

SINGLE BLIND RANDOMIZED CONTROLLED CLINICAL STUDY TO EVALUATE THE EFFICACY AND SAFETY OF *SHIVAGUTIKA* IN DYSLIPIDEMIA

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ABSTRACT

Objective: To evaluate the effect and safety of trial drug *Shivagutika* on Lipid profile and Apolipoprotein B in dyslipidemia and comparison with control drug *Navaka Guggulu*. **Study Design:** Randomized, single blind controlled clinical study of 45 days duration with pre and post test assessment. 60 patients diagnosed with dyslipidemia were randomly selected and assigned into two groups, Group A (Control) and Group B (Test), each group consisting minimum of 30 patients. Group A patients received *Navaka Guggulu* and Group B patients received *Shiva Gutika* for 45 days. Blood samples of both the groups for Lipid profile, Apolipoprotein B and Safety Assessment were evaluated before starting the treatment (0th day) and after the completion of the treatment (46th day). **Results:** Both Group A & Group B drugs showed significant result in reducing Lipid Profile & Apolipoprotein B in Dyslipidemia. *Shivagutika* had edge over *Navaka guggulu* in reducing the components of Lipid profile like S. Triglycerides, LDL, HDL, VLDL, Total Cholesterol and Cholesterol/HDL ratio. On Apolipoprotein B *Navaka Guggulu* showed better results than *Shivagutika*. **Interpretation & Conclusion:** The result obtained in this study support the hypothesis i.e trial drug is better than control drug. Hence in this study design *Shivagutika* when compared to *Navaka guggulu* has shown a better result for Dyslipidemia. The safety assessment of drugs both clinically & statistically shows a significant result, which implies that the drug of trial & control group are safe in this study design for the said interval, for the said duration & for the said dosage.

Keywords: *Shiva Gutika*, *Navaka Guggulu*, Dyslipidemia

INTRODUCTION

Hyperlipidemia, hyperlipoproteinemia or dyslipidemia is the condition of abnormally elevated level of any or all lipids and /or lipoproteins in the blood¹. Epidemiological studies have established a strong correlation between premature coronary artery disease (CAD) and cardiovascular disease (CVD) and serum cholesterol levels. World Health

Organization (WHO) in 2002 reported that high cholesterol level is one of the main non-communicable disease-related risk factors in India².

Conventional treatment principles for hypercholesterolemia aim to reduce cholesterol biosynthesis, which will lead to lower blood levels. Most of the drugs (statins) available today are inhibitors of 3-

hydroxy-3-methylglutarylcoenzyme A reductase, which is involved in cholesterol biosynthesis in the liver. Literature shows that the use of statins has a risk of chronic toxic effects including carcinogenic, teratogenic, and mutagenic changes over a lifetime of use³. Other drug therapy includes resins, niacin and fibrates which give rapid relief but long term side effects such as hepatic or renal impairment, malaise, hyperglycemia, constipation, flatulence, nausea, diarrhea, gallstones, myositis and liver enzyme elevation. Most of these lipid lowering drugs are contraindicated in patients with Chronic liver disease, severe renal failure, gout and gall bladder disease⁴. Hence there is a need for more natural methods to control cholesterol levels. *Ayurveda* emphasizes various dietic regimens, *panchakarma* procedures, wide range of herbal and mineral drugs in the management of *medoroga*, which are *kaphamedohara*, *sthoulyahara* and *hrudya* either individually or in combination. During past few decades there has been extensive research carried out in this regard and effective treatment modalities have been found. But these treatment modalities mainly include *snehapana*, *vamana*, *virechana* which are inpatient oriented, time consuming and costly. *Shivagutika* is one of the herbomineral drugs contexted in various *ayurvedic* classics for the treatment of *kaphamedoja vikara* like *prameha*, *medoroga*, *sthoulya*, *granthi*, *gulma*, *arbudha*. The main ingredient of *Shivagutika* is *shilajatu* along with, *karkata shungi*, *trikatu*, *chaturjataka*, *gomutra* and honey⁵.

Shilajatu possesses *rasayana* (rejuvenation), *vrishya* properties (aphrodisiac). It is useful in the treatment of *prameha* (diabetes mellitus), *pandu* (anemia), *gulma* (tumor), *pleeharoga* (splenic disorders), *sthaulya* (obesity), *shotha* (swelling), *jvara* (fever), HIV etc.⁶ It has significant anti-inflammatory, analgesic, immunomodulatory, antiviral and antioxidant activity. Experimental studies on lipid profile of hyperlipidemic albino rats, *shiljatu* has proven a significant effect against simvastatin⁷. The above men-

tioned trial gives a potential proof to conduct human clinical trials. Hence an attempt was made to find a safe, cost-effective and a promising remedy against dyslipidemia.

MATERIALS AND METHODS

Drug Source

Shiva Gutika and *Navaka Guggulu* were purchased from GMP certified SDM Ayurveda Pharmacy, LN nagar, Kuthpady, Udupi, Karnataka which were prepared as per the literature reference.

Sample Source

60 patients diagnosed with Dyslipidemia were taken for the study from the OPD and IPD of the Government Ayurveda Medical College and Hospital, Mysore and from the special camps conducted for the study.

Method of collection of data

60 patients fulfilling the inclusion criteria of either sex were randomly selected. They were assigned into two groups A & B of 30 patients each.

a) Diagnostic criteria

Patients were diagnosed on the basis of the lipid profile, showing any one or more of the following criteria.

- Serum cholesterol >200 mg/dl
- Serum Triglycerides >150 mg/dl
- Serum LDL >130 mg/dl
- Serum VLDL >40 mg/dl
- Serum HDL <40 for male <30 for female
- Ratio of HDL to Cholesterol >4.5
- Apolipoprotein B >125mg/dl

b) Inclusion Criteria

- Men and women age more than 20 years and below 60 years.
- Patients fulfilling the diagnostic criteria.
- Both fresh and treated cases were included (Flush out period of 7 days was maintained for treated cases).

c) Exclusion criteria

- Patients having history of serious cardiac disorders like myocardial infarction, cardiac failure, etc.
- Patients having any major illness, insulin dependent diabetes mellitus, Type II diabetes mellitus that is poorly controlled
- Patients having a history of untreated thyroid disorder
- Hyperlipidemia due to drugs (e.g., glucocorticoids)
- Pregnant females and lactating mothers
- Renal insufficiency

d) Subject withdrawal criteria

- Occurrence of a serious adverse event
- Subject had an acute reaction (allergy, shock and so on) to the investigational product
- Detection of a systemic disease that was not discovered at the screening stage

- Unable to progress because of worsening of preexisting disease
- Subject’s withdrawal of consent
- Subject is uncooperative
- Investigator’s decision to terminate the process for the sake of the subject’s health

e) Investigations:

Specific investigation –

- Serum Lipid Profile (12 hr fasting blood sample), Apolipoprotein B was investigated as a biomarker for hyperlipidemia.
- Other Blood investigations – Hb %, TC, DC, ESR, RBS to rule out other diseases.
- Blood Urea, Serum Creatinine, Liver function test for safety assessment.
- Urine investigations - Urine Sugar, microscopic, albumin were done to rule out other systemic diseases or complications.

f) Intervention (Drugs and posology)

The selected patients were randomly allocated into two groups as follows:

	GROUP A	GROUP B
Drug	Tab <i>Navaka guggulu</i>	Tab <i>Shivagutika</i>
Dose	2gram per day in two equally divided doses.	2gram per day in two equally divided doses.
Duration	45 days	45 Days
<i>Anupana</i>	Water	Water
Route / Mode	Oral	Oral
<i>Kala</i> (Timings)	Morning and night- after meals	Morning and night- after meals

g) Assessment parameter

- Assessment was done by post test Lipid profile and Apolipoprotein B measurement.
- The assessment was done before starting the treatment i.e. 0th day and after the completion of the treatment i.e. 46th day.

h) Assessment of safety

- Liver function test, serum Creatinine and blood urea were done before and after intervention.

Statistical Method

The data was collected before & after intervention and assessed statistically by using descriptive statistics, paired sample ‘t’ test. Analysis

was done by using Service product for statistical solution (SPSS) for windows software.

OBSERVATION

Among the 60 patients registered in the study, the incidence of Dyslipidemia was more in the age group of 51-60 yrs (48.33%), 53.33 % patients had no comorbidity of other diseases, 16.66% patients had a history of diabetes mellitus and 16.66% patients had a history of Hypertension, 10% patients had a history of both diabetes mellitus and hypertension. 76.66% patients were fresh cases and 23.33 % were treated cases. 23.33% patients had a family

history of dyslipidemia and 76.66% had no family history of dyslipidemia. 73.33% patients had mixed diet habit and 26.66 % patients were vegetarians. 26.66% patients had a habit of daily walking and 65% patients were not following any Exercise Pattern. Maximum number of patients had over weight (46.66%), while 33.33% been obese, 20% had normal BMI and no one was under weight or morbidly obese.

RESULTS:

Effect on Lipid Profile & Apolipoprotein B

1. S. Triglycerides: There is significant change in mean value for group A from 242.3 to 219.3 & for group B 299.7 to 218.8. If we analyze the mean value, Group B is far better than group A.
2. S. LDL: There is significant change in mean value for group A from 116.4 to 112.4 & for group B 122.6 to 117.3. If we analyze the mean value, Group B is far better than group A.
3. S. HDL: There is significant change in mean value for group A from 45.73 to 45.70 & for group B 46.78 to 45.70. If we analyze the mean value, Group B is far better than group A.
4. S. VLDL: There is significant change in mean value for group A from 48.44 to 43.87 & for group B 59.95 to 43.77. If we analyze the mean value, Group B is far better than group A.
5. Total Cholesterol: There is significant change in mean value for group A from 206.53 to 204.84 & for group B 212.6 to 203.9. If we analyze the mean value, Group B is far better than group A.
6. T.Chol/HDL ratio: There is significant change in mean value for group A from 4.50 to 4.48 & for group B 4.54 to 4.49. If we analyze the mean value, Group A and group B drugs have similar effect on T.Chol/HDL ratio, with slightly better results in Group B.
7. Apolipoprotein –B: There is significant change in mean value for group A from 119.9 to 118.3 & for group B 116.73 to 116.8. If we analyze the mean value, Group A is better than group B.

Safety Assessment:

1. Blood Urea: In group A mean value changed from 21.86 to 21.70 & in group B from 21.7 to 21.8. If we analyze the mean value, both the drugs are safe for the said dosage, duration & intervention. Statistically the slight increase of Blood urea mean value I Group B implies that the drug of group A is less toxic than drug of Group B.
2. S. Creatinine: In group A mean value changed from 0.89 to 0.90 & in group B from 0.88 to 0.93. If we analyze the mean value, both the drugs are safe for the said dosage, duration & intervention. Mean values also interpret that both the drugs of group A & group B in a longer duration may give some toxic effects, so it is safer for the interventional duration beyond that cautious approach can be adopted.
3. Total Bilirubin: In group A mean value changed from 0.65 to 0.62 & in group B from 0.63 to 0.66. If we analyze the mean value, both the drugs are safe for the said dosage, duration & intervention. Statistically the increase of Bilirubin mean value in Group B implies that the drug of group A is less toxic than drug of Group B.
4. SGOT: In group A mean value changed from 26.46 to 25.63 & in group B from 28.9 to 26.2. If we analyze the mean value, both the drugs are safe for the said dosage, duration & intervention.
5. SGPT: In group A mean value changed from 29.26 to 27.55 & in group B from 31.76 to 30.63. If we analyze the mean value, both the drugs are safe for the said dosage, duration & intervention.
6. GGT: In group A mean value changed from 29.2 to 28.6 & in group B from 29.80 to 39.56. If we analyze the mean value, both the drugs are safe for the said dosage, duration & intervention. Statistically the increase of GGT mean value in Group B implies that the drug of group A is less toxic than drug of Group B.

7. S. Alk. Phoapate: In group A mean value changed from 70.66 to 73.66 & in group B from 70.86 to 71.60. If we analyze the mean value, both the drugs are safe for the said dosage, duration & intervention. Mean values also interpret that both the drugs of group A & group B in a longer duration may give some toxic effects, so it is safer for the interventional duration beyond that cautious approach can be adopted.
8. Serum Total Protein: In group A mean value changed from 7.003 to 7.039 & in group B from 7.21 to 6.97. If we analyze the mean value, both the drugs are safe for the said dosage, duration & intervention.

DISCUSSION

Discussion on diseases Dyslipidemia:

There is no precise term for dyslipidemia in the *Ayurvedic* classics. Literature shows that scholars have tried to use distinct nomenclature for dyslipidemia, e.g., *Rasagata Sneha Vriddhi* (increase in lipids in plasma), *Rasa Raktagata Sneha Vriddhi* (increase in the lipids in plasma and blood), *Medovriddhi* (generalized lipid increase), *Medoroga* or *Medodosha* (obesity), *AAMA Medodhatu* (abnormally formed adipose tissue). A detailed study of hyperlipidemia with regard to the pathophysiology reveals its similarity to *Asthayi Medo Dhatu Vriddhi* (abnormal increase in circulating lipids). This excessively increased circulating lipid is *AAMA* in nature is also termed as *bahuabadha medas* in the context of *prameha*⁸.

Recent research on Dyslipidemia carried out at I.P.G.T and R.A, Jamnagar by Shivam et.al concluded that Dyslipidemia is *Aama, Kapha, Kleda* and *Avaranaajanya* disease. The researches on dyslipidemia suggest that, *Laghu, Ruksha,* and *Kashaya Rasa* dominant formulation is more effective against serum cholesterol and S.LDL, while *Laghu, Ushna,* and *Katu Rasa* dominant formulation is effective in condition of hypertriglyceridemia⁹.

Achieving *Dhatusamyata* is the main aim of treatment in *Ayurveda*. So the treatment of dyslipidemia should be also planned for achieving *Dhatusamyata*. *Nidana* of Dyslipidemia vitiates *Jatharagni, Rasa Dhatvagni, Mamsa Dhatvagni, Meda Dhatvagni* and increase *Ama, Kapha, Kleda, Apakva Rasa, Abaddha Meda* and *Mamsa* in the body. Hence, the first aim of the treatment is to correct *Jatharagni, Rasa Dhatvagni, Mamsa* and *Meda Dhatvagni*, and then to remove excessive *Ama, Kapha, Kleda, Meda* and *Apakva Rasa* from the body. It is also necessary to restore the normal function of above mentioned *Agni, Dosha,* and *Dhatu* for constant normal function.

Discussion on Shivagutika:

1. *Shivagutika* is indicated in *Swasa, Kasa, Prameha, Shotha, Granthi, Slipada* etc¹⁰ all most all these disorders have the involvement of the *Kapha Dosha* as a major *Samprapti Ghataka*. *Shivagutika* has *Katu Tikta Rasa, Laghu Ruksha Guna, Anushna Veerya* and *Katu Vipaka*. Dyslipidemia is mainly due to vitiation of *doshas* like *Kledaka Kapha, Samana Vata* and *Pachaka Pitta* and *dooshyas* like *Rasa* and *Medo dhatu*. *Shivagutika* being majorly *Kapha Vatahara* will helpful in the *Samprapti Vighatana* of the disease Dyslipidemia.

2. In *Shivagutika*, *Shilajitu* is the main ingredient which possesses *Tikta, Katurasa, Kashaya Anurasa, Saraguna, Katu Vipaka, Ushna Veerya, Shoshaka, Chedana, Lekhana* and *rasayana* properties and acts as *medohara* and *stoolahara*¹¹. These properties will be helpful to pacify the *pradhana dhosha Kapha* and *Dushyas* like *Meda* and *Rasa*. *Shilajatu* is also used as *yogavaha* as it increases efficacy of many drugs. Apart from this the other drugs in *shivagutika* have *kaphavata shamaka* property.

3. The Principle of management of *Avarana* is *Shodhana* treatment and the use of *Naimittika Rasayanas* like *Shilajitu* and *Guggulu*.¹² Dyslipidemia will be having *Avaranaajanya Samprapti*. *Shivagutika* is also *Naimittika Rasayana* with *Shilajitu* as main ingredient, and hence helpful

in the removal of *Kapha Avarana* to *Vata* and to pacify *Meda* and *Kleda*.

Discussion on *Navaka Guggulu*:

1. *Navaka Guggulu* has *Katu-Kashaya Rasa*, *Laghu-Ruksha-Tikshna Guna*, *Ushna Virya* and *Kapha Vata Shamaka* properties which will have opposite action on *Kapha Dosha* as well as *Meda Dhatu*¹³.

2. All the contents of *Navaka Guggulu* have *Deepana* property. Majority of the drugs have *Pachana* and *Yakriduttejaka* property. Most of the drugs possess the property of *Ushna Virya* and are being able to improve *Medodhatvagnimandhya*. In this *Yoga*, *Sunthi* is the best *Amapachaka*¹⁴ which improves the *Medodhatvagni* by removing the *Aama*.

3. In Dyslipidemia, there is *Sanga* type of *Srotodushti*, produced by vitiated *Kapha* and *Meda*. *Sunthi*, *Maricha* and *Haritaki* possess the *Srotoshodhana* property which helps to clear the *Sroto Sanga* and regulate the function of *Medovaha Srotas*.

CONCLUSION

Effect on Lipid profile & Apolipoprotein B:

The overall outcome analysis shows both clinically & statistically the trial drug is better than the control drug on lipid profile & Apolipoprotein B in dyslipidemia. If we analyze component wise lipid profile analysis, both the drugs are benefited in lowering dyslipidemia but few components are better in control drug and few components are better in trial drug.

Shivagutika has showed comparatively greater results in lowering S. Triglycerides, LDL, HDL, VLDL, Total Cholesterol & Cholesterol/HDL ratio in comparison with *Navaka Guggulu*. On Apolipoprotein B *Navaka Guggulu* showed better results than *Shivagutika* in reducing the values.

The results obtained in this study supports the hypothesis i.e. trial drug is better than control drug. Hence *shivagutika* when compared to *navaka*

guggulu has shown better result for dyslipidemia in this study design.

Safety Assessment:

The overall safety profile shows both the drugs are safer on long term use with more than 90% of normal values before & after intervention for LFT & RFT.

So the safety assessment both clinically & statistically shows a significant result, which implies that the drug of trial & control group are safe in this design study for the said interval, for the said duration & for the said dosage.

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	BEFORE TREATMENT						AFTER TREATMENT						
		groups	N	Mean	Std. Deviation	Std. Error Mean		groups	N	Mean	Std. Deviation	Std. Error Mean	
Effect on Lipid Profile & Apolipoprotein B	TGL_BT	Group A	30	242.3967	125.3087	22.87813	TGL_AT	Group A	30	219.38	115.1523	3.83841	
		Group B	30	299.7533	160.2794	29.26288		Group B	30	218.833	78.36303	2.612101	
	LDL_BT	Group A	30	116.4267	12.9926	2.37211	LDL_AT	Group A	30	112.4167	15.23216	0.507739	
		Group B	30	122.6	12.77357	2.33212		Group B	30	117.3967	11.3896	0.379653	
	HDL_BT	Group A	30	45.7333	5.77583	1.05452	HDL_AT	Group A	30	45.7	5.44806	0.181602	
		Group B	30	46.7833	5.82646	1.06376		Group B	30	45.4467	5.03544	0.167848	
	VLDL_BT	Group A	30	48.44	25.02422	4.56878	VLDL_AT	Group A	30	43.8787	23.02871	0.767624	
		Group B	30	59.9513	32.05582	5.85256		Group B	30	43.772	15.66574	0.522191	
	TCL_BT	Group A	30	206.5367	45.53558	8.31362	TCL_AT	Group A	30	204.8433	36.98693	1.232898	
		Group B	30	212.6	29.53268	5.39191		Group B	30	203.9	28.98079	0.966026	
	Safety Assesment	tel_hdl_BT	Group A	30	4.5067	0.73482	0.13416	tel_hdl_AT	Group A	30	4.4833	0.6103	0.020343
			Group B	30	4.5467	0.58706	0.10718		Group B	30	4.4967	0.47957	0.015986
apolipo_BT		Group A	30	119.9333	26.17439	4.77877	apolipo_AT	Group A	30	118.3	21.82872	0.727624	
		Group B	30	116.7333	17.39983	3.17676		Group B	30	116.8	18.78811	0.62627	
bloodurea_BT		Group A	30	21.8667	6.06706	1.10769	bloodurea_AT	Group A	30	21.7033	5.36132	0.178711	
		Group B	30	21.7	4.6249	0.84439		Group B	30	21.8	5.14882	0.171627	
screat_BT	Group A	30	0.8967	0.18111	0.03307	Group A	30	0.9073	0.15445	0.005148			
screat_BT	Group B	30	0.8887	0.15527	0.02835	screat_AT	Group B	30	0.938	0.24654	0.008218		

	Group A	30	0.659	0.20365	0.03718		Group A	30	0.6297	0.2021	0.006737
tbil_BT	Group B	30	0.6393	0.29476	0.05382	tbil_AT	Group B	30	0.668	0.26308	0.008769
	Group A	30	26.4667	11.53326	2.10568		Group A	30	25.6367	8.155507	0.27185
sgot_BT	Group B	30	28.9	11.53809	2.10656	sgot_AT	Group B	30	26.2667	7.58371	0.25279
	Group A	30	29.2667	13.75884	2.51201		Group A	30	27.5533	10.43993	0.347998
sgpt_BT	Group B	30	31.7667	17.89564	3.26728	sgpt_AT	Group B	30	30.6333	12.31059	0.410353
	Group A	30	29.2	17.30537	3.15951		Group A	30	28.6	14.91262	0.497087
ggt_BT	Group B	30	29.8	17.14924	3.13101	ggt_AT	Group B	30	39.5667	39.95465	1.331822
	Group A	30	70.6667	19.1155	3.49		Group A	30	73.667	23.48636	0.782879
sap_BT	Group B	30	70.8667	16.00374	2.92187	sap_AT	Group B	30	71.6	21.24991	0.70833
	Group A	30	7.0037	0.51594	0.0942		Group A	30	7.0397	0.52918	0.017639
STP_BT	Group B	30	7.21	0.48661	0.08884	STP_AT	Group B	30	6.9767	0.46807	0.015602