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A CLINICAL TRIAL ON THE THERAPEUTIC EFFECT OF *AMRITAMANJARI RASA* IN *AMAVATA* W.S.R. TO RHEUMATOID ARTHRITIS

Dr. GauthamPandit[1], Dr. Tony Thomas[2], Dr. ShrilathaKamath.T[3], Dr. G. ShrinivasaAcharya[4]

[1]Final year P.G. scholar,

[3]Associate professor, [4]Professor and Head, Department of P.G. studies in Kayachikitsa, S.D.M.C.A., Udupi, Karnataka, India

[2]Clinical practitioner,Cherupushpam Ayurveda clinic, Koothrappally, Kottayam, Kerala, India

ABSTRACT

Background: *Amavata* is a disease which is mentioned as a *krichchrasadhya vyadhi* in Ayurveda. It presents mainly with symptoms like joint pain, swelling, warmth and stiffness, greatly affecting the quality of life of a person and crippling him or her ultimately. It can be compared with the Rhumatoid arthritis mentioned in the modern medical science and their treatment principles mainly include the use of steroids and non-steroidal anti-inflammatory drugs. These drugs cause serious adverse effects on prolonged usage. Ayurveda promises a therapeutic outcome and this present study was aimed at evaluating the therapeutic efficacy of *Amritamanjari Rasa* in patients suffering from *Amavata*/Rheumatoid Arthritis. **Methods:** The 15 participants suffering from *Amavata*/Rheumatoid Arthritis included in the study were selected from SDM Ayurveda Hospital, Udupi, during the period November 2014 to March 2015. The parameters pain, swelling, stiffness of the joints, tenderness, warmth, general function, walking, hand grip, foot pressure, ring test, range of movement, ESR were assessed. They were administered with *Amritamanjari Rasa* 125 mg tab tid with *Anupana – ArdrakaSvarasa* (5 ml) for a period of 14 days. The response of the intervention was assessed on day 0, day 7, day 14, day 21 and day 28 with the scoring pattern and the results were analysed statistically using paired‘t’ test. **Results:** The parameter of Pain, Swelling, Stiffness, Tenderness, Warmth, Foot pressure, Range of movement and ESR showed highly significant results and the results seen in the parameters of General functions, Walking test, Grip test and Ring test were significant. **Conclusion:** The study on *Amritamanjari Rasa* was found to be efficacious in relieving the cardinal symptoms and general symptoms of *Amavata* and improvement in functional ability of the patients.

Keywords: *Amavata*, Rheumatoid Arthritis, *Amritamanjari Rasa*.

INTRODUCTION

The main objectives of human pursuit are *Dharma* (discharge of duty), *Artha* (acquirement of wealth), *Kama* (gratification of desire) and these three are further responsible for the ultimate salvation, *Moksha*. And as our literatures postulate above

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said objectives are fulfilled solely depending upon the *Ayu* (health) and the *Shastra* (science) responsible for its maintenance is called *Ayurveda*. *Ayurveda* the science of life is so called because it is the one which highlights *Hita* and *Ahita* i.e. things to be done and the one to be avoided and thus maintaining harmony between the body, mind and soul combination of which is called as *Ayu*. Further this concept of *Ahita* is the reason for various diseases one among them being *Amavata*[1].

Amavata is a condition which presents with the symptoms like pain, swelling, stiffness and loss of function of the affected joints.It is due to the formation of *Ama* which gets associated with the *dosha* forming *Sama* state and gets mobilized by *VataDosha*. It later enters the *KaphaSthana*and produces the disease. Its clinical presentation resembles with the condition Rheumatoid Arthritis (RA)[2].

Rheumatoid arthritis (RA) is a chronic systemic inflammatory polyarthritis that primarily affects small arthrodial joints of the hands and feet in a symmetrical pattern. It is a heterogeneous disease with variable severity, unpredictable course and a variable response to drug treatment. The disease prevalence worldwide is approximately 0.8 %(0.3% to 2.1%) of the total population. In India, the prevalence of RA is 0.5% to 0.75%. More than 75% patients develop the disease between the age group of 30yrs and 50 yrs. Women are found to be affected with RA 2 to 4 times more often than men[3].

Ayurveda explains two important treatment modalities *Shamana* (oral and topical applications) and *Shodhana* (eliminative therapies) in the treatment of *Amavata*. Among the different oral formulations referred, *Amritamanjari Rasa* has been selected with an intention of evaluating its therapeutic efficacy on *Amavata*.

MATERIALS AND METHODS

The selection of the study sample was done from the OPD and IPD of SDM college of Ayurveda by the method of random sampling. The subjects fulfilling the inclusion criteria and diagnostic criteria were included on the basis of the symptoms of *Amavata* they presentedwith. They were subjected to complete history taking and physical examination according to the detailed proforma prepared. All the subjective and objective parameters were scored and assessed. The written consent was obtained from the study subjects.

They were administered *Amritamanjari rasa* in a dose of 125 mg TID with the *anupana* of *ShuntiKashaya* for the duration of 14 days. The follow up was taken on Day 0, Day 7, Day 14, Day 21, Day 28 with the scoring pattern and the results were analyzed statistically using paired‘t’ test.

Diagnostic criteria:

Patients were diagnosed on the basis of signs and symptoms of *Amavata* and the criteria as approved by ARA, 1987 revision such as Morning stiffness*(*Stabdata*) (>1hour), Arthritis of three or more joints*(*Shoola* and *Shotha* in three or more joints), Arthritis of hand joints*, Symmetrical arthritis*, Rheumatoid nodules, Rheumatoid factor, Radiological changes.

* Duration of 6 weeks or more. N.B. Diagnosis of R.A. made with four or more criteria.

Inclusion Criteria:

1. Patients presenting with signs and symptoms of *Amavata* like *Sandhi Shoola, Sandhi Shotha* and *Stabdatha.*
2. Patients diagnosed as Rheumatoid Arthritis, fulfilling the 1987 ACR revised criteria for diagnosis.

3. Patients between the ages of 16 to 70 years.

Exclusion Criteria:

1. All connective tissue disorders other than Rheumatoid Arthritis.
2. Systemic Lupus Erythematosus.
3. Any other systemic disorders like diabetic mellitus.

Subjective Parameters:

Pain, Swelling and Stiffness of the joints

Objective Parameters:

Tenderness, Warmth, General functional capacity, Walking test, Hand grip test, Foot pressure, Ring test, Range of movement and ESR

The grading of the subjective and objective parameters are specified in the table no 1.

RESULTS

In this study on Rheumatoid Arthritis the selected patients were assessed for the parameters like Pain, Swelling, Morning stiffness, Tenderness, Warmth and functional abilities like time required for walking 30 meters, General function test, Grip test, Foot pressure, Ring test and Range of movement. The results of study, on each parameter were analysed statistically calculating the mean, standard- deviation, standard errors and 'p' values by using the paired't' test. The regular follow ups were taken every week and the mean scores were taken and compared.

In the parameter of pain the mean score before treatment was 1.494 which got reduced to 0.936 after treatment with mean difference of 0.558. The mean score after the completion of the study was 0.95 i.e., on 28th day. In the parameter of swelling the mean score before treatment was 1.038 which got reduced to 0.698 after treatment with mean difference of 0.340. The mean score after the completion of the study was 0.72 i.e., on 28th day. In the parameter of stiffness the mean score before treatment was 0.597 which got reduced to 0.467 after treatment with mean difference of 0.130. The mean score after the completion of the study was 0.46 i.e., on 28th day.

In the parameter of warmth the mean score before treatment was 0.340 which got reduced to 0.172 after treatment with mean difference of 0.168. The mean score after the completion of the study was 0.18 i.e., on 28th day. In the parameter of general function, the mean score before treatment was 1.333 which got reduced to 1.200 after treatment with mean difference of 0.133. The mean score after the completion of the study was 1.26 i.e., on 28th day. In the parameter of walking test the mean score before treatment was 3.000 which got reduced to 2.533 after treatment with mean difference of 0.467. The mean score after the completion of the study was 2.6 i.e., on 28th day. In the parameter of hand grip the mean score before treatment was 1.733 which got reduced to 1.533 after treatment with mean difference of 0.200. The mean score after the completion of the study was 1.6 i.e., on 28th day. In the parameter of foot pressure the mean score before treatment was 28.167 which got improved to 31.000 after treatment with mean difference of 2.833. The mean score after the completion of the study was 30.6 i.e., on 28th day. In the parameter of ring test the mean score before treatment was 17.920 which got reduced to 15.993 after treatment with mean difference of 1.927. The mean score after the completion of the study was 16.05 i.e., on 28th day. In the parameter of range of movement the mean score before treatment was 22.391 which got improved to 26.768 after treatments with mean difference of 4.377. The mean score after the completion of the study was 26.36 i.e., on 28th day. In the parameter of ESR the mean score before treatment was

70.467 which got reduced to 59.200 on the 28th day with mean difference of 11.267.

In the subjective parameters like pain, swelling and stiffness in the joints when compared before and after treatment showed statistically significant difference with P<0.001. Likewise objective parameters like tenderness, warmth, foot pressure, range of movement and ESR showed good improvement with statistically significant difference of P<0.001 and the grip test with a difference of P=0.012. Other parameters like general functional capacity, walking test and ring test had a difference in mean values before treatment and after treatment without any statistically significant difference. The results observed in all the parameters assessed are tabulated in the table no 2 and the weekly assessment of the parameters are diagrammatically represented in the diagram no 1, 2 and 3.

OVERALL EFFECT OF THE TREATMENT

Among the 15 patients studied, 1 patient (6.66 %) showed major improvement with > 75 % improvement, 2 patients (13.33 %) showed moderate improvement with 50-75 % improvement, 8 patients (53.3 %) showed minor improvement with 25-49 % improvement and 4 patients (26.6 %) were left with no improvement i.e., < 25 % improvement. The overall effect of the treatments are represented in table no 3.

PROBABLE MODE OF ACTION OF *AMRITAMANJARI RASA*:

Amritamanjari Rasa was administered in a dosage of 125mg tid with *Anupana* of 5ml *Ardraka svarasa. Amritamanjari Rasa* consist of drugs which are in general *Kapha Vata Shamaka* thus efficacious in alleviating the major *Dosha* involved in *Amavata*, and it is indicated in *Jvara, Shoola, Agnimandya, Aruchi, Ajirna, Adhmana, Chardi* etc. which are also seen as clinical features of *Amavata*. The formulation consists of *Hingula* which has *deepana-pachana* properties helpful in the *amapachana* and *rasayana* properties helpful in tissue rejuvenation. The *shudda Vatsanabha* contains *Aconitine, Bikhaconitine* and *Indaconitine* which all possess analgesic, anti-inflammatory and antipyretic qualities beneficial in reducing the joint pain. The *Pyperine, Piperonal* has carminative properties beneficial in improving the digestion. The ginger is being studied to know its anti-arthritic and anti-emetic properties. The *Jathiphala* contains *Myristicin* and *Myristin* which has an anti-inflammatory property again beneficial in relieving pain and inflammation. The lemon acid present in *Jambira* which once digested provides an alkaline effect within the body and is found useful in conditions where acidity is a contributory factor as in case of rheumatic conditions. *ShuntiSvarasa* which is given as *Anupana*, is *VataKaphaShamaka, Shothahara* and is indicated in *Amavata, Vatavyadhi, Ajirna* etc. which shows it as equally effective to counteract *Amavata*. It consists of chemical constituents like Gingerol, Zingiberol, Zingerone and Shogaol which can suppress gastric contractions. Both fresh and dried rhizomes suppress gastric secretion and reduce vomiting. They also possess sedative activity thus relieving the stress and anxiety building in the patients due to the disease and anti-inflammatory, antipyretic and analgesic activities relieving the pain, swelling and stiffness. Thus it is quiet effective in *Nidraviparyaya, Sandi Shoola, SandiShotha*. Apart from all the above mentioned qualities the commonest qualities which all the drugs of the *Amritamanjari rasa* possesses is the *agnideepaka* quality which could have had a major role to play in relieving the symptoms of

Amavata as the *ama* is the main culprit in this disease process[4].

CONCLUSION

Ama and *Vata* are the chief factors responsible for *Amavata* in association with the involvement of *Dhatu* and it is a disease observed to occur after the 3rd decade of life, but none of the age groups are exempted. The prevalence rates are more common in females, that too in housewives. The disease is most common in the age group between 41-70 years, with *Vata Kapha Prakruti*. The occupation, diet, and dietary habits are seen to have a major role to play in the disease pathogenesis. *SandhiShoola, SandhiShotha, Stabdatha*, were the cardinal symptoms observed in *Amavata* in association with the symptoms like *Angamarda, Gaurava, Agnimandya* and *Aruchi.* The clinical presentation of *Amavata* matches with that of Rheumatoid Arthritis.

The treatment with *Amritamanjari Rasa* showed better results in the remission of the cardinal symptoms, most of the associated symptoms and over the objective criteria's. The improvement observed by the medication is definite as proved by tests of statistical significance. The treatment has been found to be effective and equally safe without any adverse effects. Repetition and continuation of the regimen for a longer duration is advisable as the illness has a chronic course.

TABLES AND DIAGRAMS

Table no 1:Showing the grading and scoring of the parameters.

PARAMETERS	GRADING	SCORES
Joint pain	No pain	0
	Mild pain	1
	Moderate pain	2
	Severe pain	3
Joint stiffness	Stiffness lasting for 0-5 min	0
	Stiffness lasting for 5 min-2 hrs	1
	Stiffness lasting for 2 hrs-8 hrs	2
	Stiffness lasting for more than 8 hrs	3
Swelling	Absent	0
	Mild	1
	Moderate	2
	Severe	3
Warmth	Absent	0
	Mild	1
	Moderate	2
	Severe	3
Tenderness	No tenderness	0
	Says tender	1
	Patient winces	2
	Winces and withdraws	3

	Not allowed to be touched	4
General functional capacity	Complete ability to carry on all usual duties without handicap	0
	Adequate normal activity de-spite handicap of discomfort or limited joint movement	1
	Limited only to little or none of the usual occupation or self-care	2
	Bedridden or confined to wheel chair, little or no self-care	3
Range of movement	Calculated by using a goniometer	
Foot pressure	Calculated by the ability of the patient to press a weighing machine	
Grip strength	Calculated by the patient's ability to compress the inflated ordinary sphygmomanometer cuff under standard conditions	
Knuckle swelling	Calculated with the help of a jewellers ring by noting the ring number which passes through the knuckle with least resis-tance. Any change in the number of ring after treatment was noted.	
Walking test	Time taken to walk a distance of 30 meters.	

Table no 2: Showing the effects of the treatment.

Parameter	**Mean**		**Difference in means**	**Paired 't' test**			
	BT	**AT**		**S.D**	**S.E.M**	**'t'**	**P**
Pain	1.494	0.936	0.558	0.751	0.0413	13.493	<0.001
Swelling	1.038	0.698	0.340	0.561	0.0316	10.756	<0.001
Stiffness	0.597	0.467	0.130	0.337	0.0186	7.021	<0.001
Tenderness	1.015	0.630	0.385	0.689	0.0379	10.149	<0.001
Warmth	0.340	0.172	0.168	0.530	0.0314	5.360	<0.001
General func-tions	1.333	1.200	0.133	0.352	0.0909	1.468	=0.164
Walking test	3.000	2.533	0.467	1.356	0.000	0.350	=0.204
Grip test	1.733	1.533	0.200	0.407	0.0743	2.693	=0.012
Foot pressure	28.167	31.000	2.833	3.640	0.665	4.264	<0.001
Ring test	17.920	15.993	1.927	12.670	1.034	1.862	=0.065
Range of movement	22.391	26.768	4.377	16.512	0.889	4.923	<0.001
ESR	70.467	59.200	11.267	9.231	2.383	4.727	<0.001

Table no 3: Showing the overall effect of the treatments.

Treatment effect	Number of patients	Percentage
Major improvement (>75%)	1	6.66%
Moderate improvement (50-74%)	2	13.33%
Minor improvement (25-49%)	8	53.3%
No improvement (<25%)	4	26.6%

Diagram no 1: Showing the changes in subjective parameters before treatment and during follow up.

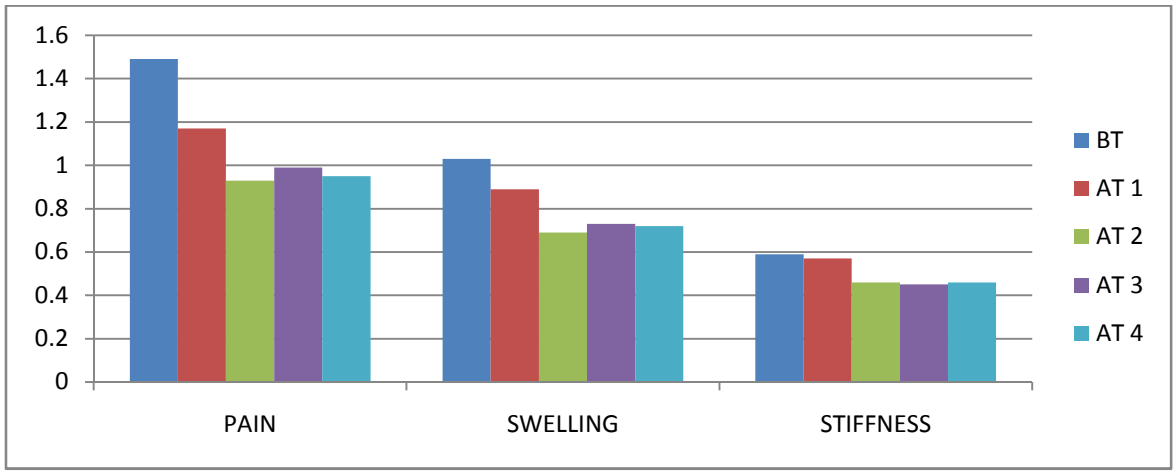
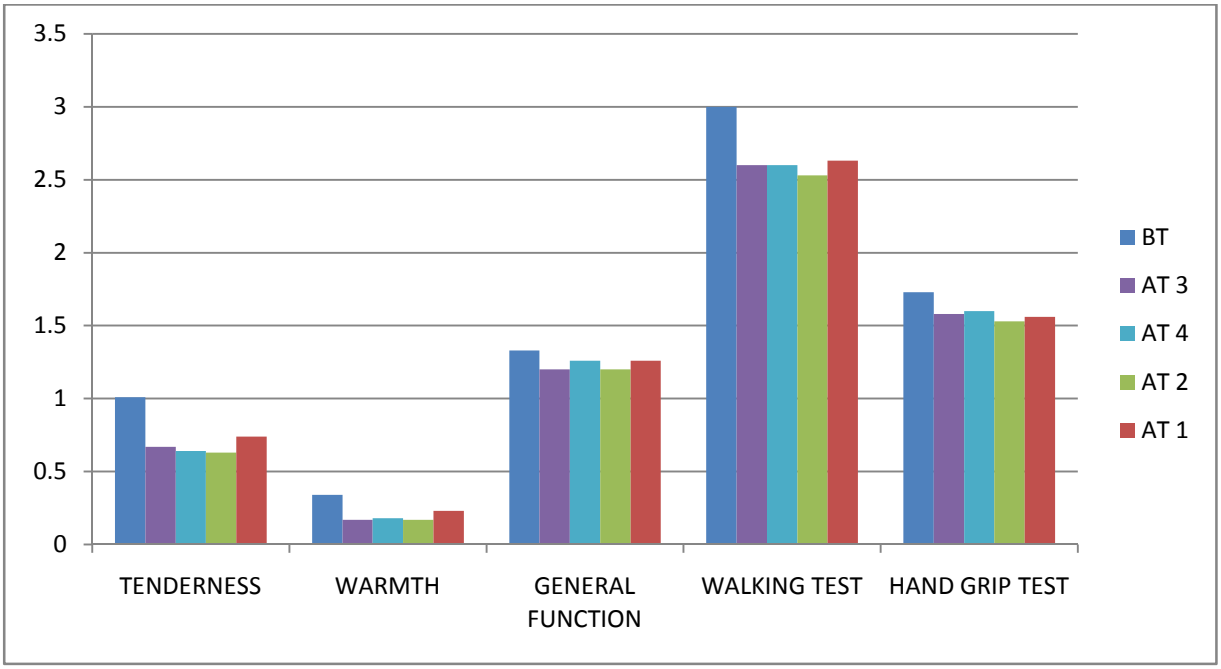
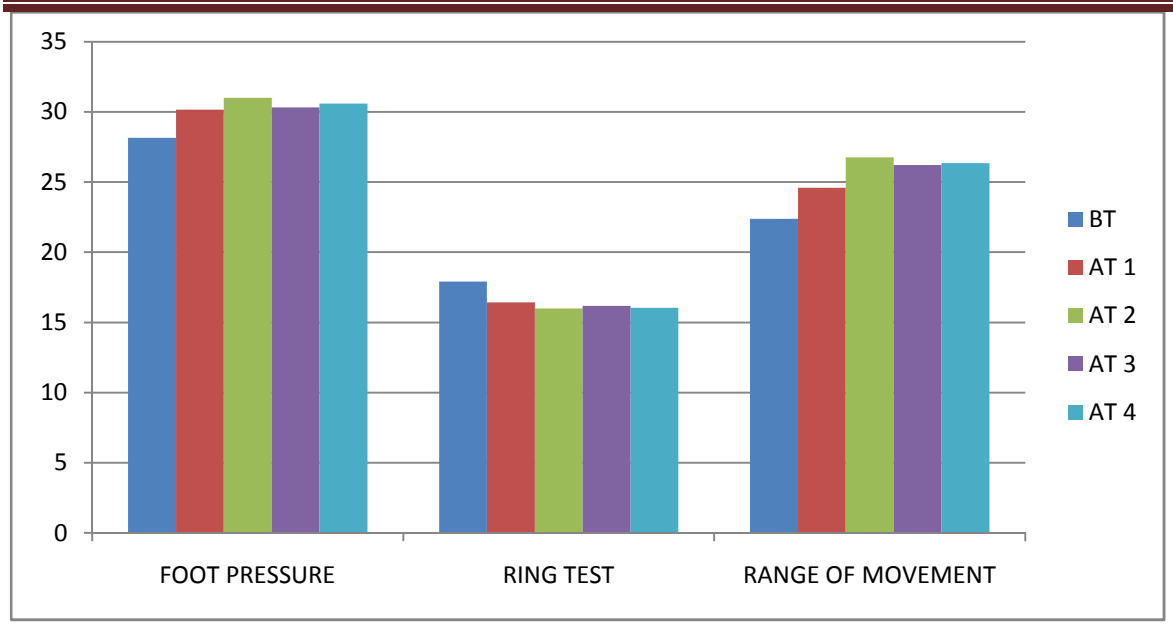


Diagram no 2 and 3: Showing the changes in objective parameters before treatment and during follow up.





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CORRESPONDING AUTHOR

Dr. GauthamPandit
Final year P.G. scholar,
Department of P.G. studies in Kayachikitsa, S.D.M.C.A.,
Udupi, Karanataka, India
Email: gauti.dr99@gmail.com

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