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ANALYSIS OF DYSLIPIDAEMIC PATTERN OF INDIAN TYPE 2 DIABETES INDIVIDUALS USING AMERICAN DIABETES ASSOCIATION GUIDELINES

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ABSTRACT

Aims and Objectives-To analyse the lipid parameters of type 2 diabetes individuals not on any anti lipid drugs using American diabetes association guidelines. **Methods** --200 type 2 diabetes individuals attending out-patient department of Karnataka institute of endocrinology and research were randomly selected. They should not be taking any anti lipid medications. Fasting plasma glucose, post prandial plasma glucose, HBA1c, lipid profile, BMI, waist circumference and BP of these subjects were measured. **Results-** Diabetes subjects were in the age range of 20 to 70 years and 67.5% were males. The duration of diabetes was between new to 20 years. Family history was positive in 47% of the subjects. Hypertension was present in 37% of the subjects. LDL was <100, 100-129, 130-159, 160-189 and >190mg/dl were present in 23%, 34%, 20%, 9% and 2% of the diabetes subjects. HDL was less than 40 mg/dl in 67%, 40 to 60 mg/dl in 32.5% and more than 60 mg/dl in 0.5% of the diabetes subjects. Triglycerides were <150, 150-199, 200-499 and more than 500 mg/dl in 40%, 21.5%, 31.5% and 7% of the diabetes subjects. So the LDL and Triglyceride targets were achieved in 23%, 40% of the individuals respectively. HDL levels of 45 mg/dl in men and 55 mg/dl in women were achieved in only 12.6% and 7.7% respectively. **Conclusions**- The proportion of type 2 diabetes patients with lipid levels outside of clinical target values was high. Patients with established dyslipidaemia will require advice regarding diet, exercise and improvement in glycaemic control. This study suggests that an active strategy of early detection and drug treatment for dyslipidaemia is needed for 80 to 90% of type 2 diabetic patients.

KEYWORDS: Dyslipidaemia, atherogenic, Type 2 diabetes.

INTRODUCTION

The term hyperlipidaemia refers to an increase in concentration of one or more plasma or serum lipids, usually cholesterol and triglycerides and the term dyslipidaemia is used for either an increase or decrease in concentration of one or more plasma lipids. Type 2 diabetic patients have markedly increased risk of coronary heart disease than similarly dyslipidaemic non diabetic subjects.[1] The results of the Strong Heart Study indicate that LDL cholesterol is an independent predictor of cardiovascular disease in patients with diabetes, along with age, albuminuria, fibrinogen, HDL cholesterol (inverse predictor), and percent body fat (inverse predictor)[2] Atherogenic dyslipidaemia (diabetic dyslipidaemia) is characterized by 3 lipoprotein abnormalities: elevated very-low-density lipoproteins (VLDL), small LDL particles, and low high-density-lipoprotein (HDL) cholesterol (the lipid triad)[3,4] Despite the high and widespread prevalence of dyslipidaemia among people with and without diabetes, only 2.2 %[5] of adults without diabetes and 32 %[5] of diabetic patients were receiving treatment with diet, exercise, or drugs to reduce lipid levels and less than one third of patients with established cardiovascular disease received such treatment.[5] Furthermore, among those who were being treated, only 1 % reached the American Diabetes Association (ADA) goal of LDL < 100 mg/dl[6]

AIMS AND OBJECTIVES-To analyse the lipid parameters of type 2 diabetes individuals with respect to American diabetes association guidelines.

Methods --200 type 2 diabetes individuals attending out-patient department of Karnataka institute of endocrinology and research were randomly selected. They should not be taking any anti lipid medications. Fasting plasma glucose, post prandial plasma glucose, HBA1c, lipid profile, BMI, waist circumference and BP of these subjects were measured. Diagnosis of diabetes

was made by using American diabetes association diagnostic criteria.

Those patients who agreed to participate in the study were informed of the programme and schedule of the study. Informed consent was obtained from all participants. The patient's personal data, medical, family, dietary history and daily activities were recorded. Height and weight for BMI calculation were also measured and recorded using a data collection form. After 12 hours of fasting (overnight) 10 ml blood was collected into appropriate tubes and taken to Chemical Pathology Laboratory for analysis.

The height and body weight of each subject were measured using the weighing balance with height attachment to the nearest decimal point with shoes and outer garments removed. Body weight status was estimated by the body mass index (BMI) computed in metric units as weight (kg)/height^2 (m^2).

All samples were determined for glycated hemoglobin concentration using the HPLC method on the Bio-Rad variant2 turbo analyzer. Serum total cholesterol concentration was determined by automated enzymatic CHOD-PAP method using commercial kits (Roche) on Hitachi C311 autoanalyzer. Serum HDL cholesterol was measured by precipitation method (Roche). The LDL cholesterol concentration was calculated for each sample according to the Friedewald formula. Serum triglycerides concentration was determined by automated enzymatic GPO-PAP method using commercial kits (Roche) on Hitachi 311 autoanalyzer.

The ADA guidelines recommend an HDL cholesterol level of 45 mg/dl in men and 55 mg/dl in women, an LDL cholesterol level of < 100 mg/dl, and a triglycerides level of <150 mg/dl as clinical targets for lipids in type 2 diabetes.

Statistical Methods: Descriptive statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean ± SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5 % level of significance. The following assumptions on data is made, Assumptions: 1.Dependent variables should be normally distributed, 2.Samples drawn from the population should be random, Cases of the samples should be independent Analysis of variance (ANOVA) has been used to find the significance of study parameters between three or more groups of patients, Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups.

Statistical software: The Statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1 Systat 12.0 and R environment ver.2.11.1 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc**.**

RESULTS

Age range from 21-70 years.

135 of the participants were males.

The duration of diabetes range from new to more than 20 years.

Family history was positive in 47% of the subjects.
Hypertension was present in 37% of the subjects.

LDL was <100, 100-129, 130-159, 160-189 and >190mg/dl were present in 23%, 34%, 20%, 9% and 2% of the diabetes subjects.

HDL was less than 40 mg/dl in 67%, 40 to 60 mg/dl in 32.5% and more than 60 mg/dl in 0.5% of the diabetes subjects.

Triglycerides were <150, 150-199, 200-499 and more than 500 mg/dl in 40%, 21.5%, 31.5% and 7% of the diabetes subjects.

So the LDL and Triglyceride targets were achieved in 23%, 40% of the individuals respectively. HDL levels of 45 mg/dl in men and 55 mg/dl in women were achieved in only 12.6% and 7.7% respectively.

We have evaluated lipid parameters in comparison to the level of HBA1c. The cholesterol and triglyceride levels were higher when HBA1c is >8%. LDL and HDL levels do not change with increase in HBA1c.

Table 1: Age distribution of patients studied.

Age in years	Number of patients	%
21-30	6	3.0
31-40	20	10.0
41-50	57	28.5
51-60	74	37.0
61-70	34	17.0
>70	9	4.5
Total	200	100.0

Table 2: Total cholesterol distribution.

TCL(mg/dl)	Number of patients	%
<200	83	41.5
200-239	117	58.5
>240	-	-
Total	200	100.0

Table 3: Total LDL distribution.

LDL(mg/dl)	Number of patients	%
<100	46	23.0
100-129	68	34.0
130-159	40	20.0
160-189	18	9.0
>190	4	2.0
Not recorded	24	12.0
Total	200	100.0

Table 4: Total triglyceride distribution.

TGL (mg/dl)	Number of patients	%
<150	80	40.0
150-199	43	21.5
200-499	63	31.5
>500	14	7.0
Total	200	100.0

Table 5: Total HDL distribution.

HDL(mg/dl)	Number of patients	%
<40	134	67.0
40-60	65	32.5
>60	1	0.5
Total	200	100.0

Table 6: Correlation of Study variables according to levels of HbA1c.

Variables	HbA1c					P value
	<7%	7-8%	8-9%	9-10%	>10%	
Age in years	54.72±12.88	54.56±10.44	48.52±8.85	52.86±10.70	51.70±10.66	0.092+
BMI(kg/m2)	26.80±4.07	27.10±5.62	25.66±3.57	29.07±15.02	24.67±3.82	0.060+
Waste circumference (cm)	92.35±7.34	95.82±8.98	92.82±9.11	90.18±14.83	88.52±10.19	0.008**
Duration of DM in years	5.95±6.61	5.12±5.36	4.55±6.07	7.54±6.67	4.81±5.48	0.242
FBS(mg/dl)	120.68±19.19	135.60±26.81	162.61±38.87	194.86±54.51	240.78±65.15	<0.001**
PPBS (mg/dl)	201.03±49.26	224.48±52.59	263.30±56.62	320.55±81.63	371.55±77.96	<0.001**
Total cholesterol (mg/dl)	189.65±29.83	196.78±34.89	185.33±31.30	212.79±66.54	204.84±51.19	0.083+
TGL (mg/dl)	164.20±78.61	208.02±112.31	247.38±190.66	269.44±233.69	225.53±183.55	0.157
HDL(mg/dl)	37.61±9.00	38.73±8.33	37.03±8.83	34.45±6.90	37.51±7.94	0.307
LDL(mg/dl)	120.03±26.16	121.51±34.37	107.45±25.58	126.00±34.93	123.21±33.28	0.174
VLDL(mg/dl)	31.13±15.67	41.56±22.60	49.50±38.07	56.10±46.41	45.13±36.78	0.066+

Table 7: Correlation of lipid parameters with HBA1c.

Lipid parameters	HbA1c					P value
	<7% (n=29)	7-8% (n=41)	8-9% (n=36)	9-10% (n=29)	>10% (n=65)	
Total cholesterol (mg/dl)						
• <200	11(37.9%)	17(41.5%)	10(27.8%)	14(48.3%)	31(47.7%)	0.340
• 200-239	18(62.1%)	24(58.5%)	26(72.2%)	15(51.7%)	34(52.3%)	
• >240	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	
Triglycerides(mg/dl)						
• <150	15(51.7%)	15(36.6%)	11(30.6%)	14(48.3%)	25(38.5%)	0.200
• 150-199	8(27.6%)	10(24.4%)	11(30.6%)	1(3.4%)	13(20%)	
• 200-499	6(20.7%)	14(34.1%)	10(27.8%)	10(34.5%)	23(35.4%)	
• >500	0(0%)	2(4.9%)	4(11.1%)	4(13.8%)	4(6.2%)	
HDL(mg/dl)						
• <40	22(75.9%)	24(58.5%)	26(72.2%)	22(75.9%)	40(61.5%)	0.286
• 40-60	7(24.1%)	17(41.5%)	9(25%)	7(24.1%)	25(38.5%)	
• >60	0(0%)	0(0%)	1(2.8%)	0(0%)	0(0%)	
LDL (mg/dl)						
• <100	5(17.2%)	8(19.5%)	13(36.1%)	7(24.1%)	13(20%)	0.358
• 100-129	11(37.9%)	16(39%)	13(36.1%)	8(27.6%)	20(30.8%)	
• 130-159	10(34.5%)	9(22%)	3(8.3%)	5(17.2%)	13(20%)	
• 160-189	2(6.9%)	3(7.3%)	2(5.6%)	2(6.9%)	9(13.8%)	

• >190	0(0%)	1(2.4%)	0(0%)	1(3.4%)	2(3.1%)	
VLDL(mg/dl)						
• <30	16(55.2%)	15(36.6%)	11(30.6%)	13(44.8%)	23(35.4%)	
• 30-60	11(37.9%)	20(48.8%)	19(52.8%)	9(31%)	32(49.2%)	0.397
• >60	2(6.9%)	6(14.6%)	6(16.7%)	7(24.1%)	10(15.4%)	

DISCUSSION

Type 2 diabetes is associated with a cluster of interrelated plasma lipid and lipoprotein abnormalities, including reduced HDL cholesterol, a predominance of small dense LDL particles, and elevated triglycerides. These abnormalities occur in many patients despite normal LDL cholesterol levels. These changes are also a feature of the insulin resistance syndrome (also known as the metabolic syndrome), which underlies many cases of type 2 diabetes. In fact, pre-diabetic individuals often exhibit an atherogenic pattern of risk factors that includes higher levels of total cholesterol, LDL cholesterol, and triglycerides and lower levels of HDL cholesterol than individuals who do not develop diabetes.[7,8] Insulin resistance has striking effects on lipoprotein size and subclass particle concentrations for VLDL, LDL, and HDL.[9,10]

The NCEP, ATP III[11] recommends aggressive LDL reduction for patients with diabetes (i.e., an LDL goal < 100 mg/dl). Likewise, the ADA recommends in its position paper that the major emphasis for treating diabetic dyslipidaemia should be placed on lowering LDL cholesterol levels to < 100 mg/dl, even in patients with no history of CVD[12] The optimal goal for LDL cholesterol is <100 mg/dl. When using this clinical end point, a substantial percentage 77 % of patients in this study would require intervention and ongoing monitoring to ensure that the recommended LDL cholesterol goal is reached and maintained.

The optimal goal for HDL cholesterol is 45 mg/dl in men and 55 mg/dl in women. When using this clinical end point, 87.3 % of men and 92.3% of women patients in this study were found to require intervention and ongoing monitoring. Triglycerides concentration of 60 % patients was in the high and borderline risk categories. Similar results were found among urban African-Americans with type 2 diabetes[13] In this study, Cook et al found that the percentages of African-Americans with LDL ≥ 100 mg/dl was 86 %, HDL < 45mg/dl was 74 % and high and borderline triglycerides was 19 %. In another study in Malaysia, Ismail et al[14] found that 90.9 % of their subjects had LDL-cholesterol ≥ 100 mg/dl, 52.6 % had HDL-cholesterol < 45mg/dl and 27.3 % had triglycerides > 200 mg/dl.

Glycaemic control and gender were important determinants of having lipid values in high and borderline high risk categories. Cook et al[12] also found that African-American women had significantly greater odds of having an LDL above target, an HDL cholesterol level below clinical goal and lesser odd of having triglycerides level above clinical goal compared to men. They, however, did not analyse for glycaemic control. Ismail et al[13] found in their type 2 diabetics, that ethnicity was an important determinant for LDL and HDL cholesterol; glycaemic control for LDL cholesterol and triglycerides and gender for HDL cholesterol.

In the present study

1. The hypertriglyceridemia percentage was higher in our group of Indian patients whereas LDL and HDL abnormality percentage were similar.
2. We have evaluated lipid parameters in comparison to the level of HBA1c. The cholesterol and triglyceride levels were higher when HBA1c is >8%. LDL and HDL levels do not change with increase in HBA1c.
3. The findings in our study indicate that lowering LDL cholesterol along with increasing HDL cholesterol comprises an important target for intervention in our population. Triglyceride levels can be reduced by glycemic control and reduction of carbohydrate percentage in the diet.

CONCLUSIONS

The proportion of type 2 diabetes patients with lipid levels outside of clinical target values was high. Patients with established dyslipidaemia will require advice regarding diet, exercise and improvement in glycaemic control. This study suggests that an active strategy of early detection and drug treatment for dyslipidaemia is needed for 80 to 90% of type 2 diabetic subjects.

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