Pharmacolitical Research

WORLD JOURNAL OF PHARMACEUTICAL RESEARCH

SJIF Impact Factor 8.084

Volume 12, Issue 21, 523-532.

Research Article

ISSN 2277-7105

A CLINICAL STUDY TO EVALUATE THE EFFECT OF NITYA VIRECHANA IN AMAVATA W.S.R RHEUMATOID ARTHRITIS

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Article Received on 09 October 2023,

Revised on 30 Oct. 2023, Accepted on 19 Nov. 2023

DOI: 10.20959/wjpr202321-30340



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ABSTRACT

Background: Amavata is a disease characterized by the involvement of morbid vata, pitta, kapha dosha and Ama. When a person endowed with *Mandagni* & if indulges in the specific etiological factors such as Virudda ahara, Cheshta etc leads to the formation of ama which gets provoked by morbid Vatadosha and mobilized to different Kaphasthanas resulting in the formation of Amavata. [1] Amavata mimics Rheumatoid arthritis in modern parlance. The worldwide prevalence of this disease is approximately 0.8% (0.3% to 2.1%) of the population. In India the prevalence of Rheumatoid Arthritis is 0.5% to 0.75%. [2] Virechana is one amongst the Samshodhana karma, mentioned in classics which removes the morbid doshas through Adhomarga of shareera.[3] Nitya virechana karma is one such treatment selected for Amavata it helps in *nirharana* of vitiated *dosha*, ama and purana mala. [4] **Objective:** To evaluate the efficacy of Nitya *Virechana* with *Gandharva Hastadi Erandataila*^[5,6] in patients suffering from Amavata (Rheumatoid Arthritis) as per guidelines of

classical text books. **Design:** It is a Single blind clinical study with pre- test and post-test design, carried out in S.D.M. Ayurveda Hospital, Udupi. **Study Selection:** A single group consisting of 20 Patients diagnosed as *Amavata*, according to the diagnostic criteria having either gender selected for the study. **Intervention:** After selecting a patient diagnosed with

Rheumatoid Arthritis based on selection criteria, individual is given *Nitya virechana* for 7 days. *Nitya Virechana* on day 1 to day 7 - The subject is administered with *Gandharva hastadi Earandataila* in empty stomach, in a dose of 25 ml in morning followed with *shunti kashaya* as *anupana*. Day 1st and 7th day comparison is done. *Amavata lakshanas* and inflammatory markers like-CRP, RA, ESR and ASLO are assessed. **Result:** *Nitya Virechana karma* shown extremely significant changes in the symptoms like pain, redness, swelling, warmth, tenderness, range of movement, *Angamarda, Aruchi, Alasya, Gouravata, Sandhishula, Sandhishotha, Agnimandhya, Utsahani, and <i>Nidraviparyaya* and also significant changes noted in inflammatory markers.

KEYWORDS: Amavata; Rheumatoid Arthritis; Nitya Virechana; Gandharva hastadi eranda taila.

INTRODUCTION

Rheumatoid arthritis affects about 1% of the population. Women are affected 2 to 3 times more often than men. Onset may be at any age, most often between 35 years and 50 years, but can be during childhood (see Juvenile Idiopathic Arthritis) or old age.

Rheumatoid arthritis is a chronic systemic autoimmune disease that primarily involves the joints. Rheumatoid arthritis causes damage mediated by cytokines, chemokines, and metalloproteases. Characteristically, peripheral joints (e.g., wrists, meta carpo-phalangeal joints) are symmetrically inflamed, leading to progressive destruction of articular structures, usually accompanied by systemic symptoms. Diagnosis is based on specific clinical, laboratory, and imaging features. Treatment involves drugs, physical measures, and sometimes surgery. Disease-modifying antirheumatic drugs can reduce symptoms and slow disease progression.^[1]

Although rheumatoid arthritis involves autoimmune reactions, the precise cause is unknown; many factors may contribute. A genetic predisposition has been identified and, in White populations, localized to a shared epitope in the HLA-DRB1 locus of class II histocompatibility antigens. Unknown or unconfirmed environmental factors (e.g., viral infections, cigarette smoking) are thought to play a role in triggering and maintaining joint inflammation. Risk factors for rheumatoid arthritis include the following: Smoking, Obesity, Sex, Hormones, Drugs, Changes in microbiome of the gut, mouth, and lung.^[7]

While rheumatoid arthritis is a chronic illness, meaning it can last for years, patients may experience long periods without symptoms. Typically, however, rheumatoid arthritis is a progressive illness that has the potential to cause joint destruction and functional disability. The joint inflammation of rheumatoid arthritis causes swelling, pain, stiffness, and redness in the joints. In some patients with rheumatoid arthritis, chronic inflammation leads to the destruction of the cartilage, bone and ligaments causing deformity of the joints. Damage to the joint can occur early in the disease and be progressive. Moreover, studies have shown that the progressive damage to the joints does not necessarily correlate with the degree of pain, stiffness, or swelling present in the joints $\bar{A}mav\bar{a}ta$ & rheumatoid arthritis may be compared for the sake of better understanding. $\bar{A}mav\bar{a}ta$ is one such disease where in authors characterized the pain as Vrischika damśavat vedana. It is a disorder characterized by Āma dosa, Vāta dosa, Kapha dosa morbidity. This is a disease where in Rasavaha srotas is primarily involved. Because of this the pain also spreads from one joint to another joint very quickly. As Rasavaha srotomūla is Hridaya it leads to the involvement of whole body in short span of time. Being a disease of madhyama roga mārga, involvement of marma (Hridaya) makes this disease more and more critical. The treatment proper is also not unidirectional, for e.g. the antagonistic treatment of Kapha doşa and Vāta doşa must be carried out simultaneously, gambiradhātu (asthi), uttānadhatu (rasa), makes the treatment more a puzzle.

Hence a treatment which should alleviate morbid *Vāta*, *pitta*, *kapha* is required in *āmavāta*. *Virechana* is one such śodhana procedure fulfilling the above criteria. Acharya Charaka has said that the doṣas controlled by *Samśamana* are having the possibility of reoccurrence while such a prospect is absent when the doṣas are managed by *Samśodhana* Only one treatment protocol will not help to curtail the disease. The author opines that a full planned course of śodhana measures like *vamana*, *virecana*, & basti along with the use of other external and internal treatments will help over a period of time to curb this grave disease.

MATERIALS AND METHODS

Source of data

- **Patient source**: Subjects diagnosed as Amavata will be selected from OPD and IPD of Sri Dharmasthala Manjunatheshwara Ayurveda Hospital, Kuthpady, Udupi.
- **2 Method of collection of data:** It is a randomized open clinical trial with pre and post-test design to evaluate the effect of *Nitya virechana* in the management of *Amavata*. A

detailed proforma has been prepared considering the points pertaining to history signs, symptoms & examinations as mentioned in Ayurvedic classics and allied sciences to confirm the diagnosis.

Design of the study: An open label single group clinical study.

Table no. 1.

Intervention:	
Drug name	Gandharvahastadi Erandam
■ Dose	25ml / day
Route of administration	Oral
■ Time of administration	Morning at 8:30Am to 10 Am
Anupana	Shunti kashaya
Duration	07 days
Duration of clinical study:	
Duration of treatment	07 days
Duration for Follow up	14 days
Total duration of study	14 days

Diagnostic Criteria

1) Samanya Amavata Lakshana: Angamardha, Aruchi, Trushna, Gourava, Sandhi shotha, Sandhishoola, Ajirna, Alasya and Apaka.

2) ACR Revised criteria^[8]

- Morning stiffness in and around joints for at least 1 hour.
- Soft tissue joint swelling observed by physician at least 3 joint groups (R or L: MCP, PIP, wrist, elbow, knee, ankle, MTP).
- Arthritis of hand joints (MCP, PIP or wrist).
- Symmetrical swelling of one joint area in (2) above.
- Rheumatoid nodule.
- Positive Serum Rheumatoid factor.
- Radiograph changes on wrist/hands: erosions or juxta-articular osteoporosis.
- For classification purposes, a patient shall be said to have rheumatoid arthritis if he/she has satisfied at least four of these seven criteria. Criteria 1 through 4 must have been present for at least 6 weeks.

Table no. 2.

Inclusion criteria:	Exclusion criteria:
 Subjects fulfilling diagnostic criteria 	 Subjects with systemic illness like DM, HTN
of Amavata /Rheumatoid arthritis.	which will hamper the treatment
 Subjects aged between 18-70 years 	 Pregnancy and Lactating women.
 Subjects who are fit for Nithya 	 All connective tissue disorders other than
virechana karma.	Rheumatoid arthritis.

Assessment Criteria

The signs and symptoms of *Amavata*/Rheumatoid Arthritis and Inflammatory markers ESR, CRP, ASO and RA will be assessed before and after treatment.

Subjective parameters: Amavata lakshanas like Angamardha, Gourava, Alasya, Avipaka, Shoonatanga, Aruchi, Sandhishula and Sandhishotha.

Objective Parameters

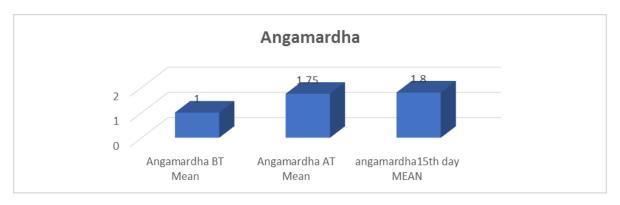
- On Zeroth day before treatment and on 7th day, after treatment inflammatory markers –
 ESR, ASO, CRP and RA factor has been assessed.
- Rheumatoid Arthritis Patient ACR/EULAR 2010 criteria.

OBSERVATIONS AND RESULTS

Table No. 3: Showing the effect on Angamardha within the groups.

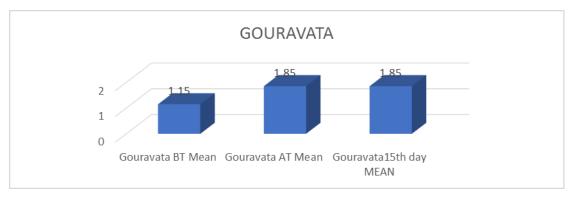
Parameter	Negative rank			Positive rank			Ties	Total	Z value	P value	Interpretation	
	N	MR	SR	N	MR	SR			value	value		
Ang-m BT-AT	0	0	0	15	8.0	120.00	5	20	-3.873	0.000	HS	
Ang-M BT-15 TH DAY	0	0	0	16	8.50	136.00	4	20	-4.00	0.000	HS	

Number, MR- Mean rank, SR-Sum rank, HS-Highly- Significant



Graph no:1.

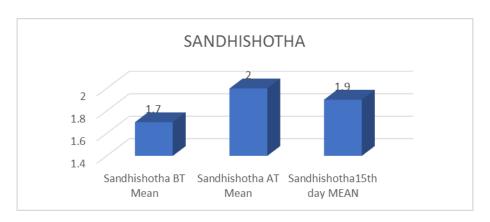
Parameter		Negati rank		Positive rank			Ties	Total	Z value	P value	Interpretation	
	N MR SR N MR SR			varue	value							
Grouvata BT-AT	1	8.50	8.50	3	2.00	6.00	17	20	-3.500	0.00	HS	
GrouvataBT- 15 TH DAY	1	8.50	8.50	15	8.50	127.50	4	20	-3.500	0.00	HS	



Graph no. 2.

Table No. 5: Showing the effect on sandhishotha within the groups.

Parameter	Negative rank			Positive rank			Ties	Total	Z	P	Intomputation
	N	MR	SR	N	MR	SR	ries	1 Otai	value	value	Interpretation
San-sho BT-AT	0	0.00	0.00	6	3.50	21.00	14	20	-2.449	0.014	HS
San-sho BT15 TH DAY	2	4.50	9.00	6	4.50	27.00	12	20	-1.414	0.157	HS

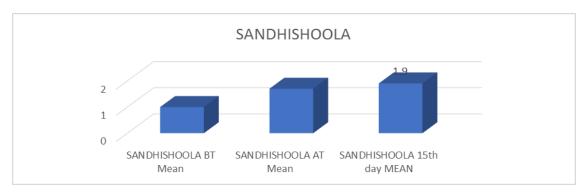


Graph no. 3.

Table No. 6: Showing the effect on sandhishoola within the groups.

Parameter	Negative rank			P	Positive rank			Total	Z	P	Interpretation
	N	MR	SR	N	MR	SR	Ties	Total	value	value	interpretation
SAN-SH BT-AT	0	0.00	0.00	14	7.50	105.00	6	20	-3.712	0.00	HS
SAN-SH BT-15 TH DAY	0	0.00	0.00	18	9.50	171.00	2	20	-4.243	0.00	HS

Number, MR- Mean rank, SR-Sum rank, HS-Highly- Significant



Graph no:4.

CRP LEVEL

Table no 7: showing the effect on CRP level within the group.

Parameter	Mean score	N	Difference In Mean	% OF CHANGE	S.D	S.E.M	T	P	Interp Retation
BT	21.17	20	5.92	27.96	25.78	5.76	3.072	0.006	S
AT	15.25	20							

Number, MR- Mean rank, SR-Sum rank, HS-Highly- Significant.



Graph no 5:

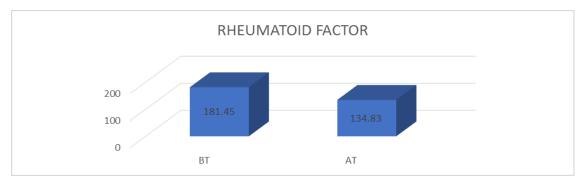
The mean value of CRP level was 21.17 before the treatment which was reduced to 15.25 after the treatment and showed 27% of improvement with t value 3.072 and p value 0.006, which was statistically significant change.

RA FACTOR

Table no 8: showing the effect on RA factor within the group.

Parameter	Mean score	N	Difference In Mean	% OF CHANGE	S.D	S.E.M	T	P	Inter Pretation
BT	181.45	20	46.62	27.70	248.62	55.48	3.863	0.001	HS
AT	134.83	20							

Number, MR- Mean rank, SR-Sum rank, HS-Highly- Significant



Graph no. 6.

The mean value of RA factor level was 181.45 before the treatment which was reduced to 134.83 after the treatment and showed 27.70% of improvement with t value 3.863 and p value 0.001 which was statistically highly significant change.

ASLO TITER

Table no 9: showing the effect on ASLO titer within the group.

Parameter	Mean score	N	Difference In Mean	% OF CHANGE	S.D	S.E.M	Т	P	Inter pretation
BT	197.04	20	38.50	19.53	152.4	34.09	3.32	0.004	S
AT	158.53	20							

Number, MR- Mean rank, SR-Sum rank, HS-Highly- Significant.



Graph no. 7.

The mean value of ASLO Titer level was 197.04 before the treatment which was reduced to 158.53 after the treatment and showed 19.53% of improvement with t value 3.32 and p value 0.004 which was statistically significant change.

Overall effect of the treatment on cardinal symptoms

The assessment of the overall effect of the treatment revealed that, maximum patients showed improvement in signs and symptoms of the disease and the inflammatory markers also shown a major improvement level in the titer numbers but showing positive titer to negative titer

was shown in very minimum number. All the patients in this clinical study of *Nitya Virechana* showed different degrees of remission after some time. From above observations it is clear that the patients of *Amavata* who are treated with *Nitya Virechana* showed good response to the treatment with regards to cardinal symptoms. Clinical parameters, and overall effect of the treatment. Most of these improvements are found to be statistically significant as per the paired t test.

CONCLUSION

The principal treatment in *Amavata* is to reduce the pain, stiffness, swelling, discomfort and to prevent deformities by following different modalities of treatment which even includes *samshodhana*. The treatment protocol of *Amavata* includes *Shodhana* and *Shamana Chikitsa*. Keeping this in mind the *Nitya Virechana* with *Gandharva hastadi Eranda taila* has been planned in the present study. Maximum numbers of patients were seen in the age group of 31-60 years. Majority of the patients were found addicted to beverages like tea and coffee. Maximum patients indulged in day sleep and having irregular or constipated bowel habits. Features like *Agnimandhya*, *Angamardha*, *Sandhishoola*, *Sandhishotha*, *Gouravata* were seen in maximum number of patients. Elevated CRP, RA, ASLO and ESR levels wear seen in almost all the patients.

In this clinical study of 20 patients. Significant results were seen in: swelling, redness, CRP level, ASLO titre. Highly significant results seen in *Agni*, *Ama*, *Gouravata*, *Sandhishoola*, *Ajeerna*, Pain, Rheumatoid factor, ESR. Not significant results are seen in *Angamardha*, *Aruchi*, *Trishna*, *Sandhishotha*.

REFERENCE

- Madhavakara, Vijayarakshita, Srikantadatta, Shastri Sudarshana. Madhava Nidana with Madhukosha Sanskrit commentary and Vidyotini Hindi commentary. edition 2009, Varanasi: Chaukambha Prakashana, 1(568): 508-512.
- 2. FauciS. Anthony, Braaunwald Eugene, kasper l Dennis. HauserL. Dan, Jameson, Larry J., Loscalzo Joseph et.all Editors, Harrison's Principle of Internal Medicine, 17th Edition. New York Mc Graw Hill, 2: 2754, pg no-2083.
- 3. Vangasena samitha, shri Harihara prasad tripati, Hindi commentatry, Reedited 2016 Varanasi Chaukamba publication, p.no.729.
- 4. Chakradatta, savimersha Bhavartha sandeepani, Hindi commentatry, Shri JagadishT, Edited by Bhishagratna PT Bhramashankar M, Varanasi Chaukamba prakashana,

P.NO.225.

- 5. Caraka samitha by Agnivesa with Ayurveda dipeka commentary of Chakrapanidatta Edited by Vaidya Jadavaji Trikamji acharya Varanasi Chaukamba prakashana, P.NO.83.
- Sushruta samitha, Nibanda sangraha commentary by Dalhana and Nyayachandrika by Gayadas, edited by Yadav sharmana and Narayana Ram Acharya, Reprint 2008, Varanasi; Chaukamba Sanskrita samsthana, Pno: 205.
- 7. Search results for: rheumatoid arthritis MSD Manual Professional Edition (msdmanuals.com).
- 8. FauciS. Anthony, Braaunwald Eugene, kasper l Dennis. HauserL. Dan, Jameson, Larry J., Loscalzo Joseph et. all Editors, Harrison's Principle of Internal Medicine, 17th Edition. New York Mc Graw Hill, 2: pp-2754, pg no-2083.