

AN OPEN RANDOMIZED COMPARATIVE CLINICAL STUDY ON THE EFFECT OF RASONA PINDA AND NAVAKA GUGGULU IN AMAVATA

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Received: 24-06-2022; Revised: 20-07-2022; Accepted: 28-07-2022

Abstract

Amavata makes a person to be dependent on others for his routine activities if untreated. Amavata, according to Ayurveda is rasavahshrotho vikara, due to the vitiation of ama and vata dosha sandhi shoola and sandhi shotha along with the symptoms of ama. The pathology of ama and vata are opposite and so care should be taken while treating this disease. Amavata is compared to Rheumatoid Arthritis in modern parlance as pain and swelling in the joints are the clinical findings. Rheumatoid Arthritis is the most common persistent inflammatory arthritis. The clinical course is prolonged with intermittent exacerbations and remissions. Study Type: Interventional, Estimated enrolment: 40 participants, Allocation: Randomized, Endpoint Classification: Comparative Study, Intervention Model: Double group assignment, Masking: Open label study, Primary Purpose: Treatment. Among the 20 Patients registered for the study there was 10% moderate response and 90% marked response in Group A and in Group B, 25% patients had moderate response, 70% of the patients had marked response and 5% patient had mild response in treatment. The study revealed that Rasona pinda and Navaka guggulu is very effective in reducing the symptoms of Amavata.

Key Words: Amavata; Rheumatoid arthritis; Navaka Guggulu; Rasona pinda.

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Cite This Article

Shekar Sharma, Waheeda Banu. An open randomized comparative clinical study on the effect of Rasona pinda and Navaka guggulu in Amavata. Ayurpharm Int J Ayur Alli Sci. 2022;11(7):66-72.

INTRODUCTION

Ayurveda gives a lot of importance to Ahara (food), Vihara (activities), Dinacharya (daily regimen) and Ritucharya (seasonal regimen) the components of swastha vritta (preventive, as they play a vital role in maintenance of health. Lifestyle of the present scenario such as junk foods, stress and strain makes the subject to unfollow the rules and regulations mentioned in Ayurvedic classics and to be a victim of disease. One such crippling disorder is Amavata. Indulgence in specific etiological factors, causes simultaneous vitiation of vata dosha as well as kapha dosha which in turn initially afflicting the sacral region; later gradually stiffens the whole body manifesting as amavata^[1] and is paralleled to the rheumatoid arthritis of biomedicine.

Ama (undigested metabolic waste) is invariably involved in all stages of pathogenesis hence the name amavata. Vitiated vata dosha in association with ama circulates in the whole body and then localizes in the different locations of kapha dosha with predilection of joints causing pain swelling as well as stiffness of the joints related to extremities head and trunk. The subject may suffer from other systemic features like body ache, lack of taste in the mouth, excessive thirst, lack of enthusiasm, heaviness of the body and febrile illness. Amavata is categorized into three types based on the relative dominance of the dosha as vatanuga, pittanuga and kaphanuga amavata.^[2]

This crippling disease will make a person dependent on others for his daily needs. Involving the madhyama roga marga, this illness poses difficulties in the curative approach.

Rheumatoid arthritis (RA) is a chronic multisystem disease of unknown cause.^[3]

Although there are a variety of systemic manifestations, the characteristic feature of established RA is persistent inflammatory synovitis, usually involving peripheral joints in a symmetric distribution. The potential of the synovial inflammation to cause cartilage damage and bone erosions and subsequent changes in joint integrity is the hallmark of the disease. Despite its destructive potential, the course of RA can be quite variable. Some patients may experience only a mild oligoarticular illness of brief duration with minimal joint damage, but most will have a relentless progressive polyarthritis with marked functional impairment. The prevalence of RA is ~0.8% of the population (range 0.3–2.1%); women are affected approximately three times more often than men. The prevalence increases with age, and sex differences diminish in the older age group.^[4] If a earning elder person of the family suffers from this crippling disease, then the whole family have to suffer with this crisis. Thereby severity of this crippling disease, Amavata ranges from affecting the working life to survival. Clearing the ama and pacification of vata dosha is the sheet anchor of treating amavata. Langhana (fasting), shodhana (purification), shamana (palliative), brimhana (nourishing) and rasayana (rejuvenation) form the complete treatment of amavata.^[5] Balanced approach that clears the ama and pacifies the vata dosha is effective in the management of amavata.

Rasona pinda^[6] acts as vatakapha hara (reduces Vata Kapha) and it also is vyadhi hara (controls disease), rasayana. Navaka Guggulu^[7] a Samana Oushadhi (palliative drugs), it is Kaphahara and shola (pain), shotahara (reduces swelling). So an effective treatment which clears the ama and pacifies the vata dosha is effective in management of Amavata. Hence an effort was put in this regard to study Amavata (Rheumatoid Arthritis) under the title “An open randomized comparative clinical study on the effect of Rasona pinda and Navaka guggulu in Amavata”

OBJECTIVES OF THE STUDY

- To evaluate the therapeutic effect of Rasona Pinda in reducing the signs and symptoms of Amavata.
- To evaluate the therapeutic effect of Navaka Guggulu in reducing the signs and symptoms of Amavata.
- To compare the therapeutic effect of Rasona Pinda and Navaka guggulu in reducing the signs and symptoms of Amavata.

MATERIALS AND METHODS

Study Type: Interventional, Estimated enrolment: 40 participants, Allocation: Randomized, Endpoint Classification: Comparative Study, Intervention
Model: Double group assignment, Masking: Open label study, Primary Purpose: Treatment

Patients and randomization

Participants were selected for the study from I.P.D & O.P.D. of Karnataka Ayurveda Medical College and Hospital, Mangalore. Rasona pinda and Navaka Guggulu were prepared in the Department of Rasa Shastra and Bhaishajya Kalpana, Karnataka Ayurveda Medical College, Mangalore.

Patients suffering from Amavata / rheumatoid arthritis with minimum 6 months history having Score ≥ 6 points as per ACR/EULAR (2010) Classification Criteria for RA, Erythrocyte Sedimentation Rate (ESR) of ≥ 28 mm/hr, Serum C-reactive protein (CRP) ≥ 0.80 mg/dL at screening, Disease Activity Score 28 (DAS28) ≥ 3.2 of both sex of age between 16 to 70 years with the history of more than five years of illness were screened under strict diagnostic, inclusion and exclusion criteria. Pregnant Females, subjects with history of inflammatory joint disease, subjects suffering from systemic disorders like Diabetes Mellitus, subjects with history of juvenile

idiopathic arthritis. The subjects satisfying the criteria of the study were included to participate in this clinical study, after signing a detailed informed consent and were then registered for the study. The registered participants were treated with Rasona Pinda and Navaka Guggulu. The outcome measures were assessed at baseline and by the completion of the interventions.

Intervention

The patients selected for the study were randomly divided into 2 groups of 20 each by adapting the permuted block randomization method.

Group 1

The subjects was treated with oral administration of Rasona Pinda Powder, 10gm was orally administered half an hour before breakfast with 150ml of eranda moola kwatha as anupana for 28 days

Group 2

The subjects was treated with Navaka Guggulu in the dose of 2 tablets of 500 mg thrice daily before food with lukewarm water for 28 days.

Duration of the study

Group 1

The study includes 28 days of medication with Rasona Pinda followed by another 30 days of follow up period. Total duration of study: 58 days.

Group 2

The study includes 28 days of oral intake of Navak guggulu, followed by another 30 days of follow up period. Total duration of study: 58 days.

Follow up

30 days after treatment.

Diagnostic criteria

Clinical diagnosis of amavata, based on typical history and clinical presentation of progressive involvement of joints with pain swelling and stiffness that is worst in morning and night. The (2010) American College of Rheumatology - European League against Rheumatism (ACR-EULAR) classification Criteria for RA.

Procedures and outcomes

Primary Outcome Measures were change in the symptom score of joint pain, joint swelling, joint stiffness and joint tenderness from the base line at completion of intervention. The severity of symptom was evaluated by four point categorical scale -0=absent, 1=mild, 2=moderate, 3=severe; Change from baseline in Erythrocyte Sedimentation Rate (ESR) at completion of intervention expressed as mm at first hour. Secondary outcome measures included Change from baseline in Disease Activity Score 28 (DAS28) at completion of intervention and the expressed values are 0=best to 10=worst. Change from Baseline in

Health Assessment Questionnaire-Disability Index (HAQ-DI) Score at completion of intervention and the total possible score ranges from zero to three. Zero means no difficulty and three mean worst possible difficulties. Change from baseline in the disability index at completion of treatment. The day of randomization and the first dose of intervention are defined as day 0 and the day of completion of intervention is the time point of primary outcome of the clinical trial.

Statistical analysis

42 Patients suffering from Amavata / rheumatoid arthritis were screened under strict diagnostic, inclusion and exclusion criteria. 42 Eligible participants were invited to participate in this clinical study and after signing a detailed informed consent, they were registered study. Among 42 patients 02 patients were dropped

from the study for various reasons. Descriptive statistical analysis of these patients was analysed and presented by using the software SPSS. The parametric and nonparametric data obtained by assessing the pain swelling tenderness and stiffness were analysed by paired t test to note the significance of treatment with in the individual group. Wilcoxon signed rank test was used to compare the results between the groups

Patient involvement

None of the participants were involved in preparing the research question or selecting the regimen, primary and secondary outcome measures, nor were they involved in establishing the plans for recruitment, design, or implementation of the study. No participants were asked to suggest the interpretation or writing up of results.

RESULTS

Demographic profile

40 % patients in group A were between the age 41-50, in group B, 45 % of patients were between the age of 31-40 yrs.: In rroup A maximum of 65% patients were females and in group B, 50 % of patients were females and 50 % of patients were males In Group A maximum number of patients belongs to Hindu religion (60 %), in Group B maximum number of patients belongs to Hindu religion (60 %). In group A, 90% of the patients were from middle class economic status and 10% from poor economic status. (Table 1)

Observations of personal history

In Group A of majority of 95% of patients were married. In B Group 100% of patients were married. 85 % patients in group A, 80% of patients in group B, were having a mixed diet. In group A 60% of the patients sleep was disturbed due to pain, in VPS group and Group B, 55% there was sound sleep. (Table 2)

Table 1: Demographic data

Age	Group A	%	Group B	%	Total	%
20-30	1	5%	2	10%	3	7.5%
31-40	7	35%	9	45%	16	37.5%
41-50	8	40%	4	20%	12	30%
51-60	4	20%	5	25%	9	22.5%
Gender						
Male	7	35%	10	50%	50%	42.5%
Female	13	65%	10	50%	50%	57.5%

Table 2: Personal history of patients

Martial	Group A	%	Group B	%	Total	%
Married	19	95%	20	100%	39	97.5%
Unmarried	1	5%	0	0%	1	2.5%
Diet	Group A	%	Group B	%	Total	%
Veg	3	15%	4	20%	7	17.5%
Mixed	17	85%	16	80%	33	82.5%
Sleep	Group A	%	Group B	%	Total	%
Disturbed	12	60%	9	45%	21	52.5%
Sound	8	40%	11	55%	19	47.5%

Comparative results of Group A and Group B

Comparative results of Group A and Group B after treatment and follow up of primary outcome measures are mentioned in Table 3. Comparative results of Group A and Group B after treatment (secondary outcome measures) are elaborated in Table 4.

Overall response after treatment of both the groups are mentioned in Table 5.

Over all response of Group A and Group B after follow-up

Among the 20 Patients registered for the study there was 10% moderate response and 90% marked response in Group A and in Group B, 25% patients had moderate response, 70% of the patients had marked response and 5% patient had mild response in treatment. (Table 6)

DISCUSSION

Rasona pinda is effective in reducing the severity of amavata as revealed in the study with improvement in primary and secondary outcome measures. During the course of the study as there was no adverse reactions and it can be said as safe in the above said dosages. Since these interventions have not resulted in complete remission of the illness judicious planning of these procedures for a longer period may prove more effective.

The study revealed that Raona pinda and Navaka guggulu is very effective in reducing the symptoms of Amavata. Reduction in the symptoms of Pain, increased range of joint movement proves the effect of treatment in ameliorating the vitiated Vata dosha. Morning stiffness, joint swelling and impaired digestion that is reduced by Rasona pinda.

Table 3: Over all comparative result of Group A and Group B of Primary Outcome Measures

Sl.No.	Primary Outcome Measures	Overall result after treatment		Overall result after follow-up	
		Group A	Group B	Group A	Group B
		Mean±SD	Mean±SD	Mean±SD	Mean±SD
1	Pain	0.75±0.444	0.90±0.718	0.40±0.503	0.55±0.510
2	Swelling	0.90±0.553	1.00±0.649	0.55±0.510	0.65±0.587
3	Joint tenderness	0.95±0.510	1.05±0.394	0.60±0.503	0.75±0.444
4	Morning stiffness	1.05±0.887	1.25±0.851	0.65±0.671	0.80±0.768
5	Jwara	0.30±0.470	0.35±0.489	0.20±0.410	0.25±0.444
6	Angamardha	0.30±0.470	0.35±0.489	0.20±0.410	0.25±0.444

Table 4: Over all comparative result of Group A and Group B of Secondary Outcome Measures

Sl.No.	Secondary Outcome Measures	Overall result after treatment		Overall result after follow-up	
		Group A	Group B	Group A	Group B
		Mean±SD	Mean±SD	Mean±SD	Mean±SD
1	ESR	23.45±4.407	25.75±5.684	18.25±2.337	20.60±2.873
2	CRP	7.95±2.373	8.40±2.186	6.60±1.635	7.15±1.599
3	HAQ	3.65±0.516	3.78±0.716	3.25±0.380	3.43±0.613
4	DAS28	4.94±0.466	5.14±0.411	4.50±0.457	4.74±0.434

Table 5: Over all response of Group A and Group B

Sl.No.	Grouping	Response	Group A		Group B	
			No. of Subjects	%	No. of Subjects	%
1	0% - 25%	Poor	0	0%	0	0%
2	25% - 50%	Mild	0	0%	4	20%
3	50% - 75%	Moderate	15	75%	15	75%
4	75% - 100%	Marked	5	25%	1	5%
	Total		20	100%	20	100%

Table 6: Over all response of Group A and Group B after follow-up

Sl.No.	Grouping	Response	Group A		Group B	
			No. of Subjects	%	No. of Subjects	%
1	0% - 25%	Poor	0	0%	0	0%
2	25% - 50%	Mild	0	0%	1	5%
3	50% - 75%	Moderate	2	10%	5	25%
4	75% - 100%	Marked	18	90%	14	70%
	Total		20	100%	20	100%

This vyadhihara rasayana indicates its efficacy in counteracting the Ama by this medication. The improvement recorded in the study is also statistically highly significant. Also the treatment has not given complete relief from the symptoms. This indicates that the same treatment may be more effective in different dosage pattern and duration of treatment.

Thus this definitely paves way for newer clinical studies in revealing the effect of Rasana Pinda and Navaka guggulu in patients suffering from lingering disease Amavata.

Reduction in the symptoms of Pain, increased range of joint movement proves the effect of treatment in ameliorating the vitiated Vata dosha.

Morning stiffness, joint swelling and impaired digestion that is reduced by Rasona pinda. This vyadhihara rasayana indicates its efficacy in counteracting the Ama by this medication. The improvement recorded in the study is also statistically highly significant. Also the treatment has not given complete relief from the symptoms. This indicates that the same treatment may be more effective in different dosage pattern and duration of treatment. Thus this definitely paves way for newer clinical studies in revealing the effect of Rasona Pinda and Navaka guggulu in patients suffering from lingering disease Amavata.

CONCLUSION

Rasona pinda was found to be more effective in being able to tackle amavata in comparison to Navaka Guggulu in relieving the symptoms in case of the patients with chronic disease. Rasona pinda acts as vatakapahara and it also is vyadhi hara rasayana. Navaka Guggulu as Samana Oushadhi, it is Kaphahara and shoola, shotahara. The improvements observed by the medications are definite as proved by tests of statistical significance although the time factor of the study was limited. Further detailed study might land up in providing a better proof about the complete efficacy of Rasona pinda and

Navaka guggulu. Vyadhihara Rasayana, shoolahara, shothahara in the form of Rasona pinda was found to be more effective in being able to tackle amavata in comparison to Navaka Guggulu in relieving the symptoms.

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Source of Support: Nil

Conflict of Interest: None Declared