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Original Research Article

Prospective Randomized Open Label Comparative Study of Efficacy of Atorvastatin Alone and Atorvastatin with Omega 3 Fatty Acids in Patients with Dyslipidaemia Attending Tertiary Care Hospital

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Abstract

Background: Dyslipidaemia is an important modifiable cardiovascular risk factor which is highly prevalent in the Indian population. Atorvastatin reduces low-density lipoprotein cholesterol (LDL-C), but a large proportion of patients have elevated triglycerides and residual cardiovascular risk. Omega-3 fatty acids have been demonstrated to lower triglycerides, and may offer added benefit when used in combination with statins.

Methods: This prospective, open-label, randomized comparative study was carried out between February 2020 to August 2021 at a tertiary care hospital- Aryabhatta. One hundred dyslipidaemia patients were assigned to either Group A (atorvastatin 10–20 mg once daily) or Group B (atorvastatin 10–20 mg + omega-3 fatty acids 1 g twice daily) with a random allocation. Treatment duration was 12 weeks. Lipid profiles were evaluated at baseline, 6 weeks and 12 weeks. Statistical analysis was conducted with SPSS, and $p < 0.05$ was considered statistically significant.

Results: There was a statistically significant improvement among the study and control groups in the 12 weeks for all lipid parameters ($p < 0.001$). The combination therapy group also showed much decreased triglycerides and slightly increased high-density lipoprotein cholesterol (HDL-C) as compared to atorvastatin monotherapy. Both groups had a significant reduction in LDL-C, which was slightly greater in the combination group. Tolerability of both regimens was good with minimal adverse effects.

Conclusion: Atorvastatin plus omega-3 fatty acids was more effective than atorvastatin alone, especially in the reduction of triglycerides and similarly safe. Combination therapy can help in the management of patients with mixed dyslipidaemia; however, large multicentric trials are required to determine long-term cardiovascular outcomes.

Keywords: Dyslipidaemia; Atorvastatin; Omega-3 fatty acids; Triglycerides; LDL cholesterol; Combination therapy; Cardiovascular risk.

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Introduction

Metabolic dyslipidaemia is a disorder of lipid metabolism with elevated levels of total cholesterol (TC), LDL-C and triglycerides in blood, and reduced concentrations of HDL-C [1]. It is a leading modifiable risk factor for atherosclerosis and subsequent cardiovascular diseases (CVD), including coronary artery disease, stroke, and peripheral arterial disease. It may develop in primary form genetically or it can be secondary to sedentary life, obesity, diabetes mellitus, hypothyroidism, and high saturated fat use [2,3]. Increasing lipid deposition within the arterial walls results in plaque formation, endothelial dysfunction and heightened risk of thrombotic incidents. Dyslipidaemia is a major public health problem worldwide. International epidemiological data indicate that high cholesterol is a significant cause of ischemic heart disease globally [4]. In developing countries like India, rapid urbanization, dietary transitions, and reduced physical activity

have led to a sharp rise in lipid abnormalities. Indian populations are particularly predisposed to atherogenic dyslipidaemia characterized by elevated triglycerides, low HDL-C, and relatively normal or mildly elevated LDL-C levels [5]. This pattern raises the cardiovascular risk even with relatively low cholesterol level as opposed to Western societies. With CVD emerging as the leading cause of death in India, optimal lipid management is essential.

Medical therapy plays a crucial role in the management of lipids. Atorvastatin, an HMG-CoA reductase inhibitor that is widely used clinically, cannot only inhibit the synthesis of cholesterol in the liver but also increases circulating LDL-C clearance by enhancing LDL receptors [6].

There has been strong evidence for its efficacy in LDL-C reduction and its effect on cardiovascular morbidity and mortality. Nevertheless, despite the use of appropriate statin therapy, a significant number of patients continue to exhibit elevated triglycerides as well as persistent residual cardiovascular risk.

Omega-3 polyunsaturated fatty acids, in particular eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), reduce circulating levels of triglyceride by inhibiting hepatic very low-density lipoprotein (VLDL)-triacylglycerol production and stimulating triacylglycerol clearance [7,8]. They also have anti-inflammatory, anti-thrombotic and plaque-stabilizing properties that could lead to further cardiovascular benefits other than lipid-lowering.

Statins are still the remains of treatment for dyslipidaemia, but statin monotherapy alone may not effectively treat patients with mixed dyslipidaemia, in particular those with hypertriglyceridemia [9]. A high proportion of patients who receive statins persist in having elevated triglyceride levels and low HDL-C, leading to residual cardiovascular risk. This residual risk underlines the importance of supplementary therapy against other lipid fractions, different from LDL-C [10].

Omega-3 fatty acids have been considered an add-on therapy option based on the triglyceride-lowering and cardioprotective benefits [11]. It has been observed in several international studies that combining omega-3 fatty acids with statins may provide superior improvements in lipid parameters than statin therapy alone. However, the Indian tertiary care-based settings remain limited, particularly in real-world clinical settings.

With the increasing prevalence of dyslipidaemia in India and the typical lipid profile patterns observed among Indian patients, it is important to assess the relative efficacy of atorvastatin monotherapy versus atorvastatin plus omega-3 fatty acids. A prospective randomized research on this issue in a tertiary care hospital will give locally pertinent information to assist clinicians in the optimization plan for managing strategies and might lessen cardiovascular risks among these patients.

Objectives

- To compare the effectiveness of atorvastatin alone versus atorvastatin in combination with Omega-3 fatty acid in dyslipidemic cases for attenuation of LDL-C.
- To assess and compare both regimens regarding other lipid parameters such as total cholesterol, triglycerides, HDL-cholesterol and VLDL.
- Safety and tolerability profile of atorvastatin monotherapy versus combination with omega-3 fatty acids throughout the study duration.

Materials and Methods

Study Design: The present study was planned as a multicentre drug utilization study to compare the effect of atorvastatin alone versus a combination of atorvastatin and omega-3 fatty acid in adult dyslipidaemia subjects. A prospective model was selected to follow up results after intervention during a limited period. Randomization effectively balanced the two treatment groups, and as this was an open-label study, both investigators and participants were aware of the treatment provided to each participant. By comparing the ratio, we were able to evaluate differences in lipid profile improvement and safety between the two treatment strategies.

Study Setting: The research was carried out at a tertiary care hospital, Aryabhatta of the General Medicine Department in association with the Pharmacology Department. The hospital is related to a population with a high presence of clinic patients with metabolic and cardiovascular conditions that generates a representative patient base for recruiting as well as follow-up. All laboratory tests were conducted in the central hospital's clinical laboratory with standardized protocols.

Study Duration: The study was conducted in 18 months, from February 2020 to August 2021. This duration entailed patient recruitment, baseline measures, intervention studies, follow-up assessments and data analysis.

Sample Size: A total of 100 patients with the diagnosis of dyslipidaemia were included in the study. The subjects were divided into two groups of 50 patients allowed treatment arms. The sample size was calculated according to the feasibility (e.g., enrolment during study period) and availability of eligible subjects, as well as previous

comparative studies on lipid-lowering treatments. The number of patients was appropriate to detect a clinically relevant difference in the comparison between the two groups.

Inclusion Criteria: Eligible patients were between 18 and 70 years of age and diagnosed with dyslipidaemia according to lipid profile variables. Eligible participants had elevated levels of LDL-C and triglycerides according to standard diagnostic criteria. Only those who agreed to participate and provided written informed consent were included.

Exclusion Criteria: Patients with moderate to severe hepatic failure, renal failure, pregnant or lactating women were not included in the study. Patients known hypersensitivity or intolerance to statins or secondary causes of dyslipidaemia (eg, untreated hypothyroidism, nephrotic syndrome) were also excluded in order to eliminate confounding factors affecting levels of lipids and treatment responses.

Randomization: Patients were assigned to two groups after enrollment by the computer-based random number table with no selection bias. Atorvastatin was administered to group A and atorvastatin plus omega-3 fatty acids was given to group B. Randomization sequence was concealed up to assignment in order to avoid selection bias.

Intervention Details: At discharge, group A patients received atorvastatin 10–20 mg once a day according to baseline lipid profile and clinical assessment. Patients in group B were given the same atorvastatin dose, 20 mg and omega-3 fatty acids for 1 gram twice daily. The treatment course for both groups was 12 weeks. All subjects were recommended to keep the standard lipid-lowering diet and healthy lifestyle during the study.

Outcome Measures: The primary endpoint was the absolute decrease in LDL cholesterol level at the end of treatment. Secondary outcomes measured were the total cholesterol, triglyceride, HDL cholesterol and VLDL levels. Adverse effects including myalgia, gastrointestinal symptoms and changes in liver enzyme levels were used to evaluate safety.

Data Collection Procedure: At baseline, assessed for detailed medical history, physical examination and laboratory examination including complete lipid profile. Follow-up evaluations were performed at 6 and 12 weeks after treatment onset. Blood specimens were obtained following an 8- to 12-hour overnight fast. Lipid parameters were assayed by enzymatic colorimetric methods in the hospital laboratory. Medication compliance and adverse event frequency were recorded at every follow-up visit.

Statistical Analysis: The data was recorded in Microsoft excel and analyzed by SPSS. Mean ± standard deviation (SD) was used for continuous variables. Paired t-test was used to compare within groups for changes from baseline. The independent t-test was used for between-group comparisons. Comparisons of qualitative variables were done with the Chi-square test. A p-value of less than 0.05 was considered statistically significant.

Ethical Considerations: The study protocol was reviewed and approved by the Institutional Ethics Committee of Aryabhatta tertiary care hospital approved the study protocol. Written consent was given by all participants at recruitment. Patient data were strictly maintained and patient confidentiality was respected according to protocols established for human biomedical research guidelines.

Results

One hundred patients with dyslipidaemia were recruited and 100 of them completed the study. They were randomized in equal numbers into two groups: Group A (Atorvastatin only, n=50) and Group B (Atorvastatin + Omega-3 fatty acids, n=50). The total follow-up period was 12 weeks for all the patients, and they were included in the final analysis.

Baseline Characteristics: The average age of participants in Group A was 52.4±9.6 years and those in Group B were 51.8 ±8.9 years. The common age group was 41–60 years in both the groups. There was no gender bias in the two groups, male/female = 60/40% (Group A), 58/42% (Group B). There was no difference in the baseline lipid parameters between the two groups demonstrating homogeneity prior to intervention. The average of the baseline LDL-C values was 164.3 ± 18.2 mg/dL in Group A and 166.1 ± 17.5 mg/dL in Group B, and the mean levels of triglycerides were 228.5 ± 34.6 mg/dL and 231.2 ± 36.1 mg/dL, respectively for groups A and B. Mean total cholesterol and HDL-C were similar, as were comparable. With respect to comorbidities, hypertension (38% vs 40%) and type 2 diabetes mellitus (32% vs 30%) were present in similar proportions of patients in groups A and B, respectively. There was no significant difference between groups at preintervention ($p > 0.05$).

Table 1: Baseline Characteristics of Study Participants

Parameter	Group A (n=50)	Group B (n=50)	p-value
Mean Age (years)	52.4 ± 9.6	51.8 ± 8.9	>0.05
Male (%)	60%	58%	>0.05
LDL-C (mg/dL)	164.3 ± 18.2	166.1 ± 17.5	>0.05
Triglycerides (mg/dL)	228.5 ± 34.6	231.2 ± 36.1	>0.05
Total Cholesterol (mg/dL)	242.7 ± 21.4	244.1 ± 20.9	>0.05
HDL-C (mg/dL)	38.6 ± 5.4	39.1 ± 5.1	>0.05
Hypertension (%)	38%	40%	>0.05
Diabetes Mellitus (%)	32%	30%	>0.05

Comparison of Lipid Profile: The levels of lipid profile were reduced significantly in both groups after 12 weeks of treatment as compared with pre-treatment values. The mean LDL-C decreased in Group A from 164.3 ± 18.2 mg/dL to 118.6 ± 15.4 mg/dL ($p < 0.001$). Triglycerides significantly declined from 228.5 ± 34.6 mg/dL to 178.2 ± 28.3 mg/dL ($p < 0.001$). Mean LDL-C decreased from 166.1 ± 17.5 mg/dL to 112.4 ± 14.6 mg/dL ($p < 0.001$) in Group B. Triglycerides had a greater decrease from 231.2 ± 36.1 to 150.6 ± 25.7 mg/dL ($p < 0,001$).

Both groups experienced a modest yet significant increase in HDL-C levels.

Table 2: Within-Group Comparison of Lipid Parameters

Parameter	Group A (Baseline)	Group A (12 Weeks)	Group B (Baseline)	Group B (12 Weeks)
LDL-C	164.3 ± 18.2	118.6 ± 15.4*	166.1 ± 17.5	112.4 ± 14.6*
Triglycerides	228.5 ± 34.6	178.2 ± 28.3*	231.2 ± 36.1	150.6 ± 25.7*
Total Cholesterol	242.7 ± 21.4	196.8 ± 18.7*	244.1 ± 20.9	187.3 ± 17.9*
HDL-C	38.6 ± 5.4	41.2 ± 4.8*	39.1 ± 5.1	43.6 ± 4.6*

***p < 0.001 compared to baseline**

Between-Group Comparison: Group B showed a greater mean decrease than Group A from the baseline level of triglycerides (80.6 mg/dL vs 50.3 mg/dL; $p < 0.001$). LDL-C reduction also tended to be higher in Group B, but the difference was only marginal (53.7 vs 45.7 mg/dL, $p < 0.05$).

Table 3: Between-Group Comparison of Mean Reduction

Parameter	Mean Reduction Group A	Mean Reduction Group B	p-value
LDL-C	45.7 mg/dL	53.7 mg/dL	<0.05
Triglycerides	50.3 mg/dL	80.6 mg/dL	<0.001
Total Cholesterol	45.9 mg/dL	56.8 mg/dL	<0.05
HDL-C (Increase)	+2.6 mg/dL	+4.5 mg/dL	<0.05

Triglyceride Reduction Analysis: The decrease of triglycerides was more pronounced in the combined treatment group. By week 12, triglyceride levels had dropped from baseline to less than 150 mg/dL in 72% of patients in Group B and in only 48% in Group A; the difference was significant ($p < 0.01$), indicating that the combination of omega-3 fatty acids results in a more potent reduction of triglyceride levels.

Adverse Effects: Overall, both treatment plans were well tolerated. Muscle pain was described in 6% of Group A and 8% of Group B patients; mild gastrointestinal upset was slightly more common in Group B (12%) than in Group A (6%). Liver enzyme elevation not exceeding normal levels was observed in 4% of patients in Group A and 6% of those in Group B, but no patient was withdrawn due to it.

Table 4: Adverse Effects Observed

Adverse Effect	Group A (n=50)	Group B (n=50)
Myalgia	3 (6%)	4 (8%)
GI Disturbances	3 (6%)	6 (12%)
Elevated Liver Enzymes	2 (4%)	3 (6%)

Overall, the combination therapy was superior to atorvastatin alone for triglyceride lowering with a similar safety profile.

Discussion

Interpretation of Results: This ongoing prospective randomized open-label comparative study was conducted to assess the efficacy and safety of atorvastatin monotherapy versus a combination of atorvastatin with omega-3 fatty acids in patients with dyslipidaemia. The results showed that both treatment algorithms significantly reduced the values of lipid profile after 12 weeks of therapy. Nevertheless, combined treatment was more effective, particularly for decreasing triglycerides.

Levels of triglycerides were significantly reduced in both groups, the decrease was more marked in patients on combination therapy. This observation has clinical implications as hypertriglyceridemia is a prevalent lipid abnormality in Indian population which leads to residual cardiovascular risk despite achieving control over LDL-C. The potentiated triglyceride-lowering effect of omega-3 fatty acid supplementation could be due to their ability to lower hepatic VLDL synthesis and increase the clearance of triglycerides.

Regarding LDL-C lowering, both groups experienced marked changes from baseline. While monotherapy of atorvastatin is effective mainly in the reduction of LDL-C, the combination group showed a modest additional decline. This phenomenon indicates that adjunctive omega-3 treatment may have a small additional effect on LDL-C lowering, which was slighter than the decrease in triglycerides.

HDL-C concentrations increased in both groups, a moderate increment, but statistically significant, with the combination treatment group showing a higher HDL-C increase. Any HDL-C improvement, although slight, might translate into further cardio protection. Overall, these findings imply that combination treatment leads to more extensive changes in lipid profile with respect to atorvastatin monotherapy.

Comparison with Previous Studies: Interpreted in the context of previously published global studies on statin and omega-3 combination therapy, the results of this study align well. Pivotal international studies have shown that when omega-3 fatty acids are added to statins, triglyceride lowering beyond statin mono therapy is significantly achieved [12]. Similar trends in increased triglyceride lowering with combination therapy in Western trials were observed, particularly among patients with mixed dyslipidaemia [13]. Moreover, previous trials have demonstrated that statin use can significantly decrease levels of LDL-C and cardiovascular events; however, the existence of residual cardiovascular risk remains in many patients, particularly those with hypertriglyceridemia [14]. The results are in agreement with these reports and provide evidence that omega-3 fatty acids may be an additive therapy for this persistent lipid abnormality.

While omega-3 supplementation has been studied in high-risk patients through large cardiovascular outcome trials, there are limited data available from Indian tertiary care settings [15]. The current report adds to the region-specific evidence, which is especially applicable in people with atherogenic dyslipidaemia of high triglyceride and low HDL-C.

Strengths: The current study has several advantages. The prospective nature facilitated the structured follow-up and evaluation of treatment over time. Random allocation reduced the selection bias and provided comparability between groups. The study is performed in a real-world tertiary care hospital setting, which increases the generalizability of the results to everyday clinical practice, especially in comparable healthcare centres.

Limitations: This study has some limitations despite its strengths. The open-label nature may induce observer and performance bias, since investigators and patients were not blinded for the treatment allocation. The number of 100 patients is large enough to detect differences, and population-based conclusions cannot be taken from this analysis.

Follow-up duration was rather short (12 weeks), precluding analysis of long-term cardiovascular outcomes. The study was also conducted in a single center, thus its external generalizability may be constrained. The findings of the present study need to be investigated further in a larger, multicentric series with longer follow-up time to assess long-term clinical gains.

Conclusion

In conclusion, both atorvastatin monotherapy and atorvastatin plus omega-3 fatty acids therapy were effective in changing the lipid profile of subjects with dyslipidaemia. The combination therapy, however, had better efficacy in mainly lowering triglyceride levels and modestly improving HDL-C, but with a similar safety profile. These results suggest that combined use of omega-3 fatty acids with atorvastatin may be useful in patients with mixed dyslipidaemia or stubborn hypertriglyceridemia. Combining the regimen may be an acceptable practice, particularly for high-risk patients. However, larger many studies with longer follow-up are needed to demonstrate long-term cardiovascular benefits.

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