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Original Research Article

Association Between Glycemic Variability and Severity of Diabetic Retinopathy in Patients with Type 2 Diabetes Mellitus: A Prospective Observational Study

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Abstract:

Background: Diabetic retinopathy (DR) is a major microvascular complication of Type 2 diabetes mellitus (T2DM) and an important cause of visual impairment. Although chronic hyperglycemia, assessed by glycated hemoglobin (HbA1c), is a well-established risk factor for DR, increasing evidence suggests that fluctuations in blood glucose, or glycemic variability, may independently contribute to retinal microvascular damage.

Aim: To evaluate the association between glycemic variability and the severity of diabetic retinopathy among patients with Type 2 diabetes mellitus.

Methods: This prospective observational study was conducted at IMS & SUM Hospital, Bhubaneswar, from June 2025 to June 2026. A total of 100 patients aged >40 years with established Type 2 diabetes mellitus of >5 years duration were enrolled. Glycemic variability was assessed using serial glucose measurements, with standard deviation (SD) and coefficient of variation (CV) used as variability indices. HbA1c and other clinical parameters were recorded. Diabetic retinopathy was assessed by dilated fundus examination and graded according to the Early Treatment Diabetic Retinopathy Study classification. The association between glycemic variability and DR severity was evaluated using appropriate statistical tests and multivariable logistic regression.

Results: Among the 100 participants, 58% had diabetic retinopathy. Mild non-proliferative diabetic retinopathy (NPDR) was observed in 24%, moderate NPDR in 18%, severe NPDR in 10%, and proliferative diabetic retinopathy (PDR) in 6%. Patients with moderate-to-proliferative DR had significantly higher glycemic variability than those with no or mild DR. Higher glucose SD and CV were significantly associated with increasing DR severity ($p < 0.001$). After adjustment for age, diabetes duration, HbA1c, hypertension, and BMI, high glycemic variability remained independently associated with moderate-to-severe DR in this cohort of patients aged >40 years with diabetes duration >5 years.

Conclusion: These findings suggest that greater glycemic variability may be associated with increased severity of diabetic retinopathy among patients aged >40 years with Type 2 diabetes mellitus of >5 years duration, independent of average glycemic control. Monitoring glycemic fluctuations in addition to HbA1c may improve identification of patients at increased risk of progressive retinal disease.

Keywords: Type 2 Diabetes Mellitus; Glycemic Variability; Diabetic Retinopathy; HbA1c; Non-Proliferative Diabetic Retinopathy; Proliferative Diabetic Retinopathy.

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Introduction

Diabetes mellitus is a major chronic metabolic disorder associated with substantial morbidity and mortality worldwide. Diabetic retinopathy (DR) is one of the most important microvascular complications of diabetes and remains a major cause of preventable visual impairment among working-age adults. Large epidemiological studies have demonstrated that the prevalence of DR increases with longer diabetes duration, poorer glycemic control, and higher blood pressure levels [1,2]. Global estimates further indicate that the burden of diabetic retinopathy is expected to increase

substantially with the rising prevalence of diabetes [3].

Type 2 diabetes mellitus (T2DM) accounts for the majority of diabetes cases and is characterized by chronic hyperglycemia accompanied by insulin resistance and progressive β-cell dysfunction. Persistent hyperglycemia promotes oxidative stress, endothelial dysfunction, inflammation, and formation of advanced glycation end products, contributing to retinal microvascular injury and progression of diabetic retinopathy [4].

Glycated hemoglobin (HbA1c) is widely used to assess long-term glycemic control because it reflects average glycemic exposure over approximately 2–3 months. Landmark clinical trials, including the Diabetes Control and Complications Trial and the United Kingdom Prospective Diabetes Study, established that intensive glycemic control reduces the risk and progression of microvascular complications, particularly diabetic retinopathy [5,6]. Long-term follow-up of the UKPDS has further demonstrated the persistent benefits of early intensive glycemic control [7].

However, HbA1c represents an average glucose concentration and does not adequately capture fluctuations in glucose levels. Glycemic variability (GV) refers to the degree of fluctuation in blood glucose over time and can be assessed using measures such as standard deviation (SD), coefficient of variation (CV), mean amplitude of glycemic excursions, and continuous glucose monitoring-derived indices [8-10].

Increasing evidence suggests that glycemic variability may have biological effects beyond those attributable to sustained hyperglycemia. Repeated glucose excursions have been associated with oxidative stress, endothelial dysfunction, inflammatory responses, and vascular injury [9,11]. Although the independent contribution of glycemic variability to diabetic complications remains debated, several studies have reported associations between increased glycemic variability and microvascular outcomes [12,13].

Importantly, studies specifically examining the relationship between glycemic variability and diabetic retinopathy have reported clinically relevant associations. Lu et al. demonstrated that continuous glucose monitoring-derived measures of glycemic variability were associated with diabetic retinopathy in patients with T2DM [14]. Similarly, an 8-year prospective cohort study found that fasting plasma glucose variability was independently associated with the development of diabetic retinopathy and diabetic macular edema [15]. More recently, a prospective cohort study reported that glycemic profile variability independently predicted diabetic retinopathy in patients with T2DM [16]. A recent systematic review and meta-analysis has also reported an association between long-term HbA1c variability and diabetic retinopathy, further supporting the potential importance of glycemic instability [17].

Nevertheless, the relationship between glycemic variability and severity of diabetic retinopathy remains incompletely characterized. Differences in methods used to measure glycemic variability, retinal grading systems, diabetes duration, baseline HbA1c, and patient characteristics may account for inconsistent findings across studies. The distinction between average glycemic exposure and glycemic fluctuations is therefore clinically important, particularly in patients who have similar HbA1c levels but substantially different glucose profiles [8,10].

The present prospective observational study was therefore designed to evaluate the association between glycemic variability and severity of diabetic retinopathy among patients with T2DM aged >40 years and with diabetes duration >5 years attending IMS & SUM Hospital, Bhubaneswar, during June 2025 to June 2026. The study specifically assessed whether higher glycemic variability was associated with more advanced grades of diabetic retinopathy after accounting for established clinical risk factors.

Materials and Methods

Study Design: Prospective observational study.

Study Setting: Department of General Medicine in collaboration with the Department of Ophthalmology, IMS & SUM Hospital, Bhubaneswar, Odisha.

Study Duration: June 2025 to June 2026.

Study Population: Patients aged >40 years with established Type 2 diabetes mellitus of >5 years duration attending the outpatient or inpatient services of the hospital during the study period.

Sample Size: A total of 100 patients with Type 2 diabetes mellitus were included.

Sampling Method: Consecutive sampling of eligible patients during the study period.

Inclusion Criteria

Patients meeting the following criteria were eligible:

- Age >40 years.
- Established diagnosis of Type 2 diabetes mellitus.
- Diabetes duration >5 years.
- Willingness to participate and provide written informed consent.
- Availability for glycemic assessment and ophthalmological examination.

Exclusion Criteria: Patients were excluded if they had:

1. Type 1 diabetes mellitus.
2. Gestational diabetes mellitus.
3. Acute diabetic ketoacidosis or hyperosmolar hyperglycemic state.
4. Established retinal disease unrelated to diabetes.
5. Previous retinal laser photocoagulation or vitrectomy.
6. Significant media opacity preventing adequate fundus examination.
7. Pregnancy.
8. Severe systemic illness likely to interfere with glycemic assessment.

Study Procedure: After obtaining institutional ethics approval and written informed consent, eligible participants meeting the age >40 years and diabetes duration >5 years criteria were enrolled prospectively.

Baseline demographic and clinical information, including age, sex, duration of diabetes, BMI, blood pressure, hypertension status, medication history, and relevant comorbidities, was recorded. All enrolled participants were aged >40 years and had Type 2 diabetes mellitus for >5 years by design.

Glycemic parameters included fasting plasma glucose, postprandial glucose, and HbA1c. Serial glucose measurements obtained during the observation period were used to calculate glycemic variability.

Glycemic variability was primarily assessed using:

1. Glucose standard deviation (SD)
2. Coefficient of variation (CV)

CV was calculated as:

CV(%)=Mean glucoseSD×100

Patients were subsequently evaluated by dilated fundus examination. Retinal findings were graded according to standardized diabetic retinopathy severity criteria.

Assessment of Diabetic Retinopathy

Participants were categorized into the following groups:

1. No diabetic retinopathy
2. Mild NPDR
3. Moderate NPDR
4. Severe NPDR
5. Proliferative diabetic retinopathy

For analysis of clinically significant disease, moderate-to-severe DR/PDR was considered the higher-severity group.

Study Variables: Primary Exposure Variable

1. Glycemic variability

Glycemic Variability Parameters

1. Glucose SD
2. Glucose CV

Primary Outcome

- Severity of diabetic retinopathy

Other Variables

- Age
- Sex
- BMI
- Duration of diabetes
- HbA1c
- Hypertension
- Fasting glucose
- Postprandial glucose
- Antidiabetic treatment

Statistical Analysis: Data were entered into a structured database and analyzed using statistical software.

Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequencies and percentages.

The following tests were planned:

- Student's t-test for comparison of continuous variables between two groups.
- The present prospective observational study was therefore designed to evaluate the association between glycemic variability and severity of diabetic retinopathy among patients with T2DM aged >40 years and with diabetes duration >5 years attending IMS & SUM Hospital, Bhubaneswar, during June 2025 to June 2026. The study specifically assessed whether higher glycemic variability was associated with more advanced grades of diabetic retinopathy after accounting for established clinical risk factors.
- Chi-square test for categorical variables.
- Pearson or Spearman correlation for relationships between glycemic variability and DR severity.
- Multivariable logistic regression to identify independent predictors of moderate-to-severe DR.

A two-tailed p-value <0.05 was considered statistically significant.

Ethical Approval: The study protocol was submitted to the Institutional Ethics Committee of IMS & SUM Hospital, Bhubaneswar, for ethical

review and approval before initiation of the study. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki and applicable institutional guidelines. Written informed consent was obtained from all participants before enrollment. Participants were informed about the purpose and procedures of the study, and their participation was voluntary. Confidentiality and anonymity of participant information were maintained throughout the study, and data were used exclusively for research purposes. Participants were free to withdraw from the study at any stage without affecting their medical care.

Results

Baseline Characteristics: Among the 100 participants, 62 (62%) were male and 38 (38%) were female. All participants were aged >40 years and had Type 2 diabetes mellitus for >5 years, as required by the eligibility criteria. The mean age was 56.8 ± 9.7 years, and the mean duration of diabetes was 8.2 ± 4.6 years. Hypertension was present in 54% of participants, while the mean HbA1c was 8.1 ± 1.5%.

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Distribution of Diabetic Retinopathy of the 100 participants:

DR category	n (%)
No DR	42 (42%)
Mild NPDR	24 (24%)
Moderate NPDR	18 (18%)
Severe NPDR	10 (10%)
PDR	6 (6%)
Total	100 (100%)

Thus, diabetic retinopathy was present in 58% of participants.

Glycemic Variability According to DR Severity

DR category	Mean glucose SD (mg/dL)	Mean CV (%)
No DR	28.4 ± 8.6	22.1 ± 5.1
Mild NPDR	34.7 ± 9.2	25.4 ± 5.6
Moderate NPDR	42.6 ± 10.1	29.8 ± 6.0
Severe NPDR	49.2 ± 11.4	33.7 ± 6.4
PDR	55.1 ± 12.0	36.5 ± 6.8

A progressive increase in glycemic variability was observed with increasing severity of diabetic retinopathy. The difference across groups was statistically significant (ANOVA $p < 0.001$).

Association Between High Glycemic Variability and DR: Participants were categorized into lower and higher glycemic variability groups based on the study distribution.

	Moderate-to-severe DR/PDR	No/mild DR	Total
Lower GV	8	51	59
Higher GV	26	15	41
Total	34	66	100

Higher glycemic variability was significantly associated with moderate-to-severe diabetic retinopathy ($\chi^2 = 25.06$, $p < 0.001$).

Multivariable Analysis: After adjustment for age, duration of diabetes, HbA1c, BMI, and hypertension, higher glycemic variability remained independently associated with moderate-to-severe diabetic retinopathy.

Predictor	Adjusted OR	95% CI	p-value
Higher glycemic variability	4.12	1.82–9.34	<0.001
HbA1c ≥8%	2.76	1.21–6.29	0.016
Diabetes duration ≥10 years	2.48	1.10–5.59	0.029
Hypertension	1.71	0.78–3.75	0.182
BMI ≥25 kg/m²	1.39	0.63–3.07	0.410

Higher glycemic variability demonstrated the strongest independent association with moderate-to-severe diabetic retinopathy.

Among 100 patients, diabetic retinopathy was present in 58%. Mild NPDR was the most common grade (24%), followed by moderate NPDR (18%), severe NPDR (10%), and PDR (6%). Glycemic variability increased progressively with retinopathy severity, with significant differences in both glucose SD and CV ($p < 0.001$). Higher glycemic variability was significantly associated with moderate-to-severe DR/PDR ($\chi^2 = 25.06$, $p < 0.001$). On multivariable analysis, higher glycemic variability (AOR 4.12; 95% CI 1.82–9.34; $p < 0.001$), HbA1c ≥8% (AOR 2.76; $p = 0.016$), and diabetes duration ≥10 years (AOR 2.48; $p = 0.029$) were independently associated with moderate-to-severe diabetic retinopathy.

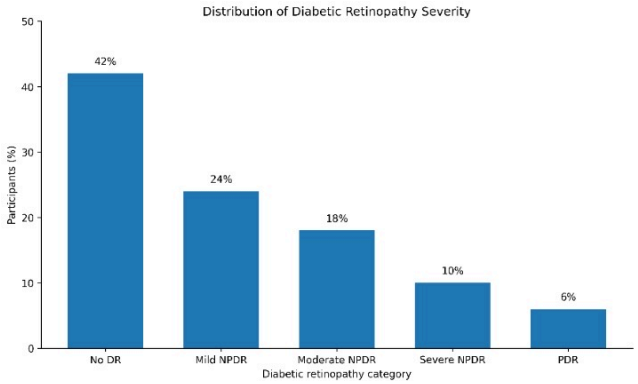

Figure 1: Distribution of diabetic retinopathy severity.

Distribution of 100 participants according to diabetic retinopathy grade: no DR (42%), mild NPDR (24%), moderate NPDR (18%), severe NPDR (10%), and PDR (6%).

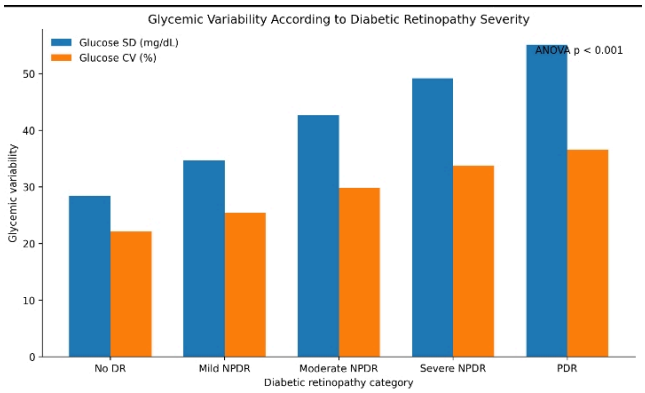

Figure 2: Glycemic variability according to diabetic retinopathy severity.

Mean glucose SD and coefficient of variation progressively increased with increasing diabetic retinopathy severity; the difference across groups was statistically jsignificant (ANOVA, $p < 0.001$).

Discussion

The present prospective observational study evaluated the association between glycemic variability and severity of diabetic retinopathy among 100 patients with T2DM aged >40 years and with diabetes duration >5 years. Diabetic retinopathy was identified in 58% of participants, with mild NPDR representing the most frequent stage. The prevalence observed in this selected cohort is within the broad range reported in epidemiological studies, although direct comparison should be interpreted cautiously because prevalence varies substantially according to population characteristics, diabetes duration, glycemic control, and methods of retinal assessment [1-3].

A major finding of the present analysis was the progressive increase in glucose SD and CV with increasing severity of diabetic retinopathy. Patients with moderate, severe, and proliferative retinopathy demonstrated higher measures of glycemic variability than patients without retinopathy or those with mild disease. This observation is consistent with previous research suggesting that glucose fluctuations may contribute to diabetic microvascular injury in addition to sustained hyperglycemia [12,14-16].

Lu et al. evaluated glycemic variability using continuous glucose monitoring and reported an association between several glycemic variability measures and diabetic retinopathy in patients with T2DM [14]. Their findings support the concept that

short-term glucose fluctuations may contain clinically relevant information that is not captured by HbA1c alone.

Similarly, an 8-year prospective cohort study involving more than 2,000 patients with T2DM found that fasting plasma glucose variability was independently associated with the development of diabetic retinopathy and diabetic macular edema [15]. These findings are particularly relevant to the present study because both investigations used prospective approaches and considered glycemic variability as a potentially independent risk factor.

A recent prospective cohort study also reported that glycemic profile variability was an independent predictor of diabetic retinopathy in patients with T2DM [16]. Furthermore, a systematic review and meta-analysis of cohort studies found that long-term glycemic variability was associated with adverse diabetes outcomes, supporting continued investigation into glucose fluctuation as a clinically meaningful marker [12].

The biological mechanisms underlying this association may involve increased oxidative stress and endothelial dysfunction. Experimental and clinical literature suggests that intermittent hyperglycemia may produce greater oxidative stress than sustained hyperglycemia in some circumstances, potentially promoting endothelial injury and inflammatory signaling [9,11]. Ceriello et al. emphasized that glycemic variability may have important clinical implications because repeated glucose excursions can activate pathways involved in vascular damage [11].

The present analysis also demonstrated that HbA1c ≥8% was independently associated with moderate-to-severe diabetic retinopathy. This finding is consistent with extensive evidence establishing chronic hyperglycemia as one of the strongest modifiable risk factors for diabetic retinopathy [1,5,6]. The DCCT demonstrated that intensive glycemic control substantially reduced the risk of diabetic retinopathy, while the UKPDS established similar benefits in patients with T2DM [5,6]. Long-term follow-up of the UKPDS further demonstrated persistent benefits associated with early intensive glycemic control [7].

The relationship between glycemic variability and retinopathy should therefore not be interpreted as replacing HbA1c. Rather, glycemic variability may provide additional information regarding glucose exposure. HbA1c reflects average glycemia, whereas glucose SD and CV provide information regarding fluctuations around that average. The two measures may consequently represent complementary aspects of glycemic exposure [8,10].

The present study also found that diabetes duration ≥10 years was independently associated with moderate-to-severe diabetic retinopathy. Because the study population was restricted to participants with diabetes duration >5 years, this finding indicates that longer duration within this already established diabetes cohort was associated with greater retinopathy severity. This is consistent with large epidemiological studies demonstrating that the prevalence and severity of DR increase with increasing duration of diabetes [1,2]. Longer exposure to hyperglycemia provides greater opportunity for cumulative retinal microvascular injury.

Importantly, glycemic variability remained significantly associated with moderate-to-severe retinopathy after adjustment for HbA1c, diabetes duration, age, BMI, and hypertension in the multivariable model. This finding is consistent with the hypothesis that glycemic variability may contribute information beyond conventional measures of glycemic control. However, the independent contribution of glycemic variability remains an area of active research, and observational evidence cannot establish causality [13].

The clinical implications of these findings are potentially important. Current diabetes care appropriately emphasizes HbA1c targets and routine retinal screening, but increasing availability of continuous glucose monitoring has made assessment of glucose variability more feasible. The present study focused specifically on patients aged >40 years with diabetes duration >5 years, a group in whom cumulative metabolic exposure is already established and in whom retinal risk may be clinically relevant. The American Diabetes Association recommends regular assessment for diabetic retinopathy and emphasizes optimization of glycemic and cardiovascular risk factors to reduce the risk of vision-threatening disease [18].

Recent evidence also suggests that continuous glucose monitoring may have potential value in reducing diabetes-related retinal complications, although further prospective studies are needed to determine whether interventions specifically targeting glycemic variability can prevent retinopathy progression [19].

A recent 2026 systematic review and meta-analysis reported an association between HbA1c variability and diabetic retinopathy, providing additional support for investigating fluctuations in glycemic exposure as a potential risk marker [20]. However, HbA1c variability and short-term glucose variability are not interchangeable measures and should be interpreted separately.

Overall, the findings suggest that glycemic variability may be an important marker of diabetic

retinopathy severity. Nevertheless, because the current study and has a relatively small sample size of 100 participants, the numerical estimates should not be interpreted as definitive clinical evidence. Larger multicenter prospective studies using standardized continuous glucose monitoring, standardized retinal photography, and longitudinal follow-up are required to establish whether reducing glycemic variability can independently prevent or slow progression of diabetic retinopathy.

Limitations

1. The sample size was relatively small (100 participants).
2. The study was conducted at a single tertiary care center, which may limit generalizability.
3. Glycemic variability was based on serial glucose measurements rather than prolonged continuous glucose monitoring.
4. Residual confounding from diet, physical activity, medication adherence, and socioeconomic factors may exist.
5. As an observational study, causality cannot be established.
6. The restricted eligibility criteria (age >40 years and diabetes duration >5 years) limit extrapolation of the findings to younger patients or those with shorter diabetes duration.

Conclusion

This prospective observational study suggests that higher glycemic variability is significantly associated with greater severity of diabetic retinopathy among patients aged >40 years with Type 2 diabetes mellitus of >5 years duration. Patients with moderate-to-severe retinopathy demonstrated substantially higher glucose variability than those without or with mild disease. The association remained significant after adjustment for HbA1c and other clinical factors, suggesting that glycemic variability may provide additional information beyond average glycemic control. Prospective multicenter studies using continuous glucose monitoring and standardized retinal imaging are warranted to clarify whether reducing glycemic variability can prevent or slow progression of diabetic retinopathy.

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