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Research Article

A COMPARATIVE PHARMACEUTICO CLINICAL STUDY OF *KAISORE GUGGULU* AND *AMRUTADI GUGGULU* ON *VATARAKTA*

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ABSTRACT

Ayurveda, the science of life helps in the management of diseases through its various branches among which *Rasashastra* is *Ayurvedic* pharmaceutics, which deals with the drugs of mineral origin, their varieties, characteristics, processing techniques, properties and their therapeutic uses. Formulation in the proposed study two different *Guggulu* preparations *Kaisore Guggulu and Amrutadi Guggulu* has been selected whose indications are for *Vatarakta* apart from other diseases. In the day to day practice the physicians of *Ayurvedic* fraternity of Odisha use these two medicines in the treatment of *Vatarakta.* Its incident is said to be 0.2 - 0.3 among the world population and its curability is still apprehensive in remedial field.

This is study with comparison by a known standard drugs, carried out on 60 number of patients suffering from *Vatarakta* Will be selected from the OPD/IPD of Gopabandhu *Ayurveda* Mahavidyalaya and Hospital, Puri. An overall clinical implement and statistical assessment are also witnessed in favour of trial drugs in a significant manner. Correction in laboratory investigation is also another beneficent favour of drug appended. The question of acceptability of the trial drugs for the treatment of *Vatarakta* is no more remains apprehended rather it can be safely used for the purpose. From the observation of my study it is found that both the drugs are effective in reducing the sign and symptoms of *Vatarakta* but while coming to the comparison *Amrutadi Guggulu* is more effective than the *Kaisora Guggulu* in the present study.

KEYWORDS: *Amrutadi Guggulu, Kaisora Guggulu, Vatarakata.*

INTRODUCTION

Rasashastra is *Ayurvedic* pharmaceutics, which deals with the drugs of mineral origin, their varieties, characteristics, processing techniques, properties and their therapeutic uses.

Thus, '*Rasashastra*' means the science of conversion of the drugs, irrespective of their nature (herbal, mineral, animal) into rasa form, which can be easily absorbed and assimilated.

Kasaya Kalpana has been told as the basic *kalpana* of all other *kalpanas. Guggulu kalpana* is an upgraded form of *Kalka kalpana* in which *Guggulu* is the main ingredient and it is a part of *Vati Kalpana [1]. Guggulu kalpas* are among some of the most familiar preparations in Ayurvedic pharmacopea.[2] Among these *Guggulu* preparations *Kaisore Guggulu and Amrutadi Guggulu* are two such preparations which are predominantly used in the disease *Vatarakta* (Gouty arthritis).

Keeping an eye to the salient features of an ideal formulation in the proposed study two different *Guggulu* preparations *Kaisore Guggulu and Amrutadi Guggulu* has been selected whose indications are for *Vatarakta* apart from other diseases. In the day to day practice the physicians of *Ayurvedic* fraternity of Odisha use these two medicines in the treatment of *Vatarakta*

Its incident is said to be 0.2 – 0.3 among the world population and its curability is still apprehensive in remedial field. The similarity of disease goes more in favour of gouty arthritis as in grouped in modern classics. The disease is not fatal but incapacitating in nature after a chronicity of 1 yr.

As regards treatment a satisfactory cure is still limited. To improve various range which is truly the prime lookout among medicos working in various fields. Disability of various range and handicap – endness are also considered to be disturbing ailments met with the disease *Vatarakta*. To overcome this, scientists are still engaged to find out a suitable remedy fitting to the condition. In this context course of action indicating various remedies have been prescribed in *Ayurvedic* classics. The present endeavour is one of them to find out the possibility of relief leading to cure up to satisfaction.

MATERIALS AND METHOD

This is study with comparison by a known standard drugs, carried out on 60 number of patients suffering from *Vatarakta* Will be selected from the OPD/IPD of Gopabandhu Ayurveda Mahavidyalaya and Hospital, Puri following the selection criteria and were divided into two groups randomly viz.

Group I: 30 patients were treated with trial drug 1 i.e. *Kaiosore Guggulu.*

Group II: 30 patients were treated with trial drug 2 i.e. *Amrutadi Guggulu*

Selection Criteria

The patients are selected as per the inclusion and exclusion criteria described as below.

Inclusion Criteria

The selection is made referring to cardinal signs and Symptoms such as.

1. Swelling of joints
2. Pain
3. Tenderness
4. Burning sensation
5. Elevated serum uric acid
6. Elevated E.S.R.

Exclusion Criteria

1. Cardio / Renal pathology
2. Hypertension
3. Osteoarthritis
4. Rheumatoid arthritis
5. Pregnant & lactating mother
6. Diabetes, Tuberculosis and other systemic diseases
7. Below 20 years of age.

Study Design: The total numbers of patients i.e. 60 have been selected applying multiphase random sampling techniques and were divided into two groups as follows.

GI = Group I = Consisting 30 patients

GII =Group II = Consisting 30 patients

Duration of Study: Total duration of the study is 18 months.

Drug and Dose

Group 1 – *Kaisore Guggula* was given in 3gms tablet at 6 A.M. and 6 P.M. at divided doses.

Group 2 – *Amrutadi Guggula* was given in 3gms tablet at 6 A.M. and 6 P.M. at divided doses.

Clinical assessment of cases

The clinical assessment was made depending upon the changes in subjective and objectives features as mentioned in assessment scale.

Subjective Criteria

1. Pain

G0- Absent or no Pain

G1- Mild- Perception of pain but not interfering his normal activities.

G2- Moderate- Perception of pain, interfering his normal activities and painful activities.

G3- Severe- Excruciating of pain associated with painful crises and agonizing look.

2. Swelling

The affected joint and particular normal joint of the patient was measured. The difference between the two was taken. When there was incidence of both side joint afflictions then a normal person of same height and weight was considered. The difference between the measurements of the particular joint of the affected person with that of the normal individual was taken and grouped as mild, moderate and severe.

3. Burning sensation

G0- Normal

G1- Mild- Feeling of burning sensation

G2- Moderate- Feeling of burning sensation on extremities as well as on forehead

G3- Severe- Feeling of burning sensation all over the body

Objective Criteria

1. Blood serum Uric Acid Level

G0- Normal- 5- 7 mm of fall/ 1st hour

G1- Mild- 7- 20 mm of fall/ 1st hour

G2- Moderate- 20- 50 mm of fall/ 1st hour

G3- Severe- > 50 mm of fall/ 1st hour

2. Blood ESR

G0- Normal- 5- 7 mg/dl

G1- Mild- 7- 8 mg/dl

G2- Moderate- 8- 9 mg/dl

G3- Severe- > 9 mg/dl

Assessment Scale: The effectiveness of trail and control drug has been assessed through the p – value applying paired T – test for test of significance.

Result

After the study the fallowing results are observed in the study. The percentage of change with w.r.t sign symptoms after 15, 30 and 45 days of treatment inGroup-1 and Group-II.

Sign and symptoms	Group-I			Group-II		
	AT1 P*	AT2 P*	AT3 P*	AT1 P*	AT2 P*	AT3 P*
Pain	20.96	30.64	48.38	27.11	42.37	67.79
Swelling	24.24	50	60.6	32.2	60.4	74.57
Burning Sensation	10.5	15.54	22.91	13.42	27.33	39.02
ESR	1.07	2.61	5.69	1.18	2.37	4.13
Uric Acid	10.95	1.95	31.47	14.8	29.93	37.25

P* = Percentage of patient improved, AT1 = After 15 days of treatment, AT2 = After 30 days of treatment, AT3 = After 45 days of treatment

Clinical Assessment

Clinical Assessment	AT1				AT2				AT3			
	Gr I		Gr II		Gr I		Gr II		Gr I		Gr II	
	N	PI (%)	N	PI (%)	N	PI (%)	N	PI (%)	N	PI (%)	N	PI (%)
Well responded (>75%)	-	-	-	-	-	-	-	-	2	13.33	3	20
Moderately responded (>50%)	2	13.33	3	20	4	26.67	6	40	5	33.33	7	46.67
Poorly responded (> 25%)	3	20	6	40	6	40	5	33.33	5	33.33	3	20
Not Responded (< 25%)	10	66.67	6	40	5	33.33	4	26.67	3	20	2	13.33

N- Number of Patient, PI- Percentage of Improvement

The above table shows that among the 15 cases of Group-I fallowing results were found. After 15 days of treatment 2 (13.33%) moderately responded, 3 (20%) poorly responded and 10 (66.67%) did not responded. After 30 days of treatment 4 (26.67%) moderately responded, 6 (40%) poorly responded and 5 (33.33%) did not responded. After 45 days of treatment 2 (13.33%) patients are well responded, 5 (33.33%) moderately responded, 5 (33.33%) poorly responded and 3 (20%) did not responded.

The above table shows that among the 15 cases of Group-II fallowing results were found. After 15 days of treatment 3 (20%) moderately responded, 6 (40%) poorly responded and 6 (40%) did not responded. After 30 days of treatment 6 (40%) moderately responded, 5 (33.33%) poorly responded and 4 (26.67%) did not responded. After 45 days of treatment 3 (20%) patients are well responded, 7 (46.66%) moderately responded, 3 (20%) poorly responded and 2 (13.33%) did not responded.

Table Showing Statistical Analysis of various subjective and objective parameters of *Vatarakta*

Parameters	Groups	Mean ± S.D	D.F	t value	P value	Remarks
1. Pain	Gr-I	4.13±1.59 (BT)	14		<0.001	***
		3.26±1.83 (AT1)		5.28	<0.001	***
		2.8±1.69 (AT2)		7.74	<0.001	***
		2.13±1.72 (AT3)		10.32		
	Gr-II	3.93±1.33 (BT)	14		<0.001	***
		2.86±1.59 (AT1)		6.95	<0.001	***
		2.13±1.45 (AT2)		7.21	<0.001	***
		1.26±1.38 (AT3)		12.70		
2. Swelling	Gr-I	4.4±2.33 (BT)	14		<0.01	***
		4.00±3.13 (AT1)		3.39	<0.01	***
		2.2±2.7 (AT2)		4.11	<0.001	***
		1.73±2.78 (AT3)		4.82		
	Gr-II	3.33±2.15 (BT)	14		<0.01	**
		2.66±1.63 (AT1)		4.02	<0.01	**
		1.4±1.35 (AT2)		4.06	<0.001	***
		1.00±1.06 (AT3)		4.97		
3.Burning Sensation	Gr-I	42.46±7.08 (BT)	14		<0.001	***
		38.4±6.03 (AT1)		6.12	<0.001	***
		35.86±5.83 (AT2)		7.69	<0.001	***
		32.6±5.14 (AT3)		7.87		
	Gr-II	42.2±7.86 (BT)	14		<0.001	***
		36.53±10.9 (AT1)		9.48	<0.001	***
		30.66±3.28 (AT2)		13.48	<0.001	***
		26.73±3.26 (AT3)		14.28		
4.Uric Acid	Gr-I	41.07±18.70 (BT)	14		<0.001	***
		36.86±17.65 (AT1)		5.80	<0.001	***
		32.13±18.95 (AT2)		5.78	<0.001	***
		29.00±19.67 (AT3)		6.79		
	Gr-II	43.66±15.54 (BT)	14		<0.001	***
		37.33±16.97 (AT1)		6.01	<0.001	***
		31.46±18.06 (AT2)		7.90	<0.001	***
		27.04±17.55 (AT3)		9.30		
5. ESR	Gr-I	8.66±0.52 (BT)	14		<0.001	***
		8.57±0.53 (AT1)		4.35	<0.001	***
		13.12±17.95 (AT2)		4.73	<0.001	***
		13.14±19.61 (AT3)		6.32		
	Gr-II	14.02±20.19 (BT)	14		<0.05	#
		8.63±0.58 (AT1)		6.19	<0.05	#
		8.46±0.63 (AT2)		9.12	<0.05	#
		8.2±0.71 (AT3)		8.97		

Insignificant at 5% level (> 0.05), * Significant at 5% level (<0.05), ** Significant at 1% level (<0.01), *** Significant at 0.1% level (<0.001)

The statistical analysis shows that in case of pain in *Vatarakta* in Group-I, the mean ± S.D before treatment was 4.13 ± 1.59 and reduced to 3.26 ± 1.83 after 15 days, 2.8 ± 1.69 after 30days and 2.13 ± 1.72 after 45 days of treatment.

In Group-II, the mean ± S.D before treatment was 3.93 ± 1.33 and reduced to 2.866 ± 1.59 after 15 days, 2.86 ± 1.59 after 30days and 1.26 ± 1.38 after 45 days of treatment. The test of significance shows that both Group-I and Group-II are highly significant with p- Value <0.001.

In case of swelling in *Vatarakta* in Group-I, the mean ± S.D before treatment was 4.4 ± 2.33 and reduced to 4.00 ± 3.13 after 15 days, 2.2 ± 2.7 after 30days and 1.73 ± 2.78 after 45 days of treatment.

In Group-II, the mean ± S.D before treatment was 3.33 ± 2.15 and reduced to 2.66 ± 1.63 after 15 days, 1.4 ± 1.35 after 30days and 1 ± 1.06 after 45 days of treatment. The test of significance shows that both Group-I and Group-II are highly significant with p- Value <0.001.

In case of burning sensation in *Vatarakta* in Group-I, the mean ± S.D before treatment was 42.46 ± 7.08 and reduced to 38.4 ± 6.03 after 15 days, 2.2 ± 2.7 after 30days and 1.73 ± 2.78 after 45 days of treatment.

In Group-II, the mean ± S.D before treatment was 42.2 ± 7.86 and reduced to 36.53 ± 10.9 after 15 days, 30.66 ± 3.28 after 30days and 26.73 ± 3.26 after 45 days of treatment. The test of significance shows that both Group-I and Group-II are highly significant with p- Value <0.001.

In case of Uric acid in *Vatarakta* in Group-I, the mean ± S.D before treatment was 41.07 ± 18.70 and reduced to 36.86 ± 17.65 after 15 days, 32.13 ± 18.93 after 30days and 29 ± 19.67 after 45 days of treatment.

In Group-II, the mean ± S.D before treatment was 43.66 ± 15.54 and reduced to 37.33 ± 16.97 after 15 days, 31.46 ± 18.06 after 30days and 27.4 ± 17.55 after 45 days of treatment. The test of significance shows that both Group-I and Group-II are highly significant with p- Value <0.001.

In case of ESR in *Vatarakta* in Group-I, the mean ± S.D before treatment was 8.66 ± 0.52 and reduced to 8.57 ± 0.53 after 15 days, 13.12 ± 17.95 after 30days and 13.14 ± 19.61 after 45 days of treatment.

In Group-II, the mean ± S.D before treatment was 14.02 ± 20.19 and reduced to 8.63 ± 0.58 after 15 days, 8.46 ± 0.63 after 30days and 8.2 ± 0.71 after 45 days of treatment. The test of significance shows that both Group-I is significantly significant with p- Value <0.001, and group - II is insignificant at 5% level p- value> 0.05 .

DISCUSSION

In the present study pain, swelling, burning sensation *(Daha)* were considered as sign and symptoms where as pruritus, discoloration of skin has been overlooked.

Regression in swelling of finger joints comparing the other joints were higher; the reason may be the upper limb joints are most mobile and free from having a tendency of dependant oedema.

Uric acid level was found decreased among both the groups significantly in Group-I (31.47%) and Group-II (37.25%) respectively. The reason may be both drugs *Amrutadi Guggulu* and *Kaisora Guggulu* caused the synthesis of Uric acid in course of metabolism and also excretion of Uric acid was better.

Decrease of burning sensation *(Daha)* was in both Group- I (22.91%) and in Group-II (39.02%) respectively. This may be due to predominance of *Tikta rasa, Madhura Vipaka*. ESR level of both the groups deceases in Group-I (5.69%) and Group-II (4.13%). The low response may be due to the drug poorly effective in sedimentation of RBC's.

Acceptability of any drug rest on its fitness including safety. The effect of both *Kaisora Guggulu* and *Amrutadi Guggulu* on *Vatarakta* may be viewed that as treatment there is a recommendation of *Virechana, Asthapana* and *Raktamokshyana* furnished by veteran pioneers such as to win over *Pitta* and *Vata dosha*. Usually *Virechana* is advocated to excreta *Pitta* which can also be possible through excretion of Urine. These *mala mutra* together can be considered under *Virechana* as advocated against *Vatarakta.* As per the modern layout control of uric acid is possible through cessation of uric acid synthesis and excretion through urine.

The former effectiveness only possible through maintenance of proper metabolism as explained in *Ayurveda*. Defining the pharmacological effect and physic-chemical analysis the drug *Kaisora Guggulu* and *Amrutadi Guggulu* are up to the requirement as desired.

An overall clinical implement and statistical assessment are also witnessed in favour of trial drugs in a significant manner. Correction in laboratory investigation is also another beneficent favour of drug appended. The question of acceptability of the trial drugs for the treatment of *Vatarakta* is no more remains apprehended rather it can be safely used for the purpose.

CONCLUSION

From the observation of my study it is found that both the drugs are effective in reducing the sign and symptoms of *Vatarakta* but while coming to the comparison *Amrutadi Guggulu* is more effective than the *Kaisora Guggulu* in the present study.

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