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PHARMACEUTICAL PREPARATION OF SIMHANADA GUGGULU WITH ITS CLINICAL EFFICACY IN AMAVATA

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ABSTRACT

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. Rheumatoid arthritis has generated universal interest among research scholars around the world. Many efforts have been made at this institute and other research centres 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. The disease *Amavata*, still remains a formidable disease, being capable of producing severe crippling deformities and functional disability. Today's scenario most of the people affected from this disease specially, old people. In Modern medicine, lesser number of drugs are available along with more side-effects. Also, less improvement and longtime treatment. So, Ayurvedic drugs such as Simhanada *guggulu* as mentioned in *Chakradatta* Samhita, Erand *taila* etc are given a new hope for such a disease along with no side-effects.

Key Words: *Amavata*, Simhanada *guggulu*, Erand *taila*, rheumatoid arthritis

INTRODUCTION

Ayurveda, an ancient system of medicine explains well about bone disorder like *Amavata*, Vata-*rakta*, Sandhi-*vata* etc. Among these, *Amavata* is a disease which is caused due to hypo-functioning of digestive fire. "*Amavata*" is a clinical entity vividly described by *Madhavakara* in 7th AD with well-defined aetiopathogenesis and clinical presentation with specific emphasis "*Mandagni*" and Ama playing the central role, it affects "*Rasavaha srotas*". *Amavata* is the disease affecting *Abhyantara* and Madhyama *Roga* Marga, as it involves Marma, *Asthi* and Sandhi. The disease *Amavata*, still remains a formidable disease, being capable of producing severe crippling deformities and functional disability. Today's scenario most of the people affected from this disease specially, old people. In Modern medicine, lesser number of drugs

are available along with more side-effects. Also, less improvement and longtime treatment. So, Ayurvedic drugs are given a new hope for such a disease along with no side-effects. A large no. of patients come in our hospital (GACH, Patna) OPD to get treated for *Amavata*. So, I decided to do research work on this problem. For this purpose, a formulation "Simhanada Guggulu" has been selected. It has been mentioned in *Chakradatta Amavata Chikitsaprakaranam* verse-31-36, which contains ingredient such as *Triphala*, Shuddha *Gandhaka*, Shuddha *Guggulu*, Eranda *taila*. Our classical text documented this drug having very good effects on *Amavata*. The features of *Amavata* are much identical to Rheumatoid Arthritis.

From the modern point of view, this disease looks similar to Rheumatoid Arthritis in its clinical appearance. Rheumatoid Arthritis is a systemic autoimmune disorder with chronic joint inflammation, pain and stiffness. RA commonly affects joints in the hands, wrists and knees.

AIMS AND OBJECTIVES

The aims and objectives of the present study are as follows:

- 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 *Amavata*.
- To find out if the drug has any side effects.

In order to accomplish the above aims and objectives, the entire study was divided into two parts:

- Conceptual study
- Clinical study
- Conceptual study:

Drug reviews as well as Ayurvedic and Modern literature have been studied extensively to know the profile and therapeutic options. This has been discussed in detail in the previous chapter of the dissertation.

CLINICAL STUDY

Current clinical research work was planned to evaluate the effect of trial drug in the management of *Amavata* (Rheumatoid arthritis).

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.

Inclusion Criteria:

- Patients who were ready for trial.
- Age group between 21-70 years.
- Selected signs and symptoms based on both ayurvedic and modern context.

Exclusion Criteria:

- Patients who were not ready for trial.
- Age group below 21 and above 70 years.
- They having complications like joint deformity.
- Patients having any other systemic illness.

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 Mild pain Moderate pain Severe pain	0 1 2 3
Stiffness in joints	No stiffness 0-10 minutes 10-120 minutes More than 2 hours	0 1 2 3
Swelling in joints	No swelling Mild swelling Moderate swelling Enormous swelling	0 1 2 3
Mobility of joints	No pain on moving Mild pain in moving Moderate pain on moving Severe pain on moving	0 1 2 3
Tenderness in joints	No tenderness Mild tenderness Moderate tenderness Severe tenderness	0 1 2 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.
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	$P < 0.001$

OBSERVATION & 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

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). 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). 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). 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). 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). 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). 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). 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). 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). 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). 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). 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). 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). 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). 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). 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). 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). 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). 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). 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). 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). 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). 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). 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).

CONCLUSIONS

This therapy provided statistically highly significant relief in general signs and symptoms such as *Aruchi, Sarujam Shotha*, Agni *Daurbalya, Nidraviparyaya* and *Koshthabaddhata*, 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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