

## 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.<sup>1</sup> *Ama* an intermediate product raised out of sluggish status of digestive fire<sup>2</sup>. This moves all over the body along with *vata pradhana dosha*<sup>1</sup>. 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 Hypocrites 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 selfcare 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 *hastha* (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) *utsaha hani* (lethargy), *vairasya* (distaste), *daha* (burning sensation), *bahumutrata* (polyuria), *kukshikatinya* (hardness in abdomen) *kukshi shola* (pain abdomen) *nidraviparyaya* (reversal of sleep), *trishna* (thirsty), *chardi* (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 manage<sup>1</sup>.

*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 *Amavata*<sup>1</sup>. 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 *shelshmathana* of *asthisandhi*.

Rheumatoid arthritis is a chronic, progressive, autoimmune arthropathy characterized by symmetrical infliction 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 background<sup>6</sup>.

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 mainstay 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 remission<sup>7</sup>.

Different modalities based on the principles symbolically mentioned in *Bruhatrayee* (*Charaka*, *Sushruta*, 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 *vatanubandi* (*shoola pradhana*), *pittanubandi* (*raganvitha*) and *kapha pradhana* (*shotha kandu* and *gouravayukta*) also mentioned<sup>2</sup>. 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 *asadhya* even<sup>1</sup>.

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) *snehapana* (*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 *saindvadhya taila sidda anuvasana basti* has to be administered, followed by *ksharabasti*<sup>4</sup>.

*Yogaratanakara*, *Bhava Mishra* and writers of *baishjya 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.<sup>3</sup>

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 *shashtika*, 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<sup>3</sup>.

### **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, Udipi. 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 *Kayachikitsa* 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: - 90days

Evaluation: - on 0<sup>th</sup> day, 15<sup>th</sup> day, 45<sup>th</sup> day, 75<sup>th</sup> and 90<sup>th</sup> 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 90<sup>th</sup> day

**Observations:**

Based on clinical observations and action of *simhanada guggulu* in the body, we can have following opin-

ions 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 Manjunatheswara Ayurveda Hospital, Kuthpady of Udupi district and Karnataka state. Among them,

Patients belonging to

*Vataprakruthi* - 02

*Pitta prakruthi* patients - 05

*Kapha prakruthi* - 00

*VataPittaprakruthi*-25

*Vatakapha* – 05

*PittaKapha*- 11

*Sama prakruthi* - 06

*Prakruthi* 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), *samaprakruti* (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 prakruti* (1) *vatapita* (14) *pitakapha* (10) *vatakapha* (2) *samaprakruti* (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**

Prakruthi And Effect	V	P	K	Vp	Pk	Vk	Sama
Poor (No Response)	1	0	0	0	0	0	0
Mild	2	3	0	4	1	00	1
Moderate	1	2	0	15	10	2	2

**Table 2: Morning Stiffness**

Prakruthi And Effect	V	P	K	Vp	Pk	Vk	Sama
Poor (No Response)	0	0	0	2	0	0	0
Mild	0	2	0	7	4	0	2
Moderate	0	2	0	15	7	3	2

**Table 3: Tenderness**

Prakruthi And Effect	V	P	K	Vp	Pk	Vk	Sama
Poor (No Response)	0	2	0	2	0	0	0
Mild	2	1	0	16	8	0	3
Moderate	0	0	0	6	3	4	2

**Table 4: Swelling**

Prakruthi And Effect	V	P	K	VP	PK	VK	SAMA
Poor (No Response)	0	0	0	0	0	0	0
Mild	0	1	0	1	1	0	0
Moderate	0	0	0	5	2	1	3

**Table 5: Grip Power**

Prakruthi And Effect	V		P		K		VP		PK		VK		SAMA	
	L	R	L	R	L	R	L	R	L	R	L	R	L	R
Poor (No Response)	0	0	1	1	0	0	0	0	0	0	0	0	0	0
Mild	2	2	3	2	0	0	9	9	1	0	3	3	2	2
Moderate	0	0	0	0	0	0	2	1	0	0	0	1	0	0

**Table 6: Pressing Power**

Prakruthi And Effect	V		P		K		VP		PK		VK		SAMA	
	L	R	L	R	L	R	L	R	L	R	L	R	L	R
Poor (No Response)	0	0	1	1	0	0	0	0	0	0	0	0	0	0
Mild	2	2	4	3	0	0	12	12	2	1	2	2	2	2
Moderate	0	0	0	1	0	0	13	13	9	10	3	3	4	4

**Table 7: Walking**

Prakruthi And Effect	V	P	K	VP	PK	VK	SAMA
Poor (No Response)	0	0	0	0	0	0	0
Mild	2	3		13	7	2	6
Moderate	0	2	0	8	1	1	0

## 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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