

A COMPARATIVE STUDY OF THE EFFICACY OF VAITARANA BASTI AND ERANDAMOOOLADI BASTI IN THE MANAGEMENT OF AMAVATA – A STUDY PROTOCOL

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ABSTRACT

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Background: *Amavata* is the common type of problem the present world is facing. *Amavata* is made up of two words, *Ama* and *Vata*, means the incomplete digestion of food which results in incomplete formation of *amarasa* which circulates in all over the body and approaches in the target cells and which produces the pathology like pain, swelling, stiffness of joints and fever and general debility. Even though this disease is not life threatening but it hampers the daily activity of person. *Amavata* is a particular type of disease mentioned in Ayurveda since the period of (16th cent. A.D) under

the category of *vata kapha* disorders. *Nidanas* of *Amavata* explained by *Acharya Madhavakara* are *viruddh aahara*, *viruddha chesta*, *mandagni* and exercises after *snigdha ahara* etc. Whereas treatment of *Amavata* was first explained by *Acharya Chakra Datta*. **Aim and Objectives:** To study the comparative effect of *Vaitarana Basti* and *Erandamooladi Basti* in *Amavata* and to compare the effect of *Vaitarana Basti* and *Erandamooladi Basti* on RA factor, E.S.R., Sr. Uric Acid and Anti- CCP. **Methodology:** We will plan the 60 patients which will be divided randomly into two groups (30 in each). Group A- *Vaitarana Kala Basti* 960 ml will administer for 16 days and Group B- *Erandamooladi Kala Basti* 960 ml will administer for 16 days. **Results:** Changes will be observed in subjective and objective parameters. **Conclusion:** *Vaitarana Basti* and *Erandamooladi Basti* will reduce the symptoms of *Amavata* and will be lowering the RA factor, E.S.R., Sr. Uric Acid and Anti- CCP level.

KEYWORDS: *Vaitarana*, *Erandamool*, *Kalabasti*, *Amavata*, *Ricinus Communis*, *RheumatoidArthritis*.

INTRODUCTION

Human life is considered as a valuable opportunity to attain the four prime goals of life i.e. *Dharam, Artha, Kama, Moksha*. To achieve all these things, one needs a healthy and calm life. Whole the ancient society tried to achieve all these prime four goals of life. So, they had a smooth, sound, safe, assured steady and healthy life style.

According to Ayurveda, *Ama* is a product of improper metabolism and its origin *Mandagni* (Decreased digestive power) has been considered as important factors for the pathogenesis of most of diseases. This *ama* circulates in the body by *vyanavayu* and *vata* gets vitiated and it gets accumulated in the *sandhi* causing pain, stiffness and swelling in the joints. Since *Ama* is having equal *gunas* to *kapha* its affinity is most towards *sleshmasthanas* and hence the *sthana-samsraya* of the disease occurs at *sleshmasthanas* i.e. synovial joints, heart, lungs, muscle fasciae etc. In *Amavata* *rasa vahasrotasa* is involved. *Vata* is chief functional operator of all body movements.

This disease mainly involves the locomotor system but it is also an autoimmune systemic disease affecting the cardiovascular, nervous, respiratory, reticuloendothelial system and excretory system of the body. Its etiology is still unknown and treatment according to modern medical science is also expensive, prolonged and creates many side effects. It also affects the life of an individual to a larger extent. In Ayurveda there is an emphasis on a therapeutic program for managing the patients of *Amavata* instead of a single drug therapy. This therapeutic program is more or less etiologically oriented and aims at *samprapti vighatan* (Breaking the pathogenesis).

The line of management of *Amavata*: *Basti chikitsa* (Medicated enema) specially *Vaitarana* *Basti* is considered as chief regimen for treatment of *Amavata*. *Basti* directly acts on *vata* and is considered as *ardhachikitsa*. *Basti* procedure is expelling body toxins and vitiated *doshas* (humors) by introducing medicated liquids or oils through anal, urethral or vaginal route.^[1] In ancient times the *Basti* apparatus used for *Basti* was made up of urinary bladder of animals. So, this method is called *Basti* and used mainly for *Vata dosha*.

Rational of the study

Amavata is one of the most crippling disorders characterized by *shoola, sotha, sthambha, ushanta, vaivarnata* due to *vikrit vata* associated *Ama*.^[2] The disease starts with minor signs and symptoms may develop and extend to all over body. As the disease becomes severe

additional symptoms like *kanja*, *pangulya* are seen. *Amavata* presents with more similar features of rheumatoid arthritis and it exhibits either as mono or poly arthritis with involvement of pain, inflammation, stiffness and tenderness.

The incidence of Rheumatoid Arthritis is reported to be 1 to 1.5% of general population with male to female ratio 1:3. In females before the age of 45 years is 1:6. Prevalence increased with age, with 5% of women and 2% of men over 55 years being affected.

In modern medical science treatment adopted in Rheumatoid Arthritis management includes NSAIDs (Non-steroid Anti-inflammatory Drugs) immune dilators and long-term pain suppression is achieved by DMARDs (Diseases Modifying Anti Rheumatic Drugs) but most of the NSAIDs have side effects regarding gastrointestinal system and whereas DMARDs have side effects of bone marrow, renal and hepatic suppression. Many treatment methods and formulations have been explained and successfully tried in. But system of Ayurveda still has a great scope in the treatment of *Amavata*. In *Ayurveda Basti* is considered as main treatment for *Amavata*. In *Amavata Vaitaranaa Basti* is considered as drug of choice for *Amavata* and *Erandamooladi Basti* is described by many *Acharyas* for *Kaphavritta Vata*.^[3] So, this topic has been selected to evaluate the efficacy of the Basti for the study of *Amavata*.

Ayurveda offers multiple options for the management of painful condition. In condition of *Amavata* mainly *Vata Dosha* and *Ama* gets vitiated.

Concept of *ama*

Ama as a result of the *Agnimandya* process. More over, it has been stressed that all types of *Ajirna* are the key factors in the production of *Ama*.

Etymology

The word *Ama* is derived from the root word “Am” with suffix “*ninj*”. It means improper or partially digested matter.

In which substances undergo digestion but not completely digested.

Which is either incompletely digested or partially digested is *Ama*.^[4]

Substances does not digest properly and remains yet to undergo for digestion is being called *Ama*.^[5]

Substances produces pain or create pressure on *Srotomukha* and accumulates on the *Srotomukha* is called *Ama*.^[6]

Definition of *ama*

There are various definitions of *Ama* available in different classics. Some of these are given below.

Due to hypofunction of *Ushma* (Agni) the first dhatu Rasa is not properly digested, instead the Anna Rasa undergoes fermentation or putrefaction (*Dusta*) being retained in the *Amashaya*. This Rasa is called *Ama*.

The above properties

Ama svarupa^[8]

The following properties can be classified in the following ways. Property which can be felt by touch.

- *Dravatva*
- *Pichchilata*
- *Snigdhtavata*

Properties which can be perceived by eyes.

- *Tantumatva*
- *Avipakvata*
- *Asamyukata*
- *Anekavarnayukatata*
- *Pichchilata*
- Properties which can be perceived by smell
- *Durgandha*

Properties which can be known by questioning

- *Guruta*
- *Avipakvata*

Doshas and *Dushyas* when mixed with *Ama* are known as *Sama* and the diseases produced by these are termed as *Sama* diseases.

To know the pathological condition of *Ama* in the body the distinguished features of Doshasin the body in *Samavastha* and *Niramavastha* should be well known. *Samadoshas* and their symptoms are stated as *Samavastha*.

Process of *ama* formation

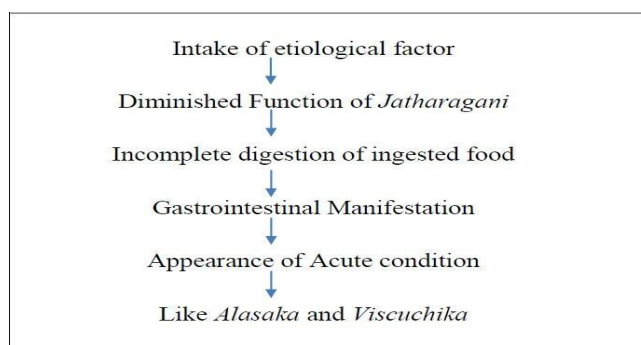
Ama formation in body takes place by two ways:

- Acute *Ama* formation^[10]
- Gradual *Ama* formation^[11]

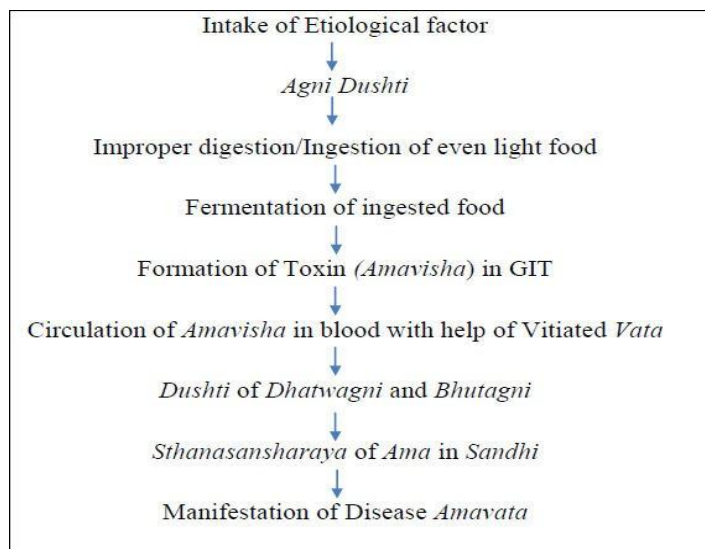
Acute *Ama* formation is described in *Trividh kukshiya* Vimana which is responsible for manifestation of disease like *Alasaka* and *Visuchika*.

While gradual *Ama* formation is responsible for manifestation of systemic disease like *Amavata*.

Pathogenesis of acute *ama* formation



Pathogenesis of gradual *ama* formation



Samprapti ghataka

Dosha: Tridosha, mainly Vata (Vyana, Shamana, Apana) and Kapha (Kledaka, Bodhaka, Sleshaka).

Dhatu: Rasa, Mansa, Asthi, Majja.

Upadhatu: Snayu, Kandara.

Srotasa: Annavaha, Rasavaha, Asthivaha, Majjavaha.

Srotodushti: Sanga and Vimarg gaman.

Udbhava sthana: Amashaya-chiefly production of Ama, Pakvashaya-Mula Sthana of Vata

Adhisthana: Whole body.

Vyakti sthana: Whole body (Sandhi) **Roga marga:** Madhyama Roga Marga **Avayava:** Sandhi.

Vyadhi swabhava: Mainly Chirakari.

Definition of amavata

Simultaneously, vitiated Ama and Vata when lodge in the Trika-Sandhi leading to Stabdhata of that body part this condition is known as Amavata.

According to Madhava Nidana specific etiological factor of Amavata as follows.

1. Viruddhahara
2. Viruddhachesta
3. Mandagni
4. Nishchalata

Any type of exertion immediately after taking Snigdha ahara are the main causative factor responsible for production of Amavata.

Viruddha ahara**Definition**

The Ahar dravyas which provoke Dosha but can't eliminate from the body are called as Viruddha Ahara and it is opposite to Sapta Datu These are Dhatushaithilyakara and Dashaprakopaka Acharya charaka coined term Ahita for Viruddhahar.^[13] Viruddha Ahara is one of the most important factors responsible for Amavata.

18 types of Viruddha Ahara are monitored in Charaka Samhita as follows:^[14]

- Desha Viruddha (Place)

- *Kaal Viruddha* (Time)
- *Agniviruddha* (Digestion power)
- *Matra Viruddha* (Dose)
- *Satmya Viruddha* (Suitability)
- *Dosha Viruddha* (Against of Dosha)
- *Sanskara Viruddha* (Processing)
- *Virya Viruddha* (Active principles)
- *Kostha Viruddha* (Bowels)
- *Avastha Viruddha* (State of health)
- *Krama Viruddha* (Order)
- *Parihara Viruddha* (Contra indication)
- *Upachara Viruddha* (Prescription)
- *Paka Viruddha* (Cooking)
- *Samyoga Viruddha* (Combination)
- *Hrita Viruddha* (Palatability)
- *Sampat Viruddha* (Richness of quality)
- *Vidhi Viruddha* (Rules of eating)

Viruddha cheshta

In classics *Viruddha cheshta* is not mentioned clearly *Viruddha cheshta* indicates all those activities of the body which have an adverse effect on the normal physiology of body. Thus, when normal physiology of body is disturbed the vitiation of *Agni* takes place. This vitiated *Agni* leads to the production of *Ama*. *Viruddha Cheshta* also causes vitiation of *Vata*. Both factors when combine produce *Amavata*.

In *Viruddha Cheshta* following factors can be considered, which are responsible of *DoshaUtklesha*.

- *Vega Vidharana*
- *Anudirna Vega Udirana*
- *Diwaswapa*
- *Ratrijagarana*
- *Ativyayama*
- *Vishama Shayya Shayana*
- *Ativyavaya*

Mandagni

Mandagni is considered as diminished function of *Jatharagni*, *Dhatwagni* and *Bhutagni* but it is quite possible that function of *Jatharagni* is normal in patient but due to diminished function of *Dhatwagni* and *Bhutagni* *Ama* formation takes place which circulate in blood and combined with *Vata*. *Mandagni* is a predisposing factor of all diseases. If without considering *Agni* take other *Nidanas* then they are more prone to get affected from disease of *Ama*. Among the three types of *Agni* *Jatharagni* is very important. The ingested food is digested by all these types of *Agni* instantness of strength of *Jatharagni* is very necessary because it also augments the functions of *Bhutagni* and *Dhatvagni*.

Nischalata

A person who is lazy and less active by his nature. In such person continuous consumption of nutritious or even normal diet produces accumulation of *Kapha* dominance *Dhatus*. Also, due to sedentary habits, *Agni* gets vitiated which in turn leads to vitiation of *Dashas* and production of *Ama*, it along with *Ama* causes pathogenesis of *Amavata*.

Exercise after *snigdha ahar*

Snigdha Ahara which is *Guru*, causes vitiation of *Agni* in the body and production of *Ama*. Where *Vyayama* just after *Snigdha Bhojana* causes Vitiation of *Vayu* and also *Khavaigunya* in *Sandhis*. During *Vyayama* there is excessive mobilization of *Sandhis*. This over use of *Sandhi* may cause *khavaigunya* within them. Thus, *Vyayama* after taking food act as *khavaigunya* producing *Nidana* and combination of it with *Snigdha Bhojana* makes a specific *Nidana* for *Amavata*. *Vyayama* is one of causes that migrate the *Dosha* outside from *Koshtha* and in this situation they get enlodged in *Sandhi*.

Purvarupa

Amavata is not distinctly mentioned in *Brihatrayi*. Only *Vangasena* has given *Shiroruja* and *Gatraruja* as *Purvarupa* of *Amavata*. Early clinical manifestation of the signs/symptoms maybe considered as *Purvarupa* of the disease.

Rupa (Signs and Symptoms)

Madhavakara, *Bhavamishra* and other have described the *Rupa* of *Amavata*. These can be categorized as follows.

1. *Pratyatma Rupa*
2. *Samanya Rupa*

3. *Pravridhdha Rupa*
4. *Doshanubandha Rupa*

<i>Pratyatam</i>	<i>Samanya</i>	<i>Pravridhdha</i>	<i>Doshanubandha</i>		
			<i>Vata</i>	<i>Pitta</i>	<i>Kapha</i>
<i>Sandhishoola</i>	<i>Angamarda</i>	<i>VrishchikvatVedna</i>	<i>Shoola</i>	<i>Daha</i>	<i>Staimitya</i>
<i>Sandhishotha</i>	<i>Aruchi</i>	<i>Agnidaurbalya</i>		<i>Raga</i>	<i>Guruta</i>
<i>Stabdhata</i>	<i>Trishna</i>	<i>Praseka</i>			<i>Kandu</i>
<i>Sparshasayata</i>	<i>Alasya</i>	<i>Nidra Viparayaya</i>			
	<i>Gaurava</i>	<i>Vidvibaddhata</i>			
	<i>Jwara</i>	<i>Viparayaya</i>			
	<i>Apaka</i>	<i>Daha</i>			
	<i>Shuntaanganama</i>	<i>Bahumutrata</i>			
		<i>Antrakunjan</i>			

Treatment protocol

Langhana - Ten types of *langhana* are mentioned in *caraka Samhita*.

The pathology originates from *amashaya* due to poor digestion ultimately resulting in the formation of *ama*, so *langhana* prevents further formation of *ama*. So *langhana* is the first measure for the management of *Amavata*.

Svedana- *Ruksha sveda* is advocated and it is beneficial because of its *usna guna* it digests the *ama* presented in affected area and also dilates the channels. Then obstruction of channel is removed and results in perspiration.

Capillary circulation- The arterioles divide into smaller muscle walled vessels called metarterioles and these in turn feed into capillaries. The opening of capillaries is surrounded on the upstream side by minute smooth muscle pre capillary sphincters. It is unsettled whether the metarterioles are innervated, and it appears that the precapillary sphincters are not. However, they can of course respond to local or circulating vasoconstrictor substances in resting tissue, most of capillary collapsed. In active tissue, the metarterioles and precapillary sphincter dilates. The intracapillary pressure rise, overcoming the critical closing pressure of the vessels, and blood flows through all of the capillaries. Relaxation of the smooth muscles of metarterioles and precapillary sphincters is due to action of vasodilator metabolites formed in active tissue.

When capillaries are stimulated mechanically, they empty probably due to contraction of pre capillary sphincter.^[16]

So due to *svedana*, paused/ *vidagdha* (ingenious) *rasa* comes in re-transmission.

Tikta katu rasa

These *dravya* are *laghu*, *usna* and *tiksana* in properties, which are useful for *ama pacana* and *margavishodhaka*. So, they do *pacana* of *dosa* and *strotolodhana* so *dosa* comes towards *kostha* from *sakha*.^[17]

So, when *doṣa* again comes in *kostha* from *sakha* then after we should do *virecana*.

Virecana

Virecana (Therapeutic purgation) is a *sodhana* therapy (bio purification therapy) by virtue of which the *dosa* are eliminated via *adhomarga*.

According to line of treatment *Virecana* should administered after *langhana*, *svedana*, *dipana* and *pacana* because *dosa* are in *nirama* state and migrate from *sakha* to *kostha*, so *Virecana* with suitable drugs should be administered. *Eranda taila* is the drug of choice for purpose of *Virecana* in *amavata*. It not only performs *Virecana* action but also control the *vata dosa* by its *snigdha guna*.

Snehapana

The therapeutic measures so far employed are likely to cause *ruksata* in *dhatu* and *sandhi* (joints) and provocation of *vata* which any further aggravation of disease. *Snehapana* should be done after *virecana karma* not before.

Basti

In sequence of treatment protocol *basti* is the last procedure because as diseases attain chronicity the *vata* becomes more *Pravridha* and *basti* is very useful in this stage.

Basti acts as *rasayana* in line of treatment.

Cakrapani has recommended *saindhavadi taila* as *anuvasana basti* and *Vaitarana basti* for *niruha Basti* *Acharya Charaka* has mentioned the *Erandamooladi Basti* for the *Kaphavritta Vata* in *SiddhiSthana*.

Niruha basti

It eliminates the residual *ama/ dosa* brought to the *kostha* and is helpful in *anaha*, *vibandha* etc.

Anuvasana basti

It is helpful in the *ruksata* of *sandhi* and control *Vata* by *snehana* guna and nourishes the body.

AIM AND OBJECTIVES

Compare the effect of *Vaitarana Basti* and *Erandamooladi Basti* in *Amavata*.

OBJECTIVES

To evaluate the effect of *Vaitarana Basti* on RA factor, E.S.R., Sr. Uric Acid and Anti-CCP level.

To evaluate the effect of *Erandamooladi Basti* on RA factor, E.S.R., Sr. Uric Acid and Anti-CCP level.

To compare the effect of *Vaitarana Basti* and *Erandamooladi Basti* on RA factor, E.S.R., Sr. Uric Acid and Anti-CCP level.

Case definition

A diagnosed case of *Amavata* with clinical symptoms of multiple joint pain, tenderness, morning stiffness and swelling from 6 months to 1 year.

Diagnostic criteria of *amavata*

The sign and symptoms of *Amavata* mentioned in *Ayurveda* will be basis of Diagnosis. Criteria is follows.

- Multiple joint pain
- Tenderness
- Morning stiffness
- Joint Swelling

Research questions

Whether the *Vaitarana Basti* is as effective as *Erandamooladi Basti* to reduce the symptoms of *Amavata*?

Hypothesis Null hypothesis

Vaitarana Basti is not as effective as *Erandamooladi Basti* to reduce symptoms of *Amavata*.

Alternate hypothesis

Vaitarana Basti and *Erandamooladi Basti* have remarkable effect in reduction of symptoms of *Amavata*.

Study type

Interventional

Trial design

Randomized Open Interventional Comparative Clinical Trial.

Sample selection technique

Simple Randomization by lottery method.

METHODOLOGY**Posology**

960 ml of *Vaitarana Basti*.

960 ml of *Erandamooladi Basti*.

Inclusion criteria

- All the patients having classical features of *Amavata* like *sandhi shoola*, *shoth*, *stabdhata* (stiffness), *ushanata*, *sparshayata*, *vaivarnata* will be selected for the present clinical research work. Detailed research proforma will be prepared incorporating all features seen in the patients of *Amavata*.
- Patients of age group between 20 to 45 years.
- Patients fit for *basti chikitsa*.

Exclusion criteria

- Patients having systematic pathologies like cardiac disease, renal diseases and SLE (Systemic lupus Erythematosus).
- Patients having tuberculosis of spine, spinal tumors, vertebral fractures, surgical conditions and pregnant and lactating women.
- Patients of age group below 20 years and above 45 years.

Table 2: Interventions of the groups.

Grouping	Group A	Group B
Sample size	30	30
Intervention	<i>Vaitarana Basti</i>	<i>Erandamooladi Basti</i>
Dose	960ml	960ml
Duration	16 days	16 days
Follow up	20 days	20 days

Criteria for discontinuing or modifying allocated intervention

- Patients willing to quit in between be allowed to quit and will be replaced.
- If any acute illness or complication develops, patient will be treated accordingly and will be excluded from study.
- Irregular follow up.

Follow up: 20 days

Primary outcome

We will see the effect of *Vaitarana Basti* and *Erandamooladi Basti* on pain and *stambha*

Secondary outcome

We will see the effect of *Vaitarana Basti* and *Erandamooladi Basti* on RA factor, E.S.R. and Anti- CCP.

DISCUSSION

The disease *Amavata* is difficult to cure because of its chronicity, complication and morbidity. The description about *Amavata* seems to be not found in *vedic* and *Samhita* period.

After medieval period it started dominating and nowadays it is very common dreadful disease. *Chakrapani* introduced the effective drugs and treatment first time for the *Amavata*. *Amavata* is a disease caused due to two pathological factors viz. *Ama* and *Vata*. Due to *Agnimandya* (Low digestive fire), unripe, uncooked, immature and undigested material is formed which is nothing but *Ama*. Drugs like *Vatsanabh*^[20] and *Ahiphena*^[21] relieve pain by inducing sleep and relaxing muscles. Drugs like *Guduchi*, *Nagara*, *Rasna*, *Musta*, *Pippali*, and *Chitraka* help in improving *Agni* and helps in digestion of *Ama*. *Guggulu* due to its property of *bhagnasandhakara* prevents the erosion of bone, osteoporosis and deformity of joints.^[22] It also reduces the inflammation of synovial membrane, connective tissue and

ligaments of affected joints due to its *shothahara* property. Drugs like *Nirgundi* and *Shatapushpa* act as pain reliever. Some drugs by virtue of its *prabhava* act as *Amavataghana*.

Amavata is a debilitating disease in view of its chronicity and complications. In the modern era NSAIDS and Corticosteroids are the mainstay of treatment in this condition. However, they have severe adverse effects and have limitations for long term therapy. So, to counter these challenges there is need to adopt ayurvedic system of medicine which are easily available and cost effective.

Probable mode of action of *vaitarana basti*

As a whole, the qualities of *Vaitarana Basti* can be considered as *Laghu*, *Ruksha*, *Ushna*, *Tikshna*. Majority of the drugs are having *Vata-Kapha Shamaka* action. Owing to this property, antagonism to *Kapha* and *Ama* the *Basti* help in significant improvement in sign and symptom of disease. The *Tikshna Guna* of *Basti* helps in overcoming the *Srotodushti* resulting due to '*Sanga*'. Thus, *Basti Dravya* after reaching to large and small intestine get absorbed from intestine, due to *Laghu*, *Ushna*, *Tikshna* and *Ruksha Guna* of *Vaitarana Basti Dravya*, it breaks the obstructions and expels out the morbid material from all over the body thus help in breaking down the pathogenesis of disease. *Niruha Basti* helps in elevating the *Avarana* of *Vata* by *Kapha*. Reduction in this *Avarana* was seen as there was improvement of *Kaphavrita* Vyana symptoms. *Basti* helps in *Vatanulomana* thus helping correcting the *Apanavata*, *Basti* therapy may be stimulator for Gastro-intestinal tract and also for whole body functions. Regulatory peptides like serotonin, entero-glucagon and vasoactive intestinal polypeptide (VIP) are produced in the colon. Many of the peptides have a role in the functioning of the basal ganglia and some of the substances among them, such as (Cholecystokinin) and VIP (vasoactive intestinal polypeptide), are stimulators of the dopaminergic neuronal system. It is possible that *Basti* by stimulating many factors in GIT physiology effect on regulatory functions of these peptides either by moderation or by stimulation. Thus, *Basti Karma* exerts largely systemic action exerting local action in Gastro intestinal tract by operating through large intestine involving enteric nervous system. *Basti Karma* can activate the autonomic nervous system and thereby help in the evacuation of *Basti Dravya*. The effects of ***Basti*** can be endo colonic (acting on the tissue of the colon), endo colonic (acting inside the colon) and diacolonic (systemic action). Modern pharmacokinetic studies have also proved that drug administration via the rectum can achieve higher blood

levels of the drug than administration through the oral route due to partial avoidance of hepatic first-pass metabolism. The rectum has a rich blood and lymph supply and drugs can cross the rectal mucosa as they can cross other lipid membranes. Thus, un-ionized and lipid-soluble substances are readily absorbed from the rectum. The portion absorbed from the upper rectal mucosa is carried by the superior hemorrhoidal vein into the portal circulation, whereas that absorbed from the lower rectum enters directly into the systemic circulation via the middle and inferior hemorrhoidal veins. Thus, administration of drugs in the *Basti* form has faster absorption and provides quicker results.

Statistical analysis

Data will be analyzed on the basis of appropriate statistics Paired t-test, unpaired test and Chi square test by using SPSS software, 24.0 version and Graph Pad Prism 7.0 version and $p < 0.05$. will be considered as level of significance.

Time Duration till Follow up

In both groups initially 16 days of treatment and follow up period after 20 days.

Time schedule of enrolment, Interventions

Vaitarana Basti and *Erandamooladi Basti* with dose 960 ml will be given after CTRI registration. From 0 days to 16 days continuously empty stomach.

Recruitment

30 in each group, Group A and Group B will be recruited randomizing sampling method. Total 60 Subjects (30 subjects in each group).

Group A

30 subjects will be given an established procedure of *Vaitarana Basti* for 16 days.

Group B

30 subjects will be given an established procedure of *Erandamooladi Basti* for 16 days.

Methods

First, we will search literature review, then frame plan of work, medicine collection, authentication of raw drugs, medicine preparation, both recruitment of patients, data collection, adverse effects observe if any and analysis.

Data collections method

Randomized sampling

Subjective parameters

- *Shoola* (Pain)
- *Sthambha* (Stiffness)

Objective parameters

- RA factor
- E.S.R.
- Sr. Uric Acid
- Anti – CCP

Investigations

The patients who will be fulfilled the inclusion criteria will be subjected for hematological investigations before initiation of treatment an informed consent will be taken from the patient and his relatives and after that patient will be evaluated for the both subjective and objective parameters and grading will be noted according to the case Performa.

Data management

Data coding will be done by Principal investigators.

Statistical methods

Paired t- test and unpaired for objectives parameters, non- parametric and Chi square test for subjective parameters.

Ethics and Dissemination

Research ethical approval, after critical evaluation and presentation the ethical committee has taken the research topic.

Consent or assent

Subjects will be given detail information regarding their treatment in their own language. Then written consent will be taken from patients before starting the study.

Dissemination Policy

Will be in the form of paper publication, presentation and Monograph.

Strengths

If proposed study will result in the positive outcome, then it will be established new mode of management for the *Amavata*. In society, we will be provided economical and effective for pain reduction and stiffness.

Limitations

Will be convincing the patients for *Basti* procedure and for hospitalization.

CONCLUSION

Conclusion will be mentioned after the analyzing data.

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