

CLINICAL EVALUATION OF CODED AYURVEDIC COMPOUND DRUG IN THE MANAGEMENT OF AAMVATA (RHEUMATOID ARTHRITIS)

ANIL MANGAL¹ AND A.D.JADHAV²

Department of Clinical Research, Central Research Institute (Ayurveda),
CCRAS, Podar Hospital Campus, Worli, Mumbai - 400018 Maharashtra (India)

Abstract: A number of popular preparations of Guggulu are being practiced for the treatment of many *vatavyadhis* and other related disorders. *Aamvata* (Rheumatoid arthritis), is a very common disease throughout the world. It is a chronic systemic inflammatory disorder, which affects the joints of the body causing painful swelling in them. It makes life miserable and crippling due to unknown causation, claiming the maximum loss of human working power. 109 cases along with involvement of joints having clinical features of *Aamvata* were selected and diagnosis was confirmed on the basis of proforma advocated by Central Rouncil for Research in Ayurveda and Siddha. The study indicates significant improvement in the clinical parameters, ESR, R.A. titre. Almost all cases whichever completed the treatment, improved from their signs and symptoms, therefore, the Ayurvedic compound drug Sunthi, Guggulu and Godanti (1:2:1) is found to be effective with no side effects and toxicity in the management of *Aamvata*.

Keywords: Guggulu, *Aamvata*, Rheumatoid arthritis, *Commiphora Wightii* Bhan.

Introduction

Rheumatoid arthritis is the greatest crippling disease of unknown causation, claiming the maximum loss of human working power and chiefly affecting synovial membranes of multiple joints. Female and male patient ratio is almost 3:1 (Current medical diagnosis and treatment 1986). The disease is widely prevalent. As per a survey in U.S. (Health statistics series B.No.20. Department of U.S.) 1,08,45,000 (6.4% of total population of U.S.) persons suffering from arthritis in United States of which majority belongs to Rheumatoid arthritis. The survey showed that RA was second amongst the disease, which produced the chronic limitations of major activities. The main cause of Rheumatoid arthritis remain unknown but the etiopathogenesis of Rheumatoid arthritis involves diverse and complex factors such as genetic background, Rheumatoid factor, immune complexes, complement activation, lymphocytes, arachidonic acid, metabolites, free radicals etc.

The arthritis has been described in detail in the classical period of Ayurveda under the heading of *Vaatrakta*. Later on Madhava (9th AD)¹ offered the excellent description of the disease entity *Aamvata*, which is very similar to Rheumatoid arthritis. Madhavkar describes etio-pathology of *Aamvata* that a man with weak digestion(*mandagneh*), if he possess a sedentary life (*nishchalysya*) or if he indulges into *viruddha ahara* and *vihara* e.g., excessive exercise after taking heavy and fatty food, *ama* is produced and *vata* gets vitiated.

This *ama* provoked by *vata* (*vayuna preritah*) circulates in the body especially towards *shleshma sthanas*. That is resultant of cardinal symptoms of *Aamvata* are painful swelling of the joints (*sarujamshotham*) of hands, feet, ankle, knee, hip, spinal column and stiffness (*jadyata*) fever (*jwara*), loss of appetite (*aruchi*), indigestion (*apaka*), constipation (*vidbadhata*), gurgling (*antrakujanam*) etc. The Principle of the treatment for *Aamvata* is

1. Research Officer (Ayurveda)

2. Research officer (Ayurveda)

described in Ayurveda is based on *langhan*, *deepan* and *pachan* of *apakva ama avastha* followed by the suppression of aggravated *vata*.

The CCRAS is continuously engaged in finding out safe with better efficacious and affordable of treatment for challenging diseases like *Aamvata*, *medoroga*, *vyanvalavaishmya*, *manodwega*, *raktalpta* etc. In the present study, 109 cases have been treated with Ayurvedic compound drug (Sunthi, Guggulu and Godanti) and results are reported.

Materials and Methods

Preparation of drug

Sunthi (*Zingiber officinalis* Rosae.), Guggulu (*Commiphora wightii* Bhan.) and Godanti are mixed in 1:2:1 ratio. Guggulu and Godanti were taken in purified form. The proposed drug was prepared and supplied from pharmacy of Central Research Institute, Patiala, Punjab (under the supervision of Central Council for Research in Ayurveda and Siddha. Department of AYUSH, Ministry of Health & FW., Government of India).

Dose schedule

Presently single blind study is conducted at OPD/IPD of Central Research Institute,

Mumbai. Four tablets (each tablet 500mg) of the drug (combination of Sunthi, Guggulu and Godanti) thrice a day alongwith lukewarm water was given to the 109 patients for 45 day.

Criteria for inclusion / Diagnosis¹⁹ (American Rheumatism Association 1988 Revision)

1. Morning stiffness* 2. Arthritis of three or more joint areas* 3. Arthritis of hand joints* 4. Symmetrical arthritis* 5. Rheumatoid nodules 6. Rheumatoid factor and 7. Radiological changes (*Diagnosis of RA made with 4 (or) more criteria) and Age group between 12 – 60 years of either sex were included in the study.

Criteria for exclusion

1. Age below 12 years and above 60 years 2. Chronicity below 6 weeks (or) more than five years 3. Gout, Osteoarthritis, Ankylosing spondylitis 4. Arthritis with malignancy 5. Psoriatic arthritis, Osteomyelitis, Rheumatic fever and Associated with any other serious systemic diseases / complications.

Criteria for assessment

Clinical symptoms were assessed on the basis of scoring in their category i.e. ESR

Clinical Symptoms Assessment Scoring

Morning stiffness	Severe : 6	Moderate : 4	Mild : 2			
Pain on rest	Severe : 9	Moderate : 6	Mild : 3			
Pain on motion	Severe : 9	Moderate : 6	Mild : 3			
Swelling	Severe : 15	Moderate : 10	Mild : 5			
Tenderness	G 4 : 20	G 3 : 15	G 2 : 10		G 1 : 5	
Muscle power	G0 : 10	G1 : 8	G2:6	G3:4	G4:2	G5 : 0
Restricted movements	Fully restricted : 6	Partially restricted : 3	No restriction : 0			
Subcutaneous nodules	Present : 2	Absent : 0				
Functional status	Grade 4 : 6	Grade 3 : 4	Grade : 2		Grade : 0	

(Erythrocyte sedimentation rate) and RA factor (Rheumatoid arthritis test) are done for the assessment. The assessment was done before the drug administration, 15 days, 30 days and 45 days subsequently. The interpretations of results were done on the basis of response above 75%, 50%, and 25% and less than 25% are good, fair, poor and no response respectively.

Observations and Results

Following observation has been made out in various aspects i.e. sex, age, education etc.

The observations done on the basis of sex wise distribution infers that the females

Table 1. Sex wise distribution of patients

Sex	Patients (n=109)	%
Male	18	16.51
Female	91	83.48

Table 2. Age wise distribution of patients

Age group (in years)	Patients (n=109)	%
19-30	17	15.59
31-40	37	33.94
41-50	34	31.19
51-60	21	19.26

Table 3. According to education wise

Education status	Patients (n=109)	%
Illiterate	13	11.92
Read & Write	17	15.59
Primary School	21	19.26
Middle School	29	26.60
High School	18	16.51
College	11	10.09

(83.48%) are mostly affected than the males (**Table 1**). RA is most frequent during the fourth and fifth decade of life. 80% of patients developed the disease between the age of 35 and 50. In this study, age group 31-40 yrs (33.94%) and 41-50 yrs (31.19%) are dominant (**Table 2**).

Number of middle school educated persons are more affected than others. Most of them are females (**Table 3**). 38.53% patients were intaking lacto-ova food in this study, while 34.86% were on vegetarian food (**Table 4**).

Table 4. Diet wise distribution

Diet	Patients (n=109)	%
Veg	38	34.86
Non-Veg	29	26.60
Lacto-ova	42	38.53

The analysis done on bowel habit distribution shows that most of the patients were constipated (**Table 5**).

Table 5. According to bowel habit

Bowel habit	Patients (n=109)	%
Regular	42	38.53
Constipation	67	61.46

According to occupation housewives were found more affected than the others categories (**Table 6**).

Table 6. Occupation wise distribution

Occupation	Patients (n=109)	%
Desk work*	33	30.27%
House wife	65	59.63%
Field work	11	10.09%

* = Service

Table 7. According to sleeping condition

Type of sleep	Patients (n=109)	%
Good	21	19.26%
Disturbed	60	55.04%
Insomnia	28	25.68%

Disturbed sleep is noticed in this study. 60 patients (55.04%) were suffering from disturbed sleeping habits (**Table 7**).

Table 8. According to condition of the disease

In days	Patients (n=109)	%
42-180	04	3.66
181-360	15	13.76
361-541	35	32.11
542-722	26	23.85
723-901	13	11.92
902-1081	02	1.83
1082-1261	14	12.84

Most of the cases were chronic. Minimum period was 60 days and highest 1261 days (**Table 8**).

Table 9. Distribution of Prakriti

Prakriti	Patients (n=109)	%
Vata	02	1.83%
Kapha	01	0.91%
Vatapitta	34	31.19%
Pittakapha	23	21.10%
Vatakapha	49	44.95%

The analysis done on *prakriti* wise distribution shows that majority of *Aamvata* patients belonged to *Vatakapha prakriti* (44.95%) (**Table 9**).

Results and Discussion

Morning stiffness has been reduced up to 64.98%. Pain on rest was similarly reduced. Pain on motion has been reduced up to 60.34%. Swelling and tenderness was reduced up to 62.88%, 63.40% respectively. Restricted movement has been also improved up to 50.80%. Subcutaneous nodules have been reduced up to 62.40%. Functional status condition has been improved after treatment (**Table 10** and **Figure 1**).

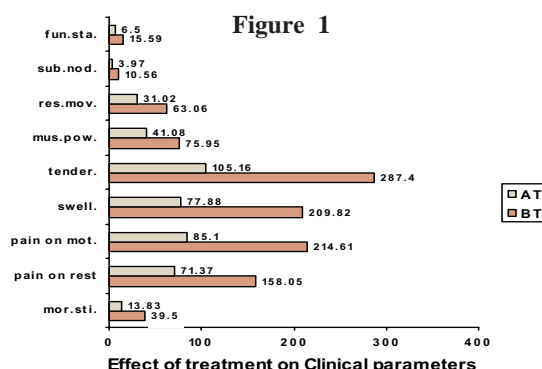
Table 10. Effect of treatment on clinical parameters in patients of *Aamvata*

Clinical parameters	Number of Patients (n=109)		
	Mean score		% of mean diff.
	B.T.	A.T.	
Morning Stiffness	39.5	13.83	64.98
Pain on Rest	158.05	71.37	54.84
Pain on Motion	214.61	85.10	60.34
Swelling	209.82	77.88	62.88
Tenderness	287.40	105.16	63.40
Muscle Power	75.95	41.08	45.91
Restricted Movements	63.06	31.02	50.80
Subcutaneous Nodules	10.56	03.97	62.40
Functional Status	15.59	06.50	58.30

Table 11. Effect on E.S.R. in patients of *Aamvata*

Number of (n=109)	Mean ESR		% of Mean diff.
	B.T.	A.T.	
	306.42	192.69	37.11

Mean of ESR is in BT condition 306.42 and after it has been 192.69 mm/hr. Percentage of mean difference is 37.11% (Table 11).

**Table 12.** Effect of therapies on Rheumatoid arthritis (RA) test in patients of *Aamvata*

Total Number of Patients (n=109)	Rheumatoid arthritis (RA) test					
	Before Treatment (Positive)		After treatment			
	No. of pt's	%	Positive		Negative	
			No. of pt's	%	No. of pt's	%
	41	37.61%	21	19.26%	20	18.34%

Before treatment RA test has been positive in 41 cases, while after treatment was present only in 21 cases (Table 12).

Overall Results

The patients treated with Sunthi, Guggulu and Godanti combined tablets showed good response by 29.35% and fair response by 44.95% (Table 13 and Figure 2).

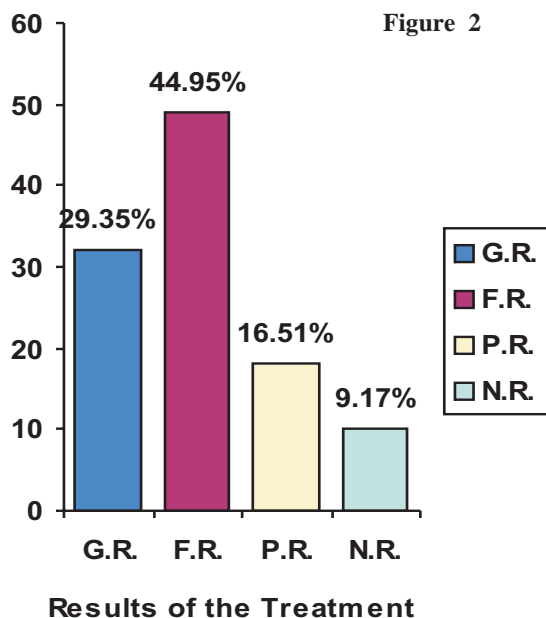
Table 13. Results of the Treatment

Results	Patients (n=109)	%
Good response	32	29.35
Fair response	49	44.95
Poor response	18	16.51
No response	10	09.17

Adverse events observed: Most of the patients did not show any type of adverse reaction except three cases who had itching or burning sensation for some time.

Aamvata (Rheumatoid arthritis=RA) is a widely prevalent disease and affects most of the population. In recent years the rheumatology has become one of the most active fields in medical science. The rheumatoid associations have been established in many countries having good numbers of physicians and surgeons discussing and finding out the solution to this chronically disabling disease. In Ayurveda, Madhava¹ (9th A.D.) offered the excellent description on this disease entity *Aamvata*, which is very similar to RA. Onset of disease, patient complaints are pain, swelling, stiffness, raised temperature, fatigueness, loss of appetite etc. Usually we noticed during the study that knee joints, metacarpal joints were more affected. Restrictions of movements, pain of the joints were more at the night. Anorexia, indigestion, loss of appetite were the common complaints.

The main object of this trial is to evaluate the efficacy of Ayurvedic compound drug Sunthi, Guggulu and Godanti (1:2:1) in controlling



various grades of the disease - Rheumatoid arthritis. The standard criteria used for diagnosis and certain functional tests have been performed to as an objective proof. E.S.R., R.A. factor have been estimated pre and after completion of dose schedule. Follow up studies have been done on the patients who improved with the treatment.

The observations done on the basis of sex wise distribution data clearly showed that the incidence of RA is more prone in females. Most of the females are practicing faulty diets and are having lesser manual works, which lead to *agnimandya* and then help in pathogenesis of RA. The analysis done on bowel habit shows that maximum patient were constipated. Constipation is a major causative factor of *Aamvata*. *Vata*kapha *prakriti* patients (44.95%) are mostly suffering from *Aamvata*. Clinical symptoms i.e. morning stiffness is seen in all patients because the predominance of *kapha dosha* is in morning. It was seen that the stiffness decreased gradually as the day was progressing. Rise in temperature is also in

maximum patients that appears due to the formation of *Aamdosha*.

Sunthi (*Zingiber officinalis* Rosae.), a constituent of trial drug, has been described to have *deepana* and *pachana* effect resulting in inhibition of the formation of *Aam* alleviator of *vata* and *kapha dosha* and is of value in the relief of *sotha* and *sula*.¹⁸ Guggulu (*Commiphora wightii* Bhan.) is another component, which is highly important in this formulation recorded in Ayurvedic literature for the conditions of vitiated *vata* and *kapha dosha*.¹⁶ It has also been evaluated for anti-arthritic and anti-inflammatory actions.^{5, 12, 15} Guggulu has been considered as a potential *vatahara* and useful for the treatment of *Aamvata*. This effect has been demonstrated in the clinical and experimental studies.^{6, 7, 8} Godanti, the third component is a drug of mineral origin which has been classified under *sudha varga* and its properties are *deepan*, *balya*, *vatapitta shamak*, *sulahar*, *jwarghna* and useful for the treatment of *pittaj jwar*, *vismajvar*, *sirahsula* etc.² It is source of natural calcium existing in the form of calcium sulphate, which has cooling, antacid and astringent properties.¹³

Conclusion

The Ayurvedic compound drug Sunthi, Guggulu and Godanti (1:2:1) may have better approach and scope in the successful management of *Aamvata* (Rheumatoid arthritis) irrespective of *prakriti* and age. The symptoms of morning stiffness and pain on motion being best controlled. The results of the study indicates that the drug combination of Sunthi, Guggulu and Godanti is a balanced and judicious formulation, the components of which acted synergistically in breaking the complex of pathogenesis of the disease by *amapachan* and improves digestion and other associated symptoms like stiffness, swelling, tenderness

etc. have been simultaneously reduced. Godanti, a purified natural calcium supplement plays an important role in bone nourishment.

Acknowledgements

Author(s) and team highly gratitude to Dr. G. S. Lavekar, Director and the Deputy Director (Tech.) CCRAS, New Delhi for encouraging and providing the facilities.

References

1. **Madhava:** *Madhav Nidan*. Hindi commentary by N.N. Shastri. Motilal Banarasi Das, New Delhi, Ch.25/1-12, pp 424-427 (1979).
2. **Sharma, P.V:** *Dravya Guna Vigyan*. Vol. 3rd. Chowkhambha Bharati Academy, Varanasi, 12th ed. (1991).
3. **Kumar, Anil and Kumar, Naresh :** Effect of herbo-mineral combination (Sunthi Guggulu Godanti) in Aamvata (Rheumatoid Arthritis). *Jour. Res. Ayu. Sidd.* Vol. XXIV: 3-4, pp 14-30 (2003).
4. **Anonymous:** *Wealth of India (raw materials)*. Vol. XI-X-Z CSIR, New Delhi, 1976 reprint, pp 89-106 (1989).
5. **Arora, R.B. and Gupta, Lalit et al. :** Standardization of Indian indigenous drug and preparations-II: chemical and biological standardization of *Commiphora mukul* (guggulu). *Jour. of Res. Ind. Med.* Vol. VII, No.2, pp 6-13 (1972).
6. **Bhattacharya, C :** Guggulu and Rheumatic disease. *Rheumatism*. Vol.11, pp 16 (1975).
7. **Gujral, M. L. and Saxena, P. N :** An experimental investigation of anti-arthritis effect of some indigenous and modern medicine. *Ind. Jour. Med. Res.*, Vol. 44, pp 657 (1956).
8. **Gulati, O. P. et al.:** Anti-inflammatory activity of *Guggulu* in white rats. *Rheumatism*. Vol.8, pp 83 (1972).
9. **Kar, A. C. et al.:** Management of Aamvata (Rheumatoid Arthritis) with Ayurvedic drug combination – A clinical trial. *Jour. Res. Ayu. Sid.* Vol. XX: 3-4, pp 166-172 (1999).
10. **Kishor, P. et al.:** Clinical studies on the treatment of Aamvata (Rheumatoid Arthritis) with *Sunthi-guggulu*. *Jour. Res. Ayu. Sid.* Vol. III: 3-4, pp 133-146 (1982).
11. **Kishore, P. and Padhi, M. M :** Further clinical evaluation of *Sunthi-guggulu* in the treatment of Aamvata-Rheumatoid Arthritis. *Jour. Res. Ayu. Sid.* Vol. IX: 3-4, pp 89-104 (1988).
12. **Mahesh, B. et al.:** The anti-inflammatory effects of few indigenous drugs in relation to histamine and 5 HT depletion. *Ind. Jour. Physio. Pharmacol.* 11-14 (abstract) (1967).
13. **Nadkarni, K.M:** *Indian Materia Medica*. Vol. II Popular Prakashan Pvt. Ltd. Mumbai, pp 48 (1982).
14. **Raut, A. A. et al.:** Anti-Rheumatic formulations from Ayurveda. *Ancient Sciences of Life*. Vol. XI: 1-2, pp 66-69 (1991).
15. **Satyavati, G. V. et al.:** *C. mukul* Engl. and *Tinospora cordifolia* Willd. A study of anti-inflammatory activity. *Rheumatism*. Vol.4, pp 141 (1969).
16. **Anonymous:** *Susruta Samhita chi.* 5/45-46. Comm. by Shastri A.D. 12th ed. Chaukhambha Sanskrit Sansthan, Varanasi (2001).
17. **Anonymous:** *Charak Samhita*. Comm. by Shastry K.N. and Chaturvedi G.N. 16th ed. Chaukhambha Bharti Academy, Varanasi (1989).
18. **Narhari, Pandit:** *Raj Nighantu chi.* 28/242. edited by Dr. I. Tripathi. Krishan Das Academy, Varanasi pp 138 (1982).
19. [http:// www.rheumatology.org](http://www.rheumatology.org)

Address for correspondence: Dr. Anil Mangal, Research Officer, Dept. of Clinical Research, Central Research Institute (Ay.), CCRAS, Podar Hospital Campus, Worli, Mumbai - 400018 (India). E-mail: dranilmangal@yahoo.com.