in Amavata vis-a vis Rheumatoid Arthritis." Background and Objectives - Amavata is a disease caused due to the vitiation of vata and ama. Vitiated vata Propels ama throughout the body through Dhamanis and takes ashraya in the shleshma sthana especially in sandhis. [1] Rheumatoid Arthritis is one among the disease which can be brought under the umbrella of Amavata due to the prevalence such a way that both samprapthi vighatana and symptomic relief can be achieved. Keeping this in mind, the present study was planned an open label single arm study to evaluate the combined efficacy of Erandamooladi Niruha Basti and Hinguvadi choorna in the management of Amavata. Methods - 30 subjects of Rheumatoid Arthritis was selected from OPD and IPD of SKAMCH&RC Bengaluru and taken into single group. Results - The effect of treatment in the group were assessed by applying Wilcoxon Singed Rank test and paired t test for within the group analysis showed statistically highly significant result with P value (<0.001). **Interpretation and Conclusion** – It can be concluded from the study, the combined efficacy of Erandamooladi niruha basti and Higuvadi Churna has given good result in the management of Amavata vis-a-vis Rheumatoid Arthritis.

KEYWORDS: Amavata, Rheumatoid Arthritis, Erandamooladi Niruha Basti, Hinguvadi Churna.

INTRODUCTION

Ayurveda, the science of life emphasize mainly on two goals such as maintenance of health and the curing of the ailment. Amavata (Rheumatoid Arthritis) is one of the challenging diseases thus developed due to the unhealthy habits and unawareness of the importance of maintaining health, equilibrium of Agni and Doshas, Amayata is the prime disease which makes the person crippled and unfit for an independent life. It possess a challenge to the physicians due to its chronic nature, difficulty, complications. The term Amavata is originated from the words Ama and Vata. The assay mark of Amavata is the progressive pathological influence of Ama and Vata in the synovial joints and the resultant degeneration of joints. The sign and symptoms of Amavata are more or less resembling with Rheumatoid Arthritis.

Rheumatoid Arthritis is a chronic inflammatory disease of unknown etiology marked by a symmetric, peripheral polyarthritis.^[2] It is the most common form of chronic inflammatory arthritis and often results in joint damage and physical disability. The prevalence of Rheumatoid arthritis is approximately 1% of the global population and in Indian population it is around 0.9%; Women are affected 3 times more often than men.^[3] The incidence of Rheumatoid Arthritis increases between 25 and 55 yrs of age; hence it hampers with the creative years of life. Despite the awareness of the disease, proper explanation for the cause and source of Rheumatoid Arthritis are still obscure in modern science. Hence no rational curative measures are known. Anti-inflammatory analgesics and Disease Modifying Anti Rheumatic Drugs are the drugs of choice in contemporary system of medicine. The Ayurvedic line of treatment defends a good deal on the pathogenesis and the stage of disease. Ayurveda emphasizes Shodhana (purificatory) and Shamana (curative) treatments in Amavata. Among Shamana oushadhis, many preparations are with easily available and cost effective ingredients which is an important factor considering the chronicity in the disease pathogenesis and hence need for a prolonged duration of the treatment. Here a sincere attempt has been made to provide a better management of RA, considering the need of the present study entitled, "An open label single arm study to evaluate the efficacy of Hinguvadi choorna Erandamooladi niruha basti in Amavata vis-a-vis Rheumatoid Arthritis" is found beneficial in alleviating the signs and symptoms of the above condition.

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OBJECTIVE OF THE STUDY

To evaluate the combined efficacy of *Hinguvadi churna* and *Erandamooladi niruha basti* in the management of *Amavata* vis-à-vis Rheumatoid Arthritis.

MATERIALS AND METHODS

A. Soursce Of Data

a) Literary source

 Available e- book and imprint resources related to Ayurveda and contemporary science about disease, therapy and drugs are documented for the intended study.

b) Sample source

- Minimum of 30 subjects with clinical features of Amavata (Rheumatoid Arthritis) coming under the inclusion criteria approaching the OPD and IPD of SKAMCH&RC, Bengaluru was selected for the study.
- The sample collection was initiated with post approval from the Institutional Ethics Committee.

c) Drug Source

The identified raw drugs required for the clinical study were purchased from approved vendors and post purchase of the raw drugs were authenticated by the faculty of *Dravya Guna*, Sri Kalabyraveshwara Swamy Ayurvedic Medical College Hospital &Research Centre, Bengaluru.

The formulation was prepared in the Department of *Rasa shastra* and *Bhaishajya kalpana* of Sri Kalabyraveshwara Swamy Ayurvedic Medical College Hospital &Research Centre, Bengaluru under the guidance.

B. Method of Collection of Data

1) Study Design

Open label single arm study.

2) Sampling Technique

 The subjects who fulfill the Inclusion and Exclusion criteria and complying with the informed consent (IC) were selected by simple random sampling technique.

3) Sample Size

 Subjects Diagnosed as Amavata (Rheumatoid Arthritis) of either gender was assigned into single group comprising of 30 subjects

D. Inclusion Criteria

- Subjects presenting with lakshanas of Amavata were selected.
- Subjects presenting with the signs and symptoms of Rheumatoid Arthritis were selected.
- Subject of age group 20-60 years irrespective of gender.
- Persons who are indicated for *basti karma*(enema therapy).

E. Exclusion Criteria

- Subjects with other systemic and metabolic disorder such as Diabetes and Hypertension which interfere with the treatment.
- Subjects presenting with complications of Rheumatoid Arthritis.
 - Persons who are not indicated for basti karma.

F. Investigations

- Blood for Hb %
- Total Count
- Differential Count
- Erythrocyte Sedimentation Rate
- Rheumatoid factor
- Anti citrulinated protein antibody
- C-reactive Protein
- RBS

G. Intervention

- The study was intervened for a duration of 16 days.
- Minimum of 30 subjects with Amavata (RA) were selected.

Administration of Drug

• *Hinguvadi churna* orally 6 gm per day, 2gmTID, B/F with ushnajala *anupana* for 8 days was given.

Eranda Mooladi Niruha Basti [5](Yoga Basti Pattern-8 days)

Poorvakarma

- Abyanga-stanika abyanga (oilation) with moorchita tila taila.
- Swedana-Nadi sweda(sudation)

Pradana karma

Table no. 1: Ingredients and quantity of Basti.

Er	Eranda Mooladi Niruha Basti						
An	Anuvasana Basti						
Br	Bruhat Saindhavadi taila 100 ml						
Ni	Niruha Basti						
Ing	gredients	Matra (Dose)					
1	Makshika	30 ml					
2	Saindhava Lavana	10 gm					
3	Bruhat saindhavadi Taila	80 ml					
4	Kalka Choorna	25 gm					
5	Eranda mooladi Qwatha	400 ml					
6	Go mutra	50 ml					

The procedure was done in *Yoga Basti* pattern. Table no. 2:

Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	
A	N	A	N	A	N	A	A	

A-Anuvasana Basti

N- Niruha Basti

Paschat karma

• Lift the legs, patting to the buttocks, and anticlockwise massage to the adomen.

Total duration of study: 16 Days.

Assessment criteria

The clinical findings were noted in specially designed case proforma and assessment was done on Day 1 (Before intervention), Day8 (After *erandamooladi niruha basti* along with oral medication), and Day 16 (Follow Up-After the completion of the course of intervention). The assessment was done based on Subjective and Objective parameters, which include diagnostic parameters as per CCIM for the clinical

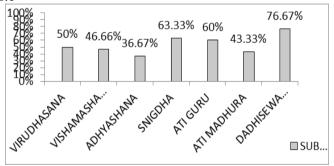
symptoms, VAS(visual analog scale), numerical rating scale, RAPID 3 (Routine Assessment of patient Index Data) score, grip strength, pressing power, foot pressure and basti samyak lakshana(symptoms of proper administration).

OBSERVATION

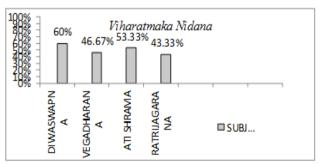
Out of 36 subjects registered, 30 subjects completed the research study. Maximum people fall under 30-40 years of age group(11 in number) with female ratio more(3:2). Majority of subjects indulge in mixed diet (26), day sleep(19), and was vata- kapha prakruti.

Observation on nidana (etiological factors)

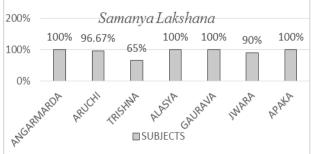
Aharatmaka nidana: graph no:1



Viharatmaka nidana graph no :2



Observation on samanya lakshana



Graph no:3

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Observation on pravrudha amavata lakshana

Table no: 3.

Pravruddha Amavata	Total							
Lakshana	Sandhi Shoola		Sandhi Shotha		Sparsha Asahishnuta			
Hasta	30	100%	28	93.33%	27	90%		
Pada	27	90%	27	90%	27	90%		
Gulpha	23	76.66%	20	66.66%	20	66.66%		
Trika	20	66.66%	20	66.66%	20	66.66%		
Janu	30	100%	30	100%	30	100%		
Agni Dourbalya	28		93.33%					
Utsahahani	30		100%					
Vairasya	25		83.33%					
Bahumutrata	9		30%					
Nidra Viparyaya	25		83.33%					
Kukshishoola	3		10%					
Vidbaddhata	2		6.66%					

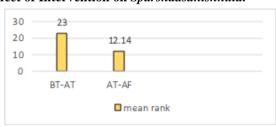
Results: Effect of intervention on Sandhishoola.



Graph no 4.

Effect of intervention on *Sandhishotha* from BT-AT was found statistically Highly Significant (Z= -4.80, p=0.001), there was persistent medicinal effect on AT-AF which was found statistically highly Significant (Z= -4.57, p=0.001)

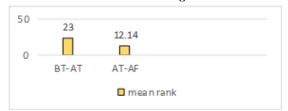
Effect of Intervention on Sparshaasahishnuta.



Graph no: 5.

Effect of intervention on *Sparshaasahishnuta* from BT-AT was found statistically Highly Significant (Z= -4.90, p=0.001), there was persistent medicinal effect on AT-AF which was found statistically highly Significant (Z= -4.13, p=0.001)

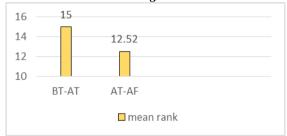
Effect of intervention on Stabdhagatratha.



Graph no: 6.

Effect of intervention on *Stabdhagatratha* from BT-AT was found statistically Highly Significant (Z=-4.90, p=0.001), there was persistent medicinal effect on AT-AF was found statistically highly Significant (Z=-3.50, p=0.0012)

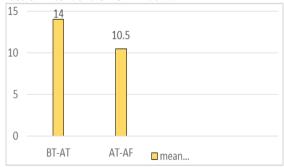
Effect of intervention on Angamarda



Graph no: 7.

Effect of intervention on *Angamarda* from BT-AT was found statistically Highly Significant (Z= -4.86, p=0.001), the persistent medicinal effect on AT-AF was found statistically highly Significant (Z= -4.42, p=0.001)

Effect of intervention on Aruchi.

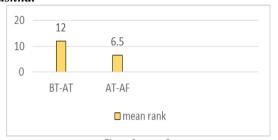


Graph no: 8.

Effect of intervention on *Aruchi* from BT-AT was found statistically Highly Significant (Z= -4.60, p=0.001), the persistent medicinal effect on AT-AF was found statistically highly Significant (Z= -4.24, p=0.001)

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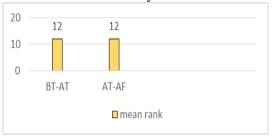
Effect of intervention on subjective Parameter *Trushna*.



Graph no: 9.

Effect of intervention on *Trushna f*rom BT-AT was found statistically Highly Significant (Z= -4.38, p=0.001), the persistent medicinal effect on AT-AF was found statistically highly Significant (Z= -3.46, p=0.001)

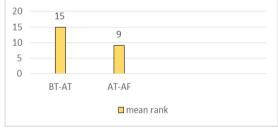
Effect of intervention on Alasva



Graph no: 10.

Effect of intervention on *Alasya* from BT-AT was found statistically Highly Significant (Z= -4.796, p=0.001), the persistent medicinal effect on AT-AF was found statistically highly Significant (Z= -4.564, p=0.001)

Effect of intervention on Gaurava



Graph no: 11.

Effect of intervention on *Gaurava* from BT-AT was found statistically Highly Significant (Z= -4.90, p=0.001), the persistent medicinal effect on AT-AF was found statistically highly Significant (Z= -4.12, p=0.001)

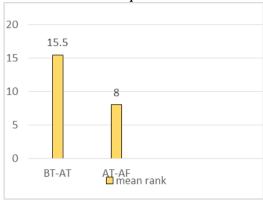
Effect of intervention on Jwara



Graph no: 12.

Effect of intervention on *Jwara* from BT-AT was found statistically Highly Significant (Z= -4.09, p=0.001), the persistent medicinal effect on AT-AF was found statistically highly Significant (Z= -2.11, p=0.017)

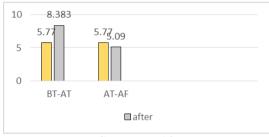
Effect of intervention on Apaka



Graph no: 13.

Effect of intervention on *Apaka* from BT-AT was found statistically Highly Significant (Z= -4.95, p=0.001), the persistent medicinal effect on AT-AF was found statistically highly Significant (Z= -4.60, p=0.001)

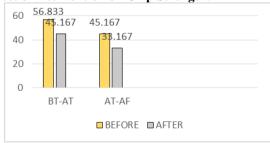
Effect of intervention on RAPID3



Graph no: 14.

Effect of intervention on RAPID3 from BT-AT was found statistically Highly Significant (t = 10.553, p=0.0011), the persistent medicinal effect on AT-AF was found statistically highly Significant (Z= 6.934, p=0.0011)

Effect of intervention on Grip Strength.



Graph no: 15.

Effect of intervention on Grip Strength from BT-AT was found statistically Highly Significant (t = 6.115, p=0.001), the persistent medicinal effect on AT-AF was found statistically highly Significant (Z= 5.422, p=0.001)

DISCUSSION

Ama and vata are the two major components in the pathogenesis of amavata. The ama is best treated by ununctous measures. Contrary to this the vata dosha gets alleviated by unctuous treatment. Thus, the treatment of these two major components is contradictory posing difficulty in planning the treatment. Hence a balanced approach that clears the ama and pacifies the vata dosha is effective in the management of amavata.

Hinguvadi churna is explained under amavata rogadikara according to bhaishajya ratnavali and chakradatta. All the ingredients having ushna veerya, thus it acts as amapachana and deepana in action. Hinguvadi churna is having antipyretic, anti-inflammatory and analgesic action. For amaja vikaras and rasapradoshaja vikaras langana is the first line of treatment. Here hinguvadi will do langhana in terms of pachana.

Erandamooladi niruha basti is deepana lekhana in action and it pacifies janga, uru, pada trika prishta shoola and is kapha vatahara in action, thus effective in this condition. Research studies in gomutra proves, improvement in conditions like allergies, rheumatoid arthritis, viral infections tuberculosis etc. it can promote the bioavailability or bioactivity or the uptake of drugs in combination therapy and reduce the dose and duration of the treatment.

Brihat saindhavadi taila [6] used as anuvasana basti. It is multi herbo mineral oil which contains fourteen important herbs, three types of lavana and kshara in equal quantity and mastu, kanji, kwata and erandataila in one prasta quantity.the majority of the drugs are katu and tikta rasa pradana. katu is vatakapha shamaka and tikta is pittakapha shamaka.katu rasa is agnideepaka and amapachaka in action. hence combination of these drugs having katu and tikta rasa are useful in amavata.in this formulation 82% drugs are having ushna veerya. Thus swedavarodha, anaha, shotha, vibhanda is pacified by ushna veerya. Rasna is having vatashamaka, amapachana, vedanastapana, shotagna properties.

The base of brihat saindhavadi taila is eranda taila which is having vatakaphahara, deepana, bhedana, krimigna, amashodana, shrotovishodana, shotahara, vrushya, kushtagna, and angamarda prashamana properties. It acts by the formation of alkali ricinoleate as a result of saponification in the dueodenum which gently stimulates the intestines glands and peristalsis and is painless, speedy, certain and fairly mild purgative operating within 2-6 hours leading to 2-4 loose motions. The combination of these drugs causes digestive, hepatoprotective and laxative properties.

Ushnajala is having the properties of *deepana*, *pachana*, *laghu*, *ushna* and *bastishodaka*. It does *agnideepana* and *amapachana*.

Because of these properties, the combined administration of *hinguvadi churna* and *erandamooladi niruha basti* shows significant result in this study.

CONCLUSION

Amavata is a Madhyama Rogamarga Vyadhi presenting with Sandhioshoola, Sandhishotha, Sandhistabdata along with Samanya and Pravruddha Amavata Lakshana. In the present study, maximum patients were married females belonging to middle-class family, belonging to Hindu religion and Vata kapha prakruthi, Madhyama Sara, Samhanana, Satwa and Pramana along with Avara Abhyavarana Shakti, Jarana Shakti and Vyayama Shakti.

The intervention employed in this study was combined administration of *Hinguvadi churna* and *yogabasti - Brihat saindavadya taila anuvasana and Erandamuladi niruha* with *gomutra* as *avapa dravya*. All the assessment parameters- *Angamarda, aruchi, trishna, alasya, gaurava, jwara, apaka*, RAPID3 score and grip strength showed statistically highly significant results.

Hence the following alternate hypothesis can be accepted. There is efficacy in the combined administration of *Hinguvadi churna* and *yogabasti*(with *Erandamuladi niruha* and *Brihat saindavadya taila anuvasana*) in *Amavata* vis-à-vis Rheumatoid Arthritis.

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