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HbA1c Levels and its Correlation with Diabetic Retinopathy

Salve Amrita Shivaji[1*], Sonia Nankani[2]

[1]Junior Resident, Department of Ophthalmology, Bombay Hospital Institute of Medical Sciences, Mumbai, India
[2]Ex-Professor and HOD, Department of Ophthalmology, Bombay Hospital Institute of Medical Sciences, Mumbai, India

***Address for Correspondence:** Dr. Salve Amrita Shivaji, Junior Resident, Department of Ophthalmology, Bombay Hospital Institute of Medical Sciences, Mumbai, India
E-mail: salveamrita@gmail.com

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ABSTRACT

Background: Diabetic retinopathy (DR) is a significant and vision-threatening complication of type 2 diabetes mellitus, which is a microvascular complication. Chronic hyperglycaemia is a key factor in the pathogenesis and evolution of DR and glycated haemoglobin (HbA1c) is an indicator of long-term glycemic regulation.

Methods: The study is an observational cross-sectional study that took place over two years in a tertiary care teaching hospital. 220 patients who had type 2 diabetes mellitus (T2DM) were enrolled according to pre-determined criteria of inclusion and exclusion. A detailed ophthalmic examination of both eyes was performed in each subject, which included best-corrected visual acuity (BCVA) using Snellen's charts, color vision, Amsler's grid, anterior segment slit lamp biomicroscopy, intraocular pressure measurement by Schiotz tonometer, fundus evaluation under mydriasis using direct/indirect ophthalmoscopy and slit lamp biomicroscopy using 90D.

Results: The prevalence of diabetic retinopathy in the present study was found to be 18.2%. The increased levels of HbA1c were significantly and progressively correlated with the prevalence and severity of DR. No retinopathy was observed in the patients with HbA1c of 7 or less, with advanced non-proliferative and proliferative retinopathy mostly observed among patients with HbA1c exceeding 8.5%. Chronic hyperglycemia, increased duration of diabetes, presence of hypertension, oral hypoglycemic agents' intake, and raised serum creatinine were also significantly related to DR.

Conclusion: High HbA1c levels have a close relationship with the onset and the severity of diabetic retinopathy. Regular monitoring of HbA1c and strict glycemic control, as well as early ophthalmic screening, are necessary to avoid the ocular complications

Key-words: HbA1c, Diabetes mellitus, Diabetic retinopathy (DR), Glycaemic control, glycated hemoglobin (HbA1c), Microvascular complications

INTRODUCTION

Diabetes Mellitus, according to WHO, is defined as a group of metabolic disorders sharing the phenotype of hyperglycemia, and is defined as a condition where an individual has more than 2 readings of fasting plasma glucose of 126mg/dl or 2-hour postprandial glucose level of over 200mg/dl or glycosylated hemoglobin (HbA1c) of over 6.5%.

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The pathogenesis of this long-lasting hyperglycemia is the malfunction of insulin secretion, its activity, or both. DM is categorized into 2 types: Type 1 is insulin-dependent diabetes mellitus (IDDM), which contributes to approximately 10% of cases, and Type 2 is non-insulin-dependent diabetes mellitus (NIDDM), which contributes to approximately 90% of cases [1-3].

Diabetes mellitus is widespread across the globe, with a prevalence standing at 9.3 per cent, with nearly 463 million cases. It is estimated to increase to 578 million (10.2%) by the year 2030. Diabetes has a prevalence of 8.9% in India [4]. The complications of diabetes mellitus are categorized into macro vascular complications, with 50% prevalence, and micro vascular complications, which involve the kidney, the retina, and the nervous system, which involved 27% of T2DM patients. DR is one of the

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significant microvascular complications of the diabetic disease that are classified as Non-Proliferative Diabetic Retinopathy (NPDR) and Proliferative Diabetic Retinopathy (PDR), which happen in the early stage and advanced stage of DR, respectively [5]. The patients with retinopathy are asymptomatic at the onset but progressively develop floaters, distortion, and blurred vision that can eventually develop into irreversible conditions. Blindness risk among diabetes patients is nearly five times greater than that of non-diabetic patients after taking possible confounding factors into account [6].

The duration of diabetes, type 1 diabetes, hyperglycemia, hypertension, pregnancy, and elevated levels of HbA1C are the most significant risk factors of diabetic retinopathy (DRP), along with smoking. The release of VEGF can be caused by hypertension, which causes an increase in stress in endothelium cells and their elongation, proving the increase in perfusion. In controlled clinical trials of patients with type-2 diabetes mellitus and hypertension, the United Kingdom Prospective Diabetes Study demonstrated that slight BP control markedly reduces the risk of both progression of DR and deterioration in visual acuity. For each 10 mmHg decrease in mean systolic blood pressure, a 13% reduction was found for microvascular complications [7].

The Wisconsin Epidemiological Study of Diabetic Retinopathy showed a positive correlation between the severity of retinopathy and high levels of HbA1c after 10 years of diabetes mellitus [3]. Glycosylated hemoglobin is the non-enzymatic addition of a sugar residue to hemoglobin. Quantization of glucose can occur when glucose is non-enzymatically bound to one of its terminal portions of an Hb chain. This is directly proportional to blood glucose level. Since the life span of RBCs is 120 days, this test, taking into consideration the dynamics of the production and disposal of RBCs, shows the mean blood glucose in 2- 3 months. Currently, it is agreed that a fractionated value of the HbA1c is the best method of measuring glycosylated hemoglobin. The normal range of HbA1c is less than 6.9% of the total hemoglobin. DR is commonly one of the leading causes of blindness, and as such, there must be an initiative to diagnose and treat DR early enough. One of the risk factors is poor glucose control, and glycosylated hemoglobin shows the long-term blood glucose level [8].

MATERIALS AND METHODS

Research design- This is an observational, cross-sectional study to evaluate the HbA1c levels and assess the correlation with Diabetic Retinopathy. The study was conducted in the Tertiary care hospital and teaching institute. The study duration was for 2 years, from October 2014 to September 2016. Diagnosed cases of diabetes were selected for the study by the physician, including those who had attended the ophthalmology outpatient department, as well as the inpatients. Patients with type 2 diabetes mellitus were selected for the study. Well-informed consent was taken for the study. The study objectives were to evaluate the glycated hemoglobin (HbA1c) levels and their analysis for the severity of diabetic retinopathy. Data were systematically analyzed and recorded to determine the relationship between glycemic control and diabetic retinopathy.

Exclusion criteria

1. Those with hazy media, severe for fundus investigation was excluded.
2. Previous diagnosis history for retinal laser photocoagulation.
3. Pregnant women were not allowed for the study.
4. Those who were early diagnosed with non-diabetic maculopathies, consisting of central serous retinopathy, macular degeneration associated with age, drug-induced macular degeneration and macular or retinal dystrophies were excluded from the study.
5. Patients diagnosed with chronic liver disease and non-diabetic renal disorders, including glomerulonephritis, obstructive uropathy, renal parenchymal diseases, and post-renal transplantation status, were excluded.
6. Patients with deficiency in Haemoglobinopathies and glucose-6-phosphate dehydrogenase (G6PD) were excluded.
7. Anemia patients with a deficiency in vitamin B12 and folate were not included in the study.
8. Rheumatoid arthritis patient along with those receiving antiretroviral therapy (ART), ribavirin, or dapsone, were excluded.
9. The early history of splenectomy was not included.

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Inclusion criteria

1. Patients diagnosed with type 2 diabetes mellitus were included in the study.
2. Well-informed and written consent is required for the study.

Sample Size

A total of 220 patients were included in the study.

Sample size is 220 (≈223) according to the formula of prevalence rate, taking 17.6% as prevalence according to the CURES eye study [9].

$$n = Z2\ [P\ (1- P)]\ /\ d^2$$

n - Sample size

Z - Standard value for 5% error of significance p - Prevalence/incidence

d -5% error of significance

Procedure- Selected patients with type 2 diabetes mellitus were enrolled based on certain inclusion and exclusion criteria and were included in the study. Medical examination, along with comprehensive general, ophthalmic, and systemic assessment, was performed. Ophthalmic assessment included the examination of the visual acuity by utilizing Snellen's chart, test for color vision, Amsler grid assessment, and the intraocular pressure was also measured by Schiotz tonometer. Fundus was investigated under pharmacological mydriasis by means of 10% phenylephrine, eye drops of 1% of tropicamide, which was followed by indirect ophthalmoscopy and slit-lamp biomicroscopy performed by a 90D lens. Different grades were given to Diabetic retinopathy under the ETDRS classification. The diabetic macular oedema was classified as the macular oedema (CSME) or non-CSME. Different biochemical assessments were performed, including the fasting and the postprandial plasma glucose, glycated hemoglobin (HbA1c), serum creatinine, and lipid profile. The immunoturbidometric assay was used for estimating the HbA1c level in the COBAS INTEGRA system. Various other ancillary investigations were performed, including fundus photography, fundus fluorescein angiography, optical coherence tomography, and ocular ultrasonography.

Statistical Analysis- Collected data was entered into excel sheet and was analysed using SPSS software Ver 27 and Sigma Plot Ver. 12. Mean & standard deviation were used to represent the quantitative data, and Unpaired T test was performed to compare the study groups. Frequency and Percentage was used to represent the quantitative data. Chi-square test was used to assess the association among the study groups. p-value<0.05 was maintained for statistical significance.

RESULTS

Table 1 shows the gender and age distribution of diabetic retinopathy among 220 patients diagnosed with type 2 diabetes mellitus. 18.2% of patients were observed with diabetic retinopathy, while 81.8% had no retinopathy condition. Males were more predominant than females for the retinopathy condition. Age distribution revealed that the probability of diabetic retinopathy increases with age, showing no cases in the age group of 30 to 40, while high cases were observed in 51 years of age group. The results revealed that old age is significantly related to diabetic retinopathy.

Table 1: The distribution of Diabetic Retinopathy regarding age and gender among Type 2 Diabetes Mellitus patients

Variable	Category	No DR (No.)	No DR (%)	DR (No.)	DR (%)	Total (No.)	Total (%)
Gender	Male	127	70.6	29	72.5	156	70.9
	Female	53	29.4	11	27.5	64	29.1
	Total	180	100	40	100	220	100
Age (years)	30–40	14	7.8	0	0	14	6.4
	41–50	50	27.8	4	10	54	24.5
	51–60	79	43.9	18	45	97	44.1
	Above 60	37	20.6	18	45	55	25
	Total	180	100	40	100	220	100

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Table 2 shows the association between diabetes duration and the severity profile of diabetic retinopathy. No cases of retinopathy were observed over 5 years. Progression of diabetic retinopathy regarding the severity and prevalence was observed between the 6 to 10-year-olds, with more non-proliferative and proliferative alterations after 11 years. The highest proportion of cases was observed above 15 years, revealing a strong association with retinopathy, depending on duration.

Table 2: The distribution of severity of Diabetic Retinopathy

Duration of DM (Years)	No DR (%)	Mild NPDR (%)	Moderate NPDR (%s)	Severe NPDR (%)	Very Severe NPDR (%)	Early PDR (%)	High-Risk PDR (%)
Up to 5 years	100	0	0	0	0	0	0
6 to 10 years	81.8	9.1	6.1	1.5	0	1.5	0
11 to 15 years	63.3	4.1	24.5	0	2	2	2
Above 15 years	41.2	29.4	17.6	0	0	5.9	5.9

Table 3 shows the distribution of diabetic retinopathy among patients who have received different treatment modalities. The diabetic retinopathy was observed among 40 patients, out of whom the highest proportion of 20 (50%) cases was observed in oral hypoglycaemic agents (OHA). Patients treated with a combination of OHA and insulin showed a high proportion of diabetic retinopathy, 12 cases out of 35 (30%), indicating a high disease burden. Those who had received insulin, 9 DR patients were observed. Findings suggested that diabetic retinopathy is mostly observed among oral hypoglycemic treatment modalities.

Table 3: The distribution of Diabetic Retinopathy based on treatment modality

Treatment Modality	DR (No.)	No DR (No.)	Total (No.)
Insulin	8 (20.0%)	11 (6.1%)	19
Oral Hypoglycaemic Agents (OHA)	20 (50%)	143 (79.4%)	163
OHA + Insulin	12 (30%)	23 (12.8%)	35
No treatment	0	3	3
Total	40	180	220

Table 4 showed the progressive association between poor glycaemic control and diabetic retinopathy, where the prevalence rose steadily among patients with post-prandial plasma glucose levels. The highest burden was observed among patients with post-prandial plasma glucose levels above 300 mg/dl. The demonstration of the HbA1c analysis revealed that glycemic control of ≤7% showed no retinopathy, while high levels of HbA1c were related to high frequency and severity of retinopathy. Patients with high HbA1c levels showed advancement in the non-proliferative and proliferative stages.

Table 5 showed the significant relationship between the levels of serum creatinine and the diabetic retinopathy condition. In case of patients, having their normal level of serum creatinine level as (≤1.2 mg/dl, 93.9% of patients did not have DR condition, while retinopathy was present among 57.5% of patients. Contrastingly, a high level of serum creatinine of >1.2 mg/dl was observed among 42.5% of DR patients, rather than 6.1% of patients without DR. About 12.7% of patients have a high level of creatinine. These findings suggested a strong association between improper renal function and the DR condition, indicating that high renal involvement reflects systemic microvascular damage among diabetic patients.

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Table 4: The association between the Post-Prandial Plasma Glucose and HbA1c Levels along with the diabetic retinopathy

Parameter	Category	No DR (No.)	DR / Grade-wise Distribution (No.)	Total (No.)	No DR (%)	DR / Grade-wise (%)	Total (%)
Post-Prandial Plasma Glucose (mg/dl)	Up to 140	68	DR: 4	72	37.8	10	32.7
	141–200	88	DR: 8	96	48.9	20	43.6
	201–300	24	DR: 11	35	13.3	27.5	15.9
	Above 300	0	DR: 17	17	0	42.5	7.7
	Total	180	40	220	100	100	100
HbA1c (%)	Up to 7	126	Mild NPDR: 0; Mod NPDR: 0; Severe NPDR: 0; Very Severe NPDR: 0; Early PDR: 0; High-Risk PDR: 0	126	100	0	100
	7.1–8.5	52	Mild NPDR: 2; Mod NPDR: 3; others: 0	57	91.2	8.8	100
	8.6–10	2	Mild NPDR: 6; Mod NPDR: 9; others: 0	17	11.8	88.2	100
	Above 10	0	Mod NPDR: 7; Severe NPDR: 6; Very Severe NPDR: 2; Early PDR: 3; High-Risk PDR: 2	20	0	100	100
	Total	180	Mild NPDR: 8; Mod NPDR: 19; Severe NPDR: 6; Very Severe NPDR: 2; Early PDR: 3; High-Risk PDR: 2	220	81.8	18.2	100

Table 5: The distribution of the Diabetic Retinopathy based on the serum creatinine level

Serum Creatinine (mg/dl)	No DR (No.)	No DR (%)	DR (No.)	DR (%)	Total (No.)	Total (%)
Up to 1.2	169	93.9	23	57.5	192	87.3
Above 1.2	11	6.1	17	42.5	28	12.7
Total	180	100	40	100	220	100

The distribution of macular involvement and the severity of diabetic retinopathy were shown among the patients in the study. About 96% of patients were observed with normal macula, suggesting no macular oedema, while a few patients included the diabetic macular condition, 3% of patients showed macular oedema (CSME) and 1% of cases with non-CSME were observed. Regarding diabetic retinopathy severity, 82% of patients did not have retinopathy, indicating a high proportion of individuals with no renal complications. The most frequent stage was observed among 8% of cases with a moderate level of non-proliferative diabetic retinopathy, which was followed by 4% of mild non-proliferative diabetic retinopathy, and the severe form was observed among 3% of cases. Remaining 1% of cases were noted for advanced stage, with severe form of non-proliferative diabetic retinopathy, early proliferative diabetic retinopathy, and high-risk proliferative diabetic retinopathy among patients (Table 6).

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Table 6: The distribution of Diabetic Macular Oedema and the severity index of Diabetic Retinopathy

Category	Subcategory	Percentage (%)
Macular Status	Normal	96
	CSME	3
	Non-CSME	1
Diabetic Retinopathy Status	No DR	82
	Mild NPDR	4
	Moderate NPDR	8
	Severe NPDR	3
	Very Severe NPDR	1
	Early PDR	1
	High-Risk PDR	1

DISCUSSION

A study was conducted to examine the interrelations between the glycosylated hemoglobin levels, blood pressure (systolic and diastolic), and triglycerides with DRP among the diabetic population. Glycosylated hemoglobin, systolic and diastolic blood pressure are also at a high level, and this contributes to the development of diabetic retinopathy. Thus, it is also advisable to closely monitor the blood sugar and blood pressure levels of patients with diabetes with a view to avoiding the development of retinopathy [10].

A cross-sectional study was done on a sample of 327 diabetics with type 2 who visited the primary healthcare centres in Al-Majmaah City, KSA. The systematic random sampling technique was used to collect the data under the direct investigation method. The researchers were able to draw a conclusion that both HbA1c level and DR are strongly correlated. The patient should be empowered by the health professional with the knowledge about diabetes, its complication and lifestyle change (diet, exercise, and weight loss, etc.). An ophthalmologist should conduct the retinal screening regularly [11].

The study aimed to establish the correlation of glycosylated hemoglobin with retinal nerve fiber layer thickness (RNFLT) and central macular thickness (CMT) in the diabetic population of North India. Slit lamp fundoscopy using a +78 D lens and spectral-domain (SD) optical coherence tomography to measure the RNFLT and CMT, and the retinopathy stage by using the ETDRS classification, were carried out on all patients. In addition to that, blood tests were commissioned, such as fasting (FBS) and post-prandial (PPBS) blood sugar and glycosylated hemoglobin (HbA1c). The study concluded that diabetic retinopathy is associated with neurodegeneration as demonstrated by the thinning of nerve fiber layers, and is negatively associated with HbA1c [12].

A study was conducted to establish the relationship between Diabetic Retinopathy and the level of HbA1c. The study concluded that diabetes and length of stay are the risk factors in the onset or progression of Diabetic retinopathy in type 2 Diabetes and that the patients with poor glycemic control were found to have severe diabetic retinopathy when compared to the patients with good glycemic control. The severity of diabetic retinopathy is directly related to the level of HbA1c [13].

A study was done to assess the relationship between HbA1c level and grade of diabetic retinopathy, to examine the level of diabetes patients' awareness of diabetic retinopathy, and to determine the systemic risk factors of diabetic retinopathy. The research indicated that there is a positive correlation existing between high level of HbA1c and the severity of diabetic retinopathy, which is positive. The lack of awareness among patients about the condition seems to lead to late diagnosis of the condition in patients with advanced retinal changes and significant visual loss. The results indicate that frequent eye examination, improved patient education, and management of blood glucose and blood pressure levels are effective in minimizing the burden of diabetic retinopathy [14].

A study was done to verify which is most effective between HbA1C and fasting plasma glucose (FPG) in identifying diabetic retinopathy longitudinally in the Japanese population. It was clarified that the greater the level of FPG and HbA1c, the greater the incidence of retinopathy in the 4 years. There was no clear threshold. FPG and HbA1c were nearly equal in the detection ability of the incidence of retinopathy, which indicated that the risk of retinopathy can be detected using HbA1c only [15].

CONCLUSIONS

This study demonstrates a strong and consistent association between poor glycemic control, reflected by elevated HbA1c levels, and both the occurrence and

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severity of diabetic retinopathy in patients with type 2 diabetes mellitus. Patients with HbA1c levels ≤7% showed no evidence of retinopathy, whereas progressively higher HbA1c levels were linked with increasing prevalence and severity of non-proliferative and proliferative diabetic retinopathy. Longer duration of diabetes emerged as another major determinant, significantly contributing to advanced retinal changes. Elevated post-prandial plasma glucose and higher serum creatinine levels were also significantly associated with retinopathy, suggesting poor metabolic control and concurrent renal involvement as indicators of widespread microvascular damage. A greater disease burden was observed among patients on oral hypoglycemic agents, reflecting more severe disease status. These findings highlight the importance of regular HbA1c monitoring, strict glycemic control, timely ophthalmic screening, and comprehensive management of systemic risk factors to prevent vision-threatening complications and reduce overall healthcare burden.

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CONTRIBUTION OF AUTHORS

Research concept- Sonia Nankani
Research design- Sonia Nankani
Supervision- Sonia Nankani
Materials- Salve Amrita Shivaji
Data collection- Salve Amrita Shivaji
Data analysis and interpretation- Salve Amrita Shivaji
Literature search- Salve Amrita Shivaji
Writing article- Salve Amrita Shivaji
Critical review- Sonia Nankani
Article editing- Sonia Nankani
Final approval- Sonia Nankani

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