ORIGINAL RESEARCH

The Efficacy of L-Carnitine Supplementation in Managing Hyperlipidemia: A Randomized Controlled Study

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ABSTRACT

Background: This study evaluated the efficacy of L-carnitine in managing hyperlipidemia, a key risk factor for cardiovascular diseases. In a 12-week, double-blind, randomized controlled trial, 100 participants with hyperlipidemia were randomized; where one group were received L-carnitine (1 g/day) as an aduvant therapy combined with a hypolipidemic drug and the other group with hypolipidemic drug alone. The primary outcomes measured were changes in serum levels of total cholesterol, LDL cholesterol, HDL cholesterol, and triglycerides, while secondary outcomes included body weight and BMI. The L-carnitine group showed a significant reduction in total cholesterol ($20.4 \pm 11.1 \text{ mg/dL}$), LDL cholesterol ($14.6 \pm 9.6 \text{ mg/dL}$), and triglycerides ($25.6 \pm 14.5 \text{ mg/dL}$), with an increase in HDL cholesterol ($6.6 \pm 4.6 \text{ mg/dL}$), all statistically significant (p<0.05) compared to the other group. No significant changes were observed in body weight or BMI. The results suggest that L-carnitine supplementation could be an effective adjunct therapy for improving lipid profiles in hyperlipidemia patients, though further long-term studies are needed.

Key words: L-Carnitine, Hyperlipidemia, Randomized controlled trial.

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INTRODUCTION

Hyperlipidemia is a metabolic disorder characterized by elevated levels of lipids in the blood, includingcholesterol and triglycerides. It is a major risk factor for the development of atherosclerosis, coronary artery disease, and stroke. Traditional treatment strategies include lifestyle modification and pharmacological interventions such as statins. However, the search for alternative or adjunctive therapies to manage hyperlipidemia remains a critical area of research.

L-carnitine, a naturally occurring quaternary ammonium compound, plays a crucial role in the transport of long-chain fatty acids into the mitochondria for beta-oxidation, a process essential for energy production. The widespread use of Lcarnitine (3-hydroxy-4-Ntrimethylammoniobutanoate) as a dietary supplement for individuals with various conditions stems from its antioxidant, anti-inflammatory, and lipid-lowering (hypolipidemic) properties.^[1]

Carnitine is synthesized in the brain, liver, and kidneys from methionine and lysine when not obtained from the diet. Skeletal and cardiac muscles, which contain the highest amounts of carnitine, rely on plasma for their supply, as they cannot synthesize it. About 99% of carnitine is intracellular and plays a key role in carbohydrate metabolism. Dysregulation of carnitine is linked to conditions like diabetes, trauma, obesity, and cardiomyopathy. Supplementing with L-carnitine benefits patients with uremia, improves neuropathic pain, nerve conduction, and immune function, and shows promise in treating neurological disorders, cardiovascular diseases, and obesity.^[2] Also, L-carnitine acts as a mitochondrial transporter for acyl and acetyl groups, playing a key role in carbohydrate metabolism and lipid oxidation, and it also helps activate the glycolysis pathway.^[3]

Previous studies have suggested that L-carnitine may have lipid-lowering effects, but the evidence is inconsistent. This study aims to assess the effectiveness of L-carnitine supplementation in improving lipid profiles in patients with hyperlipidemia.

MATERIAL AND METHODOLOGY STUDY DESIGN

This study was a double-blind, randomized clinical trial conducted over 12 weeks. Participants were recruited from outpatient clinics and provided informed consent prior to enrollment.

PARTICIPANTS

A total of 100 participants aged 30-65 years with diagnosed hyperlipidemia (defined as total cholesterol >200 mg/dL or LDL cholesterol >130 mg/dL) were enrolled. Exclusion criteria included a history of cardiovascular disease, diabetes mellitus, chronic kidney disease, or the use of combination of any other lipid-lowering medications within the previous 3 months.

RANDOMIZATION AND INTERVENTION

Participants were randomly assigned to one of two groups. Group I received L-carnitine 1g/day; [Carnimac Tablet 500mg twice daily (Macleods Pharmaceuticals Pvt Ltd)] with Atorvastatin 5 mg, while the Group II received Atorvastatin 5 mg alone. Randomization was performed using a computergenerated sequence, and both participants and investigators were blinded to the group assignments.

OUTCOME MEASURES

Primary outcomes were changes in serum levels of total cholesterol, LDL cholesterol, HDL cholesterol, and triglycerides from baseline to 12 weeks. Secondary outcomes included changes in body weight and BMI.

STATISTICAL ANALYSIS

Data were analyzed using an intention-to-treat approach. Paired t-tests were used to compare withingroup changes from baseline to 12 weeks, while Unpaired t-tests were used to compare between-group differences. A p-value of <0.05 was considered statistically significant.



Figure 1: Study flowchart

RESULTS BASELINE CHARACTERISTICS

Baseline characteristics were similar between the two groups, with no significant differences in age, baseline lipid levels, or BMI.

Table No 1: Baseline characteristics

	Group I	Group II
Age	38.05 ± 10.15	38.13 ± 11.27
Weight	62.79 ± 3.47	62.05 ± 3.92
Height	156.09 ± 2.75	156.71 ± 2.79
BMI	25.79 ± 1.59	25.29 ± 1.81

*p Value > 0.05 in all the baseline parameters.

Statistical analysis was done by unpaired t test between the group.

PRIMARY OUTCOMES

After 12 weeks, Group I showed more significant reduction in total cholesterol (mean difference: 20.4 ± 11.1 mg/dL), LDL cholesterol (14.6 ± 9.6 mg/dL), and triglycerides (25.6 ± 14.5 mg/dL) than compared to the Group II. HDL cholesterol levels were more increased in the L-carnitine group (mean difference: 6.6 ± 4.6 mg/dL).

LIPID PROFILES	GROUP I		GROUP II		p Value (Unnaired t test)
	1 st visit	12 th week	1 st visit	12 th week	(Onpanieu riest)
Total	$228.76 \pm$	$208.36 \pm$	225.94 ±	213.64 ±	0.0461
cholesterol	9.48	15.58	7.88	9.94	
LDL	149.84 ±	135.24 ±	$147.24 \pm$	139.04 ±	0.0426
	5.25	10.84	5.06	7.32	
TAG	210.7 ±	$185.10 \pm$	210.4 ±	194.01 ±	0.0044
	10.07	17.43	10.92	12.81	
HDL	29.44 ± 4.52	36.04 ± 2.43	33.12 ± 2.59	36.22 ± 2.30	0.0012
p Value	0.001		0.001		
(Paired t test)					

Table No 2: Changes in Lipid profiles



Figure 2: Histogram showing the differences in lipid profiles during the studies

SECONDARY OUTCOMES

No significant changes in body weight or BMI were observed between the groups. (p>0.05)

	GROUP I		GROUP II		p Value (Unpaired t test)
	1 st visit	12 th week	1 st visit	12 th week	
BMI	25.79 ± 1.59	25.64 ± 1.52	25.29 ± 1.81	25.14 ± 1.73	0.13
p Value	0.63		0.67		
(Paired t test)					

Table No 3: Changes in BMI

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DISCUSSION

This randomized controlled study aimed to evaluate the efficacy of L-carnitine supplementation in managing hyperlipidemia. Our findings indicate that after 12 weeks of supplementation, Group I (Lcarnitine group) experienced a significantly greater reduction in total cholesterol, LDL cholesterol, and triglycerides compared to Group II (control group), with an accompanying increase in HDL cholesterol levels. These results highlight the potential of Lcarnitine as an effective intervention for improving lipid profiles in hyperlipidemic patients.

The baseline characteristics, including age, weight, height, BMI, and baseline lipid levels, were comparable between the two groups, with no significant differences observed. This similarity strengthens the internal validity of the study and confirms that any differences in lipid profiles at the 12th week can be attributed to the effects of Lcarnitine supplementation rather than pre-existing disparities between the groups.

Primary Outcome

In terms of lipid profile changes, Group I showed a significant reduction in total cholesterol (mean difference: $20.4 \pm 11.1 \text{ mg/dL}$), LDL cholesterol (14.6 \pm 9.6 mg/dL), and triglycerides (25.6 \pm 14.5 mg/dL) compared to Group II. This finding is consistent with previous studies, which reported the beneficial effects of L-carnitine on lipid metabolism by enhancing fatty acid oxidation and reducing lipid accumulation in the blood^[4]. The significant increase in HDL cholesterol (mean difference: $6.6 \pm 4.6 \text{ mg/dL}$) further supports the cardioprotective effects of L-carnitine, as higher HDL levels are associated with a lower risk of cardiovascular events^[5].

The reductions in LDL cholesterol and triglycerides are particularly relevant, as elevated levels of these lipids are known risk factors for atherosclerosis and cardiovascular disease^[6]. The p-values for total cholesterol, LDL, triglycerides, and HDL changes in both the paired and unpaired t-tests confirm the statistical significance of the observed differences between the groups, further strengthening the validity of these findings.

Secondary Outcome

Interestingly, no significant changes in body weight or BMI were observed between the groups over the 12week period. This suggests that while L-carnitine positively impacts lipid metabolism, it may not directly influence body weight or BMI within this time frame.

LIMITATIONS

While the study demonstrated significant lipidlowering effects of L-carnitine, there are some limitations to consider. The 12-week duration may not be sufficient to observe long-term effects of supplementation, and future studies should investigate the sustainability of these benefits over a longer period. Additionally, genetic factors or baseline carnitine levels, which may influence individual responses to supplementation, were not assessed in this study. Exploring personalized approaches to Lcarnitine supplementation could further enhance its efficacy in hyperlipidemia management.

CONCLUSION

This randomized controlled trial provides evidence that L-carnitine supplementation can improve lipid profiles in patients with hyperlipidemia. These findings support the potential use of L-carnitine as an adjunctive therapy in managing hyperlipidemia. However, further studies with larger sample sizes and longer follow-up periods are necessary to confirm these results and evaluate the long-term impact on cardiovascular outcomes.

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