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*Original Research Article*

# Association of Lipid Profile with Diabetic Retinopathy - A Comparative Study

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## ABSTRACT

Diabetic retinopathy (DR) remains a leading cause of visual disability and blindness. It is a major microvascular complication of diabetes and is frequently accompanied by lipid exudation. Dyslipidemia leads to development of hard exudates and Clinically Significant Macular Edema (CSME). These, in turn, interfere with vision. The elevated lipid levels are associated with endothelial dysfunction which appears to play an important role in the pathogenesis of Diabetic Retinopathy, particularly in relation to breakdown of blood-retinal barrier. The current study was undertaken to determine the association of serum lipid profile with diabetic retinopathy and its severity. 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 subcategorized depending on the severity / grade of retinopathy and presence or absence of CSME. All the three groups had a near equal sex distribution with only a slight male predominance. A significant correlation was found between the patient age and diabetic retinopathy. In the present study, the duration since diagnosis of diabetes (diabetic age) ranged from 5 - 25 years. It is found that patients with retinopathy significantly had a longer mean duration of diabetes as compared to those diabetics without retinopathy. Most of the diabetics included in the study had poor glycemic control suggested raised FBS and PPBS levels. The mean values of FBS and PPBS were higher in group 1 (diabetics with diabetic retinopathy) as compared to that in group 2 (diabetics without diabetic retinopathy), reinforcing the fact that the development and progression of DR is influenced by the level of hyperglycemia. The present study showed statistically significant correlation between diabetic retinopathy and raised total cholesterol level ($p = 0.016$). Hypercholesterolemia was significantly associated with the occurrence of diabetic retinopathy and CSME. Mean serum total cholesterol concentrations were higher in subjects with severe NPDR, very severe NPDR and PDR as compared with subjects without DR ($p=0.046$). No correlation was found between diabetic retinopathy and visual acuity. Thus, this study reinforces the observation that there is a strong association between dyslipidemia and diabetic retinopathy including CSME.

***Key words:*** Diabetes Mellitus, diabetic retinopathy, clinically significant macular edema, dyslipidemia, hyperglycemia.

## INTRODUCTION

It is estimated that diabetes mellitus affects 4 percent of the world's population, almost half of whom have some degree of diabetic retinopathy at any given time. [1,2] Diabetic retinopathy is a very common, potentially preventable, long-term, microvascular complication of Diabetes Mellitus and a leading cause of visual disability and blindness. [3] It is considered

the hallmark of generalized microangiopathy occurring in a diabetic patient. 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 was 18.0%6. In a population-based study in South India, diabetic retinopathy was detected in 1.78% of the diabetic patients screened. [4,5]

While there are multiple risk factors which have been associated with the development and progression of diabetic retinopathy, the duration of the disease and the age of the patient are said to be the strongest predictors. Other risk factors like hypertension, pregnancy, blood glucose level control and presence of nephropathy are shown to have a strong association. Dyslipidemia, microalbuminuria, BMI and smoking are some of the factors whose role as predictors of diabetic retinopathy is not well established. [6-8]

Diabetic retinopathy is frequently accompanied by lipid exudation. [9] Elevated serum lipid levels are associated with an increased risk of retinal hard exudate in persons with diabetic retinopathy. Although retinal hard exudate usually accompanies diabetic macular edema, increasing amounts of exudate appear to be independently associated with an increased risk of visual impairment. [10] The elevated lipid levels are also associated with endothelial dysfunction, which appears to play an important role in the pathogenesis of diabetic retinopathy, particularly in relation to the breakdown of blood-retinal barrier.

The association between serum lipid levels and diabetic retinopathy has been investigated in few studies. Some studies show a positive relationship between serum cholesterol and low-density lipoprotein levels and retinal hard exudation. Other studies show serum triglyceride levels as being important in the progression of retinopathy. Certain other studies show no relationship between serum lipid levels and diabetic retinopathy. [11]

The current study was undertaken to determine the association of serum lipid profile with diabetic retinopathy and its severity. The conflicting reports in the literature regarding the association between serum lipid levels and diabetic retinopathy and the paucity of studies relative to the existing case load warranted this study.

## MATERIALS AND METHODS

The study was carried out in the department of Ophthalmology, K R Hospital, and Mysore during the period of December 2010 to December 2011 after obtaining ethical clearance. 300 patients, out of these, 100 diabetic patients with retinopathy served as the study group and 100 diabetic patients with no retinopathy formed the control group. Simultaneously, 100 age and sex matched healthy persons were also studied as controls. Study subjects were allocated to one of the following three groups:

**Group I:** Diabetic patients with different stages of retinopathy includes 100 patients

**Group II:** Diabetic patients without retinopathy includes 100 patients

**Group III:** Non-diabetic control persons includes 100 patients

Criteria for inclusion were patients with Type II diabetes mellitus cases - established cases [on anti diabetic medications] aged of more than 40 years with duration of diabetes more than 5 years. Patients with significant hazy media which impairs visualization of the fundus, those with pupillary abnormalities which prevent adequate dilatation for fundus visualisation, those on hypolipidemic drugs and those who have been treated earlier with either LASER or Intravitreal anti-VEGF injections were excluded from the study

Data was collected using a piloted proforma meeting the objectives of the study after an informed consent. A detailed history of each patient was obtained regarding the age, duration of diabetes, the antidaibetic treatment they were on and any associated illness. The duration of diabetes was reckoned from the time of diagnosis.

All the study subjects had a thorough ophthalmic evaluation which included slit-lamp biomicroscopic examination of anterior segment, best corrected visual acuity (BCVA) of each eye was recorded using Snellen chart, detailed fund us examination after mydriasis with 1% tropicamide and 5% phenylephrine eye drops using direct ophthalmoscopy, indirect ophthalmoscopy with +20D lens and stereoscopic slit lamp biomicroscopy of the disc and macula using + 78D Volk lens. All cases were examined for the presence or absence of diabetic retinopathy. Those cases with fund us showing features of diabetic retinopathy were graded into five classes on the basis of ETDRS classification. Thus, a total of six categories were made based on the fund us picture of the patients -

1. No diabetic retinopathy.
2. Mild NPDR.
3. Moderate NPDR.
4. Severe NPDR.
5. Very severe NPDR.
6. PDR.

Patients with diabetic retinopathy were further subclassified into 2 groups based on presence or absence of CSME. Fasting blood sample was collected under asepsis from the anterior cubital vein using disposable syringe to assess lipid profile and blood sugar level. Postprandial blood sugar level estimation was also done.

Dyslipidemia was defined using NCEP ATP III guidelines as:
Total cholesterol ≥ 200 mg/dl
HDL cholesterol < 40 mg/dl
LDL cholesterol ≥ 100 mg/dl
Triglycerides ≥ 150 mg/dl

The data obtained was then compared with each grade of diabetic retinopathy and its association with each of the three groups was determined statistically. Data was analysed using SPSS (Statistical Presentation System Software) for windows software (version 16.0). All group data were presented as frequency distribution (proportion) and the average value was presented as means ± SD for the normal distribution data. The minimal level of significance was set at $p<0.05$.

## RESULTS

Subjects were divided into 3 groups.
**Group 1:** diabetics with diabetic retinopathy
**Group 2:** diabetics without retinopathy
**Group 3:** nondiabetics

Each group comprised of 53 males and 47 females. (fig.1) Mean age in each group was 61.45 ± 6.99, 57.96 ± 6.07 and 61.05 ± 7.47 years. The duration since diagnosis of diabetes mellitus (diabetic age) ranged from 5-25 years. The mean duration in group 1 and group 2 was 9.04 ± 4.65 and 6.24 ± 1.29 years respectively. 74% of the patients in group 1 and 79% in group 2 were on oral hypoglycemic (OH).(tab.1)

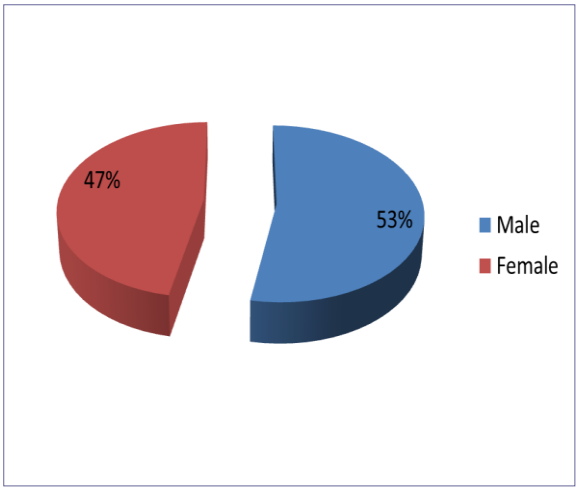


**Figure 1: Diagram showing sex distribution**

**Table 1: Age, duration and treatment modality**

| | | Group 1 | Group 2 | Group 3 |
|---|---|---|---|---|
| Age (years) | | 61.45±6.99 | 57.96±6.07 | 61.05±7.47 |
| Duration of diabetes (years) | | 9.04±4.65 | 6.24±1.29 | - |
| Treatment modality | OH | 74% | 79% | - |
| | Insulin | 26% | 21% | - |

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 theses 30 patients (30%) had CSME. (tab.2)

**Table - 2: Distribution of severity of diabetic retinopathy and presence of CSME**

| Diabetic retinopathy grade | 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%)** |

**Table - 3: Mean values of lipid subfraction in each group**

| Mean | Group 1 | Group 2 | Group 3 |
|---|---|---|---|
| Total Cholesterol | 229.09±30.01 | 215.32±49.15 | 152.55± 26.52 |
| Triglycerides | 238.95±66.53 | 179.93±20.49 | 129.51±15.44 |
| HDL | 46.9±9.10 | 51.33±13.76 | 53.38±7.98 |
| LDL | 96.78±27.07 | 131.93±16.39 | 101.02±17.33 |
| FBS | 133.73±56.41 | 104.57±35.33 | 83.08±12.66 |
| PPBS | 217.6±87.86 | 179.75±20.49 | 124.88±12.17 |

The mean value of total cholesterol was higher in both group 1 and group 2 with value being higher in group 1 (229.09mg/dl) as compared to group 2 (215.32mg/dl). Triglyceride levels also followed the similar trend with group 1 having mean value of 238.95mg/dl and group 2 having 179.93 mg/dl. (tab.3)

**Table - 4: Lipid profile and severity of diabetic retinopathy**

| 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 | |
| | Normal | 12(27.9%) | 13(43.3%) | 2(18.2%) | 1(14.3%) | 1(11.1%) | 29 | 0.016 |
| 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 | |

**Table–5: Mean values of the lipid subfractions in subjects categorized according to severity of diabetic retinopathy**

| Lipid parameter | Mild NPDR | Mod.NPDR | sev.NPDR | v.sev.NPDR | PDR | Group 2 |
|---|---|---|---|---|---|---|
| Cholesterol | 215.6±30.6 | 221.3±49.4 | 235.0±39.7 | 234.4±44.7 | 254.67±35.6 | 229.0±30.0 |
| Triglyceride | 241.1±16.9 | 232.4±18.8 | 245.7±22.2 | 231.0±26.7 | 243.0±13.6 | 179.9±20.4 |
| HDL | 48.7±9.1 | 47.5±4.9 | 45.72±10.8 | 40.4±7.8 | 42.56±10.8 | 51.3±13.7 |
| LDL | 92.1±18.9 | 106.03±20. | 80.45±22.3 | 97.8±13.7 | 166.22±27.0 | 131.9±16.3 |

**Table - 6: Glycemic control and severity of diabetic retinopathy**

| Blood sugar | | Diabetic retinopathy | | | | | Total | p value |
|---|---|---|---|---|---|---|---|---|
| | | Mild NPDR | Moderate NPDR | Severe NPDR | Very severe NPDR | PDR | | |
| FBS | High | 27(62.8%) | 16(53.3%) | 9(81.8%) | 4(57.1%) | 9(100%) | 65 | 0.003 |
| | Normal | 16(31.2%) | 14(46.7%) | 2(18.2%) | 3(42.9%) | 0(0%) | 35 | |
| PPBS | High | 29(67.4%) | 24(80.0%) | 11(100%) | 6(85.7%) | 9(100%) | 79 | 0.061 |
| | Normal | 14(32.6%) | 6(20.0%) | 0(0%) | 1(14.3%) | 0(0%) | 21 | |

**Table - 7: Mean values of the blood sugar levels in subjects categorized according to severity of diabetic retinopathy**

| Mean | Group 1 | Group 2 | Group 3 |
|---|---|---|---|
| FBS | 133.73±56.41 | 104.57±35.33 | 83.08±12.66 |
| PPBS | 217.6±87.86 | 179.75±20.49 | 124.88±12.17 |

In group 1, most of the patients, in all severity groups had raised total cholesterol (67%) and raised triglyceride levels (91%). However only the rise in total cholesterol was statistically significant (p= 0.016). (tab.4)

Serum total cholesterol concentrations were higher in subjects with severe NPDR, very severe NPDR and PDR compared with subjects without DR (p =0.046). (tab.5)

Most of the subjects in group 1 had uncontrolled diabetes suggested by elevated FBS and PPBS levels.(tab.6) Mean FBS level and PPBS levels were higher in group1 as compared to group 2. (tab.7)

**Table - 8: Mean value of various lipid subfractions and CSME**

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

When the lipid subfractions in DR subjects with and without CSME were analysed 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). (tab.8)

## DISCUSSION

It is believed that the Indian population generally has an unusually efficient glucose metabolism. But with westernisation and the associated weight increase and sedentary lifestyle, the former advantage is lost and incidence of diabetes has increased. Paralleling this high prevalence of diabetes is a concern that the complications of diabetes, mainly diabetic retinopathy is increasing. [12]

Hyperglycemia and dyslipidemia are two major metabolic disorders seen in patients with diabetes mellitus. The role of diabetic dyslipidemia in the development of microvascular complications has received much less attention. [13] This study aimed to determine the relationship between plasma lipid profile and the severity of diabetic retinopathy in type 2 diabetes patients.

The present study had a near equal sex distribution with only a 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). [14] Similar male preponderance was also seen in the CURES Eye study, [15] UKPDS study [16] Gupta et al [17] and the Andhra Pradesh Eye Disease study (APEDS). [18] However the difference with respect to the sex distribution was not statistically significant in the current study (p =1).

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. Dondana et al, [4] CURES Eye Study [15] and APED Study [18] 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. There may be some bias in estimating the real duration of diabetes in these patients, as the discovery of diabetes could have been delayed due to lack of symptoms and the insidious onset of type 2 diabetes. 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 (UKPDS, [16] DCCT, [19] WESDR/Klein et al, [20] Larsson et al, [21] Wong et al, [22] Varma et al [23] Wisconsin Epidemiological Study of Diabetic Retinopathy (WESDR) also found that risk of retinopathy is directly related to the duration of diabetes. [20] In India, virtually all studies have shown an increased prevalence of DR as the duration of diabetes increased [24] (Gupta et al, [17] APEDS study, [18] Agarwal et al. [25]

In the present study most of the subject in the group 1 had poor glycemic control suggested by raised FBS and PPBS levels. The CURES Eye Study observed a linear trend between prevalence of DR and poor glycemic control. [15] Wisconsin Epidemiological Study of Diabetic Retinopathy (WESDR) found that risk of retinopathy is related to the control of blood glucose levels. [25]

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 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 [7] and Larsson et al [21] also found significant correlation

between higher levels of serum total cholesterol and retinopathy. Rema et al (CURES eye study) [15] and Haddad et al [26] found that both 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. 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.

In contrast to the present study, Gupta et al [17] demonstrated that diabetics with raised LDL levels showed higher prevalence of Diabetic retinopathy (38%) compared to others (28.3%) (p=0.05). Lyons et al [19] and the EURODIAB Complications Study [28] found that triglyceride level was related to all levels of retinopathy.

The present study found a significant association between hypercholesteremia and CSME (p=0.003). This was in accordance with the study by Al-Bdour et al [7] Wisconsin Epidemiological Study of Diabetic Retinopathy (WESDR) [8] and CURES eye study. [11]

The drawbacks of the study are that the fundus photograph, which is the standard pattern of recording of fundus changes were not taken for all patients. In such conditions it is more common to underestimate than to overestimate fundus changes related to diabetic retinopathy. In the present study CSME was diagnosed by Slit lamp biomicroscopy with 78D/ 90D lens. Because of the non-availability, the newer, the more sensitive method of assessing retinal thickening such as with optical coherence tomography were not used. The study did not evaluate other risk factors for the development of retinopathy like anemia. Also, the referral of uncontrolled diabetics to the tertiary centre would have allowed the possibility of selection bias to creep into the study.

## CONCLUSION

The present study demonstrated 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. The current treatment for diabetic retinopathy is laser photocoagulation. With the advent of systemic lipid lowering therapy over the last decade, there may be potential for medical therapy also. There is some anecdotal evidence of the effect of lipid lowering agents in reducing hard exudates. [9] 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. Rigorous lipid control, in addition to its known health benefits in preventing cardiovascular disease, may also lessen ocular morbidity and associated health care costs, thereby potentially improving quality of life and vision among people with type 2 diabetes.

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