

**A CLINICAL STUDY TO EVALUATE ANTI-HYPERLIPIDEMIC EFFECT OF TGL COMPOUND IN
DYSLIPIDEMIA VIS-A-VIS MEDODUSHTI****Tiwari Akanksha^{1*}, Dileep Kumar², Tripathi Arun Kumar³, Singh Deshraj⁴**¹P.G. Scholar, Dept. of Kayachikitsa, Rishikul State Ayurvedic College, Haridwar, Uttarakhand, India.²P.G. Scholar, Dept. of Samhita, Dr. BRKR Govt. Ayurvedic College, Hyderabad, India.³Professor, Kayachikitsa, Director, Ayurved and Unani Services, Dehradun, Uttarakhand, India.⁴Medical Officer, Dept. of Kayachikitsa, Rishikul State Ayurvedic College, Haridwar, Uttarakhand, India.**ABSTRACT**

Dyslipidemia is a biochemical derangement found in number of disorders like Diabetes mellitus, Hypertension, Hypothyroidism etc. Dyslipidemia is an important risk factor for atherosclerosis, coronary artery disease and cerebrovascular disease. Epidemiological studies predict that for each 1% reduction in level of LDL-C there is 1% to 1.5% reduction in the risk of major cardiovascular events. Fewer than one half of patients in the United States discharged from the hospital with proven coronary disease receive treatment for Dyslipidemia given the proof that treating Dyslipidemia brings major benefits. Thus global views emphasize the need for early; effective interventions against the Atherogenic Dyslipidemia associated with Diabetic and Non-Diabetic cases and with metabolic syndrome to reduce the risk of premature cardiovascular diseases. In *Ayurveda*, it can be better correlated with *Medodushti* which is a functional condition and just a precursor stage of *Medoroga* and can be easily reversible by effective regimen. A single blind Study was carried out in OPD and IPD patients of Kayachikitsa department of Rishikul Campus, Haridwar for 90 days. Total 20 patients were registered for the trial and treated with *TGL compound* (Self-formulated drug). All the concerned approvals were obtained and data was analyzed under statistical parameters. A significantly reduction of cholesterol level, Triglycerides, VLDL, CHO/HDL Ratio and highly significant reduction of LDL and LDL/HDL Ratio was found. This research also proved the major role of *Agni* and *Ama* in pathogenesis of Dyslipidemia, and all the drugs having *Dipana*, *Pachana*, *Ama nashaka*, *Kapha-Medohara*, *Rasayana* and *Srotoshodhaks* quality will be highly effective.

KEYWORDS: Dyslipidemia, *Medodushti*, Ayurveda, Lipids.**INTRODUCTION**

The two main lipids in blood are Cholesterol and Triglycerides. They are carried in lipoproteins, globular particles that also contain proteins known as apoproteins. Lipoproteins are transport vehicle of lipids which transport lipids between peripheral tissues and liver. Cholesterol is an essential element of all animal cell membranes and forms the backbone of steroid hormones and bile acids. Triglycerides are important in transferring energy from food into cells.¹⁻²

In Dyslipidemia there is increased lipids in the blood resulting either from an increased rate of synthesis or from a decreased lipoprotein breakdown rate³. The raised level of cholesterol leads to deposition of lipids (mainly in form of esterified cholesterol) in the wall of arteries and causes Atherosclerosis. Atherosclerosis affects various regions of the circulation preferentially and yield distinct clinical manifestations depending on the particular circulatory bed affected⁴. In Allopathic system of medicine, we have a wide range of drugs like statins, resins, fibric acid derivatives, nicotinic acid etc. which are quiet effective in normalizing the lipid levels but they also have side effects like headache, nausea, bowel upset, rashes, sleep disturbances, Myalgia, increase level of Serum Transaminase which can further leads to Liver damage etc⁵. A recent research on Atorvastatin has proved that a

high dose of Atorvastatin for longer duration make the patients prone for development of Diabetes⁶.

Dyslipidemia cannot be directly correlated with any disease conditions describes in *Ayurvedic* classics but the concept of *Abaddha Meda* expounded by *Acharya Chakrapan*⁷ have similarity with the condition of Dyslipidemia describe in modern science. The symptoms of Dyslipidemia described in modern text shows resemblance with *Aam*, and with many of *Rasa dushti*, *Rakta dushti*, and *Medodushti janya* symptoms. Many attempts were made by various scholars of *Ayurveda* to clinically correlate it to *Rasagata sneha vridhhi* (increased lipids in plasma), *Raktagata sneha vridhhi* (increased lipids in blood), *Rasaraktagata sneha vridhhi* (increased lipids in plasma and blood)⁸. Being a disorder of *Meda dhatu*, we have correlated it with "*Medo dushti*" (*Aam dushit Meda dhatu*).

AIMS AND OBJECTIVES

The aims and objectives of the study were:

- To study the aetiopathogenesis of Dyslipidemia and work out the *Ayurvedic* correlations.
- To evaluate the efficacy of TGL compound in the management of Dyslipidemia by using various scientific parameters.

- To provide a reliable, cost effective *Ayurvedic* treatment for Dyslipidemia.

Anupana : Luke warm water
Duration : 90 days

MATERIAL & METHODS

The study was single blind Study and carried out in OPD and IPD patients of Kayachikitsa department of Rishikul Campus, Haridwar for 90 days. Total 20 patients were registered for the trial and treated with **TGL compound** (Self-formulated drug). All the concerned approvals were obtained.

According to NCEP (National cholesterol education program) adult treatment panel 3, following range value was taken for diagnosis of dyslipidemia.⁹

- S. Cholesterol : {>200mg/dl}
- S. Triglycerides: {>150mg/dl}
- S. LDL : {>130 mg/dl}
- S. VLDL: {>40 mg/dl}
- S. HDL: {<40 mg/dl}
- Cho/HDL. Ratio : {>4.97}
- LDL / HDL Cho. Ratio : {>3.55}

Inclusion Criteria

- Diagnosed & confirmed cases of Dyslipidemia on the basis of investigation.
- Patient between the age group of 20-60 years of either sex who fulfill the criteria of Objective and Subjective parameters
- Newly diagnosed case of NIDDM with optimal control Diabetes was also considered under study.

Exclusion Criteria

- Patients with age below 20 years & above 60 years
- Patients suffering from type 1 Diabetes mellitus and uncontrolled Diabetes mellitus or uncontrolled Hypertension.
- Drug induced or uncontrolled Dyslipidemia.
- Patient having systemic illness like Tuberculosis, Carcinoma and Endocrine disorders or major illness like Renal or Liver disorder.
- Patient having the past history of Myocardial infarction & Unstable Angina.
- Patient having clinical features of CCF.

Ingredients of TGL COMPOUND

The formulation composition of TGL Compound along with the proportion and part used of individual components is depicted at table no.1

Method of preparation of TGL COMPOUND

The content of *Trikatu churna* i.e. *Pippali*, *Maricha*, and *Shunti* were taken in powder form and mixed with *Guggul* resin purified by *Triphala* decoction. A fresh paste of *Lahsuna* was taken. After mixing above mixtures, tablets weighted 500mg each were prepared with the help of tablet forming machine.

Drug Trial Schedule

Drug:	TGL compound
Form:	Tablet
Dose:	2 Tablets (Each 500 mg.) Twice in a day
Mode of administration:	Oral
Time of administration:	before meal

RESULT & DISCUSSION

Dyslipidemia is a disorder of *Agnimandya* and *Sama Rasa* formation which leads to obstruction in the channels hence to manage this condition the selected drug should be of *Dipana*, *Pachana*, *Kaphanashaka*, *Medhoghna* and *Srotoshodhaka* properties. The researches on Dyslipidemia suggest that *Laghu*, *Ruksha*, and *Kashaya* Rasa dominant formulation is more effective against Cholesterol and LDL, while *Laghu*, *Ushna*, *Katu* Rasa dominant formulation is effective in condition of hypertriglyceridemia¹⁵⁻¹⁶. TGL compound fulfills all requirements which we needed in the management of *Medodushti*. The contents of TGL compound are *Trikatu*, *Guggul*, and *Lahsun (Rasona)*. The objective assessment of results was based on laboratory investigations and data was analysed by using statistical "paired t test". Results was highly significant (p < 0.001) in lowering Sr. LDL and LDL/HDL Ratio while it was significant in lowering Sr. Cholesterol (p < 0.01), Sr. VLDL (p < 0.01), Sr. Triglycerides (p < 0.05) and cholesterol/HDL ratio (P < 0.05). A significant increased in level of HDL was also noted which is known as "good cholesterol", helps in removal of LDL Cholesterol from arterial walls and preventing the process of atherosclerosis.

CONCLUSION

The contents of TGL compound are *Pippali*, *Maricha*, *Shunthi*, *Guggulu* and *Lahsuna* contain *Ushna*, *Tikshna Guna*, *Katu Rasa* and *Deepana*, *Pachana* property and thus increase *Agnibala* and reduces *Kapha*, *Aam* and *Kleda*. *Trikatu* and *Guggulu* possesses *Lekhana* property and thus had decreased *Meda* and *Sthaulya*. *Lasuna* possesses *Deepana*, *Pachana*, *Anulomana* and *Sroto Vibandhahara* property and thus removes the *Avarana* of *Vata* caused by *Kapha* and *Meda*. *Guggul* content of TGL compound is more useful in Pre-Diabetic and Dyslipidemic patients while *Lasuna* is more useful in the patients of Dyslipidemia with Hypertension. *Lasuna* has additional advantage of improving digestion process. Hence it can be concluded by present clinical trial that due to its *Guggul* content TGL Compound can be used in *Kapha*, *Meda* and *Kleda Bahula Sampraptijanya Vyadhi*. These drugs basically are *Katu* and *Tikta Rasa pradhan*, *Ushna Veerya* and *Laghu Ruksha Guna*, this formulation helps in eliminating vitiated *Kapha*. It also corrects the vitiated both *Medas* and *Kapha* being the main entity of the *Samprapti*, thus by breaking the *Samprapti* (correcting the vitiation of *Medas* and *Kapha*) treats the disease. As the drug is *Ushna* it also increased improving the *Dhatvagni*, (as Ayurveda believes that the disease is *Amajanya*). In this way the properties of all five contains of drug help in *Samprapti Vighatana* of the disease.

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Table 1: Properties TGL Compound

Name	<i>Pippali</i> ¹⁰	<i>Marich</i> ¹¹	<i>Sunthi</i> ¹²	<i>Guggulu</i> ¹³	<i>Lashun</i> ¹⁴
Botanical name	<i>Piper longum</i>	<i>Piper nigrum</i>	<i>Zingiber officinalis</i>	<i>Commiphora mukul</i>	<i>Allium sativum</i>
Family	<i>Piperaceae</i>	<i>Piperaceae</i>	<i>Zingiberaceae</i>	<i>Burseraceae</i>	<i>Lilliaceae</i>
Ras	<i>Katu</i>	<i>Katu</i>	<i>Katu</i>	<i>Tikta, Katu</i>	<i>Pancha ras except Amla</i>
Guna	<i>Laghu, Snigdha, Tikshna</i>	<i>Tikshna, laghu</i>	<i>Laghu, Snigdha</i>	<i>(Puran guggulu)-Tikshna, Laghu, Ruksha, Vishad, Sukshma, Sar, Sugandhi</i>	<i>Snigdha, Tikshna, Picchila, Guru, Sar</i>
Virya	<i>Anushnshita</i>	<i>Ushna</i>	<i>Ushna</i>	<i>Ushna</i>	<i>Ushna</i>
Vipak	<i>Madhura</i>	<i>Katu</i>	<i>Madhura</i>	<i>Katu</i>	<i>Katu</i>
Doshakarma	<i>Kaphavaatsham aka</i>	<i>Kaphavaatshamaka</i>	<i>Kaphavaatshamaka</i>	<i>Vaatshamaka, Medoavartavaatshamaka</i>	<i>Kapha vaatshamaka</i>
Active principle	Piperine (4-5%), pipartine	piperin (5-10%), piperidine (5%), piperittine.	Zingiberene (35.6%), Zingiberol	Raal (35-61%), resin (29.3%)	allyl-propyl sulphide 6%, diallyl-disulphide
Prabhav				<i>Tridosahar</i>	
Proportion	1/3	1/3	1/3	1	1
Form	Powder	Powder	Powder	Resin	Paste

Table 2: Statistical analysis of Overall parameters

	Mean score \pm S.D		% relief	't' Value	P Value
	B.T	A.T			
S.Cholesterol	225.45 \pm 56.3	187 \pm 47.4	17.03%	3.6216	<0.01 S
S.Triglycerides	226.6 \pm 83.89	178.7 \pm 80.7	21.1%	2.6527	<0.05 S
S.HDL	39.85 \pm 6.72	41.35 \pm 8.26	3.7%	(-) 0.812	>0.05 NS
S.LDL	152.25 \pm 49.3	106.75 \pm 35.	29.9%	5.7496	<0.001 HS
S.VLDL	45.25 \pm 27.5	31.2 \pm 18.91	31.04%	3.3227	<0.01 S
Cholesterol/HDL Ratio	5.87 \pm 1.98	5.01 \pm 1.36	14.%	2.80	<0.05 S
LDL/HDL Ratio	3.97 \pm 2.10	2.75 \pm 1.03	30.7%	4.63	<0.001 HS

