

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 Hyperlipidemia, 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 'paired -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 marg*a 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 *Medo-Dosha*, *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 complications³.

According to Ayurvedic perspective, it is clear that *Kapha (Kledaka)*, *Vata (Samana & Vyana)*, *Meda* (fat/lipids) & *Medhodhatwagni* are involved in the pathogenesis of *Sthoulya*. Hence the drug has to be such that it shows significant action on these factors. *Vyoshadi Sakthu*⁴ and *Chavyadi Sakthu*⁴ are mentioned under the context of *Medorogadhikara* in *Bhaisajya Ratnavali* and *Yogaratanakara*.

MATERIALS AND METHODS:

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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
4. Both obese and non-obese.

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
	BT	AT						
S. Cholesterol	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
	BT	AT						
S. Cholesterol	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

VLDL	36.700	29.655	7.045	0.68	2.432	0.544	12.953	<0.001
HDL	41.15	42.550	1.400	0.6	0.940	0.210	6.658	<0.05

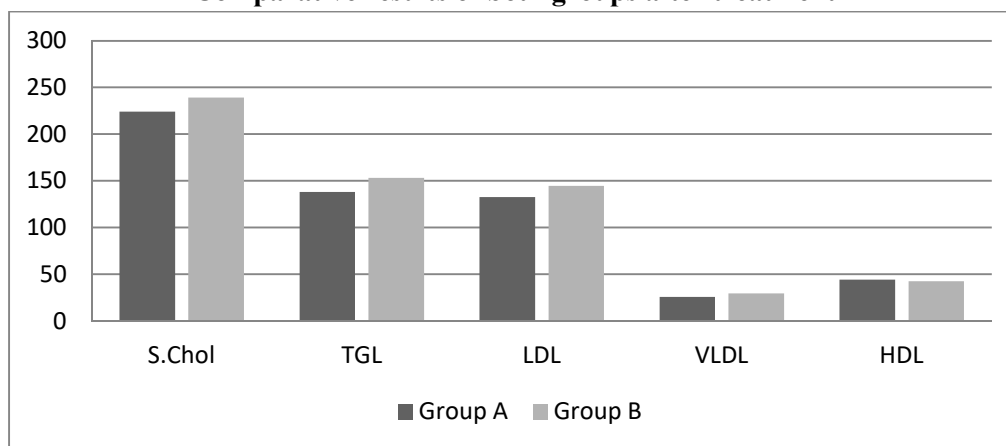
COMPARATIVE EFFECTS OF GROUP ‘A’ AND GROUP ‘B’

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 60days of treatment in both the groups.

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

Assessment criteria	Mean		Men difference	SD		t- Value	P-Value
	Grp A	Grp B		Grp A	Grp B		
S.Chol	224.27	239.1	21.830	12.004	1.585	3.908	<0.001
TGL	138.1	153.15	19.350	9.241	1.599	7.487	<0.001
LDL	132.75	144.65	18.450	13.740	1.483	5.032	<0.001
VLDL	25.865	29.655	8.585	5.169	2.432	1.206	<0.05
HDL	44.3	42.55	2.200	1.609	0.940	1.652	=0.266
WEIGHT	0.3	0.5	0.2	0.47	0.51	1.28	=0.2
BMI	0.05	0.06	0.01	0.08	0.06	0.6	= 0.5

Comparative results of both groups after treatment



OVERALL ASSESSMENT OF THE TREATMENT:

	Group A		Group B		Total	
	NO	%	NO	%	NO	%
No relief (0%)	0	0	2	10	2	10
Mild relief (0.1-24%)	8	40	16	80	24	60
Moderate relief (50-74%)	10	50	2	10	12	40
Marked relief (75%-99%)	2	10	0	0	2	10
Complete relief (100%)	0	0	0	0	0	0

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, Sthiraa, 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 process 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 process *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.

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