EFFECT OF VYOSHADI SAKTHU AND CHAVYADI SAKTHU ON ELEVATED LIPID PROFILE – A COMPARATIVE CLINICAL STUDY

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ABSTRACT
Hyperlipidemia is the term used to denote the raised serum levels of cholesterol or triglycerides or both and is characterised by abnormally high concentration of lipids in blood caused by abnormal lipid and lipoprotein metabolism and has the risk of producing complications like Cardiovascular diseases, Obesity, Atherosclerosis etc. Obesity is the major health issue faced by many developing and developed countries and India stands one among these. And this comes under the banner of lifestyle disorders. In Ayurveda this may be interpreted as Medoroga (Obesity). In Hyperlipidaemia, the excess accumulated fat should be eliminated through Lekhana action which can be achieved through the oral administration of Vyoshadi Sakthu and Chavyadi Sakthu with butter milk considering their Lekhana and Medohara properties. This is the Single armed open clinical study of 40 samples fulfilling the diagnostic and inclusion criteria irrespective of sex were selected. Assessment was done based on Lipid profile values on 0th day (before trial) and 60th day (after trial). Based on grading, data obtained were analysed for statistical significance using tread − t’ test. The results were statistically significant with p value <0.001. Vyoshadi Sakthu and Chavyadi Sakthu have given a significant result on S. Cholesterol, S. LDL, and S. VLDL. The possible reason of improvement could be attributed to the Lekhana property of drugs in both the groups. If patients were subjected to reversal in lifestyle changes including diet control and proper exercises the result would be even better.

Keywords: Hyperlipidemia, Medoroga, Lekhana, Vyoshadi Sakthu, Chavyadi Sakthu

INTRODUCTION
Hyperlipidemia is one such disease complex in which Fast foods, lack of exercise, stress, various addictions etc. are some of the factors which contribute greatly to such disorders. These generally act by impairing the metabolism of an individual, making him prone to series of disorders.
WHO in its report states that high cholesterol contributes to 56% of cases of CAD and causes about 4.4 million deaths every year.¹ In Indians, Angina occur at a relatively young age and is more severe and extensive².

Hyperlipidaemia has gained worldwide interest in its ability to participate in the pathology of atherosclerotic diseases like coronary heart disease (CHD) and CVA which dominates the scenario of diseases causing morbidity and mortality in the world. Hyperlipi-
daemia is the term used to denote raised serum levels of cholesterol or triglycerides or both. Nikolai Anitschkow in 1912 discovered the role of cholesterol in Atherogenesis. Since then raised levels of cholesterol and triglycerides have decided as prime modifiable risk factors in atherosclerotic diseases. Also raised total cholesterol is a major cause of disease burden in both the developed and developing world as a risk factor for ischemic heart disease and Stroke. Its prevalence has increased three fold between 1975 and 2016 and continues to rise. According to WHO estimation in 2016, more than 1.9 billion adults are overweight, of these over 650 (13%) million were obese (11% men, 15% women). 12.6% women and 9.3% men in India are obese. Prevalence of obesity is more in women when compared to men.

Obesity is one among the metabolic disorder which has high mortality and morbidity. It has been clearly explained in Ayurveda as ‘Vikaran darunaan krutva nashayantyashu jeevitam.’

Co-existence of cluster of conditions such as central obesity, hypertension, dyslipidaemia, increased blood glucose levels which predispose to cardio vascular disease is called as ‘Metabolic syndrome’. Hence obesity is a powerful amplifier for metabolic syndrome. In pathogenesis of Sthoulya the vata marga gets obstructed by the increased Medo dhatu blocking the Medo vaha srotases. Vata kindles the Jataragni, though Jataragni is too high, which is evidenced by the increased appetite of patient, still the BMR (Basic metabolic rate) is very low, as the Dhatvagni level at Meda is low. The Medo dhatvagni mandya leads to abnormal upachaya of Medo dhatu, further leading to deprivation of nourishment to ‘Uttara dhatu’ (further dhatu). Ati Sthoulya is a Santarpana janya vyadhi i.e. disturbance between energy consumption and expenditure takes place leading to Sthoulya.

Though, there is no precise terminology for hyperlipidaemia mentioned in the Ayurveda classics, various scholars have tried to use distinct nomenclature for the same like Rasagata Sneha Vriddhi, Rasa Raktagata Sneha Vriddhi, Medovriddhi, Medoroga or Medodosha, Ama Medo Dhatu etc. A detailed study of hyperlipidaemia reveals its similarity to Asthayi Medo Dhatu Vriddhi on the basis of its pathophysiology. Also this excessively increased Asthayi Medo Dhatu is Ama in nature due to which it is retained in the body for a longer time resulting in further complications.

According to Ayurvedic perspective, it is clear that Kapha (Kledaka), Vata (Samana & Vyana), Meda (fat/lipids) & Medhodhatwugni are involved in the pathogenesis of Sthoulya. Hence the drug has to be such that it shows significant action on these factors. Vyoshadi Sakthu and Chavyadi Sakthu are mentioned under the context of Medorogadikara in Bhai-shirtsay Ratnavali and Yogaratnakara.

MATERIALS AND METHODS:
ICEC No. – ICEC/KC/04
Study design
Randomized comparative clinical trial was adopted. In this clinical trial, 40 patients fulfilling the diagnostic and inclusion criteria were selected and randomly assigned into 2 groups - Group A and Group B of 20 patients each. Group A patients were given Vyoshadi Sakthu and Group B were given Chavyadi Sakthu.

Method of sampling: Lottery method.
Total number of patients for the study was 46. In that 4 patients were not registered. So total 42 patients were registered for the study. In that 40 patients completed the clinical trial. Number of dropouts in group A was 1. There was 1 dropout in group B.

DIAGNOSTIC CRITERIA: patients with elevated lipid profile.

INCLUSION CRITERIA:
1. Patients aged between 20-60yrs
2. Serum lipid levels more than normal -
   S. Cholesterol - 201mg/dl or more
   S. Triglycerides - 161mg/dl or more
   S.LDL - 131mg/dl or more
   S.VLDL - 41mg/dl or more
3. Patients having the BMI upto 40 kg/m2
EXCLUSION CRITERIA:
1. Patients having H/O serious Cardiac disorders like MI, Cardiac failure etc.
2. Patients having IDDM, DM that was poorly controlled or newly diagnosed or if the patient was taking new therapy.
3. Hyperlipidaemia due to drugs (like glucocorticoids etc.)
4. Pregnant females and lactating mothers.

INTERVENTION:
The patients in Group A were treated with Vyoshadi Sakthu with a dose of 6gms twice a day before food, with 50ml of butter milk as Anupana. The patients in Group B were treated with Chavyadi Sakthu with a dose of 6gms twice a day with butter milk as Anupana. The duration of study was 60days. 30 days after the treatment schedule follow up was done.

Total study duration: 90 days.

ASSESSMENT CRITERIA:
Objective parameters –
Objective parameters were assessed mainly on the basis of biochemical investigations like lipid profile, BMI, before and after treatment in terms of percentage relief and statistical evaluations.

OBSERVATION:
Among 40 patients, 52% of the patients were males while 50% were females. 59% of patients belonged to the age group of 31-45 years, 34% of patients in the age group of 46-60 years. Rest 7% belongs to the age group of 16-30 years. About 77% were married due to selective age group. This incidence may be due to stressed life, peaked due to familial responsibilities. In this study maximum number of patients were business man (38.63%). Maximum number of patients had sedentary work schedule (59%), followed by 30% patients complained of mental stress and 34% with physical stress. Maximum number of patients had mixed diet (88%). After the therapy, in Group A, 8 patients had Mild improvement (1-25%) while 10 patients had Moderate improvement (25% - 50%) and 2 patients had marked improvement (50-70%) where as in Group B, 2 patients has no change (0%) and 16 patients had Mild improvement (1-25%) while 2 patients had Moderate improvement (25% - 50%) and no one has marked improvement.

RESULT:
The results were assessed on the basis of objective criteria such as S. Cholesterol, LDL, Triglyceride, VLDL and HDL. Both the individual effect (using paired ‘t’ test) of objective parameters on 0th and 60th day in Group ‘A’ and Group ‘B’ were computed. Finally the overall effect of the treatment and also the comparative effect of the treatment between Group ‘A’ and Group ‘B’ were compared.

| Table 1: Effect of Vyoshadi Sakthu based on assessment of parameters after 60days of treatment (Group A) |
|--------------------------------------------------|---|---|---|---|---|---|---|
| Lipid value | MEAN | MD | % | SD | SE | t-value | P value |
| S. Cholesterol | BT | AT | 246.10 | 224.270 | 21.830 | 4.63 | 12.004 | 2.684 | 8.133 | <0.001 |
| TGL | 157.450 | 138.100 | 19.350 | 2.85 | 9.241 | 2.066 | 9.364 | <0.001 |
| LDL | 151.200 | 132.750 | 18.450 | 2.94 | 13.740 | 3.072 | 6.005 | <0.001 |
| VLDL | 34.450 | 25.865 | 8.585 | 6.24 | 5.169 | 1.156 | 7.428 | <0.001 |
| HDL | 42.100 | 44.300 | 2.200 | 3.08 | 1.609 | 0.360 | 6.114 | <0.001 |

| Table 2: Effect of Chavyadi Sakthu based on assessment of parameters after 60days of treatment (Group B) |
|--------------------------------------------------|---|---|---|---|---|---|---|
| Lipid value | MEAN | MD | % | SD | SE | t- value | P value |
| S. Cholesterol | BT | AT | 250.35 | 239.100 | 11.250 | 0.31 | 1.585 | 0.354 | 31.736 | <0.001 |
| TGL | 156.80 | 153.150 | 3.650 | 0.19 | 1.599 | 0.357 | 10.212 | <0.001 |
| LDL | 147.55 | 144.650 | 2.900 | 0.44 | 1.483 | 0.332 | 8.744 | <0.001 |
COMPARATIVE EFFECTS OF GROUP ‘A’ AND GROUP ‘B’
The assessment criteria of Group A and Group B are compared and analysed by unpaired t test. Comparison is done between the results obtained after 60 days of treatment in both the groups.

**Table 3: COMPARATIVE EFFECTS OF GROUP ‘A’ AND GROUP ‘B’**

<table>
<thead>
<tr>
<th>Assessment criteria</th>
<th>Mean</th>
<th>Men difference</th>
<th>SD</th>
<th>t- Value</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Grp A</td>
<td>Grp B</td>
<td>Grp A</td>
<td>Grp B</td>
<td></td>
</tr>
<tr>
<td>S.Chol</td>
<td>224.27</td>
<td>239.1</td>
<td>21.830</td>
<td>12.004</td>
<td>3.908</td>
</tr>
<tr>
<td>TGL</td>
<td>138.1</td>
<td>153.15</td>
<td>19.350</td>
<td>9.241</td>
<td>7.487</td>
</tr>
<tr>
<td>LDL</td>
<td>132.75</td>
<td>144.65</td>
<td>18.450</td>
<td>13.740</td>
<td>5.032</td>
</tr>
<tr>
<td>VLDL</td>
<td>25.865</td>
<td>29.655</td>
<td>8.585</td>
<td>5.169</td>
<td>1.206</td>
</tr>
<tr>
<td>HDL</td>
<td>44.3</td>
<td>42.55</td>
<td>2.200</td>
<td>1.609</td>
<td>1.652</td>
</tr>
<tr>
<td>WEIGHT</td>
<td>0.3</td>
<td>0.5</td>
<td>0.2</td>
<td>0.47</td>
<td>1.28</td>
</tr>
<tr>
<td>BMI</td>
<td>0.05</td>
<td>0.06</td>
<td>0.01</td>
<td>0.08</td>
<td>0.6</td>
</tr>
</tbody>
</table>

**OVERALL ASSESSMENT OF THE TREATMENT:**

<table>
<thead>
<tr>
<th></th>
<th>Group A</th>
<th>Group B</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NO</td>
<td>%</td>
<td>NO</td>
</tr>
<tr>
<td>No relief (0%)</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Mild relief (0.1-24%)</td>
<td>8</td>
<td>40</td>
<td>16</td>
</tr>
<tr>
<td>Moderate relief (50-74%)</td>
<td>10</td>
<td>50</td>
<td>2</td>
</tr>
<tr>
<td>Marked relief (75%-99%)</td>
<td>2</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Complete relief (100%)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**DISCUSSION**

Discussion on follow up:
Out of 40 patients, 4 patients in Group A felt sour belching and burning in the chest but there was moderate relief found in lipid values after follow up. Where as in Group B, patients had mild improvement with no adverse effects found on follow up. So we can assume that the effect of treatment is retaining after follow up without taking medicine.
Discussion on dropouts:
There was 1 drop out in Group A. Group B had 1 drop out.

Reasons for drop outs-
1 patient in Group A reported no change in her lipid values after taking medicine only for a week. Other patient in Group B consulted allopathic physician and stopped this clinical trial without any reason. Hence they were excluded from the study.

Discussion on probable mode of action of drugs:

**Vyoshadi Sakthu:**

Vyoshadi Sakthu encounters Vata and Kapha Doshas by virtue of its Katu-Tikta Rasa dominance & Ushna-Virya. Vatahara action was also achieved by Laghu and Snigdha property. Katu-Tikta Rasa performs Medo-kledaka Shoshana action.

Ushna Virya also helps in Kleda and Meda vilayana action. Katu-Rasa, Ushna-Virya encounters Dhatvagni mandya & potentiates the weakened Dhatvagni and help in Ama Pachana thereby alleviates Aparipakwa and Ama dhatu.5,6

Due to Katu-Rasa, all the involved channels were dilated i.e. “Srotamsi Vivrunoti” action. Katu-Rasa and Ushna-Virya will check over Medovaha and Mam savaha Srotodushti.

Hyperlipidemia if seen through the lens of Ayurveda, may be taken as Medo Dosha as Bahu abaddha medas which circulates all over the body. Tikta, Katu, Kashaya Rasa causes medo vilayana.

The drugs such as Trikatu, Triphala, Vidanga, Patha, Shhiraa, and Chitraka were Rooksha, Sukshma and Ushna in nature thus penetrates into the deeper channels and remove sanga/obstruction.

Yava is a best drug of choice in Sthoulya. Hence by virtue of above properties, the Samprapti vighatana was done.

**Chavyadi Sakthu:**

In Chavyadi Sakthu, maximum ingredients are having Katu, Kashaya and Tikta rasa. These Tikta rasa drugs poscess the lekhana, karshana and rasa, Meda, Kleda Upashoshana properties.

Yava has Madhura rasa, by the virtue of its property helps to maintain the body strength.

The ingredients of Chavyadi Sakthu process Laghu Rooksha and Teekshna gunas which helps to alleviate Kapha and Meda all over the body and it poscess Sara guna, by which the effect can be seen very quickly.

The ingredients of Chavyadi Sakthu having Ushna veerya and Katu vipaka which act as vata kapha shamaka, karshana, lekhana, ama pachana, dhatu samshoshana properties.7,8

Thus doing the function of Sroto-vibhandha nashana and act as kapha hara & medo hara.

Chavyadi Sakthu stabilizes Agni in its normal level. When Pachaka Agni becomes stabilized, the Medodhatvagni progressively comes to a state of equilibrium and its functional aspect become normal. It results in Srotovishodhana. Consequently when the obstruction in the Srotas gets removed, Vatanulomana occurs followed by Medovilayana.

**CONCLUSION**

After completion of the study, the following conclusions were drawn:

Vyoshadi Sakthu showed clinical and statistically significant effect on elevated lipid profile. Whereas, Group B shows highly significant result only in S. Chol and LDL and moderate significant result in TGL, VLDL and HDL.

On comparison between the two groups, there were no statistical differences found in the outcome variables.

To calculate the overall effect, the Mean difference and percentage were calculated which was better in group A.

Thus null hypothesis was accepted and alternate hypothesis (H_1) is rejected, there is significant effect of Vyoshadi Sakthu and Chavyadi Sakthu on elevated Lipid parameters.

**REFERENCES**


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