

Clinical Research

A comparative study of *Rasona Rasnadi Ghanavati* and *Simhanada Guggulu* on *Amavata* with special reference to Rheumatoid arthritis

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Abstract

The present study was aimed to assess the clinical effectiveness of Rasona Rasnadi Ghanavati and Simhanada Guggulu along with Rasona Rasnadi Lepa in Amavata, and to compare the effect of these two therapies in the treatment. Total 101 patients of Amavata were registered for the present study and were randomly divided into two groups. In group A- Rasona Rasnadi Ghanavati 2 Vati thrice/day was given for 3 months, while in group B- Simhanada Guggulu 2 Vati thrice a day for 3 months was adminstered. Along with this, Rasona Rasnadi Lepa was applied locally over affected joints twice daily in both groups. The effects of therapy in both groups were assessed by a specially prepared proforma. The results of the study showed that both the groups showed significant relief in symptoms; however, compared to Simhanada Guggulu, Rasona Rasnadi Ghanavati showed better result in the management of Amavata. Simhanada Guggulu or Rasona Rasnadi Ghanavati along with Rasona Rasnadi Lepa can be used as an effective ayurvedic intervention in the treatment for rheumatoid arthritis.

Key words: Ama, Amavata, Rasona Rasnadi Ghanavati, Rheumatoid arthritis, Simhanada Guggulu,

Introduction

Amavata is a chronic, degenerative disease of the connective tissue mainly involving the joints. Swelling and pain in multiple joints are the main features of Amavata (Rhematoid arthritis).^[1,2] Constant use of incompatible food articles and strenuous exercise immediately after consumption of fatty foods leads to indigestion. This results in the formation of Ama which gets circulated throughout the body by Vyana Vayu. This then accumulates at Shlesmasthana, and especially at the Shleshakakapha, i.e., in the joints leading to the manifestation of symptoms of the disease. Body pain, loss of appetite, fever, weakness, excessive thirst and heaviness are also manifested.^[3] Involvement of joints restricts the normal body movements which may lead to contracture of muscle and permanent deformities.^[4] Blood investigations show a high erythrocyte sedimentation rate (E.S.R.) and positive Rheumatoid

Address for correspondence: Dr. Raja Ram Mahto, Lecturer, Department of Kayachikitsa, SKSS Ayurveda Medical College, Sarabha, Ludhiana, Punjab-141105, India. Email: mahtorajaram@yahoo.com, Mob: +91-9256031109 arthritis (RA) factor in 30-40% cases. Prognosis of Amavata is poor especially in those cases where Tridosas are involved. [5] The principles of treatment of Amavata are Langhana and Swedana; and drugs having Tikta, Katu Rasa, Deepana, Virechana, Snehapana and Basti properties. [6]

Many Ayurvedic formulations are claimed to be effective in Amavata, however, scientific evidence needs to be produced. The need to establish a firm scientific basis for classical Ayurvedic formulations is now being felt. Though ample research work has been done on the disease Amavata, satisfactory results have not been obtained till date.

A clinical study was planned to assess the clinical effectiveness of Rasona Rasnadi Ghanavati and Simhanada Guggulu along with Rasona Rasnadi Lepa, and to compare the effect of these two therapies in the treatment of the condition

In the study, in the test drug group, Rasonadi Kwatha and Rasnasaptaka Kwatha^[7] have been selected for making Rasona Rasnadi Ghanavati. Due to its Katu Tikta Rasa, Ushna Virya, Rasayana Prabhava, Amapachaka and Vatashamaka properties, it helps to disrupt the Samprapti of Amavata. In the control group,

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the drug of choice of Amavata, i.e., Simhanada Guggulu, [8] as it is easy to prepare and is easily available. The drugs of Simhanada Guggulu are having mostly Ama and Vata Shamaka property. Lepa was used locally over the involved joints of both the group, by mixing the Rasona Rasnadi Churna with Eranda taila. Both of these drugs are well known for having Vata-Kaphahara and Shula-Shothahar action. Thus, the combination as a whole was used.

All the raw drugs for the purpose of research work were collected from the Pharmacy of Gujarat Ayurved University, Jamnagar. The correct identity and authenticity of raw materials was confirmed by studying its organoleptic and powder microscopy, and then comparing them with the characters mentioned in Ayurvedic Pharmacopia of India. Later, subject experts of Pharmacognosy department, of Institute for Post Graduate Teaching and Research in Ayurved (I.P.G.T. and R.A.), Gujarat Ayurved University confirmed the identification.

Aims and Objectives

- 1. To study the etio-pathogenesis of Amavata.
- To assess the effect of Rasona Rasnadi Ghanavati with Rasona Rasnadi Lepa on Amavata.
- 3. To evaluate the role of Simhanada Guggulu with Rasona Rasnadi Lepa on Amavata.
- 4. To compare the clinical effectiveness of Rasona Rasnadi Ghanavati and Simhanada Guggulu with Rasona Rasnadi Lepa on Amavata.

Materials and Methods

Patients fulfilling the criteria for the diagnosis of the disease were registered for the present study irrespective of their age (between 18 to 60 years), sex, religion, occupation and other parameters. The patients were selected from the Out Patient Department of Department of Kayachikitsa I.P.G.T. and RA, Gujarat Ayurved University, Jamnagar hospital.

Criteria for selection

Patient's having the classical features of Amavata^[9] like Angamarda, Aruchi, Trishna, Alasya, Jwara, Sandhishula, Sandhishotha, and modern parameters of Rheumatoid arthritis (RA)^[10] like morning stiffness, pain, tenderness, swelling, fever, raised E.S.R. etc. were included for the present study. The criteria for diagnosing RA as laid down by American Rheumatism Association (A.R.A.)^[11] in 1988 was also taken into consideration. Both Seropositive and seronegative RA factor cases RA. Chronicity for more than 10 years, having severe crippling deformity, cardiac disease, pulmonary tuberculosis and Diabetes mellitus patients were excluded. A detailed research proforma was prepared incorporating all the signs and symptoms seen in the disease.

Investigations

The routine hematological and biochemical investigation, RA factor and C-reactive protein (C.R.P.) test were done before and after treatment. Routine stool and urine examination were conducted during the study to see for any changes in the biological system.

Criteria for assessment

The results of the therapy were assessed on the basis of clinical signs and symptoms mentioned in the Ayurvedic classics. The improvements in the condition of patients were assessed on the basis of *Roga Bala*, *Agni Bala*, *Deha Bala*, *Chetasa Bala* and as well as by American Rheumatism Association (ARA 1967) criteria of degree of disease activity.

Clinical assessment

The changes observed in the signs and symptoms were assessed by adopting suitable scoring method and by using appropriate clinical tools.

A. Rogabala

Rogabala was used to assess the degree of disease activity as well as the symptoms of Amavata.

The detail of scoring pattern adopted for assessment of clinical sign and symptoms are given below:

| Symptoms | Score |
|--|-------|
| Pain in joint | |
| No pain | 00 |
| Mild pain of bearable nature, comes occasionally | 01 |
| Moderate pain, but no difficulty in joint movement, appears frequently and requires some Upashaya measures for relief | 02 |
| Slight difficulty in joint movements due to pain or severe pain, requires medication and may remain throughout the day | 03 |
| More difficulty in moving the joints and pain is severe, disturbing sleep and requires strong analgesics | 04 |
| Swelling of the joint | |
| No swelling | 00 |
| Slight swelling | 01 |
| Moderate swelling | 02 |
| Severe swelling | 03 |
| Stiffness of the joints | |
| No stiffness or stiffness lasting for 5min | 00 |
| Stiffness lasting for 5 min to 2 hrs. | 01 |
| Stiffness lasting for 2 to 8 hours | 02 |
| Stiffness lasting for more than 8 hours | 03 |
| Tenderness of joints | |
| No tenderness | 00 |
| Subjective experience of tenderness | 01 |
| Wincing of face on pressure | 02 |
| Wincing of face with withdrawal of affected parts on pressure | 03 |
| Resists to touch | 04 |

B. Degree of disease activity^[12]

In the above criteria the maximum score is 30, which represents an average of grade 3 (severely active). By dividing the total score by 10 the grade of disease is obtained and denoted by figures 0 - 3 [Table 1].

C. Dehabala^[13]

Dehabala score which was used to assess any improvements in the symptoms are given below:

| | Score |
|--|-------|
| Swara Varna Yoga (Revitalization of speech and | |
| luster) | |
| Patient looks cheerful | 00 |
| Patient looks gloomy | 01 |
| Patient looks tired and lethargic | 02 |
| Patients looks depressed | 03 |
| Sharira Upachaya (increase in body mass/weight and gain in muscle wasting) | |
| Weight increase by more than 2 kg | 00 |
| Weight increased by 2 kg | 01 |
| Weight increased by 1 kg | 02 |
| Weight before treatment/No increase in weight | 03 |
| Balavriddhi (increase in body strength) | |
| Patient with normal body strength and able to do his work as usual | 00 |
| Reduced body strength than normal but does not interfere with routine works | 01 |
| Reduced body strength to a level where patients gets fatigued with the little work | 02 |
| Patient feels fatigue on minimal walk/walking/ daily activity | 03 |

D. Agni bala^[14]

Scoring according to Jirna Ahara Lakshana:

| Presence of all (five) symptoms after 6 hrs | - | 0 } | Pravara |
|---|---|-----|----------|
| Presence of four symptoms after 6 hrs | - | 2) | |
| Presence of three symptoms after 6 hrs | - | 4 } | Madhyama |
| Presence of two symptoms after 6 hrs | - | 6 | |
| Presence of one symptom after 6 hours | - | 8 | Avara |

Agnibala score which was used to assess the digestion related symptoms are given below:

| -/ | |
|--|----|
| Ruchirahara Kale (Taste and appetite) | |
| Equal willing towards all Bhojya Padartha | 00 |
| Willing towards some specific Ahara or Rasavishesha | 01 |
| Willing towards only most liking food and not to other | 02 |
| Unwilling for food, but takes meal | 03 |
| Total unwilling for meal | 04 |
| Abhyavarana-Abhilasha (Revival and improvement in | |
| hunger) | |
| Person taking food in normal quantity twice a day | 00 |
| Person taking food in moderate quantity twice a day | 02 |
| Person taking food in less quantity twice a day | 04 |
| Person taking food in less quantity once a day | 06 |
| Person not at all taking food | 80 |
| Ahara Kale Samyagajaranam (Digestion of ingested | |
| food within time) – | |
| Jirna Ahara Lakshana symptoms were considered, | |
| which are as given below: | |
| Utsaha | |
| Laghuta | |
| Udgar Shuddhi | |
| Kshut Trishna Pravritti | |

E. Chetasa bala^[14]

Chetasbala score which was used to assess symptoms by comparing it with the before treatment status are given below:

| Nidralabho Yathakale (Sleep in proper time and cessation in symptom Nidra-Viparyaya) | |
|--|----|
| Sound sleep for 8 hours | 00 |
| Sleep 8 hours but disturbed leading to day sleep | 01 |
| Sleep less than 8 hours and disturbed leading to day sleep | 02 |
| Vaikarika Swapnanama Adarshanam (No pathological dreams) | |
| Dreams absent (Sound sleep) | 00 |
| Some dreams but physiological | 01 |
| Presence of pathological dreams | 02 |
| Mana <i>Buddhi Indriya Avyapatti</i> (Proper and unaltered functioning of mind, intellect and sensories) | |
| Normal | 00 |
| Mild problem in orientation | 01 |
| Moderate problem in orientation | 02 |
| Absence of orientation | 03 |
| Sukhen cha pratibodhanam (Feeling of well being) | |
| Feeling complete healthy | 00 |
| Feeling much cheerful | 01 |
| Some improvement in feeling of well-being | 02 |
| | |

Follow-up

A follow-up was done one month after completion of the treatment to check for any recurrences.

Dietary restrictions

The patients were strictly advised to follow certain restrictions and guidelines regarding food, food habits and life style. They were instructed to avoid all the possible causes of Agnimandya.

Groups

Total 101 patients of Amavata (Rheumatoid arthritis) were registered for the present study. They were randomly divided into two groups. Out of these, 84 patients completed the study and there were 17 drop-out cases.

(I) Rasona Rasnadi Ghanavati group (Group A)

In this group 51 selected patients of Amavata were registered, out of which 43 completed the trial. These patients were given Rasona Rasnadi Chanavati (250 mg Vati) in the dose of 2 vati three times a day with Anupana Koshna Jala for 3 months. Along with this, Rasona Rasnadi lepa was applied locally over affected joints twice a day for 3 months.

(II) Simhanada Guggulu group (Group B)

In this group, 50 selected patients of Amavata were registered, out of which 41 completed the trial. These patients were given Simhanada Guggulu (500 mg in the Vati form) in the dose of 2 vati three times a day with Anupana Koshna Jala for 3 months. Along with this, Rasona Rasnadi lepa was applied locally over affected joints twice a day for 3 months.

The dose of Rasona Rasnadi Lepa^[15] was decided according to the number of joints involved.

Yathochita Malotsarga

Table 1: For diagnostic as well as for assessment purpose, the degree of disease activity was estimated on the basis of criteria laid down by American Rheumatism Association (1967)

| Grade | 0 | 1 | 2 | 3 |
|---|---------------------------------|-----------------------------------|-------------------------------------|--|
| Fatigue | Not there | Full time work despite fatigue | Patient must interrupt work to rest | Fatigued and requiring long term rest |
| Grip strength | 200 mmHg or more | 199 to 120 mmHg | 119 to 70 mmHg | Under 70 mmHg |
| Westergren erythrocyte sedimentation rate (E.S.R.) (in 1st hour) | 0 to 20 | 21 to 35 | 36 to 50 | Above 50 |
| Haemoglobin (in gm%) | 12.5 or more | 12.4 to 11 | 10.9 to 9.5 | <9.5 |
| General function | All activity without difficulty | Most activity but with difficulty | Few activity cares for self | Little self care mainly on chair and bed |
| Patients estimate | Fine | Almost well | Pretty good | Pretty bad |
| Physicians' estimate of RA activity Apart from these criteria of ARA (1967) two other criteria were added here. | Inactive | Minimally active | Moderately active | Severely active |
| Foot pressure (in kg) | 25-21 | 20-16 | 15-10 | <10 |
| Walking time (for 25 feet in number of seconds) | 15-20 | 21-30 | 31-40 | >40 |

Observations

In this study majority of patients, i.e., 73.26% belonged to the age group of 31-50 years and 84.15% were female. The 79.20% patients were Hindu, 91.08% were married, 71.28% patients were housewives, 67.32% were from low income group and 79.20% of the patients were consuming analgesic and steroids. Majority of the patients had *Vata-Kapha Prakriti* (46.53%) and 50.49% had *Vata-Pitta Parkriti*. The percentage of patients in other groups considered was as follows: *Mandagni* (53.46%), *Madhyama Satva* (56.43%), *Madhyama Sara* (96.03%) and *Madhyama Samhanan* (92.07%). The 37.62% patients had menopause.

Most of the patients, i.e., 42.57% had positive family history of RA, 62.37% of patients had gradual onset and 51.48% had chronicity of more than 2 years. In this study, RA factor was found positive in 31.68% of patients and raised E.S.R found in 78.21% of the patients. All the patients showed aggravation of the disease during *Sheetkaala* and *Meghodaya Kaala*. Most of the patients were found to be indulged in *Viruddhahara* (95.04%), *Atiguru* (24.75%), *Bhojanattora Vyayama* (87.12%), *Divaswap* (52.47%), *Vishamashana* (78.21%), and *Snigdha Ahara* (22.77%). With respect to cardinal symptoms, *Sandhishula*, *Sandhigraha* and *Sparsha-Asahyata* was observed in all the patients, i.e., 100%, followed by *Sandhishotha* in 96.03% of patients.

With respect to general symptoms, the percentage of patients exhibiting each symptom was as follows: Angamarda (82.17%), Aruchi (31.68%), Gaurva (71.28%), Apaka (79.20%), Shoonta-Anganama (90.09%), Alasya (98.01%), Trishna (40.59%) and Jwara in 7.92% patients. Maximum patients experienced Utsaha-hani (98.01%), 83.16% experienced Agni-daurbalya followed by 60.39% for Anaha, 52.47% Vid-Vibaddhata, 51.48% Nidraviparyaya and 45.54% had Kukshi-Kathinta.

It was observed that *Proximal Interphalangeal Joint* (P.I.P) was involved in 97.02% of the patients. 84.15% patients had wrist, 82.17% knee, 63.36% ankle, 59.40% elbow, 57.42% shoulder,

46.53% neck, 32.67% hip and 25.74% patients had meta carpo phalangeal joint involvements.

Results

Effect of trial drugs in cardinal symptoms Dehabala Pariksha

In *Dehabala Pariksha*, 60.25% of the improvement was recorded in the *Swaravarna Yoga*, 43.41% in *Sharir Upachaya* and 50.64% improvement in *Balavriddhi* after the treatment in group A, while 65.43% of the improvement was recorded in the *Swaravarna Yoga*, 54.47% in *Sharir Upachaya* and 51.76% improvement in *Balavriddhi* recorded in group B. Both the results were statistically highly significant (*P*<0.001) [Tables 2-7]

Agni Bala Pariksha

In Agnibala Pariksha, 80.76% of the improvement was recorded in the Ruchira-Aharkale, 63.49% in Abhyavarana Shakti and 54.95% improvement in Jarana Shakti after the treatment in group A, while 84.41% of the improvement was recorded in the Ruchira-Aharkale, 65% in Abhyavarana Shakti and 50.43% improvement in Jarana Shakti recorded in group B. Both the results were statistically highly significant (P < 0.001).

Chetas Bala Pariksha

In Chetasbala Pariksha, 43.75% of the improvement was recorded in the Nidralabho-Yathakale, 84% in Vaikarikanam Swapananam Adarshanama, 83.33% in Mana-Buddhi-Indriya Avyapti and 54.26% improvement in Sukhana Cha Pratibodhanama after the treatment in group A, while 44.44% improvement was recorded in the Nidralabho-Yathakale, 57.14% in Vaikarikanam Swapananam Adarshanama 90% in Mana-Buddhi-Indriya Avyapti and 54.47% improvement in Sukhena Cha Pratibodhanama recorded in group B. Both the results were statistically highly significant (P < 0.001).

General functional capacity

The 23.63% improvement was recorded in general functional

Table 2: Total effect of therapy on Sandhi Shula (left and right side joints) in group A and B in the trial

| Sandhi Shula | Group | Group A (left) | | Group B (left) | | Group A (right) | | Group B (right) | |
|------------------------------|-------------|----------------|-------------|----------------|-------------|-----------------|-------------|-----------------|--|
| Improvement in % | No. of pts. | % of imp.* | No. of pts. | % of imp. | No. of pts. | % of imp. | No. of pts. | % of imp. | |
| Unchanged (0-25) | 01 | 2.32 | 01 | 2.43 | 01 | 2.32 | 0 | 00 | |
| Mild improvement (26-50) | 10 | 23.25 | 06 | 14.63 | 11 | 25.58 | 11 | 26.82 | |
| Moderate improvement (51-75) | 13 | 30.23 | 23 | 56.09 | 14 | 32.55 | 21 | 51.21 | |
| Marked improvement (76-99) | 09 | 20.93 | 09 | 21.95 | 07 | 16.27 | 07 | 17.07 | |
| Complete remission (100) | 10 | 23.25 | 02 | 4.87 | 10 | 23.25 | 02 | 4.87 | |

*imp - Improvement

Table 3: Total effect of therapy on Sandhi Shotha (left and right side joints) in group A and B in the trial

| Sandhi Shotha | Group | Group A (left) | | Group B (left) | | Group A (right) | | Group B (right) | |
|------------------------------|-------------|----------------|-------------|----------------|-------------|-----------------|-------------|-----------------|--|
| Improvement in % | No. of pts. | % of imp. | No. of pts. | % of imp. | No. of pts. | % of imp. | No. of pts. | % of imp. | |
| Unchanged (0-25) | 01 | 2.32 | 01 | 2.56 | 01 | 2.38 | 01 | 2.63 | |
| Mild improvement (26-50) | 07 | 16.27 | 03 | 7.69 | 07 | 16.66 | 06 | 15.78 | |
| Moderate improvement (51-75) | 11 | 25.58 | 14 | 35.89 | 11 | 26.19 | 80 | 21.05 | |
| Marked improvement (76-99) | 03 | 6.97 | 04 | 10.25 | 03 | 7.14 | 06 | 15.78 | |
| Complete remission (100) | 21 | 48.83 | 17 | 43.58 | 20 | 47.61 | 17 | 44.73 | |

*pts - Patients

Table 4: Total effect of therapy on Sandhi Graha (left and right side joints) in group A and B in the trial

| Sandhi Graha | Group | Group A (left) | | Group B (left) | | Group A (right) | | Group B (right) | |
|------------------------------|-------------|----------------|-------------|----------------|-------------|-----------------|-------------|-----------------|--|
| Improvement in % | No. of pts. | % of imp. | No. of pts. | % of imp. | No. of pts. | % of imp. | No. of pts. | % of imp. | |
| Unchanged (0-25) | 01 | 3.22 | 03 | 7.31 | 01 | 3.22 | 02 | 4.87 | |
| Mild improvement (26-50) | 08 | 18.60 | 07 | 17.07 | 06 | 13.95 | 11 | 26.82 | |
| Moderate improvement (51-75) | 19 | 44.18 | 21 | 51.21 | 16 | 37.20 | 15 | 36.58 | |
| Marked improvement (76-99) | 07 | 16.27 | 05 | 12.19 | 11 | 25.58 | 09 | 21.95 | |
| Complete remission (100) | 08 | 18.60 | 05 | 12.19 | 09 | 20.93 | 04 | 9.75 | |

Table 5: Total effect of therapy on Sparsha-Asahayata (left and right side joints) in group A and B in the trial

| Sparsha-Asahyata | Group | Group A (left) | | Group B (left) | | Group A (right) | | Group B (right) | |
|------------------------------|-------------|----------------|-------------|----------------|-------------|-----------------|-------------|-----------------|--|
| Improvement in % | No. of pts. | % of imp. | No. of pts. | % of imp. | No. of pts. | % of imp. | No. of pts. | % of imp. | |
| Unchanged (0-25) | 00 | 00 | 02 | 4.87 | 01 | 2.38 | 00 | 00 | |
| Mild improvement (26-50) | 12 | 27.90 | 14 | 34.14 | 10 | 23.80 | 15 | 36.58 | |
| Moderate improvement (51-75) | 15 | 34.88 | 14 | 34.14 | 12 | 28.57 | 14 | 34.14 | |
| Marked improvement (76-99) | 05 | 11.62 | 06 | 14.63 | 09 | 21.42 | 07 | 17.07 | |
| Complete remission (100) | 11 | 25.58 | 05 | 12.19 | 10 | 23.80 | 05 | 12.19 | |

Table 6: Comparative effects of test drugs in Group A and Group B on overall improvement in cardinal symptoms of *Amavata* in the trial (By paired t test)

| Cardinal symptom | Gr. | ʻn' | Mean | score | Х | % Relief | S.D.± | S.E.± | 'ť | Р |
|------------------|-----|-----|-------|-------|-------|----------|-------|-------|-------|---------|
| | | | B.T. | A.T. | | | | | | |
| Sandhi-Shula | Α | 43 | 18.30 | 5.74 | 12.56 | 68.61 | 4.74 | 0.72 | 17.34 | <0.001 |
| | В | 41 | 21.34 | 7.48 | 13.85 | 64.91 | 5.14 | 0.80 | 17.23 | < 0.001 |
| Sandhi-Shotha | Α | 43 | 7.81 | 1.91 | 5.91 | 75.59 | 3.06 | 0.46 | 12.62 | < 0.001 |
| | В | 41 | 8.14 | 1.90 | 6.24 | 76.64 | 4.33 | 0.67 | 9.22 | < 0.001 |
| Sandhi-Graha | Α | 43 | 16.81 | 5.37 | 11.44 | 68.05 | 3.90 | 0.59 | 19.21 | < 0.001 |
| | В | 41 | 18.78 | 7 | 11.78 | 62.72 | 6.01 | 0.93 | 12.54 | < 0.001 |
| Sparsha-Asahyata | Α | 43 | 14.53 | 4.84 | 9.70 | 66.72 | 4.05 | 0.61 | 15.67 | < 0.001 |
| | В | 41 | 16.78 | 6.26 | 10.51 | 62.64 | 4.44 | 0.69 | 15.14 | < 0.001 |

B.T.- Before treatment; A.T.- After treatment

Table 7: Overall effect of therapy on *Amavata* on 84 patients belonging to Group A and Group B

| Effects | Grou (<i>n</i> = | • | Group B (<i>n</i> = 41) | | |
|-------------------------------|----------------------|-------|-----------------------------|-------|--|
| | No. of pts. | % | No. of pts. | % | |
| Unchanged (<25%) | 0 | 0 | 0 | 0 | |
| Mild improvement (26-50%) | 80 | 18.60 | 07 | 17.07 | |
| Moderate improvement (51-75%) | 15 | 34.88 | 24 | 58.53 | |
| Marked improvement (76-99%) | 14 | 32.55 | 80 | 19.51 | |
| Complete remission (100%) | 06 | 13.95 | 02 | 4.87 | |

capacity after the treatment in group A, while 19.64% improvement was recorded in group B.

Degree of disease activity

The 18.05% of the improvement was recorded in degree of disease activity after the treatment in group A, while 21.91% improvement recorded in group B.

Effect on erythrocyte sedimentation rate

The 8.80% reduction in the elevated ESR levels was recorded after the treatment in group A, while 14.32% reduction was recorded in group B.

Comparison

Though results of both the groups were statistically highly significant (P < 0.001) the data pertaining to the effect of test drugs on improvement on Sandhishula, Sandhishotha, Sandhigraha and Sparsha-Asahyata have been summarized, suggests that the drug used in group A was more effective.

So from the obtained data, it may be inferred that the treatment schedule of group A is more effective than test drug of group B when overall improvements in cardinal symptoms are concerned.

Overall effect of therapy

In Rasona Rasnadi Ghanavati group 34.88% of patients showed moderate improvement, while in Simhanada Guggulu group 58.53% of patients belonged to the same category. On the other hand, 6 (13.95%) patients in Rasona Rasnadi Ghanavati group got complete remission, however, only 2 (4.87%) patients from Simhanada Guggulu group could have a similar experience.

Total effect of therapy

The 68.91% of patients in group A, while 65.16% of patients in group B showed improvement in condition. Both the results were statistically highly significant.

Thus patients belonging to group A showed better improvement in their condition as compared to group B patients.

Aggravation during one month follow up

In a one month follow up study, more aggravation was found in Sandhishula, Sandhigraha and Sparsha-asahyata in Simhanada Guggulu treated group; while Rasona Rasnadi Ghanvati group showed more aggravation in Sandhishotha.

Discussion

Sedentary life style, stressful situations and fast food dietary patterns are responsible factors for the manifestation of disease. The etiological factors like *Guru Ahara*, *Viruddhahara*, *Viruddha Cheshta*, *Mandagni*, *Snigdhabhuktavata Vyayama* etc^[16] are responsible for *Amavata*. Derangement of *Agni*, that is *Agnimandya*, (hypo-functioning of *Agni*) is a chief factor responsible for the formation of *Ama*.

Asthis (bones) and Sandhis (joints) are the most affected parts in Amavata. Root source of these are Majjavaha Srotas^[17] which are directly afflicted with Viruddha Ahar-Vihar^[18] So we can say that Viruddha Ahara and Viruddha Cheshta both contribute as Nidanas in pathogenesis of Amavata. Again Vyayama is said to be a causative factor for the Shakha Gati of Doshas.^[19] If there is already Ama condition and Vyayama is done, the increased Vata will take the Ama to the Shakha then causing its Sthanasamshraya in the Sandhis, leading to Amavata. After studing the etiopathogenesis of Amavata, it is found that above factors individually or together lead to the Kapha Prakopa or Vataprakopa or both Along with this role of psychological factors also should be considered.

In Amavata, partially digested dietary substances accumulated at the level of intestine may cause Gastro-enteritis. Part of the Ama may get absorbed through the intestinal mucosa, and circulating through the entire body may perform a role of antigen, consequently vitiating the Dosha to cause different disorders. The basic pathogenesis of Rheumatoid arthritis is Antigen-antibody complex mediated tissue injury (Autoimmune antibody production).

The pathogenesis of Amavata bears some similarity to the recently described intestinal permeability syndrome (IPS). The impetus for IPS is a process by which some agent or combination of agents initiate an inflammatory response in the digestive tract. Persistent gastrointestinal inflammation eventually disrupts the integrity of the mucosal lining of the gut, and tiny perforations allow for molecules larger than usual to cross this barrier. This includes molecules' from dietary protein and fats, bacteria, parasites and fungi. In response to this infiltration, an immune response is initiated, and the body begins to manufacture specific antibodies to these antigens. Once activated, these antibodies then circulate and 'look' for more antigens. If any tissue has markers similar to the exogenous antigen, the antibody initiates an immune response and the tissue destruction begins (Galland 1993).^[20]

It was observed that the hand joint involvement was seen in 100% patients. Amavata is a disease which starts mainly in the small joints, especially PIP. (PIP is regarded as the most busy joint as a person uses this joint atleast 2000 times everyday if he is in the conscious state). Newer studies also indicate that the hand joint is most prone for Rheumatoid arthritis, because of the small amount of bursae. As the bursae is a sac of synovial fluid, it acts as a shock absorber, and decreases the chances of inflammation. [21] The finger joint like PIP and the MCP joint which do not have bursae, are most prone to RA. This is in accordance to the A.R.A. criteria of 1988, that states that atleast one hand joint involvement is mandatory for diagnosing a case of Rheumatoid arthritis. [22] More aggravation of Vata Dosha occurs at Sandhi Sthana due to obstruction of

Srota by the Kleda of more virulent Ama which is formed due to combination with Tridosha in to the Srotas at Sandhisthana. This can cause an increase in the chances of Sthana-Samshraya.

While mentioning about the management of Amavata, which is a disease condition of Ama and Vata dominance, Acharyas explained that drugs which have Deepana, Ama-Pachana, and Vatashamaka properties are useful in Amavata Chikitsa. Due to chronic nature of the disease Rasayana, immuno-modulator drugs are very helpful for the rejuvenation of the all Dhatus. Most of the drugs of both groups have Katu Tikta Rasa, Ushna Virya, Rasayana, Amapachaka and Vatashamaka properties which help to disrupt the pathogenesis of Amavata.

Ghanavati group shows better result in relieving Sandhishula (68.61%), while Simhanada Guggulu group showed better result relieving Sandhishotha (76.64%). Sandhishula is due to Vataprakopa, and in Ghanavati almost all drugs have Vata-Kaphashamaka properties with Ushna Tikshna Guna, which further stops Ama formation and Vayu Vikriti. Acharya Charaka had used Rasna in Vatavyadhi Chikitsa as a Shreshtha Vataharanam^[23] which may have acted as a factor in relieving Sandhishula.

Sandhisotha may be due to the Avarana of Kapha. Simhanada Guggulu has Srotoshodhaka, Lekhana and Agnidipana properties, which elevates the Agni and checks further Ama formation. This may be the probable cause of the result obtained by Simhanada Guggulu group.

The relief provided by both groups Ghanavati and Guggulu in Sandhigraha and Sandhi Sparsha-Asahyata was statistically highly significant. However, Ghanavati showed better result in both these symptoms.

Sandhigraha and Sparsha Asahyata may be due to the Avarana of Kapha and Vyana-Samana Vayu Dushti. Due to their Katu Tikta Rasa, Ushna Virya, Rasayana Prabhava, Amapachaka and Vatashamaka properties, ingredients of Rasona Rasnadi Ghanavati help to disrupt the pathogenesis of RA, which may be the cause behind Ghanavati giving better symptom relief.

Probable mode of action of Rasona Rasnadi Ghanavati

Rasona Rasnadi Ghanavati has 10 ingredients. Most of the drugs have Katu Tikta Rasa, Ushna Virya, Rasayana, Amapachaka and Vatashamaka properties, which help to disrupt the pathogenesis cycle of Amavata. The properties of each of the 10 ingredients are as follows: Nirgundi has Shula and Shothahar Prabhava; Lahsuna has Medhya, hypolipidemic and Rasayana; Rasna has Shula and Shothahara; Shunthi has Amapachaka and Rasayana; Guduchi has Rasayana and immunomodulatory properties; Amaltas is Mrudu-virechak and Kusthaghna Rasayana; Punarnava acts as haematinic and Shothahara and liver protective; Gokshura is liver protective and Shothahara; Eranda is Shula - Shothahara and Rasayana and Devadaru has Amapachaka and Shothahara Prabhava. Each drug has unique properties which help to minimize the symptoms and destroy the Samprapti. Also, they help to develop the immune power, helping the patients to regain the Dehabala and lusture.

Tikta and Katu Rasa present in Rasona Rasnadi Ghanavati possess antagonistic properties to Ama and Kapha which are

the chief causative factors in this disease. Because of their Agnivriddhikar property, they improve the digestive power. Thus, Amarasa is digested and excessive production of Kapha is reduced which in turn removes the obstruction of the Srotas. Because of Tikshna Guna and Ushna Virya it also alleviates vitiated Vata. The Tikshna and Ushna properties of Rasona Rasnadi Ghanavati do not allow the Ama to linger at the site of pathogenesis; thus reducing Srotorodha and pain. It also possesses antagonistic actions to Sheeta and Ruksha Guna of Vata. Thus, Rasona Rasnadi Ghanavati controls Ama and Vata together and inhibits the pathogenesis of RA. Rasona Rasnadi Ghanavati has anti oxidant properties which neutralize the Ama (Free radical like substance) by scavenger action and Rasayana effect. The Rasayana drug activates cellular metabolism, modulates the immune system and increases and activates body's own antioxidants and radical scavengers.[24]

Probable mode of action of Simhanada Guggulu

The Simhanada Guggulu has ingredients which have Ushna Veerya, Katu Vipaka, Ruksha and Snigdha Guna properties, along with drugs such as Triphala, Gandhaka, Guggulu and Eranda oil which have has Rasayana effects. The properties of its other ingredients are as follows: Triphala is Rasayana, Mridu-Virechaka, antioxidant; Guggulu has Shulahara, Shothahara, Rasayana properties; Gandhaka is Kushthaghna Rasayana and Eranda oil is Vaatanuloman, Vrishya Rasayana. Among these, Triphala and Guggulu have proved anti-oxidant properties. [2]

In the first stage of disease pathogenesis, Amotpatti takes place. At this stage, Simhanada Guggulu shows Amapachana as all the general pharmacodynamic properties of Simhanada Guggulu, i.e., Lahgu, Tikshna, Ruksha Guna, Katu, Tikta Rasa, and Ushna Veerya are against the Guru, Snigdha, Picchila and Sheeta properties of Ama. Also, Simhanada Guggulu has some anti-oxidant properties which act against Ama. Later, Yugapata Prakopa of Doshas is checked by Vata-Kaphahara action of drugs. Further, Ama formation is stopped by the Deepneeya action. In the Srotoabhishyanda, it shows Srotoshodhana and relieves the symptoms of Sandhishula, Shotha, Aalsya and Aruchi by its analgesic and anti-inflammatory action. Also associated symptoms like Vibandha and Anaha are reduced by Anulomana, i.e., purgative properties of the drug due to Eranda oil and Triphala. Most of the drugs are Vata-Kapaha Shamaka and Agnivardhaka, so it is very suitable for the Samprapti Vighatana of the disease and to combat the main culprits of Vata, Kapha(Ama) and Mandagni, the root causes of Amayata.

Probable mode of action of Rasona Rasnadi Lepa

The *Lepa* acts through dilution of the accumulated toxins and increasing the peripheral vascularization. On the other hand, it inhibits the synthesis and release of acetylcholine in the inflamed joints. This effect of *lepa* can be attributed to the *Shothahara* and *Shulahara* (antiinflammatory) properties of majority of the drugs.^[24]

Most of the drugs of Rasona Rasnadi Lepa have Laghu, Tikshana, Ruksha Guna, Katu, Tikta Rasa, and Ushna Veerya properties, all of which act against Ama. It first relieves the Pratyatma Lakshana of Amavata locally. These include:

Sandhishula, Sandhishotha, Sandhigraha and Sparsha-asahyata by its Vednasthapana, Shula-shothahara, and anti-inflammatory effect. When we use the Rasona Rasnadi lepa locally, it produces the local counter irritant effect and dilutes the accumulated Doshas. It also absorbs the Doshas by Ushna Tikshna Guna, which leads to Shamana of viatiated Ama and Vata. Hence, it can be concluded that the local application of Rasona Rasnadi lepa with the medical intervention is very beneficial against the symptoms of Amavata.

Conclusion

At the end of the study, following conclusions can be drawn on the basis of observations made, results achieved and thorough discussion: The disease Amavata is produced by the Tridosha, though Ama and Vata are the inititaing factors for its pathogenesis. Viruddha-Ahara Sevana and doing moderate to severe exercise after meal were found as prominent etiological/ promoting factors in majority of patients. Better results were observed in Sandhishula, Sandhigraha and Sparsha-Asahyata in Ghanavati group. This may be due to the Vata-Kaphshamaka properties and Ushna Tikshna Guna of the drugs. On Dehabala, Agnibala and Chetasbala associated symptoms, both the groups provided statistically highly significant results. No side effects of the research drugs were observed during the clinical study. Lastly, it can be concluded that both the groups show significant results; however with respect to complete remission rate, Group A therapy is more effective than group B in the management of Amavata.

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