

“CLINICAL EVALUATION OF EFFICACY OF SIMHANADA GUGGULU IN THE MANAGEMENT OF AMAVATA”

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ABOUT THE ARTICLE

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ABSTRACT

Background- The disease Amavata i.e. Rheumatoid arthritis is a challenge for the physician because of its apparent chronicity, incurability, complications, morbidity and crippling nature. About 0.5-1% of the world's population suffers from Rheumatoid arthritis (Harrison 2017). Rheumatoid arthritis has generated universal interest among research scholars around the world. Many efforts have been made at this institute and other research centers to study different aspects of Amavata. The present study conducted clinical trials on Amavata. Till date no satisfactory treatment has been available for Amavata disease. The main objective of the treatment of this disease is to provide relief in the form of reduced pain and discomfort, prevention of further disease process, loss of joint function, maintaining productive and active life and above all to restore the vitality of the body (oja) or a good immune status. In this study the medicine Simhanada Guggulu is used against the Amavata where analysis of efficacy will be determined.

KEYWORDS: Amavata, Rheumatoid arthritis, Simhanada Guggulu

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INTRODUCTION

Amavata is one of the major diseases in the present era, which is mainly induced due to the highest erroneous habits gradually developing in the society. Symptoms of Amavata are more similar to those of Rheumatoid Arthritis in the current era. Rheumatoid arthritis is a chronic, systemic inflammatory disease involving the joints.

There is no any effective treatment for Rheumatoid arthritis even today, but Ayurveda can give a proper solution to this problem. To see the above fact, we feel that Ayurveda has good basic principles of medicine for the treatment of disease. To fulfill this aim, we selected the problem for study. The present dissertation entitled “A Pharmaceutical preparation of Simhanada Guggulu and its clinical efficacy in Amavata¹ (Rheumatoid arthritis)” was

selected for the present study with following aims and objectives:

- To study the aetiology, pathogenesis and symptomatology of Amavata according to Ayurvedic science.
- To study the aetiology, pathogenesis and symptomatology of Rheumatoid arthritis according to Modern science.
- To evaluate the clinical efficacy of an oral drug i.e. Simhanada Guggulu in the management of Amavata².
- To find out if the drug has any side effects. Simhanada Guggulu was subjected to all Organoleptic parameters and Physico-chemical tests were performed and their results were compared with the Standard parameters.

The results of all the test parameters of Simhanada Guggulu were normal or within normal limits when compared with the standard parameters.

MATERIALS AND METHODS

Selection of Patient:

The patients attending the OPD & IPD of the Govt. Ayurvedic College and Hospital, Patna and fulfilled the criteria of inclusion were selected randomly on the basis of classical signs and symptoms described in various Ayurvedic texts.

Diagnostic Criteria:

The RA patients registered in the present study were diagnosed based on criteria set by the American College of Rheumatology (American Rheumatism Association revised in 1987). This has been described earlier in the review of "Modern literature". These criteria are as follows:

1. Morning stiffness: Morning stiffness in and around the joints for more than one hour.
2. Arthritis of three or more joint areas: Simultaneous soft tissue swelling or fluid (not bone over growth alone) in at least three joint areas observed by a Physician for at least six weeks. The 14 possible joint areas involved are the right or left proximal interphalangeal, metacarpophalangeal, wrist, elbow, knee and metatarsophalangeal joint.
3. Arthritis of Hand joints: Swelling of at least one area in the wrist, metacarpophalangeal joints or proximal interphalangeal joints for at least six weeks.
4. Symmetric Arthritis: Simultaneous involvement of the same joint areas on both sides of the body.
5. Rheumatoid Nodules: Subcutaneous nodules on bony prominence or extensor surfaces or juxta-articular regions observed by a Physician.
6. Serum Rheumatoid Factor: Demonstration of abnormal amounts of serum rheumatoid factor by any method for which the result has been positive in less than 5 percent of normal control subjects.
7. Radiographic changes: Typical radiographic changes of wrist radiographs, which should include localized or most marked erosion or uneven bony decalcification in the joints involved.

Guidelines for classification:

- ☐ As per the above 7 criteria if a patient has more than 4, he/she can be diagnosed as Rheumatoid Arthritis.
- ☐ Patients with two or more clinical diagnoses are excluded.

In addition, the diagnostic criteria described in the Ayurvedic literature for Amavata by Madhavakara and other Acharyas have been applied.

A proforma was prepared incorporating all the signs and symptoms described in Ayurvedic classics as well as Modern texts. It also included Dashavidha pariksha on Ayurvedic lines. A detailed clinical history was noted and a complete physical examination was performed based on the proforma. Routine pathological investigations were performed before and after drug treatment.

Method of study:

- ☐ IEC: Approval from the Institutional Ethics Committee (IEC) for MD/MS (Ay.) research work was obtained prior to initiating this study/trial.
- ☐ Consent: Written informed consent was obtained on the prescribed proforma before the patient was included in the trial. Before taking consent, they were explained the merits and demerits of the research plan.
- ☐ CRF: A Clinical Research Proforma was prepared to note down all the details of the patients and their illness.
- ☐ Drug: The raw material of trial drug i.e. Simhanada Guggulu was procured from College Pharmacy. It was processed according to classical texts to prepare the drug Simhanada Guggulu. The preparation details have been previously described in the Pharmaceutical Study section.
- ☐ Drug Administration: The trial drug was given orally.
- ☐ Dose: 1000 mg twice a day.
- ☐ Duration of Study: 90 days.
- ☐ Diet for patients: Patients were advised to take their regular light diet and milk.
- ☐ Pathya-apathya:

All patients registered for the current study were given advice on what to do and what not to do.

Do's: Eat light and hot food.

Drink lukewarm water. Take a bath with hot water.

Stay in warm places in winter.

Don'ts: Do not consume restricted foods.

Don't eat heavy food. Avoid exposure to cold. Don't work too hard.

CRITERIA FOR ASSESSMENT:

The results of therapy were evaluated on the basis of clinical signs and symptoms described in Ayurvedic classics as well

as ARA 1988. All patients were assessed for relief of signs and symptoms and objective parameters after completion of the trial. The grading/scoring system adopted to objectively assign the subject characteristics as follows:

Subjective Parameters	Grade	Score
Pain in joints	No pain	0
	Mild pain	1
	Moderate pain	2
	Severe pain	3
Stiffness in joints	No stiffness	0
	0-10 minutes	1
	10-120 minutes	2
	More than 2 hours	3
Swelling in joints	No swelling	0
	Mild swelling	1
	Moderate swelling	2
	Enormous swelling	3
Mobility of joints	No pain on moving	0
	Mild pain in moving	1
	Moderate pain on moving	2
	Severe pain on moving	3
Tenderness in joints	No tenderness	0
	Mild tenderness	1
	Moderate tenderness	2
	Severe tenderness	3

Functional Assessment:

Functional assessment such as walking time, grip strength etc. was not performed as most of the patients were in the first stage.

Criteria for Assessment of the total Effect of Treatment:

The following are the criteria for assessing the total effect of treatment on patients with Amavata:

Cured	100% relief in signs and symptoms.
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Markedly improved	Patients with 75% - 99% improvement in signs and symptoms.
Moderately improved	Patients with 50% - 74% improvement in signs and symptoms.
Partially improved	Patients with 25% - 49% improvement in signs and symptoms.
Unchanged	No change in signs and symptoms or less than 24% improvement.

Statistical Analysis:

The overall information collected with respect to demographic data is given in percentages. The scoring of the criterion assessment was analyzed statistically in terms of BT (Before Treatment), AT (After Treatment), SD (Standard Deviation) and SE (Standard Error). Paired "t-test" was performed.

The obtained results were explained as follows:

Insignificant	$P > 0.05$
Significant	$0.001 \leq P \leq 0.05$
Highly significant	$P < 0.001$

OBSERVATIONS AND RESULTS

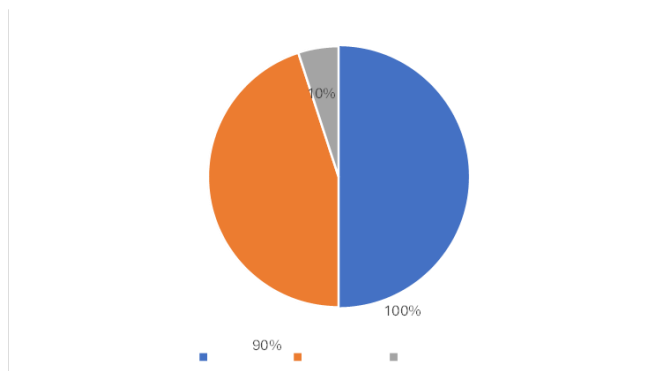
DEMOGRAPHIC STUDY:

The results thus obtained were evaluated and analyzed on statistically recorded signs and symptoms and on routine blood tests before and after treatment.

The observations made during the study were presented as follows:

Types of Patients	No. of Patients	Percentage (%)
Registered	30	100.00
Completed	27	90.00

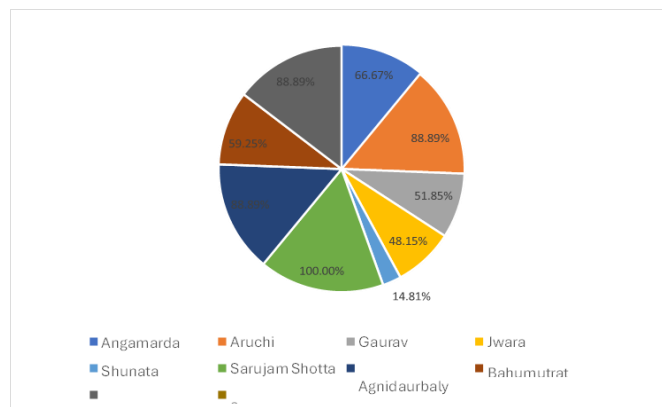
Discontinued	03	10.00
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A total of 30 patients with Amavata were taken in the present study, of whom 03 patients had discontinued before completion of treatment at various stages.

TABLE: 5.27 DISTRIBUTION OF GENERAL SIGNS AND SYMPTOMS OF 27 PATIENTS OF AMAVATA

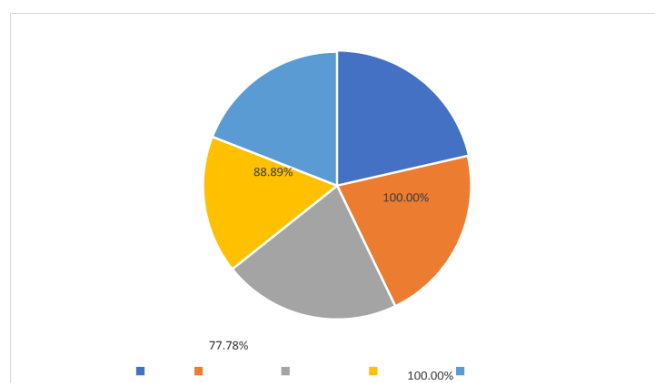
Sr. No.	Signs & Symptoms	No. of Patients	Percentage (%)
1.	Angamarda	18	66.67
2.	Aruchi	24	88.89
3.	Gaurav	14	51.81
4.	Jwara	13	48.15
5.	Shunata	04	14.81
6.	Sarujam Shotta	27	100.00
7.	Agnidaurbalya	24	88.89
8.	Bahumutrata	16	59.25
9.	Nidraviparyaya	24	88.89
10.	Koshthabaddhata	22	81.48



This table shows the percentage incidence of symptoms in patients with Amavata. The above table shows that all the 27 patients (i.e 100.00%) were suffering from Sarujamshotha, Angamarda was found in 18 patients (i.e 66.67%), Aruchi, Agnidaurbalya and Nidraviparyaya were found in 24 patients (i.e 88.89%), Gaurav was found in 14 patients (i.e 51.85%), Jwara was found in 13 patients (i.e 48.15%), Shunata was found in 04 patients (i.e 14.81%), Bahumutrata in 16 patients (i.e 59.25%) and Koshthabaddhata in 22 patients (i.e 81.48%).

TABLE: 5.28 DISTRIBUTION OF CARDINAL SIGNS AND SYMPTOMS OF 27 PATIENTS OF AMAVATA

Sr. No.	Cardinal Signs & Symptoms	No. of Patient	Percentage (%)
1.	Pain	27	100.00
2.	Stiffness	27	100.00
3.	Swelling	27	100.00
4.	Mobility	21	77.78
5.	Tenderness	24	88.89



RESULTS

30 patients were registered for the proposed study, 03 of them could not undergo the trial for the full duration due to various reasons, so they were dropped out. Remaining 27 patients turned up for complete follow-ups and were statistically analysed and the results obtained are described below:

TABLE: 5.29 EFFECT OF TRIAL DRUG (SIMHANADA GUGGULU) IN GENERAL SIGNS AND SYMPTOMS OF AMAVATA

Signs & Symptoms	Mean		Percentage (%) Relief	SD	SE	t-Value	P-Value
	BT	AT					
Angamarda	0.85	0.30	65.22	0.80	0.15	3.61	<0.05
Aruchi	1.41	0.33	76.32	0.92	0.18	6.09	<0.001
Gaurav	0.70	0.22	68.42	0.70	0.13	3.57	<0.05
Jwara	0.67	0.26	66.67	0.70	0.13	3.31	<0.05
Shunata	0.19	0.11	40.00	0.27	0.05	1.44	>0.05
Sarujam Shotha	1.48	0.33	77.50	0.99	0.19	6.03	<0.001
Agni Daurbalya	1.22	0.22	81.82	0.83	0.16	6.24	<0.001
Bahumutrata	1.11	0.85	26.67	0.82	0.16	1.87	>0.05
Nidraviparyaya	1.37	0.33	75.68	0.90	0.17	6.00	<0.001
Koshthabaddhata	1.22	0.19	84.85	0.85	0.16	6.31	<0.001

DISCUSSION

EFFECT OF THERAPY ON ANGAMARDA:

The mean score of Angamarda, before treatment was 0.85 and after treatment it changed to 0.30, resulting in a 65.22% difference in mean score which was statistically significant ($P<0.05$).

EFFECT OF THERAPY ON ARUCHI:

The mean score of Aruchi, before treatment was 1.41 and after treatment it changed to 0.33 giving 76.32% difference in mean score which was highly significant statistically ($P<0.001$).

EFFECT OF THERAPY ON GAURAV:

The mean score of Gaurav, before treatment was 0.70 and after treatment it changed to 0.22, resulting in a 68.42% difference in mean score which was statistically significant ($P<0.05$).

EFFECT OF THERAPY ON JWARA:

The mean score of Jwara, before treatment was 0.67 and after treatment it changed to 0.26, resulting in a 66.67% difference in mean score which was statistically significant ($P<0.05$).

EFFECT OF THERAPY ON SHUNATA:

The mean score of Shunata, before treatment was 0.19 and after treatment it changed to 0.11 giving 40.00% difference in mean score which was insignificant statistically ($P>0.05$).

EFFECT OF THERAPY ON SARUJAM SHOTHA:

The mean score of Sarujam Shotha, before treatment was 1.48 and after treatment it changed to 0.33, resulting in a 77.50% difference in mean score which was statistically highly significant ($P<0.001$).

EFFECT OF THERAPY ON AGNI DAURBALYA:

The mean score of Agni Daurbalya, before treatment was 1.22 and after treatment it changed to 0.22 giving 81.82% difference in mean score which was highly significant statistically ($P<0.001$).

EFFECT OF THERAPY ON BAHUMUTRATA:

The mean score of Bahumutrata, before treatment was 1.11 and after treatment it changed to 0.85 giving 26.67% difference in mean score which was statistically insignificant ($P>0.05$).

EFFECT OF THERAPY ON NIDRAVIPARYAYA:

The mean score of Nidraviparyaya, before treatment was 1.37 and after treatment it changed to 0.33 giving 75.68% difference in mean score which was highly significant statistically ($P<0.001$).

EFFECT OF THERAPY ON KOSHTHABADDHATA:

The mean score of Koshthabaddhata, before treatment was 1.22 and after treatment it changed to 0.19 giving 84.85% difference in mean score which was statistically highly significant ($P<0.001$).

EFFECT OF THERAPY ON PAIN:

The mean score of Pain, before treatment was 1.63 and after treatment it changed to 0.37 giving 77.27% difference in mean score which was highly significant statistically ($P<0.001$).

EFFECT OF THERAPY ON STIFFNESS:

The mean score of Stiffness, before treatment was 1.44 and after treatment it changed to 0.33 giving 76.92% difference in mean score which was highly significant statistically ($P<0.001$).

EFFECT OF THERAPY ON SWELLING:

The mean score of Swelling, before treatment was 1.59 and after treatment it changed to 0.30 giving 81.40% difference in mean score which was highly significant statistically ($P<0.001$).

EFFECT OF THERAPY ON MOBILITY:

The mean score of Mobility, before treatment was 0.93 and after treatment it changed to 0.41 giving 56.00% difference in mean score which was statistically significant ($P<0.05$).

EFFECT OF THERAPY ON TENDERNESS:

The mean score of Tenderness, before treatment was 1.26 and after treatment it changed to 0.48 giving 61.76% difference in mean score which was significant statistically ($P<0.05$).

EFFECT OF THERAPY ON TLC:

The mean score of TLC, before treatment was 8925.93 and after treatment it changed to 7651.85 giving 14.27% difference in mean score which was highly significant statistically ($P<0.001$).

EFFECT OF THERAPY ON NEUTROPHILS:

The mean score of Neutrophils, before treatment was 65.26 and after treatment it changed to 62.89 giving 3.58% difference in mean score which was statistically significant ($P<0.05$).

EFFECT OF THERAPY ON LYMPHOCYTES:

The mean score of Lymphocytes, before treatment was 29.44 and after treatment it changed to 31.96 giving 8.55% difference in mean score which was statistically significant ($P<0.05$).

EFFECT OF THERAPY ON EOSINOPHILS:

The mean score of Eosinophils, before treatment was 2.63 and after treatment it changed to 2.52 giving 4.23% difference in mean score which was statistically insignificant ($P>0.05$).

EFFECT OF THERAPY ON MONOCYTES:

The mean score of Monocytes, before treatment was 2.26 and after treatment it changed to 2.22 giving 3.28% difference in mean score which was statistically insignificant ($P>0.05$).

EFFECT OF THERAPY ON BASOPHILS:

The mean score of Basophils, before treatment was 0.41 and after treatment it changed to 0.40 giving 2.72% difference in mean score which was statistically insignificant ($P>0.05$).

EFFECT OF THERAPY ON Hb%:

The mean score of Hb%, before treatment was 12.45 and after treatment it changed to 12.64 giving 1.55% difference in mean score which was statistically significant ($P<0.05$).

EFFECT OF THERAPY ON ESR:

The mean score of ESR, before treatment was 29.74 and after treatment it changed to 23.19 giving 22.04% difference in mean score which was significant statistically ($P<0.05$).

EFFECT OF THERAPY ON RA FACTOR:

The mean score of RA factor, before treatment was 16.11 and after treatment it changed to 14.07 giving 12.64% difference in mean score which was significant statistically ($P<0.05$).

TOTAL EFFECT OF THERAPY

Effect of Therapy	No. of Patients	Percentage (%)
Cured	00	00.00
Markedly Improved	09	33.33
Moderately Improved	13	48.15
Partially Improved	05	18.52
Unchanged	00	00.00

CONCLUSION

his therapy provided statistically highly significant relief in general signs and symptoms such as Aruchi, Sarujam Shotha, Agni Daurbalya, Nidraviparyaya and Koshtabaddhata, while providing statistically significant relief in Angamarda, Gaurava and Jwara.

The therapy provided statistically highly significant relief in cardinal signs and symptoms such as Pain, Stiffness and Swelling while providing statistically significant relief in Mobility and Tenderness.

The therapy provided statistically highly significant change in TLC while providing statistically significant change in Neutrophils, Lymphocyte, Hb%, ESR and RA factor.

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