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**Dr. Venkataswamy**  
Associate Professor,  
Department of  
Ophthalmology,  
RVMIMS&RC, Siddipet,  
Telangana, India

**Dr. Chinthala Narsaiah**  
Associate Professor,  
Department of  
Ophthalmology,  
RVMIMS&RC, Siddipet,  
Telangana, India

**Dr. Manoj Patruni**  
Assistant Professor,  
Department of Community  
Medicine, RVMIMS&RC,  
Siddipet, Telangana, India

**Corresponding Author:**  
**Dr. Manoj Patruni**  
Assistant Professor,  
Department of Community  
Medicine, RVMIMS&RC,  
Siddipet, Telangana, India

## Study to ascertain the relation of lipid profile among diabetic retinopathy patients attending ophthalmology unit, RVM hospital, Siddipet, Telangana state

**Dr. Venkataswamy, Dr. Chinthala Narsaiah and Dr. Manoj Patruni**

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### Abstract

**Introduction:** According to WHO, diabetic retinopathy is responsible for 3-7% of the total blindness in Asia. According to the World Diabetes Atlas, India is projected to have around 77 million people with diabetes. Hyperglycemia and dyslipidemia are two major metabolic changes seen of diabetes mellitus. Diabetes is commonly accompanied by disturbances in the production and clearance of plasma lipoproteins.

**Methodology:** Hospital based observational study. This study was carried out in the department of Ophthalmology, RVM Hospital, Siddipet, Telangana state during the period of January 2019 to February 2020. Convenience sampling method and Stratified random method is used to collect the data. Study sample is 300. Data analyzed using SPSS (Statistical Presentation System Software) (version 21.0).

**Results:** Each group comprised of 53 males and 47 females. Mean age in each group was  $61.25 \pm 6.19$ ,  $56.94 \pm 5.97$  and  $61.85 \pm 6.77$  years. Among the study patients, the duration since diagnosis of diabetes mellitus ranged from 5-25 years. The mean duration in group 1 and group 2 was  $9.04 \pm 4.65$  and  $6.24 \pm 1.29$  years respectively. In the group 1, Mild NPDR retinopathy was present in 43 % of patients, moderate NPDR in 30 % of patients, severe NPDR retinopathy in 11% of patients, very severe NPDR in 7% and proliferative retinopathy in 9% of patients. Among these 30 patients (30%) had CSME. On observation of lipid sub fractions in DR subjects with and without CSME, it was found that mean serum cholesterol concentration was significantly higher in the retinopathy subjects with CSME as compared to those without CSME ( $p=0.001$ ).

**Conclusion:** The present study demonstrated statistically significant correlation between diabetic retinopathy and hypercholesterolemia.

**Keywords:** Diabetes, diabetic retinopathy, hyperglycemia, triglycerides

### Introduction

It is estimated that diabetes mellitus affect 9% percent of the world's population, almost half of whom have some degree of diabetic retinopathy at any given time <sup>[1, 2]</sup>. According to WHO, diabetic retinopathy is responsible for 3-7% of the total blindness in Asia <sup>[3]</sup>. In India the prevalence of diabetic retinopathy in general population is 3.5%. And the prevalence of diabetic retinopathy in the population with diabetes mellitus is 18% <sup>[4]</sup>. According to the World Diabetes Atlas, India is projected to have around 77 million people with diabetes <sup>[5]</sup>. There is a growing concern for Asia being the region for diabetic epidemic <sup>[5, 6]</sup>. Hyperglycemia and dyslipidemia are two major metabolic changes seen of diabetes mellitus. Diabetes is commonly accompanied by disturbances in the production and clearance of plasma lipoproteins. Moreover, development of dyslipidemia may be a harbinger of future diabetes. A characteristic pattern, termed diabetic dyslipidemia, consists of low high density lipoprotein (HDL), increased triglycerides, increased total cholesterol and postprandial lipemia <sup>[7]</sup>. This pattern is most frequently seen in type 2 diabetes.

**Aims & Objectives:** To study the relationship between diabetic retinopathy and serum lipid level and to evaluate the relationship between serum lipid levels and the severity of diabetic retinopathy.

**Methodology:** Hospital based observational study. This study was carried out in the department of Ophthalmology, RVM Hospital, Siddipet, Telangana state during the period of

January 2019 to February 2020. Prior to the study ethical clearance was obtained from RVM Institute Ethics Committee. During the study, verbal and written consent was obtained from all the study participants. Convenience sampling method and Stratified random method is used to collect the data. Study sample is 300, out of these, 100 diabetic patients with retinopathy are in study group and 100 diabetic patients with no retinopathy, 100 age and sex matched healthy persons were selected as controls. Inclusion Criteria: Type II diabetes mellitus cases, Patients with age of more than 40 years, duration of diabetes more than 5 years. Exclusion criteria: Patients with pupillary abnormalities which prevent adequate dilatation for fundus visualization and patients on hypolipidemic drugs.

**Statistical analysis:** Data analyzed using SPSS (Statistical Presentation System Software) (version 21.0). All group data were presented as frequency distribution (proportion) and the average values were presented as means ± SD for the normal distribution data. Following statistical methods were employed like, Descriptive statistics, One-way ANOVA and post hoc test, Chi-square test, Contingency

coefficient analysis. The minimal level of significance was set at  $p < 0.05$ .

**Results**

**Table 1:** Sex Distribution among study participants

Sex	Number of patients	Percentage
Male	53	53%
Female	47	47%
Total	100	100 %

Each group comprised of 53 males and 47 females. Mean age in each group was  $61.25 \pm 6.19$ ,  $56.94 \pm 5.97$  and  $61.85 \pm 6.77$  years.

**Table 2:** Age distribution and Duration of diabetes among the study participants

	Group 1	Group 2	Group 3
Age (years)	$61.25 \pm 6.19$	$56.94 \pm 5.97$	$61.85 \pm 6.77$
Duration of diabetes (years)	$9.04 \pm 4.65$	$6.24 \pm 1.29$	-

Among the study patients, the duration since diagnosis of diabetes mellitus ranged from 5-25 years. The mean duration in group 1 and group 2 was  $9.04 \pm 4.65$  and  $6.24 \pm 1.29$  years respectively

**Table 3:** Distribution of severity of diabetic retinopathy and presence of CSME (Clinically significant macular edema)

Type of Diabetic retinopathy	frequency	CSME
Mild NPDR	43 (43.0%)	17 (56.67%)
Moderate NPDR	30 (30.0%)	9 (30.0%)
Severe NPDR	11 (11.0%)	2 (6.67%)
Very Severe NPDR	7 (7.0%)	1 (3.33%)
PDR	9 (9.0%)	1 (3.33%)
Total	100 (100%)	30 (100%)

In the group 1, Mild NPDR retinopathy was present in 43 % of patients, moderate NPDR in 30 % of patients, severe NPDR retinopathy in 11% of patients, very severe NPDR in 7% and proliferative retinopathy in 9% of patients. Among these 30 patients (30%) had CSME.

**Table 4:** Lipid profile and severity of diabetic retinopathy among the study participants

Lipid profile	Category	Diabetic Retinopathy					Total	P value
		Mild NPDR	Moderate NPDR	Severe NPDR	Very severe NPDR	PDR		
Cholesterol	High	31 (72.1%)	17 (56.7%)	9 (81.8%)	6 (85.7%)	8 (88.9%)	71	0.016
	Normal	12 (27.9%)	13 (43.3%)	2 (18.2%)	1 (14.3%)	1 (11.1%)	29	
Triglycerides	High	39 (90.7%)	27 (90.0%)	10 (90.9%)	6 (85.7%)	9 (100%)	91	0.883
	Normal	4 (9.3%)	3 (10.0%)	1 (9.1%)	1 (14.3%)	0 (0%)	9	
HDL	Low	4 (9.3%)	3 (10.0%)	1 (9.1%)	3 (42.9%)	3 (33.3%)	14	0.06
	Normal	39 (90.7%)	27 (90.0%)	10 (90.9%)	4 (57.1%)	6 (66.7%)	86	
LDL	High	2 (4.7%)	5 (16.7%)	0 (0%)	1 (14.3%)	0 (0%)	8	0.212
	Normal	41 (95.3%)	25 (83.3%)	11 (100%)	6 (85.7%)	9 (100%)	92	

In group 1, most of the patients, had raised total cholesterol (67%) and raised triglyceride levels (91%). However elevated total cholesterol was statistically significant ( $p = 0.016$ ).

**Table 5:** Mean value of various lipid sub fractions and CSME

Mean	With CSME	Without CSME
Total Cholesterol	$239.2 \pm 25.5$	$205.0 \pm 53.2$
Triglycerides	$249.1 \pm 70.6$	$234.5 \pm 64.7$
HDL	$50.4 \pm 9.1$	$45.3 \pm 8.7$
LDL	$99.3 \pm 34.3$	$95.6 \pm 23.4$
FBS	$129.1 \pm 48.9$	$135.7 \pm 59.5$
PPBS	$205.0 \pm 62.9$	$222.9 \pm 96.5$

On observation of lipid sub fractions in DR subjects with and without CSME, it was found that mean serum cholesterol concentration was significantly higher in the retinopathy subjects with CSME as compared to those without CSME ( $p = 0.001$ ).

**Table 6:** Severity of diabetic retinopathy and visual acuity among the study participants

Visual Acuity	Mild NPDR	Mod. NPDR	Sev. NPDR	V.Sev. NPDR	PDR
6/6	4 (9.3%)	9 (30.0%)	2 (18.2%)	--	--
6/9 - 6/12	16 (37.2%)	7 (23.4%)	7 (63.6%)	--	5 (55.6%)
6/18 - 6/36	23 (53.5%)	13 (43.3%)	2 (18.2%)	6 (85.7%)	3 (33.3%)

≤ 6/60	--	1 (3.3%)	--	1 (14.3%)	1 (11.1%)
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Visual acuity did not show a linear trend for the severity of diabetic retinopathy. Most of these patients were old and had various types and grades of cataract, correction for which could not be done.

**Table 7:** Visual acuity and serum lipid levels among the study participants

Lipid parameters	Visual acuity		
	6/6	6/9 – 6/36	≤ 6/60
Total Cholesterol	201.8 ± 42.5	201.08 ± 38.6	208.81 ± 46.3
Triglycerides	186.0 ± 41.7	168.29 ± 52.3	159.43 ± 54.6
HDL	42.53 ± 7.73	42.53 ± 11.6	46.4 ± 11.6
LDL	123.74 ± 7.73	128.76 ± 7.73	131.47 ± 11.6

On observation the concentrations of serum lipids with different levels of visual acuity. There were no significant differences in lipid concentrations with different grades of vision.

## Discussion

In the present study, 200 patients having type II diabetes mellitus of age group ranging from 45 to 80 years were studied. 100 age and sex matched controls were also studied. The patients were categorized with respect to the presence or absence of diabetic retinopathy. In the group having retinopathy, patients were sub categorised depending on the grade of retinopathy and presence or absence of CSME. The present study had a nearly similar sex distribution with slight male predominance. The male to female ratio [M: F] was 53: 47. In a clinical cohort in Chennai diabetic retinopathy appeared to be prevalent more in the males compared to females (sex ratio 2: 1)<sup>[8]</sup>. Similar male preponderance was reported in the CURES Eye study<sup>[9]</sup>, Gupta *et al.*<sup>[10]</sup> and the Andhra Pradesh Eye Disease study (APEDS)<sup>[11]</sup>. However the difference with respect to the sex distribution was not statistically significant in the current study ( $p = 1$ ). The Mean age in each group was 61.25±6.19, 56.94±5.97 and 61.85±6.77 years. The relationship of retinopathy with age was in concordance to that found in many other studies. Like several other epidemiologic studies, this study also showed an increased prevalence of DR with increasing age. CURES Eye Study<sup>[12]</sup>, Dondana *et al.*<sup>[13]</sup> also have found significant correlation between the patient age and diabetic retinopathy. In the present study, the duration since diagnosis of diabetes (diabetic age) ranged from 5 – 25 years. The mean duration of diabetes in group 1 and group 2 was 9.04±4.65 and 6.24±1.29 years respectively. The association of longer duration with a higher the risk of DR ( $p=0.000$ ) was in accordance with previously published reports WESDR/Klein *et al.*<sup>[14]</sup>, Larsson *et al.*<sup>[15]</sup>, Wong *et al.*<sup>[16]</sup>. It is obvious that patients with retinopathy significantly had a longer mean duration of diabetes. In India, virtually all studies have shown an increased prevalence of DR as the duration of diabetes increased (Gupta *et al.*<sup>[18]</sup>, APEDS study<sup>[11]</sup>, Agarwal *et al.*<sup>[21]</sup>). The CURES Eye study has found that for every five year increase in duration of diabetes, the risk for DR increased by 1.89 times<sup>[11]</sup>.

The present study showed statistically significant correlation between diabetic retinopathy and raised total cholesterol level ( $p = 0.016$ ). Increased cholesterol level was significantly associated with the occurrence of all grades of retinopathy. The mean value of total cholesterol in group1, group 2, and group 3 were 229.09±30.01mg/dl, 215.32±49.15 mg/dl and 152.55± 26.52 mg/dl respectively. The mean total cholesterol was higher in group 1 as compared to group 2 and group 3. The mean triglyceride level was also higher in group 1 as compared to group 2 and group 3. However this correlation was not statistically

significant ( $p = 0.8$ ). Al-Bdour *et al.*, while investigating the risk factors associated with diabetic retinopathy among diabetic patients, found positive relation between diabetic retinopathy and hypercholesterolemia ( $p=0.04$ ). This finding is in accordance with the findings of the present study<sup>[17]</sup>. Larsson *et al.*, also found significant correlation between higher levels of serum total cholesterol and retinopathy. In the present study although both total cholesterol and triglyceride levels were elevated in group 1 as compared to group 2 and group 3, only hypercholesterolemia was statistically significant. Rema *et al.* (CURES eye study) studied the association of serum lipids with diabetic retinopathy in urban South Indians. 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. The Hoorn Study, a large population based study to determine the potential risk factors for retinopathy in diabetic and nondiabetic individuals showed that retinopathy, and hard exudates in retinopathy in particular, are related to elevated serum total and LDL cholesterol levels. Agarwal *et al.*<sup>[21]</sup> and Sachdev *et al.*<sup>[22]</sup> also observed raised level of total and LDL cholesterol and reduced level of HDL/LDL cholesterol ratio in patients with diabetic retinopathy. These results are partly in concordance with the present study as hypercholesterolemia but not hypertriglyceridemia was found to be a risk factor for retinopathy in the current study. The present study found a significant association between hypocholesterolemia and CSME ( $p=0.003$ ). This was in accordance with the study by Al-Bdour *et al.* Who found significant association between the development of diabetic maculopathy and hypercholesterolemia<sup>[18]</sup>. Higher total cholesterol level was positively associated with presence of CSME, in a cross-sectional analysis of participants with diabetes in the Wisconsin Epidemiological Study of Diabetic Retinopathy (WESDR). The present study did not find correlation between serum lipid levels and visual acuity. This may be because of the fact that most of the patients included in the study had various types and grades of cataract and correction for the same could not be done during statistical analysis. CURES eye study showed that visual acuity decreased with increase in severity of retinopathy<sup>[9]</sup>. ETDRS study has found that elevated serum cholesterol at baseline increased the risk of visual loss by 50% compared to lower serum cholesterol levels<sup>[23]</sup>.

## Conclusion

Numerous studies have shown an association of lipid fractions with macrovascular complications of diabetes (e.g. coronary artery disease), while relatively few have looked at

the association of serum lipids with microvascular complications such as diabetic retinopathy and the available results are conflicting. The present study demonstrated a statistically significant correlation between diabetic retinopathy and hypercholesterolemia. Increased cholesterol level was significantly associated with the occurrence of all grades of retinopathy especially severe NPDR, very severe NPDR and PDR. It also showed that hypercholesterolemia is significantly associated with CSME. No correlation was found between lipid profile and visual acuity. Further studies are required to establish the causal relationship between dyslipidemia and diabetic retinopathy. If established, these data can lend additional support to current treatment guidelines recommending aggressive lowering of elevated lipids among diabetic patients, thereby potentially improving quality of life and vision among people with type 2 diabetes.

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