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A CLINICAL STUDY ON THE ROLE OF BHAGOTTARA ALAMBUSADYA CHURNA IN THE MANAGEMENT OF AMAVATA (RHEUMATOID ARTHRITIS)

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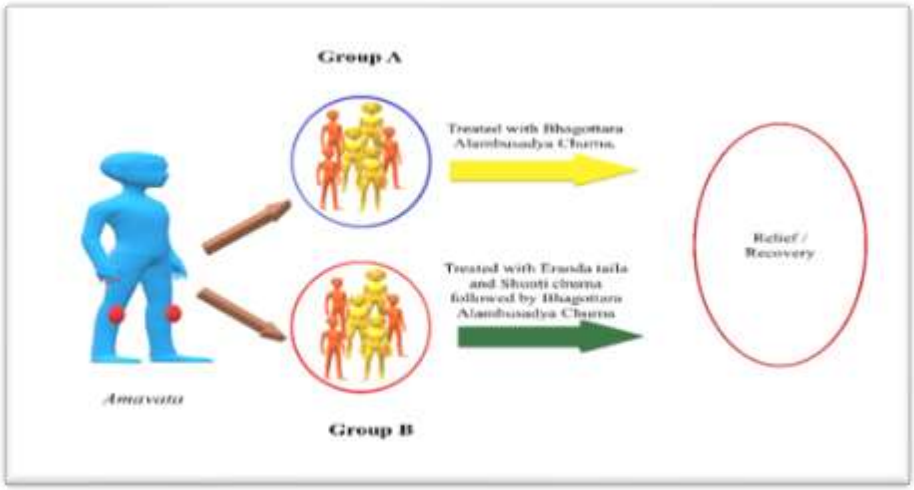
ABSTRACT

Ayurveda is the oldest Indian system of medicine and holds a prominent position in the treatment of chronic and debilitating ailments. It has been in use for decades of ancient history and provides excellent effects over several abnormalities. Among various diseases, *Amavata* is a chronic inflammatory articular condition primarily affecting small joints. Many treatment regimens are available to date at Amavata considered a prevailing condition in millions of patients. The present study aimed to find out the efficacy of *Bhagottara Alambusadya Churna* along with/ without *Erandataila* and *Sunti churna* in *Amavata*. In this present study, a total of 60 patients were taken and divided into two groups: group A was treated with a trial drug *Bhagottara Alambusadya Churna* and group B was treated with *Eranda taila* and *Sunti churna* orally along with *Bhagottara Alambusadya Churna*. After 45 days, the results showed that both treatment groups A and B were effective in pacifying the symptoms of *Amavata*. Moreover, group B patients have shown statistically higher better results in alleviating the symptoms of *Amavata*. To conclude, this study has supported the role of *Bhagottara Alambusadya Churna* with *Eranda taila* and *Sunti churna* to be potential in the treatment of *Amavata*.

Key words: *Amavata*, *Ama*, *Bhagottara Alambusadya Churna*, *Eranda taila*, Rheumatoid arthritis, *Shunti churna*, *Vata.*

Graphical Abstract:



INTRODUCTION

Amavata is a prevalent disease in the current society which is a serious concern for many people in forming their day-to-day activities. Many factors are responsible for this condition which includes lifestyle change, dietary habits, and social environment. It has been found that globally 0.8% of the population, and in India 0.5% to 0.75% have been affected by this disease[1]. Surprisingly the female population is the ones who are most affected compared to males with a ratio of 1:2-3[2]. Mostly 75% of the cases are reported between the age of 30 to 50 years.

The causative factors of *Amavata* are *Virudha ahara-vihara-chesta, Mandagni, Nischalata* (physical inactivity), and *Snigdha bhuktatwo Vyayama* (doing exercise soon after consuming *Snigdha, Guru ahara*. Moreover, *Ama* and *Vata* are the two major pathogenic factors involved. The vitiated *Vata* in association with *Ama* afflicts the *Sleshma sthana*. Further involvement of other *dosas* like *Kapha* & *Pitta* leads to *dosadushya samurchana* and *Stana samsraya* in *Trikasandhi pradesha* thus manifesting the disease *Amavata.* The general signs and symptoms are *Angamarda* (bodyache), *Aruchi* (anorexia), *Trishna* (thirst), *Alasya* (lack of enthusiasm), *Gourava* (heaviness of the body), *Jwara* (fever), *Apaka* (indigestion), and *Angasunata* (swelling of the body parts (joints))[3]. Further, the exacerbation stage affects multiple joints with other systemic symptoms. It is a *Vata-Kapha-Ama pradhana Tridoshaja, Madhyama-roga marga vyadhi*. The general management *of Langhana, Deepana, Pachana, Swedana, Virecana, Vasti,* etc. can be adopted based on the condition[4].

Amavata can be correlated to Rheumatoid arthritis due to similar clinical features. Rheumatoid arthritis is a progressive debilitating chronic inflammatory autoimmune disorder. It affects the synovium of the joint which results in warm, swollen, and painful joints. While the etiology is mostly considered unknown, various factors including obesity, age, lack of exercise, genetic predisposition, injury, gender, and environment may be responsible for the development of the disease.[5,6]

Upon diagnosis, allopathic treatment is initiated with anti-inflammatory therapies such as glucocorticoids to reduce pain and inflammation, coupled with the administration of disease-modifying anti-rheumatic drugs (DMARDs)[7]. Even though this is generally considered a treatment of choice, these drugs are associated with adverse side effects and risk factors. To overcome these side effects herbal drugs can be used which are cost-effective, harmless, and with the least side effects.

Among the various standard herbal drug usage recommended for *Amavata, Bhagottara Alambusadya churna* was selected for the present study. It has been mentioned in the text Chakradatta, *Bhagottara*

Alambusadya churna has been used in the treatment of *Amavata along with other ailments including Vatarakta*, swelling in joints of *trika, janu* and *uru, Jwara* and *Aruchi* conditions[8]. Generally, a drug shows its effects depending on the properties of the ingredients and their different combinations. The combination of *Bhagottara Alambushadya churna* includes complex ingredients that are *Alambusha, Gokshura, Haritaki, Vibhitaki, Amlaki, Shunti, Guduchi*, and *Syama* Trivruth. *Eranda taila*[9] and *Shunti churna*[10] for the action of *Dipana, Pachana*, and *Koshtashuddhi* were selected for comparative clinical studies.

1.1 Objectives

To evaluate the efficacy of *Bhagottara Alambusadya Churna* and its comparison before and after *Dipana Pachana Koshtashuddhi* treatment with *Shunti Churna* and *Eranda taila* in *Amavata.*

2. Materials and Methods

2.1 Study Design

The patients enrolled for *Amavata* in the Department of Kayachikitsa, I.P.G.A.E & R at S.V.S.P, Kolkata, West Bengal, India have been included in the present study. To perform the studies, the institute's ethical clearance has been obtained with the reference number SVP / 2455 (7) / 2020. A total of 60 patients have been included in the present study and were randomly assigned into two groups (1. group A and 2. group B) and were treated with prescribed drugs for 45 days. The patients of group-A were treated with *Bhagottara Alambusadya Churna* with lukewarm water. While group- B patients were treated with *Eranda taila* and *Shunti Churna* for 3days followed by *Bhagottara Alambusadya Churna* for 45days.

2.2 Selection Criteria of the Patients

The Patients willingness to participate in the clinical study was obtained using a specifically designed case sheet proforma and used regularly**.** Cases that were reported to O.P.D and I.P.D of Kayachikitsa, resembling *Amavata* were strictly screened for their suitability to be included under trial. After exclusion and inclusion criteria the patients were considered for the studies.

2.2.1 Inclusion criteria

- Patients agree to follow the study protocol and give their consent for a clinical trial.
- Patients with classical signs and symptoms of *Amavata* mentioned in *Ayurvedic* texts like *Sandhishoola* (pain in the joints), *Sandhi shotha* (Swelling of joints), *Sandhi graha* (morning stiffness), *Angamarda* (Bodyache), *Aruchi* (loss of taste), *Trishna* (thirst), *Alasya* (lack of enthusiasm), *Gourava* (heaviness), *Jwara* (fever) and *Ajeerna* (indigestion).
- Age between 20- 60 years.
- Both male and female patients were randomly selected irrespective of social, economic, educational, and religious status.
- Presence of any four of the following criteria according to the American College of Rheumatology-

1. Morning stiffness of more than 1 hour. 2. Arthritis of 3 or more joints. 3. Symmetrical arthritis for more than 6 weeks. 4. Arthritis of hand joints for more than 6 weeks. 5. Presence of rheumatoid nodules. 6. Serum rheumatoid factor positive. 7. Typical radiological, radiographic changes of hand and wrist.

2.2.2 Exclusion criteria

- Patients below the age of 20 years & above 60 years of age.
- Chronic alcohol addiction.
- Patients suffering from any major medical or surgical diseases like malignancy, CKD, CVD, CVA, HTN, DKA, and psychiatric problems.
- Pregnant women and lactating mothers.
- Patients are not willing to give consent.

2.3 Preparation of *Bhagottara Alambusadya Churna.*

All the ingredients of *Bhagottara Alambusadya Churna* shown in Table 1 have been taken according to the requirement and dried in sunlight. Further, all the components were finely powdered and stored in an airtight container for further studies[11,12,13].

Table 1: Composition of *Bhagottara Alambusadya Churna*.

Sl. No	Name	Latin name	Part used	Quantity
1.	*Alambhusha*	Sphaeranthus indicus Linn.	Whole plant	1 Part
2.	*Gokshura*	Tribulus terrestris	Fruit	2 Part
3.	*Haritaki*	Terminalia chebula Retz.	Fruit	3 Part
4.	*Vibhitaki*	Terminalia bellerica Roxb.	Fruit	4 Part
5.	*Amlaki*	Phyllanthus Emblica Linn.	Fruit	5 Part
6.	*Shunti*	Zingiber officinale	Dried Rhizome	6 Part
7.	*Guduchi*	Tinospora cordifolia Willd.	Stem	7 Part
8.	*Trivruth*	Operculina turpetum	Root	28 Parts

2.4 Treatment Study Design

A total number of 60 patients were randomly divided into two groups:

Group-A: 30 patients were treated with *Bhagottara Alambusadya Churna* (3gm) twice daily after food with lukewarm water for 45 days.

Group- B: 30 patients were treated with *Shunti Churna* (3gm) and *Eranda taila* (5ml) on empty stomach for three days followed by *Bhagottara Alambusadya Churna* (3gm) twice daily after food with lukewarm water for 45 days.

Patients were regularly followed up at an interval of every 15 days for 45 days.

2.5 Assessment Parameters

The following scoring system was used for subjective and objective measures and analysed before and after therapy to assess the efficacy of the treatment.

2.5.1 Subjective Parameter

To assess the effect of therapy on the basis of subjective parameters, different scores were given as shown in table 2.

Table 2: Subjective Parameter scoring system

S. No	Rupa	Absent	Mild	Moderate	Severe
1.	*Sandhi shoola* (joint pain),	0	1	2	3
2.	*Sandhi Shotha* (swelling of joints)	0	1	2	3
3.	*Sandhi graha* (morning stiffness)	0	1	2	3
4.	*Angamarda* (bodyache)	0	1	2	3
5.	*Gourava* (heaviness of the body)	0	1	2	3

2.5.2 Objective Parameter

To assess the effect of therapy on the basis of objective parameters ESR and Serum RA factor levels were assessed before and after treatment.

2.6 Clinical Assessment

The present criteria have been followed in this study. a) complete relief: 100 % relief of the cardinal signs and symptoms viz – *Sandhi shoola, Sandhi shotha, Sandhi graha, Angamarda,* and *Gourava;* b) marked improvement: on an average ≥75 % to <100% relief of the above-mentioned cardinal signs and symptoms; c) moderate improvement: on an average ≥50 % to <75% relief of the above-mentioned cardinal signs and symptoms; d) mild improvement: on an average ≥25 % to<50% relief of the above-mentioned cardinal signs and symptoms, no improvement: <25 % relief of the above-mentioned cardinal signs and symptoms[14]

3. Results

Amavata patients (a total of 60) were undergone treatment with *Bhagottara Alambusadya Churna* and the data was collected at regular intervals. The demographic data of the patients were collected and shown in table 2. Furthermore, it has been observed that in the 41.67 % of patients most of them were found to be in the age group of 41-50 years. In addition to this, we found that the female population has been affected mostly by 86.67%.

Table 2: Demographic observation of the patients.

Demographic Observation	Predominance	No. of Patients	Percentage
Age	41-50 years	25	41.67%
Sex	Females	52	86.67%
Occupation	Housewives	34	56.67%
Chief complaint	Sandhi shoola, Sandhi graha	60	100%
Chronicity	1-5 years	32	53.33%
Mode of onset	Gradual	43	71.675
Agni	Mandagni	35	58.33%
Koshta	Krura koshta	43	71.67%
Sharira Prakruthi	Vata-Kaphaja	43	71.67%
Bowel habit	Irregular	39	65%
Lifestyle	Sedentary	48	80%
Sleep	Disturbed	36	60%

The 60 patients included in the present study were randomly divided into two groups: group A and group B. Group A was given *Bhagottara Alambusadya Churna* with lukewarm water for 45 days. Group B was given *Eranda taila* with *Shunti Churna* for 3 days followed by *Bhagottara Alambusadya Churna* for 45 days. The subjective results showed that the symptoms of *Amavata* in group A- *Sandhishoola, Sandhishotha, Sandhigraha, Angamardha,* and *Gourava* were relieved effectively at 56.9%, 46.36%, 50%, 52.89%, and 49.41% respectively. The symptoms were reduced after treatment and were statistically significant (shown in table 3). In group B- *Sandhishoola, Sandhishotha, Sandhigraha, Angamardha,* and *Gourava* were relieved at a percentage of 68.19%, 53.89%, 55.12%, 58.82%, and 53.65% respectively, and were also statistically significant. The statistical data before and after treatment were shown in table 4.

Table 3: Effect of treatment on subjective parameters in group A patients**.**

Subjective parameters	n	Mean score		MD	% Of Relief	SD	SE	t value	P-value
		BT	AT						
Sandhi shoola	30	1.93	0.83	1.1	56.9%	0.71	0.12	8.46	<0.001
Sandhi shotha	27	1.51	0.81	0.70	46.36%	0.54	0.1	6.75	<0.001
Sandhi graha	30	1.86	0.93	0.93	50%	0.49	0.08	10.8	<0.001
Angamardha	26	1.38	0.65	0.73	52.89%	0.53	0.1	6.98	<0.001
Gourava	30	1.7	0.86	0.84	49.41%	0.53	0.09	8.6	<0.001

n = Sample number, BT= Before treatment, AF= After treatment, MD = Mean difference, SD= Standard deviation, SE= Standard error

Table 4: Effect of treatment on subjective parameters in group B patients.

Subjective parameters	n	Mean score		MD	% Of Relief	SD	SE	t value	P-value
		BT	AT						
Sandhi shoola	30	1.76	0.56	1.2	68.19 %	0.55	0.1	11.93	<0.001
Sandhi shotha	30	1.8	0.83	0.97	53.89 %	0.76	0.14	6.92	<0.001
Sandhi graha	30	1.56	0.7	0.86	55.12 %	0.43	0.07	10.93	<0.001
Angamardha	30	1.53	0.63	0.9	58.82 %	0.31	0.05	15.58	<0.001
Gourava	26	1.23	0.57	0.65	53.65 %	0.48	0.09	6.5	<0.001

n = number of samples, BT= Before treatment, AF= After treatment, MD = Mean difference, SD= Standard deviation, SE= Standard error

In regard to objective parameters, ESR and Serum RA factors are important characteristic features in *amavata*. The levels of ESR and Serum RA factor relief percentages were shown in table 5 for group A and identified as 45.6 and 37.37, respectively and the data was statistically significant before and after treatment. And also in group B, the levels of ESR and Serum RA factor relief percentages were found to be 52.75 and 50.16 respectively. The statistical data before and after treatment were shown in table 6.

Table 5: Effect of ESR and Serum RA factor before and after treatment on objective parameters in group A patients.

Objective parameters	n	Mean score		MD	% Of Relief	SD	SE	t value	P value
		BT	AT						
ESR	30	46.3	47.96	21.1	45.6 %	7.29	1.33	15.84	<0.001
Serum RA Factor	30	51.73	32.2	19.53	37.75%	10.54	1.92	9.98	<0.001

Table 6: Effect of ESR and Serum RA factor before and after treatment on objective parameters in group B patients.

Objective parameters	n	Mean score		MD	% Of Relief	SD	SE	t value	P-value
		BT	AT						
ESR	30	47.96	22.66	25.3	52.75 %	8.69	1.58	15.92	<0.001
Serum RA Factor	30	56.9	28.36	28.54	50.16%	12.99	2.37	12.02	<0.001

Table 7: Treatment and its comparison between groups A and B and overall, in 60 patients.

Overall Effect	Group A (30 Patients)		Group B (30 Patients)		Total (60 Patients)	
	No. of Patients	Percentage of Patients	No. of Patients	Percentage of Patients	No. of Patients	Percentage of Patients
Moderate improvement (≥50 % - <75% relief)	3	10%	20	66.67%	23	38.33%
Mild improvement (≥25 % - <50% relief)	27	90%	10	33.33%	37	61.67%

The effect on the clinical assessments in groups A and B and overall treatment are shown in table 7 after 45 days. In group A, patients treated with *Bhagottara Alambusadya churna* showed 10 % moderate improvement and 90% mild improvement. Furthermore, in group B, patients treated with *Eranda taila* and *Shunti churna* followed by *Bhagottara Alambusadya churna* showed a moderate improvement of 66.67% and a mild improvement of 33.33%. Overall, after 45 days of treatment, 61.67% of patients showed mild improvement and 38.33 % showed moderate improvement.

DISCUSSION

Amavata is a progressive debilitating chronic disease of joints that is characterized by damage to cartilage and results in stiffness, joint pain, and impaired mobility. The disease is believed to be a result of both mechanical and biological events. While the etiology is largely considered unknown, it is believed to be multi-factorial. *Pravridha lakshana* and *upadrava* of *Amavata* can be considered as extra articular manifestation of *Amavata*. The prognosis of *Amavata* depends on the number of vitiated *dosas* involved, the presence or absence of *upadrava*, and the chronicity of the disease. *Amavata* can be treated using *Nidana parivarjana, Bahirparimarjana Chikitsa (Ruksha sweda, Upanaha sweda & Lepa)* and *Antah parimarjana Chikitsa* (*Shodana* and *Shamana*). Moreover, specifically, *Pathya* and *Apathya* have also been mentioned.

In the present study, patients have been treated with *Bhagottara Alambusadya churna, Eranda taila*, and *Shunti churna*. Moreover, the action of *Shunti* on

Amapachaka and *Eranda taila* has *Virecaka* property thus helping in eliminating the vitiated doshas. Further, *Bhagottara Alambusadya churna* contains *Alambusha, Gokshura, Haritaki, Vibhitaki, Amlaki, Shunti, Guduchi*, and *Syama Trivruth* which are having properties like *Triodoshahara, Vatanulomana, Amadoshahara, Dipana, Pachana, Shotahara, Vedanastapana, Rasayana, Dahashamana, Virechaka*. Thus, the drugs are very effective in alleviating the symptoms *of Sandhishula, Sandhishota, Sandhigraha, Angamardha*, and *Gourava*.

A group of 60 patients was divided into two groups: group A and group B. Group A was treated with *Bhagottara Alambusadya churna* for 45 days and group B was treated with *Erandataila* and *Shunti churna* for 3 days followed by *Bhagottara Alambusadya churna* for 45 days. Overall treatment effect in patients of *Amavata* displayed mild to moderate improvement i.e ≥25 % to <75% relief. Based on the clinical analysis, the effect of the drug in alleviating the subjective cardinal symptoms *of Sandhishoola*, the percentage of relief was 59.6 % in group A, whereas 68.19 % in group B. Similarly, for *Sandhishota*, the percentage of relief was found to be 46.36 % in group A, whereas 53.89 % in group B. Again, for *Sandhi graha*, the percentage of relief was determined as 50 % in group A in contract to 55.12 % in group B. Furthermore, the percentage of relief *Angamardha* was identified as 52.89 % in group A, whereas 58.82 % in group B. In addition to this, we have also found the percentage of relief for *Gourava*, to be around 49.41 % in group A in comparison to 53.65 % in group B. The effect of the drug in alleviating the objective parameter ESR, the percentage of relief was found to be 45.6 % in group A in comparison to 52.75 % in group B. In another objective parameter, RA factor percentage of relief was determined as 37.75 % in group A, whereas 50.16 % in group B. Based on all the statistical data, it can be stated that patients of group B (treated with *Bhagottara Alambusadya churna, Erandataila*, and *Shunti churna*) showed marked improvement in all parameters, in comparison to patients of group A (treated with *Bhagottara Alambusadya churna).*

CONCLUSION

Amavata is a chronic inflammatory destructive polyarthritic systemic disease. *Agnimandya*, the formation of *Ama* along with the vitiation of *Vata* and other doshas settled in *Sleshmastana* leads to the manifestation of *Amavata*. *The Bhagotara Alambusadya churna* standard of care herbal drug used to treat *Amavata which* contains *Alambusha, Gokshura, Haritaki, Vibhitaki, Amlaki, Shunti, Guduchi, Syama Trivruth.* The *Eranda taila* has *Vatanulomana, Virechaka* property, and is considered as best in Amavata condition. The properties of *Dipana, Amapachana, Anulomana, Shotahara, Srotoshodan*, and *Rasayana* alleviate the aggravated doshas, reduce the symptoms of *Amavata*, and decrease the ESR and Serum RA Factor level. Both the treatment group A and group B were found effective in pacifying the symptoms of *Amavata*. The group B patients treated with *Eranda taila, Shunti churna*, and *Bhagottara Alambusadya churna* were statistically found to be highly effective in alleviating the symptoms of *Amavata.* The present study has provided considerable data to support the usage of *Bhagottara Alambusadya churna* along with *Eranda taila and Sunti churna*. Further validation is required to support the present study in a larger-scale clinical approach.

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