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Original Research Article

Diabetic retinopathy among newly diagnosed diabetics

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Abstract

Background: Diabetes is a major metabolic disorder affecting diverse populations. Approximately 415 million people worldwide have diabetes, a number expected to increase by 200% by 2030. Diabetic retinopathy (DR) is a leading cause of preventable blindness.
Aim and Objective: To estimate the prevalence and associated risk factors of diabetic retinopathy among newly diagnosed diabetic patients.
Materials and Methods: A cross-sectional observational study at the Ophthalmology Department at MIMER Medical College, Pune, Maharashtra, India. After obtaining Institutional Ethical Committee approval, 138 newly diagnosed diabetic patients visiting the Ophthalmology OPD were selected using purposive sampling. After obtaining informed consent patients underwent comprehensive ophthalmological evaluations and were classified using the Early Treatment Diabetic Retinopathy Study (ETDRS) system. The data was analysed using SPSS software version 21 and represented in form of frequency and percentages. Statistical analysis was applied and p-value <0.05 was considered significant.
Results: The mean age of the 138 subjects was 55.61 ± 9.16 years. Diabetic retinopathy was observed in 15 (10.9%) of subjects. Mild, moderate, and severe non-proliferative DR prevalence was 4.3%, 3.6%, and 2.2%, respectively, while proliferative DR was present in 0.8% of subjects. Logistic regression identified HbA1c levels as significant predictors of DR.
Conclusions: Age and HbA1c levels are significant predictors of DR, highlighting the need for early screening and intervention in diabetic patients to prevent vision loss.

Keywords: Diabetic retinopathy, Newly diagnosed diabetics.

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1. Introduction

Diabetes mellitus is a global health epidemic affecting diverse populations across various demographic backgrounds. 537 million adults (20-79 years) are living with diabetes - 1 in 10. This number is predicted to rise to 643 million by 2030 and 783 million by 2045.[1] The estimates in 2019 showed that 77 million individuals had diabetes in India, which is expected to rise to over 134 million by 2045.[2] India, home to one of the largest diabetic populations in the world, has seen a dramatic rise in diabetes prevalence due to rapid urbanization, lifestyle changes, and genetic predisposition.[3] Type 2 diabetes mellitus (T2DM) accounts for 85-90% of cases.[4]

Rising T2DM prevalence in developing countries due to various factors alongside increased life expectancy, leads to complications like diabetic retinopathy (DR), a major cause of preventable blindness.[5-7] The pathophysiology of DR involves damage to the retinal blood vessels due to chronic hyperglycemia, resulting in increased vascular permeability, capillary occlusion, and neovascularization.[8-10] These changes can lead to macular edema, retinal hemorrhages, and, in severe cases, retinal detachment, which may cause permanent vision loss.[11,12]

The demographic profile of patients with DR varies significantly depending on age, gender, ethnicity, and socioeconomic status. Studies have shown that advanced age,

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male gender, and poor glycemic control are associated with a higher risk of developing DR.[13,14] In the Indian context, factors such as low awareness, limited access to healthcare, and higher rates of undiagnosed diabetes contribute to an increased prevalence of DR, particularly in newly diagnosed diabetics.[15,16]

Dilated fundus examination (direct and indirect ophthalmoscopy) and fundus photography are used to visualize and document retinal changes in DR.[17] Optical coherence tomography (OCT) provides high-resolution images for assessing macular thickness and edema.[18] Fluorescein angiography identifies retinal non-perfusion and leakage.[19] The ETDRS classification system is used to grade DR severity and guide management.[20]

Given the lack of comprehensive data on DR in newly diagnosed diabetics in Maharashtra, this study aims to estimate the prevalence of DR and identify demographic and clinical predictors of DR in this population. By focusing on newly diagnosed cases, we can better understand the early manifestations of DR and highlight the need for timely screening and intervention to prevent disease progression and associated complications.

2. Materials and Methods

This cross-sectional observational study was conducted in the Department of Ophthalmology at MIMER Medical College, Pune, among 138 newly diagnosed patients with diabetes mellitus. The study was approved by the Institutional Ethics Committee (IEC). Patients were selected using purposive sampling, and those visiting the Ophthalmology Outpatient Department (OPD) within one month of their diabetes diagnosis were considered for inclusion. Written informed consent was obtained from all participants.

2.1. Inclusion criteria

1. Newly diagnosed type 2 diabetic patients (diagnosed within the last month).
2. Age ≥ 18 years.
3. Patients willing to undergo a comprehensive ophthalmological examination.

2.2. Exclusion criteria

1. Patients with a previous diagnosis of diabetic retinopathy or other retinal diseases.
2. History of ocular trauma or surgery.
3. Patients with systemic conditions that may affect the retina (e.g., hypertensive retinopathy).
4. Pregnant women and patients on corticosteroid therapy.

2.3. Ophthalmological examination

A detailed ophthalmological examination was conducted for all selected participants, which included visual acuity testing, slit-lamp examination, refraction, and dilated fundus examination using an indirect ophthalmoscope. Those suspected to have diabetic retinopathy (DR) were evaluated further by a Vitreo-Retina consultant/surgeon to confirm the diagnosis.

2.4. Additional investigations

Patients diagnosed with DR underwent further evaluation using Optical coherence tomography (OCT) to assess macular thickness and detect the presence of macular edema. Fluorescein angiography was selectively performed to identify areas of retinal non-perfusion, leakage, and neovascularization, aiding in the classification of DR severity.

2.5. Classification

Patients were classified based on the Early Treatment Diabetic Retinopathy Study (ETDRS) classification system into the following categories: mild non-proliferative diabetic retinopathy (NPDR), moderate NPDR, severe NPDR, very severe NPDR, early proliferative diabetic retinopathy (PDR), and high-risk PDR.

2.6. Data collection and statistical analysis

Demographic details, including age, sex, educational qualifications, and occupation, were recorded. HbA1c levels were measured for all patients. Data was entered into Microsoft Excel sheets and analyzed using SPSS software version 21. Quantitative data were represented as mean ± standard deviation (SD). Categorical and nominal data were expressed as percentages. The t-test or Mann-Whitney test was used to analyze quantitative data, while categorical data were analyzed using the chi-square test. A p-value of <0.05 was considered statistically significant.

3. Results

The study was a cross-sectional observational study carried out among 138 newly diagnosed patients with diabetes mellitus. Mean age of the study subjects with diabetes was 55.61 years with over a third (37.7%) of the subjects were over 60 years of age. The **table 1** presents the distribution of the study participants according to the age.

Table 1: Distribution of the study participants according to the age. (n=138)

Age group (years)	N	%
40-49	23	16.7%
50-59	63	45.7%
60-69	33	23.9%
≥ 70	19	13.8%

Note: the frequency and percentages are calculated column wise.

The current study showed male predominance with 80 (58.0%) males and 58 (42.0%) females out of total 138 participants.

3.1. Diabetic retinopathy

In our study we found 15 (10.9%) cases were diagnosed with diabetic retinopathy while 123 (89.1%) did not. As we categorized them **Figure 1** shows the categorization of DR based on NPDR.

Out of 15 cases of DR, more cases had mild and moderate NPDR with equal percentages, while few cases were of severe NPDR and proliferative DR.

3.2. Association with gender

There was no association between prevalence of diabetic retinopathy with either male or female gender (p-0.58).

3.3. Glycated haemoglobin

Mean Hba1c levels were significantly higher among cases with diabetic retinopathy as compared to cases without retinopathy. We also observed a significant increase in mean HbA1c levels with increasing severity of diabetic retinopathy ($p<0.01$). **Table 2** shows the distribution of HBa1c among the cases of DR and non-DR.

On logistic regression analysis, both age and glycated haemoglobin were found to be true predictors of development of retinopathy among diabetics. **Table 3** represents binary logistic regression for predictors of DR.

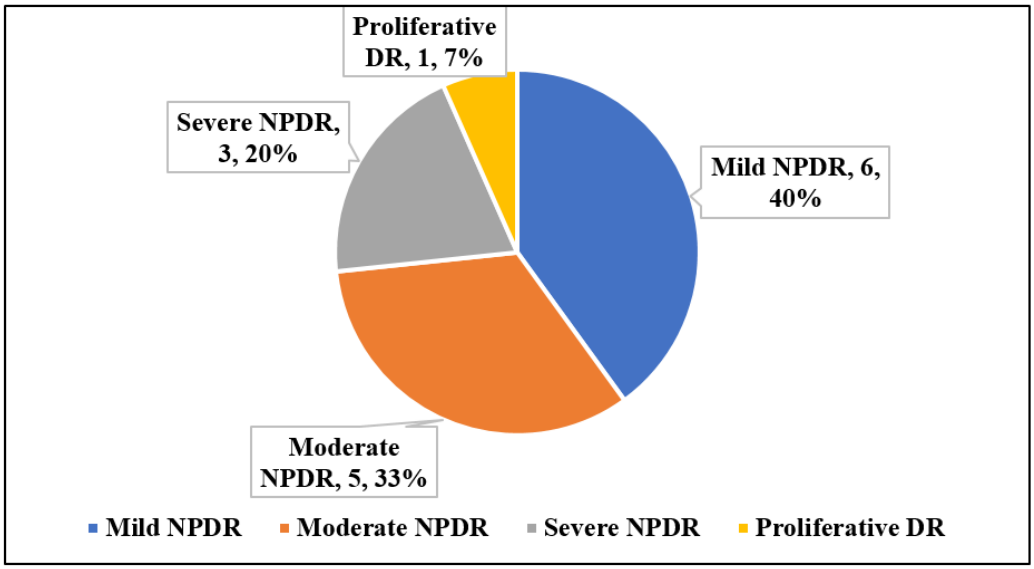

Figure 1: Distribution of subjects based on type of diabetic retinopathy (n=15)

Table 2: Glycated haemoglobin levels among cases of diabetic retinopathy

Diabetic Retinopathy	N	HbA1c	
		Mean	SD
No	123	7.18	1.36
Mild NPDR	6	7.64	2.46
Moderate NPDR	5	8.09	2.25
Severe NPDR	3	8.89	2.24
Proliferative DR	1	10.35	0
Total	138	7.71	1.93

Table 3: Binary logistic regression analysis for predictors of diabetic retinopathy

Variables	B	S.E.	Wald	df	p-value	Odds Ratio	95% CI Lower	95% CI Upper
Age	0.085	0.011	61.06	1	<0.01	1.09	1.07	1.11
HbA1c levels	0.761	0.274	7.72	1	<0.01	2.4	1.25	4.69

4. Discussion

The present hospital-based observational cross-sectional study aimed to determine the prevalence of diabetic retinopathy (DR) in newly diagnosed patients with Diabetes Mellitus and to study the relationship between glycosylated hemoglobin (HbA1c) and the severity of DR. The study included 138 newly diagnosed diabetic patients visiting the Ophthalmic Department of our hospital. Detailed general and systemic examinations were performed, followed by ophthalmoscopy using dilated fundoscopy.

Similar studies assessing DR among newly diagnosed patients with T2DM have shown varying sample sizes compared to our study. Rema et al.,[21] Hao et al.,[24] Shah et al.,[25] Chung et al.,[31] and Sofizadeh et al.[1] had significantly larger sample sizes. In contrast, Abdollahi et al.,[22] Hamid et al.,[23] Damor et al.,[26] Roy et al.,[27] Khan et al.[28] and Setia and Tidake[29] included fewer patients, providing a spectrum of findings based on different study populations. Cai et al.'s systematic review and meta-analysis aggregated data from 77 studies of 26 countries,[32] offering a broad perspective on the prevalence and factors associated with DR in newly diagnosed T2DM patients.

4.1. Demography

The higher incidence of Type 2 Diabetes Mellitus (T2DM) in the middle-aged group was evident in our study, with a mean age of 55.61 years, and a male predominance of 58%. Similar findings were reported by Rema et al.,[21] Khan et al.,[28] Hao et al.[24] and Damor et al.[26] However, some studies like Hamid et al.[23] and Abdollahi et al.[22] reported female predominance.

4.2. Percentage of diabetic retinopathy

The prevalence of DR in newly diagnosed T2DM in our study was 10.9%, which contrasts with other studies presented in **Table 4**.

Table 4: Incidence of diabetic retinopathy in newly diagnosed diabetic patients

Studies	Percentage of Diabetic Retinopathy
Current study	10.90%
Rema et al.[21]	7.30%
Abdollahi et al.[22]	13.80%
Hamid et al.[23]	23.10%
Hao et al.[24]	20.30%
Shah et al.[25]	18%
Chung et al.[31]	6.80%
Roy et al.[27]	23.20%
Damor et al.[26]	16%
Setia and Tidake.[29]	42.50%
Khan et al.[28]	15.81%
Sofizadeh et al.[1]	17.20%
Cai et al.[32]	13.10%

*Note: Pooled prevalence in his systematic review and meta-analysis.

In our study, out of 15 cases of DR, 6 (4.3%) had mild NPDR, 5 (3.6%) had moderate NPDR, 3 (2.2%) had severe NPDR, and 1 (0.8%) had proliferative DR. This contrasts with Damor et al.,[26] who reported 79.2% mild NPDR and no cases of severe NPDR or PDR. Abdollahi et al.[22] and Setia and Tidake[29] also reported different distributions of DR severity.

4.3. Predictive factors for development of diabetic retinopathy

The mean age was significantly higher in cases with DR compared to those without (62.96 vs. 55.53 years; $p<0.05$). Logistic regression analysis indicated that age was a true predictor of DR development, consistent with studies by Rema et al.[21] and Chung et al.[31]

4.4. Glycemic control (Glycated Hemoglobin)

The mean HbA1c levels were significantly higher in cases with DR compared to those without. There was a significant increase in mean HbA1c levels with increasing DR severity ($p<0.01$). The prevalence of DR was 28.8% in cases with good glycemic control, rising to 57.8% in cases with poor control ($p<0.01$). Similar associations were reported by Khan et al.,[28] Shah et al.,[25] and Damor et al.[26] However, Hao et al.[24] found no significant association between HbA1c levels and DR.

In summary, this study highlights the significant prevalence of DR among newly diagnosed diabetic patients and underscores the importance of early detection and glycemic control to prevent DR progression. The findings align with previous research, reinforcing the value of HbA1c as a predictive marker for DR.

5. Limitations

The use of purposive sampling and a single-center design limits the generalizability of the findings. The sample size, constrained by available resources, may affect statistical power. The cross-sectional nature of the study precludes causal inferences, and the absence of a control group limits the ability to isolate diabetes' impact on retinopathy prevalence. Additionally, potential confounders such as hypertension and lipid levels were not adjusted for, and other risk factors like lifestyle and blood pressure were not explored. Future research with larger, multi-center cohorts and random sampling, incorporating additional risk factors and longitudinal designs, is recommended to validate these findings and address these limitations.

6. Conclusion

This hospital-based observational cross-sectional study found a 10.9% prevalence of diabetic retinopathy (DR) among newly diagnosed patients with type 2 diabetes mellitus (T2DM). Higher age, hypertension, and poor glycemic control (indicated by elevated HbA1c levels) were significant predictors of DR. The study's findings are

consistent with previous research, underscoring the importance of early detection and stringent control of blood sugar levels to prevent the development and progression of DR. The significant association between HbA1c levels and DR severity highlights the utility of HbA1c as a marker for long-term blood glucose control and a predictor of DR risk.

7. Key messages

1. Diabetic retinopathy (DR) is a major cause of preventable blindness.
2. This study found DR prevalence at 10.9% among newly diagnosed diabetics.
3. Age and HbA1c levels are key predictors of DR.
4. Early screening and intervention are crucial to prevent vision loss in diabetic patients.

8. Source of Funding

None.

9. Conflict of Interest

None.

10. Ethical Approval

Ethical No.: IEC/MIMER/2023/INST/932.

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