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Research Article

A Clinical Evaluation of Management of *Amavata* with *Rasonadi kwatha*, w.s.r. to Rheumatoid Arthritis

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Abstract

Purpose: To evaluate the role of *Rasonadi kwatha*, a classical medicament in the management of *Amavata*, w.s.r. to Rheumatoid Arthrits, which is attributed with best *Amavatahara* property, considering a trend of progressively increasing incidence of the condition.

Methods: The trial drug *Rasonadi kwatha* was prepared as per the classical method of *Kashaya kalpana*. Total of 47 patients of *Amavata* fulfilling the inclusion criteria were registered, of which 30 completed the course of intervention, in a single armed, prospective, open label, cohort study, with pre and post-intervention analysis design. Descriptive data including Mean, Standard Deviation (SD), Standard Error (SE), t-value and percentages were calculated for all variables in the trial group. The post treatment changes were assessed by paired Student t-test, taking 0.05 as the level of significance.

Results: Effect of the intervention on Subjective criteria including Signs and symptoms of *Amavata* and objective criteria including Disease Activity Score 28, Grip strength, Foot Pressure and Range of Movement was statistically significant with P value 0.001 after completion of treatment. The trial drug showed 36.67% of Moderate improvement and 53.33% of mild improvement in subjects of *Amavata* in the present study.

Conclusion: The formulation *Rasonadi kwatha* is efficacious in management of the disease *Amavata* w.s.r. to Rheumatoid Arthritis. The formulation is *Ruksha* (Dry) and *Ushna* (Hot potency) and thus it is a potent *Amapachaka* (digesting the *Ama*), breaking the primary pathogenesis of the disease. It showed statistically significant improvements in *Samanya lakshanas* and good results in *Pradhana lakshanas* of *Amavata*.

Keywords: Amavata, Disease Activity Score 28, Rheumatoid Arthritis, *Rasonadi kwatha*

Introduction

Rheumatoid Arthritis (RA) is one of the commonest debilitating diseases by virtue of its chronicity and complications. The incidence of RA is reported to be 1 to 1.5% of general population with female to male ratio of 3:1 and is progressively increasing in incidence owing to erroneous lifestyle and food habits.[1]

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Amavata displays many features in common with a collection of signs and symptoms that are typically diagnosed as RA.[2] All the diseases of systemic origin have their base in *Agnimandya* (poor digestive capacity), as described by *Vagbhata*. One among these is a serious agonizing painful condition called *Amavata*.

The present study was taken up to evaluate the role of a classical combination *Rasonadi kwatha*, in the management of *Amavata* w.s.r. to Rheumatoid Arthritis, which is attributed with best *Amavata*hara property, taken from *Amavata chikitsadhikara* of *Bhaishajya ratnavali*.[3]

The objective of the study was to assess the role of the research drug '*Rasonadi kwatha*' in management of *Amavata* w.s.r. to Rheumatoid Arthritis.

Selection of Intervention

Trial drug in the present study was selected considering the easy availability of ingredients (Garlic, Dryginger and Vitex negundo), cost effectiveness and convenience and compliance. The combination is *Katu* (Pungent), *Tikta* (Bitter) in taste and except *Amla* (Sour) all others *tastes* are present in small amounts, it is mainly *Ruksha (Dry)* and *Teekshna (penetrating)* in property, *Ushna* (Hot) in potency, predominantly *Katu (Pungent) vipaka, Kapha-vatahara* and *Deepana* (digestive). The formulation *Rasonadi kwatha* is *Ruksha (Dry)* and *Ushna (Hot potency)* and is *Amapachaka* in nature. It acts a gainst the properties of *Ama*, and it reduces the generalized *Amalakshanas* which are nothing but *Samanyalakshanas* of *Amavata*. The formulation is potent enough to act at the level *Asthi Sandhi* (bone joints) which is a part of *Madhyama rogamarga* (deepseated internal diseases).

Materials & Methods

A single armed, prospective, open label, cohort study, with pre and post-intervention analysis design was conducted at ALN Rao Memorial Ayurvedic Medical College Hospital, Koppa, Chikkamagaluru district, Karnataka, India during January and October 2011. The patients attending Out Patient Department (OPD) and In-Patient Department (IPD) were thoroughly assessed for the classical *lakshanas* of *Amavata* and signs and symptoms of Rheumatoid Arthritis. The detailed history and examination findings were noted on 0 day (before trial), 15th day (during trial), 30th day (after trial) and 75thday (45 days of followup) and the changes in observations were documented in a specially designed Case proforma. Institutional Ethical Clearance Number assigned to the study is 191/CPCSEA.

Inclusion Criteria

- Age group >20 years and <60 years
- Patients diagnosed as having *Amavata* on the basis of classical symptoms and Rheumatoid Arthritis on basis of ACR (American College of Rheumatology) criteria for diagnosing Rheumatoid Arthritis[4]
- <1 year of chronicity
- Both fresh and treated (discontinuing the existing medicines)

Exclusion Criteria

- Other complicated arthritic diseases
- Complications of RA including deformities, contractures, nodules, etc
- Other serious systemic, complicated diseases
- Pregnant and lactating women

Diagnostic criteria

Primary criteria

Signs of *Amavata* i.e. *Pradhana Lakshanas, Shoola (Tenderness), Shopha (Swelling), Stabdhata* (Stiffness) (with grading 0–absent, 1-mild, 2-moderate, 3-severe) of Joints, vis-à-vis Rheumatoid Arthritis.

Secondary criteria

Samanya lakshanas of *Amavata*, i.e. *Angamarda* (Generalized body ache), *Aruchi* (Tastelessness), *Aalasya* (Lack of enthusisasm), *Jwara* (Feverishness), *Apaka* (Lack of digestion) (with grading 0–absent, 1-mild, 2-moderate, 3-severe).

Assessment criteria

On 0 day (before trial), 15th day (during trial), 30th day (after trial) and 75th day (45 days of follow up), analysis of role of the trial drug in breaking the pathology of *Amavata* was assessed based on:

Subjective parameters

- *Pradhana* and *Samanya lakshanas* of *Amavata*

Objective parameters

- DAS28 (Disease Activity Score 28)[5] and the response of the disease to the clinical intervention, using EULAR response criteria
- Grip strength with appropriate grading
- Foot pressure with appropriate grading
- Goniometric assessment of range of movement
- Functional ability (RA Quality of Life[6])

Investigations

- Erythrocyte Sedimentation Rate (ESR)
- Rheumatoid factor (RF) test
- Radiological: X-ray of afflicted joints (if needed)

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Intervention

Sample size	30 irrespective of gender
Drug	*Rasonadi kwatha*
Dose	25 ml twice daily (6 am and 6 pm), *Ananna kala*
Anupana	Hot water q.s. (if required)
Duration of treatment	30 days
Follow up	45 days after completion of treatment schedule (without any medication and with strict diet advised)

The trial drug was prepared according to the classical method of *Kwatha kalpana*[7], in the Pharmacy attached to the institution. Preparation was in two batches of 40 lts each, bottled in 450ml containers. 2g/l of Sodium benzoate as a preservative was added.

Statistical Analysis

Descriptive data including Mean, Standard Deviation (SD), Standard Error (SE), t-value and percentages were calculated for all variables in the trial group. The post treatment changes were assessed by paired Student t-test, taking 0.05 as the level of significance.

Results

In the present study totally 47 patients of *Amavata* fulfilling the inclusion criteria were registered under the trial group. Out of 47 patients, 10 patients did not come back for any follow up and 7 patients discontinued after 1st follow up visit, against medical advice. So, a total of 30 patients completed the study. Major part of the sample (50%) were in age group of 41 and 50yrs and Females (90%). 40% of the sample had family history of *Amavata*. 80% were non-vegetarians. 46.7% had *Krura koshta* (Constipated) and 66.67% had reduced *aharashakti* (Digestive capacity) and vyayama shakti (Physical strength). 83.33% were from *Anupa desha* (Marshy land). *Sandhi Shoola (Tenderness)* was common in all the subjects (100%), *Sandhi Stabdhata (Stiffness)* 93.34% and *Sandhi Shopha (Swelling)* in 90%.

Among *Samanya lakshanas Angamarda* (Generalized body ache) (100%), *Apaka* (Lack of digestion) in (80%) and *Aalasya* (Lack of enthusiasm) (96.7%) were predominantly present. *Viruddha ahara* (improper food habits) (46.7%), Early morning (86.7%) and Cold season (86.7%) were predominant Aggravating factors. *Pathya ahara* (Wholesome food) (53.3%), Day time (60%), Hot season (60%), Movements (53.3%) and use of *Ushna* (Hot potency) *Ruksha* (Dry) food and regimens (90%) were predominant Relieving factors. Among the subjects, 63.3% were positive for Rheumatoid factor.

Effect of *Rasonadi kwatha* on *Pradhana lakshana* was statistically significant with P value 0.001 after completion of treatment.

Effect on *Samanya lakshanas* was statistically significant with P value 0.001 after completion of treatment, except for *Trushna* which was statistically insignificant with P value >0.1.The intervention showed moderate improvement of 63.3% in Disease Activity Score 28 (DAS 28) after completion.

Effect on Grip strength, Foot Pressure and Range of Movement was statistically significant with P value 0.001 after completion of treatment. Overall, the trial drug *Rasonadi kwatha* showed 36.67% of Moderate improvement and 53.33% of mild improvement in subjects of *Amavata* in the present study. Details are depicted in Table No. 1-4 and Graph No.1.

Assessment of Disease Specific Quality of Life (QoL)[5]

Disease specific QoL questionnaire measured all the subjective parameters of the disease and the patients' feeling of improvements in their day to day activities comprehensively. This could be used as a valuable tool in assessing the subjective improvements in the patients. 54% of patients showed a significant improvement in the domains of dressing and grooming, rising, eating, walking, hygiene, reach, grip and activities after the completion of treatment duration and 37% of patients showed improvement after follow up of 45 days.

Table 1.Effect of trial drug on *Pradhana lakshanas* AT and AF

Pradhana Lakshana	**Result after treatment (30 days)**		**Result After follow up**	
	Percentage	**P value**	**Percentage**	**P value**
Shoola (Tenderness)	52%	<0.001	41.33%	<0.001
Shopha (Swelling)	58.49%	<0.001	39.62%	<0.001
Stabdhata (Stiffness)	50%	<0.001	44%	<0.001

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Table 2.Effect of trial drug on *Samanya lakshanas* AT and AF

Pradhana Lakshana	Result after treatment (30 days)		Result after After follow up	
	Percentage	p value	Percentage	p value
Angamarda (Generalized body ache)	72.58%	<0.001	66.12%	<0.001
Aruchi (Lack of digestion)	83.33%	<0.001	75%	<0.001
Trushna (Increased thirst)	-18.18%	>0.1	45.45%	<0.001
Aalasya (Lack of enthusiasm)	66.07%	<0.001	62.50%	<0.001
Apaka (Indigestion)	79.59%	<0.001	69.38%	<0.001

Table 3.Effect of trial drug on objective parameters AT and AF

Objective parameters	AT		AF	
	Percentage	p value	Percentage	p value
DAS28	63.33%	-	33.33%	-
Grip strength	40.32%	<0.001	33.87%	<0.001
Foot pressure	43.24%	<0.001	29.72%	<0.001
Functional assessment	65.71%.	<0.001	51.42%	<0.001

Table 4.Overall result of the trial drug

Trial group	Result of the treatment							
	Remarkable improvement		Moderate improvement		Mild improvement		No improvement	
	No of patients	%	No	%	No	%	No	%
After treatment	0	0	11	36.67%	16	53.33%	3	10%
After follow up	0	0	06	20%	19	63.33%	5	16.67%

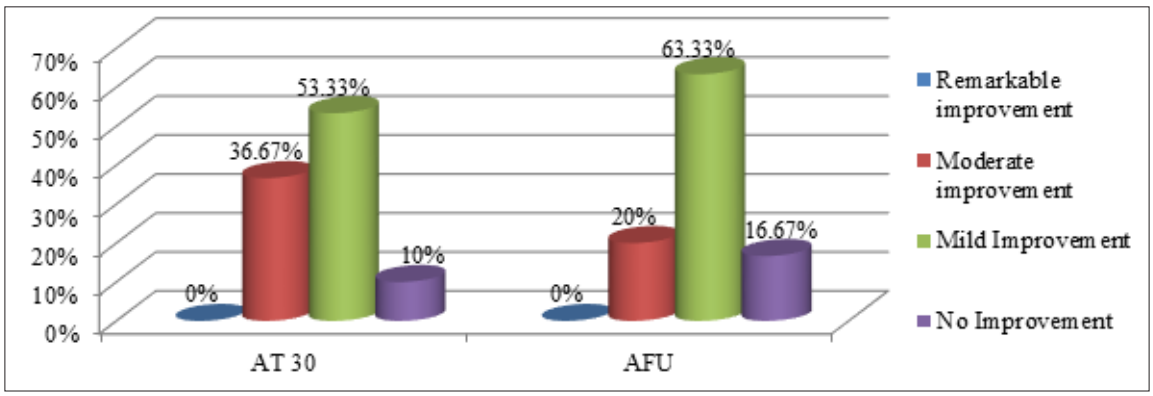

Figure 1.Overall effect of the trial drug *Rasonadi kwatha* in management of *Amavata*

Discussion

Recent trends of management of RA highlights using Disease Modifying Anti Rheumatic Drugs (DMARD) of varied classes for early arrest of disease progression in terms of Subjective and functional parameters.[8] Other treatments include Non steroidal anti-inflammatory drugs (NSAID) and Gluco corticoids along with other non-pharmacological approaches of management[9]. All the pharmacological interventions, including Methotrexate, a common DMARD, are proved to have multiple Adverse Effects, including Hepato-Renal toxicity.[10]

The present study based on Ayurvedic principles of treating the condition as per the clinical and pathological stage, (stage of *Ama*) have shown significant improvements in the symptoms (of *Ama* and *Amavata*) and considerable improvements in ESR which is used in the DAS28 calculation of the samples. Also there was a significant improvement in functional aspects (Foot pressure, Grip strength, Range of Movement and RA quality of life questionnaire).

During the study it was observed that:

- *Amavata* mostly affects people of age group 41-60 years.

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- Positive family history may be a risk factor for causality of *Amavata*.
- The trial drug is most effective in *Avastha* of the disease with *Kapha* and *Vata* predominance and should be avoided in case of involvement of *Pitta* in the *samprapti*.
- There were no significant changes in RA factors observed.
- The formulation is cost effective in the management of *Amavata.*
- *Nidana parivarjana* (avoiding the causative factors) had a major role in controlling the progression of this disease.
- The formulation had a good effect in improving the quality of life in the patients and Disease specific Quality of Life Questionnaire could be used as a valuable and handy tool in assessing the subjective outcomes in the patients.
- The phytochemical analysis shows that the ingredients of the formulation have active ingredients which are anti-inflammatory, anti-arthritic, anti-rheumatic and also immune-modulator and immune stimulator in their action

Conclusion

The formulation *Rasonadi kwatha* is *Ruksha* (Dry) and *Ushna* (Hot potency) and thus it is *Amapachaka (*breaking the pathological stage of *Ama)* in nature. It showed very significant improvements in *Samanya lakshanas (*Symptoms of Rheumatoid Arthritis) and good results in *Pradhana lakshanas (*Signs of Rheumatoid Arthritis) statistically. Objective criteria (DAS 28, Range of movement, Grip strength and Foot pressure) also showed significant improvements.

After completion of intervention, the trial drug *Rasonadi kwatha* supported Research Hypothesis that, the formulation is efficacious in management of the disease *Amavata* w.s.r. to Rheumatoid Arthritis. Also, the combination had good effect even in the period of follow up with strictly advised *Pathyapathya* (diet regimen) during the whole study.

Conflict of Interest: None

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