

A Clinical Study to Evaluate the Efficacy of Vyoshadi Sakthu on Elevated Lipid Profile

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Abstract

This single-armed open clinical study explores the efficacy of Vyoshadi Sakthu in managing hyperlipidemia, a condition marked by elevated levels of cholesterol and triglycerides, posing substantial health risks such as cardiovascular diseases and obesity. Administered orally with buttermilk, Vyoshadi Sakthu leverages its Lekhana and Medohara properties to target excess fat accumulation. The study involved 20 participants meeting diagnostic criteria, with lipid profiles assessed at baseline and after a 60th day Vyoshadi Sakthu trial. Statistical analysis, employing the paired t-test, revealed significant reductions in serum cholesterol, LDL, and VLDL levels ($p < 0.001$) post-intervention. These findings suggest a meaningful impact on lipid metabolism attributed to Vyoshadi Sakthu's Lekhana properties. Additionally, the study highlights potential synergies between Vyoshadi Sakthu treatment and lifestyle modifications, including dietary adjustments and regular exercise. This integrated approach may enhance treatment outcomes, emphasizing holistic management strategies for hyperlipidemia and related metabolic disorders. The results contribute to the growing evidence supporting Ayurvedic interventions' therapeutic efficacy in hyperlipidemia management. However, larger controlled studies are required to validate these findings and ensure the long-term safety and efficacy of Vyoshadi Sakthu. This underscores the importance of integrating traditional knowledge systems like Ayurveda into contemporary healthcare practices to address the complexities of metabolic disorders effectively.

Keywords: Hyperlipidemia, Medoroga, Lekhana, Vyoshadi Guggulu

Introduction:

Hyperlipidemia is a complex disease influenced by various factors such as fast food consumption, sedentary lifestyle, stress, and addictions. These factors often disrupt an individual's metabolism, rendering them susceptible to a range of disorders. The World Health Organization (WHO) reports that high cholesterol contributes to 56% of cases of coronary artery disease (CAD) and results in approximately 4.4 million deaths annually. In India, angina occurs at a younger age and tends to be more severe and extensive. Hyperlipidemia plays a significant role in the pathology of atherosclerotic diseases like coronary heart disease (CHD) and cerebrovascular accidents (CVA), which are major contributors to morbidity and mortality worldwide¹.

Hyperlipidemia is characterized by elevated serum levels of cholesterol or triglycerides, or both. The discovery of cholesterol's role in atherogenesis by Nikolai Anitschkow in 1912 marked a pivotal moment in understanding the link between lipid levels and cardiovascular diseases. Raised levels of total cholesterol and triglycerides are identified as prime modifiable risk factors for atherosclerotic diseases, contributing significantly to the global burden of ischemic heart disease and stroke. The prevalence of

hyperlipidemia has increased threefold between 1975 and 2016 and continues to rise. WHO estimates indicate that over 1.9 billion adults worldwide are overweight, with more than 650 million classified as obese. In India, 12.6% of women and 9.3% of men are obese, with a higher prevalence among women. Obesity, a metabolic disorder associated with high mortality and morbidity, is described in Ayurveda as 'Vikaran darunaan krutva nashayantyashu jeevitam³.'

Metabolic syndrome, characterized by a cluster of conditions including central obesity, hypertension, dyslipidemia, and increased blood glucose levels, predisposes individuals to cardiovascular diseases. Obesity exacerbates metabolic syndrome, acting as a potent amplifier. According to Ayurveda, the pathogenesis of obesity (Sthoulya) involves obstruction of the vata marga by increased Medo dhatu, leading to blockage of the Medo vaha srotases⁴. Despite elevated appetite due to heightened Jataragni, the basic metabolic rate (BMR) remains low, indicating reduced Dhatvagni levels in Meda. This leads to abnormal accumulation of Medo dhatu, depriving 'Uttara dhatu' of nourishment. Ati Sthoulya results from disturbances in energy consumption and expenditure. Though Ayurvedic classics do not mention hyperlipidemia explicitly, various scholars have used distinct terms such as Rasagata Sneha Vriddhi, Rasa Raktagata Sneha Vriddhi, Medovriddhi, Medoroga, or Ama Medo Dhatu to describe similar conditions. Hyperlipidemia shares similarities with Asthaya Medo Dhatu Vriddhi in terms of pathophysiology, characterized by excessively increased Ama-infused Medo dhatu retention in the body, leading to complications^{5,6}.

From an Ayurvedic perspective, Kapha (Kledaka), Vata (Samana & Vyana), Meda (fat/lipids), and Medhodhatwagni are implicated in the pathogenesis of Sthoulya^{7,8}. Hence, effective treatment should target these factors. Vyoshadi Sakthu, mentioned in the context of Medorogadhikara in Bhaishajya Ratnavali and Yogaratnakara, could offer therapeutic benefits in managing hyperlipidemia.

Materials and Methods

The approach I took in conducting my clinical trial on hyperlipidemic patients using Vyoshadi Sakthu.

Patient Selection:

- You selected 20 patients who met the diagnostic and inclusion criteria for the study.

2. Intervention:

- Patients were given Vyoshadi Sakthu as the treatment for hyperlipidemia.

3. Sampling Method:

- The lottery method was used for sampling.
- Initially, 26 patients were considered, but 4 were not registered, resulting in 22 registered patients.
- Eventually, 20 patients completed the clinical trial, with 1 dropout.

Diagnostic criteria: patients with elevated lipid profile indicating Hyperlipidemia.

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 with Vyoshadi Sakthu with a dose of 6gms twice a day before food, with 50ml of 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 20 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, 8 patients had Mild improvement (1-25%) while 10 patients had Moderate improvement (25% - 50%) and 2 patients had marked improvement (50-70%).

Result: The results were assessed on the basis of objective criteria such as S. Cholesterol, LDL, Triglyceride, VLDL and HDL. The effect (using paired‘t’ test) of objective parameters on 0th and 60th day was computed. Finally the overall effect of the treatment was analyzed.

Table 1. Effect of Vyoshadi Sakthu based on assessment of parameters after 60days of treatment.

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. Results after treatment

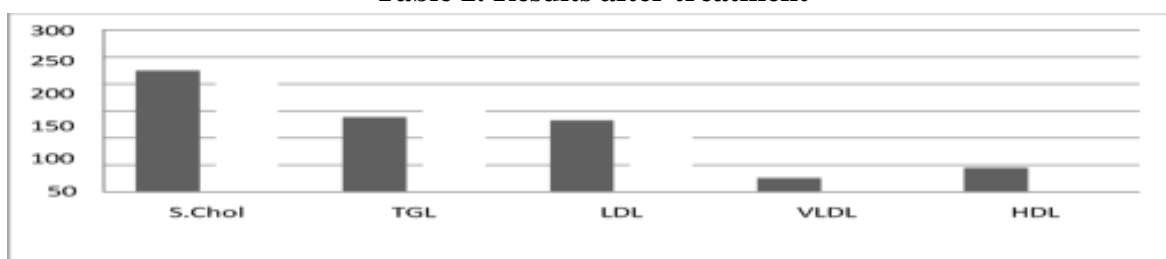


Table 3. OVERALL ASSESSMENT OF THE TREATMENT:

	NO	%
No relief (0%)	0	0
Mild relief (0.1-24%)	8	40
Moderate relief (50-74%)	10	50
Marked relief (75%-99%)	2	10
Complete relief (100%)	0	0

Follow-Up Discussion:

- 4 out of 20 patients experienced symptoms such as sour belching and burning in the chest during the follow-up period.
- Despite these symptoms, there was moderate relief observed in their lipid values, indicating that the treatment's effects persisted even after the follow-up period, suggesting sustained efficacy of the treatment.

Dropout Discussion:

- 1 patient dropped out of the study.
 - The reason for dropout was reported as no perceived change in lipid values after only one week of medication.
 - Despite the absence of a specific reason provided, the patient decided to discontinue the clinical trial.
- Overall, while some patients experienced mild adverse effects during follow-up, the data suggests that the treatment's efficacy persisted beyond the active intervention period. However, the dropout highlights the importance of addressing patient expectations and concerns to ensure continued participation in clinical trials.

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* ac- tion. *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 di- lated i.e. “*Srotamsi Vivrunoti*” action. *Katu-Rasa* and *Ushna-Virya* will check over *Medovaha* and ***Mamsavaha 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 chan- nels and remove *sanga/ obstruction*.

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

Conclusion:

The study concludes that Vyoshadi Sakthu demonstrated clinically and statistically significant efficacy in reducing elevated lipid profiles. This finding highlights its potential as a promising treatment option for hyperlipidemia. Further research is needed to investigate its long-term effects and evaluate its suitability as an adjunct or alternative therapy in managing cardiovascular risk factors. Vyoshadi Sakthu's multifaceted mode of action, addressing dosha imbalance and promoting lipid metabolism, suggests its value in holistic approaches to cardiovascular health within both Ayurvedic and conventional medical frameworks.

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