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To study the association of dyslipidemia with macular edema and hard exudates in diabetic maculopathy in an industrial hospital in Chhattisgarh

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ABSTRACT

Purpose: To study the affect of LDL cholestrol, HDL cholestrol and triglycerides with diabetic maculopathy in type 2 diabetic patients.
Materials and Methods: An informed written consent was obtained in every case.
A 5ml blood sample was withdrawn. All the patients detailed history, general physical examination and ocular examination including visual acuity, intraocular pressure by applanation tonometry, slit lamp examination and fundus examination by biomicroscopy were done. Optical coherence tomography and fundus photograph were also taken.
Conclusion: Patients who were having diabetic retinopathy had higher values of LDL and total cholestrol as compared to those who were not having diabetic retinopathy.
Patients who were having diabetic retinopathy changes had non-significant differences in the level of HDL and triglycerides as compared to those who were not having diabetic retinopathy changes.
Patients with changes of diabetic retinopathy had significantly higher values of foveal thickness as compared to those without changes of diabetic retinopathy. Foveal thickness had correlation with total cholesterol levels.

1. Introduction

Diabetic retinopathy is most common complication of diabetes mellitus.[1] It is one of the leading causes of blindness among working-aged adults around the world.[2] In spite of being potentially serious problem, and the highly prevalence of diabetes in India, there are few precise contemporary estimates of the worldwide prevalence of diabetic retinopathy.[2] According to a study based on National Survey 2015-19, the prevalence of diabetic retinopathy among diabetic patients was 16.9%, while the prevalence of sight-threatening diabetic retinopathy and mild retinopathy was 3.6%, and 11.8% respectively.[3]

Types of diabetic retinopathy

1. Non-proliferative Diabetic retinopathy. The fundus findings of non-proliferative DR (NPDR) are micro-aneurysms, dot and blot hemorrhages, splinter hemorrhages, cotton wool spots and intraretinal micro vascular abnormalities.
2. Proliferative Diabetic retinopathy (PDR) is characterized by the growth of subtle new blood vessels on the surface of the retina which are suggestive of neovascularisation. These abnormal vessels bleed easily, resulting in vitreous hemorrhage, subsequent fibrosis, and tractional retinal detachment.[4]

Diabetic macular edema is the common cause of decreased vision from diabetic retinopathy. The decrease in vision is due to an increase in the amount of extracellular fluid within the retina which further leads to distortion of the retinal architecture. It frequently takes on a pattern of cystoid

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macular edema. This accumulation of fluid within the retina is because of the disruption of the barriers within the blood vessels and possibly the pigment epithelium of retina.[5] The increasing incidence of diabetes across the globe suggests that diabetic retinopathy and diabetic macular edema will be major contributors to loss of vision and associated functional impairment for years to come.[6]

Macular edema can be of two types, focal and diffuse.

1. Focal macular edema is characterized by areas of focal leakage on fluorescein angiography from specific capillary lesions (microaneurysms, segments of dilated capillaries), which often is accompanied by surrounding hard exudates rings. This signifies focal area of breakdown of inner blood retinal barrier.
2. Diffuse macular edema is characterized by enhanced visibility of retinal capillary bed, diffuse leakage of the fluorescein, scarcity of hard exudates and in severe cases, cystoids macular edema.[7,8]

Evidence from observational studies have found a link between serum lipids and diabetic eye disease. Elevated total and LDL cholesterol levels, and triglycerides were associated with progression of retinopathy, proliferative retinopathy, and the development of macular edema. Besides, a high total cholesterol to HDL cholesterol ratio and elevated LDL cholesterol were each associated with the development of clinically significant macular edema.[9] Increased lipid concentrations are known to cause endothelial dysfunction due to reduction in the bioavailability of nitric oxide. Lipid peroxidation in lipoproteins in the vascular wall causes a local increase in the levels of reactive carbonyl species which causes recruitment of macrophages, cellular activation, and proliferation by advanced lipo-oxidation end products. It affects the structure and function of the vascular wall. Consequently, it was proposed that, hyperlipidemia might contribute to diabetic retinopathy and macular edema by endothelial dysfunction and breakdown of the blood retinal barrier leading to exudation of serum lipids and lipoproteins. Dysfunctional vascular endothelium is considered as one of the important factor in the pathology of diabetic vascular complications.[10]

1.1. Hard exudates

Retinal hard exudates are common finding in the patients of diabetic retinopathy. These hard exudates are composed of lipo-proteinaceous material (fibrinogen and albumin) that leaks from the compromised blood–retinal barrier. They get deposited in the outer plexiform layer of the retina.[11] Higher total and LDL cholesterol were associated with the presence of hard exudates with type 2 diabetes.[12] Studies have shown that elevated serum lipid levels have a significant association with retinal hard exudate formation in type 2 diabetics. Hypolipidemic agents help in reducing the occurrence of these retinal findings in diabetic patients.[13]

Screening and prompt treatment of diabetic retinopathy are still not among the top healthcare priorities in many regions across the globe, because the impact of other causes of preventable blindness remain an issue.[14] This study aims to study the association of dyslipidemia with macular edema and hard exudates in diabetic maculopathy. We plan to evaluate the effect of LDL cholesterol, HDL cholesterol and triglycerides with diabetic maculopathy in type 2 diabetic patients.

2. Materials and Methods

2.1. Study site

Department of Ophthalmology, Jawaharlal Nehru Hospital and Research Centre, Bhilai (Chhattisgarh), India.

2.2. Study population

Patients attending the Department of Ophthalmology, J.L.N. Hospital and Research Centre, Bhilai who fulfilled the inclusion and exclusion criteria were enrolled into the study.

2.3. Study design

A hospital based prospective and observational study.

2.4. Sample size

Patients with type 2 DM with changes of diabetic retinopathy including clinically significant macular edema and hard exudates.

2.5. Estimated sample size

40 patients.

Golubovic-Arsovska M found diabetic patients that manifested diabetic maculopathy had significantly higher values of total lipids 9.49 ±2.02 g/L vs 8.06 ±0.84 g/L as compared to the control group with DM type 2 without changes associated with diabetic maculopathy.

So,

M1±SD1=9.49 ± 2.02 M2±SD2=8.06 ± 0.84

N = minimum required sample size in each of the groups

D = difference in mean =1.43

SD2 = Squared pooled deviation=0.84

1.96 = conventional multiplier for alpha 0.05

1.26= conventional multiplier for power 90%

Minimum sample size is N= (2[(1.96+1.26)]^2 [SD]^2)/D^2

= 2(10.37)(0.84)/(1.43)2 =36 minimum samples in each group

(36 is minimum sample size in each group, any sample size greater than 36. . . i.e., 40, 45 can be taken. It will reduce

the chance of losing data and will further increase the power of the study).

2.6. Study duration

February 2021 to November 2021.

2.7. Inclusion criteria

This study included 80 patients diagnosed with type 2 diabetes mellitus fulfilling all the exclusion criteria attending department of ophthalmology, outpatient department of JLN hospital, Bhilai. They were divided in two groups.

Group A- comprised 40 patients of type 2 diabetes mellitus with changes of diabetic retinopathy including clinically significant macular edema and hard exudates.

Group B- comprised of 40 patients of type 2 mellitus without associated changes of diabetic retinopathy

2.8. Exclusion criteria

1. Presence of coexistent proliferative retinopathy
2. Pseudophakia
3. Associated vascular occlusion
4. Hazy ocular media that obviated good clinical examination and fundus photography
5. Debilitating systemic illness that would not allow regular drink examination
6. Patients with uncontrolled hypertension
7. Patient already taking hypolipidemic drugs
8. Recent h/o ocular surgery and lasers within 6 months
9. Type 1 diabetes mellitus

Only one eye of each patient was included. In unilateral disease, affected eye was included. In bilateral disease, the more severely affect eye was included. If both eyes were affected gossamer extent the right will be included.

2.9. Ethical concern

The study had been carried with full permission from the ethical committee.

2.10. Methodology

This study included 80 patients diagnosed with type 2 diabetes mellitus fulfilling all the exclusion criteria attending department of ophthalmology, outpatient department of JLN hospital, Bhilai. They were divided in two groups.

Group A- comprised 40 patients of type 2 diabetes mellitus with changes of diabetic retinopathy including clinically significant macular edema and hard exudates.

Group B –comprised of 40 patients of type 2 mellitus without associated changes of diabetic retinopathy.

2.11. Statistical analysis

All data were tabulated in Microsoft Excel Worksheet (Microsoft office system 2020; Microsoft Corporation, Redmond, Washington, USA).

Interpretation and analysis of obtained results was carried out by using, Statistical Package for Social Sciences (SPSS 20.0) for windows.

The statistical analysis was done as follows:

The descriptive statistics were computed. Range, mean and standard deviation (SD) was estimated for quantitative variables and frequency counts with percentages for qualitative variables. Results were shown as the mean values + standard deviations. Then the inferential statistical analysis was done.

Continuous variables were compared using the unpaired t test, whereas the Mann-Whitney U test was used for those variables that was not normally distributed. Categorical variables was analyzed using either the chi square test. Pearson's correlation was performed to evaluate correlation between the variables of lipid profile with hard exudates.

Statistical significance

1. $P>0.05$ is not significant
2. $P<0.05$ is significant
3. $P<0.01$ is highly significant

3. Results

In group A, 22 patients (55%) were in the range of 40 to 59 years, 16 patients (40%) were between 60 to 79 years, and 2 patients (5%) were >80 years. In group B, 18 patients (45%) were between 40 to 59 years, and 22 patients (55%) were between 60 to 79 years. The mean age of patients in group A and group B is 60.77±9.83 years and 62.75±7.23 years, respectively. The difference between the mean age of the groups was non-significant (p-value 0.309).

In group A, there were 20 male patients (50%) and 20 female patients (50%). Male to female ratio is 1:1. In group B, there were 17 male patients (42.5%) and there were 23 female patients (57.5%). Male to female ratio is 1:1.35. The difference between the groups was non-significant (p-value 0.501).

In group A, the mean duration of diabetes mellitus was 10.55± 6.84 years while in group B, the mean duration of diabetes mellitus was 9.07± 4.45 years. The difference between the groups was non-significant (p-value 0.256).

In group A, 9 patients (22.5%) had diabetes for ≤5 years, 17 patients (68%) had diabetes for 6-10 years, 5 patients (12.5%) had diabetes for 11-15 years, 5 patients (12.5%) had diabetes for 16-20 years and 4 patients (10%) had diabetes for >20 years. In group B, 8 patients (20%) had diabetes for ≤5 years, 22 patients (55%) had diabetes for 6-10 years, 6 patients (15%) had diabetes for 11-15 years, 2 patients (5%) had diabetes for 16-20 years and 2 patients (5%) had diabetes for >20 years.

In group A, the mean fasting blood sugar was 184.57± 55.99 mg/dl while in group B, the mean fasting blood sugar was 165.92± 21.52 mg/dl. The difference between the groups was non-significant (p-value 0.052).

In group A, the mean HbA1C was 7.03± 0.38 while in group B, the mean HbA1C was 6.91± 0.29. The difference between the groups was non-significant (p-value 0.122).

In group A, the mean blood urea was 14.27±4.39 mg/dl while in group B, it was 15.05±4.21 mg/dl (non-significant; p-value 0.423). In group A, the mean serum creatinine was 0.84±0.14 mg/dl while in group B, it was 0.84±0.13 mg/dl (non-significant; p-value 0.793). In group A, the mean 24 hour urinary protein was 71.07±12.53 mg while in group B, it was 73.87±12.18 mg (non-significant; p-value 0.316).

In group A, the mean total cholesterol was 215.82±40.43 mg/dl while in group B, it was 168.25±41.39 mg/dl (significant; p-value <0.001). In group A, the mean LDL was 141.5±36.10 mg/dl while in group B, it was 100.12±69.75 mg/dl (significant; p-value 0.0013). In group A, the mean HDL was 47.67±5.95 mg/dl while in group B, it was 47.82±6.15 mg/dl (non-significant; p-value 0.91). In group A, the mean triglycerides was 130.2±22.75 mg/dl while in group B, it was 129.75±23.62 mg/dl (non-significant; p-value 0.93).

In group A, the mean foveal thickness was 341.32±69.86 μm while in group B, it was 236.47±11.01 μm. The difference between the groups was significant (p-value <0.0001).

In group A, the correlation coefficient of foveal thickness with total cholesterol, LDL, HDL, and triglycerides was 0.606, 0.528, 0.035 and 0.035 respectively.

In group A, 4 patients had grade 1 hard exudates, 9 patients had grade 2 hard exudates, 11 patients had grade 3 hard exudates, 6 patients had grade 4 hard exudates, and 10 patients had grade 5 hard exudates. The correlation coefficient of hard exudates with total cholesterol was 0.43. The correlation coefficient of hard exudates with LDL was 0.511. The correlation coefficient of hard exudates with HDL was 0.197. The correlation coefficient of hard exudates with triglycerides was 0.0035.

4. Discussion

The present study was conducted in Jawaharlal Nehru Hospital and Research Centre, Bhilai (Chhattisgarh). This was a prospective, and observational study to study the association of dyslipidemia with macular edema and hard exudates in diabetic maculopathy. 80 patients who attended the department of Ophthalmology were included in the study. They were divided in two groups.

Group A- comprised 40 patients of type 2 diabetes mellitus with changes of diabetic retinopathy including hard exudates and clinically significant macular edema.

Group B- comprised 40 patients of type 2 mellitus without associated changes of diabetic retinopathy

The different factors found in the study can be discussed under following headings:

4.1. Age distribution

In the present study, in group A, 22 patients (55%) were between 40 to 59 years, 16 patients (40%) were between 60 to 79 years, and 2 patients (5%) were >80 years. The mean age of patients in group A is 60.77±9.83 years. In group B, 18 patients (45%) were between 40 to 59 years, and 22 patients (55%) were between 60 to 79 years. The mean age of patients in group B is 62.75±7.23 years. The difference between the mean age of the groups was non-significant (p-value 0.309). Our study was comparable with most of the studies; some of the following are as follows:

Idiculla J et al (2012) reported that age range of 32-85 years and mean (SD) of 56.41(+9.91) years.[13] Deepa C K et al (2021) reported that majority of diabetic patients were in the age group 61-70 years (58%). Mean age of patients was 58.07 ± 6.95 years.[15] Silpa D et al (2021) reported that 12% of the diabetic patients in <50 years, 45% in 51-60 years, 36.4% in 61-70 years and 6.6% in >70 years. Mean age was 59.8±7.4 years with highest being 86 and lowest 36 years.[16]

Decline in lean body mass and the increase in body fat particularly visceral adipocytes (“central obesity”) that accompanies aging may contribute to insulin resistance. It has recently been proposed that an age-associated decline in mitochondrial function contributes to insulin resistance in elderly.[17]

4.2. Gender distribution

In the present study, in group A, male patients were 20 (50%) and females were 20 (50%). Male to female ratio is 1:1. In group B, male patients were 17 (42.5%) and females were 23 (57.5%). Male to female ratio is 1:1.35. The difference between the groups was non-significant (p-value 0.501).

Silpa D et al (2021) reported that percentage distribution of the diabetic patients according to gender showed equal male: female ratio of 1:1.[16] Ezhilvendhan K et al. (2021) reported that majority of diabetes mellitus participants were males (57.5%) with a male: female of 1.35:1.[18]

4.3. Duration of diabetes mellitus

In group A, the mean duration of diabetes mellitus was 10.55± 6.84 years while in group B, the mean duration of diabetes mellitus was 9.07± 4.45 years. The difference between the groups was non-significant (p-value 0.256).

Prakash G et al. (2016) reported that diabetic retinopathy patients had longer diabetes duration (11±1.8 years) than patients without diabetic retinopathy (9±2.5 years); p-value 0.04. Silpa D et al. (2021) reported that percentage distribution of the diabetic patients according to duration of diabetes showed 42.6% in15 years group. Mean duration

of diabetes mellitus in the sample population was 12.7±5.4 years.[16] Ezhilvendhan K et al (2021) reported that the patients with diabetic retinopathy had significantly longer duration of diabetes at the time of presentation than those without retinopathy (7.9 vs. 6.2 years: P <0.001).[18]

This result is expected given the fact that the longer the duration of the disease, the longer patients are exposed to many risk factors and the higher the incidence of various DM-related chronic complications, which may be caused by the interaction of multiple factors.[19]

4.4. Biochemical parameters

Fasting Blood sugar (FBS) values: In group A, the mean fasting blood sugar was 184.57± 55.99 mg/dl while in group B, the mean fasting blood sugar was 165.92± 21.52 mg/dl. The difference between the groups was non-significant (p-value 0.052).

Prakash G et al. (2016) reported that diabetic retinopathy patients had comparable fasting blood sugar value (130.37±38.58) than patients without diabetic retinopathy (133.08±42.28); p <0.81.[20] Deepa C K et al. (2021) reported that 40% patients had fasting blood sugar between 100-140 mg/dl and 60% patients were above 140mg/dl with mean value of 156.22±37.21.[15]

HbA1C values: In group A, the mean HbA1C was 7.03± 0.38 while in group B, the mean HbA1C was 6.91± 0.29. The difference between the groups was non-significant (p-value 0.122).

Cetin EN et al (2013) that the mean HbA1c was significantly higher in the patients with DME (8.6±1.6) compared to patients without DME (7.9±1.7, P=0.008).[21]

Prakash G et al (2016) reported that diabetic retinopathy patients had higher HbA1c value (9.4±0.50) than patients without diabetic retinopathy (8.6±0.20); p <0.001.[76] Silpa D et al (2021) reported that the mean HbA1c was 7.56%.[16]

Renal Function Tests: In group A, the mean blood urea was 14.27±4.39 mg/dl while in group B, it was 15.05±4.21 mg/dl (non-significant; p-value 0.423). In group A, the mean serum creatinine was 0.84±0.14 mg/dl while in group B, it was 0.84±0.13 mg/dl (non-significant; p-value 0.793). In group A, the mean 24-hour urinary protein was 71.07±12.53 mg while in group B, it was 73.87±12.18 mg (non-significant; p-value 0.316).

Tamadon MR et al (2015) reported that the mean (±SD) serum creatinine in patients with proliferative retinopathy, non-proliferative retinopathy and patients without retinopathy was 1.13 ± 0.43, 1.17 ± 0.95 and 0.98 ± 0.17 respectively which the difference was not significant (P= 0.107). Mean (±SD) of urine albumin level in patients with proliferative retinopathy, non-proliferative retinopathy and without retinopathy was 19.8 ± 6.6, 18.5 ± 6.7 and 16.8 ± 6.3 mg/day respectively that the difference was significant (P=0.012). Mean (±SD) of albumin in patients with proliferative retinopathy was significantly more than it in patients without retinopathy (P= 0.009).[22] Thool AR et al (2021) reported that the mean (±SD) of serum creatinine in patients with no DR, mild non-proliferative diabetic retinopathy (NPDR), moderate NPDR, severe NPDR and proliferative diabetic retinopathy (PDR) were: 1.12 ± 0.41, 1.21 ± 0.53, 1.35 ± 0.49, 1.55 ± 0.22 and 1.70 ± 0.23 respectively; P = 0.007.[23]

Lipid profile: In group A, the mean total cholesterol was 215.82±40.43 mg/dl while in group B, it was 168.25±41.39 mg/dl (significant; p-value <0.001). In group A, the mean LDL was 141.5±36.10 mg/dl while in group B, it was 100.12±69.75 mg/dl (significant; p-value 0.0013). In group A, the mean HDL was 47.67±5.95 mg/dl while in group B, it was 47.82±6.15 mg/dl (non-significant; p-value 0.91). In group A, the mean triglycerides was 130.2±22.75 mg/dl while in group B, it was 129.75±23.62 mg/dl (non-significant; p-value 0.93).

Golubovic-Arsovska M (2007) reported that the diabetic patients had significantly higher values of total lipids (9.49 ± 2.02 g/L vs. 8.06 ± 0.84 g/L), triglycerides (2.02 ± 1.23 mmol/l vs. 1.24 ± 0.37 mmol/l), total cholesterol (6.03 ± 1.13 mmol/l vs. 5.21 ± 0.62 mmol/l) and cholesterol (4.02 ± 0.72 mmol/l vs. 3.48 ± 0.46 mmol/l) as compared to the control group. Although values of HDL (1.39 ± 1.01 mmol/l) and LDL (3.69 ± 1.0 mmol/l) cholesterol were higher in the examined group than in the control one, there were no statistically significant differences (1.39 ± 1.01 mmol/l vs. 1.30 ± 0.33 mmol/l) and (3.69 ± 1.0 mmol/l vs. 3.60 ± 0.72 mmol/l) respectively.[71] Prakash G et al (2016) reported that the mean levels of triglycerides (with DR 148.54±23.70 vs without DR 135.08±20.47; p-value 0.04) and HDL (with DR 43.50±6.78 vs without DR 48.75±9.63; p- value 0.03) were significantly different between participants with and without DR. HDL was associated with a reduced likelihood of having more severe diabetic retinopathy levels (P = 0.02). While triglyceride showed significant positive association with DR severity (P = 0.05). Total cholesterol (P = 0.40) and LDL (P = 0.11) were not significantly associated with DR severity.[20] Malik SH et al (2018) reported that the serum levels of total cholesterol (with DR 248.8±44.6 vs without DR 215.5±48.8; p <0.05) and Low Density Lipoprotein-Cholesterol (LDL-C) (with DR 132.8±28.7 vs without DR 114.26±26.6; p <0.05) were considerably raised in patients presented with diabetic retinopathy while lipid profile values for Triglycerides (with DR 185.3±35.2 vs without DR 178.4±26.1; p >0.05) and High Density Lipoprotein – Cholesterol (with DR 38.2±12.0 vs without DR 36.1±12.3; p >0.05) were almost identical between two groups.[24] Salaria NS et al (2019) reported that the mean value of total cholesterol was higher in both group I (diabetic patients with retinopathy) and group II (diabetic patients with no retinopathy) with value being higher in group I (229.09 mg/dl) as compared to group II (215.32 mg/dl).

Triglyceride levels also followed the similar trend with group I having mean value of 238.95mg/dl and group II having 179.93 mg/dl. But only total cholesterol value had statistical significance p < 0.05.[25]

4.5. Foveal thickness

In group A, the mean foveal thickness was 341.32±69.86 μm while in group B, it was 236.47±11.01 μm. The difference between the groups was significant (p-value <0.0001).

Goebel W et al. (2002) found that in diabetic patients, retinal thickness was increased to 307 ±136 μm in the fovea while it was 153 ±15 μm in normal controls. The differences between diabetics and controls were highly significant (P < 0.001).[26]

Jiang J et al (2018) found that the mean thickness of the fovea was 215.8 ± 18.9 μm in the diabetes group and 222.0 ± 18.6 μm in the control group (0.04).[27]

Vascular dysfunction, the basic pathology underlying diabetes, can occur in early stages of DR, in the absence of structural and functional abnormalities of the retina. The fovea has the highest density of cones and therefore has an increased metabolic demand. The foveal regions may therefore be more susceptible to microvascular or ischaemic insults because of the above structural features.[27]

Correlation of foveal thickness with lipid profile in patients of diabetic retinopathy. In group A, the correlation coefficient of foveal thickness with total cholesterol, LDL, HDL, and triglycerides was 0.606, 0.528, 0.035 and 0.035 respectively.

Baishya KB et al (2018) calculated the Pearson's correlation test between serum lipid profile and diabetic macular oedema: Total cholesterol (r= -0.06), HDL (r=0.0011), LDL (r= -0.26), VLDL (r=-0.2214), and Triglyceride (r=0.013).[28]

Table 1: Comparison of lipid profile between group a and Group B

	Group A	Group B	P value
Total Cholesterol (mg/dl)	215.82±40.43	168.25±41.39	<0.001
LDL (mg/dl)	141.5±36.10	100.12±69.75	0.0013
HDL (mg/dl)	47.67±5.95	47.82±6.15	0.91
Triglycerides (mg/dl)	130.2±22.75	129.75±23.62	0.93

In group A, the mean total cholesterol was 215.82±40.43 mg/dl while in group B, it was 168.25±41.39 mg/dl (significant; p-value <0.001). In group A, the mean LDL was 141.5±36.10 mg/dl while in group B, it was 100.12±69.75 mg/dl (significant; p-value 0.0013). In group A, the mean HDL was 47.67±5.95 mg/dl while in group B, it was 47.82±6.15 mg/dl (non-significant; p-value 0.91). In group A, the mean triglycerides was 130.2±22.75 mg/dl while in group B, it was 129.75±23.62 mg/dl (non-significant; p-value 0.93).

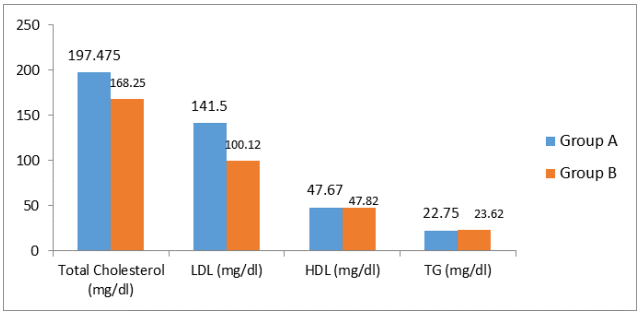

Fig. 1: Comparison of lipid profile between Group A and Group B

Table 2: Comparison of foveal thickness (μm) in Group A and Group B

	Foveal Thickness(μm)	
	Mean	Standard deviation
Group A	341.32	69.86
Group B	236.47	11.01
P value	<0.0001	
Sig.	Sig	

In group A, the mean foveal thickness was 341.32±69.86 μm while in group B, it was 236.47±11.01 μm. The difference between the groups was significant (p-value <0.0001).

4.6. Distribution of severity of hard exudates and their correlation with lipid profile in patients of diabetic retinopathy

In group A, 4 patients had grade 1 hard exudates, 9 patients had grade 2 hard exudates, 11 patients had grade 3 hard exudates, 6 patients had grade 4 hard exudates, and 10 patients had grade 5 hard exudates. The correlation coefficient of hard exudates with total cholesterol was 0.43. The correlation coefficient of hard exudates with LDL was 0.511. The correlation coefficient of hard exudates with HDL was 0.197. The correlation coefficient of hard exudates with triglycerides was 0.0035.

Sachdev N et al (2010) reported that the retinal hard exudates were significantly associated with serum cholesterol (P<0.001), serum LDL (P=0.008) and serum triglyceride (P=0.013) levels.[29] Idiculla J et al. (2012) reported that retinal hard exudate formation was found to have statistically significant correlation with the presence of dyslipidemia (p=0.02), increased total cholesterol (p=0.002) and LDL levels (p=0.001) and the correlation with triglyceride levels showed a trend towards significance (p=0.07)[30] Silpa D et al. (2021) reported that severity of hard exudates was significantly associated with serum

cholesterol (p value<0.01), LDL (p value<0.01), and triglycerides (p value<0.01).[16]

5. Conclusion

The present study showed that:

1. There is no significant difference in age and gender differences in patients of type 2 diabetes mellitus with and without changes of diabetic retinopathy.
2. There is no significant difference in fasting blood sugar, HbA1C levels and renal function tests in patients of type 2 diabetes mellitus with and without changes of diabetic retinopathy.
3. Patients with changes of diabetic retinopathy had significantly higher values of total cholesterol and LDL as compared to those without changes of diabetic retinopathy.
4. Patients with changes of diabetic retinopathy had non-significant differences in the level of HDL and triglycerides as compared to those without changes of diabetic retinopathy.
5. Patients with changes of diabetic retinopathy had significantly higher values of foveal thickness as compared to those without changes of diabetic retinopathy. Foveal thickness had correlation with total cholesterol levels.

Severity of hard exudates showed significant correlation with lipid profile(total cholesterol, LDL, HDL, and triglycerides) of the patients.

6. Limitations

1. Large population based study should be done to assess the significance of this results.
2. Evaluation of diabetic retinopathy with other systemic factors like hypertension, and concomitant medications was not considered.
3. The subjects included in the study were mostly the central Indian origin, hence its application to world population is limited. Duration of the study was limited.

7. Source of Funding

None.

8. Conflict of Interest

None.

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