



RESEARCH ARTICLE

A CLINICAL EVALUATION OF ALAMBUSHADI CHURNA (Y.R.) IN AMAVATA

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ABSTRACT

Amavata is disease caused by vitiation of Vata by Ama, which is the product of incomplete digestion and metabolism. Agni in Ayurveda includes the digestive processes of gastrointestinal tract as well as the metabolic processes in the tissues. Ama could therefore be produced by flawed digestion in gastrointestinal tract or in the tissues by defective metabolic processes. Ama thus produced is said to circulate and block the vessel of the joints and get deposited there causing inflammation by producing symptoms such as stiffness, swelling, and tenderness in small and big joints, making a person lame. The symptoms of Amavata are identical to rheumatism, which include rheumatoid arthritis and rheumatic fever. It is observed that rheumatism is an autoimmune disorder, which is among the collagen disorders having strong and significant parlance with Amavata. Various drug trials were already carried out on Amavata, yet there is a lacuna in the management of Amavata. Hence, in the present clinical study, 30 patients were selected and kept on 'Alambushadi Churna. All the patients were investigated for complete blood count, RA titer, ASO titer, CRP titer, urine routine, and microscopic, before and after treatment. The collected data was distributed according to age, sex, and prakruti, and a t-test was applied for the clinical assessment of the subjective and objective parameters of 'Alambushadi Churna.

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INTRODUCTION

With the march of time, most of the dietary habits, social structure, life style, and environment have been changing. Occurrence of Amavata on large scale is one of the outcomes of this modification. It is commonest among chronic inflammatory joint diseases in which joints become swollen, painful, and stiff. It is a debilitating disease in view of its chronicity and complications. Therefore, it has taken the foremost place among the joint disorders. It continues to pose challenge to physician due to severe morbidity and crippling nature and claiming the maximum loss of human power making it a biggest worldwide burning problem irrespective of races. It is equated with Rheumatoid Arthritis, an inflammatory Auto-immune disorder. The lives of more than one million people are physically impaired due to Rheumatic disorders and one fifth of these are severely disabled.

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The onset is more frequent during 4th and 5th decade of life with 80% of patients developing the disease between the ages of 35 to 50 years. Women are affected approximately 3 times more often than men. Pregnancy is often associated with remission of the disease in the last trimester with subsequent relapses after delivery. About 10% of the patient will have an affected first degree relative. A genetic susceptibility to altered immune responses probably is important in R.A. Amavata was first described as an independent disease in Madhava Nidana. It is a disease of Madhyama Roga Marga as it affects Sandhis and Hridaya Marma. Though Ama and Vata are the predominant pathogenic factors but the disease represents Tridoshic vitiation. The affliction of Sandhis by Vata dosha in association with Ama reflects the equal role of both Dosha and Dushya in the causation of this disease. Moreover, the chief pathogenic factors, being contradictory in nature possess difficulty in planning the line of treatment. While studying this condition I came across various Ayurvedic preparations, which gives better relief to patient. Alambushadi Churna is one of them, which is mentioned by Yog-ratnakar.

Aims and Objectives

- To review the complete literature available on Amavata.
- To review the detail literature on the Alambushadi churna.
- To establish the activity and efficacy of Alambushadi churna in Amavata.
- To find out or to propose the mode of action of Alambushadi churna in Amavata.
- To find out effect of expected virechan karma of Alambushadi churna on shotha in Amavata.

MATERIALS AND METHODS

Medium of dissertation- English It was supplemented with Ayurvedic terminology wherever necessary in Sanskrit.

Literature- All available Ayurvedic classics, modern texts, magazines, journals, attending seminars, conferences, and CME on rheumatology.

Study centre- Patients consulting the O.P.D. & I.P.D. of Kayachikitsa department of Ayurved Mahavidyalaya, Sion and S.R.V. Ayurved Hospital, Sion, Mumbai-22 was selected for the present study irrespective of their sex, religion occupation, socio-economic status etc.

Type study-Randomized Open labelled study

No. Of Patients-Total no. of patients were included in this study are 30.

Drug-Alambushadi churna, ref. - Amavata chikitsa, Yog-ratnakara

S.No.	Sanskrit Name	Latin Name	Quantity
1.	Alambusha*	Spharanthus indicus	1 part
2.	Gokshur	Tribulus terrestris	2 parts
3.	Triphala	Terminalia chebula Terminalia bellerica Emblica officinalis	4 parts
4.	Sunthi	Zinziber officinalis	8 parts
5.	Guduchi	Tinospora cordifolia	16 parts
6.	Trivrit	Operculina turpenthum	Equal part to all above ingredients

Doses- 6 Gms Churna ,Vyan kala and Udan kala, **Anupan-**Ushnodak

Duration of treatment- Six weeks

Inclusion criteria

- Patients above 15yrs and below 60yrs were selected of any sex, race, and occupation.
- Patients having signs and symptoms of Amavata mentioned in Ayurvedic texts.
- Polyarthrititis with inflammation of joint conditions.
- Patients who are ambulant and requiring treatment with an anti- inflammatory drug and not receiving regular anti – inflammatory or analgesic drugs.
- Willing to come for regular follow – up.

Exclusion criteria

- Pregnant, lactating or women at a risk of becoming pregnant
- Patients having disabling arthritis, bed-ridden patient or patients having permanent deformity was not chosen.
- Unwilling to come for regular follow-up.
- K/C/O Tuberculosis, HIV, Syphilis, Cardiac diseases
- Patients taking regular steroids, anti inflammatory drugs and methotrexate.

Criteria for Diagnosis

The patients were diagnosed on the basis of special Performa incorporating all signs and symptoms of the disease. Also the detailed clinical history was taken and complete physical examination was carried out. Rheumatoid factor test was carried out in all the patients. In addition, routine Haematological, Stool, Urine, Serum Uric Acid Test and CRP were also carried out to rule out other pathologies.

Moreover, the criterion's laid down by American Rheumatism association 1988 was also followed which are:

- Morning stiffness lasting for more than one hour.
- Arthritis of three or more joints area.
- Arthritis of hand joints
- Symmetrical arthritis
- Presence of rheumatoid nodules
- Presence of rheumatoid factor
- In addition to this
- Oedema of joints
- Elevated CRP level

Diagnosis of Amavata is made with four or more criteria.

Criteria for Assessment

All patients registered for the trial were investigated for the following

- General and systemic examination at every weekly visit upto 6 weeks
- Blood examinations - CBC, RA, CRP, Sr. Uric acid were done before and after the trial

Follow up

All the patients were called for assessment of clinical (subjective) evaluation after every seven days. All the symptoms like sandhishoola, sandhishotha, grahata and stabdhata etc. were graded into four grade scale.

Parameters of assessment-

- 1) Subjective improvement
- 2) Objective improvement

1. Subjective improvement- symptoms of Amavata and its upadrava mentioned in the text or practically observed were assessed at each follow-up. Presence or absence of the symptoms was registered into CRF.

Symptoms which commonly come across and major symptoms were graded into four grade scales. Changes in the gradation of each symptom were studied in each follow-up.

The improvement in the patients is assessed on the basis of Roga Bala, Agni Bala and Deha Bala.

a) Sandhishoola

Sandhishoola (Pain in joints)	Score
No pain	0
Mild pain	+
Moderate pain, but no difficulty in moving	++
Severe difficulty in moving due to pain	+++
Measurement of pain was done according to VAS, Pain Face scale and Numerical rating scale.	

b) Sandhishotha (Swelling in joints)

No swelling	0
Slight swelling	+
Moderate swelling	++
Severe swelling	+++
Measurements of circumference of joints were taken with the help of thread.	

c) Sparshasahatva (Tenderness in joints)

No tenderness	0
Subjective experience of tenderness	+
Wincing of face on pressure	++
Wincing of face and withdrawal of the Affected part on pressure	+++
Resist touching	+++

Overall Assessment of Therapy

Overall assessment of the therapy was done taking consideration all the three points- subjective, objective and laboratory findings

Assessment of tolerability

Patients undergoing clinical trial of the drug were monitored for all the signs and symptoms to keep a watch on the complications. Effect of the drug was observed on all the patients. Patients were even observed for side effects, severe complication and untoward effects of drug if any. Symptoms like vomiting, loose motion, headache, itching, signs of vatavridhi were specially enquired.

Statistical analysis- All the data generated and collected during the study was putted to statistical analysis to reach to final results and conclusions. Whenever, possible efforts were made to present the data in the form of T test, probability correlation and other statistical methods. All such analysis has been done with help of computer software and required charts and graphs have also been prepared with computer software.

OBSERVATIONS/RESULTS

DISCUSSION

A) Effect on Symptoms & pathological variations are noted as follows:-

Cardinal Features: Regarding the cardinal features of Amavata, all the patients had Sandhishoola (100%). Sandhishotha was present in 100%), Sandhigraha in 100% and Sparshasahatva in 100%.

Blood investigations of patients on Day 0 and Day 42

S.No.	Blood test	Day 0	Day 42	Effect
1.	Hemoglobin gm %	10.02±1.45S.E. .37	10.56±0.72 S.E.1.37P= 0.001	Highly significant
2.	RBC (mil/cu.mm)	3.36±0.56S.E.0.056	3.59±0.36 S.E.0.056 P=0.023	Significant
3.	WBC (/cumm)	10546.67±805.05	10223.23±1148.82P=0.11	Not significant
4.	ESR (mm/1hr)	68.8±25.78S.E.19.74	47.9±23.05S.E.19.74P=0.001	Highly significant
5.	Sr.Uric Acid mg/dl	6.61±1.77S.E.1.68	5.03±1.23S.E.1.68P=0.004	Highly Significant
6.	HS-CRP (mg/dl)	2.58±1.69	1.26±0.96P=0.0002	Highly Significant

Symptoms of patients on Day 0 and Day 42

S.No.	Symptom	Day 0	Day 42	Effect
1.	Shohta(cm)	36.24±9.24S.E.1.76	30.57±9.11S.E.1.76P=0.007	Highly significant
2.	ROM(cm)	33.08±4.94S.E.5.68	17.24±9.21S.E.5.68P=0.001	Highly significant
3.	Walking Speed 50ft/sec	104.65±14.14S.E.31.9	81.55±22.17S.E.31.9P=0.0002	Highly significant
4.	Duration of Morning stiffness(min)	117.93±60.51S.E.36.74	62.67±42.17S.E.36.74P=0.004	Highly significant

d) Sandhistabdhata (morning Stiffness in joints)

No Stiffness or Stiffness lasting for 5 mins.	0
Less than 30min	+
30-60min	++
More than 60min	+++
Morning stiffness assessed on how severe patient awakening and how long it lasts +++	

General Features: Among the various general features of Amavata, Angamarda and Vibandha was found in (100%)., Gaurava (90%), Jwara (60%),Daurbalya in 46.6% of patients, Aruchi (40%) and Symptoms like Antrakujana, Kukshikathinya, Asyavairasya, Daha, Trishna, Bahumutrata etc. were reported in 5 to 30% of the patients.

Srotasa: Maximum number of patients had the dushti of Asthivaha, Rasavaha, Majjavaha, Purishavaha, Raktavaha and

Annavaaha srotasa, which is in accordance with the main srotasa involved in the disease process.

Involvement of Joints: Majority of the patients presented with, Knee joint (83.3%), Wrist joint (6.7%) and Ankle joint (10%) etc.

Rheumatoid Nodules & Deformity: In this study, 3.3% of the patients had Rheumatoid Nodule and 3 patients had deformity of the joints. It may be due to chronic nature of the disease (Table no. 30).

Rheumatoid Factor: 33.33% patients, in this study were seropositive.

CRP: Majority of the patients (86.6%) with elevated C reactive proteins level i.e. greater than 0.3mg/dl.

B) Effect of the Treatment

In this study the effect of treatment was assessed on the basis of changes observed after the treatment in Rogabala, Agnibala, Dehabala and laboratory investigations. The results are discussed parameter wise as here under:

a) Effect on Rogabala: It includes Cardinal Features, Associated Symptoms, and Physiological Normalcy of Vata, Mutra and Purisha and Degree of Disease activity.

b) Effect on Cardinal Features:

- **Sandhishoola:** 57.53% relief was observed in Sandhishoola among the patient
- **Sandhishotha:** 60% patients got total relief in sandhishotha. 36.6% got moderate relief and 3.4% got mild relief. Here again better improvement was observed as Alambushadi Churna antagonises the excessive Kapha (Ama) production due to its Katu-Tikta rasa, Ushna Virya and Katu vipaka, Vata-Kaphahara, Deepana, Pachana and Shothahara property. Also Virechana pacifies Kaphavata, ignites hampered Agni (Mandagni) leading to Amapachana leading to relief in above all symptoms.
- **Sandhigraha:** 70% patients got moderate relief, 23.3% had total relief and 6.7% got mild relief in sandhigraha.

C) Mode of Action of a Drug

a) Probable Mode of Action of Alambushadi Churna: In the first stage of the disease Amotpatti is there and Alambushadi Churna does Amapachana as all the pharmacodynamic property of Alambushadi Churna i.e. Laghu-Tikshna-Ruksha guna, Katu-Tikta rasa, Ushna virya are against the guru, Snigdha, Pichchila, Sheeta properties of Ama. Later the Yugapata prakopa of disease is checked by Vata-kaphahara action of the drug. Further Ama formation is stopped by the Deepaniya action. In the Srotoabhishyanda it does Srotoshodhana and relieves the symptoms of Sandhishoola, Shotha, Alasya, Aruchi etc. by its analgesic (Vedana prashamana) and antiinflammatory (Shothahara) action. Also the associated symptoms like Vibandha, Anaha, etc. are reduced by Anulomana i.e. purgative property of the

drug. As most of the drugs (75%) are Vata-kaphashamaka and Agnivardhaka, so it is very suitable for the Samprapti Vighatana of the disease and to combat the main culprit Vata and Kapha (Ama) and Mandagni, which are the root source of Amavata.

B) Probable Mode of Action of Virechana Karma: Action of Virechana on Amavata can be understood by the following properties of it.

- Virechana has direct effect on Agnisthana and hampered Agni (Mandagni) is one of the initiating factors in Amavata. It pacifies the vitiated Kapha and Vata dosha.
- It has the property of Srotovishodhana; hence the Srotorodha (Srotoabhishyanda) present in the disease Amavata mainly in Sandhishthana is cleared by Virechana leading to relief of the symptoms.
- Virechana is indicated in Sannipaitik condition of morbidity (B.S.) and hence helpful in the disease Amavata.
- Virechana works well by clearing the morbid doshas, which adhere to Bahya (Rasa etc.) and Madhyama (Marma-Asthi-sandhi) Roga Marga with the tiryaka gamana.
- Virechana helps to normalize the pratiloma gati of vata, which produces symptoms like Anaha, Antrakujana, Kuskshikathinya, Kukshishoola etc. in the disease Amavata.
- Virechana therapy has been given as one of the measures for combating the disease Amavata by Acharya Chakradatta (Chapter 25/1).

Summary / Conclusion

At the end of the study, following conclusion can be drawn on the basis of Observations made, Results achieved and thorough Discussion in the present context and can be summarized as below:

- The concept of Ama is prevailing since Vedic period. Reference about Sandhi vikriti caused by Sleshma vikriti is available in Atharvaveda.
- Amavata as a disease finds first time its detailed description in medieval period text Madhava Nidana.
- Amavata is Chronic disease in nature (Arthritis rank second as the most prevalent chronic ailment after heart disease) and has insidious onset.
- As the word suggests, in Amavata, the pivoting entities in disease process are Ama and Vitiated Vata. Pathogenesis of Amavata is initiated by Ama, occupying various Sleshma sthanas, mainly joints. All the subtypes of Vata are involved either earlier or in the later stages of Amavata.
- All the Nidanas of Amavata ultimately results in Vataprakopa and Mandagni (Ama production) initiating further pathogenesis.
- Many rheumatological conditions show similar characteristics with Amavata but it resembles like Rheumatoid Arthritis.
- The prevalence of R.A. is three times more common in women than in man.
- The fact is corroborated clinically, exhibited by mode of presentation of disease activity i.e. maximum number of

patients showed increased activity of disease in Sheeta and Varsha ritu during clinical trial. According to patients, their symptoms aggravated in cold-humid conditions.

- Maximum number of patients in this study sample was having Krura Kostha (86.6%), so administration of Anulomana drug should be emphasized in treatment of Amavata.
- All the Cardinal Features were present in all the patients i.e. Sandhishool, Sandhishotha, Sandhigrah and Sparshasahatva. Associated Symptoms mostly found were Daurbalya Angamarda, Vidbadhata.
- In this study it is observed that Alambushadi Churna by its virechan karma reduces the Shotha, Morning stiffness, Kriyaskashtata and increases range of movement of joints and decrease in the time of walking 50 feet.
- It is noted that Alambushadi Churna works much better in Samavastha of Amavata.
- It was observed during the treatment that the drug should be used upto samyak virechana and amapachan stage. Beyond this stage it aggravates Vata leading to increase in disease symptoms.
- After samyak virechana Basti therapy is needed to prevent the aggravation of Vata.
- Alambushadi Churna used in the present study, proved to be a good Amapachak and Anti-inflammatory formulation. Due to certain limitations, it was not possible to carry out chemical analysis of this yoga. In future, a Pharmacological as well as Phytochemical study may be planned.
- To ascertain the mode of action of Alambushadi Churna its trial on large sample is recommended.
- As definitive co-relation was found between the stated properties of Ama and free radicals, it opens gate for another study to find out whether the formulation possess Anti-oxidant properties as well.
- As the disease Amavata, is a chronic disease of Madhyama Roga Marga i.e. Marma-Asthi-sandhi less results were obtained. Most of these patients were suffering from the disease since long that also contributed for slow recovery. Patients of this disease require long duration of the therapy. However, results of this therapy provide good hope for the patients of Amavata. Alambushadi Churna being good Shothahara (antiinflammatory), amapachak may prove a good drug for the management of the disease Amavata.

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