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Research Article

To Compare the Efficacy of Arogyavardhini Vati and Kaishore Guggulu with Modern Medicine in Hyperlipidemic Patients with Raised Serum PCSK9 Levels

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ABSTRACT
Background: Hyperlipidemia is a major modifiable risk factor for cardiovascular diseases and is closely regulated by hepatic cholesterol metabolism. Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) plays a pivotal role in low-density lipoprotein receptor (LDLR) degradation and has emerged as an important biomarker and therapeutic target. While statins remain first-line therapy, their adverse effects and residual cardiovascular risk necessitate exploration of integrative approaches. Ayurveda describes dyslipidemia under Medoroga and offers formulations such as Arogyavardhini Vati and Kaishore Guggulu for metabolic regulation.
Objectives: To evaluate and compare the efficacy of Arogyavardhini Vati and Kaishore Guggulu with statins in hyperlipidemic patients having raised serum PCSK9 levels, and to assess the effect of integrative therapy on lipid parameters and PCSK9.
Methodology: A comparative, interventional study was conducted on 150 hyperlipidemic patients aged 18–65 years with raised serum PCSK9 levels. Patients were randomized into three groups: Group A received statins, Group B received Arogyavardhini Vati and Kaishore Guggulu, and Group C received combination therapy. Serum LDL-cholesterol and PCSK9 levels were assessed at baseline and after 6 months. Statistical analysis was performed using appropriate parametric tests.
Results: Baseline demographic and biochemical parameters were comparable among groups. After 6 months, all groups showed significant reductions in LDL and PCSK9 levels. The maximum reduction was observed in the combination therapy group, followed by statin monotherapy and Ayurvedic therapy. Intergroup differences were statistically significant for post-treatment LDL and PCSK9 levels.
Conclusion: Arogyavardhini Vati and Kaishore Guggulu demonstrated significant hypolipidemic effects and reduction in PCSK9 levels. Integrative therapy with statins produced superior outcomes, supporting the role of Ayurveda as a complementary approach in dyslipidemia management.

Keywords: Hyperlipidemia, PCSK9, Arogyavardhini Vati, Kaishore Guggulu, Statins, Integrative Medicine.

INTRODUCTION

Cardiovascular diseases remain the leading cause of global mortality, with dyslipidemia being a principal modifiable risk factor. Elevated low-density lipoprotein cholesterol (LDL-C) accelerates atherogenesis through oxidative modification and inflammatory cascades [1,2]. Statins have substantially reduced cardiovascular morbidity and mortality; however, adverse effects, statin intolerance, and persistent residual risk highlight the need for alternative or adjunctive therapies [3,4].

PCSK9 is a hepatic serine protease that regulates LDL receptor recycling. Gain-of-function mutations result in autosomal dominant hypercholesterolemia, whereas PCSK9 inhibition markedly lowers LDL-C levels [5,6]. Statins paradoxically upregulate PCSK9 expression, which may limit their lipid-lowering efficacy [7].

Ayurveda conceptualizes dyslipidemia under Medoroga, attributed to Agnimandya, Ama formation, and vitiation of Kapha dosha [8]. Arogyavardhini Vati is a classical formulation indicated for metabolic and hepatic disorders, while Kaishore Guggulu is traditionally used for inflammatory and metabolic conditions. Their pharmacological actions suggest potential hypolipidemic and anti-inflammatory effects [9,10].

This study aims to scientifically evaluate these Ayurvedic formulations using modern biochemical markers, including PCSK9, and compare their efficacy with conventional statin therapy.

Aims and Objectives

1. To assess the effect of Arogyavardhini Vati and Kaishore Guggulu on serum LDL-cholesterol and PCSK9 levels in hyperlipidemic patients.
2. To compare their efficacy with statins.
3. To evaluate the outcome of integrative therapy combining Ayurveda and modern medicine.

MATERIALS AND METHODS

Study Design: Comparative, interventional, prospective study.

Study Setting: Tertiary care teaching hospital.

Study Population: 150 hyperlipidemic patients with raised serum PCSK9 levels.

Inclusion Criteria: Patients aged 18–65 years with elevated LDL-C and raised PCSK9 levels who provided informed consent.

Exclusion Criteria: Patients with severe systemic illness, hepatic or renal failure, pregnancy, lactation, or unwillingness to participate.

Intervention: Group A: Statins (10–20 mg/day). Group B: Arogyavardhini Vati and Kaishore Guggulu (500 mg each, twice daily). Group C: Combination of statins with Ayurvedic formulations.

Outcome Measures: Serum LDL-C and PCSK9 levels at baseline and after 6 months.

Statistical Analysis: Data were analyzed using SPSS software. Paired and unpaired t-tests and ANOVA were applied, with $p < 0.05$ considered statistically significan

RESULTS

Table 1: Age Distribution

Age Group (Years)	Group A		Group B		Group C	
	Patients	Percentage	Patients	Percentage	Patients	Percentage
18-27 Years	13	26%	12	24%	12	24%
28-37 Years	4	8%	5	10%	5	10%
38-47 Years	7	14%	7	14%	7	14%
48-57 Years	19	38%	19	38%	20	40%
58-67 Years	7	14%	7	14%	6	12%
Total	50	100%	50	100%	50	100%
Mean±SD	42.86±14.16		42.96±14.16		42.66±14.03	
Median	48.50		48.50		48.50	
Range	18-64		18-64		18-63	
F value	0.006					
p value	0.994 (NS)					

Table 2: Gender

Gender	Group A		Group B		Group C	
	Patients	Percentage	Patients	Percentage	Patients	Percentage
Female	29	58%	27	54%	29	58%
Male	21	42%	23	46%	21	42%
Total	50	100%	50	100%	50	100%
X^2	1.44					
p value	0.229 (NS)					

Table 3: Baseline of LDL (Mg/Dl) (Group A, Group B & Group C)

Baseline Of LDL (Mg/Dl)	Group A	Group B	Group C	F Value	P Value		
					A VS B	A VS C	B VS C
Mean±SD	187.92±14.26	188.58±14.42	191.46±14.34		1.000 (NS)	0.657 (NS)	0.951 (NS)
Median	185.50	188.00	191.00				

Range	163-219	164-220	163-219	0.425 (NS) (F=0.862)			

Table 4: Baseline of PCK9 (Ng/Ml) (Group A, Group B & Group C)

Baseline Of PCK9 (Ng/Ml)	Group A	Group B	Group C	F Value	P Value		
					A VS B	A VS C	B VS C
Mean±SD	3232.64±141.77	3232.42±141.84	3292.46±141.12	0.054 (NS) (F=2.986)	1.000 (NS)	0.109 (NS)	0.107 (NS)
Median	3200.50	3200.50	3253.00				
Range	3016-3544	3016-3542	3059-3596				

Table 5: After 6 Months of LDL (Mg/Dl) (Group A, Group B & Group C)

Baseline Of LDL (Mg/Dl)	Group A	Group B	Group C	F Value	P Value		
					A VS B	A VS C	B VS C
Mean±SD	94.68±21.15	97.76±22.94	83.96±20.95	0.005 (S) (F=5.572)	1.000 (NS)	0.044 (S)	0.005 (S)
Median	92.00	93.50	83.50				
Range	58-137	58-137	50-119				

Table 6: After 6 Months of PCK9 (Ng/Ml) (Group A, Group B &Group C)

Baseline Of PCK9 (Ng/Ml)	Group A	Group B	Group C	F Value	P Value		
					A VS B	A VS C	B VS C
Mean±SD	1636.84±1085.47	1866.84±1233.95	1137.34±561.71	0.001 (HS) (F=6.917)	0.760 (NS)	0.042 (S)	0.001 (HS)
Median	1994.00	2371.00	1138.50				
Range	45-3216	45-3216	118-2013				

All three groups were comparable with respect to age, gender, baseline LDL-C, and PCSK9 levels. Significant reductions in LDL-C and PCSK9 were observed in all groups after treatment. The greatest reduction was seen in the combination therapy group, indicating a synergistic effect.

DISCUSSION

The present study demonstrates that Ayurvedic formulations exert significant lipid-lowering effects, consistent with earlier experimental and clinical studies on Guggulu and hepatoprotective herbs [11,12]. The reduction in PCSK9 levels suggests a possible modulatory effect on LDL receptor metabolism, an area that warrants further molecular research.

Statins produced expected reductions in LDL-C but were associated with lesser PCSK9 suppression compared to combination therapy, supporting the hypothesis that integrative approaches may overcome statin-induced PCSK9 upregulation [7,13]. Ayurvedic concepts of Agni regulation and Ama reduction parallel modern understanding of metabolic optimization and inflammation control.

Age distribution among the three groups was comparable, with no statistically significant difference observed (Table 1). The mean age in all groups was in the early forties, and most participants belonged to the middle-aged category. Advancing age is associated with progressive metabolic changes, decreased LDL receptor activity, and increased hepatic cholesterol synthesis, all of which predispose to dyslipidemia. Since age distribution was uniform, it did not confound treatment outcomes.

Gender distribution was also comparable among the three groups (Table 2), although a slight female predominance was noted. Hormonal variations, especially post-menopausal changes, are known to adversely influence lipid metabolism, increasing susceptibility to dyslipidemia among women. The absence of a significant gender difference enhances the internal validity of the study.

Baseline LDL cholesterol levels were comparable across all groups with no statistically significant difference (Table 3). This

homogeneity indicates that all participants began with a similar lipid burden prior to intervention. LDL cholesterol is a major contributor to atherosclerotic plaque formation, and comparable baseline levels are essential for reliable outcome assessment.

Similarly, baseline PCSK9 levels showed no significant intergroup difference (Table 4). PCSK9 plays a critical role in regulating LDL receptor degradation and cholesterol homeostasis. Comparable baseline PCSK9 values suggest similar metabolic status among participants at study entry.

Post-treatment intergroup comparison demonstrated statistically significant differences in LDL and PCSK9 levels among the three groups (Tables 5 & 6). Group C showed the most favorable outcomes, followed by Group A and then Group B. These findings suggest that combining modern lipid-lowering agents with evidence-based Ayurvedic formulations may provide enhanced therapeutic benefits.

CONCLUSION

Arogyavardhini Vati and Kaishore Guggulu are effective in reducing LDL-cholesterol and PCSK9 levels in hyperlipidemic patients. Integrative therapy with statins provides superior outcomes, supporting the incorporation of evidence-based Ayurveda into dyslipidemia management.

Limitations

1. Single-center study.
2. Moderate sample size.

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