

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 30days. 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*.

INTRODUCTION

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 stiffness¹. 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 *vata-kapha doshas* which plays key role in manifesting the disease and also the action of immune boosting, immune modulation is known for its efficacy.

Among the different oral formulations indicated in *amavata*, *Simhanada Guggulu*⁴ was selected as it is *tridosahara* 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 permutated 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(\pm 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. *Stabdhatata* (Stiffness in body)
7. *Sandi Shoola* (pain in joints)
8. *Sandi Shotha*(swelling in joints)

Objective Parameters

1. ACR Revised criteria⁵.
2. Circumference of joints oflimbs.
3. Range of joint movement.
4. General functional capacity.
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 socio-economic 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 *Vishamasana*, 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 *Vatakapaha Prakruti* i.e. 50 % and 30 % belonged to *Vatapitta Prakruti* rest 20 % belonged to *Pittakapaha 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 % of *Pravara Samhanana* and rest 13.3% showed *Avara Samhanana*. 100% 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 *angamarda* 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(\pm 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 *SimhanadaGuggulu* 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 *Shamana*. 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 Im-

provement, 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.

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

Pa- rame- ter	Group	Table No : 1										
		Mean		BT- AT	% Relief	Within the group				Between groups		
		BT (±SE)	AT (±SE)			SD	SEM	T	P	Mean	t	P
San- dis- hoola	GR Group	2.733 (±0.118)	1.733 (±0.182)	1.00 0	37.03	0.458	0.704	5.123	<0.00 1	0.667	1.544	= 0.13 4
	SG Group	2.800 (±0.107)	2.133 (±0.133)	0.66 7	23.8	0.488	0.126	5.292	<0.00 1	0.933		

Sandi shota	GR Group	3.000 (±0.000)	2.067 (±0.185)	0.93 3	31.1	0.458	0.133	7.897	<0.00 1	0.933	3.552	=0.0 01
	SG Group	2.733 (±0.118)	2.200 (±0.107)	0.53 3	19.5	0.725	0.162	6.164	=0.00 1	0.533		
Stabd-hata	GR Group	1.267 (±0.153)	0.200 (±0.107)	1.06 7	88.91	0.884	0.228	5.172	<0.00 1	1.067	3.347	= 0.00 2
	SG Group	1.200 (±0.107)	0.800 (±0.107)	0.40 0	33.33	0.799	0.206	3.055	= 0.009	0.400		
Range of movement	GR Group	63.748 (±2.535)	71.290 (±2.534)	7.54 2	11.83	12.20	0.657	11.47 7	<0.00 1	7.542	2.863	= 0.00 4
	SG Group	22.391 (±1.943)	26.768 (±2.260)	4.37 7	19.51	16.51	0.889	4.923	<0.00 1	4.377		
Ring test	GR Group	17.920 (±1.120)	15.993 (±0.445)	1.92 7	10.75	12.67	1.034	1.862	= 0.065	1.927	0.939	= 0.34 8
	SG Group	19.353 (±0.442)	18.407 (±0.408)	0.94 7	4.8	1.678	0.137	6.909	<0.00 1	0.947		
Grip test	GR Group	1.733 (±0.135)	0.200 (±0.0884)	1.53 3	88.45	0.860	0.157	9.761	< 0.001	1.533	9.146	<0.0 01
	SG Group	2.167 (±0.145)	2.067 (±0.143)	0.10 0	4.61	0.305	0.055 7	1.795	< 0.001	0.100		
Foot pressure	GR Group	25.867 (±1.212)	29.133 (±1.069)	3.26 7	12.60	4.218	0.770	4.242	<0.00 1	0.100	0.426	= 0.67 2
	SG Group	28.167 (±0.912)	31.000 (±0.695)	2.83 3	10.0	3.640	0.665	4.264	<0.00 1	3.640		

Table 2- Overall Effect of treatment

Effect	Percentage of Improvement	Guduchi Rasayana Group		Simhanada Guggulu Group	
		No. of Patients	Percentage	No. of Patients	Percentage
Major improvement	>75	5	33.3	2	13.3
Moderate improvement	50-75	7	46.6	8	53.3
Mild improvement	25-49	3	20	5	33.3
Unchanged	<25	0	0	0	0

Source of Support: Nil

Conflict Of Interest: None Declared

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