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EFFECT OF ADD ON THERAPY WITH OMEGA 3 FATTY ACIDS AMONG DIABETIC AND NON-DIABETIC DYSLIPIDEMIC PATIENTS ON RANDOM BLOOD GLUCOSE- A COMPARATIVE, RANDOMISED, OPEN LABEL, PROSPECTIVE STUDY

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Keywords:

Dyslipidemia, Diabetes, Omega 3 Fatty acids, Random blood glucose, RBS

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ABSTRACT: Background: Diabetes is one of the leading non communicable disease-causing various health complications like Cerebrovascular accidents, micro and macrovascular complications. In Indian population, very few comparison studies have been conducted to evaluate the glucose lowering effect of omega 3 fatty acid between diabetic and non- diabetic dyslipidemic patients. Hence the present study was planned to compare the efficacy of omega 3 fatty acid among diabetic and non-diabetic dyslipemic individuals. **Materials And Methods:** This study is a comparative, randomized, open-label, prospective interventional study which compared the efficacy of omega 3 fatty acids as add on therapy among diabetic and non-diabetic Dyslipidemic patients.50 Patients of 25 each of diabetic dyslipidemia and non-diabetic dyslipidemia attending the out-patient department of Internal Medicine, Rajiv Gandhi Government General Hospital, Chennai were given 1 gram of omega 3 fatty acid- fish oil capsule per day once daily to take orally for 8 weeks and monitored for random blood glucose at baseline (0 weeks), after 4 weeks and after 8 weeks of treatment. **Results:** At 4 weeks and 8 weeks post intervention, RBS levels have drastically decreased in patients with diabetic dyslipidemia. (Group A)with P value of 0.0001 and 0.0001 respectively which are extremely statistically significant. **Conclusion:** Omega 3 fatty acids can be safely employed for use in Diabetes with Dyslipidemia.

INTRODUCTION: Diabetes is one of the leading non communicable disease. Dyslipidemia is a major risk factor for macrovascular complications in patients with type-2 diabetes mellitus and affects 10%-73% of this population. Approximately, 80% of deaths in patients with DM Type- 2 are attributable to cardiovascular disease (CVD).

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Asian Indians have higher risk of coronary artery disease than whites. According to the World Health Organization (WHO) estimates, the prevalence of dyslipidemia in the Southeast Asia is 30.3%, the Western Pacific is 36.7%, Europe, 53.7% and America, 47.7% [1].

Dyslipidemia is one of the major causes of atherosclerotic cardiovascular diseases, such as coronary artery disease, ischemic cerebrovascular disease, and peripheral vascular disease. Dyslipidemia involves an imbalance of cholesterol levels, including low-density lipoprotein cholesterol and high-density lipoprotein cholesterol

in the blood [2]. Major risk factors for dyslipidaemias are advanced age, white race, genetic factors, unhealthy lifestyle, pre-existing diabetes and hypertension *etc*.

A family history of premature ischemic heart disease is an important indicator of risk and should instigate a search for treatable risk factors such as hyperlipidemia, hypertension, and diabetes mellitus. Obesity blunts the treatment of other risk factors and increases the risk of coronary events. In addition, obesity often is accompanied by diabetes mellitus, hypertension, metabolic syndrome and dyslipidemia. Foremost is the treatment of obesity and its accompanying risk factors which forms an important component of any management plan which is affected by a diet low in saturated and trans-unsaturated fatty acids and a reduced caloric intake to achieve optimal body weight, a cornerstone in the management of chronic IHD. Weight loss and regular exercise in patients with the metabolic syndrome or overt diabetes mellitus.

Diabetes Mellitus accelerates coronary and peripheral atherosclerosis and is often associated with dyslipidemias and carries high mortality rates. Aggressive control of LDL fixing the target LDL cholesterol <70 mg/dL and control of hypertension coexistent in diabetic patients maintaining target blood pressure as120/80 mmHg, that are frequently found in diabetic patients is highly effective [3]. The patient with diabetes should be educated about nutrition, exercise, lifestyle modification and medications aimed at lowering the plasma glucose (American Diabetes Association, 2017) [4].

Insulin is the mainstay for treatment of virtually all patients with type 1and many with type 2 diabetes [5]. A variety of sulfonylureas, meglitinides, GLP-1 agonists, and inhibitors of

DPP-4 are used as secretagogues to stimulate insulin release [6]. Metformin is the only member of the biguanide class of oral hypoglycemicdrugs available for use today [7].

Omega 3 fatty acids namely alpha linolinic acid (ALA), docosahexanoic acid (DHA) and eicosapentanoic acid (EPA)are rich in foods like Fish and other seafood (especially cold-water fatty fish, such as salmon, mackerel, tuna, herring, and sardines), Nuts and seeds (such as flaxseed, chia seeds, and walnuts), Plant oils (such as flaxseed oil, soybean oil, and canola oil), Fortified foods (such as certain brands of eggs, yogurt, juices, milk, soy beverages, infant formulas)

Omega 3 fatty acids exert antiatherosclerotic effect by promoting intracellular catabolism of apolipoprotein B-100 containing lipoproteins, suppressing hepatic apoB production, stimulating plasma triglyceride clearance via lipoprotein lipase (LPL), increasing the VLDL to LDL conversion rate, reducing LDL synthesis and attenuating postprandial lipemia [8]. Omega 3 fatty acids greatly reduce triglycerides in diabetic dyslipidemia and familial hypertriglyceridemia.

A number of well designed randomized clinical trials on Omega 3 fatty acids found that it significantly reduced lipid levels in patients with diabetes with dyslipidaemia. In addition, studies have demonstrated that omega 3 fatty acids also possess anti oxidant and anti inflammatory properties.

In Indian population very few comparison studies had been conducted to evaluate the glucose lowering effect of omega 3 fatty acid between diabetic and non- diabetic dyslipidemic patients. Hence the present study was planned to compare the efficacy of omega 3 fatty acid among diabetic and nondiabetic dyslipidemic individuals.

Objectives:

Primary Objective: To analyse the efficacy of omega 3 fatty acids as add on therapy among diabetic and non- diabetic dyslipidemic patients by assessing Random Blood Glucose.

Secondary Objective: To draw a comparison of the efficacy of omega 3 fatty acids among diabetic and nondiabetic dyslipidemic patients.

Study Methodology:

Study Design: This study was a comparative, randomised, open-label, prospective interventional study between patients of diabetic dyslipidemia and non- diabetic dyslipidemia**.**

Study Centre: Institute of Internal Medicine, Rajiv Gandhi Government General Hospital, Chennai.

Study Period: April 2019-March 2020.

Study Duration: 8 weeks for each subject.

Study Sample: 50 Patients- 25 patients of diabetic dyslipidemia and 25 patients of non-diabetic dyslipidemia.

Study Population: Patients of diabetic dyslipidemia and non-diabetic dyslipidemia attending the out-patient department of Internal Medicine, Rajiv Gandhi Government General Hospital, Chennai.

Eligibility Criteria:
Inclusion Criteria:

- Age: 40-65 years
- Sex: Both male and female
- Patients of Type 2 Diabetic Dyslipidemia on anti-diabetic and hypolipidemic drugs for more than 3 months.
- Patients of non- diabetic dyslipidemia.
- Patients willing to give informed consent to participate in this study.

Exclusion Criteria:

- Patients with sea-food allergy
- Patients with bleeding disorders, liver diseases.
- Patients on anti-coagulants, oral contraceptive pills and immunosuppressants.
- Patients who were not willing to give consent to participate in the study.
- Patients who were enrolled in another trial.

Study Procedure: The study was commenced after obtaining approval from the Institutional Ethics Committee, Madras Medical College. Patients with diabetic dyslipidemia and nondiabetic dyslipidemia attending the outpatient and inpatient department of Internal Medicine were explained about the study purpose and procedure in their regional language and informed consent from willing patients were obtained in the prescribed format. Demographic details of the patients were obtained. They were screened by history, general examination and baseline investigations. Patients who fulfilled the inclusion criteria were randomised and enrolled in the study. Participants of the study were given 1 gram of omega 3 fatty acid- fish oil capsule per day once daily to take orally for 8 weeks.

Screening: The patients were screened with detailed clinical history, physical examination and baseline investigations.

Recruitment: Those who fulfilled the inclusion criteria were recruited for the study.

Randomization: The enrolled patients were randomized either group by simple randomization.

Treatment Plan:
Group A: (Diabetic Dyslipidemia Patients): 1 gram of Omega 3 fatty acid capsule once daily after food for 8 weeks as add on therapy to antidiabetic and hypolipidemic drugs

Group B: (Non-Diabetic Dyslipidemia Patients): 1 gram of Omega 3 fatty acid capsule once daily after food for 8 weeks as add on therapy to hypolipidemic drugs with or without treatment to diseases other than diabetes.

Investigations and Follow Up: Random blood glucose was done at baseline (0 weeks), after 4 weeks and after 8 weeks of treatment.

Instruction to Patients: The patients were instructed clearly to regularly take the medicines, to report any adverse and to collect their drugs soon after completion of the capsule.

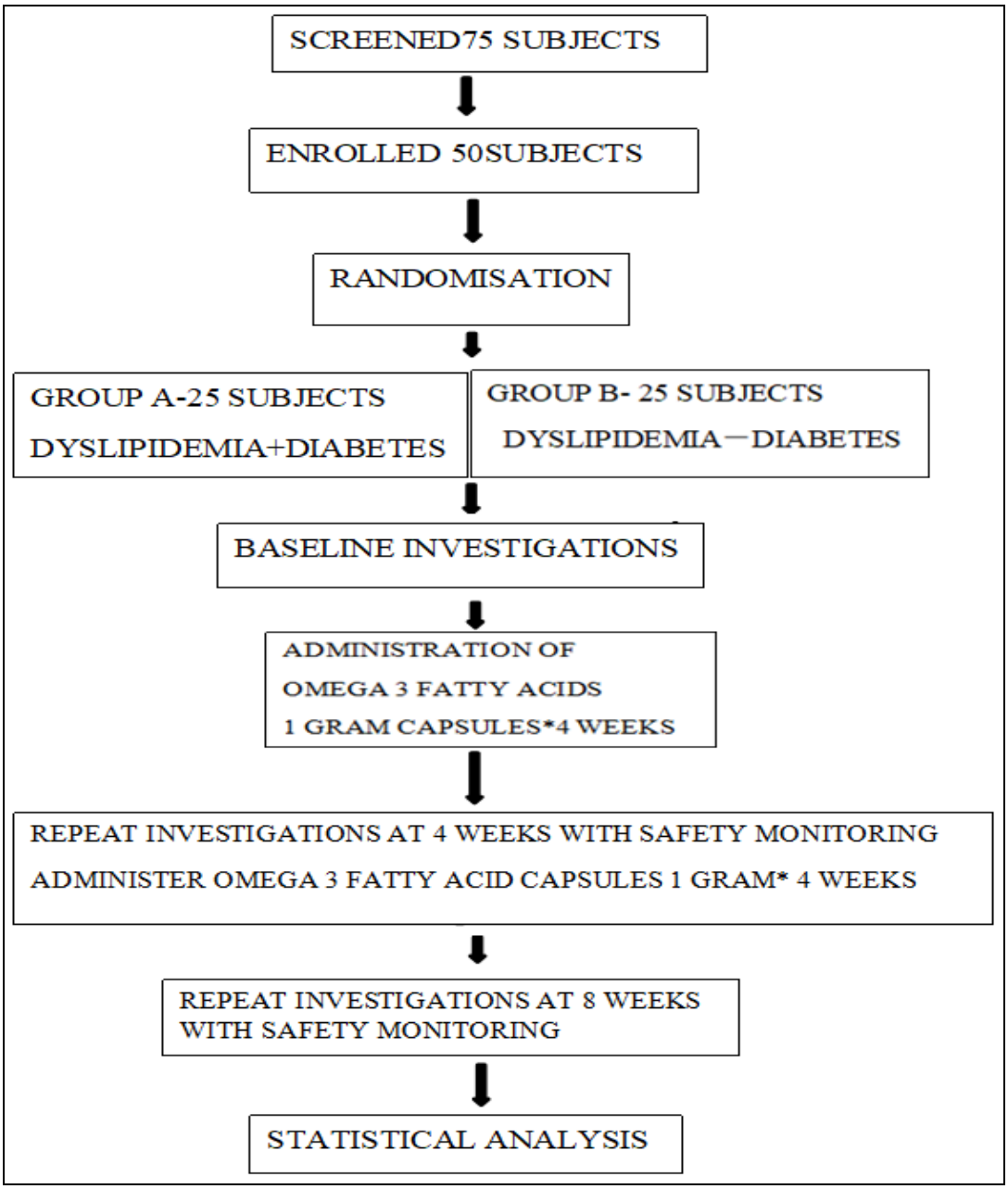
Compliance: Patient compliance was monitored by the empty drug bottles returned at each visit.

Adverse Events: Adverse event if any, reported by the patient or observed on clinical or laboratory investigations were recorded and necessary action was taken.

Statistical Analysis: The data obtained was subjected to statistical analysis. Age distribution was analyzed using ANOVA. Sex distribution was analyzed by Chi square test. The data from biochemical investigations which were performed at 0^{th}, 4^{th} and 8^{th} week were analysed using Student‘t’ test. The difference within the groups before and after treatment was analyzed using student’s paired t-test whereas the difference

between group A and group B were analyzed using students unpaired t-test. The probability 'p' value < 0.05 is considered to be statistically significant.

Study Flowchart:



RESULTS:

TABLE 1 AGE DISTRIBUTION:

Age (In Years)	Group A (Diabetic and Dyslipidemic Patients)		Group B (Nondiabetic and Dyslipidemic Patients)	
	Number	Percentage	Number	Percentage
40-49	11	44	8	32
50-59	7	28	4	16
60-65	7	28	13	52
Total	25	100	25	100

Table 1 shows the age distribution of Group A and Group B. Age group 60- 65years had more number of patients followed by age group 40- 49 years.

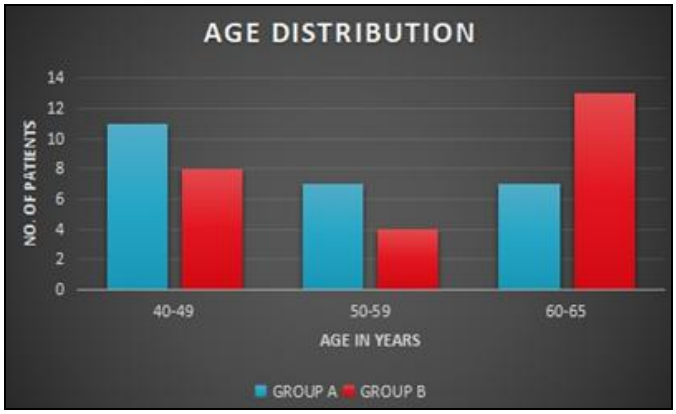


FIG. 1: AGE DISTRIBUTION. Fig. 1 is the graphical representation of **Table 1** in the form of clustered column chart.

TABLE 2: MEAN AGE DISTRIBUTION

Group	No of Patients	Mean Age in Years	SD
Group A	25	56.84	9.69
Group B	25	51.76	9.70
P Value		0.07	

Table 2 shows the mean age of both the study groups. The mean age was 56.84 in group A and 51.76 in group B. There was no statistical significance between the two groups.

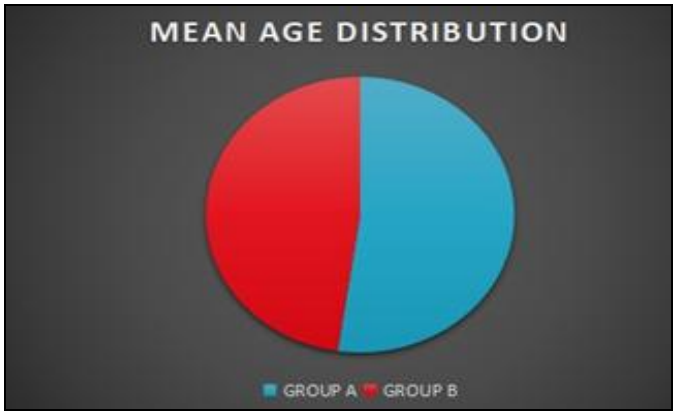


FIG. 2: MEAN AGE DISTRIBUTION Fig. 2 depicts graphical representation of **Table 2** in the form of pie chart.

TABLE 3: SEX DISTRIBUTION

Groups	Group A (Diabetic Dyslipidemia)		Group B (Non Diabetic Dyslipidemia)	
	Number	Percentage	Number	Percentage
Male	12	48	11	44
Female	13	54	14	56
Total	25	100	25	100

Table 3 shows the sex distribution in both the groups. Males were more in number compared to females in both groups.

FIG. 3: SEX DISTRIBUTION. Fig. 3 depicts graphical representation of **Table 3** in the form of clustered column char.

TABLE 4: RBS (PRE AND POSTINTERVENTION 4 WEEKS, 8 WEEKS)

RBS	Group A		Group B	
	Baseline	4 Weeks	Baseline	8 Weeks
Mean	183.48	162.76	183.48	156.54
SD	90.3	71.29	90.3	67.63
P Value	0.32		0.2	
Mean Difference/Confidence Interval	20.72 (From -21.37 to 62.81)		26.94 (From-13.98 to 67.86)	

Table 4 shows the results of comparison of the data on RBS at baseline and at 4 weeks and at 8 weeks.

Even though there is a mild decrease in the mean, the p value between baseline and 4 weeks post intervention is 0.32 which says that the difference in the reduction of RBS is not statistically significant.

Though there is a mild decrease in the mean, the p value between baseline and 8 weeks post intervention is 0.2 which also is not statistically significant.

FIG. 4: RBS-PRE AND POST INTERVENTION. Figure depicts graphical representation of **Table 4** in the form of a column chart.

TABLE 5: (RBS): POST INTERVENTION BETWEEN TWO GROUPS

RBS	4 Weeks		8 Weeks	
	Group A	Group B	Group A	Group B
Mean	50.60	-6.84	58.52	-6.64
SD	59.62	32.69	63.76	44.98
Mean Difference/Ci	57.44 (From 30.10 to 84.78)		65.16 (From 33.78 to 96.54)	
P Value	0.0001		0.0001	

Table 5 depicts the comparison of RBS levels post intervention between diabetic (Group A) and non diabetic (Group B).

At 4 weeks post intervention, RBS levels have significantly decreased in patients with diabetic dyslipidemia. (Group A) with P value of 0.0001, which is extremely statistically significant. At 8 weeks post intervention also, RBS levels have significantly decreased in patients with diabetic dyslipidemia. (Group A) with a P value of 0.0001, which is also extremely statistically significant.

FIG. 5: DIFFERENCE IN RBS BETWEEN TWO GROUPS. Fig. 5 depicts graphical representation of Table 9 in the form of a clustered column chart.

DISCUSSION: In this comparative, randomised, open labelled, prospective, interventional study between patients of diabetic dyslipidemia and non-diabetic dyslipidemia, 50 subjects were enrolled and randomised into group A (subjects with dyslipidemia and diabetes) and group B (subjects with dyslipidemia without diabetes). Age group 60-65 years had more number of subjects, the mean age in group A was 56.84 and that in group B, 51.76 which imply no statistical significance. Likewise the males were more in number when compared to females, which also had no effect on the results. The random blood glucose was done at baseline, 4 weeks and at 8 weeks post intervention (1gram of ω 3 fatty acids capsules 1 gm/ day). The reduction in RBS from baseline is not statistically significant among the two groups, the mean difference being 20.72 and 26.94 at 4 and 8 weeks respectively. After we had compared pre and post intervention values, we started intragroup comparison between group A and B, the increase or decrease in various parameters post intervention. The reduction in RBS was more pronounced in group A, mean values of 50.60,58.52 when compared to group B whose mean values were -6.84, -6.64 at 4 weeks and 8 weeks respectively.

Our study was similar to the study conducted by Shaylika Chauhan *et al* [3], the inference being "Omega 3 fatty acids is more effective in reducing S. Triglycerides in patients with diabetes with dyslipidemia than in control groups. The limitations of our study were small sample size, investigations done thrice ie. at baseline, at 4 weeks and at 8 weeks, making it more cumbersome for patients, concomitant drugs used for diabetes and dyslipidemia not being taken into account for the study.

CONCLUSION: Omega 3 fatty acids significantly reduced glucose levels in diabetes patients with dyslipidemia and hence can be safely employed for use in them.

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CONFLICTS OF INTEREST: There are no specific conflicts of interest.

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