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Original Article

Effect of Statin Monotherapy versus Combination Therapy with Statin and Omega-3 Fatty Acid on Dyslipidaemia among Type 2 Diabetes Patients: A Comparative Study

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ABSTRACT

Background: Dyslipidemia among diabetes mellitus patients is an independent modifiable risk factor for various macrovascular complications accounting for 10-73% . Omega 3 fatty acids were found to reduce triglycerides and increase HDL cholesterol. Statins when combined with Omega 3 fatty acids form more aggressive treatment for dyslipidemia than statin monotherapy in reducing deaths due to coronary artery disease.
Aim: To compare the effects of statin monotherapy versus combination therapy with statin and omega-3 fatty acids on lipid parameters among Type 2 diabetes patients with dyslipidaemia.
Methods: In a prospective, interventional, hospital-based study. 105 adults were screened for dyslipidaemia from 07/08/2022 to 06/10/2022. Eligible participants were randomised to atorvastatin 10 mg daily monotherapy or atorvastatin 10 mg plus omega-3 fatty acids 1 g daily combination for 6 weeks. Fasting lipid profiles were measured at baseline and 6 weeks. At the end of 6weeks, lipid profile were repeated in both the groups. Comparison of lipid parameters were done to determine the effects of monotherapy and combination therapy. Analyses used standard parametric tests SPSS v21.
Results: The prevalence of dyslipidemia was found to be 64.8% of 105 study population. The mean difference values of total cholesterol, triglycerides and low-density lipoprotein showed marked decrease in the study subjects who received Atorvastatin and omega 3 fatty acid than those who received Atorvastatin alone and the mean difference was statistically significant. HDL levels increased more in subjects who received Atorvastatin monotherapy than in combination therapy and the mean difference was statistically significant.
Conclusion: In dyslipidaemic adults with Type 2 diabetes, adding omega-3 fatty acids to atorvastatin yields superior reductions in atherogenic lipids, while HDL gains favoured statin alone. Findings support combined therapy when triglyceride lowering is a priority.

Keywords*: dyslipidaemia; Type 2 diabetes; statins; omega-3 fatty acids; triglycerides; HDL.*

1. Introduction

Type 2 diabetes mellitus (T2DM) confers elevated Type 2 Diabetes is a non-communicable disease of major concern in both developed and developing countries. Diabetes mellitus is a heterogenous group of disorders characterized by hyperglycemia which may be due to defective insulin secretion, resistant insulin action or both. Diabetic patients have increased risk of atherogenesis which is due to abnormalities in lipoprotein metabolism leading to plaque formation [1] . These atherogenic plaques occlude the vasculature leading to cardiovascular and cerebrovascular events. India is an epicentre for global diabetes epidemic harbouring around 69 million diabetics in 2015 and stands as the second highest in the world diabetic population[2]

Dyslipidaemia among diabetes mellitus patients is an independent modifiable risk factor for various macrovascular complications accounting for 10- 73%[3,4,5,6,7]. Dyslipidaemia refers to increase in total cholesterol, triglycerides, Low Density Lipoprotein (LDL) and decrease in High Density Lipoprotein (HDL). Dyslipidaemia may be ascertained to overproduction of lipoproteins or disorders with the clearance of these lipoproteins.[8] Increased levels of LDL surge the process of atherogenesis by rapid infiltration of LDL into the arterial wall, increased retention in the extracellular matrix9 and increased oxidation.[10] Dyslipidemia can be primary (familial) or secondary (due to a certain cause). Physical inactivity, diet rich in saturated fats, increased intraabdominal fat are the major determinants of dyslipidemia. The National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults as given by Adult Treatment Panel III (ATP III) suggested HMG CoA reductase inhibitors i.e., Statins for lowering of LDL cholesterol and reduction of triglycerides to an extent. Omega 3 fatty acids were found to reduce triglycerides to a larger extent in addition to increasing the levels of HDL cholesterol.[8] Statins when combined with Omega 3 fatty acids form more aggressive treatment for dyslipidemia than statin monotherapy in reducing deaths due to coronary artery disease.[11,12]

A few studies were conducted pertaining to the current topic in some parts of India. However, there is paucity of information on the level of reduction in lipid profile parameters with statins and omega 3 fatty acid in the selected area of study. Hence, the present study has been taken up to compare the effect of statin monotherapy and combination therapy with statin and omega 3 fatty acid on dyslipidemia in type 2 diabetes patients.

2. Methodology

1.1. Study Design and Setting

Prospective interventional, hospital-based study conducted in a tertiary-care centre, Guntur Andhra Pradesh, from 07/08/2022 to 06/10/2022. Ethical approval was obtained; written informed consent was secured.

1.2. Participants

Adults (30–70 years) with Type 2 diabetes with dyslipidemia. **Exclusions:** pregnancy/lactation, current lipid-lowering therapy, bedridden/critically ill.

1.3. Sample Size and Randomisation

Sample size of 105 was taken Considering the prevalence of Type 2 diabetes patients with dyslipidemia as 61.0% based on a previous study at Guntur, the sample size for the present study is estimated by the formula=4PQ/d2 where P is the prevalence i.e., 61, Q = 100-P = 31.d is the absolute error taken as 10% Substituting the values in the formula, N = 95.16. Adding 10% of loss to follow up, adjusted sample size rounded to 105.Patients were selected by using simple random selection. All the 105 Diabetic patients were screened for Dyslipidemia using lipid profile test. Patients with dyslipidemia were consecutively allocated into each group (first patient into group A and second patient into group B and so on)

- **Group A (Combination):** Atorvastatin 10 mg + omega-3 fatty acids 1 g capsule contain- ing eicosapentaenoic acid and docosahexaenoic acid daily for 6 weeks.
- **Group B (Monotherapy):** Atorvastatin 10 mg daily for 6 weeks.

1.4. Outcomes and Measurements

Fasting lipid profile at baseline and 6 weeks: TC, TG, LDL, HDL (mg/dL). Primary outcome: mean change within groups; secondary: between-group differences.

1.5. Statistical Analysis

Continuous variables summarised as mean ± SD; within-group comparisons via paired tests; between-group via independent t-tests. Significance at P = 0.05. Analyses performed using SPSS v21.

3. Results

- **General information of study subjects**

Most of the study subjects (34.3%) belong to the age group of 51-60 years followed by 61-70years (26.6%).

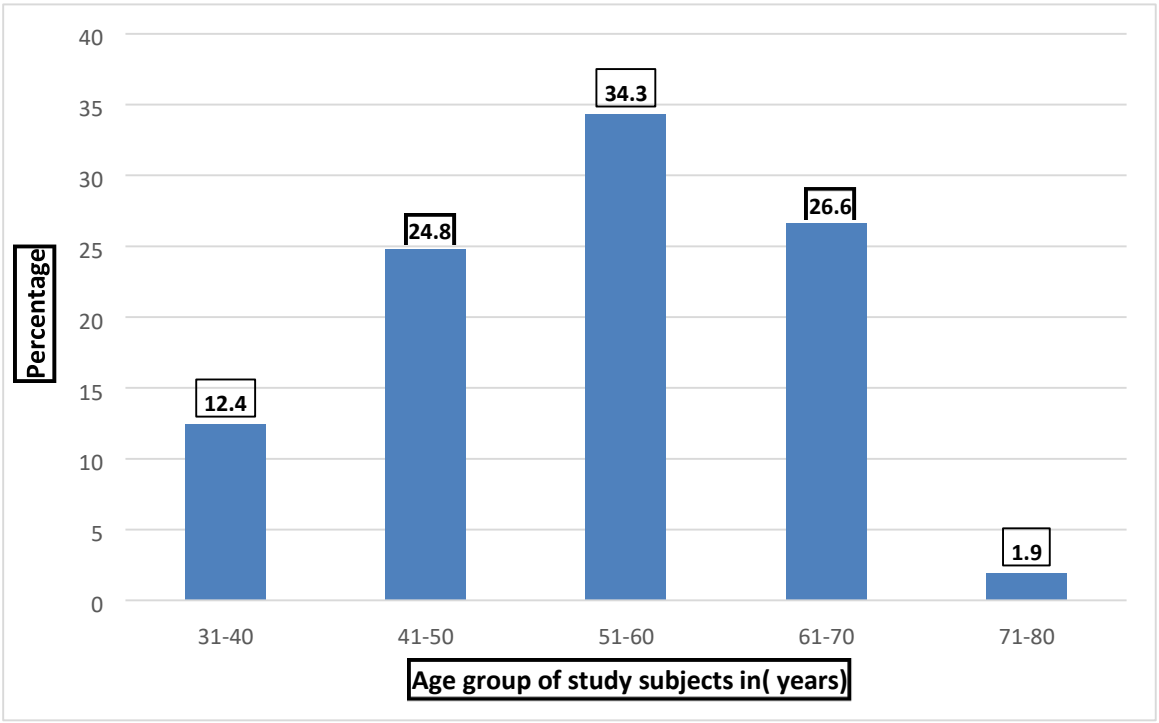

Figure 1: Figure showing the distribution of the study subjects according to their age group

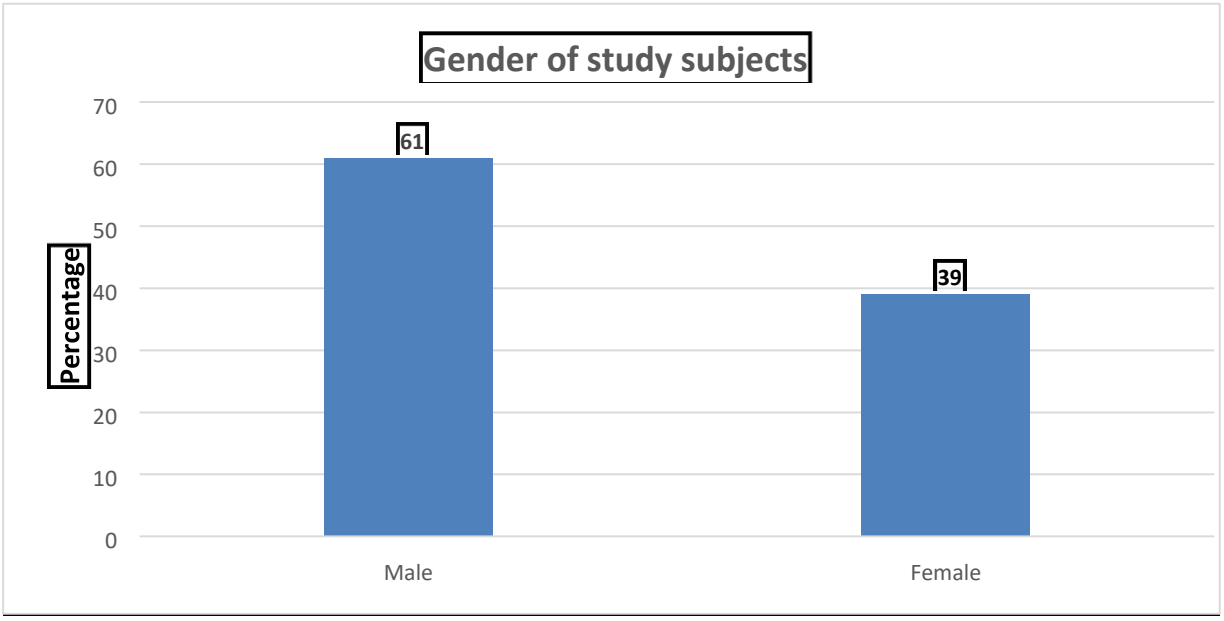

Figure 2: Figure showing the distribution of the study subjects based on gender

- **Prevalence of dyslipidemia**

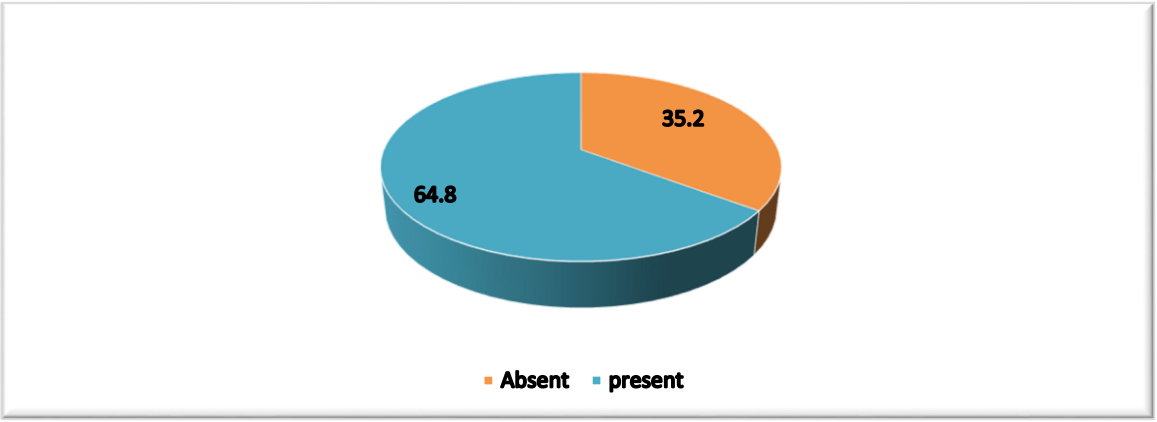

Figure 3: Figure showing prevalence of dyslipidaemia among the study subjects (N = 105)

Table 1: Prevalence of Dyslipidemia among the Study Subjects (N = 105)

Dyslipidemia	Number	Percentage
Present	68	64.8%
Absent	37	35.2%
Total	**105**	**100.0%**

Among the study subjects,64.8% were found to have dyslipidaemia whereas 35.2% of them had lipid parameters within normal limits

- **MEAN DIFFERENCE IN LIPID PARAMETERS**

Table 2: Difference in mean lipid parameters after combination therapy with Atorvastatin and Omega 3 Fatty Acid (Group A) N=34

Parameter	Mean change (mg/dL)
Total Cholesterol	−20.74 ± 7.38
Triglycerides	−24.15 ± 13.39
LDL	−17.47 ± 9.64
HDL	+4.74±2.35

After intervention with combination therapy for 6 weeks, the mean decrease in triglycerides was found to be higher as compared to total cholesterol and LDL levels

Table 3: Difference in mean lipid parameters after monotherapy with Atorvastatin for 6weeks (Group B) (N= 34)

Parameter	Mean change (mg/dL)
Total Cholesterol	−15.18 ± 8.34
Triglycerides	−17.03 ± 8.83
LDL	−10.79 ± 4.68
HDL	+6.44 ± 2.72

After intervention with monotherapy for 6 weeks, the mean decrease in triglycerides was found to be higher as compared to total cholesterol and LDL levels. Improvement in in HDL levels was observed to be more in monotherapy than in combination therapy.

- **Between-Group Comparison**

Table 4: Improvement in lipid parameters after six weeks of combination therapy with Atorvastatin And omega 3 fatty acids (N=34)

Parameter	A (mg/dL)	B (mg/dL)	t-test	(p) value
Total Cholesterol	−20.74 ± 7.38	−15.18 ± 8.34	t = 2.90, p < 0.005	
Triglycerides	−24.15 ± 13.39	−17.03 ± 8.83	t = 2.58, p < 0.012	
LDL	−17.47 ± 9.64	−10.79 ± 4.68	t = 3.63, p < 0.001	
HDL	+4.74 ± 2.35	+6.44 ± 2.72	t = −2.76, p < 0.007	

Overall, it was found that the mean total cholesterol level has decreased by 20.74 mg/dl (from 183.59 to 162.85), mean triglyceride level decreased by 24.15 mg/dl (from 211.09 to 186.94), mean LDL decreased by 17.47 mg/dl (from 105.59 to 88.12) and mean HDL increased by -4.74 mg/dl (from 39.50 to 44.24) after daily treatment with Atorvastatin and Omega 3 Fatty acid for 6 weeks. It has been observed that the difference in means of all the lipid parameters is statistically significant.

Table 5: Improvement in lipid parameters after six weeks of monotherapy with Atorvastatin (N=34)

Lipid parameter	Mean ± SD Baseline (mg/dl)	Mean ± SD After 6 weeks of Atorvastatin (mg/dl)	Overall improvement in Mean (mg/dl)	t test	Statistical significance (P)
Total Cholesterol	183.79 ± 39.79	168.62 ± 33.77	15.18 ± 8.34	10.60	< **0.001**
Triglycerides	212.32 ± 123.28	195.29 ± 117.71	17.03 ± 8.83	11.24	< **0.001**
Low Density Lipoprotein	103.09 ± 35.25	92.29 ± 33.57	10.79 ± 4.68	13.42	< **0.001**
High Density Lipoprotein	37.38 ± 8.10	43.82 ± 7.73	-6.44 ± 2.72	-13.80	< **0.001**

Overall, it was found that the mean Total cholesterol level has decreased by 15.18 mg/dl (from 183.79 to 168.62), mean Triglyceride level decreased by 17.03 mg/dl (from 212.32 to 195.29), mean LDL decreased by 10.79 mg/dl (from 103.09 to 92.29) and mean HDL increased by -6.44 mg/dl (from 37.38 to 43.82) after daily treatment with Atorvastatin monotherapy for 6weeks. It has been observed that the difference in means of all the lipid parameters is statistically significant

Table 6: **Effect of combination therapy (Atorvastatin and Omega 3 fatty acid) (Group A) and monotherapy (Atorvastatin) (Group B) on dyslipidemia: (N = 68) Comparision of improvement of Mean lipid levels in Group A and Group B**

Lipid parameter	Mean difference in Group A	Mean difference in Group B	t test	Statistical significance (P)
Total Cholesterol	20.74 ± 7.38	15.18 ± 8.34	2.90	< **0.005**
Triglycerides	24.15 ± 13.39	17.03 ± 8.83	2.58	< **0.012**
Low Density Lipoprotein	17.47 ± 9.64	10.79 ± 4.68	3.63	< **0.001**
High Density Lipoprotein	-4.74 ± 2.35	-6.44 ± 2.72	-2.76	< **0.007**

Independent t test revealed that the mean difference values of total cholesterol, triglycerides and low density lipoprotein showed marked decrease in the study subjects who received Atorvastatin and omega 3 fatty acid than those who received Atorvastatin alone and the mean difference was statistically significant. HDL levels increased more among the study subjects who received Atorvastatin monotherapy than in combination therapy and the mean difference was statistically significant.

1. Discussion

a. Prevalence of Dyslipidemia

In the present study, prevalence of dyslipidemia was observed to be 64.8%. Among the study subjects with dyslipidemia, 21.0% had elevated Total Cholesterol (TC), 37.1% had elevated Triglycerides (TG), 19.0% had elevated Low Density Lipoprotein (LDL) and 36.2% had low levels of High Density Lipoprotein (HDL). The prevalence of high TC, TG and low HDL were found in males and high LDL was observed in females. Prevalence of hypercholesterolemia was observed to be higher (31.8%) in elderly age group (61-70 years) which may be due to atherogenesis. Hypertriglyceridemia was higher (30.8%) in 41-50 years age group which can be attributed to insulin resistance or higher levels of unmanaged stress which can trigger the production of triglyceride levels in the blood. LDL levels were higher (40.0%) among individuals in the age group of 51-60 years which may be due to sedentary lifestyle and increased intake of processed foods. Low HDL (31.6%) was found in 51-60 years which may be due to insufficient dietary intake of unsaturated fats.

M Estari et al in a study conducted at Warangal stated that the prevalence of dyslipidemia was observed to be higher in males (52.7%) than in females (42.9%). Among males, hypercholesterolemia was more in elderly age group (40.5%) followed by those individuals in the age group of 40-59 years (38.4%). The prevalence in younger age group (20 39 years) was observed to be 14.8%. Hypertriglyceridemia was found to be higher among middle age group (45.1%). Low levels of HDL were observed in middle aged males (7.7%) than in females (1.5%) of same age group. Among females, hypercholesterolemia, hypertriglyceridemia was seen in elderly population (62%) followed by those in middle aged group (46.5%).[21]

In a study by AM Sawant, Dhanashri Shetty, et al, a total of 1805 subjects were taken up for the study. Out of the total study subjects, 1128 were males and 677 were females. It was observed that individuals between 31-40 years of age had significant increase or decrease in lipid parameters. Among them, 77.6% had raised LDL, 65.7% had decreased levels of HDL, 42.6% had hypertriglyceridemia and 42.6%. had hypercholesterolemia.[13] The results of our study showed higher prevalence of triglyceridemia in most of the patients (37.1%) followed by low levels of HDL (36.2%). This discrepancy may be due to variation in the sample size and different geographical locations suggestive of not only varied dietary habits but also lifestyle.

b. **Comparison of statin monotherapy with statin and omega 3 fatty acid combination therapy on dyslipidemia**:

In the present study, combination therapy with statin (atorvastatin) and omega 3 fatty acid (Group A) had shown a remarkable decrease in the lipid levels compared with statin therapy alone. In the study subjects who had received combination therapy, the mean decrease in total cholesterol, triglycerides, low density lipoprotein was 20.74 ± 7.38, 24.15 ±
13.39, 17.47 ± 9.64 respectively and the mean increase in high density lipoprotein was 4.74
± 2.35 and the mean improvement of lipid levels was found to be statistically significant (p
< 0.001). In the study subjects who received atorvastatin alone (Group B), it was observed that the mean decrease in total cholesterol, triglycerides, low density lipoprotein was 15.18 ± 8.34, 17.03 ±
8.83, 10.79 ± 4.68 and the mean increase in high density lipoprotein was 6.44 ± 2.72 and the difference in means was found to be statistically significant (p ¡ 0.001). The mean difference was higher in triglycerides levels and among those who received combination therapy as compared to monotherapy. This can be attributed to impaired synthesis of triglycerides due to decreased enzymatic activity involved in triglyceride synthesis and reduction in hepatic fatty acid synthesis by intake of omega 3 fatty acids.[22] Mean LDL decrease was almost equal in both the groups. Independent t test revealed that the difference in means of the lipid parameters were found to be higher in Group A as compared to Group B and the difference was found to be statistically significant.

In a study by Myung Won Lee et al conducted a study on patients with persistent dyslipidemia despite of treatment with statin for 6 months who were assigned into 3 groups. Group 1 included those who received 4 g omega 3 fatty acid and statin, Group 2 received 2 g omega 3 fatty acid and statin, Group 3 received statin alone for 8 weeks. After the treatment, it was observed that the decrease in TC, TG and LDL was higher in those who received 4g of omega 3 fatty acid and statin combination with a mean change of (-16.8, -124.0,-8.7),compared to statin alone (- 11.6, -77.4, -5.63). Increase in HDL was greater in those who received 2g of omega 3 and statin combination (+3.9) than with 4g of omega 3 and statin combination (+0.15) and statin alone. There was statistically significant decrease in triglyceride levels among those who received 4 g of omega 3 fatty acid and statin.[15].

In a study by Ji Eun Jun et al, a group received combination therapy with 1000mg of omega 3 fatty acid, 5 mg of atorvastatin and calcium whereas another group received Atorvastatin monotherapy. In consistent with the results of the present study, Ji Eun Jun et al reported that there was reduction in TG, Non-HDL, TC and increase in HDL levels in the combination therapy group and the difference was significant. In statin monotherapy group, there was no significant change in TG, Non-HDL and TC. It was also observed that there was no significant change in LDL and HDL levels in both the groups[16].

Maki KC et al stated that combination therapy with simvastatin and 4g of omega 3 fatty acid and monotherapy with 20mg of simvastatin for 6 weeks resulted in significantly larger decrease in TC, TG, non-HDL, VLDL, and the percentage change

was- 31alone (-26%, 29%, -34%, 22%) respectively. Similar to the findings of the present study, the percentage change was higher in triglycerides than other lipid parameters. The increase in HDL levels was found to be higher with omega 3 and simvastatin combination as compared to simvastatin alone and the increase was not significant[23]

Similar findings were observed in a study by Bays HE et al on coadministration of omega 3 fatty acid with atorvastatin, it was observed that there was significant decrease in TG and VLDL with not only omega 3 fatty acid and atorvastatin combination but also with atorvastatin monotherapy. It was also reported that there was significantly greater decrease in TG and VLDL on combination therapy[24].

In a study by Jong Shin Woo et al, it was stated that combination therapy of atorvastatin (40mg) and omega 3 fatty acid (4g) was given in dyslipidemic patients for a period of 8 weeks. On comparision, significant decrease was observed in TG and VLDL levels among those who received combination group than in monotherapy (-18.5%, 14.1% versus +10.9%,+15.8%).

It was also found that there was decrease in TC and LDL in both the groups but the result was not significant.[14]
In a study by Nordoy A et al, 4g of omega 3 fatty acid along with 20 mg of simvastatin was given to 22 members and 20mg simvastatin monotherapy was given to 20 members. In line with the findings of the present study , they observed that there was decrease in the levels of cholesterol, triglycerides and VLDL in both the groups and the reduction of TG was statistically significant (p¡0.007) . However, the reduction in TC was of borderline significance (p=0.052). It was also reported that levels of HDL remained unaffected in both the groups.[25]

2. Conclusion

It has been observed that both combination therapy and monotherapy showed significant de- crease in total cholesterol, triglycerides and low density lipoprotein levels. However, the combination therapy with omega 3 fatty acids and atorvastatin showed better therapeutic results in improving dyslipidemia than atorvastatin monotherapy in Type 2 Diabetic study subjects. The increase in HDL levels showed better results by statin monotherapy than combination therapy. Omega 3 fatty acid when combined with atorvastatin was effective in reducing the concentration of triglycerides when compared to other lipid parameters. The present study was emphasized on the effect of omega 3 fatty acid and statin on dyslipidemia but the influence of dietary habits, body mass index were not considered. Hence further research can be made in this area. Concomitant use of Atorvastatin and omega 3 fatty acid had significantly improved the lipid profile and can be recommended for the treatment of dyslipidemia thereby preventing atherosclerosis, coronary artery diseases and stroke which are the sequelae of deranged lipid parameters.

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