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ORIGINAL RESEARCH ARTICLE



Assessment of Diabetic Retinopathy And Its Association With Glycemic Control In Newly Diagnosed Diabetes Patients.

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Abstract

Introduction: Diabetes Mellitus Type 2 is a major health concern worldwide, with a high number of cases resulting in various types of complications affecting target organs like Brain, Heart, Kidneys, and Eyes with the eyes presenting as Diabetic Retinopathy (DR), which is nowadays becoming a reason of preventable blindness. Low glycemic control, ageing, and delay in the diagnosis have enhanced the risk of DR. The study highlights the significance of the screening process and the accurate management to help prevent the effects of DR

Methodology: This cross-sectional, hospital-based observational study was carried out over a one-year period in a tertiary care center in India to evaluate Diabetic Retinopathy and its association with glycemic control. 80 newly diagnosed adult patients with type-2 Diabetes Mellitus were enrolled after obtaining institutional ethical approval and informed consent. Participants underwent detailed clinical assessment, including demographic profiling, laboratory evaluation of glycemic status using HbA1c levels, and comprehensive ophthalmological examination for the detection and grading of Diabetic Retinopathy. Patients were categorized into retinopathy and non-retinopathy groups. Statistical analyses were performed to assess associations and identify predictors of Diabetic Retinopathy among newly diagnosed diabetic patients.

Result: Among the 80 newly diagnosed type-2 diabetic patients, Diabetic Retinopathy was observed in 44% (35/80), predominantly mild non-proliferative disease (40%), followed by moderate (31%), severe non-proliferative (20%), and proliferative retinopathy (9%). Age and gender did not differ significantly between groups ($p=0.21$; $p=0.81$). The duration of diabetes was longer in the retinopathy group (2.5 ± 0.4 vs 1.5 ± 0.3 months; $p=0.058$) but not significantly different. Multivariate analysis identified diabetes duration (OR 1.14; $p<0.001$), HbA1c (OR 1.28; $p=0.0256$), and age (OR 2.08; $p<0.05$) as significant predictors.

Conclusion: The study concluded that the Diabetic Retinopathy is a common finding even among newly diagnosed type 2 Diabetes Mellitus patients and is significantly associated with poor glycemic control. Higher HbA1c levels and increasing duration of diabetes emerged as independent predictors of Diabetic Retinopathy.

Key words: Diabetic Retinopathy, HbA1c, Glycemic Control, Type 2 Diabetes, Risk Factors.

1 | INTRODUCTION

Type 2 Diabetes Mellitus is a chronic metabolic disorder characterised by persistent hyperglycaemia due to impaired insulin secretion, insulin action, or a combination of both. It

is associated with disturbances in carbohydrate, fat, and protein metabolism and, if inadequately controlled, leads to long-term damage, dysfunction, and failure of various organs, particularly the eyes, kidneys, nerves, heart, and blood vessels (1, 2). An estimated 537 million adults aged 20–79 years are

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currently living with Diabetes Mellitus worldwide. The global burden of the disease is projected to rise substantially, reaching approximately 643 million by 2030 and 783 million by 2045 (1). According to estimates from 2019, India alone accounted for nearly 77 million individuals with diabetes, a figure anticipated to exceed 134 million by 2045. India thus represents a significant contributor to the global diabetic population. The steadily increasing incidence of diabetes in the country has been attributed to multiple factors, including rapid urbanisation, lifestyle modifications, and underlying genetic susceptibility (2). Type 2 Diabetes Mellitus (T2DM) accounts approximately 85 to 90% of cases (3). Also, the incidence of T2DM has increased due to multiple parameters, and has led to several complications, such as Diabetic Retinopathy (DR), a leading cause of preventable blindness (4). Pathophysiology of Diabetic Retinopathy includes damage to the blood vessels of the retina under hyperglycemic conditions, which results in increased vascular permeability, capillary occlusion, and neovascularisation. These alterations can result in macular oedema, retinal haemorrhages, and retinal detachment, resulting in loss of vision (5). The demographic parameters of patients suffering from DR depend on age, gender, socioeconomic level, and ethnicity. Several studies have shown that factors like age, being male, and poor glycemic index are associated with high risk for development of DR (6). Several other factors, like reduced awareness, low access to the healthcare system, and a high rate of undiagnosed diabetic conditions, can enhance the incidence of DR, specifically among newly diagnosed diabetes patients. Assessment of dilated fundus, both direct and indirect ophthalmoscopy, with the photography of fundus aids to observe and record the changes in the retina due to DR. High-resolution images can be obtained by Optical coherence tomography (OCT), which helps to investigate the presence of macular oedema as well as thickness of macula. Fluorescein angiography helps to identify the non-perfusion areas and also the leakage in the retina. The ETDRS classification system is used for the grading system for the severity of DR (7). Diabetic Retinopathy (DR) is a major microvascular complication of Diabetes Mellitus. The initiation of the development of the DR changes can begin in the early stage of diabetes and assessment is a major reason to the prevention of blindness globally. Risk for

the development of DR is initiated at the early stage of diabetes and increases with low glycemic control, long-term progression of disease, hypertension, and dyslipidemia. Newly diagnosed patients with diabetes show some early retinal changes, indicating the significance of accurate screening and regulation. Glycated hemoglobin (HbA1c) is a biomarker for the evaluation of glycemic control, and elevated HbA1c levels have been integrated with the progression of DR. Early identification of the potential management of glycemic control can decrease the risk of damage to the retina and result in the loss of vision. The association between the glycaemic status and DR among newly diagnosed diabetes patients helps to implement the prevention and also to improve the long-term outcomes (8).

2 | METHODOLOGY

Research design

The study is a cross-sectional observational study for the evaluation of Diabetic Retinopathy and its relationship with glycemic control among diagnosed type 2 diabetic patients. The study was conducted in the Ophthalmology Department in a tertiary care setting in Eastern India for a duration of one year. A total of 80 patients diagnosed with Diabetes Mellitus were selected for the study. 35 patients were diagnosed with Diabetic Retinopathy and grouped as group 1, and 45 patients were without Diabetic Retinopathy, categorised as group 2. Written and verbal consent was obtained for the study. Ethical approval was obtained from the Institutional Ethics Committee (IEC). A comprehensive evaluation for the identification of Diabetic Retinopathy was performed and was graded accordingly using standard clinical evaluation protocols. The glycemic control was evaluated using laboratory parameters, such as glycated hemoglobin (HbA1c) levels during diagnosis. The association and its impact of the association between Diabetic Retinopathy and glycemic control were evaluated. The study was done based on certain inclusion and exclusion criteria as well.

Inclusion criteria

- Patients aged above 18 years were selected for the study.

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- Diagnosed patients with type 2 Diabetes Mellitus were selected.
- Patients visiting only the tertiary care hospital for diagnosis were included.
- Well-written and verbal consent was taken for the study.
- The availability of the HbA1c measurement was required during prognosis.

Exclusion criteria

- Diagnosed diabetes for more than one year was not considered for the study.
- Any history of panretinal photocoagulation or other retinal laser therapy was excluded.
- Any ocular disease that can complicate the evaluation of the fundus was not selected for the study.
- Visually impaired patients were not included.
- Presence of any renal disorder, Chronic kidney disease, renal transplantation, or undergoing erythropoietin therapy was not considered.
- Unwilling participants were not considered for the study.

Procedure

The study was conducted as an observational, hospital-based analytical investigation involving a total of 80 newly diagnosed patients with type-2 Diabetes Mellitus. Eligible participants were consecutively recruited over the study period after fulfilling predefined inclusion criteria. Detailed demographic and clinical data, including age, gender, duration of diabetes, and treatment regimen, were recorded using a structured proforma. Glycemic status was assessed, and all participants underwent comprehensive ophthalmological evaluation for the presence and severity of Diabetic Retinopathy using standard clinical diagnostic criteria. Based on fundoscopic findings, patients were categorized into those with Diabetic Retinopathy and those without retinopathy, and further stratification of retinopathy severity was performed into mild, moderate, severe non-proliferative, and proliferative stages.

Descriptive statistical analysis was used to summarize baseline demographic and clinical characteristics. Continuous variables were expressed as mean with standard deviation, while categorical vari-

ables were presented as frequencies and percentages. Comparative analysis between patients with and without Diabetic Retinopathy was carried out to evaluate differences in demographic factors, duration of diabetes, and treatment modalities. Appropriate inferential statistical tests, including the independent sample t-test and analysis of variance, were applied to assess statistical significance, with a p-value of less than 0.05 considered significant.

To identify independent predictors of Diabetic Retinopathy, multivariate logistic regression analysis was performed. Variables such as age, gender, duration of diabetes, HbA1c levels, and treatment modalities were included in the regression model to adjust for potential confounding factors. Odds ratios with corresponding 95% confidence intervals were calculated to determine the strength of association between risk factors and the occurrence of Diabetic Retinopathy. This methodological approach enabled both descriptive assessment of disease burden and analytical evaluation of determinants associated with Diabetic Retinopathy in newly diagnosed diabetic patients.

Statistical analysis

Data analysis was done using SPSS version 27. Sample size estimation was done on the basis of the identification of 0.5% difference for HbA1c level change with 1.8% of standard deviation. The intra-cluster correlation coefficient was considered as 0.03, with 0.05 of two-sided alpha and 90% of power. Participants were analysed on the basis of the baseline laboratory values of HbA1c $\geq 6.0\%$. Comparison among groups was performed by the use of analysis of covariance (ANOVA). Two-sided statistical tests were performed. The p-values of <0.05 were considered for maintaining the statistical significance.

3 | RESULT

Figure 1 shows the distribution of study population according to the ages, where majorly patients were in the age group 50 to 59 years, 43.8% were observed. This is followed by 60 to 69 years of age, 25.0% was observed to be in this group. 18.8% were seen under 40 to 49 years of age and only 12.5% patients were more than 70 years of age.

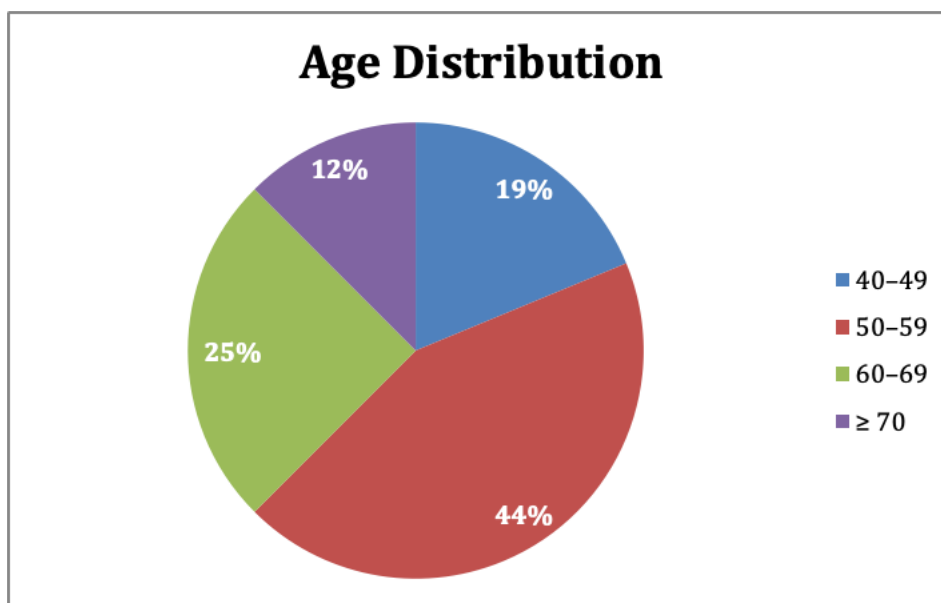


Fig. 1: Distribution of age according to the number of patients

Table 1 showed the demographic features of 80 patients having their mean value of age is 54.6 years. Males were more predominant over females, with 55% of males and 45% of females. The mean dura-

tion of diabetes was 2.1 months. Majorly, 76.3% of patients were regulated by oral hypoglycemic agents, and 12.5% of patients were received with the insulin therapy and 11.2% with the combinational therapy.

Table 1. Baseline and demographic features of the newly Diagnosed Type 2 Diabetic Patients

Parameters	Total (n = 80)
Age (years), mean	54.6
Gender	
Male	44 (55.0%)
Female	36 (45.0%)
Duration of Diabetes (month), mean	2.1
Treatment Regimen	
Oral hypoglycemic agents	61 (76.3%)
Insulin	10 (12.5%)
Combination therapy	9 (11.2%)

Table 2 showed the prevalence and the severity index of the Diabetic Retinopathy patients among the Diabetes Mellitus patients. 35 patients were observed with diabetic retinopathy and 45 patients had no incidence of Diabetic Retinopathy. About the severity index of 35 patients, commonly observed were the mild non-proliferative DR among 14 patients. This is followed by the moderate non-proliferative DR among 11 patients, with severe non-proliferative DR observed in 7 patients only. 3 patients were observed with the proliferative DR. These result findings revealed that half of the patients observed with DR, also highlighted the early importance of

screening and glycemic control for the prevention of the progression.

The comparative analysis between patients with Diabetic Retinopathy and those without Diabetic Retinopathy demonstrates both similarities and distinct differences across demographic and clinical variables. The mean age of patients with Diabetic Retinopathy was marginally higher than that of patients without retinopathy, with values of 56.8 ± 12.1 years and 54.2 ± 13.0 years, respectively; however, this difference was not statistically significant, indicating comparable age distribution between

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the two groups. Gender distribution was also similar across groups. Males constituted a slightly higher proportion in the Diabetic Retinopathy group, whereas females were marginally more frequent in the non-retinopathy group, but these differences were not statistically significant, suggesting that gender was not differentially associated with the presence of Diabetic Retinopathy in the study population. The study found that the duration of diabetes among DR group was found to be 2.5 ± 0.4 months as com-

pared to 1.5 ± 0.3 months ($P = 0.058$). Although not significant, the duration is still higher in DR group. Regarding treatment regimens, oral hypoglycemic agents were the most commonly used therapy in both groups, with a higher proportion observed in patients with Diabetic Retinopathy, although this difference did not reach statistical significance. The use of insulin alone and combination therapy was comparable between the two groups, with no statistically significant differences as shown in Table 3 .

Table 2. The rate prevalence and the severity index of the Diabetic Retinopathy among the total 80 diabetic patient

Diabetic Retinopathy Status	Number of Patients (n=80)	Percentage (%)
Present	35	44
Severity Level of Diabetic Retinopathy patients		
Mild Non-Proliferative DR	14	40
Moderate Non-Proliferative DR	11	31
Severe Non-Proliferative DR	7	20
Proliferative DR	3	9

Table 4 showed that by using multivariate logistic regression analysis, it was found that higher HbA1c levels are significant independent predictors of Diabetic Retinopathy, with each incremental increase associated with higher odds of disease occurrence. Increasing age also showed a statistically significant association with Diabetic Retinopathy. In contrast, gender and treatment modalities, including insulin, oral hypoglycemics, and combination therapy, were not significantly associated with Diabetic Retinopathy after adjustment for confounders. The regression model indicates that each additional years of diabetes duration increased the odds of Diabetic Retinopathy by 14% (OR 1.14; 95% CI 1.07–1.21; $p < 0.001$). Higher HbA1c levels were associated with a 28% increase in odds (OR 1.28; 95% CI 1.12–1.45; $p = 0.0256$). Increasing age showed a significant association (OR 2.08; 95% CI 1.99–2.12; $p < 0.05$). Male gender and treatment modalities did not demonstrate statistically significant associations with Diabetic Retinopathy.

4 | DISCUSSION

The study by Raman et al. (2009) has reported the prevalence of Diabetic Retinopathy among diabetic

patients in India. The study findings have highlighted the prevalence of DR among 18% population selected for the study. The incidence was associated with poor glycemic control and use of insulin. The study also revealed that Diabetic Retinopathy affects a substantial proportion of patients, highlighting the requirement for initial screening. The results have highlighted the significance of ophthalmic assessments and strict glycemic control for the prevention of progression of disease (9). The review by Wong et al. (2016) has provided an overview of DR as a crucial microvascular complication of diabetes and is a leading cause of global blindness. The study demonstrated the risk and severity of DR, which are associated with poor glycemic control, hypertension and diabetes. The paper highlighted that early stage of disease, which is asymptomatic, making screening necessary for identification. The author of the study has discussed the advancement in diagnostic imaging and multiple treatments, including laser therapy, intravitreal anti-VEGF agents, and corticosteroids, with improved management of the disease. The review study demonstrated the significance of systemic control for diabetes and several cardiovascular risk parameters for reducing the progression of disease and the loss of vision (10).

Table 3. The comparative analysis for the demographic and the clinical features for the patients with or without DR

Characteristic	Diabetic Retinopathy (n = 35)	No Diabetic Retinopathy (n = 45)	p-value
Age (years), mean (SD)	56.8 (12.1)	54.2 (13.0)	0.21*
Gender Male	21(60%)	23(51.11%)	0.81**
Gender Female	14(40%)	22(48.88%)	0.81**
Duration of Diabetes (months), mean (SD)	2.5 (0.4)	1.5 (0.3)	0.058
Treatment Regimen			
Oral Hypoglycemics	30 (85.71%)	31 (68.88%)	0.18**
Insulin	5 (14.29%)	5 (11.11%)	0.42**
Combination Therapy	3 (8.57%)	6 (13.33%)	0.36**

*t-test; **ANOVA

Table 4. The Multivariate Logistic Regression Analysis for DR patients

Variable	Odds Ratio (OR)	95% Confidence Interval (CI)	p-Value
Duration of Diabetes (months)	1.14	1.07 – 1.21	0.0587
HbA1c Levels	1.28	1.12 – 1.45	0.0256
Age (years)	2.08	1.99 – 2.12	<0.05
Gender (Male)	1.18	0.52 – 2.70	0.76
Insulin Use	1.62	0.81 – 3.24	0.2
Oral Hypoglycemics	0.65	0.24 – 1.78	0.38
Combination Therapy	0.62	0.16 – 2.45	0.46

Yau et al.'s (2012) study has provided a meta-analysis estimating of the prevalence and the risk factors for DR among the diabetic population. The study demonstrated that one-third of the population has a specific form of DR, and approximately 10% have complications like loss of vision, such as proliferative retinopathy or diabetic macular oedema. The study reported that poor glycemic control and hypertension can predict the severity of the disease. The study authors have revealed the variations with high prevalence observed among populations, with the challenge in the availability healthcare services for screening. The study findings revealed the need for improved screening strategies, strategies for improving public health initiatives to reduce the burden of diabetic eye problems (11). Klein et al. (1984) have assessed the association between glycemic control and the incidence of DR among the diabetic population. The study demonstrated the strong association of poor levels of glycemic control, which is assessed using glycosylated haemoglobin (HbA1c) and the high progression of retinopathy. The population with a high level of glucose in the blood were associated with an increased risk of development of retinopathy and reducing the disease. The study findings have revealed that multiple evidences support the significance of glycemic regulation or delay in

the DR has contributed to the development of clinical guidelines (12).

5 | CONCLUSION

The study concluded that the Diabetic Retinopathy is a common finding even among newly diagnosed Diabetes Mellitus patients and is significantly associated with poor glycemic control. Higher HbA1c levels and increasing duration of diabetes emerged as independent predictors of Diabetic Retinopathy, emphasizing the pivotal role of early metabolic control in preventing microvascular complications.

The study concluded that out of a total of 80 diabetic patients, Diabetic Retinopathy (DR) was observed among 43.8% and was mostly common among the 50–59-year age group. Mild non-proliferative DR was the most common form, concluding the significance of early identification. Elevated HbA1c levels were the independent predictors for DR, with an increase in the ODDS by 14% and 28%. Newly diabetes with longer duration of symptoms was observed among patients with DR than Non-DR group, but it was insignificant. Factors that were not significantly associated with DR included age, gender, and type of diabetes treatment, such as

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oral hypoglycemics, insulin, or combination therapy. These findings highlighted the critical significance of long-term glycemic control for the prevention of the progression of DR. The need for early screening, specifically among the middle-aged diabetic patients, has been associated with glycemic management. This helps to reduce the risk of DR and reinforces the need for ophthalmic assessment for diabetic people who are at risk.

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