

## Clinical evaluation of an Ayurvedic formulation in management of rheumatoid-arthritis

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### Abstract

The aim of the study was to evaluate the efficacy of an Ayurvedic formulation in the management of Rheumatoid arthritis in order to establish the true efficacy of the formulation. A herbomineral formulation comprised of six medicinal plants - *Vitex negundo*, *Cyperus rotundus*, *Nyctenthes arbartristis*, *Simlex glabra*, *Delphinium denudatum*, and *Withenia somnifera*, in combination of Maha yogaraj Guggulu Vaiswanar churna and Simhanada Guggulu was given as decoction to 140 patients aged between 12-60 years and of either sex for a period of one year. The diagnosis and evaluation of response of therapy was made according to subjective/ objective observations as per Performa prepared using score system in which points were assigned according to the involvement and severity of

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various findings which were recorded initially, periodically and at the end of the trial. Out of 140 subjects studied under trial, practically 97 subjects completed the treatment of which 39 (40.20%) subjects showed good response (relief of 75% and above) and 30( 30.92%) subjects had fair response i.e. relief between 50% to 74% while 15 (15.46%) subjects experienced poor response and no response of the treatment was observed in 3 (3.09 %) subjects. This study demonstrated the Ayurvedic herbo-mineral formulation examined clinically could be used in management of the rheumatoid arthritis

### Introduction

Rheumatoid arthritis (RA) is a chronic, systemic inflammatory disorder that may affect many tissues and organs, but principally attacks synovial joints. About 1% of the world's population is affected by rheumatoid arthritis, women three times more often than men. The disease generally sets in the people between the ages of 40 and 50, but people of any age can be affected. The disease manifests in swelling, pain, redness, stiffness and warmth in the affected region and may lead to deformity of joint and restriction to mobility. As such, besides some painkillers, anti- inflammatory and immune-suppressant drugs with serious side effects,

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there are no treatments which are considered completely effective and able to produce definite long-term relief.

One of the treatment alternatives drawing increasing attention lies in Ayurveda the traditional Indian system of medicine, that has been used in the Indian population for the treatment of such chronic diseases for several thousand years. The exact cause of RA is not known but this has been recognized as an auto immune disorder. In Ayurveda RA is described as 'AAMVAT' and its cause is very well explained<sup>2</sup>. The term Aamvat is derived from two terms Ama and Vata. Ama means formation of toxin that is produced by imbalanced body fire. The toxin ama is carried by imbalanced vata (one of the three energetic forces) and reaches the kapha (one of the three energetic forces) dominated places like joints etc. This toxin becomes sticky due to imbalanced doshas and blocks the vital channels which nourish the body.

The ama which gets harbored in joints acts like a foreign substance and triggers the immune system. This leads to inflammation of linings of joints. Ama is caused by imbalance of doshas resulted from indigestion due to Imbalanced foods and lifestyles, lowered body fire, sedentary work, over physical exertion involving lot of joint movements<sup>3</sup>. In recent past, trials of several therapies have been reported mostly with the Hetuvyadhiviparita drugs like sunthi Guggulu, Sunthi Guduchi, Vatagajankush Ras, Maharasnadhi Kwath & Yogaraj Guggulu, Amavatari Ras, Maharasnadhi Kwath<sup>4,5</sup> Panhkarma treatment consisting of Snehana, Swedana, Virechana and Vasti has also been found to be significantly effective in most of the subjects.

Though according to modern medicine there is no specific cause of the RA, the concept of

Ayurveda suggesting the production of ama or impaired metabolism invites the attention of researchers to combat disease by eliminating the causative factor. The treatment according to Ayurveda in addition to alleviation of the disease, it also aims at augmenting the process of digestion both at intestinal and cellular level. One of the authors (AR) is an Ayurvedic physician practicing Ayurveda for the last 28 years in his hospital 'Arogyadham'. He conducted a clinical trail on 150 subjects using a herbal formulation comprised of six medicinal plants - *Vitex negundo*, *Cyperus rotundus*, *Nyctenthes arbortristis*, *Simlex glabra*, *Delphinium denudatum*, and *Withania somnifera*, in combination of Maha yogaraj Guggulu Vaiswanar churna and Simhanada Guggulu, the drugs prescribed in Ayurveda for treatment of RA, to study the efficacy of the formulation in treatment of the RA and also studied the mode of action of the formulation based on the pharmacodynamic principles. Results of the study are reported herein.

### Materials and Method

The subjects for the study were those visited Arogyadham Global Aids Research Foundation for treatment of RA. The nature, aim, procedures, and possible risks and benefits of the study were explained to the eligible subjects. Both verbal and written informed consents were obtained prior to the screening.

### Inclusion criteria

The inclusion criteria were the following.

1. Age between 11 to 60 years
2. Sex- either sex
3. Chronicity between 6 to 5 weeks
4. Morning stiffness

5. Pain on motion or tenderness in at least one joint
6. Swelling of one joint
7. Swelling of at least one other joint
8. Symmetrical joint swelling
9. Subcutaneous nodules over bony prominences
10. Typical **roentgenographic** changes which must show demineralization/ degenerative changes
11. Positive test of rheumatoid factor in serum
12. Synovial fluid a poor mucin clot with dilute acetic acid
13. Synovial histopathology consistent with rheumatoid arthritis
14. Characteristic histopathology of rheumatoid nodules evidenced by biopsy

#### **Exclusion criteria**

The exclusion criteria were the following.

1. Age below 11 and 60 years or above
2. Chronicity
3. Gout
4. Osteoarthritis
5. Tubercular arthritis
6. Gonorrhoeal arthritis
7. Arthritis with malignancy
8. Acute pyogenic arthritis
9. Psoriatic arthritis
10. Osteomyelitis
11. Rheumatic fever
12. Ankylosing spondylitis

13. Serious complications associated with any other systemic disease

#### **Criteria for diagnosis and evaluation of response of therapy**

The diagnosis and evaluation was made according to subjective/ objective observation as per proforma prepared using score system in which points were assigned according to the involvement and severity of various findings which were recorded initially, periodically and at the end of the trial (Table 1) and results of response of therapy were expressed as per the classification shown in Table 2.

#### **The diet recommended / provided to the subjects in lunch was comprised of rice, pulse, vegetable curry and chapati.**

A herbomineral formulation comprised of six medicinal plants - *Vitex negundo*, *Cyperus rotundus*, *Nyctenthes arbortristis*, *Simlex Glabra* ,, *Delphinium denudatum*, and *Withania somnifera*, in combination of Maha yogaraj Guggulu Vaiswanar churna and Simhanada Guggulu was given as decoction to 140 patients aged between 12-60 years and of either sex for a period of one year. In Maha yogaraj Guggulu Vaiswanar churna and Simhanada Guggulu total number of 35 ingredients existed out of which 27 (77.14%) were of plant origin while 8 (22.86%) were metals/minerals derivatives. The Decoction is to be taken Morning and Evening before Meals 2 times a day All 6 Herbs (5 gms each) mix together total 30gms divided means 15gms in Morning and evening to be taken as decoction half morning and evening at least for a year.

#### **Results and Discussion**

**(a) Incidence of age:** Observation regarding the incidence of age in Amavata patients

revealed highest number of incidence i.e. 31 (22.14%) in the age group of 21 to 30 years, 30 (21.42%) in the age group of 31-40, 27 (19.28%) in the age group of 41 to 50 years, 22 (15.71%) in the age group of 11 to 20 years, 21 (15%) in the age group of 51-60 while 9 (6.42%) subjects were in the age group of 61 and above.

**(b) Incidence of sex:** Regarding the incidence of sex in the subjects, females dominated the males, the proportion being 73 (52.14%) : 67 (47.85%).

**(c) Chronicity:** As regards the chronicity of illness highest number of patients i.e. 77(55%) had chronicity within 365 days, 21(51%) subjects between 366 to 730 days, equal number of 18 (12.85%) subjects between 731 to 1095 days and above 1461 days while 6(4.28%) subjects between 1096 to 1460 days.

**(d) Involvement of joint:** Study of the incidence of joint involvement revealed the highest number of 96 (68.57%) subjects afflicted with right knee joint followed by 92(65.71%) subjects being afflicted with the left knee joint. The other joints commonly involved were right ankle, Left MTP, I.P.T. of right hand, MTP joints of left hand, left ankle, right wrist and elbow, left wrist and elbow.

**(e) Presenting signs/symptoms:** Incidences of clinical signs and symptoms are given in Table 3. Swelling, pain, tenderness and morning stiffness were present in all the patients while 120 (85.71%) subjects had restriction of joint movement, 107 (76.42%) subjects had loss of appetite, 97 (69.28%) subjects had constipation and 63 (45%) subjects had anorexia. Incidences of loose motions and subcutaneous nodules were observed in 06 (4.28) and 01 (0.7) subjects, respectively.

Results in relation to age group, sex and chronicity are presented in Tables 3-5, respectively. Out of 140 subjects, 97 completed the treatment. Observation on the therapeutic effect of the drug showed good response in 39 (27.85%) subjects, fair response in 30 (21.42%) subjects while 15 (10.71%) subjects demonstrated poor response. The results in relation to sex as shown in table 3 indicate slightly more pronounced effect in case of females than the males. Data given in table 4 reveal that the highest subjects (10) showing good response were in the age between 41-50 years, 8 in the age between 31-40 years and 11-20 years, 7 in the age between 21-30 years, 05 in the age between 51-60 years followed by 01 in the age > 61 years. The highest subjects (10) showing fair response were in the age between 51-60 years followed by 06,05,04,04 and 01 in the age group between 11-20, 31-40, 21-30, 41-50 and >61 years, respectively. The % of the subjects having poor response was low in all age groups except 21-30 and 31-40 years. Only 03 subjects in the age group 11-20 (02) and 51-60 (01) years demonstrated no response.

Out of 140 subjects studied under trial, practically 97 subjects completed the treatment of which 39 (40.20%) subjects showed good response (relief of 75% and above) and 30( 30.92%) subjects had fair response i.e. relief between 50% to 74% while 15 (15.46%) subjects experienced poor response and no response of the treatment was observed in 3 (3.09 %) subjects.

<b>1. Subjective</b>			
<b>1.1 Morning stiffness points</b>	<b>Score</b>		<b>Score</b>
Severe	06	<b>2.5 Restriction of joint movement</b>	
Moderate	04	Fully restricted	06
Mild	02	Partially restricted	03
Nil	00	Not restricted	00
<b>1.2. Pain on rest</b>		<b>2.6 Subcutaneous nodule</b>	
Severe	09	Present	02
Moderate	06	Nil	00
Mild	03	<b>2.7 Functional Status</b>	
Nil	00	Grade	06
<b>2. Objective</b>		Grade	04
<b>2.1 Pain in motion</b>		Grade	02
Severe	09	Grade	00
Moderate	06	<b>2.8 Fever</b>	
Mild	03	Present	02
Nil	00	Absent	00
<b>2.2. Swelling</b>		<b>2.9 Elevated E.S.R. (first hour)</b>	
Severe	15	71mm or more	06
Moderate	10	41 mm -70 mm	04
Mild	05	20 mm - 40 mm	02
Nil	00	> - 20 mm	00
<b>2.3 Tenderness</b>		<b>3.0 Digestive impairment</b>	
G1	20	<b>3.1 Constipation</b>	
G2	15	Regularly	03
G 3	10	Frequently	02
G4	05	Occasionally	01
Nil	00	Nil	00
<b>2.4 Muscle power</b>		<b>3.2 Loss of appetite</b>	
G0	10	Appetite lost	02
G1	08	Appetite	01
G2	06	Normal	00
G 3	04	<b>3.3 Anorexia</b>	
G4	02	No inclination for food	02
Nil	00	Lesser inclination for food	01
		No anorexia	00
		<b>3.4 Loose motions</b>	
		Present	02
		Absent	00

**Table 1: Criteria for diagnosis and evaluation of response of therapy**

<b>A. Good response</b>	1. Presenting symptomatology of the disease as mentioned in the criteria for assessment.
	2. Laboratory parameters inclined towards normalcy.
<b>B. Fair response</b>	1. 50% and above relief in presenting clinical symptomatology of the disease as per criteria of assessment.
	2. 25% and above relief in presenting clinical symptomatology of the disease as per criteria of assessment.
	3. Significant improvement in laboratory parameters.
	4. Significant improvement in laboratory parameters
<b>C. No response</b>	1. No relief in symptomatology or otherwise
<b>D. Dropouts/LAMA Left against medical advice</b>	1. Willful discontinuation of the treatment during the trial.
	2. Development of any serious complication.
	3. Aggravation of the disease.
	4. Any pronounced toxicity of the drug.

**Table 2 Classification of results**

### **Ayurvedic Modus Operandi of Clinical Analysis**

An effort was also made to analyze the pharmacodynamic principles of different ingredients of the formulations which was used in the combination of Maha yogaraj Guggulu, Vaiswanar churna and Simhanada Guggulu. The analysis on the presence of Rasa revealed that these 35 drugs have 62 constituents. Rasas out of which Katurasa dominates with 23(27.9%) followed by Tiktarasa being 16 (25.80%) and Kasayarasa being 10 (16.12%) 4(6.45%) and 3(4.83%) This indicates that this combination may render destruction of Ama and promote Deepama of Agni. The combination of drugs possesses 89 constituent Gunas out of which Laghu Guna dominates with 25 (28.08%) followed by Ruksha being 17 (19.10%) which are contradictory to the properties of ama and kapha The properties like snigdha being 16.85% is also significant of alleviation of vata. Next to these lies Tikshna Guna being

11.23% which is likely to act as srotasodhan. Other properties like Guru sita ushma sara sukshma and Pichhila also co exist to lesser extent. The distribution of virya as happened in these 35 drugs are 35 in total. Out of which Ushma virya is predominant being 68.57% followed by Sita being 22.85% while Anushnasita was 8.57% this model seems to be potent for Ama vata and kaphanasak and likely to alleviate the pain, improve the circulation and reduce the stiffness of the joints by absorbing accumulated tissue fluid. The vipaka of these 35 drugs also exist in a typical proportion as katu being 51.42% is likely to counteract the features of ama while madhura being 48.58% is the ideal end product of the drugs responsible for alleviation of vata. The individual Dosis action of the drugs occur in the proportion of Vatahara 59.61% followed by kaphakara as 34.06% while pittahara action was only 5.76% as such this makes a significant model for reversal of the disease process attributed

to Ama and vata. The other individual actions of the drugs as enumerated in the compendiums of Ayurvedic Materia Medica are 38 in total out of which Dipana accounts 28.94% followed by Vedanaamak /Sulahara 23.68 pachana and sothahara action both

account for 18.42% while Amahara happens to be only 26.3% of proportion This model further corroborates the adaptability of this combination as both Hetuviparat and vyadhiviparia in case of aamvata.

Results	Male	Female	Total
Good response	18	21	39 (27.85%)
Fair response	13	17	30 (21.42%)
Poor response	06	09	15 (10.71%)
No response	02	01	03 (2.14%)
Drop out	28	25	53 (37.85%)

**Table 3. Results in relation to sex**

Results	Age groups ( in years )						Total
	11-20	21-30	31-40	41-50	51-60	61 & above	
Good response	08	07	08	10	05	01	39 (27.85%)
Fair response	06	04	05	04	10	01	30 (21.42%)
Poor response	01	04	05	01	02	02	15 (10.71%)
No response	02	0	0	0	01	0	03(2.14%)
Drop out	07	14	12	12	03	05	53 (37.85%)

**Table 4. Results in relation to age group**

Results	Chronicity (in days)					Total
	0-365	366-730	731-1095	1096-1460	1461-above	
Good response	21	08	06	03	01	39 (27.85%)
Fair response	17	03	05	02	03	30 (21.42%)
Poor response	07	03	02	0	03	15 (10.71%)
No response	02	0	01	0	0	03(2.14%)
Drop out	20	07	04	01	11	53 (37.85%)

**Table 5. Results in relation to chronicity**

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