A CLINICAL STUDY TO EVALUATE ANTI-HYPERLIPIDEMIC EFFECT OF TGL COMPOUND IN DYSLIPIDEMIA VIS-A-VIS MEDODUSHTI

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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. In Dyslipidemia there is increased lipids in the blood resulting either from an increased rate of synthesis or from a decreased lipoprotein breakdown rate. 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 affected. 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 etc. A recent research on Atorvastatin has proved that a high dose of Atorvastatin for longer duration make the patients prone for development of Diabetes.

Dyslipidemia cannot be directly correlated with any disease conditions describes in Ayurvedic classics but the concept of Abaddha Meda expounded by Acharya Chakrapan 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 vridhī (increased lipids in plasma), Raktagata sneha vridhī (increased lipids in blood), Rasaraktagata sneha vridhī (increased lipids in plasma and blood). 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 aetipathogenesis 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.

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**

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

**Exclusion Criteria**

a) Patients with age below 20 years & above 60 years
b) Patients suffering from type 1 Diabetes mellitus and uncontrolled Diabetes mellitus or uncontrolled Hypertension.
c) Drug induced or uncontrolled Dyslipidemia.
d) Patient having systemic illness like Tuberculosis, Carcinoma and Endocrine disorders or major illness like Renal or Liver disorder.
e) Patient having the past history of Myocardial infarction & Unstable Angina.
f) 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**

<table>
<thead>
<tr>
<th>Drug: TGL compound</th>
<th>Form: Tablet</th>
<th>Dose: 2 Tablets (Each 500 mg) Twice in a day</th>
<th>Mode of administration: Oral</th>
<th>Time of administration: before meal</th>
</tr>
</thead>
</table>

**Anupana:** Luke warm water

**Duration:** 90 days

**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, Medhognha and Srotoshodhaka properties. The researches on Dyslipidemia suggest that Laghu, Raksha, and Kashaya Rasa dominant formulation is more effective against Cholesterol and LDL, while Laghu, Ushna, Katu Rasa dominant formulation is effective in condition of hypertriglyceridemia.\(^{15-16}\) 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 increase 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 Pippiali, 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 Sampraptiyanya Vyadhi. These drugs basically are Katu and Tikta Rasa pradhan, Ushna Veerya and Laghu Raksha 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.

**REFERENCES**

3. Taber’s cyclopedic medical dictionary, p.1034.

Cite this article as:

Source of support: Nil, Conflict of interest: None Declared

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Table 1: Properties TGL Compound

<table>
<thead>
<tr>
<th>Botanical name</th>
<th>Pippalit</th>
<th>Marichit</th>
<th>Sunthit</th>
<th>Guggulit</th>
<th>Lashunit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family</td>
<td>Piperaceae</td>
<td>Piperaceae</td>
<td>Zingiberaceae</td>
<td>Burseraceae</td>
<td>Liliaceae</td>
</tr>
<tr>
<td>Ras</td>
<td>Katu</td>
<td>Katu</td>
<td>Katu</td>
<td>Tikta</td>
<td>Katu</td>
</tr>
<tr>
<td>Guna</td>
<td>Laghu, Snigdha, Tikshna</td>
<td>Laghu, Snigdha, Tikshna</td>
<td>Laghu, Snigdha</td>
<td>(Puran guggulu)-Tikshna, Laghu, Ruksha, Vishad, Sukshma, Sar, Sugandhi</td>
<td>Snigdha, Tikshna, Picchila, Guru, Sar</td>
</tr>
<tr>
<td>Virya</td>
<td>Anushnshita</td>
<td>Ushna</td>
<td>Ushna</td>
<td>Ushna</td>
<td>Ushna</td>
</tr>
<tr>
<td>Vipak</td>
<td>Madhura</td>
<td>Katu</td>
<td>Madhura</td>
<td>Katu</td>
<td>Katu</td>
</tr>
<tr>
<td>Doshakarma</td>
<td>Kaphavaatshamaka</td>
<td>Kaphavaatshamaka</td>
<td>Kaphavaatshamaka</td>
<td>Vaatshamaka, Medoavartavaatshamaka</td>
<td>Kapha vaatshamaka</td>
</tr>
<tr>
<td>Active principle</td>
<td>Piperine (4-5%), piplartine</td>
<td>piperin (5-10%), piperidine (5%), piperittine.</td>
<td>Zingiberene (35.6%), Zingiberol (29.3%)</td>
<td>Raal (35-61%), resin (29.3%)</td>
<td>allyl- propyl sulphide 6%, diallyl-disulphide</td>
</tr>
<tr>
<td>Prabhav</td>
<td>Tridoshahar</td>
<td>Tridoshahar</td>
<td>Tridoshahar</td>
<td>Tridoshahar</td>
<td>Tridoshahar</td>
</tr>
<tr>
<td>Proportion</td>
<td>1/3</td>
<td>1/3</td>
<td>1/3</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Form</td>
<td>Powder</td>
<td>Powder</td>
<td>Powder</td>
<td>Resin</td>
<td>Paste</td>
</tr>
</tbody>
</table>
Table 2: Statistical analysis of Overall parameters

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