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Correlation of Retinopathy with Cardiovascular Complications in Patients with Type 2 Diabetes Mellitus: A Monocentric Retrospective Observational Study

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ABSTRACT

Background:

India is the "Diabetes capital of the world". Coronary Artery disease is most common cause of death in Type 2 Diabetes Mellitus (T2DM) & Diabetic retinopathy is the most common and specific marker of microvascular complication.

Objective:

To study prevalence of diabetic retinopathy in Type 2 diabetic patients and to evaluate risk of cardiovascular complications in Type 2 diabetic patients with retinopathy.

Method

Monocentric observational study was conducted on subjects with T2DM at J.K Hospital Bhopal from Oct 1, 2019- Sep 30, 2021. After Fundus examination, only those with diabetic retinopathy further underwent cardiovascular evaluation including ECG, 2D ECHO.

Results

Amongst 58 males and 52 female subjects with T2DM; where mean age of participants was 55.12 ± 11.2 years, majority had NPDR (84.5%); followed by PDR (15.5%). 42.7% patients belonged to age group of 61 yrs and above. 41.8% patients with diabetic retinopathy had T2DM for duration of 11-15 years. 40.9% were on Insulin with OHA. Most common co-morbidity present was Hypertension (26.4%). Mean HbA1c in subjects with NPDR is 9.4; 11.6 in subjects with PDR. 64.7% patients with PDR showed ischemic electrocardiographic changes and abnormal echocardiographic findings. Ischemic changes in ECG (suggestive of cardiovascular disease) has statistically significant correlation with progression of retinopathy to NPDR (p=0.017), PDR (p=0.050). Abnormal changes in ECHO has statistically significant correlation with progression to NPDR (p=0.003), PDR (p=0.126).

Conclusion

Older age group and people with longer duration of diabetes showed high incidence of diabetes related complications and significant correlation between development of diabetic retinopathy (NPDR), its progression to PDR and occurrence of cardiovascular disease.

KEYWORDS: HbA1c, PDR, NPDR, T2DM, ECG, ECHO

I. INTRODUCTION

Diabetes Mellitus (DM) is a major global health issue that has reached alarming levels both in industrialized world as well as developing world. India is deemed as the "**Diabetes capital of the world**". [(1,2)]

T2DM is the most common form of diabetes mellitus which comprises about 90% of the diabetic population in the world. [(3)] According to WHO, number of people living with diabetes rose from 108 million in 1980 to 422 million in 2014, with greater increase in prevalence in low- and middle-income countries.[(4)]

Most patients with T2DM are at a risk of having concomitant chronic complications of diabetes at the time of diagnosis due to long asymptomatic phase between actual onset of diabetic hyperglycemia and clinical diagnosis, which is approximately 4–7 years. [(5,6)]

Major burden of diabetes is a result of its complications, which can be divided into **macrovascular complications**(including myocardial infarction (MI), angina, stroke and peripheral arterial disease (PAD) and **microvascular complications** (retinopathy, nephropathy, neuropathy). [(7,8)] Data estimates in

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2019 showed diabetes to be the ninth leading cause of death with about 1.5 million deaths directly caused by diabetes. [4], out of 4.2 million deaths that occurred due to diabetes and its complications.[3]

Diabetic retinopathy is the most common microvascular complication of diabetes that causes irreversible blindness in working age population, [7,9] whereas Coronary heart disease is the main cause of morbidity and mortality in persons with diabetes. [10] Type 2 diabetes has been described a **coronary heart disease (CHD) "risk equivalent**". [6]

Indians have genetic predisposition for development of coronary artery disease due to unique clinical and biochemical abnormalities: higher waist circumference despite lower body mass index, dyslipidaemia and low levels of high density lipoproteins, increased insulin resistance, lower adiponectin and higher highly sensitive C-reactive protein levels.;hence they are more likely to develop complications related to diabetes at an early age (20-40 years). [11,12,13]

However, most of these complications can be detected in their early stages by screening programmes for timely diagnosis, regardless of patient age and thereby prevent or delay development of complications by providing appropriate care at the earliest. Most of the diabetes preventive measures in Indian communities have been secondary or tertiary prevention programs that target adults with T2DM, which includes health education, health fairs, fitness programs, nutrition education etc. [14]

This study was aimed at assessing the prevalence of retinopathy and cardiovascular complications in patients with type 2 Diabetes Mellitus and to study the role of retinopathy (microvascular) as an indicator of cardiovascular (macrovascular) complications in these patients.

II. MATERIALS AND METHODS

2.1 Study participants and their evaluation

It was a monocentric retrospective observational study conducted at L.N. Medical college and J.K. Hospital, Bhopal: a tertiary care facility in Central India over a two year period from Oct 1, 2019 up to Sep 30,2021.

Study was started after taking permission from ethics committee of the institute. In this study, 110 patients aged 40yrs and above, from OPD and IPD of the hospital, who were diagnosed with type 2 diabetes and had developed diabetic retinopathy were included.

Laboratory diagnosis of diabetes mellitus was confirmed by latest criteria laid by the American Diabetes Association (ADA). HbA1c levels (calculating average blood glucose level in past 3 months, along with fasting and 2-hour postprandial blood sugar levels of all these patients were obtained from records. [1,15]

As per ADA, fasting plasma glucose (FPG) level of more than/ equal to 126 mg/dL (7.0 mm/L) with blood sample preferably taken after an 8 hour overnight fast, is consistent with the diagnosis. Patients with an Hb A1c greater than 6.5% (48 mmol/mol) are diagnosed as having DM.

Two-Hour Oral Glucose Tolerance Test (OGTT): In this test, DM is diagnosed if the plasma glucose (PG) level in the sample taken 2 hours after ingestion of 75 gm of anhydrous glucose dissolved in water is more than/equal to 200 mg/dL (11.1 mmol/L).

In patients with classic symptoms of hyperglycemia (increased thirst, increased hunger, and increased urination) random plasma glucose more than 200 mg/dL is also sufficient to diagnose DM. [1] Standard lab values of markers were taken to be: HbA1C (<6.5% [13]), D-dimer (<500 ng/ml)[14]*, IL6 (< 4.40 pg/ml) [15]*.

After taking consent, all of the above patients were subjected to detailed history and thorough clinical examination. Ophthalmic examination esp. Fundus examination was done after dilating pupils of these patients with tropicamide to look for presence of diabetic retinopathy by direct ophthalmoscopy. Visual acuity testing, anterior segment examination was also done. All cases of diabetic retinopathy were graded into 4 classes on the basis of ETDRS (early treatment diabetic retinopathy study) classification.[16]

Only those patients who had developed diabetic retinopathy were subjected to electrocardiography (ECG) and echocardiography (2 D ECHO) for cardiovascular evaluation, to look for the presence of ischemic changes, arrhythmia, systolic/diastolic dysfunction.

A standard Performa for recording the clinical profile and investigations was made. These patients were also assessed for comorbidities like Hypertension and dyslipidemia.

Hypertension is one of the most common comorbidities that affects about 70% of individuals with T2DM.[17,18] It is defined as a value of > 140/ 90 mm/Hg. Blood pressure was recorded twice, 10 min apart in both arms, when the patient is seated comfortably with back supported. All patients whose baseline values were high, they were retested over a period of 15 days to confirm hypertension (>140/90 mm/hg) and to rule out presence of "White Coat Phenomenon" [19]

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Dyslipidemia; Lipid profile of patients was tested in the fasting blood sample. Values above the goal of therapy (total cholesterol > 200 mg/dl, low density lipoprotein (LDL) > 100 mg/dl and triglycerides >150 mg/dl) was considered abnormal.[19]

2.2. INCLUSION CRITERIA:

All T2DM adult patients >40 years of age, with retinopathy were included in the study.

2.3. EXCLUSION CRITERIA:

Type 1 diabetes mellitus
Refusal to be a part of the study
Pregnancy
Past History of Ischemic heart disease

2.4. STATISTICAL ANALYSES

Data will be analysed statistically. Analysis will be done in the form of percentages, proportions and represented as tables, charts, graphs wherever necessary. Appropriate tests of significance will be applied.

III. RESULTS

Following are the results obtained from cross sectional study conducted in a tertiary care hospital over a period of 2 years done on 110 subjects, all of whom had T2DM and had developed diabetic retinopathy. Mean age group of study participants ± SD = 55.12 ± 11.2.

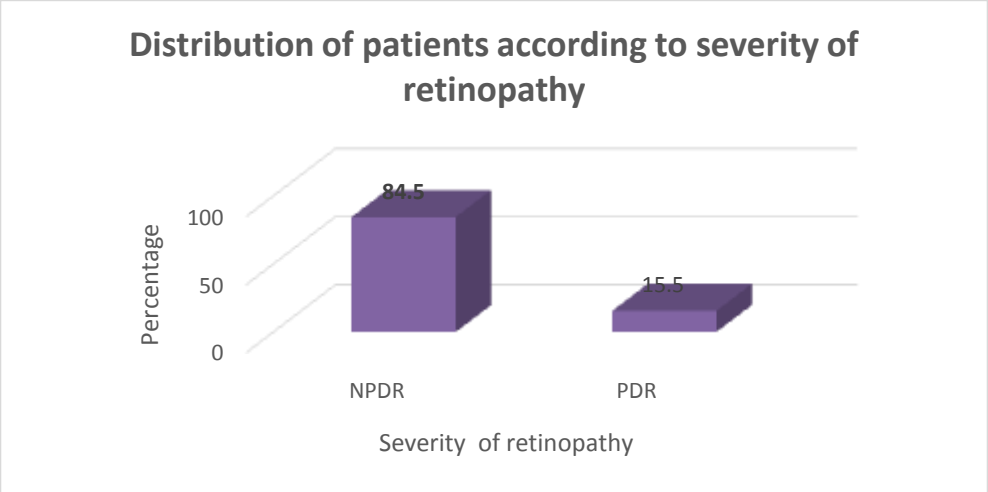

Fig Ia. Proportional distribution of patients according to severity levels of diabetic retinopathy
The above graph shows that a. majority of patients in this study have NPDR (84.5%);It is followed by PDR (15.5%).

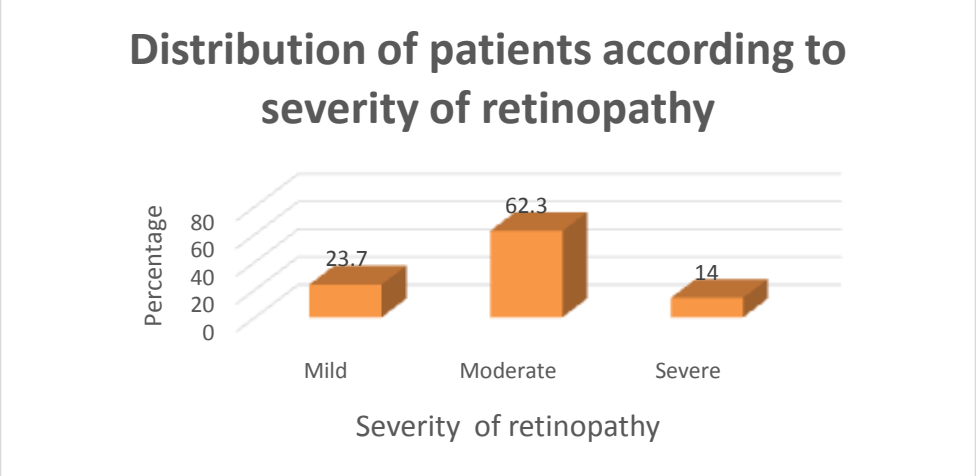

Fig Ib. Proportional distribution of patients according to severity levels of diabetic retinopathy: The above graph shows that most of whom have moderate NPDR (62.3%) followed by mild NPDR (23.7%).

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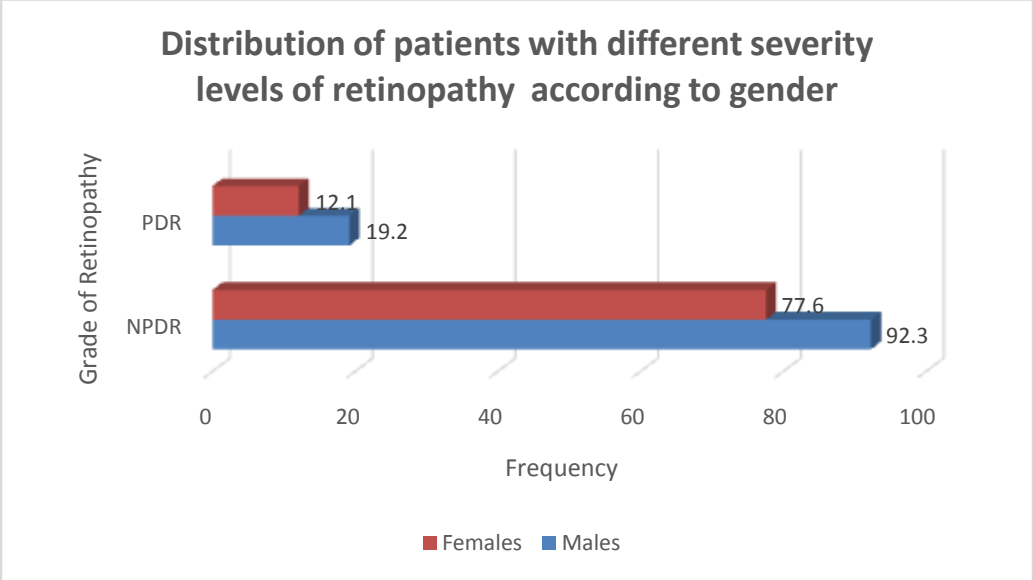

Fig II a. Distribution of patients of retinopathy according to gender

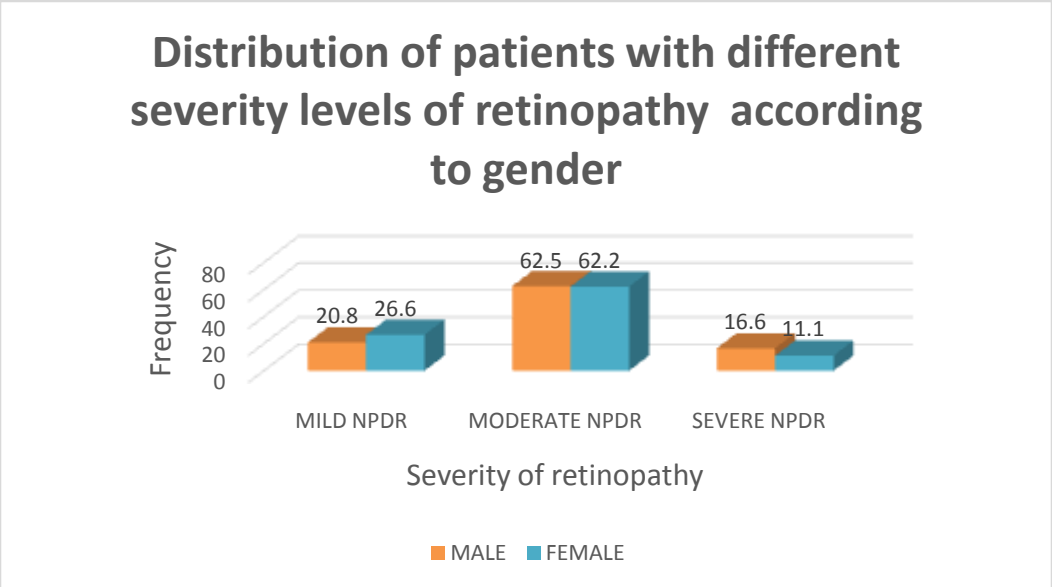

Fig IIb. Distribution of patients with different severity levels of retinopathy according to gender

The above graphs shows the proportional distribution of study participants with different severity levels of retinopathy according to the gender.

a. Out of 110 patients, 58 (52.7%) were male while 52 (47.3%) were females. Male : Female ratio = 1.11

b. Among both genders, majority of these patients had developed NPDR: 92.3% females, 77.6% males, followed by PDR which is seen in 19.2% females, 12.1% males.

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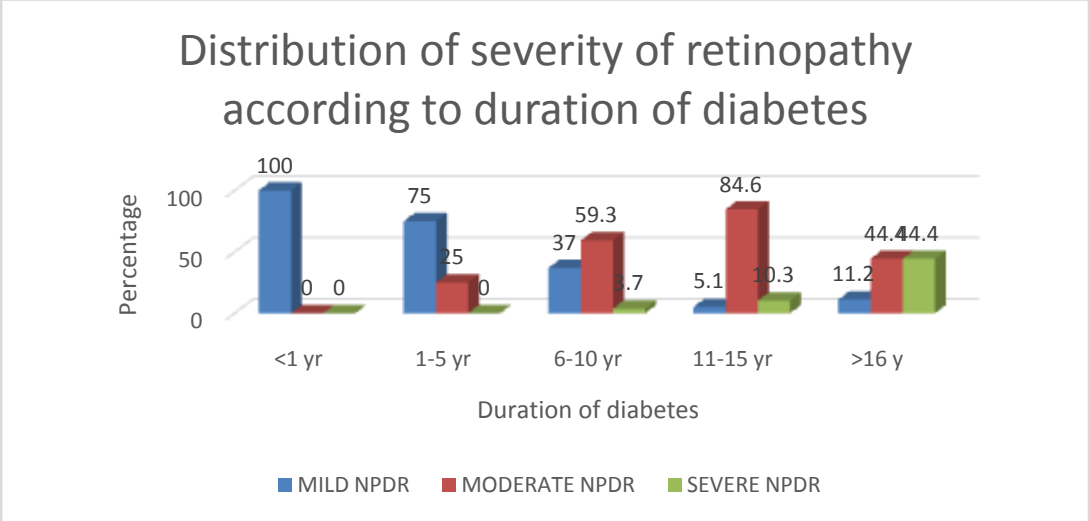

Fig III Distribution of severity of retinopathy according to duration of diabetes

Fi**gure IIIa**.illustrates thatmaximum proportion of patients with diabetic retinopathy i.e. 41.8% of patients had Diabetes mellitus for duration of 11-15 years and least proportion of patients i.e. 3.6% had Diabetes for 1-5 years.

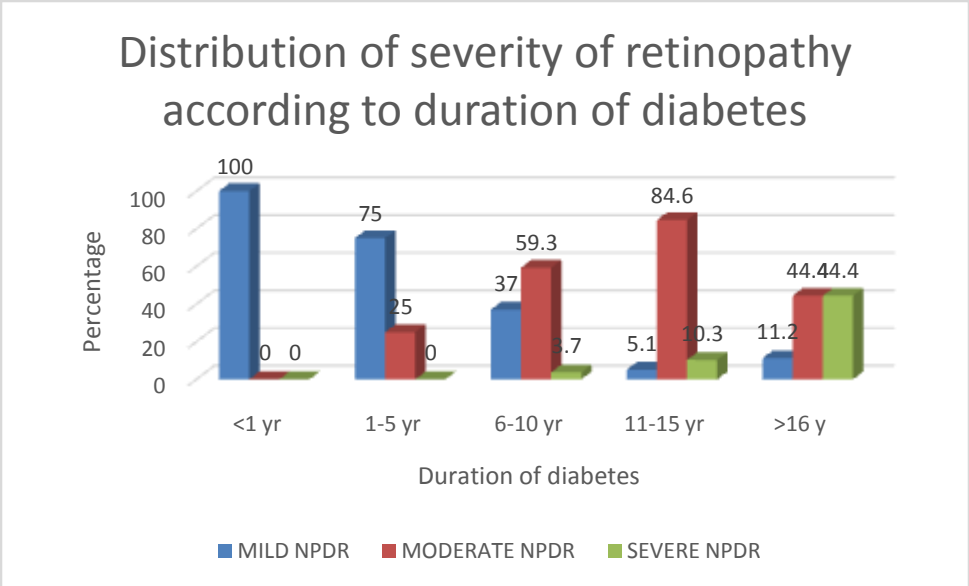

Fig III Distribution of severity of retinopathy according to duration of diabetes

Fig IIIb. Shows that majority of patients in age group of 11-15 yrs had developed NPDR (84.8%); b. Of those that developed NPDR (84.8%); most of them had moderate NPDR (71.7%)

Table I**Proportional distribution of patients with different severity levels of retinopathy according to the age group**

a.

AGE (IN YEARS)		**NPDR**	**PDR**
41-50 (n=22)	**Frequency**	20	2
		(90.9%)	(9.1%)
	Percentage (%)		
51-60 (n=41)	**Frequency**	35	6

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	Percentage (%)	(85.4%)	(14.6%)
61 and above (n=47)	**Frequency**	38 (80.9%)	9 (17%)
	Percentage (%)		

b.

AGE (IN YEARS)		**MILD NPDR**	**MODERATE NPDR**	**SEVERE NPDR**
41-50 (n=20)	**Frequency**	5 (25)	10 (50)	5 (25)
	Percentage (%)			
51-60 (n=35)	**Frequency**	8 (22.9)	21 (60)	6 (17.1)
	Percentage (%)			
61 and above (n=38)	**Frequency**	10 (26.4)	20 (52.6)	8 (21)
	Percentage (%)			

In this study, **a.** Maximum proportion of patients belonged to age group of 61 yrs and above i.e. 42.7%. Least proportion comprised of patients belonging to 41-50 year age group i.e. 20%. **b**. In all age groups, there was higher prevalence of moderate NPDR followed by PDR. The age distribution in present study was highly significant with p value of <0.001. Mean age of study participants was 55.12 ± 11.2 years.

- Most of the patients i.e. 96.4% had Fasting blood sugar >100mg/dL; whereas 94.5% had post prandial blood sugar >140mg/dl. Majority of patients in this study had HbA1c in the range of 9.1 and beyond. In these patients with HbA1c 9.1 and above, most patients had NPDR (80.4%) followed by PDR (19.6%). Of patients with NPDR, most patients had moderate NPDR (64.9%). Mean HbA1c in subjects with NPDR is 9.4, whereas it is 11.6 in subjects with PDR.
- In this study, 59.1% of patients were on Oral Hypoglyemic agents (OHA) alone where as 40.9% were on Insulin with OHA.

Out of the subjects who were on OHA, 89.2% had developed NPDR followed by PDR (10.8%). Out of the subjects who were on Insulin therapy, most of them had developed NPDR (77.8%) followed by PDR (22.2%).

- In this study, most common co-morbidity present was Hypertension seen in 26.4% of patients, followed by hypo-thyroidism seen in 7.3%. Majority of patients with PDR (35.3%) had hypertension followed by NPDR (34.4%).
- Majority of patients who developed PDR (64.7%) showed ischemic changes on ECG suggestive of coronary artery disease/ cardiovascular disease followed by NPDR (57%).The results shows that ischemic changes in ECG (suggestive of cardiovascular disease) has statistically significant correlation with progression of retinopathy to NPDR (p=0.017), PDR (p=0.050).

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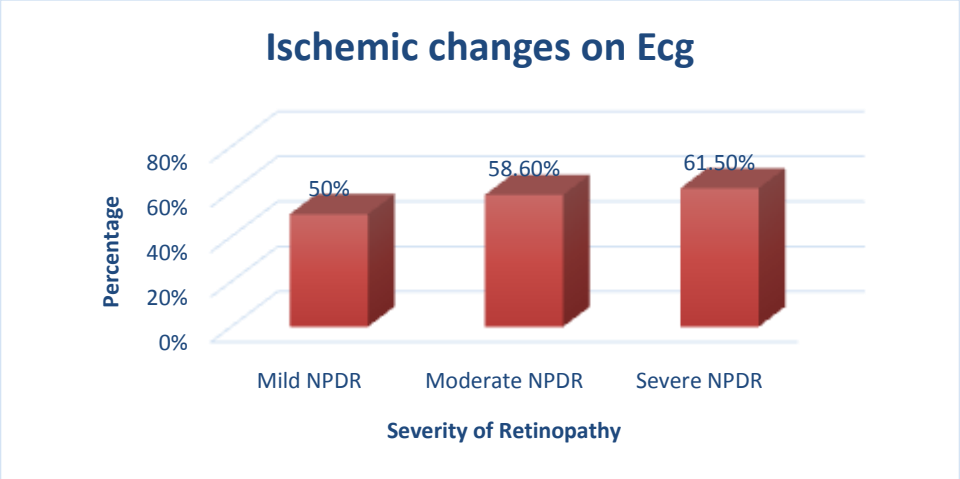

Fig IVPercentage of Ischemic changes on ECG in different clinical levels of retinopathy:

Above graph shows that among patients with NPDR, ischemic changes on electrocardiograph were most prevalent in patients with severe NPDR (61.5%).

- Most of the patients with PDR (64.7%) had abnormal ECHO findings suggestive of cardiovascular disease, followed by patients with NPDR (41.9%). Amongst these patients with NPDR, majority of patients with moderate NPDR (69.2%) had abnormal echocardiographic findings. Least prevalence of abnormal ECHO findings was seen in patients with mild NPDR (12.8%). The results shows that **abnormal changes in ECHO (suggestive of cardiovascular disease) has statistically significant correlation with progression of retinopathy to NPDR (p=0.003), PDR (p=0.126).**

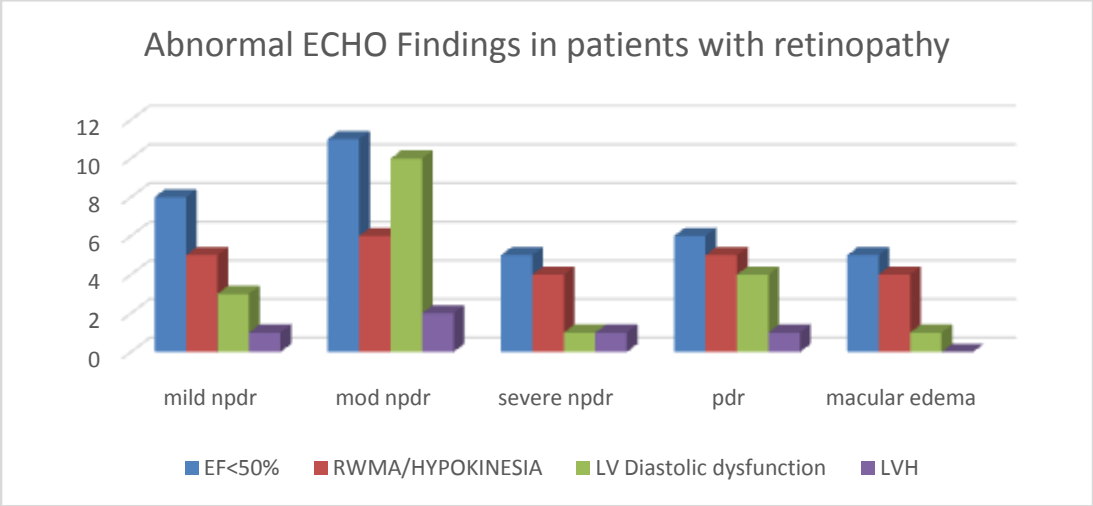

Fig V. ECHO Findings in patients with retinopathy

- The above graph shows that majority of patients who had abnormal findings on ECHO had PDR i.e. reduced Ejection fraction (35.3%)

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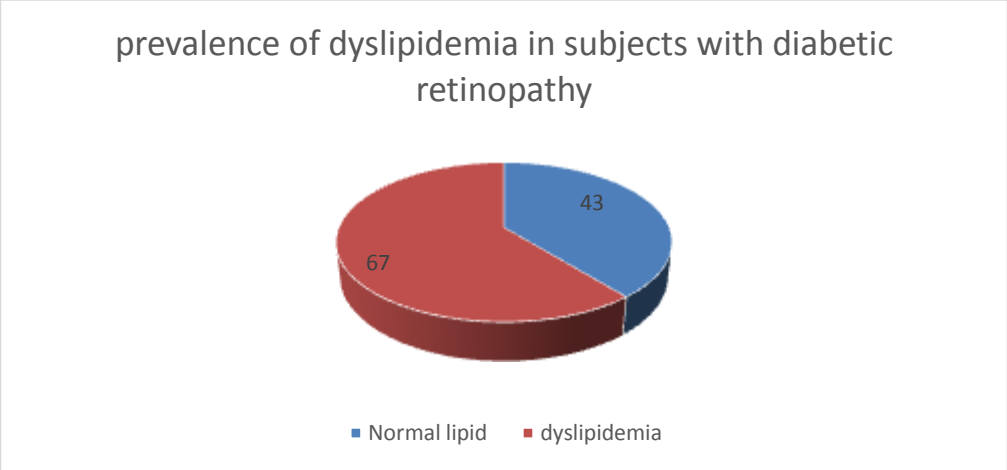

Fig VI. A. Percentage of dyslipidemia in subjects with diabetic retinopathy

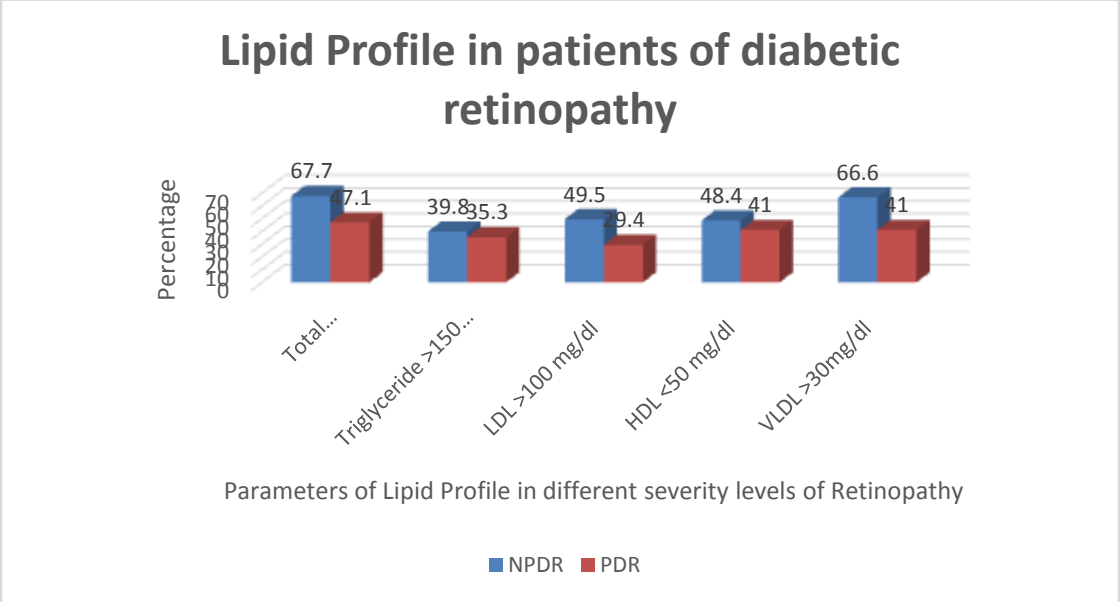

Fig VI. B. Lipid Profile in patients of diabetic retinopathy

Fig VI. A. elucidates the proportional distribution of study participants according to the derangement in lipid profile, majority of them had dyslipidemia i.e. 60.9%, whereas 39.1% participants had normal lipid profile. Among the participants included in the study, majority of patients with PDR (58.8%) had dyslipidemia. Amongst patients with NPDR, most of patients with severe NPDR (61.5%) had dyslipidemia. **Fig VI. B**. shows that hypercholesterolemia was most prevalent in patients with NPDR (67.7%) followed by PDR (47.1%). Among patients with NPDR, it was most prevalent in patients with moderate NPDR (63.5%) followed by mild NPDR (22.2%). Hypertriglyceridemia was more prevalent in patients with NPDR (39.8%), followed by PDR (35.3%).

- There was significant correlation of Hypertriglyceridemia with progression to PDR (p=0.055). There was higher prevalence of patients with low HDL levels in patients with NPDR (48.4%) followed by PDR (41%), with significant correlation of low HDL levels with progression to PDR (p=0.010).
- In this study, there are 11 patients having **macular edema** (10% patients with diabetic retinopathy), of which 8 are male (13.8% males), 3 are female (5.8% females). Most of them belonged to age group of 61 yrs and above (14.9%) and had diabetes for duration of

20 or more years (12.5%) followed by 11-15 yrs of age (10.9%).

- Most of the patient who developed macular edema had been on insulin therapy in addition to oral hypoglycemic agents (13.3%). Most of these were more likely to develop hypercholesterolemia (72.7%) and was associated with low HDL levels (63%). Majority (54.5%) of patients with macular edema have Hypertension
- Majority of patients with macular edema showed ischemic changes on ECG (72.7%) and also had abnormal finding on echocardiography (72.7%).

IV. DISCUSSION

Diabetes Mellitus is a major cause of morbidity and mortality all over the world. [19] Diabetic retinopathy is one of the most common microvascular complication of diabetes, which is also one of the major cause of loss of vision in working age group.[3,9] Cardiovascular complications are the most common cause of mortality in these patients.[20]

In this study done on 110 patients with T2DM, diabetic retinopathy was more commonly found in males followed by female with Mean age of 55.12 ± 11.2 years. It was more prevalent in patients who had T2DM for longer duration or had poor glycemic control (in form of higher glycated haemoglobin). Most of these patients had coexistent Hypertension. Patients who developed retinopathy; PDR followed by NPDR were more likely to develop cardiovascular diseases (detected by ischemic changes on ECG and abnormal echocardiographic findings). Statistically significant correlation was seen between ischemic changes in ECG (suggestive of cardiovascular disease and progression of retinopathy to NPDR (p=0.017), PDR (p=0.050).

The present study showed that presence of retinopathy in patients with T2DM may help predict cardiovascular complications in these patients i. e. microvascular complications may act as an indicator of macrovascular complications.

V. CONCLUSION

This study highlights importance of early screening of diabetes and its complications as well as assessment of cardiovascular risk factors at the time of diagnosis in all the patients with T2DM. Significant correlation was obtained between development of diabetic retinopathy (NPDR), its progression to PDR and occurrence of cardiovascular disease. Therefore, efforts should be made for effective screening of diabetes so that complications can be prevented and optic fundus examination should be made mandatory for all patients with type 2 diabetes mellitus as it is a non invasive, cost effective screening tool which can be easily carried out even at the peripheral centres. The findings of this study provide the impetus to direct the patients with diabetic retinopathy for timely cardiac evaluation to reduce the prevalence or delay the occurence of myocardial infarction and heart failure in these patients.

VI. LIMITATION

This is an observational study done on a small population. As the Hba1c was collected only on admission and patient follow up could not be done. Larger studies are needed to further confirm the findings based on patient follow up. Prognosis cannot be predicted based on HbA1c.

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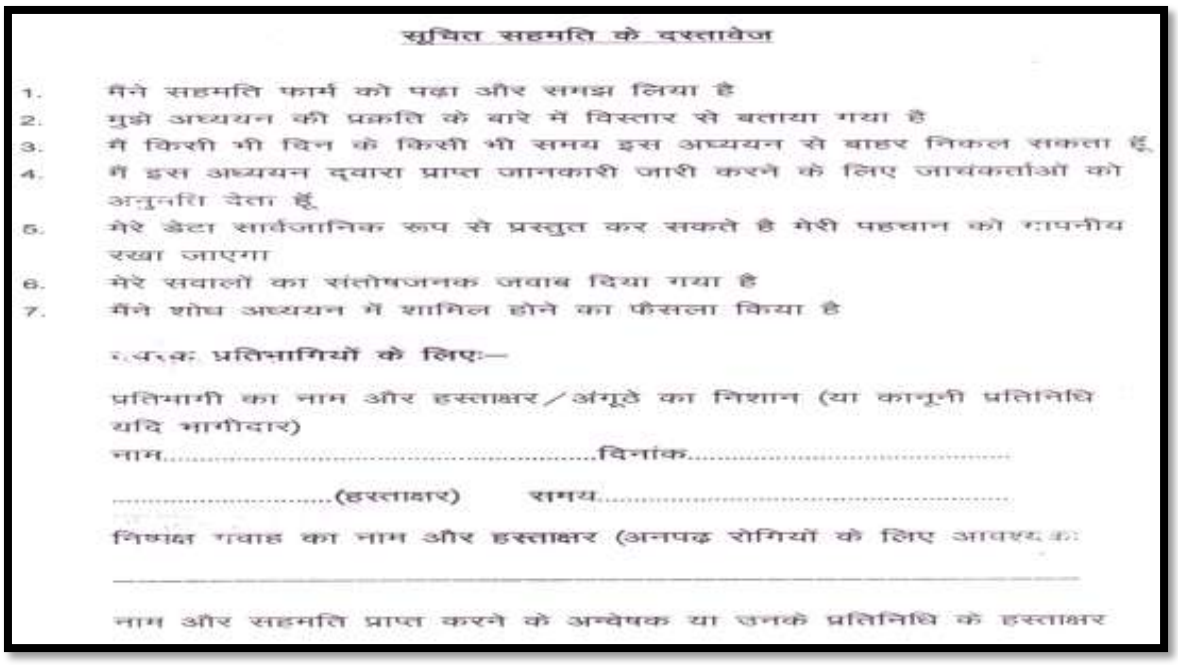

सूचित सहमति के दस्तावेज

1. मैंने सहमति फार्म को पढ़ा और समझ लिया है
2. मुझे अध्ययन की प्रकृति के बारे में विस्तार से बताया गया है
3. मैं किसी भी दिन के किसी भी समय इस अध्ययन से बाहर निकल सकता हूं
4. मैं इस अध्ययन द्वारा प्राप्त जानकारी जारी करने के लिए आवश्यकताओं को अनुमति देता हूं
5. मेरे डेटा सार्वजनिक रूप से प्रस्तुत कर सकते है मेरी पहचान को गोपनीय रखा जाएगा
6. मेरे सवालों का संतोषजनक जवाब दिया गया है
7. मैंने शोध अध्ययन में शामिल होने का फैसला किया है

प्रतिभागियों के लिए:—

प्रतिभागी का नाम और हस्ताक्षर/अंगूठे का निशान (या कानूनी प्रतिनिधि यदि भागीदार)

नाम.....दिनांक.....

.....(हस्ताक्षर) समय.....

निष्पक्ष गवाह का नाम और हस्ताक्षर (अनपढ़ रोगियों के लिए आवश्यक)

नाम और सहमति प्राप्त करने के अन्वेषक या उनके प्रतिनिधि के हस्ताक्षर

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INFORMED CONSENT

Study Number:

Title-:"A Study On The Correlation of Retinopathy with Cardiovascular Complications in patients with Type 2 Diabetes Mellitus."

Subject's Initials:
Subject's Name:
Date of Birth/Age:

1. I confirm that I have read and understood the information sheetdated for the above study and have had the opportunity to ask questions. ( )
2. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason without my medical care or legal rights being affected. ( )
3. I understand that the sponsor of the clinical trial, others working on the sponsor's behalf, the Ethics Committee and the regulatory authorities of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information related to third parties or published. ( )
4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purposes. ( )
5. I agree to take part in above study. ( )

Signature/Thumb impression of the subject /Legally accepted representative
Date:
Signatory's Name:

Signature of the Investigator:
Date: