COMPARATIVE THERAPEUTIC EFFECT OF GUDUCHI RASAYANA AND SIMHANADA GUGGULU IN AMAVATA

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ABSTRACT

Objective: To compare the therapeutic efficacy of Guduchi Rasayana and Simhanada Guggulu in patients suffering from Amavata. Study design: An open randomized comparative clinical trial with pre and post-test design. Study Selection: 30 patients suffering from Amavata/Rheumatoid Arthritis were selected for the study from SDM Ayurveda Hospital, Udupi, during the period November 2016 to March 2017. Intervention: Group A: Patients were administered with Eranda taila 20ml in empty stomach for a period of seven days, followed by Guduchi Rasayana 12cap OD in empty stomach for 30 days. Group B: Patients were administered with Simhanada Guggulu 1g tid for period of 30 days. Main Outcome of Measures: The response of the intervention was assessed in both the groups before the treatment and after the treatment with the scoring pattern and the results were analyzed statistically using paired ‘t’ test within the group and unpaired ‘t’ test between the groups. Results: The observations noted after the treatments were statistically significant in subjective and objective criteria in both the groups. Guduchi Rasayana showed better results on overall improvement with 33.3% of major improvement, 46.6% of moderate improvement and 20% of mild improvement. Whereas Simhanada Guggulu shown 13.3 % of major improvement, 53.3 % had moderate improvement and 33.3 % had mild improvement. Conclusion: Both the Groups were found to be efficacious in relieving the cardinal symptoms of Amavata and improving in functional ability, whereas Guduchi Rasayana showed comparatively better improvement.

Keywords: Amavata, Rheumatoid Arthritis, Guduchi Rasayana, Simhanada Guggulu.
The basic pathology of *amavata* begins with the morbid functioning of *jatharagni* (digestive fire). Impaired functioning of the *jatharagni* (digestive fire) causes formation of *ama* in association with vitiation of *vata dosha*. The vitiated *vata dosha* mobilises the *ama* all over the body and this *ama* tends to localize in the different *kapha sthana* with predilection for joints. Finally in the joints the illness causes pain swelling and stiffness\(^1\). The disease pathology involves *madhyama rogamarga* afflicting *marma* (vital organs). *Amavata* is been used to correlated with Rheumatoid Arthritis due to its equivalence in aetiology, pathology, clinical manifestation, prognosis and therapeutics.

Rheumatoid arthritis (RA) is a chronic systemic inflammatory polyarthritis which chiefly affects small diarthrodial joints of the hands and feet in a symmetrical pattern. It is a heterogeneous disease with variable severity, unpredictable course and an inconsistent response to drug management. Worldwide disease prevalence is about 0.8% (0.3% to 2.1%) of the inhabitants. The prevalence of RA in India is approximately 0.5% to 0.75%. More than 75% patients build up the disease among age period of 30 and 50yrs. Disease is seen more often in Women than men with the ratio 2 to 4.\(^2\)

Rheumatoid Arthritis being crippling in nature exhibits with severe pain and swelling in the joints makes difficulty to carry out routine activities and brings down the quality of life. Despite of the latest medical developments, patients suffering from this disease have not established a complete and long term relief. Hence, there is a necessitate exploring for a more effective treatment. In Ayurveda the main treatment modalities include *Shamana*, *Shodhana* and *Rasayana Chikitsa*. Literature emphasises on the use of *vyadihara Rasayana* in the chronic disease. The disease pattern of *Amavata* is chronic and crippling in nature, forming the irreversible structural deformity. Hence *vyadihara Rasayana* is of much use to deal better with the management of *Amavata*. *Guduchi* is one such drug processes *Rasayana property*\(^3\) and widely mentioned as well as made use in clinical practice to manage *Amavata* has been selected for the study as it helps in stimulating digestion, helps in pacifying *vatakapha doshas* which plays key role in manifesting the disease and also the action of immune booating, immune modulation is known for its efficacy.

Among the different oral formulations indicated in amavata, *Simhanada Guggulu*\(^4\) was selected as it is *tridoshahara* and *ama pachaka* and *Eranda Taila* being main ingredient possessing *dosha nirharana* quality which is proved for its efficacy has been selected for the comparison.

By means of the rising incidences as well as the chronic lingering character of the disease, study is aimed to provide safe and effective treatment in this disease. The study will help to investigate the unexplored areas of the *Rasayana Chikitsa* in this regard. Study will also create way to uptake future researches in this field.

**OBJECTIVES**

1. To evaluate the therapeutic effect of *Guduchi Rasayana* in patients suffering from *Amavata*.

2. To evaluate the therapeutic effect of *Simhanada Guggulu* in patients suffering from *Amavata*.
3. To compare the therapeutic effect of *Guduchi Rasayana* and *Simhanada Guggulu* in patients suffering from *Amavata*.

**Materials & Methods**

The study was initiated after obtaining the institute human ethic Committees Permission (Ref.no SDMCAU/ACA-49/EC46/14-15. DATE: 23/04/2015)

*Guduchi Rasayana* (Batch no.-160840, Mfg.Date-June 2016) and *Simhanada Guggulu* (Batch no.-170224, Mfg.date-June 2016) was obtained from S.D.M. Ayurvedic Pharmacy, Udupi.

**Source of data**

30 diagnosed Patients of Amavata were allocated into 2 group using permuted block randomization method, as group A (Guduchi Rasayana) and group B (Simhanada Guggulu) 15 in each group respectively, fulfilling the age group of 16 to 70 years, willing to sign the informed consent and not suffering from connective tissue disorders other than Rheumatoid Arthritis or with any other major systemic disorders selected from IPD/OPD of SDM Ayurveda Hospital, Udupi.

Statistical analysis in both the groups before the treatment and after the treatment was done based on Sigma Stat Statistics software version 3.5 with the Mean(±SE),Standards deviation and the results were analyzed statistically using paired ‘t’ test within the group and unpaired ‘t’ test between the groups.

**Study design**

Study Type: Interventional
Allocation: Permuted block Randomization
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment

Masking: open label
Primary Purpose: Treatment

**Intervention**

**GROUP A – Guduchi Rasayana group (GR)**

Initially 15 patients were treated with 20 ml of *Eranda taila* orally every day morning in empty stomach for 7 days as *shodhana* prior to *Rasayana* treatment. From 8th day onwards for the next 30 days, patient received *GuduchiRasayana* in a dose of 12cap OD in empty stomach during early morning with an *anupana* of lukewarm water.

**GROUP B – Simhanada Guggulu group (SG)**

In this group the selected 15 patients received *Simhanada Guggulu* orally in a dose of 1 g TID before food with the *Anupana* of lukewarm water for 30 days.

**Follow up duration**- 30 days

**Total duration of study** - 38 days of intervention followed by 30 days of follow up period.

**Diagnostics Criteria:**
- Signs and symptoms of *Amavata*
- Criteria for diagnosis of Rheumatoid Arthritis as approved by American Rheumatism Association (ARA)

**Criteria for Assessment**

Symptoms of Amavata were assessed in both the groups before the treatment, during the treatment and after the treatment and the results were analyzed statistically using paired ‘t’ test within the group and unpaired ‘t’ test between the groups.

**Subjective Parameters:**
1. *Angamarda* (body ache)
2. Aruchi (anorexia)
3. Gaurava (heaviness of body)
4. Jvara (fever)
5. Agnimandya (reduced appetite)
6. Stabdhata (Stiffness in body)
7. Sandi Shoola (pain in joints)
8. Sandi Shotha(swelling in joints)

Objective Parameters
1. ACR Revised criteria
2. Circumference of joints of limbs.
3. Range of joint movement.
5. Hand Grip test.
6. Foot pressure.

Results and observations

OBSERVATIONS
Among the 30 patients taken for the study 43.3 % were belonged to the age group of 31-40 years, followed by 33.3 % in the age groups of 41-50. In 51-60 years of age group 16% and 6.6% patients belonged to 61-70. Out of total 30 patients, 20% were males and 80% were females.90% belonged to Hindu Religion and 10 % were Muslims. Majority of 40 % had completed their Higher Secondary School education; followed by Junior college about 30%.100% of patients were married in the present sample. Majority of the patient belonged to middle class i.e. 50%, 23.3% were from lower and upper middle class. Remaining 3.3% of patients hailed from rich socioeconomic status. Maximum numbers of patients were housewives i.e.66.6 %, 16.6 % of patients were employees, 10% were businessmen and 6.6% were manual labourers. Out of 30 patients, only 16.6 % of the patients were restricted to vegetarian diet, and the remaining 83.3 % of the patients had the dietary habit of taking mixed diet. 70% patients diagnosed as Amavata followed Vishmasana, 16.6% patients followed Adhyasana and 7.5 % patients followed Samashana. An enquiry about the addiction revealed that only 6.6% of the patients had the addiction of consuming ethanol and 3.3% were addicted to tobacco. 33.3% of the patients had the habit of taking coffee or tea regularly; rest 56.65% individuals had no addiction. Out of the 30 patients, maximum of 76.6 % of the patients complained of disturbed sleep. Remaining 23.3 % had sound sleep. 33.3 % had the history of oral NSAID intake before the commencement of the study, 13.3 % of the patients had history of using oral NSAID along with DMD and rest 46.6% of the patients has no treatment history as such for the presenting complaints.

Majority of Patients was Vatakapha Prakruti i.e. 50 % and 30 % belonged to Vatapitta Prakruti rest 20 % belonged to Pittakapha Prakruti. Analysis of the symptoms revealed that 23.3 % patients exhibited Kevala Vataja Amavata and 56.6 % had vata-kaphaja predominance rest 13.3 % exhibited Tridoshaja involvement. 83.3% with MadhyamaSara, 13.3 % patients had Pravara Sara followed by 10% of Avara Sara. 70% recorded Madhyama Samhanana, 16.6 % ofPravara Samhanana and rest 13.3% showed Avara Samhanana. 70% patients had Madhyama Pramana. 90 % of patients having Madhyama Satva which was followed by 10% of individuals showing Pravara Satva. 76.6 % of patients had Madhyama Satmya and 23.3% of individuals showed with Pravara Satmya. 56.3 % of patients had Avara Abhyavaharana Shakti fol-
lowed by 43.3% having that of Madhyama Abhyavaharana. 63.3% of the patients had Avara Jarana Shakti and rest 36.6% was having Madhyama Jarana Shakti. 30% had Madhyama Vyayama Shakti and none of them prove to have had Pravara Vyayama Shakti.

Among the 30 individual, 46.6% had the insidious onset, 36.6% had gradual onset followed by sudden onset of 16.6%. 90% of patient was identified to having the symptom of angamar-da whereas only 3.3% showed symptoms of Jwara. 76.6% patients were having the complaint of agnimandya. 83.3% patients were having prominent symptoms of aruchi. 66.6% of patients were suffering from the symptoms pertaining to gauravata. 70% patients were showing symptoms of alasya.

RESULTS
Statistical analysis in both the groups before the treatment and after the treatment was done based on Sigma Stat Statistics software version 3.5 with the Mean(±SE), Standards deviation and the results were analyzed statistically using paired ‘t’ test within the group and unpaired ‘t’ test between the groups (Table no.1).

Effect of Treatment on Sandi Shoola-The initial mean score on Sandi Shoola was 2.733 which reduced to 1.733 after the treatment in GR Group and in SG Group initial mean was 2.800 before the treatment and reduced to 2.133. This indicates that the better response was in Guduchi Rasayana Group and it was statistically found to be significant as the P value is < 0.001.

Effect of Treatment on Sandi shotha- The statistical analysis revealed that the initial mean score on sandhi shotha which was 3.000 reduced to 2.067 after the treatment in GR Group and in SG Group 2.733 before the treatment was reduced to 2.200. This indicates that the better response was in Guduchi Rasayana Group and it was statistically found to be significant as the P value is = 0.001.

Effect of Treatment on stabdatha-In GR Group the initial mean score on Stabdatha was 1.267 which reduced to 0.200 after the treatment and in SG Group mean score 1.200 before the treatment was reduced to 0.800 with p value = 0.002 between the groups.

Effect of Treatment on Range of movement-The initial mean score in GR Group was 63.748 which increased to 71.290 after the treatment whereas in SG Group 22.391 before the treatment was increased to 26.768 after the treatment with a p value = 0.004.

Effect of Treatment on Ring Test-The initial mean score of ring Test was 19.353 and reduced to 18.407 after the treatment in GR Group while in SG Group 17.920 before the treatment was reduced to 15.993 after the treatment and in between the group the p value was = 0.348.

Effect of Treatment on Foot Pressure-The initial mean on foot pressure was 25.867 and improved to 29.133 after the treatment in GR Group whereas 28.167 before the treatment was improved to 31.000 in SG Group. This indicates that Guduchi Rasayana more effective than Simhanada Guggulu in increasing the foot pressure with p value = 0.672.

OVERALL EFFECT OF TREATMENT
After the full course of Guduchi Rasayana and Simhanada Guggulu patients were analyzed
for their symptoms. It was found that 33.3% of patients had major improvement, 46.6% had moderate improvement, 20% had mild improvement and none had the symptoms unchanged in Guduchi Rasayana group. In Simhanada Guggulu Group, 13.3% of patients had major improvement, 53.3% had moderate improvement, 33.3% had mild improvement and 0% of the patients had the symptoms unchanged (Table No.2).

**DISCUSSION**

Amavata considered as a serious disease due to its crippling nature presenting with severe pain, swelling in the joints and causing disability to perform the routine activities. Shodhana, Shamana, Rasayana are the treatment of any disease. The efficacy of Rasayana excel in the form of treatment by virtue of its optimal dosage targeting the samprapthi ghataka of disease. Shamana medication is difference from Rasayana treatment in regards of dose as well as duration of treatment. Rasayana being one of supreme most treatment modality of Ayurveda could hold the key to it.

**Mode of action:** Nitya shodhana by using Eranda taila was administered in a dose of 20ml orally early morning in empty stomach for a period of 7 days as prerequisite to the Rasayana, which amplifies the absorption of the drug and in assimilating it for better action of Rasayana.

**Guduchi Rasayana:** Aqueous extract of the Guduchi in a dosage of 12 capsules, where each capsules is of 500mg once in a day early morning empty stomach was administered. As it is in concentrated form it can be infer that its action will also be more than the regular drug. To some extent it can be taken as similar to Ghana administration. Guduchi having Ka-

shaya, Katu and TiktaRasa is effective in conditions of Morbid Vata and Kapha Dosha though it undergoes Madhuravipaka. It is Laghu in nature thus gets digested and assimilated easily in the body; it is Ushna Veerya Dravya hence effective in counteracting Kapha vata Dosha which is the pathological basis of Amavata. Guduchi contains Alkaloids, Diterpenoid Lactones, Glycosides, Steroids, Sesquiterpenoid, Aliphatic compound, Anti oxidants. Its anti-inflammatory, Anti-oxidant property is established.

**Simhanada Guggulu:** contains Haritaki (Terminalia chebula), Amalaki (Embilica officinalis), Vibitaki (Terminalia belerica), Shuddha gandaka (Purified sulphur), Shuddha Guggulu (Commiphora mukul), Eranda taila(Ricimus communis). Compound formulation of these drugs will have its effect on the tridosha Shamaka with its specific action over Vata and Kapha Dosha. It can be inferred that eranda taila and Haritaki presents its action as Mala Bhedana resulting in mild Shodhana also as ama nirharana. Other Drugs which are basically used are Rasayana as well as Shama-

na. Here it can be understood that it yields dual effect of Shodhana as well as Rasayana. Guggulu as key ingredient having Kapha medhohara as well shotha hara property curb the pathological process as disease is shotha pradhana and Kapha being the morbid dosha involved in the production of the disease.

The dosage pattern and time of administration was adopted from the Pippali Rasayan i.e 24gm crude Guduchi was converted into aqueous extract, capsulated to 500gm and orally administered 12cap every day in empty stomach. Both the medication are safe effective and used partially in 30 days in these
study but the same medication can be used for longer duration for complete remission of the symptoms.

Limitations of the study: As the sample size was small of 30 patients, for the universal acceptance, study can be done with the larger sample size. Duration of the study can be extended for the better results.

Kramataha shodana by means of vamana and virechana can be adopted prior to the Rasayana for the better management of the disease.

**CONCLUSION**

Both Guduchi Rasayana and Simhanada Guggulu groups showed statistically significance in remission of signs and symptoms as well as by improving the quality of life in terms of improving the functional ability. It was observed in Guduchi Rasayana Group after the trial that 33.3 % of patients had major improvement, 46.6 % had Moderate improvement and 20% had Mild Improvement, None of them were noted under unchanged group. This is pointing towards efficacy of Guduchi Rasayana in overall symptomatology of Amavata. Comparing this with the Simhanada-Guggulu Group showed 13.3% had Major Improvement, 53.3% had Moderate and 33.3% had Mild Improvement. Again none of them were found unchanged condition. The effectiveness of the Guduchi Rasayana is supreme comparing to that of Simhanada Guggulu as evidenced by the various outcome measures and the statistical analysis.

**REFERENCES**


**Table 1- EFFECT OF GUDUCHI RASAYANA AND SIMHANADA GUGGULU ON THE SYMPTOMS OF AMAVATA.**

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