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A CLINICAL STUDY TO EVALUATE THE EFFECT OF NAVAKA GUGGUL ON HYPERCHOLESTEROLEMIA- A SINGLE BLINDED PLACEBO CONTROLLED RANDOMIZED STUDY

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ABSTRACT :

The plasma level of lipids is indicative of not only the severity of various co-morbid conditions such as Diabetes mellitus but also reflects the inherent genetic characteristic, lifestyle and food habits of an individual. A high level of Cholesterol is of prime concern as it is the solo risk factor for atherogenic diseases. The present study has been planned and carried out to evaluate the efficacy of *Navaka guggul* in the management of high cholesterol.

After thorough review of both ancient and modern literatures, hypercholesterolemia can well be correlated with *Poshaka (asthayi) meda vriddhi* which is related to *Kaphaj vikar* in Ayurvedic system.Finally it can be concluded that the drug under study has shown enthusiastic results in reducing the overall value of serum Cholesterol. 40% patients showed good effect, 50% showed moderate effect and approximately 3% showed mild effect.

Key words: Cholesterol, *Kaphaj Vikar, Navaka Guggul, Meda vriddhi*

What's already known about this topic?: Various data from clinical and experimental studies have shown the relation between hyperlipidaemia and atherosclerotic diseases. Till date very little data is available on the effect of Navak Guggul on cholesterol levels.

What does this study add?: The drug under trial has shown highly promising results in treating hypercholesterolemia, which should be further be evaluated on larger subjects. It has also opened the way for treatment of other *kaphaj* diseases which are result of deleterious food & lifestyle habits of modern society.

INTRODUCTION: Multiple facts from clinical, experimental and epidemiological studies have proved the relationship between hyperlipidaemia and atherosclerotic diseases such as Coronary artery disease, cerebral stroke and Peripheral vascular disease. The plasma level of lipids are indicative of not only the severity of various co-morbid conditions such as Diabetes mellitus, Renal diseases or Hepatic malfunctioning but also reflects the inherent genetic characteristic, lifestyle and food habits of an individual.Lipids are basically group of heterogenous metabolically active substances, continuously circulating in plasma in form of lipoproteins to accomplish various important biological functions in addition to serve as major source of energy. They exist in a state of dynamic equilibrium between peripheral tissues, gastrointestinal tract and liver. According to their physical properties, they have been grouped into Phospholipids, Cholesterol, Free fatty acids and Triglycerides. Of all the four types, high level of Cholesterol is of clinical concern as it is the independ-

ent prime risk factor for atherogenic diseases. Among lipoproteins, LDL constitutes richest source of cholesterol by weight and is therefore also commonly called as bad cholesterol.Although, there is no exact terminology for high cholesterol mentioned in the Ayurvedic classics, various learned scholars have used various nomenclatures for the same like *Rasa Raktagata Sneha Vriddhi, Medovriddhi, Medoroga, Ama Medo Dhatu* etc. In classical *Ayurvedic* texts, the word *Medo Roga* has been interchangeably used as *Sthaulya Roga*.Only Aadhamalla while commenting on *Sharangdhara Samhita*, tried to differentiate between the two types of *Medo Dosha*[1]

1. *Medo Vridhi*: Adiposity including its clinical features (*Sthaulya*)
2. *Medo Dosha*: Lipid disorders where *Meda* acts as an etiological factor in the genesis of other diseases.

Based on the various opinions mentioned above, hyperlipaedemia can well be correlated with *Medodosha* as interpreted by Acharya Aadhamalla.

The present study has been planned and carried out to evaluate the efficacy of *Navaka guggul* in the management of high cholesterol.

Conceptual Study: According to Acharya Charaka, the *Sarabhaga* or the *Annarasa* of the ingested food which is the result of action of both the *Jatharagni* and the *Bhutagnis* is directly absorbed from the *Amashaya* and is circulated throughout the body by means of *Dhamanis*. After the action of *Bhutagnis*, the *Upadana Medo Dhatu* thus formed is further subjected to the action of *Medodhatvagni*[2]. Chakrapani has mentioned two types of *Dhatus*[3] viz., *Asthayi* and *Sthayi Dhatus* after the action of *Dhatvagni*. Of these, the *Asthayi Dhatus* are the precursors of the *Sthayi Dhatus* and are circulated throughout the body by means of *Srotas* which is specific for each *Dhatu*. The *Asthayi* or *Poshaka Medo Dhatu* thus formed circulates through the *Medovaha Srotas* for nourishing the *Medo Dhatu*. This is in accordance with the Ayurvedic principle – "*Dhatu Pushyati Dhatutaha*[4] i.e; nourishment of the *Dhatus* via the *Dhatus* themselves. *Asthayi Medo Dhatu* undergoes two *Pakas* or reactions viz; the *Prasada Paka* leading to the nourishment of the same *Sthayi Dhatu* and *Kitta Paka* leading to the formation of the *Sweda*.The lipoproteins synthesized by the liver can be correlated with *Asthayi* or *Poshaka Medo Dhatu*. They can also be referred to the '*Abaddha Medas*'which can be literally translated as unbound or freely circulating fat. These lipoproteins transport the triglycerides, cholesterol and other lipids which are the byproducts of *Bhutagnipaka* to different structures of the body as per the tissue requirement. According to Vagbhatta[5] when *Dhatvagni* is hypo-functional, it leads to increased synthesis of the *Dhatu* whereas its hyperfunctioning will lead to a quantitative decrease. The same can be applied to *Medodhatvagni* which on impairment would eventually lead to either *Atisthaulyata* or *Karshyata*.In case of the hypo-functioning of the *Medodhatvagni*, homologous nutrients present in circulation as the *Poshaka Medo Dhatu* (comprising of different categories of lipoproteins) will be in excess in circulation leading to the condition of increased quantity of *Abaddha Meda* or *Asthayi Medo Dhatu* which is known as Hypercholesterolaemia.As per Ayurvedic theory as *Meda* and *Kapha* are homologous in character, therefore in

present research work, the symptoms of *Kapha Vriddhi* have been chosen as subjective criteria for high Cholesterol.

MATERIAL AND METHODS:

Inclusion criteria:

- Cholesterol level above 200 mg/dl.
- Patient should be in age group 20 to 70 years.
- Patient willing to participate for a study period of 2 months.

Exclusion criteria:

- Patients of secondary hyperlipidaemia such as Diabetes mellitus, Nephrotic syndrome, Thyroid and Liver dysfunction.
- Patient having any other disease requiring emergency treatment such as Coronary artery disease or Malignancy.
- Patient participated in another drug trial within period of last 6 months.

Assessment criteria:

- Subjective criteria : *Alasya, Gauravta, Tandra and Prasek*[6]
- Objective criteria : Serum Cholesterol value recorded by appropriate laboratory method.

Final assessment of results:

Subjective assessment

75 to 100% disappearance of symptoms- Effectively cured.

50 to 74% disappearance of symptoms- Well cured.

25 to 49% disappearance of symptoms- Fairly cured.

0 to 24% disappearance of symptoms- Poorly cured.

Objective assessment :

- Patient showing reduction in serum Cholesterol between 0 to 10mg- Grade I (No effect).
- Patient showing reduction in serum Cholesterol between 11to 30mg- Grade II (Mild effect).
- Patient showing reduction in serum Cholesterol between 31 to 50mg – Grade III (Moderate effect).
- Patient showing reduction in. serum Cholesterol between 51 and above- Grade IV (Good effect).

Drug details:Study drug-*Navaka guggul*[7] 500mg filled in capsule form.

Placebo: Prefilled Sugar capsules 500mg

RESEARCH METHODOLOGY:

Study type: Single blind Placebo controlled comparative study.

Study site: Digamber Jain charitable Ayurvedic chikitsalaya, Chawani, Indore (MP).

Sample size: 60 patients divided randomly into two equal groups.

Group A given Study drug (Navaka Guggul)

Group B given Placebo drug (Prefilled Sugar capsules)

Drug dosage and vehicle: 2 capsules containing 500mg of drug each, twice daily with lukewarm water after meals.

Duration of treatment: 2 month (follow up at monthly interval.)

Dietary advice:To strictly restrict the daily intake of *madhur,amla,lavana* and heavy(*guru)*diet

OBSERVATION AND RESULT:

S. No	Symptoms	N	B.T. Mean	A.T. Mean	Difference Mean	% Relief	SD±	SE ±	't'	P
1	*Gaurav*	27	1.85	**0.81**	**1.037**	**56.00**	**0.52**	**0.10**	**10.41**	<0.001
2	*Alasya*	24	1.29	**0.46**	**0.833**	**64.52**	**0.48**	**0.10**	**8.48**	<0.001
3	*Tandra*	21	1.14	**0.38**	**0.7619**	**66.67**	**0.44**	**0.10**	**8.00**	<0.001
4	*Prasek*	18	1.06	**0.28**	**0.77777**	**73.68**	**0.43**	**0.10**	**7.71**	<0.001

Treatment TABLE 1 -Paired't' test for subjective parameters– Group A

TABLE 2 -Paired't' test for objective parameters – Group A

BIOCHEMICAL N=30	B.T. Mean	A.T. Mean	Difference Mean	% relief	SD±	SE±	't'	P
S.Cholesterol (mg/dl)	**242.23**	203.23	39	16.10↓	15.52	2.83	13.76	<0.001

TABLE 3 -Paired't' test for subjective parameters– Group B

S. No	Symp-toms	N	B.T. Mean	A.T. Mean	Difference Mean	% Re-lief	SD±	SE±	't'	P
1	*Gaurav*	21	1.29	1.14	0.143	11.11	0.55	0.12	1.20	Insignificant
2	*Alasya*	26	1.08	1.08	0	0	0.53	0.10	00	Insignificant
3	*Tandra*	26	1.04	1.04	0	0	0.53	0.10	00	Insignificant
4	*Prasek*	18	0.94	1.00	-0.056	↑5.88	0.41	0.10	↑0.57	Insignificant

TABLE 4-Paired't' test for objective parameters – Group B

BIOCHEMICAL N=30	B.T. Mean	A.T. Mean	Difference Mean	% relief	SD±	SE±	't'	P
S.Cholesterol (mg/dl)	235.37	239.33	-3.96	1.69↑	9.46	1.73	↑2.30	<0.05

TABLE 5 -Comparison of Percentage relief in symptoms between both the groups

S. No.	Symptom	% Relief in Group A	% Relief in Group B
1	*Gaurav*	**56.00**	11.11
2	*Alasya*	**64.52**	0
3	*Tandra*	**66.67**	0
4	*Prasek*	**73.68**	↑ 5.88

↑ - indicates worsening of symptom

From above table it is observed that in study group, values for all the Subjective parameters as well as cholesterol value shows statistically highly significant reduction after treatment [Table1&2] whereas Placebo group shows statistically insignificant effect in all the Subjective parameters including *Prasek* which increased post treatment.[Table3&4]. Cholesterol level also increased significantly.Regarding comparison % relief in symptom Group A is better than group B with *Prasek* showing maximum relief. [Table 5]

TABLE 6-Final assessment of result on Symptoms

S.NO.	Category	Relief in symptoms Group A		Relief in symptoms Group B	
		No.of patients	% of patients	No. of patients	% of patients
1.	Effectively cured	12	40	0	0
2.	Well cured	14	46.67	3	10
3.	Fairly cured	3	10	5	16.67
4.	Poorly cured	1	3.33	12	40
5.	Worsening of symptoms	0	0	10	33.33

TABLE 7 -Final assessment of result on cholesterol

S.NO.	Category	Reduction in cholesterol level Group-A		Reduction in cholesterol level Group-B	
		No. of patients	% of patients	No. of patients	% of patients
6.	Good effect	12	40	0	0
7.	Moderate effect	15	50	0	0
8.	Mild effect	1	3.33	2	6.67
9.	No effect	2	6.67	28	93.33

DISCUSSION: After thorough review of both ancient and modern literatures, hypercholesterolemia can well be correlated with *Poshaka (asthayi) meda vriddhi* which is treated as *Kaphaj vikar*[8] in Ayurvedic system of medicine. The trial drug is supposed to have specific effect on cholesterol level.*Triphala*[9] by virtue of its *kapha-pittashamak,Agnideepak, and kledashoshak* property is able to decrease cholesterol level. *Trikatu*[10] by virtue of its *meda-kaphahar, ushna* and *sthooltanashak* property is able to reduce cholesterol level. *Vidanga*[11] and *Chitraka*[12] work by virtue of their *ushna, tikshna, laghu* and *ruksha* property. *Nagarmotha*[13] acts by its *deepana, pachana, kapha-pittashamak* property and *katu-tikta rasa*. *Guggulu*[14] exert its effect via *ruksha* and direct *medahara* property.

Regarding symptomatic relief, out of 30 patients, 40% got effectively cured, 47% got well cured10% got fairly cured and 3% got poorly cured. (**Table 6).**No significant side effects have been reported in any subject.

CONCLUSION: Finally it can be concluded that the drug under study has shown effective results in reducing the overall value of serum Cholesterol. 40% patients showed good effect, 50% showed moderate effect and approximately 3% showed mild effect (**Table7**).

To conclude, the drug under trial has shown highly significant results in treating hyperlipidaemia, which should be assessed on larger population. It has also opened the way for treatment of other *kaphaj* diseases which are result of undisciplined dietary and daily regimen of modern society.

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