EVALUATION OF VARIATIONS IN EFFECTS OF SIMHANADA GUGGULU IN AMAVATA PATIENTS OF DIFFERENT PRAKRUTHI WITH SPECIAL REFERENCE TO RHEUMATOID ARTHRITIS

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ABSTRACT

Amavata is the most troublesome disease among human population at present. It afflicts rasavaha and annavaha srotas primarily extending to various joints of the body where it lodges.¹ Ama an intermediate product raised out of sluggish status of digestive fire². This moves all over the body along with vata pradhana dosha¹. It persists for long time and slowly makes the person dependent or confined to bed. This challenging problem needs focus on concept of personalized medicines. Prakruti is one of the aspects in the genesis of disease; hence this forms the essence of personalized medicine in the science of ayurveda. Hence an effort is made here to evaluate individual Prakruti of amavata patients and to study its variations in effectiveness based on unique prakruti.

Keywords: Amavata, Ama, Simhanada guggulu, Prakruti

INTRODUCTION

Modern medicine targets therapy to broadest patient population in generalized approach, but the concept of personalized medicine in our country has been found for as long as people have been practicing medicine. From Charaka to Hypocrates all have practiced the personalized approach for treating a disease. Tridosha theory considers prakruti based medicine thus making it a holistic science. Hence this forms the basis for personalized medicine of ayurvedic science. Prakruti based medicine can play a vital role in this changing scenario of global health wisdom as ayurveda offers its modalities by way of ahara (diet) vihara (lifestyle) and oushadha (medicine) which are the three pillars of prakruti based medicine making it the holistic science. An integrative global approach probably could do wonders to health science benefitting broad spectrum of patients.

About Amavata:

Amavata is a chronic persisting crippling disease and it fluctuates as per changes in climate, food and habits of the sufferer. Primary signs and symptoms include angamarda (body ache), aruchi, trishna, alasya (lethargy), gourava (heaviness) and jwara (fever). As the disease continues advanced features start appearing and at last ending with various deformities locally just like any other vata pradhana diseases. Thus, making
oneself to confine to bed or dependent on self-care even, which is expressed clearly by pioneer of this disease Madhavakara by name. Such symptoms include saruja shotha (painful swelling) wherever ama lodges in various bony joints like hashta (hand), pada (foot), shira (near to head or cervical spines), gulpha (ankle), trika (sacral area), janu (knee). The affected individual experiences severe pain compared with that of scorpion bite along with the advanced features of agni dourbalya (lack of appetite), praseka (excessive salivation) aruchi (unable to taste) gourava (heaviness) utasa hanti (lethargy), vairasya (distaste), dha (burning sensation), bahumutra (polyuria), kukshikatinya (hardness in abdomen) kukshi shola (pain abdomen) nidraviparyaya (reversal of sleep), trishna (thirsty), charadi (vomiting), bhrama (giddiness), moorcha (loss of consciousness), hrutgraha (catching pain in chest), vitvibaddhata (constipation) jadya (stiff), antrakujana (gurgling sound in intestine) and anaha (feeling of fullness in stomach) along with various complications which are difficult to manage1. 

Ayurveda considers ama as the initial factor concerned with the disease produced out of agnimandya. Lack of appetite due to which malfunction of digestion and metabolism takes place leading to the formation of an intermediate substance. This ama is detrimental to srotas (channels of body) due to its adhesive nature, while circulating in the body along with the vitiated vata. Thus produces a hectic disease called Amavata1.2. Though Amavata and Rheumatoid Arthritis cannot be considered equivalent disease entity, striking similarities are observed in its etiopathogenesis and presentation of features. It can be considered that Rheumatoid Arthritis is an example of one variety of similar presentation under broad heading of Amavata disease. It is observed that micro vascular injury due to inflammatory mediators, especially synovia which is very close to srotoavarodha and srotoabhishyanda caused by ama in shelshmasthana of asthisandhi. Rheumatoid arthritis is a chronic, progressive, autoimmune arthropathy characterized by symmetrical inflection of bony joints along with the extra articular manifestations. It is predominantly featured by joints pain, morning stiffness, tenderness, swelling due to synovial effusion, increased temperature locally and chances of discoloration over effected skin along with systemic features of different kind.

Rheumatoid arthritis is seen throughout the world and affects approximately 0.8% of the population. Women are affected usually 3 times more than men. The onset is more frequent during the 4th and 5th decades of life with 80% of patients developing the disease between the age of 35 and 50. Genetic factors are thought to explain approximately 60% of the disease susceptibility of RA. It has been estimated that HLA genes contribute about 1/3rd of the genetic susceptibility to RA. Epidemiologic studies in Africa emphasized that climate and urbanization have major impact on incidence and severity of RA in groups of similar genetic background6.

Clinical criteria for the diagnosis of RA is based on number of joints affected, serum rheumatoid factor, duration of the symptoms (<6 weeks>) and acute phase reactants (CRP & ESR). The mainstream of treatment in RA starts with the use of Non-steroidal anti-inflammatory drugs, followed by the early use of small molecule Disease modifying anti-rheumatic drugs (DMARDS) and corticosteroids for the induction of remission7.

Different modalities based on the principles symbolically mentioned in Bruhatrayee (Charaka, Sushrutha, and Vagbhata samhitha) different treatment protocol and big list of preparations of multiple combinations to pacify the effect of amavata. Prior to this, different types based on predominant symptoms like vata-nubandi (shoola pradhana), pittanubandi (raganvitha) and kapha pradhana (shotha kandu and gouravyukta) also mentioned3. It is told that, having features of one dosha as sadhya, two dosha involvement being kruchra and if all tridosha actively participates becomes yapya or asadhy even1.

Among the treatment principles mentioned in classics consists of different kinds of procedure to be given in various levels of the disease. It includes langana (fasting), swedana (process of sudation), intake of katu rasa pradhana as well as the drug to increase the digestive fire (deepana), virechana (purgation) snehapan (eranda taila sevana) basti (enema) espe-
cially kshara basthi are important. Further it is added that rukshasweda (sudation without sneha baga) which consist of valuka sweda, upanaha sweda, once again tying poultice devoid of oily substances are preferred. As ama should not be fluctuated saindyadhya tala sidda anuvasana basti has to be administered, followed by ksharabasti.

Yogaratnakara, Bhava Mishra and writers of baishhya ratnavali also felt compiled and added many other information regarding the treatment.

Simhanada Guggulu

This being a potent preparation in use for thousands of years having good record of controlling the disease. It contains decoction of triphala (fruits of haritaki, vibhitaki, amalaki) 3 pala (about 150 ml), purified Sulphur and guggulu 1 pala (about 50 grams) each and castor oil 1 kudava (about 160 ml) being ingredients. All individual items put together are subjected to boil in an iron vessel. It alleviates vata, pitta and kapha and useful in controlling limping, lameness etc. predominantly in amavata even if already rejected by many physicians. Diet during the period should consist of shali and shashhtika, rice variety with ghee, oil and meat soup. It is known as simhanada as it destroys the valor of disease elephants and stimulates digestive fire also, hence being potent and very specific simhanada guggulu was used for the study.

Aim and Objectives

1. To study clinical effect of Simhanada guggulu in patients of amavata with special reference to Rheumatoid Arthritis
2. To assess the impact of treatment in different prakruthi patients decided prior to the study
3. To infer the variations in effectiveness of Simhanada guggulu in different prakruthi individuals as observed by the clinical trials
4. To develop safe, personalized and cost effective ayurvedic formula for Rheumatoid Arthritis.

Inclusion Criteria: -

a. 20-60 years of patients irrespective of caste, sex or creed
b. Patients of amavata who has signed the consent form for the study
c. Morning stiffness (sthabdatha) in and around joints lasting at least 1 hour before maximal improvement
d. Soft tissue swelling along with pain in three or more joints
e. Symmetrical swelling
f. Criteria of 3- 6 must have been present for 5+/-4 years

Exclusion Criteria: -

1. Below and above age group mentioned
2. Complicated cases as well as serious other systemic diseases

Study design

This research includes two phases.

First phase: Selection of Amavata sufferer between 20-60 years of age and having the history of same 5+/-4 years. Screened and selected from OPD of Sri Dharmasthala Manjunatheshwara Ayurveda Hospital, Kuthpady, Udupi. Diagnosis is made as per classics and allied sciences. Visual analogue scale is used for most of the subjective features like pain, heaviness. Blood analysis includes complete haemogram, ESR, RA factor before and after the study.

Prakruthi evaluation and detection

Prakruthi of each subject would be assessed prior to the treatment, using the validated questionnaire based on physical, physiological and psychological characteristics as well as clinical judgement of senior ayurvedic experts. Physique, skin texture, hunger, thirst, digestive capacity, temperament and memory are some of the attributes evaluated to determine individual constitution. The questionnaire also considers information regarding ethnicity, maternal and paternal family history of diseases, history related to diseases, allergies, dietary and excretory habit evaluations. Predominant prakruthi was ultimately decided as per the information and input of evaluation.

Second Phase: 54 patients out of 105 patients screened with prompt and completeness of intervention are taken for research study. After screening criteria fulfilled subjects were administered orally an ayurvedic drug formulation simhanada guggulu after food in capsule form for a period of 90 days, in the dosage of 1-gram TID with periodical assessment of effect of
drug as observed variations in the signs and symptoms.

**Source:**

Patients for the current study were screened out from the OPD section of Sri Dharmasthala Ayurveda Hospital, Kuthpady, Udupi, Karnataka State as per guidelines of classics and allied sciences

**Age Group:** - Diagnosed cases of aged 20-50 years were selected

**Study type:** - single blind randomized interventional clinical trail

**Method of administration:** - Oral route

**Drug:** - *Simhanada guggulu*

**Dosage:** - 2 capsules of 500mg three times a day after food along with lukewarm water

**Duration:** - 90 days

**Evaluation:** - on 0th day, 15th day, 45th day, 75th and 90th day of drug administration

**Pathya- Apathya:** General instructions to the patients during treatment period includes avoiding of dairy foods, cheese substances, sweets, fried and roasted as well as spicy foods along with other instructions mentioned in classics.

**Method of assessment of treatment:** -

The changes in the subjective and objective parameters before as well as during periodic visits and after treatment considered for assessment of safety and efficacy of drug

1. **Clinical assessment:** - done as per grading according to the criteria with regards to severity of pain Morning stiffness, tenderness, swelling and fever. Grading is also done for symptoms mentioned in Ayurveda using the parameter specially made for the study

2. **Assessment on biochemical or serological values**

were recorded before treatment and after treatment to compare the effect

3. **Functional assessment:** this includes recording assessment of Walking time grip power, pressing power before as well as periodic visits and ultimately on 90th day

**Observations:**

Based on clinical observations and action of *simhanada guggulu* in the body, we can have following opinions though the inferences made here may not be ultimate since it is the first step for a challenging question

Out of 54 patients who completed the study with clinical benefits treated in OPD section of Sri Dharmasthala Manjunatheshwara Ayurveda Hospital, Kuthpady of Udupi district and Karnataka state. Among them, Patients belonging to

*Vatapakruthi* - 02

*Pitta prakruthi* patients - 05

*Kapha prakruthi* - 00

VataPittapakruthi-25

Vatakapha – 05

PittaKapha- 11

*Sama prakruthi* - 06

Pakruthi of each subject assessed based on physical, physiological as well as psychological characteristics and clinical judgement of senior experts.

Based on the *prakruti* of everyone, the clinical response shown by the patients after the treatment with *simhanadaguggulu* was assessed. Patients of *Amavata* got maximum benefit from pain who belongs to vatapitta prakruti (6), vatakapha prakruti (2), sama-prakruti (2) Prakruthi compared to other subjects who underwent same regimen.

Reduction in morning stiffness has much reduced in patients of vatapita (4), vatakapha (2), and samaprakruti (2).

Marked reduction in tenderness seen in pita (2), vatapitta (2), samapakruti (1).

Effects on swelling maximum observed vata (2), pita (4), vatapita (19), pitakapha (8), vatakapha (4) and samaprakruti (3).

Among the Function test easement effect on walking time moderate to maximum observed vatapita (8), Vatakapha (1), pitta (2), pitta kapha (1).

**Effect on clinical changes of function tests**

Grip power

In Left hand:

*Pita prakuti* (1) vatapita (14) pitakapha (10) vatakapha (2) samapakruti (4) was observed.
In Right hand:
Pita (2) vatapita (15) pitakapha (11) vatakapha (1) samaprakuruti (4) was observed.
Clinical changes of pressing power in foot:
Marked reduction was not at all seen in all 54 patients in the whole group.

Clinical changes in walking time:
Marked reduction seen in patients of vatapita (4) pitakapha (3) vatakapha (4).
Apart from the above marked effect on different symptoms, it was also noted clinical effects of moderate, mild and poor responses as shown in the table.

Table 1: Pain

<table>
<thead>
<tr>
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<th>V</th>
<th>P</th>
<th>K</th>
<th>Vp</th>
<th>Pk</th>
<th>Vk</th>
<th>Sama</th>
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Table 2: Morning Stiffness

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Table 3: Tenderness

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Table 4: Swelling

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Table 5: Grip Power

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Table 6: Pressing Power

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DISCUSSION & CONCLUSION
The basic idea of this work is to find out the link between the treatment outcome and human prakruthi types as per ayurveda concepts which may help other researcher to take up the projects in this direction to establish the relationships, which is the basis of personalized medicine in ayurveda. In our study patients with prakruthi type, combination with vata found maximum relief from pain, reduction in the morning stiffness, reduction in the swelling. This preliminary study gives an indication that treatment outcome in amavata patients with simhanada guggulu are linked with prakruti types. This is preliminary study and results obtained by this cannot be generalized, because further study with higher sample size is required to establish the relationship between treatment outcome and prakruti types.

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