A CLINICAL STUDY OF HARITAKYADIYOGA IN THE MANAGEMENT OF HYPER TRIGLYCERIDEMIA

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ABSTRACT

The present clinical study was designed to study the hyper triglyceridemia associated with obesity and to see the response of Haritakyadi yoga. Hyper triglyceridemia is one of the major lifestyle disorders which have been referred to as the Santaranjanya Vyadhi in the classical texts. There is in urgent need of natural strategies that are affordable and efficacious. The health care system has been the frequent coexistence of elevated triglycerides with other conditions that affect cardiovascular disease risk, such as depressed high-density lipoprotein, cholesterol, obesity, metabolic syndrome and type 2 diabetes.

Aims and Objectives

To study the role of Ayurvedic medicine Haritakyadi yoga in the management of hyper triglyceridemia in controlled clinical drug trial.

MATERIAL AND METHODS

Plan of study

Hyper triglyceridemia was based on the presence of elevated triglyceride level was more than 150 mg/dl in lipid profile test according to NCEP ATP III guideline; diagnosed patient irrespective of age, sex, religion, etc were registered form O.P.D. of kaya-chikitsa department of M.M.M. Govt. Ayurveda College, Udaipur, Rajasthan, India (Registration number: RAU/07/1525).

Inclusion criteria

Patients fulfilling the following general and diagnostic criteria were selected for the present study-

- Diagnosed Patients of Hyper triglyceridemia as per NCEP ATP III guideline.
- Patient of Hyper triglyceridemia with obesity, diabetes mellitus type-2, metabolic syndrome.

INTRODUCTION

Hyper triglyceridemia disease is a result of lifestyle factors such as over nutrition. Which have been referred to as the Santaranjanya Vyadhi in the classical texts. Hyper triglyceridemia is defined as the presence of raised or abnormal level of triglyceride level in the blood. The raised levels of triglyceride have been identified as the primary modifiable risk factor in cerebrovascular disease and It’s role has been appreciated in the manifestation of serious diseases like ischemic heart disease, diabetes, stroke etc. Triglyceride are fat molecule that are composed of three long chain fatty acid attached to glycerol, fat cells accumulate triglyceride which are the body’s primary source of stored energy. Hyper triglyceridemia can be divided into primary and secondary types. Primary triglyceridemia have genetic susceptibility, found in less than 5% of cases. Secondary triglyceridemia might have subtle inherited metabolic defect that confer susceptibility. Elevated plasma triglyceride concentration is a common biochemical finding, but the evidence for the benefit of treating this lipid disturbance remains less robust than that for treating elevated low-density lipoprotein–cholesterol. Part of the difficulty in the provision of specific recommendations has been the frequent coexistence of elevated triglycerides with other conditions that affect cardiovascular disease risk, such as depressed high-density lipoprotein,
Body mass index (BMI) < 40

Exclusion criteria
- Patient of primary hyper triglyceridemia.
- Patient’s age more than 80 years and below 10 years.
- Patients having history of serious cardiac disorders like myocardial infarction, cardiac failure, etc.
- Patients having any major illness, insulin-dependent diabetes mellitus, diabetes mellitus that was poorly controlled.
- Hyperlipidemia due to drugs (e.g., glucocorticoids)
- Pregnant females and lactating mothers
- Renal insufficiency

Study Design
A total no. of 30 patients of hyper triglyceridemia were selected in the study and given Haritakyadi yoga.
Dose-500 mg 2 capsule twice a day (Drug extract 2 g/day),
Duration- two month,
Anupana- lukewarm water,
Kala- before meal,
Lipid profile test were done before treatment and after two month initializing treatment.

Preparation of Haritakyadi yoga
Ingredients of Haritakyadi yoga follows:

<table>
<thead>
<tr>
<th>Name</th>
<th>Latin Name</th>
<th>Part</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haritikā' Extract</td>
<td>Terminalia chebula Ratz.</td>
<td>2 part</td>
</tr>
<tr>
<td>Bibhitakā' Extract</td>
<td>Terminalia Bellirica Roxb.</td>
<td>1 part</td>
</tr>
<tr>
<td>Amalaki Extract</td>
<td>Emblica officinalis</td>
<td>1 part</td>
</tr>
<tr>
<td>Shunti Extract</td>
<td>Zingiber officinale</td>
<td>1 part</td>
</tr>
<tr>
<td>Guduchi Extract</td>
<td>Tinospora cordifolia</td>
<td>1 part</td>
</tr>
<tr>
<td>Nagarmotha Extract</td>
<td>Cyperus rotundus</td>
<td>1 part</td>
</tr>
<tr>
<td>Rasanja Extract</td>
<td>Berberis aristata</td>
<td>1 part</td>
</tr>
<tr>
<td>Gomutra Kshara ghan</td>
<td>Gomutra Kshara</td>
<td>1 part</td>
</tr>
</tbody>
</table>

Pathya-Apapathy/ Dietary management
All the registered patients were advice to follow specific dietary changes and exercises patterns.

Assessment of therapy
Criteria of assessment
During the trial the patient were assessed on the following biochemical assessment (complete lipid profile).
- Serum cholesterol (ch.)
- Serum triglyceride (Tg.)
- Serum high density lipoprotein (HDL)
- Serum low density lipoprotein (LDL)
- Serum very low density lipoprotein (VLDL)
- Body mass index (BMI) - the body mass index or Quetelet index, a measurement that compares a person weight and height, was also assessed.

Statistical analysis
The data was mainly analyzed using Student’s unpaired t test and obtained results were interpreted as

<table>
<thead>
<tr>
<th>Statistical significance</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insignificant</td>
<td>P &gt; 0.05</td>
</tr>
<tr>
<td>Significant</td>
<td>P &lt; 0.01</td>
</tr>
<tr>
<td>Highly significant</td>
<td>P &lt; 0.001</td>
</tr>
</tbody>
</table>

The overall effect of the therapy was judged based on assessment of the lipid profile for which B.T. and A.T. was devised.

Guideline for lipid profile
According to National Cholesterol Education Program ATP III guideline

OBSERVATION AND RESULT
The study was conducted on 30 patients. Among the patients, 73.33 % were in the age-group of 31-60 years; 56.67 % were males, 86.67 % were married, 76.67 % were vegetarian, 83.33 % were educated and 70 % were Hindu by religion. The Prakriti Pariksha revealed that 30 % of the patients had kapha pradhan prikriti, 43.33 % had vata kapha pradhan prikriti, 26.67 had pitta pradhan prikriti, 80 % had tamasic prikriti, 50 % were madhyama vyayama shakti and 50 % were aver vyayama shakti, 53.33 % were madhyama aahara shakti, 63.33 % had madhyama satava, 50 % of each madhyama and shhula sanghan, 66.67 % had madhyama pramana. The majority of the patient characterized by body weight 70-85 Kg, BMI greater than 25 Kg/m².

Effect of therapy
Effect on symptoms
Through the Haritakyadi yoga there was a relief of symptoms like chalasfig (6.15 %), chalodarsthan (10.7 %), javoprodha (21.9 %), krachavyavata (0 %), nirdhadhiyak (25.8 %), dorgandha (24.1 %), swedabadh (12.5 %), kshudhadhiyak (19.4 %), pipasadhiyak (19.6 %), shethiyak (11.4 %), gurutak (17.8 %), kshudra shvasa (33.3 %), shigdhagatrata (30 %) and vyayamahastha (38.8 %). The relief of chalasfig, chalodarsthan, javoprodha, nirdhadhiyak, dorgandha, swedabadh, shethiyak, gurutak, kshudra shvasa, shigdhagatrata, vyayamahastha was statistically significant (P < 0.05), on kshudhadhiyak, pipasadhiyak the relief was highly significant (P < 0.001) and krachavyavata relief was non significant. Average relief in symptoms (objective parameter) was 19.38 % in the patients.

Effect on lipid profile
On statistical evaluation by unpaired ‘t’ test Haritakyadi yoga was found to decrease serum triglyceride (23.94 %), serum cholesterol (5.95 %), increase H.D.L. (4.86 %), decrease L.D.L. (8.68 %) and V.L.D.L. (8.65 %).
Overall effect of therapy

In this drug trial 30 patients completed the full course of treatment. Statistical data mean improvement in treatment is as follows:

<table>
<thead>
<tr>
<th>Object</th>
<th>Mean difference</th>
<th>% relief</th>
<th>S.D.</th>
<th>S.E.</th>
<th>T value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (kg)</td>
<td>1.833333</td>
<td>1.45</td>
<td>0.266</td>
<td>6.88</td>
<td>&lt; 0.001</td>
<td></td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>0.863333</td>
<td>0.94</td>
<td>0.172</td>
<td>5.00</td>
<td>&lt; 0.001</td>
<td></td>
</tr>
<tr>
<td>Triglyceride</td>
<td>2.76</td>
<td>0.43</td>
<td>0.266</td>
<td>4.44</td>
<td>&lt; 0.001</td>
<td></td>
</tr>
<tr>
<td>Cholesterol</td>
<td>23.94</td>
<td>5.19</td>
<td>0.438</td>
<td>9.81</td>
<td>&lt; 0.001</td>
<td></td>
</tr>
<tr>
<td>HDL</td>
<td>2.102</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td></td>
</tr>
<tr>
<td>LDL</td>
<td>2.40</td>
<td>2.40</td>
<td>2.40</td>
<td>2.40</td>
<td>2.40</td>
<td></td>
</tr>
<tr>
<td>VLDL</td>
<td>2.37</td>
<td>2.37</td>
<td>2.37</td>
<td>2.37</td>
<td>2.37</td>
<td></td>
</tr>
</tbody>
</table>

BT: Before Treatment, AT: After Treatment

Adverse effect

During the study no adverse event or effect was noted.

DISCUSSION

Thus, Haritkyadi yoga is a true formulation possessing pharmacological activity. All the patients followed strict dietary restrictions as well as lifestyle changes. The above findings are consistent with the Amapachana, Lekhna and Vatanuloman. It is Laghu, Ruksha rasa thus it effect is Dipan, Pachan, Kapha shaman and Pipasadhikya. Serum triglycerides showed a better response to Haritakyadi yoga than serum cholesterol; the response however was not significant, which may be due to the fact that the stored triglyceride in our body is changed every 2-3 weeks due to its constant synthesis and utilization whereas it takes a longer duration to work on cholesterol. Haritakyadi yoga showed better results on other objective parameters related to obesity (i.e., body weight, BMI, body circumferences) which shows its depletory action on Shathyi Medo Dhatu. Thus, Haritakyadi yoga was seen to reduce the levels of bad cholesterol (serum LDL) and increase the levels of good cholesterol (serum VLDL); thereby correcting dyslipidemia. HDL is known to have protective action against atherosclerosis and to reduce the risk for cardiovascular disease.

Mode of action of Haritakyadi yoga

The total effect of the Haritakyadi yoga is tridosha shanaka especially Kapha Vata Shama. It is Katu in rasa thus it effect is Dipan, Pachan, Kapha shaman and Vatanuloman. It is Laghu, Ruksha and Tikshna in guna so it is Raktashodhak, Agnimandhar, Amahar, Nidrahar and Annadvashar. Haritakyadi yoga is Katu in vipaka and ushna in vira thus it’s Agnidipak, pachan and vatanuloman. According to modern science-

- Amalki, Shuntitha, guduchi and mustak have hypcholesterolaemic effect. They may lower serum cholesterol, triglycerides, LDL and phospholipids without affecting HDL levels.
- Amalki, guduchi and Rasaut have hypoglycemic effect they may control the secretion of insulin.
- Triphala guduchi, mustak have hepatoprotective effect. So they regulate metabolism in the body.
- So haritakyadi yoga is effective in hypertriglyceridemia due to hypcholesterolaemic, hypoglycaemic and hepatoprotective effect and also depaan- pachan guna which reduces agnimandhya and amoapatti and srotovarad.

CONCLUSION

Hyper triglyceridemia can be treated on the principal of agni samayakaran and apatarpana because hyper triglyceridemia arises due to medo-dusti. Haritakyadi yoga showed a better result on lipid profile (subjective parameters) as compared to objective parameters. Dietary and lifestyle changes are supportive to therapy in hyper triglyceridemia and obesity.

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