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Efficacy and Safety of Ayurvedic Formulations in the Management of Dyslipidaemia: A Pilot Clinical Trial

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ABSTRACT

Dyslipidaemia (Medoroga) is a metabolic disorder associated with vitiation of *Kaphadosha* and *Medadhatu*, commonly linked with obesity and sedentary lifestyle. Ayurvedic management aims to correct *Agnimandya* and reduce lipid imbalance. To evaluate the efficacy and safety of Ayurvedic treatment in improving lipid profile and clinical symptoms in dyslipidaemiapatients. A total of 30 patients (18 males, 12 females), mainly aged 41–50 years and overweight/obese, were enrolled. The intervention was administered for 12 weeks. Lipid profile and clinical symptoms were assessed at baseline, 6th week, and 12th week. Safety parameters including liver and kidney function tests were also monitored.Significant improvement was observed in lipid parameters. Total cholesterol reduced from 244.8 ± 16.2 to 196.3 ± 13.5 mg/dL ($p < 0.001$), LDL from 158.6 ± 13.4 to 118.4 ± 11.2 mg/dL ($p < 0.001$), and triglycerides from 208.4 ± 18.6 to 162.7 ± 15.4 mg/dL ($p < 0.001$). HDL increased from 39.2 ± 4.8 to 46.1 ± 4.2 mg/dL ($p < 0.01$). Clinical symptoms such as *Gaurava, Alasya,* and *Swedadhikya* showed marked reduction. No significant adverse effects were observed SGOT, SGPT, and serum creatinine remained stable. Overall, 12 patients showed marked improvement, 11 moderate, and 7 mild improvement. Ayurvedic intervention demonstrated significant lipid-lowering and symptom-relieving effects without adverse events. The results suggest effective management of Medoroga through correction of *Agnimandya,Ama* formation, and *Kapha–Meda* imbalance using *Lekhana* and *Medohara*principles.

Keywords: Dyslipidemia, *Medoroga,*Lipid profile, *Guggulu, Triphala, Agnimandya,Kaphadosha, Medadhatu*, Metabolic disorder

INTRODUCTION

Dyslipidemia represents a significant public health issue, characterized by abnormal lipid levels in the bloodstream, including elevated total cholesterol (TC), low-density lipoprotein (LDL), triglycerides (TG), and/or reduced high-density lipoprotein (HDL). It is among the most critical modifiable risk factors for cardiovascular diseases (CVDs), which continue to be the leading cause of morbidity and mortality globally [1]. The rising prevalence of sedentary lifestyles, unhealthy dietary practices, obesity, and metabolic disorders has led to a marked increase in dyslipidaemia cases, particularly in developing nations such as India [2]. The pathophysiology of dyslipidaemia involves disruptions in lipid metabolism, resulting in the accumulation of atherogenic lipoproteins in the bloodstream. Elevated LDL cholesterol is pivotal in the development of atherosclerosis, as it promotes plaque formation within arterial walls, thereby heightening the risk of coronary artery disease, stroke, and peripheral vascular disorders [3].

Conventional management of dyslipidaemia predominantly involves lifestyle modifications and pharmacological interventions, including statins, fibrates, niacin, and cholesterol absorption inhibitors. Among these, statins are extensively prescribed due to their efficacy in reducing LDL cholesterol levels [5]. Nevertheless, the long-term administration of these medications is frequently associated with adverse effects such as hepatotoxicity, myopathy, gastrointestinal disturbances, and an elevated risk of diabetes mellitus [6]. Furthermore, challenges

related to drug adherence, cost, and patient preference for natural therapies have spurred increased interest in alternative and complementary medical systems. In this regard, Ayurveda, the traditional medical system of India, provides a holistic approach to managing metabolic disorders, including dyslipidemia. Although dyslipidemia is not explicitly identified as a distinct disease entity in classical Ayurvedic texts, its clinical manifestations can be correlated with conditions such as Medoroga, Sthaulya, and disorders involving the vitiation of Kaphadosha and Medadhatu [7]. Ayurvedic management emphasizes the rectification of underlying metabolic imbalances through Shodhana (purification) and Shamana (palliative) therapies, complemented by dietary and lifestyle modifications. Various herbal formulations have been traditionally employed for their lipid-lowering and metabolic regulatory effects. Among these, Guggulu (Commiphoramukul) is one of the most extensively researched substances for its hypolipidemic properties. It contains

active compounds known as guggulsterones, which are believed to reduce cholesterol synthesis and enhance lipid metabolism [9]. Similarly, *Triphala*, a polyherbal formulation comprising *Terminaliachebula, Terminaliabellirica*, and *Emblicaofficinalis,* has demonstrated antioxidant, anti-inflammatory, and lipid-lowering effects in various experimental and clinical studies [10]. Recent scientific evidence suggests that Ayurvedic formulations may offer a safer and effective alternative or adjunct to conventional therapy in the management of dyslipidemia. Several clinical studies have reported significant reductions in total cholesterol, LDL, and triglycerides, along with improvements in HDL levels following Ayurvedic interventions [11,12]. Despite these promising findings, there remains a necessity for systematic clinical evaluation of Ayurvedic formulations employing standardized research methodologies. Pilot clinical trials are instrumental in generating preliminary evidence regarding the efficacy and safety of such interventions, which can subsequently inform large-scale randomized controlled trials.[13] Consequently, the present study was conducted to evaluate the efficacy and safety of selected Ayurvedic formulations in patients with dyslipidaemia. The study aims to assess changes in lipid profile parameters, including total cholesterol, LDL, HDL, and triglycerides, along with improvements in associated clinical symptoms. [14] Additionally, safety was evaluated through the monitoring of liver and kidney function parameters. The findings of this study may contribute to the expanding body of evidence supporting the role of Ayurveda in the management of dyslipidaemia and provide a foundation for future research in this domain.[15]

MATERIALS AND METHODS

2.1 Patient Population and Study Design

This study was conducted as a prospective, open-label, single-arm pilot clinical trial over a period of 12 weeks. A total of 30 patients diagnosed with dyslipidaemia were enrolled from the OPD of Kayachikitsa. All patients were assessed at baseline (0 week), 6th week, and 12th week to evaluate treatment response.

2.2 Inclusion and Exclusion Criteria

Inclusion Criteria

Patients aged **30–65 years**

Diagnosed with dyslipidaemia (Total cholesterol >200 mg/dL, LDL >130 mg/dL, or triglycerides >150 mg/dl)

Willing to participate and follow treatment

Exclusion Criteria

Patients with severe systemic diseases (renal, hepatic, or cardiac disorders)

Patients already taking lipid-lowering drugs

Pregnant or lactating women

2.3 Medication (Intervention)

All patients received Ayurvedic treatment for 12 weeks:

Guggulu-based formulation – 500 mg twice daily after meals

TriphalaChurna – 5 g at bedtime with lukewarm water

Patients were also advised a low-fat diet and regular physical activity during the study period.

2.4 Measurements and Assessment

Biochemical Parameters

Total cholesterol

LDL

HDL

Triglycerides

Clinical Parameters

Gaurava (heaviness)

Alasya (lethargy)

Swedadhikya (excess sweating)

Assessment Schedule

Baseline (0 week)—before treatment

6th week – during treatment

12th week – after treatment

Scoring System

Clinical symptoms were graded on a **0–3 scale**:

0 = Absent

1 = Mild

2 = Moderate

3 = Severe

2.5 Outcomes and Sample Size Determination

Primary Outcome

Improvement in lipid profile (Total cholesterol, LDL, HDL, triglycerides)

Secondary Outcome

Improvement in clinical symptoms

Sample Size

A total of 30 patients were included in this pilot study based on feasibility.

Calculation of Improvement

Improvement was calculated using:

Where: $Percentage\ Improvement = (Baseline\ Value - Final\ Value)/(Baseline\ Value) \times 100$

Baseline value = measurement at 0 week

Final value = measurement at 12th week

RESULT

A total of 30 patients, 18 were males and 12 were females. Most patients belonged to the 41–50 years age group. The majority of participants were overweight or obese, suggesting a possible association between increased body weight and dyslipidaemia.

3.1 Effect on Lipid Profile

A gradual and consistent improvement in lipid parameters was observed at the 6th week and 12th week following treatment.

Table 1: Effect of Treatment on Lipid Profile (n = 30)

Parameter	Baseline (0 Week)	6th Week	12th Week	p-value
Total Cholesterol	244.8 ± 16.2	218.5 ± 14.8	196.3 ± 13.5	<0.001
LDL	158.6 ± 13.4	138.2 ± 12.6	118.4 ± 11.2	<0.001
HDL	39.2 ± 4.8	42.6 ± 4.5	46.1 ± 4.2	<0.01
Triglycerides	208.4 ± 18.6	182.3 ± 16.9	162.7 ± 15.4	<0.001

Total cholesterol, LDL, and triglycerides showed highly significant reduction ($p < 0.001$)

HDL showed significant improvement ($p < 0.01$)

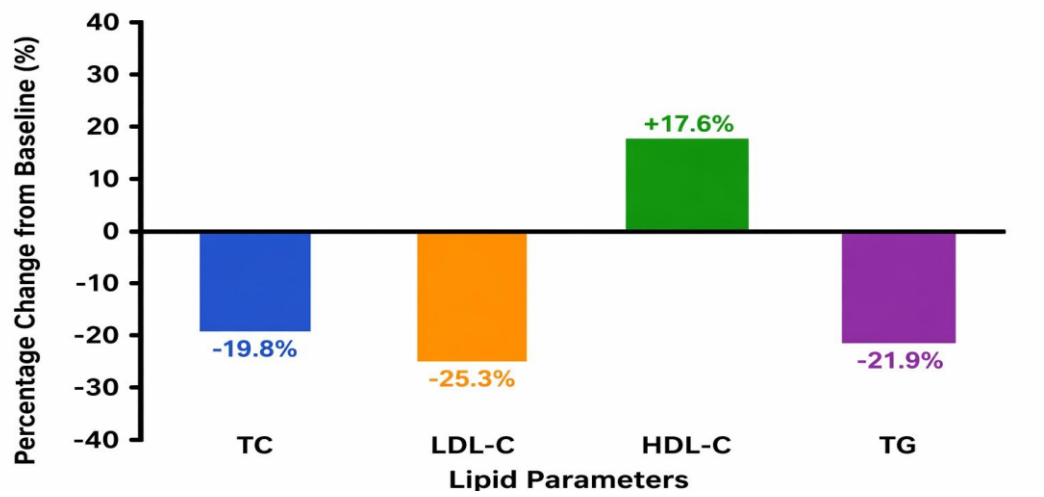

Figure 1:Percentage change from baseline in serum lipid parameters at the end of treatment.

3.2 Clinical Outcomes and Safety Evaluation

Patients showed improvement in clinical symptoms, and no adverse drug reactions were reported during the study.

Table 2: Clinical Symptoms and Safety Parameters (n = 30)

Parameter	Baseline	6th Week	12th Week
***Gaurava*(Heaviness)**	2.5	1.6	0.8
***Alasya*(Lethargy)**	2.3	1.5	0.9
Swedadhikya	1.9	1.2	0.6
SGOT (U/L)	29.1	29.5	30.0
SGPT (U/L)	30.4	31.2	31.5
Serum Creatinine (mg/dL)	0.92	0.93	0.94

3.3 Overall Treatment Response

Out of 30 patients showed improvement in lipid profile and clinical symptoms after 12 weeks of treatment, show significant improvement.

Table 3: Overall Treatment Response (n = 30)

Response Category	Number of Patients
Marked Improvement	12
Moderate Improvement	11
Mild Improvement	7

DISCUSSION

The present study demonstrated a significant improvement in lipid profile parameters following 12 weeks of Ayurvedic treatment. Notably, there was a marked reduction in total cholesterol, LDL, and triglycerides, accompanied by an increase in HDL levels. These findings suggest that the intervention was effective in rectifying lipid imbalances and enhancing overall metabolic status. The progressive improvement observed at the 6th and 12th weeks indicates a sustained therapeutic effect. In Ayurveda, dyslipidaemia is associated with *Medoroga,* primarily caused by the vitiation of *Kaphadosha* and *Medadhatu.* The common *Nidana* (causative factors) include excessive consumption of fatty, oily, and heavy foods (*Snigdha, Guru Ahara*), lack of physical activity (Avyayama), and a sedentary lifestyle. These factors lead to *Agnimandya*(impaired digestion) and the formation of *Ama,* which plays a crucial role in the development of metabolic disorders. The *Samprapti* (pathogenesis) involves derangement of *Jatharagni* and *Dhatvagni*, leading to improper metabolism of lipids and accumulation of *Medadhatu*.[16] This results in obstruction of body channels (*Srotorodha*) and further aggravation of *Kaphadosha*. The accumulation of abnormal lipids in circulation can be understood as a manifestation of *Medodhatudushti*, which parallels modern concepts of dyslipidaemia.[17] The improvement observed in this study can be attributed to the action of Ayurvedic formulations such as*Guggulu* and *Triphala,* which possess *Lekhana* (scraping), *Deepana* (digestive), and *Medohara* (lipid-reducing) properties. These drugs help in correcting *Agnimandya*, reducing *Ama*, and normalizing lipid metabolism. The significant reduction in lipid parameters and improvement in symptoms like *Gaurava* and *Alasya* support their therapeutic role.[18] Lifestyle and dietary modifications also played an important role in the management of patients. Participants were advised to follow a low-fat, high-fiber diet, avoid junk and oily foods, and engage in regular physical activity. Such measures help in reducing *Kapha* and *Meda accumulation* and improve overall metabolic health. [19,20] The combined effect of medication and lifestyle changes contributed to the overall positive outcomes observed in the study. Out of 30 patients, 28 showed varying degrees of improvement, indicating a high response rate to the treatment. The results of this pilot study are encouraging and suggest that Ayurvedic formulations may play a beneficial role in managing dyslipidaemia. Furthermore, no adverse effects or significant changes in liver and kidney function parameters were observed, indicating that the treatment was safe and well-tolerated.

CONCLUSION

The present clinical study involving 30 patients demonstrated a significant and progressive improvement in dyslipidaemia following 12 weeks of Ayurvedic intervention. The majority of participants were males (60%) and belonged to the 41–50 years age group, with most being overweight or obese, indicating a strong association between increased body weight and Medroga (lipid disorder). A marked improvement in lipid profile was observed. Total cholesterol reduced from 244.8 ± 16.2 mg/dl at baseline to 196.3 ± 13.5 mg/dL at 12 weeks ($p < 0.001$). Similarly, LDL decreased from 158.6 ± 13.4 to 118.4 ± 11.2 mg/dL ($p < 0.001$), and triglycerides reduced from 208.4 ± 18.6 to 162.7 ± 15.4 mg/dL ($p < 0.001$). HDL showed a significant increase from 39.2 ± 4.8 to 46.1 ± 4.2 mg/dL ($p < 0.01$), indicating improved lipid balance and metabolic regulation. Clinically, symptomatic relief was also evident, with reduction in*Gaurava* (2.5 to 0.8), *Alasya* (2.3 to 0.9), and *Swedadhikya*(1.9 to 0.6) over 12 weeks. Liver and renal parameters remained stable, with SGOT (29.1 to 30.0 U/L), SGPT (30.4 to 31.5 U/L), and serum creatinine (0.92 to 0.94 mg/dL) showing no adverse changes, confirming safety. Out of 30 patients, 12 showed marked improvement, 11 moderate improvement, and 7 mild improvement, giving an overall positive response in all participants. From an Ayurvedic perspective, the results can be attributed to correction of Agnimandya, reduction of Ama, and pacification of *Kapha*and *Meda*dushti through formulations possessing *Lekhana, Deepana,* and *Medohara* properties (e.g., *Guggulu, Triphala*). Overall, the study suggests that Ayurvedic management is effective, safe, and clinically beneficial in Medoroga (dyslipidemia).

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