

Original Research Article

Study of serum lipid profile and serum lipo-protein (a) in type II diabetes mellitus patients compared to non-diabetics

J. Prathyusha Rao¹, Abhinav Thota^{2*}

¹Department of General Medicine, Bhaskar Medical College, Yenkapally, Moinabad, Telangana, India

²Department of Dr. Patnam Mahender Reddy Institute of Medical Sciences, Chevella, Telangana, India

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*Correspondence:

Dr. Abhinav Thota,

E-mail: abhinavthota@gmail.com

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ABSTRACT

Background: This study helps us in evaluating present Indian scenario of lipid and diabetic portfolio, and advices about how aggressive treatment should be for immediate control of blood sugars and lipids are to minimize the cardiovascular risks. The objective of this study was to evaluate the serum lipid profile and lipo-protein (a) levels in comparison to patients with type II diabetics with non-diabetics.

Methods: It was a hospital-based case control study conducted on patients presenting with signs and symptoms of diabetes mellitus and confirmed on doing appropriate investigation. 200 patients of which 100 were non-diabetic (control) and 100 type II diabetic patients, of which fifty were type II diabetics were on oral hypoglycemic agents (OHA) and 50 were on insulin only, were selected after matching for age and sex. Lipid profile, serum lipoprotein (a), ECG, 2D echo was studied in these patients.

Results: The males were more (74%) than females (26%) among the cases. Fasting blood sugar, post prandial blood sugar and HbA1c were significantly more in cases. Triglycerides, LDL, VLDL and lipoprotein (a) were significantly more in cases. ST shift (mm) and T wave inversions were significantly more in cases compared to controls ($p < 0.05$). Mean ejection fraction was significantly reduced in cases compared to controls. FBS and PPBS were not significantly different in two groups of OHA and insulin but HbA1c was significantly better controlled in insulin group than OHA group.

Conclusions: Lipid profile and lipoprotein (a) as well as ECG and 2D echo parameters were significantly worse in diabetes patients. Hence appropriate management is important to prevent risk of complications.

Keywords: Lipid profile, Diabetes, Insulin, ECG, 2D echo

INTRODUCTION

Cardiovascular disease has emerged as a major health burden worldwide. A rise in the prevalence of CVD in the early half of twentieth century and a subsequent decline in the later half have been well documented in the industrialized countries. However, the scenario is reversed in developing countries especially India with a steady escalation in prevalence of CVD. Diabetes as a metabolic disorder is on rising at alarming rate all over the world and has been a reason of concern due to the complications

associated with it. Type 2 diabetes mellitus is the predominant form of diabetes worldwide, accounting for 90% of cases globally.¹⁻³

It is projected to increase to 438 million by 2030 from current estimate of 285 million in 2010. Currently up to 11 per cent of India's urban population and 3 per cent of the rural population above the age of 15 have diabetes. Diabetes affects all the people in the society, not just those who live with it. The WHO estimates the mortality from diabetes and heart disease cost that India would have to

bear at around \$210 billion every year and is expected to increase to \$335 billion in the next ten years.⁴

With India having the highest number of diabetic patients in the world, this disease is posing an enormous health problem in the country. Calling India the diabetes capital of the world, the International Journal of Diabetes in developing countries says that there is an alarming rise in prevalence of the diabetes. Economic drift and its consequent changes in life style in India have lead to this alarming increase in the prevalence of diabetes which has now become the greatest health threat.⁵

The relation between alteration of serum lipid profile and vascular complications is more significant in diabetics than in non-diabetics among the general population. Lipid abnormalities lead to micro vascular and macro vascular diseases in diabetic patients, lipoprotein abnormalities correlated with large vessel disease are seen in diabetics and non-diabetic population, however atherogenesis is accelerated in diabetics.^{5,6} Coronary artery disease is one of the important complications of diabetics. Diabetes is associated with a marked increase by a factor of two to four times increased risk of coronary artery disease.⁷ The plasma cholesterol levels and lipoprotein (a) play a major strong predictor role in the risk of cardio vascular events both in diabetics and patients with coronary artery disease.^{8,9}

Dyslipidemia is commonly seen in diabetes. Type II diabetes mellitus is one of the most common cause of hyperlipidemia, the hyperglycemia and hyperlipidemia in type II diabetes have additive risk for cardio vascular disease.¹⁰

Hence identification, evaluation, follow up of serum lipid profile, lipoprotein (a) in type II diabetic mellitus is very important. This study was conducted, in view of the limited number of studies on serum lipid profile and serum Lp (a) in South Indians, especially type 2 diabetic individuals for CAD risk, as well as to bring forth light the contribution of lipid profile and Lp (a) to predisposition to CAD in type 2 diabetes mellitus. This study helps us in evaluating the present Indian scenario of lipid and diabetic portfolio, and advices about how aggressive a treatment should be for immediate control of blood sugars and lipids are to minimize the cardiovascular risks. The aim of the study was to evaluate the serum lipid profile and lipoprotein (a) levels in comparison to patients with type II diabetics with non-diabetics and to study the serum lipid profile and lipo-protein (a) levels in comparison to patients with type II diabetics on oral hypoglycemic agents and type II diabetics on insulin.

METHODS

A total 200 patients of which 100 were non-diabetic (control) and 100 type 2 diabetic patients, of which fifty were type II diabetics were on oral hypoglycemic agents (OHA) and 50 were on insulin only, were selected after

matching for age and sex. Lipid profile and serum Lp (a) was studied in these patients.

Source of data

It was a hospital-based case control study conducted on patients presenting with signs and symptoms of diabetes mellitus and confirmed on doing appropriate investigation at Shadan hospital, Hyderabad during study period from June 2012 to 2014. Hundred as controls, 100 type II diabetics according to revised criteria of ADA and WHO. All clinically diagnosed cases who attended the out-patient department as well as in-patients were included in the study. Age and sex matched the healthy individuals were taken as controls randomly. Each patient gave inform consent and the study was approved by ethical and research committee of the hospital to use human subjects in research studies.

Inclusion criteria

Patients with following criteria were included- (a) above 35 years; (b) type II diabetics on OHA; and (c) type II DM on insulin.

Exclusion criteria

Patients with following criteria were excluded- (a) patients with type I DM; (b) type II diabetics on statin therapy; (c) hypertensive patients, patients with coronary artery disease as co-morbid condition, high levels of serum homocysteine; and (d) patients on drugs that alter serum Lp (a) levels like: aspirin, oral contraceptive drugs, estrogen replacement therapy, antiepileptic drugs; and (e) prediabetes (impaired fasting glucose, impaired glucose tolerance) patients

Method of collection of data

A detailed history was taken and a detailed physical examination was done as per the proforma to study the clinical profile of patients, blood parameters and imaging as required. All diabetic patients were type 2, on oral anti-diabetic agents.

Diabetes mellitus was ruled out in non-diabetic group by fasting and postprandial blood glucose as analyzed by GOD-PAP (glucose oxidase-phenol 4-aminophenazone peroxidase) method. 10 ml of blood was drawn at the time of admission and lipoprotein electropherogram processed within 6 hours by EDC Helena laboratories electrophoretic auto-analyzer. Samples were refrigerated at 4 degree centigrade till analysis was done. Serum lipoprotein (a)-cholesterol, LDL-C, VLDL cholesterol and HDL cholesterol were directly observed. Serum Lp (a) was calculated from the Lp (a)- C value by the following formula.

$$Lp(a) = Lp(a) - C \times 3$$

This method had a correlation coefficient (0.95) with Friedewald's equation. Electrophoretic values for LDL are 6-7% lower than the conventional method. Resting electrocardiogram with 12 standard leads was taken as soon as possible and repeated serially and ST segment was monitored. Relevant investigations including biochemical and non-invasive imaging were done.

Following investigations were conducted: routine investigations (done for all cases), ECG in all 12 leads, hemoglobin (%), total count (TC) and differential counts (DC), erythrocyte sedimentation rate (ESR), blood sugar (BS) at the time of admission, fasting and 2nd hour blood glucose, blood urea, serum creatinine, urine analysis-albumin/sugar/microscopy, serum lipoprotein (a), total cholesterol, HDL cholesterol, VLDL cholesterol, LDL cholesterol, triglycerides, echocardiogram, HbA1c, serum homocysteine levels, chest X-ray- PA view.

Statistical analysis

Results on continuous measurements were presented on mean \pm SD and results on categorical measurements were presented in number (%). Significance was assessed at 5% level of significance. Student t test (two tailed, independent) had been used to find the significance of study parameters on continuous scale between two groups (inter group analysis). Chi square/Fisher exact test had been used to find the significance of study parameters on categorical scale between two groups with the help of SPSS statistical software package version 21.0 for windows.

RESULTS

The males were more (74%) than females (26%) among the cases. Similar number were there in controls as it was age and sex matched case control study (Table 1). Fasting blood sugar (mg/dl), post prandial blood sugar (mg/dl) and

HbA1c were significantly more in cases compared to controls ($p<0.05$) (Table 2).

Triglycerides (mg/dl), LDL (mg/dl), VLDL (mg/dl) and Lp (a) (mg/dl) were significantly more in cases compared to controls ($p<0.05$) except total cholesterol. HDL was significantly less in cases compared to controls ($p<0.05$) (Table 3).

ST shift (mm) and T wave inversions were significantly more in cases compared to controls ($p<0.05$). The affection of walls of the heart as seen in ECG was not seen significantly different in cases and controls except right+inferior and inferior+posterior walls seen more affected in controls than cases ($p<0.05$) (Table 4).

On comparison of 2D echo findings, it was observed that mean ejection fraction was significantly reduced in cases compared to controls. Regional wall motion abnormality and LV diastolic dysfunction was more common in cases than controls ($p<0.05$). There was no significant difference between the two groups (Table 5).

FBS and PPBS were not significantly different in two groups of OHA and insulin but HbA1c was significantly better controlled in insulin group than OHA group (Table 6).

When lipid parameters were compared between OHA and insulin groups, it was found that the lipid profile did not differ significantly in two groups ($p>0.05$) (Table 7).

Except anterior wall affection seen more in OHA group, all other ECG findings were not significantly different in two groups of OHA and insulin ($p>0.05$) (Table 8). The mean ejection fraction was seen significantly reduced in OHA group patients compared to insulin group patients ($p<0.05$). But other findings of the 2D echo were similar in two groups (Table 9).

Table 1: Sex wise distribution of cases and controls.

Sex	Cases (N=100)		Controls (N=100)	
	Number	%	Number	%
Male	74	74	75	75
Female	26	26	25	25
Total	100	100	100	100

Table 2: Comparison of blood sugar parameters in cases and controls.

Blood sugar parameters	Cases (N=100)	Controls (N=100)	T value	P value
Fasting blood sugar (mg/dl)	167.70 \pm 59.80	86.20 \pm 8.28	6.037	<0.001
Post prandial blood sugar (mg/dl)	238.30 \pm 81.31	107.20 \pm 19.11	7.019	<0.001
HbA1c	9.44 \pm 2.31	5.41 \pm 0.30	7.742	<0.001

Table 3: Comparison of lipid profile parameters in cases and controls.

Lipid profile parameters	Cases (N=100)	Controls (N=100)	T value	P value
Triglycerides (mg/dl)	194.62 \pm 54.25	127.80 \pm 29.15	2.800	0.008
Total cholesterol (mg/dl)	196.87 \pm 39.92	167.72 \pm 26.28	0.457	0.061

Continued.

Lipid profile parameters	Cases (N=100)	Controls (N=100)	T value	P value
HDL (mg/dl)	34.85±10.03	44.05±7.54	3.348	0.027
LDL (mg/dl)	141.86±31.83	100.95±21.42	0.060	0.092
VLDL (mg/dl)	45.80±19.60	24.65±6.12	2.667	0.011
Lipoprotein (a) (mg/dl)	23.38±11.81	14.16±5.27	4.783	0.001

Table 4: Comparison of ECG findings in cases and controls.

Lipid profile parameters	Cases (N=100)	Controls (N=100)	T value	P value
ST shift (mm)	1.38±0.82	1.08±0.24	3.511	0.0005
T wave inversions	2.14±0.81	1.21±0.44	9.993	<0.001
Wall involved	Cases	Controls	Chi square	P value
Anterior	56%	42%	3.381	0.054
Inferior	18%	16%	0.035	0.85
Posterior	0%	2%	0.505	0.25
Lateral	25%	22%	0.1113	0.73
Right+inferior	1%	12%	8.227	0.0041
Inferior+posterior	0%	6%	4.296	0.038

Table 5: Comparison of 2D echo findings in cases and controls.

2D echo findings	Cases (N=100)	Controls (N=100)	Chi square/ t value	P value
Papillary muscle dysfunction	9%	2%	3.463	0.062
Mean ejection fraction	50.2±4.8%	59.8±2.9%	17.118	<0.0001
Regional wall motion abnormality	73%	51%	9.359	0.0022
LV diastolic dysfunction	78%	62%	5.357	0.021

Table 6: Comparison of blood sugar parameters between insulin group and oral hypoglycemic agent group (OHA).

Blood sugar parameters	OHA (N=50)	Insulin (N=50)	T value	P value
Fasting blood sugar (mg/dl)	171±60.70	152±47.20	5.846	0.05
Post prandial blood sugar (mg/dl)	242±91.20	219±42.80	6.914	0.05
HbA1c	9.46±2.27	7.94±2.10	7.621	0.018

Table 7: Comparison of lipid profile parameters between insulin group and oral hypoglycemic agent group (OHA).

Lipid profile parameters	OHA (N=50)	Insulin (N=50)	T value	P value
Triglycerides (mg/dl)	189.45±52.65	178±66.85	2.901	0.89
Total cholesterol (mg/dl)	186.45±48.45	184.20±47.80	0.0457	0.4240
HDL (mg/dl)	38.48±7.05	45.65±11.85	3.482	0.088
LDL (mg/dl)	141.46±35.14	134.24±28.78	2.457	0.667
VLDL (mg/dl)	47.60±21.68	42.58±16.78	2.521	0.062
Lipoprotein (a) (mg/dl)	22.10±8.74	20.45±7.28	2.481	0.053

Table 8: Comparison of ECG findings between insulin group and oral hypoglycemic agent group (OHA).

ECG findings	OHA (N=50)	Insulin (N=50)	T value	P value
ST shift (mm)	1.36±0.78	1.34±0.46	0.156	0.43
T wave inversions	2.09±1.02	1.98±0.82	0.594	0.11
Wall involved	Cases	Controls	Chi square	P value
Anterior	35%	21%	4.191	0.049
Inferior	12%	6%	1.526	0.28
Posterior	0%	0%	-	-
Lateral	14%	11%	0.183	0.51
Right+inferior	1%	0%	0	0.67
Inferior+posterior	0%	0%	-	-

Table 9: Comparison of 2D echo findings between insulin group and oral hypoglycemic agent group (OHA).

2D echo findings	OHA (N=50)	Insulin (N=50)	Chi square/ t value	P value
Papillary muscle dysfunction	8%	6.9%	0	0.34
Mean ejection fraction	51.8±1.94	54.8±2.02	7.574	<0.0001
Regional wall motion abnormality	72%	65%	0.834	0.23
LV diastolic dysfunction	76%	72%	0.234	0.21

DISCUSSION

Most of the diabetic patients in the study group were males (74%) compared to females (26%) which implicated that incidence of diabetics was greater among male population than compared to females.

The mean age of cases studied in the present study is comparatively younger ($p < 0.05$) than similar studies, except Mohan et al, with which the age is comparable.^{11,13,14} In the present study the mean age is in 5th decade, which is comparable to Mohan et al.¹¹ This may be due to occurrence of acute cardiovascular events in an earlier age in South Indian patients compared to western population, parallel to the trend of raising CAD in developing countries. The ratio between male and female patients in both control and cases were appropriated in all studies. Gender bias was removed as both the groups are sex matched.

In our study the mean FBS values of patients were 167.7 ± 59.8 well above the ADA criteria to diagnose the diabetics and the PLBS which was higher than upper limit 238.3 ± 81.31 cut off value of 140 mg/dl whereas control group had blood glucose values of 86.2 ± 8.28 and 107.2 ± 19.11 for FBS and PLBS respectively suggestive of normal glycemia. These values correlate well with clinical diagnosis

In our present study the total triglycerides, total cholesterol, total LDL, VLDL and Lp (a) were significantly raised in the case group (type II DM), compared to controls. Simultaneously HDL levels were decreased in case compared to controls. Our findings corroborated with study conducted by Mazzone et al where he documented an increase in total triglycerides levels.⁵ A study conducted by Otamera et al also documented increased levels in total triglycerides, total cholesterol and LDL, decreased HDL levels which was similar to our study.¹⁵ Surekha et al found that HDL levels were depressed in type II diabetic patients, with mean HDL of 36.24 ± 4.96 in type II DM to 41.54 ± 3.46 in control subjects.¹⁶ Our present study was also very similar to above study with 34.85 ± 10.03 in type II diabetic to 44.05 ± 7.54 in control.¹⁷ Haffner et al documented high levels of total cholesterol, VLDL, total triglycerides in type II DM, the above statement holds true to our presents study. The reason for increase in total cholesterol, LDL, total triglycerides is because of increase in incidence of obesity, sedentary life, lack of physical activity, diet and other risk factors, also due to increase in availability of more acetyl co. A, the starting substance for synthesis of

fatty acids and cholesterol and also due to decreased suppression of tissue lipolysis in diabetic mellitus due to lack of insulin.

In our present study increased in Lp (a) levels is noticed in cases (type II DM), compared to controls. Fijino et al have found increased levels of Lp (a) In both types of diabetic mellitus and also stronger association of LP(a) levels in diabetic mellitus with complications.¹⁸ In the present study type II patients have higher LP (a) levels (23.38 ± 11.8) compared to non-diabetic patients (14.16 ± 5.27). The difference of mean was statistically very significant ($p < 0.001$). These results were comparable to Mohan et al study but with increased significance of Lp (a) level in type II diabetic.¹⁴

The ECG finding showed ST shift (mm) more in cases 1.38 ± 0.82 than controls 1.08 ± 0.24 with a suggestive significance between the group ($p = 0.19$). The T wave inversions in cases was 2.14 ± 0.81 and in controls 1.21 ± 0.44 . This shows a moderate significance ($p = 0.02$) between the groups. Diabetic patients had increased incidence of anterior wall ($p = 0.54$), inferior wall ($p = 0.22$) and lateral wall MI ($p = 0.062$) than compared to non-diabetics.

The present study diabetic individuals had PMD 9% than controls 2%. This shows a slightly large increase in number of PMD defects in cases than controls. The mean ejection fraction of cases was 50.2 ± 4.8 than that of controls is 59.8 ± 2.9 . There was a moderate significance in ejection fraction values between the two groups ($p = 0.049$). The RWMA of the cases was around the 73% than that of controls was 51% there am moderate significance between the groups ($p = 0.0154$). The LV diastolic dysfunction in the case was about 71% compared to controls that were around 62%. There was a moderate significant between two groups ($p = 0.021$). So, in our study diabetic individuals have a higher incidence of RWMA, LV diastolic dysfunction, and papillary muscle dysfunction compared to non-diabetic population. The mean ejection fraction was less in the case group compared to control group. This was comparable to Neki et al.¹⁹

In our study the mean FBS values of OHA group were 171 ± 60.70 and insulin group was 152.0 ± 47.20 , well above the ADA criteria to diagnose the diabetics and the PLBS which was higher than upper limit cut off value of 140mg/dl, OHA group had PLBS of 242 ± 91.20 whereas insulin group had PLBS values of 219 ± 42.80 . These values co relate well with clinical diagnosis. So, there was suggestive significance in FBS and PLBS of the two

groups ($p=0.05$). In our study the mean HbA1c levels of OHA is 9.46 ± 2.27 and that of insulin group was (type II DM) is 7.94 ± 2.10 . HbA1c levels were significantly raised in OHA group, this increased values in the OHA compared to insulin were very significant ($p=0.018$).

In our present study there was slight decrease in total triglyceride level in OHA group (5-8%) when compared to significance decrease of TAG in insulin group (18%) ($p=0.058$). The LDL levels were slightly decreased in OHA group (10-12%), when compared to insulin group there was slight decrease in LDL ($p=0.0667$). The total cholesterol was almost same in both OHA group and insulin group (20-25%). Hence no significance between the two groups ($p=0.414$). The HDL levels slightly increased in OHA groups (5-10%), HDL was moderately increased in insulin group. There was suggestive significance between the two groups ($p=0.088$). The VLDL levels of OHA group were slightly higher than that of insulin group. There was a suggestive significance between the two groups ($p=0.062$). Our present study correlated the same inference of lipid profile with a study done by Keidan et al.²⁰ The Lp (a) levels of OHA group were 22.10 ± 8.74 , of that insulin group was 20.45 ± 7.28 there was a slight decrease of Lp (a) of OHA group (2-3%), there was slight to moderate decrease of Lp (a) (5-6%) in insulin group. There was a suggestive significance between the two groups ($p=0.053$). The present study correlated the same inference of lipid profile with a study done by Keidan et al.²⁰

The ECG finding showed ST shift (mm) slightly increase values in cases of OHA 1.36 ± 0.78 than insulin group 1.34 ± 0.46 with a negligible significance between the groups ($p=0.43$). The T wave inversions in OHA group was 2.09 ± 1.02 and in insulin group was 1.98 ± 0.82 , this shows a negligible significance ($p=0.11$) between the groups. Anterior wall MI was prominent in OHA group compared to insulin group with moderate significance ($p=0.049$), while other wall MI were of negligible significance between the two groups.

The present study, OHA group diabetic individuals had PMD 8% than insulin group 6.9%. This shows a very less increase in number of PMD defects in OHA than insulin group ($p=0.34$). The mean ejection fraction of OHA was 51.8 ± 1.94 than that of insulin group is 54.8 ± 2.62 . There was a suggestive significance in ejection fraction values between the two groups ($p=0.057$). The RWMA of the OHA was around the 72% than that of controls was 65% there was no or very less significance between the groups ($p=0.23$). The LV diastolic dysfunction in the OHA was about 76% compared to insulin that was around 72%. There was no significance between two groups ($p=0.21$).

CONCLUSION

Lipid profile and Lp (a) as well as ECG and 2D echo parameters were significantly worse in diabetes patients.

Hence appropriate management is important to prevent risk of complications.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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