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A Clinical Study To Evaluate The Effect of *Amritadi Churna* On *Amavata* w.s.r. To Rheumatoid Arthritis.

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ABSTRACT: -

Rheumatoid Arthritis is an enigmatic disease. Its historical background is not known. But in the recent years the disease has been extensively probed by development in immunology, biochemistry and radiology. Ayurvedic physicians have also benefited from these new medical advances. RA is often considered a benign disease, but it may cause considerable disability, crippling, and death. Patients sometimes recover spontaneously and achieve complete remission but, in most cases, the disease becomes chronic, resulting in functional deterioration of the joints and disability. There has been extensive scientific research in Ayurvedic therapies during recent years. The present study is intended to focus on the clinical evaluation of an herbal preparation *Amritadi churna* quoted by Acharya Chakrapani in Chakradatta in the management of *Amavata* (Rheumatoid Arthritis). The results were quiet promising for futuristic studies with other herbal preparations.

KEYWORDS: Amavata, Rheumatoid Arthritis, Amritadi Churna, Functional Assessment.



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INTRODUCTION

Amavata is portrayed in Ayurveda as a joint disorder clinically manifesting as inflamed, painful and stiff ankle, knee, hip, wrist, elbow, and shoulder joints. The symptoms of Amavata (Rheumatoid Arthritis) are compared with Rheumatoid Arthritis (RA) in conventional medicine. The incidence of Rheumatoid Arthritis ranges from 0.3 to 2.1% in most populations of the world and the rate is much higher in females than in males. The prevalence increases with age and sex difference diminishes in the older age group. It is seen throughout the world and affects all races. The peak incidence of onset of RA is in persons 30 to 60 years old, but no age is immune actually. The severity of Rheumatoid Arthritis varies from mild oligo-articular disease of short duration and nominal or no joint damage to poly-arthritis noticeable functional with impairment. The causes Amayata of (Rheumatoid Arthritis) are incompatible diet, poor digestion, and sedentary habits¹. Impaired digestion due to feeble *Agni* (digestive power) contributes to the formation of Ama in the intestine which further reaches to all parts of the body. RA is generally treated with Nonsteroidal Anti Inflammatory drugs (NSAIDs). These drugs do not modify disease progression². They have a tendency to cause adverse effects in gastrointestinal system ranging from mild dyspepsia and heartburn to ulceration of the stomach and duodenum, and many produce fatal consequences. In one survey, 27% of the patients suffering from arthritis in the U.S.A. had used complementary alternative medicine therapies (CAM)³. In a survey in India, 43% had used CAM therapies⁴. modifying therapies. such Disease methotrexate, leflunomide, sulfasalazine, gold salts, penicillamine, azathropine, cyclophosphamide, and chlorambucil, are used to modify the course of the disease but have serious toxic effects. These toxic effects include aplastic anemia (potentially life threatening), liver toxicity, gastrointestinal toxicity, leucopenia and skin rashes. Considering all the above, an attempt has been made to evaluate the efficacy of an Ayurvedic herbal formulation *Amritadi churna* in the patients of *Amavata*.

MATERIAL & METHODS

Selection of Patients

30 patients of *Amavata* fulfilling the criteria of diagnosis were registered from the OPD of GAMC& Hospital, Jammu irrespective of their sex and religion. Out of these patients, 2 patients left the treatment before the completion of the course. Remaining 28 patients completed the full course. Patients were treated for known symptoms of *Amavata* with the selected drugs for 45 days as per International conference of Harmonization-Good Clinical Practices Guidelines (ICH-GCP).

Inclusion criteria

- 1. Subjects having classical signs and symptoms of *Amavata* between the age group of 15-60 years were considered for the present study.
- 2. Patients fulfilling the criteria laid down by the American Rheumatism Association (ARA) were selected and registered.

Exclusion Criteria

- 1. Chronicity less than 6 weeks and more than 10 years.
- 2. The patients who had deformities like ulnar deviation, swan neck deformities, ankylosis of wrist & elbow etc.
- 3. Patients with other systematic diseases like Diabetes Mellitus, Hypertension.
- 4. Pregnant and lactating women.

DIAGNOSTIC CRITERIA

A special Performa was prepared

incorporating all the signs and symptoms based on both Ayurvedic as well as Modern descriptions. All the points in the perspective of Dosha, Dusya, Srotasa and Agni on Ayurvedic line were also included in the Performa. A detailed clinical history was taken initially and complete physical examination of each patient was carried out on the basis of Performa. RA factor test, Haemogram, ESR, urine and biochemical investigation like serum uric acid, serum cholesterol, blood sugar level, total proteins and albumin globulin ratio were carried out in all the patients. In addition, the criteria laid down by American Rheumatism Association 1988 for the Diagnosis of the Disease was also followed for the confirmation of Rheumatoid arthritis, which is as follows:-

- 1. Morning stiffness lasting for more than one hour.
- 2. Arthritis of three or more joints
- 3. Arthritis of hand joints
- 4. Symmetrical arthritis

- 5. Presence of rheumatoid nodules
- 6. Presence of Rheumatoid factor
- 7. Radiological changes such as particular osteoporosis, loss of articular cartilage or erosion.

CRITERIA FOR ASSESSMENT

The results of the therapy were assessed on the basis of classical signs and symptoms described in Ayurveda and mentioned by ARA 1988. Functional capacity of the patients was evaluated along with laboratory investigations. The details of assessment criteria are mentioned below:

CLINICAL ASSESSMENT

The indoor patients were examined daily and the outdoor patients were assessed weekly, and changes observed in the signs and symptoms were assessed by adopting suitable scoring method and the objective signs by using appropriate clinical tools.

The details of scoring pattern adopted for assessment of clinical signs and symptoms is as follows:

[1] Pain in joint

Signs & symptoms	Score				
No pain	0				
Mild pain of bearable nature, comes occasionally	1				
Moderate pain, but no difficulty in joint movement, appears frequently	2				
and requires some <i>Upasaya</i> measures for relief					
Slight difficulty in joint movements due to pain or severe pain,					
requires medication and may remain throughout the day					
More difficulty in moving the joints and pain is severe, disturbing sleep					
and requires strong analgesics					

[2] Swelling of the joint

Signs & symptoms	Score
No swelling	0
Slight swelling	1
Moderate swelling	2
Severe swelling	3

[3] Stiffness of the joints

Signs & symptoms				
No stiffness or stiffness lasting for 5 min	0			
Stiffness lasting for 5 min to 2 hrs.	1			
Stiffness lasting for 2 to 8 hrs	2			
Stiffness lasting for more than 8 hrs	3			

[4] Tenderness of joints

Signs & symptoms	Score
No tenderness	0
Subjective experience of tenderness	1
Wincing of face on pressure	2
Wincing of face with withdrawal of affected parts on pressure	3
Resists to touch	4

[5] Redness of joints

Signs & symptoms	Score
Redness observed before treatment	2
Reduction in redness after treatment	1
No redness	0
No change after treatment	2

[6] Warmth of joint

The temperature of the joint surface was measured using the digital skin temperature measuring instrument. The temperature was compared with the normal body surface. The rise in the temperature of joint surface was scored as follows:

Signs & symptoms	Score
Raised temperature when compared to the normal body surface	2
Fall in local warmth	1
Normal temperature	0
No change after treatment	2

[7] Knuckle swelling: To measure the knuckle swelling, jeweler's rings were used. In this method the rings were tried starting from the highest number and the number of the ring which passes through the knuckle easily with least resistance was noted. Any change in the number of ring after the treatment was recorded.

[8] Muscle wasting:

To have an objective view of muscle wasting, the circumference of arm, forearm, thigh and leg were measured using a measuring tape both before and after the treatment. The circumferences were taken at the midpoint of these parts.

9) General symptoms of Amavata like Agnimandya (low digestive power), Aruchi (Anorexia), Apaka (Indigestion), Angamarda (Body ache), Trisna (thirsty), Gaurava (heaviness), Alasya (laziness), Jvara (fever), Praseka (salivation), Utsahahani,

Asyavairasya, Daha (burning sensation), Bahumutrata (Polyurea), Kuksikathinya, Kuksisula (Abdominal pain), Nidraviparyaya, Chardi (vomiting), Bhrama (confusion),

Murcha (syncope Hrtgaurava, Vidvibandha (constipation), Amatisara, Antrakuja, Anaha, Daurbalya (debility), Klama and Siroruja (headache) were scored as mentioned below:

Signs & symptoms				
Symptom observed before treatment	2			
Mild relief after treatment	1			
Complete relief after treatment	0			
No improvement after treatment	2			

FUNCTIONAL ASSESSMENT:

Following periodical functional tests were performed to assess the improvement of *Amavata* (RA) patients.

- [1] Walking time: The patients were requested to walk a distance of 25 feet and the time thus taken was noted before and after the intervention.
- [2] **Grip Strength:** The patient's capacity to squeeze an inflated ordinary sphygmomanometer cuff was recorded before

and after the intervention.

- [3] Foot pressure: To evaluate the functional capacity of the legs, foot pressure was recorded by the ability of the patients to press a weighing machine.
- [4] **Joint movement:** The range of movement of each affected joint was measured by using the goniometry both before and after the treatment.
- [5] General functional capacity:

Signs & symptoms	Score
Complete ability to carry on all routine duties without handicap	0
Adequate normal activity despite slight difficulty in joint movement	1
Few activities are persisting but patient can take care of himself	2
Few activities are persisting and patient requires an attendant to take care of himself	3
Patients is totally bed ridden	4

(III) INVESTIGATIONS:

- [1] Rheumatoid factor: The serum of the patients was tested for rheumatoid factor as an aid to diagnosis and to assess the severity of the disease activity. The method adopted for this purpose was that of latex agglutination test.
- [2] Hematological Investigation: The routine hematological examination of blood was carried out which included total leukocyte count, differential count, hemoglobin percent, packed cell volume and erythrocyte sedimentation rate. The method employed for the ESR rate was Wintrobe's corrected method.
- [3] Urine Examination: Routine U/E was carried out to detect to exclude the UTI conditions like gonorrhea etc.
- [4] Stool analysis: Routine stool examination was undertaken to detect any presence of mucus ova, cyst etc. Investigations
- [5] Biochemical investigations: In the biochemical investigations serum cholesterol and serum uric acid were carried out.

CLINICAL STUDY

Trial type

Prospective Open Clinical trial

Sample size:

Total 30 patients were registered fulfilling all the inclusion criteria.

Source of data

Patients from OPD and IPD of, GAMC & Hospital, Jammu fulfilling the criteria were selected for this study.

Method of preparation of drug:

The drug was selected from the Ayurvedic texts namely *Amritadi Churna*⁵. The combination having five drugs namely *Amrita (Tinosporia cordifolia)* stem, *Shunthi (Zingiber officinalis)* rhizome, *Gokshura (Tribulus terrestris)* whole plant, *Mundi (Sphaeranthus indicus)* whole plant and *Varuna (Crataeva nurvala)* bark and leaves. All five drugs were taken in equal quantity. The drugs were grounded and a fine powder was prepared.

Posology:

The patients were advised to take 5 g of *Amritadi churna* B.D. with lukewarm water.

Duration of treatment - 45 days.

Overall Assessment Of The Therapy:

To assess the overall effect of the therapies, the criteria laid down by ARA was adopted.

OBSERVATIONS AND RESULTS

Statistical analysis was done for subjective and objective parameters before treatment, after treatment, and Follow up. Analysis was done by calculating Mean, Standard Deviation (S.D.), Standard Error (S.E), t-value and p-Value at 0.001 levels.

Table 1: Effect of Amritadi churna on cardinal features of Amvata

Signs & Symptoms	Mean		Mean %	S.D.	S.E.	't	ʻp'	Significance
	B.T.	A.T.						
Sandhishula (Joint pain)	2.51	0.86	65.73	0.36	0.09	16.72	< 0.001	Highly
								significant
Sandhishotha (Swelling)	1.73	0.60	65.31	0.32	0.08	12.82	< 0.001	Highly
		. 3						significant
Stabdhata (Morning	1.67	0.37	77.84	0.48	0.13	10.00	< 0.001	Highly
stiffness)					400			significant
Sparshashatva	2.39	0.80	66.52	0.42	0.11	13.95	< 0.001	Highly
(tenderness)								significant
Warmth	0.30	0.00	100.0	0.71	0.19	1.37	>0.10	Insignificant
Redness	0.40	0.00	100.0	0.89	0.29	1.64	>0.10	Insignificant

Effect on General symptoms of Amavata

In this group 100% relief was observed in the symptoms like *Anaha*, *Antrakunjana*, *Hrillasa*, *Jvara*, *Jadya* and *Kukshishula*. 90% improvement was seen in *Asyavairsaya*, *Bhrama* and *Hritgaurava*, 87.5% in *Aruchi* and *Apaka*, 85% in *Alasya* 83.5% in *Angashunyata* and *Khanja*, 81.5% in *Asthibheda*, 80% in *Agnimandya* and *Daha*, 77.5% in *Gaurava*,

72.5% in *Angamarda*, 62.5% in *Dourbalaya*, 50% in *Angavaikalya* 40% in *Mamsakshaya* and *Vibandha* and no relief was observed in *Angashosha* and *Bahumutrata*.

Table 2: Effect of Amritadi churna on the circumference of the limbs in patients of Amavata

Circumference (in cms)	Mean		Mean %	S.D.	S.E.	' t	ʻp'	Significance
	B.T.	A.T.						
Arm	25.00	25.19	0.76	0.25	0.06	2.85	>0.10	
								Insignificant
Fore arm	25.12	25.20	0.32	0.14	0.03	2.28	< 0.05	Significant
Thigh	33.91	34.13	0.64	0.22	0.06	3.66	< 0.01	Significant
Calf	31.03	31.13	0.32	0.07	0.02	2.76	< 0.05	Significant

Table 3: Effect of Amritadi Churna on functional parameters in patients of Amavata

Functional Parameter	ctional Parameter Mean Mean % S.D. S.E.		S.E.	't	ʻp'	Significance		
	B.T.	A.T.						
Range of movement	88.33	91.54	11.18	7.56	1.29	4.28	< 0.001	Highly
(in degrees)		-						significant
Foot Pressure in (Kgm)	22.42	24.85	10.83	1.65	0.44	5.50	< 0.001	Highly
		0.00			T 40.			significant
Hand grip (in mm of Hg)	87.57	98.78	12.80	12.31	3.29	3.40	< 0.01	Highly
	400							significant
Walking time (in seconds)	27.42	22.85	16.66	2.87	0.76	5.95	< 0.001	Highly
		1						significant
General Functional	2.3	1.2	47.8	0.83	0.27	4.02	< 0.01	Significant
Capacity								

Table 4: Over all effect of Amritadi churna on patients of Amavata

Result	Number of patients	Percentage Improvement
Complete Remission	- 11	/
Major Improvement	16	57.14
Minor Improvement	10	35.71
Unimproved	02	7.14

DISCUSSION

Ama is the prime causative factor in of (RA). pathogenesis Amavata (undigested food) is the produced due to diminution of Jatharagni as Dhatavagni. In this combination five drugs (except Gokshuru) possess Ushana Virya (Hot) property and 4 are Katu (Bitter) and Tikta (Pungent)in Rasa. By virtue of these properties, the Agni rekindles alleviating Mandagni. This checks further production of Ama at root level. Moreover, these properties promote digestion of Ama. So the trial drug by virtue of its properties might have improved Agni, checked Ama production and helped in digestion of existing Ama. The second causative factor was Vata. Though vitiation of all the Doshas is there but vitiation of Vata plays the leading role in Amavata. All the drugs of the combination are Vata and Kapha Shamaka as well. Guduchi is Tridoshahara, and four of them possess Snigdha guna and three Madhura Rasa (sweet essence) while the five are of Ushana Virya (hot) in nature. These all properties might have pacified Vata and brought it to normal position. In this combination Gokshuru & Varuna are Shothaghna (anti-inflammatory) and Guduchi & Varuna have Vedana shamaka (analgesic) property. So, the combination was effective to relieve the pain and swelling, which were the

chief complaints of the patients.

CONCLUSION

The trial drug in this study was a very good combination of Shoolaghana (analgesic), (anti-inflammatory) Shothaghna and Amapachaka (Ama eliminator) Dravyas. Guduchi and Shunthi with their Rasayana property, not only cured the disease but also improved the immunity (Vyadhikshamatava) of patients. Shunthi due to the its Deepana(appetizer) and Pachana Guna (digestive) not only improved the Mandagni but also helped in Ama Pachana. No untoward effect was seen in the patients during the treatment. On the basis of observations of the studies, internal administration of Amritadi Churna may be recommended for the management of Amavata along with other potent drugs and Panchkarma interventions for better results.

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