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A Comparative Cross-sectional study on the Fasting and Postprandial Lipid levels as a Risk factor for Retinopathy in Patients with Type 2 Diabetes Mellitus

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ABSTRACT:

Background: The global prevalence of diabetes mellitus (DM) continues to rise, posing a significant public health challenge worldwide. Type 2 DM accounts for a substantial portion of this burden, characterized by chronic hyperglycaemia resulting from defects in insulin secretion, action, or both. Diabetic retinopathy, a microvascular complication of DM, is a leading cause of visual disability and blindness globally. **Objective:** To assess the relationship and importance between fasting dyslipidaemia vs postprandial dyslipidaemia as a risk factor for Diabetic retinopathy in these people. **Methods**: A study was conducted among diabetic patients in outpatient and inpatient units over 2 years. The sample size was determined based on the prevalence of diabetic retinopathy. Patients were recruited through purposive sampling. Demographic data were collected, fasting and 6-hour postprandial lipid levels were analysed. Ophthalmic evaluation was performed to assess diabetic retinopathy. **Results**: The study included 160 patients with a mean age of 56.66±8.16 years, with nearly equal gender distribution. Diabetic retinopathy was present in 18.8% of patients, with varying severity. There were significant associations between retinopathy and parameters such as random and postprandial blood glucose levels, HbA1c, and duration of DM. Additionally, There were significant differences in lipid profiles between patients with and without retinopathy, both in fasting and postprandial states. **Conclusion**: This study highlights the significant association between dyslipidaemia, particularly elevated triglycerides and LDL cholesterol, and the presence of retinopathy in patients with Type 2 DM. These findings show the importance of maintaining lower lipid levels for the prevention and management of diabetic retinopathy.

Introduction

Every country faces a public health burden as a result of the diabetes mellitus pandemic, particularly because the WHO predicts that diabetes will rank as the seventh greatest cause of death by 2030. In the current world, one of the biggest issues is the rising prevalence of Type 2 diabetes mellitus (T2DM). Diabetes mellitus (DM) is a collection of metabolic illnesses typified by persistently high blood sugar levels. These might be caused by abnormalities in insulin production, action, or both.(1,2) Approximately 50% of individuals diagnosed with diabetes mellitus experience varying levels of diabetic retinopathy at any one time, representing around 4% of the worldwide population.(3,4) In Asia, diabetic retinopathy accounts for 3-7% of all cases of blindness, according to WHO.(5) In the general population of India, the prevalence of diabetic retinopathy is 3.5%. and among those with diabetes mellitus, the prevalence of diabetic retinopathy is 18.0%.(6) Diabetic retinopathy was found in 1.78% of the diabetic individuals examined in a population-based research conducted in South India.(6,7) About 51 million individuals with diabetes are expected to live in India, according to the World

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Diabetes Atlas. Concern over Asia being the region with the highest rate of diabetes epidemic is rising.(8,9) India is predicted to be home to 51 million people with diabetes, according to the World Diabetes Atlas. There is growing concern that Asia has the greatest prevalence of the diabetes epidemic.(3)

One of the most frequent long-term microvascular complications of diabetes mellitus that may be prevented is Diabetic Retinopathy, which is also the main reason for loss of sight and visual impairment.(10) While the onset and advancement of diabetic retinopathy have been linked to several risk factors. However, it is unclear how well-established function dyslipidemia, microalbuminuria, BMI, and smoking have in predicting diabetic retinopathy.(11,12) Lipid exudation is often seen in conjunction with diabetic retinopathy.(13) In patients with diabetic retinopathy, elevated blood lipid levels are linked to a higher incidence of retinal hard exudate.(14) Increased blood-lipid levels are also linked to endothelial dysfunction, which seems to be a major factor in the development of diabetic retinopathy, especially when it comes to the disruption of the blood-retinal barrier.

In persons with type 2 DM, persistent postprandial hypertriglyceridemia may create a proatherogenic milieu that causes atherosclerosis and microvascular damage. Since we spend the majority of the day in the postprandial period, there is growing evidence that atherosclerosis is a postprandial phenomenon, at least concerning lipids.(6) Whether diabetic individuals with microvascular dysfunction exhibit more aberrant postprandial lipid metabolism than those without is a matter of debate. Against this background, this study aims to assess the relationship and importance between fasting dyslipidemia vs postprandial dyslipidemia as a risk factor for Diabetic retinopathy in these people.

Materials and Methods

This study employed a comparative cross-sectional design conducted over two years at Aarupadai Veedu Medical College and Hospital (AVMCH) among diabetic patients attending the outpatient and inpatient units. The sample size was calculated as 160 based on a similar study by Salaria NS et al.,(15) targeting a prevalence of diabetic retinopathy at 18% with 6% absolute precision, and a 5% significance level (n = [Z1-α/2^2 P(1-P)]/α^2, where P is prevalence and α is precision). Diabetic patients aged 30 to 75 years, diagnosed according to the American Diabetes Association (ADA) criteria, attending the General Medicine department at AVMCH were included, while those with renal or liver disease, hypothyroidism, significant media haze, or prior eye treatments (e.g., LASER or intravitreal anti-VEGF) were excluded. Primary outcome assessed was the presence of diabetic retinopathy, while exposure variables included age, gender, retinopathy severity, smoking, alcohol use, hypertension, obesity, duration of diabetes, and lipid profile levels. Sampling employed a purposive technique. Data collection involved demographic profiling, fasting, and six-hour postprandial lipid level analysis via autoanalyzer, including measurements of serum total cholesterol, triglycerides, LDL, HDL, and blood sugars. Ophthalmic assessments included slit-lamp biomicroscopy of the anterior segment, best corrected visual acuity (BCVA) on Snellen chart, and fundus evaluation post-mydriasis using direct and indirect ophthalmoscopy with a +20D lens, plus stereoscopic slit-lamp biomicroscopy of the disc and macula using a +78D Volk lens. Diabetic retinopathy, if detected, was classified into five grades according to ETDRS classification.

Statistical analysis: All the data were entered in an Excel sheet and analysed using SPSS v27.0 operating on Windows 10. The continuous data were summarised as mean and standard deviation and categorical data as frequency and percentage. The summarised data were represented using tables, figures, bar charts, and pie diagrams. The mean difference between continuous data was analysed using an unpaired t-test and categorical data using a chi-square test. The correlation between the continuous data was done using Pearson's coefficient correlation. For all statistical purposes, a p-value of <0.05 was considered statistically significant.

Results

The present study included 160 patients fulfilling inclusion criteria, with a mean age of 56.66±8.16yrs of age. Among them, 49.4% were female and 50.6% were male. There is no significant difference in gender distribution with retinopathy among patients. The severity of the retinopathy among the study population was graded into 5 categories mild, moderate, severe, very severe, and absent (Table 1). There is no significant difference in the presence of a history of hypertension, smoking, and alcohol consumption with the presence of retinopathy. There is a significantly higher mean level of random blood sugar in patients with retinopathy than those without. There is a significantly higher mean level of postprandial blood glucose in patients with

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retinopathy than those without retinopathy. There is a significantly higher mean level of HbA1c in patients with retinopathy than those without retinopathy. There is a significantly higher mean duration of diabetes mellitus in patients with retinopathy compared to patients without retinopathy. There is no significant difference in the mean level of hemoglobin, total leucocyte count, serum urea, and creatinine with the retinopathy group. Comparison of the fasting and 6th-hour lipid profile between the retinopathy and control group showed significant results (Table 2). On comparison of the mean level of lipid profile during fasting, there is a significantly higher level of cholesterol, triglycerides, LDL, VLDL, and a significantly lower level of HDL in patients with retinopathy compared to patients without retinopathy. On comparison of the mean level of lipid profile during the 6hr, there is a significantly higher level of cholesterol, triglycerides, LDL, VLDL, and significantly lower level of HDL in patients with retinopathy compared to patients without retinopathy (Table 3). Within the group without retinopathy, there was significantly higher mean level of triglycerides and LDL cholesterol during the 6th hour sample compared to the fasting lipid profile (Table 4). However, there was an elevation in cholesterol level and VLDL and a decrease in HDL level, but these were not statistically significant.

Discussion

A typical microvascular consequence of diabetes mellitus, diabetic retinopathy is the primary reason for vision loss in working-age individuals worldwide. Retinal microvascular abnormalities arise and worsen because of the oxidative stress, inflammation, and growth factors released by chronic hyperglycaemia, including vascular endothelial growth factor (VEGF). These abnormalities include haemorrhages, exudates, micro-aneurysms, and eventually neovascularization and fibrosis, which, if ignored, can cause blindness or vision impairment.(16) Dyslipidaemia may exacerbate retinal damage by increasing oxidative stress. Several studies have shown a strong association between dyslipidaemia and the severity of diabetic retinopathy (DR). Elevated levels of low-density lipoprotein cholesterol (LDL-C) and triglycerides are linked to an increased risk and progression of this disease.(17)

The present study included 160 patients fulfilling inclusion criteria, with a mean age of 56.66±8.16yrs of age. Among them, 49.4% were female and 50.6% were male. Like the present study, Ezhilvendhan K et al., documented with a mean age of 57.8±5.8yrs and there was no significant difference with retinopathy group. Also, there was marginal male preponderance like present study.(18) On fundus examination, retinopathy was present in 18.8% of the patients. Among them, 7.5% had severe NPDR, 6.3% with moderate grade, 3.1% with very severe, and 1.9% with mild NPDR. The American Diabetes Association (ADA) reports that over 28.5% of adult diabetics aged 40 years and older in the United States have diabetic retinopathy. This statistic is based on data from the National Health and Nutrition Examination Survey (NHANES) conducted between 2005 and 2008.(19,20) In patients with retinopathy, there were significantly elevated levels of random blood sugar, postprandial blood glucose, HbA1c, and a longer duration of diabetes mellitus compared to those without retinopathy ($p<0.05$).

Similar to the present study, Agrojya P et al., shown to be significantly positively correlated with systolic and diastolic blood pressure, LDL cholesterol, triglycerides, and 24-hour urine albumin when it comes to the severity of diabetic retinopathy. Additionally, Diabetic Retinopathy was very positively correlated with both the length of diabetes mellitus and the history of smoking. Diabetic Retinopathy showed a negative correlation with both eGFR and HDL cholesterol. The study found a strong correlation between the severity of diabetic retinopathy and blood lipid levels.(21) Another study in line with to present study by Ezhilvendhan K et al., documented that there is significantly higher FBS, PPBS, HbA1c, and duration of diabetes mellitus among the patients with diabetic retinopathy compared to patients without retinopathy.(18)

In patients with retinopathy, there were significantly higher levels of cholesterol, TGL, LDL, and VLDL, along with significantly lower levels of HDL, both during fasting and at the 6-hour postprandial period compared to those without retinopathy ($p<0.05$). Moreover, within the retinopathy group, the 6-hour sample showed even higher levels of these lipid parameters compared to the fasting sample ($p<0.05$). Conversely, in the group without retinopathy, while triglycerides and LDL levels were significantly higher at the 6-hour mark compared to fasting, changes in cholesterol and VLDL were not statistically significant. Additionally, there was a decrease in HDL levels, though not statistically significant.

In a study comparable to this one, Suryabham L et al. found that postprandial levels of serum total cholesterol,

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TGs, LDL-C, and VLDL-C were significantly elevated than those in the fasting state ($p<0.001$), and the postprandial and fasting states of the controls ($p<0.001$). In contrast to the fasting state, the postprandial state's blood HDL-C level was considerably lower ($p<0.001$). Furthermore, there was a significant difference ($p<0.001$) between the postprandial and fasting HDL-C levels and the values in the corresponding control groups. The results of this study showed that the lipid profile, a cardiovascular risk factor, was significantly higher in the postprandial state than it was in fasting. Additionally, it was higher in the Type 2 DM patients' postprandial and fasting states than in the corresponding control groups.(22)

A study by Madhu SV et al. shows that male type 2 diabetes individuals who received an oral fat challenge had a different postprandial (PP) response of blood triglycerides (TG) than controls. Even after accounting for fasting TG levels, the PP hypertriglyceridemia persisted and was evident in both diabetes patients and controls despite having comparable fasting TG levels.(23) According to other research, serum triglyceride levels have a significant role in how retinopathy develops. There is no correlation between blood lipid levels and diabetic retinopathy, according to a few additional research.(24)

Another study by Ezhilvendhan K et al., found that there is significantly higher mean level of cholesterol, LDL, TG and lower mean of HDL among patients with retinopathy compared to patients without retinopathy.(18) The serum triglyceride ($p= 0.001$) levels and total cholesterol ($P= 0.014$) were higher in patients with diabetic retinopathy as compared to those without diabetic retinopathy. This association was maintained even after adjusting for age, as age by itself is a significant risk factor for hyperlipidemia.(25) Similar results were obtained by Haddad et al.(26) The Hoorn study, a large population-based study to determine the potential risk factors for retinopathy in diabetic and non-diabetic individuals showed that retinopathy, and hard exudates in retinopathy in particular, are related to elevated serum total and LDL cholesterol levels.(27) Patients with diabetic retinopathy also showed decreased levels of HDL/LDL cholesterol ratio and increased levels of total and LDL cholesterol, according to studies by Agarwal et al. and Sachdev et al. These findings somewhat agree with the current study, which indicated that hypercholesterolemia, but not hypertriglyceridemia, was a risk factor for retinopathy.(28) Different research by Singh N et al., revealed that people with severe NPDR, very severe NPDR, and PDR had greater blood total cholesterol values than subjects without DR ($p<0.05$). There were no discernible changes in the lipid concentrations with the severity of DR, except for one measure. Even after controlling for age, length of diabetes, HbA1c, and albumin excretion rate, elevated triglycerides were still shown to be a significant risk factor for both proliferative and moderate and severe non-proliferative retinopathy and proliferative retinopathy in the EURODIAB trial.(29) However, Mathur A et al. discovered a link between diabetic retinopathy and serum lipids. There was a significant difference ($p<0.05$) in triglyceride levels between those with and without diabetic retinopathy, suggesting a positive correlation between triglycerides and the development of diabetic retinopathy. Conversely, no correlation was found between total cholesterol and low-density lipoprotein levels and the incidence of diabetic retinopathy. In contrast, a study by Cetin EN et al., concluded that lipid levels were not significantly associated with severity of diabetic retinopathy or existence of macular edema despite the significant correlation with mean blood glucose, HbA1c, and total cholesterol levels.(30) Consistent with this, Zhang et al.'s study discovered a favourable relationship between high blood triglyceride levels and the degree of DR in type 2 diabetes patients, even when other risk factors like hypertension and glycemic management were taken into account.(19) Likewise, a meta-analysis conducted by Sabanayagam et al. demonstrated a noteworthy correlation between dyslipidemia and Diabetic retinopathy, wherein elevated levels of lipoprotein-C were associated with an increased risk of Diabetic retinopathy advancement.(31)

In a study of 160 patients, the average age was 56.66 years, with an almost equal number of men and women. Retinopathy was detected in 18.8% of the participants, with varying levels of severity. There were no significant correlations between retinopathy and gender, history of hypertension, smoking, or alcohol use. They also had significant dyslipidemia, characterized by higher levels of cholesterol, triglycerides, LDL, and VLDL, and lower levels of HDL, especially during the 6-hour postprandial period. These findings emphasize the vital role of managing blood sugar & lipid levels in diabetic patients to prevent the onset and progression of retinopathy.

Conclusion

In this study involving 160 patients, the average age was 56.66 years, with a nearly equal gender distribution.

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Retinopathy was present in 18.8% of the patients, with varying severity levels, but no significant associations were found with gender or history of hypertension, smoking, or alcohol consumption. Physical parameters and vital signs also did not show significant alterations between patients with /without retinopathy. However, higher levels of random blood sugar, postprandial blood glucose, HbA1c, and longer duration of diabetes mellitus were seen in retinopathy patients. Additionally, they exhibited significant dyslipidaemia, with higher cholesterol, triglycerides, LDL, and VLDL & lower HDL levels, particularly evident during the 6-hour postprandial period. These findings underscore the importance of glycaemic control and lipid management in diabetic patients to prevent the development and progression of retinopathy.

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Table 1: Showing the severity of retinopathy

		Count	**N %**
Severity of NPDR	Absent	130	81.3%
	Mild	3	1.9%
	Moderate	10	6.3%
	Severe	12	7.5%
	Very severe	5	3.1%

Table 2: Comparison of fasting and 6th hr lipid profile between the groups

		Fundus examination for Retinopathy				**p-value**
		Absent		**Present**		
		Mean	**SD**	**Mean**	**SD**	
Fasting	Cholesterol	245.98	30.18	259.4	32.60	**0.03***
	Triglycerides	170.75	19.80	182.07	27.14	**0.01***
	LDL	125.17	15.921	136.27	21.86	**0.002***
	HDL	36.06	5.24	32.07	5.77	**0.05***

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	VLDL	34.15	3.96	37.42	5.42	**0.01***
6 hour	Cholesterol	248.47	30.9	282.83	31.94	**0.02***
	Triglycerides	183.10	24.75	194.90	28.37	**0.02***
	LDL	135.44	26.90	150.77	33.44	**0.008***
	HDL	34.19	5.35	31.17	5.78	**0.05***
	VLDL	36.62	4.95	42.98	5.67	**0.02***

Table 3: Comparison of lipid parameters at fasting and 6th hr in the retinopathy group using paired t-test

Retinopathy present		**Mean**	**SD**	**p-value**
Cholesterol	Fasting	259.40	32.609	**0.01***
	6hr	282.83	31.946	
Triglycerides	Fasting	182.07	27.146	**0.001***
	6hr	194.90	28.377	
LDL	Fasting	136.27	21.86	**0.04***
	6hr	150.77	33.44	
HDL	Fasting	32.07	5.777	**0.05***
	6hr	31.17	5.784	
VLDL	Fasting	37.413	5.4292	**0.001***
	6hr	42.980	5.6754	

Table 4: Comparison of lipid parameters at fasting and 6th hr. in the without retinopathy group using paired t-test

Retinopathy absent		**Mean**	**SD**	**p-value**
Cholesterol	Fasting	245.98	30.188	0.56
	6hr	248.47	30.964	
Triglycerides	Fasting	170.75	19.803	**0.01***
	6hr	183.10	24.757	
LDL	Fasting	125.17	15.921	**0.01***
	6hr	135.44	26.903	
HDL	Fasting	36.06	5.246	0.54
	6hr	34.19	5.351	
VLDL	Fasting	34.151	3.9606	0.63
	6hr	36.620	4.9515	