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CLINICAL EFFICACY OF *SUNTHI GUGGULU GODANTI BHASMA* IN THE MANAGEMENT OF *AMAVATA* (RHEUMATOID ARTHRITIS)

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Abstract

A single blind clinical study was conducted at C.R.I. (Ay), Jaipur, in order to evaluate the efficacy of the combination of Sunthi, Guggulu, Godanti, in the Management of Amavata (Rheumatoid Arthritis), during the period 2004 and 2005. A total 47 well established cases of Amavata were selected for the study, as per the protocol designed by CCRAS, New Delhi and the criteria of selection of the patients was based on 1987 Revised criteria of American College of Rheumatology (ARA1987), for the classification, diagnosis of Rheumatoid Arthritis. The drug Sunthi, Guggulu and Godanti Bhasma (1:2:1 ratio) 2 gms thrice a day with warm water was administered to the patients. The improvement of subjective and objective parameters was assessed and highly significant improvement was observed after six weeks of treatment. Out of 47 cases studied, 15 (31.91%) cases got good response, 15 (31.91%) got fair response, 8 (17.02%) got poor response and 03 (6.39%) cases did not get any response, while 06 (12.77%) cases were dropped out from the study. After the overall assessment, it has been observed that the drug combination of Sunthi + Guggulu + Godanti is highly effective in the management of Amavata (Rheumatoid Arthritis) and no adverse effects were observed.

Introduction

Amavata (Rheumatoid Arthritis), a systemic disease mainly affecting the joints has still remained a problem of medical science. It is considered a crippling disease for its painful features and destructive progress leading to disability and deformity. Madhavakara (900 AD) has identified first time the disease *Amavata* as separate entity and described the disease in detail. On the other hand, description of *Amavata* is not found in the ancient *Ayurvedic* classics as a separate entity.

In Charak Samhita (1000 B.C.) the relation of *"Ama"* with localized pain digestive disorders are described.

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Chakrapani was mentioned about *Amavata* in his commentary on Charaka Samhita. In Susruta Samhita the relation of *"Ama"* with localized pain has been described. Vagbhata opined the disease in which *Ama* is involved should be termed as *Sama.*

It is a poly articular joint disease described in ancient Indian system of medicine has high resemblance with Rheumatoid Arthritis of the modern medicine. It is an auto immune disease that causes chronic inflammation of the joints; it can also cause inflammation of the tissue around the joints as well as other organs in the body. While Rheumatoid Arthritis is a chronic illness, meaning it can last for years, patients may experience long periods without symptoms. Typically, however, Rheumatoid Arthritis is a progressive illness that has the potential to cause joint destruction and functional disability. There is no known cure for Rheumatoid Arthritis. To date the goal of treatment in Rheumatoid Arthritis is to reduce joint inflammation and pain, maximizes joint function and prevents joint destruction and deformity. There are disadvantages in the presently available potent synthetic drugs because of their toxicity and re-appearance of symptoms after discontinuation. Therefore, the search for screening and development of drugs for their anti-inflammatory activities is unending problem and there is much scope of finding anti-rheumatic drugs from indigenous plants.

In the last one and a half decade, various drugs have been studied by the C.C.R.A.S. for the management of *Amavata*. Among them *Guggulu* preparation in different formulations have been found quite effective in the management of *Amavata*. Keeping this in view, the present study has been planned with *Sunthi, Guggulu, Godanthi* (1:2:1 ratio) for its management.

A clinical study was conducted on 47 patients, suffering from Rheumatoid Arthritis on OPD & IPD level, at Central Research Institute of Ayurveda, Jaipur. The criteria of selection of patients were based on signs and symptoms and Laboratory investigations as mentioned in the classical texts.

Material and Methods

A total number of 47 well-established cases of *Amavata* were registered for this clinical study, during the period of 2004 and 2005, from CRI (Ay), Hospital, Jaipur.

Drug, Dose and Duration

For this study, the drug *"Sunthi, Suddha Guggulu* and *Godanthi"* has been taken on the ratio of 1:2:1 and prepared in the form of *Churna* and administered in the dose of 2 gms thrice daily along with water for 6 weeks.

Criteria of Inclusion

Age between 12 years to 60 years, chronicity between 6 weeks to 5 years, morning stiffness, Arthritis of 3 or more joint areas, Arthritis of hand joints, Symmetrical Arthritis, Rheumatoid nodules, Serum Rheumatoid factor, Radiographic changes.

Criteria of Exclusion

Age below 12 years and more than 60 years, Chronicity less than 6 weeks more than 5 years, Gout, Osteo-Arthritis, Tubercular Arthritis, Gonorrheal Arthritis/syphilitic Arthritis, Arthritis with malignancy, Acute pyogenic arthritis, Psoriatic arthritis, Osteomyelitis, Rheumatic Fever, Ankylosing spondylitis, Arthritis with serious complications, Bursitis, Osteoporosis, Diabetic Arthritis.

Gradation of Parameters with specific scores for the assessments of results

For assessment of the results a special scoring pattern has been adopted for individual parameters. Before treatment and after treatment, data on signs/symptoms and other parameters taken into account for diagnosis and for assessment of result of treatment will be tabulated and analyzed using suitable statistical methods.

Subjective		**Scores**
1. **Morning Stiffness**		
i. Severe	- patient can not rise from bed for few hours	6
ii. Moderate	- patient cannot rise from bed for few hours in morning or evening	4
iii. Mild	- can rise from bed but feels difficulty	2
2. **Pain on rest**		
i. Severe	- excruciating pain with painful cries	9
ii. Moderate	- frequent complaints of pain	6
iii. Mild	- reveals pain on asking	3
Objective		
3. **Pain on motion**		
i. Severe	- Excruciating pain with painful cries	9
ii. Moderate	- Frequent complaints of pain	6
iii. Mild	- Reveals pain on asking	3
4. **Swelling**		
i. Severe	- Considerably above the landmarks and with positive fluctuations 15	
ii. Moderate	- Covering bony landmarks	10
iii. Mild	- Not masking bony landmarks	5
5. **Tenderness**		
G4-Will not allow touching		20
G3-Winces and withdraws		15
G2- Winces on touch		10
G1- Patient says the joint is tender		5
6.**Muscle Power (whole assessable)**		
G0 No contraction		20

G1 - Flicker of contraction 8
G2 - Movement of a joint possible with gravity eliminated but not possible Against gravity 6
G3 - Muscle contraction possible only against gravity 4
G4 - Muscle contraction possible against gravity and resistance combined 2
G5 - Normal power 0

7. **Restriction of joint motion (of movable joints)**
Fullyrestricted 6
Partially restricted 3
No restriction 0

8. **Subcutaneous nodule**
Present 2
Absent

9. **Functional Status**
Grade IV - No contraction 6
Grade III - Flicker of contraction 4
Grade II - Movements with gravity 2
Grade I - Contraction possible against gravity and resistance 0
Grade 0 - Normal power

10. **Fever**
Present 2
Absent 0

11. **Elevated E.S.R. (1st hour)**
71 mm or more 6
41 mm - 70 mm 4
20 mm - 40 mm 2
0 mm - 20 mm 0

12. **Digestive impairment**
a. Constipation
Regularly 3
Frequently 2
Occasionally 1
b. Loss of appetite
Appetite lost 2
Poor appetite 1
Normal appetite 0
c. Anorexia
No inclination for diet 2
Less inclination for diet 1
No anorexia 0

The score in points from 2 to 7 will be multiple according to number of involvement of joints. As such the score may be more than 100. The percentage of relief may be calculated accordingly. For illustration total score before treatment 250, if reaches 150 after treatment the percentage of relief will be $\frac{250-150}{250} \times 100 = 40\%$

Classification of the Results

Good Response- 75% and above relief in symptomatology & Lab. Parameters tending towards normalcy.

Fair Response- 50% and above relief in presenting symptomatology & Significant improvement in laboratory parameters.

Poor Response- 25% and above relief in presenting symptomatology & Insignificant improvement in lab. Parameters.

No Response- No relief in symptomatol - ogy and no improvement in lab. Parameters.

Withdrawal from the study-

Discontinuation of the treatment during the trial, development of any serious complication, aggravation of the disease & any pronounced toxicity of the drug.

Follow up details-

1st follow-up - After two weeks
2nd follow-up - After four weeks
3rd follow-up - After six weeks

Observation of study

The majority of patients 12 in each were registered under the age groups 31-40 yrs and 51-60yrs (25.53% each) (Table-I). Maximum 37 (78.72%) cases were females (Table-II). 30 (63.82%) cases were registered as per the duration of illness, under up to 730 days (Table-III). Maximum 21(44.68%) number of cases were of *Vata- Pittaj Prakriti* (Table -IV).maximum 19 (40.42%) cases were desk workers (Table-V). Majority of patients 19 (40.42%) were illiterates as compared to educated sections (Table- VI).

Out of 47 cases studied, 15 (31.91%) cases got good response, 15 (31.91%) got fair response, 8 (17.02%) got poor response and 03 (6.39%) cases did not get any response, while 06 (12.77%) cases were dropped out from the study (Table -VII).

Based on numerical score before and after treatment Percentage of relief was assessed. 47.40% relief was found on over all parameters. In each parameter, 36.36% of relief in morning stiffness, 70.08% in Pain on rest, 57.11% in Pain on Motion, 67.81% in Swelling, 59.62% in Tenderness, 54.77% in Muscle power, 47.86% in Restricted movements, 50.00% in Sub cutaneous nodules and 43.21% relief in Functional status, 40.00% in fever, 40.00% in constipation, 42.31% in loss of appetite, 58.33% in anorexia, 3.80% in ESR were found (Table- VIII).

By the statistical analysis (Student T test), Clinical Recovery of the drug of *"Sunthi +Guggulu+ Godanti Bhasma"* was found highly significant ($P<0.001$) in relieving morning stiffness, pain on motion, swelling on joints, tenderness, muscle power, restriction of joint motion and Anorexia; only significant effect (<0.025) was found in loss of appetite and statistically insignificant effect was observed ($P<0.1$) in treating Subcutaneous nodule, fever, Constipation and ESR - (Table-VIII).

Table -I
Showing the incidence of age group

Age group in years				
Up to 20	**21-30**	**31-40**	**41-50**	**51-60**
03	9	12	11	12

Table -II
Showing the incidence of sex

Sex		
Male	Female	Total
10	37	47

Table-III
Showing the duration of illness

Duration of illness in days					
Up to 365	366-730	731-1095	1096-1460	1461-1825	Total
15	15	3	5	9	47

Table-IV
Showing the incidence of *Sariraka & Manasika Prakriti*

Sariraka Prakriti								***Manasika Prakriti***							
V	***P***	***K***	***VP***	***VK***	***PK***	***S****	***T***	***S***	***R***	***T***	***SR***	***ST***	***RT***	***S1***	**Total**
-	-	-	21	16	10	-	47	-	-	-	21	10	16	-	47

*V=Vata, P=Pitta, K=Kapha, VP=Vatapitta, VK=Vatkapha, PK=Pittakapha, S*Sannipat, S-Satwa, R-Rajas, T-Tamas, SR-Satwarajas, ST-Satwatamas, RT-Rajastamas, S1 -Sama*

Table-V
Showing incidence of Occupation

Occupation	**No. of patients**
House wife	15
Desk work	19
F. W. with physical labour	13
Total	**47**

Table -VI
Showing incidence of Educational Status

Educational Status	
Illiterate	19
Read & write	07
Primary School	05
Middle School	06
High School	08
College	02
Total	**47**

Table-VII
Showing the Overall Result of treatment

Sex	Result of treatment					Total
	Good Resp.	Fair Resp.	Poor Resp.	No Resp.	LAMA/ Drop Out	
Male	5	4	0	1	-	10
Female	10	11	8	2	6	37
Total	**15**	**15**	**8**	**3**	**6**	**47**

Table-VIII
Showing the effect of therapy in signs and symptoms

Symptoms	Mean B.T.	Mean A.T.	Mean Diff.	Mean%	Number	S.D.	S.E.	t Value	P Value
Morning stiffness	4.29	2.73	1.56	36.36%	41	1.92	0.30	5.19	< 0.001
Pain on rest	38.82	11.62	27.21	70.08%	39	16.50	2.64	10.30	< 0.001
Pain on Motion	43.56	18.68	24.88	57.11%	41	14.83	2.32	10.74	< 0.001
Swelling on joints	47.80	15.39	32.41	67.81%	41	23.67	3.70	8.77	< 0.001
Tenderness	59.80	24.15	35.65	59.62%	40	23.30	3.68	9.68	< 0.001
Muscle power	45.60	20.63	24.98	54.77%	40	15.48	2.45	10.20	< 0.001
Restriction of joints motion	16.71	8.71	8.00	47.86%	21	9.74	2.12	3.77	< 0.005
Subcutaneous nodule	2.00	1.00	1.00	50.00%	2	1.41	1.00	1.00	> 0.1
Functional status	4.50	2.56	1.94	43.21%	36	1.76	0.29	6.64	< 0.001
Fever	0.37	0.22	0.15	40.00%	41	0.76	0.12	0.13	> 0.1
Constipation	0.73	0.44	0.29	40.00%	41	0.96	0.15	0.96	< 0.1
Loss of appetite	0.63	0.37	0.27	42.31%	41	0.67	0.10	2.56	< 0.025
Anorexia	0.59	0.24	0.34	58.33%	41	0.57	0.09	3.80	< 0.001
ESR	4.16	4.32	-0.16	-3.80%	38	0.25	0.36	-0.43	> 0.1

Discussion

In this study, the effect of *Sunthi, Guggulu,* and Godanthi on *Amavata* was observed carefully, in the improvement of clinical symptoms, complications and reduction in the ESR levels.

Sunthi (Zinziber officinale) is having *Kapha Vata Samaka* property due to its *Katu Rasa, Snigda Guna and Ushna Veerya.* It has *Sotha Prasamana, Jwaraghna* and *Vedana Sthapana* properties. It is also useful in *Agnimandhya, Aruchi and Adhmana* (Ref- Bh. Pr. Ni.). In Charaka Samhita, *Sunthi* has been as *Sothahara* drug (Ref. Ch. Chi. 12/21, 22, 23, 25, 27).

Guggulu (Balsamodendron Mukul) is having *Vatahara* property due to its *Madhura Ushna, Snigda* and *Pichhila Gunas, Kaphahara* property due to *Tikta, Katu* and *Teeksna Gunas* and *Pithahara* property due to *Kasaya* and *Madhura Gunas.*

It has *Vedana Sthapana, Sothahara, Deepana, Rasayana* and *Balya* properties and used in *Amavata, Sandhivata, Vibandha, Agnimandhya* and all *Vatavyadhis* (Ref- Bh. Pr. Ni.). It is proved as hypolipidaemic, atherosclerotic, anti arthritic, anti-inflammatory and anti Rheumatic action (Ref- Database, CCRAS).

Godanthi (Calcium sulphate) ($CaSo_4 2H_2o$) is having *Vata Pithahara* properties and acts as *Jwaraghna, Sulahara* and *Balya.* (Ref. P.V.Sarma Vol-II).

Hence, the synergetic action of the above drugs can be corroborated in getting significant results of this clinical study.

In Ayurveda *Guggulu,* the oleo gum resin of *Boswellia serrata* Roxb is used for the treatment of rheumatism and the activity has attributed to the presence of pentacyclic triterpenoid acid (Gupta *et.al.*1987). *Guggulu* an oleo gum resin has been in use for a variety of metabolic disorders including Rheumatoid Arthritis (Satyavati, 1969). The therapeutic properties of *Commiphora mukul (Guggulu)* have been reviewed by Bhatt (1987). Vyas and Sukla (1987), tested purified *Guggulu* for its anti-rheumatic activity. *'Zinziber officinale (Sunthi)* is described in Ayurvedic system of medicine to be useful in inflammation and rheumatism and its mechanism of action is reported to be related to inhibition of Prostaglandin (Sreevastava, 1992). In Ayurveda *"Godanthi"* established as *Sulahara, Jwaraghna, Balya* and *Vatahara. Clinical* trials with *Sunthi, Guggulu* and gum *Guggulu* with gold showed much improvement in patients of Rheumatoid Arthritis (Ref- CDRI, Lucknow- 1987).

Conclusion

After going through the statistical analysis of the data, we may conclude that, the study has shown significant improvement on *Amavata.* There was improvement in all the subjective parameters and also observed improvement in walking time, pressing power and grip strength. Further regular study is required over a large number of cases to draw a definite conclusion.

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सारांश

आमवात की चिकित्सा में शुण्ठी गुग्गुलु एवं गोदन्ती भस्म की चिकित्सात्मक प्रभावकारिता

एच.एम.एल. मीणा, बी.आर.मीणा, एम.एम.शर्मा एवं जी.बाबु

प्रस्तुत शोधपत्र मे आमवात में शुण्ठी, गुग्गुलु एवं गोदन्ती भस्म के प्रभाव का एक चिकित्सात्मक अध्ययन महाराव शेखाजी केन्द्रीय आयुर्वेद अनुसंधान संस्थान, जयपुर में

किया गया। वर्ष 2004 एवं 2005 में कुल 47 रोगियों पर यह अध्ययन पूर्ण किया गया। जिसमें से 31.91 प्रतिशत रोगियों को उत्तम लाभ, 31.91 प्रतिशत रोगियों को मध्यम लाभ, 17.02 प्रतिशत रोगियों को अल्प लाभ मिला और 6.39 प्रतिशत रोगियों को कोई लाभ नही मिला तथा 12.77 प्रतिशत रोगी चिकित्सा क्रम को पूर्ण नहीं कर सकें। सारांशतः शुण्ठी गुग्गुलु एवं गोदंती भस्म का प्रभाव आमवात के रोगियों में बहुत अच्छा रहा।