



RESEARCH ARTICLE

A Comparative Study between the Effect of Conventional Antilipidaemic Therapy with Statins and Hypolipidaemic Therapy with N - Acetyl Cysteine as Adjunct in Hyperlipidaemic Patients

Joseph Stalin D*

Assistant Professor, S. A. Raja Pharmacy College, Raja Nagar, Vadakangulam – 627116.

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ABSTRACT

This is a comparative study between the effect of conventional antilipidaemic therapy with statins and hypolipidaemic therapy with n - acetyl cysteine as adjunct in hyperlipidaemic patients. It was an open controlled randomized study. Totally 82 patients were enrolled for this study. All the patients enrolled for the study were divided in to two groups at random and categorized as Group 1 and Group 2. The baseline serum lipid profile was measured for all the 82 patients and documented on the patient data sheet. Then Group 1 was given atorvastatin 40 mg/day as they were already taking that along with drugs for diabetes and/or hypertension. Group 2 patients additionally received N – Acetylcysteine 600 mg/day orally. Both the groups of patients were monitored for compliance, and for ADRs and side effects. At the end of 6 months the lipid profile of the patients were measured again as the end point. Then the lipid profiles of Group 1 were compared with those of Group 2. The results showed that the reduction in serum total cholesterol, triglyceride, and LDL levels was significant in Group 2. There was no significant effect of therapy on serum LDL, VLDL, and HDL levels between the groups. The study gives a strong evidence for the effect of N – Acetylcysteine, when given as adjunct with conventional lipid lowering therapy, on serum total cholesterol and triglyceride levels in dyslipidaemic patients.

KEYWORDS

Atorvastatin, Cholesterol, N – Acetylcysteine, LDL, Lipid profile.

INTRODUCTION

N-acetyl cysteine (NAC) comes from its precursor amino acid L-cysteine. NAC reduces mucus and helps with breathing in various lung conditions. Also it prevents problems such as heart attack and stroke in people with serious kidney disease. NAC has the ability to prevent complications of chronic bronchitis¹.

In 2006, Rasha et al studied the modulatory effect of N-Acetyl cysteine supplementation on

hepatic glutathione concentration and lipid peroxidation status². In 2011, Panomvana et al studied the Pharmacodynamic Effect of N-Acetylcysteine as Adjunctive Therapy in Mild Systemic Lupus Erythematosus Patients³. In 2010, Alkisti et al conducted a Comparative study on the antilipidemic effect of N-acetylcysteine and sesame oil administration in diet-induced hypercholesterolemic mice⁴. In 2011, Oner et al studied the Clinical, endocrine and metabolic effects of metformin vs N-acteylcysteine in women with polycystic ovary syndrome⁵. In 2006, Caglikulekci et al studied the Effect of N-acetylcysteine on blood and tissue lipid peroxidation in lipopolysaccharide-

***Address for Correspondence:**

Joseph Stalin D

Assistant Professor,

S. A. Raja Pharmacy College, Raja Nagar,

Vadakangulam – 627116.

E-Mail Id: joseph25may@aol.com

induced obstructive jaundice⁶. Forouzan et al studied the Effects of N-acetyl cysteine on serum lipoprotein (a) and proteinuria in type 2 diabetic patients⁷.

The objectives of this study were

1. To find whether N – Acetylcysteine has the capacity to reduce serum lipid levels indyslipidaemic patients.
2. To compare the level of changes in the serum lipid levels between a group of hyperlipidaemic patients treated without N – Acetylcysteine (Group 1) and a group treated with N – Acetylcysteine (Group 2).

MATERIALS AND METHODS

Approval from the Ethics Committee and consent from the enrolled patients were obtained before the start of the study.

Design of Study: Randomized Controlled Study

Sample Size : 82 patients

Study Duration : 6 months (180 days)

No. of Groups : 2

Drugs Used:

Group 1 (41 patients): Atorvastatin 40 mg/day (Storvas 40 mg tablets)

Group 2 (41 patients): Atorvastatin 40 mg/day + N – Acetylcysteine (600 mg tablets)

Parameter Measured: Serum Lipid Profile

All the 82 patients enrolled for the study were divided in to two groups randomly. Group 1 and Group 2, 41 patients each. The patients were tested for all parameters of blood; also they were subjected to Ultrasound Scanning to ensure that the patients were not having any infectious diseases and other disorders like hypothyroidism, etc.

Then the baseline lipid profile was taken for all the 82 patients and documented. Then Group 1 was given Atorvastatin 40 mg/day as they were already taking that along with drugs for diabetes and/or hypertension. Group 2 patients additionally received N – Acetylcysteine 600 mg/day orally.

Both the groups of patients were monitored for compliance, and for ADRs and side effects. At the end of 6 months the lipid profile of the patients were taken again as the end point. Then the lipid profiles of Group 1 were compared with those of Group 2.

Statistical Tool

All the data were recorded in the Master Chart. The Data Analysis was done using GraphPad InStat 3. Mean, Standard Deviation, Student unpaired t-test and ‘p’ values were calculated for quantitative variables. The ‘p’ values were two-tailed and obtained by using the student’s unpaired t-test, with the standard deviations of each value to be different. The ‘p’ value less than 0.05 was considered to imply a significant relationship. The comparative charts were drawn using the mean of the values of different parameters.

RESULTS

Changes in Lipid Profile

Changes in Serum Total Cholesterol Level

Fig.1 and Table 1 imply that the mean change in serum total cholesterol levels in Group 1 was not significant and that of Group 2 was significant.

Table 1: Changes in Serum Total Cholesterol Level

Study Groups	Serum Total Cholesterol (mg/dL) [mean]		‘p’ value
	Base-line	End-point	
Group 1	267.2 ± 15.65	251.74 ± 15.64	0.1624
Group 2	287.67 ± 15.71	261.97 ± 15.68	0.0360

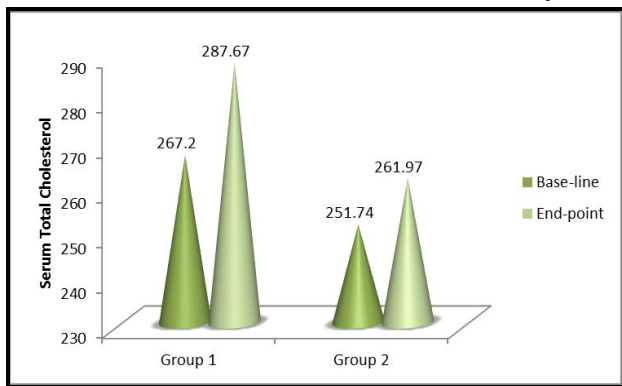


Figure 1: Statistical Representation of Changes in Serum Total Cholesterol Level

Changes in Serum LDL Level

There was decrease in serum LDL level in both Group 1 and 2. Fig.2 and Table 2 imply that the mean change in serum LDL levels in Group 1 and Group 2 were not significant.

Table 2: Changes in Serum LDL Level

Study Groups	Serum LDL (mg/dL) [mean]		'p' value
	Base-line	End-point	
Group 1	186.22 ± 19.77	177.9 ± 19.42	0.3556
Group 2	205.08 ± 9.91	193.34 ± 10.08	0.1057

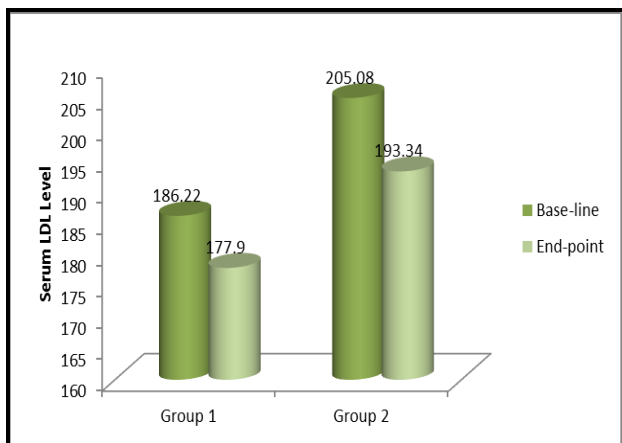


Figure 2: Statistical Representation of Changes in Serum LDL Level

Changes in Serum Triglyceride Level

Fig.3 and Table 3 imply that the mean change in serum triglyceride levels in Group 1 was not significant. But the same was significant in Group 2.

Table 3: Changes in Serum Triglyceride Level

Study Groups	Serum Triglycerides (mg/dL) [mean]		'p' value
	Base-line	End-point	
Group 1	248.6 ± 18.26	233.22 ± 18.39	0.1171
Group 2	265.08 ± 22.33	229.69 ± 21.04	0.0365

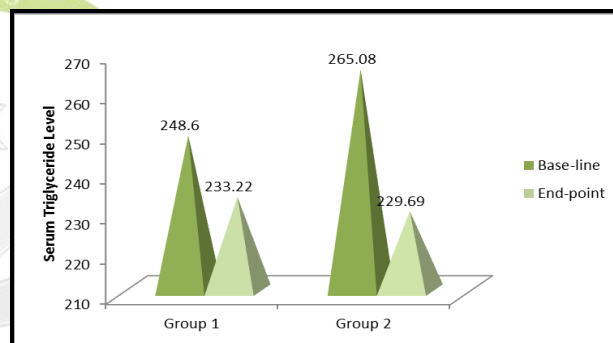


Figure 3: Statistical Representation of Changes in Serum Triglyceride Level

Changes in Serum HDL Level

Fig. 4 and Table 4 imply that the mean change in serum HDL levels in Group 1 and Group 2 were not significant.

Table 4: Changes in Serum HDL Level

Study Groups	Serum HDL (mg/dL) [mean]		'p' value
	Base-line	End-point	
Group 1	29.01 ± 1.52	30.15 ± 1.29	0.2392
Group 2	29.09 ± 1.61	31.01 ± 1.68	0.1077

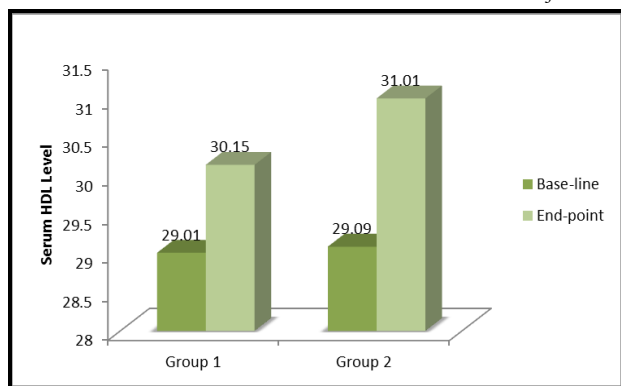


Figure 4: Statistical Representation of Changes in Serum HDL Level

Changes in Serum VLDL Level

VLDL levels decreased in both the groups. Fig.5 and Table 5 imply that the Mean change in serum VLDL levels in Group 1 and Group 2 were insignificant.

Table 5: Changes in Serum VLDL Level

Study Groups	Serum VLDL (mg/dL) [mean]		'p' value
	Base-line	End-point	
Group 1	72.87 ± 15.35	67.97 ± 15.31	0.6288
Group 2	81.37 ± 8.68	73.74 ± 8.69	0.2074

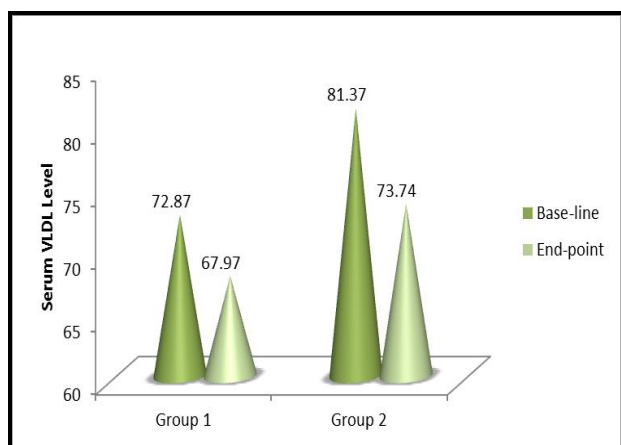


Figure 5: Statistical Representation of Changes in Serum VLDL Level

DISCUSSION

The study results show that the total cholesterol and triglyceride levels in Group 2 were statistically significant. But, there were no significant changes in other lipid parameters in either Group 1 or Group 2. Hence it is clear that N-Acetylcysteine possesses the power to reduce serum total cholesterol and triglyceride levels, but ineffective in reducing LDL and VLDL, and raising HDL levels. Further studies on higher doses of Green Tea Extract are to be done in different cardiac conditions to get the most of it.

CONCLUSION

All the results of the study clearly indicate that N-Acetyl cysteine when given in combination with Atorvastatin lowers serum total cholesterol and triglyceride levels in hyperlipidaemic patients.

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